

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. letter	Stanley Stein to Chris Jennings (2 pages)	02/22/2000	P6/b(6)
001b. fax	To: Jeffrey Lipton (3 pages)	06/12/1999	P6/b(6)
001c. letter	Barry Freedman to Caroline and Stanley Stein (1 page)	07/23/1999	P6/b(6)
001d. report	re: personal medical (16 pages)	07/30/1999	P6/b(6)
001e. letter	Stanley Stein to Linda Granowetter (2 pages)	02/22/2000	P6/b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20472

FOLDER TITLE:

Errors [Folder 1]

2012-0463-S

rc748

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Presidential Records Act - [44 U.S.C. 2204(a)]

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C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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From: Abigail C. Smith on 02/22/2000 03:45:18 PM

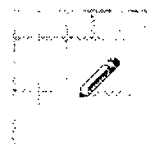
Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP

cc:

Subject: Background briefing on medical errors initiative

----- Forwarded by Abigail C. Smith/WHO/EOP on 02/22/2000 03:45 PM -----

 Margaret M. Suntum
02/22/2000 02:48:33 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: Background briefing on medical errors initiative

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

February 22, 2000

PRESS BRIEFING BY
SENIOR ADMINISTRATION OFFICIALS
ON PRESIDENT'S INITIATIVE TO REDUCE MEDICAL ERRORS

The James S. Brady Press Briefing Room

1:50 P.M. EST

MR. KENNEDY: The President unveiled some landmark initiatives to reduce preventable medical errors, and here to amplify on that and provide additional background are two senior administration officials.

SENIOR ADMINISTRATION OFFICIAL: Good afternoon. I'm

an administration official that is not a doctor, and I have one over here who is. So you can refer to him as Dr. Administration Official. I'm going to quick summary, and then just enable you to do some Q's and A's, and I'll ask the doctor to come up.

Today, as you saw, the President announced his response and the administration's response to the Institute of Medicine's report that was released at the end of November, just a few months ago. Largely, his report and the recommendations that are outlined in the report that he endorsed today endorse the IOM recommendations, but in many ways go beyond them, and underscores his commitment to agree with the IOM that we move towards eliminating at least 50 percent of preventable errors over the next five years.

The President's -- the initiative that he unveiled was a multifaceted initiative. There are administrative initiatives, executive actions, legislative initiatives, and then there will be other initiatives that we'll be working with the states on as we move forward to implement a program that we believe will go a long way to eliminating preventable medical errors and enhancing patient safety.

We believe that this initiative very significantly complements the work that the President and all the departments and agencies and the Congress have been doing on patients' bill of rights legislation, but we view this issue to be a separate initiative, an initiative oriented towards patient improvements, quality improvements in patient safety enhancement -- whereas the patients' bill of rights is oriented towards processes within health plans and access to services that are covered within the health plans, or should be covered, and assessable. We'll get to that if you have any questions.

Clearly, the problem of preventable errors has been very well-documented. I won't go through that. We've given you some backup on that. Many of you have reported on it already. The President's initiative calls for the establishment of a new patient safety center within the Agency for Health Care Research and Quality at the Department of Health and Human Services. That was consistent with the IOM recommendations. It calls for the development of a new regulation that will require all hospitals participating in the Medicare program, fully over 6,000 hospitals, to implement patient safety initiatives, including medications, safety-oriented approaches. It calls for the development of new standards by FDA to deal with and help prevent medical errors caused by proprietary drug names and packaging that are easily confused with other drugs.

Health care professionals and patients have, for a long time, for a longstanding period of time, indicated that these were very real issues and led to actual implementation problems and compliance problems related to medication errors. And as we move forward, we are going to be fully implementing the VA

patient safety initiatives that have been outlined in your papers, as well as moving towards mandatory initiatives at DOD, and I can outline those shortly.

This is all done in the context of a broader commitment to ensuring that we take all actions necessary, within the government and with our private sector partners, to develop an environment that enhances the desires and commitment to implement medical-error initiatives. And that includes reporting systems. Reporting systems are not the only component that is necessary to have enhanced quality, but they are an important component that we believe needs to be part of the process.

The President's proposal endorses a combination of mandatory and voluntary-approach reporting systems, mandatory being oriented to reports of deaths and serious injuries, and voluntary reporting dealing with all other errors, as well as those incidents that are categorized as near-misses and/or close calls. This is very consistent with the IOM recommendation.

We do this in the context of a state-based approach. We endorsed the approach that the mandatory reporting should be done by all 50 states within three years. It should be focused on the definitions that I've just outlined. But it should also be done in such a way that incorporates public reporting of health care systems and hospitals, but not of individual patients and not of individual health care professionals. The orientation is not to orient this towards blame, but orient it towards an environment of working collaboratively to address these concerns.

Now, as we do this, we believe it's important that we implement initiatives to make sure these reporting systems work most appropriately. And what we do -- how we do that is, we are supporting the expansion of peer review protections within hospitals, which are oriented towards systems in hospitals that, following an error, they do follow-up investigations to see what causes those and other like errors, and whether -- and to determine whether or not they're system-wide problems. If they are system-wide problems -- and I think we call these secondary effects, or secondary issues -- if a hospital finds that out and implements initiatives to address those concerns, those issues are protected from discovery and liability.

Any individual case in which there has been harm, in which someone has died, people individually would still have access to all the information they would need in a malpractice suit, for example.

We also are working towards the development of showing that we're leading the way in this area by developing information -- comparable information standards, so when people are reporting these errors, that we're comparing apples to apples, so that when a hospital does report from all parts of a state, that information is comparable and it is something that you can

compare one to another in appropriate ways.

Lastly, as we move towards these mandatory-voluntary systems, we are leading the way in a number of different areas by implementing mandatory programs at the VA, the DOD, mandatory reporting at FDA, and voluntary initiatives program-wide at the VA, which we can talk about in some detail.

I'll conclude with that, other than to say this -- our announcement today, we had witnesses, including our administration representative here with me today, testifying before the Congress. The Senate had a hearing -- it was a joint committee hearing between the Senate Help Committee, formerly known as the Labor Committee; and the Labor-HHS Appropriations Committee. The recommendations were very well received. The hearing went very well. We had Senator Specter, Senator Jeffords, and Senator Harkin here today with the President indicating their strong support of working collaboratively this year to get initiatives done. We're very encouraged by the response.

We've had very broad-based support from a wide range of experts in this area. We think we start in a good place. We look forward to working with all interested parties to get this job done. And with that, we'll open it up for any questions you may have.

Q Aren't you going to have an onslaught of malpractice suits as a result, if the government is going to certify that a major error was made in medical treatment?

SENIOR ADMINISTRATION OFFICIAL: Well, actually, all we are suggesting is reporting deaths and near-misses that should be reported anyway today. In fact, under the AMA Code of Ethics and just the general practice of hospitals, if you have these incidents you are supposed to report it to your patients. Moreover, if you die or if you have the wrong leg amputated, you probably know that. Moreover, we have 18 states who already have mandatory systems in place and we have not seen an increase in incidents of liability concerns whatsoever.

Q You have 18?

SENIOR ADMINISTRATION OFFICIAL: Eighteen have mandatory hospitals. There are 21 states who have mandatory reporting systems. The other three actually focused on nursing homes, and there's two others that have voluntary reporting systems. There's a total of 23.

Q If this was such a good idea, how is it that both the American Medical Association and the American Hospital Association are so vehemently opposed to it?

SENIOR ADMINISTRATION OFFICIAL: Well, actually, I

think it's not a fair characterization to say that they're vehemently opposed to the whole proposal. In fact, if you talk to them individually, you'll find that most of the recommendations they widely support and accept and want to work with us on. There is one issue that both of them have raised issues about, primarily oriented to mandatory reporting and concerns about what the implications are of mandatory reporting.

We believe that we've addressed them by laying the foundation for a much more workable system than currently exists. We think they haven't had a lot of time to review these recommendations. We look forward to working with them. We had today, for example, a number of hospital associations saying very supportive things. The American College of Physicians today said very supportive things. The New York Hospital Association we've worked with today who are out there at your stakeout. So I think this is an area where, with collaboration and a working partnership that we've had in the past, we will be able to address some of their concerns.

Q Are you disappointed that they didn't show up today at the presentation?

SENIOR ADMINISTRATION OFFICIAL: The AMA had representatives today, and I think we've worked well with the American Hospital Association in the past, I think we will in the future. They can choose not to come to any event that we have. I think they believe that their statement speaks for itself as it relates to their current review of these recommendations, but we think over time, we'll have a very good working relationship and we'll get agreement.

Q Why did you not, on the federal level, make this mandatory, the reporting? One, does that require congressional action? That's not something that can be done -- the mandatory reporting right now is a federal program; the President can do that through executive order or some other executive fiat. He couldn't make mandatory reporting in all 50 states without congressional legislation. Is that correct? And two, would you like to have done that?

SENIOR ADMINISTRATION OFFICIAL: Well, as I think we worked very carefully in the report to indicate, we believe that mandatory systems in place today are positive, but they can be done better. And before you require that all states have them implemented, we should have some of these other initiatives that we recommend in this report underway, so that they can work in the best way possible.

We also feel that, as does the Institute of Medicine, that these should be state-based rather than federally based approaches. And our conversation with the NGA and other states led us to conclude that there's a lot of interest at the state level in moving in this direction. Rather than requiring them to

do that, we think that we can provide some of the support systems at HHS and other agencies throughout the federal government to do it right. And we anticipate that they will. If they do not after three years, then we will support approaches to ensure that all 50 states do have reporting systems.

Q The provisions on reporting, and shielding of information liability -- it seems to protect the hospitals but leave the doctors open to exposure. That is, if a hospital has a, you know, a poor system that leads to mistakes, that material is protected from litigation. But a doctor who's at the end of the chain who makes a mistake seems to be exposed here.

SENIOR ADMINISTRATION OFFICIAL: I'll have the doctor respond to that. But I will say this, that our reporting system explicitly exempts physicians and other health care professionals from public reporting of this data.

Q But it doesn't protect the institution. Anybody who's got a -- any smart ambulance-chasing lawyer's going to figure out what case was involved.

SENIOR ADMINISTRATION OFFICIAL: We've also proposed a peer review protection extension from what currently exists for the peer review organizations, so that it would extend beyond that to these systems as well. We believe that when the hospital industry looks at that, that they will be pleased at the peer review extension and they'll see that that will allow them to have a healthier and more constructive reporting system that won't put people at risk for having made the report.

In addition to that, we're going to limit the disclosed mandatory reporting process to very serious errors -- preventable deaths, and serious events which cause a long-lasting problem for the patient.

That's going to be a clearly delineated list, and we're going to work with the Quality Forum to describe that list. The Quality Forum, you will recall, is the organization that the Vice President kicked off, but is a private sector organization, including the hospital industry and the physicians and the purchasers, and we're going to ask them to come up with a list that ought to be reported. Therefore, the physicians and providers will have a voice in what that limited list of disclosed items ought to be on the mandatory reporting system.

Q Can you explain that expansion of the peer review protections?

SENIOR ADMINISTRATION OFFICIAL: Yes. Right now, if you have a system, if you have a reporting process within the peer review organizations, then that secondary data set, that aggregation of the events that occurs in the hospital is protected by the peer review statute from being discovered. It

certainly doesn't protect the primary database, the chart, the medical record, but it does protect the secondary data set. So that prevents a system like we're describing from being used for a fishing expedition or by someone who wants to just go find out if there are individuals who might have been harmed.

Because, number one, that data should have been told to the patient in the first place, so the data will have been already disclosed, and secondly, we think that for the hospitals and for the medical community to address this in a constructive way, they have to feel comfortable that if they do this reporting, it will be protected by the peer review protections.

Q A couple of years ago, the American Medical Association had its own study in which it looked at the incidence of medical mistakes and took upon itself to try to police its own members. Is this an indication, this proposal today, that they haven't done a good enough job of it?

SENIOR ADMINISTRATION OFFICIAL: Not at all. In fact, we admire the leadership that the AMA has taken in initiating the National Patient Safety Foundation at the AMA. We believe that what they've done has been to help us to understand that there is a large professional role in the area of improving from the information that we can gather through these reporting systems, but we also recognize that there needs to be a balance between the reporting systems that are focused on learning, and the reporting systems that respond to the public's need to know that their hospitals are safe and that the hospitals not only are safe in terms of the reporting of publicly disclosed information that I mentioned earlier, but we also believe that the hospitals ought to describe to potential patients which patient safety practices they have in place.

So that if you were going to go to a hospital, you would be able to find out easily, do they have a computerized order entry system, do they have a bar coding system for their blood transfusions, and know that that hospital has or doesn't have those practices in place. We think what this does is complement what the AMA has been doing, by taking the professional responsibility for reducing errors through a learning process.

Q And to fast-forward three years, assuming that you have tons of information in place about medical error, then what? In other words, how does that immediately roll over into your goal of reducing preventable medical errors by 50 percent? In other words, you've got the data, then how do you implement?

SENIOR ADMINISTRATION OFFICIAL: Well, what you're referring to is the statement that we made that we believe that the states will be able to put successful programs into place, and we want to help them to do that in every way that we can, through better information, help in understanding best practices,

understanding how the reporting systems can be done best.

But we also feel we need to evaluate those systems. If within three years we determine that the state-based systems are not working well, then there is a federal inter-agency health committee, representing all of the groups within the federal government that have an interest in, and a commitment to, health care quality, who will evaluate those results and make a recommendation at that time about whether something different from a state-based program is needed.

Q Do you have a target at three years?

SENIOR ADMINISTRATION OFFICIAL: No later than three years is the target.

Q Right. But does something have to happen in three years, specifically?

SENIOR ADMINISTRATION OFFICIAL: At the state level, yes.

Q Do individual hospitals have to cut errors 50 percent within five years? And if not, how do you realistically expect to reach that 50 percent reduction goal?

SENIOR ADMINISTRATION OFFICIAL: Well, first, hospitals have different rates of errors, we suspect, although we don't have much information on this at the present time. We're not suggesting that every hospital reduce its rate of errors by 50 percent. There are hospitals who have already instituted programs and have demonstrated substantial reductions already. But we do believe across the nation there should be a 50 percent reduction within five years, which was the Institute of Medicine's recommendation as well.

Q What are the keys to make sure that happens?

SENIOR ADMINISTRATION OFFICIAL: Well, let me explain. The approach that we're taking is, looking at all of the different levers that the federal government has in order to make that happen. Through the Health Care Financing Administration, we have conditions of participation that will require that every hospital have a patient safety program in place. Through the Food and Drug Administration, we will enhance the reporting system for adverse events of drugs. Through the VA and the Defense Department, we have exemplary programs that we think that the private sector will pick up on. Through the Agency for Health Care Research and Quality, we will institute a research program that will show best practices and demonstrate that they really are best.

So there's not a single program. We don't believe that this is such an easy problem that it can be answered with a

single answer, but rather that multiple are going to be necessary.

Q A lot of attention has been paid to things like sawing off the wrong limb, leaving something in a body cavity during an operation. But the President also talked today about the difficulty of wrongful identification of drugs, sometimes having the wrong interaction between drugs, which is a little more prosaic. Do you have any percentage of the number of serious medical errors which are caused by the wrong drugs?

SENIOR ADMINISTRATION OFFICIAL: Yes, we do. We believe -- the data that's available, the best data that's available suggests that at least 7,000 deaths per year occur because of adverse events that are caused by drugs. About 10 percent of the admissions to hospitals in this country are caused by drugs that have an adverse effect, either because they were prescribed wrong, or because they may have been prescribed correctly, but they still had an adverse effect. So it is a very, very serious problem.

There are those who have calculated that between -- at least 19 percent, and as many as a quarter of the adverse events that occur in this country are due to drug errors.

Q A quarter of the adverse -- now, the study showed, what, 44,000 to 80,000--some odd deaths, so you're talking about presumably a quarter of that?

SENIOR ADMINISTRATION OFFICIAL: We're talking about different studies. One study said 19 percent to a quarter of the errors, not the deaths, but the errors are due to drug errors. Another study said that 7,000 of the deaths are due to drug-related errors. And let me emphasize also that these numbers that I'm quoting are in the context of somewhere between 2.5 and 4 percent of people who go into the hospital who have a serious event that occurs to them while they're in the hospital that was preventable.

Ironically, this is not just an American problem. The same numbers have come out of Australia and the United Kingdom. So we recognize that this is a global problem, not just an American problem.

Q Even if you achieve the worthy goal of reducing medical mistakes by 50 percent, they still count as one of the leading causes of death in this country. Are you raising the bar high enough with a 50 percent reduction?

SENIOR ADMINISTRATION OFFICIAL: We think that 50 percent is achievable. We would like to continue to make improvements beyond that, but let me give you an example of how we might be able to do better over a longer period of time.

The physicians who are anesthesiologists, the guys who basically put patients to sleep when they're getting surgery, started a program about two decades ago in which they looked for systematic ways in which they could prevent errors in the operating room. Changing the dials, for example, so that the dials in every operating room were consistent, and you wouldn't have to learn a new system every time you went to a new machine.

They have reduced the number of errors in anesthesiology seven-fold in two decades. And we're talking about a one-half fold decrease in five years. So I think what we can say is, we are confident that the 50 percent reduction is achievable. But I also think it's fair to say that we won't stop at five years, we'll continue to look for ways to improve beyond that as well.

Q What can a patient do?

SENIOR ADMINISTRATION OFFICIAL: What patients ought to do is to learn what measures -- what practices their hospitals ought to be putting into place in order to reduce errors. If I were a patient going to a hospital today, I'd want to know how the hospital dispensed drugs. I'd want to know if they had a computerized order entry system, if they had a double-check system in the pharmacy, if they had potassium chloride, for example, which is a very toxic drug, in concentrated forms on the unit. And, in fact, we have a list which has been put together by the National Patients Safety Partnership, led by the VA, of about 10 or 15 practices that every hospital ought to undertake.

But we're going to ask the Quality Forum, the group I mentioned earlier, to come up with a list that they will issue -- the hospitals, the purchasers, all these groups together will put together a list of practices that every hospital ought to have in place, and will make that available to the public very soon.

But let me just say one other issue about the individual patient, or person. I think there are certain things that people can do to be sure they're sharing decision-making with their physician, and that they're engaged in that decision-making process. Nothing could help that more than people asking questions, to be sure they understand what their drugs are, understand why their drugs are being given, and when they go back in to see the physician, bring those drugs with them to be sure that the right drugs were dispensed.

Q Are doctors being taught to educate more their patients in terms of what they're doing?

SENIOR ADMINISTRATION OFFICIAL: There are some model programs in medical schools and residency programs to educate physicians not only to share decision-making with their patients, but also to institute some of these best practices. The amount of education, though, in many medical schools is disappointing.

The Senate Help Committee introduced legislation about a year and a half ago to institute special programs called Centers for Education and Research in Therapeutics across the country, which have now been established -- there are four of them around the country -- to try to do a better job of helping physicians to understand how they can reduce those errors.

Q One of the main criticisms of the New York system, which has a mandatory reporting system, is the information falls into a black hole at times, and that as a consumer, as a patient, unless you're in the know, you have no idea where to access that information. What's your goal for the states to do as far as patient -- or anyone -- public accessibility? I mean, one proposal in New York is that hospitals be made to post their reported errors. How do you envision -- how easy should it be for patients and the public to get the information?

SENIOR ADMINISTRATION OFFICIAL: Clearly, we want to make sure that it's accessible information for beneficiaries, for patients, for anyone -- family members. The issue is, though, as you present that information you need to make sure it's usable information that is comparable from institution to institution. And one thing that we have focused on in these recommendations is to develop appropriate comparable information standards to do that, and not only just to do that in a fair way for all the institutions, but in a presentable way for patients and their families.

You can have all the information you want, but if you can't understand what they're showing you, it doesn't mean anything. And one of the recommendations in the report that we've unveiled is working with the Quality Forum and others to develop that type of information. But we believe that just saying, go post the information, before you know how best to do that could be not as productive as it otherwise might be.

Q Can you describe exactly what needs to be in legislation in order to make this happen -- I mean, related to that comment?

SENIOR ADMINISTRATION OFFICIAL: Well, in our overall recommendations, in terms of our recommendations today, we have administrative actions that include the regulation for conditions of participation for all hospitals and the FDA standards. We have budget initiatives which will require congressional review and approval, ranging from funding VA and DOD and HHS for the development of the patient safety center. And then there's collaborations, I would suggest, with the state. And I'm sure, in fact, this upcoming week when the governors come, next week, we're going to have a whole health forum, and I'm sure this issue is going to come up as well with the governors.

Q -- in Congress?

SENIOR ADMINISTRATION OFFICIAL: Well, Congress -- again, the appropriation in the budget process they're going to have to be looking at those particular initiatives, yes -- as well as the center.

Q If they want to produce patient safety legislation, what can they put in it to be useful to you?

SENIOR ADMINISTRATION OFFICIAL: Well, I think clearly they've already indicated a desire to work with us to have adequate funding in these areas. The authorization for the development of this new Center within the arc. And I think also just any type -- there may be some new authority the FDA will require in doing some of the medication work that they're doing.

SENIOR ADMINISTRATION OFFICIAL: And the peer review protections will need congressional consideration as well.

SENIOR ADMINISTRATION OFFICIAL: Yes, which may be federal or state.

Q Does the government have a watchdog to ensure patient safety and making sure, you know, Medicare and Medicaid programs, you know, run well? Does it have one --

SENIOR ADMINISTRATION OFFICIAL: Well, the Health Care Financing Administration uses the peer review organizations as their method of monitoring and improving health care quality. So for the Medicare program, we count on the PROs. We also count on the accrediting organizations, like the Joint Commission for the Accreditation of Health Care Organizations and CQA, who accredit those organizations.

For physicians, as you know, physicians are licensed by the states and they get their certification from their professional societies. So it's fair to say there isn't a single place that would be the watchdog agency or the watchdog site. But there are multiple places in the health care system who have responsibility for assuring that patient safety is in place.

MR. KENNEDY: We'll take one more question.

Q Yes, given the widespread under-reporting in existing mandatory reporting programs in states that already have them, how do you intend to assure that reporting is done, that there's compliance? And also, do you contemplate any penalties for people who fail to report?

SENIOR ADMINISTRATION OFFICIAL: Well, let me answer the second part first. Because these are state programs, it's up to the states to decide what and whether they would have any penalties in place.

We believe, and consistent with one of the previous

questions, that if this information is disseminated, and if it's safe -- if the peer review protections are in place, and the publicly disclosed information is limited to the lists that we both described earlier -- then we believe that there will be an incentive for people to report, because they'll learn from the reporting, and they'll be able to compare their institution with other institutions; further, that patients are going to be looking for that kind of information, not only to know that the hospital is safe, but that it has safe practices in place.

We believe that those kinds of incentives will increase the amount of reporting that occurs, and also increase the value of the disseminated information to the public.

SENIOR ADMINISTRATION OFFICIAL: Can I just add one last thing, and that is that -- and Joe's going to kill us, so -- okay -- is that if we're real successful at reducing the errors, at least the 50 percent, and our goal would be to eliminate all preventable errors, except we can't -- clearly that will also have the beneficial impact for all providers of avoiding unnecessary and expensive litigation associated with liability problems.

When people raise the issue of, I'm concerned about liability, it's sort of interesting to me, because if we do this right, if we do this well, this will remove a lot of the problems that people currently have with the liability concerns, because if you eliminate the errors in the first place, we believe that you can eliminate some of the excessive litigation that we're seeing in the health care delivery system right now.

Q Would you object to any putting together of this with patients' bill of rights out of Congress?

SENIOR ADMINISTRATION OFFICIAL: On that issue, getting a strong, enforceable patients' bill of rights done this year is a high priority. So, too, is this. We believe they're complementary initiatives. As long as one doesn't slow down the other, and does not ensure that neither gets done, we'd be open to that. But we would evaluate those in that context.

THE PRESS: Thank you.

END

2:20 P.M. EST

Message Sent To: _____

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ABC NEWS

SHOW: GOOD MORNING AMERICA (7:00 AM ET)

February 22, 2000, Tuesday

TYPE: Newscast

LENGTH: 280 words

HEADLINE: PRESIDENT BILL CLINTON UNVEILS PLAN TO COMBAT DEATH RATE DUE TO MEDICAL ERRORS; MOST CRIBS IN HOTELS UNSAFE; TEXAS PRISON STANDOFF ENDS; FUEL TRUCK BUMPS INTO AMERICAN AIRLINES JET AFTER IT LANDED; HOCKEY GAME BETWEEN BRUINS AND CANUCKS TURNS VIOLENT; SURVIVAL SKILL SAVES LOST 10-YEAR-OLD SKIER

ANCHORS: ANTONIO MORA

BODY:

ANTONIO MORA, anchor:

President Clinton unveils a plan today to combat the high death rate due to medical errors, as many as 98,000 a year. If approved by Congress, hospitals would be required to disclose serious and deadly mistakes.

Parents who travel should take heed. The Consumer Product Safety Commission announces today that it found most cribs in hotels and motels around the country unsafe. Inspectors say hazards include loose scr--include loose screws, soft bedding, and holes that could trap an infant.

A tense standoff at a Texas prison ended this morning. Officials say two death-row inmates in Livingston, Texas, have released the prison guard they were holding hostage. The female guard was overpowered yesterday afternoon as she was taking one inmate back to his cell.

A mishap last night at Chicago's O'Hare International Airport. A fuel truck bumped into the nose of an American Airlines jet shortly after it landed. Several people were treated for minor injuries.

A violent night in the NHL. After fighting Vancouver's Donald Brashear early in the game, the Bruins' Marty McSorley struck Brashear in the head with his stick as the game was ending. The Canucks immediately attacked McSorley, who later admitted his actions were stupid. Brashear was taken off the ice on a stretcher and diagnosed with a concussion.

Finally, skiers on a New Hampshire mountain cheered as a 10-year-old boy was returned to his family yesterday. Ryan Lanagan, of Massachusetts, survived a night of 15-degree temperatures by burying himself in snow to stay warm. He learned survival skills from his older brother.



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That's a look at the news at 7:07.
LANGUAGE: English

LOAD-DATE: February 23, 2000



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Online NewsHour

ONLINE FOCUS

MEDICAL MISTAKES

February 22, 2000



Gwen Ifill leads a discussion on the president's proposed guidelines to reduce the number of medical mistakes, after this background report.

The Health Unit is a partnership with the Henry J. Kaiser Family Foundation.

[Click here to listen to this segment in RealAudio](#)

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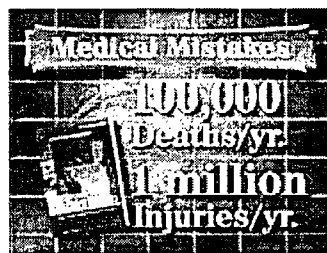
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SUSAN DENTZER: Last fall, a report from the National Institute of Medicine noted that roughly 100,000 Americans may die, and a million may be injured each year, as a result of preventable medical mistakes. Today President Clinton seized on that report's recommendations, proposing major changes in health care in hopes of slashing the error rate.



PRESIDENT CLINTON: Just think about it. We can cut preventable medical errors in half in five years, reduce concerns about lawsuits and about medical mistakes, avoid needless injuries and deaths, save lives, and make the world's best health care system much better for all Americans.

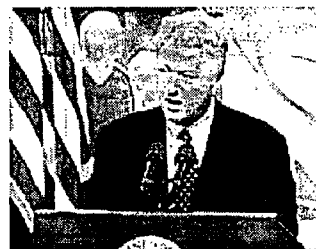
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SUSAN DENTZER: To accomplish it, the president proposed several specific steps. These included creating a new center for quality improvement in patient safety at the Federal Agency for Health Care Research and Quality.



PRESIDENT CLINTON: My budget includes \$20 million to support the center, which will invest in research, develop national goals, issue an annual report on the state of patient safety, and translate findings into better practices and policies. Second, we will ensure that each and every one of the 6,000 hospitals participating in Medicare has patient safety programs in place to prevent medical errors, including medication mistakes. These new systems save lives and, over time, of course, also save money.

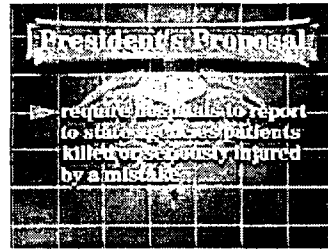
Handwriting errors



SUSAN DENTZER: Among other things, the president said those new systems should allow doctors to enter their prescription drug orders into computers instead of writing them down on paper. That could eliminate countless fatal mistakes that occur each year simply because nurses and other aides misread doctors' poor handwriting.

PRESIDENT CLINTON: Hospitals that have already taken these steps have eliminated -- listen to this -- two out of three medication errors. This is very significant. We tend to think all of our problems are the result of some complex, high-tech glitch. We just want to make sure, if people can read the prescriptions -- two out of three of these errors can be eliminated.

SUSAN DENTZER: The president's most controversial proposal would require all hospitals to report to state agencies when patients were killed or seriously injured because of a medical mistake. But he noted that tough questions remain about how to gather and disseminate information about errors without creating additional legal liability for the health care providers that divulge it.



PRESIDENT CLINTON: We also want to replace what some call a culture of silence with a culture of safety, an environment that encourages others to talk about errors, what caused them, and how to stop them in the first place. So we'll support legislation that protects provider and patient confidentiality, but that does not undermine individual rights to remedies when they have in fact been harmed.

SUSAN DENTZER: Today's announcement by the president now seems likely to spur action in Congress, where lawmakers from both parties are trying to craft bipartisan error reduction plans that they hope to enact this year.



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CNN

SHOW: CNN TODAY 13:00

February 22, 2000; Tuesday

Transcript # 00022207V13

TYPE: LIVE REPORT

SECTION: News; Domestic

LENGTH: 507 words

HEADLINE: President Clinton Unveils Series of Initiatives to Curb Rate of
Medical Errors

BYLINE: Natalie Allen, Major Garrett

HIGHLIGHT:

Nearly 100,000 men, women and children die each year in the United States
because of mistakes by medical personnel. Today, President Clinton unveiled a
series of initiatives aimed at dramatically curbing that rate over the next
several years.

BODY:

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NATALIE ALLEN, CNN ANCHOR: Nearly 100,000 men, women and children die each
year in the United States because of mistakes by medical personnel. Today,
President Clinton unveiled a series of initiatives aimed at dramatically curbing
that rate over the next several years.

CNN's Major Garrett has been following the story. He joins us from the White
House -- Major.

MAJOR GARRETT, CNN WHITE HOUSE CORRESPONDENT: Natalie, at the top of the
president's statement this afternoon, he set a national goal of reducing the
rate of medical errors by 50 percent over five years. He put together a
three-point proposal to do that.



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First of them is asking hospitals to work with the states to create a system of mandatory reporting of all serious medical injuries that result in death or serious harm to a patient. Step two would be voluntary reporting also coordinated with the states of less serious medical errors. The third step is putting all 500 hospitals that the Department of Defense contracts with on a mandatory system of reporting serious medical issues.

In his comments today the president said he wants to change the way the medical profession views the entire problem of medical errors.

(BEGIN VIDEO CLIP)

WILLIAM J. CLINTON, PRESIDENT OF THE UNITED STATES: We also want to replace what some call a culture of silence with a cultural of safety, an environment that encourages other to talk about errors: what caused them and how to stop them in the first place. So, we will support legislation that protects provider and patient confidentiality but that does not undermine individual rights to remedies when they have in fact been harmed.

(END VIDEO CLIP)

GARRETT: Congress is also very interested in this topic, and this morning the president's point man on the issue of medical errors, Doctor Joel -- John Eisenberg was on Capitol Hill, and he said that the entire issue of medical errors has created a brand new awareness of this issue.

(BEGIN VIDEO CLIP)

JOHN EISENBERG, DIR., AGENCY FOR HEALTH CARE RESEARCH AND QUALITY: I've often thought that if this -- if health care quality were a disease and it were listed as the fifth or eight leading cause of death, that people would not hesitate for a moment in calling for a major research agenda. Now that the quality agenda has taken more life through the issue of patient safety, I think that it's easier for us to explain the rational for a major national agenda in health care research.

(END VIDEO CLIP)

GARRETT: Congress is debating this issue right now, and a bill is pending before the Senate and the House. Some Republicans are a little bit resistant to new federal regulations, although the president expressed confidence this afternoon that a bipartisan solution can be reached.

Major Garrett, CNN, the White House.

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LANGUAGE: ENGLISH

LOAD-DATE: February 22, 2000



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CNN

SHOW: CNN EARLY EDITION 07:00

February 22, 2000; Tuesday

Transcript # 00022203V08

TYPE: PACKAGE/LIVE REPORT

SECTION: News; Domestic

LENGTH: 583 words

HEADLINE: President Clinton Seeks Mandatory Reporting of Serious Hospital
Mistakes

BYLINE: Carol Lin, Elizabeth Cohen

HIGHLIGHT:

President Clinton takes action today to force hospitals to report serious
mistakes: those that kill or injure patients. Under the president's plan,
hospitals would not have to include names of the personnel involved in
accidents.

BODY:

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CAROL LIN, CNN ANCHOR: President Clinton takes action today to force
hospitals to report serious mistakes: those that kill or injure patients.

CNN's medical correspondent Elizabeth Cohen is on Capitol Hill and she has
details on the story.

(BEGIN VIDEOTAPE)

ELIZABETH COHEN, CNN MEDICAL CORRESPONDENT (voice-over): If a hospital makes
a mistake that kills someone, in most states it doesn't have to tell the
government. According to White House sources, the administration wants to
change that. It plans to announce today that it supports mandatory reporting to



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state governments when a hospital mistake kills or causes serious injury, and voluntary reporting of less serious medical errors and "close calls."

The White House hasn't said exactly what it will do to support such state programs. Under the president's plan, hospitals would not have to include names of the personnel involved in accidents.

HENRI MANASSE, NATIONAL PATIENT SAFETY FOUNDATION: The whole notion of the report here is not to figure out who can we shoot now because they were such terrible people, but let's do the investigation, let's understand how these things happen, let's learn from that.

COHEN: While the National Patient Safety Foundation favors mandatory reporting, the American Hospital Association opposes it, saying 18 states already have mandatory reporting systems and they don't work because hospital employees fail to report errors fearing reprisals. But the AHA does support voluntary reporting.

CARMELA COYLE, AMERICAN HOSPITAL ASSOCIATION: We need to make certain that care givers are talking about their mistakes, but we're not opening them up to lawyers and lawsuits.

COHEN: While solid numbers are hard to come by, a report last year by the Institute of Medicine said that medical errors kill up to 98,000 patients a year, making it perhaps the fourth-leading cause of death in the United States. The administration plan also requires blood banks to report serious errors, hospitals to come up with error reduction programs, and the Food and Drug Administration to set up an online reporting system for adverse drug reactions.

The administration also calls for \$20 million for the creation of a new center for quality improvement and patient safety to do more research on how to put a stop to medical errors.

(END VIDEOTAPE)

COHEN: Now, the study of medical errors is a relatively new science, and experts are hoping that if there is mandatory reporting, that that way hospitals can share with one another how to avoid mistakes -- Carol.

LIN: Elizabeth, why isn't the Clinton administration asking for the names of doctors to be reported?

COHEN: Well, the culture now has been what some people call "name you, blame you, shame you," and it's really been targeted at getting to individuals. And the thinking is that that doesn't really help, that you don't really cure mistakes when that helps -- when that happens. And as a matter of fact, about 95 percent of the errors that happen are not human errors, they're systems errors. They're systems that fail in a hospital. So they're thinking that we really need to get to the systems not to the individuals.

LIN: Interesting. Thank you very much, Elizabeth Cohen on Capitol Hill.

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CNN

SHOW: CNN LIVE EVENT/SPECIAL 12:52

February 22, 2000; Tuesday

Transcript # 00022204V54

TYPE: LIVE EVENT

SECTION: News; Domestic

LENGTH: 1001 words

HEADLINE: President Clinton Announces Initiatives to Reduce Medical Mistakes

BYLINE: Frank Sesno

HIGHLIGHT:

President Clinton announces a number of steps his administration will take to reduce by half over five years the number of preventable medical deaths estimated by the Institute of Medicine to cause up to 98,000 lives per year, laying out both new steps and new dollars to tackle the task.

BODY:

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FRANK SESNO, CNN ANCHOR: I'm Frank Sesno in Washington. We want to take you now over to the Eisenhower Executive Building next to the White House where President Clinton is making some remarks, expected to unveil a series of initiatives to reduce preventable medical errors by 50 percent over the next five years, cited as the eighth leading cause of death in the United States, thousands of preventable medical deaths and injuries. Let's listen.

(JOINED IN PROGRESS)

WILLIAM J. CLINTON, PRESIDENT OF THE UNITED STATES: I thank Senator Jeffords, Senator Specter and Senator Harkin for being here. They had an important hearing today. And I can tell you that -- I was talking to them for a few moments outside -- they are passionately interested in and very well informed about this



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issue. And as we all know, when we have a bipartisan commitment in the Congress to solving a problem in America it normally gets solved. And I thank you all very much for your dedication.

(APPLAUSE)

I want to thank all the people who are here from the national governor. John of Arc (ph), I like that. That's pretty good.

(LAUGHTER)

Tom Garthwaites (ph), Sue Bailey, Paul London (ph), all the people here from all the other agencies who've worked so hard on this, thank you very, very much.

Thank you, Ken Kaiser (ph). Thank the leaders representing consumers, health care plans and providers, business, labor and quality experts who are here.

And of course I want to thank the National Academy of Science's Institutes of Medicine for its landmark report.

Secretary Shalala said the IOM study focused new light on what has been a high priority of ours, which is ensuring that all Americans get the highest quality health care in the world. Secretary Herman pointed out that this is about more than saving lives. The dollar cost of -- it's about more than money, and it's even about more than saving lives because it's about the toll in lost trust in the health care system. We heard a lot about it when the IOM study came out.

But we know that if we do the right things, we can dramatically reduce the times when the wrong drug is dispensed, a blood transfusion is mismatched or a surgery goes awry.

As I have said many times and I will say again, I'm not here to find fault, I'm here to find answers. We do have the best health care system in the world, the finest health professionals in the world. New drugs, new procedures, new technologies have allowed us to live longer and better lives.

Later this year when researchers finish the mapping of the human genome, it will lead to even greater advances in our ability to detect, treat and prevent so many, many diseases. But the growing advances have been accompanied by growing complexity in our health care delivery system.

And I might say, it's complicated by the choices we have made about how we finance it and operate it.

So the time has plainly come, as a result of the IOM study, to just take a step back and ask ourselves: How can we redesign the system to reduce error? Have we given all of our care givers adequate training? Do they adequately coordinate with and communicate with one another? Do all settings have the right kinds of teams and systems in place to minimize mistakes?

These are the kinds of questions that were asked and answered in our landmark efforts as Americans to improve aviation safety and workplace safety. And if these questions are properly asked and answered in the context of the health



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care system, they will dramatically reduce errors there as well.

Last December, I directed our own health care quality task force to analyze the IOM study, to report back with recommendations about how we can follow the suggestions they made to protect patients and promote safety. This morning, I received the task force report and I am proud to accept all its recommendations.

Our goal is to prevent -- to reduce preventable medical errors by 50 percent within five years.

Today, I announce our national action plan to reach that goal.

First, we agree with the need to establish a focal point within the federal government to target this challenge. So today I propose the creation of a new center for quality improvement and patient safety. My budget includes \$20 million to support the center, which will invest in research, develop national goals, issue an annual report on the state of patient safety, and translate findings into better practices and policies.

Second, we will ensure that each and every one of the 6,000 hospitals participating in Medicare has patient safety programs in place to prevent medical errors, including medication mistakes. These new systems save lives and, over time, of course, also save money. I commend hospitals for the steps they have already taken, and we'll work with them and other health care experts to develop this regulation in the coming months.

Third, as we seek to make sure that the right systems are in place, we need to make sure they are working. Today I am releasing our plan for a nationwide state-based system of reporting medical errors, to be phased in over time.

This will include mandatory reporting of preventable medical errors that cause death or serious injury and voluntary reporting of other medical mistakes, and so-called near misses or close calls.

SESNO: President Clinton is ticking through a number of steps that he is now proposing and will take in the goal of the administration to reduce by half over five years the number of preventable medical deaths, estimated by the Institute of Medicine to cause up to 98,000 lives per year. The president is laying out both new steps and new dollars to tackle that task and accepts a task force report on the subject at this event.

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The American Health
Quality Association

Facsimile Cover Sheet

To: Chris Jennings
Company:
Fax:
Phone:

From: Sylvia Gaudette, Director of Gov't Affairs
Phone: (202) 331-5790
Fax: (202) 331-9334
E-mail: Sgaudette@ahqa.org
Date Sent: Tuesday, February 22, 2000

Number of pages (Including Cover): 3

FYI

I thought you would appreciate a copy of AHQA's press release re: the President's proposal on medical errors.

Sylvia

FOR IMMEDIATE RELEASE
February 22, 2000

CONTACT: Sara Foer
202/331-5790 ext. 311

PRESIDENT CLINTON RECOGNIZES PROs AS A SOLUTION TO REDUCING MEDICAL ERRORS

Washington, DC -- Today, the American Health Quality Association (AHQA) responded to the Clinton administration's Quality Interagency Coordination Task Force (QuIC) proposal to utilize the Peer Review Organizations (PROs) as key partners in reducing medical errors. AHQA represents the national network of PROs.

President Clinton accepted the QuIC's proposed concept of a national demonstration project to reduce medical errors. The project builds on the PROs' current national error reduction program, which minimizes the administrative burden on hospitals.

"President Clinton has recognized the quality improvement abilities of PROs by choosing them to be national leaders in his plan to address medical errors," stated William E. Golden, MD, FACP, the president of AHQA. "This shows that the president is justifiably proud of the PROs' achievements. His administration has invested wisely in making PROs the health care quality experts they are."

AHQA is disappointed, however, that the QuIC's recommendations stop at demonstration projects. While President Clinton appropriately calls on the National Quality Forum and the Agency for Healthcare Research and Quality to develop new measures for identifying medical errors, he requires that the PROs run only a demonstration project involving "up to 100 hospitals." The PROs currently partner with 6,000 hospitals in a national error reduction program that shares best practices and assures strict confidentiality of medical information.

"Given the significance of medical errors and the availability of the national PRO network, President Clinton should take advantage of the PROs to implement the new error reduction system in all 6,000 hospitals," stated David G. Schulke, AHQA's executive vice president.

MORE...

PROs AS SOLUTION2

The PROs possess a well-established track record for working with the medical community to improve care. AHQA recently published a report called "A Pillar of Quality" that highlighted the results of 500 projects, such as:

- Heart attack deaths reduced by 10 percent;
- Diabetes complications (blindness, amputation, kidney failure, and death) decreased;
- 1,285 strokes prevented by increased use of anticoagulants (blood thinners);
- Pneumonia complications and death lowered by giving patients antibiotics within four hours of hospitalization; and,
- Flu immunizations increased among African-Americans.

"I am very encouraged that the president has asked the PROs to play such an integral part in leading the national effort to reduce medical errors," added Golden. "The American public should feel confident that the PROs will succeed in improving their health care as well as making it more reliable."

Congress established the PROs in 1983 to investigate cases of poor quality care. During the 1990s, the PRO system evolved to become a national network of quality improvement experts who systematically evaluate the delivery of health care in a region and institute projects to educate and alter the clinical behavior of institutions, health professionals, and patients.

QIOs are staffed with clinical experts, communication experts, and data and statistical professionals who work together to analyze and collaborate with the health care system in their communities. PROs work individually with hospital staffs and physicians' offices. They are also increasingly engaged with home health care systems, nursing homes, academic health centers, and community groups, such as heart associations and cancer coalitions.

AHQA plans to continue its work with Congress and the administration as this plan and possible legislation evolves.

###

The American Health Quality Association is a national, not-for-profit membership association of independent, community-based Quality Improvement Organizations (QIOs) representing the 50 states, the District of Columbia, and the U.S. territories. QIOs work collaboratively with health care practitioners, health plans, and hospitals, to analyze health care patterns, to identify opportunities for improvement, and to interpret and share information about current science and best practices with physicians, hospitals, and health plans.

For a copy of "A Pillar of Quality", please call Sara Fox at 202-261-7571.

**JEWISH HEALTHCARE FOUNDATION
OF PITTSBURGH**

Fax Transmission

Date: 2/23/00

To: Chris Jennings

Address: _____

Given the headlines, I thought you would
be interested in our latest efforts on medical

Telephone Number: errors. Call if you have any

Fax Number: questions.

Verification Number: Karen

From: Karen Wolk Feinstein

Address: Jewish Healthcare Foundation of Pittsburgh

Centre City Tower, Suite 2330

650 Smithfield Street

Pittsburgh, PA 15222

Telephone No: (412) 594-2555

Fax Number: (412) 394-5464

Number of Pages Following: 13

Verify: YES _____ NO _____

MESSAGE: _____

For Immediate Release:
February 22, 2000

Contact:
Ken Segel
Director, Pittsburgh Regional
Healthcare Initiative
412-594-2558
Community Leaders are available
for comment (see attachment)

Pittsburgh Regional Healthcare Initiative Unveils Nation's Most Ambitious Attack on Medical Errors

***Commitment of Corporate Leaders, Cooperation of Competing Health
Systems and Unprecedented Scope of Goals Distinguish Pittsburgh Effort***

PITTSBURGH – A pioneering regional health care improvement effort led by a coalition of civic, corporate and health care leaders today announced the commitments of more than thirteen health care institutions, many of them competitors, to collaboratively attack two major patient safety problems: medication errors and hospital-acquired infections.

Simultaneously, the Pittsburgh Regional Healthcare Initiative (PRHI) released a statement from the region's leading corporate executives outlining unprecedented expectations and support of area hospitals and health systems in their efforts to improve performance on patient safety measures and other healthcare quality indicators.

Together, these efforts position the region to be a global leader in healthcare quality and health systems performance.

Patient safety problems are a major and growing national concern. As the prestigious Institute of Medicine recently validated in its groundbreaking report, "To Err is Human: Building a Safer Health System," hospital-based medical mistakes are anywhere from the 4th to 8th leading cause of death in this country. Of those, medication errors alone account for more than 7,000 deaths annually, while infections acquired in hospitals affect

-more-

Pittsburgh Regional Healthcare Initiative (DRAFT)

February 22, 2000

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two million patients a year, 90,000 of whom die. PRHI studies further indicate that for certain major clinical procedures, local infection rates exceed the national infection rate of 7% of all patients.

Region's Largest Health Systems and Corporations Join Effort

Health system leaders committing to the terms of the community charter agreement that will govern the region's patient safety projects include: Children's Hospital of Pittsburgh, Fay West Health System, Highmark Blue Cross Blue Shield, Mercy Health System, Monongahela Valley Hospital, UPMC Health System, West-Penn Allegheny Health System and others (*see attached list*). Additional commitments are expected in coming weeks.

Corporate CEOs endorsing the statement of the "CEO Working Group to Hospital Executives and Chairs Regarding Corporate Expectations and Support for a Regional Healthcare Strategy" include: Martin G. McGuinn, Mellon Financial Corporation, Chair of the CEO Working Group; Paul H. O'Neill, Alcoa; Alain J. P. Belda, Aloc; Thomas A. Corcoran, Allegheny Technologies; James S. Broadhurst, Eat 'n Park Corporation; David S. Shapira, Giant Eagle; William R. Johnson, H. J. Heinz Company; Thomas H. O'Brien, PNC; James E. Rohr, PNC; Raymond W. LeBouef, PPG Industries; and Thomas J. Usher, USX Corporation. Additional corporate commitments are expected in the near future.

The CEO Working Group Statement challenges area hospitals to take specific measures to improve patient safety, including the implementation of computerized medication ordering systems at hospital pharmacies (referred to as "automated order entry systems"). It also calls on health system leaders to make collaborative management infrastructure improvements to advance the region's goals. These include the development of electronic patient records systems that are compatible across competing institutions and the implementation of advanced accounting systems to support clinical

-more-

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quality improvement efforts. Nationally, a small group of purchasers (The Leapfrog Group) has begun to take similar actions. The PRHI effort marks the first significant regional commitment by corporate leaders to patient safety.

In urging their colleagues to support common efforts to improve patient safety, regional health care executives Anthony Lombardi (Monongahela Valley Hospital), Charles O'Brien (West Penn Allegheny Health System) and Jeffrey Romoff (UPMC Health System) noted that the region's hospitals can "distinguish southwestern Pennsylvania as the nation's leader in quality of clinical care and controlled costs." These are key steps to improving the health of the population, financial performance, retaining regional patients, and attracting national and international patients in an era when health systems are increasingly accountable for measurable results.

Mellon Chairman and Chief Executive Officer Martin G. McGuinn endorsed this strategic focus. "As in any other business, the future belongs to institutions that can produce the highest quality product and manage their resources accordingly," he said. "In health care, corporate leaders have influence both as large purchasers for their employees and as health system trustees, so I think it's important to develop consensus among our peers regarding our expectations and commitments."

PRHI Chair Paul O'Neill stresses that through these efforts, southwestern Pennsylvania may produce some important lessons for federal policymakers. "Washington can't solve our health care problems by fiddling with reimbursement and subsidy policies," said O'Neill, who is also chairman of Alcoa. "We intend to show that direct support for institutions and regions that organize themselves to deliver better care is a large part of the answer."

-more-

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PRHI Co-Chair Karen Wolk Feinstein, president of the Pittsburgh-based Jewish Healthcare Foundation, noted that the initiative has already attracted national attention. "Within a month of the Institute of Medicine report, we received a visit from Don Berwick, director of the Institute for Healthcare Improvement and one of the IOM study's principal authors," she said. "He knows of no other community that is working together so extensively to dramatically improve the delivery of care."

The patient safety projects will be chaired by Mark Laskow, vice president of the Hillman Company. Laskow noted that one of the first steps will be consultations with international leaders in industrial quality improvement in early March. "We're proceeding to structure a sustainable, powerful process," he said.

Copies of both the **Community Charter** and the **CEO Statement** to hospital executives and trustee leaders are attached to this press release. Background on the issue of medical errors is also attached. For more extensive background, a copy of the Institute of Medicine's report is available on the web at www.nap.edu/catalog/9728.html.

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Press Availability

The following health care and corporate leaders can be contacted for comment by members of the media:

- Paul O'Neill, Chairman, Alcoa
Chair, Pittsburgh Regional Healthcare Initiative
Phone: 412-553-3295 FAX: 412-553-4947
- Karen Wolk Feinstein, Ph.D., President, The Jewish Healthcare Foundation
Co-Chair, Pittsburgh Regional Healthcare Initiative
Phone: 412-594-2550 FAX: 412-232-6240
- Mark Laskow, Vice President, Hillman Company
Chair, PRHI Project Committee
Phone: 412-338-3630 FAX: 412- 338-3624
- Martin G. McGuinn, Chairman and CEO, Mellon Financial Corporation
Phone: 412-234-4967 FAX: 412-234-7525
- Charles M. O'Brien, CEO, West Penn Allegheny Health System
Phone: 412-578-5144 FAX: 412-578-1296
- Jeffrey Romoff, President, UPMC Health System
Phone: 412-647-4800 FAX: 412-647-4801
- Anthony Lombardi, CEO, Monongahela Valley Hospital
Phone: 724-258-1000 FAX: 724-258-1365

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In addition, the PRHI can facilitate contact with several national leaders who are familiar with the PRHI approach outlined in this release, or who are providing specific guidance:

- Arnold Milstein, MD, William Mercer, Inc.
Dr. Milstein is medical director of the Pacific Business Group on Health and a key advisor to the Leapfrog Group, a coalition of large corporate healthcare purchasers.
Phone: 415-743-8803 FAX: 415-743-8950
- Michael Millenson, William Mercer, Inc.
Mr. Millenson is the author of the Pulitzer-Prize nominated *Demanding Medical Excellence: Doctors and Accountability in the Information Age*.
Phone: 312-902-5146 FAX: 312-902-7626
- Don Berwick, MD
Dr. Berwick is director of the Institute for Healthcare Improvement and a member of the panel that produced the Institute of Medicine report.
Phone: 617-754-4800 FAX: 617-754-4848
- David Helms
Mr. Helms is president of the Association for Health Service Research and the Alpha Center
Phone: 202-296-1818 FAX: 202-296-1825
- Lynn Etheredge
Mr. Etheredge, is a leading authority of federal health care policy and a member of the Jackson Hole Group.
Phone: 301-654-4185 FAX: 301-657-4214
- Judy Miller Jones
Dr. Jones leads the National Health Policy Forum, an influential, Washington, D.C.-based health care think tank.
Phone: 202-872-1390 FAX: 202-862-9837

###

PITTSBURGH REGIONAL HEALTHCARE INITIATIVE
(Formerly Working Together Consortium Healthcare Initiative)

**STATEMENT TO HOSPITAL EXECUTIVE AND CHAIRS
REGARDING CORPORATE EXPECTATIONS AND SUPPORT
FOR A REGIONAL HEALTHCARE STRATEGY**

The CEO Working Group

Introduction

As leaders of many of the community's largest private employers, we recognize the importance of quality healthcare to the future of Southwestern Pennsylvania. The lives and well being of our employees depend on it. But health care is also the single largest sector of our economy, and it is vulnerable in the present difficult market environment. Fortunately, a future leadership role for local institutions can be secured by aggressively building on the region's reputation for healthcare excellence.

As in our own industries, the greatest gains are likely to come from a relentless focus on constantly improving the quality of the product, in this case patient care. In addition to healthier residents, these strategies can contain costs responsibly, help the region attract desirable employees, and bolster our talent pool and credibility in research and high technology industry.

In this document we indicate specific actions we hope will occur within our healthcare delivery systems over the next four years and the specific commitments we make to support those steps. These efforts support the goals and strategies of the Pittsburgh Regional Healthcare Initiative (PRHI).

What We Support

1. Establishing The World's Best Patient Safety Record.

We strongly support the collective identification and execution of major quality projects by area hospitals. We understand that the elimination of medication errors and hospital-acquired infections have been chosen as collective priorities to help improve health system performance "across the board." Specifically, we endorse:

- a. The formal commitment of hospitals, insurers and purchasers to these goals.
- b. The implementation of proven methods of quantifying and benchmarking results with national exemplar hospitals.
- c. The implementation of medication safety measures determined to be critical to patient well-being, such as automated medication order entry systems at hospital

PITTSBURGH REGIONAL HEALTHCARE INITIATIVE

pharmacies. We hope that these systems can be fully operational in all area hospitals that serve our employees by December 1, 2000.

- d. The implementation of infection control measures determined to be critical to patient safety.

2. Clinical Quality Improvement

We support the clinical quality improvement initiatives of the PRHI, targeting improved outcomes for total hip and knee replacement, c-sections, depression, diabetes, and cardiac surgery. The specific expectations of these initiatives have been communicated to the hospital community separately from this Charter.

3. Management Infrastructure Improvements

Reaching desired performance levels in health care will require the adoption of state-of-the-art management and information systems. These infrastructure improvements are necessary to help clinicians and managers alike monitor and constantly improve patient outcomes.

Making these necessary investments in information systems is difficult for area institutions in the current healthcare environment. Therefore, we stand prepared to assist you in realizing the following goals:

- a. The implementation of electronic patient record systems that is compatible across the community's major health systems. As in the banking industry, a common standard of electronic data interchange among competing institutions will serve the interests of consumers and competing institutions.
- b. The sharing of an electronic information systems backbone, with appropriate firewalls between institutions.
 - The region's hospitals can proportionally invest in shared information systems to leverage financial and quality efficiencies (protections for patient confidentiality and privileged institutional data are assumed).
- c. The implementation of activity-based cost accounting systems (ABC). We hope that as soon as possible but no later than July 1, 2001, you can demonstrate that your hospital has implemented and maintains a cost accounting system that links specific activity-based units of service with clinical outcomes (the quality of the "product"), and that you make these data routinely available to your physicians and staff for process improvement purposes.
 - Given the existence of a sophisticated system for tracking risk-adjusted patient outcomes in every Pennsylvania hospital, our region can set a national benchmark for clinical quality at efficient cost by systematically linking this information with sophisticated cost-tracking methods. We will work with you to secure appropriate national recognition and support for this endeavor (see "What We Will Do," below).

PITTSBURGH REGIONAL HEALTHCARE INITIATIVE

4. Capacity Control

We support the removal of waste and duplication from the healthcare sector, especially where unnecessary capacity threatens the quality of clinical care. We expect that you will avoid, and eliminate where practicable, the duplication of existing capacity.

What We Will Do In Return

In return for your commitment to these steps, we will take the following actions:

1. We will endorse and help to seek federal grants and national private foundation awards to support your start-up work on these initiatives. With your full collaboration, we will seek to secure financial support from national sources within the first two years of this initiative.
2. We will endorse and advocate your proposal to secure national demonstration status from the federal Health Care Financing Administration for these activities.
3. Each corporation will consider a financial contribution to help support the foregoing patient safety initiatives. The patient safety project budget is expected to approximate \$450,000 per year.
4. As the hospital community begins to show quality gains as a result of these efforts, we will help broker streamlined administrative relationships with area insurers and third-party administrators. A goal will be to free resources to support improvement processes.
5. We will highlight to our local employees those hospitals that participate in and make progress under the foregoing regional safety, quality improvement, and capacity initiatives. We will communicate our support to the local media on an annual basis.
6. We will endorse a template for oversight of these initiatives by health system Boards of Trustees, including concrete, uniform indicators to track progress. We will ask that it be employed at health systems where we serve as directors, and distribute it to our senior staff who serve on hospital boards for the same purpose.
 - We recognize the importance of trustee leadership and support to the success of such ambitious initiatives. We also recognize that today such initiatives are rarely tracked as priority agenda items by area boards.
7. We will encourage the civic organizations that we help lead to support these projects.

Further Incentives

To the extent there are significant regional variations in willingness to participate or make progress in these initiatives, we will consider instructing our directors of employee benefits to:

1. seek to restructure our healthcare purchasing contracts to require area hospitals, as a contractual condition of providing services to our employees, to implement the

PITTSBURGH REGIONAL HEALTHCARE INITIATIVE

specific data collection steps, safety measures, and management upgrades specified above.

2. where our healthcare purchasing contracts are held by a third party insurer, seek to renegotiate our contracts with that third-party to stipulate that they request area hospitals to implement these same provisions.

Conclusion

We hope that our commitment to increased, specific engagement with the local healthcare sector will support your continuing efforts to become the highest quality & most efficient healthcare organizations in the country. We look forward to working with you to fulfill the terms of this charter for the long-term vitality of the healthcare industry in Southwestern Pennsylvania.

SIGNATURES ON FILE

Martin G. McGuinn, Mellon Financial Corp.

James S. Broadhurst, Eat 'n Park

Paul H. O'Neill, Alcoa

Alain J. P. Belda, Alcoa

Thomas A. Corcoran, Allegheny Technologies

David S. Shapira, Giant Eagle

Thomas H. O'Brien, PNC

James E. Rohr, PNC

Raymond W. LeBoeuf, PPG

Thomas J. Usher, USX

William R. Johnson, H. J. Heinz Co.

FOR MORE INFORMATION:

Pittsburgh Regional Healthcare Initiative, 650 Smithfield Street, Suite 2330, Pittsburgh, PA 15222, 412/594-2567

**CHARTER AGREEMENT
WORKING TOGETHER CONSORTIUM
HEALTHCARE INITIATIVE
December 31, 1999**

Background

Through a dedicated effort to create error-free, precision-performance healthcare, more than 75 leaders are working together to see SW Pennsylvania lead the nation in:

- Quality of clinical care
- Controlled costs through waste-free delivery
- Increased recognition among national and international patients seeking care at centers of excellence that can prove best outcomes at efficient costs.

To galvanize progress toward these goals, the members of the Leadership Obligation Group of the Working Together Healthcare Initiative have chosen to commit to two unprecedented performance goals: the elimination of medication errors and hospital-acquired infections in participating Southwest Pennsylvania hospitals.

More than 5,000 years ago, Hippocrates wrote: "As to diseases, make a habit of two things – to help or at least to do no harm." While healing can never be promised to anyone, *safety* in the quest for healing – safety from all preventable medication mistakes and safety from all avoidable infections – can and should be guaranteed to all. Some treatment problems are not preventable – for example, the first-time drug allergy or the infection of untraceable origin. Nonetheless, an impressive body of evidence also indicates that enormous improvement is achievable if a genuine and sustained commitment is present.

This document marks our formal commitment to that improvement. Specifically, our goal is to create national distinction for Southwestern Pennsylvania hospitals by eliminating avoidable adverse drug events (ADEs) and preventable nosocomial infections (NIs).

From Aspiration to Achievement

Progress toward these goals will be backed by specific obligations and validated methodologies. In particular, the signatories to this charter agree to:

- Create and participate in separate stakeholder work groups on medication errors and infections to provide coordination, cross-institutional learning and guidance. Representatives from diverse constituencies will be represented on each group.
- Select and apply a well-tested common method of: (1) quantifying results by each hospital and (2) benchmarking program-wide results with national exemplar hospitals. For ADEs, this will be based on a computerized analysis of hospital discharge data. For NIs, this will be based on the Centers for Disease Control and Prevention's National Nosocomial Infection

system (NNIS). Both systems will be supplemented by random sample chart audits by an expert third party.

- Supply to each hospital a "starter kit" of high-yield improvement methods in the ADE and NI areas. The kits would be based on the successes of national exemplar hospitals.
- Develop a specific system of recognition and support for hospitals that achieve breakthrough levels of performance. The criteria for recognition and support and their specific form will be agreed upon by all stakeholder groups prior to their initiation.

Accountability for Results

The signatories of this agreement recognize that success will depend on the individual commitment of the institutions and leaders who are committing themselves to these goals.

Overall accountability to support this initiative's success will be the responsibility of the Leadership Obligation Group of the Working Together Consortium Healthcare Initiative.

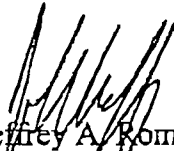
Day-to-day management will be delegated by the LOG to the stakeholder work groups, with assistance from appropriate staff and/or qualified consultant capacity.



Anthony M. Lombardi
President & CEO, Monongahela Valley Hospital, Inc.



Charles M. O'Brien
President & CEO, West Penn Allegheny Health System



Jeffrey A. Romoff
President, UPMC Health System

**PITTSBURGH REGIONAL HEALTHCARE INITIATIVE:
Medication Error and Nosocomial Infection Projects**

CHARTER AGREEMENT ENDORSEMENTS

ORGANIZATION	NAME	TITLE
Allegheny General Hospital	Connie M. Cibrone	President & CEO
Children's Hospital of Pgh.	Ronald L. Violi	Chairman & CEO
Citizens General Hospital	David T. Hunnell	V.P., Patient Support Services
Canonsburg General Hospital	Barbara A. Bensaia	President & CEO
Fay-West Health System	Rodney L. Gunderson	Chief Executive Officer
Forbes Health System	Barry H. Roth	President & CEO
HealthAmerica	Francis S. Soistman, Jr.	President & CEO
Highmark Blue Cross Blue Shield	David M. O'Brien	Executive Vice President, Health Services
Latrobe Area Hospital	Douglas A. Clark	Executive Director
Lifecare Hospitals of Pittsburgh, Inc.	April Stevens	CEO
Monongahela Valley Hospital	Anthony M. Lombardi	President & CEO
Pittsburgh Mercy Health System	Gregg G. Zoller	President & COO
UPMC Health System	Jeffrey A. Romoff John W. Paul	President Executive Vice President
UPMC McKeesport	Ronald H. Ott Janice Merlerkas	President & CEO Director, Medical Mgmt. & Quality
UPMC South Side	Marcie S. Caplan	CEO
West Penn Allegheny Health System	Charles M. O'Brien	President & CEO

As of 2/22/00

Endorsers-charter agreement (medication errors)

Error Reporting Systems

Although the previous chapter talked about creating and disseminating new knowledge to prevent errors from ever happening, this chapter looks at what happens after an error occurs and how to learn from errors and prevent their recurrence. One way to learn from errors is to establish a reporting system. Reporting systems have the potential to serve two important functions. They can hold providers accountable for performance or, alternatively, they can provide information that leads to improved safety. Conceptually, these purposes are not incompatible, but in reality, they can prove difficult to satisfy simultaneously.

Reporting systems whose primary purpose is to hold providers accountable are “mandatory reporting systems.” Reporting focuses on errors associated with serious injuries or death. Most mandatory reporting systems are operated by state regulatory programs that have the authority to investigate specific cases and issue penalties or fines for wrong-doing. These systems serve three purposes. First, they provide the public with a minimum level of protection by assuring that the most serious errors are reported and investigated and appropriate follow up action is taken. Second, they provide an incentive to health care organizations to improve patient safety in order to avoid the potential penalties and public exposure. Third, they require all health care organizations to make some level of investment in patient safety, thus creating a more level playing field. While safety experts recognize that errors resulting in serious harm are the “tip of the iceberg,” they represent the small subset of errors that signal major system breakdowns with grave consequences for patients.

Reporting systems that focus on safety improvement are “voluntary reporting systems.” The focus of voluntary systems is usually on errors that resulted in no harm (sometimes referred to as “near misses”) or very minimal patient harm. Reports are usually submitted in confidence outside of the public arena and no penalties or fines are issued around a specific case. When voluntary systems

focus on the analysis of "near misses," their aim is to identify and remedy vulnerabilities in systems before the occurrence of harm. Voluntary reporting systems are particularly useful for identifying types of errors that occur too infrequently for an individual health care organization to readily detect based on their own data, and patterns of errors that point to systemic issues affecting all health care organizations.

The committee believes that there is a need for both mandatory and voluntary reporting systems and that they should be operated separately. Mandatory reporting systems should focus on detection of errors that result in serious patient harm or death (i.e., preventable adverse events). Adequate attention and resources must be devoted to analyzing reports and taking appropriate follow-up action to hold health care organizations accountable. The results of analyses of individual reports should be made available to the public.

The continued development of voluntary reporting efforts should also be encouraged. As discussed in Chapter 6, reports submitted to voluntary reporting systems should be afforded legal protections from data discoverability. Health care organizations should be encouraged to participate in voluntary reporting systems as an important component of their patient safety programs.

For either type of reporting program, implementation without adequate resources for analysis and follow-up will not be useful. Receiving reports is only the first step in the process of reducing errors. Sufficient attention must be devoted to analyzing and understanding the causes of errors in order to make improvements.

RECOMMENDATIONS

RECOMMENDATION 5.1 A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should

- designate the Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states including a nomenclature and taxonomy for reporting;
- require all health care organizations to report standardized information on a defined list of adverse events;
- provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state

YES \$ 25 →
3m/yr

choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and designate the Center for Patient Safety to:

- (1) convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and**
- (2) receive and analyze aggregate reports from States to identify persistent safety issues that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).**

Mandatory reporting systems should focus on the identification of serious adverse events attributable to error. Adverse events are deaths or serious injuries resulting from a medical intervention.¹ Not all, but many, adverse events result from errors. Mandatory reporting systems generally require health care organizations to submit reports on all serious adverse events for two reasons: they are easy to identify and hard to conceal. But it is only after careful analysis that the subset of reports of particular interest, namely those attributable to error, are identified and follow up action can be taken.

The committee also believes that the focus of mandatory reporting system should be narrowly defined. There are significant costs associated with reporting systems, both costs to health care organizations and the cost of operating the oversight program. Furthermore, reporting is useful only if it includes analysis and follow-up of reported events. A more narrowly defined program has a better chance of being successful.

A standardized reporting format is needed to define what ought to be reported and how it should be reported. There are three purposes to having a standardized format. First, a standardized format permits data to be combined and tracked over time. Unless there are consistent definitions and methods for data collection across organizations, the data cannot be aggregated. Second, a standardized format lessens the burden on health care organizations that operate in multiple states or are subject to reporting requirements of by multiple agencies and/or private oversight processes and group purchasers. Third, a standardized format facilitates communication with consumers and purchasers about patient safety.

The recently established Forum for Health Care Quality Measurement and Reporting is well positioned to play a lead role in promulgating standardized reporting formats, including a nomenclature and taxonomy for reporting. The Forum is a public/private partnership charged with developing a comprehensive quality measurement and public reporting strategy. The existing reporting systems (i.e., national and state programs, public and private sector programs) also

represent a growing body of expertise on how to collect and analyze information about errors, and should be consulted during this process.²

RECOMMENDATION 5.2 The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should

- describe and disseminate information on existing voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;
- convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;
- periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and
- fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

Voluntary reporting systems are an important part of an overall program for improving patient safety and should be encouraged. Accrediting bodies and group purchasers should recognize and reward health care organizations that participate in voluntary reporting systems.

The existing voluntary systems vary in scope, type of information collected, confidentiality provisions, how feedback to reporters is fashioned, and what is done with the information received in the reports. Although one of the voluntary medication error reporting systems has been in operation for 25 years, others have evolved in just the past six years. A concerted analysis should assess which features make the reporting system most useful, and how the systems can be made more effective and complementary.

The remainder of this chapter contains a discussion of existing error reporting systems, both within health care and other industries, and a discussion of the committee's recommendations.

REVIEW OF EXISTING REPORTING SYSTEMS IN HEALTH CARE

There are a number of reporting systems in health care and other industries. The existing programs vary according to a number of design features. Some programs mandate reporting, whereas others are voluntary. Some programs receive reports from individuals, while others receive reports from organizations. The advantage of receiving reports from organizations is that it signifies that the

institution has some commitment to making corrective system changes. The advantage of receiving reports from individuals is the opportunity for input from frontline practitioners. Reporting systems can also vary in their scope. Those that currently exist in health care tend to be more narrow in focus (e.g., medication-related error), but there are examples outside health care of very comprehensive systems.

There appear to be three general approaches taken in the existing reporting systems. One approach involves mandatory reporting to an external entity. This is the approach typically employed by states that require reporting by health care organizations for purposes of accountability. A second approach is voluntary, confidential reporting to an external group for purposes of quality improvement (the first model may also use the information for quality improvement, but that is not its main purpose). There are medication reporting programs that fall into this category. Voluntary reporting systems are also used extensively in other industries such as aviation. The third approach is mandatory internal reporting with audit. For example, the Occupational Safety and Health Administration (OSHA) requires organizations to keep data internally according to a standardized format and to make the data available during on-site inspections. The data maintained internally are not routinely submitted, but may be submitted if the organization is selected in the sample of an annual survey.

The following sections provide an overview of existing health care reporting systems in these categories. They also include two examples from areas outside health care. The Aviation Safety Reporting System is discussed because it represents the most sophisticated and long-standing voluntary external reporting system. It differs from the voluntary external reporting systems in health care because of its comprehensive scope. Since there are currently no examples of mandatory internal reporting with audit, the characteristics of the OSHA approach are described.

Mandatory External Reporting

State Adverse Event Tracking

In a recent survey of states conducted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), it was found that at least one-third of states have some form of adverse event reporting system.³ It is likely that the actual percentage is higher because not all states responded to the survey and some of the nonrespondents may have reporting requirements. During the development of this report, the Institute of Medicine (IOM) interviewed 13 states with reporting systems to learn more about the scope and operation of their programs. The remainder of this section relates to information provided to the IOM. Appendix D summarizes selected characteristics of the reporting systems in these states, and includes information on what is reported to the state, who is required to submit reports, the number of reports received in the most

recent year available, when the program began, who has access to the information collected and how the state uses the information that is obtained. This is not intended as a comprehensive review, but rather, as an overview of how some state reporting systems are designed.

States have generally focused their reporting systems on patient injuries or facility issues (e.g., fire, structural issues). Reports are submitted by health care organizations, mostly hospitals and/or nursing homes, although some states also include ambulatory care centers and other licensed facilities. Although the programs may require reporting from a variety of licensed facilities, nursing homes often consume a great deal of state regulatory attention. In Connecticut, 14,000 of almost 15,000 reports received in 1996 were from nursing homes.

Several of the programs have been in place for ten years or longer, although they have undergone revisions since their inception. For example, New York State's program has been in place since 1985, but it has been reworked three times, the most recent version having been implemented in 1998 after a three-year pilot test.

Underreporting is believed to plague all programs, especially in their early years of operation. Colorado's program received 17 reports in its first two years of operation,⁴ but ten years later, received more than 1000 reports. On the other hand, New York's program receives approximately 20,000 reports annually.

The state programs reported that they protected the confidentiality of certain data, but policies varied. Patient identifiers were never released; practitioner's identity was rarely available. States varied in whether or not the hospital's name was released. For example, Florida is barred from releasing any information with hospital or patient identification; it releases only a statewide summary.

The submission of a report itself did not trigger any public release of information. Some states posted information on the Internet, but only after the health department took official action against the facility. New York has plans to release hospital-specific aggregate information (e.g., how many reports were submitted), but no information on any specific report.

Few states aggregate the data or analyze them to identify general trends. For the most part, analysis and follow-up occurs on a case-by-case basis. For example, in some states, the report alerted the health department to a problem; the department would assess whether or not to conduct a follow-up inspection of the facility. If an inspection was conducted, the department might require corrective action and/or issue a deficiency notice for review during application for relicensure.

Two major impediments to making greater use of the reported data were identified: lack of resources and limitations in data. Many states cited a lack of resources as a reason for conducting only limited analysis of data. Several states had, or were planning to construct a database so that information could be tracked over time but had difficulty getting the resources or expertise to do so. Additionally, several states indicated that the information they received in reports from health care organizations was inadequate and variable. The need for more standardized reporting formats was noted.

A focus group was convened with representatives from approximately 20 states at the 12th Annual conference of the National Academy of State Health Policy (August 2, 1999). This discussion reinforced the concerns heard in IOM's telephone interviews. Resource constraints were identified, as well as the need for tools, methods, and protocols to constructively address the issue. The group also identified the need for mechanisms to improve the flow of information between the state, consumers, and providers to encourage safety and quality improvements. The need for collaboration across states to identify and promote best practices was also highlighted. Finally, the group emphasized the need to create greater awareness of the problem of patient safety and errors in health care among the general public and among health care professionals as well.

In summary, the state programs appear to provide a public response for investigation of specific events,⁵ but are less successful in synthesizing information to analyze where broad system improvements might take place or in communicating alerts and concerns to other institutions. Resource constraints and, in some cases, poorly specified reporting requirements contribute to the inability to have as great an impact as desired.

Food and Drug Administration (FDA)

Reports submitted to FDA are one part of the surveillance system for monitoring adverse events associated with medical products after their approval (referred to as postmarketing surveillance).⁶ Reports may be submitted directly to FDA or through MedWatch, FDA's reporting program. For medical devices, manufacturers are required to report deaths, serious injuries, and malfunctions to FDA. User facilities (hospitals, nursing homes) are required to report deaths to the manufacturer and FDA and to report serious injuries to the manufacturer. For suspected adverse events associated with drugs, reporting is mandatory for manufacturers and voluntary for physicians, consumers, and others. FDA activities are discussed in greater detail in Chapter 7.

Voluntary External Reporting

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

JCAHO initiated a sentinel event reporting system for hospitals in 1996 (see chapter 7 for a discussion on JCAHO activities related to accreditation). For its program, a sentinel event is defined as an "unexpected occurrence or variation involving death or serious physical or psychological injury or the risk thereof." Sentinel events subject to reporting are those that have resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition, or an event that meets one of the

following criteria (even if the outcome was not death or major permanent loss of function): suicide of a patient in a setting where the patient receives around-the-clock care; infant abduction or discharge to the wrong facility; rape; hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; or surgery on the wrong patient or wrong body part.⁷

The Joint Commission requires that an organization experiencing a sentinel event conduct a root cause analysis, a process for identifying the basic or causal factors of the event. A hospital may voluntarily report an incident to JCAHO and submit their root cause analysis (including actions for improvement). If an organization experiences a sentinel event but does not voluntarily report it and JCAHO discovers the event (e.g., from the media, patient report, employee report), the organization is still required to prepare an acceptable root cause analysis and action plan. If the root cause analysis and action plan are not acceptable, the organization may be placed on accreditation watch until an acceptable plan is prepared. Root cause analyses and action plans are confidential; they are destroyed after required data elements have been entered into a JCAHO database to be used for tracking and sharing risk reduction strategies.

JCAHO encountered some resistance from hospitals when it introduced the sentinel event reporting program and is still working through the issues today. Since the initiation of the program in 1996, JCAHO has changed the definition of a sentinel event to add more detail, instituted procedural revisions on reporting, authorized on-site review of root cause analyses to minimize risk of additional liability exposure, and altered the procedures for affecting a facility's accreditation status (and disclosing this change to the public) while an event is being investigated.⁸ However, concerns remain regarding the confidentiality of data reported to JCAHO and the extent to which the information on a sentinel event is no longer protected under peer review if it is shared with JCAHO (these issues are discussed in Chapter 6).

There is the potential for cooperation between the JCAHO sentinel event program and state adverse event tracking programs. For example, JCAHO is currently working with New York State so that hospitals that report to the state's program are considered to be in compliance with JCAHO's sentinel events program.⁹ This will reduce the need for hospitals to report to multiple groups with different requirements for each. The state and JCAHO are also seeking to improve communications between the two organizations before and after hospitals are surveyed for accreditation.

Medication Errors Reporting (MER) Program

The MER program is a voluntary medication error reporting system originated by the Institute for Safe Medication Practice (ISMP) in 1975 and administered today by U.S. Pharmacopeia (USP). The MER program receives reports from frontline practitioners via mail, telephone, or the Internet. Information is

also shared with the FDA and the pharmaceutical companies mentioned in the reports. ISMP also publishes error reports received from USP in 16 publications every month and produces a biweekly publication and periodic special alerts that go to all hospitals in the United States. The MER program has received approximately 3,000 reports since 1993, primarily identifying new and emerging problems based on reports from people on the frontline.

MedMARx from the U.S. Pharmacopoeia

In August 1998, U.S. Pharmacopeia initiated the MedMARx program, an Internet-based, anonymous, voluntary system for hospitals to report medication errors. Hospitals subscribe to the program. Hospital employees may then report a medication error anonymously to MedMARx by completing a standardized report. Hospital management is then able to retrieve compiled data on its own facility and also obtain nonidentified comparative information on other participating hospitals. All information reported to MedMARx remains anonymous. All data and correspondence are tied to a confidential facility identification number. Information is not shared with FDA at this time. The JCAHO framework for conducting a root cause analysis is on the system for the convenience of reporters to download the forms, but the programs are not integrated.

Aviation Safety Reporting System at NASA

The three voluntary reporting systems described above represent focused initiatives that apply to a particular type of organization (e.g., hospital) or particular type of error (e.g., medication error). The Aviation Safety Reporting System (ASRS) is a voluntary, confidential incident reporting system used to identify hazards and latent system deficiencies in order to eliminate or mitigate them.¹⁰ ASRS is described as an example of a comprehensive voluntary reporting system.

ASRS receives "incident" reports, defined as an occurrence associated with the operation of an aircraft that affects or could affect the safety of operations. Reports into ASRS are submitted by individuals confidentially. After any additional information is obtained through follow-up with reporters, the information is maintained anonymously in a database (reports submitted anonymously are not accepted). ASRS is designed to capture near misses, which are seen as fruitful areas for designing solutions to prevent future accidents.

The National Transportation Safety Board (NTSB) investigates aviation accidents. An "accident" is defined as an occurrence that results in death or serious injury or in which the aircraft receives substantial damage. NTSB was formed in 1967 and ASRS in 1976. The investigation of accidents thus preceded attention to near misses.

ASRS operates independently from the Federal Aviation Administration (FAA). It was originally formed under FAA, but operations were shifted to the National Aeronautics and Space Administration (NASA) because of the reluctance of pilots to report incidents (as differentiated from accidents) to a regulatory authority. FAA funds the ASRS, but NASA administers and manages the program independently. ASRS has no regulatory or enforcement powers over civil aviation.

ASRS issues alerts to the industry on hazards it identifies as needed (e.g., ASRS does not go through a regulatory agency to issue an alert or other communication; Linda Connell, Director of ASRS, personal communication, May 20, 1999). If a situation is very serious, it may issue an alert after only one incident. Often, ASRS has received multiple reports and noted a pattern. The purpose of ASRS alerts and other communications is to notify others of problems. Alerts may be disseminated throughout the industry and may also be communicated to the FAA to notify them about areas that may require action. ASRS does not propose or advocate specific solutions because it believes this would interfere with its role as an "honest broker" for reporters. As a result, although some reported problems may be acted upon, others are not. For example, ASRS has been notifying FAA and the industry about problems that have persisted throughout its 23-year history, such as problems with call signs. To date, no agency has been able to find a permanent solution. However, ASRS continues to issue alerts about the problem to remind people that the problem has not been solved.

ASRS maintains a database on reported incidents, identifies hazards and patterns in the data, conducts analyses on types of incidents, and interviews reporters when indicated. It sends out alert messages, publishes a monthly safety bulletin that is distributed to 85,000 readers and produces a semi-annual safety topics publication targeted to the operators and flight crews of complex aircraft. Quick-response studies may be conducted for NTSB and FAA as needed (e.g., if an accident occurred, they may look for similar incidents). ASRS receives over 30,000 reports annually and has an operating budget of approximately \$2 million.¹¹

A more recent program is the Aviation Safety Action Programs. The de-identification of reports submitted to ASRS means that organizations do not have access to reports that identify problems in their own operations. In 1997, FAA established a demonstration program for the creation of Aviation Safety Action Programs (ASAP).¹² Under ASAP, an employee may submit a report on a serious incident that does not meet the threshold of an accident to the airline and the FAA with pilot and flight identification. Reports are reviewed at a regular meeting of an event review committee that includes representatives from the employee group, FAA and the airline. Corrective actions are identified as needed.

Mandatory Internal Reporting with Audit

Occupational Safety and Health Administration

OSHA uses a different approach for reporting than the systems already described. It requires companies to keep internal records of injury and illness, but does not require that the data be routinely submitted. The records must be made available during on-site inspections and may be required if the company is included in an annual survey of a sample of companies.¹³ OSHA and the Bureau of Labor Statistics both conduct sample surveys and collect the routine data maintained by the companies. These agencies conduct surveys to construct incidence rates on worksite illness and injury that are tracked over time or to examine particular issues of concern, such as a certain activity.

Employers with 11 or more employees must routinely maintain records of occupational injury and illness as they occur. Employees have access to a summary log of the injury and illness reports, and to copies of any citations issued by OSHA. Citations must be posted for three days or until the problem is corrected, whichever is longer. Companies with ten or fewer employees are exempt from keeping such records unless they are selected for an annual survey and are required to report for that period. Some industries, although required to comply with OSHA rules, are not subject to record-keeping requirements (including some retail, trade, insurance, real estate, and services). However, they must still report the most serious accidents (defined as an accident that results in at least one death or five or more hospitalizations).

Key Points from Existing Reporting Systems

There are a number of ways that reporting systems can contribute to improving patient safety. Good reporting systems are a tool for gathering sufficient information about errors from multiple reporters to try to understand the factors that contribute to them and subsequently prevent their recurrence throughout the health care system. Feedback and dissemination of information can create an awareness of problems that have been encountered elsewhere and an expectation that errors should be fixed and safety is important. Finally, a larger-scale effort may improve analytic power by increasing the number of "rare" events reported. A serious error may not occur frequently enough in a single entity to be detected as a systematic problem; it is perceived as a random occurrence. On a larger scale, a trend may be easier to detect.

Reporting systems are particularly useful in their ability to detect unusual events or emerging problems.¹⁴ Unusual events are easier to detect and report because they are rare, whereas common events are viewed as part of the "normal" course. For example, a poorly designed medical device that malfunctions routinely becomes viewed as a normal risk and one that practitioners typically find ways to work around. Some common errors may be recognized and re-

ported, but many are not. Reporting systems also potentially allow for a fast response to a problem since reports come in spontaneously as an event occurs and can be reacted to quickly.

Two challenges that confront reporting systems are getting sufficient participation in the programs and building an adequate response system. All reporting programs, whether mandatory or voluntary, are perceived to suffer from underreporting. Indeed, some experts assert that all reporting is fundamentally voluntary since even mandated reporting can be avoided.¹⁵ However, some mandatory programs receive many reports and some voluntary programs receive fewer reports. New York's mandatory program receives an average of 20,000 reports annually, while a leading voluntary program, the MER Program, has received approximately 3,000 reports since 1993. Reporting adverse reactions to medications to FDA is voluntary for practitioners, and they are not subject to FDA regulation (so the report is not going to an authority that can take action against them). Yet, underreporting is still perceived.¹⁶ Of the approximately 235,000 reports received annually at FDA, 90 percent come from manufacturers (although practitioners may report to the manufacturers who report to FDA). Only about 10 percent are reported directly through MedWatch, mainly from practitioners.

The volume of reporting is influenced by more factors than simply whether reporting is mandatory or voluntary. Several reasons have been suggested for underreporting. One factor is related to confidentiality. As already described, many of the states contacted faced concerns about confidentiality, and what information should be released and when. Although patients were never identified, states varied on whether to release the identity of organizations. They were faced with having to balance the concerns of health care organizations to encourage participation in the program and the importance of making information available to protect and inform consumers. Voluntary programs often set up special procedures to protect the confidentiality of the information they receive. The issue of data protection and discoverability is discussed in greater detail in Chapter 6.

Another set of factors that affects the volume of reports relates to reporter perceptions and abilities. Feedback to reporters is believed to influence participation levels.¹⁷ Belief by reporters that the information is actually used assures them that the time taken to file a report is worthwhile. Reporters need to perceive a benefit for reporting. This is true for all reporting systems, whether mandatory or voluntary. Health care organizations that are trained and educated in event recognition are also more likely to report events.¹⁸ Clear standards, definitions, and tools are also believed to influence reporting levels. Clarity and ease helps reporters know what is expected to be reported and when. One experiment tried paying for reporting. This increased reporting while payments were provided, but the volume was not sustained after payments stopped.¹⁹

Although some reporting systems that focus on adverse events, such as hospital patients experiencing nosocomial infections, are used to develop incidence rates and track changes in these rates over time, caution must be exercised when calculating rates from any type of adverse event reporting system for several

reasons. Reporting systems are considered to be "passive" in that they rely on a report being submitted by someone who has observed the event.²⁰ "Active" systems work with participating health care organizations to collect complete data on an issue being tracked to determine rates of an adverse event²¹ (e.g., the CDC conducted an active surveillance study of vaccine events with four HMOs linking vaccination records with hospital admission records²²).

The low occurrence of serious errors can also produce wide variations in frequency from year to year. Some organizations and individuals may routinely report more than others, either because they are more safety conscious or because they have better internal systems.²³ Certain characteristics of medical processes may make it difficult to identify an adverse event, which can also lead to variation in reporting. For example, adverse drug events are difficult to detect when they are widely separated in time from the original use of the drug or when the reaction occurs commonly in an unexposed population.²⁴ These reasons make it difficult to develop reliable rates from reporting systems, although it may be possible to do so in selected cases. However, even without a rate, repetitive reports flag areas of concern that require attention.

It is important to note, however, that the goal of reporting programs is not to count the number of reports. The volume of reports by itself does not indicate the success of a program. Analyzing and using the information they provide and attaching the right tools, expertise and resources to the information contained in the reports helps to correct errors. Medication errors are heavily monitored, by several public and private reporting systems, some of which afford anonymous reporting. It is possible for a practitioner to voluntarily and confidentially report a medication error to the FDA or to private systems (e.g., MER program, Med-MARx). Some states with mandatory reporting may also receive reports of medication-related adverse events. Yet, some medication problems continue to occur, such as unexpected deaths from the availability of concentrated potassium chloride on patient care units.²⁵

Reporting systems without adequate resources for analysis and follow-up action are not useful. Reporting without analysis or followup may even be counterproductive in that it weakens support for constructive responses and is viewed as a waste of resources. Although exact figures are not available, it is generally believed that the analysis of reports is harder to do, takes longer and costs more than data collection. Being able to conduct good analyses also requires that the information received through reporting systems is adequate. People involved in the operation of reporting systems believe it is better to have good information on fewer cases than poor information on many cases. The perceived value of reports (in any type of reporting system) lies in the narrative that describes the event and the circumstances under which it occurred. Inadequate information provides no benefit to the reporter or the health system.

DISCUSSION OF COMMITTEE RECOMMENDATIONS

Reporting systems may have a primary focus on accountability or on safety improvement. Design features vary depending on the primary purpose. Accountability systems are mandatory and usually receive reports on errors that resulted in serious harm or death; safety improvement systems are generally voluntary and often receive reports on events resulting in less serious harm or no harm at all. Accountability systems tend to receive reports from organizations; safety improvement systems may receive reports from organizations or frontline practitioners. Accountability systems may release information to the public; safety improvement systems are more likely to be confidential.

Figure 5.1 presents a proposed hierarchy of reporting, sorting potential errors into two categories: (1) errors that result in serious injury or death (i.e., serious preventable adverse events), and (2) lesser injuries or noninjurious events (near-misses).²⁶ Few errors cause serious harm or death; that is the tip of the triangle. Most errors result in less or no harm, but may represent early warning signs of a system failure with the potential to cause serious harm or death.

The committee believes that the focus of mandatory reporting systems should be on the top tier of the triangle in Figure 5.1. Errors in the lower tier are issues that might be the focus of voluntary external reporting systems, as well as research projects supported by the Center for Patient Safety and internal patient safety programs of health care organizations. The core reporting formats and measures promulgated by the Forum for Health Care Quality and Measurement should focus first on the top tier. Additional standardized formats and measures pertaining to other types of errors might be promulgated in the future to serve as tools to be made available to voluntary reporting systems or health care organizations for quality improvement purposes.

The committee believes there is an important role for both mandatory and voluntary reporting systems. Mandatory reporting of serious adverse events is essential for public accountability and the current practices are too lax, both in

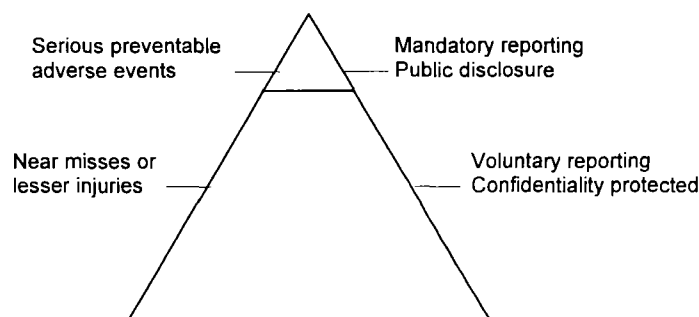


FIGURE 5-1 Hierarchy of reporting.

enforcement of the requirements for reporting and in the regulatory responses to these reports. The public has the right to expect health care organizations to respond to evidence of safety hazards by taking whatever steps are necessary to make it difficult or impossible for a similar event to occur in the future. The public also has the right to be informed about unsafe conditions. Requests by providers for confidentiality and protection from liability seem inappropriate in this context. At the same time, the committee recognizes that appropriately designed voluntary reporting systems have the potential to yield information that will impact significantly on patient safety and can be widely disseminated. The reports and analyses in these reporting systems should be protected from disclosure for legal liability purposes.

Mandatory Reporting of Serious Adverse Events

The committee believes there should be a mandatory reporting program for serious adverse events, implemented nationwide, linked to systems of accountability, and made available to the public. Comparable to aviation "accidents" that are investigated by the National Transportation Safety Board, health care organizations should be required to submit reports on the most serious adverse events using a standard format. The types of adverse events to be reported may include, for example, maternal deaths; deaths or serious injuries associated with the use of a new device, operation or medication; deaths following elective surgery or anesthetic deaths in Class I patients. In light of the sizable number of states that have already established mandatory reporting systems, the committee thinks it would be wise to build on this experience in creating a standardized reporting system that is implemented nationwide.

Within these objectives, however, there should be flexibility in implementation. Flexibility and innovation is important in this stage of development because the existing state programs have used different approaches to implement their programs and a "best practice" or preferred approach is not yet known. The Center for Patient Safety can support states in identifying and communicating best practices. States could choose to collect and analyze such data themselves. Alternatively, they could rely on an accrediting body, such as Joint Commission for Accreditation of Healthcare Organizations or the National Committee for Quality Assurance, to perform the function for them as many states do now for licensing surveys. States could also contract with peer review organizations (PROs) to perform the function. As noted in Chapter 4, the Center for Patient Safety should evaluate the approaches taken by states in implementing reporting programs. States have employed a variety of strategies in their programs, yet few (if any) have been subject to rigorous evaluation. Program features that might be evaluated include: factors that encourage or inhibit reporting, methods of analyzing reports, roles and responsibilities of health care organizations and the state in investigating adverse events, follow up actions taken by states, in-

formation disclosed to the public, and uses of the information by consumers and purchasers.

Although states should have flexibility in how they choose to implement the reporting program, all state programs should require reporting for a standardized core set of adverse events that result in death or serious injury, and the information reported should also be standardized.

The committee believes that these standardized reporting formats should be developed by an organization with the following characteristics. First, it should be a public-private partnership, to reflect the need for involvement by both sectors and the potential use of the reporting format by both the public and the private sectors. Second, it should be broadly representative, to reflect the input from many different stakeholders that have an interest in patient safety. Third, it should be able to gather the expertise needed for the task. This requires adequate financial resources, as well as sufficient standing to involve the leading experts. Enabling legislation can support all three objectives.

The Forum for Health Care Quality Measurement and Reporting meets these criteria. The purpose of this public-private partnership (formed in May, 1999) is to develop a comprehensive quality measurement and public reporting strategy that addresses priorities for quality measurement for all stakeholders consistent with national aims for quality improvement in health care. It is to develop a plan for implementing quality measurement, data collection and reporting standards; identify core sets of measures; and promote standardized measurement specifications. One of its specific tasks should relate to patient safety.

The advantage of using the Forum is that its goal already is to develop a measurement framework for quality generally. A focus on safety would ensure that safety gets built into a broader quality agenda. A public-private partnership would also be able to convene the mix of stakeholders who, it is hoped, would subsequently adopt the standards and standardized reporting recommendations of the Forum. However, the Forum is a new organization that is just starting to come together; undoubtedly some time will be required to build the organization and set its agenda.

Federal enabling legislation and support will be required to direct the Forum for Health Care Quality Measurement and Reporting to promulgate standardized reporting requirements for serious adverse events and encourage all states to implement the minimum reporting requirements. Such federal legislation pertaining to state roles may be modeled after the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA provides three options for implementing a program: (1) states may pass laws congruent with or stronger than the federal floor and enforce them using state agencies; (2) they may create an acceptable alternative mechanism and enforce it with state agencies; or finally, (3) they may decline to pass new laws or modify existing ones and leave enforcement of HIPAA to the federal government.²⁷ OSHA is similarly designed in that states may develop their own OSHA program with matching funds from the federal government; the federal OSHA program is employed in states that have not formed a state-level program.

Voluntary Reporting Systems

The committee believes that voluntary reporting systems play a valuable role in encouraging improvements in patient safety and are a complement to mandatory reporting systems. The committee considered whether a national voluntary reporting system should be established similar to the Aviation Safety Reporting System. Compared to mandatory reporting, voluntary reporting systems usually receive reports from frontline practitioners who can report hazardous conditions that may or may not have resulted in patient harm. The aim is to learn about these potential precursors to errors and try to prevent a tragedy from occurring.

The committee does not propose a national voluntary reporting system for several reasons. First, there are already a number of good efforts, particularly in the area of medications. Three complementary national reporting systems are focused on medication errors: FDA, the Institute for Safe Medication Practice, and U.S. Pharmacopeia. The JCAHO sentinel events program is another existing national reporting program for hospitals that will also receive reports on medication and other errors. These reporting systems should be encouraged and promoted within health care organizations, and better use should be made of available information being reported to them.

Second, there are several options available about how to design such a voluntary reporting system. Better information is needed on what would be the best approach. At least three different approaches were identified. One is a universal, voluntary reporting system, modeled after ASRS. The concern with this approach is the potential volume of reports that might come forward when such a system is applied to health care. Another concern is that any single group is unlikely to have the expertise needed to analyze and interpret the diverse set of issues raised in health care. The experience of ASRS has shown that the analysts reviewing incoming reports must be content experts who can understand and interpret these reports.²⁸ In health care, different expertise is likely needed to analyze, for example, medication errors, equipment problems, problems in the intensive care unit (ICU), pediatric problems, and home care problems.

Another approach is to develop focused "mini-systems" that are targeted toward selected areas (e.g., those that exist for medications) rather than a single voluntary program. This approach would manage the potential volume of reports and match the expertise to the problems. It is possible that there should be different mini-systems for different issues such as medications, surgery, pediatrics, and so forth. If such mini-systems are formed, there should be a mechanism for sharing information across them since a report to one system may have relevance for another (e.g., surgical events that also involve medications).

A third possibility is to use a sampling approach. For example, in its post-marketing surveillance of medical devices, FDA is moving away from a universal reporting system for hospitals and nursing homes to one in which a representative sample of hospitals and nursing homes keeps complete data. Its pilot test found that both the quantity and the quality of reports improved when FDA

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worked with a sample of hospitals who were trained in error identification and reporting and could receive feedback quickly. By periodically renewing the sample, the burden on any organization is limited (although participation in the sample may have the side benefit of helping interested organizations build their internal systems and train practitioners in error detection).

Lastly, establishing a comprehensive voluntary reporting system modeled after ASRS would require an enormous investment of time and resources. The committee believes that recommending such an investment would be premature in light of the many questions still surrounding this issue.

The committee does believe that voluntary reporting systems have a very important role to play in enhancing understanding of the factors that contribute to errors. When properly structured, voluntary systems can help to keep participating health care organizations focused on patient safety issues through frequent communication about emerging concerns and potential safety improvement strategies. Voluntary systems can provide much-needed expertise and information to health care organizations and providers.

The continued development of voluntary reporting efforts should be encouraged. Through its various outreach activities, the Center for Patient Safety should describe and disseminate information on voluntary reporting programs throughout the health care industry and should periodically convene sponsors and users of voluntary reporting systems to discuss ways in which these systems can be made more effective. As a part of developing the national research agenda for safety, the Center for Patient Safety should consider projects that might lead to the development of knowledge and tools that would enhance the effectiveness of voluntary reporting programs. The Center should also periodically assess whether there are gaps in the current complement of voluntary reporting programs and should consider funding pilot projects.

In summary, this chapter and the previous chapter outlining the proposed Center for Patient Safety together describe a comprehensive approach for improving the availability of information about medical errors and using the information to design systems that are safer for patients. Although this chapter focuses on using reporting systems to learn about and learn from errors that have already occurred, Chapter 4 focused on how to create and disseminate new knowledge for building safer delivery systems. Both of these strategies should work together to make health care safer for patients.

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Building Leadership and Knowledge for Patient Safety

Errors in the health care industry are at an unacceptably high level. A national commitment to achieve a threshold improvement in patient safety is needed. This will require strong leadership, specification of goals and mechanisms for tracking progress, and an adequate knowledge base. This chapter proposes the development of the Center for Patient Safety within the Agency for Health Care Policy and Research (AHCPR) to serve as a focal point for these activities. Experience from other industries suggests that unless a Center is created or designated to keep attention focused on patient safety and enhance the base of knowledge and tools, meaningful progress is not likely. Although existing efforts to improve patient safety are valuable, they are inadequate. There is no way of knowing if these efforts are attending to the most critical issues or if they are actually reducing errors. There must be greater attention placed on evaluating current approaches for reducing errors and building new systems to improve patient safety.

RECOMMENDATIONS

RECOMMENDATION 4.1 Congress should create a Center for Patient Safety with the Agency for Health Care Policy and Research. This Center should

- **set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety; and**
- **develop knowledge and understanding of errors in health care by developing a research agenda, funding Centers of Excel-**

lence, evaluating methods for identifying and preventing errors and funding dissemination and communication activities to improve patient safety.

National goals for safety should be established through a process involving consumers, providers, health care organizations, purchasers, researchers, and others. The goals should also reflect areas that represent opportunities for significant improvement. In carrying out its activities in the areas of research and dissemination, the Center for Patient Safety should collaborate with universities, research centers, and various groups involved in education and dissemination, such as the National Patient Safety Foundation.

The committee believes that initial annual funding of \$30 to 35 million for a Center for Patient Safety would be appropriate. This initial funding would permit a center to conduct activities in goal setting, tracking, research and dissemination. Funding should grow over time to at least \$100 million, or approximately 1% of the \$8.8 billion in health care costs attributable to preventable adverse events (see chapter 2). This level is modest compared to the resources devoted to other major health issues. The committee believes a 50% reduction in errors over five years is imperative.

WHY A CENTER FOR PATIENT SAFETY IS NEEDED

As discussed in Chapter 2, errors in health care are a leading cause of death and injury. Yet, the American public is seemingly unaware of the problem, and the issue is not getting the attention it should from leaders in the health care industry and the professions. Additionally, the knowledge that has been used in other industries to improve safety is rarely applied in health care. Although more needs to be learned, there are actions that can be taken today to improve safety in health care. Medical products can be designed to be safer in use, jobs can be designed to minimize the likelihood of errors, and much can be done to reduce the complexity of care processes.

Although multiple agencies are concerned with selected issues that influence patient safety, there is no focal point for patient safety in health care today. Public- and private-sector oversight organizations, such as state licensure units, accrediting bodies, and federal certification programs devote some attention to patient safety, but patient safety is not their sole focus. The National Patient Safety Foundation conducts educational programs, workshops, and various convening activities but its programs and resources are limited. The Food and Drug Administration (FDA) focuses only on drugs and devices through the regulation of manufacturers. The Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) mission is to improve quality of care through accreditation. This may include issues relevant to patient safety, but patient safety is not its sole focus. Many states operate reporting programs or other oversight programs for patient safety but they take a variety of approaches and focus.

Although anesthesiology applied some of the techniques of system analysis and human factors during the 1980s, the concepts are just beginning to diffuse through the health care industry. The advantage of this lag is that we can learn about building safe systems from the experiences of others. The problem is that there has to be a substantially greater commitment to getting more and better information to advance the science and apply the techniques to health care.

The next section describes how attention to safety issues has been applied in two areas: aviation and occupational health. Both of these examples illustrate how broad-based safety improvements can be accomplished.

HOW OTHER INDUSTRIES HAVE BECOME SAFER

The risk of dying in a domestic jet flight between 1967 and 1976 was 1 in 2 million. By the 1990s, the risk had declined to 1 in 8 million.¹ Between 1970 (when the Occupational Health and Safety Administration was created) and 1996, the workplace death rate was cut in half.² Health care has much to learn from other industries about improving safety.

Aviation

Health care is decades behind other industries in terms of creating safer systems. Much of modern safety thinking grew out of military aviation.³ Until World War II, accidents were viewed primarily as individually caused and safety meant motivating people to "be safe." During the war, generals lost aircraft and pilots in stateside operations and came to realize that planning for safety was as important to the success of a mission as combat planning. System safety continued after the war when several military aviation safety centers were formed in the early 1950s. Human factors started to enter the picture at around the same time. In 1954, the Flight Safety Foundation was formed to design aircraft cockpits using better human engineering. In the mid-1960s, the University of Southern California began its first advanced safety management programs and included a heavy emphasis on human factors. By the 1970s, principles of system safety began to spread to other industries, including rapid rail and the oil industry.

Building on the successful experience and knowledge of military aviation, civilian aviation takes a comprehensive approach to safety, with programs aimed at setting and enforcing standards, accident investigation, incident reporting, and research for continuous improvement.

The Federal Aviation Administration (FAA), housed in the Department of Transportation, has regulatory oversight of the industry and an explicit charge for ensuring safety. Accident investigations are conducted by the National Transportation Safety Board (NTSB), an independent federal agency, which has no regulatory or enforcement power but can issue recommendations to the FAA

for regulatory action. Confidential incident reporting (defined as an occurrence associated with the operation of an aircraft that affects or could affect the safety of operations) is conducted through the National Aeronautics and Space Administration Aviation Safety Reporting System (ASRS), which is discussed in Chapter 5.

Research into safety is an integral component of the aviation industry strategy. The national research agenda is set through several mechanisms. First, a formal process determined how to allocate approximately \$60 million committed to the Aviation Safety Program for FY 2000 (Cynthia Null, Ames Research Center, personal communication, May 24, 1999). Workshops and meetings were held with multiple agencies and organizations to define the work in the specific program area; participants included NASA, FAA, Department of Defense, all levels of airline employees (pilots, maintenance workers, flight attendants, air traffic controllers), airlines, manufacturers, and others. Existing resources are being redirected consistent with the priorities. Other research that supports safety is funded through "base research" in which in-house researchers propose and carry out research projects for development. Research into human factors is part of the base research program.

The Aviation Safety Reporting System may also conduct "topical research," which could include structured callback studies on a certain topic or basic research. This area of work is funded within ASRS' main program, but funding is not often available (Linda Connell, Director of ASRS, personal communication, May 20, 1999). Human factors researchers at Ames may also tap into the ASRS database to generate hypotheses which can then be tested through other research.

Finally, the FAA itself maintains several databases that aggregate a variety of statistics (e.g., airline operations such as departures, hours and miles flown, history of safety recommendations to different parts of the industry and responses to them). FAA and NASA coordinate their research efforts to minimize duplication. For example, both agencies may jointly contribute to a single effort, or they may fund different, but complementary, aspects of an issue.

Charles Billings, M.D., designer and founder of the Aviation Safety Reporting System, has stated his belief that aviation would not be as safe as it is today without the FAA.⁴ By setting standards, maintaining multiple databases to monitor trends, and supporting research to constantly improve systems, the FAA (in collaboration with other agencies such as NASA and NTSB) has made flying safer.

Occupational Health

The Occupational Safety and Health Act of 1970 created both the Occupational Safety and Health Administration (OSHA), housed in the Department of Labor, and its research arm, the National Institute for Occupational Safety and Health (NIOSH), housed in the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services. OSHA's purpose is to encourage employers and employees to reduce workplace hazards and to imple-

ment new, or improve existing, safety and health programs. It provides for research in occupational health and safety, maintains reporting and record-keeping systems, establishes training programs, and develops and enforces mandatory standards for job safety and health.⁵ OSHA is administered through a combined federal-state approach. States that develop their own programs and have an approved plan receive up to 50 percent of the plan's approved operating costs.

OSHA requires employers with 11 or more employees to routinely maintain records of occupational injury and illness as they occur. These records are not submitted to OSHA, but must be made available during inspection and shared with OSHA if the company is selected for an annual tracking survey. OSHA and the Bureau of Labor and Statistics both conduct sample surveys to collect the routine data maintained by companies. These surveys are used to construct population rates or to examine particular issues of concern.

A related incentive for employers to create a safe environment is the worker's compensation program. Under state law, employers must pay the premium for insuring workers against the medical costs of injuries sustained while on the job. Responsibility for the costs associated with workers compensation further encourages employers to improve the safety systems in their companies.

Responsibility for research and for identifying new safety improvements is housed in a separate agency. The National Institute for Occupational Safety and Health (NIOSH) has the responsibility for conducting research and making recommendations for the prevention of work-related illnesses and injuries.⁶ It conducts and funds research on safety and health problems, provides technical assistance to OSHA, and recommends standards for OSHA adoption. Although OSHA provides input into the NIOSH research agenda, it is set mainly through input from other stakeholders, including company requests. Information gathered by NIOSH from these companies for research purposes is not shared with OSHA for regulatory purposes.

A major agenda for research was established in 1996 through the National Occupational Research Agenda (NORA). Input was obtained from 500 public and private organizations to provide a framework for safety research during the next decade and to guide intramural and extramural funding decisions. Twenty-one research priorities were selected and are now being implemented, mostly by shifting existing resources so that over time, more monies are directed to the priority areas. For example, in 1998, NIOSH and three institutes at the National Institutes of Health (NIH) committed \$24 million over three years to certain priority areas.⁷ For 1999, NIOSH's operating budget is \$200 million, of which \$156 million is for intramural and extramural research projects (Janice Klink, Associate Director for Policy, Planning, and Legislation, NIOSH, personal communication, May 19, 1999).

Lessons Learned

There are several key points to be taken from the experiences in aviation and occupational health. In each of these areas, there was a growing awareness of safety concerns and the need to improve performance. This led to comprehensive strategies, which included the creation of a national focal point for leadership, development of a knowledge base, and dissemination of information throughout the industry.

In both areas, there is a designated government agency with regulatory responsibility for safety, which is separate from the agency responsible for research. Although the entity responsible for research may generate reports that are useful to the regulatory authority in setting standards, data and information collected from organizations are not available for use in enforcing standards on a particular organization.

Both areas recognized the need to rapidly expand the knowledge base on safety and to establish ongoing processes for the diffusion of this knowledge. The creation of a carefully constructed research agenda was developed with broad-based input from the industry and is implemented through both public- and private-sector programs to draw upon the best expertise in the academic and scientific communities.

Finally, substantial resources were devoted to these initiatives. Achieving steady improvement requires that adequate resources be sustained over a sufficient period of time. The safety improvements did not occur because of a one-time effort. The results were achieved through an ongoing commitment of resources and leadership.

Although some of these components can be found in health care today—regulatory oversight, research and dissemination—there is no cohesive effort to improve safety in health care, and the resources devoted to enhancing and disseminating the knowledge base are wholly inadequate. Given the experience of other industries, health care is not likely to make significant safety improvements without a more comprehensive, coordinated approach.

OPTIONS FOR ESTABLISHING A CENTER FOR PATIENT SAFETY

Objectives

The objectives of a Center for Patient Safety are to provide leadership for safety improvements throughout the industry, to establish goals and track progress in achieving results, and to expand the knowledge base for improving safety in health care.

A central objective of the Center for Patient Safety is to provide visibility to safety concerns. The leadership of the Center must possess the requisite expertise

and stature to communicate with a broad audience to raise awareness of safety concerns and convene stakeholders to identify strategies for improving safety.

Expanding the knowledge base requires the formulation and implementation of a research agenda. Such an agenda should include short-term, focused studies as well as long-term, population studies. Expanding the knowledge base also requires effective methods for diffusing the new knowledge to a variety of audiences, including those in the industry and the general public.

The Center should develop a limited number of high-priority goals based on careful analysis of areas in which improvements will result in the greatest gains in terms of reduced morbidity and mortality and reduced costs. Specific goals identify priority areas for the industry so the industry can respond supportively. Specific goals also provide a basis for tracking change. Safety efforts must be evaluated to determine whether actual improvements are being achieved and to ensure that resources are allocated to high-priority areas that will have the most impact on patients.

Implementation Options

The committee believes that an organization designated as the focal point for patient safety should have the following characteristics. First, it should be involved in a broader agenda for improving quality. Patient safety is part of general quality improvement, even if certain safety problems may utilize distinct knowledge and expertise. It would not be desirable to have one agency focused on quality issues and a separate agency focused on patient safety.

Second, the agency should possess the core competencies required to undertake the broad array of tasks identified. Although some may be carried out through partnership arrangements, the agency should have adequate expertise and funding to engage in strategic planning, convening, tracking, research and evaluation, and information dissemination activities.

Finally, the designated agency should be able to work collaboratively with other health- and non-health-related safety agencies. For example, it should consult with NTSB and ASRS to understand how an entire industry sets safety as a priority and becomes safer over time. Experts from OSHA may also offer guidance on their experience in encouraging companies to build safety systems within their own organizations. Collaboration with the National Patient Safety Foundation might be desirable in carrying out various agenda-setting and education activities.

The committee discussed three alternative organizational arrangements for a Center for Patient Safety. One option considered was the creation of a new, free-standing agency whose sole purpose is to focus on patient safety issues. A second alternative was to place such a center within NIH, as a defined division or institute. A third option was to place the proposed Center for Patient Safety within the AHCPR.

The committee decided that placing the Center within AHCPR was the best option for several reasons. Although a dedicated agency might be most able to maintain a focus on patient safety, this option should be pursued as a last resort, given the resources and time required to establish a new agency. NIH has the expertise and industry respect to drive a basic research agenda and has built partnerships with other agencies, but its agenda is already very broad and does not routinely involve analyses of systems of care or quality measurement or improvement.

AHCPR is already involved with a broad range of quality-of-care issues, including quality measurement, quality improvement, and identification of best practices. The Consumer Assessment of Health Plans (CAHPS) is a standardized measurement and reporting tool in which consumers report their experience with specific aspects of their health plans to assess the features that form the basis of overall satisfaction. The goal is to provide consumers and purchasers with objective information for choosing among health plans. Another initiative is the support of evidence-based practice centers. These are five-year contracts awarded to 12 institutions to review scientific literature on assigned clinical care topics and to produce evidence reports and technology assessments, conduct research on methodologies and the effectiveness of their implementation, and participate in technical assistance activities.

AHCPR also is engaged in activities specifically related to patient safety, and these activities constitute a good base of experience upon which to expand. AHCPR has sponsored research in the area of patient safety, specifically in the areas of medication errors, diagnostic inaccuracies, inaccurate information recall by patients, and system failures in adverse drug events.⁸ A recent Memorandum of Understanding was executed with the National Institutes on Aging to cofund a grant to examine adverse drug events among a geriatric population in an ambulatory setting. Technologies tested in AHCPR-sponsored research that would improve patient safety include computerized monitoring of adverse drug events, computer-generated reminders for follow-up testing, standardized protocols, and computer-assisted decision making.

A new AHCPR endeavor initiated in 1998 is the establishment of Centers for Education and Research in Therapeutics (CERTs). CERTs will conduct research to increase understanding of ways to improve the appropriate and effective use of pharmaceuticals and other interventions to avoid adverse drug events. CERTs will also increase knowledge of the possible risks of new drugs and combinations of drugs, as they are prescribed in everyday practice. CERTs are being implemented in collaboration with FDA.⁹

AHCPR also has experience in collaborating with other relevant organizations. It has provided support for meetings on patient safety and is a member of the National Patient Safety Partnership, a public-private group dedicated to reducing preventable adverse medical events. AHCPR participates in the Quality Inter-agency Coordinating Committee (QuIC), which is developing an initiative on reducing medical errors. AHCPR also sponsors the User Liaison Program (ULP) as

a vehicle to link states, local health policy makers and researchers to disseminate research to states, conduct workshops, and provide technical assistance.¹⁰

Finally, the agency's reauthorization legislation for FY 2000 is expected to include explicit language defining a focus on reducing medical errors and improving patient safety.

FUNCTIONS OF THE CENTER FOR PATIENT SAFETY

Creating an information infrastructure and building a better evidence base for patient safety are critical to taking a more strategic approach to reducing medical errors and improving patient safety. The goal is to improve decision making by policy makers, regulators, health care organizations, and others, so that decisions are based on evidence rather than anecdote. Good information can and should be used to guide the development and continuous improvement of standards and to support communication and outreach efforts.

The Center for Patient Safety should build an information infrastructure and resource for patient safety. It should have a broad agenda comprised of multiple programs. In its first five full years of existence, it should deliver the following products:

1. Establish a limited set of high-priority goals for improving patient safety based on expert opinion and review of the evidence on errors.

2. Assess progress toward national goals by compiling aggregate information from state adverse event reporting systems, voluntary reporting systems, health care organizations, and other sources; and periodically conducting a representative survey of health care organizations.

3. Develop a research agenda, conduct and fund intramural and extramural research to assess the magnitude of errors, and the role of human factors, and test and evaluate approaches for preventing errors.

4. Define feasible prototype systems (best practices) and tools for safety in key processes, including both clinical and managerial support systems for:

- medication systems (from prescribing to administering),
- operating rooms and surgery processes,
- emergency departments,
- management of diagnostic tests, screening, and, information,
- intensive care units,
- neonatal intensive care units,
- care of frail elderly (e.g., falls, decubitus, etc.),
- the use of simulation and simulators in health care, and
- team training and crew resource management applications in health care.

5. Develop instructional methods, demonstration projects, and technical support to ensure widespread implementation of the prototype systems and tools identified above.

6. Conduct periodic evaluations of error reporting systems for two purposes: assessing the impact of mandatory reporting systems in various states and identifying best practices in program design and implementation; and assessing the usefulness of voluntary reporting systems in identifying important safety improvements and determining whether current levels of participation by health care organizations are adequate or additional incentives are needed.

7. Provide support to health care organizations for internal quality improvement demonstration projects to prevent and reduce errors.

8. Develop tools and methods for educating consumers about patient safety.

9. Issue an annual report on progress made to improve patient safety, and recommend changes for continuously improving patient safety to appropriate parties, such as FDA, states, accrediting agencies, professional associations, group purchasers, and health care organizations.

In setting the research agenda, the Center for Patient Safety should establish a formal process to gather input on priorities, methodologies and approaches for research. Advice should be obtained from a wide range of people and organizations who will use and can benefit from the availability of information. It should look at the experiences of other industries and the processes they employed, such as aviation and occupational health, as already described. Initial areas for attention might include the following:

- enhance understanding of the impact of various management practices (e.g., maximum work hours and overtime) on the likelihood of errors;
 - apply safety methods and technologies from other industries to health care, especially human factors and engineering principles;
 - increase understanding of errors in different settings (e.g., ambulatory or home care) and for vulnerable populations (e.g., children, elderly);
 - establish baseline rates of specific types of errors and monitor trends;
 - monitor error rates that accompany the introduction of new technologies;
- and
- increase understanding of the use of information technology to improve patient safety (e.g., automated drug order or entry systems, reminder systems).

In conducting research and developing prototype systems, the Center should consider providing support for the establishment of several Centers of Excellence in academic or applied research settings and which can gather expertise from diverse settings as needed. Centers of Excellence might focus on particular types of errors (e.g., medication-related errors), errors in particular settings or clinical specialties (e.g., intensive care), or types of interventions or strategies

that might be applied across many areas and settings (e.g., interdisciplinary teams).

In establishing Centers of Excellence, the Center for Patient Safety will want to learn from and coordinate with the Veterans Health Administration (VHA), which has pursued a similar strategy on a much smaller scale. As part of its comprehensive program in improving patient safety throughout their delivery system, the Veterans Health Administration has committed \$6 million to establish four Patient Safety Centers of Inquiry, focused on researching new knowledge in patient safety, with special emphasis on transferring safety technologies from other high-risk industries to health care, and on disseminating existing knowledge.¹¹

It is also imperative that the Center for Patient Safety focus adequate attention on the communication of information on and knowledge of patient safety. The support and production of more and better information on medical errors and patient safety will be of little use without explicit mechanisms identified for dissemination of the information and recommended actions. Although dissemination of information is sometimes an afterthought, there are attributes that can improve outreach. Important factors that have been identified are translating raw data into summary measures and information that can be used; presenting information in formats that are tailored to different audiences; and providing multiple ways to access the information, such as print, television, radio, videotaped presentations, online services, and face-to-face presentations. The information also needs to be timely and to come from a credible source.¹²

At the present time, there are few objective sources for the latest information on patient safety. Improvements may be made in practice within health care organizations, but there is no way to disseminate such information to a broader audience. An important responsibility of the Center for Patient Safety should be to work to increase the frequency of communication about patient safety to multiple audiences. In carrying out its responsibilities to communicate information and knowledge on safety, the Center should work closely with existing organizations that have related objectives, including public and private organizations; policy, educational and accrediting entities and quality oversight organizations.

The National Patient Safety Foundation (NPSF) is an existing organization that may be able to serve this resource and dissemination role. The National Patient Safety Foundation was formed by the American Medical Association in 1997 as an independent, nonprofit research and education organization, whose mission is to improve patient safety in the delivery of care. The AMA's goal was to establish linkages with other health care organizations dedicated to improving patient safety.

NPSF is well positioned to "translate" concerns and findings about patient safety between many different parties because of the broad base of representation on its board that can communicate with various constituencies and its proven ability to convene a mix of stakeholders. NPSF's core strategies include activities to raise awareness and foster communication and dialogue to enhance patient safety and to develop information, collaborative relationships, and edu-

cational approaches that advance patient safety.¹³ It supports an annual grant program for innovative research to prevent patient injuries; has conducted a benchmark survey to capture consumer attitudes, experience and expectations about health care safety; conducts regional forums to bring together community and health leaders in local communities and convenes national conferences that brings together leaders in patient safety from around the world.¹⁴ NPSF has also begun developing a clearinghouse function to collect patient safety information that can be accessed by both health professionals and consumers.

The National Patient Safety Partnership is a voluntary public-private partnership, comprised of the American Hospital Association, American Medical Association (AMA), American Nurses Association, Association of American Medical Colleges, JCAHO, National Patient Safety Foundation of the AMA, and Department of Veterans Affairs as charter members. Additional members include AHCPR, FDA, HCFA, NIOSH, and the Department of Defense, Health Affairs. Its primary concerns have focused on year 2000 (Y2K) issues and adverse drug events.¹⁵

The deliverables previously identified for the Center for Patient Safety include the development of tools and methods for educating consumers about patient safety. Although consumers are an important audience, there are many other constituencies that must be reached, including health professionals and managers, health care organizations, state and national policy makers, regulators, pharmaceutical companies and medical device manufacturers, professional groups and associations, medical and health care training centers, and various forms of media. Although AHCPR and the Center for Patient Safety will disseminate their work on patient safety through current mechanisms (e.g., reports, newsletters, internet), the NPSF and the National Patient Safety Partnership are existing organizations that can support a broad approach for dissemination activities.

RESOURCES REQUIRED FOR A CENTER FOR PATIENT SAFETY

In determining what would be an adequate level of funding for a Center for Patient Safety, the committee considered three things: (1) research investments made to address health care issues of a similar magnitude; (2) investments in safety research in other industries; and (3) operating budgets for research initiatives with similar programs.

The United States invests significant resources in research to reduce the morbidity and mortality associated with various diseases and health concerns. As noted in Chapter 2, medical errors among hospitalized patients ranks as a leading cause of death, exceeding the number of deaths in 1997 due to motor vehicle accidents, breast cancer, or AIDS. NIH funding in 1998 for AIDS was estimated at \$1.6 billion and for breast cancer, \$433 million.¹⁶ Another funding comparison in health care is to examine research centers that have a more focused agenda. The National Institute for Deafness and Other Communication

Disorders has funding of approximately \$230 million in FY99.¹⁷ The National Institute of Nursing Research received funding of approximately \$63 million in FY99.¹⁸ These are examples of “smaller” institutes at NIH.

The success of other industries in improving safety is undoubtedly attributable in part to the commitment made to enhancing the knowledge base. As noted previously, the NIOSH operating budget for 1999 is \$200 million, of which \$156 million is for intramural and extramural research projects. The Aviation Safety Program at NASA Ames Research Center allocated approximately \$60 million for FY 2000.

Another funding comparison is the resources devoted by AHCPR to different programs. In FY 1999, \$2 million was appropriated for the CERTs, newly established research centers; twice that amount is expected for FY 2000 to continue funding.¹⁹ The Evidence-Based Practice Centers at AHCPR are funded at more than \$3 million per year (Nancy Foster, AHCPR, personal communication, July 22, 1999). AHCPR also conducts a Medical Expenditure Panel Survey for which almost \$35 million was appropriated in FY 1999.²⁰

Finally, the Veterans Health Administration created several centers within its own system devoted to research and improved understanding about medical errors. It committed \$6 million over 4 years.

Initial annual funding of \$30 to 35 million for the Center for Patient Safety would be reasonable. This estimate is based on the functions that the center is to perform. Goal setting would involve convening a broad set of audiences for input into goals and a research agenda. Regional meetings and other mechanisms may be employed to gather input. It is estimated that approximately \$2 million would be needed for goal setting activities. Tracking progress on meeting goals would require periodic data collection from health care organizations. The Harvard Medical Practice Study reviewed over 31,000 hospital records and cost approximately \$3 million. The development and implementation of a national survey is estimated at \$5 million. To implement a research agenda, it is estimated that five Centers of Excellence would be formed, each with a specific focus of attention. Each Center of Excellence should be initially funded at \$5 million, growing over time to \$15 million each. Dissemination of information to the industry, general public, policy makers and others is estimated initially at \$5 million. The estimate of initial funding seems modest in light of the investments made to address health concerns of similar magnitude.

The committee believes that the growth in the funding level is necessary to communicate to researchers, states, professional groups and health care organizations that this will be a sustained effort. In the absence of a significant long term commitment to funding, researchers are unlikely to re-orient their focus to patient safety. The patient safety initiatives of other groups, such as states, professional associations and health care organizations are likely to be far more successful if accompanied by a steady flow of new knowledge, tools, and prototype systems. It can take several years to create awareness about safety and build interest. The growth in funding recognizes that initial funding should be at

a lower, but sufficient, level to begin work in the area, but should grow over time as the efforts evolve and expand.

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