Patient Safety and Risk Management in Medicine

From Theory to Practice

Yaron Niv
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Springer

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Preface

Give me the courage to understand my mistakes today, so that tomorrow I can see in a better light, what I did not see in the dim light of Yesterday.
Maimonides (1135–1204)

Medical Risk Management and Patient Safety

Introduction

In 1999, the American Institute of Medicine (IOM) announced that "to err is human" and that when mistakes or failures occur in medical treatment that result in harm to the patient and even death, one should not look for culprits but investigate and check what caused the malfunction to prevent similar events in the future. There is no human being who does not make mistakes, and this fact is also true for caregivers and health care systems that deal with human life. The change in perception to understand this has been brought about a revolution in the health care system and has greatly contributed to patient safety. Health institutions investigate and assess themselves regularly and seek to improve and promote patient safety.

It is estimated that in Israel, there are approximately 10,000 deaths per year as a result of medical treatment failures and that the financial expenditure due to these cases is close to 3 billion NIS per year.

The decision to write a textbook on this subject took shape over many years in which we have been engaged in practicing and teaching patient safety and risk management in medicine and assisting medical teams to form an understanding of the importance of this subject for assuring patient safety, as well as the well-being of caregivers and the prosperity of medical organizations.

In many courses we have instructed on the subject, we were surprised to meet professional, experienced, and committed caregivers and managers, with very limited, if at all, knowledge and skills in the field of medical risk management and patient safety.

Therefore, we believe that assimilation of the subject in faculties of medicine, schools of nursing, and in all the frameworks structured to teach health care professionals, should be mandatory.

The book deals with basic principles and concepts, the scope of the phenomenon of iatrogenic damage, and the development of risk management

practices in medicine and organizational safety culture, emphasizing human and organizational factors, legal and safety aspects, risk management processes in medical organizations, partnership with patients for assuring patient safety, evaluation and measurement, and current trends. In addition, a large chapter is devoted to risk management during the coronavirus pandemic, during which the inexhaustible capabilities of the Israeli health care system were manifested.

The target audiences for this book are doctors, nurses, pharmacists, psychologists, occupational therapists, physiotherapists, managers, and all those working in health care institutions who are directly or indirectly involved in patient care.

In our opinion, patients should take a more active role in assuring patient safety and health care professionals and medical organizations should encourage them and empower them to do so. Though patients are not the target audience of this book, they may benefit from being familiar with its content.

Ariel, Israel — Yaron Niv
Ariel, Israel — Yossi Tal

Acknowledgments

We want to thank the countless people who consciously and unconsciously contributed to the writing of this book, who were a source of inspiration and challenge for us, and first and foremost to our families who supported and understood our strong desire to write this book and witnessed the countless days and nights we dedicated to writing it.

We thank the many students we have met over the years, in many dozens of courses on risk management and patient safety, whose challenging questions have stimulated us to look for solutions and new ways to face the many challenges of patient safety risks. They are the ones who raised the need to write this book as a response to the great gap in knowledge and tools in this important field.

We thank many colleagues who consider the areas of risk management and patient safety as important cornerstones for providing quality and safe health services.

And finally, we would like to thank AJE for careful linguistic editing and Springer-Nature publishing house for the fruitful partnership in publishing this book.

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Yossi Tal is a Social and Cognitive Psychologist, specialized in Risk Management, Safety and Training methodologies. Dr. Tal started his professional career as a Psychologist in the IAF (Israeli Air Force), after graduating in Psychology from the Bar-Ilan University. Dr. Tal headed the branch of Human-Factors in flying for 15 years. He was in charge of investigations and research in various areas of human factors, training, and of the development of recommendations to reduce contribution of human error in military aircraft accidents. For the last 25 years, Dr. Tal has focused professionally on risk management in medicine and patient safety and is a consultant to several medical organizations, including Maccabi Healthcare Services and Leumit Healthcare Services. He has developed, coordinated, and instructed numerous academic courses on medical risk management and patient safety, and currently he is involved in several research projects in his field of expertise, continues to teach and consult and is active in the board of Israeli Society of Patient Safety and Risk Management in Medicine (NASBAR/ISRM).

Yaron Niv is a Clinical Professor of Medicine at Ariel University in Israel. He graduated from Tel Aviv University Medical School, did his internship and residency in internal medicine and gastroenterology at Sheba Medical Center. He did his postdoctoral work at UCSF and was a visiting professor at Baylor University Medical Center in Dallas, UCSD San Diego, and the Autonomous University of Madrid, Spain. His research concerns the biology and screening of colorectal cancer, Helicobacter pylori-related diseases, mucin secretion in the gastrointestinal tract, quality assurance, and patient safety. He was till recently the Senior Deputy Director General of the Israeli Ministry of Health and responsible for the quality of medical treatment and patient safety. During the COVID-19 pandemic, Prof. Niv served as the Chairman of the National Quality and Inspection Committee for COVID-19 disease patients admitted to general hospitals, Chairman of the National Risk Management Committee for COVID-19 pandemic and immunizations, and Chairman of the National Team for Ventilation and ARDS of Covid-19 Pandemic (2020–2022). He was the founder and president of the Israeli Society of Patient Safety and Risk Management in Medicine (NASBAR/ISRM). He has published more than 300 articles in high-quality peer-reviewed journals.

Risks and Adverse Events in Medicine

1

1.1 What Is Risk?

We operate in a high-risk environment in both our private and professional lives; many organizations are subject to a constant struggle to identify, understand, and reduce risks to ensure their own existence and prosperity. Our responses to risks are often generated automatically. For example, if we approach an intersection when a yellow traffic light is illuminated, we will assess the chances of a safe passage and act accordingly—sometimes, we will press the brake pedal and sometimes the gas pedal. Small cues change the situation and define it as dangerous or safe. Our behavior is influenced by an accumulation of past experiences in similar situations—the degree of success in crossing intersections when the yellow traffic light is illuminated and many clues as to the degree of risk. Our reaction patterns to risks in our environment are based on learning from different situations in the past and our many errors in different risk situations.

If an elderly patient enters the clinic with his hands on his chest and says, "I have strong pain," the receptionist will immediately call the doctor for fear of a heart attack. If the patient enters the clinic with his hands in his pockets and says, "It hurts a lot," the receptionist will most likely instruct him to sit down and wait patiently for his turn. If the receptionist knows the patient as a "cardiac patient," she will try to advance the patient's turn without him doing or saying anything.

Defining what risk is and understanding the meaning of risk in a medical environment is therefore necessary for intelligent and effective medical risk management.

There are two approaches to defining risk: the objective approach and the subjective approach. The objective approach is based on the fact that risk can be evaluated and measured in light of information collected about it in the past, which may indicate the probability of its realization and its severity in the future. The subjective approach represents the great variation among different people and organizations regarding the perception of the severity of the same risk and methods for making decisions based on the information about the risk. Naturally, the objective approach is more supported by those involved in exact science, while the subjective approach is more supported by those involved in the social and behavioral sciences.

An example of the almost unbridgeable gap between the two approaches can be seen in the behavior of two patients of the same age with similar healthcare backgrounds and socioeconomic statuses whose family doctor recommended that they undergo a colonoscopy. The objective risk assessment presented by the family doctors of the patients is the same, but the perception of the risk of colon cancer for each of the patients is different. That perception is influenced by many factors to which the patients have been exposed in the past, including their attitude

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toward the health system, past experiences with medical tests, the degree of familiarity with the family doctor and their trust in him, the family medical background, the perception of risk in the test itself, the degree of social and family pressure to perform the test, the degree of trust in the test's ability to detect colon cancer, and more.

Risk is described as the potential for an occurrence that may cause harm. Since it is a matter of potential and not certainty, in order to assess the severity of a risk, one must assess the probability of its realization and the severity of the damage it will cause if it is realized. The accepted formula for risk assessment is the degree of damage multiplied by the probability of occurrence. The two factors—probability and degree of damage—are usually evaluated on a scale of 1–5, and the 5 × 5 matrix is an accepted tool for assessing the severity of a risk. A risk assessed at a score of 25 (probability = 5, degree of damage = 5) is the most serious, while a risk assessed as 1 (probability = 1, degree of damage = 1) is not serious at all. A typical example of a risk assessment matrix is shown in Table 1.1.

The FMEA (failure mode and effect analysis) risk analysis tool developed by the JCI (Joint Commission International), which uses scales of 1–10 to evaluate each of the risk factors, is used to conduct risk audits in health institutions. In addition to assessing the probability (P) and the degree of severity (S), a probability of detection factor (PB) is also used to calculate the RPN score (risk priority number), which reflects the priority for controlling medical risks.

As mentioned before, the accepted definition of risk is as follows: Risk is a measure of the probability and severity of adverse effects [1]. However, there are differences in the definitions used by different bodies that affect the perception and principles of risk management. For example, the International Society for Risk Analysis (SRA) published 13 definitions of risk in the invitation to its first conference in 1981, and since then, the number and variety of definitions have grown [2].

Although the basic and accepted definition makes sense, it runs into many practical problems. Among them, how can one estimate the probability of risk materialization? Is it based on past experiences? And if so—what is the relevance of past experiences for assessing the probability of the risk materializing at this precise moment? In addition, it is not possible to ignore the characteristics of the specific situation for which we are trying to evaluate the probability of risk materialization, which significantly affects the probability; these characteristics include the background and experience of the medical staff; the factors that may affect the medical staff's human factors, including stress, load, fatigue, and burnout; the characteristics of the patient and his medical background; and the quality of the medical infrastructure (for an extensive discussion of the aspects of the complexity of the basic definition of risk, see [3]).

For example, suppose we want to assess the risk of perforation (puncture) during a colonoscopy. In an article published in 2009, summarizing a study of a very large population of subjects who underwent colonoscopy (277,434), it was found that 228 had perforation of the intestine. Therefore, the probability of perforation is 0.082%. It was also found that factors such as age, comorbidity, and obstruction as an indication for colonoscopy and having previously undergone invasive procedures increase the probability of perforation [4]. After assessing the

Table 1.1 The risk assessment matrix

		Severity of damage				
Severity		Negligible	Minor	Major	Serious	Catastrophic
Probability		A	B	C	D	E
Very improbable	1	1	2	3	4	5
Improbable	2	2	4	6	8	10
Moderate	3	3	6	9	12	15
Frequent	4	4	8	12	16	20
Very frequent	5	5	10	15	20	25

probability of perforation in a colonoscopy test and comparing it to the benefits of the procedure, the benefit of lowering the probability of dying from colon cancer by performing the procedure is clear [5].

In light of this average probability, a practical question is asked regarding the probability of perforation in patient X, who will undergo a colonoscopy in a given hour at a large medical center in the center of the country. Obviously, the probability varies as a function of many factors, such as the performance of the specific team in the past, the psychological and physical condition of the team at the time of the procedure, the medical condition of the patient, and the quality of the equipment. Furthermore, the probability calculation was published in 2009 for a population of patients who underwent colonoscopy in 1995–2005 under the United States Medic-Aid program, Medic-Cal, serving the population of California. What, then, is the relevance of this assessment for a patient in Israel in 2023?

A similar problem also exists regarding the assessment of the expected severity of the damage. In the study cited above, it was found that 50–100% of the patients who experienced a colonoscopy perforation had to undergo a laparotomy (opening the abdomen via surgery) to close the perforation, with a postoperative morbidity of 39% and a mortality of 25%. These data indicate that there are also different probabilities for the levels of damage, not only for the actual realization of the risk. According to the example of colonoscopy perforation, 75% of those who experience perforation will not die from postoperative complications, and 61% will not suffer from postoperative morbidity.

Moreover, damage has many meanings. In the context of risk management, damage is closely associated with financial losses, and in the context of patient safety, it is associated with physical and/or psychological harm caused to the patient. However, the concept of damage has additional important meanings, including psychological damage to the patient that might affect his future reaction to medical recommendations; effects on the treating staff, including the "second victim" phenomenon, which can impair the professional functioning of the medical staff; and systemic effects of the risk realization in the organization in the form of "defensive medicine."

A risk to patient safety is anything related to the provision of medical treatment that has the potential to cause physical/mental/financial damage to the patient, the caregivers, or the organization and that is not related to the natural development of a disease.

1.2 What Is an Adverse Medical Event?

Based on the definition of risk, an adverse event is the realization of a risk. If there is a risk of perforation during the colonoscopy, when a perforation occurs, it is an adverse event. That is, any iatrogenic damage (damage caused as a result of the medical treatment that is not a result of the natural development of the disease) is an adverse event.

An adverse medical event is an unexpected and unwanted occurrence during the medical treatment, before or after it, in which physical and/or mental damage is caused or could have been caused to the patient, caregivers, or the organization.

This definition was adopted in a slightly modified form by the Ministry of Health in a report written by Prof. Haim Hershko summarizing lessons learned from 100 investigation committees published in June 2016: "An adverse event is defined as an unwanted or unplanned development or outcome in a medical treatment process (including all previous actions) to the therapeutic process and those that come after it), which ended in harm or may end in harm to the patient" [6]. Any definition of the terms "risk" and "adverse event" has many practical consequences, including in terms of what to report, to whom, in what manner, and with what urgency as well as what is expected from the party receiving the report.

Indeed, the number and variety of definitions of the concept of an adverse event are the same as

the number of systems for reporting adverse events. We will review some of these definitions to obtain an idea of the variety and the lack of standardization.

After the publication of the Institute of Medicine (IOM) report in 1999, the US Congress authorized the National Quality Forum (NQF) to define a list of serious adverse events that must be reported by healthcare institutions in the United States.

In 2002, an initial list of 27 types of serious adverse events (or serious reportable events, SREs) was sorted into six categories: surgical events (wrong-side surgery, wrong patient surgery), events related to products or equipment (death or significant damage to the patient as a result of the incorrect use of medical equipment), events related to patient protection (suicide or attempted suicide), medical treatment events (death or significant harm to a patient as a result of drug treatment), environmental events (death or significant harm to a patient as a result of electric shock), and criminal events (sexual assault). Since then, the list has been updated several times, and different versions have been used across the United States (List of SREs) [7]. The list refers to adverse events in hospitals and is not applicable to ambulatory healthcare settings even though all categories and some events may be relevant to all healthcare systems.

The JCI (Joint Commission International), which assigns an international standard for quality and safety to healthcare institutions around the world, examines their considerations regarding sentinel events—serious events that require immediate measures to be taken to prevent their recurrence. The definition refers to events with serious harm or risk of serious harm, even if in the end, no serious harm was caused to the patient, but there was nevertheless a risk that such harm would occur.

The wide variety of definitions for an adverse event may result from the multiple perspectives from which it is possible to define an event as adverse according to the unique needs and interests of an organization. Some important considerations that impact the choice of definition are described below.

1.3 Results of an Adverse Event: Severity of Damage

The outcome of an adverse event is undoubtedly an important factor in dealing with that event. The following types of adverse events are classified according to the damage they cause:

Events with serious damage—death: Special attention is usually required for this type of event. Among other actions, reporting such an event is an obligation usually imposed by the regulator of the parties involved in the incident and their managers; the professional liability insurer requires reporting them in accordance with the terms of the insurance policy, and the management of medical institutions wish to receive immediate reports in order to take the necessary actions within the framework of managing the incident to reduce damages and attend to the patients and their families.

In the following, we will refer specifically to events according to their damage level and specifically to those with severe consequences, with the intention of distinguishing them from other events, providing sufficient warning of serious issues and raising awareness of their occurrence.

Sentinel event: An adverse event with serious consequences that requires immediate action to prevent the recurrence of similar events in the future. In a sentinel event, there is often a collapse of all the layers of protection designed to prevent an adverse occurrence of this magnitude, and therefore, they require immediate intervention [8]. The JCI defines a sentinel event as follows: "A sentinel event is an unexpected event involving death or serious physical harm or mental injury or the risk thereof. Serious injury refers specifically to the loss of an organ or function. The phrase 'or the risk thereof' includes any change in the process which can significantly change the probability of a serious adverse outcome."

The JCI distinguishes between two types of sentinel events: reviewable—those that require an investigation (RCA—root cause analysis) and not reviewable—events that do not require an investigation, i.e., events that did not end in damage (near misses) or that ended with only minor

Table 1.2 Examples of reviewable sentinel events covered by the JCI sentinel incident policy

No.	Reviewable sentinel events
1	Any patient death, paralysis or coma or other major permanent loss of function associated with a medication error
2	A hospital performing a wrong invasive procedure or operating on the wrong side of the patient's body, on the wrong site of the patient's body or on a wrong patient
3	Any perinatal death unrelated to congenital condition in an infant having birth weight greater than 2500 g
4	Assault, homicide or other crime resulting in patient death or major permanent loss of function
5	Hemolytic transfusion reaction involving major blood group incompatibilities

damage to the patient. Table 1.2 presents a selection of 5 examples of sentinel events that require investigation out of 12.

Never events are a concept coined in 2001 by Ken Kizer, who was the CEO of the NQF. These are particularly serious events, such as performing surgery on the wrong side, which can be prevented. Over the years, the list has expanded, and today, it includes 29 events in 7 main categories similar to NQF categories.

The incidence of never events is very low, but in most cases, their consequences are extremely serious. In a 2013 report, it was estimated that in the field of surgery in the United States, approximately 4000 never events occur every year [9]. In 2011, the Ministry of Health in Israel published a circular from the CEO on the subject of "Never Events" [10] in which four incidents of this type are defined: accidentally leaving a foreign object in the body during surgery; performing surgery on the wrong organ; causing a second- or third-degree burn during surgery; and making an error in blood transfusion or its products that leads to death. In addition to reporting to the patient and relevant parties, the circular requires a thorough investigation and its examination within the framework of a control and quality committee.

A near miss is an event that had no direct negative consequences but that would otherwise be adverse, which means that the process of an adverse event took place, but in terms of the consequences, the patient was not harmed. In quite a few health institutions in Israel, it is customary to call this type of event a "near miss" or "almost an incident," and this is, of course, not true since the incident happened but no damage was caused. JCI also treats "close calls/near misses" events as "adverse events" in the "sentinel event" category, and they thus do not need to be investigated, as seen in the following examples in Table 1.3, based on [8].

Table 1.3 Sentinel events not reviewable by the JCI sentinel incident policy

No.	Non-reviewable sentinel events
1	Any close call ("near miss")
2	Any sentinel event that has not affected a recipient of care (patient, individual, resident)
3	Medication errors that do not result in a death or major permanent loss of function
4	Minor degrees of hemolysis not caused by a major blood group incompatibility and with no clinical consequences

1.4 Adverse Events According to Medical Specialties

Certain specialties in medicine have a particularly high probability for the occurrence of adverse events, and therefore, they receive unique attention. These include events related to the medication administration process (ADE—adverse drug events), including errors in the type of medication, adverse reactions, allergic reactions, and overdose [11]; events in surgery; events related to pregnancy and childbirth; events related to dentistry; imaging events; laboratory events; and more.

It is estimated that approximately one-third of all adverse events in hospitals in the United States are related to drug therapy, affecting approximately two million hospitalizations per year and prolonging hospitalizations by 1.6–4.7 days. In community healthcare, adverse events occur during 3.5 million visits per year, resulting in approximately one million emergency room visits and 125,000 hospitalizations [11].

Insurance companies usually publish lists of medical specialties according to their level of risk based on the scope of the claims submitted and

their cost. The leading medical specialties in the United States, based on the scope of claims, are general surgery and obstetrics and gynecology although the volume of compensation paid in pediatrics and pathology is higher [12]. In Israel, the order is slightly different: obstetrics and gynecology and then surgery (MRM company website of the Madanes Insurance Agency).

1.5 Adverse Events According to the Nature of the Event

There are many classification methods for classifying adverse events according to the nature of the problem manifested in the event. In general, it can be said that there are those relevant to hospitals and those relevant to community healthcare systems. However, there are quite a few types of events common to both therapeutic environments, including identification errors, diagnostic errors, infections, falls and bruises, and more. Among the events that characterize a hospital environment are the development of pressure sores, operating on the wrong organ, operating on the wrong patient, and leaving a foreign object in the body. Among the events that characterize the community are failure to ensure continuity of care, multi-pharmacy, and compliance problems.

The most critical adverse events are events related to errors in diagnosis. Errors in diagnosis often have significant consequences for patient safety due to a lack of treatment provision, incorrect treatment provision, or delays in treatment provision. The basis for the definition of an error in diagnosis is very broad. One can rely on a report by the medical staff involved, a complaint/lawsuit by the patient, a revision of tests, a retrospective examination of medical records, a second opinion, or the activation of computerized tools through which it is possible to identify cases that have documented symptoms indicating a certain illness but without a proper process of examination, follow-up, diagnosis, and treatment.

Despite the importance of errors in diagnosis for patient safety, they do not receive sufficient attention from health systems [13]. One of the reasons for this is apparently that it is very difficult to assess the incidence of this type of event and its severity. According to claims data in the United States in the years 1985–2009, presented in Table 1.4, more than 25% of claims are related to errors in diagnosis [14].

Table 1.4 Causes of malpractice claims in the United States in 1985–2009

Causes of claims	Percent of all claims (%)
Errors in diagnosis	27
Improper performance	14
Failure to supervise or monitor care	11
Failure to recognize a complication	4
Medication errors	3.5
Miscellaneous	40

A study that dealt with the way doctors make decisions concluded that doctors make errors in diagnoses in 10–15% of cases [15].

Additional studies based on different research approaches, including postmortems, surveys of patients, and healthcare providers, "standard patient" profiles, second opinions, revisions of laboratory test results, medical malpractice claims, and reports of adverse events, supported these assessments [16]. There is great promise for detecting diagnostic errors in the expanding use of trigger tools and the use of big data technologies for proactive detection of cases with characteristics of adverse events [17]. In the definition of a trigger of "patients who were hospitalized within two weeks after a visit at a doctor in the community," 20% of diagnostic errors were found, which is higher than the 2% found in a normal population of hospitalized patients. More diagnostic errors were also found in the detection of discrepancies between laboratory answers and the dispensing of drugs [18].

1.6 Preventable and Nonpreventable Adverse Events

An important criterion in the classification of adverse events used by healthcare systems for the purpose of financial accounting for medical ser-

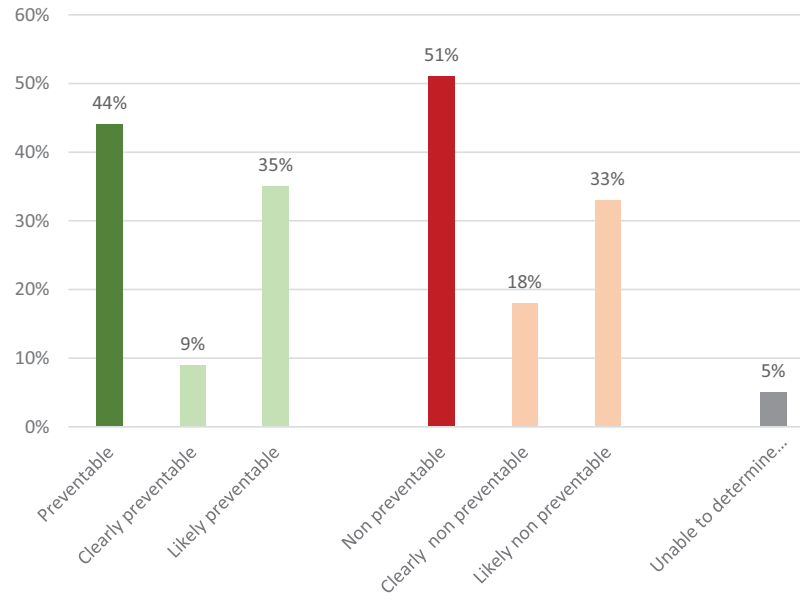

Fig. 1.1 Adverse events according to the doctor's ability to prevent them

vices provided to a patient who was injured during medical treatment is the classification of the event as preventable or nonpreventable.

In the IOM report "To Err is Human" published in 1999, reference was made to the question of whether the incident could have been prevented. It was found that close to 50% of deaths related to adverse events in the US hospital system could have been prevented. According to a report by the Comptroller General of the United States Department of Health and Human Services from 2008, it was found that approximately 44% of all adverse events were preventable, of which 9% were clearly preventable and 35% were highly likely to be preventable, as detailed in Fig. 1.1.

There are various criteria for determining whether an event could have been prevented. In Table 1.5, some of the criteria for defining an adverse event as preventable or nonpreventable are presented.

In a review published in 2008 of eight studies that dealt with the issue of the proportion of preventable adverse events out of all adverse events [20], it was found that on average, 43.5% of adverse events were preventable.

Table 1.5 Major factors that explain the doctor's ability to prevent a given event (Based on: [19])

Preventability rationale	Percentage of events
Preventable events (n = 133)	
Error was related to medical judgment, skill, or patient management	58%[a]
Appropriate treatment was provided in a substandard way	46%
The patient's progress was not monitored adequately	38%
Nonpreventable events (n = 155)	
Event occurred despite proper assessment and procedure followed	62%
Patient was highly susceptible to event because of health status	50%
Care provider could not have anticipated event, given information available	35%

[a]More than one factor could have been attributed

Key Messages: Risk

- We operate in an environment characterized by a high level of professional and personal risks.
- Most of our methods for coping with risks are automatic and based on past experiences.
- There are two approaches to addressing risks: an objective-scientific approach based on data and a subjective approach.
- Humans tend to act based on a subjective assessment of risk and do not give enough weight to objective information.
- Understanding the concept of risk is important for intelligently dealing with risks.
- There are many definitions of risk. However, most of them refer to two central features of risk: the probability of materialization and the severity of the damage.
- There is practical difficulty in assessing the probabilities of risks and the severity of the damage they may cause.
- The definition of risk that a certain organization adopts affects the way it deals with the risks in its areas of activity.
- The concept of damage is not limited to financial or physical damage. A risk that has materialized may have a psychological effect on the patient, functionally on the caregivers, and systemically on the organization.

Key Messages: Adverse Events

- An adverse event is the realization of a risk.
- There are many definitions for an adverse event that arise from different perspectives on the same occurrence.
- An organization's choice of definition of an adverse event affects the organization's approach to everything related to risk management and patient safety.
- The definition of the severity of the adverse event derives not only from the level of damage that was actually caused but also from the potential for damage that was encapsulated in the event. Therefore, even some of the "near miss" events are included in the definition of serious adverse events.
- There are many criteria for classifying and referring to adverse events in medicine, including the severity of the damage caused by the event, the uniqueness of the event, the medical field in which the event occurred, the nature of the event, and whether the event was preventable.
- It is estimated that approximately 50% of adverse events are preventable.

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The Scope of Iatrogenic Harm

2

2.1 The Scope of the Iatrogenic Harm Phenomenon

Lucian Leape, the founder of the National Safety Foundation, reported in 2000 that based on information from various sources, approximately one million serious accidents and approximately five million "near misses" occur in the United States each year [1].

A report by the Institute of Medicine (IOM) published earlier, in 1999, and based on data from 1984 collected from hospitals in the state of New York, estimated the number of preventable adverse events (PAEs) that resulted in death to be between 44,000 and 98,000. In 1997, according to this report, there were 33.6 million hospital discharges in the United States, and the analysis of the data published by the IOM in 2000 indicated an upper value of 98,000 preventable deaths [2]. These estimates motivated the US federal government to initiate intervention programs to address the phenomenon and encouraged various Western countries to take the initiative to allocate resources to mitigate the scope of iatrogenic damage.

Much criticism has been raised regarding the methodology that led to these estimates, among them that it is based on old data (30,000 records from 51 hospitals in New York randomly sampled from all discharges in 1984) and data from the New York State Hospital System only, which does not reflect the medicine in the United States as a whole. In any case, according to the aforementioned IOM report, serious adverse events occurred with 3.7% of hospitalizations, and 58% of them could be considered preventable events (PAEs). A total of 13.7% of these events ended in death. However, it should be noted that in an earlier study conducted in Utah and Colorado in 1992, the estimates were lower, and based on them, it was calculated that this figure was 44,000 deaths across the whole US hospital system per year [3]. An estimate published in 2009 determined that the number of diagnostic errors in hospitals and ambulatory medicine that cause death in the United States is 40,000–80,000 every year [4].

Many years after the publication of the IOM report in 1999, the data presented in it were widely cited and served as a basis for estimating the extent of preventable medical errors that caused deaths in hospitals. However, an article published in 2012 presented what everyone involved in risk management in medicine already knows: the reporting of adverse events contains only partial information about the scope of the phenomenon [5].

The findings of four papers that applied GTT methodologies to identify adverse events in medical records according to a defined trigger, such as the cessation of drug treatment or atypical laboratory results, which may indicate an adverse event that caused harm to the patient, were weighed based on the sample size and other

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parameters. This study concluded that the lower limit of preventable deaths per year was 210,000 [6]. However, with reference to the search limitations and incomplete information in the medical records, it was estimated that approximately 400,000 patients die each year in US hospitals as a result of preventable medical errors and that serious damage occurs in 10–20 times more cases than reported.

The question therefore arises: what are the causes of the gaps between the research on which the publication was based in 1999 and a more recent assessment, published in 2013? The answer seems to lie in the different methodologies for detecting preventable events (PAEs): the study upon which the IOM publication was based used a methodology in which medical records were reviewed by doctors, followed by an examination of the event by nurses, and finally, the definition of the event as PAE by doctors, whereas the GTT methodology appears to be more suitable than other methods for detecting PAE events because it uses defined rules for initial adverse event detection [7]. It is also possible that part of the gap originates from fundamental differences between the health systems in 1984, when the study cited IOM cited in 1999 was conducted, and the 2012 study, which was based on four studies published in 2008–2011, 25 years later.

The study conducted in 2012 [6] classified PAEs into four categories of damage: F—required prolonged hospitalization; G—permanent damage was caused; H—prolonged intervention was needed; and I—contributed to the patient's death. In the four studies, the rate of incidents at all levels of damage was between 14% and 21%, and the death rate was in the range of 0.60–1.4%. However, it should be noted that there were some important limitations in the four studies on which the publication was based, among them the fact that deaths as a result of medical errors in hospitalization may also occur long after discharge from the hospital [8].

The quality and completeness of documentation in patients' records strongly affect the GTT methodology's ability to identify adverse events, as it is based solely on medical records. In a study in which a comparison was made between errors found in direct observation and a review of medical records, it was found that the extent of errors found from the former was much higher [9].

A study published in 2008 that examined the quality of the medical records of cardiac patients randomly sampled in a variety of hospitals in the United States [10] found that the average score given to the records was 12.5 out of 20, which is 63% out of 100, i.e., a rather low score. It was also found that in hospitals whose scores were particularly low (0–10), mortality rates were 40% higher than those that received high scores for patient records management (15–20). In a study published in 2019, a comparison was made between the information recorded in patients' medical records in the emergency rooms of two university hospitals in the United States and the actions taken in practice as observed by observers; it was reported that in some cases, there are gaps between the documentation in the records and the actual treatment [11].

The partial picture of the extent of preventable events (PAEs) may also have been influenced by the caregivers' awareness that an error had indeed occurred. For example, it was found that 20–40% of the errors in diagnosis are only discovered in postmortems [1].

In a book published in 2011 that discusses strategies for reducing the volume of adverse events and improving patient safety [12], one chapter is dedicated to evaluating the rate of adverse events in medicine. In a review of studies on the subject published in 1964–2004 (some of which have been mentioned above), it was shown that the scope of adverse events in hospitalization systems (in the United States, Australia, the United Kingdom, and Canada) ranged from 3.7% to 36% of all hospitalizations and mortality rates from medical errors ranged from 2% to 20.8% of all such errors. The three most common types of events were related to drug therapy, diagnosis, and surgical procedures. The range highlights the fact that we do not know the true scope of the iatrogenic damage phenomenon and that we rely on estimates that are inherently far from accurate.

In an article published in 2016, it was claimed that medical errors are the third leading cause of death in the United States, after heart disease and cancer [13]. The statistics of the causes of death cited in this article are based on various sources, mainly on the International Classification of Diseases (ICD); therefore, deaths that do not appear in ICD coding, such as deaths caused by human errors and system failures, are not included. This is despite the fact that with the development of the fields of risk management and patient safety, it has become clear that factors such as poor communication, errors in diagnosis, poor decision-making, and inadequate skills of caregivers can cause patient death.

2.2 Causes of the Nonreporting of Medical Errors

Voluntary reports by caregivers, considering their involvement in adverse events, are valued among professionals in the field of risk management and patient safety as particularly important; a culture of transparency and learning from errors cannot exist without the voluntary, timely, and reliable reporting of errors [14].

Caregivers' reports of adverse events are influenced by the disparate needs of five parties:

- The interests of the society that represents the patients who expect complete transparency and full disclosure of errors and failures.
- The interests of caregivers and their professional organizations, which encourage reporting but also fear the professional status of the caregivers.
- The interests of medical malpractice insurance companies that wish to reduce financial losses for themselves and their insured.
- The interests of the legal system, which strives to bring the law to bear on those who caused harm during medical treatment.
- The interests of the regulatory system that tries to fulfill all these interests while focusing on the benefit to both patients and caregivers.

Caregivers may experience conflict due to the fear of being harmed following reports of their own errors by their managers, colleagues, patients, and their families as well as by the media and regulatory authorities. Therefore, it can be assumed that caregivers voluntarily report mainly incidents with real damage that cannot be ignored and rarely report incidents with minor harm and "near misses," in which harm could have been caused to the patient but in the end did not occur. Lucian Leape [14] cites Michael Cohen [15], who enumerates the characteristics of a successful system for reporting adverse medical events. Of the seven characteristics listed, the first three are intended to protect caregivers from harm that may be caused to them as a result of their reporting such events:

- The system is nonpunitive—those who make reports should not fear retaliation and punishment as a result of the report.
- The system is confidential—the identifying details of a patient, the reporter, and the institution are not transferred to a third party.
- The system is independent—the system is not related to any authorities that can punish the reporter or the institution.

To resolve the dilemma of which is better—a voluntary reporting system or one based on mandatory reporting—Leape recommends a voluntary system. However, it is also stated that in some cases, caregivers refrain from reporting due to the complexity of the reporting process since the information they are required to supply in the reporting phase is too detailed, and because the platforms and technologies used to report adverse events in medicine are not sufficiently user friendly.

With the intention of promoting the reporting of adverse events and exhausting the learning potential from them, the World Health Organization [16] published the MIM PS (Minimal Information Model for Patient Safety). This is a multilayer model, the first layer of which contains the basic and common information for all adverse events; the additional layers are dedicated to the type of event, the damage level, and

more. The model allows for the accumulation of information from different reporting systems for the purpose of processing and analyzing large databases, such as the study that analyzed the adverse event reports of the Maccabi Health Care Fund [17]. This model makes the process of reporting adverse events much easier and more accessible for caregivers than before.

Key Messages: The Scope of the Iatrogenic Damage Phenomenon

- The extent of iatrogenic damage as a result of medical treatment is unknown and depends on the methodology used to evaluate such damage.
- The extent of iatrogenic damage according to estimates from 2013 is much higher than the estimates published in 1999 and based on a study from 1984. Iatrogenic damage is the third leading cause of death in the United States after heart disease and cancer.
- The scope of adverse events in different hospitalization systems (in the United States, Australia, Great Britain, and Canada) is between 3.6% and 36%, and the mortality rates as a result of medical errors range between 2% and 20.8%. The main adverse events are related to drug treatment, diagnosis, and surgical procedures.
- Among the adverse events, it is of particular importance to refer to events that could have been prevented—PAEs. According to various estimates, they make up more than 50% of all adverse events.
- Caregivers face difficulty in reporting adverse events for fear of damage to their status in the eyes of managers, colleagues, and patients. There is also difficulty in reporting due to a lack of clarity about what and to whom to report, an organizational culture that does not encourage reporting, and due to a cumbersome reporting process.

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3 Development of Patient Safety and Risk Management in Medicine

3.1 Definitions

Patient Safety: A state in which the risk of causing harm to patients, caregivers, and the organization as a result of medical treatment is identified and controlled. The accepted definition of patient safety is a state of absence of damage as a result of preventable adverse events during medical treatment [1].

Risk Management: Risk management comprises concepts and methodologies that help make risks in medical care manageable and are applied to identify, evaluate, and control risks as well as draw lessons from adverse events.

Quality in Health Care: This concept includes approaches and methodologies aimed at reducing variance in the provision of medical care that use measurement as a means of promoting quality in medical care. The accepted definition of quality in medicine comes from the American Institute of Medicine (IOM Institute of Medicine) from 2001 [2], which describes the characteristics of quality care as safe, effective, patient-centered, timely, and equitable.

3.2 What Are the Differences Between Safety, Risk Management, and Quality

Even though the three areas often mix and integrate with each other, and there is undoubtedly an overlap among them, it can be said that safety, as a state of the absence of risk, will always remain the goal, while risk management and quality are the means to achieve this goal. A basic comparison among the three areas is shown in Table 3.1.

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Table 3.1 Comparison of safety, risk management and quality

Characteristics	Safety	Risk management	Quality
Basic assumptions	• Risks are a characteristic of every reality. There are high-risk work environments: Aviation, medicine, nuclear reactors, etc.	• Risks can be managed by identifying, evaluating, and reducing the probability of their occurrence and controlling the severity of their damage.	• It is possible to improve processes and thus reduce the risks at the same time as creating higher quality products/services and doing so more efficiently.
	• It is possible to control risks.	• There are three basic approaches to risk management: Reactive, proactive and interactive.	• The means promoting quality by defining indicators and monitoring them continuously.
	• Safety can be improved by using personal protective measures and measures to contain the risk that may reduce its effects.	• Reactive risk management is learning from adverse events in order to reduce the probability of their recurrence.	
Strategies for mitigating risk	• Defense and risk containment.	• Identifying and studying the risks and defining controls to reduce the probability of their occurrence and/or the severity of the damage.	• Improved monitoring and measurement of the process and products, thereby improving the quality of products/services and reducing risks.
Requirements for application	• Identifying hazardous work environments.	• Conceptual change from protection against the risks to proactive activity.	• Definition of critical processes.
	• Development of effective protection, containment and resilience measures.	• Investing resources in identifying and reducing risks.	• Defining process and product quality indicators in critical processes.
	• Implementing these means.	• Maintaining a systematic and continuous process of identifying, evaluating and improving controls.	• Learning quality management methods and implementing them in the organization.
		• Commitment of senior management.	• Establishing a quality management infrastructure in the organization.
		• Legislation that encourages learning and not punishment.	• Senior management commitment.
Effect on risks	• There is no effect on the risk itself.	• Reducing the probability of risk materialization and/or the severity of the damage if the risk materializes.	• Reducing the probability of risks materialization and/or their severity.
		• Possibility of creating other risks.	• Improved process/product quality and efficiency.

3.3 Importance of Risk Management

In a review of risk management history in the years 1991–2002, it is claimed that risk management is one of those ideas based on the belief that a logical and systematic approach to the uncertainty regarding the future will allow us to live wisely and creatively while avoiding the unnecessary waste of resources [3]. In his book *Against the Gods: The Remarkable Story of Risk*, the author Peter Bernstein, argues that if everything is a matter of luck, risk management is a meaningless concept. Expecting that luck will happen is contrary to the truth because it separates the event from its causes [4]. Bernstein describes

how thinking about risk management developed as a result of changes in mathematical concepts, in our understanding of the subject of probability and in the interest in gambling and the laws governing it.

Risk management is anchored in cultures, beliefs, and attitudes that individuals, companies, and organizations develop and adopt. The approach regarding risk management is conditioned by the belief that risks can be managed and are not the result of either good or bad luck but of actions or a lack of actions. Furthermore, the reality we create and live in can be seen as a consequence of our approach to risks. Dramatic events in human history—inventions, wars, natural and human-made disasters—affect our perception of risks and our belief in our ability to manage them. Such major disasters that have been burned into the human consciousness and affected our approach to risks include the sinking of the Titanic, the reactor disaster in Chernobyl, the crash of the space shuttles Challenger and Columbia, the global financial crisis that started in 2008 and resulted in banks and large companies collapsing, and more recently, the coronavirus pandemic that clarified the importance of considering the whole range of risks it provoked and not just direct risks of morbidity as a result of the spread of the different variants of the virus. All these, in addition to natural disasters such as earthquakes, volcanic eruptions, floods, and tsunamis, are relevant here. Risk management is therefore opposed to the notion that what happens to us is a matter of luck and that the future is completely uncertain.

We can argue that the field of risk management developed following the exhaustion of the possibilities of the field of safety, which mainly focuses on protecting against risks and containing them, an approach that did not solve the fundamental problem of the existence of risks and the challenge of controlling them.

The basic concept of risk management is anchored in the world of insurance. Insurance companies sell policies for future risks; when a person buys a policy, he buys insurance in case the risk materializes, and then he will receive compensation aimed at covering the amount of damage he has suffered. A critical question insurance companies face is how to assess which risks will materialize in the future and what the damages will be if they do materialize. Without this knowledge, the insurance company could lose a great deal of money. To manage the information about the risks, an insurance company evaluates—in light of past experience, the analysis of future trends and probabilistic and actuarial models—the different types of risks according to the probability of their materialization and the degree of damage they may cause if they materialize. Using such information, the insurance company will be able to calculate the amount of compensation it will have to pay to its policyholders. This amount, plus overheads and a profit component, is the basis for the pricing of the policy. Changes in risk assessments as a result of changes in their realization will lead to an increase in premiums. This basic model, which includes identifying risks, methods for evaluating them, and calculating premium costs, which keep insurance companies in a positive balance, is the foundation of the risk management concept.

The idea that future risks can be identified and evaluated based on past experience and that control measures can be determined whose implementation may reduce the chances of their occurrence and the damages caused by them if they do occur is the foundation of all risk management programs. This is a proactive idea; i.e., there is no need to wait for the risk to materialize, but it is possible to prepare for it and reduce its negative consequences ahead of time. An important element in risk management is learning from adverse events in which risks have materialized in order to improve risk assessment and control over their reduction, i.e., the means to reduce the probability of their materialization and, if they materialize, the severity of the damage caused.

The quality field is a natural development of the risk management field. Because a significant part of the controls aimed at mitigating risks are related to the improvement of work processes and decreasing variance based on the assumption that safe products are the result of correct and proven work processes, the quality field aims to improve key work processes in the organization

by measuring them and making them standardized, thereby reducing the risks that individuals and companies will be exposed to.

3.4 History of Risk Management

A historical review of risk management indicates that the linguistic roots of the word risk are probably in the Old French "risqué," which means a danger that has an element of chance [5]. The word "hazard," which is often mentioned in the context of risk management, probably originates in the land of Israel in the days of the Crusaders from the Arabic name of a dice game [6].

Although it was already common to gamble in ancient Egypt, as evidenced by a wall painting in a tomb dated to 3500 BCE, it was only during the Renaissance that the mathematical and statistical basis of the theory of gambling began to be formed. The well-known Western numerical system appeared in Europe only in the tenth–twelfth centuries, and only during the Renaissance did it completely replace the ancient Roman numerical system. The first treatise on the probabilities in card games, dice, and other gambling games was written by Girolamo Cardano, a sixteenth-century mathematician, physicist, and gambler. The book was published posthumously in 1663 [7]. Another well-known scientist who contributed to the understanding of the field was Galileo, who wrote a short essay on the game of dice in 1630 [4].

An early form of life insurance was practiced in Greece and Rome and was provided by trade and craft guilds. With the spread of trade in the Middle Ages, new forms of insurance appeared against disaster risks, including floods and droughts.

The English company Lloyds, which is probably the most famous insurance company, was founded in 1687 in a cafe near the Tower of London, which used to be frequented by captains of merchant ships who passed information on the voyages they had or planned to take part in, on weather, on various risks involved in the voyages, and more. Those who were willing to share the risks of a particular voyage and the expected profit signed their names on a special board and accepted the terms of the contract. This is how the term "underwriter" came to be.

The industrial revolution in the nineteenth century sparked interest in risk management because it added risks caused by the integration of new technologies into production processes and everyday life. The invention of the steam engine and its adoption in industry and transportation changed the attitude of the general public and governments toward risks. The public was exposed, for the first time, to disasters on a large scale as a result of train collisions and derailments. Since the Industrial Revolution, the exposure to risks has been increasing: the spread of nuclear reactors for energy production, the usage of massive sea tankers, an enormous increase in civil aviation, the expansion of space utilization for commercial purposes, and the development of chemical and biological industries—these are only examples of risk factors that did not exist until the industrial revolution.

Six stages in the historical development of the field of risk management based on the reviews of Louis Rubin and James Vesper [3, 5] are presented in Table 3.2.

The development of risk management is therefore a consequence of, on the one hand, increasing exposure to risks and, on the other hand, growing public awareness of the cumulative effects of exposure to personal and environmental risks, as well as the development of concepts and methodologies for risk management, along with a belief that risks can be managed. Organizations committed to coping with adverse events have developed work processes aimed at defining standards to reduce risks. The current thinking on risk management ranges from being based on guidelines and procedures that define how each individual in the organization should act in relation to each risk to a more flexible paradigm that refers to unique risks as well as routine risks, problems, and opportunities. In *The Economist*, a British economic journal founded in the nineteenth century that reflects an independent and accepted position on economic issues, it has been said that risk management is one of the responsibilities for which managers are paid, but most companies still have no idea what is required in terms of risk management [8].

Table 3.2 The development stages of the field of risk management

Phase	Development
Phase 1	Humans are motivated to protect themselves from known risks.
Phase 2	There is an attempt to divide the individual risks among a group of stakeholders in order to reduce the risk exposure of each individual, thus creating the demand for insurance services.
Phase 3	Scientists are interested in and attempt to formulate the laws of probability—essentially gambling in statistical and mathematical terms.
Phase 4	With the beginning of the industrial revolution, there is a significant increase in the exposure to various types of risks and their severity; the need arose for the state to become involved in order to regulate and control the use of the new technologies and make them safe.
Phase 5	In the last several decades, an attempt has been made to design systems and processes in order to reduce their risks a priori and to improve existing processes through the application of quality concepts.
Phase 6	In the future, there will be an assimilation of risk management principles in all areas of activity, not only the areas traditionally marked as high risk; the promotion of patient safety culture, not only reactions to adverse events; and the wide use of technology an AI to monitor systems for immediate risk identification and control.

3.5 Motivation to Engage in Risk Management Activities

The motivation, especially that of managers, to engage in risk management and patient safety is an important issue to examine since the position of management in promoting a safety culture in a medical organization is the key to promoting patient safety in practice (see a detailed discussion on this topic in Chap. 4). It is equally important to understand the effect of managers' responses to errors and failures and learn from them on the motivation of their subordinates to voluntarily share and report errors and failures. An issue that has almost no reference in the literature is what factors cause managers to be reluctant and unwilling to deal proactively with these issues. Common sense says that we do not like to deal with our errors and failures or those of our subordinates or organizations, and we prefer to deal with successes rather than failures. One extensive review on learning from failures and errors [9] analyzes the factors that motivate learning from such issues, dividing them into three groups:

- The opportunity, which is the available information about errors and failures as well as "near miss" events.
- The motivation, which is the desire to learn from errors is hindered mainly by managers and organizations with a punitive approach.
- The ability, which includes the attitudes and qualities that can be developed through education and training and the adoption of successful learning processes.

To understand the extent to which the topic of risk management and safety is rooted in our daily existence even without us noticing it, we will refer to the issue of motivation to engage in risk management from five different aspects that drive the development of the field of patient safety and risk management in general and medicine in particular:

- The evolution of the animal world.
- The hierarchy of our needs as humans.
- The professional ethics of doctors and other caregivers.
- Our empathy as humans for the suffering of others.
- Economic aspects.

Walter Cannon, an American physician and physiologist, formulated the "fight or flight" principle in 1915. According to this principle, every organism is constantly engaged in assessing the level of threat it encounters, especially when confronting other organisms. Risk assessment is instinctive and immediate; it causes a series of physiological reactions that allow the organism to fight or flee, depending on the results of the risk assessment. Among the physiological reactions, we can mention the secretion of adrenaline that causes blood to flow to the muscles of the limbs,

the dilation of the pupils, "tunnel" vision that focuses on the threat or the target, the acceleration of the heart rate, rapid breathing, and more. These physiological changes can be interpreted as a mechanism of evolutionary risk management designed to assess the risks and increase the chances of survival. In case of an error in the risk assessment, the organism may pay with its life.

In the world of medicine, the motivation for patient safety draws inspiration from Hippocrates, a Greek physician who lived around 370–460 BCE and formulated the doctors' oath that forms the basis of medical ethics to this day. Opinions differ as to the origin of the saying "Primum no Nocere" or "First do no harm." Some attribute it to Hippocrates, and it appears in different versions in the doctors' oath. The practical meaning of this statement is that before any medical procedure, the caregiver must think about possible risks and make sure that the treatment he intends to provide will not harm the patient. Furthermore, the therapist must perform the treatment while taking the necessary precautions to reduce the risk of harm to the patient as much as possible. This is the first ethical obligation of every caregiver.

The principle "thou shalt love thy neighbor as thyself" (Leviticus Chapter 19, 18), to which Rabbi Akiva attributed great significance and stated that it is a fundamental rule in Judaism and a principle that is also fundamental to the concept of morality in Christianity, is the basis for understanding the suffering of others and a central motive for preventing harm in medical treatment: If I empathize with others, I will try to do everything possible to prevent him from suffering. Empathy is at the root of the "second victim" phenomenon, in which a therapist who has inadvertently caused harm to a patient experiences a wide range of psychological and physiological phenomena that may impair her professional functioning and well-being (see a detailed discussion of this topic in Chap. 14).

Economic motives have great meaning in every activity in modern society, and they have a central place in the development of the field of risk management in medicine. Currently, it is not possible to practice medicine without having valid professional liability insurance, which serves as a source of compensation for victims of medical errors. The direct cost of medical errors in compensation payments to victims in the United States reaches approximately $3.6 billion annually. The indirect costs increase the total cost—additional hospitalizations, loss of working days, costs of support systems, and more—to approximately 40 billion dollars a year in the United States. As already mentioned, mortality as a result of medical errors is the third leading cause of death after mortality from heart disease and cancer.

In Israel, according to a report by a Knesset research committee published in June 2017, in 2005–2015, the Israeli government's medical institutions compensated victims of medical errors with approximately 2.32 billion NIS following malpractice claims. In general, there was an almost twofold increase in the volume of payments for medical malpractice claims in those years, from approximately NIS 138 million in 2005 to approximately NIS 262 million in 2015.

It is impossible to discuss the motivation for risk management without referring to psychologist Abraham Maslow's concepts regarding the need for safety—that is, security in physical existence [10]. According to Maslow, as presented in Fig. 3.1, in the hierarchy of human needs, the need for safety ranks after physiological needs.

When physiological needs are satisfied, an array of new needs appears, called safety needs in physical existence. If these needs are not satisfied, they become the organizers of behavior; that is, there is a very strong motivation to satisfy them. Moreover, such needs become not only the organizer of behavior in the present but also the main goal in life, sometimes at the expense of satisfying physiological needs. Maslow assumed that humans prefer a safe world in which there is order and predictable laws and that unexpected occurrences (adverse events) and uncontrollable risks would be very rare. Humans prefer familiar situations over unfamiliar ones, the known over the unknown. The tendency to adopt religious beliefs, practices, value principles, and life philosophies can be interpreted as a tendency motivated by the need for safety.

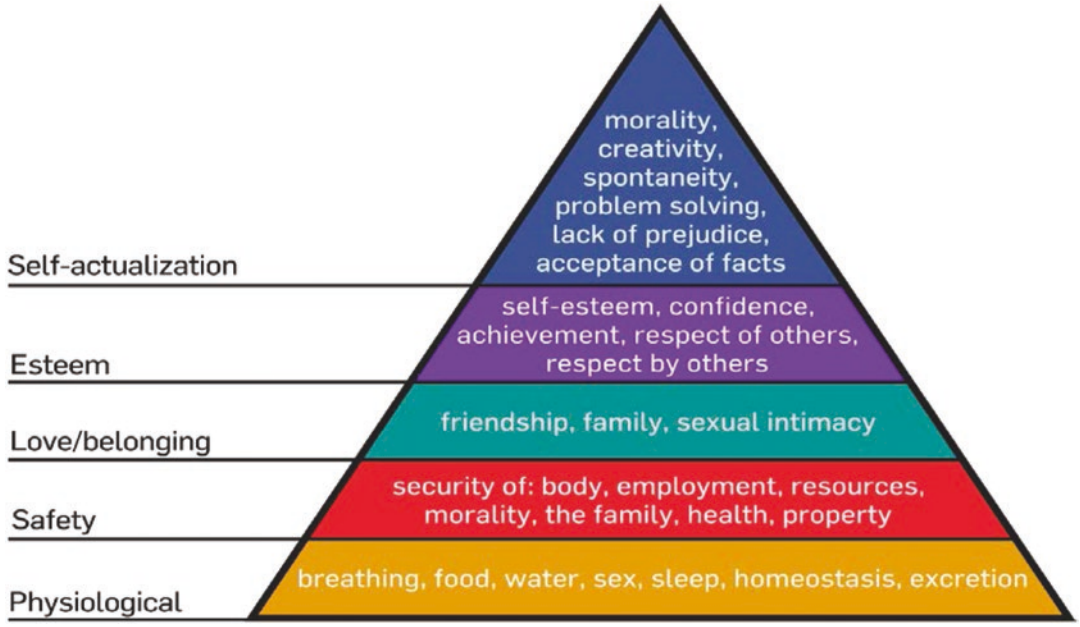

Fig. 3.1 Maslow's hierarchy of needs. (https://commons.wikimedia.org/wiki/File:Maslow%27s_Hierarchy_of_Needs.svg)

An organization, like an organism, will act to manage and control risks when its safety needs are not met and less so when it experiences a sense of security and control. Following a major crisis in an organization, safety needs become the organizers of its behavior until stability and a sense of safety are restored. To restore safety, the organization is ready to give up fundamental goals for which it exists. Due to their nature, risks materialize and cause more damage to organizations that do not experience an existential threat, do not take appropriate precautions, and cause less harm to organizations that manage their risks routinely as an organizational strategy. As already mentioned, there is a clear preference for the known over the unknown, and from this preference stems the motivation of an organization to adopt risk management concepts and practices. Risk management embodies a promise to turn the unknown into the known, thus eliminating elements of uncertainty that cause anxiety.

Compulsive obsessive neurosis is a neurosis in which the desire for safety is acutely expressed. Those who suffer from it try to bring order and stability to their world so that uncontrollable, unexpected, and unknown risks do not materialize. Those who suffer from it protect themselves with rituals, laws, and formulas for every situation to avoid surprises. The way the global financial system managed its risks before the crisis of 2008 reminds us of the symptoms of this neurosis. In those years, the banks suffered from widespread fraud and embezzlement, which perhaps explain the obsessive measures they took in their attempt to defend themselves against any possibility of fraud. In light of the financial scandals that took place at, among others, Enron, Worldcom, and Tyco, the US Congress passed the Sarbanes-Oxley Act in 2002, named after Congressmen Paul Sarbanes and Michael Oxley, which was designed to protect shareholders and the general public from accounting errors and fraudulent practices by large corporations [11]. The law established deadlines for reporting and published rules regarding reporting requirements. It is possible that the obsessive need for safety explains the demand of many organizations for complex mathematical models, which if known values are input into them, yield results regarding the assessment of future risks.

Many studies have examined the motivation of employees for safety, but only a few have examined the motivation of managers and organizations for safety and risk management. However, it seems that it is possible to infer, to a certain extent, based on individual and organizational motivations for dealing with safety. For example, in one study, a strong relationship was found between motivation for safety and the need for job security [12]. That is, employees who showed motivation for safety at work also developed motivation for employment security (certainty of employment) and vice versa. In our opinion, this finding strengthens the aspiration for the need for safety as an organizer of behavior: it is possible that in organizations where safety incidents occur frequently, the sense of security that employees have in their workplace is challenged, and vice versa—where the sense of occupational security of the employees is challenged, safety may also be affected.

J. Andriessen, a Dutch researcher in the field of organizational and industrial psychology, proposed that rather than considering safety behavior as one whole, we distinguish its components [13]. For example, there are two types of behaviors that make up safe behavior [14]:

- Safety compliance—compliance with safety laws, such as wearing protective equipment and working according to procedures.
- Safety participation—participation in activities that increase safety in the organization, such as voluntary safety activities.

The psychological empowerment of employees is a subject that also receives research attention in the context of work safety. In a study that investigated the issue in a variety of industries, nearly half of the participants in empowerment-based safety training reported that they or a coworker had an improved attitude toward health and safety following the training [15].

An extensively researched area is the influence of managers on employee motivation for safety. For example, it has been found that management's commitment to safety is a major factor affecting the safety atmosphere in the organization [16]. It has also been found that management greatly influences safe behavior and safety results in an organization [17]. The explanation for managers' influence on safety in an organization is that different aspects of the work environment affect the way we think about the expectations for the results of behaviors, which in turn affect behaviors and then the accident rates in the workplace [18].

Table 3.3 Four dimensions of safety behavior structures

	Focus on oneself	Focus on others
Focus on the future	• Knowing the risks at work and legal aspects related to safety	• Participation in health and safety committees
	• Behaviors that prevent damage and risks to health	• Behaviors that contribute to shared responsibility for a safe work environment
Focus on the present	• Behavior designed to protect oneself from acute harm	• Behaviors aimed at compensating for lack of knowledge, experience or vigilance among other workers and thus at preventing damage and losses
	• Safe performance of activities and tasks in a manner that does not harm the safety of others	• Teamwork to crosscheck critical stages in high-risk activities

Table 3.3 presents safety behaviors in four dimensions and is based on the assumption that safety behaviors can be categorized according to time span—future or present—and according to the factor that they may affect—oneself or others [14].

The factors shown in the table indicate that the psychological empowerment of employees, the management's commitment to safety, and identification with the organization are related to safety behaviors more than are factors related to personal safety and that psychological empowerment has a strong influence on behaviors with regard to the future and safety of others.

In view of the importance of psychological empowerment on the part of management as a factor in achieving safety results, the question arises as to whether health systems attribute sufficient weight to this factor. We are not aware of studies on this question in the world of medicine. Medical teams often find themselves caught in a sort of trap between management's demands to provide high-quality and safe health services on the one hand and strict control over the time allotted for patient visits and the means used on the other hand. This, in addition to pressure from patients to provide them with the most advanced medicine without delay, is accompanied by pressure from the regulation and legal systems. Psychological empowerment, which increasingly occupies an important place in the understanding of employee motivation, especially in light of its prominent effect on safety, therefore requires special attention on the part of health system managers.

3.6 Effect of the Economic Crisis in 2008 on the Perception of the Importance of Risk Management

The global economic crisis in 2008 raised the issue of financial risk management and its adaptation to be more effective in preventing future crises. Paradoxically, it can be said that the financial systems in the Western world are pioneers in orderly and systematic risk management. Protocols based on the Sarbanes-Oxley Act, the activity of COSO (Committee of Sponsoring Organizations of the Treadway Commission)—an independent financial committee founded in 1987 in the United States and designed to help organizations improve in the areas of internal audit, risk management, governance, and deterrence against embezzlement—and Basel 2—an international committee for the supervision of banks that formulated standards for their activity and capital adequacy and published agreements on this subject in 2004—defined how a financial institution should properly manage its risks. However, in retrospect, it seems that this approach could not prevent the collapse of large financial systems.

In this context, we believe that formal and bureaucratic processes of risk management, even though they are successfully able to deal with known risks to some degree, cannot deal with unknown risks. The field of risk management should be flexible, refer to a changing reality inside and outside the organization, and act continuously to detect, evaluate, control, and monitor risks while constantly examining its mechanisms and learning from adverse events. It is dangerous for risk management to indulge in quantitative models only and eliminate the contributions of common sense and qualitative approaches.

In the risk management analysis of the financial crisis that occurred in 2008, it was claimed that, among other issues, complicated mathematical models that were developed to predict outcomes and probabilities based on past performance have failed and that they should be rethought [19]. Among other conclusions, it was said that we learned a lot about the limitations of models and that risk control is not as good as it should be. The crisis highlighted two important points in the context of risk management that have implications for the future:

- Businesspeople, economists, and academics deal with risks differently than company managers. In the context of risk, diversity is important to academics, while the most important thing to managers and businesspeople is loss as a result of risk materialization. If the risk of loss or damage is too high, in most cases, managers will withdraw from the situation.
- In risk management, there is no magic solution that will solve all problems all the time. Companies that wish to take risks seriously should develop an integrative approach and not just classify risks into groups: operational risks, market risks, credit risks, etc. For example, most of the officials in the field of risk management specialize in credit risks and are not skilled in thinking about other types of risks. In other words, without an integrative view of risk management, the organization is likely to encounter significant problems.

The failure of financial risk management, as it was practiced until 2008, raised the need to re-examine the applicability of mathematical models based on past data for future risk management, as was argued in an article by Arvan Michel-Kerjan [20]. It is about a new architecture of risk management known as risk management 2.0. The claim is that in every field, there is a trend of rapid changes that require rapid decision-making based on information that is not always available. It is of course preferable to gather all the necessary information and then make decisions, but the reality is that managers have to make decisions in situations of uncertainty, sometimes with a complete lack of knowledge. To address this reality, many companies practice traditional risk management—known as risk management 1.0—which focuses on examining the current state of the company and analyzing what could go wrong. However, in order for companies to properly manage their risks, they must look outside their own walls because these days, companies are much more dependent on each other than in the past. We are used to solving problems when the questions are clearly formulated based on clear knowledge and an understanding of the history of the problem. However, past information does not shape the future when the rate of change is very rapid. We used to study the data of the past and draw diagrams where one axis was the severity of the damage and the other axis was the probability risk materialization, but today, risk management 1.0 has largely become obsolete.

At one of the conferences that dealt with risk management and patient safety that took place in Israel in 2015, a risk survey conducted at one of the major hospitals was presented. The survey, which was very detailed, compiled 3 years worth of data and described a long list of clinical and operational risks. However, a question immediately arose regarding the relevance of the survey in light of the many changes that have taken place since then in the Israeli health system and most likely also in the hospital where it was conducted. Certain risks obviously lost their strength, and other risks emerged that the survey did not address. From this, it is clear that risk management must be dynamic and adapted to the rate of change in the discipline it analyzes; otherwise, risk management actions are unnecessary and even dangerous.

The new approach to coping with risks, risk management 2.0, aims to address unknown risks and the relations and interfaces among different risks, since as mentioned, it is no longer possible to address each risk separately [20]. For example, the vice president of risk affairs at Danone testified that he makes little use of mathematical models even though they are applied for certain risks [19] and works to implement a new approach that relies much more on interviews and the exchange of opinions and ideas with colleagues outside the company and within subsidiaries worldwide. This approach is based on listening, challenging operational managers with questions, analyzing risks based on common sense, making sound judgments, and engaging in good management.

In the last pages of his book, Peter Bernstein described the difficulties faced by many companies in the world [4]. According to him, "There is nothing more soothing or convincing than the computer screen, with its impressive sets of numbers, brilliant colors and graphs. When we stare at the passing show, we are so absorbed and we tend to forget that the computer only answers questions and does not ask them. Those who live only by numbers may find that computers have replaced the oracles that people turned to in ancient times."

Phil Rosenzweig from the Harvard Business School [21] agrees with Bernstein's approach and warns managers against relying on models that seem convincing due to their sophistication and the impressive amount of data in them, which may create the illusion that we understand the factors and reasons involved, when in fact, this is far from true. He calls this phenomenon the Delusion of Rigorous Research and claims that we forget to take into account that the quality of the data may be poor.

Risk management since the 2008 economic crisis has therefore placed the risk manager in a different position than that of an implementer of techniques, methodologies, and models. The risk manager must now adopt integrative strategic

thinking and look at all the organization's activities and the relationships among them, as well as relevant external realities and their impact on the organization. Risk management 2.0 is not separated from the organization's core activities but is part of it, influences it and is affected by it; it is flexible and constantly examines existing paradigms, challenges managers and employees with essential questions, and is not afraid to "slaughter sacred cows" in order to ensure that the organization survives and prospers.

Key Messages: Safety, Risk Management, and Quality in Medicine

- Among the three disciplines—safety, risk management, and quality—there is confusion and overlap. However, it is important to understand the uniqueness of each field as a separate discipline with its own basic concepts, principles, goals, and methods of operation.
- The field of risk management developed due to the motivation of people to protect themselves from known risks. The future challenge of the field is to maintain and develop a safety culture that covers all areas of a company's activity.
- The practice of risk management is based on Maslow's hierarchy of needs, the "fight or flight" instinct, ethical principles in medicine, empathy for the suffering of others, and the cost of damages caused during medical treatment.
- The question of the effectiveness of the protocols for risk management that exist in the global financial system, which arose following the global economic crisis in 2008, has required the formulation of new concepts for risk management (Risk Management 2.0) due, among other factors, to rapid technological changes and a great deal of information about possible risks.

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4 Safety Culture and Its Improvement in a Medical Organization

4.1 Development of the Concepts "Organizational Safety Culture" and "Safety Climate"

After World War II, researchers began to show interest in organizational climate and organizational culture, trying to understand how organizational characteristics affect performance.

The concept of organizational climate is related to variables such as service level, safety, and innovation and replaces previous references that were general and unfocused [1]. Due to the lack of a precise definition, the terms "safety culture," "safety atmosphere," and "safety climate" are used interchangeably. While the concept of "organizational culture" refers to a broad spectrum of permanent characteristics, the other two concepts refer to the characteristics of an organization that define its attitudes and actions in the field of safety.

A "safety climate" according to Dov Zohar [2] is "a shared perception of employees regarding the relative importance of safe conduct in their behavior at work." It implies a shared social understanding regarding the importance of safety in relation to the goals of the organization. A safety atmosphere communicates to employees the order of priority of safety in work processes—a positive safety atmosphere increases the frequency of safe behaviors and a negative safety atmosphere decreases the frequency of safe behaviors. Confusion among different concepts creates a lack of research clarity and casts doubt on the validity of some studies in which there is no clear distinction among them. A safety climate should therefore refer to employees' perceptions of the importance of safety in the organization.

There are gaps between the statements of managers regarding the importance of safety, especially in organizations where employees face high risks at work and employees' perception of the priorities regarding safety versus the importance attributed to production. An analysis of the indices in a 40-item questionnaire designed to assess the safety climate in an organization [2] revealed that only eight of the indices define a safety climate. In later studies, the number of indicators was reduced [3], and four indicators for an organizational safety climate were defined: management's commitment to safety, rewards for safe behavior, the effect of required output on safety, and the effect of safe behavior on social status.

Due to the instability of the factors that have made up the concept of a "safety climate," in the last decade, a tendency has developed to link one central factor, mainly "management commitment" to safety results [4]. It has been found that employees' attitudes regarding managers' commitment to safety have direct predictive validity regarding safe behavior at work and the severity of injuries (measured in days of absence from

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work) and indirect predictive validity regarding the total rate of safety incidents per 100 employees per year and the rate of days of absence per 100 employees per year [5, 6].

To examine the impact of a safety climate on errors in the provision of medical care, four main dimensions have been defined: the caregivers' perception of management's commitment to safety, the priorities of safety versus production, the implementation of formal safety procedures, and the dissemination of information on safety issues to caregivers [7]. A direct relationship has been found between the managers' perception of safety and the level of safety in the organization. It has also been found that the relationship between the level of detail for procedures and the rate of errors in the treatment is not straightforward. That is, there is an optimum level of detail for procedures where the rate of errors is the lowest, and if the procedures are too detailed or not enough so the rate of errors increases. Authors have explained these findings as being due to the complexity and great variation of the work processes in hospitals that do not allow full "coverage" of a given medical practice in the procedures.

The explosion of American space shuttles Challenger, in 1986, and Columbia, in 2003, were significant catalysts for adoption of the concept of safety culture as a foundation for preventing accidents, disasters, and systemic failures. In the official report of the Columbia Accident Investigation Board, Report Volume I, August 2003 [8], in the chapter dealing with the causes of the accident (Chapter 5, p. 97), it is stated, among other causes, that "In our opinion, NASA's organizational culture contributed to the accident not less than the sponge." The investigative committee assigned NASA's organizational culture the same weight in causing the accident as the technical failure of the insulation tiles that fell apart. Later in the same paragraph, organizational culture is defined as fundamental values, norms, beliefs, and behaviors that characterize the organization's functioning.

According to the authors of the report, the organizational culture defines for employees the basic assumptions in their work and influences their decision-making. Corporate culture is a strong "force" that survives restructuring or personnel changes in management, which can be positive or negative. In Chapter 8 of the report, the committee details the influence of the culture on the actual decision-making and behavior of NASA managers: the culture made it possible to fly with flaws and to treat problems as routine. The risk assessments in the project were not updated as required because the review did not go up the management hierarchy. Additionally, a safety system that was weakened over the years was not able to analyze the risks and intervene but only to confirm existing risk assessments.

The investigation report of the Challenger crash in 1986 [9] also referred to the weakness of the safety system at NASA, which did not mandate reporting problems, lacked risk analysis processes, and misinterpreted the importance of the problems: "Unfortunately, the Rogers report's recommendation to establish a significant and independent safety system that would deal with reliability and quality assurance problems was not implemented as required."

According to the Columbia crash investigation report, as stated above, a weakened safety system was a significant factor in the accident: "NASA should establish an office for safety, reliability and quality assurance, headed by a deputy director who reports directly to the NASA director. He will have direct authority for safety, reliability and quality assurance throughout the agency. The office should be assigned the necessary personnel to ensure full fulfillment of all its functions and should be independent of any other NASA program."

Chapter 8 of the report states that managers' responsibility is to promote a clear and mandatory culture of safety in the organization. NASA managers believed that the safety culture in their organization was solid, even though it had not changed since the Challenger days and had conflicting goals. The operational pressure to launch impaired the ability to ensure mission safety. Leaders create the organization's culture, and it is their responsibility to change it if it is not right. Senior managers must take responsibility for risk, failure, and safety by maintaining an aware-

ness of the effects that their decisions have on the system: "Leaders are responsible for establishing the conditions that lead their subordinates to success or failure."

The concept of "safety culture" appeared for the first time in 1986 in a report of the INSAG [10], the body that advises the International Atomic Energy Agency on safety issues. In many places in the report, on the Chernobyl nuclear disaster, the lack of a "safety culture" was cited as an important factor in the causation of the disaster.

In 1991, INSAG published a special report entitled "Safety Culture," [11] which aimed to define what safety culture means in the nuclear industry and how it can be evaluated and improved. The definition in this report is specific to safety in nuclear reactors and is different from the definition of safety culture derived from the more general concept of organizational culture: "Safety culture is that set of characteristics and attitudes in organizations and individuals, which states that safety issues in nuclear plants receive the attention required by their significance."

According to this definition, safety culture is an array of characteristics and attitudes of organizations and individuals who place safety issues with a nuclear reactor as a high priority for attention. According to this publication, there are three levels of commitment to safety culture: policymakers, managers, and employees.

1. **Policy level commitment:** should provide a clear statement of safety policy, define management structure, allocate and assign resources, and define self-regulation procedures.
2. **Management level commitment:** should define responsibilities, define and control safety practices, provide qualifications and training, define rewards for safe behavior and sanctions for unsafe behavior, and conduct audits, reviews, and comparison activities.
3. **Individual level (employees) commitment**: should adopt and practice a questioning attitude, adopt a rigorous and prudent approach, and understand the importance of sound communication with other employees, managers, and customers.

One of the suggestions regarding organizational safety culture has been to refer to it according to the goals it is supposed to achieve and to define a series of activities that can be examined and evaluated [12]:

- Reduction in accidents and injuries.
- Assurance that safety issues receive the appropriate attention.
- Assurance that the employees in the organization share the same perceptions and attitudes with regard to risks and accidents.
- Increases in employees' commitment to safety.
- Definition of the format and quality of a safety plan

The relationship between safety culture and safety climate in high-risk organizations is very difficult to prove due to methodological difficulties (most studies rely on attitude questionnaires and not on proven results), but the relationship does appear to exist to one degree or another [13].

4.2 Safety Culture in Medicine

The interest in organizational safety culture in medicine arose after the publication of the IOM report [14], "To Err is Human." For the first time, the organization's importance was emphasized in removing obstacles and barriers to safe conduct ("plugging the holes in the Swiss cheese") and protecting caregivers who intend to do well but do not and thus may err. The report explicitly states that the health system does not look to blame in order to punish, but rather, its purpose is to prevent human errors. The saying "no name, no shame, no blame" has become common among risk managers in medical institutions, and over the years, it has been included in the corporate safety culture. A positive safety culture is characterized by communication based on mutual trust, a common perception regarding the importance of safety, confidence in the effectiveness of preventive measures (risk controls), and support for caregivers [15].

As mentioned previously, "safety climate" is defined as caregivers' perception of how safety is managed in their organization, while "safety culture" is a broader concept. The impact of safety culture on an organization's activity can be classified into several categories [16]:

- Staff experiences and responses: morale, innovation, job satisfaction, employee turnover, and health.
- Patients' experiences and reactions: patient complaints, satisfaction, quality of care, mortality rates, and sense of dignity in receiving care.
- Organizational results: evaluations by external bodies, waiting times, quality of medical records, volume of patients, employee absences, clinical effectiveness, and patient and community involvement.

A model that outlines the components and interrelationships among culture, climate, and outcomes in a medical system is presented in Fig. 4.1. According to this model, the culture consists of values and contextual factors (the immediate and distant environment in which the organization operates) and affects the safety climate, which consists of behavioral values, a focus on safety and quality, feedback, and communication in response to errors and work processes. Culture and climate affect a series of outcomes, including the quality and safety of medical treatment, job satisfaction, iatrogenic harm, and mortality prevalence.

To examine the impact of safety culture and safety climate on the results of healthcare organizations, the authors of the model scanned a series of studies from 2006 to 2012. Despite methodological and cultural differences and differences in the sample size, these studies found some similar effects of safety culture on the results of a health organization, including a relationship between leadership and the level of performance of a hospital, which was manifested in, for example, a reduction in the volume of patient complaints, a relationship between teamwork and a decrease in the scope of mortality in the hospital, a relationship between a negative atmosphere and an increase in burnout among nurses, and a relationship between caregiver dissatisfaction and a decline in the quality of care.

The assumption is that compared to a culture of guilt and shame, a culture that fosters learning from errors leads to a reduction in harm caused to patients during medical treatment. This assumption is supported by many studies, including the AHRQ report published in the UK [17]. Therefore, in cultures with a safety orientation, learning from errors is a fundamental value; caregivers feel safe reporting errors, and the management attributes value to training and developing employee awareness of patient safety issues.

The relationship between organizational culture and the safety of medical care was examined in a study conducted in 30 VA (veterans' affairs) hospitals in the United States, where employees were asked to rate the level of safety and the organizational culture [18]. The results point to a positive relationship between safety level and involvement and entrepreneurial culture and a negative relationship between hierarchical culture and safety level. The authors claim that in order to improve safety culture, initiative, team learning, and new ways of solving problems must be promoted. In contrast, emphases on hierarchy, procedures, guidelines, and control were found to inhibit a positive safety culture due to the fear of negative consequences and the imposition of blame following the reporting of errors and safety issues. Among the 30 hospitals included in the study, the three hospitals where the safety culture was evaluated as the highest and the three hospitals where the safety culture was evaluated as the lowest were selected. A comparison was made between these two extreme groups using the CVF (Competing Values Framework), the organizational culture dimensions defined by Robert Quinn [19]. According to this approach, the system of interrelationships between an organization and its environment can be characterized along two perpendicular axes: structure (flexibility, control) and focus (internal, external). Classification of organizations on these two axes creates four dimensions of organizational culture: group, entrepreneurial, hierarchical, and rational. On comparing the three hospitals with

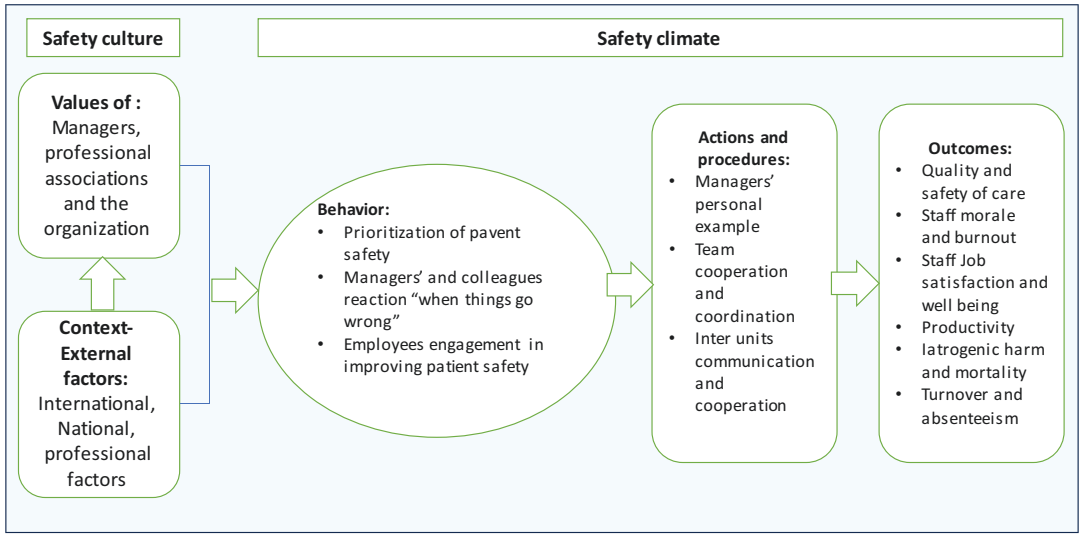

Fig. 4.1 The relationship between safety culture, safety climate and organizational results. [20]

the highest level of safety to the three with the lowest level, it was found that the former were characterized by a group and entrepreneurial organizational culture while the latter were characterized by a hierarchical culture.

In a study published in the UK in 2010 [21], which used several methods (surveys, semi-structured interviews, observations, document analysis, and employee diaries), the following issues emerged: the complexity of managing patient safety in the absence of clear definitions of responsibility for the subject, differing definitions of errors and adverse events, barriers to providing quality care (such as poor physical infrastructure or a lack of beds), awareness of risks, communication problems between various sectors, a lack of training on patient safety issues, the criticality of management's involvement, the values and priorities of the general manager (among others, on the question of whether business goals are given more weight than safety), management's attitudes in relation to safety and staff satisfaction and the ability to manage changes. Factors such as a lack of skilled staff, work that does not follow safety procedures, poor documentation, stress and workload, and difficulty relating the quality of the work to the results were also noted.

4.3 Typology of Safety Culture

Attempts have been made to describe different types of organizational safety cultures in health institutions and to test their impact on safety and clinical outcomes. One of the assumptions is that the key to the typology of organizational culture lies in the way information flows in the organization. In this context, three types of organizational culture have been described—pathological, bureaucratic, and creative [22]—and these are shaped by the preferences of the managers of the organization. Employees respond to the preferences of managers since employees who align with the preferences of management are rewarded and those who do not may be punished. Focusing on managers' and employees' personal needs creates a pathological culture, focusing on the needs of the department (departmental turf) creates a bureaucratic style, while focusing on tasks fosters the formation of a generative culture, characteristic of organizations, marking problems and opportunities for changes and innovation. The characteristics of the three types of cultures in the context of information processing and flow are presented in Fig. 4.2.

A pathological culture is characterized by excessive preoccupation with personal power,

Fig. 4.2 Characteristics of the three types of safety cultures [22]

Pathological	Bureaucratic	Generative
Power oriented	**Rule oriented**	**Performance oriented**
Low cooperation	Modest cooperation	High cooperation
Messengers shot	Messengers neglected	Messengers trained
Responsibilities shirked	Narrow responsibilities	Risks are shared
Bridging discouraged	Bridging tolerated	Bridging encouraged
Failure→ scapegoating	Failure→ justice	Failure→ inquiry
Novelty crushed	Novelty→ problems	Novelty implemented

needs, and respect; a bureaucratic culture is characterized by excessive preoccupation with regulations, duties, and the interests of the department; and a generative culture is characterized by engaging in the task and everything related to it. In a generative culture, information flows without delay and reaches those who need to receive it in the required format and at the appropriate time. The behavior of the employees is influenced by the management policy, according to which the most important goal is the completion of the task. Organizations with a generative culture tend to be proactive in obtaining the information necessary to carry out a task. On the other hand, organizations with a pathological culture treat information as private property to be used in power struggles within the organization. When something goes wrong in an organization with a pathological culture, the tendency is to find a scapegoat. In an organization with a bureaucratic culture, the tendency is to "do justice," that is, to locate the person responsible and deal with him in accordance with regulations and the law. In a generative culture, the motivation is to locate the root problems in the system and solve them. Since the process of coping with problems that are not easily identified involves processes of information flow, including identifying risks, reporting, solving problems, and implementing the required changes, there is apparently a direct relation between processing and information flow and the organizational safety culture [23]. Organizations with a better organizational safety culture are characterized by better information processing and flow.

The way organizations respond to adverse events may indicate the existence of hidden failures such as suppression, containment, poor public relations, local correction (pathological and bureaucratic cultures) or systemic corrections, and investigation in order to derive lessons learned with the aim of decreasing the probability of recurrence (generative culture), as presented in Fig. 4.3.

A question arises as to how safety culture affects performance related to patient safety in a medical environment and how differences, sometimes very large ones, in the rate of adverse events between hospitals and departments with similar characteristics, can be explained. From an examination of different operating patterns of regional administrations in Italy that reflected the organizational culture in that region, it can be concluded that organizational culture consisting of thought, emotion, and action that define the response to risks and opportunities supports this hypothesis [24].

An organizational safety culture therefore includes thought, emotion, and action, which define the response to risks and opportunities. These issues were studied in nursing systems in two hospitals affiliated with the same medical school in the United States [25] with a combination of quantitative and qualitative methodologies. The study, which focused on errors in medication administration, showed that the better the characteristics of the unit's safety culture (transparency, lack of judgment toward the reporter, learning from errors), the higher the rate of errors in administering medication. This find-

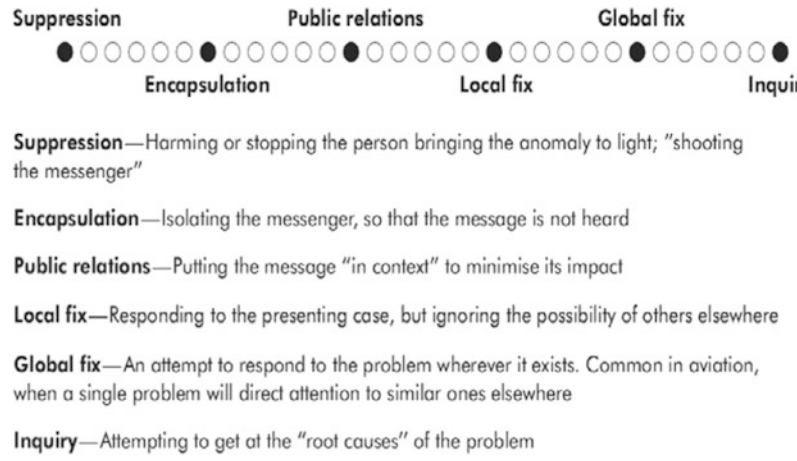

Fig. 4.3 The sequence of reactions to the occurrence of an adverse event [22]

ing was contrary to the research hypothesis. The suggested explanation was that a good safety culture, in which managers encourage the reporting of errors, shows an understanding that "to err is human" and encourages the discussion of errors, resulting in a higher tendency among the medical staff to report their errors. It was also found that factors that encourage reporting are related to the quality of the relationships in the unit, the perception of the nursing director's role as a mentor, and the attribution of importance to the functioning of the unit as a whole.

4.4 How to Measure Safety Culture in a Medical Environment

As mentioned, "safety culture" and "safety climate" are concepts that are sometimes used interchangeably. For practical reasons, when it comes to measurement, it is easier to measure a safety climate, which is a reflection of the safety culture in the eyes of the employees, than to measure the safety culture—a broader concept that is defined in different ways. It should also be noted that some of the tools developed to measure safety culture refer only to employees' perception of the issue of patient safety, while others refer to the issue from a broader perspective. Measuring safety culture in a medical organization with standard and valid tools, as mentioned below, contributes to patient safety:

- Assessing whether the organization's focus is on understanding what the elements of safety culture are in order to promote them in routine activities.
- Presenting the status of the safety culture in the organization at a given time and targeting the elements that require improvement.
- Presenting differences between successive measurements for the purpose of tracking changes in safety culture in the organization.
- Comparing similar units and similar organizations for the purpose of lateral and systemic learning and formulating activities for improvement.

It is important to note that other indicators of safety, such as the reporting rates of errors and adverse events, are not necessarily reliable, and the methodology of examining records, observations, and safety rounds requires the investment of many resources and persistence. Compared to these, measuring the organizational safety culture using standard tools is simple and inexpensive and may serve as a valid and reliable measure of safety culture in an organization.

Since these are standardized tools that assess culture, there is an inherent problem of cross-cultural transfer. A tool developed and validated for hospitals in the United States, for example, is not necessarily suitable for hospitals in Israel due to the different operational concepts, poorer allocation of resources, and different social compositions that characterize Israeli society and

undoubtedly also influence the organizational culture in general and the safety culture in particular.

In 2011, an independent British organization that specializes in advancing quality in medicine, The Health Foundation, published a review of effective tools for measuring safety culture in medical organizations. The review found more than 25 different tools for measuring safety culture in medical environments. The authors focused on five tools that are common and studied more extensively than others and are thus more valid and reliable:

1. Hospital Survey on Patient Safety Culture (HSOPSC) from AHRQ.
2. Manchester Patient Safety Assessment Framework (MaPSaF).
3. Safety Attitudes Questionnaire (SAQ).
4. Patient Safety Culture in Healthcare Organizations.
5. Safety Climate Survey.

We will refer to the first three tools above, which represent different concepts for measuring safety culture that were developed and validated in different countries and frameworks.

1. The AHRQ—HSOPSC (US Agency for Healthcare Research and Quality) promoted the development of tools for evaluating safety culture in hospitals, nursing homes, and community medicine. The most common and tested tool is the Hospital Survey on Patient Safety Culture (HSOPSC). The tool has 42 items associated with 12 dimensions of safety culture. The questionnaire has been validated in many studies. For example, a study published in 2010 [26] tested the psychometric qualities of the tool. The study was based on a large database in the United States, which included 331 hospitals, 2267 units in the hospitals, and 50,513 staff members who answered the questionnaire. The results of the study indicated good psychometric qualities of the tool, except for 2 of the 12 dimensions: staffing and questions referring to managers as promoters of safety. This tool has been used in the United States, Belgium, Norway, Saudi Arabia, Turkey, Lebanon, Spain, the Netherlands, and Israel.

   In Israel, a translated and adapted version of the tool was used three times, in 2012, 2015, and 2019. In 2012, 36 general hospitals participated in a study using the tool, and in 2015 and 2019, psychiatric and geriatric hospitals were added [27]. In each hospital, 500 medical staff members were randomly sampled. A total of 3529 staff members responded to the questionnaire in 2012 and 6194 staff members responded in 2019. The sample included doctors, nurses, imaging technicians, laboratory staff, pharmacists, and other health professionals. The organizational safety culture score was calculated as the average of the percentage of answers that respondents "agreed" or "strongly agreed" with. Among others, the following findings stood out: Israeli hospitals have awareness and conduct activities to improve patient safety to a moderate to high degree. Most of the respondents indicated that there are positive and supportive team relations within the hospital's departments, which is in stark contrast with the great need to improve cooperation and continuity of care among the departments. Most of the employees (57% on average) stated that they are greatly afraid of a punitive approach to reporting errors and adverse events. This is the element that was rated as the lowest among the survey elements, and it is a serious detriment to the recruitment of medical teams to participate in activities for promoting patient safety. It was also found that the size of the hospital affects the levels of patient safety, as most of the components were rated more positively in the small hospitals than in the medium and large hospitals. In the large hospitals, the managers' support regarding patient safety was found to be the lowest of all hospitals.

   Comparing the 2019 and 2015 measurements with those of 2012, it was found in the manager's support component regarding safety that the hospitals that were internationally accredited by the JCI (Joint Commission International) received higher scores.

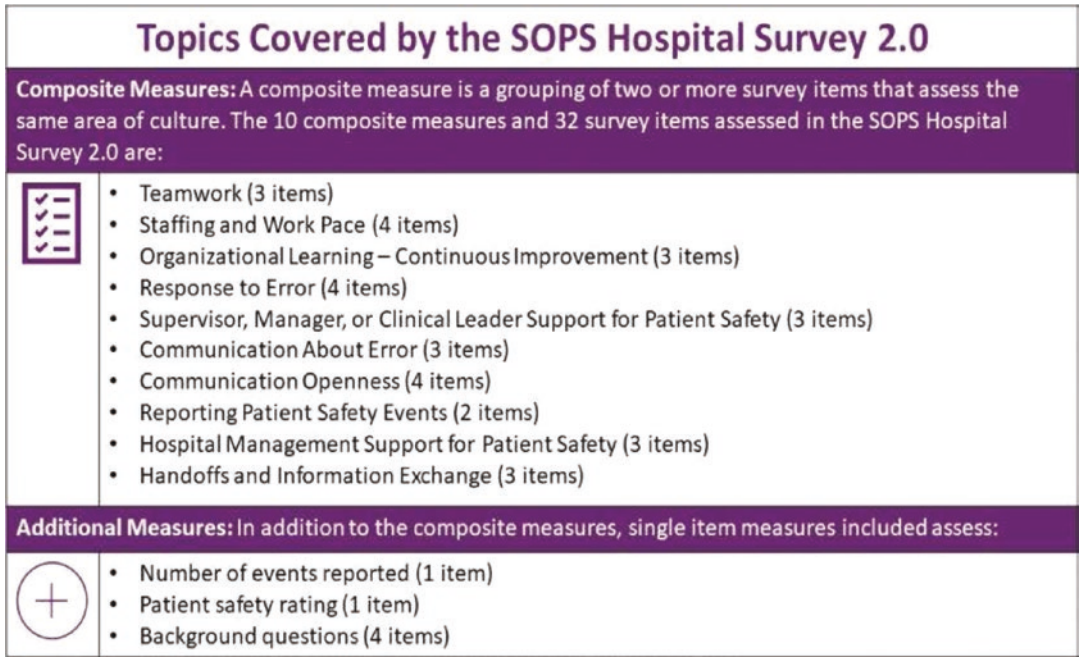

Fig. 4.4 Topics covered by HSOPS ver. 2.0 (https://www.ahrq.gov/sops/surveys/hospital/index.html)

In 2019, version 2.0 of HSOPS was published with 10 main topics + 3 additional measures, presented in Fig. 4.4.

2. **Manchester Patient Safety Assessment Framework (MaPSaF):** The tool was developed by researchers at the University of Manchester for the National Patient Safety Agency (NPSA) in Great Britain in order to help the British Ministry of Health (NHS) monitor the progress of healthcare organizations in implementing a safety culture. The tool is mainly implemented in the UK as part of safety culture workshops. It has ten dimensions of safety culture and is intended to reflect the level of organizational maturity in this matter. The tool was developed based on the typology of safety culture of Westrum [22] and a tool used in oil industries. Special versions of the tool have been developed for different medical environments, including hospitals, community clinics, and ambulance services.

   In Fig. 4.5, ten dimensions of the tool reflect five types of safety culture according to their level of development, with the worst safety culture being "pathological" and the most developed being "generative."

3. **Safety Attitude Questionnaire (SAQ):** This questionnaire was developed from the Flight Management Attitude Questionnaire (FMAQ), designed to assess the managerial culture in the cockpit in civil aviation based on human factors. The tool consists of six attitude dimensions related to safety culture. The tool has been adapted for use in "pilot cabin" -like medical environments, including operating rooms and intensive care and community clinics.

   The SAQ is one of the most popular and widely used tools in the healthcare field. It has been found that there is a positive relationship between high scores in the tool and positive outcomes related to patients and the medical team [28]. Among the advantages of the tool is its simplicity and validity in another industry (aviation) that allows a comparison between industries and between different units [29].

   Figure 4.6 presents the six dimensions of the SAQ and examples of phrases included in each dimension [29].

   Among the various tools used to measure and evaluate safety culture, there are differ-

10 factors of MaPSaF:

1. Continuous improvement
2. Priority given to safety
3. System errors and individual responsibility
4. Recording incidents
5. Evaluating incidents
6. Learning and effecting change
7. Communication
8. Personnel management
9. Staff education
10. Teamwork

Types of organizational safety culture:

Pathological – Reactive – Bureaucratic – Proactive - Generative

Fig. 4.5 The factors of the MaPSaF tool and types of safety cultures

Domain	Example of statements
1. Safety climate: perception of strong and proactive commitment to safety	I would feel perfectly safe being treated in this ICU
2. Teamwork climate: perceived quality of collaboration between team members	Our doctors and nurses work together as a well coordinated team
3. Stress recognition: acknowledgment of how performance is influenced by stressors	I am less effective at work when fatigued
4. Perception of management: approval of managerial action	Hospital management is doing a good job
5. Working conditions: perceived quality of the work environment, staffing and equipment	The ICU equipment in our hospital is adequate
6. Job satisfaction: positivity about the work experience	The hospital is a good place to work

Fig. 4.6 The six dimensions of the SAQ and examples of statements

ences in terms of simplicity, psychometric validity, and scope of use. However, there are also broad common denominators since most of the tools refer to similar dimensions of safety culture, including leadership, perception of risk, characteristics of the work environment, error reporting, the system's response to those involved in adverse events,

attitudes and behaviors concerning safety, communication, and information flow [30].

In the summary of the publication of The Health Foundation [31], which reviews different methodologies for measuring and evaluating safety culture, a comparison among five main tools is presented. Likewise, we reviewed the top three tools, and the two recommended tools are the HSOPSC (AHRQ) and the SAQ. However, it seems that MaPSaF is unique since it is delivered in workshops that also include an intervention to improve safety culture and not just measurement.

4.5 How to Improve Safety Culture

Measuring and evaluating safety culture in a medical organization increases management and employee awareness of the importance of the issue and identifies weak points, which allows actions to be taken to remedy them. It is also important to consistently monitor the organization's safety culture through periodic measurement to identify changes in the various dimensions and compare the organization's scores to the scores of similar organizations. It should be noted that the tools described above are often used to evaluate the effectiveness of intervention programs to improve organizational safety culture.

For example, a study conducted in five hospitals in Belgium in 2010 [32] reported on an initial assessment of safety culture using the AHRQ tool HSOPSC. Based on the gaps found, an intervention plan was defined, and 16–26 months later, another measurement was made to evaluate the changes the tool had prompted. It was found that only in the "management support regarding patient safety" dimension was there an improvement, while in the other dimensions, no differences were found. The authors of the study hypothesized that the period of time between the first measurement and the second may have been too short for it to be possible to detect changes. Therefore, it was recommended to conduct the measurements once every 3 years to allow organizations to implement the required improvements to their safety culture.

In some cases, the very process of assessing safety culture using one tool or another is seen as an intervention plan to improve safety culture. This was the hypothesis of a study published in 2015 [33] in which the MaPSaF tool was used in community clinics in the Netherlands. The questionnaire was administered in ten clinics as part of a workshop on safety culture, and ten other clinics served as a control group. Later, interviews were conducted with 24 doctors and 24 nurses from all the clinics that participated in the study in order to understand which factors influence changes in safety culture. It was found that for a safety improvement program to be effective, it must include, in addition to evaluation using one tool or another, additional interventions such as workshops and activities to improve the flow of information, teamwork, and the training of managers and medical teams.

In a review of different strategies to improve safety culture in hospitals published in 2013 [34], 20 controlled quantitative studies that met methodological standards of pre- and post-intervention measurement, or controlled historical studies, were examined in depth. Eleven different strategies to improve safety were found, and two of them were found to help improve the safety culture: safety rounds in the presence of managers and departmental programs that include a variety of interventions. The review's authors claim that although the topic of safety culture occupies an increasing place in intervention programs in health systems to improve patient safety, there is little evidence regarding the effectiveness of the various strategies. In an article on the topic of safety culture in Israeli hospitals published in 2019 [35], it is claimed, among other things, that the role of hospital management is to promote safety culture in such a way that all the hospital's employees understand their contribution to patients' safety, similar to what is customary in other high-risk industries.

The question of whether it is possible to change safety culture, quality of care, and patient safety results through a targeted intervention program in a relatively short term was answered positively in a study published in 2020 [36]. In the study, a comparison of safety culture was conducted based on the AHRQ questionnaire

administered in a large hospital in Israel between 2015 and 2017. A comparison was also made between the two periods of time in which the questionnaire was administered in different indices of clinical care quality. It was found that the intervention plan that was implemented between the two safety culture measurements resulted in a significant improvement in the safety culture indicators (in seven indicators, the increase was significant, and in six other indicators, there was a significant improvement). There was also a significant improvement in 18 of the 24 clinical quality indicators included in the intervention program.

Key Messages: Safety Culture

- Safety culture has been seen in recent years as a concept that, on the one hand, explains the extent of errors and failures in the medical system and, on the other hand, carries the promise of improving safety results if promoted consistently.
- There is no broad consensus in healthcare systems or in high-risk industries regarding the definition of the concept of "safety culture," how it is measured, or strategies for promoting it. There is frequent overlap and confusion among the concepts of "organizational culture," "safety culture," and "safety climate."
- The level of safety culture is a significant factor in accidents and adverse events and first arose in the investigation committees for the Chernobyl disaster and later in the investigation committees for the Challenger and Columbia space shuttle accidents.
- Of the various factors that make up "safety culture," the management's perception of safety, the priorities given to the issue in relation to other issues, and the way the employees perceive the priorities are of particular importance.
- The most common methodology for evaluating "safety culture" involves questionnaires, where three tools are the most common and have been validated more than others: the AHRQ—HSOPSC questionnaire, which was translated into Hebrew and distributed in government hospitals in Israel; the MaPSaF; and the SAQ.
- In the classification of safety cultures, the most common reference is to three types of safety culture: pathological, bureaucratic, and generative. A pathological culture is characterized by a lack of interest on the part of management in safety issues and a reactive attitude toward the issue of safety, while a generative culture is characterized by proactivity and high priorities for safety.
- There is little empirical evidence proving the relationship between safety culture and safety outcomes, and more studies are needed to prove it.
- Safety culture improvement is linked to changes in management's perceptions of the issue of safety and the evaluation of safety culture through effective tools and the construction of intervention plans in the dimensions in which the organization needs to improve.

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5 The Human Factor: Human Errors in Medicine

5.1 What Are Human Errors?

There are many different definitions of the term "human error." In most cases, it is the result of a task that a person intended to carry out but was unable to carry out as intended due to some disruption on his part. Human error can therefore occur under the following conditions: when a person intends to perform or performs a task; when the task is defined; when there are clear criteria for defining success in carrying out the task; and when it is clear that the task was not accomplished, though not as a result of force majeure or random factors. For example, a nurse who gave a patient an expired injection did not make an error but did not follow the procedures that require checking the expiration date of a medicine before administering it to the patient. On the other hand, the action of a nurse who administers an incorrect dose of medicine can be considered an error.

After an examination of numerous definitions of the concept of human error in various industries, including medicine and aviation [1], the main characteristics of human errors were formulated as follows: the activity is performed by a human being; the activity takes place at the interface between a person and another system (person, machine, and environment); the activity is intentional and freely chosen; and the activity does not comply with the standards for its execution. These characteristics constitute a broad common denominator of most definitions of human error, with the exception of errors made in cognitive activity, without any physical activity, such as an error in judgment resulting from a doctor not taking into account critical information about the patient existent in the patient's medical record.

It is widely accepted that the human factor manifested in human errors is responsible for approximately 80% of all accidents and adverse events, since in most cases, adverse events and accidents are affected by variability in the performance of human actions and, therefore, can be attributed to human malfunction and dysfunction.

In the context of risk management and patient safety, there are two main and contrary approaches to human error. Each approach represents a theoretical concept that relates to the causes of errors and approaches for reducing them.

(A) The traditional approach, known as the **"person approach,"** according to which human error is a direct result of a person's malfunction, which may stem from his limitations as a human being (sensory, motor, and cognitive limitations), poor motivation, fatigue, or lack of knowledge. The adoption of this approach is manifested in the tendency of managers to punish and denounce the belief that this is the way to prevent such errors by a certain employee and by others who will see and be seen. The premise of

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this approach holds that a person has almost complete control over his actions, and therefore, if he has made an error, it is likely that he did not do everything he could have done to prevent it from happening.

(B) A relatively new approach, known as the **"system approach,"** according to which human errors are indeed performed by humans, but their causes are often systemic—poor designing of a work environment, poor work processes, insufficient allocation of resources, poor teamwork, inappropriate equipment, or overload of tasks. The implication of adopting this approach is that to reduce human errors, one must improve the systemic aspects and understand that erring is human and abandon the "name, blame, and shame" approach, which does not help reduce the extent of the phenomenon and can even achieve the opposite by causing professionals to fear reporting errors and adverse events. According to this approach, errors are more the result of system characteristics and less the direct responsibility of humans [2, 3].

James Reason, a psychologist from the University of Manchester who, for many years, was involved in human factors research in aviation and later also in medicine, and published several books in the field including "Human Error" [4], believes that errors are a human characteristic and cannot be completely prevented: "We cannot change human nature but we can change the conditions under which humans operate" [3]. The essence of the system approach is, therefore, that the most effective way to reduce human error is to design and build systems in light of the assumption that humans can make errors. The system should be simple and easy to operate, be able to warn in advance of the possibility of a mistake being made, and contain errors that are made before they cause harm.

The person approach has many shortcomings in terms of promoting patient safety. Among the most prominent of them is the lack of trust it arouses among employees toward managers regarding the understanding of the factors that led to a given error. The employees are familiar with the system in which the error occurred because they are the ones who deal with it on an ongoing basis and are aware of the deficiencies that enable them to commit errors. On the other hand, it is convenient for managers to adopt the human approach since doing so places the responsibility for adverse events and accidents on employees and may free them from responsibility for adverse events and their results.

In organizations that adopt the person approach, the voluntary reporting of errors and adverse events, which is very important for improving the system, is compromised. Employees will not report their errors unless the error causes actual harm to a patient. Because of this, the system loses countless opportunities for learning, drawing lessons, and being improved. Therefore, the learning is based on events that cause serious damage and thus cannot go unreported. On the other hand, the extremism of the system approach may compromise the sense of personal responsibility of professionals, who have a very important role in detecting systemic failures, alerting others about them and taking the necessary precautions.

In one book dealing with reliability and human errors in medicine [5], human error is defined as "failure to perform a given task (or performing a prohibited action) that may cause disruption of planned operations or damage to property and equipment." In the world of medicine, the concept of harm refers mainly to the harm that may be caused to patients, and usually "performing a prohibited action" is not an "error" but a violation of procedures and instructions. In addition, an error is not necessarily viewed in terms of its harmful result since most errors end up with no harm at all. This definition demonstrates how many definitions of the human error concept do not properly exhaust the complexity of the human error phenomenon.

James Reason's book, first published in 1990, is an important milestone in understanding the broad nature of human errors, their types and ways to reduce them and defines human error as "all cases in which a planned course of mental or physical activity fails to achieve the planned

result, and when it is not possible to attribute this failure to the intervention of any random factors" (p. 9). This definition, which adds the types of mental and physical activities in which errors may occur, faithfully reflects the phenomenon.

The Institute of Medicine (IOM) report from 1999 [6], To Err is Human, defines human error as "the failure to complete an action as planned, or the use of an incorrect plan to achieve the goal, accumulation of errors causes accidents." This definition adds two elements to the previous definitions: the choice of a wrong plan of action and the idea that in order for an accident to occur, an accumulation of errors is necessary since usually one error does not cause an accident.

The definition of the term "human error" and reference to it is influenced to a considerable extent by one's emotions, position, and personal experiences. This is the reason it is important to be familiar with the different definitions of the concept and the practical consequences of adopting a specific definition.

Some argue that the term "human error" is used to describe the results of human behavior, causal factors of accidents, and the behavior itself. This may stem from the lack of clarity of different definitions of the concept in the literature, which may be the reason that in different industries and publications, the range of "human error" as a major factor in accidents is noted as 30–100% [1].

In a handbook dealing with human error and reliability that focuses on the nuclear industry [7], human error is defined as performance outside the acceptable range when the limits of the acceptable range are determined by the system. According to this definition, an error is an action that exceeds the limits set by the system. To reduce the probability of errors, the operator should be familiar with the acceptable limits and be competent to perform the operation within these limits, and an external party from within the system should monitor and evaluate the operation to determine whether it was performed within the acceptable limits or if a "human error" occurred.

The definition of human error [4] presented above emphasizes the element of the undesired result that differs from the plan before the action is carried out. Other definitions [8] Meister [9] emphasize the cognitive components of the error, which include the characteristics of the stimulus, the processing of the information related to the stimulus and the response, a determination of when a disturbance in any of these components can end in error due to giving an incorrect meaning to the stimulus, the incorrect planning of a response and no response.

An important element common to all definitions according to this review is the intention to achieve a specific and desired result. Because of this, all actions that are spontaneous and involuntary are excluded from the definition of "human error." Some suggest that the decision as to whether "human error" has indeed occurred should be based on comparing the result obtained with the desired, planned result [7]. In this context, it is important to note cases of actions that were corrected during the operation (recovered errors). This term refers to mistakes that occurred but whose effect was canceled out or compensated for by some corrective action so that at the end of the day, the desired result was achieved. In such cases, it would not be correct to ignore the occurrence of human error, as in other cases, such error will not necessarily be corrected and can thus cause unwanted results.

A set of guidelines for investigating and classifying human errors in air accidents [10] defines human error as actions that deviate from the original intention of the operation or, alternatively, that do not achieve the desired goal. This definition is largely practical for accident investigators because it generates questions such as what caused the operator to deviate from the original intention and what caused the desired goal to not be achieved. Understanding these factors may lead to defining actions to control or reduce similar errors in the future.

Another definition of human error [11] emphasizes the following elements: there was no intention to make an error during the execution of the action, the action was goal-oriented, and the desired result of the operation was not achieved within acceptable limits.

Attempts to define human error in medicine have led to the formulation of a new concept—

lathology [12], which refers to all aspects of human error in medicine, lath (error in Greek). This concept specifically concerns medical errors, even though most of its references to error are based on other disciplines.

5.2 Causes of Human Error

Investigating the causes (etiology) of human errors is important for preventing the reoccurrence in the future of errors that have already occurred, as well as for designing systems and tools to reduce opportunities for errors on the one hand and to contain the errors, eliminate them, or reduce their damage on the other hand. A perusal of the publications dealing with the causes of human error reveals that their suggestions depend mainly on their professional discipline:

- Psychologists propose an etiology based on the functioning of the cognitive system: perception, memory, and thinking (information processing), as well as factors that affect the level of performance and functioning: mental stress, task load and fatigue, organizational culture and safety culture, teamwork, morale, motivation, burnout, and effects of the "second victim" phenomenon.
- Engineers propose an etiology based on the characteristics of the work environment, the design of work interfaces, work processes, human limitations, and the reliability of performance.
- Organizational consultants and engineers suggest an integrative etiology, which refers to managerial aspects, resource allocation, managerial response to employee failures, organizational goals, regulation, and effects of the organization and the system on the employee.

In the world of medicine, it is accepted to divide the causes of human error according to their degree of influence. Thus, for example, the factors can be divided into four levels [13]:

- Level 1: Factors affecting the functioning of a single care-giver: poor designing of medical equipment, technical complexity of the work processes, and multiple competing tasks that make it difficult to maintain awareness of the situation.
- Level 2: Factors affecting teamwork and functioning: failures in teamwork resulting from a lack of coordination between different professional parties, adopting suboptimal work norms and performing the same task in different ways, adopting shortcuts, and relying on incomplete or unverified information.
- Level 3: Factors related to management: a lack of required resources (personnel and equipment), a lack of learning from adverse events, poor safety culture, learning new roles and tasks while working without formal training, and a lack of proactive risk management to identify risks before they crystallize as adverse events.
- Level 4: Regulatory factors: a lack of infrastructure for sharing information about adverse events, risk management, and systemic lessons; a lack of standards for the operation of safety rounds and risk surveys; and a lack of uniform standards for reporting human errors; focusing on systemic and equipment failures rather than failures in the way equipment is used.

As mentioned above, in terms of characteristics, the concept of human error is defined as the activity of a human being in the interface with another system out of a free choice that exceeds the accepted performance limits.

The question then arises: is a mistaken judgment that did not lead to one act or another a human error? This is a relevant question since it can be argued that as long as the wrong act is not performed, there is no human error. On the other hand, misjudgment can be regarded as a harbinger of human error, at least of the type that requires judgment before execution. Thus, for example, a mistake in pressing a certain activation button, selecting an incorrect item from a list of items on the computer, or reading data incorrectly does not require prior consideration. However, from the point of view of risk management and patient safety, every action, even the simplest action, should be supported by a risk assessment so that the necessary precau-

tions can be taken to ensure the safety of the treatment (the various types of errors will be detailed below in the section dealing with the typology of errors).

Human error occurs in the interface between a person and another system—another person, a machine, the environment, or a combination thereof. According to this characteristic, a judgment that does not come to fruition and does not affect another person, a machine, or the environment is not a human error. Even actions that were not performed by free choice but as a result of external pressure or coercion cannot be considered human error. Free choice and intention are required for human error to occur. Thus, for example, an accidental encounter with someone in a corridor that causes a patient's fall cannot be considered a human error because there is no element of free choice or intention. Likewise, errors that are the result of deliberate deception by some party, such as providing partial or incorrect information, cannot be considered human errors either. Actions taken after crossing the limits of human physical or psychological capabilities are also not human errors [1]. This is an important distinction, as it helps differentiate between human error and human limitations. Thus, for example, the failure to perform an action after 48 h without sleep cannot be considered a human error but a direct and predictable result of extreme physical and mental fatigue.

The limits of what is accepted are defined by the system in which the person operates and performs his tasks—that is, the regulator of the professional field, such as the Ministry of Health, professional unions, the courts, and society. The limits of what is accepted, even within the same professional field, may differ in different systems, countries, and organizations. For example, the limits of what is acceptable for a family doctor in China are different from those of a family doctor in the United States, the Netherlands, or Israel. However, to be able to define a certain action as human error, there is always a need to compare it to a performance standard with acceptable limits. As long as the results of the operation are within acceptable limits, there is no human error.

To simplify the understanding of the causes of human errors, it has been proposed to classify them into two main categories [11]:

(A) Endogenous factors that cause errors from an internal source (endogenous errors). Endogenous errors have internal causes such as failures of the cognitive system. To understand the roots of endogenous errors, it is necessary to refer to knowledge from the fields of psychology, physiology, and neurology.
(B) Exogenous factors that cause errors from an external source (exogenous errors). Exogenous errors have external factors related to the context and circumstances in which the activity is carried out. For example, environmental factors may increase the probability of errors, including the presentation of ambiguous, missing, and confusing information, which may cause errors in the processing of the information, even though the cause of the error is exogenous.

It has been claimed that approximately 70% of accidents in the industry are caused by human factors since the high level of complexity of the systems that humans operate increases the probability of errors [2]. Thus, the distinction between endogenous and exogenous errors seems artificial and simplistic; errors often occur in complex circumstances involving both internal and external influences.

Intensive care units are characterized by a large number of therapeutic procedures performed by doctors and nurses routinely. Thus, for example, one study found that on average, 178 procedures are performed per day, with 1.7 errors per patient per day [14]. Doctors and nurses were found to contribute equally to errors, although nurses performed a greater number of procedures. A significant number of these errors were attributed to communication problems within the team. The conclusion of the abovementioned study was that the application of human engineering principles in the work environment and the definition of work processes in intensive care units could reduce the scope of errors.

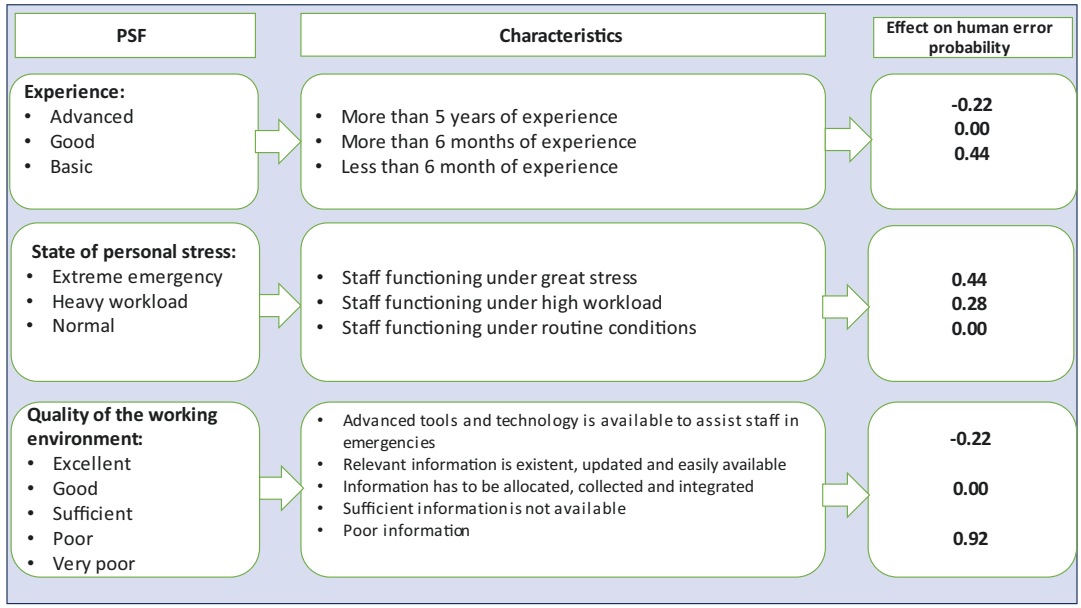

Fig. 5.1 Factors affecting human error (PSFs [Performance Shaping Factors]). (Based on [16])

In another study, risks of errors in laparoscopic surgeries and means of recovery from errors (resiliency) were examined [15]. On average, 14 risks for errors were found for each operation, as were 12 means of recovery from errors. Most of the risks of errors, as well as recovery measures, were related to human factors.

In the engineering approach to human error, an attempt is made to build quantitative models that attribute different weights to the various factors, with the challenge being estimating the probability of human error under changing conditions of a given system based on information about errors in the operation of similar systems in the past. There are many models of this kind applied in various high-risk industries. The origin of most of these models is in the nuclear industry, where it is important to evaluate the risks of various scenarios in advance that may develop in the operation of a reactor.

Among first-generation models of HRA (human reliability analysis) which assist engineers in assessing the probability of human errors under various conditions, we can list: Human Error Assessment and Reduction Technique (HEART), Empirical Technique to Estimate Operator's Error (TESEO), Systematic Human Action Reliability Procedure (SHARP), Technique for Human Error Rate Prediction (THERP), and others.

Each model has its unique advantages and disadvantages. The models are assessed according to their simplicity, flexibility, reliability, and consideration of different environments and processes. As already mentioned, most of the first-generation HRA models were developed for nuclear and chemical industries, thus lacking the applicability for other sectors.

Thanks to the simplicity of first-generation HRA models they are still used today although more advanced models from the second and third generations are also used [16].

In evaluating cognitive errors (HCR—human cognitive reliability), the probability of error of each factor affecting human performance (PSF—performance-shaping factor) is evaluated. Figure 5.1 presents a reference to three main factors: the level of competence, the level of stress, and the quality of the infrastructure in the organization. It turns out that as a staff member's level of competence advances—he has more than 5 years of experience in performing his role—the degree of influence on the probability of error decreases by −0.22, while an inexperienced staff

member adds 0.44 to the probability of error. Functioning in a stressful emergency mode adds 0.44 to the probability of error, while functioning in a routine mode does not add to the probability of errors. A low level of stress adds 0.28 to the probability of making an error since complacency affects performance and the level of caution decreases. The same goes for the factory's infrastructure quality levels [16].

The quantitative methods presented above reinforce the qualitative insights according to which experience and training affect the probability of errors as well as stress levels—pressure that is too high or too low increases the probability of errors. Additionally, the quality of the work environment contributes to the increase or decrease in human errors.

5.3 Typology of Human Errors

From what has been said thus far in this chapter, it can be understood that the concept of human error does not have one clear definition. One of the reasons for the multitude of definitions is the lack of agreement regarding the basic essence of human error and the possibility of approaching it as a cause, a process, or a result. A typology of human error attempts to characterize different types of human error and distinguish among them. The understanding of these different types is especially important for those involved in the study of the human factor in accidents and failures. Different types of errors may indicate different causation processes. Therefore, if one wants to reduce the probability of errors, one must understand what type of human error caused a specific event.

A question that must be considered in the context of human errors is, are human errors and their characterizations unrelated to a certain content world, or should they be considered in a specific context—for example, are human errors in aviation different from human errors in medicine? A common claim is that the causes of human errors may be different in different content worlds, as may their consequences, but the basic essence of human errors is similar across contexts. Based on this assumption, it is possible to classify such errors into categories that are not related in terms of unique characteristics to a certain field of occupation or to certain circumstances. This concept is supported, among other things, by similar models of investigating human factors in accidents in different industries [17].

According to James Reason, there is no agreement upon the classification of human errors, nor does it seem that there is a division that most of those dealing with the human factor would accept [3] since a category is often defined according to a specific need. Almost everyone who has published an academic article dealing with the human factor has defined human error differently, and the result is countless classifications, some very practical and some completely theoretical, some very specific and some general and relevant to a wide range of fields and situations. However, all taxonomies attempt to answer three questions: What, under what circumstances, and how?

One widely accepted approach to the typology of human errors was developed by Reason and is based on a theoretical framework first formulated in 1974, according to which there are three activity levels of humans [15] that can be distinguished. Therefore, any cognitive activity can be classified into one of the following categories [18]:

(A) **Skill-based activity**—skill-based level (SBL): An activity at this level is controlled by patterns of action and procedures arranged in time and space stored in one's memory. It can be said that the activity at this level is automatically controlled, and the errors are due to distraction of the automatic activity, which does not take into account the changes in the situation. For example, if, during a physical examination of a patient by an experienced family doctor who has performed such examinations thousands of times, a person bursts into the room with an urgent request, the doctor may miss an important stage of the examination. Behavior at this level is characterized by sensorimotor activity that occurs automatically without conscious control. In popular language,

these activities are performed "automatically" since they have been performed many times in the past and do not require an investment of attention. The advantage of this method of operation is that attention may be directed to performing several mental operations at the same time. The disadvantage is that in this mode of operation, it is possible to miss various nuances of the situation or task that require consideration, which may cause errors and end in failures. Thus, any unexpected occurrence may disrupt the sequence and cause an error and failure.

(B) **Rule-based activity**—rule-based level (RBL): An activity at this level is aimed at solving familiar problems based on rules stored in the memory and is suitable for solving situations that are familiar from the past. Rules are invoked if a known condition that has a known resolution attribute is detected. The pattern of a rule-based activity is as follows: if A, B, and C are fulfilled, then D, E, and F must be done. For example, if a 60-year-old man enters the clinic complaining of chest pain, staff should check whether the patient has a cardiac problem that requires evacuation to a hospital. If the man is 20 years old, there is a possibility that the situation will not arouse suspicion of a cardiac problem, and the medical examination will be directed toward identifying a musculoskeletal problem. Another example would be the diagnosis of cervical cancer in young women: A young 28-year-old woman who complains to her family doctor about vaginal bleeding does not fit the typical pattern of a woman with suspected cervical cancer, and the doctor may miss the diagnosis if he thinks that the bleeding may have originated from sexual intercourse.

Rule-based activity is actually thinking in patterns, the advantage of which is saving mental resources and time since it is based on rules created over many experiences in the past and/or on procedures and instructions formulated by the cognitive system based on accumulated experience in performing a given task in the past. The disadvantage of using templates is that in medicine, no situations are completely identical to each other, and each situation is unique since each patient is unique, each therapist is unique, and each encounter is unique. The templates provide only a general frame of reference, and to avoid errors, one should focus on the difference, that is, ask what in the general template is not suitable for the particular patient and why this patient does not fit the pattern? The templates embody private and organizational professional experience and enable great efficiency in professional work, so the temptation to use them is great, but they also contain quite a few pitfalls. The errors in this type of activity result from a partial or incorrect identification of the situation, choosing an inappropriate template to solve the problem and not considering that the situation may require a different approach.

(C) **Knowledge-based activity**—knowledge-based level (KBL): an activity that is applied in new situations for which real-time solutions must be planned, using conscious analytical processes combined with information stored in the memory. This activity is aimed at a solution that requires the analysis of the problem, collection of relevant information, definition of alternatives for solving the problem and selection of a preferred alternative, as well as preparation for changes during implementation as a result of new information and/or the degree of success in implementing the planned solution. An example of this type of action is the arrival of a patient to an emergency room in an ambulance after being found unconscious by passersby. In this situation, it is not clear which pattern should be activated since it is not clear what the patient's medical background is, what preceded the loss of consciousness, and what caused it. A conscious review and evaluation process is therefore required that relates to each item of information collected. Let us say that the patient's mouth smells of alcohol and his clothes are dirty; the thinking pattern that may arise

among the medical staff is that the person is a homeless drunk, and a chain of actions relevant to these circumstances will follow in their minds. If the patient is neatly dressed, the thought pattern that might emerge is that of a lawyer having a heart attack. It is clear that the use of templates facilitates and optimizes the handling of this type of situation, but the maximum amount of information possible must be collected to formulate a correct course of action that will ensure the safety and quality of the required medical treatment.

Errors at this level are related to internal and external influences on the cognitive system, such as workload, mental stress, and a lack of sufficient or reliable information about the problem that needs to be solved. It is also reasonable to assume that there are interpersonal differences involved in different approaches to solving problems as well as cultural and social influences. As the expertise in performing a particular task increases, it moves from a level of knowledge-based activity (KBL) to a level of rule-based activity (RBL) and to an automatic skill-based format (SBL). However, there are some tasks, such as flying a fighter jet or open-heart surgery, that, due to their inherent complexity and variability will never be performed as SBL or RBL. The two high activity levels KBL and RBL occur only after a problem has been identified that requires a deviation from the SBL mode of activity.

Tables 5.1 and 5.2 summarize the typology of human errors in the context of [3] activity levels [18].

Table 5.1 Level of activity and types of mistakes

Performance level	Error type
Skill-based level (SBL)	Slips and lapses
Rule-based level (RBL)	RB mistakes
Knowledge-based level (KBL)	KB mistakes

In 2010, Daniel Kahneman, a Nobel laureate in the field of behavioral economics, published the book "Think Fast, Think Slow" [19], in which he summarizes the research he conducted with Amos Tversky. Kahneman suggests that humans have two cognitive systems: one that thinks quickly and is responsible for quick and automatic responses to familiar situations and the other that thinks slowly and comes into play when it is necessary to solve a new problem. The two systems differ in many ways and in the type of errors they enable. The activation of the fast system is automatic, unconscious, efficient, and energy-saving. This system is used when driving under relatively normal conditions, understanding relatively simple sentences, recognizing that one object is further away than the

Table 5.2 Distinctions among the three types of errors

Factor	KB errors	RB errors	SB errors
Type of activity	Problem solving		Routine
Focus of attention	Focused on information relevant to the problem		External
Awareness state	Conscious processes	Mainly automatic based on existing schemas and rules	
Ability to project the type of error	Differs	Varies to a large extent; strong but erroneous behaviors (habits)	
Ratio of errors to opportunities to err	The number of errors is low, but they stem from a significant number of opportunities to err	Although the number of errors is large, they stem from a small number of opportunities to err	
Impact of environmental factors	Dominance of external factors	Low to moderate—the significant factors are internal (frequency of performing the task in the past)	
Simplicity of detection	The detection is difficult and usually happens after external intervention		The detection is simple and effective
Consideration of changes	There is no preparation and readiness for change	It is unknown when the change will occur	The consideration of change does not happen in a timely manner

other, etc. The slow system is activated voluntarily when it is necessary to solve a new problem that requires collecting and analyzing information, examining alternatives, and making decisions. As long as the fast system "gets along" in dealing with reality, the slow system "rests" and is in no rush to get in on action. The slow system is seen as "lazy" and usually does not interfere with the activity of the fast system. The problem is that we operate in a changing reality, where nothing is truly the same as situations we have encountered in the past. Therefore, the responses of the fast and automatic system are correct in most cases, but that system is also prone to errors as a result of cognitive biases (many of which were detailed in Kahneman's book) that naturally generate errors. Among the known cognitive biases, we can mention various optical illusions that cause us to perceive and interpret visual stimuli incorrectly, as well as the availability bias, which causes us to perceive new stimuli in light of the stimuli we have recently encountered, and the confirmation bias, which causes us to treat information as confirming our previous beliefs and attitudes. Moreover, this last type of bias makes us actively seek information that confirms our beliefs and ignore information that contradicts them. The fast system operates according to rules (heuristics) formed on the basis of past experiences. Naturally, these rules are generalizations, so to apply them, the fast system simplifies the problems we encounter into questions for which we have a ready answer. Here are some examples presented by Kahneman:

- The question is whether it is worth investing in the company's shares and whether the value of the stock will increase or decrease. The fast system translates the question into a simple rule—How much do I value the company?—allowing us to answer the question quickly.
- The question is how happy one is in one's life right now. The fast system translates this complex question into a cognitive rule—What is my mood now?—allowing one to answer the question immediately.
- The question is how far the particular candidate in a political party will go. This is a complex question that cannot truly be answered since the answer is related to many factors that do not depend only on the candidate himself. The fast system translates the complex question into a simple question: to what extent does the candidate look like a winner in the elections?

Since the operation of the fast system is based on rules that are correct in most but not all cases, the system is prone to errors related to an application that is not correct for a given situation—that is, it is applied generally to a situation that is not sufficiently familiar and in which it would actually be correct to activate the slow system, which, as mentioned, is lazy by nature and enters into action by a voluntary decision or when the automatic system has created a problematic situation that requires the intervention of the slow system.

On a practical level, it is recommended to adopt the typology of human errors based on the insights of Reason [3] and Rasmussen and Jensen's classification of cognitive activity levels [18]. This typology may be useful in the investigation of human factors of adverse events in order to reach an understanding of what type of human error led to the adverse event, thereby guiding us to understand the factors and circumstances that may have contributed to its occurrence. As mentioned above, to reduce human errors, it is necessary to address the causes of errors according to their types and according to the circumstances in which they occurred. Kahneman's contribution [19] allows us to understand how our cognitive system works through the slow and fast systems and what the weaknesses of both systems are that enable them to make errors.

Figure 5.2 presents the relations among the types of tasks, the state of awareness, the characteristics of the cognitive activity in each situation, and the typical errors in each situation.

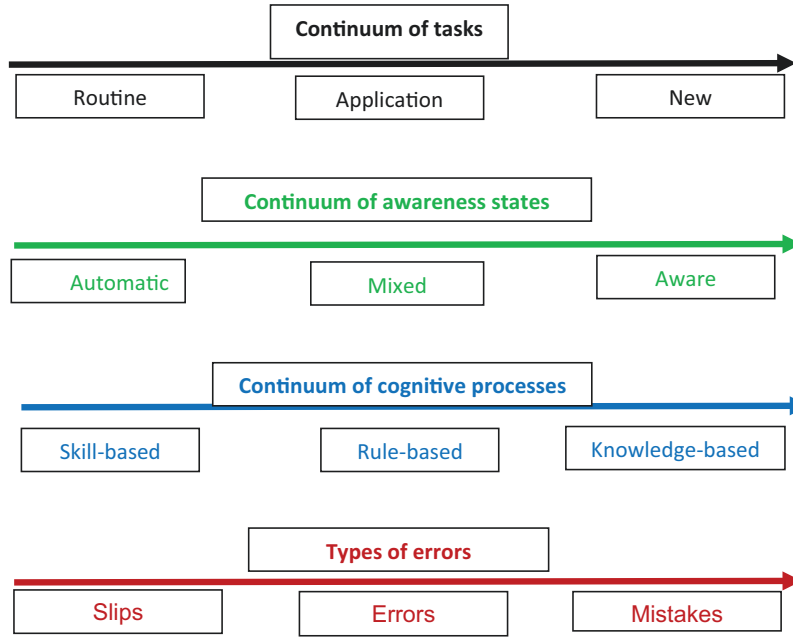

Fig. 5.2 Typology of errors—summary

5.4 Therapist and His Influence on Errors in Medical Treatment

Our experience shows that the level and quality of human performance change constantly and is affected by a series of physiological, psychological, social, cultural, and environmental factors. Thus, the probability of errors occurring while performing a defined task changes all the time and is affected by the factors that affect the quality of our performance. Understanding the factors that increase the probability of human error is important to build systems and processes capable of reducing the probability of such errors on the one hand and raising awareness of personal situations that indicate that the probability of an error is high.

We also know from experience, which is supported by many studies, that fatigue, workload, mental stress, distractions, poor motivation, tiring work routines (burnout), poor planning of equipment and work processes, poor teamwork, poor morale, lack of knowledge, and poor training all increase the probability of errors of various types and decrease the level of performance of tasks in different content worlds, including medicine. Most of the studies on the effects of the human factor on errors and performance levels have been conducted in aviation and high-risk industries, such as nuclear reactors, the military and petrochemical industries, and a minority have been conducted in the medical field. However, since in all cases we are dealing with human beings, it is often possible to generalize from studies conducted in one content world to other content worlds, including medicine [20].

In a review of the human factors issue in medicine published in 2016 in the British Medical Journal [21], the authors claim that in recent decades, there has been considerable and noteworthy progress in the assimilation of insights in the field of HFE (human factors ergonomics) in the world of medicine, which has been expressed in the designing of the work environments, work processes, medical equipment, and references to the functional characteristics of the teams as part of the system designed to provide medical services. However, the authors list a series of gaps in the implementation of HFE in medicine and offer ways to bridge them. Table 5.3 presents the gaps in a summarized version.

Table 5.3 Gaps in the field of human factors (Based on [21])

Topic	Current focus	The knowledge gap
Investigation of adverse events	Implementation of methodologies such as RCA (root cause analysis), which, according to some sources, may hinder organizational learning due to emphasizing one explanation rather than many explanations and may thus help prevent the occurrence of many adverse events	The adoption of alternative methods of documenting and investigating adverse events in order to broaden organizational reflection and learning; there are methodologies in various industries (STAMP, HFACS) that relate to interactions between a series of systemic factors that contribute to the occurrence of adverse events, including political, regulatory, organizational and team factors
Patient safety culture	Survey questionnaires and benchmarking	A combination of qualitative methods, for example, ethnographic, in order to collect richer information than questionnaires alone enables by use of a variety of methods to study the safety culture through, for instance, workshops and conversations with the staff
Job requirements, decision-making, workload, situational awareness	Focusing only on adverse events and on "what went wrong"	The implementation of methods such as cognitive analysis of tasks that provide deeper insights into how complex tasks and teamwork are performed, as well as a better understanding of the occurrences preceding errors ("near miss" events, alerts)
Teamwork	Teamwork practice and simulations	The application of research findings regarding work environment that examined the impact of autonomy, control, workload, and job satisfaction on productivity, efficiency, and safety
Information technologies and medical equipment	The degree of use and acceptance among medical staff	The application of sociotechnical concepts and insights in the design of computer systems and medical equipment in order to take into account the effects of computer systems and medical equipment on work processes
Checklists	Compliance and standardization	The application of principles of participatory planning according to which all stakeholders must be involved in the process of defining checklists in order to create solutions adapted to specific needs

The gaps described above indicate the need for a leap forward in adopting the principles of the human factor in the field of medicine. The more advanced principles from the field of human factors that have been developed in recent decades, including methodologies for investigating adverse events that express a variety of interactions among different factors, qualitative and dynamic methods for evaluating safety culture, and insights into the characteristics of teamwork, are still not sufficiently applied in medicine. It is important to note that all the gaps listed in the table above are directly or indirectly (most of them directly) related to various aspects of risk management and patient safety. Professional and committed attention to closing these gaps will undoubtedly advance the field of human factors in medicine in terms of reducing human errors and improving performance and patient safety.

5.5 Reducing the Probability of Human Error

Although most of the adverse events in medicine, as well as in other high-risk industries, are caused by human error; thus, to reduce the probability of human error, the working environment of the

medical teams, the work processes and guidelines, and the technologies and resources available to them in performing complex tasks must be improved. People are affected by workload, mental stress, mental burnout, reward, motivation, organizational culture, and safety in the organization where they work, must be treated with understanding and empathy.

An investigation of adverse events can help in understanding what makes human error possible and thus serve as a basis for systemic changes to reduce the probability of their recurrence under similar circumstances. In the last decade, an understanding has been established that human errors are a phenomenon/process/result that cannot be completely eliminated. Human errors are the result of the way we process information and carry out goal-directed activities. Many factors can affect an individual's ability to perform a task in a planned manner, including the complexity of the task, the availability of sufficient or reliable information, the workload, fatigue, mental stress, overly complex and unclear work processes, communication problems, and poorly defined work interfaces. The main question in the context of human errors is how to behave after an error has occurred to allow, based on understanding the error and its causes, a reduction in the probability of similar errors in the future. This sounds simple and true, in light of, among other things, the experience of high-risk industries in reducing human errors, but especially complex for application in the world of medicine.

The main obstacle to adopting the approach of learning from errors in the world of medicine is related to the therapists' perception of personal responsibility for successes as well as their failures and the understanding that no therapist operates in a vacuum and is always part of a system whose various components have reciprocal effects. Therefore, when an error occurs, it is not correct to punish the wrongdoer "so he can see and be seen" and instruct him to do what he has done countless times with success, but rather, the systemic factors that enabled the error did not prevent it and did not contain it should it be identified. A similar position is found in a review written in Milos Janishek's book *Medical Error and Harm* from 2010 in the Lancet journal [22]. Where the system fails, fixes should be implemented, and things should improve. This improves performance in aviation, spacecraft, washing machines, and robots and reduces the probability of future failures. In medicine, the opposite happens: medical errors and failures are accompanied by an aura of secrecy, a sense of personal failure, poor communication, defensiveness, and denial. As a result, the public expects unfailing perfection in medical practice. At the same time, fear of lawsuits does not make things any easier for doctors or patients.

As in many other fields, changing attitudes toward a certain subject sometimes requires adoption of an extremely different new paradigm. This has also happened with the adoption of the systemic model in the areas of risk management and patient safety. The systemic approach almost freed medical staff members from responsibility for their errors and the resulting harm to patients. The questions asked in this context are as follows: Have we not gone too far? Are medical staff members truly released from responsibility for their actions when they make an error, even if they operate in a system that is far from perfect? Do they not have responsibility for their knowledge? Their skill? For good communication with patients and colleagues? Do they not have a moral obligation to share their errors with colleagues and learn lessons in order to err less in the future? Do they not have an obligation to disclose to their patients that they have made an error and do everything possible to correct and compensate for the results of the error? Do they not have an obligation to say to themselves and their colleagues, "I don't know enough," or "I'm not skilled enough to perform this action"? Do they not have an obligation to report when they encounter risks with the potential to cause harm to patients? There are many more questions concerning the responsibility, values, and ethics of people who have chosen to take care of others as a means of livelihood. In our opinion, there is room for balancing the two approaches, the systemic approach and the human factor approach, to promote patient safety and avoid neglecting the main players in the field of patient safety—the members of the medical staff—and their mobilization in the joint effort to promote patient safety.

In the introduction to Lucian Leape's book [23], Donald Berwick notes the great progress that has been made in recent decades in the field of patient safety. The author, however, enumerates the gaps that still remain in the field of educating and training medical teams regarding risk management and patient safety: "Professional training hardly mentions the topic [patient safety], the scientific toolbox of patient safety is almost not provided to the doctors, nurses, or medical managers of tomorrow. No one graduates from medical school without learning about the Krebs cycle and hearing about the discovery of insulin, but almost everyone will receive their diplomas without learning a single minute about human error, or without being familiar with the work of James Reason."

How can human errors be reduced in medicine? Table 5.4 summarizes the recommended strategies for reducing the probability of human error at the caregiver level, that is, activities that caregivers can perform to reduce the probability that they will make an error while providing medical care.

To reduce the probability of human errors, continuous effort must be made to improve the working environments of medical teams, reduce their workload and stress, and improve their teamwork and communication.

Table 5.5 presents 12 strategies that medical organizations are recommended to adopt to reduce the probability of human errors by medical teams.

Key Messages: The Human Factor

- There are many definitions of human error. A widely accepted definition in the professional community of risk managers and patient safety experts is "all cases in which a planned course of mental or physical activity fails to achieve the planned result and when this failure cannot be attributed to the intervention of any random factors".
- It is accepted that approximately 70–80% of all adverse events are the result of human error.
- Two approaches to human error are accepted: the personal approach, according to which humans are the source of human errors and should do everything they can to avoid errors, and the systemic approach, according to which, in order to reduce the probability of human error, the work environment must be improved, workload and stress must be reduced, and the characteristics of the therapists' cognitive system must be addressed.
- The causes of human error are many and varied. Which factor is emphasized depends on the professional field dealing with the errors. Behavioral scientists especially emphasize the aspects of the cognitive system and what can interfere with its normal functioning, while engineers emphasize the systemic aspects of the work environment, the work processes, and the tools used in providing medical care.
- Human errors can be classified into three main categories according to the characteristics of the activity in which they occurred: skill-based errors in routine and familiar activities, rule-based errors in familiar activities for which there are rules of execution, and knowledge-based errors in new and complex activities.
- Despite the great progress that has occurred in recent decades in promoting patient safety and understanding the causes of human errors in medicine, there are still large gaps in regard to the investigation of human factors, the assimilation of a safety culture, and the understanding of the contributions of workload, stress, fatigue, and burnout.
- The paradigm shift from personal responsibility for human errors to a systemic paradigm has been accompanied by a radical adoption of the systemic paradigm, almost neglecting the fact that there is much to be done at the indi-

vidual level to reduce the probability of human error.

- In addition to the first victim, the patient who suffered harm as a result of a medical error, evidence is accumulating that therapists involved in adverse events experience a series of personal and professional effects that have been named the "second victim phenomenon".
- Twelve strategies are recommended at the individual level to reduce the probability of human errors in medical activity, and 12 organizational strategies are recommended to reduce errors in medical organizations.

Table 5.4 Twelve strategies to reduce human error at the therapist level

No.	Activity	Detail
1	Developing self-awareness for personal and professional abilities and gaps that require closure	Gaps in knowledge, skills, attitude, communication skills, and teamwork
2	Studying and understanding the factors that increase the probability of human error, and adopting behaviors that reduce the impact of these factors	Knowledge, experience and skills, workload, mental stress, organizational culture, and work environment
3	Learning from the errors of others	Studying reports on adverse events, case studies for learning, and professional articles in the fields of safety and risk management
4	Eliminating the attitude of "it won't happen to me"—even the best makes errors under certain conditions	As long as it does not happen to an individual, he thinks that errors happen only to others. However, errors happen to everyone, even the best and most experienced. It is important to understand and adopt the approach that humans are not immune to errors
5	Using proven aids that reduce the probability of human error	Using checklists [24], planning and preparing for complex operations, using simulations to acquire skills in complex activities, using other staff members as backup in complex situations and emergencies, paying attention to computerized alerts, regularly handling routine tasks such as documentation, reviewing test results, and using reminders
6	Empowering patients and encouraging their participation in the treatment process	Viewing patients as sources of critical medical information, to validate the treatment before it is delivered, and as partners in the success of the medical treatment
7	Learning about and understanding the concept of SA (situational awareness)	The concept refers to the way we use our cognitive resources in order to distinguish between the essential and the insipid, to hypothesize about the consequences of our activity in the present for the future, and by that, to avoid errors in the future [25]

(continued)

Table 5.4 (continued)

No.	Activity	Detail
8	Adopting a reflective approach to personal errors	There are two approaches to reactions after an error occurs: an impulsive approach, which holds that "it already happened, let us move on," and a reflective approach—stopping for learning and understanding (reflection). The reflective approach enables personal development through self-learning from errors, resulting in continuous improvements in personal performance [26, 27]
9	Understanding how the cognitive system works: "think fast, think slow" [19]	Understanding that our cognitive system works in two main ways: Automatically—Prone to errors due to distraction and conscious—prone to errors of information processing, poor planning, and misjudgment
10	Understanding the effect of cognitive biases, and how they can cause human errors [19]	Cognitive biases of various types may cause us to consider only part of the information available to us and direct us to a certain action that is not necessarily correct, and thus, they make us prone to errors
11	Understanding the typology of human errors in different types of functioning	Skill-based tasks, rule-based actions, and knowledge-based actions; understanding what can be done to reduce errors in the execution of these tasks and actions [18]
12	Understanding the concept of the second victim and its effect on caregivers involved in adverse events	Therapists who have been involved in adverse events experience a wide range of effects that may impair their professional functioning and their personal lives to the point of manifesting in symptoms similar to PTSD [28, 29]

Table 5.5 Twelve strategies to reduce human errors in a medical organization

No	Activity	Detail
1	Adopt an organizational culture of safety in all its dimensions and renounce the culture of guilt	Safety culture is discussed in detail in Chap. 4. Likewise, the IMA's (Israeli Medical Association) position is defined in a special position paper on the subject [30]
2	Maintain managerial control over the implementation of work processes and compliance with the regulations applicable to the organization	Any medical organization is based on legislation, MOH (Ministry of Health) regulations, the procedures and guidelines of a parent organization, internal organizational guidelines, professional guidelines, position papers of unions and professional societies, and more
		Working according to the set of standards mentioned above is intended to ensure the quality and safety of treatment
3	Involve active practitioners in organizational decision-making	Care providers have relevant knowledge and experience to improve patient safety; therefore, representing their point of view in organizational decision-making processes is critical for making optimal decisions related to changing work processes, adopting new technologies, establishing new facilities, developing computerized systems, and ensuring patient safety and more
4	Clearly define management policy on risk management and patient safety	Most medical institution managers have learned to attribute value to risk management and patient safety. However, in most institutions, a clear policy on safety and risk management is not defined and implemented
5	Enact constant managerial monitoring of workload, mental stress, and burnout of employees	Many studies have demonstrated a relationship between high levels of workload, stress, fatigue, and burnout, a decrease in performance level, and an increase in the probability of errors. If management engages in proactive efforts to reduce extreme levels of these factors, this may improve the quality and safety of care

Table 5.5 (continued)

No	Activity	Detail
6	Provide positive reinforcement for safe behavior that promotes patient safety	Managers tend to react harshly to medical errors, especially when significant harm has been caused to a patient. The value of this response is questionable because there are no caregivers who make mistakes with the intention of harming their patients. However, it is rare to find medical organizations in which positive reinforcement is given for safe or safety-promoting behavior such as reporting "near-miss incidents," stopping the chain of causation of an adverse event by identifying errors and failures in the process, reporting risks and not just adverse events, and making suggestions to optimization designed to improve patient safety and more
7	Back and support caregivers involved in adverse events	Therapists who have been involved in adverse events experience a wide range of effects that impair their professional functioning and personal lives, to the extent of symptoms similar to PTSD [28, 29]. Therefore, organizational planning is required to support and back up caregivers experiencing a crisis following involvement in an adverse event
8	Adopt a systemic approach to human error	This involves the adoption of a systemic approach that aims to identify the failures in the system that enable the occurrence of human errors [3]. The systemic approach enables the correction of such failures and the reduction of the probability of human errors in the future
9	Invest in tools to reduce the probability of human errors—Checklists, computer alerts, and improved work environment	The therapists' work environment and the means at their disposal, including computerized technologies, affect the probability of human error occurrence. Therefore, various aids designed to reduce the probability of human errors, such as checklists, computerized alerts, decision support systems, guideline and procedure accessibility, and advanced measures to monitor and control the treatment processes, including reminders, barcodes, and treatment status reports that are generated automatically, should be implemented and assimilated.
10	Train all employees of the organization, especially new employees, on patient safety and risk management	Most therapists and other workers in the health care system are not sufficiently familiar with the topics of risk management and patient safety. Therefore, it is unfeasible to expect them to apply the principles and insights of these fields in their daily work. It is also important that new employees, before starting work, learn the safety policies and risk management practices in the organization as well as the approach to errors and the work processes related to providing safe care in the organization
11	Widely distribute lessons learned from investigations and other risk management activities	Most risk management activities, including investigations, end with conclusions and recommendations on what needs to be done in order to reduce risks. It is important that the lessons of risk management activities be widely distributed in the organization and serve as a trigger for professional discussions in various sectors in order to raise awareness of critical risks and ways of dealing with them
12	Promote proactive risk management activities	This involves the proactive detection of risks in the work processes and environment that allow human error to occur, that is, poor protections or a lack of sufficient protections, according to the Swiss cheese model of risk management [3]. Proactive activity refers to safety rounds and risk surveys using various methodologies, including JCI's FMEA and more. It should be noted that in most organizations, reactive actions are mainly carried out following the reporting of adverse events, and not enough proactive actions are taken

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6 Organizational Factor in Patient Safety and Risk Management

6.1 Position of Regulators Regarding Risk Management Activities in Health Institutions

The regulation of risk management and patient safety in health institutions is focused on the instructions of the administration/medical division in dealing with the structure and function of risk management units in hospitals and health funds, procedures for managing adverse events or processes at risk, and the obligation to report. There should be a specific reference to the functioning of risk management units during an emergency, such as during the COVID-19 pandemic. According to these instructions, the role of the treatment safety unit is to identify adverse events, map processes with risk potential, and draw local and systemic conclusions that will help formulate courses of action to reduce the rate of adverse events in the institution and ensure treatment safety. Together with the management of the medical institution, the unit is supposed to lead and improve the organizational safety culture and climate, engage in education and training, and encourage all staff members in their various roles to report malfunctions, errors, and adverse events that harm patients and result in damage, "almost harm" or "near misses" for systemic learning and preventing similar incidents in the future. For this purpose, these units should be standardized according to the size of the medical institution. The staff should include senior doctors, nurses, and legal advisors who have undergone training in treatment safety issues. Staffing in a general hospital may be as follows: for institutions with up to 400 beds, there is a doctor, a nurse, a part-time legal advisor, and a secretary; for institutions with 800 beds, there will be two doctors, two nurses, a half-time legal advisor, and two secretaries; for institutions with over 800 beds, there will be three doctors, three nurses, a legal advisor, and three secretaries; and in a psychiatric or geriatric hospital, there will be a doctor, a nurse, and a secretary. In HMOs at the headquarters level, a department will be established that will include a senior doctor, a nurse, a secretary, and subunits with a similar composition in HMO districts.

The team must establish an institutional mechanism for the systematic investigation of adverse events that includes root cause investigations, inspection committees, and quality control committees; the mechanism must indicate how to organize the information in a computerized manner that will enable systemic information analysis, identify trends and patterns of recurring events, draw conclusions, draw lessons, define recommendations, and ensure their implementation. Periodic reports to the management of the medical institution will form the basis for managerial decisions and continuous improvements. A report will be made to the Ministry of Health for each type of procedure, and the staff will partici-

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pate in the forums of the Ministry of Health and present their experience to foster lateral learning. The treatment safety unit will have working interfaces with all the institutional committees (quality, records, procedures, resuscitation, infections, recycling, procurement, and institutional review board) and with the relevant units (quality, inquiries and public complaints, and legal department).

There should be structured regulations about the role of the safety unit in handling lawsuits due to medical malpractice or a directive to carry out a risk management plan in each of the content worlds of the subject. The duties of the unit/department should include reactive, interactive, and proactive risk management. In the event of an adverse incident, the director of the medical institution or the director of the patient safety unit will determine how and by whom an investigation will be conducted, what its content will be, what tools to use, and how the relationship with the patient and his family will be managed.

The obligation to report on adverse events should be detailed for each county by the Ministry of Health's Medical Division Circular. The rationale for reporting is a process that aims to minimize malfunctions and medical errors to ensure safe and high-quality medical treatment. A condition for this is the ability of the health system to continuously learn from the accumulated experience of those within it, from the experience of others, and from pre-assessments of risks that can lead to failures. Systemic causes can only be found with the help of their targeted investigations according to the obligation of the medical institutes in the following cases: an unexpected and adverse event that happened in the process of or after a medical treatment that caused death or damage. Examples include errors in drug treatment; damage to the therapeutic sequence; rare complications of surgery; errors in identification, diagnosis, or treatment; defects in the transfer of information; death during pregnancy or childbirth; suicide attempts during hospitalization or leave from the hospital; infection as a result of blood transfusion; hospitalization after dental treatment; damage during medical experiments; damage to a newborn; and fetal death over 32 weeks of pregnancy. In addition, there are some events defined as "never events." Examples are inadvertently leaving a foreign object in the body during surgery or an invasive procedure, performing surgery on the wrong organ/side, causing a second-degree burn or higher during an operation, and incorrectly administering a blood transfusion or its products.

Support programs should be established by the central government, in which the medical institution is rewarded for its good deeds in matters of treatment safety to promote safety in medical institutions, community clinics, and general, geriatric, and psychiatric hospitals. The programs address the proactive improvement of work processes in the centers to prevent the risk of errors in medical care and result in directing the attention of the institutions' management to the issue of patient safety. This model consists of reporting indicators and observations on events that should not happen ("never events"), safety indicators, reports of "near-miss" events, organizational learning from adverse events, patient identification at different stations, work processes in the operating room, patient identification in institutes and departments, training in treatment safety and conducting investigations, safety rounds, and departmental projects. Following pandemics such as that of COVID-19, quality and safety instructions are published recommending the updating of the procedures regarding the duties of the emergency risk management units. When managing a crisis, in addition to adverse events that occur routinely and that do not disappear in a crisis, there is the crisis itself and its scenarios, which are exceptional events in themselves, as well as the unexpected results of crisis management, that must be dealt with. The work of risk management units is divided into reactive (or retrospective), interactive, and proactive activities, all of which should be more strongly expressed during a crisis. It can be said that the risk manager should be the manager's adviser on crisis matters, including how to investigate, manage, and learn on the move from his own conduct.

6.1.1 Types of Activities During an Epidemic (in Continuous Cooperation with the Infection Prevention Unit)

(A) **Reactive activities**
1. Reporting adverse events related to the crisis.
2. Conducting targeted investigations to draw lessons during the crisis.
3. Conducting weekly/monthly analysis of all reports and the dissemination of knowledge for immediate systemic learning.
4. Conducting in-depth and summary analysis at the end of the crisis for future needs.

(B) **Interactive activities**
1. Assisting management in handling adverse events as they occur.
2. Implementing recommendations and insights.

(C) **Proactive activities**
1. Actively participating in all forums and representation opportunities related to risk management and patient and staff safety.
2. Actively participating in defining and planning new work processes, procedures, planning structures, teams, hospitalization and treatment policies, and treatment safety guidelines.
3. Conducting frequent safety rounds and immediate counseling.
4. Training teams on how to maintain treatment safety during a crisis.

The significant and comprehensive process that has shaped the safety culture in developed countries such as the USA, Canada, and OECD countries has not yet happened in Israel. A government institution has not been established to centralize the activity to advance treatment safety, and no significant regulatory measures have been implemented, as was done in Canada, for example [1]. There is room to begin a complex process to promote treatment safety and risk management in medicine that can include legislation, regulation, improving measurement and evaluation, research, updated information, communication with the public, and education in medical and nursing schools and health institutions.

6.1.2 The Israeli Pilot Act 2012: An Example of Risk Management and Safety Culture

The Pilot Law regulates the safety of civil aviation and the efficiency and regularity of air traffic through the Chicago Convention—the Convention on International Civil Aviation. The law authorizes the Civil Aviation Authority (RTA) to grant licenses, approvals, and certificates to all entities and people involved in the Israeli aviation industry, including flight attendants, aircraft, airlines, manufacturers, testing institutes, airport operators, and pilots, to monitor compliance with instructions. The pilot law, pilot regulations, and all the licenses, approvals, and instructions issued under these also authorize the RTA to enforce violations of such instructions. The issue of safety at airports is anchored in the 1992 regulations and covers a variety of safety issues and their regulation at airports, starting with aviation operations with an operational reference book and moving on to route specifications and their marking, safety teams, emergency plans, and the responsibilities of each person in a lead role, including risk management plans for a wide range of scenarios. The pilot law can serve as an example for risk management and medical treatment safety as well as for any other area where there is a real and tangible danger to human life. The 1984 regulations address the investigation of accidents and incidents to aircraft and specify the form of notification of incidents and its receipt, the appointment of investigators and their powers, the appointment of public investigation committees and their powers and work procedures, the writing of reports and their conclusions, the implementation of report recommendations, systemic investigations, and penalties. Under Article 20 of these regulations, the chief investigator

determined that the disclosure of information from the following could adversely affect the possibility of obtaining information for an ongoing investigation or at the time of another investigation in the future, and information would not be provided for any purpose other than the purpose of the investigation, meaning that all the following will remain confidential:

1. Testimonies or statements of those responsible for the safety of operating the aircraft.
2. Communication among those responsible for the safety of operating the aircraft
3. Medical or personal information related to people who were involved in an accident or incident
4. Cockpit voice recordings and transcripts of these recordings
5. Opinions expressed during the analysis of the information, including information on flight records

If a request for the disclosure of information is submitted to a committee or team, it will be forwarded to the chief investigator for a decision on the aforementioned matter.

Sections 104 to 141 address the essence of a "safety investigation" aimed at learning and drawing conclusions. The law frees the chief researcher from any management or command restrictions and states that the researcher will work according to the law only and that his performance will be in line with the provisions of the law, including decisions regarding the confidentiality of his findings.

Section 140 of the law refers specifically to safety investigations:

(a) A person in possession of safety information, as defined in section 139(a), shall keep it a secret, shall not disclose it to others, and shall not make any use of it, except by the provisions of this law or according to a court order.
(b) Notwithstanding what is stated in subsection (a), the chief investigator may include in the final report, as defined in item 118, citations from the recording or transcript that are safety information as defined in section 139(a) if he finds that this is essential to illustrate the findings of the safety investigation or its conclusions.

6.1.3 Laws Dealing with the Regulation of Treatment Safety Promotion Activities in the USA, Denmark, and Italy

In 2008, the United States Congress passed a special law on reports of adverse events related to the safety of treatments and public institutions—that is, related to patient safety organizations (PSOs), whose role is to receive the reports, analyze them, and draw conclusions from them for systemic learning (https://www.govinfo.gov/content/pkg/FR-2008-11-21/pdf/E8-27475.pdf).

In California and Illinois, laws were enacted in 2019 that require a fixed ratio between the number of nurses and the number of patients treated by each nurse in general hospitalization and in the intensive care units (two patients per nurse in intensive care units, three per nurse in increased care units, one per nurse in operating rooms, and five per nurse in inpatient care units). Unannounced inspections are carried out by the state, and hospitals that do not comply with the said ratio are heavily fined. Additionally, the option is given to anonymously report adverse events or report them non-anonymously while maintaining the confidentiality of the data.

In 2003, a treatment safety law was passed in the Danish parliament following the finding that 9% of hospitalizations in Denmark were accompanied by adverse events. The purpose of the law was to ensure a complete and reliable report on adverse events and systematic learning from them. Hospitals are required to collect information on adverse events, research them, analyze them, draw conclusions from them, and implement organizational changes accordingly. The

law protects those who report in real time from criminalization and punishment. After 2 years of the implementation of the law, it was found that doctors reported 85% of the incidents in which they were involved, and nurses reported 89%. The emphasis on correct and immediate reports resulted in a significant improvement in organizational safety culture in Denmark.

In 2017, a treatment safety law was enacted in Italy following an announcement by the World Health Organization that one out of every ten hospitalized patients was injured during their hospitalization. Italy recognized the right of its citizens to safe hospitalization, and the law includes a description of the relationship between the hospitalized person and the medical institution and the right of the patient to choose between treatments, to refuse treatment, to coordinate expectations with the therapists, and to report issues with any action.

6.1.4 Human Resource Management: Recruitment and Training

As with any issue in the health care system, it is very important to select and train the people involved in treatment safety and risk management. There are several advanced courses for specific degrees in treatment safety and risk management in medicine in many countries, but the exact subjects covered by such training are not yet institutionalized, and the requirements for risk manager positions are not anchored in law or binding circulars. It is recommended to recruit risk managers from among doctors and nurses who attend targeted courses and further learn from the experience of leaders in the profession, similar to the establishment of the other medical professions. It is of course possible to learn from experience gained in aviation and other industries and adapt lessons to the world of medicine, as has indeed been done over the last two decades. The topic of risk management in medicine is taught in one form or another in faculties of medicine, in nursing schools, and as part of bachelor's and master's degrees in health systems management. Care must be taken to raise the minimum requirements for risk managers and define them according to accreditation requirements that include a substantial section on the subjects of human resources, appropriate training, and documentation.

6.2 Effect of the Work Environment on the Quality of Care: Aspects of Human Engineering

Ergonomics, or human engineering, is a science that deals with understanding the functional interactions between man and his environment, in his work, at home, and in his leisure pursuits and puts man at the center of these interactions. The working assumption is that as the efficiency of the work of a therapist exposed to ergonomic loads decreases, the quality of that work is affected, the therapist's patience decreases, and the chance that he will make a mistake increases. The goals of ergonomics are to improve the degree of functional compatibility of the environment with the characteristics of the people who function within it, to increase efficiency at work, and to reduce the level of risk by ensuring a good match between the environment and the needs of individuals and their abilities and desires. The principles of ergonomics include planning and designing according to the user's requirements, taking a systemic approach, and referencing improvements in both health planning and execution (Fig. 6.1).

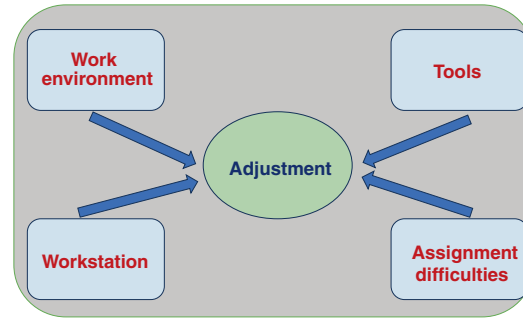

Fig. 6.1 Flow chart of working adjustment

6.2.1 There Are Five Types of Ergonomics: Physical, Specific Needs, Cognitive, Corrective, and Preventive

1. Physical ergonomics is the study of human anatomy, the physiological and biomechanical properties of physical activity, the interaction between work teams and users, the reduction of physical and mental loads that may cause physical (e.g., skeletal, muscular, and ocular) or mental injuries, the design of products to treat or prevent skeletal problems (e.g., manufacturing chairs, tables, and computer keyboards that are comfortable and physiologically adapted to the consumer's structure), and the understanding of the correct position of the human body when performing an activity (e.g., bending and performing surgery). The loads on the body are caused by exerting great force (effort) over time, performing repeated actions with a certain organ, exerting direct pressure on an area of the body, exerting extreme force (effort) in a one-time fashion (e.g., carrying, lifting, and pushing loads), maintaining a static position (e.g., prolonged sitting), experiencing extreme/asymmetrical joint postures, operating in a harmful environment (e.g., in terms of lighting, vibration, climate, radiation, and visual load), and experiencing work under pressure. Many examples of actions related to ergonomics that directly affect the therapist and the patient include a surgeon working with extensive bending and prolonged standing, which cause a decrease in accuracy, cumulative fatigue of the lower limbs and back; a nurse bending to pick up a heavy patient and the patient falling; a dentist sitting in a large bend with his hands in the air, which causes a decrease in accuracy due to the static work of the upper limbs; computer workers in a static position facing continuous visual load, which may increase their chances of making a mistake; a stretcher engaged in carrying loads and continuous pushing, which comes with a danger of falling; radiologists who operate in a dangerous work environment for long time periods; and auxiliary workers dealing with high-risk tasks (e.g., transfers, changing diapers, making beds, undressing, and dressing). More than 40% of the days of absence related to occupation are a result of ergonomic injury.
2. Ergonomics of specific needs is a subtype of physical ergonomics that deals with planning alternatives for people with specific needs (e.g., people with disabilities, especially tall/short people, people with special employment, and people with robotic limbs) and creating spaces suitable for people with specific physical or cognitive needs (autism and athletes).
3. Cognitive ergonomics deals with systems studying mental processes and how they affect the relationships between people and other system elements. This area examines processes such as perception, memory, thinking, the speed of response to external stimuli, and decision-making in routine and stressful situations created by work or mental stress.
4. Corrective ergonomics, a branch of ergonomics responsible for evaluating the space where people work, checks that steps are taken to protect the physical and mental integrity of people working in such environments, and in the case of ergonomic problems, offers suggestions to improve the functioning of the system.
5. Preventive ergonomics deals with raising awareness among employees regarding workplace safety and the importance of physical and mental health and means of mitigating stimulus loads (physical and mental fatigue, alarm fatigue).

There are quite a few ergonomic risks in medical institutions, such as repetitive movements, poor posture, heavy load lifting, holding static body postures, and deficiencies in the work environment. The challenges are also many: the expansion of services, changing technologies, many or fragmented work areas, the increasing average age of patients, and an increasing number of overweight patients. The organization can offer three types of solutions: engineering, managerial, and those related to the human factor.

6.2.2 Solutions to Reduce Physical Damage Include the Following

- In transporting equipment, dedicated carrying carts that enable workers to push the equipment instead of pulling it can be used. It is important to ensure that passages are not too narrow and that they allow passage with different means of transportation.
- In transferring patients, a crane and stretchers with wheels can be used.
- In terms of posture, prolonged bending positions should be avoided (by raising chairs and changing the height of beds).
- In routine and repetitive work, staff should be rotated between assignments and roles throughout the workday.

6.2.3 Changing the Work Environment

- The equipment should be laid out according to the process and sequence of work (e.g., frequently used accessories should be close to hand in front of the employee).
- Transparent cabinets will allow staff to see what is inside and save time searching.
- Workstations should be placed at an appropriate height.
- Staff should keep their head and shoulders in an upright and neutral position to allow a position where the arms are relaxed and elbows are close to the body.
- When in a position that requires prolonged sitting, staff should allow a comfortable position for the legs and fit dedicated work chairs whose height can be adjusted according to the type of work.
- Protective measures should be enacted.

6.2.4 Ergonomic Solutions to Reduce Errors

- Staff should have a plan for writing medicine prescriptions.
- The arrangement of medicines in the medicine storage room should be planned.
- Computing alerts should be sent.
- When a desired value is exceeded, a sound should be played.

Approximately one million medication errors per year occur in US hospitals (see also Chap. 7). Among the common mistakes are mistakes in the drug/dosage and use of the drug despite a known hypersensitivity. Approximately 7000 hospitalized patients in Israel die each year as a direct result of medication errors. Drug distribution is the most common operation in the health system that involves many teams from different fields of specialization and has a high risk of serious complications as a result of a mistake in administration (anticoagulants, opiates, and chemotherapy).

6.2.5 Work Environment Has a Significant Impact on Medication Safety in the Following Areas

- Medication registration (errors in manual copying, computerization, dose control, patient identification, cross-checking with tests, duplication of treatment, and alerts).
- Medicine storage rooms (noise, accessibility for everyone, order and organization, similarity in the names/packages of the medicines, cleanliness, medicines at risk of being damaged, and temperature control).
- Protective equipment (hoods, goggles, and gloves for cytotoxic treatment, spill kits, eyewash devices, and containers for sharp objects and drug residue).

6.2.6 There Is a Need for Built-in Control Processes Within the Patient's Computerized Record Related to, For Example

- Lists and catalogs for choosing which drugs to prescribe.
- Overdose alerts.
- The relationship between dose and body weight.

- Sensitivity to medications, as indicated by the individual and the admission letter.
- Recommendations on drugs of choice.
- Patient age.
- Patient gender.
- Interactions between drugs.
- Connections between laboratory tests and drugs and between diagnoses and drugs.

One of the most well-known and popular models is the Swiss cheese model, developed by James Reason in 1997 and named for a type of cheese with holes. Each layer of protection is likened to a slice of cheese and is designed to prevent risk from passing through it and materializing into an adverse event. Typical layers of protection are procedures and protocols, the knowledge and experience of medical teams, a suitable work environment for carrying out the task, etc. However, like the holey Swiss cheese, there is no perfect protection that guards against all risks; there are holes in each layer through which risk may pass and manifest as an adverse medical event. There are two types of holes: active failures (AF) and latent/chronic holes (latent conditions, LC). Active holes are caused by the poor functioning of medical staff members, while latent holes are caused by incorrect management decisions, a lack of resources, the incorrect definition of work processes, a lack of management control, insufficient training, etc. Holes of both types are dynamic so that each event is a unique situation that allows the transition through the layers of protection to be compromised. However, latent holes are more or less permanent. Therefore, when adverse events are investigated, it is important to focus more on latent events than on active events since the latter are specific to each event and are related to the members of the medical staff. The more carefully planned the work environment is according to the desired treatment results, the smaller the chance of failure or mistakes. If the connection to the oxygen source on the wall of the intensive care unit is different from the connection to the vacuum or other medical gas containers, the danger of the patient not being connected to oxygen when needed will be zero. If the patient's bed is protected by handles and is not too high off the floor, the chance of a patient falling or falling with damage will decrease.

There is no doubt that in light of the increase in the complexity of medical treatment, the coping ability of staff members is decreasing. There is therefore a need to emphasize human engineering and cognitive psychology to successfully deal with the ever-increasing demands, difficulties, and obstacles. Modern systems that support operations and prevent obstacles are needed in all areas of medical practice. A typical example comes from the field of treatment in intensive care units. The cases of patients hospitalized in such units are difficult and complex, and despite the great skill of the medical and nursing staff, quite a few mistakes occur during treatment due to the complexity involved and the high dependence on various types of equipment. In the intensive care unit, many diagnostic and therapeutic operations are performed on patients who are confined to bed, and some are on ventilators. Intubation for invasive ventilation, cannulation of central veins, and arteries for fluid administration and monitoring, dialysis, and ECMO therapy are all extremely complex procedures with a high chance of errors and failures. In a study conducted in Israel, an average of 178 different activities per patient per day were observed, with a wide opening for errors and significant failures. Errors have been found in approximately 1.7% of the operations (0.95%) [2]. In a period of 4 months, more than 1000 mistakes can be expected, although only 476 mistakes are reported independently, 29% of which have the potential to be life-threatening. It has been found that doctors make more mistakes than nurses. One explanation for this is that the distribution of patients between nurses and doctors is different, as a doctor is responsible for six patients, while each nurse has only two patients under her care; furthermore, doctors give consultations in intensive care outside the department, and some doctors are still only interns and thus have lower skill levels than more experienced nurses. A significant part of the mistakes could be prevented by smart human engineering and improving com-

Electronic light detector to open a faucet only when in use:

An evacuation hole in the rim of the sink to prevent water leakage when it overflows:

Operating a mower while the operator is holding the handle:

A safe plug socket:

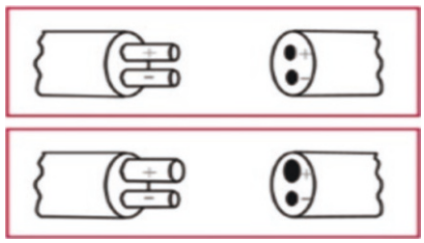

Fig. 6.2 Examples from different content worlds. (**a**) Electronic light detector to open a faucet only when in use. (**b**) An evacuation hole in the rim of the sink to prevent water leakage when it overflows. (**c**) Operating a mower while the operator is holding the handle. (**d**) A safe plug socket

Identification step to prevent identification errors and enable the use of a barcode:

Different colors for medical gas connections:

A different syringe tip for intravenous feeding and injections:

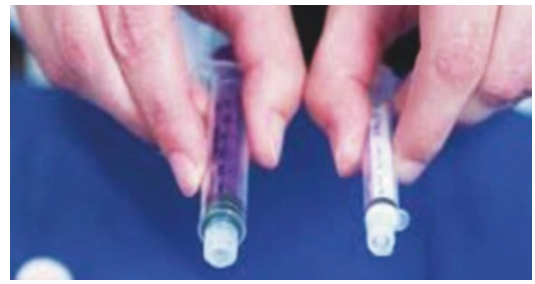

Fig. 6.3 Examples from the medical world. (**a**) Identification step to prevent identification errors and enable the use of a barcode. (**b**) Different colors for medical gas connections. (**c**) A different syringe tip for intravenous feeding and injections

munication between doctors and nurses, such as having clinical rounds and shift transfers together.

Many models aim to prevent the possibility of an error or mistake being made in a medical process. The assumption is that in almost all areas of life, human errors may be made, and using different types of technologies, it is possible to help people avoid making mistakes and, if possible, even direct them to perform only the desired/correct action (Figs. 6.2 and 6.3).

6.2.7 Surry Model to Prevent Operational Failure (Fig. 6.4)

- When an employee is aware of the risk, he should take the necessary steps to avoid being harmed.
- When the employee does not recognize the risk or the danger, his chance of being injured in an accident increases since he has no incentive to take precautions.
- The risk is highest when there is no sign of danger; therefore, the worker cannot avoid it.
- The lower the risk is, the more likely the worker is to perceive signs of danger, understand them, know how to defend himself, and decide to take evasive actions.
- There should be alerts and signs of risk/danger in the system.
- Ergonomic planning/training should be offered so that people can promptly detect signs of danger.
- Appropriate training should be provided so that employees not only recognize but also understand the meaning and consequences of signs they observe.
- Employees should practice their responses to emergencies and various situations that involve risk so that they know how to avoid injury.
- A safety climate, such as management and awareness of safety issues, will motivate people to take the necessary steps to avoid risks at work.
- Designing a work environment with protective equipment and other equipment will help staff deal with hazards located in the workplace.

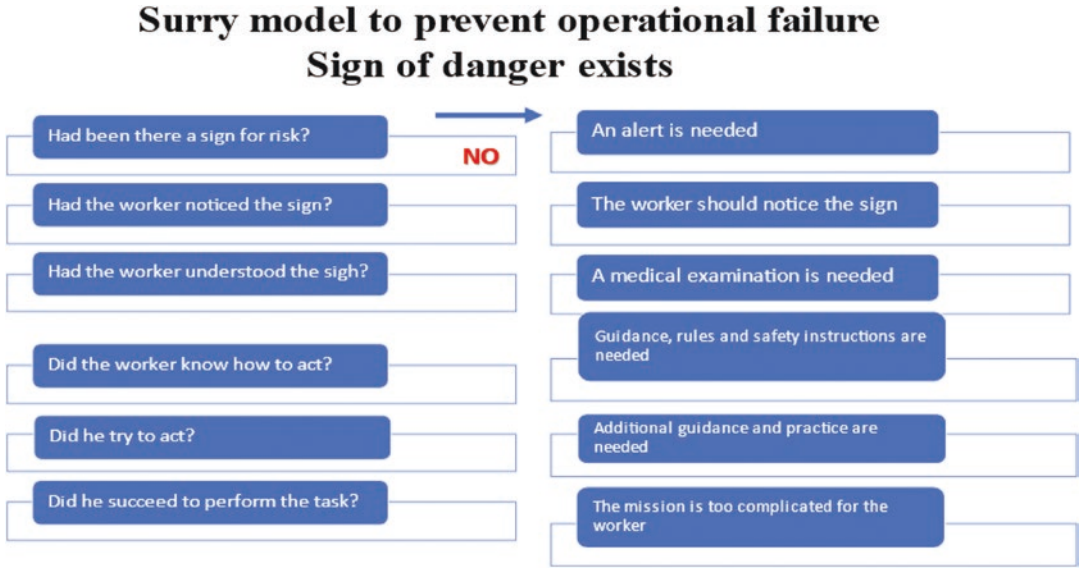

Fig. 6.4 SURRY model for preventing operational failure

6.3 Information Systems and Organizational Computing and Their Effect on Treatment Safety

The possibilities of computerization have dramatically changed the face of medicine, ranging from the individual aspect of the computerized record to the inexhaustible research possibilities that allow for learning from the treatment results of millions of patients in a short period. The management of the case has become more accurate and efficient with the help of the computerized record, including pulling the results of the laboratory tests, X-rays, pathologies, and all other auxiliary tests. The management of medical institutions has also improved immeasurably in terms of quality and safety due to the ability to immediately check the performance of the various departments through updated control panels that draw all the information from various medical, laboratory, imaging, and administrative sources. At the department level, it is possible to check the performance of the staff as well as the performance of all the physicians, especially in surgical departments and in performing diagnostic and therapeutic procedures. This allows for the early detection of mistakes and failures, and education and training to prevent the same mistakes from being repeated. For computerized medical records to improve patient safety, users, doctors, nurses, and consultants must use them effectively. There are barriers to this and many possibilities for failure [3]. The user must have learning and typing skills, an understanding of the structure of the medical file, motivation to be accurate, a comprehensive description of the patient's condition, and a clear strategy for determining the correct form of writing. Medical institutions should have software and hardware support systems, the technology should be user-friendly, and the software should be responsive and functional. If filing reports in the computerized medical file is too complex or complicated or takes longer than expected, the system's effectiveness is reduced and opens up possibilities for mistakes and failures. The correct use of the medical record will lead to better treatment, improved quality and safety, instructive follow-up, and knowledge sharing that will enable a therapeutic sequence between therapists inside and outside the medical institution. In addition, emphasis should be placed on the completeness of the information and the integration of all content to create a comprehensive treatment plan with unambiguous recommendations. The use of decision-support programs and warnings of unwanted or unexpected results and drug interactions has added a very important layer in maintaining treatment safety.

A chronic problem related to information systems in health care is that there is still no uniformity in medical records among different medical institutions, hospitals, and communities and even in different departments within the same institution. There are considerable difficulties related to the links among the various medical records and the danger of losing valuable and important information for the continuation of the treatment. The goal is to move toward a uniform medical record that will accompany individual citizens in all the health institutions where they receive treatment, will be accessible to the primary doctor and experts needed for consultations, and will also be used during hospitalization.

The optimal solution is to establish a national medical record that would allow various care providers access to the medical information from a patient's record regardless of the relationship between them and the health insurance company by which the patient is insured. This will shorten the diagnostic and therapeutic process and eliminate unnecessary tests. Of course, one must take into account the necessity of protecting the confidentiality of medical information on the one hand and the exposure of the parties handling legal claims for medical malpractice on the other. Recently, national programs for digital health have been launched in many countries to help healthcare systems become more sustainable, advanced, innovative, renewing, and constantly improving by optimally leveraging information and communication technologies. The goal is that the establishment of organizational, process, and technological infrastructures and the implementation of a policy promoting systemic inno-

vation will lead to personalized treatment, promote health and disease prevention, promote the development and implementation of digital tools and systems that increase operational and administrative effectiveness, and improve availability and communication.

The computerized integration of the safety factors of the patient, therapist, and medical organization has led to the creation of different models for improving general safety in a medical institution, such as the SEIPS model = Systems Engineering Initiative for Patient Safety [4]. This model is based on the design of the system and its effect on processes and results and contains interactions between various components that affect the safety of the patient, the therapist, and the entire organization.

Advanced computer systems enable the optimization of information transfer and communication processes. The fewer tasks relying on human memory there are, the more critical information for the correct and safe treatment of patients improves. Labeling lists, computerizing protocols, setting up alerts regarding abnormal tests, closing the circle of reference to life-threatening results, identifying patient deterioration, and providing computerized decision-making support are all important to prevent failures and mistakes [5]. Computerized automation is important in all the processes that support treatment, such as preparing medicines, planning radiation therapy, monitoring patients, and administering intravenous drugs. Nevertheless, there may be numerous human errors and failures.

A study carried out in the USA examined the effect of computerized information on the safety of care over 4 years in Medicare hospitals and included three applications: a computerized medical record, lists of the nursing staff, and the PACS (Picture Archiving and Communications System) imaging archive [6]. The use of the computerized medical record was significantly correlated with a decrease in acquired infections, a trend that increased over the years of the study. There was no change in the number of thromboembolic events or bleeds. The nurses' lists and PACS did not bring about a real change. Because many studies have not shown an overall improvement in treatment safety despite the use of digital tools of various types, a technology was proposed to improve computerized records called SAFER (Safety-related Research), which offers intervention in critical issues in eight areas (hardware and software, clinical content, interface between staff and computers, workflow, communication, people involved in data transfer, organizational issues, regulation, measurement, and monitoring) that do not generate automatic alerts in the record indicating that, for example, immediate intervention and appropriate communication are needed upon receipt of a life-threatening laboratory result [7]. A systematic review of the medical literature in 2013 revealed 109 studies that examined interventions aimed at reducing errors in diagnosis, of which 32 tested a technological intervention [8]. The researchers found that technological intervention via cell phone text messages, for example, was the most effective in reducing diagnostic errors and in testing the implementation of a device or procedure. Recently, considerable progress has been made in preventing harm to hospitalized patients by electronically extracting warning data from computerized records; for example, when a pathological result of a blood count or culture is obtained, this is a "trigger" for an alert to be sent [9]. It has been found that with this method, it is possible to discover 90% of potential adverse events, and this method is much more effective than reports by staff members.

6.4 Managers' References to Safety Culture and Adverse Events

The most common and tested tool for evaluating the organizational safety culture, the AHRQ, comprises 12 dimensions of the safety culture, four of which include questions related to organization managers' views on the conduct of the staff members, the expectations for superiors, support from management, communicative openness, and nonpunitive approaches. In these four dimensions, 15 questions deal directly with the manager's conduct with the team regarding

reporting adverse events. The accepted perception of organizational safety culture today, following the publication of the IOM in 1999, is that organizations are not looking for culprits but intend to learn from incidents to prevent similar incidents in the future. The questionnaire inquires whether the managers consider employees' suggestions for improvement regarding patient safety, praise employees who follow procedures and do not ignore safety problems, create a work climate that promotes safety and shows that it is a top priority, and allow staff members to express themselves freely, note incidents that may negatively affect patients, feel they can contact their superiors freely, and be assured that they are not blamed for errors and incidents they report.

In the AHRQ questionnaires sent to the Israeli general hospitals in 2012, 2015, and 2019, the following results were obtained in the aforementioned four dimensions: scores of managers' expectations and their activity to promote safety—72% (2012), 70% (2015), and 69% (2019); media openness—63% (2012), 69% (2015), and 64% (2019); managers' support for patient safety—64% (2012), 68% (2015), and 65% (2019); and a nonpunitive approach to reporting errors—43% (2012), 49% (2015), and 46% (2019). It is extremely surprising to see that despite the investment in the education and training of teams between 1999 and 2019, there was no significant change in the organizational safety culture on these issues over the years.

When a significant adverse event occurs, there is an opportunity for an investigation, the level of which is determined by the risk manager or the director of the medical institution according to its severity and the damage caused. The investigation is carried out by the risk manager or another person at the medical institution who is selected to carry it out, and information on the identified risks is submitted to the institute director, who can then draw lessons and determine actions to prevent more such adverse events in the future. If the investigation raises questions of medical negligence, there is an opportunity for an inspection committee to be established according to the Patient's Rights Law. If the investigation points to a systemic failure, there is room to consider the establishment of a control and quality committee to check processes and conduct a retrospective study accordingly.

6.5 Continuity of Care: Work Interfaces Between Treatment Factors Inside and Outside the Health Organization

The importance of the therapeutic sequence inside and outside the organization, in transferring shifts in the department, in transferring patients from one department to another, in transferring patients to the operating room, imaging centers, nuclear medicine, or endoscopy institute, in taking and receiving the result of a laboratory test, as well as in admitting a patient to hospitalization and releasing him to the community, cannot be exaggerated. The treatment sequence is based on a frequently updated record and effective communication between all the treating factors. A therapeutic sequence can be defined as continuous treatment over time provided by many therapists in different settings and managed by the same primary doctor who integrates and implements the recommendations. The transition from the concept of a reactive response to the exacerbation of chronic disease to a proactive plan intended to prevent exacerbation or imbalance determines the efficacy of a therapeutic sequence.

The quality of treatment over time depends on the treatment sequence and the flow of clinical information among the different treatment providers from different disciplines. In medical care today, from the patient's point of view, it is very important to identify the treating factors and the patient's personal and direct relationship with them. On the part of therapists, the integration of the clinical information drawn from many therapists in different fields of medicine is important [10]. The emphasis in the definition of the therapeutic sequence is placed on the combination of several segments into one therapeutic complex, as this significantly promotes the quality and safety of the treatment over time.

It is very important to continue treating specific issues, such as administering statin treatment as secondary prevention after myocardial infarction and rehabilitation that accelerates recovery and restores patients' self-confidence. When a patient is released from hospitalization after a heart attack and does not go to a rehabilitation institution or does not continue treatment with statins, the prognosis is worse. In an inpatient setting, the therapeutic sequence is tested at every stage in which the patient is exposed to medical intervention, for example, the administration of medication (danger of errors in the type, dosage, and timing of medication when there is poor communication between the provider and implementor of the instructions), the transfer of a patient (danger of errors when communication between the sending and receiving departments is poor or when there is a lack of information about background diseases and sensitivity to medications or the type of test needed when referring to an imaging institute), and shift transfers between nurses (inaccuracy in details may put the patient at risk of incorrect follow-up treatment or inappropriate reference to the result of a blood test or imaging). A lack of continuity of treatment can be related to the patient (e.g., he does not go to the family doctor or the rehabilitation institution despite it being recommended) or to institutional reasons (e.g., there is no appropriate recommendation in the disease summary due to forgetfulness or a lack of knowledge). An effective sequence of care has a notable impact on patient satisfaction but also, above all, on important aspects of case management and the complex work of a multidisciplinary team. Communication between therapists and an updated record available at the various treatment stations are necessary for the continuity of effective treatment. In patients with severe chronic diseases, the therapeutic sequence is particularly important and includes coordination between many medical and health professions over time, the integration of consultant recommendations, and primary care follow-up, all the while with constant consideration of the results of auxiliary tests, laboratory tests, imaging, and diagnostic and therapeutic procedures. The effectiveness of the therapeutic sequence from the patient's point of view is of great importance. In a study of attitudes conducted among diabetic patients (as an example of a chronic disease), four requirements emerged for the success of the treatment sequence: continuity of follow-up and treatment over time, a personal relationship with a recognized therapist who knows the patient and is attentive to his needs, flexibility in managing a treatment when a change is needed, and coordination between the different therapists in the community or between the community clinic and the hospital when the need for hospitalization arises [11].

Three elements characterize the quality of the treatment continuum: the strength of the health insurance funds committed to primary care in the community according to the law, the quality of the primary doctors in the community that act as specialist family doctors, and a computerized personal medical record and digital support [12]. The central management of the insured in each HMO by one central regulation and the close supervision of the regulator significantly promote the sequence of treatment. This has a direct effect on the quality and safety of treatment, as was manifested during the COVID-19 pandemic. The importance of communication about diagnostic and therapeutic activities and their coordination and integration is complex, and there are a large number of specialists relative to primary care medicine doctors, which results mainly in chronic diseases that require frequent and numerous transitions between therapists and account for a significant proportion of mortality cases. Organizational failure in the therapeutic sequence results in repeated hospital admissions and many emergency medicine department referrals due to adverse drug interactions [13, 14]. Three fundamental components of the treatment continuum can be distinguished: the correct use of the clinical information accumulated in the past for correct treatment in the present, regulated and regular access to the therapeutic frameworks according to the patient's needs, and a continuous personal relationship between the patient and the therapists [15, 16].

The World Health Organization (WHO) has compiled a list of several topics that characterize a successful treatment sequence according to the

literature: a positive evaluation of the primary family physician, trust in caregivers, the option for the patient to receive treatment from the family physician at home, access to primary mental health care, and continuity of care will reduce hospital admissions by 13% and visits to emergency departments by 27%; home hospitalization reduces health expenses and the need for hospitalization by 19% [17].

6.6 Activity to Promote Quality Versus Risk Management Activity and Treatment Safety

Risk management activity—reactive, interactive, and proactive—is mainly intended to maintain the safety of the treatment although another goal is maintaining quality. Sometimes, there is an overlap or a lack of precise definition that will cross between activities that prioritize quality priority and those that prioritize safety. In terms of definitions, activities for the advancement of quality deal with actions aimed at improving the results of treatment, which themselves can sometimes cause adverse and unexpected events. A new drug has the potential to improve the cure rates and may cause unexpected side effects; an invasive procedure that is a breakthrough for a specific treatment may result in an unexpected complication. For example, aortic valve implantation with therapeutic catheterization and without surgery significantly shortens hospitalization time and avoids chest opening and well-known complications such as sternum infection and systemic failure but does not rule out complications associated with the implantation itself. Therefore, any new treatment, be it a drug, diagnostic or therapeutic procedure, or surgical approach, requires an accurate assessment and a risk management plan that covers all the theoretical possibilities of harming the patient.

Activity to promote quality is mainly expressed in two areas: a system of quality indicators that measure processes and outcomes and annual quality plans with the intention of continuous improvement. The quality indicators are intended to increase the required behavior and maximize the use of a therapeutic approach that relies on clinical guidelines and established research. Quality indicators should be scientifically proven, compliance with them will improve the quality of treatment significantly, and the indicators represent a large population of patients, can be measured digitally and without overloading the medical staff, and can provide goals for continuous improvement [18]. Care must be taken not to choose an indicator that may cause damage through an administrative change that aims to promote the indicator and achieve the goal but harms another medical activity that is not measured and needs resource prioritization that is not correct [19].

As an example, the Israeli national program for quality indicators in hospitals, mother and child care stations, and ambulance companies does not directly include safety indicators, such as the outcomes of operations and invasive procedures, but it does have indicators that leverage conduct that prevents adverse events, such as giving prophylactic antibiotics before operations, performing computed tomography or MRI for a patient with CVA within 25 min of admission to the medical center (to allow early treatment), and providing therapeutic cardiac catheterization in STEMI (ST Elevation MI) within 90 min of diagnosis. These and other actions showed a decrease in mortality in patients who received treatment according to the requirements of the indicator compared to those who did not [20–22]. That is, for the quality indicators, there is also a clear element of risk management, patient safety maintenance, adverse event prevention, and in some cases, even mortality avoidance. A national plan for safety measures does not yet exist in Israel or OECD countries, but it is in the advanced stages of preparation.

Departmental and institutional quality plans (issues in the focus of the institution's management) are an integral part of the accreditation requirements and must be renewed every year to achieve continuous improvement in the institution's performance and treatment outcomes. Quality plans should contain risk management elements as an integral part of maintaining patient safety.

Support programs (incentive models) for treatment safety and risk management should be operated by the regulator in general as well as by geriatric and psychiatric hospitals and HMOs. These annual programs aim to create a national standard for an organizational culture that promotes treatment safety and risk management in medical institutions. The programs establish uniform guidelines for the activity by defining the indicators that make up the action in the field and encouraging institutions to promote treatment safety and risk management activities through financial incentives. By identifying and defining risk points and implementing correct work processes, it will be possible to significantly reduce mortality due to failures and errors in treatment, as well as high expenses due to medical malpractice claims. Such programs include reactive and proactive components based on safety indicators. **Process indicators** include patient safety training, safety rounds, projects to promote the safety of the treatment, and projects to promote the safety of the therapist. **Outcome measures** include learning from adverse events through investigations, implementing systemic recommendations, reporting adverse events and "near-miss" events, and asking employees to participate in a questionnaire regarding their attitudes toward treatment safety [23].

6.7 Regulation and Accreditation

The accreditation process checks health institutions' compliance with procedures, knowledge, laws, and regulations in all areas of practice in the medical institution. A structured process with accountability was implemented in the USA following the initiative of the Medicaid and Medicare organizations as part of the JC (Joint Commission). Following a structured inspection process once every 3 years, medical institutions receive an accreditation standard and are supposed to improve their treatment quality and safety each year. The test book contains over 1000 standards that must be met to receive accreditation. Every few years, a new edition of the book is published that is adapted based on scientific and medical progress and the improvements required in the approach of institutional directors and staff members according to social changes and demands. In addition to the JC, more than seven international accreditation organizations are currently active (Fig. 6.5).

Fig. 6.5 International accreditation organizations

The oldest and most accepted organization is the JCI (Joint Commission International), which is a branch of the US JC. The implementation of the accreditation standard by the JCI began in Israel in 2005 at the urging of Clalit Health Services (the largest of the four Israeli HMOs) out of a desire to maintain standardization in work processes and uniform criteria for the safety and quality of care. In 2012, the Israeli Ministry of Health decided to adopt the JCI standard for all general hospitals in Israel and to condition the renewal of each hospital's license on the successful completion of an audit. Over the next few years, a comprehensive move was made in all hospitals to implement the accreditation requirements and successfully pass the 3-year inspections. In 2020, following the outbreak of the COVID-19 pandemic, JCI inspections in Israel were stopped, and they began again at the beginning of 2023.

The JCI standards deal mainly with patient safety, and for this purpose, there is a special chapter in the accreditation book containing six International Patient Safety Goals (IPSGs) [24]. The purpose of this chapter is to promote and improve patient safety. Possible failures, expected mistakes, and "holes in the Swiss cheese" are highlighted, and solutions are offered that managers in the institutions and staff members should implement to minimize the possible damage. As much as possible, the standards rely on systemic solutions. Measurable elements (MEs) are proposed for each standard. During the test, scores are given for each measurable element—met, partially met, or not met. The medical institution is required to have a written policy, clear regulations, and protocols from which the standards and measuring elements are drawn.

6.7.1 IPSG Standards Are as Follows

IPSG 1: The correct identity of patients is confirmed. The institution has a process to improve accurate patient identification at all levels and all stations.

IPSG 2: There is a process to improve the effectiveness of communication, verbal, or telephonic, between different therapists. There should be an accurate reporting mechanism for abnormal and life-threatening outcomes and clear and accurate communication when transferring a shift.

IPSG 3: The safety of high-risk drugs is being improved. It is very important not to confuse drugs with similar names or similar packaging—drugs that look-alike/sound-alike. The careful handling of concentrated electrolytes is very important.

IPSG 4: There is a need for an identification and verification process during surgery or an invasive procedure and the marking of the operated organ. A "time-out" process is carried out immediately before an incision, and a sign-out process is performed at the end of the surgery.

IPSG 5: In terms of contamination prevention, hygiene guidelines and processes for the prevention of lateral contamination across the entire institution are needed. Improvement in the results of hospitalization and surgery and the prevention of infection within the hospital must be proven.

IPSG 6: Damage caused by falls must be prevented.

6.7.2 In Addition to IPSG Standards, Safety Standards and Required Measurable Elements Appear in Each of the 14 Chapters of the JCI Book

AOP—Assessment of Care, PCC—Patient-Centered Care, ACC—Access to Care, ASC—Anaesthesia and Surgical Care, MMU—Medication Management, QPS—Quality Improvement and Patient Safety, ASC—Anaesthesia and Surgical Care, COP—Care of Patient, ACC—Assessment of Patients, GLD—Governance, Leadership, and Direction, PCI—Prevention and Control of Infections, SQE—Staff Qualification and Education, FMS—Facility Management and Safety, MOI—Management of Information.

For example, the QPS chapter on improving quality and safety deals with integrating these ideas into the daily work of the teams. The chapter addresses the skills of those responsible for the safety and quality of care, data collection to measure these concepts, systemic learning from failures, investigations, inspection or control and quality committees, organizational culture, and safety climate.

6.8 Dedicated Information Systems for Risk Management and Treatment Safety

Information systems are a cornerstone of the correct and effective management of risks and the safety of treatments in every aspect. Information systems can be divided into four content worlds: computerized medical records (patient files), clinical data analysis and documentation systems, risk management systems—adverse event reports, and administrative information systems. Extracting information from all four types of systems and analyzing it can provide a complete picture of the patient's condition and the quality and safety of his treatment.

The importance of computerized medical records that inform care providers of the patient's clinical condition, details of any acute illnesses, and medical history data (chronic diseases, operations, diagnostic and therapeutic procedures, hospitalizations, laboratory tests, imaging results, pathology results from biopsies or surgery, etc.) at any given moment cannot be exaggerated. The importance of clinical information, especially when a patient is hospitalized or during an appointment with a doctor in the community or hospital outpatient clinics, saves valuable time and optimizes the treatment.

The documentation and analysis systems for clinical data make it possible to import data into computerized records from all service providers, medical institutions, diagnosis institutes, and laboratories. Critical results that are added to the patient's medical file in real-time and give warning to caregivers can save lives and prevent adverse events that would otherwise result from a lack of information and errors in treatment. The read-back interfaces between these systems and the computerized records verify and confirm the transfer of critical information.

Computerized systems for reporting adverse events exist in modern medical institutions, hospitals, and communities. These systems allow staff members to directly report, identify, or anonymously, adverse or "near-miss" events for further investigation and treatment of the case, as well as systemic learning and/or defense against future lawsuits. These systems are secure and user-oriented and report IP addresses according to the content and authority decided by the organization.

Administrative information systems, which provide important logistical knowledge, can be used for research into the safety of treatments and the deepening of knowledge on specific topics, such as the administration of high-risk drugs (according to dispensing and supply data), cost–benefit tests (outcomes vs costs), length of hospitalization after surgery, and mortality after intrusive procedures.

A dedicated risk management information system must be in every medical institution, hospital, and community pharmacy. The system cannot be generic but should be completely adapted to the complex and unique space of each medical institution. Therefore, the system must be well-planned, broad, and sufficiently detailed to contain everything required from ensuring medical risk management and maintaining the safety of the treatment. There is a need for skilled teams to help systems like this operate and to further support the end users—doctors, nurses, and risk managers. The system must be prepared to receive reports on adverse and other events in various categories (near misses, events with serious clinical consequences, disability or death, investigation results, root cause investigations, results of an inspection committee and a control and quality committee, and lawsuits due to medical negligence); to collect data and indicators, process and outcome indicators; to enable the

collection of data in various categories (search engines); and to produce reports, tables, and graphs for systemic learning. The system must have an effective interface with the medical record and the other information systems of the medical institution while clearly defining the form of data collection, analysis of accumulated knowledge from the relevant literature, court rulings, and systemic learning from other institutions in the country and other parts of the world must be added to the system.

In this era of artificial intelligence and digital capabilities, through smart analysis of data, it is possible to accurately predict treatment complications, rehospitalizations, and unexpected mortality and perhaps even to proactively eliminate root cause investigations or complicated retrospective investigations in the future and to replace complex models such as FMEA (failure mode and effects analysis), RCA (root cause analysis), 5M, and fishbone. There are commercial risk management information systems that can be purchased and adapted to the needs of the organization and those created by the organization according to specific characteristics and sometimes for certain purposes only (e.g., reports on adverse events). Examples of commercial systems include Origami Risk's cloud-based healthcare risk management software, which contains a large part of the above and should meet all of the needs of the medical organization in risk management [25], RL Suite, MedTrainer, Healthicity Compliance Manager, Quantros Safety Suite, Ability Riskwatch, ECFS +, ActionCue CI, Allocate HealthAssure, and Censint [26].

It should be noted that many of the off-the-shelf systems intended for risk management were not developed for the medical world but mainly for the financial world and high-risk industries. Therefore, there is a need for many adaptations of these off-the-shelf products to the specific needs of risk management in a healthcare organization, which sometimes makes the adaptation effort more complex than the dedicated development of a risk management and treatment safety system that matches the needs of the medical organization.

6.9 Risks in Computerized Medical Record Management

Medical records, be they manual or digital, are intended to be used as a tool by the therapist to document the treatment given and the medical judgment exercised within that activity. Full and proper registration, in real-time, is an available and convenient option for preserving information, serves the patient's best interests, enables proper follow-up, and prevents errors resulting from the transmission of missing information between different therapists. The management of the medical record should be mandated by patient's rights laws, where the staff is responsible for its ongoing and up-to-date management and preservation [27]. Such records are an integral part of medical treatment, and they include various types of documents and documentation relating to the patient's medical condition. These records help maintain a continuity of care, serve as a means of reporting and communication between therapists, enable the control and monitoring of medical practices and their evaluation, are a tool for risk management and data analysis for policy-making and decision-making, are a basis for research and the promotion of health and medicine, are forensic evidence, and are a tool for pricing, collection, and financial accounting. When an allegation of medical negligence is raised against the treating staff, the record serves as authentic and weighty evidence regarding the conduct during the medical treatment in real time, and the court grants it a presumption of reliability, as long as it is not proven otherwise. Missing or incorrect registration may damage the sequence of transfer of information between the therapists and the patient. As a result, the therapeutic decisions made may be based on incomplete (or even erroneous) information and are not of high quality, so the patient may receive treatment that is not optimal and may even be harmful (e.g., if a record regarding drug sensitivity is omitted). In terms of the legal aspect, if it is determined by the court that the record was indeed missing or

defective in the context of the disputed conduct since the treating staff (and the medical institution itself) were responsible for the complete record and subsequently for maintaining the record and did not comply with this obligation, this could mean transferring the burden of persuasion/evidence from the patient to the therapist. In a normal state of affairs, when a plaintiff submits a claim to the court regarding medical negligence, he has the burden of proving that the defendant's medical institution acted negligently or contrary to the standards of accepted medical care. For this purpose, the record is used as evidence to prove his claims. When the registration in the record is defective or missing or when parts of the record are lost, the claimant may find himself in a situation where he is prevented from proving his claims. In such a case, the defendant (the medical institution) is seen as the one who caused the claimant "evidentiary damage," that is, the institution damaged the patient's ability to bring evidence that substantiates the latter's claims. As a result, and regarding evidence concerning the disputed issue, the court's authority to transfer the burden of proof of those facts, which, if they had been recorded as required, would have been easy for the judge to assess, to the shoulders of the medical institution.

6.9.1 Existence of a Computerized Medical File Is a Cornerstone in the Provision of Quality and Safe Medical Service and Especially in Six Key Elements That It Enables

1. High-quality treatment during the stages of treatment within the department/clinic based on high-quality, accurate, reliable, and accessible documentation of the medical history and the entire treatment framework.
2. The possibility of integrating technology-based advantages (e.g., medical decision-support systems that require medical information about the patient as a basis for their operation).
3. Treatment continuity between care providers—in the transition to and from the treating department/clinic, in the transfer of information from the hospital to the health fund, which includes the medical treatment in particular.
4. The collection and documentation of therapeutic information from various treatment factors, including medical staff, consultants, nursing staff, paramedical staff, information from medical devices, and laboratories, as well as other therapeutic factors.
5. The flexibility of the solution in expanding the application and adding processes for the use of a wide variety of areas of specialization and making medical information accessible to the patient as a basis for his active integration into the treatment process empowers him and increases his satisfaction.
6. The collection and integration of information reported by the health system authorities to improve the treatment processes at the systemic level that rely on computerized reporting from the intraorganizational medical file.

Computerized medical records have brought about a real transformation in the health system and medical institutions. The transition from a manual list, written and typed by medical secretaries, to information added on the computer by the therapist has made documentation and information much more accurate and comprehensive. The ability to save data directly during clinical encounters; to extract data from laboratories, imaging centers, summaries of operations, and diagnostic and therapeutic procedures; and to receive in real-time all the necessary information everywhere and even far from the medical institution as well as the standardization of the quality of the data and the ability to analyze the results for optimal treatment and research purposes all unequivocally testify to the importance of computerized records. However, there are barriers and risks in moving from a manual record to a digital record. These may be related to the therapist, the patient, or the record. Many therapists have had difficulty typing after many years of manual writing or dictation, which prevented them from ade-

quately dividing their attention between the patient and the computer and sometimes caused them to miss inputting important data that they forgot and did not type or that they entered in the wrong way or location. Patients do not always appreciate the time required for documentation, and many do not like the feeling that the therapist is focusing on typing and "talking to the computer" rather than them. Such records, at least in the beginning, were not sufficiently developed, and much time has been needed to address failures and obstacles. It has also taken considerable time and the investment of human and other resources to optimize these records and reach a situation where the data can be easily entered and, above all, efficiently retrieved for treatment and research needs. A critical step in the development of the digital record has been the open interfaces with laboratory data software and diagnostic institutes on the one hand and administrative programming (patient registration and demography in the resident registry) on the other.

It can be said that today, computerized medical records are advanced in terms of quality and efficiency. There are still many barriers and possible failures that must be taken into account in terms of risk management plans and treatment safety. All the mistakes that exist in the transmission of clinical and demographic information can also occur in digital records. Mistakes can occur in patient identification, referrals for testing, diagnosis, drug treatment (type of drug, dose, and route of administration), surgical treatment, and sequence of treatment. Errors unique to digital records can happen without the therapist's knowledge due to programming errors, for example, while pulling the test results of another patient, a therapist may select an incorrect referral, the wrong date, etc. Support programs based on clinical guidelines that are not frequently updated can lead to incorrect test and treatment directions.

Quite a few lawsuits have been filed for improper registration in the computerized record, mainly due to lack of proper use of the cut and paste function, failure to evaluate the data, a lack of communication between the digital systems, or noncompliance with HIPAA (Health Insurance Portability and Accountability Act 1966) regulations—a federal law requiring the protection of patient data [28]. Unexplained additions or omissions in the electronic medical file, delayed typing, subjective comments, ignored warnings—all of these have been used as a basis for lawsuits. Therefore, computerized medical records should meet clear legal requirements according to the policy of the medical institution—what is required for the record to be complete and comply with accreditation, which data can be transferred to it and which cannot, and what is required to release data from the record should all be dictated by the policy.

The following risks must be taken into account and handled with care: hidden data in a record of which therapists are unaware, such as the author of certain data, input times, and changes made to existing lists (metadata); the quality of the documentation and adherence to regulatory regulations; and compatibility between the printed format and the digital data. One should be careful not to preemptively enter results that have not yet been formally accepted and be mindful of replacing all data in templates with correct data, which can be difficult due to the volume of data. Critical test results can sometimes be missed, and implementing training programming according to accepted clinical guidelines can be illegal if they are not properly filled in or updated. Human errors (e.g., prescribing a drug that the patient is allergic to) should be prevented as much as possible. By law, medical records belong to the patient, and he can demand them from the medical institution at any time (Table 6.1).

Table 6.1 Data retention times for medical authorities according to the Israeli "Public Health Regulations (Retention of Records), 1976"—medical records must be kept for different periods

File	Save time
The medical file of a patient in a general hospital	20 years after hospitalization or last treatment; 7 years after the patient's death
The medical file of a patient in the outpatient clinics	7 years
Patient's record summary or summary letter to the family physician	100 years
Laboratory test results book	10 years after the last registration
Surgical registry	10 years after the last registration
Book of anesthesia	10 years after the last registration
Birth registry	100 years after the last registration

6.10 Risk Management of Online Medicine

Online medicine (remote health services and telehealth/telemedicine) appeared following advances in the technological capabilities of remote communication, which include not only telephone or wireless communication but also the ability to transfer images and display a real-time image of participants and various medical materials, such as X-rays and ECG charts. With the advancement of technology, full virtual participation in operations and procedures and even surgery performed by robots have become possible. Initially, the role of online medicine was mainly to enable specialist consultations in remote locations with limited resources, for example, when there is a shortage of medical professionals from certain areas in a remote hospital. Later, it became an important tool in scientific conferences and remote scientific meetings, and today, most patients' needs can be fulfilled with the help of remote or digital medicine. The quality of online medicine has improved over the years, but patient safety has not kept pace. For example, in an online medical procedure, a doctor can include, in addition to the anamnesis and medical history, other tests that the subject can perform himself after acquiring a skill, such as measuring his temperature, pulse, and blood pressure, but cannot provide a comprehensive physical examination. In addition, the lack of face-to-face meetings may damage the impression of the doctor as a reliable clinician. Another dimension that is not fixed is the documentation and legal meaning of virtual meetings about medical records, which are supposed to include test results, treatment plans, and the doctor's diagnostic and therapeutic thoughts. The situations that allow proper and safe online care and the situations in which face-to-face care is required must be precisely specified. It must also be ensured that online service does not cause an irreversible interruption or elimination of face-to-face service, and expectations for such service should be appropriately managed. Each medical institution engaged in online treatment should have a detailed and comprehensive dedicated file that contains details on the service, the indications, the target audience, alternatives, research evidence of effectiveness and safety, the means of securing information, the responsibility of the therapist, compliance with treatment safety procedures, and, especially, the orientation of the therapists in all of the aforementioned situations medical conditions in which remote medicine technologies, control, and testing procedures should not be used to diagnose and treat patients. Therapists should undergo unique training with an emphasis on the caution that must be exercised when determining diagnosis and treatment. The importance of patient identity, information security, informed consent for online treatment, medical record management, continuity of care, professional and legal responsibility, and the ability to identify deteriorating clinical conditions and emergencies that require immediate evacuation to a hospital are emphasized. The circular emphasizes that the professional and legal responsibility for the actions of the service providers within the framework of remote health services is the same as the professional and legal responsibility in the provision of frontal health services.

As the majority of the population in developed countries obtained smartphones, this gave a significant boost to online medicine, and with the help of advanced technology, it is possible to collect clinical data and transmit it remotely. The gap between when accepted clinical studies begin investigating the use of a specific technology and the treatment outcomes might cause a significant delay in technologies being developed in a proper direction and unsafe or quality clinical use [29].

The COVID-19 pandemic caused an uptick in the use of online medicine out of fear of contagion in patient-therapist encounters on the one hand and the need to prevent the overload and insufficiency of medical institutions on the other hand. The progress of introducing digital means into everyday life, which once was slow and took years, has become fast and now advances daily. In the absence of proper and organized research, the hasty introduction of online medicine may endanger patient safety. For example, in an examination of 53 studies that compared six different monitoring devices, a discrepancy was found between the various devices and their measurement accuracy, especially during physical activity [30]. The need inevitably arose to institutionalize online medicine and allow safe and uniform use across different countries according to the capabilities of each country. There is a place for international clinical guidelines and standards and clear national and international regulations that provide for carefully guarding the patient's data and taking into account the needs of medical insurance. The regulation should address all aspects of telemedicine, such as informed consent, medical malpractice, matching expectations, cognitive failure, automation, and communication of measurement devices or treatment algorithms.

The NHS, the health system in England, suggests five steps for evaluating online medicine and ensuring its safety: gathering information related to the safety of online care and learning to report adverse events on the subject, opening unique learning centers for online/digital care and medical and nursing staff training, establishing a knowledge center for centralized data collection, preparing learning centers, creating training and writing clinical guidelines, implementing a special program for the safe absorption and assimilation of new digital technologies (Medical Devices Safety Program), and preparing an orderly and comprehensive risk management plan to prevent adverse events and promote patient safety [31].

It is estimated that doctors in the USA have seen 50–175 times more patients via online medicine during the COVID-19 pandemic than before the outbreak of the disease [32]. The use of remote medicine has become common and includes not only medical advice but also nursing and pharmacists. This platform is used for monitoring, diagnosis, treatment, and specialist consultations as needed. The ability to address urgent issues via remote medicine is limited, as is the case for anything that requires a thorough and reliable physical examination. There is a lawsuit risk when decisions are made without a physical examination, and this prospect must be taken into account. In many cases, the patient should be referred to a medical institution for further evaluation. The advantages of online medicine are many despite its limitations: access to medical services is easy and fast, there are benefits for those living in small communities or remote areas in receiving expert advice, prolonged follow-up and treatment of chronic patients at home is possible, and treatment is often possible sooner than at a brick-and-mortar institution. However, the risk of legal action is greater with remote medicine than with normal medicine because sometimes there is a lack of compliance with the required quality of care (standards of care), a lack of appropriate licensing, limited therapeutic options, and no possibility of a physical examination; furthermore, decisions must be made without such examinations, and patients may not be able to medication if the care provider is not able to send them a prescription. Therefore, plans must be prepared for detailed risk management that takes into account the limitations and safety issues before this service is provided.

The regulatory approach is different across countries, but common to all of them is the requirement that the quality of care is the same as that in regular medicine in all aspects of the inter-

action between therapist and patient. In the USA, there are clinical guidelines from scientific associations and societies that cover most of the medical aspects of telemedicine. The American Telemedicine Association [33] defines the necessary standards for quality care, and the American Gastroenterology Association [34], the American College of Radiology [35], the American Academy of Dermatology [36], and other associations offer specific clinical guidelines for these professions. It is very important to establish a formal license to practice remote medicine, which will also affect professional liability, medical malpractice claims, and finance charges. Because there are different laws among different states in the USA and there is no geographic restriction in the provision of telemedicine, a license to practice telemedicine valid for all US states, Interstate Medical Licensure Compact (IMLC), has been developed by the Federation of State Medical Boards. Doctors must meet certain requirements and fill out an online questionnaire [37]. Emphasis is placed on the need for informed consent practices that include everything required of normal medicine but also emphasize the advantages and disadvantages of remote medicine. It is not approved to give a prescription for a medicine based on a remote examination, as was decided in a ruling in 2008 [38]. Since then, it has not been allowed to provide a prescription without a physical examination of the patient. The Center for Health Policy in the USA (Center for Connected Health Policy) reports once every 6 months on changes in the laws of various countries regarding telemedicine and calls on all doctors and practitioners of telemedicine to stay up to date with these changes [39].

6.11 Risk Management of External Suppliers

A significant part of medical care in medical institutions is currently provided by external providers, both those within the same medical organization and those from other settings. Nonmedical services such as laundry, information and computing technologies, information security, and food supply can be provided by external companies for many years. However, buying medical services that do not exist at a given medical center for various reasons has become extremely common and allows for the expansion of diagnosis and treatment options under the same roof. Examples include physiotherapy treatments for a patient after surgery in a hospital that does not have a physiotherapist, anesthesia services for invasive procedures in an institute that does not have anesthesiologists, and psychiatric consultation in a general hospital that does not have such a department or service. Anesthesia, emergency medicine, X-ray, laboratory, and pathology services are based on outside providers in many hospitals and medical institutions around the world. Using external providers provides a solution for high-quality service when the required human resources or equipment are not at the disposal of the medical institution and allows for considerable savings in education and training or in buying an expensive device and introducing a new procedure. However, since the medical institution has no control over the training and experience of the service provider, there is a fear of operational failure to the point of medical negligence [40].

6.11.1 Medical Institution Is Responsible for Every Operation Performed on Its Patients Under Its Roof; Therefore, There Are Several Requirements When Contracting with an External Provider [24]

1. The provider must have the necessary training, skills, and experience to provide the required service.
2. The permits and certificates necessary to perform the service should be produced according to regulatory requirements.
3. A suitable and binding contract should be signed.
4. The parties should have appropriate medical malpractice insurance.

5. There should be a monitoring and control mechanism just as with the regular staff.
6. A risk management and treatment safety trustee should be appointed who works jointly with the risk and safety management department of the organization purchasing the services to identify and reduce risks and keep treatment safe according to the organization's standards.

The medical institution must prepare a detailed risk management plan that will contain all the possibilities of failure in contracting with an external provider, such as insufficient service, service that fails to meet the required level, incorrect pricing, negligence, or an adverse event caused by the care of an external provider. The risk must be characterized, identified, and evaluated qualitatively and quantitatively, and a detailed response plan should be prepared for potential failures in the future.

6.12 Procurement and Logistics Risk Management

A medical institution such as a clinic or a hospital is a very complex organization that includes, in addition to specific medical areas, services for all the associated requirements, such as hotels, catering, cleanliness, transportation, security, and general routine maintenance in addition to the maintenance of medical devices, laundry, water supply, electricity supply, and sewage. This complexity is related to procurement (medical and general) and logistics, which should be managed wisely and according to clear regulatory and economic criteria. As is customary with external service providers, here, too, the contract for procurement needs should be made according to clear and written rules, based on detailed contracts, and by the needs of the institution. The JCI devotes an entire chapter to the subject of facility management and safety (FMS) [24]. For example, the supply chain for medicines is susceptible to many failures, from production to the transfer of medicines to the right consumer, in the right quantity, with the right quality, and at the right time. In a review of nine studies on possible mistakes in the drug supply chain, 50 fundamental failures were found, mostly related to the supply and supplier but also to price, logistics, the drug market, and regulations [41]. A detailed guide for dealing with possible failures in supply chains for medical institutions was prepared and published in 2013 by the American Agency for International Development (USAID); the guide contains a detailed description of supply chains, possible failures, and appropriate risk management plans [42]. A working plan is also presented that allows for analyzing risks in a supply chain and choosing the appropriate response to each risk (Fig. 6.6).

Fig. 6.6 The risk management process

Key Messages: The Organizational Factor

- Regulations on risk management and the safety of the treatment and the patient in the health institutions focus on three areas of the administration/medical division: the structure and function of the risk management units and treatment safety in hospitals and HMOs, procedures for managing an adverse event or risky process and reporting obligations, and a support plan detailing the patterns of action required to receive designated budgets that do not require the payment of fees and may be voluntarily subscribed to.
- The significant and comprehensive process that shaped the safety culture in developed countries such as the USA, Canada, and OECD members has not yet been replicated in Israel. A governmental institution has not been established to centralize the efforts to advance treatment safety, and no significant regulatory steps have been taken, as was done in Canada, for example. There is room to advance treatment safety and risk management in medicine through legislation, regulation, improved measurement and evaluation mechanisms, research, updated information, advanced communication, and education in medical and nursing schools and health institutions.
- In light of the increase in the complexity of medical treatment, staff members' ability to cope with this complexity is decreasing. There is therefore a need to emphasize human engineering and cognitive psychology to enable the successful handling of ever-increasing demands and successfully navigating difficulties and obstacles. Modern systems that support operations and prevent obstacles are needed in all areas of medical practice.
- The fewer tasks that are imposed on human memory, the better the critical information for the correct and safe treatment of patients will be. Checklists, computerized protocols, alerts regarding abnormal tests, closed circles of reference to life-threatening results, patient deterioration identification, and computerized decision-making support are all important to prevent failures and mistakes.
- One innovation in organizational safety culture, following the publication of the IOM in 1999, is that organizations are not looking for culprits, and the intention is to learn from adverse events and prevent similar incidents in the future.
- Three elements characterize the quality of the treatment continuum in Israel: the strength of the four health insurance funds (HMOs) committed to primary care in the community according to the national Safe Health Law; the quality of the primary doctors, most of whom are specialist family doctors; a computerized personal medical record; and digital means of support.
- Risk management activity, which is retrospective, interactive, and prospective, is mainly intended to maintain the safety of a given treatment, although it also helps maintain its quality. Sometimes, there is an overlap or a lack of precise definition across activities that prioritize quality and those that prioritize safety. In such definitions, activities to advance quality aim to improve treatment outcomes, which themselves can sometimes cause adverse and unexpected events.
- The JCI standards mainly address patient safety, and there is a dedicated chapter in the accreditation book containing six International Patient Safety Goals (IPSGs). The purpose of this chapter is to promote and improve patient safety.

- Information systems are a cornerstone for the correct and effective management of risks and treatment safety in every aspect. Information systems can be divided into four groups: computerized medical records (patient files), clinical data analysis and documentation systems, risk management systems—adverse event reports, and administrative information systems. Extracting information from all four types of systems and analyzing it can yield a complete picture of the patient's condition and the quality and safety of his treatment.
- The following risks must be taken into account and handled with care: hidden data in a record that are not easily accessible to users, such as the identity of the author, input time, changes made to existing lists, the quality of documentation, adherence to regulations, and compatibility between the printed format and the digital data. One should be careful not to type in advance results that have not yet been formally received and to replace all data in templates with correct information. Due to the large amount of data involved, critical test results can sometimes be missed, and implementing instructional programming according to accepted clinical guidelines can be illegal if results are not filled in or updated. Warnings and correction mechanisms should be added to prevent human error.
- There are five actions that can be taken to evaluate online medicine and ensure its safety: gathering information related to the safety of online care and learning to report related adverse events, opening unique learning centers for online/digital care and training the medical and nursing teams, establishing a knowledge center for centralized data collection, preparing learning and training centers, and writing clinical guidelines.

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7 Errors in Medication Administration

7.1 Characterization, Types of Errors, and the Scope of the Phenomenon

Drug therapy has been a cornerstone in medicine since ancient times. Different groups of drugs are aimed at different goals, and what they have in common is their means of biological action and the results of the treatment.

The process of administering the medication begins with a doctor's order, then involves the preparation of the medication (commercial or pharmaceutical preparation), administration to the patient by a nurse in a hospitalized patient, or self-collection from the pharmacy for a patient receiving ambulatory care.

Within each drug group, there is a clear definition of each drug and its composition, activity, side effects, associated allergy effects, doses, route of administration (oral, skin, rectal, intravenous infusion or injection, bone, muscle, or subcutaneous), timing (continuous, several times a day, connection with meals, and/or certain foods and drinks), and interactions with other drugs (increasing activity, decreasing activity, toxicity). For example, antibiotics are a treatment against bacterial infections, but within this group, some subgroups target certain bacteria and are ineffective for others, some have a sharp and clear purpose (certain bacteria), and some offer a wide range of effectiveness against many bacteria (broad spectrum). Sometimes broad-spectrum antibiotics are effective against a variety of bacteria but may cause bacterial resistance if given without proper professional supervision.

Mistakes in the administration of drugs can occur in any of the steps mentioned, in the drug itself, or in its preparation, dosage, method of administration, and timing, or there may be an adverse drug-to-drug interaction. A mistake can be particularly disastrous if it occurs in the administration of a high-risk drug such as chemotherapy or concentrated electrolytes. In these cases, extreme caution is needed, and measures that prevent the possibility of human error include a clear form of administration, clear and supervised preparation instructions, and information on changes in the form of the drug or its packaging. Medicines with similar names or packaging (look-alike, sound-alike, LASA) receive special treatment in terms of accreditation and special standards and storage, and monitoring guidelines [1].

Allergy to drugs takes on special importance because, in many cases, it is not predictable; in most cases, it does not depend on the dose, route, or rate of administration and can cause severe morbidity (severe urticaria, anaphylaxis, anaphylactic shock) or death. A first exposure to a drug to which there is an allergy usually does not result in a severe reaction the way repeated exposures do once the cellular and humoral immune systems are prepared against it. It is extremely important to document drug allergies and to inform patients and caregivers to prevent repeated

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exposure and risk to life in the future. The implications must also be understood because many people documented as being allergic to a certain drug are not actually allergic to it. One should not attribute every phenomenon to allergy and prohibit the future use of a drug that may be extremely important in future treatments. An excellent example is the high frequency of "penicillin allergy," which is frequently recorded in the medical record and prevents further use of penicillin derivatives. In cases where the initial reaction was uncertain (not necessarily anaphylaxis or a corresponding rash but other symptoms such as coughing or nausea), the patient should be referred to an allergy clinic to rule out a wrong allergy diagnosis.

In a study carried out in Boston, it was found that 19% of adverse events in hospitals are related to drugs [2]. Similar findings were also found in a study from Colorado [3]. Providing drug treatment in emergency medicine is a complex process that requires the continuous cooperation of the doctor who prescribes the drug, the pharmacist who verifies the prescription and dispenses it, and the nurse who administers it to the patient. In an examination of 334 reports of medication errors in 11 emergency departments, it was found that 39% of the cases were due to record input mistakes, 12% in the verification process, 11% in the dispensing process, and 38% in the patient administration process [4].

Computerized support may prevent errors in the administration of drugs at any stage of the process. Computer systems allow support for the doctor in prescribing, the pharmacist in dispensing it, and, especially, for matching the drug to the patient and his other medications (medication reconciliation), thus enabling safe treatment without negative drug interactions [5]. The introduction of these systems has been proven to be effective in dramatically reducing adverse events in the administration of drugs, up to 86% of the time before their activation [6–12]. It can be said that the safety of drug treatment relies on computerized information systems in most medical institutions. Particularly advanced is the chain of government hospitals in the United States (the Veteran Health Administration), which has developed a barcode-based software system—BCMA (barcode medication administration)—in which the patient is presented with a scannable barcode and a corresponding barcoded medicine from the pharmacy. Before administering the medicine, the nurse scans the barcode on the patient's hand and receives verification of the medication before administration [13]. Any inconsistency in the patient's identity or the name, dosage, administration method, or time of the medication immediately produces an appropriate warning. Despite the significant improvement in the safety of medication administration that occurred following the use of computerized information systems, there are still quite a few mistakes, mainly due to incorrect programming [14]. Computerized information systems for drug selection have also created several new problems, such as incorrect selection of a drug from a list of drugs due to poor human engineering in editing the drug lists for selection, as well as problems related to the up-to-datedness of drug lists in the system.

7.2 Causes of Errors in the Medication Administration Process

The process of administering medicine begins with production, continues with marketing, storage, dispensing, prescription by the doctor, pharmaceutical preparation, collection from the pharmacy, and preparation for administration by a nurse, and ends with administration to the patient in one of the approved means of administration. This process is long and complex, and there is much variation among different types of drugs. In each of the parts of the process, failures may occur that can endanger the patient, depending on the type and degree of failure. With high-risk drugs such as chemotherapy and concentrated electrolytes, errors and failures in preparation can have disastrous results.

Mistakes may happen when giving medicine in a hospital while distributing the medicine to patients, or when patients are discharged with incorrect instructions about taking or not taking certain medicine. Mistakes in administering the

medication can also occur due to determining the wrong dose of the medication or giving the patient a medication that he should not be given, whether due to a negative interaction of the drug with other medications taken by the patient or to the sensitivity of the patient.

In regard to drugs held in a pharmacy and issued by a professional pharmacist according to a medical prescription, the chance of making a mistake in the name, route of administration, or dosage of the drug is extremely low. When administering a drug issued to a hospital ward, preparation/administration by a nurse, and intravenous administration, the chance of making a mistake is higher, especially in the dose and rate of administration. Calculation of a suitable concentration for an intravenous infusion of concentrated electrolytes has a high chance of a mistake occurring due to the need for invoicing operations.

There is no need to explain the dangers of giving the wrong medication to a patient. A medication error can occur at several points in the treatment chain. Errors in the administration of the drug treatment can be due to various factors and can also be made by different officials in the treatment stations. Errors can be made by the doctor who prescribes the treatment, the nurse who administers the treatment, or the pharmacist who prepares the medicine or issues the prescription. For the court to determine that a patient who received the wrong medication is entitled to compensation for the damages he suffered as a result, it must first be proven that the wrong treatment was given due to the negligence of the responsible medical entity. As mentioned, a mistake in administering the medicine can be made by any of the parties involved in the matter—from the doctor who prescribed the medicine, to the pharmacist who dispensed the medicine, to the nurse who administered the medicine. The test for determining whether a mistake is the result of negligence in the administration of medicine is fixed in the provisions of the law. Essentially, to the extent that the error in administering the medicine was caused by an unacceptable level of skill and/or degree of caution on the part of the responsible party, then it will be determined that it is medical negligence. To the extent that the patient was harmed due to the negligence, there are grounds for claiming compensation due to medical negligence. In most cases, giving the wrong medication to a patient is considered negligence, which qualifies the patient for compensation. However, not every error in drug treatment is considered negligence—for example, if there is a medical dispute regarding a drug treatment that boils down to opposing schools of thought in medicine, the court may see this error as being within the scope of the doctor's accepted level of discretion and hence will determine that there was no medical negligence in the administration of the drug. At the same time, as mentioned earlier, since this is a sensitive issue, a high degree of caution is required when giving medication to patients, so usually, a mistake in giving medicine to a patient, in the type of medicine, or in the dose and/or timing, is a fairly common reason for a medical malpractice claim.

7.2.1 Common Examples of Medication Administration Errors

- Administering a drug with a prohibited interaction—Sometimes a patient is given a drug that is not suitable for his condition and/or according to his health data. For example, giving antibiotics to a patient who is sensitive to antibiotics (penicillin) may cause the patient to have edema or difficulty breathing and thus cause a life-threatening situation. Administering a nonsteroidal anti-inflammatory drug (NSAID) as a pain reliever to a patient taking anticoagulants may cause life-threatening bleeding.
- Failure to provide the required drug treatment to a patient—Another error in drug administration can occur when the appropriate drug treatment is not given to a patient; for example, there is a failure to match the appropriate antibiotic treatment in terms of the type and/or dose to a patient suffering from an infection or a failure to provide urgent treatment to restore blood circulation with TPA in cases of ischemic stroke.

- Administering medicine in the wrong dose—If, for example, another "0" is accidentally added to the dose prescribed by the doctor, poisoning can result, which is considered negligence in dispensing the medicine.
- Not giving prophylactic antibiotics before surgery—There are several operations for which the patient must be given prophylactic antibiotic treatment before surgery, an action that reduces the chance of infection in the surgical area. Strict regulations determine which patients and which operations should be preceded by antibiotic treatment. The violation of this guideline may be considered medical malpractice due to a failure to administer medication.
- Delay in giving medication—Sometimes, the patient is given medication in the appropriate dose and type but at the wrong frequency, too early, or too late.

7.3 How to Reduce Errors in the Medication Administration Process

The safe preparation of drugs is necessary to avoid mistakes at every stage. A risk management plan for the safe preparation of medicines should include the following steps [15]:

(A) The medicine preparation room should be closed and isolated from noise to allow sufficient concentration and prevent distractions in preparing medicine.
(B) The possibility of an allergy should be checked.
(C) The institution's policy for identifying patients should be followed. Two supporting IDs must be used.
(D) It must be ensured that the patient receives the correct medication for his medical condition.
(E) Knowledge and experience are needed to accurately prepare the correct concentration of the drug.
(F) Practitioners should not rely on memory and should use a checklist.
(G) The patient should be communicated with before and after the administration of the drug; his questions should be answered, and he should be warned of possible side effects and monitored after administration.
(H) Corners should not be cut, and practitioners should make sure to work "by the book."
(I) The effectiveness date should be checked before the medicine is administered.
(J) Vague and incomprehensible instructions should be clarified to ensure safety and prevent damage.
(K) Technologies should be used to identify drugs and patients to minimize the possibility of error.
(L) Any error, adverse event, "near miss" event, or side effect should be reported.
(M) Practitioners should be prepared to treat the side effects of risky drugs such as insulin, anticoagulants, sedatives, and opiates.
(N) Practitioners should be vigilant regarding the patient's reactions and respond promptly to complaints.
(O) The patient should be involved in the process of administering the medicine by verifying not only his identifying details but also complaints, illnesses, etc.

7.3.1 For Each Medicine, Observe Seven "Correct" Moves (7 Rights)

The right patient, the right medicine, the right dose, the right route of administration, the right time, the right reason for administration, and the right and accurate documentation (Table 7.1).

Table 7.1 Sources for updating patient medications, point-of-care resourcing for deprescribing

Resources	Comments
Beer Criteria	List of medications that pose the highest risk to older adults
Bruyere Research Institute https://deprescribing.org	Guidelines and algorithms for discontinuing proton pump inhibitors, antihyperglycemics, antipsychotics, benzodiazepines, cholinesterase inhibitors
Electronic health records, such as Epic or NextGen	Autodiscontinuation of expired medications—reduce polypharmacy
Epocrates https://www.epocrates.com	Check for drug–drug and drug–herbal interactions
Medstopper https://medstopper.com	Allows users to enter a medication list and receive recommendations regarding which medications can potentially be discontinued or switched

7.4 Polypharmacy: Consequences and Means of Reduction

Polypharmacy has been a common phenomenon in the last decade. Thanks to the improvement of socioeconomic situations, nutritional security, and advanced medicine, life expectancy in developed countries has increased significantly, and together with this, the number of chronic diseases that can be prevented by drug treatment has increased. As an example, millions of people take aspirin (as primary or secondary prevention for ischemic heart disease or stroke), drugs against acid reflux from the stomach to the esophagus, or a number of other drugs depending on the chronic background diseases that increase over the years and the aging process.

Taking multiple medications is not without the risk of side effects (each drug on its own) and drug interactions that can increase the activity of a drug or weaken it or even cause side effects that are not expected from each drug on its own. Taking multiple medications can make it difficult for the patient to take their medications regularly; the frequency of administration is not always the same for different medications, and there are some that should be taken at different times of the day. This may inhibit compliance, which is a very important factor in treatment success and the achievement of the desired results. Polypharmacy should always be taken into account when a patient is admitted to a hospital or is examined for the first time and receives treatment for a disease that is already being treated by another drug. Every time a new patient is admitted, his medication list must be carefully reviewed and approved. In any case, where a chronic disease such as hypertension is balanced by one drug or drug combination, prescribing another drug for the same purpose should be avoided.

Several tools have been developed that can help in reducing the number of medications, focusing only on the minimum number necessary (see Table 7.1). None of these tools has been proven to be better than the others, and any of them can be used [16]. It is particularly important to reduce the possible number of medications as much as by regular follow-up and monitoring of the patient while constantly being alert for side effects and attempting to prevent drug interactions. At each transit station of a patient, whether at the primary care doctor, a consultant doctor, an emergency medicine department, or a hospital, practitioners must go through the list of medications and make sure there are no unnecessary or ineffective medications. Clinical pharmacists should be as highly trained as possible.

Key Messages: Errors in Medication Administration

- Errors in the administration of medicine can occur in the choice of the medicine itself or its preparation, dosage, route of administration, or timing as well as through negative drug interactions. A mistake can be particularly disastrous if it occurs in the administration of a high-risk drug such as chemotherapy or concentrated electrolytes. In these cases, extreme caution and measures that prevent the possibility of human error are needed. Medicines that have similar names and similar packaging (LASA—look-alike, sound-alike) receive special treatment in terms of accreditation and special standards and storage, and monitoring guidelines.
- Computerized support may prevent errors in the administration of medication at any stage of the process. Computer systems include support for the doctor in prescribing the medicine, for the pharmacist in dispensing it, and especially in matching the drug to the patient and his other medications (medication reconciliation), thus enabling safe treatment without negative drug interactions. The introduction of these systems has been proven to be effective in dramatically reducing adverse events in the administration of drugs up to 86% of the time before their activation. A risk management plan for the safe preparation of medicines should include all possible failures in the process of administering the medicine, from prescription to administration. At each stage, all failures must be identified, and a systematic plan must be prepared to prevent them. In addition, seven "right" moves (7 rights) must be observed: the right patient, the right medicine, the right dose, the right route of administration, the right time, the right reason for administration, and the right and accurate documentation.
- Multiple medications are defined as the regular intake of five or more medications, a very common phenomenon among adults and at-risk populations. The factors that increase the likelihood of multiple medications are a patient having several diseases, multiple caregivers, mental illnesses, cognitive disorders, a lack of updated medical records, the continued automatic administration of drugs, and treatment directed at indicators and not necessarily at individual clinical improvement.

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8 Medico-Legal Aspects of Patient Safety and Risk Management

8.1 What Is Medical Malpractice, and How Is It Determined?

The performance of a diagnostic or therapeutic procedure, surgery, medication administration, or medical follow-up that is not in accordance with the law, regulations, procedures, or clinical guidelines prevailing at that time in defining the standard of care and that leads to an adverse event/complication or death is defined as medical negligence. When it is not possible to point out a significant deviation from what is accepted, the definition is a mistake, failure, or complication. In other words, medical negligence is a deviation from a reasonable standard of conduct. A plaintiff claiming negligence has the burden of proving that there is damage such as medical disability, functional disability, a loss of earnings, a need for treatment for disability or rehabilitation, pain, or suffering and that it was the negligence that caused the damage (there is a causal relationship or liability). The reasonable standard is based on legislation, verdicts, clinical knowledge, scientific cases, professional literature, Ministry of Health practices, position papers, and clinical guidelines from professional associations.

The medical record plays an important legal role in preventing claims of medical malpractice. Keeping documentation of the patient's medical history allows a therapeutic sequence between different therapists to be traced and serves as a reminder to each therapist. It is a tool through which it is possible to prove medical conduct in real time and constitutes authentic evidence. A record that fulfills its therapeutic/clinical role will usually also meet the requirements of its legal role. A lack or defect in the record will result in a reversal of the burden of proof from the plaintiff to the defendant. If the therapist proves that there was no negligence, then there is no liability for damage.

Negligence is determined by judges, who are not necessarily experts in the field in question. That is why it is important to establish the standards according to which the case will be examined. In recent years, there has been a significant increase in the number of lawsuits and national expenditure on medical malpractice suits as a result of increased awareness of damages caused during medical treatment and the willingness of the public to bring a suit to court. Evidence of the expansion of liability in torts can be found in several areas:

1. There is an increased obligation for practitioners to update their existing medical knowledge.
2. A worse outcome will result if the practice in the institution and the accepted standard are not the same.
3. The burden of explaining to the patient all of the existing tests and treatments, even if these are not common practice, has increased.

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4. Liability has been expanded to include the "violation of autonomy," which is recognized as a type of damage worthy of compensation in isolation from physical damage.
5. The responsibility to monitor the patient and his medical information, received from various sources, has been expanded.

8.1.1 Concept of Punishment for Medical Errors, Concept of Compensation, and the Alternative of "No-Fault"

A basic assumption is that the goal of the medical team is the correct and efficient treatment of the patient, and the whole intention of its members is to do good for the patient and take care of his well-being. An error in medical treatment that causes a serious negative result or death can be considered negligence when the therapist does not meet the requirements of reasonable actions for a doctor providing reasonable treatment, and the determination of this is left to the court's decision. However, even in a clear case of medical negligence, the element of intent to harm does not exist, and the practitioner's conduct was done in good faith. The punishment for medical errors has undergone many changes throughout history according to what is accepted in each period and the context of the punishments accepted in different societies and cultures.

For example, Hammurabi's laws are the most well-known and comprehensive codex of laws from the ancient Middle East and were the first to be rediscovered in modern times [1]. The set of laws we have access to was compiled and enacted in the last year of the reign of Hammurabi, King of Babylon, and the sixth ruler of the first Babylonian dynasty in the eighteenth century BCE. The collection of laws, which originally included approximately 300 laws, was published toward the end of Hammurabi's reign and was written in cuneiform in the Akkadian language. A reference to doctors appears together with reference to other professionals and is simple and blunt regarding the reward for success and the punishment for failure in treatment: "If a doctor operated on the man because of a significant wound, and saved the man's life, or saved the man's eye from a festering wound, he will receive 10 shekels of money; if [the patient] is a free man, he will receive five shekels of money; if [the patient] is a man's slave, the owner of the slave will pay two shekels to the doctor; if a doctor operated on a man with a significant wound and caused the man's death, or operated on his eye and destroyed the man's vision, they will cut off his fingers; if a doctor operated on a significant wound of a slave of a free man, and caused his death, he shall pay a price equal to the value of the slave; if he opened a festering wound in the eye, and destroyed his sight, he will pay, in money, half of the surgery fee; if a doctor fixed a broken bone or healed a diseased stomach, the patient will pay five shekels of silver to the doctor; if [the patient] is a free man, he will pay three shekels of silver; if he is a slave, the owner of the slave will pay two shekels of silver to the doctor." This concept of reward and punishment has changed significantly in the modern era, as the concept of compensation is now anchored in civil law and requires proof of negligence, damage, and a causal connection between them; it has even been replaced by a "no-fault" approach and fixed compensation upon proof of negligence beyond the therapist's fault according to the professional liability insurance used in those countries (see Chap. 9).

8.2 Harm in Medical Malpractice

Medical malpractice claims fall under the tort law that deals with charges created as a result of damages caused and based on the tort of negligence, whose foundations are the duty of care, breach of duty, damage, and a causal connection between the violation and the damage caused. The requested remedy is financial compensation aimed at restoring the injured party to the state he was in before the negligent act occurred. The estimation of the amount of compensation and its ruling by the court consists of various clauses called heads of damage. Heads of damage that

can appear in a medical malpractice claim are no different from those that exist in other personal injury claims, and it is customary to divide them into monetary and nonmonetary damages. It must be noted that to win a suit regarding either of the aforementioned heads of damage, it is necessary to prove, according to the opinion of a professional expert, a link between the damage caused to the plaintiff as a result of the negligent act and the significant increase in expenses compared to his condition before the injury.

Heads of pecuniary damage include medical expenses, mobility expenses, expenses for third-party help, housing adjustment expenses, loss of earning capacity, and opinion seeking. Medical expenses include expenses for medical treatments that the victim will need in the future, hospitalizations, medications, rehabilitation procedures, and mental or social support. The amount of compensation is determined concerning the possible financial participation of the insurance companies, the regulator, and the health fund, where the defendant needs to prove that the insurance company covers the type of treatment required by the plaintiff so that he is not charged the treatment cost in full.

Another head of damage is the loss of earning capacity, which refers to the impairment of the plaintiff's ability to earn a living as a result of the injury, and its assessment is based on the individual's education, his amount of earnings before the injury, his position, his professional status, and the promotion opportunities that would be denied to him.

The heads of nonmonetary damages include compensation for shortened life expectancy, mental and physical pain, and suffering. The more serious the damage and the younger the victim, the higher the amount of compensation will be.

8.2.1 Subjects and Objects of the Claim

The main lawsuits filed against Israeli government hospitals in 2003–2017 appear in the following table (data courtesy of Inbal Insurance Company) (Table 8.1).

Table 8.1 Subjects of the main lawsuits filed against government hospitals in 2017–2013

Event	Total	Rate (%)
Complications during a surgery/procedure	30	56
Delay in diagnosis	5	9
Falls	3	6
Death during surgery/invasive procedure (during or after)	3	6
Error/complication in administering medicine/vaccination	2	4
Failure to diagnose	1	2
Bleeding as a result of damage to blood vessels	1	2
Lack of informed consent	1	2
Patient rights—other	1	2
Misdiagnosis	1	2
Defective device	1	2
Damage to a nearby organ	1	2
Death—other	1	2
Death as a result of the administration of the medicine/blood products	1	2
Discharge despite the need for further follow-up/hospitalization	1	2
Total number	**54**	**100**

8.2.2 Examples of Verdicts in Israel and the USA (Table 8.2)

- A large colonic polyp was excised, and the procedure resulted in perforation. The Supreme Court rejected the claim and agreed with the district court that the risk of perforation, in this case, was not under the doctor's control.
- There was a perforation (rupture) during a colonoscopy that was followed by urgent surgery. The claim was accepted because the court concluded that the defendant did not take reasonable precautions.
- There was a delayed cancer diagnosis; for 4 years, the deceased complained of abdominal pain. The claim was accepted because the necessary tests were not performed, and there was no continuous and informative follow-up in the medical record.
- Colon cancer was missed during a colonoscopy. The claim was accepted with 65% of the responsibility attributed to the doctor and 35% attributed to the private institute.

Table 8.2 Lawsuits against hospitals in the USA—classification by specialty (according to Ref. [2])

Specialty	Chance of being sued (%)	Chance of paying compensation [3] (%)
Neurosurgery	19.1	3.1
Vascular and chest surgery	18.9	3.8
General surgery	15.3	4.2
Orthopedic surgery	14.2	3.9
Plastic surgery	12.7	2.8
Gastroenterology	11.6	1.3
Obstetrics	11.0	2.9
Urology	10.5	2.5
Pulmonology	9.3	0.9
Oncology	9.1	1.9
Cardiology	8.6	1.0
Gynecology	8.3	3.2
Neurology	7.8	1.4
Internal medicine	7.7	1.3
Emergency medicine	7.6	1.4
Anesthesia	7.3	1.6
Radiology	7.2	1.6
Ophthalmology	6.7	1.2
Nephrology	6.0	0.4
Pathology	5.6	1.3
Dermatology	5.4	1.2
Family practice	5.2	1.0
Pediatrics	3.1	0.5
Psychiatry	2.6	0.5
Other	4.0	0.7
Total	7.4	1.6

8.3 Legal Investigation Procedure for a Negligence Claim

A medical institution learns about the filing of a negligence claim against it when it receives the claim statement. It must contact its insurance agency, hire the services of a lawyer, and prepare a statement of defense. Since medical malpractice can be brought to court up to 7 years after an incident, and in the case of a child, the years until his majority must be added to this limit, many times, a lawsuit is filed regarding an already forgotten case, and many times, the people involved are no longer serving at the medical institution because they have retired or left for another reason. Of course, it is desirable to establish an archive of investigations of adverse events and the files of the patients involved in incidents in which there is a certain danger of being sued to prepare for future lawsuits. When there is documentation of the case in real time, including an investigation and its conclusions, the case can be effectively defended. The news of a lawsuit can be a surprise, and the institution may only learn about it upon receiving the filing papers or hearing a news report or, indirectly, when a lawyer requests the medical file from the archive. After receiving the statement of claim, a procedure for studying and investigating the case is followed, a discussion is held in the risk management forum, together with the parties concerned and a lawyer, to discuss the chances of successfully defending the case; a decision is made regarding whether to settle the case outside of the court in a mediation and settlement process or to confront the plaintiff in court. The willingness of the medical and nursing staff involved in the case to be actively involved in the defense of the case is of great importance in this decision. The insurance company participates in the procedure and sometimes presses for an out-of-court settlement to avoid setting precedents or to minimize the damages as much as possible.

Not every failure or error in treatment that results in damage is negligence. The test for the existence of negligence is whether there was a deviation from the standard and care that can be expected from a "reasonable doctor." Medical negligence, by definition, refers to poor medical treatment that a patient receives from a doctor and/or medical staff who do not use the appropriate level of skill and caution that reasonable doctors and/or other medical staff would use, resulting in damage to the patient (sometimes even death). Medical negligence can manifest in several ways: in making an incorrect decision regarding the nature of the medical treatment, in providing the wrong treatment, or in providing a certain treatment when another treatment or no treatment at all is required. There may be medical negligence in the actual decision not to treat the patient,

despite the existence of certain symptoms that require treatment, and there may be medical negligence even in the case of correct medical treatment but not in an optimal way. Negligence can manifest in failing to perform tests to detect the medical problem, in giving the wrong medicine, in operating without the correct method or in carelessness, in not supervising the patient after an operation or medical procedure, and in many other ways.

To prove the tort of medical negligence, it is necessary to prove that all of these have taken place cumulatively:

- The therapist violated his duty of care toward the patient by not treating him with the proper skill or by not taking the appropriate and acceptable precautionary measures.
- The patient was harmed as a result of the treatment.
- There is a clear causal connection between the negligent treatment (violation of the duty of care) and the damage, and among other things, the therapist could and should have foreseen the damage caused to the patient.

Initially, an in-depth examination must be carried out to understand if there was medical negligence that gave rise to the claim. The examination procedure includes the collection of all the medical material related to the subject, an in-depth study, and consultation with a medical expert. Whenever a decision is made to file a claim, it is mandatory to attach medical opinions, sometimes from several medical experts. As a rule, it is not possible to know precisely how long a legal procedure may last since the duration of the procedure is affected by the facts of the case and its circumstances. However, it is usually several years. At the same time, if the procedure ends in a settlement, it goes without saying that it will be shorter than a procedure that continues until a final and conclusive verdict. Later, a decision is made regarding the procedure, lawsuit, mediation, settlement, or waiving of the lawsuit when the chance of winning it is low.

8.4 Interplay Between the Legal System and Risk Management and Patient Safety

Rulings in all courts, especially in the Supreme Court, constitute an inexhaustible source of systemic learning and information for the prevention of medical malpractice. Treatment safety forums in which investigations and judgments are presented promote the knowledge and understanding that proper conduct, transparency, adherence to informed consent, and work performed in accordance with procedures can save many human lives as well as many expenses for handling the claims received.

The world of law and the world of medicine often meet in different formats, including tort claims, disciplinary proceedings, police complaints, and work accidents. These meetings with the legal world have far-reaching effects on the medical world. Most of the tort claims for medical negligence end in a settlement, and every year, several thousand decisions and judgments are published, discussing various aspects of professional responsibility in medicine. In a significant number of these judgments, in addition to case analyses that happened in the past, one can also find general forward-looking statements, which are of great value to anyone whose treatment safety, risk management, and quality assurance in medicine are part of their daily work. If a lawsuit ends in a verdict, rather than a settlement, it raises the chance that at the center of the discussion was an innovative, complex, and controversial issue that made it difficult for the parties to the lawsuit to reach an agreement on their own. Such rulings are an excellent source for study and research [4].

A different aspect of the interface between the legal system and risk management and treatment safety is the "defensive medicine" phenomenon. Mistakes in the healthcare system can happen as in any other system because "to err is human." The American Institute of Medicine (IOM) issued a statement in 1999 that declared that "to err is

human" and that "one should not look for culprits" but instead investigate and correct processes that will prevent similar mistakes in the future. A severe lack of doctors and nurses can lead to a heavy workload and increase the rate of errors. The complexity of some cases requires a multi-professional and multiparticipant team for treatments to be successful and save lives. In the last two decades, there has been an exponential increase in the number of lawsuits for medical negligence and a similar increase in the compensation amounts determined through verdicts, mediations, and settlements. The judges see before them victims of mistakes and their suffering and thus treat the health system, despite its state of constantly operating at a deficit, as a "deep pocket" for compensating plaintiffs. Healthcare institutions invest human capital and funds in their legal defense at the expense of investing in systemic learning, personnel, and equipment to prevent future failures. Fear of lawsuits can cause experienced and professional doctors to abandon their profession, and there may be a shortage of experts in professions at risk of negligence lawsuits [5].

8.5 What Are Patient Rights Laws and What Are Their Implications for Risk Management Activities and Patient Safety?

Patient rights laws have been enacted over the last two decades and are milestones in risk management activities and the maintenance of treatment safety in many countries. The purpose of such laws is to clearly and unambiguously define the rights of a person seeking medical treatment or receiving medical treatment and to protect his dignity and privacy. Usually, the term "therapist" is defined broadly: doctor, dentist, intern, nurse, midwife, psychologist, occupational therapist, physiotherapist, communication therapist, nutritionist-dietitian, clinical criminologist, podiatrist, surgeon podiatrist, chiropractor, or any professional recognized as a healthcare provider. The laws guarantee continuity of treatment, the preservation of the patient's dignity and privacy, the right to treatment at emergency departments, and informed consent for any treatment, which includes providing information on the diagnosis, prognosis, description of the treatment, its benefit, the expected chances and risks, and the possibility of alternative or innovative treatments. The laws require that a record be kept and handed over to the patient and the maintenance of medical confidentiality. In Israel, three statutory committees were established: an **inspection committee** that examines patient complaints (its materials are not confidential), a **control and quality committee** that evaluates medical activity (its materials are confidential), and an **ethics committee** that has the authority to require life-saving treatment despite the objection of the patient or his guardian and to transfer materials from the medical file to the extent necessary or to discuss any case in which an urgent decision is needed regarding the treatment of the patient or his rights [3]. The laws expand on the subject of informed consent and state that no medical treatment will be given without consent, which must be based on the extent of the medical information provided to the patient about his diagnosis and prognosis; the essence of the procedure, its purpose, and its expected benefit; the chances of the proposed treatment succeeding; the risks involved, including side effects, pain, and discomfort; the chances and risks of alternative medical treatments or a lack of medical treatment; and details on whether the treatment is innovative. The information will allow the patient to make an informed decision voluntarily and independently. In the case of urgent treatment, there should be agreement among three doctors. A significant portion of the medical malpractice lawsuits since the publication of the law include the issue of informed consent. The plaintiffs, in addition to the specific subject of the lawsuit, have tried to prove to the court that there was no informed consent in their case according to the spirit of the law and that they did not receive a detailed explanation of the chances and risks or errors made, which is why they originally accepted the treatment. Violation of the patient's autonomy due to lack of informed consent has

become an integral part of many lawsuits. Informed consent is an integral part of the duty to patients, protects their autonomy, and allows them to be partners in crucial decisions concerning their health. In principle, the interaction between the therapist and the patient is based on trust, and the patient must understand and agree to any diagnostic or therapeutic approach. The patient's participation in the first stages of the treatment decision will also lead to improved treatment results and the patient's experience. No medical treatment should be provided without informed consent, and the necessary information must be provided to reach this consent for treatment. This explanation of the treatment should emphasize the chances and risks involved. Informed consent must be obtained in writing, by letter, or by way of behavior, and certain treatments (e.g., operations except for minor surgery, vascular catheterization, dialysis, ionizing radiation, in vitro fertilization, chemotherapy, hypnosis, egg donation, termination of pregnancy, amniocentesis) require a written document. If the risks involved in the examination are explained to the plaintiff before he consents, then the consent is valid and binding, and the doctors who performed the examination should not be attributed an act of assault or any act of tort. If the risks are not explained to him, then the consent is void, and the examination is considered an act of assault that constitutes a tort. A significant number of legal claims for medical negligence include a claim that the surgery or procedure was performed without informed consent and that under the circumstances if the patient had understood that a possible complication was expected, he would not have agreed to receive the proposed treatment.

The health system has had to expand the informed consent forms used for diagnostic and therapeutic interventions, including those that are not included in the patient rights laws. A situation of heterogeneity has arisen among the various health institutions, and there is thus great variation in these institutions' usual practices. Many places use general consent forms that are not specific to the surgery or procedure performed. Examples can be found of very complicated and complex surgeries where the explanation given before the surgery and the form signed by the patient are neither intended nor sufficient to prove informed consent. It is necessary to understand precisely how informed consent must be obtained, what information must be provided to the patient, what level of detail to provide in the explanation, how to deliver that information (while being sensitive to the cultural component), what the alternatives to the treatment are, what the risks involved are, and what the chances and risks of the alternative treatments are. In addition to obtaining the patient's signature, there must also be a process for proving that a sufficient explanation was given and that the patient understood it.

A study carried out by the AHRQ (American Agency for Research on Quality in Healthcare) shows that 40–80% of the information given to patients is immediately forgotten, and approximately half of what is remembered is inaccurate. Another study shows that 45% of doctors still take a paternalistic approach, and 20% of clinicians believe that a patient's lack of understanding regarding a medical procedure does not constitute a safety problem. These studies strengthen the argument that the approach to informed consent must be changed and its importance must be emphasized from every aspect, including both medical and legal [6, 7].

Patient rights laws have had direct consequences on risk management activities in health institutions. The three committees have pushed medical practice in the direction of treatment safety and have enabled in-depth research on adverse events and systemic learning.

In Israel, the lack of confidentiality of the results of inspection committees has led to an almost complete cessation of morbidity/mortality meetings and a significant decrease in root cause investigations, as these activities are nonconfidential according to the Israeli Patient's Rights Law. The law was preceded by a ruling of the Supreme Court in the case of Gilad versus Hadassah Medical Center, in which the court ordered the medical center to convey to the family of a patient who had committed suicide in the hospital the results of the investigation carried

out by management. The court justified its decision by saying that the dominant intention in carrying out the investigation was systemic learning, not preparing a legal defense; therefore, there was no privilege involved, as is customary between a defendant and his lawyer. As a result, the concept of "defensive medicine" was claimed, which has led to multiple and unnecessary actions by medical staff, such as unnecessary laboratory tests, numerous imaging tests, and even invasive procedures, to avoid missing any possible diagnosis or treatment and thus prevent lawsuits.

8.5.1 Patient Rights Laws Generally Include the Following 12 Principles

1. The right to receive medical treatment is granted to everyone in need. Neither medical institutions nor therapists are allowed to discriminate among those seeking medical treatment on the grounds of religion, race, sex, nationality, country of origin, etc. The medical treatment will be given by the conditions and arrangements used in the country's health system. In a medical emergency, the person in need will receive urgent medical care without any conditions. The patient has the right to receive adequate medical treatment both in terms of the professional level and quality of the medical care and in terms of the human relationships involved.
2. The patient is entitled to information regarding the identity and role of each person who treats him.
3. The patient has the right to request another opinion regarding his treatment. The therapist and the medical institution will assist the patient in everything necessary to exercise this right.
4. A patient who moves from one therapist to another or from one medical institution to another is entitled, at his request, to cooperation between the therapists and the medical institutions to ensure the proper continuation of the treatment.
5. The patient is entitled to maintain his dignity when receiving medical treatment.
6. The patient is entitled to maintain his privacy while receiving medical treatment.
7. When there is a danger to his life or in a medical emergency, the patient is entitled to receive medical treatment. The therapist he is referred to will examine him and treat him to the best of his ability. If the patient is in danger and is against receiving medical treatment, the therapist may provide the necessary treatment even against the patient's will. This can be done only after the approval of the ethics committee, one of which must be appointed and operated in every medical institution.
8. No medical treatment will be given to the patient unless he has given his consent. This consent must be "informed consent," that is, only after the patient has been given all the details related to the diagnosis; the essence of the proposed medical treatment; the chances of success of the treatment; the risks of the treatment, including pain and discomfort; and the chances and risks of receiving alternative medical treatments or no treatment. The information must be given to the patient as early as possible and in a way that will allow him to understand so that his consent to medical treatment is "informed" and of his own free will.
9. Consent to medical treatment can be given in writing, orally, or by way of behavior expressing consent.
10. The patient has the right to receive medical information from his medical record, including a copy of that record, from the therapist or the medical institution. Despite the above, with the approval of the ethics committee, a therapist may decide not to provide the patient with complete information or to provide him with only partial medical information if the information may cause him harm or endanger his life.
11. A therapist or employee of a medical institution shall keep confidential any information concerning the patient who comes to them

while they are performing their duties or during their work.

12. A therapist or a medical institution may provide medical information to another person if the patient has given his consent. Additionally, information will be provided to the authorities if the therapist or the medical institution must provide information according to various laws or if the information is given to another therapist to ensure continued medical treatment.

8.5.2 Examples of Ruling in Negligence Claims

With an increase in the number of lawsuits and the amount of compensation awarded by the courts according to the data published by the insurance companies, it seems that the healthcare system is becoming increasingly involved in the field of negligence. Data from risk management companies indicate that there was a 30% increase from 2006 to 2017 in the number of cases reaching the courts. The average amount of compensation has increased over the years; in 2017, it was $133,989—which is 2.4 times the amount in 2006. From the data submitted by HMOs, it appears that 20% of the claims for compensation are paid after financial negotiations and of the claims that reach the courts, approximately 80% end in a settlement before reaching a verdict. In this situation, the tendency of the public to apply for compensation has increased. Between 2005 and 2015, 32.2 billion NIS were paid for negligence claims in Israeli government medical institutions. There was also a twofold increase in the total amount of payments for medical malpractice claims, growing from 138 million NIS in 2005 to 262 million NIS in 2015.

8.5.3 Perception of Negligence Cases in the Eyes of the Court

A reasonable doctor acts according to the accepted laws and clinical guidelines at the time. In a case where a "reasonable doctor" would have acted accordingly, this would not be considered negligence, and in a case where a "reasonable doctor" would have acted otherwise, these actions would be considered negligence. Reasonable care refers to the choice of treatment given to the patient. Negligence may occur due to not sending a laboratory test, a lack of follow-up on the results of a test, or a mistake in the interpretation of the information. It is important to differentiate between negligence and deviation from reasonable care. The claimant must submit an expert opinion since claims that are not accompanied by an expert opinion are usually rejected. In determining the appropriate level of caution, one must balance two central considerations that work in opposite directions. On the one hand, a sufficiently high level of caution is required to protect the injured from further injury and to ensure that proper care is taken so that damage is avoided. This is especially true in the medical context, where human life, physical integrity, and quality of life are often at stake. On the other hand, it is appropriate to avoid overburdening bodies whose normal activity, by nature, may cause damage. Reducing the imposition of responsibility upon these entities and actions is necessary, from an economic point of view as well as others, such as public interest in the activity that creates the risk. In cases of medical negligence, the imposition of an excessively severe duty of care may harm the ability of doctors to exercise judgment based on the best of their knowledge and professional skill and may encourage an undesirable phenomenon of defensive medical practice that seeks to minimize exposure to negligence claims, even at the cost of harming the health of patients, the specific patients in each case and patients in general. Setting a normative threshold that is too high may therefore lead to an undue burden on the activity of the medical system and, in the long term, even harm patients' well-being and health.

An examination of 225 cases that were decided between 1.1.2013 and 31.12.2017 and were entered into "Nevo," the Israeli judgments database, under the topic "Torts—medical negligence" found that in 145 cases, a violation of the duty of due care was alleged: 71 alleged the negligent performance of a medical procedure, 45

alleged negligence in diagnosis, 23 alleged negligence in the choice of treatment, 11 alleged negligence in monitoring the condition of a hospitalized patient, and 8 alleged negligence in postoperative care. Obstetrics and gynecology cases made up 46% of the claims and 55% of the total compensation payments to the claimants. The court ruled in favor of the plaintiffs in 48% of the cases.

8.6 Informed Consent

Doctor-patient relationships are a central issue in medicine and essential for providing quality and safe care based on medical ethics and maintaining the patient's dignity and privacy. The paternalistic attitude that was accepted until the middle of the twentieth century concentrated the powers of decision in the hands of the therapist based on the premise that the doctor is the one who best knows what is appropriate for his patients. The delivery of the information to the patient was done according to the doctor's understanding and desire; doctors used to hide bad news, and there was no informed consent required. This situation changed at the end of the twentieth century when the doctor-patient relationship was founded on trust on the part of the patient, detailed information being explained understandably, and expectations between the therapist and patient matching. The new approach is reflected in the informed consent detailed in patient rights laws. Each person is the owner of his own body, and therefore, there is a legal need for his consent to any medical operation. The most desirable situation is to reach the best decision for each specific patient, according to his objective medical-scientific data and according to his personality, needs, feelings, beliefs, and subjective culture. The decision should be made based on the medical data, as the doctor clarifies them, and on a variety of subjective data specific to the patient, as he clarifies them. Only open and correct communication between the patient and the doctor can lead to an optimal decision. Performing any medical activity without informed consent is a violation of patient autonomy and grounds for a lawsuit for assault. However, there is room for setting a reasonable judicial limit because it is not possible to burden a patient who is not a doctor with all the possible diagnostic tests, and this does not help him reach a reasonable decision.

Negligence, a lack of informed consent, and violation of autonomy are not the same; the grounds for each of these three issues are mutually exclusive. When negligence in medical treatment is proven (based on the elements of the damage and the causal relationship), there is no point in discussing the violation of the duty of disclosure and the lack of informed consent. If negligence in medical treatment is not proven, the court moves on to examine the reason for the violation of the duty of disclosure and the lack of informed consent (based on the damage component and the causal relationship). No clear rules have been formulated for examining the limits of the duty of disclosure and its scope. A ruling can distinguish between elective treatment and urgent treatment, between essential treatment and treatment designed to improve quality of life, between diagnostic and screening tests related to pregnancy and other tests, and between private medicine and public medicine. A balance must be struck between sufficient information for making an informed decision and information that will "flood" the patient in a way that will make it difficult for him to make a decision. The duty of disclosure does not include remote and insignificant risks. The "joint decision-making" model allows for the combination of the doctor's obligation to disclose the risks and possibilities of the treatment and the patient's disclosure of his preferences and goals. The duty of disclosure on behalf of the doctor according to this standard extends to almost any data that the whole patient population or part of it considers important, and for this purpose, and to make it easier for the doctor, pre-prepared databases are offered. Explaining treatment alternatives, prospects, and risks is an important step in medical treatment. The impairment of autonomy due to a lack of informed consent constitutes a head of damage within the tort of negligence. Violation of the core of the right to choose, the "hard core" of the human right that enshrines autonomy in a fundamental matter, entitles the plaintiff to significant compensation.

8.6.1 Duty of Follow-up

When a doctor offers a certain test to a patient, he must give a sufficient explanation of its importance and the need to share the results with the patient. Imposing a follow-up obligation in every case, even after a reasonable explanation, will place an unreasonable burden on the doctor. An exception to this ruling is a patient with a complex case who is in danger; then, the doctor must actively continue the follow-up and ensure that the patient receives the necessary treatment. When the patient does not follow the instructions and breaks off contact with the doctor, he cannot then sue the doctor.

8.6.2 Obligation to Transfer Information

There is an obligation to transfer information between the examining party and the attending physician. It is mandatory for the examining party to immediately refer concerning information to the attending physician and draw his attention to it. On the other hand, the attending physician must demand the results of the test and check the information in depth. It is unacceptable for him to assume that the patient will hand over the test results. The information should flow bidirectionally with joint responsibility for the attending physician and the examining physician. There must be a continuous flow of information between all the therapists, but a causal link to the damage caused must also be proven.

8.6.3 Obligation to Accurately Record a Referral or Test Result

A lack of registration can result in the courts placing the burden on the defendants to prove that they were not negligent. In less difficult cases, this will serve as support for the plaintiffs' claims regarding the defendants' negligence.

8.6.4 Confidentiality of Investigations and Protocol of Examination Committee Discussions

The protocol of the inspection committee is usually confidential unless the court orders otherwise when it finds that the need to disclose it for the sake of ensuring justice is greater than the need to not disclose it. Confidentiality can be disallowed if the protocol contains evidence that is unlikely to be found in the medical record. Thus, if it is testimony on factual matters relating to the patient's condition or the medical treatment given to him that is not reflected in the medical record but was supposed to be recorded in it, this will usually justify the disclosure, provided that these are matters of fact that are important to discover the truth. That said, disclosure of the protocol is rare, and the court orders the disclosure only if it will be of real importance to the resolution of the dispute between the parties, provided that the scope of the disclosure does not exceed the obligation to do justice in the judicial process. The position of the Israel Medical Association (IMA) is clear: a lack of confidentiality prevents systematic investigations and learning and puts the entire population at risk. The Israeli State Comptroller's position from 2012 and 2015 is similar: "No method has been formulated for conducting in-depth investigations into medical errors and drawing lessons from them."

8.7 Legal Aspects in OECD Countries

There is great variation among the 30 democracies in the OECD in the definition of medical malpractice and the tools available for legal action and compensation, but there is substantial similarity in their insurance procedures and their continual increase in the number of claims and compensation amounts. There are two main systems for determining compensation for damage due to medical treatment: the insurance market, which handles negligence claims similarly to other fields, and the "no-fault" system. In

countries where most medical services are public and the minority are private, insurance coverage is mostly supported by the state (20). In countries where most medical care is provided by private entities, professional insurance is also provided by private insurance companies. The following figure (part of a larger table that includes all OECD countries) demonstrates the differences among countries on this issue (Fig. 8.1) [8].

Key Messages: Legal Aspects of Patient Safety

- The purpose of the Patient's Rights Law in Israel was defined clearly and unambiguously: "The purpose of this law is to determine the rights of the person seeking medical treatment or receiving medical treatment and to protect his dignity and privacy." In two amendments to the law (2008 and 2010), the term "therapist" was defined broadly to include a doctor, dentist, intern, nurse, midwife, psychologist, occupational therapist, physiotherapist, communication therapist, nutritionist-dietitian, clinical criminologist, podiatrist, surgeon podiatrist, chiropractor, or any professional recognized by the general manager with a notice in the records as a healthcare provider. According to the law, three statutory committees were established: an inspection committee that examines patient complaints (its materials are not confidential), a control and quality committee that evaluates medical activity (its materials are confidential), and an ethics committee that has the authority to require life-saving treatment despite the objection of the patient or his guardian and to transfer materials from the medical file if necessary or discuss any case in which an urgent decision is needed regarding the treatment of the patient or his rights. The law has had direct consequences for risk management activities in health institutions. The three committees have pushed medical practice in the direction of treatment safety and have enabled in-depth research on adverse events and systemic learning.
- The performance of a diagnostic or therapeutic procedure, surgery, medication administration, or medical follow-up that is not in accordance with the law, regulations, practices, or clinical guidelines prevailing at the time in defining the standard of care and that leads to an adverse event/complication or death is defined as medical negligence. When there is no significant deviation from what is accepted, the action is defined as a mistake, failure, or entanglement. In other words, medical negligence is a deviation from a reasonable standard of conduct. For the tort of medical negligence to be proven, it must be proven that all of these occurred cumulatively: The therapist violated his duty of care for the patient by not treating him with the proper skill, the patient suffered damage as a result of the treatment, and there is a factual and legal causal connection between the negligent treatment and the damage.
- Patient safety forums in which investigations and judgments are presented promote the knowledge and understanding that proper conduct, transparency, adherence to an informed scheme, and work performed in accordance with procedures can save many human lives and many expenses for claims received.
- The insights at the individual and organizational level regarding what to do to avoid lawsuits and how to defend against them reveal that it is important to work according to accepted clinical

procedures and guidelines, obtain informed consent and align therapist-patient expectations, avoid unapproved procedures and unsafe treatments, manage a detailed medical record in real time, report any adverse event and provide appropriate documentation of, ensure complete transparency with the patient and his family, issue an apology in the event of a malfunction, and provide continued treatment and follow-up of a patient who has experienced any of these issues; all of these actions can minimize the chance of being the defendant in a lawsuit and strengthen the defense at the personal, institutional, and court levels.

	Claims/damages Trends Insurers loss ratio	**Premium trends** **Specialties affected**	**Market characteristics** Size, main providers Existence of insurance pool	**Insurance policy features** Trigger guarantee system Existence of caps or other restrictions
Australia	Cost, number and frequency of claims fall in 2003-04, after increasing over preceding 5 years. Average claim size continues to increase. Gross loss ratio 2003-04 of 99.[1]	Premiums collected represent € 185 m. Premiums fell by 12% in 2003-04, excl. subsidies. They had risen each of three preceding years. Previously, premium affordability issues for obstetricians, neurosurgeons and procedural general practitioners.	5 insurers mainly covering doctors in private practice, each a captive of a mutual medical defence organisation. Since 1 July 2003, cover to be provided only by authorised insurers. Government mandated pool for retirement cover. funded by practising doctors.	Protection generally on an incident occurring discretionary basis for mutual entities before 2003. Since 1/07/2003, market supplies claims made cover by way of contract. Average contract limit of AUD20m (around € 12 m). Government provides a run-off cover scheme to cope with the cost of claims of retired doctors (the Run off cover scheme).
Austria	2003; around 3 500 claims. Increase by 30% since 2002. 2003: total amount of damages: € 29 m (+54% since 2002). Loss ratio 2003; 188.8	2003: € 5.4 m. Increase of insurance and reinsurance premiums. Difficulties for establishments, gynaecologists surgeons, plastic surgeons and anaesthesiologists.	15 companies. 5 companies have withdrawn from the market.	Occurrence basis.
Belgium	Claims in 2000: € 3.4 m.	2003: € 23 m. Difficulties or higher premiums for: anaesthesiologists, obstetricians and establishments.	17 companies including 2 mutuals. Market concentration has increased. Co-insurance may be used to cover establishment.	Occurrence basis. Claims made. Mix of both: sunset clausae extended to the 3 years following policy coverage. Cap for physicians is around €5m/year or/and per occurrence year.
Canada	Number of claims is declining on average (though there are disparities between regions and specialties).	2005: CANS 310 m premiums collected by the Canadian Medical Protective Association (CMPA).	1 Mutual (non-for-profit structure), the Canadian Medical Protective Association (CMPA) covers 95% of practicing physicians. Small number of commercial insurers covering the remaining 5% of physicians.	Occurrence basis. No caps CMPA protection is provided on a discretionary basis.

Fig. 8.1 Insurance market for medical malpractice claims in a sample of OECD countries

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9 Medical Professional Liability Insurance

9.1 Principles of Risk Transfer by the Insurer

Proper management of the insurance system for medical malpractice in the health system may help prevent medical accidents and provide defense against lawsuits. A successful safety model should set four main goals: involving medical institutions in risk management, increasing the involvement of therapists, ensuring systemic learning and cooperation among medical institutions, and efficiently handling claims. The overall goal is to constantly improve the quality and safety of treatments, where the criteria for success are a decrease in the number of complaints and claims, a decrease in the amounts of payments for claims and premiums, the regulation of double insurance, and the shortening of claim processing times. The safety model should be successful both for plaintiffs who were injured by negligent medical treatment and for therapists (the medical institution and the treating staff) since it limits the possibility of human error and does not look for culprits.

In recent years, there has been a significant increase in Israel in the number of lawsuits and the amounts awarded by the courts to compensate plaintiffs (Fig. 9.1). This increase in the expenses of medical institutions has increased the national expenditure on health and burdened a system that is already lacking human resources and infrastructure. A similar increase has also been observed in other countries, such as England [1] although there has been a decrease in the amounts paid for such claims in the USA [2].

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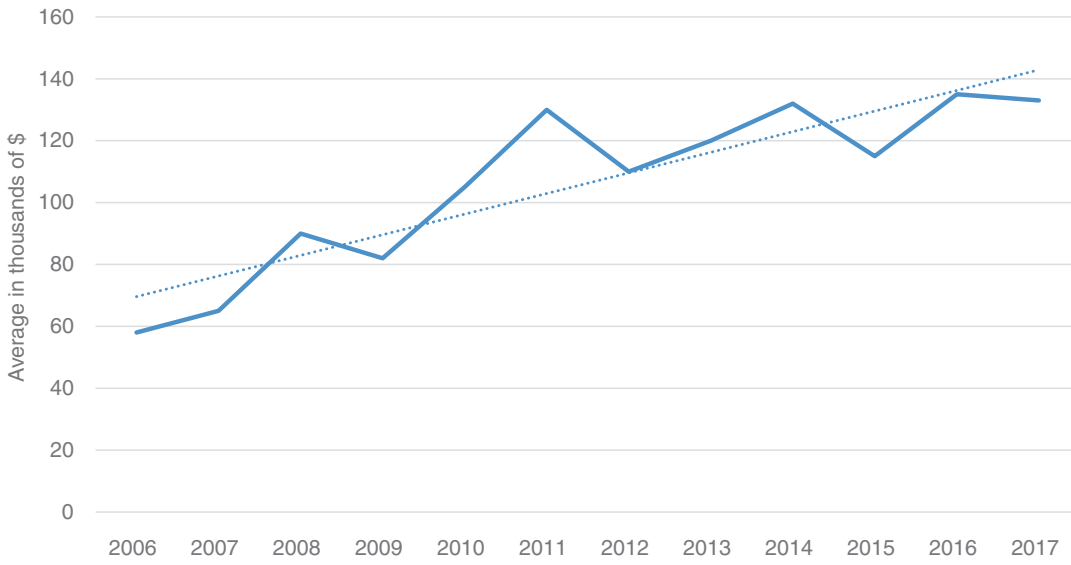

Fig. 9.1 Increase in the average compensation cost 2006–2017 (Madaness, Israel, personal communication), average in thousands of US dollars

9.2 The Israeli Method

All medical institutions in Israel have insurance arrangements for medical malpractice, although this is not enshrined in law or the procedures of the Ministry of Health. Between 1979 and 1991, doctors were covered against medical malpractice claims by the Medical Defense Union (MDU). From 1991 to 2008, insurance was arranged with foreign insurance companies by the Madaness company. The current situation is that the government institutions are insured by the Inbal company and certain funding institutions and the public/private hospitals are insured by the Harel company through the Madaness company in combination with internal funds and self-insurance. The Inbal Insurance Company is a government company established in 1978 that advises state bodies on insurance and property management issues and is subordinate to the Ministry of Finance. The chairman of the company is the accountant general of the Ministry of Finance. In addition to dealing with insurance, the company's goals are to help manage the national debt, manage the investments of the Ministry of Transportation and Tourism, manage the government travel agency, and manage the system of state loans and deposits.

In recent years, a model of self-insurance with and without catastrophe insurance has been introduced in public/private hospitals and the National Health Fund. By an agreement with the Israel Medical Association (IMA), the doctors in all IMA-associated institutions are insured under the Madaness company. Doctors who are not members of the IMA should take care to insure professional liability through one of the insurance companies independently. Collective agreements stipulate that doctors who are employed in government, public institutions, and health insurance funds are also insured for private work. This frees private institutions from insuring them.

Three government committees have dealt with the safety issue of professional responsibility over the years: the Kling Committee (1999), the Amorai Committee (2002), and the Halamish Committee (2005). The recommendations that were formulated by these committees aimed to enact an insurance law against medical malpractice, but the recommendations have not been implemented. The main recommendations of these committees were as follows:

1. To give full confidentiality to the reports of committees that investigate accusations of medical malpractice.

2. To oblige all doctors and practitioners in the paramedical professions to insure themselves against negligence claims, with insurance that will be valid even after they retire from the profession or after their death (in the case of claims against their estate).
3. To oblige any medical malpractice insurance to reference medical ethics.
4. To prohibit suing doctors, allowing suits only against the institutions where they worked.
5. To limit the amounts of claims for medical malpractice in terms of nonmonetary damages.
6. To limit the fees of lawyers representing plaintiffs in medical malpractice matters.

The compensation amounts awarded in court consist of heads of damage, some of which are fixed, immediate amounts given for pain and suffering, and some of which are given as an allowance to compensate for wage losses, caregiver funding, and other expenses.

Due to the increasing load on the courts, mediation processes have become common in the civil justice system. The mediation process plays an important role in medical malpractice claims, accompanied by a necessary condition of full disclosure, transparency, and apology.

The expenditure on legal proceedings is estimated to compose 40% of the total expenditure, and lawyers' fees range from 20% to 30% of the compensation amount paid by the claimant and approximately 15% paid by the defendant [3]. These figures should be considered in the cost of the process and the fees of the expert witnesses on both sides and sometimes also in the selection of the court. A medical malpractice claim filed without expert testimony is usually liable to be dismissed. Issues that can be improved by amending legislation or procedures are the lengthy legal process and the multiple expenses involved.

Currently, in Israel, there is no method for collecting, processing, and sharing information on adverse events, errors, and medical failures at the national level, nor is there a knowledge management system for fostering systemic learning, drawing conclusions, and improving treatment safety. There are such systems in the Ministry of Health, health funds, and other health institutions, but each system is run separately and differently, without uniformity and without sharing information. Insurance companies have databases of reports on events resulting in damage that they receive from the insured. The Inbal and Madaness companies have formal programs aimed at reducing treatment safety risks. From time to time, the Ministry of Health and the Inbal company hold learning conferences where the results of investigations, verdicts, and conclusions of inspection committees are conveyed to an audience of doctors and nurses, and similar conferences are held among health funds and hospitals.

Relative to those in the Western world, medical malpractice claims in Israel take a long time, both because the statute of limitations in the country is 7 years for an adult and 7 years plus the period up to the age of 18 for a minor and because sometimes many years pass between the incident and the filing of the claim. The time the court proceedings take is also long, and approximately 10% of cases last more than 10 years. Additionally, there has been an increase in the number of claims and the judgment amounts far above the economic inflation in the respective period (Fig. 9.1—Madaness data referring only to the institutions insured by them). In the last decade, there has been an increase of more than 200% in compensation to plaintiffs, and the average cost of claims increased from 241,800 NIS per claim in 2006 to 520,000 NIS per claim in 2016 [4].

Insurance companies, therefore, face considerable actuarial difficulty in planning premiums, which also stems from the fact that only a small part of medical malpractice cases are reported in real time as adverse events have root cause investigations carried out. Most of the cases come to the attention of the defendants when a lawsuit is filed, sometimes when the team that treated the case is no longer employed at the institution and it is difficult to reconstruct the relevant details. There are cases where the medical staff was not aware of the damage, for example, in cases of late/delayed diagnosis.

There is room for change and improvement in medical malpractice claim processes, such as making sure that all parties are aware of the goal of the insurance model, which is to encourage transparency and the transfer of information regarding the reporting of adverse events that have the potential to generate a future claim or that can provide a systemic lesson for preventing medical errors and failures and implementing conclusions and investigative recommendations. Such change can be a basis for promoting the quality and safety of treatment. The areas that require change and improvement are mandatory medical malpractice insurance, a national insurance model that addresses all aspects of treatment safety, limits on the time it takes to process a lawsuit, limits on attorney fees, the obligation to attempt mediation before handling the case in court, and knowledge management at the national level.

Other issues that must be considered to change and improve the legal approach are the "no-fault" mechanism; apologies from a medical staff member when a malfunction occurs, which do not constitute a notification of fault and is not admissible in court ("the Apology Law"); and the question of the legal confidentiality of investigations and inspection committees, which can enable deep root cause analysis and significant systemic learning. In 2014, an apology bill was submitted by three members of the parliament that proposed abolishing the use of a medical staff member's reference to an adverse event in a conversation with the patient or his relatives as evidence. The law would not significantly harm a patient's right or ability to sue for damage caused to him. The bill's contribution to the relationship between the therapist and the patient is expected to exceed the damage caused to those who still decide to sue for medical negligence. The proposed law is intended to allow members of the medical staff to have an empathetic and honest conversation with their patients and to strengthen the public's trust in the health system, its personnel, and the medical care provided within it. An amendment to the law is supposed to improve the current course of work of medical staff by reducing the stress and difficulty of dealing with unwanted results of medical treatment.

The concept of "no fault" in the field of medical professional liability is a legal approach to regulating compensation for injury during medical treatment. Providing compensation through this approach does not require proof of liability or negligence and makes the fundamental assumption that the goal of the medical team is to do right by the patient and that mistakes and failures may happen. This approach is practiced in New Zealand (starting in 1972), Finland, Norway, Denmark, and France. In Virginia and Florida, this approach exists only for neurological injuries related to birth. In the places following this approach, restrictions and criteria are set for the level of coverage and entitlement to compensation, the absence of compensation for nonmonetary damages such as pain and suffering, and the level of compensation, which is lower than that in the existing tort system in Israel. These systems are more efficient and even enforce restrictions on turning to the courts.

9.3 The Scandinavian Method

Scandinavian countries have adopted a "no-fault" method, the purposes of which are to recognize the right to compensation of a patient who has suffered damage, to facilitate access to compensation, to improve the value of the relationship between the therapist and the patient, and to promote the quality and safety of treatment through learning while avoiding the imposition of blame.

In Sweden, there has been a professional liability insurance obligation since 1996, and instead of proving negligence or guilt, the program compensates patients whose injury could have been prevented under "optimal circumstances." The plan also covers nonmonetary damage such as pain, suffering, and discomfort. The amount of compensation is determined according to the type, severity, and duration of the injury [5].

In Denmark, there is a law dealing with compensation for harm in treatment and a separate law for drug damage [6]. A government authority is responsible for the "no-fault" program and handles every case submitted to it until the amount of compensation is determined.

In Norway, the "no-fault" program, which included the public health system, was enshrined in law in 2001, and in 2009, it was extended to private medicine as well. Here, too, an independent government authority was established, operating under the supervision of the Ministry of Health. The patient must file a claim within 3 years of discovering the injury. The authorities employ medical consultants who examine the claims and provide experienced opinions to the appropriate committees [6].

The "no-fault" method has important economic and social aspects with a direct impact on the quality and safety of care. The system expands victims' access to compensation and reduces the number of lawsuits and the burden on the courts. Additional benefits include transparency and consistency in decisions, the promotion of patient safety due to doctors' willingness to report failures and a reduction in defensive medicine and expenses in the health system [7, 8].

Key Messages: Medical Professional Liability

- In recent years, there has been a significant increase in the number of lawsuits and the amounts awarded by courts to compensate plaintiffs. This increase in the expenses of medical institutions has increased the national expenditure on health and burdened a system that is lacking in human resources and infrastructure.
- The compensation amounts awarded in court consist of heads of damage, some of which are fixed, immediate amounts given for pain and suffering, and some of which are an allowance and are given to compensate for wage losses, caregiver funding, and other expenses.
- Due to the increasing load on the courts, mediation processes have become common in the civil justice system. These processes occupy an important place in medical malpractice claims, accompanied by a necessary condition of full disclosure, transparency, and apology.
- Medical malpractice claims may take a long time to surface, both because the statute of limitations for an adult is added to the period up to the age of 18 for a minor and because sometimes many years pass between the incident and the filing of the claim. The duration of the proceedings in the court may also be long, and approximately 10% of cases last more than 10 years. Insurance companies, therefore, face considerable actuarial difficulty in premium planning, which also stems from the fact that only a small part of medical negligence cases are reported in real time as adverse events, and a root cause analysis is carried out. Most of the cases come to the attention of the defendants when a lawsuit is filed, sometimes when the staff who handled the case is no longer employed at the institution and it is difficult to recover the relevant details.
- Scandinavian countries have adopted a "no-fault" method, the purposes of which are to recognize the right to compensation of a patient who has been harmed, to facilitate access to compensation, to improve the quality of the relationship between the therapist and the patient, and to promote the quality and safety of treatment through learning while avoiding the imposition of blame.

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Patient as a Partner in Promoting Patient Safety

10

10.1 Introduction

In the past, the patient's role in the medical process was expected to be rather passive and based on full trust in the medical team, their knowledge, and experience. These relationships are described as following a paternalist model [1]. According to the model presented in Table 10.1, only qualified and certified therapists are allowed to diagnose and treat diseases and all treatment decisions are made solely by them. Caregivers are the ones who look after the patient's interests, and the patient is expected to be passive in the treatment process.

The question of how much patients truly want to be involved in treatment decisions concerning them has been discussed at length. Various data have been published regarding the proportion of patients who wish to be partners in their medical care. In a review of hospitalized patients' literacy [2], it was found that 96% of the patients were interested in receiving information about therapeutic alternatives and expressing their opinions on the matter. However, 52% preferred to leave the final decision in the hands of the doctor, and 44% preferred to rely on the doctor's knowledge instead of searching on the Internet. More educated and healthier women preferred a more active role in making medical decisions than other women.

The Patient's Rights Act of 1996 (Israel) defines and regulates a series of rights that patients have in the medical treatment process, including the right to equal treatment, the caregiver's obligation to obtain the patient's informed consent for medical treatment, and the patient's right to receive medical information from his medical record. For various reasons, including workload, the devaluation of certain sections of the act, and insufficient familiarity with the language of the law, medical staff members do not always fulfill these duties as required.

The position papers of the Bureau of Ethics define the doctor-patient relationship and are in many cases a continuation of the obligations imposed on the medical teams by the Patient's Rights Act [3]. For example, if an error could have an important effect on the patient's health condition or on the continuation of his treatment, the doctor is obliged to disclose the error to the patient [3, p. 35]. The understanding that there must be a partnership between doctor and patient in order for the treatment to be successful is expressed at the beginning of the Ethics Bureau's position paper on doctor-patient relations: "*The doctor and the patient will work together to establish a system of mutual trust between them for the success of the medical treatment*" [3, p. 29]. However, it must be clear that the responsibility for the quality and safety of medical treatment rests on the shoulders of the medical staff alone. Just as it is unthinkable that upon entering the plane, the passengers would be instructed to ensure the safety of the flight, and it is unthink-

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Table 10.1 Paternalist model of a patient-healthcare worker relationship

Roles	Decisions	Functions	Responsibility for outcomes
Caregiver	What to do and how in order to address patient's health problems	Diagnose, treat, follow-up	Full responsibility for the process and its outcomes
Patient	Provide the caregiver with all the known to him information	To comply fully with caregivers' orders	Freedom from responsibility

able that patients would be held responsible for the safety of their treatment. Among those who support the absolute responsibility of the medical staff for the results and safety of the treatment process, some even claim that it is not at all appropriate to place the patients in a position to criticize the activities of the medical staff in order to avoid conflict and distrust toward the staff [4].

10.2 Challenge of Patient Participation

The main question in the context of the patient's participation in the treatment process in order to achieve high-quality and safe results is related to the gap in basic knowledge between the treating staff and the patient. However, the gap is twofold: The medical team has medical knowledge and experience but has no knowledge regarding the specific problems of the patient for which he sought treatment, while the patient has direct knowledge regarding his medical problems, his medical history and that of his family, the medications he takes, and the procedures he has undergone but has limited, if any, knowledge of the medical meaning of his condition. For the treatment to be successful and safe, both parties need to cooperate by understanding the strengths and weaknesses of the other.

However, in most cases, members of the medical staff trust their professional knowledge, while the patient, who is in a state of stress, uncertainty, mental distress, anxiety, and pain, does not understand what is required of him for the success of the medical treatment, except to say what he feels and answer the questions of the medical staff. This is why the medical team is convinced that in most cases the patient understands his role and will do everything in his power to get well soon, will provide all the information he has, and will willingly respond to their medical instructions. This is, of course, a mistake that may be the cause of errors in the medical treatment process since the patient does not necessarily know how to describe the problem he is suffering from, will not necessarily provide all the information he possesses, will not necessarily correctly understand the importance of fully answering the questions of the medical staff, will feel discomfort if he does not understand the questions of the medical staff, and will try to shorten the admission phase as much as possible out of a desire to start treatment and ease his suffering as soon as possible.

The patient may be convinced that the members of the medical staff know what his problem is, since "everything appears on the computer," he has already been asked questions by the receptionist, he has brought in a referral letter, and the nurse has asked him many questions—so what do they actually want from him? Why will they not do something right away to ease his suffering and cure him of his illness?

Poor communication between caregivers and patients is a root cause of countless medical errors, sometimes with tragic results. The caregivers must understand that it is their responsibility to communicate clearly, positively and exhaustively with the patient while empathizing with his condition and to ensure that he understands everything that is said to him and what he should do.

According to a report by the Joint Commission International (JCI), in 2011–2014, communication problems were the most common cause of sentinel events [5]. As mentioned before, the language barrier increases the probability of errors during medical treatment. For example, it was found that the chance of patients in the United States who do not speak English being rehospitalized after 30 days is 30% higher than that of

English speakers [6]. In a study that examined what patients remember after a doctor visit, it was found that patients have difficulty remembering instructions that the doctor gave orally and that the higher the patients' medical literacy is, the more details they remembered from the doctor's instructions [7]. It is estimated that a third of the population in the United States has low medical literacy [8].

The importance of parents in hospital pediatric wards was highlighted in an extensive review on medical literacy. It was found that limited literacy affects clinical outcomes. The medical teams involved in one study were trained on general principles of communication, including using simple language, verifying understanding, using additional tools such as visual aids, and encouraging patients and their families to ask questions regarding treatment, to ensure the continuity of care after discharge [2].

To address such problems, it has been suggested that practitioners first identify whether a patient has low literacy in order to adjust their communication with him by, for example, using the technique of role-playing, in which the patients are asked to explain their medical condition and the treatment plan back to the therapist and through this, making sure that they understand what is required from them [9].

Another recommended strategy is "ask me 3," which guides patients to ask the medical team three questions: What is my problem? What should I do? Why is it important that I do this? [5, 10]. Klalit Health Services (Israeli largest HMO) launched a campaign approximately one decade ago that included videos and various informational materials to encourage patients to ask these three questions. A special version for referral for medical tests was also developed: Which test am I directed to take? How will I receive the test result? Why is it important that I contact the doctor after receiving the test results? A similar set of questions is used for drug administration: Is the medicine for me? What is the medicine I am getting? Do you know whether I am sensitive to the medicine? [11, 12]. To the best of our knowledge, no studies have been conducted in Israel to evaluate the impact of the "ask me 3" method. To maintain patient safety and reduce the scope of medical errors, JCI launched a project known as "speak up." The initiative developed advice and questions for patients to ask the medical staff, as detailed in Table 10.2.

Table 10.2 Examples from JCI's "speak up" project

Topic	Description
Questions and concerns	Speak up if you have questions or concerns.
	If you still don't understand, ask again.
	It's your body, and you have a right to know.
Assuring right treatment and medication	Pay attention to the care you receive.
	Always make sure you're getting the right treatments and medicines from the right healthcare professionals.
	Don't assume anything.
Medical self-education	Educate yourself about your illness.
	Learn about the medical tests you take and your treatment plan.
Seek assistance from a trusted person	Ask a trusted family member or friend to be your advocate (advisor or supporter).
Proficiency with your medications	Know what medicines you take and why you take them.
	Medicine errors are the most common healthcare mistakes.
Choose wisely your caregivers giving preference to those checked out regularly and accredited	Use a hospital, clinic, surgery center, or other type of healthcare organization that has been carefully checked out.
Participate actively in your treatment process	Participate in all decisions about your treatment.
	You are the center of your healthcare team.

The high importance of patient participation was especially highlighted in a study in which it was found that patients detected twice as many adverse events as medical staff members did in the medical records they examined [13].

10.3 Patients Differ

Humans differ in their need for information to deal with threatening and stressful situations such as medical treatment [14]. Two main cognitive patterns in dealing with threatening situations such as a medical procedure have been characterized and scientifically validated:

(A) Monitoring Information—patients who are usually characterized by a higher basic level of anxiety and deal with stress and threat by collecting information relevant to the threatening factor.
(B) Blunting Information—patients who are usually characterized by a lower level of anxiety and prefer not to know the details about the procedure and avoid actively gathering information about it.

Research evidence shows that in a clinical context, there is a certain advantage to the information monitoring pattern, as those who follow this pattern show better adaptation to treatment and better therapeutic results than those following the information blunting pattern [15]. It has also been found that patients following the information monitoring pattern who experience a severe trauma such as war tend to develop less persistent posttraumatic symptoms [16].

The term "patient" is broader than its concrete meaning. It includes family members and other companions who can and should be mobilized to improve outcome quality and patient safety, especially in cases where the patient cannot do so due to language barriers, cognitive problems, stress, or anxiety [17].

The understanding that different patients treat medical information differently is important to avoid increasing the level of anxiety in patients whose way of coping is to avoid excess information and to provide information to those whose way of coping is to collect information relevant to their medical problem. Behavior that does not match the patient's cognitive behavior pattern may increase his anxiety level and harm his cooperation and thus the results and safety of the therapeutic process.

10.4 Patient as a Factor Affecting the Success and Safety of Treatment

The importance of patient participation in the medical process was succinctly expressed in the London Declaration, published in 2006 [18]. The declaration states, among other things, that patients are partners in the effort to reduce avoidable errors. It encouraged the joint commitment of caregivers and patients to reduce medical errors and improve patient safety. Today, patients in Western society are typically very different from those in the distant past, who treated doctors with reverence and obeyed their instructions without question, even if they did not understand them. Medical literacy has since developed, as has the media's interest in science and medicine.

The Internet, already in its early days, was flooded with medical information and is now an inexhaustible source of medical information on any subject. However, a significant amount of this information is unvalidated, irrelevant, and even misleading. Nevertheless, there are websites that specialize in presenting verified medical information to patients. The question of what patients without a medical background understand from this information and how the information guides them to act is important for anyone concerned with patient safety. Some doctors dismiss the information presented to them by patients as worthless, while others encourage patients to look at medical information on the Internet as a resource for informed decision-making. The concept of medical literacy refers to the ability of patients to derive real health benefits based on information accessible to the general public, including on the Internet.

In 2015, Eric Topol, a renowned US cardiologist and researcher, published a book with a challenging and unconventional title: "The patient will see you now: The future of medicine is in your hands." The book deals with the technological revolution in the world of medicine, made possible by the increasing distribution of smartphones, wireless communication, and applications that make medical information immediately accessible to the patient. In Topol's

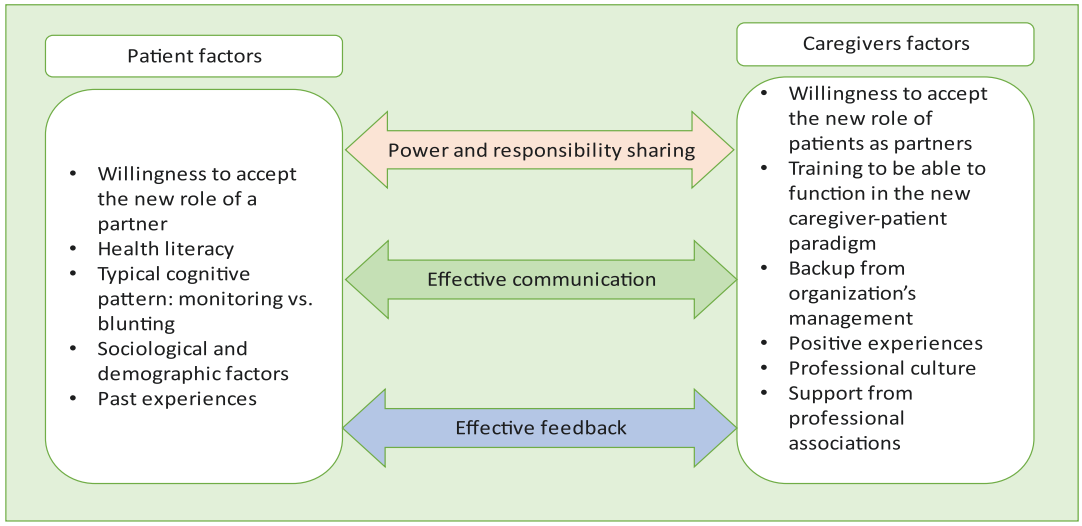

Fig. 10.1 A conceptual model of factors influencing the degree of cooperation between caregivers and patients

opinion, the roles of doctors and patients will continue to change beyond recognition; the treatment will be managed by the patient, and the paternalistic relationship between doctors and patients will disappear. The author noted that this will improve patient safety and reduce medical errors. The book has received much attention, and quite a few reviews have been written about it, most of them positive, although they have expressed reservations about the pace of the expected changes [19].

The effect of medical Internet literacy (e-health literacy) in Japan was examined [20], and it was found that the higher the level of literacy a person possesses, the healthier certain lifestyle habits he exhibits, such as increased physical fitness training and a more balanced diet.

The caregiver's role is to actively involve the patient in the treatment process in order to improve outcome quality and patient safety. The caregiver must consider factors such as knowledge, beliefs, demographics, emotions, methods for dealing with stressful situations, and the severity of the disease, all of which affect the patient's willingness to take an active part in the therapeutic process [21].

A theoretical model relating to the various factors affecting patient involvement in medical care is presented below in diagram 3. The key in the model is convincing the medical staff to share power and responsibility with the patients. Doing so is not a simple matter; it requires explanation, guidance, and training to change the culture, attitudes, and working habits that have been ingrained over many years. On the side of the patients, feedback to the caregivers on the value of their participation in the treatment process is required to strengthen the change over time. For the partnership model to work, it is necessary for both parties to be trained and adopt effective communication patterns. For patient cooperation to be successful, it is necessary to address inhibiting factors on the part of both the caregiver and the patients. The inhibiting factors on the part of the caregiver are mainly related to the changes in the conception of their traditional role and the changes in that of the patients to include being partners actively involved in a medical procedure and bearing responsibility, at least partially, for its success; improving safety by detecting errors in the process; and drawing the attention of the caregivers to this in advance to avoid preventable adverse events.

The relationships between therapists and patients are shown in Fig. 10.1.

10.5 Results of Patient Nonparticipation in the Therapeutic Process

In recent decades, the understanding that patient safety cannot be promoted without active partnership on the part of the patient has become evident. This is after the occurrence of countless adverse events, some with serious consequences for patients' health, revealing a serious communication problem between caregivers and their patients. Below is a partial list of communication problems between therapists and patients that affect patient safety.

On the patient side, there have been the following problems:

- The patient had critical medical information that he did not disclose to the caregivers (sensitivities, past treatments, medications he was taking, test results). As a result, the diagnosis and treatment process did not take into account all the relevant information.
- The patient did not follow the instructions of the medical staff due to a lack of understanding. As a result, a problem of noncompliance arose, and his medical condition deteriorated.
- The patient stopped the chain of diagnosis/treatment—he did not return to the attending physician after receiving test results, under the assumption that the doctor also received the answer, and if he did not contact him on his own initiative, then everything was fine.
- The patient stopped the continuity of treatment after being discharged from the hospital, after a visit to a medical institute, after a visit to a private doctor, after an elective procedure was performed, or after experiencing a medical event abroad.
- Due to discomfort, and even though the instructions given were not clear to him, the patient did not ask for clarification and continued the wrong treatment according to his incorrect understanding.
- The patient switched between doctors and health insurance funds without informing the medical staff of his medical history.

On the caregiver's side, there have been the following problems:

- The practitioner insufficiently listened and gave insufficient attention to the patient's complaints as a source of information relevant to ensuring the quality and safety of the care provided.
- The practitioner provided instructions in a manner and in language that was not clear to the patient due to language barriers, cognitive states, mental stress, or anxiety.
- The practitioner inadequately instructed the patient and failed to verify that he understood the instructions.
- The practitioner provided insufficient follow-up of the patient—which constituted a failure to manage the case as required, led to a loss of contact with the patient during the medical inquiry process, and caused an interruption in the continuity of treatment.
- The practitioner did not take the patient's complaints seriously enough due to prior acquaintance or similar complaints in the past.
- The practitioner paid insufficient attention to test results and failed to initiate further treatment based on test results as required, having assumed that the patient would return with the answer anyway.
- The practitioner labeled the patient a "repulsive" or violent patient and thus did not follow medical procedures as required because of this.
- The practitioner was affected by biases and cognitive phenomena—mental fixations, a sense of superiority, and a loss of situational awareness—that may affect medical decision-making and failed to give appropriate weight to the information provided by the patient.
- The practitioner failed to detail the risks of the provided medical treatment as required in the informed consent procedure.
- The practitioner did not carry out the informed consent procedure in accordance with the guidelines defined in the Patient's Rights Act [22].

10.6 Caregiver-Patient Relationship and Communication

The discussion of the caregiver-patient relationship is often characterized by two extremes: On one end, there is a paternalistic relationship in which the therapist serves as a kind of "father" who knows what is right and good for the patient and the patient is expected to accept his decisions and recommendations without questions. On the other end, there is complete respect for the patient's autonomy to decide what to do with his body. Since, in reality, the situation is much more complex, four models of caregiver-patient relationships have been proposed; the characteristics, advantages, and disadvantages of each model were discussed; and a recommended model has been developed [23]:

(A) **The Paternalistic Model**: In this model, the goal is to ensure that the patient receives the best treatment from the therapist's medical point of view. The therapist uses all the skills, experience, and tools at his disposal to ensure that the patient receives the correct treatment according to the diagnoses made. The therapist presents the patient with the relevant information to obtain his consent for the treatment he has decided is best. The basic premise of the model is that there is a correct and optimal treatment for the patient's condition and that the therapist is responsible for defining this treatment since he has the necessary knowledge and experience to make this decision. In this model, the therapist acts as a kind of guardian and represents the interests of the patient in the medical system.

(B) **The Information Model (Informative)**: This model is sometimes defined as the consumer model. In this model, the therapist perceives himself as obligated to provide the patient with all relevant information for making decisions regarding the preferred medical treatment. The assumption in this model is that the patient's values are clear and all he lacks in order to choose the right therapeutic option for him are the facts. Given the relevant information, the patient will know how to make the right decisions for him. In this model, the patient is treated as a consumer of health services.

(C) **The Interpretive Model**: The purpose of communication between therapist and patient is to clarify the patient's values and desires and help him choose the most appropriate treatment option for him. Similar to the information model, in this model, the therapist provides factual information to the patient but also refers to his values, desires, and preferences. In this model, the therapist acts as a sort of consultant, leaving the freedom of choice in the hands of the patient.

(D) **The Deliberative Model**: In this model, the therapist's role is to help the patient choose the most appropriate therapeutic alternative that can be clinically implemented. As in the information model, the therapist must provide the patient with all relevant information, and as in the interpretive model, he must clarify the patient's values and desires. However, in this model, the therapist also takes a position regarding the relative importance of the different aspects and values and tries to convey to the patient the meanings of the different alternatives.

To highlight the differences between the various models, a comparison was made among them based on several relevant criteria [23]. However, in the original comparison, there was no reference to the effect of applying each model on patient safety; therefore, we have added criteria relating to patient safety to the original comparison. The comparison in Table 10.3 shown below includes our edits and additions.

Each model has advantages and disadvantages; therefore, it is important that the caregivers assess the characteristics of the specific patient and adapt the approach to him out of respect and the understanding that his participation in the medical procedure has important ethical value, helps achieve better treatment results, and improves patient safety due to its potential to prevent errors and adverse events.

Table 10.3 Comparison among therapist-patient relationship models (Based on [23])

	Informative	Interpretive	Deliberative	Paternalistic
Patient's values	Defined, fixed, and known to the patient	Raw and contrasting, requiring clarification	Open to discussion and revision through conversation about values	Objective and shared by the caregiver and patient
Caregiver's obligations	Providing relevant factual information and implementing the patient's chosen alternative	Clarifying the patient's relevant values, providing relevant factual information, and implementing the patient's chosen alternative	Discussion of the patient's most significant values and persuasion, providing relevant factual information, and implementing the patient's chosen alternative	Promoting the patient's best interests, regardless of current preferences
Conceptions of patient's autonomy	Selection and control of the medical procedure	Self-understanding of information relevant to medical treatment	Developing self-values related to medical care	Assenting to objective values
Conception of caregiver's role	A competent technical expert	Counselor and advise	Friend or teacher	Guardian
Impact on errors in treatment	• Lack of distinction between main and inconsequential • Failure to consider the patient's unique characteristics	• Delay in providing treatment due to a long process of discussing the alternatives • Creating a feeling of insecurity in the patient		Disregarding of the patient's autonomy due to failure to take into account his values and wishes
Impact on patient's errors	Confusion and embarrassment in the face of too much information and making an inappropriate decision			• Mistakes in taking medication • Failure to arrive for follow-up • Not knowing how to behave in an emergency situation • Failure to check and control the medical procedure
Impact on compliance	Moderate level of compliance	High level of compliance		• In part of the population that trusts caregivers, compliance is high • For some of the population who see the paternal model as a violation of autonomy, there is low compliance with medical recommendations

10.7 Obstacles and Challenges in Patient Participation

Implementing the patient participation approach may require navigating certain difficulties:

(A) The caregiver's personality, as not all therapists have good communication skills such as those required to engage the patient, and some of them are very task-oriented and seek efficiency in their work but not necessarily quality and safety.
(B) A management concept that rewards efficiency and not necessarily quality and safety.
(C) Caregiver working conditions that make it difficult to find enough time to conduct a dialog suitable for the patient's participation in order to mobilize him to take an active part in the medical procedure.
(D) A lack of guidance and training provided to caregivers on how to carry out the patient participation process and manage it correctly.
(E) A lack of sufficient medical education for caregivers during their training, such as developing appropriate communication skills and treating the patient as a partner and a valuable resource for the success of the therapeutic procedure.
(F) A great difference between patients who differ in their values, desires, degree of trust in the medical system and in the specific caregiver, past experiences with the medical system, medical literacy, age, sex, characteristics of the medical condition, communication skills, and knowledge of the language. All of these factors affect the patient's willingness to receive and discuss medical information and be an active partner in his therapeutic process.
(G) Corporate culture, which can be a significant obstacle in organizations that emphasize mission, technology, and efficiency. These organizations place less value on communication with the patient and the "soft" aspects of providing treatment.
(H) E-health, which has recently boomed thanks to new technologies, has been an important solution during the COVID-19 pandemic, and poses new challenges for patient participation in medical procedures, mainly being an effective technical solution for conducting a visit between the caregiver and the patient.
(I) Different perceptions regarding the concept of patient participation, some of them extreme. One extreme is that obtaining the patient's consent for the treatment is the extent of his participation, and the other extreme is a model that may leave the patient in a state of confusion and embarrassment and make it difficult for both him and the caregiver to choose the appropriate therapeutic alternative.

Therefore, it is not enough to declare the importance of these topics and support this statement with study findings that indicate its validity. A system that wishes to promote patient participation should consider the issues raised above and define actual solutions for each of them.

Key Messages: The Patient as a Partner

- The traditional roles of the caregiver and the patient are changing. The therapist is ceasing to be the "father" in the paternal model and becoming a consultant/facilitator, while the patient has stopped being passive and obedient and has begun to take an active part in the therapeutic process.
- Key elements in changing these roles are medical literacy and linguistic accessibility.
- The changes in the roles of therapists and patients are supported by regulations that institutionalize the roles of therapists regarding the rights of patients and an ethical code that defines values and norms in the relationships between therapists and patients.
- Technological changes are accelerating patient access to up-to-date medical information and thus pose challenges

regarding the reliability of the information found on the Internet.

- Patients differ in many aspects and in their willingness to take an active part in their treatment. Two different patterns have been characterized in this context:
  - Those who monitor information (monitoring)—patients who are usually characterized by a higher basic level of anxiety and deal with stress and threat by collecting information relevant to the threatening factor.
  - Those who blunt information (blunting)—patients who are usually characterized by a lower level of anxiety and prefer not to know the details about the procedure and avoid actively gathering information about it.
- There is research evidence that patient participation improves the quality of treatment and its results, improves patient safety, and reduces the scope of errors and adverse events.
- A lack of patient participation may expose therapists and patients to a series of errors, some of which may be related to poor therapist-patient communication.
- Four models that define the relationship between therapist and patient are described in the literature, where the extremes are, on one end, a paternalistic relationship and, on the other end, a deliberative relationship in which everything related to treatment is discussed with the patient and the meaning of each course of action is made clear to him, and in the end, the patient is the one who chooses the most appropriate action according to his medical condition, values, and needs.
- Currently, at the declarative level, most therapists and managers value the patient's participation. However, on a practical level, there are many difficulties in ensuring the wide and full implementation of this idea.

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11 Risk Management and Patient Safety Processes in a Healthcare Organization

11.1 Introduction: Three Approaches to Promoting Patient Safety

As mentioned previously, there are three basic approaches to risk management with the goal of promoting patient safety:

Reactive Activity: These are activities carried out following the occurrence of an adverse event in order to learn from them and derive lessons to prevent the recurrence of similar events in the future. Typical reactive risk management activities include a safety investigation, root cause analysis (RCA), and inspection committees as defined in the Patient Rights Law [1].

Interactive Activity: These are activities carried out immediately after the occurrence of an adverse event that aims to identify and reduce the immediate risks as a result of the event. Assessing the patient's health condition after an adverse event, ensuring due diligence, reporting to relevant authorities, and assessing the condition of the caregivers involved are examples of interactive activities.

Proactive Activity: These activities are aimed at detecting, assessing, and controlling risks. Conducting safety rounds and audits, designing systems and processes with consideration of patient safety issues, and offering training and education are typical examples of proactive activities.

For a risk management activity to be effective, it must include, as mentioned, a mix of the three approaches. However, the prevailing approach is mostly reactive, and there are probably three main reasons for this:

(A) There may be a management approach that as long as "everything is fine" there is no need to take special action: "if something goes wrong, we will take care of it."
(B) There may be limited resources allocated for risk management activities in health institutions, a situation that almost does not allow proactive and interactive activities to be carried out.
(C) There may be insufficient training in proactive methodologies, most of which require knowledge, experience, planning, resources, and management support.

To promote patient safety in a medical organization, there is a need for a systematic and continuous risk management activity. This is because a high level of patient safety cannot be maintained over time without many and varied activities being carried out on an ongoing basis to preserve and advance safety.

In every medical organization, there are indications of the state of patient safety, and they must be allowed to flow freely and be dealt with decisively to reduce their inherent risks. In this

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chapter, various risk management tools are presented that are recommended for adoption and regular application in healthcare organizations. However, it should be noted that the overall situation is important and no single tool will solve all issues. In general, an interactive risk management activity is designed to contain and reduce the risks arising from the occurrence of an adverse event and the risks to the patient, care team, and organization.

A practical and effective approach to promoting patient safety in a medical organization refers to the resources available to perform diverse activities and be allocated in a planned manner to support various types of activities. In our experience, it is correct to allocate approximately 40% of the resources to interactive risk management activity, 30% to reactive activity, and 30% to proactive activity. However, the reality in health organizations in Israel is that there is a shortage of staffing in most areas of activity, which is also evident in the allocation of resources for risk management and patient safety.

According to a 2012 Medical Director's Circular [2], the patient safety unit is staffed according to the size of the hospital, where the standard for a hospital with up to 400 beds is a doctor, a nurse, and a secretary and that for a hospital with more than 800 beds is three doctors, three nurses, and three secretaries. The staff of the safety unit must be experienced senior staff and have appropriate training as defined in the circular. However, although this is a very basic standard, most of hospital units are understaffed, the turnover is high, the staff have not undergone the training required for the position, and the unit's manager is not a part of the hospital's senior management. The units' functions, as defined in the circular, are not adapted to actual regulations and staffing. Among others, the unit is required to perform the following functions: promoting safety culture in the institution, promoting education and training programs on the subject, handling reports of adverse events, promoting organizational learning from adverse events, identifying trends, providing feedback to the hospital departments, preparing periodic reports, reporting to the Ministry of Health, maintaining work interfaces with other units in the hospital, and more.

If we assume that in a hospital with up to 400 beds, only three incidents are reported per day and then the unit has to process approximately 2000 incidents per year. The handling of reports—receiving the report, filling in the details, managing the incident, providing feedback to the reporter, and inputting it into a dedicated computer system—alone consumes almost all the unit's resources. Handling an adverse event requires at least 2 working hours, and investigating an adverse event requires 20–90 working hours [3]. Therefore, if we add to the ongoing processing of approximately 2000 adverse events, investigating even 1% of them (approximately 20 adverse events) would mean that the unit is able to investigate only a few of the events. The standard staffing arrangements suggested for the patient safety units are detailed in Table 11.1.

In recent years, the Ministry of Health has launched a project to support financial activities aimed at promoting patient safety in general hospitals and in the community. The project includes eight indicators that, in the eyes of the ministry, constitute the "iron portion" of activities meant to ensure the promotion and maintenance of an adequate level of patient safety. The indicators relate to both reactive activities (reporting adverse and "near-miss" events, organizational learning, investigating, and handling systemic recommendations) and proactive activities (carrying out projects using the PDSA (plan–do–

Table 11.1 Human resources required for the patient safety unit according to the size of the hospital

Type and size of the hospital	General			Psychiatric	Geriatric
	Up to 400 beds	400–800 beds	More than 800 beds		
Physician	1	2	3	1	1
Nurse	1	2	3	1	1
Legal advisor (local decision)	0.5	0.5	1	–	–
Secretary	1	2	3	1	1

study–act) method, measuring the safety culture, training various sectors, and addressing the issue of personnel attrition. Meeting the required criteria entitles the organization to a dedicated budget to help expand its activity to advance patient safety.

This chapter describes activities that, if implemented in a systematic and persistent manner, can promote patient safety in a medical organization, with a special emphasis on activities required for the continued support of the Ministry of Health. Other activities are not systematically taught, and if they are implemented, they are based on a local initiative.

11.2 Reactive Risk Management Activities

11.2.1 Reporting of Adverse Events

In an article on medical ethics published by the Israeli Medical Association in 2010 [4], in the section dealing with the doctor–patient relations, section 18, it is stated that "the doctor will make an effort to educate his professional environment in order to improve patient safety through proper patient identification and reduction and prevention of errors in the provision of medical treatment. The doctor will report to the appropriate professional body errors that occurred in the medical treatment. Confidentiality will apply to the report, and this information will not be misused against the reporting doctor or against a member of the medical staff who made an error" (see more on this issue in Chap. 2 in the discussion on the phenomenon of iatrogenic harm).

A NASBAR (Israeli Society for Risk Management and Patient Safety) position paper dealing with "Insights from adverse events" [5] states, among other requirements, that "every staff member in a medical organization is required to report adverse events to the organization's patient safety unit."

Almost all the studies published in recent years on the subject of risk management in medicine and patient safety emphasize the importance of reporting as a central principle in reducing errors and improving the quality of medical care (Leape [6]; Vincent [7]; Barach and Small [8]; and many others). The Institute of Medicine (IOM) report published in 1999, "To Err is Human," recommends establishing reporting systems in health organizations as a crucial step to reduce physician errors [9]. What is the value of reporting adverse events from different perspectives? It is important to discuss this issue to be able to offer solutions to increase reporting, based on understanding what motivates and what prevents the reporting of adverse events in the health systems, in view of its value to caregivers, health organizations, and society. The concept of value in the context discussed here has many definitions—statistical, ethical, and financial. We refer to value here as a desirable product in the eyes of some party. This definition allows for a wide range of values, whether they are abstract, material, or spiritual. That is, a medical organization places value both on the possibility of financial savings as a result of the proper handling of adverse events and on aspects such as a positive change in organizational culture toward being blame-free (not placing blame on those who report and are involved in adverse events) and on the possibility that patients will place a positive value on the organization's efforts to prevent the recurrence of medical errors.

The handling of adverse events requires a professional setup and involves a significant investment of resources. The question of value is a question of what the organization gains based on how it handles adverse events (we addressed this question to some extent in Chap. 2, which deals with the reporting of adverse events). Our experience in risk management and patient safety shows that the values created during the management of adverse events in a medical organization are accumulated in three stages: the reporting stage, the handling stage, and the stage of implementing the conclusions and recommendations.

References to factors inhibiting and encouraging the reporting of adverse events in medicine are analyzed from three perspectives—private, organizational, and social—and in relation to three areas—cultural, legal, and economic [8]. The types of value created in the process of han-

Table 11.2 Factors that inhibit and encourage the reporting of adverse events

Stage		Reporting	Investigation	Implementing recommendations
Type of value				
Individual	Material	• Lowering the costs of malpractice claims		
	Spiritual/ cultural	• Meeting medical and ethical standards	• Participating in the process of error prevention	• Decreasing personal involvement in adverse events
		• Ensuring the system's participation in accountability for the event	• Receiving professional feedback	• Strengthening the confidence that errors can be prevented
		• Enabling stress discharge	• Increasing faith in the system	• Increasing faith in the system as a supporting and backing system
		• Ensuring professional participation		
		• Contributing to the safety and quality of care		
Organizational	Material	• Lowering the cost of malpractice claims		
		• Decreasing the scope of medical errors and their associated costs		
		• Lowering insurance costs		
		• Increasing the number of patients		
		• Increasing the quality and efficiency of working processes		
		• Receiving accreditation by official organizations		
	Spiritual/ cultural	• Producing an image of advanced and quality organization that can handle errors	• Defining working patterns and applications to deal with problems	• Enabling organizational learning
		• Sending the message to the employees that the organization has a "blame-free" culture	• Internalizing the concept of process improvement instead of placing blame	
		• Showing management's commitment to dealing with errors		
Societal	Material	• Lowering expenditure on health care		
	Spiritual/ cultural	• Creating an image of a quality and safe healthcare system		
		• Improving faith among the system, caregivers, and patients		

dling adverse events are shown in the table below. The categories are presented according to the three steps in the process of reporting an adverse event as mentioned in Table 11.2

As already mentioned, the immediate reporting of adverse events may shorten the time for processing claims and reduce compensation payments [10]. The above refers mainly to the benefits of reporting in relation to malpractice claims and not from the aspect of patient safety, perhaps because the benefits of reporting physician errors are taken for granted. In any case, in our opinion, the significance of reporting errors and their benefits lie in the reporting process itself and especially in the products that are returned to the caregiver in various forms: starting with personal feedback to the reporter, including recommendations from an incident investigation, and ending with an applied study of a phenomenon resulting from the report. A better understanding of medical errors can result from the desire to develop appropriate preventive measures, hence the need for an improved reporting system on accidents, errors, and near misses as a basic pillar of risk management activity [6].

Three types of benefits arise from reporting, and they influence each other: benefits to the reporting caregiver, benefits to the organization, and benefits to patients.

11.2.2 Benefits for the Caregiver

(A) Breaking the cycle of loneliness—Caregiver errors are not a rare phenomenon. A medical staff member who has made an error experiences feelings of guilt, shame, anxiety, uncertainty, and confusion and does not always know how to act properly when things go wrong. In the absence of a reporting system and culture, the involved caregiver may experience a feeling of loneliness in the complex situation he finds himself in. A reporting system may provide him with an adequate remedy to the distressing situation. Publications on the "second victim" phenomenon describe the personal and professional effects of involvement in an adverse event some even resulting in post-traumatic stress disorder (PTSD) [11].

(B) A sense of competence in the face of the negative occurrence—A reporting system provides the caregivers a sense that there is something that can be done and that errors in medicine are not inevitable.

(C) Legitimization—This comes from giving the caregiver legitimacy to return to normal functioning after being involved in an adverse event and creating understanding and awareness that to err is human and that even highly professional and committed caregivers may err.

(D) Creating trust between the therapist and the system—Despite the conflicts related to reporting, we assume that every caregiver prefers to be a part of a system that does not sweep errors under the rug but rather addresses them to prevent their recurrence. An effective reporting system gives the caregiver a sense of trust in the system.

(E) Professional feedback—In some cases, a caregiver error stems from a lack of knowledge, unfamiliarity with the procedures, or poor judgment. In these cases, there is room for conducting a professional dialog with the aim of examining the various alternatives that were available, evaluating each of them, determining the correct choice, etc. When a caregiver is involved in an adverse event, he naturally has a greater openness to learning at that point. Proper use of this learning opportunity may be of great value for the continuation of the caregiver's career.

(F) An operative solution for the caregiver in distress—Caregivers who are in distress following involvement in an adverse event can be given practical advice on how to behave toward the patient and his family and how to behave according to the organization's regulations and obligations toward the regulator (MOH).

11.2.3 Advantages of the Organization

(A) Organizational learning—This is a very popular term among organizations whose purpose is to create cultural and technological conditions where the knowledge of an individual in the organization will be available to all the employees of the organization. A medical organization that implements an effective reporting system contributes to the implementation of organizational learning.

(B) Creating a cross-organizational dialog—A reporting system may serve as a bridge between the various parts of the organization, including the individual caregiver, the clinic manager, the district manager, professional managers, and professionals at the headquarters. We have seen quite a few cases of an extensive organizational dynamic being created around a single adverse event aimed at preventing its recurrence. This is especially true in safety investigations based on the reports of representatives from different sectors in the organization.

(C) Improving the public image of the organization and increasing trust between the patients and the organization—An organization that deals openly and transparently with adverse events is seen by patients as more reliable than other organizations. In a competitive health market, trust and a positive image have great value.

(D) Lowering the scope of claims and the amount of compensation paid to injured patients—It is reasonable to assume that systematic identification and the control of risk factors reduce the probability of caregivers' errors, although we did not find research evidence supporting this argument.
(E) Seismograph—The reporting of adverse events may be used as an organizational seismograph to detect administrative problems and problems in medical processes. The reporting system can also be used to evaluate the success of prevention activities.
(F) Accreditation—Compliance with the accreditation standards for medical institutions, such as those issued by the JCI [12], for example, APR 9, which states that "any member of the hospital's medical staff (clinical or administrative) can report to the JCI about risks to patient safety and the quality of care without any retaliatory action from the hospital. To support safety culture, the hospital must state to staff that such reporting is desirable. In addition, the hospital must make it clear to staff that they will not take formal disciplinary actions (for example, demotions, transfers, or changes in work conditions or working hours) or informal punitive actions (for example, harassment, isolation or abuse) in retaliation for reporting safety issues."

11.2.4 Benefits for the Patient

(A) Improving patient safety—It is likely that systematic and continuous processes of learning following adverse events and systemic recommendations to prevent their recurrence affect the quality of medical care and patient safety (see case description in Chap. 9).
(B) Improving trust between the patient and the medical system—Some argue, after analyzing a series of factors [13], that most Americans do not trust their healthcare system. A patient who is convinced that the medical system treating him learns from its errors will have more trust in that system. Trust is related to compliance with medical treatment (see Chap. 10 for discussion on factors affecting the cooperation of patients with caregivers).

Patients often refuse to follow the doctor's instructions due to a lack of trust in the doctor. This phenomenon has consequences for the health condition of the patients and ultimately for their treatment costs.

11.2.5 Principles in Establishing a Reporting System for Adverse Events

Studies conducted in the United States have shown that the immediate reporting of adverse events by the doctors involved can be used for the early detection of future medical malpractice claims and for creating a knowledge base for improving the quality of medical care [10]. A study examining the hypothesis that the immediate reporting of adverse events may improve the management of claims, and its results confirmed that immediate reporting reduces the time needed to handle claims and their costs. Estimates regarding the extent of reporting by doctors before claims arise showed a reporting rate of 5–30% in the United States and 2% in the United Kingdom [14].

There are three alternatives for establishing a database on adverse events in a health system:

1. A systematic review of medical records to detect adverse events. In this approach, there is no need to wait for caregivers to report their errors, and patient files are proactively reviewed to identify adverse events. The main disadvantage of this method relates to its implementation. The amount of information that needs to be scanned to identify adverse

events in a medical organization can be enormous, and the review needs to be done by experts. Therefore, there does not seem to be a practical way to implement this solution. This method has been shown to be useful for research purposes but not for routine application [15]. Therefore, we must refer to modern AI technology, which will most likely replace the "expert eye" and enable the scanning of a large amount of data to proactively identify risks to patient safety and the risk of adverse events.

2. An initiated risk survey in a medical environment in order to identify risks before they materialize as adverse events. This option is particularly common in quality control activities but is still not common in the world of medicine. We expanded on this topic in the section dealing with proactive tools.
3. A safety culture in which doctors and other medical personnel report adverse events immediately after they occur out of awareness of the importance of reporting. The reports are classified and investigated by a dedicated professional unit. This option is the most common in health systems that promote a safety culture utilizing risk management methodologies.

An essential condition for the establishment of efficient error reporting systems for medical teams is the adoption of the "no name, no blame, no shame" approach.

The characteristics of an effective medical error reporting system are shown in Table 11.3. The characteristics presented in the table may also be used as a tool for evaluating existing systems for reporting adverse events in medicine.

Table 11.3 Characteristics of an effective medical adverse event reporting system (based on [6])

Characteristics	Description
Non-punitive	Those who report are freed from fear of punishment
Grants immunity	The identity of the reporter, the patient, and the institution are never disclosed to a third party
Independent	The program does not depend on any agency that has the authority to punish the reporter or the medical institution
Offers professional analysis	The reports are analyzed by experts who understand the clinical circumstances and are trained to identify the root causes of the adverse event
Timely	The reports are analyzed immediately, and the recommendations are quickly distributed to the relevant parties, especially when serious risk factors are identified
Follows a systemic approach	Recommendations are aimed at improving the system, work processes, or equipment
Responsive	The agency that receives the reports and disseminates recommendations, and the participating organizations agree to implement recommendations whenever possible

11.2.6 Why Should a Caregiver Report? Direct and Indirect Benefits

In a study conducted in Great Britain in which clinicians and risk management experts were interviewed regarding the attitude of doctors toward reporting adverse events, the complexity of the issue was revealed. A quote from one of the

interviews demonstrates this [16]: "I think we need to address fears and say why people don't do these things. I'm sure some people don't do it for fear of losing their jobs, or of being criticized in the press. It is possible that instead of focusing on the 'employee of the month', the CEO will praise 'the risk taker of the month', and his name will be published throughout the organization. They will not lose their jobs, but they may lose their good name with their colleagues. I think it is necessary to address these problems, and instill confidence by saying that we all make errors, no one is perfect."

The code of ethics of the American Medical Association [17] states that "Sometimes situations occur in which the patient suffers from significant medical complications that may have resulted from the mistakes or discretion of the doctors. In these situations, the doctor is ethically required to inform the patient of all the necessary facts to ensure understanding of what happened."

The ethical code of the Israeli Medical Association (IMA) Bureau of Ethics expands the ethical obligations to include informing not only the patient but also the authorized parties, while guaranteeing that the report will be confidential and will not be used against the doctor: "The doctor will report to the appropriate professional body about errors that occurred in the medical treatment. Confidentiality will apply to the report, and this information will not be misused against the reporting doctor or against a medical staff member who made a mistake."

Understanding the factors that motivate caregivers to report adverse events or those that may prevent them from reporting an error is a central challenge in any risk management activity. A risk management and patient safety system cannot exist without medical teams reporting their errors, which, as previously mentioned, is the basis for all reactive and proactive activity in both the short term and long term. The motivation to report adverse events can be internal or external, i.e., based on regulatory obligations or the institution's safety culture. In most institutions and organizations where there is a risk management activity, issues related to nursing were the first to be dealt with [18], while the coping with adverse events of doctors started only at later stages, if at all. Thus, the agenda of risk managers has traditionally been set by incidents reported by nurses rather than by physicians. We believe that this matter should be addressed in order to understand the motivation of doctors to report or avoid reporting their errors.

The primary role of doctors is to make medical decisions [19]. A meeting between a doctor and a patient held in the subjective, objective assessment plan (SOAP) format is a classic decision-making example. The doctor listens to the patient's complaints (subjective), examines him and his medical records (objective), analyzes the data, and makes an assessment according to which he decides on the treatment plan.

In the decision-making process in most cases, there is no single solution. Determining the adequacy of the decision is usually done according to the decision's reasonableness. Therefore, in many cases when an error occurs, the doctor is not always aware of it, except in cases where the decision has very harmful consequences in the immediate or long term for the patient's health. Even in such a case, it is very difficult or even impossible to point to a causal relationship between the information that was available to the doctor at the time of the decision and the decision he made. On the other hand, nurses must follow the doctors' instructions and give them feedback on the results of the treatment and the patient's condition, so it is possible to check whether the nurses followed the instructions. For example, if the doctor's order was to inject the patient with a certain drug in a certain dose, it is easy to determine if the nurse carried out the order precisely.

In most cases, doctors' errors are therefore the result of doctor–patient communication, while nurses' mistakes are errors of execution. In addition, it is easier to detect errors made by nurses than those made by doctors since nurses must accurately document their work in the patient's medical file. This documentation makes it difficult to cover up errors and continue the routine. These may be some of the reasons why risk management systems have had a much easier time starting with nursing errors. The

reporting rate of doctors regarding their own errors in "near-miss" cases is very low—only a few percentage points. We believe, however, that all medical staff members want to comply with the order primum non nocere—not to err and not to harm their patients—and if an error occurs, they would prefer to learn lessons from it to prevent the recurrence of similar errors in the future.

Studies of physicians reporting clinical errors show many barriers to reporting, including fear, shame, distrust of the system, a lack of time, arrogance, and individualism [16, 20]. Thus, physicians seem to be in a deep dilemma regarding reporting adverse events: On the one hand, they recognize the value of reporting as a basis for improving the quality and safety of medical care, and on the other hand, they avoid reporting for the following reasons:

- Fear of ruining their professional reputation—The medical community is a relatively small and intimate community where intensive professional relationships exist. The reputation of a doctor is a significant asset for him both in relation to his patients and in relation to his colleagues. Doctors fear that reporting incidents could damage their reputation. Because the organizational culture of most healthcare organizations does not sufficiently emphasize the distinction between blame and learning from errors, the reporting physician may be portrayed as a Don Quixote fighting the medical establishment's windmills.
- Fear of lawsuits—The issue of legal immunity for doctors who report their errors remains unresolved. In most cases, doctors do not feel confident that they will not be sued after reporting an adverse event. There are creative solutions to this problem, including guarantees from the insurer that his relationship with the doctor can be considered an attorney-client relationship or activity under the secrecy of a control and quality committee [1]. However, these are interim solutions and not complete solutions such as in the "Pilot Law" [21], which grants confidentiality to those who report on flight incidents.
- Fear of being the "village fool"—Since doctors are expected to perform their work without errors, and the tolerance of managers and senior doctors for errors is low, young doctors make every effort to avoid mistakes. The image of a good doctor is of a doctor who does not err and not of a doctor who learns from errors. This is perhaps why the title of the first report of the US Institute of Medicine (IOM) is "To err is human" [9]. There is therefore a need to dismantle the idea that doctors do not make errors and that those who make mistakes cannot be good doctors. Breaking this paradigm is a necessary condition for creating the proper basis for improving the quality of care and patient safety. In the health systems that exist today, a doctor who still reports his mistakes voluntarily without the threat of legal action against him may see himself as the "village fool."

It therefore seems that without significant changes in organizational and professional culture, it is unreasonable to expect an increase in the reporting of errors, especially among doctors.

11.3 Safety Investigations of and Lessons Learned from Adverse Events

The most common reactive risk management activity is conducting a safety investigation for the purpose of learning lessons to prevent the recurrence of similar events in the future. The investigation is intended to promote organizational learning in order to produce systemic lessons through a systematic methodology for identifying factors that may endanger patient safety and providing recommendations that have the potential to reduce the exposure to these risks and their outcomes.

The investigations are conducted in different ways and with different tools. The most common method used in medicine is root cause analysis (RCA), which attempts to identify the root causes of an adverse event and define recommendations

for mitigating and controlling them so that they do not pose a risk in the future. Although there are quite a few professional publications on how to carry out such investigations in the most efficient way, the question of the effectiveness of the investigation remains open.

11.3.1 Types of Investigations and Their Characteristics

Table 11.4 presents three types of investigations: administrative investigation, legal investigation, and safety investigation. It is important to be familiar with the differences among these types of investigations, as there is often confusion among them. Comparisons among the types of investigations are intended to direct the focus of risk managers to the safety investigation, its goals, and results. In Israel, the safety investigations are not confidential, and information that is part of the investigation report can be used as evidence in a legal proceeding (see more on this issue in Chap. 8, in the discussion on the confidentiality of investigations and the minutes of an inspection committee's deliberations).

Below are definitions of the basic concepts mentioned in the above table, which are common in investigative activity:

- Adverse Event: an unexpected and unwanted event before, during, or after the medical process that caused (physical or mental) harm to the patient or could have caused (physical or mental) harm to the patient.
- Investigation: a systematic process of extracting lessons from an adverse event that makes use of accepted models, analyzes information, defines findings, formulates conclusions, and recommends activities with the potential of reducing the risks exposed in the investigation. The investigation does not determine those responsible for the occurrence or assess their part in the responsibility for its occurrence.
- Investigative questions: questions defined by the function authorized to appoint an investigative team whose purpose is to focus the learning process on key issues that were expressed in the adverse event.
- Event boundaries: the delimitation of the event in terms of time, from the starting point

Table 11.4 Types of investigations and their characteristics

Type Characteristics	Administrative	Safety	Legal
What is the purpose?	To derive lessons learned concerning the unit's functioning in which the adverse event occurred in order to prevent recurrence	To define recommendations with to goal of preventing the recurrence of similar adverse events based on the identification of root causes	To find valid evidence that can be used in the legal process
Who performs the investigation?	The unit's manager or someone appointed by him	A professional team trained and specializing in safety investigation processes	An attorney, with the assistance of advisors who provide professional opinions
What is the process?	Interviewing the involved employees and determining their degree of accountability. The process is not professional, documented, or methodological	Identifying root causes utilizing a proven methodology and models, interviews, reconstructions of the occurrence, means of determining the factual data, and more. The investigation is documented in a standard formal document	Collecting factual data and interpreting it from a legal point of view in order to support the prosecutor's side or the defendant's side
What are the intended outcomes?	Personal changes and modifications in working processes	Systemic changes related to the root causes	Decision of the court of law if there was a case of medical malpractice

of the event (trigger) until the end of its occurrence, with reference, if necessary, to the results of the event.
- The results of the event: the damages caused or potentially caused to the patient, the caregivers, the staff, and the organization by the incident. The results of the event must refer to the patient's health condition, image damage to the caregivers, and financial and image damage to the organization.
- Finding: an event, a step in the process, or a fact directly or indirectly related to the process that led to the occurrence of the adverse event. The findings result from the analysis of the information collected during the investigation and reflect the meaning that the investigation team attributes to the information collected.
- Professional supervisor for the investigation: a risk manager with at least 3 years of experience in risk management in the healthcare system who has undergone appropriate training for risk managers in medicine, has independently carried out at least ten investigations, and has been authorized to do so by the director of the medical institution.
- Conclusion: overall determination of the investigation team regarding the factors that led to the occurrence of the event and the factors that contributed to its occurrence. It should be noted that a conclusion refers to causal factors in that particular event and not what needs to be done to prevent the reoccurrence of the event in the future (which is what the recommendation deals with). Conclusions may be divided into two categories: casual factors and contributing factors.
- Recommendation: one concrete action that, if implemented, has the potential to reduce a specified risk found to be a factor in the event. For each recommendation, a person responsible for its implementation and a timetable for implementation are defined.
- Task: a recommendation approved for implementation by the director of the medical institution and scheduled in the organization's work plans.

11.3.2 Criteria for Selecting an Adverse Event for Investigation

Due to a lack of resources, it is not possible to investigate all reported adverse events. Therefore, it is important to choose the right events in order to derive the maximum benefit from the process. As indicated above, given the limited staffing of risk management and patient safety units, even an investigation of 1% of the reported incidents is a complex task, hence the great importance of making the right choice. Sometimes the basic managerial instinct guides the managers of a medical institution to investigate events with serious harm, although in quite a few cases, the benefit of investigating "near-miss" events may be greater. This is because it is likely that the openness of the medical teams and the desire to cooperate with investigation teams is greater in such cases than in events in which serious harm has been caused and the sword of prosecution hovers over them.

To choose the most suitable events for a safety investigation, it is recommended that the following criteria be considered:

- An adverse event that represents a systemic problem or an accumulation of events of the same type in a relatively short period of time in a department or institution.
- The severity and frequency values of the risk exposed in event, i.e., a risk index (RI) higher than 9 or harm severity equal to/higher than 4.
- A directive from the director of the medical institution or a recommendation from a senior manager in the institution.
- An adverse event that occurred in a new process or while using a new device/medicine.

It is recommended not to investigate events that are under review by the Ministry of Health or in open legal proceedings due to the lack of legal confidentiality involved. It is also important that each medical institution determines the minimum number of safety investigations to be carried out per year and defines completing these investigations as a goal in its annual risk management plan.

11.3.3 Decision to Carry Out an Investigation

Since the process of a safety investigation requires interviewing those involved in the incident, collecting all the relevant data and analyzing it, and examining the work processes in the organization, activities that require a considerable investment of professional resources, and additional investment to implement the recommendations, the decision to conduct an investigation for a specific adverse event must be approved by the senior management of the organization. A recommendation to conduct a safety investigation will therefore be given by the following authorities:

- The manager of the risk management and patient safety unit
- The director or senior manager of the organization
- Regional/branch risk manager

The recommendation will be accompanied by a rationale for why the safety investigation is necessary, and it will only be carried out with the approval of the organization's risk and patient safety manager.

11.3.4 Appointment of the Safety Investigation Team

The safety investigation team must include a representative mix of professionals. The following professionals should compose at least part of the team:

- An employee authorized by the organization's manager to conduct safety investigations
- A professional supervisor for the investigation
- A subject matter expert in the professional field in which the event occurred

Since an investigation cannot be objective, in order to create as balanced a picture as possible regarding the circumstances of the event—what happened? How did it happen? Why did it happen? What can be done to prevent its recurrence?—it is important that the investigation be carried out with the cooperation of at least two team members. A dialog between team members that reflects different professional and personal aspects while reaching an agreement may create a balanced picture in response to the investigative questions.

11.3.5 Steps in a Safety Investigation

Safety investigations involve a series of actions that are usually performed one after the other, although sometimes the process requires a return to previous stages in light of new information exposed during it. For example, it may turn out that the adverse event that was reported is actually not the event that is important to investigate, which is instead another occurrence that is exposed during the investigation. Changing the investigated event requires a renewed preparation and updating of the boundaries of the incident and the investigative questions. Table 11.5 lists 13 stages of conducting a safety investigation, starting with the definition of the adverse event, including defining the conclusions and recommendations, and ending with the monitoring of their implementation.

Although a safety investigation is an accepted practice after the occurrence of an adverse event in a medical institution, quite a few problems are associated with proving its effectiveness [3]. Major issues concerning the RCA process and its outcomes are presented in Table 11.6, based on Gupta and Lyndon [22] and Peeraly, etc. [23]. Among them, the professional level of safety investigations, "political" biases and pressures, poor definition of recommendations, and a lack of monitoring of their implementation should be noted.

Despite the intense engagement in safety investigation of adverse events in medicine as a method for systemic learning, which appears to have the potential to reduce the risks to patient safety and the recurrence of adverse events, there is almost no empirical evidence of its effective-

Table 11.5 Steps of the safety investigation process

No.	Step	Description	Responsibility
1	Defining the adverse event	(A) After an initial examination of the report, a decision is made as to what adverse occurrence is to be investigated in order to draw lessons to prevent the recurrence of similar events in the future	Patient safety and risk management unit manager
		(B) Some adverse event reports may include more than one singular adverse occurrence. The patient safety and risk management unit manager decides which of them to focus on to gain the most benefit in terms of promoting patient safety	
2	Defining the boundaries of the event	(A) A decision by the investigation team, in cooperation with and at the discretion of the authority that appointed the team, regarding which stages of the event to start and finish collecting information about	Investigation team
		(B) The decision on the boundaries of the adverse event affects the scope of resources required to complete the investigation	
3	Defining the investigation questions	(A) General questions:	Patient safety and risk management unit manager and the investigation team
		Each investigation has four general questions to address:	
		• What happened? (at the descriptive level)	
		• How did it happen? (the process by which the event occurred)	
		• Why did this happen? (the causal factors responsible for the occurrence)	
		• What should be done to prevent the recurrence of similar events in the future? (systemic recommendations)	
		(B) Specific questions:	
		• The formulation of specific questions is intended to help the investigation team focus on addressing the risks that arise from the defined adverse event	
		• The questions refer to the facts and factors that led to the occurrence of the event	
		(C) The investigation questions should refer to the defined event within the boundaries of the event	
		(D) During the appointment of the investigation team, based on existing information from the report form, details from management, clarifying conversations, initially gathered information, etc., in-depth questions are formulated with the aim of validating the known, clarifying the unknown, and trying to describe the causation process of the event	
4	Planning the investigation	(A) The purposes of planning the investigation are as follows:	Patient safety and risk management unit manager and the investigation team
		• To define the actions to be performed and the information to be collected and studied in order to answer the investigation questions	
		• To define the order of activities based on the logic of collecting information from the bottom up and validating it from different sources	
		• To define the validation of the information from various sources	
		• To address the constraints of employee availability, information availability, and the time limits of the investigation team	
		• To define timetables for submitting the investigation report, including findings, conclusions, and recommendations	
		(B) The investigation plan is updated from time to time according to developments based on the collected information	

(continued)

Table 11.5 (continued)

No.	Step	Description	Responsibility
5	Collecting data	(A) Possible sources for information collection relevant to the investigation are as follows:	Investigation team
		• Data on the professional background of those involved in the event (general experience, experience in the procedure, history of adverse events)	
		• Interviews with those directly and indirectly involved in the event	
		• Interviews with managers	
		• Reviews of medical records	
		• Reviews of medical documents related to the event	
		• Reviews of the incident process documentation in the computer system and/or the quality management system	
		• Observation of the process by which the adverse event occurred	
		• A study of relevant procedures of the organization	
		• A study of the relevant procedures of the Ministry of Health	
		• A review of relevant professional literature	
		• Consultation with parties in parallel systems and/or with experts	
		• A review of adverse event reports in order to study similar events	
6	Analyzing the collected data	(A) The analysis of the collected information can be performed using different models. It is recommended to use the 5M model, which refers to failures, gaps, and shortcomings in five types of factors, man, machine, mission, management, and medium and in the interactions among the various factors	Investigation team
		(B) Classification of failures in the 5 M model	
		(C) If using the Swiss cheese model (SCM), failures are classified into two categories of causal factors:	
		• AF—active failure, or the actions of caregivers/employees directly involved in the incident (errors, violations, and disruptions) that caused the incident to occur	
		• LC—latent conditions, or chronic conditions in the system that allow caregivers/employees to make errors, violate instructions, or fail to perform their work	
		Note: In the systemic concept of risk management, emphasis is placed on dealing with systemic factors based on the understanding that the essential impact on risks occurs by controlling and mitigating latent conditions rather than the active factors	
		(D) From the information collected, the investigation team defines the failures that directly and indirectly contributed to the occurrence of the adverse event	

Table 11.5 (continued)

No.	Step	Description	Responsibility
7	Defining the chronological continuum of the findings	(A) From the collected information, the sequence of findings must be defined: from the starting point (first finding—trigger) to the last finding (adverse event), so that each of the findings is a necessary causal finding for the occurrence of the adverse event	Investigation team
		(B) In the sequence of findings, there is a reference to three types of findings:	
		• Causal findings—those occurrences necessary to cause the event (without one or more of which, the event could not have occurred). Usually, causal findings are described in chronological order from earliest to latest	
		• Background findings—occurrences and facts that did not cause the adverse event but are relevant to understanding the circumstances in which the event occurred (age, sex, medical condition, mental condition, socioeconomic background, medical condition, relevant protocols and guidelines, etc.)	
		• Additional findings—findings that the investigator finds in the investigation process that are not directly related to the incident but pose a risk to patient safety; therefore, in the investigator's opinion, there is room to refer to them in the investigation report	
		(C) The sequence of findings usually includes approximately 7 ± 2 findings that, in the opinion of the investigation team, describe in the most exhaustive way possible the chain of occurrences that led to the incident. Each finding differs from the others in the time/place of its occurrence	
8	Defining conclusions	(A) The investigation team defines the following:	Investigation team
		• The direct causes of the adverse event: "The event was caused by…"	
		• The factors contributing to the occurrence of the adverse event: "The following factors contributed to the occurrence of the event…"	
		Remarks:	
		• The conclusions are based on the findings and express their significance while emphasizing the systemic aspects	
		• In cases where it is not possible, due to the lack of factual information, to determine what caused the incident, it is explicitly stated in the conclusions that the causes of the incident cannot be determined	
		• In cases where it is found during the investigation that one of those involved acted in a manner worthy of mention, this fact is noted in the conclusions	

(continued)

Table 11.5 (continued)

No.	Step	Description	Responsibility
9	Defining recommendations	(A) The investigation team defines recommendations for concrete actions that have the potential, if implemented, to reduce the probability of similar events occurring in the future or reduce their severity	Investigation team
		(B) The recommendations are directly related to the conclusions	
		(C) The recommendations are validated by content experts in order to examine their relevance and applicability	
		(D) Each recommendation is formulated in operative language: it begins with "To" and indicates the person in charge of its implementation and a deadline for the completion of the implementation	
10	Approving the recommendations and transforming them into tasks	(A) All the recommendations of the investigation together with the conclusions are presented to the authority that appointed the investigation team (the director of the organization) who has the authority to approve or reject them	Organization's management
		(B) Once a recommendation is approved, it becomes a task to be performed (assignment)	
		(C) Long-term tasks are included in the organization's work plans, and short-term tasks are carried out on an ongoing basis	
11	Compiling the investigation report	(A) After defining the tasks (assignments) to be performed, a summary report of the investigation* is written according to an approved template, which includes the following parts:	Investigation team
		• Information about the investigation process: investigation team, date of appointment, date of incident report, reporting party, information collected, meetings held, consultations, external information collected, date of presentation of the investigation's recommendations to management, and date of definition of assignments	
		• The title of the investigation includes the following elements: "Investigation of event XXXX/YY dated dd/mm/yy" and the subject of the investigation	
		• A description of the incident as drafted by the investigation team (and not as reported by the reporting party)	
		• The event boundaries	
		• The results of the event	
		• The investigative questions defined jointly with the organization's manager	
		• The chronological sequence of the findings, which are classified into background/causal/additional	
		• Conclusions	
		• Assignments	
		• Appendices	
		(B) On each of the investigation pages, "confidential, personal, for internal use of the organization only" is written at the top of the page _____	
		* A suggested format for writing an investigation report is presented in Appendix A, including references to common errors in writing the report	

Table 11.5 (continued)

No.	Step	Description	Responsibility
12	Distributing the investigation report summary to relevant parties	(A) A summary of the investigation is distributed to senior managers in the organization	Patient safety and risk management unit manager
		(B) A summary of the investigation report, omitting the identifying details of the staff involved, the exact date of the event, the involved caregiver's personal details, etc., is distributed as an instructive case to all employees in the organization	
13	Recommendations completion follow-up	(A) After the investigation summary report is distributed, the patient safety and risk management unit manager ensures that each of the parties in charge of implementing the recommendations has received the report	Patient safety and risk management unit manager
		(B) Each of the parties who received a recommendation for implementation confirms to the patient safety and risk management unit manager that he received the recommendation and understood it and details the operative steps he intends to take	
		(C) Patient safety and risk management unit manager addresses the above response with approval or comments	
		(D) Once a quarter, a recommendation implementation report is produced detailing all the recommendations from adverse events investigations that have been distributed for implementation and their implementation status. The report is presented as part of a quarterly meeting of managers dedicated to the issue of patient safety.	

Table 11.6 Problems with root cause analysis in medicine

No.	Problem	Description
1	Meaning of "root cause analysis"	Promotes linear thinking toward a single root cause when most adverse events are complex and have multiple interacting parts and potential intervention points. This is an archaic concept that does not fit the current reality of interrelated systems with many interfaces, many involved parties, and teamwork
2	Quality of the process	In many cases, it is unclear what training was provided to the investigation teams before being appointed to carry out an investigation. Knowledge gaps are especially notable in human factors issues, RCA methodology, methods for dealing with biases, and recommendation definition. In addition, there are problems with cover up and not providing critical and relevant data for the investigation; patients and families often are not included in the investigative process
3	Politicization of the process	Investigations are usually conducted under significant time pressure and by teams from the organization where the event occurred; they may also suffer from a lack of independence from the organization and are subject to hindsight bias. These factors may significantly limit the ability of the team to address managerial and systemic issues and may be directed toward personal rather than systemic conclusions
4	Poor quality of recommendations and solutions	There is a tendency to focus on weak solutions such as reminders, education, and training rather than stronger solutions addressing flawed technology or flawed systems design, a lack of evidence for the effectiveness of solutions, or insufficient follow-up on the implementation of solutions

Table 11.6 (continued)

No.	Problem	Description
5	Partial and limited feedback that does not support organizational learning	In many cases, the conclusions and recommendations of RCA are not distributed widely and do not support organizational learning. In addition, professional feedback for involved staff members is rarely provided in an appropriate manner
6	Lack of generalization from the sole event into a general phenomenon	Incidents tend to be investigated in isolation—as single events within single institutions. This limits the opportunity for understanding recurrence vulnerability and may lead to focusing resources on preventing very rare events over solving broader systems issues that have greater potential to prevent harm. Systematic ways of aggregating root causes are lacking
7	Confusion about responsibility	The balance between individual and organizational responsibility is complex. While most accidents are the result of system defects, malpractice is also a serious problem that needs to be addressed. Taking an overly algorithmic approach to "just culture" can obscure complicated relationships among individual actions and organizational defects and produce a risky bias of blaming only the system
8	Problem of "many hands"	Normally, many parties from the organization and from outside are involved in an investigation. This may be positive, as many different points of view can contribute to a better understanding of what went wrong. On the other hand, a dispute may arise as to conclusions and recommendations. Typically, RCA teams focus on solutions that are within the internal control of the organization and do not assign responsibility to or make recommendations about broader problems outside of their control (e.g., equipment design, medication labeling, or the MOH's policy and regulations)

ness. However, several works have examined an subject on the individual level. In a study on children, it was found that children who reflect on their mistakes (post-failure reflectivity), a reaction called "attention to errors," later perform better in general in cognitive tasks, in contrast to those who react impulsively to their failures [24]. It can be concluded from this that reflective behavior, the main purpose of which is to understand how the failure happened (investigation), leads to improved performance in the future.

The concept of two main types of responses to errors and failures was first formulated by Jerome Kagan from Harvard University [25], and it can serve as a basis for distinguishing between two types of organizations: those that react reflectively out of an interest in understanding how the failure happened in order to make corrections for the future and those that react impulsively, thinking that it is more important to move on than to stop and learn the lessons from a failure. In 2015, the National Patient Safety Foundation (NPSF), an independent US nonprofit organization, published a document created by experts in the field of risk management and patient safety designed to improve the process and effectiveness of RCA. Among other things, this expert committee proposed changing the name of the process from RCA to RCA2, or root cause analysis and action, with the intention of emphasizing the importance of formulating recommendations and their implementation as a measure of the effectiveness of the investigation. The document was intended to ensure that the efforts made within the framework of safety investigations of adverse events in medical organizations will expose the risks and define stable systemic improvements that will make the treatment safer. The first goal set by the committee was to find methodologies and tools that would make the investigation more efficient and effective, and the second goal was to provide tools for

Table 11.7 Ten recommendations for improving root cause analysis and action (RCA2) in medicine (based on [26])

No.	Recommendation	Description
1.	Increase leadership involvement	The organization's managers should be more actively involved in safety investigation: they should understand the process, support it, provide the necessary resources for it, review its outcomes, and monitor the implementation of the resulting recommendations
2	Review effectiveness	Managers should address the issue of safety investigation effectiveness at least once a year
3	Exclude malpractice cases	Malpractice cases should not undergo a safety investigation process, and a list of such cases must be defined
4	Implement a transparent prioritization system for selecting events for safety investigations	The organization should develop and implement a formal and transparent system for selecting adverse events, near misses, and systemic failures for safety investigations
5	Minimize time between the reporting of the event and the start of the investigation	The RCA2 process should start within 72 h after the occurrence of the adverse event
6	Adjust the composition of the investigation team	RCA2 teams should be composed of four to six people. The team should include process experts, managers, and employees from various organizational levels and experts in the RCA2 process. The inclusion of a patient representative unrelated to the event should be considered. Individuals who were involved in the event should be excluded due to conflicts of interest, but they should be interviewed as part of the RCA2 process
7	Adjust the time allocation for the RCA2 process	Managers should provide the team members and other relevant employees with time, during their normal work shift, to participate in RCA2 activities
8	Use proven tools, models, and methodologies	The RCA2 team should implement proven methodologies and models (e.g., the 5M model, Swiss Cheese Model, Domino model, and five rules of causation) to be able to reconstruct the causation process and define proper conclusions and recommendations
9	Define strong, operative, and feasible recommendations	The RCA2 process should end with a formal process for defining and implementing recommendations based on the findings and conclusions of the investigation while proactively checking the feasibility of each of the recommendations within the organizational framework (see paragraphs 9–10, in Table 11.5 in this chapter)
10	Provide feedback	Based on the investigation's findings and conclusions feedback should be provided to the involved staff and patients or their families

evaluating the investigations to identify failures in order to correct them and turn them into a more effective tool for improving safety [26].

The committee published recommendations for a substantial improvement in the efficiency and effectiveness of investigations are detailed in Table 11.7 (RCA2 [Root Cause Analysis and Action]).

The above recommendations relate to increased management involvement in the investigation processes, clear definitions of which incidents are investigated and which are not, investigations commencing as close as possible to the time of the incident, the time and personnel training needed to conduct investigations, the use of appropriate methodology and tools, and the closure of the circle by providing feedback to the staff, the patients, and their families.

11.4 Introduction to Interactive Risk Management Activities

Interactive processes occur when it is possible to intervene during the event and change its outcomes. This usually happens in the department or

unit where the incident occurred and where, in addition to providing medical treatment aimed to correct the error, failure, or damage caused, there is also a direct and effective reference to risk management. This attitude, and the activity that follows it, can completely change the results of the incident, benefiting the victim and the involved staff (the "second victim"), preventing uncertainty, feelings of fear and revenge, mistrust, and even lawsuits [27].

The risk manager's role is to back up and support the involved staff, which includes reporting to the injured patient and his family, managing internal and external communications, providing administrative support in optimizing patient care (e.g., the evacuation of an operating room for a patient who is clinically deteriorating or requires urgent intervention following treatment failure) and supporting the staff who caused the failure (the second victim). Interactive risk management therefore includes the following:

- Helping manage adverse events as they occur
- Assessing the patient's condition during and after the incident and taking all the measures available to the medical institution with the goal of improving the condition of the patient and his family members
- Providing instructions on how to behave in front of the media
- Drawing immediate lessons to prevent the recurrence of similar events in the institution and similar institutions
- Disseminating the immediate lessons and assimilating recommendations and insights in a variety of ways, such as safety newsletters, training sessions, team meetings, and conferences
- Reporting to relevant parties inside and outside the institution, e.g., the insurer, the Ministry of Health, and drug and medical equipment manufacturers
- Providing professional and personal support for the staff members involved in the incident (the second victim)

11.4.1 Support for Caregivers Involved in Adverse Events (The Second Victim)

Medical staff members, who cause an error or failure in treatment and harm the patient, experience feelings of fear and guilt—fear for their reputation, fear of being fired or losing their license to practice their profession, a lack of clarity regarding their professional future, and, of course, fear for the health of the patient they harmed. To all of these is added shame, which is sometimes expressed in the denial of responsibility for the incident and the search for explanations for the damage caused. Some adopt a defensive approach to their medical practice and avoid treating patients in general and complex patients in particular [28]. Such an approach causes distrust from the patient and his family and intensifies anger at the unwanted results of treatment.

The term "the second victim" was coined two decades ago and refers to a staff member who has harmed a patient and now bears the burden of guilt, fear, and shame. In most cases, the caregiver is alone in dealing with his conscience and the ethical principles of his profession, in addition to fearing that he will lose the respect and recognition of his colleagues in the profession. His self-confidence is shaken. All these affect the continuation of his career [27]. Therefore, the concept of the second victim currently occupies an important place in the actions of the health system following an adverse event. The proclamation by the American Institute of Medicine in 1999 that to err is human dramatically changed the attitude toward failures on the part of doctors, nurses, and members of the medical team [9]. Instead of looking for culprits, efforts are now aimed at understanding the failure and its causes by conducting root cause analysis and investing in organizational, systemic, and operational factors that can limit the possibility of a similar failure in the future [29].

In addition, in most medical institutions, teams have been established whose role is to

support the "second victim," to encourage him, and to prevent severe effects that could cause him to leave the profession. These teams usually include a psychologist, a social worker, and an experienced senior doctor or nurse. Mental support and empathy help this second victim return to normal and understand that the adverse event can be leveraged for systemic learning, improving the system, and preventing similar failures in the future [30].

Approximately 30 states in the United States have formulated apology laws according to which doctors can (and should) apologize to patients who have been harmed during medical treatment without the apology standing against them in a court case or being proof of their guilt [27, 31, 32]. When the medical system stands by the rights of the second victim and supports him, his ability to recover and regain faith in himself and function optimally is rehabilitated, and this is of great importance to the medical institution and the entire system, which is often facing a lack of resources and personnel. In addition, when the doctor feels that the management of the medical institution stands behind him and that he is unlikely to be harmed himself, his ability to continue treating patients in an efficient and optimal manner is not impaired, and the feeling of being disconnected from the victim and his family is minimized or eliminated. When the injured patient receives a true and exhaustive explanation of the failure, including information on why and how it happened, what can and will be done to minimize the damage, and what will be done systematically to prevent a similar failure in the future, the chance of a lawsuit decreases [32, 33].

The probability that a staff member, the potential "second victim," will be involved in an adverse event or medical error is estimated at 50–10% of cases. Almost half of all medical staff will experience this at least once during their career. Failure to respond to these unique needs of the second victim may leave him with a lasting emotional scar, and sometimes, he may decide to retire early from the profession. Studies show that second victims express a need for key messages from their superiors after a traumatic clinical event. Among others, the need to hear from their supervisors that they continue to believe in the caregivers' professional abilities, that they trust them, and that the clinical team values them was reported. It has also been found that the involved staff member should be informed about the procedures of a formal investigation of the incident and obtain an explanation of the process [11].

The recommendations for the second victim support program include four levels of intervention:

(a) Assessing the condition of the therapist involved in the incident and defining the recommended treatment method
(b) Providing local support (department/unit)
(c) Providing support from colleagues trained in the subject (a dedicated task force) and using the unit's resources for quality, patient safety, and risk management
(d) Referring the therapist to additional providers of professional support, such as a lawyer, a psychologist, or a religious leader

11.5 Disclosure of Medical Errors

The practice of properly and immediately disclosing errors and failures in medical care has been taking shape over the past two decades. When an error occurs in medical treatment, especially when a patient is harmed, the attending physician must disclose to the patient and his family as precisely as possible what went wrong and explain in detail and in language understandable to the victim what happened, what damage was caused, whether it can be repaired and all else that is implied from the incident. In regard to

serious damage, especially irreversible damage, monetary compensation must be offered in agreement and coordination with the insurance company. Such a policy can strengthen the trust of the patient and his family members, prevent lawsuits in most cases, and strengthen the involved staff and the victim [34].

Due diligence must be conducted with full transparency. The patient, his family, or his guardians must be presented with everything known to the involved caregiver in relation to the case—a complication that happened, an error or failure in diagnosis or treatment, what can be done to correct the error, what has already been done, and what will be done and when. The due diligence process will be led by a senior staff member with experience and knowledge in the process in order to gain the trust of the patient and his family. Other staff members involved in the case should be present during the procedure to learn from it and support their colleagues. Many institutions are currently holding workshops to learn how to enact due diligence, optimize the execution of the process, and prevent feelings of guilt and shame as much as possible. The adverse event must be documented in detail in the patient's medical file without attributing blame or responsibility to a particular staff member. The documentation should present an accurate medical picture that will allow the error to be corrected and the harm minimized. The possible results of the legal due diligence procedure should be discussed after consulting with the insurance company and legal counsel since, sometimes, due diligence can be used in a medical malpractice trial against the involved staff.

Full disclosure enables a quick return to safe and quality care, minimizes harm, and prevents the generation of rumors, mistrust, and the tendency to cut off contact with the victim and his family members and, in many cases, can spur forgiveness following an apology [11]. Only through full disclosure and an apology can the incident be investigated objectively, conclusions be drawn, and similar incidents be prevented from happening again.

11.6 Introduction to Proactive Risk Management Activities[1]

Proactive risk management includes surveys to identify risks in a specified activity or medical facility. The American Joint Commission International (JCI) has developed its version for conducting a risk survey, the FMEA [35], which applies the basic principles of a proactive risk survey.

Safety rounds are a common example of proactive activity that does not require as much resource investment as risk surveys. For them to be effective, it is important that the relevant managers participate in them, that they are based on standard processes and tools, and that they are routinely conducted at regular, specified intervals—such as once a year or every 2 years.

In addition to the activities mentioned above, the following activities can be considered proactive:

1. Formulating the organization's risk management and patient safety policy—The risk management and patient safety policy document is intended to define, for all employees in the organization, the importance and goals of activities to promote patient safety.
2. Defining an annual work plan for risk management and patient safety activities—The unit in charge of risk management and patient safety in a medical organization needs an annual work plan to ensure that it does not focus exclusively on reactive activity.
3. Providing training—Professional training is required to improve knowledge and skill and to reduce the probability of errors and failures; this should also include training for action in various emergency situations and

[1]Attributing importance to proactive risk management activities and recognizing that the resources invested in this type of activity are often minimal; in 2022, NASBAR [5] published two position papers on the subject: (1) Proactive Risk management and Patient Safety Activities and (2) Education and training of Patient Safety, 2022. Some of the ideas presented here are based on those position papers.

training based on lessons learned from adverse events. For patient safety training to be effective, it must be structured, delivered routinely, be adapted to different populations, and use a variety of means.

4. Establishing control and quality committees as defined in the 1996 Patient Rights Act [1]—These committees discuss phenomena (risks) and define intervention plans to reduce them. It is likely that the trigger in most cases for bringing up an issue in control and quality committees is a large number of adverse events in a certain process or the recurrence of events with serious damage.
5. Subscribing to professional liability insurance—Professional liability insurance is a form of proactive preparation by the organization for the occurrence of adverse events and a recognition of the need to pay compensation to patients who are harmed as a result of such events. Changes in the premium may focus the risk management activities on certain risks and thus reduce them (see more on this issue in Chap. 9).
6. Using predefined checklists for critical processes—As in other high-risk sectors, including aviation and nuclear power plants, using checklists significantly reduces errors in routine processes [36].
7. Integrating aspects of risk management into the operative activity—For example, this could include a timeout procedure before surgery [37].
8. Using trigger tools—These tools define clinical and administrative parameters that can indicate the existence of patient safety issues and define intervention plans to reduce such issues. For example, triggers can include the rate of cases in which the hospital stay was prolonged beyond the average, the rate of repeat operations, or equipment orders above the average level.
9. Conducting research—This involves carrying out research activity to understand the relationship between different variables and safety results. Examples include a relationship between the reporting of "near-misses" events and the extent of events with serious damage or a relationship between different dimensions of safety culture and safety outcomes.
10. Conducting projects aimed at reducing the exposure of patients, caregivers, and the organization to risks—The accepted methodology for carrying out projects of this type is plan–do–study–act (PDSA) [38], which is supported by the Ministry of Health. In this methodology, a factor that endangers patient safety is identified, an activity is planned to reduce it (P), the activity is implemented (D), research is conducted as to the extent to which the risk has indeed been reduced (S), and the necessary corrections and adjustments are made and implemented on an ongoing basis (A).
11. Using the measurement and evaluation of safety culture in health institutions—The results of this can be used as a lever for defining intervention plans to improve the safety culture in the institution (see Chaps. 4 and 12).

On a practical level, any proactive risk management activity is based on the following principal steps, presented in Fig. 11.1:

1. Defining critical processes from the point of view of patient safety, that is, processes in which the probability of errors occurring is high and/or errors have a serious effect on patient safety. The definition of critical processes can be based on the analysis of past event reports or on new processes with high-risk potential.
2. Detecting risks in critical processes, which is carried out using a wide variety of methods: analysis of the processes, observations, interviews with medical and administrative staff members involved in the processes, and analysis of medical records. The result obtained from this step is a list of risks of different levels of severity that may materialize and cause harm to patients, caregivers, and the organization.
3. Analyzing and assessing risk to help prioritize methods for coping with various risks in light

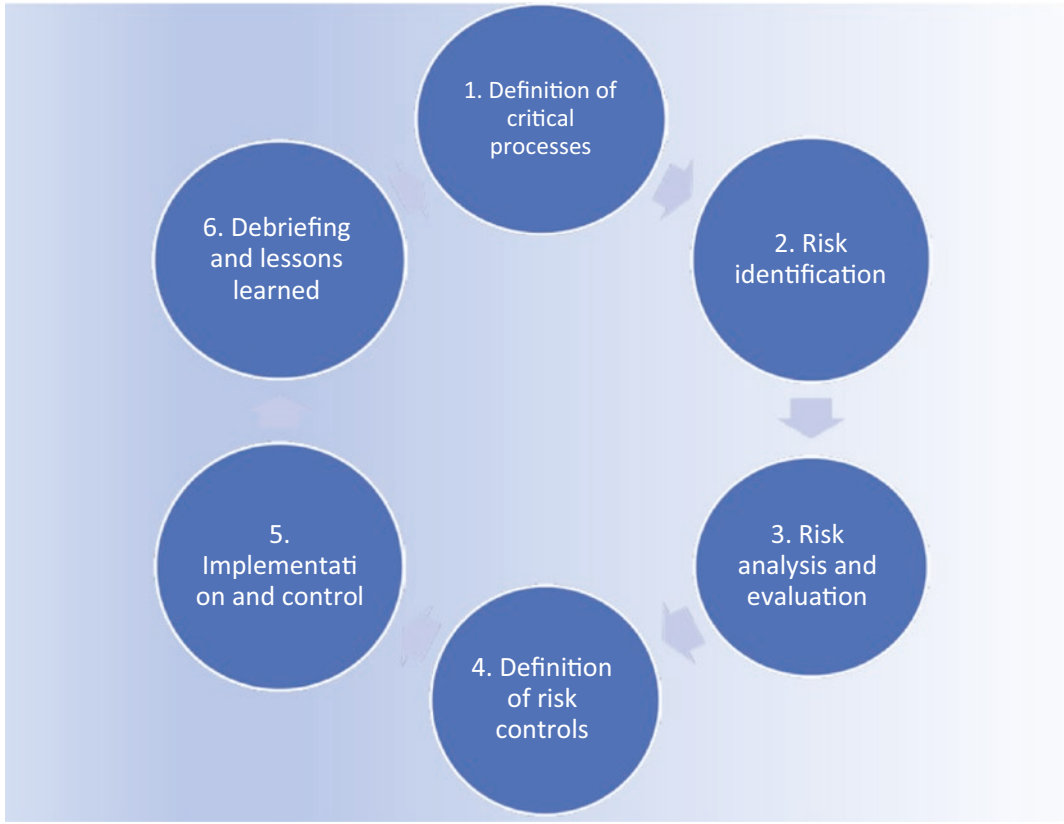

Fig. 11.1 Proactive risk management circle

of the assumption that it is not possible and may even be incorrect, to control all risks, so attention should be focused only on those whose damage potential is the highest. Risk assessment is performed using different methods. The most common method is assessing the probability of risk materialization on a scale of 1–5 (probability [*p*]) and assessing the potential damage that will be caused if the risk is materialized on a scale of 1–5 (severity [s]). The product of the two values obtained gives the risk index (risk index [RI]). The RI values form a matrix with a score range of 1–25. The higher the value is, the higher the risk and the higher priority given for its mitigation.

The risk assessment process is usually carried out by all the relevant partners in a meeting or through a dedicated assessment questionnaire.

The JCI FMEA [35] tool uses a 1–10 scale, and in addition to probability and severity, the detectability of the risk (detectability [d]) is also evaluated since risks that are difficult to detect are more dangerous than risks that are visible to the eye. The RI values are obtained by multiplying the severity, probability, and detectability of the risk.

4. Selecting risks whose RI values are the highest for further treatment. That is, controls, which are activities with the potential to reduce the risks, are defined. The implementation of the controls is intended to reduce the probability of the risk materializing and/or the severity of the damage that the risk can cause if realized. Several controls can be defined for each risk.
5. Implementing the defined controls and ensuring that they are implemented as decided.

6. Debriefing and drawing lessons. The questions asked at this stage are as follows: To what extent have the controls been implemented? To what extent did the controls reduce the risks? To what extent did the implementation of the controls create new risks? Is it necessary to change, remove, or add any controls?

11.6.1 How Can a Topic Be Chosen for a Proactive Activity?

In most organizations, the resources allocated to proactive activity are limited, so it is important to choose topics for this type of activity wisely. When choosing topics, it is recommended to refer to the following factors:

(A) The priorities of the organization's management. This may mobilize management to participate in the process and support.
(B) Processes that characterize a place/facility of a unique nature.
(C) Before launching a new activity/opening a new facility, a risk survey is conducted to prepare intervention plans in advance.
(D) Recurring events in a process or facility—A risk survey conducted when there are many adverse events or safety rounds conducted in facilities where the frequency of adverse events is high.
(E) Information about risks published in scientific articles—There may be underreporting of adverse events in certain processes that are performed with high frequency or about which there is research evidence of a high frequency of errors and complications.
(F) Reports from caregivers and employees concerning risks they encounter in daily work.
(G) Conclusions of discussions in control and quality committees indicating high-risk processes/facilities.
(H) Multiple investigations on a certain topic/at a certain facility, which indicates that individual attention to each incident, even if investigated, did not solve the problem and that there is room to initiate a proactive project using the plan–do–study–act (PDSA) method or any other acceptable approach.
(I) Analysis of serious adverse events and/or deaths. There is room to examine the extent to which these were caused by mistakes, failures, or complications in order to reduce the frequency of similar events in the future.
(J) Feedback from the insurance companies. Although the point of view of insurers is different from that of health institutions, since the main interest of the former is economic, there is room for dialog in order to locate processes and issues in which great economic damage was caused to medical institutions.

11.6.2 Advantages of Proactive Risk Management

Proactive risk management activities have many advantages, in addition to the basic fact that they serve as means of preventing risk materialization:

(A) Proactive risk management makes it possible to preempt a cure for a blow, thereby reducing the scope of errors, failures, and adverse events and enabling safer and better-quality medical care.
(B) Medical staff have a higher willingness to cooperate when the risk management activity is carried out in a positive atmosphere and not after an adverse event, as the latter may cause those involved to not cooperate, thereby harming transparency and the ability to learn lessons.
(C) Although a proactive risk management activity often requires a greater investment of time and other resources than a reactive activity, in terms of cost-effectiveness, it is a more profitable investment since systemic risks are handled and general solutions are formulated rather than specific solutions for a particular event.

(D) Since proactive risk management is carried out where the risks are realized, the information collected about them is more valid and reliable than information gathered reactively and makes it possible to suggest more effective intervention plans.
(E) A proactive process of identifying risks, which is the first step in a proactive risk management activity, allows equal expression for managers, therapists, and staff members and is based on the experience of those doing the work in the frontline.

11.7 Defining Patient Safety and Risk Management Policy in a Medical Organization

A patient safety and risk management policy document defines the importance and goals of the activities to promote patient safety and an organizational culture of safety. In the absence of such a document, the safety culture is based on regulations, procedures, and managers' references to the subject and on their response to the occurrence of adverse medical events. A safety culture that emerges spontaneously, without anchors and standards defined in a safety policy document, may be pathological-bureaucratic and not a culture that guarantees learning, support and backing for teams, transparency with patients, and their families or the initiation of proactive activities to reduce risks [39].

A policy document must be short, clear, unambiguous, and assimilated among employees. This document will serve as a kind of constitution for the organization in regard to patient safety and risk management and will stand above all procedures and guidelines. The policy document is the pillar of any activity related to risk management and patient safety and does not change frequently.

A medical organization's patient safety policy document must include the following details:

1. The mission and vision of the organization
2. The organization's goals and the importance of patient safety and risk management in the organization
3. Objectives arising from the goals of the organization and aimed at promoting patient safety issues
4. The commitment of the management and the board of directors to patient safety and risk management
5. The areas of risk management and patient safety activity in the organization.
6. Values and principles related to patient safety and risk management in the organization
7. Definition of those responsible for promoting patient safety in the organization
8. Managerial mechanisms for the follow-up and control of patient safety and risk management activities

An example of a patient safety and risk management policy document is presented in Appendix B.

11.8 Annual Work Plan for Promoting Patient Safety and Risk Management

In most medical organizations in Israel, risk management and patient safety units operate without an annual work plan that defines goals and tasks while referring to existing resources and the variety of activities that must be performed. As mentioned, the accepted approach to the issue is a reactive response to adverse events that are reported to the unit and the performance of required activities according to the type of the event, its characteristics, and its severity. In this situation, it is rare for the unit to initiate a proactive activity to promote patient safety. In our opinion, part of the problem lies in the characteristics of the medical profession, which makes long-term planning difficult since action is often triggered by the arrival of a patient who requires treatment. This approach probably also affects the way in which the issue of risk management and patient safety is treated. It can be said that the unit for risk management and patient safety is actually activated following reports of adverse events.

The MOH offers support tests for hospitals [40] and clinics in the community [41] that

reward those carrying out certain activities aimed at promoting patient safety, thus encouraging fundamental changes in certain work plans. The activities required of the health institutions are represented by eight indicators: Some are result indicators, some are process indicators, some reflect reactive activity, and some reflect proactive activity. In any case, it is not possible to pass the support tests without setting goals and formulating an orderly and balanced annual work plan to promote patient safety.

Relevant sources of information for defining an annual work plan to promote patient safety in a medical organization may be as follows:

(A) Work plans of the medical organization where the unit operates—Since the unit has to support the organization in achieving its goals, it is important that the unit's annual work plan identifies the potential risks in it and prepares appropriate intervention plans. If, for example, the organization is planning new types of activities, opening new departments and institutes, or other significant changes that may affect patient safety, the unit should include appropriate proactive risk management activities in its work plan to address these organizational initiatives.

(B) Support tests from the Ministry of Health regarding the promotion of patient safety—The Ministry of Health defines measurable activities and results. Therefore, an organization that wishes to win financial support for the promotion of safety must plan its activities in this area in order to meet the goals defined in the support tests.

(C) Analysis of adverse event reports—Reports of adverse events are an important source for identifying chronic safety problems in the organization, provided that periodic statistical analyses are performed to identify characteristics and trends. The periodic detection of chronic risks based on adverse event reports should be part of the reactive work plan, and risk management activities to reduce them should be part of the proactive work plan.

(D) Safety investigations—Including the implementation of systemic recommendations from safety investigations in the annual work plan.

(E) The scope of the expected reporting on adverse events—Using statistics of incident reports in past years, it is possible to estimate the scope of the expected reporting in the coming year and plan the resources required to handle them accordingly.

(F) Plans to advance the professional experience and professional level of the unit's staff members—This can include planned training and advanced training and participation in professional conferences to become specialized in the field of patient safety and risk management.

(G) Lawsuits and complaints—Complaints and lawsuits reflect the organization's failure to meet the expectations of regulators and patients, usually on the service level but sometimes also in terms of the quality and safety of care and cases that are perceived by patients and their families as negligence in the legal sense (see Chap. 8, legal aspects). Having a large number of complaints and lawsuits may indicate chronic safety problems in the organization that require practical attention and therefore proactive activity planned as part of an annual work plan for patient safety and risk management.

(H) Information from similar organizations—Although the flow of information among organizations regarding patient safety is far from satisfactory, sometimes, information about risks that have been identified and mitigated in one organization will motivate action in another organization. Professional conferences are an opportunity to share this type of information. Therefore, it is recommended to include activities based on findings and activities in parallel organizations in the annual work plan for patient safety.

(I) Regulators' instructions (Ministry of Health)—Regulators publish, from time to time, circulars and instructions and directly or indirectly refer to, among other factors, patient safety. A work plan for patient safety

is obliged to refer to changes and new requirements from regulators while adapting them to the organization by updating and publishing new procedures. These activities involve various parties in the organization and therefore require the investment of many resources led by the organization's risk management and patient safety unit.

(J) Professional literature—The scope of studies published in professional journals in the fields of risk management and patient safety is constantly increasing. These publications should be referred to in order to locate ideas for applied activity and research activity. It is recommended that appropriate resources be allocated to research activity in the work plan; otherwise, the chances of such activity actually being conducted are slim.

(K) Research, publication of articles, and training students—It is very important to apply insights and knowledge acquired in the unit and share it with other institutions in Israel and worldwide.

(L) Judgments—It is very important to study and draw conclusions from judgments in medical malpractice cases and include practical insights from them in the annual work plan.

A work plan for risk management and patient safety in a medical organization should be part of the organization's overall work plan, and therefore, it should be defined in the schedules and format in which the organization defines its work plan. It must also go through approval processes and be controlled, similar to the organization's general work plan.

In a medical organization that operates through branches or in different geographic regions, similar to health funds in Israel, a branch or regional plan must be defined that is adapted to the risk management and safety plan of the entire organization but that also accounts for the unique characteristics of the branch/region.

A basic structure of a work plan for risk management and patient safety is presented in Appendix C.

11.9 Safety Rounds in a Medical Institution: Principles and Application

A safety round is a process planned and managed by the risk management and patient safety unit. The round must be conducted with the participation of the institution's key personnel, and its purpose is to detect risks in a given medical environment. Conducting safety rounds in health institutions in Israel is an MOH quality index in the support tests for promoting patient safety.

The support tests define the number of rounds to be performed in each institution, the participants, and the method of execution [40].

In July 2017, the Ministry of Health, Government Medical Centers Division published a circular on the subject of safety rounds in government medical centers [42] defining what a safety round is and what its goals, participants, and execution method should be, while referring to specific issues that must be focused on. The participation of managers has been emphasized as very valuable in conducting safety rounds because it creates a feeling of "psychological security" among medical teams that helps them present problems and risks and cooperate in problem-solving processes that have been identified as important [43]. However, safety rounds require organizational mobilization, management commitment, and good organizational skills. In the areas where safety rounds have been systematically implemented, improvements in patient safety indicators have been found [44].

In a comparison between safety rounds with and without feedback, many advantages have been found for the former from the point of view of the medical teams, including a sense of effectiveness, a sense of safety, a sense of backing from the management, and readiness to perform one's job [45].

In addition to identifying risks in the process or site where the round was conducted, safety rounds can be used to detect systemic failures by extensively and systematically analyzing their findings beyond a single process or site [46].

Based on our experience conducting safety rounds in various healthcare organizations, we recommend the following:

- Safety rounds should be held at least once a year in every institute, department, unit, clinic, or service belonging to the organization.
- The safety rounds should be embedded in the work plans of the organization, similar to any other task.
- The rounds should be performed based on a dedicated tool whose components are described below.
- Managers at all levels should participate in the safety rounds to provide them with backup and show managerial commitment. As mentioned above, it is important to note that in the support tests of the Ministry of Health, managers must participate in the round.
- Feedback regarding critical risks that have been identified should be given to the site managers immediately upon the end of the round. Written feedback should be provided that includes the details of all the risks identified that require mitigation and control, along with a specification of priorities.
- Once a year, an analysis of the findings of the rounds conducted to identify systemic risks to patient safety should be performed, and an intervention plan should be defined to reduce them.

11.9.1 Principles for Performing Safety Rounds

1. Risk management and patient safety should publish the annual plan for safety rounds once a year as part of its work plan.
2. It is recommended that the following officials participate in the round:
    - The manager of the risk management and patient safety unit
    - The local risk management and patient safety manager
    - Senior management representatives (manager/deputy manager, head physician, and head nurse)
    - The manager of the site where the round is conducted
    - The head nurse at the site where the round is conducted
    - Additional personnel according to the characteristics of the department (such as pharmacist, social worker, and psychologist)
3. A list of the data required for the discussion phase of the safety round should be provided to the site's management approximately 2 weeks before the round (see below Phase A—opening discussion).
4. Each safety round should be conducted according to a detailed schedule that is published at least 30 days before its execution. The schedule should include four main stages:
    - Phase A: In the opening discussion, the focus should be on the current safety round, while referring to the summary reports of previous safety rounds and their main issues. The issues that should be discussed in the opening meeting are detailed in Appendix D, Part I. The discussion should be led by the local patient safety and risk management unit manager and should be attended by all participants in the safety round.
    - Phase B: The safety round should be carried out based on observations detailed in the appendix, in Part B.
    - Phase C: Interviews should be held with the site staff by the manager of the risk management and patient safety unit based on the list of topics outlined in Part C of the appendix. At least three staff members must be interviewed: a nurse, a doctor, and an administrative/paramedical worker. Each of the crew members should be interviewed separately.

- Phase D: A summary discussion of the safety round should be conducted by the director of the local patient safety and risk management unit with the participation of all participants in the safety round, based on the summary discussion template in Part D of the appendix.

5. A suggested schedule for the safety round is presented below (the schedule can be considerably shortened by working in parallel, provided enough crew members participate in the round).

Start	Finish	Activity	Based on
09:00	10:00	Initial discussion	Part A in Appendix D
10:00	11:30	Observations	Part B in Appendix D
11:30	12:30	Interviews	Part C in Appendix D
12:30	13:30	Break	
13:30	14:30	Preparation of the summary meeting	
14:30	15:30	Summary meeting	Part D in Appendix D

6. The safety round should be conducted based on predefined checklists that include:

- Questions and issues that will be presented during the safety round
- Activities to observe and discuss
- The staff members to be interviewed
- The documentation and medical records to be reviewed

7. The manager of the local patient safety unit should publish, no later than 14 days after the safety round, his summary report, including recommendations aimed at reducing the main risks identified. The summary report should be approved by the risk management and patient safety manager of the organization before its publication.
8. The manager of the site where the round was carried out should respond to the summary report of the safety round within 14 days of its distribution and should outline an intervention plan to eliminate/reduce identified risks.
9. A principal template for conducting safety rounds in a medical institution is presented in Appendix D.

11.10 Patient Safety Training and Education

Education and training are important components of risk management, and patient safety aimed at implementing changes and reducing exposure to risks. A study on the impact of education and training programs in the field of risk management and patient safety demonstrated an improvement in the level of knowledge of concepts related to patient safety, an improvement in staff attitudes regarding the culture of safety, and, as a result, an improvement in the processes and results of patient safety and quality [47, 48].

Schools of medicine, nursing, and all the leading health professions across the world that have integrated patient safety training into their curricula have shown an improvement in subject knowledge and student attitudes toward patient safety, as well as in the development of systemic thinking and a future commitment to patient safety [49–51]. However, the scope of training on risk management and patient safety is still limited. In a questionnaire sent [49] to 110 medical schools in the United States and Canada, only 25% of the respondents indicated that their schools had implemented a dedicated program on the subject.

Those who answered affirmatively stated that the topic of patient safety was taught and discussed in the preclinical years.

The subjects covered by the study included reporting adverse events, analyzing medical errors, improving the methods for writing prescriptions to prevent errors in the administration of drugs, handling safety indicators, understanding national goals in patient safety, and providing standardized medical care by using clinical guidelines and templates for giving instructions to patients.

Seventy-two percent of the respondents agreed that training on the issue of patient safety must be part of the curriculum in medical schools. The

authors noted that despite regulatory requirements and recommendations from medical organizations and academic institutions, the implementation of dedicated study programs in the field of patient safety is still limited.

In a systematic literature review [52], only seven studies that focused on patient safety education for students in the preclinical years were found. Only one study dealt with the training of patient safety as part of the curriculum, and the rest dealt with the integration of the subject within the rotation.

In a survey of medical students at the University of North Carolina, participants were asked about their preferences regarding studying quality issues in medicine and patient safety [53]. It was found that 79% of the students had encountered the issue of patient safety, and 47% had encountered quality issues in medicine. Over 80% of the students rated the safety issue as having equal or greater importance than basic science or clinical skills. The students' preference was to learn based on real-life examples of errors and adverse events (an average of 4.5 on a scale of 1–5).

The curriculum of the Association of American Medical Colleges (AAMC) does not require the study of quality and patient safety (QPS). Dysinger and Pappas [50] agree with this, as they see a large degree of overlap between the two topics. However, it is noted that the number of medical schools implementing dedicated curricula on the topic of patient safety is on the rise.

As part of their research, 510 medical students in their fourth year went through a 4-week rotation in community medicine, and as part of it, they carried out, in groups of 3–4, a "quality project" in all its phases, such as "prevention of pressure ulcers" and "improving medical documentation." Fifty-three percent of the students rated the rotation as "excellent" or "above average." Qualitative evaluations indicated that the project was valuable.

In 2015, the General Medical Council (GMC) in the United Kingdom in collaboration with the Medical Schools Council (MSC) published a special report with the aim of strengthening patient safety studies within the framework of the preclinical years in the United Kingdom and the Commonwealth of Nations [54]. The authors detail their motivations for writing it, including the need to define high standards for patient safety courses and professional support for the initiatives of the medical schools that wish to include the subject in their curriculum. The report contains a lot of data regarding the attitudes of medical students toward the study of patient safety. Among other results, it was found that the graduates of medical schools felt less confident about the following issues related to patient safety: collaboration with caregivers and patients to promote patient safety (24%), learning from errors and "near misses" (23%), understanding human factors (21%), and use of quality improvement methods to advance patient safety (20%).

In a NASBAR (Israeli Patient Safety and Risk Management Association) position paper "Education and training for patient safety," published in 2022, the following is stated:

- NASBAR recommends that the schools of medicine, nursing, and all health professions and organizations/medical institutions in Israel adopt and integrate the recommendations detailed in the position paper into their curricula and training.
- NASBAR recommends that the managers of patient safety units cooperate with human resources development and training departments in the promotion and implementation of patient safety curricula and training programs.

Due to the importance of patient safety training and education, the Ministry of Health defined patient safety and risk management training as one of the safety indicators in the support tests both in hospitals and in the community. The index is divided into three subindices: training for risk management and patient safety personnel, training for medical teams, and training administrative staff.

In 2020, the Canadian Patient Safety Institute (CPSI) formulated the basic qualifications that every medical staff member must acquire to provide safe and high-quality care [55]. The qualifi-

cations were defined across all relevant disciplines and validated against field factors. The CPSI defined six basic competencies:

1. The adoption and promotion of the principles of a safety culture
2. Teamwork
3. Communication
4. Proactive activity to detect and reduce risks and promote quality
5. The optimization of human and environmental factors
6. The detection and reporting of adverse events

For each of the competencies, the appropriate behaviors that express their assimilation were defined. For example, for detecting and reporting adverse events, six required behaviors were defined:

(1) Identifying adverse events related to patient safety; (2) establishing contact with patients and their families who were involved in adverse events to respond to their needs; (3) properly disclosing adverse events; (4) learning and extracting lessons from adverse events; and (5) dealing with mental stress related to involvement in adverse events in professional and constructive ways, and for subjects in management positions, providing support for families and caregivers involved in adverse events.

CPSI's publication can serve as a good source of inspiration for defining training programs in the areas of risk management and patient safety.

In our opinion, education and training activities related to risk management and patient safety include seven main layers:

1. The content of risk management and patient safety practices during and as part of basic professional training for doctors, nurses, and paramedical professionals. For example, in a dedicated 4-h program delivered to third-year medical students, 89% of the participants stated that the opportunity they had to present an error to a patient in a simulation increased their confidence in revealing errors to patients, and 94% stated that the simulation and the feedback they received were useful learning experiences.
2. Analysis of self-awareness questionnaires before and after the training indicated an increase in self-awareness regarding the strengths and weaknesses in the proper disclosure of medical errors. The conclusion of the authors of the article was that it is possible to raise and maintain awareness of the issue of patient safety and medical errors among medical students while implementing the experimental curriculum and that in the eyes of the students, this program was a valuable experience [50].
3. Professional training for risk management and patient safety personnel to fulfill positions in this field in the health system.
4. Continuing medical education (CME) for medical professionals and managers without background in this field to become acquainted with the basic principles and tools of risk management and patient safety.
5. Degree studies (first, second, and third) in the fields of health system management and quality in medicine that include courses on risk management and patient safety.
6. Targeted training activities to implement changes following investigations of adverse events and/or detection of risks in a proactive activity.
7. The publication of lessons learned through different means and for different target audiences.
8. Medical staff meetings to raise awareness of the issue of patient safety and discuss relevant issues.

In summary, when implementing education and training programs in risk management and patient safety, it is important to consider the following issues:

(A) A continuous approach to training events (LLL–life-long learning)—Building a training program, starting from studies to obtain a degree in one of the health professions, through specialization, and toward the fulfill-

ment of managerial positions until the end of one's career.

(B) Providing training near a critical crossroads in a career—For example, at the beginning of a position, at the time of acceptance into a new organization, at the launch of a new service, and at the time of receiving new equipment.

(C) An instructional guide for systemic changes, such as organizational change, technological change, the addition of services and facilities, and the publication of new Ministry of Health guidelines.

(D) Training adapted to the position—Although all medical staff members should be familiar with the principles of promoting patient safety in the organization, different professions and different positions have unique characteristics that require training adapted to the position.

(E) Utilizing instructional methods and means adapted to the subject being studied—Professionals should be trained on critical and practical issues through simulations, whereas theoretical topics can be taught through self-learning or face-to-face lessons [56].

(F) Training content based on real events—The training program should be based on real events, that is, risks and examples of adverse events relevant to the work environment and profession of the medical staff. Theoretical material should provide an understanding of the occurrence process of adverse events and proactive activities to promote patient safety.

(G) Studying and training on how to use practical tools to promote patient safety—Quite a few tools have been developed, mainly proactive ones, for application in the areas of risk management and patient safety; among them are tools applied within the framework of the JCI certification, FMEA [35], and tools for evaluating safety culture and tools for investigating adverse events [57].

Key Messages: Organizational Risk Management Processes

- Risk management processes for promoting patient safety can be divided into three categories:
  - (A) Reactive activities—Activities carried out after the occurrence of an adverse event in order to learn and draw lessons from it to prevent the recurrence of similar events in the future.
  - (B) Interactive activities—Activities carried out immediately after sometimes even during the occurrence of an adverse event, with the purpose of identifying and reducing the immediate damage resulting from the event.
  - (C) Proactive activities—Proactive activities to identify, assess, and control risks before their materialization.
- Risk management activities to promote patient safety are considered a long-term activity, and their achievements are identified as changes in the safety culture of the organization rather than in frequent changes in work processes as a result of one or another adverse event. For risk management activities to achieve their goals in improving patient safety, they must be professional, planned, systematic, and persistent and include a mix of the three types of processes described in this chapter. Focusing on only one type of activity, usually a reactive activity, is a common mistake that likely will not yield the desired result of changing a safety culture to a creative culture.
- The successful implementation of a practical and effective approach to

patient safety in a medical organization depends on the resources available to carry out the various activities and the planned allocation of the resources to the different types of activities. In our experience, it is best to allocate approximately 30% of resources to reactive activities, 40% to interactive risk management activities, and 30% to proactive activities.

- The measures that can help in the consistent promotion of patient safety are mainly proactive processes, among them being a clear definition of the organization's patient safety policy and its implementation in the organization, the definition of annual work plans as a derivative of the organization's work plans, patient safety rounds conducted with the participation of management in order to familiarize them with voices from the field on important issues related to patient safety, and the availability of a variety of educational and training activities for all sectors to raise awareness of risks and ways of dealing with them and to adopt a safety culture of learning from errors.
- A central issue arising from the variety of activities to promote patient safety is the implementation of recommendations arising from investigations, safety rounds, risk surveys, and, in fact, all risk management activities. The purpose of all risk management processes is to formulate recommendations for changes to work processes and work environments that have the potential to reduce exposure to risks or their damages if they materialize. Thus, the definition of quality recommendations is an important professional challenge for risk and patient safety managers, but perhaps even more important is making sure that the organization has adopted the recommendations.

Appendixes

Appendix A: Investigation Report Template and Common Mistakes in Writing an Investigation Report

1. **General**

Investigation of adverse event no._____
On the subject of _____
_____
Date of receipt of the report: _____
Date of completion of the investigation: _____
Investigation team members: _____
_____
_____

2. **Event Synopsis**

Describe the adverse event in a concise and comprehensible manner, emphasizing the anomalies in the event. Avoid taking a personal position or judgment.

Common mistakes to avoid:

(a) Making the description too long or too short
(b) "Cutting and pasting" the original text of the report
(c) Taking a judgmental position
(d) Lacking clarity about what went wrong
(e) Making language too technical or using too much professional slang

3. **Boundaries of the Event**

Define the point of time or the occurrence with which the event began to develop and specify the point of time and the occurrence with which the event ended.

Common mistakes to avoid:

(a) Making the event boundaries too narrow/too wide.
(b) Not correcting the boundaries during the investigation, even if the investigation moves beyond the original limits.
(c) Not defining timing or clear initiation and ending triggers.

4. **Event Results**

Describe the results of the event in three aspects: the patient, the caregivers, and the organization.

Common mistakes to avoid:

(a) Referencing damage only to the patient.
(b) Referencing immediate damage and not potential damage.
(c) Referencing only one dimension of damage: physical but not psychological damage, damage to the organization's reputation, etc.

5. **Analyzing the Event with the 5M Model**

Analyze the adverse event based on the 5M model by describing the errors, failures, and violations in each of the M categories.

Common mistakes to avoid:

(a) Confusing different categories
(b) Describing activities and not failures and mistakes

5M categories	Error/failure/procedural violation	Contribution to the event's occurrence (1–5)
MAN	Common mistakes to avoid	
The factors related to those involved in the incident, both directly and indirectly, and to the victims of the incident	(a) Excluding anyone involved	
Refer to each of those involved separately	(b) Lacking a separate breakdown of the errors and failures of everyone involved	
MACHINE	Common mistakes to avoid	
The factors related to the equipment and systems used by those involved in the event	(a) Referring only partially to the relevant categories	
Refer to the equipment, systems, and medications that played a role in the occurrence of the incident	(b) Failing to refer to computer systems, medications, or other types of medical equipment	
MISSION	Common mistakes to avoid	
The factors related to the characteristics of the task during which the incident occurred	(a) Describing the task and not the failures related to its planning and execution	
Refer to the planning and preparation for the execution of the task as well as the characteristics of the task itself: Simple–complex, new–routine, common–rare	(b) Confusing the MISSION and MAN categories	
	(c) Failing to consider the characteristics of the task: Routine–special, simple–complex, new–familiar	

5M categories	Error/failure/procedural violation	Contribution to the event's occurrence (1–5)
MANAGEMENT	Common mistakes to avoid	
The factors related to management and administration that contributed to the occurrence of the event and/or to its results	(a) Confusing the MAN, MANAGEMENT, and MEDIUM categories	
Refer to factors such as resource allocation, the existence of appropriate procedures and their implementation, control, safety culture, overall training, and the training of those involved	(b) Failing to address management's mistakes and failures	
	(c) Failing to consider the aspects of resource allocation, appropriate equipment, maintenance, and staff attrition, workload, and stress	
	(d) Referring to procedures only	
MEDIUM	Common mistakes to avoid	
The factors related to the physical and psychological environment in which the event occurred	(a) Referring to the physical environment only	
Refer to the characteristics of the physical environment in which the incident occurred, including noise, crowding, site design, and congestion, and to "soft" characteristics such as teamwork and atmosphere	(b) Confusing the MEDIUM and MANAGEMENT categories	

6. **Analysis and Description of the Event Sequence Process in the Domino Model**

- Chronologically describe the sequence of events within the boundaries of the event that led to the adverse event based on the information collected and the 5M analysis.
- Findings should be centered around a stage in the development of the event that occurred at a specified time in a specified place and was carried out by one of those involved in the incident.
- For each of the findings, indicate whether it is a causal/background/additional finding.

Common mistakes to avoid:

(a) Providing too little or too much detail
(b) Significantly deviating from the 7 ± 2 rule (too many or too few findings)
(c) Lacking background or other findings when there are any to be had
(d) Reporting "container" findings, or one finding containing several findings
(e) Failing to classify the findings according to their types
(f) Confusing the chronology of the event
(g) Exceeding the boundaries of the event
(h) Failing to refer to repeated risk events
(i) Failing to refer to positive behaviors in the sequence of event occurrence

No.	Finding description	Type of finding[a]
1		
2		
3		
4		
5		
6		
7		
8		
9		

[a]Casual/Background/Additional

7. **Conclusions** (Based on the Sequence of Findings)

- Define decisions in relation to the causes of the event on two levels: the direct causes of

the event and the factors that contributed to the occurrence of the event.
- Conclusions should refer to why the event occurred based on the investigation's findings.
- It is possible to indicate in the conclusions the noteworthy performance of any of the staff members involved in the incident and not only mistakes/failures/violations.

Common mistakes to avoid:

(a) Repeating findings
(b) Failing to answer the question: Why did the incident happen?
(c) Failing to rely on causal findings
(d) Lacking reference to additional findings
(e) Confusing causal factors and contributing factors
(f) Lacking reference to positive factors such as those that prevented serious damage

The incident was caused by:

The factors that contributed to the incident occurrence and its results are as follows:

8. **Recommendations (Based on the Conclusions)**

Define operative actions that, if implemented, have the potential to reduce the risk of recurrence of similar events in the future and/or decrease the damage caused by such events.

Common mistakes to avoid:

(a) Failing to relate the recommendations to the conclusions
(b) Using unclear wording
(c) Failing to define clear actions that have the potential to reduce the identified risks
(d) Failing to test the feasibility of implementing the recommendations
(e) Failing to identify the staff member in charge of implementation
(f) Failing to define a time schedule for implementation
(g) Failing to present the recommendations according to priority for implementation
(h) Making too many/too few recommendations

No.	Recommendation description	Person in charge of implementation	Timetable
1			
2			
3			
4			
5			
6			
7			

Appendix B: An Example of the Policy Format for Risk Management and Patient Safety

The "Safe Health" Company's Risk Management and Patient Safety Policy

1. **Details on the "Safe Health" company:**

"Safe Health" company is a company that specializes in providing high-quality medical services in the following areas: _____

The" Safe Health" company provides its services to a variety of patients, including:

_____

2. **The goals and importance of risk management and patient safety at "Safe Health":**

The goal is to ensure the provision of the company's professional services while maintaining a high level of patient safety and constantly reducing clinical risks to patients, caregivers, and the company.

3. **The commitment of the management and the board of directors to risk management:**

The management and board of directors of the "Safe Health" company are committed to carrying out systematic, continuous risk management processes in the various areas of the company's activities while maintaining transparency and providing full support for operative plans to minimize risks and their damages.

4. **Risk management activities aimed at promoting patient safety**

Risk management activities in the company refer to all areas of its activity that have an impact on patient safety, including clinical, operational, administrative, and technological processes.

5. **Values and principles of patient safety activities in the "Safe Health" company:**

Patient safety activities at the "Safe Health" company are based on the following principles, which are the necessary cornerstones for its success:

(A) Patient safety and risk management are necessary parts of the organizational and managerial culture in the company. "Safe Health" considers patient safety a valuable factor in all its activities and decision-making processes.
(B) Risk management is a significant part of the professionalism of the company's employees. The company's employees are evaluated, among other factors, based on the performance of their duties and tasks, while referring to risks to patient safety and minimizing exposure to them.
(C) Company managers and employees report fully, reliably, and immediately every adverse event known to them.
(D) Administrative confidentiality is provided for those who report—The reporting of adverse events is aimed only at learning lessons. Therefore, no action will be taken against those who report, unless the incident was caused intentionally or as a result of negligence.
(E) All the organizational units in the "Safe Health" company are partners in the effort to minimize risks the company is exposed to and operate according to a standard and agreed-upon methodology.
(F) The extraction of lessons learned from adverse events is based on a standard methodology and aims to mitigate the root causes that allowed the occurrence of the event, in addition to the immediate causes.
(G) The knowledge and insights from risk management activities in the company are available to all employees in the company and are used by them in day-to-day operations, in emergency situations, and in the execution of projects.

6. **Defining the responsibility for risk management activities:**

Every manager and employee of the company are responsible for risk management in their areas of activity and exercise this responsibility in accordance with the company's guidelines and instructions on the subject.

The responsibility for the overall management of risk management and patient safety activities in professional aspects falls on the company's risk manager, who reports to the VP of Medicine.

7. **Management mechanisms to control risk management and patient safety activities:**

The main administrative mechanisms for controlling risk management activities in the company are an annual work plan that includes defined risk management tasks for the various organizational units, a control and quality committee, the presentation and publication of investigative reports to the management, the publication of periodic statistical summaries summarizing the data reported on adverse events, semiannual status discussions among the board of directors, and quarterly status discussions among the company's management.

Appendix C: An Example of an Annual Work Plan for Risk Management and Patient Safety

"Safe Health" – Risk management and Patient Safety Annual Work Plan, 20XX	1	2	3	4	5	6	7	8	9	10	11	12	Responsibility
Ensuring ongoing handling of approximately 1,500 reports on adverse events: receiving the report, clarifying details, managing the event + feedback to those reporting and inputting it into the computer data base													RM and PS unit
Investigating selected adverse events – at least 2 investigations per unit per quarter (a total of 60 district investigations per year) – and ensuring quarterly control of compliance with the target													
Ensuring ongoing guidance of the unit's teams in conducting safety investigations													
Actively participating in relevant professional forums													
Responding to inquiries from all parts of the organization regarding patient safety and risk management													
Following up on the implementation of approximately 120 recommendations from RM and PS activities (investigations, proactive activity)													
Providing 12 monthly feedback reports to RM and PS local referents in the units and managers on the scope of the voluntarily reporting													RM and PS unit
Providing 12 monthly feedback reports to RM and PS local referents in the units and managers on the scope of "near miss" reporting													
Distributing 12 case studies for learning, following investigations of adverse events													
Holding meetings/lectures on RM and PS and the importance of reporting adverse events – at least 3 per unit; each lecture will last at least 45 minutes and will be given to a forum of at least 15 participants. Ensuring quarterly control of meeting the target													Local RM and PS referents
Assimilating the CBT module on RM and PS and among the employees; ensuring the quarterly control of the scope of use in the units													
Holding 2 meetings in each unit per year with the unit's management to present and discussing the activity in the field of RM and PS													
Providing orientation meetings with new employees hosted by the local risk managers in the units and based on the CBT+ the documentation of the meetings													

"Safe Health" - Risk Management and Patient Safety Annual Work Plan 2023	1	2	3	4	5	6	7	8	9	10	11	12	Responsibility
Conducting a 3-day course on RM and PS for clinicians and managers													RM and PS unit
Preparing for the course													
Choosing and approving the PDSA projects													Local RM and PS referents
Conducting 2 RM and PS projects in every unit using the PDSA methodology													
Ensuring ongoing supervision of the local RM and PS referents													Local RM and PS referents and RM and PS unit
Ensuring participation of risk managers in professional conferences													
Providing professionalization days for local risk managers													
Upgrading the format of safety inspections of external suppliers													Local RM and PS referents
Conducting 2 inspections per year per unit – including repeated inspections – and a quarterly inspection of compliance with the target													
Developing a new format for safety rounds in organization units in accordance with the requirements of MOH support tests													
Carrying out 1 safety round in every unit													RM and PS unit
Preparing to pass the support tests of the MOH and implementing the standards in every unit													
Preparing the organizational RM and PS annual work plan													RM and PS unit
Preparing the units' RM and PS annual work plan													Local RM and PS referents
Producing an annual summary report on RM and PS activities in the organization and presenting it to management													RM and PS unit
unplanned RM and PS activities													RM and PS unit

Appendix D: A Format for Conducting Safety Rounds in a Medical Institution

Part A: Opening Discussion

1. Were the recommendations from the previous safety rounds implemented?

   [ ] Yes [ ] No [ ] Partial [ ] Not relevant

   If not or only partially, please provide details:

   ____
   ____
   ____
   ____
   ____
   ____
   ____
   ____
   _____

2. Were there any adverse events reported that occurred in the unit where the round is being held? (The data will be prepared by the manager of the unit before the round, in the format of the table below and presented by him).

Period	Severe damage/death	Moderate damage	Minor damage	Near miss	Total
Last week					
Last month					
Last quarter					
Last 6 months					
Last year					
Other					

3. What has been done in the unit in the last year to identify and control risks that may cause harm to patients?

   ____
   ____
   ____
   ____
   ____
   ____
   ____
   ____

   ____
   ____
   ____
   ____
   ____
   ____
   ____
   ____

4. The main issues to be addressed in the safety round:

   ____
   ____
   ____
   ____
   ____
   ____
   ____
   ____

Part B: Observations

5. The safety round team will list (separately) the environmental risks that may endanger patients based on the following checklist.

Factor	Yes/ No	Comments
Unit density		
Renovations		
Furniture—Chairs, benches, nightstands		
Cables and pipes		
Beds (without rails, nonadjustable rails, low rails, etc.)		
Slippery floor		
IV stands		
Portable medical equipment		
Loose floor tiles		

Factor	Yes/ No	Comments
Uneven floors within the unit		
Blocked corridors		
Dark areas (insufficient lighting)		
Broken sinks		
Stairs (steep, broken, slippery, without supports, etc.)		
Other		
Other		
Other		

6. The safety round team will assess the level of cleanliness in the department
   [ ] Very good [ ] Good [ ] Moderate [ ] Bad [ ] Very bad
   Remarks:
   _____
   _____
   _____
   _____
   _____
   _____

7. Are equipment and medical materials on elevated surfaces secured from falling?
   [ ] Yes [ ] Partial [ ] No
   If not or only partially, please provide details:
   _____
   _____
   _____
   _____
   _____
   _____

8. Are all doors that need to be locked kept locked as required?

   8.1 Storage: [ ] Yes [ ] No
   8.2 Medicine room: [ ] Yes [ ] No
   8.3 Archive of patient records: [ ] Yes [ ] No
   8.4 Delivery: [ ] Yes [ ] No
   8.5 Other _____: [ ] Yes [ ] No

9. Does the resuscitation cart contain all the required drugs and equipment?
   [ ] Yes [ ] No

10. Is the resuscitation cart checked regularly and maintained as required?
    [ ] Yes [ ] No
    If not, please provide details: _____
    _____
    _____
    _____
    _____

11. Are all the medicine cabinets in the department maintained according to the regulations (e.g., separating toxic substances from other medicines)?
    [ ] Yes [ ] No
    If not, please provide details: _____
    _____
    _____
    _____
    _____
    _____
    _____

12. Are all patients identified using bracelets?
    [ ] Yes [ ] No
    If not, please provide details: _____
    _____
    _____
    _____
    _____
    _____

13. Are there enough biohazard bins for biological hazards?
    [ ] Yes [ ] No
    If not, please provide details: _____
    _____
    _____
    _____
    _____

14. Are there enough materials for hand hygiene in the places where they are supposed to be (near the patient beds, at the examination stations, in the toilets)?
    [ ] Yes [ ] No [ ] Other _____
    _____
    _____
    _____
    _____

15. Review 5 medical records of patients over 65 years of age and check whether risks for

pressure ulcers have been assessed and documented based on a standardized scale as required

[ ] Yes [ ] Partial [ ] No

If not or only partially, please provide details: _____

16. Review 5 medical records of patients who underwent surgical procedures. Refer to the completeness of the informed consent process and timeout as required as follows:

16a. Was the correct informed consent form used at the correct stage of the medical process and in the correct manner, and was the form signed as required?

[ ] Yes [ ] Partial [ ] No

If not or only partially, please provide details: _____

16b. Was the surgical checklist filled out and signed as required before the surgical procedures?

[ ] Yes [ ] Partial [ ] No

If not or only partially, please provide details: _____

Part C: Interviewing Staff Members in the Unit

Interview at least 3 staff members from the unit but from different sectors and with different managerial levels.

1. When you are involved in an adverse medical event, do you report it?

[ ] Yes [ ] No

If not, please provide details: _____

2. What do you think prevents the caregivers in the unit from reporting all the adverse events?

[ ] Time limitations
[ ] Lack of knowledge
[ ] Low priority
[ ] Cumbersome reporting process
[ ] Fear of punishment
Other: _____

3. Have you participated in any training related to patient safety in the last year?

[ ] Yes [ ] No

If so, please provide details: _____

4. Have you participated in training on the following topics in the last year:

4.1 Infection control and prevention: [ ] Yes [ ] No
4.2 Fall prevention: [ ] Yes [ ] No
4.3 Prevention and treatment of pressure ulcers (PUs): [ ] Yes [ ] No
4.4 CPR (ALS/ATLS): [ ] Yes [ ] No

5. In your opinion, what is the approximate percentage of adherence to hand hygiene in your unit?

[ ] Below 25% [ ] Below 50% [ ] More than 50% [ ] More than 75% [ ] 100%

6. From your point of view, what prevents the medical staff from meeting the requirements for hand hygiene?

[ ] Time limitations
[ ] Lack of awareness
[ ] Workload
[ ] Lack of facilities and materials for washing hands
[ ] Perception that wearing gloves eliminates the need to wash hands
[ ] Reluctance due to skin irritation caused by frequent hand washing

7. What bothers you regarding the safety of care in your unit?

Factor	Yes/No	Comments
Communication among staff members		
Teamwork		
Shift transfers		
Work interfaces with imaging		
Work interfaces with laboratories		
Maintaining continuity of care		
Workload		
Environmental conditions—e.g., crowding and noise		
Sterilization		
Infection prevention		
Patient falls/bruises		
Lack of equipment		
Malfunctioning equipment and equipment maintenance		
Drug administration process		
Other		
Other		
Other		

8. Did you witness any communication problems that could affect patient safety?

Between		Yes/No	Comments
Caregiver team	Patient/family		
Caregiver team A	Caregiver team B		
Management	Caregiver team		
Unit A	Unit B		
The unit	Service providers (laboratory, imaging, pharmacy)		
Other			

9. Is there anything management can do to help you or your colleagues minimize risks to patient safety?
   [ ] Yes [ ] No
   Please provide details: _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____

Part D: Conclusion

1. All the officials who participated in the round will participate in the summary conversation.
2. The manager of the risk management and patient safety unit will present the main findings of the safety round that require immediate action.
3. The manager of the risk management and patient safety unit will ask the participants the following questions:

   3.1 Do you think your participation in the round was beneficial?
   [ ] Yes [ ] No
   If not, please provide details: _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____

   3.2 What, in your opinion, are the main risks to patient safety that were found during the safety round? (Specify 3–5 main risks)
   _____
   _____
   _____
   _____
   _____
   _____
   _____

3.3 What might make safety rounds more effective?

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12 Evaluation and Measurement of Risk Management Activity and Patient Safety

12.1 The Importance of Measuring the Quality and Effectiveness of Risk Management and Patient Safety Activities

To evaluate the capabilities of a medical institution in maintaining treatment safety and risk management, quantitative measurement tools must be prepared. This task is not easy because a comprehensive risk management plan includes multiple and complex parameters that are difficult to detail and measure. To assess the organizational safety culture, several tools have been created, as detailed in Chap. 4. The most accepted tool is the Hospital Survey on Patient Safety Culture (HSOPSC) developed by the US Agency for Healthcare Research and Quality. It should be noted that this tool, like others, does not measure safety culture directly, i.e., by assessing clear results of conduct, but assumes that the attitudes of staff members will reflect the organization's approach. The direct measurement of the success or failure of a structured risk management plan should be focused on clear results such as mortality or significant adverse events, reports of adverse events or "near-miss" events, complaints related to the safety of patients and staff members, the attrition of staff members, or expenses for medical malpractice lawsuits. FMEA and other tools for planning proactive activities, such as identifying possible future failures and preventing them, RCA and other tools for conducting investigations based on structured theory, and M5, P6, and other models to sum are presented in Chap. 11.

As in any organizational action plan, here too, there is room for a structured plan for quality and safety indicators and a clear definition of the population of subjects (the denominator) and of those who met the goals (the numerator) to quantitatively assess the quality of the organization in maintaining the safety of its patients and staff members, while comparing with other organizations (benchmarking) and continuous improvement monitoring.

12.2 Defining Indicators for the Quality of the Risk Management Activity and Treatment Safety

In Israel, the national program for indicators in hospitals, ambulance companies, and mother-and-child clinics was established in 2012 and includes 80 indicators with annual improvement targets [1]. The program has several indicators that can be defined as safety indicators, as they are directly related to treatment results and the prevention of adverse events and abnormal mortality: giving antibiotic treatment 1 h before the incision in three types of surgery (colon surgeries, hip joint replacement, and cesarean sections),

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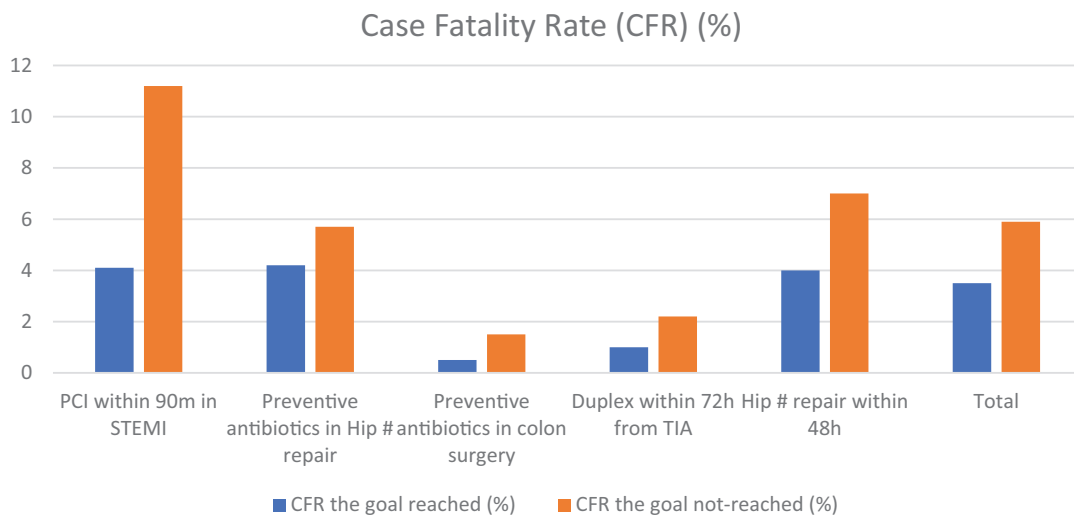

Fig. 12.1 Mortality rates in the population according to different types of quality indicators

replacing hip joints within 48 h of the fracture, and providing duplex surgery within 72 h from a transient ischemic attack (TIA). Compliance with the goals of these indicators, which have improved every year since they began being measured, has resulted in a significant decrease in mortality in the population, thus meeting the goals of the indicator, unlike with the overall population, which did not meet them [2–4]. The decrease in mortality in populations that meet the goals of the quality indicators is presented in Fig. 12.1.

In Israel, there is still no national plan for quality measures directly aimed at maintaining treatment safety, or in other words, a national plan for safety measures. Since 2018, the Ministry of Health has operated a support program for general hospitals, psychiatrists, and geriatricians, which includes quality indicators of retrospective, interactive, and prospective work. This program includes process indicators—patient identification in the medical center and the imaging institute, safety in the operating room, training in treatment safety, safety rounds, departmental projects to promote treatment safety, the rate of "near-miss" events, and learning from adverse events and outcome indicators—and events that should not happen according to a circular from the Ministry of Health Director General regarding safety measures. A national plan for safety measures is also being developed, and it will include designated measures with defined goals, similar to the national plan for quality measures, and will draw its strength from the regulations of the 2012 National Safe Health Law.

Before safety indicators in healthcare organizations can be determined, five questions must be answered: What events happened in the past, and what was their frequency? Is the reported information reliable? Are the indicators measurable and traceable? Is there a learning and implementation procedure? Certain safety measures are used worldwide, and these were determined by bodies authorized for this.

In the USA, safety measures have been prepared by an accreditation organization (The Joint Commission), the NFQ (National Quality Forum), and the AHRQ (Agency for Healthcare Research and Quality); these measures touch on, among other things, grade 3–4 acquired pressure sores, sepsis after surgery, foreign body retention in a patient following operation, injury to the mother or newborn during childbirth, respiratory failure after surgery, bleeding around the site of surgery, the rupture of a surgical wound, iatrogenic pneumothorax, and tears (perforations) during an invasive procedure [5–7]. The OECD added to this list the development of a pulmonary embolism or deep vein thrombosis, medication

errors, acquired pneumonia, and any acquired infection.

In England, the NHS (National Health System) has added a risk assessment for blood clotting complications, falls with damage, and nurses' work beyond a predefined safety cap. The leading countries in terms of safety indicators are Denmark, Canada, and Australia [8].

An example of a safety indicator is something that detects a problem that arises from a process in a hospital and can cause damage or death and that can be prevented by improving the process, for example, an unexpected result of surgery such as respiratory failure or sepsis developed within a week of elective surgery. The denominator is the number of patients who have undergone predefined types of surgery and the number of patients in whom there was such an indicator (respiratory failure or sepsis). The rules according to which the indicators are selected should meet the criteria of Mark Chassin as established for quality, process, and outcome indicators [9]. Another example is the development of a pressure ulcer in the buttock, heel, nose, or another organ while hospitalized in the internal, surgical, and orthopedic department in a patient who was hospitalized without a pressure ulcer—thus having an unwanted result of hospitalization. The denominator includes all the patients who were discharged from these wards, and the numerator is the number of patients who developed a pressure ulcer during hospitalization, grade 2 or higher, which was not present when they were admitted, and patients who acquired another pressure ulcer during hospitalization. A structured plan of safety indicators adapted to the specific hospital department or community clinic, with goals that are updated once a year, will result in continuous improvement in treatment safety.

There is a place to emphasize the International Patient Safety Goal (IPSG) indicators according to JCI requirements: ensuring patient identification, improving communication, reporting critical results, improving the safety of drugs at risk, confirming the correct surgery, confirming the right organ in the right patient, and preventing falls. Some suggestions for patient safety indicators are presented in Table 12.1.

Table 12.1 Suggestions for patient safety indicators

Indicator	Source
A foreign object left in the patient's body after surgery	OECD
Pulmonary embolism after joint replacement	OECD
Deep vein phlebitis after joint replacement	OECD
Sepsis after abdominal surgery	OECD
Suture separations in the abdominal wall after surgery	OECD
Childhood trauma after instrumental birth	OECD
Postnatal childhood trauma without using instruments	OECD
Mortality in disease with rare mortality	AHRQ
Mortality among patients undergoing surgery with treatable complications	AHRQ
Rate of pressure ulcers developed while in the hospital	AHRQ
Iatrogenic pneumothorax	AHRQ
CLABSI	AHRQ
Rate of bleeding or hematoma after surgery	AHRQ
Respiratory failure after surgery	AHRQ
Adherence to patient identification rules at several critical points such as admission to the MD, before imaging, and in the operating room	JCI
Documentation class read back in laboratories and departments	JCI
Rate documents and critical result reports	JCI
Rate of preprepared hazardous electrolyte solution use	JCI
Proportion of cases in which the operated limb is marked	JCI
Marked by the surgeon	
Rate of risk assessment performance for deep vein thrombosis in internal admission	Israel Ministry of Health
Adherence rate for hand hygiene guidelines	Israel Ministry of Health
Adverse events, "near-miss" events, and "don't happen" events reported	Israel Ministry of Health
Colonoscopy rate in people with a positive result for occult blood in the stool	Israel Ministry of Health
Errors in diagnosis and treatment	Israel Ministry of Health

CLABSI Central line-associated bloodstream infection, *JCI* Joint Commission International, *OECD* Organization for Economic Co-operation and Development, *AHRQ* Agency for Healthcare Research and Quality

Key Messages: Assessment and Measurement of Risk Management Activity and Patient Safety

The direct measurement of the success or failure of a structured risk management program should assess clear outcomes such as mortality or significant adverse events, reported adverse events or "near misses," complaints related to patient and staff safety, staff attrition, or expenses for medical malpractice claims:

- In Israel, there is still no national plan for quality measures directly aimed at maintaining treatment safety or, in other words, a national plan for safety measures. In the USA, safety measures have been prepared by the JC, NFQ, and AHRQ. The OECD, the English NHS, Australia, Denmark, and Canada have comprehensive safety indicator programs.
- An example of a safety indicator is something that detects a problem arising from a process in the hospital that can cause damage or death and that can be prevented by improving the process, such as an unexpected result of surgery, the development of a pressure ulcer, or a fall in an internal department.
- The rules according to which the indicators are selected should meet the criteria of Mark Chassin as established for quality, process, and outcome indicators.

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13 Patient Safety and Risk Management Organizations and Institutions

13.1 International Organizations

13.1.1 WHO: World Alliance for Patient Safety

In May 2002, the World Health Organization Assembly passed a resolution[1] (WHA 55.18) encouraging countries to pay as much attention to patient safety as possible; this included a requirement from the Director General of the World Health Organization to carry out a series of activities to promote patient safety, including:

- Developing global norms and standards
- Promoting evidence-based policies
- Promoting mechanisms for identifying excellence in patient safety
- Encouraging research
- Providing assistance to countries in several key areas

After the resolution passed, the World Health Organization established working groups for issues such as developing a glossary of terms used in the field, conducting risk assessment, and developing systems for reporting and learning. Additionally, expert groups were convened in areas such as blood safety, injection safety, medication safety, and more to make treatment and medical equipment safer.

In November 2003, the World Health Organization, in collaboration with professional parties in the United Kingdom, held a meeting of senior decision-makers and international experts to discuss future collaborations to promote patient safety. At this meeting, Sir Liam Donaldson, a British doctor who served as chief physician in the NHS (National Healthcare System) in Great Britain and, starting in 2004, served as the chairman of the World Alliance for Patient Safety within the framework of the World Health Organization, proposed establishing a world alliance to promote patient safety. In 2011, the Alliance published, among other resources, an education program on patient safety in various settings that is still used as infrastructure for building education and training programs in the field [1].

In February 2020, the World Health Organization published a plan called "A Decade of Patient Safety 2020–2030," which was designed to address global needs in the field of patient safety and to take strategic action at global, regional, and national levels [2]. Among the activities suggested in this framework, we will highlight the following:

[1] WHO, WHA 55.18, https://www.who.int/publications/i/item/quality-of-care-patient-safety

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- Leading and centralizing the implementation of resolution WHA72.6[2] through the Global Safety Plan 2030–2021.
- Defining global priorities, planning and implementing global challenges in patient safety (Global Patient Safety Challenges), including the challenge published in 2022: Drug treatment without harm.
- Encouraging global support through promotions and collaborations around World Safety Day, observed on September 17, which in 2022 was dedicated to safe medication [3].
- Supporting patients and their families through the Patients for Patient Safety initiative.
- Developing indicators for patient safety by establishing standards, indicators, and tools for collecting information and evaluation.
- Encouraging the identification of priority topics for research activity, conducting studies in the field, and encouraging new approaches that support digital and innovative initiatives to improve patient safety.

13.1.2 ISQUA: The International Society for Quality in Health Care

The organization was founded in 1985, inspired and encouraged by the WHO, with the vision of promoting quality in health care and patient safety through international cooperation [4] and "*inspiring and leading improvement in health, safety, and quality.*" The organization manages a peer learning program in the areas of quality and safety in medicine delivered by international experts. The program is self-paced and delivered online and includes the following topics:

- Leadership in quality and safety
- Patient-centered care
- Patient safety
- Quality improvement
- Information technologies in medicine
- External evaluation systems
- Countries challenged in the areas of quality and safety in medicine
- Critical thinking in crises

In 2018, ISQUA founded the IEEA (International External Evaluation Association), a legal entity whose purpose is to provide external evaluation services and which began its activities in Geneva in January 2019. ISQUA also conducts annual international conferences. The conference in 2023 will be held in Seoul and will deal with the following topics:

- Digital medicine and innovation
- Human resources, policy, and governance
- Patient safety and quality improvement in medicine
- Equality in medicine
- Complexity, crises, and sustainability
- External assessment
- Combined treatment

The organization grants scholarships to doctors and medical staff members from developing countries to participate in the conferences and international training programs it holds.

13.1.3 OECD: Patient Safety

The OECD (Organization for Economic Cooperation and Development) places great value on activities aimed at advancing patient safety. In the organization's opinion, there has been a noticeable improvement in the quality of medicine provided to patients in the organization's member countries, but the issue of patient safety still requires improvement [5]. To this end, the OECD has begun cooperating with the World Health Organization (WHO). The issues on which the field of patient safety is based according to the OECD are as follows:

- The patients—through empowerment and reporting
- The administration—through regulation and incentives

[2]WHO, WHA 72.6, https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R6-en.pdf

- The information infrastructure—through information sharing
- The human resource—through education and development
- Leadership and safety culture

The organization publishes comparative data on the rates of adverse events in its member countries. The rates are calculated per 100,000 procedures. For example, in 2018, information on the rate of postoperative sepsis after abdominal surgery was published [6]. The organization also focuses on measuring the safety experience from the perspective of patients, measuring safety culture, and identifying indicators of the therapeutic process in support of the existing outcome indicators.

The organization claims that the direct cost of the harm caused to patients in hospitals is approximately 15% of the total cost of activities and expenses. Since a significant part of the adverse events is preventable, the cost should be considered waste; the costs of efforts to advance safety and reduce harm are dwarfed in comparison to the costs of harm caused as a result of poor patient safety [7].

13.2 US Organizations

13.2.1 IOM (Institute of Medicine): NAM (National Academy of Medicine)

IOM was founded in 1970, and in 2015, its name was changed to NAM (National Academy of Medicine). NAM is a US nongovernmental NGO (nongovernmental organization) without profit intentions, and it is one of the National Academies of Sciences, Engineering, and Medicine.

NAM provides national and international advice on issues related to health, medicine, health policy, and the science of biochemistry. Its purpose is to provide unbiased, fact-based, and qualified information to decision-makers, professionals, managers, and the general public. The organization operates based on volunteers working in a formal system of peer review. Every year, new members are elected to the organization on the recommendation of current members based on their outstanding and continuous achievements in their field of activity.

IOM has made a significant contribution in the context of safety and quality of care thanks to the report it published in 1999, "To Err Is Human: Building a Safer Health System" [8].

The report was based on research data published in 1991, according to which every year 44,000–98,000 die in the US hospital system as a result of preventable medical errors [9]. The publication resulted in an increase in public awareness of medical errors as well as their scope and cost and triggered a series of actions taken by the US government; the report also received considerable international resonance. The publication was also a turning point at which a reality that was familiar to health system personnel became common knowledge and motivated health systems across the world to improve their quality of care and patient safety. Another IOM report—"Crossing the Quality Chasm: A New Health System for the 21st Century" [10], references ways to deal with quality and safety problems in a health system and recommendations on how to improve and adapt such systems to the twenty-first century. In 2015, NAM published a book dealing with improvements in medical diagnosis processes, which represent a significant challenge to patient safety [11].

NAM holds symposia on quality and safety issues and publishes position papers on various issues on its agenda. In 2015, for example, a symposium was held to deal with the achievements and failures 15 years after the publication of the first two reports [12]. Among the most recently published position papers, it should be noted that there was an emphasis on the need to ensure reference to systemic aspects of quality and patient safety [13].

13.2.2 JCI (Joint Commission International)

JCI is an independent US nonprofit organization that provides consulting, accreditation, and certi-

fication services to healthcare organizations around the world that are adapted to hospitals, community, or home care providers. Its mission is to continuously improve the safety and quality of medical care across the world through education. The organization is active in more than 100 countries, including in hospitals in Israel [14].

The organization is recognized as a world leader in the field of accreditation and certification in quality and patient safety, and it collaborates with health organizations, regulators, public health agencies, academic institutions, and the business sector with the aim of achieving positive results in the provision of medical care. The organization has developed international standards for quality and patient safety in important functional areas common to all health organizations across the world. The standards are defined by an advisory committee that includes experienced professionals, including doctors, nurses, managers, and public health experts representing five regions of the world: Latin America and the Caribbean, Asia and the Pacific, the Middle East, Europe, and the United States. In the field of patient safety, JCI defined six international standards known as IPSGs (International Patient Safety Goals), which are presented in Table 13.1 and include issues such as the correct identification of patients, improvement of effective communication, improvement of the processes of administering potent (high alert) drugs and more [15].

JCI also publishes a monthly journal on quality and patient safety (The Joint Commission Journal on Quality and Patient Safety) that provides up-to-date information to professionals in the field. The journal also publishes research articles, literature reviews, and opinion articles.

Table 13.1 International patient safety goals (IPSGs)

IPSG no.	IPSG
1	Identify patients correctly
2	Improve effective communication
3	Improve the safety of high-alert medications
4	Ensure safe surgery
5	Reduce the risks of healthcare-associated infections
6	Reduce the risks of patient harm resulting from falls

13.2.3 IHI (Institute of Healthcare Improvement)

The IHI was officially founded in 1991, but its activity began earlier as part of a national project in the United States led by Donald Berwick and a group of visionaries who wanted to design a health system without errors, waste, delays or unbearable costs; its mission was to improve health and the quality of care worldwide [16].

The organization has grown from an entity based on research grants to an independent organization with international influence and is active in developing and disseminating tools for promoting patient safety:

- IHI's Patient Safety Essentials Toolkit, which includes nine tools that assist risk and patient safety managers in promoting patient safety; among them are a tool to promote effective communication SBAR (situation–background–assessment–recommendation); a new activity sequence tool for carrying out RCA2 investigations; a tool for conducting FMEA (failure modes and effects analysis) risk surveys that is also used by the JCI; and an ask me three tool for incorporating the patient as a partner in preventing medical errors [17].
- The IHI Global Trigger Tool for Measuring Adverse Events, which is based on finding clues about the occurrence of adverse events in medical treatment and allows the assessment of the overall level of adverse events in a certain procedure. Trigger tools have been developed in various fields, including drug administration, drug treatment in the mental health environment, presurgical processes, intensive care in children's hospitals, community care, and pregnancy and birth processes [18].
- 5 Whys: Identifying the Root Cause—a tool for investigating adverse events to understand the root causes of the problem by asking the question "why" 5 times [19].

The IHI develops and disseminates training programs in the fields of quality and patient safety in medicine and recently founded the Open School—IHI Open School Subscriptions for

Professionals and Groups— which provides online students with relevant content for learning about how to improve quality and safety in a medical organization. Some of the content is offered free of charge. The IHI also maintains a basic certification track for those who successfully complete 13 courses in the program [20].

The conferences organized by the IHI are attended by professionals from around the world in the fields of quality, risk management, and patient safety, and ideas and studies are presented to improve the quality of care and patient safety in medical organizations [21].

The IHI publishes a weekly newsletter with regular updates on its activities [22] books, and concept documents (white papers) on topics such as digital medicine, dealing with changes, attrition, and the COVID-19 virus.

13.2.4 NPSF (National Patient Safety Foundation)

The NPSF, which has been an active nonprofit organization for promoting patient safety in the United States since 1997 and has held, among other international conferences on the subject, merged with the IHI in May 2017, and since then, they have been working jointly within the IHI [23].

13.2.5 AHRQ (Agency for Healthcare Research and Quality)

The AHRQ is a leading US organization with the goal of improving the quality and safety of care. The organization develops knowledge, tools, and information to improve the health system and assists professionals and policymakers in making informed decisions [24]. The organization was appointed by the US Congress, following the publication of the IOM report in 1999, to initiate and conduct activities aimed at improving patient safety in the US. During the next 6 years, the AHRQ funded approximately 300 studies and initiatives aimed at dealing with problems in the field of patient safety [25]. The organization's website stated that in 2010–2013, 1.3 million errors were avoided, 50,000 lives were saved, and 12 billion dollars of unnecessary expenses were saved.

The purpose of investing in research is to make the US healthcare system safer and to provide higher quality care. Educational materials published for health workers by the organization aim to apply the research results in practice. The organization also develops quality and safety indicators and information for caregivers and decision-makers.

As of 2022, the AHRQ was managing approximately 45 different programs and projects designed to promote the quality and safety of care, including the following:

- A project to identify quality indicators (QI–) that make use of existing administrative information in hospitals and are designed to help decision-makers evaluate the information already in their possession. These include quality indicators in preventive medicine, hospitalization quality, treatment safety, and pediatrics. The safety indicators defined by the organization for hospitals in 2022 are shown in Table 13.2. One score is based on the ten indices, with each index having a weight based on its frequency and severity [26].
- Comprehensive Unit-based Safety Program (CUSP Program)—a safety model that includes training tools aimed at making treatment safer by imparting the basics of teamwork between doctors, nurses, and other medical staff members. CUSP was developed

Table 13.2 AHRQ PSI 90 composite measure, v. 2022

PSI 90 patient safety and adverse events composite 1
PSI 03 pressure ulcer rate
PSI 06 iatrogenic pneumothorax rate
PSI 08 in hospital fall with hip fracture rate
PSI 09 postoperative hemorrhage or hematoma rate
PSI 10 postoperative acute kidney injury requiring dialysis rate
PSI 11 postoperative respiratory failure rate
PSI 12 perioperative pulmonary embolism or deep vein thrombosis rate
PSI 13 postoperative sepsis rate
PSI 14 postoperative wound dehiscence rate
PSI 15 abdominopelvic accidental puncture or laceration rate

in collaboration with John Hopkins University and initially focused on a defined risk, such as acquired infections (Healthcare-associated infections [HAIs]). Later, the model was applied to reduce additional risks.

- Below are some results of the CUSP implementation in the United States (as of 2017) [27]:
  - CUSP—reduced central vein-related infections by more than 41% in 1000 intensive care units
  - CUSP—reduced rates of catheter-related urinary tract infections by 30% in over 700 hospital wards (non-ICU).
  - CUSP—reduced rates of catheter-related urinary tract infections by 54% in more than 400 nursing homes.
  - CUSP—reduced postsurgical infection rates in hospitals by 25% to 40%, depending on the type of surgery and follow-up method.
- Continuing education—the AHRQ provides free continuing education in areas related to quality and safety of care and holds professional conferences. In the area of patient safety, training is provided on topics such as informed consent, and a catalog of learning resources offers courses on patient safety, self-study materials, and online training. On the PSNet website, experts present an analysis of medical errors, and in the framework of medical literacy, doctors and nurses can study topics related to safety and quality and receive continuing education (CE) credits for it [28].
- Research in the field of online medicine—the creation and distribution of research information on how to optimally apply the developing digital environment for the promotion of the quality, safety, and effectiveness of medicine for patients and their families.
- The PSO (Patient Safety Organization)—program—enacted under the Patient Safety and Quality Improvement Act in 2005—authorizes the AHRQ to recognize organizations whose mission is to promote patient safety after demonstrating that they have expertise in identifying risk factors and defining intervention plans to reduce them [29].
- Surveys on Patient Safety Culture (SOPS)—The AHRQ's safety culture surveys allow healthcare organizations to assess how employees perceive certain aspects of safety culture in hospitals, clinics, nursing homes, pharmacies, and ambulatory surgical centers [30].
- Teamwork—STTEPS (Strategics & Tools to Enhance Performance & Patient Safety)—tools proven to improve teamwork skills among medical teams and designed to achieve optimal treatment results [31].

13.2.6 ASHRM (American Society for Healthcare Risk Management)

The ASHRM is a US organization founded in 1980 based on a group of approximately 6000 members from the AHA (American Hospital Association) from various sectors—risk managers and patient safety, insurers, lawyers, and financiers. The organization promotes innovative risk management strategies through education, training, publications, communication, and interactions with leading healthcare organizations and government officials.

The ASHRM's initiatives focus on implementing safe and effective treatment practices, conserving financial resources, and maintaining a safe work environment. The strategic missions of the organization are as follows [32]:

- Promoting risk managers—defining training courses to promote and position risk managers within their organizations.
- Positioning and promoting the risk management profession—promoting the profession by leveraging relations with the AHA (American Hospital Association) to strengthen the advantages of promoting patient safety by employing leading professionals as consultants in the field.
- Institutionalizing the professional authority of the risk managers—promoting innovation and changes in the medical environment and

encouraging cooperation and a diversity of opinions.
- Holding an annual conference that brings together professionals in the field of risk management and patient safety from across the country and the world.

13.2.7 ECRI (Emergency Care Research Institute)

ECRI is a US organization founded in 1968 following the tragic death of a child in an emergency room in Philadelphia as a result of medical equipment failure. ECRI is an independent nonprofit organization committed to patient safety, efficiency, and cost-effectiveness in the healthcare system. The organization focuses on emergency medicine, resuscitation, and research in biomedical engineering and is defined by the AHRQ as a PSO (patient safety organization). The organization focuses on the following areas [33]:

- Patient safety—reducing exposure to risks to improve patient safety based on the resources and services the organization provides while focusing on medication safety and the safety of information systems.
- Evidence-based medicine (EBD)—improving clinical outcomes by assisting in the development of clinical guidelines and evaluations of medical equipment, drugs, and processes.
- Assistance in making decisions concerning medical technology—achieving savings and improving performance by using proven tools to assist in making decisions.

Every year, ECRI publishes a list of ten major technological risks. Below is the list for 2022 [34]:

1. Cyber security attacks that may disrupt the delivery of healthcare services and affect patient safety
2. Failures in the supply chain that pose a risk to patient safety
3. Defective infusion pumps that may cause errors in medication administration
4. Insufficient emergency reserves that may disrupt the care of patients in public health crisis situations
5. Failures and human errors in online medicine that can cause adverse events
6. The failure to follow the procedures with a syringe pump that may lead to errors in the administration of dangerous drugs
7. AI-based reconstruction that can distort images and damage the diagnostic process
8. Poor ergonomics and workflows for duodenoscope reprocessing that put healthcare workers and patients at risk
9. Disposable clothing that does not provide sufficient protection and poses a risk to medical staff
10. Wi-Fi communication drops and dead zones that can cause delays in patient care, injuries, and deaths

13.3 European Organizations

13.3.1 NHS

The British healthcare system considers patient safety an integral part of its quality, alongside effectiveness and patient experience, and refers to the continuous improvement of patient safety based on a safety culture and safer systems. The NHS's—strategy—maximizing the things that are done right and minimizing the things that go wrong [35]—has been published in a comprehensive document that bases the continuous improvement in patient safety on two main foundations: a safety culture and a safe system.

The NHS's strategic plan has three main goals:

1. Improving the understanding of safety—gathering insights on safety information from many sources (insight)
2. Providing skills and opportunities to improve patient safety in the entire system to patients, staff, and other partners (involvement)
3. Planning and supporting programs that bring effective and stable change in the most important areas (improvement)

Below is a breakdown of the activities aimed at achieving the above three goals:

- Adopting and promoting key principles for measuring safety and culture and implement metrics for better understanding how safe the care is
- Using new digital technologies to support learning based on what succeeds and what fails by replacing the old National Reporting and Learning System (NRLS) with a new safety learning system
- Activating a response framework for adverse events to improve responses to them and their investigation
- Implementing a new medical investigation system for examining deaths
- Improving the response to new and emerging risks supported by the new National Patient Safety Alert Committee
- Sharing insights from lawsuits to prevent harm in the future

Involvement

- Defining principles and expectations for the involvement of patients, families, caregivers, and others in providing safer care
- Defining the first syllabus for patient safety that will be system-wide and consistent and will form a framework for education and training on the subject
- Establishing a body of patient safety experts to lead safety improvement in the entire system
- Ensuring that people are equipped with the tools required to learn from successes and failures
- Ensuring that the entire health system is involved in the safety agenda

Improvement

- Implementing a national plan to improve patient safety based on current information to help prevent the inevitable deterioration and adopting intervention plans and integrating them into the system
- Implementing a plan to improve safety in maternal care to reduce stillbirths, neonatal and maternal deaths, and injury to newborns as a result of asphyxia by 50% by 2025
- Developing a plan to improve the safety of drug treatment aimed at improving the safety of high-risk drugs
- Implementing a plan to improve the safety of mental health care to better address issues such as physical restraints and sexual safety
- Collaborating with organizations in the UK to support safety improvement in priority areas, such as the safety of older people, the safety of patients with learning disabilities, and the ongoing risk of bacterial resistance
- Promoting research and innovation that support the improvement of patient safety

In 2019, the NHS published the patient safety training curriculum for caregivers [36], with five main areas of action:

1. System approach to patient safety
2. Learning from adverse events
3. Understanding and applying principles from Humam factors—performance and safety management
4. Creating safe systems—design and planning for safety
5. Being sure about safety

The syllabus focuses on knowledge, action, and the combination of the two. For example, domain 1 (implementing a systemic approach) provides the knowledge critical for performing necessary actions in domain 2 (learning from adverse events). For those who wish to develop expertise in the field of patient safety, it is recommended that they acquire knowledge in four areas: systemic thinking, the human factor, risk expertise, and safety culture.

- In the framework of the NHS, a special unit exists for the investigation of adverse events, the HSIB (Healthcare Safety Investigation Branch) [37], whose mission is "*To improve patient safety through professional safety investigations that do not assign blame or responsibility.*" The HSIB conducts approximately 30 investigations a year, recommends changes to in the UK healthcare system, and publishes an annual report on its investigations and recommendations.

13.4 Israeli Organizations

13.4.1 NASBAR: The Israeli Society for Patient Safety and Risk Management in Medicine [38]

The society began its activities at a founding meeting on 20/03/2017. Its vision is to promote patient safety in the healthcare system in Israel while cooperating with all the parties in the system and basing its actions on the knowledge and experience of doctors, nurses, medical staff, and professionals in other disciplines. NASBAR works in diverse and creative ways to reduce the scope of errors and failures during the provision of medical care and to reduce the harm of errors to patients, caregivers, and health institutions.

The society has a board of 15 directors that represents all the parties in the Israeli health system, including the Ministry of Health, health insurance funds, and insurers. The board of directors is elected by the members of NASBAR. The society continues the path of the Israeli Forum for Patient Safety that was active in the years 2007–2013 and held, among others, scientific conferences on "hot" issues in patient safety and risk management and developed a training program for risk managers in Israel.

NASBAR holds two conferences a year:

- A one-day scientific conference in which abstracts submitted to the organization's scientific committee are evaluated and some of them are approved for presentation. Approximately 350 health system personnel participated in the last conference, in November 2021, and 30 abstracts were submitted. Nine of the abstracts were presented orally at the conference, and the rest were presented as posters.
- A weekend conference was held in collaboration with another society from the IMA (Israeli Medical Association). The last conference was held in June 2022 in collaboration with the Israeli Society for Occupational Medicine, and approximately 120 professionals from the health system participated.

In 2022, the society published four position papers on principal patient safety issues under the IMA (Israeli Medical Association) on the following topics:

- Learning and extracting lessons learned from adverse events
- Providing education and training as a means of promoting patient safety
- Promoting a safety culture in a medical organization
- Being proactive in risk management in medicine

13.4.2 The Israeli Society for Quality in Medicine [39]

The Israeli Society for Quality in Medicine was founded with the aim of promoting quality and safety in the healthcare system in Israel, and it unites multidisciplinary teams. The society's vision is "*to be the professional body leading quality in the health system in Israel*"; Its mission

is to lead and guide the promotion of quality in the healthcare system in Israel at all levels while encouraging a continuous and transparent process of measurement and improvement and to advocate for the recognition of the centrality of quality in day-to-day work, management, and medical education while striving for safe, effective, equitable care focused on patient needs and preferences.

The society's goals are as follows:

- Creating national professional forums to promote quality and safety
- Initiating and activating quality and safety conferences
- Recognizing and publicizing institutions that encourage continuous improvement in hospitals and the community
- Collaborating with international professional associations in the fields of quality in health
- Encouraging the active involvement of all health system employees in promoting quality
- Creating communication channels among society, the Ministry of Health, and the clinical field to promote national quality
- Creating and distributing tools to promote quality

The company holds an annual conference in which selected works are presented orally and posters are presented on a variety of topics related to quality in medicine, including patient safety and risk management.

13.4.3 Madanes: Insurance Agency [40]

Madanes is an insurance agency that has specialized in professional liability insurance for many professions, particularly for caregivers and healthcare organizations, and the provision of services accompanying the insurance for approximately 30 years. Madanes insures, for example, patient funds, hospitals, medical organizations, and other medical service providers through collective policy arrangements.

The field of medical professional liability is managed by two subsidiaries:

- MCI (Medical Consultants International)—which manages medical professional liability claims
- MRM (Medical Risk Management)—which deals with the risk management of the insured according to professional liability policies

MRM was established to assist policyholders in developing risk management systems and risk management plans for the purpose of minimizing the risk of patient harm that might give rise to medical malpractice claims. The philosophy underlying the company's activity for risk management in medicine is that reducing the risk of harm to patients during the provision of medical treatments benefits the patients, insured, and insurers alike. The company operates with close cooperation between the company's staff and the risk management teams of the insured in order to achieve their common goals.

The company occasionally publishes a newsletter to subscribers dealing with a variety of issues related to professional liability, risk management, and patient safety. On the company's website, one can find many resources relevant to risk management and patient safety, including:

- Informed consent forms in a variety of fields jointly developed with the IMA (Israeli Medical Association).
- Publications and articles in general medicine and dentistry
- Recommendations and audit tools (e.g., medical records in a hospital and community clinic, maternity sheets, and more).
- Judgments according to various medical specialties.
- Adverse events and lessons learned from them—sheets of casefiles.
- Lectures and presentations, most of them authored by attorney Talia Halamish-Shani, who served for many years as the CEO of Madanes.
- Guidelines for doctors that refer to issues such as civil lawsuits, inspection committees, disci-

plinary procedures, criminal procedures, notification of the insurer of circumstances that may give rise to a lawsuit, and communication during a crisis.
- Relevant MOH (Ministry of Health) circulars.
- Relevant legislation—the Patient's Rights Act, the 1977 Penal Law, and the Doctors' Ordinance.
- International articles by medical specialists on risk management topics.
- FAQ—(frequently asked questions) on a variety of topics such as medical confidentiality, keeping documents, informed consent, and minors.
- A glossary of terms used in risk management and patient safety.

13.4.4 Inbal: An Insurance Company [41]

Inbal Insurance Company Ltd. was established as a government insurance company in January 1978. The Minister of Finance supervises Inbal and the company's board of directors are headed by the Accountant General in the Ministry of Finance. The company has approximately 250 employees.

Inbal Insurance Company serves as a professional and leading functional arm of the Israeli government and the Ministry of Finance and assists in realizing its goals. The company specializes in providing diverse financial management services, including consulting, insurance coverage, and insurance risk management for the government. Inbal also serves as a platform for managing projects and assets within the area of responsibility of the Accountant General and other government units through Inbal Insurance Company, Ltd., including risk management in medicine.

As part of Inbal's internal government insurance fund, there is a medical risk management unit that has been operating since 2002. The goals and objectives of the unit include the following:

- Improving the quality and safety of medical care, increasing awareness of these issues, and reducing the insurance risk for professional liability in medicine.
- Implementing risk management in the government health system for general hospitals, psychiatric hospitals, geriatric hospitals, and regional health bureaus.
- Cooperating with government ministries, various bodies interested in promoting quality and safety activities, professional medical associations, the Ministry of Health, academic institutions, etc.
- Holding seminars, conferences, workshops, and professional forums for integrated medical teams (doctors, nurses, and paramedical professions) in various fields, such as emergency medicine, surgery, midwifery, neonatology, genetics, internal medicine, and mental health, and in the subjects of medicine and law. The goal is to provide caregivers with information on procedures and issues related to medical malpractice, proper documentation in medical records, informed consent, and confidentiality.
- Developing training tools and means for sharing knowledge such as training videos and the distribution of "Inbalit" safety newsletters based on adverse event investigations that provide caregivers with insights with the aim of increasing awareness and knowledge [42].
- Constantly updating Inbal's website in order to distribute relevant and updated information regarding medical–legal issues, patient safety, and medical risk management.

The unit for managing medical and insurance risks in the government health system works aims to improve the quality of medical care and reducing the cost of professional liability lawsuits against the state in the field of medicine. This activity is focused on improving risk assessments, improving the ability to identify risks and failures while offering practical solutions to prevent them, and improving the ability to navigate the court system. The units' activities are conducted jointly with the risk management units operating in government medical institutions.

The unit produces training videos on patient safety issues such as reporting near-miss incidents, patient involvement in treatments, full disclosure, mental fixation, informed consent, and communication.

The unit's website has a variety of resources for promoting risk management and patient safety, especially in hospitals, including resources in the following areas:

- Medicine and law—medical records, informed consent, medical confidentiality, legal process, and more
- Risk management in medicine—articles, legislation, procedures, circulars, videos, and presentations
- Learning from adverse events—judgments, articles, safety newsletters
- Tools from Israel and abroad—a toolbox for preventing and dealing with burnout, a methodology for organizational learning from adverse events, a safety round in the surgical department, Global Trigger Tools, and more
- Promoting a safety culture
- Communication and the therapeutic sequence
- Medical ethics
- Transparency and proper disclosure
- The products of the unit according to the type of product and medical specialty

Inbal holds an annual conference attended by approximately 300 members of the healthcare system in Israel where relevant and current topics are presented in the areas of risk management, professional liability, patient safety, and innovation. The company also promotes the field of education and training by participating in training activities at the national level in universities and initiating training activities on the subject in government hospitals. In 2022, the company, in partnership with the IMA (Israeli Medical Association), launched an online course on risk management and patient safety [43].

13.4.5 The Division for Quality and Patient Safety: MOH [44]

Promoting patient safety is an issue that concerns both policymakers and caregivers in health systems worldwide. The Ministry of Health utilizes many measures to promote patient and caregiver safety and to prevent errors and systemic failures. One of the conditions for maintaining a high level of safety is the system's ability to continuously learn from its accumulated experience, from the experience of others and by assessing the risks of possible failures.

The goal of the division is therefore to reduce the number of adverse events through the creation of a safety culture in medical institutions, including hospitals and clinics in the community.

The division's main activities include the following:

- Collecting information by various means while cooperating with health institutions
- Identifying the causes and reasons for failures
- Using the findings as a basis for developing comprehensive and targeted prevention programs
- Promoting safety by learning from adverse events based on the motivation to improve clinical and administrative processes to avoid the reoccurrence of errors
- The division holds an annual conference in which all stakeholders participate, presenting and discussing issues of patient safety on the national level

The division receives adverse event reports from health institutions according to public health regulations, which are aggregated and analyzed by senior professionals. A primary analysis is conducted to decide whether the event was a natural outcome based on the patient's condition or if it occurred under special circumstances that

require a more extensive investigation. Adverse event analysis makes it possible to identify systemic failures, the control of which has the potential to reduce risks.

Alongside its routine activities, the division also promotes a proactive approach, which involves examining medical processes in depth in order to generate recommendations for their improvement so that they become safer.

The organization publishes safety newsletters focused on a specific topic that are distributed to all parts of the health system. Recommendations for the general public on how to prevent errors in treatment are also available on the division's website.

In 2017, the division initiated the "condition for support" project to encourage standard activities aimed at promoting patient safety in hospitals [45], and in 2020, it initiated a similar project for community healthcare funds [46]. The projects include eight indicators, including the quantity and quality of safety investigations, the reporting of adverse events and "near-miss" events, the implementation of systemic recommendations, patient safety training and education, safety rounds, and more. Organizations that receive a minimum score are given significant financial support to develop and widen their activities in advancing patient safety.

13.5 ASRS: Aviation Safety Reporting System [47]

To determine how other high-risk industries cope with learning from errors and adverse events, we will present the activities of the ASRS (Aviation Safety Incident Reporting System).

The ASRS is a voluntary, confidential, and anonymous reporting system from the United States Federal Aviation Administration (FAA) that allows pilots, air traffic controllers, technicians, ground crew, or anyone connected to the world of aviation to report "near misses" and incidents in order to improve flight safety. The ASRS collects, analyzes, and responds to reports to reduce the probability of aviation accidents.

The ASRS is managed by NASA, which is seen as a neutral third party due to its lack of enforcement authority and existing working relations with airlines. The confidential and independent nature of the ASRS is key to its long-standing success in identifying many latent systemic risks in aviation.

The FAA grants limited immunity to individual airline employees who report safety incidents that do not cause an accident as defined by the FAA. This is to encourage potential reporters to report systemic safety problems and risks without fear of penalty. The success of the system is a positive example and a model for other industries in the United States and the world that seeks to promote safety, including rail services, health care, firefighting, and offshore oil production. As of 2022, approximately 10,000 incidents per month are reported to the system, most of them by civil airline pilots.

The ASRS's site allows the following:

The voluntary reporting of safety incidents and risks

Searches in the database

The viewing of prepared reports on a wide variety of topics, such as fatigue of aircrews in civil airlines, deviations from altitude, bird strikes on planes, incidents related to a failure to follow checklists as required, teamwork, and incidents related to maintenance

The viewing of a monthly publication, CALLBACK, focusing on a "hot" topic, and the analysis of reported events

Key Messages: Patient Safety and Risk Management Organizations

- Parallel to the development of the field of patient safety following the publication of the IOM report in 1999, various organizations were established and developed to promote patient safety in its various aspects. However, some of the patient safety organizations were established before the publication of the report. Some of the bodies are state bod-

ies related to the regulator of the health system, some are nongovernmental organizations (NGOs), some are academic bodies aimed at promoting education and research in the field, and some are commercial, such as insurance companies that have a commercial interest in reducing the scope of claims and compensation paid to victims as a result of failures during medical treatment.

- It is worth noting the paucity of patient organizations aiming to promote patient safety in healthcare systems, even though patients are the main victims of a low level of patient safety.
- Most of the organizations described in this chapter have websites that contain information and resources that can help health organizations learn about and promote patient safety. There is a need for circumspection when choosing information and tools and adapting them to the specific characteristics of an organization.
- Most of the organizations described in this chapter focus on the hospital environment, and a minority of them also refer to community medical environments, which have unique characteristics. This somewhat limits the transfer of information, concepts, and tools.
- In addition to the organizations described in this chapter, there are many organizations that focus on specific sectors, such as laboratory safety, anesthesia, and medical devices.
- There is a large degree of overlap among the three fields—patient safety, risk management, and quality in medicine—as described in Chap. 3. When looking for organizations that specialize in patient safety, it is recommended to examine the other two fields as well.

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Current Trends in Risk Management and Patient Safety

14

14.1 Concepts and Principles

The foundational concept of risk management in medicine is that one should prepare for the worst and not be caught by surprise regarding treatment safety and adverse and unexpected events. The cliché "it won't happen to me because it hasn't happened yet" has no basis in reality. The frequency of occurrence and the chance that something will happen should, of course, be taken into account in planning and assessments, but they are not enough to dictate policy. Even a rare event can be extremely significant. It should also be clear to every organization that the purpose of risk management is to understand the possible and expected failures and to prevent them through appropriate organizational assessments and not to look for those guilty of the failure and seek to punish them. This concept has been changing, as described in previous chapters, since 1999 in all advanced health systems. Organizational safety culture is important in preventing failures and mistakes in medical treatment.

Important risk management principles are as follows:

1. A detailed risk management plan should be prepared for all content worlds that the medical institution deals with and should be specific for each of the departments and units, starting with the clinical/medical aspect and ending with the administrative/logistical aspect.
2. Those involved in risk management should have appropriate training, an inclusive and empathetic personality, leadership skills, and management ability to lead the issue in the organization and gain the support of the staff and managers.
3. The risk manager should be of a high rank and report directly to the director of the institution so that his words will be taken seriously by all employees.
4. The risk management plan should be orderly, transparent, and clear and contain the tools for continuous retrospective, interactive, and prospective work.
5. The members of the risk management unit should be available to the staff members and provide advice and guidance during an incident.
6. Do not look for culprits ("no name, no blame, no shame"); instead, seek to prevent systemic failure.
7. Cooperation with the victim and his family, transparency, apologies, and compensation are the new milestones in risk management and have come to replace the need for lawsuits and unnecessary and harmful publicity.
8. The second victim, the staff member who unintentionally harms the patient, should not be ignored when all he wants is to treat patients well and correctly. On the one hand, emphasis must be placed on skilled human resources in sufficient quantity to perform

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tasks, appropriate training, and burnout prevention, and on the other hand, a structured and clear rehabilitation plan should be prepared if necessary.

The COVID-19 pandemic that began at the end of 2019 and continues at the time of writing has led to intense activity on the issues of innovation in the various fields of medicine. The need to answer many questions that have arisen related to COVID-19—diagnosis, clinical course, treatment, vaccination, prevention—has led to the opening of means of diagnosis, identifying variants, assessing infection, understanding the course of the disease, and evaluating the effectiveness of vaccination and treatment. This innovation intensified the need for risk assessment in the introduction of new methods, the reporting of adverse events, and extensive systemic learning [1]. It is necessary to take into account the health values that are achieved by introducing new procedures and drugs and compare this with the financial investment, complications, side effects, and adverse events that are expected according to risk management plans [2]. Personalized medicine, which takes into account the specific suitability of the treatment to the patient (as in cases of cancer, heart disease, or diabetes), may prevent a significant number of possible failures [3].

14.1.1 Just Culture (A Culture of Safety "from Justice"): The Search for Balance Between the Human Factor and the System

A basic assumption is that the goal of the medical team is to provide correct, beneficial, and efficient treatment to the patient and to take care of his well-being. An error in medical treatment that causes a serious adverse event or death can be considered negligence if the therapist did not meet the requirement of acting as a reasonable therapist providing reasonable treatment, and this is subject to the court's decision. However, even in a clear case of medical negligence, there is no element of intent to harm, and the conduct is done in good faith. The use of punishment for medical errors has undergone many changes throughout history according to what is accepted in each period and the context of punishments accepted in different societies and cultures.

For example, Hammurabi's laws are the most well-known and comprehensive codex of laws from the ancient Middle East and were the first to be discovered in modern times [4]. The concept of reward and punishment contained therein changed beyond recognition in the modern period when the concept of compensation was anchored in civil law and required proof of the existence of accepted norms of information, deviation from them, the existence of damage, and a causal connection between all these. Later, this approach was replaced with the "no-fault" approach, which anchored the provision of fixed compensation upon proof of damage as a result of medical treatment, without blaming the therapist, through customary professional insurance.

As mentioned, the development of the concepts of safety, punishment versus training and education, looking for the guilty versus engaging in systematic learning, and preventing similar cases of error have undergone many changes throughout the world for many years, transforming from their application in Hammurabi's laws to the "no guilt" approach. In the USA, every state is free to decide its own treatment of this issue. In Virginia and Florida, the "no-fault" approach exists only for neurological injuries related to childbirth. In these programs, restrictions and criteria are set for the level of coverage and eligibility for compensation. There is no compensation for nonmonetary damage such as pain and suffering, and the amount of compensation is usually lower than in the existing torts in Israel. These systems are more efficient than others and even have restrictions on whether a case can be brought to court. This approach is also practiced in New Zealand (starting in 1972) and in France. In the United Kingdom, a law was passed in 2019 to establish an independent investigating body for adverse events, the Health Services Safety Investigations Body (HSSIB), which would maintain the confidentiality of its investigations and conclusions [5]. This law

addressed three main issues: the legal recognition of an independent investigative body with statutory powers allows legal privacy for investigations (a "safe space"), gives the established body extensive powers to conduct investigations, and supports systemic learning within the English health system (NHS).

Over the last 20 years, the approach of a culture of safety from the perspective of justice, a just culture, has developed; such a culture takes into account the possibility of human error, the preventive systemic framework, and unreasonable and undesirable human conduct that requires individual attention, including punishment. A culture of safety from the perspective of justice maintains a balance between the need for an environment in which errors and failures are reported openly, the organization's commitment to patients and caregivers, and the quality and safety of care and its results [6, 7]. This safety culture shifts the focus from errors and results to the design of the system and the behavior of all its human components. This perspective applies to various professions in medicine, such as anesthesia, surgery, emergency medicine, and intensive care as high-risk, and a focus on the use of detailed labeling lists to prevent or treat crises, the training and education of teams for risk management, practice, and simulations about how to behave during a crisis and many other methods to prevent adverse events.

A culture of safety from the perspective of justice promotes leadership, effective communication, and teamwork. In 2020, the US Congress established the Agency for Healthcare Research and Quality (AHRQ) to implement a culture of safety from the perspective of justice [8]. This institution has published guidelines on how to change the safety culture and promote treatment safety: Strategies and Tools to Enhance Performance and Patient Safety (Team STEPPS). These guidelines address leadership, effective communication, and teamwork based on sharing and mutual support among team members. Emphasis is placed on full openness and transparency and, above all, the immediate notification of any safety hazard by any member of the staff regardless of position or status [9]. According to the method laid out in the guidelines, human behavior that causes a mistake or failure can be defined in one of six ways: incorrect judgment, malicious action, careless action, dangerous action, and unintentional error. There is always a need for systemic learning and plans to prevent failures, but in addition, the nature of human behavior should not be ignored. In cases of misjudgment or unintentional error, emphasis should be placed on education and training activities. In cases of careless action or the violation of procedures, knowledge and understanding of the procedures must be checked to ensure compliance in the future. In the case of a dangerous or, of course, malicious action, punishment may be appropriate. It must also be understood whether another reasonable therapist would have acted in the same or a different way. The recurrence of the same safety problem requires an investigation and repeated practice to deepen the understanding of both the human factor and the systemic factor.

14.1.2 PROMs (Patient-Reported Outcome Measures): Listening to the Patient

The results of treatment in the eyes of the patient have been expressed in the past in health-related quality-of-life studies using structured questionnaires that weigh the patient's subjective ability to assess his condition before and after treatment and objective data showing the changes. In the last decade, an approach has been developed in which the patient evaluates the improvement in his health condition after the treatment, especially after a surgery that impacts quality of life, such as the replacement of a hip or knee joint. These data can increase the alignment of expectations between the therapist and the patient, improve satisfaction, and even directly influence the management of similar cases in the future [10, 11]. This process provides important data regarding the effect of the disease or procedure on the patient and the functional results of the treatment and occupies an important role in the "patient-at-the-center" approach. The method is

based on targeted and validated questionnaires that accurately assess the patient's condition at each stage of the treatment process, including before and after it, at regular intervals; allows the early detection of unexpected events, side effects, or patient reactions; enables early preventive intervention; and gives the patient an opportunity to provide input on or intervene in the treatment and follow-up procedures. Since the process is still in its infancy, there is room for prospective studies that can highlight its benefits for patients and refine its use to achieve the desired results. In a meta-analysis that included 50 articles, four main achievements of the PROM were described: prior active participation of the patient in the management of his illness improved directed clinical consultation, improved the quality of treatment and its exact "tailoring" to the patient's measurements, updated the standardized monitoring of the patient's condition, and improved the relationship and alignment of expectations between the therapist and the patient [12]. Quite a few failures in the process were also identified: limitations on the therapist's ability to direct an informed consultation, the inaccurate evaluation of results, unrealistic expectations from the process, blockers in the relationship between the clinician and the patient, a lack of valuable clinical information, and the provision of information that is not suitable for the patient.

The development of the PROM can be aimed generically (granting the ability to compare diseases and treatments) or at specific diseases and treatments (thousands of different questionnaires have been developed) [13]. It is still difficult to assess the method's contributions to treatment success or postprocedure courses, although prospective studies have shown an improvement in diagnostic processes and treatment outcomes [14]. One of the most important conclusions now is that the preparation of the PROM questionnaires must be done in collaboration with the patient population to achieve the best results [15]. The questionnaire must cover health status, the quality of life related to health status at every stage, and the patient's feelings (well-being), satisfaction with the treatment, symptoms, and abilities (functioning vs. disabled) [16].

14.1.3 Risk Management in Home Hospitalization

The concept of home hospitalization is not new, although there is a tendency to interchange the term "home care" with "home hospitalization." The term "hospitalization at home" is meant to indicate that there is an indication to hospitalize the patient, but this can be done at his home instead of in a hospital. In most cases, the patient has a disease or condition that requires hospitalization in an internal medicine department or another nonsurgical department (dermatology, neurology, etc.). To ensure high-quality and safe home hospitalization, proper medical and nursing support is necessary. The need for this has been leveraged during the COVID-19 pandemic mainly to prevent overburdening hospitals. When it was understood that it is possible to treat mild and moderate COVID-19 patients, and even those who need oxygen, at home, the insight spread that it is possible to support and encourage such practice.

Recently, a home hospitalization program was implemented in the US by the Centers for Medicare & Medicaid (CMS), which is operated by and under the responsibility of hospitals [17]. A review and meta-analysis article analyzed nine randomized control trials that compared home hospitalization with regular hospitalization in patients with chronic diseases such as chronic lung disease, heart failure, asthma, stroke, and neurovascular diseases [18]. No difference in mortality was found, and there was even a significant decrease in the need for rehospitalization. Fewer cases of depression and anxiety were found in the patients hospitalized at home.

In Israel, there are effective and strong health funds that have been providing home care for many years in one form or another. Hospitalization at home is desirable and may be very successful, attractive, and suitable for many patients.

Recently, the position of specialist nurse has appeared in community clinics, and there has been great progress in telemedicine and digital medicine, which can promote and support home hospitalizations in an efficient, high-quality, and safe manner.

In the definition and characterization of home hospitalizations, the following issues must be well defined:

1. Indications for hospitalization: the exacerbation of chronic diseases, acute diseases, the transfer of convalescents from hospitals, post-surgery conditions, oncology patients, and hospitalization of children
2. The selection of patients according to their condition: criteria for acceptance or exclusion and risk assessment (risk scoring)
3. Referral sources: medical centers, hospital outpatient clinics and institutes, community clinics and institutes, family doctors, directly from home
4. Initial examination location: in the hospital emergency department or a community emergency center or in the patient's home from the beginning
5. Organization and working methods: the frequency of doctor and nurse visits, consultations with specialist doctors, consultations with medical professionals, treatment by health professionals, telemedicine, the responsibility and performance of the health insurance funds and/or hospitals, and the maintenance of therapeutic continuity
6. Matching expectations with the patients: using patient-reported outcome measurement (PROM) and patient-reported experience measurement (PREM) questionnaires

It is necessary, of course, to maintain the quality and safety of the treatment, the patient, and the therapist, including building a systematic plan for risk management in each of these sections. At the time of writing, there is still no clear regulation of home hospitalizations. It is necessary to plan and adopt regulations according to the accumulated experience and to adapt risk surveys and plans to prevent risks.

14.2 Patient Safety Practices: What Truly Reduces the Risks to Patient Safety?

The most important thing in conducting risk management in an organization is ensuring ongoing and continuous organizational learning. Every event should be treated as a lever for learning, understanding, and preparing plans to prevent adverse events from happening again. This is only possible when there is an organizational culture of transparency, cooperation, and the mental fortitude to admit a mistake and see the organizational and human failures that caused it. The cornerstone for proper and efficient conduct is the effectiveness of the reports and the investigations that follow them. Reporting on an adverse event in real-time allows for an in-depth root cause investigation that covers the failures and what causes them to happen and then affect the patient. The more failures that are identified, the more effective it is to learn how to prevent them and thus prevent the next event. It is the dissemination of the conclusions of the investigations to all concerned, at the local and national level, that to systemic learning and desired behavioral changes. This can be done through conferences, workshops, information bulletins, scientific publications, and dedicated meetings at every level.

14.3 Changes in Regulations as a Lever to Advance Patient Safety

Risk management is designed to help decision-makers choose and implement the right decisions under conditions of uncertainty and limited resource availability. Consistency, uniformity, and transparency in making governmental decisions are necessary to gain the public's trust and obtain cooperation from all the players in the arena. Regulations should be based on tested and agreed-upon data, accurate risk quantification, and cost-benefit analysis. Regulations should be flexible and follow developments on the subject. The results of investigations, inspection committees, and control and quality committees should

be studied and investigated with extreme rigor, and the conclusions should be disseminated for systemic learning in an orderly and clear manner. Following regular summaries of the available knowledge, new risk management plans should be prepared, and existing plans should be updated and, importantly, disseminated among medical teams.

There is no such thing as a "zero risk" situation, so this is not the goal of such regulations. The risks must be managed with the understanding that it is impossible to reach a situation of "zero risk," but it is possible to reduce the severity and the probability that risk will be realized using a cost-benefit calculation.

The safety of the treatment, the patient, and the therapist should be at the center of the actions of the Ministry of Health and the medical institutions, and relevant guidelines should be updated and improved regularly. It is important to accurately characterize what may harm public health, which of the risks should be selected and treated and which should not, how each of the selected risks will be treated, whether the treatment is indeed successful and the threat of risk decreased, what changes after the measures are implemented and how to proceed from there. The process is dynamic and should not be unmonitored but instead checked and improved continuously.

Dealing with risks involves three strategic options: risk acceptance, avoidance, and mitigation. There should be a choice in advance that is as precise as possible and based on a systematic plan of which risks to ignore, which to avoid, and which to reduce. Risk reduction is of course the main strategy and includes reducing the probability that the risk will materialize and the severity of its impact and involves equipment and technology, instruction and training, supervision and control, and process improvement. The benefits of risk management activities, the expected damage from risk, and the cost of risk reduction must be taken into account. Regulators must choose the method that minimizes social loss while understanding that risk management in medicine involves human lives and not just financial costs. The management of limited resources, uncertainty, and the reality of having only partial information all need to be taken into account in risk management plans [19].

14.4 Second and Third Victim: Consequences and Coping

Although the patient's place is at the center of care—everything is done around and for him—the staff member who caused the error or the therapeutic failure and the staff themselves/the medical institution whose name has been damaged should not be ignored. The relevant concepts must be well defined, and a special plan must be made for the rehabilitation and healing of the second victim and the strengthening of the image of the third victim, that is the medical institution. Mistakes resulting from an overburdening workload created due to a lack of human resources, the early retirement of doctors and nurses, and continuous attrition have entered the spotlight during the COVID-19 pandemic. In a 2-year study involving 36,000 participants, primary care physicians in the USA, signs of attrition were found in approximately 50%, and 29% of the participants knew of clinics that had been closed due to the early retirement of doctors [20].

14.5 Methodologies and Tools (See Also Chap. 11)

There are many methodologies and different tools for carrying out risk management activities, starting with assessing possible damage and rating failures and ending with forms of investigation and drawing lessons. Each medical institution should adopt the appropriate tools for its activity, learn their use, and ensure excellence in their performance over time. Only in this way will it be possible to achieve good results in assimilating these tools and maximizing their capabilities for systemic learning and improving treatment safety.

Retrospective and proactive risk management activity relies on databases of results of current clinical activity (medical records), current uses of drugs (dispensing and administrative pricing

data), the results of adverse event investigations, reports of adverse events and "near-miss" events, and the results, recommendations, and conclusions of inspection committees, control and quality committees, legal opinions, and verdicts. Modern tools such as artificial intelligence (AI), business intelligence (BI), and powerful computers will enable the intensive and rapid analysis of databases and the continuous and daily use of analysis results for providing systemic learning, preventing failures that can be anticipated, and ensuring proper legal defense.

14.6 Ethics: Defining the Therapist's Duties in the Context of Treatment Safety and Risk Management—Reporting and Transparency

Full transparency and full disclosure should be practiced by every therapist, who should serve the patient's best interests. Any adverse event must be reported immediately, especially if there is a danger to the patient but also in "near-miss" events, to fuel systemic learning. Proper disclosure in the event of a mistake or failure to the patient and his family members must be made immediately and at the same time as maximum treatment is given to reduce the damage and prevent complications that could endanger the patient. The therapist must continue to respect the patient even when he has caused him harm, be open and transparent with him, and always have the best interests of the patient in mind. Sometimes, it is not easy to admit a mistake or a failure, especially when considerable damage has been done to a patient. However, even in such cases, one must apologize for the injury, provide updates on what is happening and coordinate expectations regarding the continuation of treatment and the chances, risks, and required compensation. Compensation should be given according to the extent of the damage, but this alone is not enough. Compensation should always be accompanied by an apology and acceptance of responsibility [21–23].

An apology, when harm has been caused, is suggested within the framework of the therapist–patient relationship; it is an ethical guideline and is supposed to be part of normative human behavior; however, this topic is also under discussion in several countries as a bill or "Apology Law," according to which the apology of a therapist cannot be used as evidence in a trial. Additional ethical aspects in risk management in medicine also exist in the flow of information between the risk manager and the management of the medical institution. To maintain an open and transparent dialog between the risk manager and the medical teams, there is sometimes an agreement that not all the information acquired in the investigations or in dialog after a mistake or failure that could cause harm to the reporting staff member will be passed on to the institution's management. This approach allows the risk manager a measure of discretion and protects the reporter from punishment.

An institutional ethics committee, according to the Patient's Rights Law in Israel, has the authority to order the concealment of information from a patient when this information could cause him harm. Additionally, this committee has the authority to oblige the provision of life-saving treatment to a patient who refuses to receive it and to transfer confidential medical information [24].

14.7 Research Activity, Professional Journalism

From 1968 to 2022, 129,288 articles dealing with risk management in medicine were published in medical scientific journals (keywords: risk management in medicine) (Fig. 14.1). Before 1999, only 5899 studies were published. Since the publication of a report by the Institute of Medicine (IOM) and the change in attitude that says that following an adverse event, a root cause investigation should be carried out and an attempt be made to improve the systemic structure rather than look for culprits (no name, no blame, no shame), 123,389 articles on the subject have been published (as found on PubMed). The change to

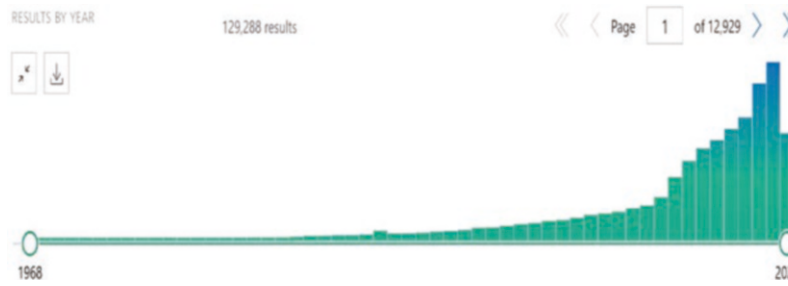

Fig. 14.1 The number of publications on risk management in medicine listed on PubMed as of 29.7.2022

a nonpunitive approach, which seeks systemic learning to prevent similar cases in the future, has resulted in intensive research activity and an exponential increase in the number of articles on this subject over the past 23 years. Indeed, in matters of risk management in medicine, as in any other field, without research and learning, there is no improvement and progress. The jump that occurred during this period would not have happened without in-depth and comprehensive research showing a significant change in patient safety following the implementation of risk surveys and risk management plans in all areas of medicine. It is the duty and the right of the clinician and the researcher to investigate practices and make them public. An article summarizing clinical practice and its results repeatedly references the foundational value of digitalization, which serves as an inexhaustible source of improvement in subject knowledge for therapists all over the world [25]. Scientific proof of the effectiveness and safety of the treatment is of great importance in choosing a strategy for managing health systems, quality plans, and treatment safety in all the content worlds in medicine. The selection of quality and safety indicators relies on scientific proof of their effectiveness and continuous improvements in medical treatment [26].

14.8 Availability of Health Services, Queues, and Patient Flow Control [27–32]

Health services that are not available and accessible to the population, even if they are high quality and safe, may fail to fulfill their tasks, may cause adverse and unexpected events, may bring harm to patients, may cause a decrease in their satisfaction, and may force patients to use expensive services. In 2001, the American Institute of Medicine (IOM) identified waiting times as a direct influence on the quality of care and as a key indicator of a health system's performance. Long waiting times may negatively affect health outcomes and cause dissatisfaction and mental stress among patients. Additionally, this may cause patients to be diverted from a public health system to a private system, to take out additional private insurance, and to significantly increase their health care spending. Great importance is given in countries undergoing reform to measuring waiting times for examinations, diagnostic and therapeutic procedures, and elective surgeries. Every 2 years, the OECD publishes information on the average wait times of its partner countries. In the Netherlands, hospitals are obliged to report the waiting times for surgeries once a month. In Canada, waiting times are sometimes measured directly by surveys and tests. In the US, waiting times are checked by phone samples. In the Veterans Affairs Community Care Network in the US, the exact waiting times are measured retrospectively in primary and consulting medicine. A significant number of quality indicators, and process indicators, measure the amount of time certain actions required in diagnosis and treatment take. Examples include the completion of computed tomography of the brain within 25 min and the provision of thrombolytic therapy within 4.5 h (TPA) of a stroke patient arriving at the hospital, the provision of therapeutic cardiac catheterization in patients with a certain type of myocardial infarction (ST Elevation MI, STEMI) within 90 min of arrival, the time from the patient's

arrival at the emergency department to the beginning of the triage process, and the rate of rehospitalization in the internal department within 30 days and more. These indicators form an important process in a given clinical situation and an operational procedure to be followed with the appropriate timing. It is not enough to perform the required action; the timing of the action is also important.

There are, as mentioned, different methods for measuring and evaluating waiting times, and different countries use different forms of measurement. For example, they may use a prospective or retrospective approach, measure the minimum time for the first or third meeting, or use a combination of several approaches. It is very important to measure the actual time that passes between the first attempt to set up a meeting and the actual execution of the meeting [30]. In 2012, a comprehensive survey was carried out that showed that 28% of the respondents waited for more than a month to see a specialist doctor [32]. This prompted patients to use private medical facilities, where appointments were almost immediately available. Additionally, the survey showed that the queues at public medical facilities were shorter for those with higher education and for residents in the center of the country. A clear distinction can be made between waiting for an appointment ("waiting at home") and waiting at a clinic or hospital for a consultation, examination, or elective surgery. The first can have a direct effect on the patient's health and the second may affect his satisfaction more than other outcomes.

In addition, to wait times (queues) for elective activities, the high-quality functioning of medical institutions is of great importance, given the regular and rapid flow of patients in emergency medicine departments. The accurate mapping of the bottlenecks in management in the emergency department and proven models for improving the efficiency of patient flow will limit the suffering of those waiting, streamline treatment, prevent unnecessary waiting, and improve patient satisfaction [31].

Key Messages: Current Trends in Risk Management and Patient Safety

- The foundational concept of risk management in medicine is that one should prepare for the worst and not be caught by surprise regarding treatment safety and adverse and unexpected events.
- Over the last 20 years, the approach of a culture of safety from the perspective of justice, a just culture, has developed; such a culture considers the possibility of human error, preventive systemic frameworks, and unreasonable and undesirable human conduct that requires individual attention, including punishment.
- In the last decade, an approach has been developed in which the patient evaluates the improvement in his health condition after treatment using PROM (patient-reported outcome measurement) questionnaires, especially after surgeries that impact quality of life, such as those to replace hip or knee joints.
- The term "home hospitalization" is intended to indicate that this is a patient who must be hospitalized, but this can be done at home instead of in a hospital. In most cases, the patient has a disease or condition that requires hospitalization in an internal ward or nonsurgical ward (dermatology, neurology, etc.). To ensure high-quality and safe hospitalization, proper medical and nursing support is necessary.
- The most important part of risk management in an organization is ensuring ongoing and continuous organizational learning. Every event must be treated as a lever for learning, understanding, and preparing a plan for the prevention of the same adverse event again in the future. This is only possible when there is an organizational culture of transparency, cooperation, and the mental forti-

tude to admit a mistake and see the organizational and human failures that caused it.

- Risk management is designed to help decision-makers choose and implement the right decisions under conditions of uncertainty and limited resource availability. Although the patient's place is at the center of care, and everything is done around and for him, the staff member who caused the error or the therapeutic failure and the staff themselves/the medical institution whose name has been damaged should not be ignored. The relevant concepts must be well defined, and a special plan must be made for the rehabilitation and healing of the second victim and for strengthening the image of the third victim, that is the medical institution.
- There are many methodologies and tools for risk management activities, from assessing possible damage and rating failures to employing various forms of investigation and drawing lessons. Each medical institution should adopt the appropriate tools for its activity, learn their use, and ensure excellence in their performance over time.
- All adverse events must be reported immediately, especially if there is a danger to the patient but also in "near-miss" events, to ensure systemic learning. The change to a nonpunitive approach, which seeks systemic learning to prevent similar cases in the future, has resulted in intensive research activity and an exponential increase in the number of articles on this subject in recent years.
- Health services that are not available and accessible to the population, even if they are high quality and safe, may fail to fulfill their tasks, may cause adverse and unexpected events, may bring harm to patients, may cause a decrease in their satisfaction, and may force patients to use expensive services. Additionally, this may cause patients to be diverted from a public health system to a private system, to take out additional private insurance and to significantly increase their health care spending.

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15 Patient Safety and Risk Management During the COVID-19 Pandemic: The Israeli Experience

15.1 The Beginning of the Pandemic and Initial Insights (Waves I and II)

The COVID-19 pandemic caused by the SARS-CoV-2 virus began in December 2019 in China and spread throughout the world, infecting 614 million people and killing 6.5 million of them as of the end of October 2022. In Israel, after 2 years and 10 months of the pandemic, 4.65 million were found to have tested positive for the virus at some point using RT–PCR tests, and 11,687 had died. The typical symptoms of the disease are fever, a dry cough, weakness and fatigue, muscle pain, and in more severe cases, pneumonia, and the development of acute respiratory distress syndrome (ARDS). Evaluations to deal with the virus have encountered a large number of unknowns and many questions without a clear answer due to the lack of controlled research. The attempt to learn from previous epidemics of viruses from the coronavirus family, including SARS and MERS, did not yield useful answers regarding the infectivity of the virus and the severe clinical picture that leads to the death of a significant number of those who end up being ventilated. The COVID-19 pandemic has raised many questions regarding treatment and prevention. There were unanswered questions, and many recommendations were given based on anecdotal impressions. Many aspects of this disease have never been studied, such as the natural course of the disease and the extent of its transmission in different populations. Hence, it has been difficult to conclude the effectiveness of the proposed treatments in the face of possible damage. There have been conflicting messages in the professional literature and the popular media about the same treatment regimen. Very quickly, policymakers realized that the right way to create useful insights includes documentation, registration, clinical trials, and the monitoring of what is published across the world through strict scientific criticism. The quality and safety of the treatments are measured according to the proven benefit from the use of verified and tested data. The principle of causing no harm (primum non nocere) is also valid during a pandemic. The need for optimal treatment while minimizing the possible damage while promptly sharing insights with colleagues is understood.

Although there was no specific treatment or vaccine for COVID-19 at the beginning of the pandemic, Israel was successful in navigating the first waves. The old and familiar practices of isolation and hygiene were the basis for prevention and optimal supportive care and helped most patients recover from severe infections. In the first year of the COVID-19 pandemic, much research effort was invested across the globe to establish treatments and vaccines to stop the pandemic.

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15.1.1 Management Strategy

The COVID-19 pandemic has challenged the world in general and the world of medicine in particular. Hospital managers had to work with their staff to respond quickly while still engaging in long-term planning. The main challenges presented by management at the various levels were, among others, planning isolation wards with all the necessary infrastructure, including responding to tests/procedures if necessary; building new units in the medical center, such as a delivery and maternity room, and equipping it (medical equipment, medicines, consumables); training staff and maintaining their physical and mental health; writing new rules; activating the system for an emergency; establishing new nonhomogeneous teams and building them organically; and preparing for an aggravating scenario of thousands of hospitalized and deceased patients. This new reality of dealing with a disease whose behavior could not be predicted is reflected in the differences in the practices of hospitals, the most prominent of which relates to the operational concept of the treatment of patients with severe COVID-19 and the manner of operating the intensive care units designated for this purpose. The tours of the hospitals and the information received show that in most COVID-19 wards, a nuclear team was defined that included a team manager specializing in intensive care medicine or anesthesiology and, under him, senior doctors, residents, fellows, and interns from all medical professions. Experience has shown that in intensive care units that are augmented with intensive care teams from different fields, such as cardiothoracic surgery, neurosurgery, and even neonatology (specialist doctors and nurses with advanced basic training in intensive care), the treatment has been better due to the familiar and uniform language of the intensive care teams, the strong ability to operate the required equipment, and the high skill in treating very complex cases. We have learned that hospitals where internal medicine COVID-19 teams have worked jointly with COVID-19 intensive care teams in charge of managing the treatment of ventilated patients, including the provision of noninvasive ventilation (NIV) and high-flow oxygen (HFOC), intubation, and ventilation, have resulted in the best results for the patient and advanced the skills of internal department teams, who received an excellent opportunity to develop knowledge and skills in intensive care, ventilation, and emergency medicine. Some have argued that the extensive experience of the internal department staff in treating ventilated and complex patients has resulted in low mortality rates. The Ministry of Health established a COVID-19 website with instructions, procedures, and information regarding the teams' conduct, protection, tests, and dedicated equipment [1].

15.1.2 Infrastructure in the Hospitals

The directive of the Ministry of Health to establish a large number of COVID-19 beds required creative thinking in the search for appropriate infrastructure and a large-scale recruitment of various professionals to establish the departments. Differences found among various hospitals were caused in large part by the hospitals having different basic infrastructures. Some established a COVID-19 complex on a separate site, including biological sorting with a front-facing triage station and a separate COVID-19 complex for obstetrics and pediatrics. The warehouses for the respiratory department had high-efficiency particulate air (HEPA) filters or negative pressure in every room. In some hospitals, patients were separated using rigid washable partitions. In addition, designated sites have been allocated for performing operations such as endoscopies, catheterizations, photographs, and dialysis for delivery rooms and preemies. Access roads were marked, and blockades were set up during the scheduled transfer of patients. In most places, a detailed logistic commission was written. In all COVID-19 wards in hospitals, cameras are widely used in the common space and hospital rooms. For reasons of individual modesty, cameras are not installed in the showers and bathrooms. The photographs are shared only with staff members. There is a sign warning about cameras at the entrance to the department, and in

addition, the information is given in the orientation procedure at the beginning of the hospitalization. The pandemic has been an opportunity to recruit workers from the medical sector, including from the nursing and health professions, laboratories, and among paramedics and students, and to purchase advanced equipment. In intensive care units, there are now advanced ventilators, advanced high-flow oxygen conserver (HFOC) devices, nitric oxide (NO) devices with monitoring capabilities (including environmental monitoring), gas devices in biological hoods, video laryngoscopes, bronchoscopes, ultrasound devices, and ECMO devices. A satisfaction survey was circulated among hospitals' Directors about the Ministry of Health regulations, and help at the COVID-19 pandemic was performed (Table 15.1).

15.1.3 Repeated Comments that Appeared in the Survey

- In all subjects, there were improvements in the timeline.
- Contact and cooperation were established with municipalities and local councils.
- There were difficulties in collecting data in the computerized program for managing medical centers and building reports.
- There was a chronic lack of intensive care doctors, anesthesiologists, internists, and intensive care nurses in the periphery of the country.
- There was a lack of laboratory workers.
- Several departments in the Ministry of Health collect the same information, which is a burden on the staff.
- There was often a wait of several hours for ambulances to discharge patients.
- There is no regulation of patients at the national level, so patients with mild and moderate cases flood the emergency rooms.
- There were difficulties in discharging dialysis patients and psychiatric patients.
- Hospitals do not receive up-to-date information on red zones where patients come from so that they can be evaluated for hospitalization.

15.1.4 Training of the Teams

The uncertainty and the lack of information about the disease required a very wide range of training preparation in response to the disturbing scenarios observed. The hospitals provided extensive training for the staff, preparing them to treat patients with COVID-19. The training was carried out in a variety of ways: Some were carried out as regular and concentrated training, some were individual, some were very specific, and some were simulations. The main subjects of the training included treating ventilated patients, treating patients with complex cases, preventing infections, detecting deterioration, using the prone position, treating respiratory failure, treating sepsis, and becoming familiar with the monitoring equipment, monitors, and pumps. Up-to-date insights into the most effective treatments were transmitted to the teams on an ongoing basis, and internal treatment protocols were updated and implemented with high frequency. The sharing of knowledge and information among teams from various fields of specialization created an opportunity for brainstorming, ongoing consultation, and the assimilation of effective therapeutic insights. Nurses from regular wards have begun working in the respiratory intensive care unit to upgrade their skills and apply their theoretical knowledge under the supervision of experienced intensive care nurses. Nursing staff have taken an active part in training on operating the equipment in the intensive care unit. In addition, training for treating an ECMO patient has been provided for the entire staff of intensive care units. In the field of training, emphasis has been placed on the issues of infection prevention, protection, and spread, and in some hospitals, observers have been trained for all COVID-19 protection positions (students) that operate 24 h a day. The hospitals have disseminated lessons learned from investigations on an ongoing basis while assimilating the insights learned. A training program has been built, and approximately 11,000 nurses, 5000 nursing students, 2500 doctors, and 1500 medical students have been trained through it. Hospitals that have used staff members from the quality and safety

Table 15.1 Satisfaction with hospital management in Israel from a survey regarding the following topics

Scope of human resources	Medical equipment	Medicines	Protective equipment	Communication with the Ministry of Health	Communication with the Home Front Command	Communication with funds	Communication with nursing institutions in the area	Communication with the municipality/ local authorities	Availability of epidemiological data	Local information systems
3.09	3.90	4.27	3.82	3.36	3.60	3.81	3.27	3.80	3.50	3.63

1 = very low, 2 = low, 3 = medium, 4 = high, 5 = very high

systems to treat COVID-19 patients have received added value from these experienced and knowledgeable people who increase the quality and safety of treatment, training, and the sequence of treatment. This reality of continuous work in an emergency has highlighted the need to continue the academic activity and training of interns during COVID-19, to continue teaching, and to allow time to read and prepare for examinations. Earlier in the crisis, the Scientific Council gave permission several times to allow assistance in the treatment of COVID-19 and reduce the damage to the specialty of intensive care.

15.1.5 Clinical Activity Not Related to COVID-19

The COVID-19 pandemic has had a direct impact on the current clinical activity in all hospitals, including on the national quality indicators. A decrease in hospital activity was observed. In the first wave, instruction was given to reduce elective activity by 30–50%. Although no order was given to reduce elective activity in the second wave, the data show that the decrease in activity continued. Hospital managers indicated several possible reasons for the decrease in activity: a. Elective procedures requiring intensive care beds were not performed, b. the plight of medical and nursing personnel in intensive care units that were required to simultaneously treat both COVID-19 patients and non-COVID-19 patients, and c. the accumulated fear of infection. According to the Union of Intensive Care Physicians, there are currently 340 intensive care beds in Israel, which equates to 4 beds per 100,000 inhabitants and is lower than the OECD average of 12 beds per 100,000 inhabitants; in Italy, the ratio is 8.6 beds per 100,000 inhabitants, and in Germany, it is 33.9 beds per 100,000 inhabitants. In addition, Israel has approximately 200 doctors specializing in intensive care, a figure that is two times lower than the OECD average. This lack is prominently expressed in the periphery of the country. In the Rebecca Ziv Hospital of the Upper Galilee, for example, only three doctors specialize in intensive care. The critical shortage that has stood out is among intensive care nurses. Dr. Eitan Wertheim, Chairman of the Association of Hospital Directors, wrote to the Ministry of Health and requested an additional 340 intensive care beds. Dr. Yaron Bar Lavie, Chairman of the Union of Intensive Care Physicians, wrote to the chairman of the Israel Medical Association and asked for his assistance in adding 1000 intensive care beds. The hospital managers recommended leaving these decisions to the discretion of individual departments, which are best position to determine the scope of their elective activity while still meeting the requisite required goals demanded by the circumstances.

15.1.6 Attrition of Staff Members

The health teams in Israel have been at the forefront of the effort to deal with the COVID-19 virus since February 2020, a long period that has resulted in the attrition of the teams. The teams have attributed their burnout to the physical difficulty involved in working with full protective equipment, their long working hours, fear of contagion, the lack of human resources due to teams going into isolation, the difficulty of finding arrangements for their children in the absence of educational frameworks, and the confrontation with high mortality and tragic outcomes of the disease. Additionally, in this matter, there have been differences among hospitals in terms of the length of the shifts, which ranged from 8 to 12 h; in terms of the duration of assignments to the COVID-19 ward and staff turnover (the range varies from a month to an unlimited time); and in terms of shift durations in the COVID-19 ward (range 2–6 h). All of this requires a targeted plan to strengthen the mental resilience of the teams and prevent them from collapsing. The hospitals were prepared with a variety of impressive programs and proactive interventions. The plans included taking teams on vacation; engaging in refreshing, proactive discussions with the teams about posttraumatic stress in all its aspects; the rotation of the teams/departments treating patients with COVID-19, including training

before entering the COVID-19 complex to reduce uncertainty and ensuring proper protection and a conversation with the department's management before, at the end of the assignment and 1 month later; coordination with kindergartens and schools for the children of staff members to be looked after; and the creation of an assistance center. The hospitals reported on the support actions they initiated for the staff members in isolation, which included the provision of accommodation in hospital dormitories, meals for those in the dormitories, a support team that included social workers, and an "examined and drive" service in response to the needs of personnel and family members. The managers reported that they make sure to visit the staff in COVID-19 wards and intensive care units daily to provide strength and keep them updated on the current status of various problems.

15.1.7 Family Visits and Patient Experience

Family visits and patient experience are very significant issues in a pandemic that necessitate isolation to preserve general health and prevent infection. Differences were also found among hospitals in this matter; however, it was evident that special consideration and sensitivity are given to the process of parting with a patient on his deathbed. In most hospitals, one or more people have been allowed to enter the ward under full protection and accompanied by a staff member to respectfully say goodbye to their loved ones. Care is taken to contact the family members if the patient deteriorates so that they can come to say goodbye. Regular visits have been very limited, and in most hospitals, these have been limited to one visitor per day, provided that the patient has not had a transplant and is not immunosuppressed. To make the stay in the hospital pleasant and alleviate loneliness, clowns, spiritual companions, and volunteers have been recruited in a variety of ways by social services or human resources. Such volunteers are accepted according to a routine admission procedure and are instructed in all the required topics (some hospitals have required a signature to indicate consent to work in the COVID-19 department). All volunteers work in full protective equipment while in the COVID-19 ward. Some hospitals have utilized inner courtyards in the wards to offer patient outings, physical therapy, and physical activity. In addition, family centers where there are information sheets in different languages have been opened in most hospitals. Zoom calls can be made with the patient who is accompanied by a social worker and a psychologist.

15.1.8 Human Resources

The required human resources mix is defined according to the reference scenario as a basis for determining the required quantities, training, and competencies of human resources. Hospitals have not reached insufficiency at any point, but it appears that a load of seriously ill patients could have caused more deaths than it did. A system has been established to collect and analyze daily information on the status of personnel in the health organizations in Israel regarding isolated, verified, and incidental exposure incidents. All potential sources for the immediate recruitment of nurses from all health professions have been identified to assist in meeting the required reinforcement needed under the current circumstances: (1) an appeal to all managers of health organizations, health funds, and the Israel Defense Force to identify all the nurses who have graduated from basic courses in the field of intensive care; (2) an appeal to university deans to share the records of students in the health professions and those with advanced basic training and specialization in acute fields; (3) the identification of personnel with advanced basic training in intensive care who are not currently employed in the field through the "practitioners" system, resulting in contact with 2879 nurses who graduated from the acute basic courses; and (4) a procedure for assigning and accepting students as part of recruiting personnel to strengthen the health system due to the spread of the SARS-CoV-2 virus based on Civil Service Commission Circular No. 8/2018 "Student Employment in the

Civil Service." Legal procedures were taken for the emergency recruitment and diversion of workers: (1) A number of doctors and 1020 nurses, 172 of whom had graduated from advanced basic training in intensive care, were transferred from private to public hospitals; (2) temporary permits to engage in nursing were given to 850 young graduates from certified nursing programs; and (3) legal documents were prepared by the Ministry of Labor to order the emergency recruitment of all students in the health professions in Israel. Working places were assigned: Of the 600 doctors recruited, 90% found a position; of the 1550 nurses recruited, 94% found a position; of the 700 health professionals recruited, including managers and accountants, 72% found a position; of the 178 paramedics recruited, 27% found a position; and of the 4418 paid working students recruited, 95% found a position. Powers were expanded, including the activities of the Committee for Action Exceptions, which made decisions regarding (1) qualified nurses working in the department for the treatment of COVID-19 patients, (2) paramedics in the COVID-19 wards in hospitals, and (3) phlebotomists who perform venous blood aspiration at patients' homes. The number of nurses studying in the integrated intensive care course increased: In 2020, 300 nurses successfully passed the licensing examination in integrated intensive care. In addition, 1170 nurses began studying in 22 integrated intensive care courses nationwide in nine general hospitals and were expected to take licensing examinations in 2021.

15.1.9 Protection and Infection

In dealing with COVID-19, a beautiful time of cooperation among the teams of the infection prevention unit arose. Beyond attending endless training and providing immediate answers to every question, they also engaged in research, systematic learning, and data collection on the infection of each staff member or patient. Among the causes of infection found during the investigations were infection following inhalation treatments such as CPAP or HFOC, prolonged close contact with a patient, mask tips that did not cover the nose well, and ill-fitting/sealing masks. It is important to note that most of the staff infections were from other staff members due to the loosening of discipline in the staff room. This conclusion led to actions that included structural and behavioral changes—staff members working in capsules, guidelines for social distancing during meals and meetings at the hospital, closing smoking areas, social distancing measures in the staff room, and proper wearing of masks and face shields. It was reported that the teams did not respond well to changing gloves and hand hygiene at the beginning of the pandemic due to the fear of removing gloves in the COVID-19 wards, but this resistance has lessened over time thanks to training and the reduction of concerns. To ensure adequate shielding, most hospitals have assigned a nurse guide and/or observer at the shielding site. Infection prevention unit teams reported a number of investigations that created significant damage to the unit's routine activities: Hand hygiene observations decreased by approximately 50%, meetings with at-risk departments were stopped, and the monitoring of the introduction of central dressings in the emergency room units and of resistant bacteria was stopped/decreased. There was a fear of higher staff infection rates due to aerosols caused by patients coughing while on HFOC. Hospitals offered various technical solutions, such as an oxygen tent connected to a vacuum above the patient, surgical masks for the patient, and the installation of a vent to remove virus-contaminated air. It is important to note that there were members among the teams who said that coveralls were not necessary and that a robe, a mask, and gloves were enough (as in the case of tuberculosis, flu, measles, etc.). For short operations that do not require hospitalization, the recommendations are that staff should protect themselves well and that there is no need for COVID-19 tests before the procedure. Inadequate infrastructure of the COVID-19 wards has contributed to the spread of infections. Secondary infections have been found in the wards in parking lots due to insufficient good ventilation there. Patients in COVID-19

intensive care units have developed secondary infections from Pseudomonas, Staphylococcus, Enterococcus, and Acinetobacter, which has caused mortality as a result of overcrowding. The teams have reported difficulty in dealing with certain consultants who refused to protect themselves to enter and examine COVID-19 patients and prefer remote counseling.

15.1.10 Diagnosis, Case Management, Treatment, and Resuscitation

15.1.10.1 Diagnosis of COVID-19 Patients

COVID-19 presents a clinical picture that could be unique and different from other viral diseases. The natural course of the disease is not entirely predictable, and the patient's deterioration may be rapid. The disease is more complex in patients with concomitant/chronic morbidity, and a comprehensive clinical judgment is necessary for the correct management of the case. Teams have reported treating patients with unusual pulmonary findings or with low saturation who still felt well and did not need ventilation, unlike others who experienced a severe and unexpected collapse after a week of illness or even after discharge. In the discussion at the National Council of Cardiology, it was said that some COVID-19 patients experience problematic and complex infarcts in the heart muscle. Cases of pulmonary embolism have been described even after hospitalization due to excessive coagulopathy and cases of myocarditis. Accumulated experience has taught us that there is no way to combat the microthrombosis and the cytokine storm that the disease causes, and we are still very far from understanding the cascade that occurs, including the damage to the blood vessels. Therefore, intervention from several angles and learning about the disease as it progresses are needed. Anticoagulation drugs play a significant role and are given in different doses depending on the severity of the disease to prevent the hypercoagulability that may appear as a result of the disease. The treatment is given in a prophylactic dose for patients with mild or moderate cases and in a full dose for patients with critical cases; this process includes the continuation of the treatment 1 month after discharge. Liver damage is also very common in those who contract COVID-19. Most critically ill patients have an increase in transaminases, and the long-term significance of this change is unclear. The basic monitoring of these patients and the comprehensive examination performed to assess the severity of the disease and adjust the therapeutic approach are found to be similar in all hospitals; however, it is important to emphasize that there is a lack of advanced monitoring and proper conditions for its performance in some hospitals. The laboratory test and imaging procedures usually include a blood count with an emphasis on lymphocytes, CRP, LDH, D-dimers, and ferritin as well as an EKG, chest X-ray, and CT scan. According to the teams, the laboratory results are not necessarily helpful, and the most important thing is the clinical evaluation. Due to the complexity of the disease and the management derived from it, in most hospitals, the nature of the daily patient visit has changed, so updating the laboratory data/indices, holding discussions, and writing instructions are done outside the department, and only physical examination and completion are done at the patient's bedside. During busy periods, the visit is done in pairs with a senior physician and an intern (a doctor inside the room conducts the visit and reports his observations and a doctor outside the room records). In addition, remote medicine and digital means are used to minimize contact as much as possible. The prognosis of patients with COVID-19 disease shows differences in terms of survival of patients. The data show that in critically ill patients treated in the intensive care unit, the mortality is 12–30%, which is lower than the 50% rate among critically ill patients treated in an internal medicine department with the advice of an intensive care physician. The patients died from severe infections, pneumothorax (despite gentle ventilation), internal bleeding due to treatment with anticoagulants, and DIC. According to a physician quoted in a morning paper, Yediot Aharonot, on 2.12.2020, the mortality rate of COVID-19 patients in the intensive care unit is

80%, much higher than the 50% rate for non-COVID-19 patients in the same unit.

Due to the burdens created by the pandemic, there was an unreasonable prolongation of the waiting time in the departments for emergency medicine. In addition, teams reported that much administrative work was required for the drugs used in treatment: filling out an individual-specific form for a new, experimental drug; writing a cover letter; filling out a consent form for each patient; and obtaining internal approval at the hospital and external approval from the Ministry of Health.

15.1.10.2 Treatment of COVID-19 Patients

Given the lack of previous experience and familiarity with SARS-CoV-2, the treatment for COVID-19 across the world was based on clinical experience from treating other viruses and the sharing of knowledge and therapeutic experience with different groups around the world. Unlike normal times when medical studies that seek to show the success of any treatment are required to meet high standards of research, during the COVID-19 pandemic, there has been no privilege of time, and many studies have been done with small groups of patients, often without adequate control groups. It seems that the follow-up and treatment of COVID-19 patients have converged to the treatment below:

- Mild cases receive supportive care, treatment of underlying diseases, DVT prophylaxis, clinical follow-up, and imaging.
- Moderate cases receive pulmonary infiltrates and distortion, with the addition of plasma from convalescents.
- Severe cases receive—dexamethasone at a dose of 6 mg per day for 10 days IV/PO, remdesivir, an antiviral drug. The dose was as follows: on the first day, 200 mg, and then 100 mg for another 2–5 days; plasma from convalescents, which is effective in the first days of the disease; treatment with anticoagulants, with a recommendation to continue treatment at home for 1–4 weeks after discharge as a prophylactic treatment; and treatment with tocilizumab, which acts against IL-6 type cytokines and is given to severe patients presenting with cytokine storm.
- Experimental drugs have also been given as compassionate drugs.
- Hadassah Medical Center in Jerusalem presented its successful experience in giving plasma from convalescent patients to lymphoma patients.
- In most places, zinc and vitamin D have not been given.
- There has been a central organizational effort by the Ministry of Health to centralize the delivery of unique treatments such as remdesivir and plasma during the crisis.

15.1.10.3 Giving Oxygen and Respiration

There are various methods for preventing the aerosolization of the virus in noninvasive ventilation and to prevent the infection of the staff. The moment of intubation is critical, and a video laryngoscope must be used and closed respiration was performed as quickly as possible to lower the chances of infection to the staff. The reports show that in all hospitals, intubation in COVID-19 patients is performed by anesthesiologists with the help of a video laryngoscope (gleidoscope) and that anesthesiologists must be on call 24/7. In invasive ventilation, muscle relaxants, pronation, and the administration of NO are used. Pronation should be applied to every ventilated patient with COVID-19, even though it requires a large team because it increases oxygen levels and improves results. In many cases, pronation does not work because people cannot lie on their belly for a long time. It is extremely important to correctly choose the timing of invasive ventilation and the timing of the ECMO connection. It was found that in both the first and second waves, there was an exaggeration of the intubation threshold—it increased in the first wave and decreased in the second. Ventilation today is protective ventilation with relatively low percentages of oxygen to prevent secondary visual damage to the ventilator and avoid the use of BPAP/CPAP. ECMO is used when other treatments fail. There has been extensive and prolonged use of muscle relaxants and

HFOC, but no clear treatment has been found. If NO is overused, can it cause damage? Does it improve mortality rates? There is also no clear answer regarding when to put a patient on ECMO, even though there is overuse of ECMO in patients without a prognosis for whom palliative medicine is suitable. There have been reports of patients who were candidates for transfer to another hospital for ECMO support but were not accepted and who died due to the delay. There is a consensus that identifying the stage that requires intervention is critical. Using the ROX index to decide on intubation can be used as a tool for making the decision. ROX is calculated as $(SPO_2/Fio_2)/RR$, and a value less than 4.8 indicates a need for intubation. Some works show that monitoring ROX once every 2 h helps in decision-making. The Sourasky (Ichilov) Medical Center in Tel Aviv has an algorithm that relies on ROX and can be used in combination with clinical judgment. A prospective study of 2325 ARDS patients showed a significant increase in mortality with delayed ventilation (failure of noninvasive ventilation). There have also been studies performed on patients with ARDS (not COVID-19) that show an increase in mortality and invasive respiratory failure if waiting more than 48 h. There is a pathophysiological mechanism linking HFOC/NIV failure in ARDS patients to increased mortality and morbidity. Several experts in intensive care believe in personalized medicine and that the treatment of a COVID-19 patient and his ventilation in the intensive care unit should not be different from any other patient depending on the severity of his illness. For ECMO, the data show that approximately 100 patients in Israel with COVID-19 have been connected to ECMO, with approximately 40% surviving. It has also been found that ECMO does not prevent pulmonary fibrosis or long-term pulmonary damage because the patients are ventilated before and after ECMO connection.

15.2 Breakdown of Wave Times and Variants [1, 2]

Waves 1 and 2 were characterized on the one hand by the prevalence of the original virus (less contagious, causes milder morbidity, and lower mortality rates) and on the other hand by closures and social distancing (before there was a vaccine). The third wave was characterized by one variant (alpha) first detected in the UK accounting for 90% of cases; this variant was more contagious and caused more severe illness than previous variants, all the while with less social distancing being practiced, although vaccinations had begun by that time. The fourth wave was characterized by a variant (delta) first detected in India; this variant is highly contagious and causes severe morbidity and emerged during a time described as the "waning of the vaccine," when the first boosters became available and few social distancing measures were still in place. The fifth wave was characterized by the highly contagious Omicron variant, which causes a relatively mild illness and a minority of severe cases that require hospitalization. Omicron has several variants that have resulted in the sixth and seventh waves, which have been significantly smaller and less fatal. In patients belonging to risk groups (elderly and immunosuppressed), a drug can be given that prevents deterioration and hospitalization. By October 2022, two more vaccine boosters were available, the last of which was bivalent, and during the fifth wave, all restrictions were lifted in Israel and most countries across the world. A summary of the pandemic five waves can be found in Table 15.2 and Fig. 15.1.

Table 15.2 Comparison of variants in the five waves

Wave and variant	Date range	Wavelength (days)	Verified cases (cumulative)	Dead (cumulative)	Ratio of deaths among patients with verified cases
1. Original	28.2.20–18.5.20	78	16,667	329	1.97
2. Original	19.5.20–10.11.20	175	304,681	1764	0.57
3. Alpha	11.11.20–12.6.21	215	518,324	3777	0.73
4. Delta	13.6.21–16.9.21	95	375,394	1585	0.42
5. Omicron	17.9.21–2.10.22	380	3,448,449	4204	0.12

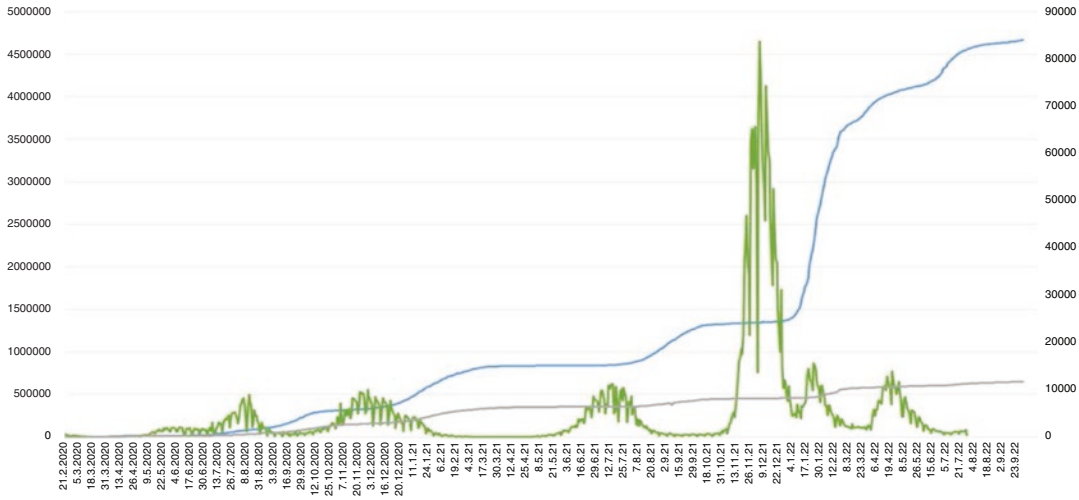

Fig. 15.1 New cases and mortality—COVID-19 pandemic in Israel. Verified accumulated (blue), verified per day (green), accumulated deaths (gray)

15.3 Convalescence, Discharge, Transfer, and Therapeutic Sequence

Geriatric patients who need nursing care and demented patients referred from geriatric institutions of all kinds have been a serious problem in general hospitals, especially when they are referred following an outbreak in their institution and taken directly to the hospital without a justified clinical reason. It is often not possible to release them back to the institution from which they came because there is no possibility of isolation or appropriate treatment for COVID-19 patients there, and they remain in hospital wards, greatly increasing the staff's workload even if their treatment is mainly palliative, and they do not have a good prognosis. In addition, the outbreaks in nursing homes around hospitals have resulted in an immediate and unreasonable load on the hospital system. The discharge policy in the first and second waves was confusing and constantly changing. Although inpatient beds were opened in the geriatric system and at the peak of morbidity, there were 1167 inpatient beds, and many patients stayed in the general hospitals for a long time even though their treatment had concluded. In the first and second waves, the hospitalization of these patients was very long and caused a burden on the wards. In addition, complex patients, dialysis patients, and those who needed invasive ventilation were not

cared for in COVID-19 wards in the geriatric system and remained in the general hospital. Transferring patients from the hospital to the COVID-19 wards in the geriatric system also involves risk. These patients are very fragile, and some collapse during transfer or immediately after and need rehospitalization. Some are injured during the transfer. The total number of transfers from general hospitals to COVID-19 wards in the geriatric system was six times higher in the second wave than in the first wave and reflected the extensive morbidity among this population. The wait times for ambulances to evacuate patients to COVID-19 wards in the geriatric system have been long and resulted in the late arrival of patients to the geriatric hospital. The mortality rate of these patients in the second wave was also higher, and most of the death events occurred during the first 2 weeks after transfer in both the first wave and the second wave. Additional rehabilitation beds for debilitated patients with a negative PCR were established during the first year of the pandemic to release the pressure on COVID-19 departments. The easing of the hospitalization system for discharging geriatric patients came with the publication of a convalescent procedure that defined the severity of the disease as mild, moderate, severe, or critical and allowed the discharge of a patient with a severe case without the need for COVID-19 tests after 20 days in the hospital and after 10 days for a patient with a mild/moderate case. The gradual opening of additional departments capable of receiving and treating geriatric COVID-19 patients has also contributed to this relief. Another difficulty has been observed in patients who need oxygen at the time of their discharge, a difficulty for which no solution has been found in the community, and many patients remain hospitalized because of this. HMO centers have been needed even at night to allow the efficient discharge of patients. The accompanying morbidity even after the disappearance of the virus, which occurs in a significant percentage of patients, has shown us that there is a need for a convalescent clinic with a consolidated plan for managed and uniform follow-up goals. In a satisfaction survey completed by hospital managers, it was found that in most hospitals, there is medium-high satisfaction with communication with the Ministry of Health, communication with the Home Front Command, communication with HMOs and nursing institutions in the area, and communication with municipality/local authorities. However, difficulty was found in producing daily reports and the availability of epidemiological data in the central computerized system. Continuous information on red cities was not provided.

15.4 Main Recommendations in the Field of Management Strategy

1. Direct treatment by intensive care doctors and nurses for seriously ill patients immeasurably improves the prognosis (according to the testimony of hospital directors, directors of internal departments, and intensive care units). A way must be found to triple the number of intensive care beds in Israel and to add intensive care beds in or near COVID-19 wards as an integral part of such wards while continuing to operate the normal intensive care units for the benefit of critical patients who are not being treated for COVID-19.
2. The primary and secondary regulations enacted for hospitals by the Ministry of Health to spread the load should be appraised positively. There is a need to expand this activity according to the loads and geographical distribution of hospitals.
3. The establishment of wards in basements, parking lots, and inappropriate buildings should be avoided as much as possible due to the distance of the wards from the hospital's logistical infrastructure and the feelings of depression they create among the staff. Converting organic wards into COVID-19 wards has been proven to be the superior option.
4. The current health system capacity threshold is unknown, and after construction and upgrade procedures have been carried out, further action must be taken to increase the capacity of the health system. In each institu-

tion and the system as a whole, a distinction must be made between the threshold of sufficiency that results in significant damage to routine medicine (low) and the threshold of sufficiency that results in a decrease in the quality of care for the critically ill and the choice of whom to treat (higher).

5. Many more beds than required were opened. The model in which each internal department has an extension in the COVID-19 wing and the same care team rotates is interesting and important and has prevented the closure of internal departments or intensive care units (infections among staff members were avoided by being extremely careful to use appropriate protection and working in capsules).
6. In terms of personnel, there was a noticeable lack of teams with training in intensive care, particularly doctors and nurses, and the lack has been extremely noticeable during the outbreak of secondary infections. In addition, there has been a lack of laboratory workers, so there is a need for extensive recruitment and training.
7. Provisions should be made for the addition of beds for COVID-19 care, not only inpatient and intensive care beds, as well as the establishment of dedicated wards in addition to the COVID-19 wards—that is, wards for women, children, and psychiatric patients.
8. It is necessary to continue the training of the treating teams to help them continuously update their knowledge, assimilate insights, and learn new protocols. In addition, the expedited and intensive training of intensive care interns should be considered with emphasis on ARDS and COVID-19. Doctors and nurses from the internal medicine department should be brought into intensive care units to learn, practice, and acclimate to the atmosphere.
9. The organization's resources, such as the Department for Quality and Patient Safety, should be used to assist in providing comprehensive treatment during the pandemic. Particularly in times of emergency, there is a place for maintaining the criteria for the quality and safety of care, risk management, and quality indicators that guarantee orderly work and the prevention of morbidity.
10. Maintaining normal clinical activity in the hospital is necessary for preventing the deterioration of patients and maintaining financial income; therefore, the morbidity and burdens must be continuously monitored and guided according to the need and not in a sweeping manner upon the cessation of elective activity.
11. Emphasis must be placed on the proper calculation of the number of patients per nurse/doctor. There should be a patient:nurse ratio of 1:5–6 in the internal COVID-19 ward, 1:2 in enhanced care (with help from the intensive care team), and 1:2 in intensive care (with help from graduates of intensive care courses), and on the ECMO team, the ratio should be 1:1 for patients and practitioners with ECMO-specific training.
12. A national resilience plan for the teams must be guaranteed, and dedicated resources must be allocated for this.
13. Caregiver and patient experience should be monitored by conducting surveys about the stay in the COVID-19 ward; corrective actions should be accordingly with reference to three leading channels of information: the patient, his family, and the staff.
14. Those suspected of being infected with COVID-19 should not be summoned for elective operations. When planning a surgery that will require more than 3 days of hospitalization, patients should be tested for COVID-19 to rule out infection before admission.
15. There was and is no place to compromise on the quality of medicine during the pandemic. The best response should be given to both patients with COVID-19 and patients who are not being treated for COVID-19.
16. A COVID-19 research team whose job is to answer clinical questions should be designated in each hospital.
17. There is an urgent need for research adjustments to advance clinical research in COVID-19.

18. Budgets for training at least 1000 intensive care nurses, with 85% of funding coming from the state each year, should be provided; training budgets should be provided for hospitals to maintain the ongoing professional competence of doctors and nurses in the treatment of ventilated COVID-19 patients, train ECMO teams, and build a knowledge sharing system for dealing with and treating COVID-19 cases according to the doctor, nurse, health professions, and multiteam sectors; an information sharing system regarding the state of mental resilience of the medical teams should be built; and uniform indicators should be developed that reflect burnout and workload.

15.5 Recommendations Regarding Staff Protection and Infection

1. Additional staff members should be recruited for the infection prevention unit to carry out investigations. The establishment of a unit for epidemiological investigations with the help of students and volunteers who have undergone several hours of training and a computer system dedicated to the subject should be considered. Help can be obtained from quality and risk management units.
2. The staff should be surveyed about their feelings regarding the effectiveness of the protection against contamination.
3. A periodic survey of all staff members should be carried out—this saves working days, prevents infection, and increases security.
4. Masks should be adjusted to the structure of each person's face to ensure sealing and prevent infection.
5. Patients with secondary contamination should be separated from the contaminated area.
6. Preventive measures against infection in hospitals should be increased. In patients who receive high-flow oxygen, protective measures for patients such as a mask or an oxygen tent with a vacuum should be considered to prevent infection of the staff, and staff should continue observing hand hygiene.
7. Management must intervene in cases where consultants avoid protecting themselves and entering the COVID-19 department.

15.6 Recommendations Regarding Diagnosis, Case Management, Treatment, and Ventilation

1. There are insufficiently clear regulations regarding ECMO. A distinction must be made between ECMO VA (venous-arterial for heart bypass, which always requires the presence of a pump technician and a chest surgeon) and ECMO VV (venous-venous for pulmonary bypass). ECMO VV should be used in all general intensive care units.
2. All COVID-19 patients should receive routine echocardiograms due to severe damage to the right side of the heart that has been found in several patients.
3. Since a large number of patients need noninvasive ventilation when hospitalized in internal wards, the need for more in-depth training of residents should be addressed. How these patients are treated in the COVID-19 internal medicine ward by the general hospital staff should be reviewed.
4. The treatment of the critically ill and intubation should be done by intensive care personnel, not as consultation but as joint work and responsibility.
5. Medical treatment with remdesivir, plasma, and steroids is not very effective. New therapies should be tested, and prospective research should be encouraged.
6. Team leaders should be appointed to make critical decisions and solve problems/errors.
7. Personnel should know when to stop giving oxygen at high pressure and switch to invasive ventilation. Long-term use of Vapotherm can lead to the destruction of the lungs.
8. The ROX index protocol may be implemented in the patient's file.
9. The administrative process related to drug treatment should be shortened.
10. It is necessary to understand what the appropriate length of hospitalization is, and a

standard for comparison with a mild/moderate/severe/critical case should be developed.
11. A COVID-19 test should be performed for every patient hospitalized for any reason, especially in non-COVID-19 intensive care units.
12. Patients should be transferred to the intensive care unit only when in critical condition and with a prognosis; at the same time, proper palliative medicine, good nursing treatment, supportive medical care, and fluids for patients without a prognosis should be provided.
13. Departments of emergency medicine should contact ambulance services for the direct referral of verified COVID-19 patients to the COVID-19 department when they are experiencing a high load. The sites within the department should be flexible—instead of having an internal wing and a surgical wing, there should be a moving/recumbent/respiratory wing.
14. There is a need for a renewed clinical protocol managed by a team of experts in the Ministry of Health with the participation of professional societies. The threshold for oxygen administration, transition to intubation, and ECMO should be refined. Objective indicators and clear and updated criteria must be published.
15. Pressure sores on the face should be prevented by using foam dressings on both sides of the face before a patient is turned over on his belly during pronation.
16. Early in treatment, nutrition assistance should be provided if needed by a nasogastric tube, without the use of TPN as much as possible, as this has shown an advantage in preventing infections.

15.7 Recommendations Regarding the Sequence of Treatment and Recovery

1. A therapeutic sequence is required for community clinics regarding home care/hospitalization for patients who are discharged from COVID-19 wards but still require oxygen administration at home. This is a complex issue that has not yet been fully resolved. The guidelines and standards must be refined.
2. Hospital teams must leave the hospital to receive training in the community.
3. All patients admitted to the hospital from red areas on the epidemiological map should be sampled before surgeries and endoscopic procedures. Periodic coverage of the staff should also be considered.
4. HMOs should be more actively involved in the treatment of mild cases so that such patients can be treated at home instead of hospitalized and in the regulation of patient transfers, especially in the evening and on weekends, to prevent the prolongation of hospitalization and the overwhelming of wards. Emphasis should be placed on dialysis treatments and dental treatments for patients with COVID-19. It is very important that the Ministry of Health establish criteria for hospital admission versus home hospitalization, taking into account that giving clexane at home can be problematic and that remote medicine is insufficient because it is necessary to examine the patient.
5. Sustainable solutions for patients with exhaustion and post-COVID-19 symptoms after they have become PCR-negative should be found instead of keeping them in the hospital.
6. Dissatisfaction among collaborators with the frontline command regarding communication, hospitalizations, and discharges and the need for epidemiological data should be addressed. Epidemiological and clinical deficit information systems should be established.
7. Overload should be avoided by the early discharge of patients who do not need hospitalization. There should be an emphasis on the rapid discharge of patients who need nursing and palliative treatment.
8. Special populations—geriatric patients (10% mortality after transfers of elderly patients), those on dialysis, those living in shelters, and those admitted for social hospitalization—should be considered in all decision-making.

9. Difficulties in releasing psychiatric patients infected with COVID-19 should be discussed.

15.8 Recruiting Researchers to Eradicate the Pandemic

In the first year of the pandemic outbreak, there were many more questions than answers regarding the structure of the virus, the mode of infection, and the severity of the disease. The most pressing question was about the health system's ability to deal with the pandemic. Within the past few months, there has been much progress in understanding the disease and ways of dealing with it on both a clinical and epidemiological level. Emphasis has been placed on collecting every significant detail for scientific analysis and sharing knowledge with all health services. It has not been clear to all concerned that the perspective of time is needed to evaluate the accumulated knowledge and to correct mistakes and incorrect theories. Several observations of COVID-19 have been typical from the beginning, and not all of them have found a satisfactory scientific explanation. There is no good correlation between a patient's clinical status and blood oxygen saturation and, sometimes, patients who feel well have a lower-than-normal saturation. On the other hand, it is sometimes difficult to detect the deterioration of a patient, and some patients need invasive ventilation within a few hours or immediately upon admission to the hospital. It was understood quite early that approximately 50% of ventilated patients died and that there was no need, therefore, to purchase many more ventilators. Therefore, every effort is now made to prevent invasive ventilation with the help of noninvasive ventilation (NIV), such as CPAP or BPAP. Attempts at pronation (laying the patient on his belly) help in weaning patients from ventilation or even preventing it if done at an early stage. The insight that a significant number of patients die due to a cytokine storm led to therapeutic attempts to provide a medicinal combination of antibodies against the virus (plasma from convalescents) and the enzymes that catalyze its division for treatment against the cytokines that resulted in the pulmonary collapse.

15.8.1 Two International Bodies Have Established Noteworthy Research Programs

The World Health Organization called on all medical institutions in the world dealing with the COVID-19 pandemic to participate in the SOLIDARITY study [3]. This is a prospective, randomized, controlled study in which there are four arms:

(a) Treatment with remdesivir, which helped in previous SARS and MERS epidemics
(b) Treatment with lopinavir/ritonavir, which is effective in inhibiting the proliferation of HIV
(c) Treatment with interferon beta-1a
(d) Treatment with chloroquine or hydroxychloroquine (in light of some anecdotal evidence of the effectiveness of antimalarial drugs in slowing the progression of the disease)

At the same time, the International Extracorporeal Life Support Association recruited 310 hospitals in 47 countries to participate in research on the ECMOCARD, or the COVID-19 Critical Care Consortium, which recruited patients ventilated due to SARS-CoV-2 and aimed to understand the clinical course of the critically ill, the factors that lead to deterioration, the factors that predict prognosis, and the most successful treatments [4]. The organization recruited the giant companies Amazon and IBM and capitalized on the capabilities of artificial intelligence and machine learning to make data mining from patient files a quick and easy task.

15.9 Learning While Treating and Applying the Initial Insights

The greatest challenges in the first year of the pandemic (2020) were gathering as much knowledge as possible about the course of the disease

and the virus, trying to prepare an updated treatment protocol, and examining ways to contain the pandemic. The Ministry of Health and the Team for the Treatment of Epidemics worked on this tirelessly. The first insights came from the experience of frontline therapists in Israel and around the world, and the therapeutic approach changed overnight. There has been great concern for the health of elderly individuals during the COVID-19 pandemic, especially for the residents of nursing homes who are among the high-risk population. Indeed, many of them were infected with COVID-19 and suffered a more severe course than younger people and a poor prognosis. Elderly individuals were mainly infected by staff members working in more than one place who were also exposed to the risks of infection in their families and the community. In a study carried out in Canada, it was found that the mortality among COVID-19 patients older than 69 years of age living in 627 nursing homes was 13.1 times higher than that among those of the same age living in their homes in the community [5]. At that time, it was understood that the mutations of the SARS-CoV-2 not only affect the level of infection and possibly the severity of the disease but also cause genetic changes in the infected patients themselves. A group of researchers from the Netherlands found mutations in the Toll-like receptor 7 (TLR7) gene, which is responsible for recognizing the virus and preventing its replication by secreting cytokines, in young people. These mutations cause the immediate immune response of the body to be neutralized and thus cause severe disease [6]. One of the problems that stands in the way of diagnosing infection from a virus is the method of testing. A group of researchers from Seattle compared self-sampling with a swab inserted deep into the nasal cavity at the individual's house to sampling by a doctor (standard for comparison) and found a sensitivity of 80% and a specificity of 97.9%. In subjects with symptoms, the sensitivity increased to 95% [7]. A team of 24 experts was formed and divided into four subteams with the following tasks: preparing a comprehensive study on the ventilation of COVID-19 patients, researching ventilators before purchasing and recommending which ones to purchase, preparing an ethics document regarding whether it is necessary to select which people receive ventilation due to lack of means, and conducting a statistical evaluation of the number of ventilators that will be needed. A course was prepared (videos, presentations, tests) that was delivered to 6000 doctors and nurses, 1500 medical and nursing students, and various training teams in every hospital. An application was prepared (with the help of commercial companies) for training on specific new kinds of ventilators. An ethics document for doctors was prepared with the help of the National Council for Bioethics. A team of experts (including the senior members of departments for quality and safety and the chief scientist in the Ministry of Health) was established to collect information from the literature. This role was later transferred to the IDF Information and Knowledge Center. At that time, we compared the first wave of the pandemic in Israel, which was short and was stopped very effectively by social distancing and building closures, to the second wave (lasting until 19.7.2020). It was found that there were 1.8 times fewer seriously ill patients, 4.9 times fewer ventilated patients, and 4.4 times fewer deaths in the second wave than in the first (Fig. 15.2). The possible reasons for this are as follows: the high rate of testing (because of symptoms or exposures), more young people being infected, more women being infected, early diagnosis, the maintenance of risk groups, the availability of better treatments, delayed ventilation after longer periods of high-flow oxygen administration or noninvasive ventilation by BCAP and CPAP, and the use of remdesivir, dexamethasone, and virus-specific antibodies. We learned that pronation—lying on the belly—and oxygen provision can prevent the need for intubation and invasive ventilation and limit complications.

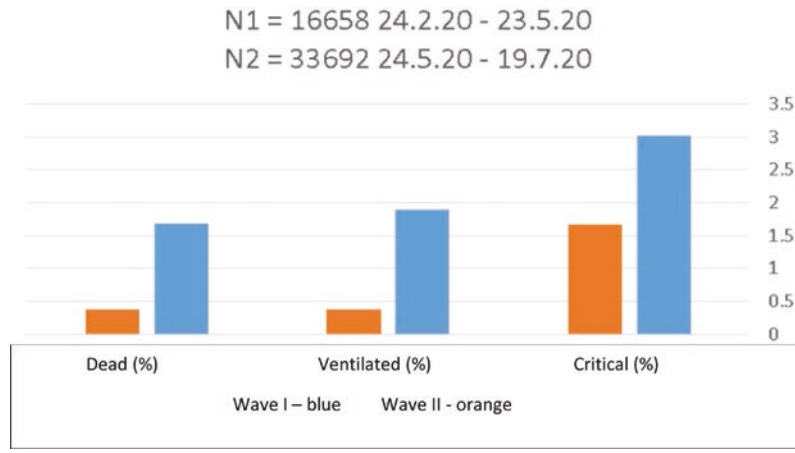

Fig. 15.2 Waves comparison

15.10 Decrease in Clinical Activity While Maintaining Performance Quality

There was fear of a decrease in diagnostic and therapeutic activity during the COVID-19 period for issues not directly related to the pandemic. Postponing necessary elective surgeries and avoiding going to the emergency room (ER) among patients with chest pain or neurological issues and denying or ignoring symptoms mainly among elderly individuals and other risk groups could lead to an increase in morbidity and mortality. Researchers in the USA have found a 40% decrease in heart catheterizations in ST-elevation MI (STEMI) patients during the COVID-19 period [8]. Fear and mental stress during a disaster, as happened during Hurricane Katrina in New Orleans, resulted in a significant decrease in the number of hospitalizations due to myocardial infarction in 1 year and a threefold increase in their number the following year [9]. The Centers for Disease Control (CDC) in Atlanta found a 42% decrease in ER visits in the USA, mainly among children and women, due to abdominal pain, digestive tract disorders, skeletal pain, hypertension, nausea, vomiting, and bruises and a fourfold increase in visits due to infectious and inflammatory diseases [10]. This issue is discussed in detail in an article in "Harefuah," which highlights the situation during the first wave of COVID-19 in which patients in acute condition were prevented from arriving at the hospitals, resulting in longer queues, the firing of staff, and economic damage [11]. For example, a case study was published regarding a 66-year-old woman who sought treatment only 5 days after a traumatic shoulder dislocation [12]. In a preliminary comparison between March 2020 and March 2019, we observed a 26.4% decrease in the activity of general hospitals, geriatricians, and psychiatrists in the national program for quality indicators. There was a decrease of 4.2% in cesarean sections, 17.2% in hip replacements, 30.7% in hysterectomies, and 11.3% in colon surgeries. In total, there was a decrease of 17.8% in all surgeries (according to recovery room indicators). A decrease of 15.6% was also observed in the diagnosis of ST-elevation MI (STEMI), 11.7% in the diagnosis of cerebrovascular accidents (CVAs or stroke), and 35.1% in cases of transient ischemic attack (TIA). In 2020, the impact of the global COVID-19 pandemic was felt in many areas of the health system in many countries. Many reports indicate that the field of quality and its measurement is among the fields affected by the pandemic. Individual studies carried out abroad show that during the pandemic, a change was observed in the national quality indicators, for example, an assessment of the median time from arrival at the hospital to the completion of CT in cases of stroke [13] or an assessment of the median time from

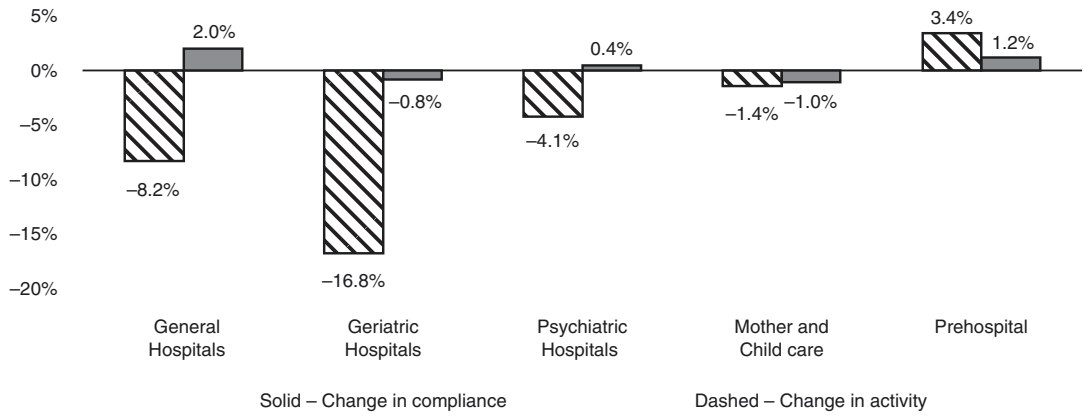

Fig. 15.3 Average activity changes between 2019 and 2020

arrival at the hospital to the performance of heart catheterization in cases of myocardial infarction of the STEMI type [14]. It should be noted that most of the published studies were carried out within a single hospital or across several hospitals in one country/province, but no works have yet been published that describe the effect of the pandemic on the quality indicators at a national level. In the USA, authorities from the Centers for Medicare & Medicaid Services decided in April 2020 to suspend activities related to the collection and reporting of data within the framework of the quality indicators program [15], which includes rating and rewarding service providers according to compliance with the indicators. In Israel, the activities of the national quality indicators program have continued in a series even during the pandemic. A comparison of the measurement year 2020 versus that of 2019 was performed for two parameters: the scope of the index activity, which was reflected in the index population, and the rates of compliance with the indices [16]. The attached figure shows the average changes in these parameters in each of the measurement areas. In the general hospitals, a decrease of approximately 8% in the scope of activity was observed on average. This was mainly contributed to by indicators measured in hospitalization or related to elective activity following a decrease in these activities during the pandemic. At the same time, the rates of compliance with the indicators did not decrease and even improved (an increase of 2% on average). The field of geriatric hospitalization was more affected than the other fields during the pandemic and had an average decrease of 17% in the scope of indicator activity. The rates of compliance with the indicator targets almost did not change (1% decrease). In the field of mental health, a slight decrease in the scope of activity was observed due to the quality indicators related to psychiatric hospitalization, but the rates of compliance with the indicators' goals were almost unaffected. The stations for mother and child care showed a nonsignificant decrease in both the scope of activity of the indicators and the rates of compliance with them, which is due to the indicators related to face-to-face meetings. In the prehospital field (ambulance services), an increase was observed in both parameters, where the rate of this increase corresponds to the natural growth of the population.

In conclusion, during 2020, the effect of the COVID-19 pandemic in Israel on the quality indicators mainly decreased the scope of the indicators' activity, but the rates of compliance with the indicators were almost unaffected and even improved in some fields (Fig. 15.3). We consider this a significant achievement that would not have been possible without the hard work and dedication of the teams, clinicians, quality personnel, and management of all service providers reporting to the program.

15.11 Quality and Patient Safety During the COVID-19 Pandemic

Healthcare quality and safety experts from Baltimore raised the question of what the role of quality of care and patient safety is during the pandemic in an opinion article in JAMA [17]. Due to the difficulty of obtaining clinical data on patients during a pandemic, it is difficult to assess treatment quality. Without systemic learning, it is not possible to improve and reach standardization either during the current pandemic, which has not yet passed, or for similar events in the future. In March 2020, the accreditation bodies in the USA announced that they would temporarily halt their monitoring of the quality and safety indicators to allow hospitals to invest all the means and efforts of their teams in the treatment of patients with COVID-19. This move would not have been necessary if the measurement of quality and safety had been digital and prospectively accompanied the activity itself. For example, along with the order to administer medicine there should be a quality measurement. The method used today is retrospective and has two main weaknesses: Even if it is mostly computerized, it still requires targeted reporting efforts and validation and also gives feedback to the service providers at a considerable delay after completion. During a pandemic, these weaknesses are exacerbated in the absence of immediate and continuous systemic learning. For example, there were no answers to the following questions: Should steroids and anticoagulants be used in patients with COVID-19? How does remote learning and treatment (TeleHealth) affect the quality of diagnosis and treatment? Does pronation prevent intubation and invasive ventilation? In Israel, the accreditation surveys by the JCI were halted, but the national program for quality indicators continued as usual.

What, then, is the role of quality, safety, and risk managers during the COVID-19 pandemic? Are they partners in managing the campaign, or should they be disabled due to the changing priorities?

In a survey conducted by the Israeli Association for Patient Safety and Risk Management in Medicine (NSBAR), risk managers of hospitals and HMOs were asked to express their opinion in a structured questionnaire about their role during the pandemic. The questionnaire was distributed to 250 risk managers, and answers were received from 57 (23%). Nearly half of the respondents believed that their skills and experience had not been utilized during the COVID-19 crisis. The healthcare system, in their opinion, has been preoccupied with survival and hardly concerned with risk management. Thirty-two (56%) of the respondents have not taken part in the decision-making processes and have not participated in the management of the medical institution. The health system is quickly and urgently prepared to navigate the COVID-19 pandemic without directing practitioners to improve the quality and safety of their care, even though these aspects should also be considered in the fight against the virus. The managers of the quality and safety units, who are doctors and nurses with a clinical background, have been called to assist teams in treating patients. Others, without a similar background, have been unable to continue their routine behavior according to plans and annual tasks determined in advance and have looked for every possible way to be engaged in the fight against the crisis. The rapid and aggressive changes that have taken place in the systems have resulted in uncertainty and inefficiency, which has inhibited successful treatment. The experience of the quality and safety of people, for example, from the assimilation of a new system or a complicated procedure and global understanding of the health system can help in implementing urgently needed changes. Measuring quality and maintaining the safety of care and risk management should be an integral part of the campaign during an epidemic, just as it is during routine and stable times. Due to the rapid changes in conduct needed during a pandemic, the system needs to be prepared for continuous improvements in treatment and even more systemic learning. Following the onset of the COVID-19 pandemic, there is room for the reevaluation of and clear procedures on these issues. In one editorial published on the subject [18], quality and safety experts from France, Australia, and England proposed a five-step strategy in which the cooperation of quality and treatment safety units can contribute to the well-being of patients, staff, and the medical institution:

1. Assess the readiness and preparation of labeling lists, collect data and facts, establish courses and practice, and promote staff safety and support.
2. Arrange meetings with patients, members of the patient's families, and members of the medical team to consolidate procedures for protection, social distancing, family visits, and infection prevention.
3. Improve the quality of care by planning the flow of patients, providing workshops for caregivers on self-protection issues and treatment, and developing open decision-making support mechanisms.
4. Reduce the danger to patients through proactive activity, such as updating guidelines for preventing infections and combatting the disease, conducting investigations, and learning from the results.
5. Rapidly and flexibly adjust learning means, leverage options for good patient care, and protect caregivers against infection, exhaustion, and erosion.

The units for treatment safety and risk management have much experience in investigating adverse and unexpected events. When managing a crisis, in addition to adverse events that happen routinely and do not disappear in a crisis, there is the crisis itself and its scenarios, which are exceptional events that are important in themselves, and the adverse results of crisis management. The work of risk management units is divided into reactive (or retrospective), interactive, and proactive activities, all of which are even more necessary during a crisis. It can be said that the risk manager is the adviser to management regarding crisis matters, including how to investigate, manage, and learn on the move based on the risk manager's own conduct.

15.11.1 Types of Activity

1. **Reactive activities include the following:**
   (a) Reporting unusual events related to the crisis
   (b) Conducting targeted investigations to draw lessons during the crisis
   (c) Conducting weekly/new analysis of all reports and disseminating knowledge to provide immediate systemic learning
   (d) Conducting in-depth and summary analysis at the end of the crisis for future needs
2. **Interactive activities include the following:**
   (a) Assisting management in managing adverse events as they occur
   (b) Implementing recommendations and insights
3. **Proactive activities include:**
   (a) Actively participating in all forums and meetings to represent risk management and patient and therapist safety
   (b) Actively participating in defining and planning new work processes, procedures, planning structures, teams and work processes, hospitalization and treatment policies, and treatment safety guidelines
   (c) Conducting frequent safety rounds and providing online advice.

15.11.2 Examples of These Activities During the COVID-19 Pandemic Include the Following

- Protection of staff, visitors, and patients
- Family visits
- Entry of consultants
- Planning of COVID-19 wards
- Planning for cooperation and communication between the internal medicine COVID-19 department and the intensive care unit
- Follow-up of side effects of new drugs
- New and unfamiliar ventilator alerts and fatigue alarm
- Fire safety in COVID-19 wards (giving oxygen and breathing with oxygen)
- Use of NO—the risk of leakage and toxicity to staff members and other patients.
- Infection of staff members—matching masks
- Release of "difficult" patients to the community
- Logistical issues and assessments in the community

- Assessments of the complications of COVID-19
- Risk management for various types of vaccines
- Investigations of any case with suspected serious complications or death after vaccination

Another example is the cyberattack on the Hillel Yaffe Medical Center; an investigation was conducted by the hospital's risk management unit together with the Ministry of Health's patient safety system and its cyber experts. Lessons were learned by all Israeli risk management units (88 participants) for systemic learning.

It seems that the treatment safety and risk management units were "forgotten" and were not part of the management at this point in the COVID-19 crisis because they were "taken for granted" and operated as normal during an unexpected and adverse event and not adjusted from their routine operation. The lack of a systematic method for crisis management, or different types of crises, did not help the risk manager participate in the decision-making. The inclusion of risk management as an integral part of every crisis has not yet happened because risk management is not yet a clear and self-evident part of hospital routines or across all areas of action in health services.

15.11.3 What Is the Right Thing to Do and How Should Risk Managers Be Integrated into Crisis Efforts and Contribute Their Skills to the Management of Future Crises?

- In a crisis, there is uncertainty, numerous frequent and urgent tasks, high physical and mental pressure due to these many tasks, a lack of knowledge, and a need to change policy "on the fly." The extent of the risks and their level of severity increase.
- The risk manager must physically sit in the "war room" and be apprised of current information on the situation. He must be a participant in every important discussion and every structural or functional plan in order to provide a perspective on the issue of the safety of the therapist and the patient and make sure in advance that it is taken into account in the early stages of planning.
- The risk management unit must conduct daily meetings and patrols within the area, monitor/inspect and scan the activity, and make sure to systematically learn from mistakes while cooperating as much as possible with units relevant to the issue of the crisis (e.g., the infection prevention unit, medical infirmary, and the pharmacy).
- There is a need for flexibility in definitions and their implementation, a clear and well-defined operating theory for times of crisis, and risk management plans prepared in advance for every possible scenario. Consideration should be given to updating the roles of the treatment safety and risk management units in the community and hospitals with a precise definition of their role during different types of crises.

15.12 Activities of the Patient Safety and Risk Management Team During the Pandemic

The risk management and treatment safety team for the COVID-19 pandemic was established by the Ministry of Health at the end of the second wave and began weekly meetings and engaged in interactive and proactive activity according to the issues raised. **For example, the sum of one of the discussions is as follows:**

15.12.1 Respiratory Alerts in the COVID-19 Wards

In COVID-19 wards, it is very important to refer to ventilator alerts for several reasons:

1. There is a relatively low nurse/patient ratio in intensive care units.
2. There is a lack of skill among the staff in complex intensive care patients.

3. The work environment can prevent staff from hearing alerts due to environmental noise, shielding, and messages received through the headphones worn by team members.
4. There is ingrained alarm fatigue among staff members.
5. Patients are separated into different rooms.

Ventilators can preoxygenate patients at 100% to ensure their oxygenation before suction is performed to stop respiration so that there is no spray of air. In the Mindray SV300-type ventilator, there is an inherent risk of making a mistake when an alert is canceled by pressing the O_2 suction button for 2 min; then, pressing OK subtly cancels the alert rule, and it is not clear that the click leads to canceling the alert rule even when the patient is disconnected, especially as other ventilators warn about disconnection or the weak flow of oxygen. The ventilators in COVID-19 wards must be connected to a central alert system to alert the staff at the control outside the patient's room. There is an "unintelligent" alert system called nurse call, which is programmed into the communication card of each ventilator, and the company has implemented a visual alert in the form of a flashing light. A smart alert system (such as a system that connects to the patient's digital file) would connect to a central communication station that would display alerts according to their importance in different areas of the display.

15.12.2 Monitoring the Screens and Cameras in Control Rooms in COVID-19 Wards

In most COVID-19 wards, there is a control room that shows what is happening in the patients' rooms through a network of cameras and central screens. There is no binding standard for professional monitoring of these cameras and screens. In some hospitals, there is a nurse in control who still handles other tasks, students, and more. In government hospitals, a job definition was created for the nurse in the control room.

15.12.3 Fire Safety in COVID-19 Wards

In a previous discussion, fire safety in COVID-19 wards was discussed following reports from abroad about a flare-up apparently due to oxygen overload. After this discussion, treatment safety guidelines were issued with recommendations for maintaining fire safety in these wards. Following additional reports from around the world, the issue of static electricity from protective clothing, which increases the risk of flare-ups, emerged. Compared to those in the rest of the world, the COVID-19 wards in Israel are better ventilated, and the wards located in parking lots have an antistatic system. Oxygen concentrations above 23% may contribute to a flare. In the examination of the COVID-19 wards at the Rambam Medical Center in Haifa, there was no abnormality in oxygen concentrations, and the issue is also being examined at general hospitals. The existing recommendations state that not all patients on noninvasive ventilation should be located in the same area and that the wards located in parking lots should be cleaned of oil.

15.12.3.1 The Decisions Reached During This Discussion Were as Follows

1. The Association of Intensive Care Physicians will examine the issue of the SV300 ventilator alerts and write an opinion regarding whether its use should be suspended.
2. The issue of the ventilator alert will be brought up for discussion in the Ministry of Health and the General Staff to determine follow-up actions.
3. The issue of connecting alerts to a central system will be examined.

15.13 Risk Management in COVID-19 Vaccination

15.13.1 The Working Method for the Administration of Vaccinations Is as Follows

1. Define the stages of the process (the sequence of actions) step by step
2. Map possible failures/mistakes for each step of the process
3. Define the source of each failure/error
4. Rate the level of risk for each failure/error
5. Determine the level of risk at which an in-depth risk prevention process must be implemented
6. Request risk management plans from all the health funds (HMOs)

A risk management program was implemented by the Safety Department in cooperation with the Pharmacy Division, the Medicine Division, Nursing Management, and the Infection Prevention Unit at the Ministry of Health to present the steps of the process that post a high level of risk for patient safety and recommendations for reducing such risk (Table 15.3). The stages of the work are detailed below, including the level of risk at each stage of the vaccination process from the moment it is stored until it is given to the patient and through follow-up.

15.13.2 Follow-Up After Side Effects and Unusual Events After the Vaccine Injection

The Ministry of Health established a clinical surveillance team that examined every unusual event following COVID-19 infection and looked for a connection between morbidity and mortality and the administration of the vaccine. An increase in myocarditis cases was found in young men after the administration of the first and second vaccines based on the number of myocarditis cases in corresponding periods before the pandemic. No evidence of deaths after vaccination was found, except for the suspected case of a 22-year-old young woman who died shortly after the injection of the vaccine. As a result, orders were given to follow patients for 30 min after injection. Hospitals were also instructed to report to the Ministry of Health any case of myocarditis that occurred following vaccination for the sake of epidemiological comparison.

15.14 Conclusions of the Committee Assigned to Check the Quality of Hospitalization of COVID-19 Patients in General Hospitals, Including the Third Wave of the Pandemic

(a) Changes were observed in morbidity, hospitalization rates, hospitalization outcomes, and mortality among the first three waves of the pandemic, following differences in diagnosis and treatment policies. The vaccination of the adult population resulted in a dramatic decrease in morbidity and the number of seriously ill patients. The appearance of variants, especially the alpha variant, caused a relative increase in morbidity among young people, children, and pregnant women who were not vaccinated in the ini-

Table 15.3 Examples of high-risk failures

Step in the process and area of responsibility	Description of the failure	Risk level	Recommendation for reducing the risk	Responsible party
General	Process management fails to include all stages	High	Nominating a process manager	Governance of the Ministry of Health
	Failure to consider every stage in the process	High	Nominating a high-level expert	Governance of the Ministry of Health
	Insufficient communication among the storage facility, pharmacists in each district, and the patients	High	Building a process for communication	Pharmacy unit in the oversight office

tial round of vaccinations. The alpha variant that infected over 90% of confirmed cases appeared to cause more severe disease than the original virus.

(b) Difficulties were reported with transferring individuals from hospitals without ECMO services to hospitals with ECMO services. The recommendation to equip every general intensive care unit with an ECMO device and train staff to operate it was renewed even more strongly than before. A lack of ventilator technicians qualified to maintain ECMO has been reported. There are only 55 employed in the entire country. There is a need for a clearer definition of the profession and clear training. Some have recommended appointing a chief respiratory technician in the Ministry of Health, similar to a chief radiologist.

(c) There has been a decrease in elective and ambulatory services and cases, even urgent ones, not related to COVID-19. It is unequivocally recommended to prevent this by sharing data on the accumulation and prevention of complications and excess mortality. It is recommended that the use of "remote medicine," including adopting and improving the tools used in such practice, be expanded and particularly implemented in outpatient clinics and institutes to prevent the neglect of patients with chronic illnesses and the deterioration of their condition while emphasizing quality, safety, and risk management. Patients with chest pain and neurological symptoms should be encouraged to go to the ER to prevent an increase in rates of morbidity and mortality from heart disease and stroke.

(d) There is a need to increase the number of intensive care doctors and nurses and infectious disease specialists. There is room for preferential training in these professions. The need is now clear for the addition of administrative personnel standards and not only for doctors and nurses.

(e) There were a substantial number of exposures and infections among medical staff members mainly from other staff members when exposed in staff rooms (common meals) or outside the hospital. At its peak, the isolation staff members affected 5517 staff members, including 598 doctors, and 1414 nurses, with a direct impact on the workload in the COVID-19 wards. An efficient and quick plan to vaccinate staff members is clearly important. Additionally, it is very important to have an established plan to prevent infection and burnout of staff members.

(f) There is a need for the direct examination of the issues of long-term COVID-19, psychiatric patients infected with COVID-19, the treatment and vaccination of pregnant women, and the expansion and regulation of remote medicine.

(g) There is a need for clinical protocols that are updated once a week and an increase in systemic learning and research collaboration.

(h) Effective drugs have not been found for the disease. Dexamethasone helped somewhat in critically ill and ventilated patients, and plasma from convalescents helped immunocompromised patients and, in several cases, even changed the course of the disease for the better. Remdesivir and Actemra and vitamin D achieved disappointing results in some hospitals but were considered helpful in others. A benefit is observed from treatment with anticoagulants, remdesivir, and vitamin D in the early stages of COVID-19. During the fifth wave, the drug Paxlovid (a combination of nirmatrelvir and ritonavir) was found effective in preventing the deterioration of the disease if given immediately upon the onset of symptoms in older patients.

(i) A request was made to supply drugs directly to pharmacies and not only according to a specific patient to avoid a delay in treatment (e.g., remdesivir).

(j) In one of the hospitals, staff successfully treated NO in patients on HFNC and in some cases prevented deterioration, which led to an increase in saturation and prevented the need for intubation.

(k) The activity of the quality, safety, and risk management units differed from one institution to another. There is room to use teams from these units to manage the pandemic in

cooperation with members of the infection prevention unit and to expand their activities in improving the quality of care and investigating adverse events and failures related to the pandemic.

(l) A central strategy that accounts for the functioning of COVID-19 wards in both large and small hospitals is recommended. In small hospitals, it is better to establish a new department with staff from different departments; in large hospitals, it is preferable to convert an entire internal medicine department. All hospitals must share their accumulated knowledge, innovations (open devices and procedures), and updated clinical protocols. In one of the small hospitals, a "pre-COVID-19" complex was established adjacent to the COVID-19 ward; this reduced the burden on the biological ER, facilitated the routing of patients, and prevented infections. Additionally, other options that have been tried successfully in hospitals should be discussed, for example, establishing homogeneous internal medicine teams and heterogeneous intensive care teams (general, cardiac, neurosurgery, chest, and children).

(m) A "heat map" of red areas can be developed based on the results of the positive laboratory tests and caution can be exercised when accepting patients from those areas.

(n) The nutritional assessment of patients hospitalized for COVID-19 is very important, especially in the intensive care unit. A direct relationship with prognosis was demonstrated for nutritional status with factors that predict mortality, from malnutrition on the one hand to obesity on the other hand. There is a place for active nutritional intervention by a dietician both at the entrance to the department and in remote consultation. In the intensive care unit, emphasis should be placed on enteral treatment and, if that is unsuccessful, on parenteral nutritional therapy, especially in ventilated patients after an accurate nutritional assessment. In ventilated patients, enteral nutrition should be started early, preferably within 4 days after arrival, particularly if there is a failure to switch to TPN. Hypophosphatemia (which prolongs ventilation), hypokalemia, and hypomagnesemia should be avoided.

15.15 Summary of Hospitalization of COVID-19 Patients in General Hospitals and Comparison of Mortality Among Waves I–III [19, 20]

In each hospital, files of patients defined as having severe and non-severe cases were sampled according to a preselection strategy prepared by the unit of statistics of the National Plan for Quality Indicators. Two cohorts were prepared: cohort A (in waves I and II) and cohort B (in wave III). The team of researchers included supervising nurses from the quality assurance department, medical students, and nurses who had undergone appropriate training, and quality and safety personnel. The data were manually entered into an Excel sheet that included the following details: **demographic details**—date of hospitalization, date of discharge or death, social security number, name, hospital, COVID-19 ward, COVID-19 intensive care unit, year of birth, gender, and the reason for admission (because of COVID-19 or treated in the ER for another reason and discharged); **background information on diseases**—diabetes, hyperlipidemia, hypertension, heart disease, kidney disease, lung disease, smoking, obesity BMI > 30, active malignancy, or immunosuppression; **clinical symptoms upon admission**—fever >38, cough, shortness of breath, headache, diarrhea, vomiting, abdominal pain, fatigue/weakness, muscle pain, change in taste and/or smell; **laboratory test results** (at admission and the most pathological)—saturation, blood pressure, hemoglobin, leukocytes, lymphocytes, albumin, calcium, sugar, sodium, potassium, BUN, creatinine, D-dimer, bacterial contamination, contamination

with resistant bacteria, or ARDS; **administration of oxygen or ventilation, supportive care**—the administration of high-flow oxygen, NIV, invasive ventilation, ECMO, pronation, NO, prism, or dialysis; **medicines**—steroids, remdesivir, plasma from convalescents, vasopressors, vitamin D, clexane, or other treatments for COVID-19; and **hospitalization outcome**—mortality, discharge target, or discharge with respiratory support. The variables were analyzed in a regression model, and the possible relationship between predictor variables at admission and during hospitalization and respiration and mortality in the two cohorts was examined.

15.15.1 Cohort Results

In the ten selected hospitals (Assuta Ashdod, Barzilai, Carmel, Holy Family, Scotch, Sharon, Ma'aini Hishu'a, Poria, Kaplan, and Beilinson), as of 5.11.2020, there had been 5810 hospitalizations, 2289 of which were defined as severe cases (note that some of the cases that were defined as mild became severe during hospitalization). Of these, the files of 1699 patients were sampled; 360 of this group were hospitalized due to another reason, and COVID-19 was diagnosed during or before hospitalization. The cohort included 1339 patients, 1027 of whom had a severe case, and 56% of them were men; the average age was 62 ± 20 years, and the median age was 64 years. This group was sampled with a higher probability to obtain more information about seriously ill patients. All results are shown after weighting by sampling probability.

The average hospitalization time increased with age and was longer in patients with underlying diseases, fever, shortness of breath, and pathological test results upon admission. Mortality in the hospital was 13.76%, and mortality within 30 days of admission was 15.86%. Invasive ventilation was used in 8.11% of patients, and connection to ECMO was used in 0.64%. A total of 47.84% were treated with steroids, 19.11% with remdesivir, 9.99% with convalescent plasma, 15.91% with vitamin D, and 63.62% with anticoagulants. The number of underlying diseases was directly correlated with the mortality rate. High-flow oxygen administration, NIV, or invasive ventilation was correlated with the male sex, higher age, heart disease, kidney disease, RA disease, fever, dyspnea, leukopenia, hypoalbuminemia, hypocalcemia, hyponatremia, and high creatinine on admission. Disturbances in taste and smell, gastrointestinal symptoms (diarrhea, nausea, vomiting, abdominal pain), and muscle pain on admission had a protective effect against the need for invasive ventilation or mortality. Of all the treatments, remdesivir and vitamin D had the most positive effect.

The third wave was characterized by an increase in the number of people infected with the alpha variant and by excessive infection and more severe disease. At the same time, as adults became vaccinated, the proportion of sick children of all ages relative to the total number of cases appeared, and some had severe symptoms, as did pregnant women. The appearance of additional variants, South African, Brazilian, Californian, New York, Ugandan, and Indian (Delta), raises clinical questions—Is the disease more contagious or does it cause more severe disease now? Is it becoming resistant to Pfizer and Moderna vaccines? The delta variant appeared at the end of the third wave and is characterized by more rapid infection and rapid spread. Israel's handling of the virus has still resulted in a large number of new patients and confirmed cases per day but has been characterized by impressive handling of the health system, resulting in a lower number of deaths than in other countries. In Israel, there have been four times more confirmed cases per million people than in Greece, but there has been a similar number of deaths per million people (Fig. 15.4). The change in treatment modalities between the waves is presented in Table 15.4.

The mortality rates in Israeli hospitals have ranged from 5% to 20%. When separating the hospitals into two groups, those with mortality rates lower than 12% and those with rates higher

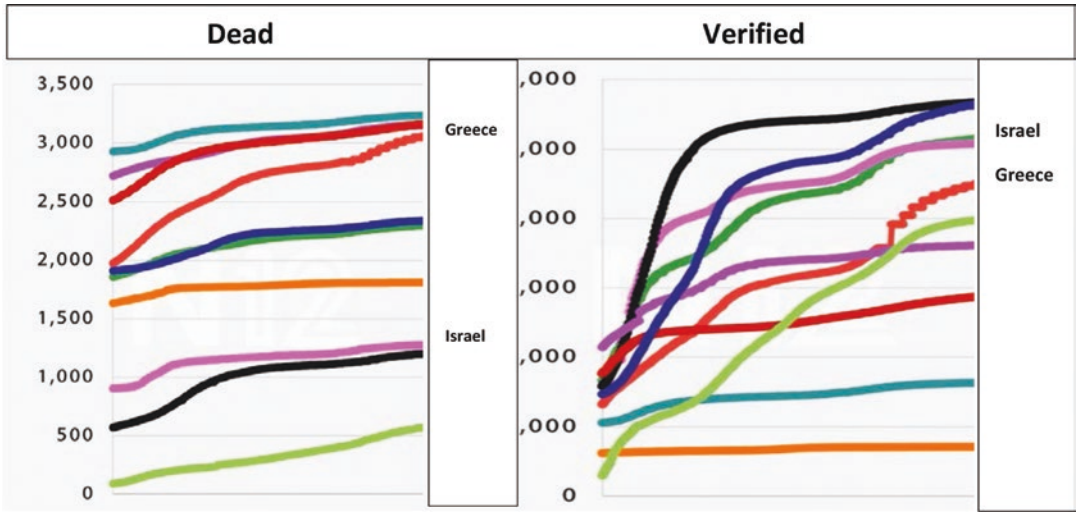

Fig. 15.4 Comparison between Israel and Greece

Table 15.4 Differences in drug treatments between the first and second waves and the third wave (% of hospitalized patients)

Treatment	Waves I + II	Wave III
Steroids	49.72	75.69
Remdesivir	18.95	14.87
Plasma	8.09	5.75
Vasopressor	8.90	13.67
Vitamin D	14.20	20.96
Anticoagulants	66.03	79.79
High-flow oxygen	19.25	31.91
Invasive ventilation	9.02	14.21
ECMO	0.70	1.50
Pronation	4.57	5.99
NO	3.43	5.17
Dialysis	2.63	3.25

than 13%, it was found that in the hospitals with higher mortality, the mix of patients was different and included overall older patients with more serious underlying diseases (Fig. 15.5). Additionally, the ratio of patients to doctors specializing in intensive care was higher in the latter group. In addition, mortality was significantly higher in patients with chronic kidney disease but lower in patients who were hospitalized with digestive symptoms [19, 20]. In a multivariable model, a positive correlation was found between the number of background diseases per patient and between specific chronic diseases, invasive ventilation, and mortality (Figs. 15.5 and 15.6).

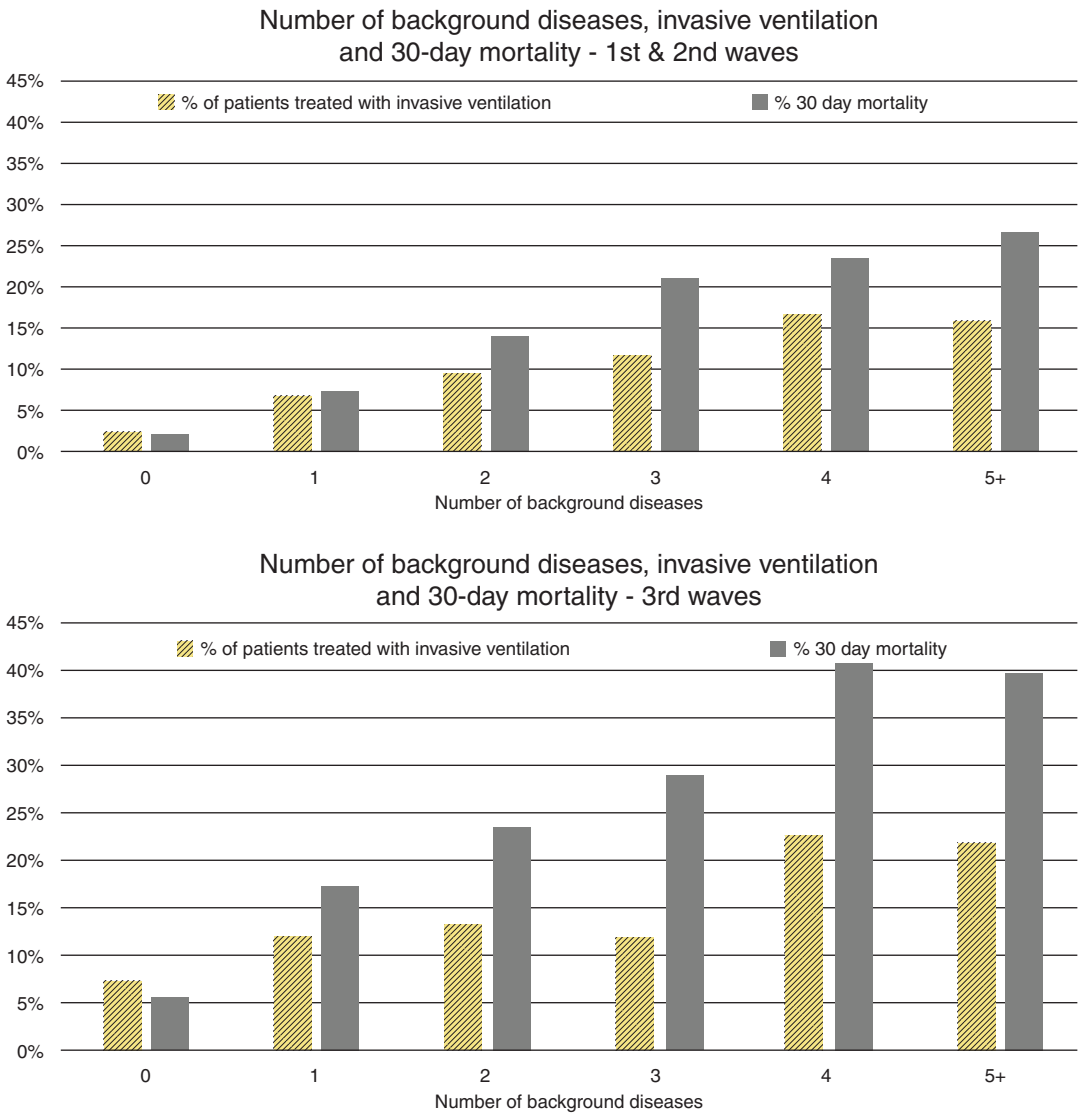

Fig. 15.5 Correlation between the number of background diseases and invasive ventilation and mortality—a multivariate analysis

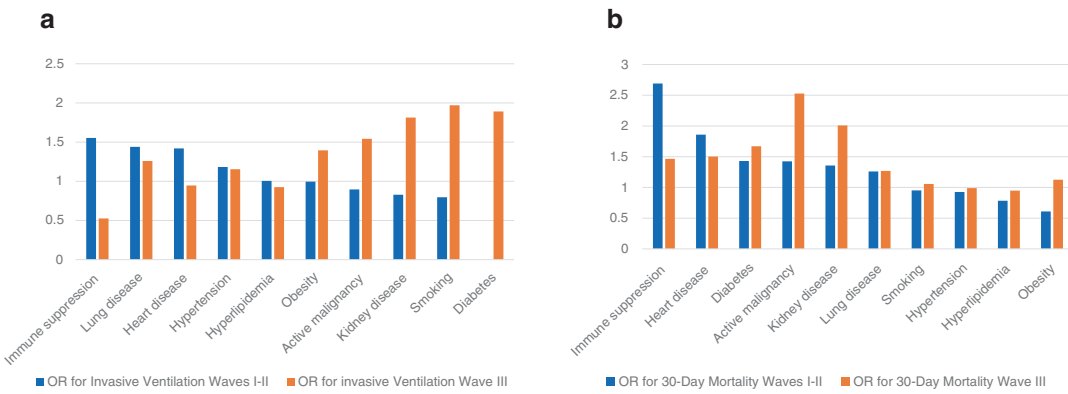

Fig. 15.6 Correlation between types of background diseases and invasive ventilation and mortality—a multivariate analysis. (**a**) Waves I–II and (**b**) wave III

15.16 Long-Term COVID-19

According to the publication of the World Health Organization, one out of every ten recovered patients among clinically ill patients continued to suffer from symptoms for an extended period [21]. This persistent syndrome is characterized by pain in the chest and muscles, fatigue, occasional shortness of breath with light exertion, and even cognitive disorders. The pathophysiological mechanism underlying the syndrome is not completely understood, but it is a multisystem injury that includes chronic inflammation, hypercoagulability, and endothelial damage that can cause blood clots to form. Disturbance in the regulation of the immunological system can cause a cytokine storm in patients with severe cases or abnormal regulation of inflammatory processes in patients with milder cases. Pro-inflammatory cytokines may form and cause damage, especially when they are not inhibited by anti-inflammatory cytokines. There are other examples of prolonged damage after other viral diseases, such as subacute sclerosing panencephalitis after a measles infection or multiple sclerosis after an Epstein–Barr virus infection. In particular, cardiovascular damage is apparently related to the receptors for angiotensin-converting enzyme 2 (ACE2) in the heart and blood vessels and thus increases the risk of damage to the endothelium and of thrombo-inflammatory disease. It should be noted that women and healthcare workers are affected by this syndrome more than other populations. This syndrome has an impact on the mental health and ability of convalescents to return to a normal life and work circle. This has far-reaching consequences on their functioning in their family, in society, and in their economic state. The health system should be prepared to treat patients with COVID-19 who develop this syndrome, recognize its existence, investigate the mechanisms that cause it, understand its course, develop diagnostic approaches, and provide appropriate therapy and rehabilitation. Topics that need to be studied and developed include a professional multidisciplinary approach, new treatment directions, updated clinical guidelines for medical teams, the establishment of appropri-

ate and accessible services, occupational and social solutions, data collection, and documentation to support advanced research to understand the syndrome and advance treatment and follow-up.

Key Messages: Patient Safety and Risk Management During the COVID-19 Pandemic—The Israeli Experience

- The COVID-19 pandemic has exerted heavy pressure on the health system, which was already chronically short on human and other resources. Elective and preventive medicine has been replaced by the treatment of severe COVID-19 patients who need intensive care. Several serious problems in the field of treatment safety have arisen due to the pandemic, including misdiagnoses, late diagnosis, and the population's avoidance of medical institutions in urgent clinical situations because of fear of infection. The lack of knowledge and the rapid progression of the disease have led to creative solutions to problems and barriers, thinking "outside the box," and extensive collaborations. Direct contact between medical staff and patients was greatly reduced. Doctors and nurses have been asked to treat patients with COVID-19 after short and inadequate training, and the clinical protocols have changed frequently and have not allowed assimilation and thorough understanding. For example, protocols have changed for treatment with anticoagulants and their dosage; the administration of oxygen or invasive ventilation' treatment with antibiotics, antiviral drugs, anti-inflammatories, and steroids; failures in preventing infections among the public and among staff; the incorrect use of laboratory tests or interpretation of their results; a morbidity burden that prevented regular activity to prevent secondary infections; and risk management and treatment safety. On the other hand, there have been extraordinary improvements in communication among teams in service and research and increased collaboration for finding quick and creative solutions for recruiting, equipping, and training personnel and strengthening teamwork and the sense of shared responsibility. Many budgets were quickly redirected to the health system to enable building facilities, buying equipment, hiring workers, conducting laboratory tests, and dispensing vaccinations, all of which were necessary to address the pandemic. Health systems have taken their rightful and important place in many countries, and the insight that health services can help contain pandemics and emergency events is necessary for a progressive, modern society.

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