

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. fax	Sue Bailey to Chris Jennings re: phone numbers (partial) (1 page)	01/21/2000	P6/b(6)

COLLECTION:

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

FOLDER TITLE:

Errors [Folder 8]

2012-0463-S

rc751

RESTRICTION CODES

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

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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)]

- b(1) National security classified information [(b)(1) of the FOIA]
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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

**Agency for Health Care Policy and Research
Liaison Office for Quality**

**U.S. Department of Health and Human Services
200 Independence Avenue, S.W., Room 638-G
Washington, D.C. 20201
(202) 690-8205
(202) 690-6154 (fax)**

FAX

Date: Dec. 1, 1999

Number of pages including cover sheet:

To: Devorah Adler

Fax: 202-456-5557

Phone:

From: Nancy Foster

Comments: E-mail is not working. Sorry!

Here is the ~~information on the~~
~~Quick ~~working on the~~ errors stuff.~~
~~Will have to you in a few minutes~~
~~via Fax or someone else's e-mail.~~

-Nancy

From:	...
To:	...
Cc:	...
Subject:	...
Date:	...

Nancy,

I've highlighted the specific section of the FY 2000 CJ that mentions errors in medicine. It is included under Priority III: Translating Research into Practice: Step 3: Fund experiments that test the effectiveness of improvement approaches - \$9.500 million. Let me know if you have any questions.

Having established the aims for improvement in Step 1 modeled on those proposed by the President's Commission, we will award demonstrations and research grants to identify and promote innovative implementation of research findings and the practice of evidence-based medicine. The Agency will leverage the substantial investments being made by these organizations in care improvement and focus our funds on the evaluation component of each intervention. Each of these grants and demonstrations will begin with the chosen aim, use a multidisciplinary approach, and be required to measure and evaluate impact within 3 to 5 years.

For each of the aims selected, we will measure and report progress toward the program goals. We will develop "lessons learned" summaries that synthesize the research findings with the work of the laboratories and the private-sector diffusion efforts. We will work with public- and private-sector partners to make available research findings, evidence-based tools, quality measures, and other information sponsored through this priority. In collaboration with our partners, we will identify the most effective ways to disseminate these findings, tools, and other information not only to the sites serving as laboratories for change, but to providers, purchasers, policymakers, consumers, and patients.

Specific activities will include:

- Grants for innovative applications and demonstrations that could include: 1) studying the implementation of evidence-based information in diverse health care settings to determine effective strategies for enhancing practitioner behavior change and improving patient behavior, knowledge, and satisfaction; 2) identifying the factors which determine the success of quality improvement strategies and to what extent these vary by the nature of the problem addressed and the target population; 3) testing innovative approaches to teaching evidence-based practice to health professionals, including physicians, nurses and dentists; 4) improving the quality of care during transitions between health care settings, including primary care, acute hospital care and long-term care settings, and between specialists to improve integration and to build on the Agency's 1997 initiative to study care at the interface of primary and specialty care; and 5) promoting the use of shared decisionmaking in clinical practice and evaluate its impact on quality, costs, and satisfaction (\$2.000 million).
- Demonstrations to develop and test methods for transferring knowledge across organizations, because so many successful QI efforts are mostly limited to single institutions, including innovations in dissemination, the use of informatics, electronic

690
7996

- medical records, and other information technology applications (\$1.000 million).
- Grants and demonstrations to develop and test effective systems approaches to reducing errors in medicine, including adverse drug events. AHCPR will also work with CDC to educate health providers about the dangers of antibiotic resistance (e.g., the superbug). (\$2.000 million).
 - Demonstrations to improve the use of quality information (both clinical and consumer generated, such as CAHPS) by consumers in both public and private settings and evaluate impact in terms of the decisions made by consumers, the changes in consumer behaviors, and any changes in quality and costs of care as a result of this information (\$1.000 million).
 - Demonstrations to improve the quality of care for minority populations and reduce/eliminate the disparities in care which exist, including a specific focus on diabetes mellitus. Asthma will also be emphasized through the development of a User Liaison Program on asthma disease management (\$3.500 million).

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Margaret E. O'Kane, President of the National Committee for Quality Assurance in Washington, DC.

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for
Health Care Quality Measurement and Reporting
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- Helen L. Smits, MD, Visiting Professor, New York University Graduate School of Public Service (New York, New York)

3 components

ATHA FY 2020
ensure
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allocated
to activities

348
025
12

OP

ATHA

Department of Veterans Affairs
Veterans Health Administration
Office of the Under Secretary for Health
810 Vermont Avenue, N.W.
Washington, DC 20420
Fax: 202.273.7090



Date: 12-20-99 # of Pages to Follow: 3
To: Devora (zap) Phone: 202.456.5557 (fax)
From: _____

Comments:

Tort info, *as discussed*
~~to follow~~

301869 3774

Please call 202.273. 5806 if you have any questions.

This transmission is intended only for the use of the person or office to whom it is addressed and may contain information that is privileged, confidential, or protected by law.

All others are hereby notified that receipt of this message does not waive any applicable privilege or exemption from disclosure and that any dissemination, distribution, or copying of this communication is prohibited.

If you have received this communication in error, please notify us immediately at the telephone number shown above. Thank you.

(2) The Office of Performance and Quality will share alerts and innovative system designs identified in the literature and through ongoing discussions with benchmarking organizations;

(3) The Office of the Medical Inspector will share alerts and innovative system designs identified in its reviews of sentinel events and other significant quality of care variations;

(4) The PSI Oversight Committee will share alerts and innovative system designs identified in its reviews of adverse events.

9. RESEARCH SUPPORT OF PSI

a. While the advantages of some system modifications will be self-evident, rigorous assessment will be needed to determine the effectiveness of others in reducing risk. Rigorously conducted research studies will also be needed, at times, to test hypotheses regarding the etiology of adverse events.

b. Support of both types of research efforts is strongly encouraged. VISNs should consider establishing programs to support local research efforts directed at these goals (see reference f for a description of a research program at several university hospitals designed to assess the effectiveness of innovations to improve the quality of patient care, relatively rapidly and inexpensively).

10. INFORMING PATIENTS ABOUT ADVERSE EVENTS

a. Background Information

(1) VHA is obligated to inform patients and their families about injuries resulting from adverse events and the options available to them. There is also evidence that patients desire acknowledgment of errors from their caregivers and that doing so reduces the likelihood that patients will take legal or administrative action (see reference t).

(2) The two primary options available to injured patients or their survivors are claims for compensation under 38 U.S.C., Chapter 11, Section 1151, and tort claims under the Federal Tort Claims Act, 28 U.S.C., Chapter 171.

(a) Claims under 38 U.S.C. Section 1151 that have been submitted before October 1, 1997, can result in payment of monthly benefits for additional disability or death incurred as the result of VA hospitalization, medical or surgical treatment, or examination, regardless of whether the disability or death was caused by negligence. Claims under section 1151 provide for the payment of a monthly benefit based on the percentage of disability and eligibility for VA medical care, without having to demonstrate negligence. Claims for 1151 benefits are processed by VBA Regional Offices.

(b) Claims under 38 U.S.C. Section 1151 that are submitted on or after October 1, 1997, can result in payment of monthly benefits for additional disability or death incurred as the result of

VA hospital care, medical or surgical treatment or examination, but only if the disability or death was proximately caused by negligence or an unforeseen event. The claims can still result in monthly benefits and eligibility for VA medical care, but benefits will not be available unless negligence or an unforeseen event is established.

(c) Tort claims may result in a settlement or in a judgment if a Federal court determines that negligence by medical practitioners caused injury or death (and jurisdictional requirements are met). The claimant frequently receives money in a lump sum payment, but structured settlements, which can include annuities, medical trusts, future payments, and reversionary interests, are also used where appropriate. Tort claims can result in monetary awards for pain and suffering, which are not necessarily included in veterans benefits. Tort settlements or judgments can also be used to provide for family members in ways that veterans benefits statutes do not allow. However, an attorney is usually retained, and attorney fees capped at 20 (administrative settlements) to 25 (litigation) percent of the damages reduce the award the veteran or survivors receive. Tort claims are processed by the Regional Councils.

(d) Veterans and survivors may pursue both section 1151 and tort claims. However, if both claims are successful, 38 U.S.C. Section 1151 benefits will be withheld until the amount that would have been paid equals the amount of the tort claim settlement or judgment.

b. Communication with Patients Regarding Adverse Events

(1) VISNs will ensure that its facility staff, typically the attending physician or treatment team, promptly inform patients and their families about pertinent clinical facts associated with injuries resulting from adverse events, assuring them that measures have been taken to maintain life and minimize disability and discomfort.

(2) VISNs will ensure that its facility staff provide appropriate and timely communication with patients and their families regarding adverse events that involve potential organizational liability. Potential organizational liability can be assessed based on discussions with practitioners and the Regional Counsel. *NOTE: Actual liability can be determined only after consideration of a claim under the provisions of the Federal Tort Claims Act, 28 U.S.C. 1346(b), 2671-2680.* The patients and their families shall be advised of appropriate remedial options. These options should include locally available interventions (e.g., arranging for second opinions, expediting clinical consultations, inpatient admission) and referral of patients to the 38 U.S.C. Section 1151 claims process and the tort claims process.

(3) One mechanism to facilitate such communication is a standing PSI group, e.g., the Chief of Staff or designee, Regional Counsel, patient representative, and PSI staff, that assesses liability issues and coordinates conferences with patients and families. To provide prompt responses, the group needs to be able to meet on short notice. Another approach is to have PSI staff assume these responsibilities with support and consultation from facility management and Regional Counsel.

(4) A collaborative relationship between Regional Counsel and VA medical center staff is necessary to ensure that appropriate and timely communication with patients occurs. Each VISN

should ensure that its staff develop an understanding with its Regional Counsel regarding the procedures for obtaining Regional Counsel input prior to discussing an adverse event with a patient.

11. REVIEW OF TORT CLAIMS

- a. Each VISN shall ensure that its staff conduct peer reviews of all new tort claims and share the findings with their Regional Counsel.
- b. Practitioners involved in new tort claims should be identified in these peer reviews and notified as soon as possible.
- c. After a tort claim has been paid, a second peer review will be conducted to determine whether reporting to the National Practitioner Data Bank is required (see reference bb).

12. EDUCATION OF PSI STAFF

VISNs are encouraged to regularly send their facility PSI staff to the educational programs of the National Patient Safety Foundation of the American Medical Association, the American Society for Health Risk Management of the American Hospital Association and similar organizations.

13. REFERENCES

- a. Allan EL, Barker KN. "Fundamentals of Medication Error Research," American Journal of Hospital Pharmacy. 47:555-571, 1990.
- b. American Society of Hospital Pharmacists. Top-priority Actions for Preventing Adverse drug events in hospitals: Recommendations of an expert panel. American Journal Health-Systems Pharmacy 747-751, 1996.
- c. Andrews LB, et al. An Alternative Strategy for studying adverse events in medical care. Lancet 349:309-313, 1997
- d. Bates DW, et al. "Potential Identifiability and Preventability of Adverse Events Using Information Systems," Journal of American Medical Informatics Association. 1994;1:404-411.
- e. Berwick DM. "Taking Actions: Leading the Reduction of Error." Keynote Address at Conference on Examining Errors in Health Care. Annenberg Center for Health Sciences, October 14, 1996.
- f. Black ER, et al. "Innovations in Patient Care: Changing Clinical Practice and Improving Quality," Joint Commission Journal of Quality Improvement. 21:376-391, 1995.

Withdrawal/Redaction Marker

Clinton Library

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001. fax	Sue Bailey to Chris Jennings re: phone numbers (partial) (1 page)	01/21/2000	P6/b(6)
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COLLECTION:

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Domestic Policy Council
Devorah Adler
OA/Box Number: 20472

FOLDER TITLE:

Errors [Folder 8]

2012-0463-S

rc751

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Office of the Assistant Secretary of Defense (Health Affairs)
1200 Defense Pentagon, Room 3E1082
Washington, DC 20301-1200

Assistant Secretary of Defense -- Dr. Sue Bailey

FAX

Date: 21 JANUO

OF PAGES: 3 (including cover sheet)

To:

MR CHRIS JENNINGS

Phone: 202-456-5560

Fax: 202-456-5557

From:

DR SUE BAILEY

Phone: (703) 697-2111

Fax: (703) 697-4197

REMARKS: ☐ Urgent ☐ For Your Information ☐ Reply ASAP ☐ Per Your Request
☐ Per our conversation ☐ Request Action By _____

COMMENTS:

Frances Stewart

P6/(b)(6)

P6/(b)(6)

LOO13

Wyatt Smith

P6/(b)(6)

Sue:

P6/(b)(6)

none

P6/(b)(6)

system used to
check of transfusion
report

regional databases
be able to talk to one
another —

reduce poss
receive contaminated
blood.



HEALTH AFFAIRS

ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301

Chris
Mr. Chris Jennings
Deputy Assistant to the President for Health Policy
White House
216 Old Executive Office Building
Washington, DC 20502

Dear Mr. Jennings,

These initiatives are in our FY01 budget, and they are OMB approved. Although the 6% increase is not impressive the \$128 million is.

I hope this helps.

Sincerely,

Sue
Dr. Sue Bailey



DOD PT safety Wking Group
~~planning~~ New Reporting Sys.

DVA model →
military aviation safety model

~~DOD part~~ look at
processes
JCAHO safety → begin
phase in this summer
~~for 10~~ 10 hospitals.

drug interactions
① first facility → April
by the end of October 2000
\$12 → \$15 300

105 CHCS sites

clinical
screening
process.

Department of Defense Patient Safety Initiatives

The Department of Defense is committed to improving patient safety in the Military Health System. As part of that commitment, the Department is proposing to spend \$128.4 million in FY01 on systems that protect our patients from medication errors and other hazards. This is a 6.0 increase over our spending in this area in FY00.

These systems include:

- The Military Computer-based Patient Record

The Military Computer-based Patient Record will give physicians the information they need to reduce errors. It will alert physicians to potential problems such as medication allergies or adverse interactions. Treatment orders will be entered directly into the computer so that bad handwriting and miscommunication cannot cause errors.

- The Pharmacy Data Transaction Service

Many patients get their prescriptions filled at several military and civilian pharmacies. This system will maintain a profile of all the medications each patient is taking, no matter where the system was filled. This will prevent problems with drug interactions and other medication errors.

- The Defense Blood Standard System

This system insures that the Department of Defense blood system meets FDA guidelines. It reduces the risk of transfusion reactions and the administration of contaminated blood. The improvements to the system that are planned allow the regional databases to be linked so that information can be shared. This will further reduce the risk of administration of contaminated blood. Another improvement will reduce errors by reducing the need to copy information from one form to another.

The Department of Defense has also assembled a multidisciplinary Patient Safety Working Group to prepare a Department-wide assessment of patient safety programs. They will develop related materials for training programs and a structure for a proactive reporting and safety improvement system.

In addition to these initiatives, the Department of Defense is working with the Quality Interagency Coordination Task Force and the Institute for Healthcare Improvement in planning a Breakthrough Series on Reducing Errors in High Hazard Environments. This collaborative series will include 23 teams from the Department of Defense. The series will start in late May. It will create a reduction in errors in high hazard environments such as emergency rooms, operating rooms, intensive care units and delivery rooms.

*high hazard
environments,
intensive care units,*

OK

CHC#2

FY01

profile both pts & providers

\$78.1

capture order →
all elements.

68.0

phased in over 3 years deployment
starts this fall → deployment

handwritten prescriptions 4x greater
than entry orders.

over 300 / 8 million beneficiaries (5 & 6 millions)
51 million visits outpatients
70 million prescriptions annual

working w/ DVA

high hazard areas.

rapid quality improvement

~~Reg~~ May

12-14 hospitals

lab & delivery, ER, OR, ICU

goal to examine common
errors → reduce 50%.

Clinical
screening
in a
real
time.
env.

PTS

privacy
protections.

Q7 to
prescriptions
that we get will
be covered.

DEC-19-1999 14:03 USA OFFICE 202 273 5787 P.02/45 121

OFFICE OF THE MEDICAL INSPECTOR

Special Report:

VA Patient Safety Event Registry: First Nineteen Months of Reported Cases Summary and Analysis

June 1997 through December 1998



Prepared by:

**The Office of the Medical Inspector (10MI)
Veterans Health Administration
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420**



**Department of
Veterans Affairs**

Report Date: July 15, 1999

DEC-15-1999 14:03 USA OFFICE 202 273 5781 F.04/45

PREFACE

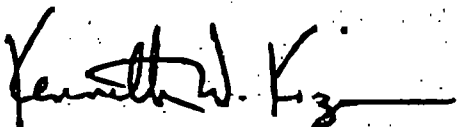
"To err is human..." but to fail to learn from error and to fail to share these lessons is unacceptable.

This fundamental principle led to the development of the VA Patient Safety Event Registry. It's a first of its kind. A system wide collection of adverse patient events that have been defined and categorized by the caregivers themselves. The data have been submitted electronically from every facility and network in the VHA. Although not yet two years old, it has already directed our attention to several key areas.

The potential for identification of preventable error through use of the Patient Safety Event Registry is great, but reporting the adverse event to the Registry is only one part of the Patient Safety Improvement Program. The analysis of the adverse event, including what actions would likely prevent the adverse event from recurring, is the key to real improvement. The numbers in the Registry merely tell us where we should focus our attention, that is, to the potentially high risk or problem-prone areas. The analyses with their accompanying actions tell us, and others like us in non-VA facilities, what we should do about them. The results of these actions should be reflected in decreasing Registry entries for those particular events in the long term throughout the VHA and all of healthcare.

This Medical Inspector's report on the VA Patient Safety Event Registry summarizes the first 19 months of the Registry's existence. It points out things we need to do to assure its validity and credibility. In short, the Registry shows the need for uniform, prompt, reliable data input from all facilities and VISNs. Each Director should review their past Network contribution to the Registry and determine what is needed to improve reporting which clearly needs to occur in some VISNs.

It is my intent that the Registry will become a valuable resource both within and outside of the VHA. Together with our other initiatives in the Patient Safety area, the VHA Patient Safety Event Registry is on the cutting edge in efforts to decrease medical errors and enhance patient safety.



Kenneth W. Kizer, M.D., M.P.H.

Executive Summary

VA Patient Safety Event Registry

The VA Patient Safety Event Registry, hereafter the Registry, located in the Chief Network Office (CNO) at VHA Headquarters, began to function in 1997, as a repository of data on sentinel and other adverse events that occurred throughout the VA healthcare system. The guidelines for reporting such events are described in the VA Patient Safety Improvement Handbook.¹ The Office of the Medical Inspector (OMI) conducted an analysis of the data entered during the first nineteen months of the Registry. The purpose of the review was two-fold: 1) to analyze the Registry as a patient safety improvement tool, and 2) to examine the reported events from June 1, 1997, through December 31, 1998. Conclusions and recommendations follow the summary and analysis.

Staff members at VA medical centers are required to report:

- Sentinel Events,
- Adverse Events Likely to Trigger Substantial Negative Publicity,
- Unplanned Clinical Occurrences,
- Allegations of Patient Abuse² and,
- Potentially Compensable Events.³

The mechanism for entering reports of adverse events into the Registry has been evolving and will continue to evolve as improvements occur. During the review period, reports of events were sent to their respective Veterans Integrated Service Network (VISN) offices⁴ and from there to the Chief Network Office in VHA Headquarters. As noted, adverse events were designated as sentinel events, unplanned clinical occurrences, or events associated with substantial actual or potential negative publicity generated as a result of media coverage.

The format of the Registry is in an easy-to-interpret form that can be examined by frequency bar charts, yielding basic benchmark data. Such data, objectively analyzed and evaluated, can be used to identify specific aspects of patient care that medical centers can use in their performance improvement initiatives.

Several areas have been identified that, when corrected, will improve the Registry significantly. For example, the Registry frequently lacked updates of already entered but

¹ VHA Handbook 1051/1 January 13, 1998.

² Allegation of patient abuse is defined as an act that involves physical, sexual, psychological or verbal abuse. While intent to abuse is not necessary, examples of abuse include harassment or ridicule of a patient, willful physical injury and/or intimidation, willful violation of personal privacy, or intentional omission of care. VHA Handbook 1051/1, January 13, 1998.

³ Ibid.

⁴ There are 22 VISNs geographically distributed, each made up of a number of primary, tertiary and secondary medical centers, and community-based outpatient clinics.

incomplete data. Also, there was marked variation from one VISN's facilities to the next in the reporting of adverse events. Attentive Registry oversight is required to assure that accurate, timely, complete and uniform data are entered from all VISNs.

National Center for Patient Safety

With the appointment of the Director, National Center for Patient Safety (NCPS), VHA underscored the importance of patient safety across the continuum of care. The responsibility for the operation of the VA Patient Safety Event Registry will be transferred to the NCPS. In addition, NCPS will be responsible for developing and implementing teaching and training curricula that address key aspects of patient safety and the root cause analyses of adverse events. The Director will also chair the Patient Safety Improvement Oversight Committee, which meets monthly at VHA Headquarters.

Reporting of Adverse Events

During the 19-month period, from June 1997 through December 1998, 3,039 adverse events were reported and registered, of which 112 were duplicates or test entries leaving 2,927 cases available for analysis.

Although facilities from each of the 22 networks reported adverse events, there was wide variation in the number reported. For instance, one VISN's facilities reported 37 adverse events while another VISN's facilities reported 320 events during the same period.⁵ Data pertinent to each adverse event were entered into 38 fields.⁶

Of the 2,927 adverse events in the Registry, 2,075 (71%) were designated by the facility, VISN or Chief Network Office as Unplanned Clinical Occurrences; 592 (20%) were designated as Sentinel Events; and 148 (5%) were designated as Adverse Media Attention. There were 76 (2.6%) adverse events (Please Update) that had no designation as to the type of incident. There were also 28 (1%) events reported as Near Miss Without Injury and 8 (0.3%) events reported as Near Miss with Injury.

Focused Reviews and Boards of Investigation

Medical centers submitted an intensive analysis of the adverse event in 85% of the total number of reported cases. There were 2,196 (75%) Focused Reviews (FR) and 301 (10%) Boards of Investigation (BoI), documented as having been received. In 465 (16%) of the reported adverse events, documented analyses of the events were lacking.

⁵ See Illustration 3 on page 6 for VISN identification and range.

⁶ From June 1997 to October 1998, there were 10 fields. In October 1998, an additional 28 fields were added.

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Reporting to the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission)

A subset of sentinel events were "subject to review" by the Joint Commission, such as, a) an adverse event that has resulted in an unanticipated death or major permanent loss of function, unrelated to the natural course of the patient's illness or underlying condition; b) suicide of a patient in a setting where the patient receives round-the-clock care; c) rape; d) hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; e) abduction of an infant or discharge to the wrong family; and f) surgery on the wrong patient or wrong body part.⁷ VHA reported 29 adverse events to the Joint Commission that included the following:

- Suicides - 7
- Other Sentinel Events - 5
- Therapeutic Misadventures - 5
- Missing/Eloped Patients - 3
- Medication Errors - 3
- Surgical/Procedure Errors/Complications - 3
- Other Unplanned Occurrences - 2
- Medical Device Failures - 1

VA Patient Safety Event Registry

The adverse events in the Registry were grouped into 17 categories. Seven of the 17 categories accounted for nearly 80% of all of the adverse events reported (see pages 5-6). Falls accounted for the most frequently reported events (542 or 19%). Attempted Suicides were second (476 or 16%). Each of the remaining 15 categories of adverse events reported by the VISNs within the designated time frame were reviewed and ranked. The fewest number reported were No Consent (for an invasive procedure) of which there were five (0.2%). Of the total, there were 710 (24%) reported deaths from all categories associated with the adverse events.⁸

Even though the Registry did not contain all of the adverse events that occurred within VHA during the time frame studied, it has real merit as a patient safety improvement tool. By aggregating adverse events and the resultant patient outcomes through a central registry, corrective changes can be made throughout the entire VHA system that could result in reductions in targeted adverse events. As all facilities within each of the 22 VISNs begin to participate uniformly in the reporting process, the Registry's validity and value will increase. Thus, the Registry will be able to demonstrate positive and negative trends and patterns that reflect advances in technology and changes in healthcare delivery systems.

⁷ Special Report on Sentinel Events. Joint Commission Perspectives, the Official Joint Commission Newsletter, 1998;18(6):19-42.

⁸ This figure represents only deaths reported to the Registry.

This Summary and Analysis Report has limitations. Such important questions as the following were not addressed:

- ◆ Why is there such a wide variation in the number of adverse events reported from one VISN to the next?
- ◆ Why is there such a wide variation in the kinds of adverse events reported across the VHA system?
- ◆ Are there valid regional differences in the frequencies and kinds of adverse events?

Conclusions

The VA has been moving toward primary ambulatory care with a corresponding reduction in the number of unoccupied inpatient beds and a reduction in lengths of stay of hospitalized patients in acute care facilities. As this transition proceeds, it is imperative that VHA track and trend serious adverse events in order to assure the veteran population, their families and significant others, and the general public, that the quality of care has not diminished and that patient safety is of the highest priority. VHA must be pro-active in planning oversight and accountability of healthcare outcomes. This can only be accomplished by assessing accurate and complete data regarding the care provided. The VA Patient Safety Event Registry represents one important feature of that oversight and accountability function. The reliability of the Registry is dependent upon timely, complete and valid data entry and careful maintenance. The value to the VA and veterans will be determined by the quality of the reviews and the frequency of use. We are reminded by Leape and others (see footnote 29 on page 23) that "early identification of risk is the key to preventing patient injuries, and this depends on maintaining a culture of trust, honesty, integrity, and open communication among patients and providers in the healthcare system."

1. After an analysis and review of the contents of the first 19 months of the VA Patient Safety Event Registry, the OMI concludes that a central trending and tracking mechanism for adverse events is a valuable and useful tool. It provides VHA additional data upon which to act to improve patient safety system-wide.
2. The reporting and analysis requirements contained in the VHA Handbook on Patient Safety Improvement are clear and concise. The wide variation in the reporting of adverse events from VHA facilities and their respective VISNs indicates a need to educate and train appropriate staff in identifying and reporting adverse events that meet the intent of the reporting requirements.
3. The number of adverse events actually reported to the Joint Commission (29 in 19 months) is low compared to the number of events that are "subject to review" by the Joint Commission.
4. There is a need to accurately define each of the data entry fields in the Registry in order to obtain more uniform and reliable data.

5. The 38 data entry fields should be reviewed periodically to assess their usefulness. Additional demographic and event-specific data fields are recommended to provide maximum benefit from the Registry.
6. There was a lack of documentation that VISNs and facilities received feedback about the quality and the timeliness of their entries from appropriate staff at VHA Headquarters.
7. Patient outcomes were not routinely recorded following the report of adverse events. A specified follow-up period should be required for applicable adverse events, for example, 30 days following a serious fall.
8. The Patient Safety Improvement Oversight Committee (PSIOC), as required, did not review all submitted analyses of the adverse events.⁹ The Registry did not contain documented recommendations from PSIOC regarding adverse event reviews that the committee did discuss.
9. The 2,927 adverse events reported in the first 19 months of the Registry's operation offer useful data and information that can contribute to improving patient safety throughout the VHA system and can be used in applicable performance improvement activities. Nearly 80% of the events reported could be grouped into seven categories (see pages 5-6). Falls accounted for the most frequently reported events.
10. Regional differences in occurrence of adverse events may be detected by a periodic (annual) evaluation of each of the 22 VISNs input into the VA Patient Safety Event Registry.
11. Ongoing maintenance and oversight of the Registry are necessary in order for it to earn facility and VISN acceptance as a reliable and useful patient safety improvement tool. An adequate, trained staff is required for its maintenance.

Recommendations

1. Staff at the National Center for Patient Safety (NCPS) and appropriate staff at VISNs and facilities should develop and conduct ongoing educational programs for Risk Managers, designees, VISN Quality Managers, and others in identifying and entering adverse events into the Patient Safety Event Registry.
2. The identification and reporting of significant adverse events should be part of new employee orientation and training should be added to the annual performance plans of applicable employees. The annual performance plan of applicable employees should include evaluations of how well this function is performed.

⁹ Changes to the requirement that PSIOC review all analyses of reported adverse events are in progress.

3. VHA leaders should determine the appropriateness and usefulness of reporting all "subject to review" adverse events to the Joint Commission. A VHA Directive containing the determination should be issued.
4. Medical center and VISN policies, directives and procedures should be reviewed to determine if appropriate reporting and analyses of adverse events and sentinel events are adequately addressed and implemented. The Director, NCPS, should monitor compliance and recommend action, as needed. The action should be in the form of further education and training.
5. All data entry fields should be accurately defined so that all participants enter reliable and valid data. Training sessions should be provided to assure uniformity.
6. Registry fields should be reviewed periodically for their usefulness. Consideration should be given to adding the following:
 - Gender
 - The age of the patient
 - The admitting diagnosis
 - Mandatory fields for the first initial of the first name and first initial of the last name and the last four numbers of the patient's Social Security number as the patient identifier
 - Preparation for the year 2000 using four-digit year inputs
 - A field for a follow-up period of not less than 30 days after the occurrence of applicable adverse events to register patient outcomes
 - In registering Falls, add whether restraints were used at the time
7. More uniform data should be entered for Field 10, *Brief Description of the Incident* and Field 11, *Extended Description of the Incident* to include taxonomy subheadings, for example, when, where, how and what.
8. Appropriate VISN and Registry staff should be accountable for updating the entries in the Registry when new data become available.
9. Appropriate Registry staff should provide timely feedback to the VISN and facility as to the quality and degree of documentation of Registry entries.
10. There should be a new field for *Recommendations* that contains either *Actions Taken* or *Closed Status* for each case presented to PSIOC.
11. Appropriate VISN and Registry staff should track corrective actions based on the oversight committee's recommendations that are entered into the Registry.
12. Appropriate facility, VISN and Registry staff should evaluate and prioritize the most prevalent adverse events and develop and implement action plans (best practices). It was noted that seven categories accounted for nearly 80% of all of the adverse events

reported. Attention to these seven categories would appear warranted. If action plans or initiatives are already in place, they should be reviewed for possible revisions.

13. VHA should consider requiring each VISN to submit an annual evaluation of their reported adverse events identifying potential areas for performance improvement and any applicable action plans addressing them.
14. VHA should provide adequate staffing to operate the Registry's reporting, analyses, follow-up, feedback, maintenance and oversight functions.

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I. Introduction

The Office of the Medical Inspector (OMI) reviewed data entered into the Patient Safety Event Registry (hereafter, the Registry) for the first 19 months of its operation. The purpose was two-fold: 1) to analyze the Registry as a reliable patient safety improvement tool, and 2) to examine the reported events from June 1, 1997, through December 31, 1998. Conclusions and recommendations follow the summary and analysis.

The Registry is a VHA-centralized program developed for tracking and trending reported serious adverse events and unplanned clinical occurrences and subsequent analyses in the form of Focused Reviews and/or Boards of Investigation. The Registry is one part of a system-wide Patient Safety strategy aimed at 1) preventing injuries to patients, visitors, and personnel, and 2) managing those injuries that do occur to minimize negative patient outcomes.¹⁰

National Center for Patient Safety

With the appointment of the Director, National Center for Patient Safety (NCPS), VHA underscored the importance of patient safety across the continuum of care. The responsibility for the operation of the VA Patient Safety Event Registry will be transferred to the NCPS. In addition, NCPS will be responsible for developing and implementing teaching and training curricula that address key aspects of patient safety and the root cause analyses of adverse events. The Director will also chair the Patient Safety Improvement Oversight Committee, which meets monthly at VHA Headquarters.

Definitions of Adverse Events

Adverse events are 1) untoward incidents; 2) iatrogenic injuries; 3) unexpected occurrences; and 4) therapeutic misadventures resulting in negative consequences. There are two major categories of adverse events: Sentinel Events and Unplanned Clinical Occurrences.

A Sentinel Event is the unanticipated loss of life, limb, or the permanent loss of function. Examples of Sentinel Events include the loss of vision resulting from medication, or a suicide by a patient who received services from a VA medical facility within the prior 30 days.¹¹

An Unplanned Clinical Occurrence (less serious than a sentinel event) is hospitalization, as a result of an event, an increase in hospital stay for more than merely observation, or an error in providing care that has the potential of resulting in an adverse event (near miss). Examples of Unplanned Clinical Occurrences include, but are not limited to, certain falls, missing patients who are found, suicide attempts, or medication errors without serious outcomes.

¹⁰ VHA Handbook 1051/1, page 1, January 13, 1998.

¹¹ Ibid.

Reporting of Adverse Events

During the 19-month period, from June 1997 through December 1998, 3,039 adverse events were reported and registered, of which 112 were duplicates or test entries leaving 2,927 cases available for analysis.

Staff members at VA medical centers are required to report:

- Sentinel Events,
- Adverse Events Likely to Trigger Substantial Negative Publicity,
- Unplanned Clinical Occurrences,
- Allegations of Patient Abuse,¹² and
- Potentially Compensable Events.¹³

When an adverse event is identified, the medical center is also obliged to inform the patient, family, and/or significant other about the resultant injury and any options available to them.

All information entered into the Registry is protected by the Privacy Act and is meant to be used as a performance improvement tool rather than a means for taking disciplinary action against individual employees.

Although facilities from each of the 22 networks reported adverse events, there was wide variation in the number reported. For instance, one VISN's facilities reported 37 adverse events while another VISN's facilities reported 320 events during the same period.¹⁴ Data pertinent to each adverse event were entered into 38 fields.¹⁵

Of the 2,927 adverse events in the Registry, 2,075 (71%) were designated by the facility, VISN or Chief Network Office as Unplanned Clinical Occurrences; 592 (20%) were designated as Sentinel Events; and 148 (5%) were designated as Adverse Media Attention. There were 76 (2.6%) adverse events (Please Update) that had no designation as to the type of incident. There were also 28 (1%) events reported as Near Miss Without Injury and 8 (0.3%) events reported as Near Miss with Injury.

Focused Reviews and Boards of Investigation

Medical centers submitted an intensive analysis of the adverse event in 85% of the total number of reported cases. There were 2,196 (75%) Focused Reviews (FR) and 301 (10%) Boards of Investigation (BoI), documented as having been received. In 465 (16%) of the reported adverse events, documented analyses of the events were lacking.

¹² Allegation of patient abuse is defined as an act that involves physical, sexual, psychological or verbal abuse. While intent to abuse is not necessary, examples of abuse include harassment or ridicule of a patient, willful physical injury and/or intimidation, willful violation of personal privacy, or intentional omission of care. VHA Handbook 1051/1, January 13, 1998.

¹³ Ibid.

¹⁴ See Illustration 3 on page 6 for VISN identification and range.

¹⁵ From June 1997 to October 1998, there were 10 fields. In October 1998, an additional 28 fields were added.

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Reporting to the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission)

A subset of sentinel events were "subject to review" by the Joint Commission, such as, a) an adverse event that has resulted in an unanticipated death or major permanent loss of function, unrelated to the natural course of the patient's illness or underlying condition; b) suicide of a patient in a setting where the patient receives round-the-clock care; c) rape; d) hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; e) abduction of an infant or discharge to the wrong family; and f) surgery on the wrong patient or wrong body part.¹⁶

VHA reported 29 (1%) of the total of 2,927 adverse events for this review period to the Joint Commission that included the following:

- *Suicides* - 7
- *Other Sentinel Events* - 5
- *Therapeutic Misadventures* - 5
- *Missing/Eloped Patients* - 3
- *Medication Errors* - 3
- *Surgical/Procedure Errors/Complications* - 3
- *Other Unplanned Occurrences* - 2
- *Medical Device Failure* - 1

The Patient Safety Oversight Committee

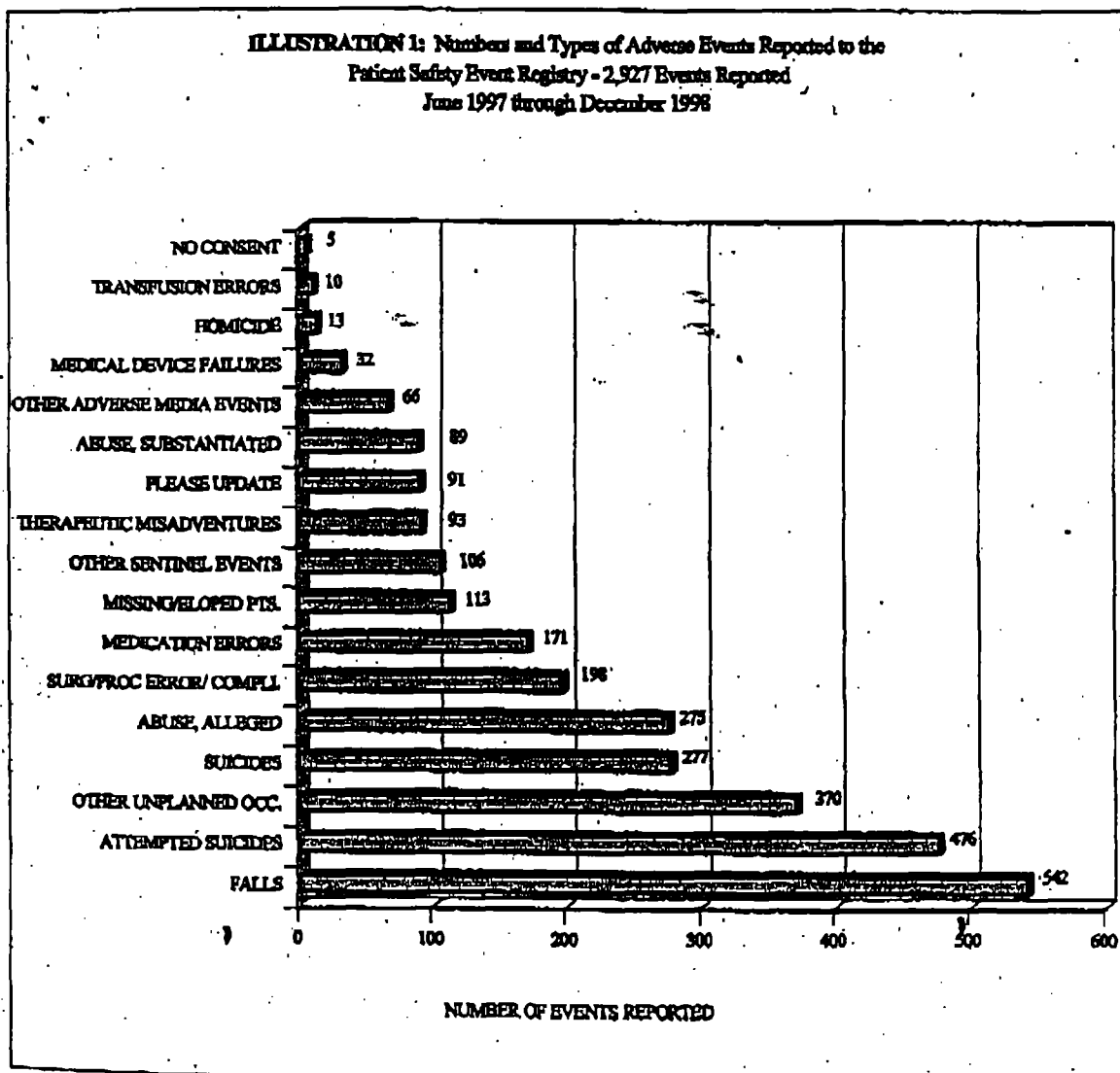
In 1997, as a component of the patient safety improvement initiative, VHA established a Patient Safety Improvement Oversight Committee (PSIOC) to review the quality of the facilities' analyses of their submitted adverse events. The oversight committee is made up of representatives from the Chief Network Office, the Office of Quality and Performance, the Office of Patient Care Services, the Office of the Medical Inspector, and clinical and administrative consultants, as appropriate. Other responsibilities of the Committee are to develop underlying themes, to trend specific problematic care systems, to identify lessons learned, to provide feedback to the field, and to designate financial awards to those facilities who develop innovative re-design of flawed existing processes. Of the total 2,497 reviews (2,196 Focused Reviews and 301 Boards of Investigation), received from June 1997 through December 1998, the oversight committee reviewed 431 analyses (17%).¹⁷

¹⁶ Special Report on Sentinel Events. Joint Commission Perspectives, the Official Joint Commission Newsletter, 1998;18(6):19-42.

¹⁷ Changes to the requirement that PSIOC review all analyses of reported adverse events are in progress.

II. Summary of the VA Patient Safety Event Registry's First Nineteen Months

The review of the Registry covered the data entered from dates of occurrence beginning June 1997 through December 1998. Since the Registry was initiated in June 1997, this marked the first such review. The results of the review may serve as benchmark information for future similar analyses. This analysis will hopefully stimulate appropriate staff at VA medical centers and VISNs to report all adverse events, as required by the Patient Safety Handbook, and appropriate staff at VHA Headquarters to maintain the Registry with updated information, as it is received. This review might also serve to stimulate individuals in medical centers and VISNs to begin to use the Registry in planning their own patient safety and performance improvement activities.



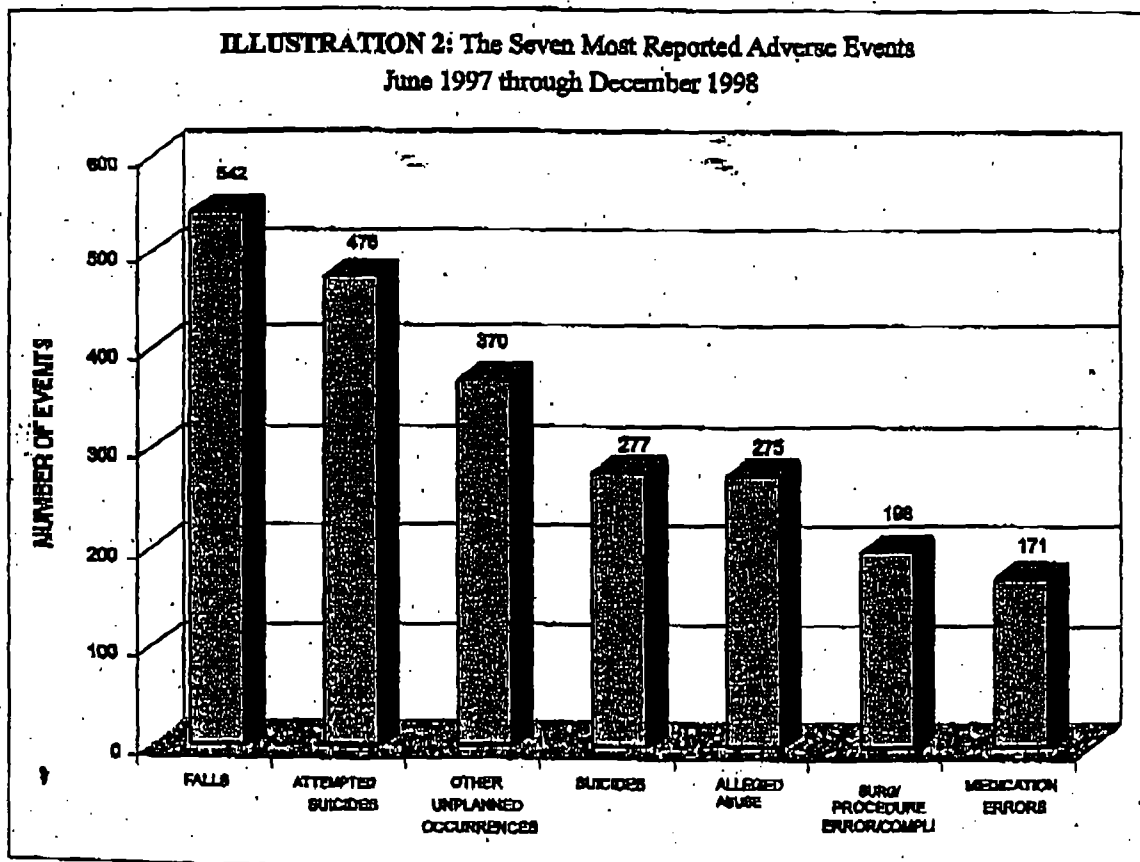
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The Registry contained 2,927 unique entries from 22 VISNs at the time the study period ended (December 31, 1998). Because data about previously entered events can be added at any subsequent time, the Registry represents a dynamic data source. Registry entries, therefore, can always be updated. A printed copy of the Registry, as of June 4, 1999, for the period from June 1, 1997, through December 31, 1998, served as the basis for this review.

The 2,927 reported events were distributed among 17 categories as each event was entered. The types and numbers of adverse events submitted are displayed on the previous page (Illustration 1).

Falls were the dominant reported event and comprised 19% of all of the events reported for this review period.¹⁸

Illustration 2 provides an overview of the seven most frequently reported adverse events. They account for nearly 80% of all of the adverse events reported in the first 19 months of the Registry.



¹⁸ Serious Falls, namely those resulting in fractures, sub-dural hematoma, and or death.

The seven groups of events constitute 79% of the total 2,927 events and include:

- Falls - 542 (19%)
- Attempted Suicides - 476 (16%)
- Other Unplanned Occurrences - 370 (13%)
- Suicides - 277 (9%)
- Alleged Abuse - 275 (9%)
- Surgical/Procedure Errors/Complications - 198 (7%)
- Medication Errors - 171 (6%)

The number of reported adverse events were examined for the same 19-month period from each VISN (Illustration 3). The variation ranged from 37 to 320 adverse events. Statistically, the mean was found to be 133, the median 125, and the standard deviation slightly more than 69.4. The 592 sentinel events are shown as the first segment of each bar.

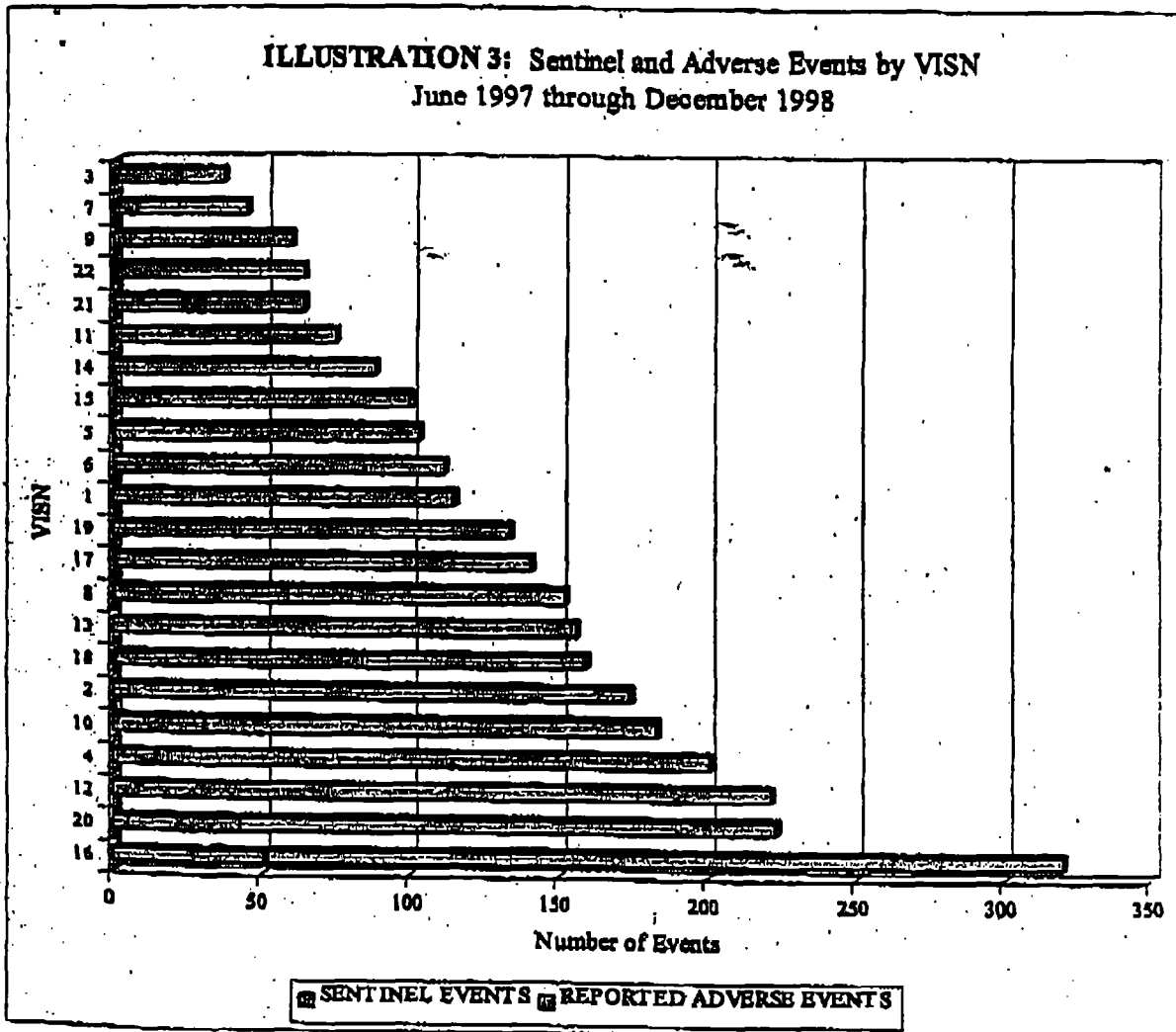
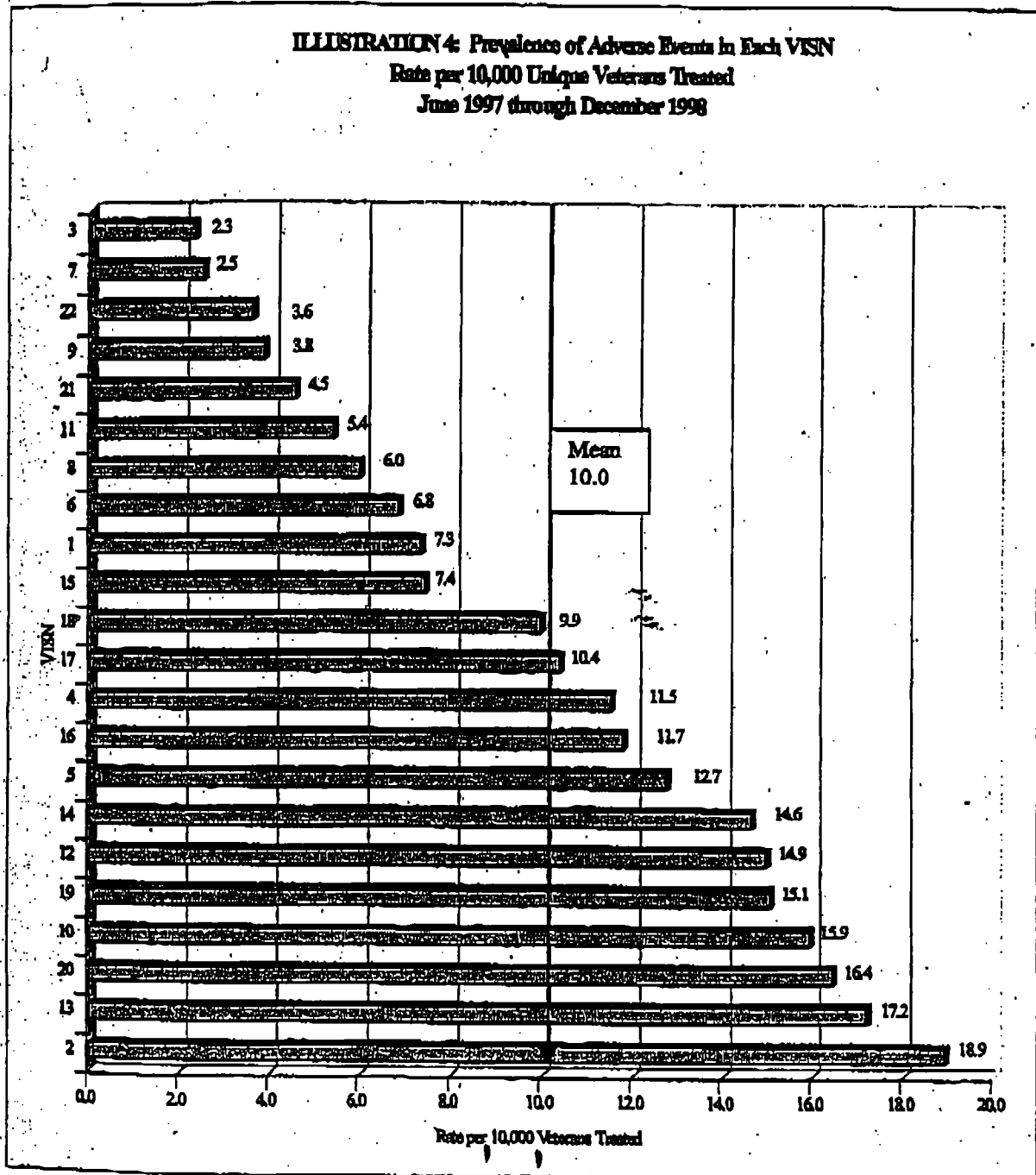


Illustration 4 shows the prevalence of adverse events in each VISN per 10,000 unique veterans treated.



III. Data Entry Fields of the Patient Safety Event Registry

There were 38 fields for data entry that comprised the Registry. Table 1 identifies the data entry fields.

TABLE 1: Data Entry Fields for the Patient Safety Event Registry June 1997 through December 1998			
1) Station Number	11) Extended Description	21) Report Date of Adverse Event	31) Date Received FR in HQ
2) VISN Number	12) Safety Date	22) Contact Phone Number	32) Date Additional Info Added
3) Person Reported	13) Presence of a BoI	23) Theme 1	33) Date Info was Changed
4) Patient Identification	14) Date BoI Initiated	24) Theme 2	34) Person Making Changes
5) Incident Date	15) Date BoI Completed	25) Theme 3	35) Class of the Event
6) Incident Time	16) Date BoI Forwarded - HQ	26) Follow-up Activity	36) Subclass of the Event
7) Service	17) Date Received BoI in HQ ¹⁹	27) Presence - (FR) Focused Review	37) Category of the Event
8) Status	18) JCAHO Notification	28) Date of FR	38) Sub-category of the Event
9) Code	19) Date JCAHO Notification	29) Date FR was Completed	
10) Brief Description	20) Contact Person	30) Date FR Forwarded - HQ	

Each of these fields is defined, as follows:

- 1) *Station Number* – Each VHA facility was assigned a three-digit number specifically identifying that facility by geographic locality.
- 2) *VISN Number* – Each VHA facility is located in a geographic locality identified by a Veterans Integrated Service Network (VISN) ranging from 1 to 22. As data were entered, the Registry prompted the reviewer for the VISN number in which the adverse event occurred. This field required only a number to be entered.
- 3) *Person Reported* – Each adverse event was associated with a person, either a patient or an employee.
- 4) *Patient Identification*¹⁹ – Each patient for whom an adverse event was entered was to be identified by the first initial of the first name, the first initial of the last name, and the last four digits of the patient's social security number.

¹⁹ First initial of first name, first initial of last name, and the last four numbers of the Social Security Number.

- 5) *Incident Date* – The date on which the adverse event occurred.²⁰
- 6) *Incident Time* – The time the adverse event occurred.
- 7) *Service* – Refers to the discipline or specialty caring for the patient at the time of the adverse event.
- 8) *Status* – Refers to the designation of inpatient or outpatient at the time the adverse event occurred.
- 9) *Code* – Refers to the sub-category assigned for each event.²¹
- 10) *Brief Description* – This field is a free text for short descriptive explanations describing the circumstances of the adverse event.²²
- 11) *Extended Description* – This field is a fully detailed explanation of the adverse event and may contain several descriptive words to several sentences.
- 12) *Safety Date* – Refers to the date the adverse event was discussed at the Patient Safety Improvement Oversight Committee Meeting.
- 13) *Presence of a BoI* – Refers to a "True" or "False" entry to signify whether a Board of Investigation is available in HQ for review.
- 14) *Date BoI Initiated* – Refers to the date the facility charged a team to implement a Board of Investigation for a specific adverse event.²³
- 15) *Date BoI Completed* – Refers to the date the facility completed the Board of Investigation concerning a specific adverse event.
- 16) *Date BoI Forwarded - HQ* – Refers to the date the facility sent the completed Board of Investigation to HQ signifying conclusions and recommendations had been drawn from the review.
- 17) *Date Received BoI in HQ* – Refers to the date the completed Board of Investigation from a specific facility was received in HQ and is to be completed and entered into the Registry by the CNO or designee.

²⁰ Sentinel Events, Unplanned Clinical Occurrences and events generating substantial negative publicity are to be reported to the VISN office within 24 hours of identification.

²¹ Falls; Attempted Suicides; Other Unplanned Occurrences; Abuse, Alleged; Suicides; Surgical/Procedure Errors/Complications; Medication Errors; Missing/Eloped Patients; Other Sentinel Events; Therapeutic Misadventures; Other Adverse Media Events; Abuse, Substantiated; Medical Device Failure; Homicides; Transfusion Errors; No Consents; and Please Update.

²² See OMI Recommendation 4 on page 28.

²³ Boards of Investigation are to be initiated as soon as possible, and no later than 10 working days after the initiation of VA Form 10-2633.

- 18) *JCAHO Notification* – Refers to the submission of information concerning the occurrence of sentinel events to the Joint Commission on Accreditation of Healthcare Organizations.
- 19) *Date JCAHO Notification* – Refers to the date that the sentinel event was reported to the Joint Commission on Accreditation of Healthcare Organizations.
- 20) *Contact Person* – Refers to the person entering information or the person who can answer questions concerning the occurrence of the adverse event at the facility.
- 21) *Report Date of Adverse Event* – Refers to the date that the occurrence of the adverse event was disclosed to HQ through the Registry.
- 22) *Contact Phone Number* – Refers to the method of telephonic contact used by the person entering information into the Registry or from whom additional information may be gathered.
- 23) *Theme 1* – Refers to the first possible grouping or commonality of the type of adverse event entered into the Registry.
- 24) *Theme 2* – Refers to the second possible grouping or commonality of the type of adverse event entered into the Registry.
- 25) *Theme 3* – Refers to the third possible grouping or commonality of the type of adverse event entered into the Registry.
- 26) *Follow-up Activity* – Refers to any additional information gathered with reference to the original adverse event.
- 27) *Presence – (FR) Focused Review* – Refers to a "True" or "False" entry to signify whether a Focused Review is available in HQ for review.
- 28) *Date of FR* – Refers to the date the facility instructed a person or team to implement a Focused Review for a specific adverse event.²⁴
- 29) *Date FR was Completed* – Refers to the date the facility completed the Focused Review concerning a specific adverse event.
- 30) *Date FR Forwarded - HQ* – Refers to the date the facility sent the completed Focused Review to HQ.
- 31) *Date Received FR in HQ* – Refers to the date the completed Focused Review from a specific facility was received in HQ and is to be completed by the CNO or designee.

²⁴ Focused Reviews are to be initiated as soon as possible, and no later than 10 working days after the initiation of VA Form 10-2633.

- 32) *Date Additional Information Added* – Refers to the date any additional information gathered with reference to the original adverse event was added to the report within the Registry.
- 33) *Date Info was Changed* – Refers to the date any additional information gathered with reference to the original adverse event was changed to the report within the Registry.
- 34) *Person Making Changes* – Refers to the contact person who enters information or updates information concerning the adverse event.
- 35) *Class of the Event*²⁵ – Refers to *Adverse Media Attention, Sentinel Event, or Unplanned Clinical Occurrence*.
- 36) *Subclass of the Event*²⁶ – Describes the type of adverse event that occurred.
- 37) *Category of the Event*²⁷ – Refers to the outcome of the patient involved in the adverse event.
- 38) *Sub-category of the Event*²⁸ – Refers to the specific injury the patient received as a result of the adverse event.

²⁵ Code Directory from the Registry includes Adverse Media Attention, Needs Updating, Sentinel Event, and Unplanned Clinical Occurrences as Class topics.

²⁶ Subclass includes Please Update; Falls; Attempted Suicide; Other Unplanned Occurrences; Abuse; Alleged; Suicide; Surgery/Procedure Error/Complication; Medication Errors; Missing/Eloped Patient; Other Sentinel Event; Therapeutic Misadventure; Other Adverse Media Event; Abuse, Substantiated; Medical Device Failure; Homicide; Transfusion Error; and No Consent.

²⁷ Category includes Major Injury/Permanent Loss of Function; Major Injury; Major Injury with No Permanent Loss of Function; Loss of Life; Other; Rape; Unspecified; Not Found; Found; Minor Injury; No Injury; and Hemolytic Reaction.

²⁸ Sub-category includes Hip Fracture; Subdural Hematoma; Unspecified; Other; Medication Overdose; Drowning; Hanging; Gunshot Wound; Laceration/Hemorrhage; Inhalation/Suffocation; Jump/Fall; Staff on Patient; Patient on Patient; Wrong Body Part; Wrong Patient; Wrong Medication; Wrong Dose; Reported to Registry; Not Reported to Registry; Lack of Treatment or Intervention; Anoxic Encephalopathy; Restraint Related; Burns; Aspiration; Defective Device; and Human Error.

Table 2 shows the various adverse event categories by each VISN for the 19-month period.

**TABLE 2: Categories of Adverse Events Entered in the
VA Patient Safety Event Registry**

VISN NUMBER	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	REGISTRY TOTALS
FALLS	24	42	1	45	33	7	5	27	2	34	27	43	17	23	20	60	40	34	14	23	8	7	542
ATTEMPTED SUICIDES	18	22	4	27	8	15	4	11	2	32	8	21	51	18	27	60	14	20	29	62	14	10	476
OTHER UNPLANNED OCCURRENCES	4	43	2	21	24	13	8	12	12	31	18	7	23	18	8	53	8	10	19	22	3	19	370
SUICIDES	5	10	10	20	10	11	8	27	11	21	9	4	11	13	3	18	6	13	25	24	13	7	277
ABUSE, ALLEGED	20	32	8	11	10	22	0	9	1	18	3	25	11	3	14	23	28	11	8	11	5	2	275
SURGICAL/PROCEDURE ERRORS/COMPLICATIONS	6	2	2	25	1	8	4	22	9	7	2	10	7	3	13	40	4	4	13	8	4	6	198
MEDICATION ERRORS	2	10	3	11	1	11	4	5	6	5	1	5	10	3	5	5	5	17	6	43	4	3	171
MISSING/DELOPED PATIENTS	1	5	2	8	1	4	5	5	0	5	2	32	1	0	4	15	5	2	6	5	2	3	113
OTHER SENTINEL EVENTS	4	3	3	0	0	3	7	13	1	4	1	16	1	2	1	13	1	21	3	8	1	5	106
THERAPEUTIC MISADVENTURES	10	2	0	9	3	4	0	6	1	4	0	2	10	0	1	8	9	18	0	1	5	0	93
PLEASE UPDATE	11	0	0	2	0	8	0	1	13	2	0	40	8	0	0	0	2	0	1	2	0	0	91
ABUSE, SUBSTANTIATED	8	3	1	7	8	3	0	8	0	9	1	8	3	2	3	10	2	1	5	4	1	3	89
OTHER ADVERSE MEDIA EVENT	0	0	1	15	2	0	3	1	2	7	0	4	0	1	2	5	11	5	1	5	1	0	66
MEDICAL DEVICE FAILURES	0	0	0	0	0	3	0	5	0	0	1	2	1	3	0	5	0	3	2	3	1	3	32
HOMICIDES	0	0	0	0	0	2	1	0	0	2	2	0	0	0	1	2	0	0	0	1	1	1	13
TRANSFUSION ERRORS	1	0	0	0	2	0	1	0	0	0	1	0	0	0	0	2	0	0	1	0	1	1	10
CONSENT	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	1	0	1	0	0	0	5
TOTALS BY VISN	116	174	37	201	103	112	45	152	60	183	75	221	186	88	100	320	141	168	134	223	64	64	2,927

IV. The Categories of Adverse Events in the Patient Safety Event Registry

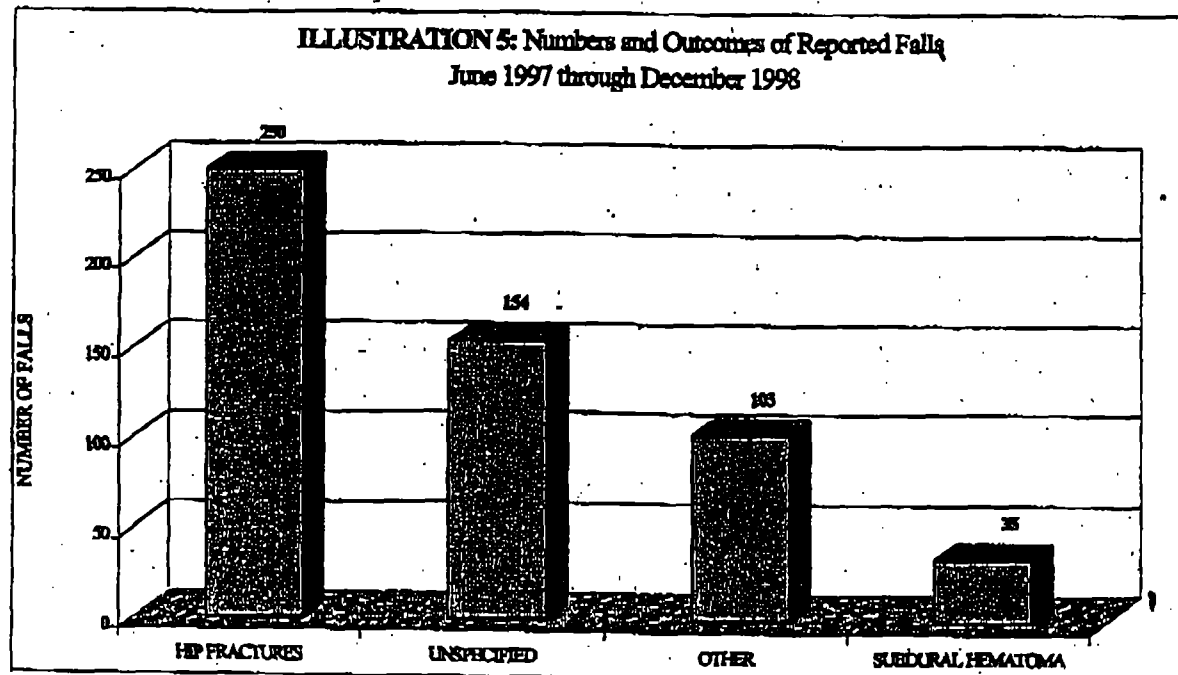
A. Falls 542 (19%) of the 2,927 Reported Adverse Events

There were 542 *Falls* reported in the Registry for the review period. The reported *Falls* were further categorized based on the description by the facility. Four sub-categories were chosen: 1) *Falls* with Hip Fractures, 2) *Falls* resulting in Subdural Hematoma, 3) *Falls* Unspecified, and 4) Other. As shown in Illustration 5, *Falls* with Hip Fractures were the most frequent.

Documentation in the Registry for most of the *Falls* did not reveal whether restraints were used at the time of the event. With the decreasing use throughout the VA system, the presence or absence of restraints at the time of the *Fall* should be recorded to determine the effects of current use on *Falls* incidence and severity.

Of the 542 reported *Falls*, the location of the patient at the time of the *Fall* was not specified in 306 (56%) events. Of the remaining 236 events, inpatients experienced 204 *Falls*, and 32 outpatients fell. Of the 542 *Falls*, 44 deaths were reported (8%).

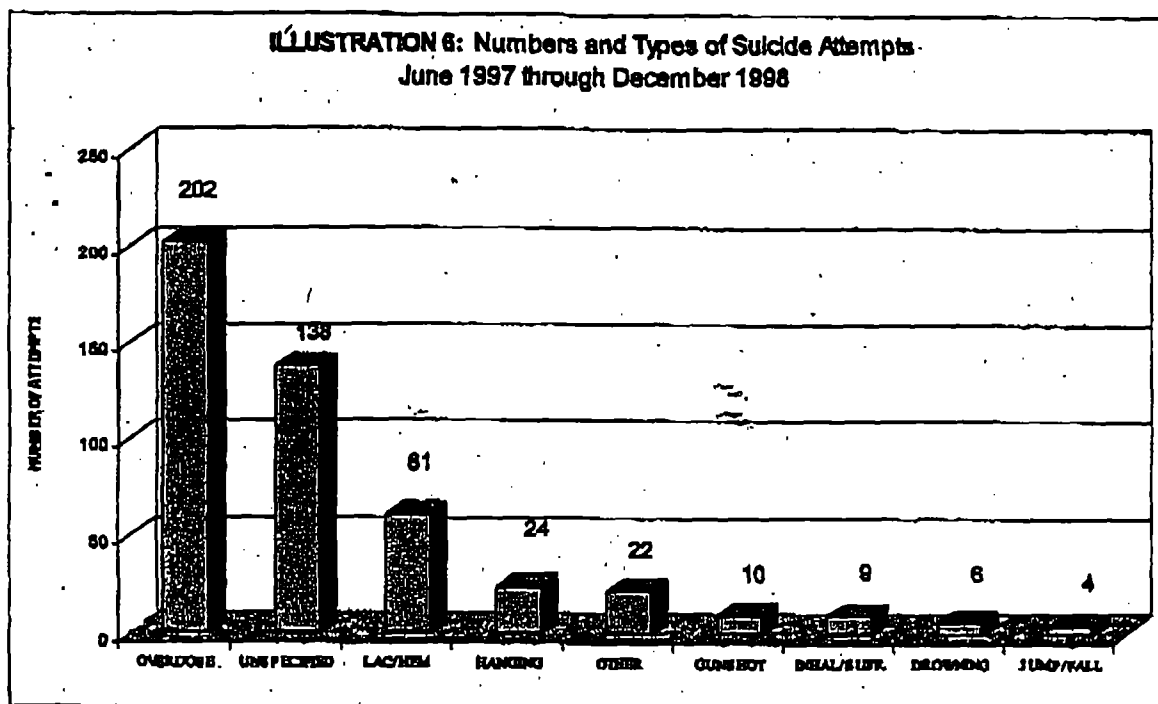
There were no *Falls* reported to the Joint Commission during this review period.



B. *Attempted Suicides* 476 (16%) of the 2,927 Reported Adverse Events

Attempted Suicides reported during the study period numbered 476 of the 2,927 reported events. Illustration 6 indicates the methods used with corresponding numbers for each. The largest number of reported *Attempted Suicides* was attributed to Medication Overdose, 202 (42%) occurrences. In 138 (29%) of the reported *Attempted Suicides*, the method was "Unspecified," that is, the method was either unknown or not designated.

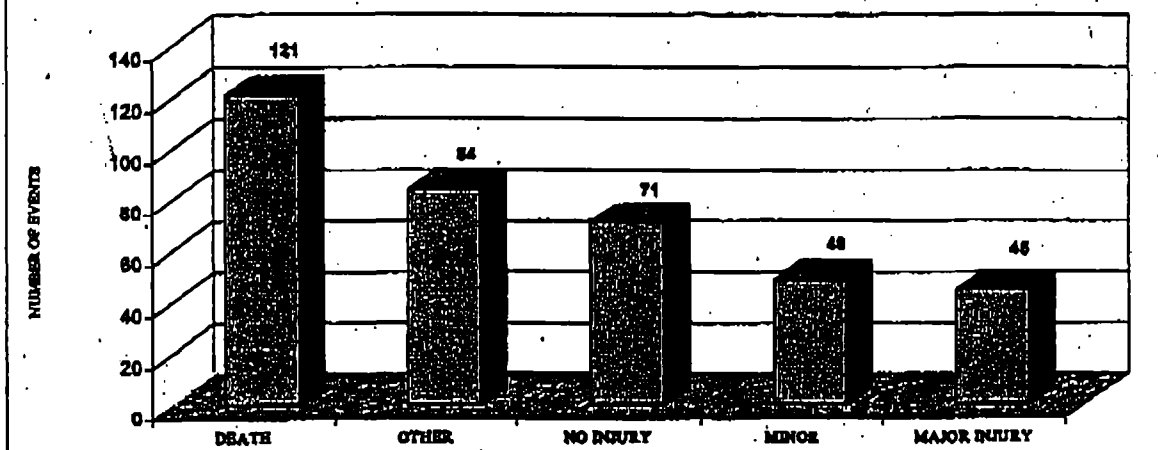
There were 213 (45%) outpatient *Attempted Suicides* and 48 inpatient attempts. In 215 (45%) of the attempts, the patient's location (inpatient or outpatient) was not specified.



C. *Other Unplanned Occurrences* 370 (13%) of the 2,927 Reported Adverse Events

Of the 370 (13%) *Other Unplanned Occurrences*, 84 (23%) were entered as "Other" which indicated no additional information was given for the adverse event. There were 138 (37%) *Other Unplanned Occurrences* for inpatients and 77 (21%) affecting outpatients with the remaining 155 (42%) events with no location designated. There were two *Other Unplanned Occurrences* reported to the Joint Commission. Illustration 7, on the next page, shows the sub-categories of *Other Unplanned Occurrences* including 121 deaths (33%).

ILLUSTRATION 7: Numbers and Outcomes of Other Unplanned Occurrences
June 1997 through December 1998



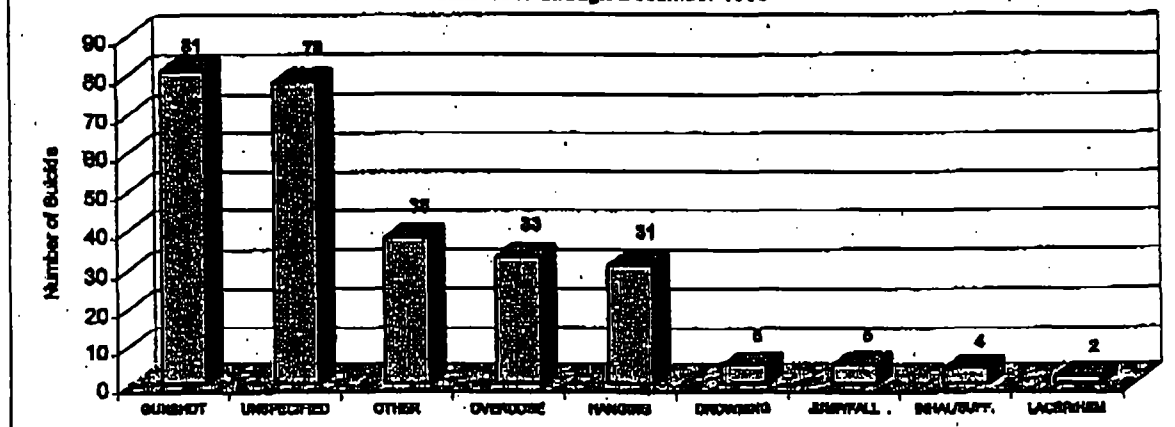
D. *Suicides* 277 (9%) of the Reported 2,927 Adverse Events

There were 277 *Suicides*. The number of reported *Suicides* combined with the number of *Attempted Suicides* totaled 753 (26%). Illustration 8 below indicates the various methods of *Suicide* with corresponding numbers of events for each. The largest number was attributed to gunshot wounds with 81 (29%) occurrences. "Unspecified" was the second highest with 78 (28%) occurrences, and "Other" was third with 38 (14%) occurrences.

In 82 *Suicides*, the patient's location (inpatient or outpatient status) was not specified and of the remaining patients, 172 (62%) *Suicides* occurred in outpatients, and 23 (8%) occurred in inpatients.

Seven *Suicides* were reported to the Joint Commission during the study period.

ILLUSTRATION 8: Numbers and Methods of *Suicides*
June 1997 through December 1998

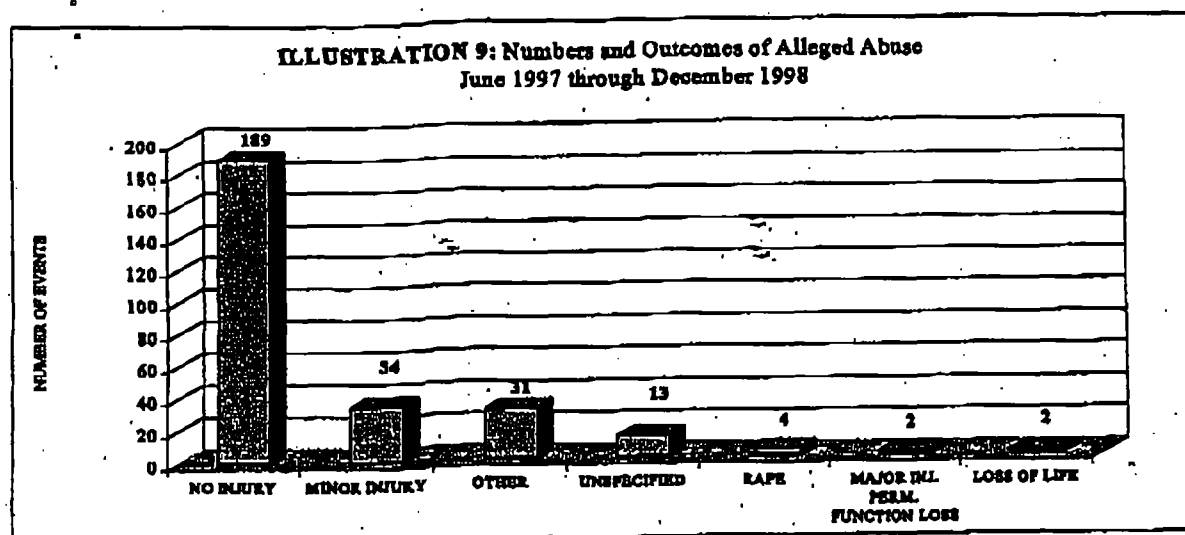


E. *Alleged Abuse* 275 (9%) of the 2,927 Reported Adverse Events

There were 275 reports of *Alleged Abuse* that were entered into the Registry during the first 19 months. For this category, it is important that the Registry information be updated to include the status of the abuser (staff, patient, visitor) and the abused (patient, staff, visitor), the type of abuse, and whether the abuse was alleged only, was witnessed, was substantiated, or was not substantiated.

The entries were divided into four sub-categories: staff on patient, patient on patient, other, and unspecified. The four sub-categories ranged from a high of 158 for Staff on Patient to a low of 29 for Patient on Patient. Illustration 9 indicates the categories of injury reported under *Alleged Abuse* including two deaths.

The location of the event was specified as inpatient for 71 (26%), outpatient for 11 (4%), and not specified in 193 (70%) of the adverse events reported.



F. *Surgical/Procedure Errors/Complications* 198 (7%) of the 2,927 Reported Adverse Events

There were 198 occurrences of *Surgical/Procedure Errors/Complications* recorded in the Registry during the first 19 months. *Surgical/Procedure Errors/Complications* were categorized into four sub-categories. These sub-categories include "Other" with 114 (58%) entries, Unspecified with 79 (40%) entries, Wrong Body Part with three (1.5%) entries, and Wrong Patient with two (1%) entries.

Three *Surgical/Procedure Errors/Complications* were reported to the Joint Commission during the study period.

G. Medication Errors 171 (6%) of the 2,927 Reported Adverse Events

There were 171 *Medication Errors* of the 2,927 reported adverse events in the Registry for the period studied. Twenty-two patients (13%) died. *Medication Errors* are grouped into five outcome sub-categories.

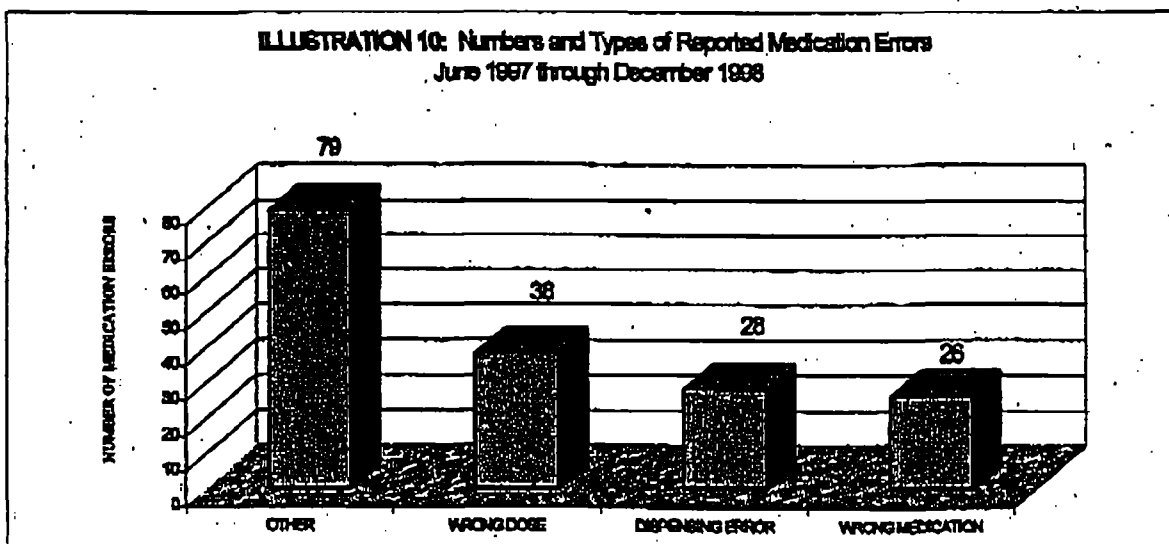
The outcome sub-categories with corresponding frequencies were as follows:

- Minor Injury – 60 (35%)
- No Injury – 45 (26%)
- Unspecified – 39 (23%)
- Loss of Life – 22 (13%)
- Major Injury/Permanent Loss – 5 (3%)

The types of *Medication Errors* and the correlation with the four outcome sub-categories are shown in Illustration 10. The types are: 1) Other; 2) Wrong Dose; 3) Dispensing Error; and 4) Wrong Medication.

Thirty (18%) of the *Medication Errors* occurred in outpatients, 35 (20%) affected inpatients, and in 106 (62%) of the *Medication Errors*, the Registry did not designate the location of the patient.

Three *Medication Errors* were reported to the Joint Commission during the study period.

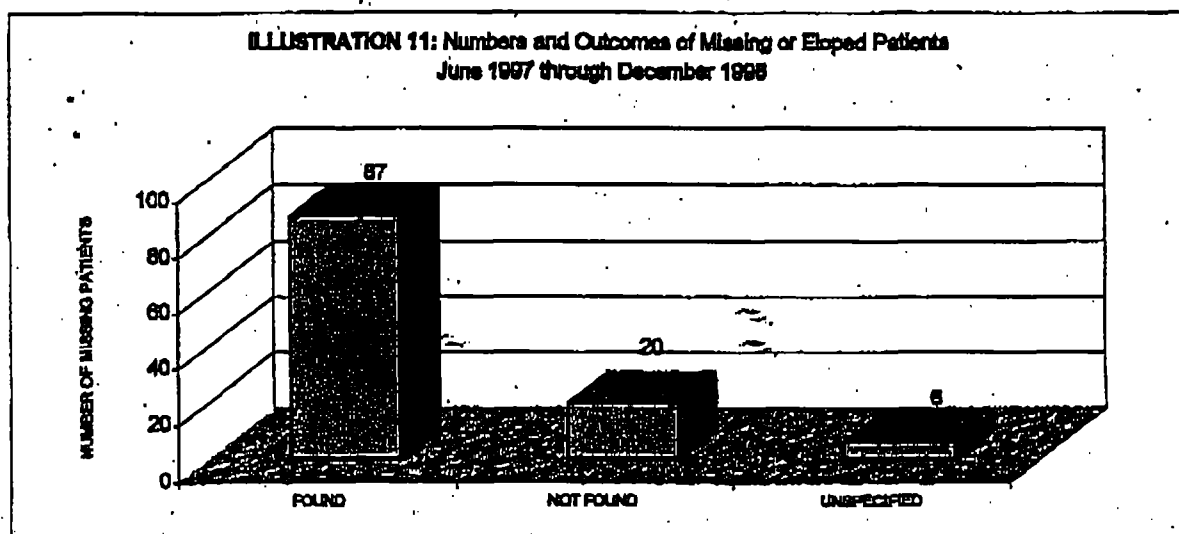


H. *Missing/Eloped Patients* 113 (4%) of the 2,927 Reported Adverse Events

There were a total of 113 *Missing/Eloped Patients* during the review period with 62 (55%) designated as inpatients, 14 (12%) designated as outpatients, and 37 (33%) patients with an unspecified designation.

The entries of reported *Missing/Eloped Patients* are divided into three sub-categories as seen in Illustration 11. *Missing/Eloped Patients* with the determination of "Found" was the largest group, 87 (77%).

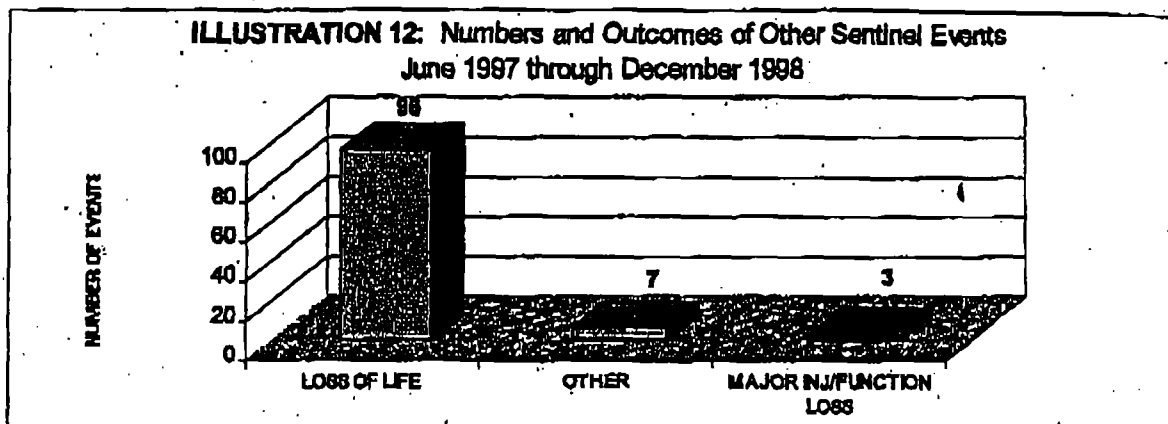
Three *Missing/Eloped Patients* were reported to the Joint Commission during the study period.



I. *Other Sentinel Events* 106 (4%) of the 2,927 Reported Adverse Events

There were 106 entries in the Registry under the category of *Other Sentinel Events*. These entries were further grouped under four headings: 1) Loss of Life; 2) Other; 3) Major Injury with Permanent Loss; and 4) No Injury. They are displayed in Illustration 12 on the next page. Examples of *Other Sentinel Events* are: 1) following a "porta-cath" insertion for IV medications, the patient sustained a severe pneumothorax; 2) a patient operating a jointer in woodshop inadvertently ran his hand into the cutters sustaining a severe injury; and 3) a patient was referred to Emergency Service for intravenous hydration, was discharged, and expired the next day at home.

Five *Other Sentinel Events* were reported to the Joint Commission.



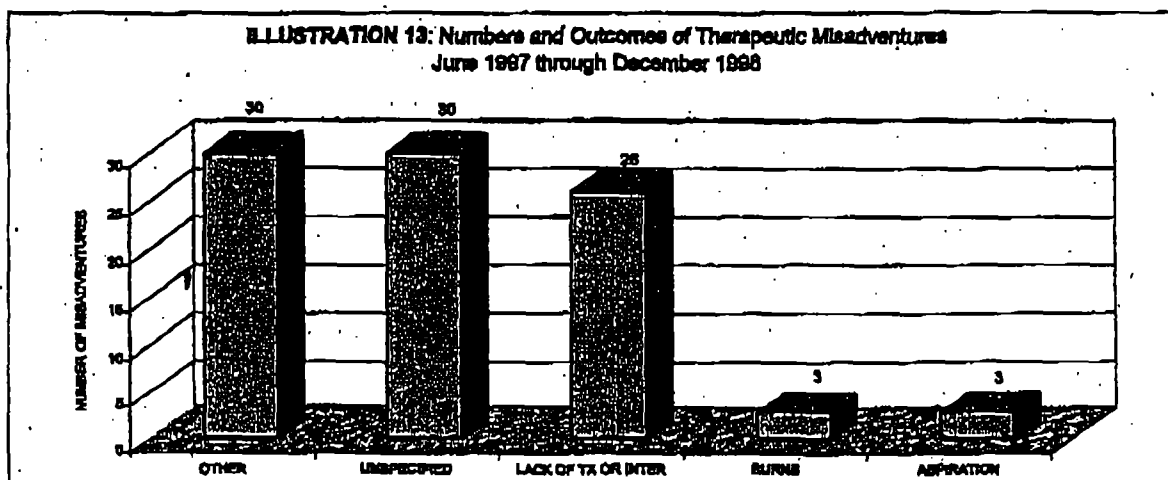
J. Therapeutic Misadventures 92 (3%) of the 2,927 Reported Adverse Events

There were 92 *Therapeutic Misadventures* of the 2,927 reported adverse events in the Registry for the period studied. Forty-seven patients (51%) died. Entries are grouped into five outcomes, as follows:

- Loss of Life – 47 (51%)
- Major Injury/Permanent Loss – 15 (16%)
- Minor Injury – 15 (16%)
- Unspecified – 8 (9%)
- No Injury – 7 (8%)

The types of *Therapeutic Misadventures* are shown in Illustration 13 and include: 1) other; 2) unspecified; 3) lack of treatment or intervention; 4) burns and 5) aspiration.

Two (2%) of the *Therapeutic Misadventures* occurred in outpatients, 35 (38%) affected inpatients, and in 55 (60%) of the *Therapeutic Misadventures*, the Registry gave the patient's location as "other," or the location was not identified.



K. Please Update 91 (3%) of the 2,927 Reported Adverse Events

There were 91 adverse events reported under the category of *Please Update*. As previously noted, this category refers to an entry with insufficient and incomplete data precluding designation into one of the other 16 categories.

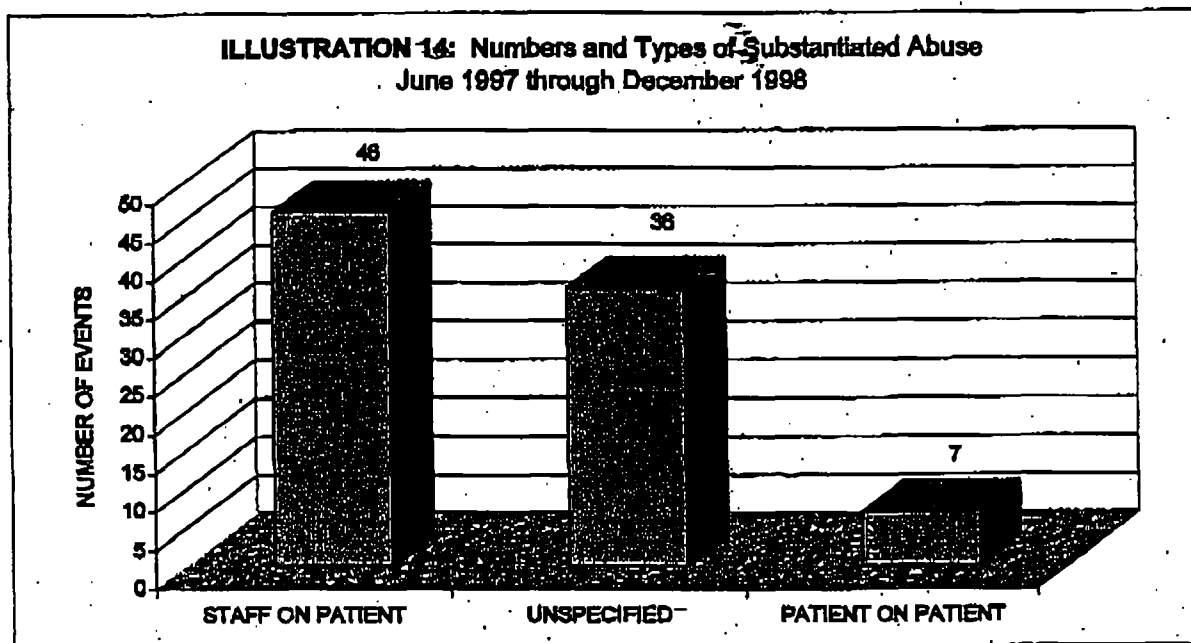
L. Substantiated Abuse 89 (3%) of the 2,927 Reported Adverse Events

There were 89 reports of *Substantiated Abuse* entered into the Registry during the first 19 months. The events reported were divided into four groups, as follows:

- No Injury – 61 (69%)
- Minor Injury – 19 (21%)
- Unspecified – 6 (7%)
- Major Injury/Permanent Loss – 3 (3%)

The events were further defined, as shown in Illustration 14. Of the 89 entries of *Substantiated Abuse*, there were four outpatients, 16 inpatients and 69 "others."

There were no Substantiated Abuse events reported to the Joint Commission.



M. Other Adverse Media Events 66 (2%) of the 2,927 Reported Adverse Events

There were a total of 66 occurrences of reported *Other Adverse Media Events* during the first 19 months. Inpatients were affected in 9 of the reported events, 21 involved outpatients, and in 36 events, the location of the patient was unspecified.

N. Medical Device Failures 32 (1%) of the 2,927 Reported Adverse Events

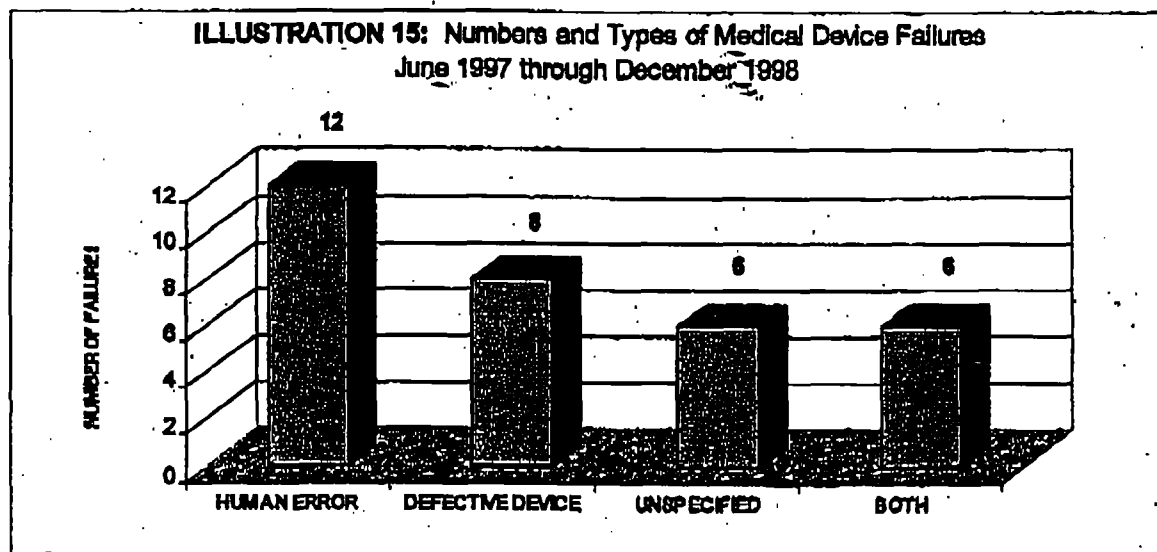
The 32 cases of *Medical Device Failures* were divided into five outcome groups, as follows:

- Minor Injury – 9 (28%)
- No Injury – 8 (25%)
- Major Injury/Permanent Loss – 7 (22%)
- Loss of Life – 6 (19%)
- Unspecified – 2 (6%)

Four sub-categories are displayed in Illustration 15 and include Unspecified, Defective Device, Human Error, and combined Defective Device and Human Error.

There were 18 unspecified locations of *Medical Device Failures*, with 10 event reports related to inpatients and four event reports related to outpatients. There were 10 VISNs in which there were no reports of significant *Medical Device Failures*.

One *Medical Device Failure* was reported to the Joint Commission during the study period.



O. Homicides 13 (0.4%) of the 2,927 Reported Adverse Events

There were 13 reported *Homicides* for the review period involving two inpatients, nine outpatients, and two patients with the designation of location not listed. Four of the events were attributed to fatal gunshot wounds with the remaining nine cases "Unspecified."

P. *Transfusion Errors* 10 (0.3%) of the 2,927 Reported Adverse Events

There were ten *Transfusion Errors* recorded in the Registry during the study period. These included seven patients with no detectable injury, two with hemolytic reactions, and one with unspecified injuries. There were no reported deaths.

The designation of the patients at the time of reported *Transfusion Errors* was specified as seven inpatients and three events for which the location was not specified.

Q. *No Consent* 5 (0.1%) of the 2,927 Reported Adverse Events

There were five occurrences of *No Consent* recorded in the Registry. One of the five patients was an inpatient, and the location of the other patients was not identified. One patient incurred unspecified minor injuries.

V. Discussion

The VHA's Patient Safety Handbook states "...the Office of the Chief Network Officer is responsible for maintaining a Sentinel Event Registry that will be used to track and monitor those adverse events reported to VHA Headquarters within 48 hours." The Registry was initiated in June 1997 with electronic entry capability. The Registry's first 19 months ended on December 31, 1998. The OMI considers the Registry a successful project but a "work in progress." Since it was begun, data entry has been simplified and additional fields have been added. In October 1998, the system was redefined as the Patient Safety Registry and Reporting System and comprised the following.²⁹

- A Patient Safety Handbook;
- A field to VHA Headquarters reporting mechanism for both sentinel events and unplanned clinical occurrences;
- A required root cause analysis for each incident reported; and
- An interdisciplinary expert review team at VHA Headquarters that provides feedback to medical treatment facilities and disseminates information to the rest.

The establishment of the National Center for Patient Safety further emphasizes the importance which VHA regards the improvement of patient safety.

The Safety Event Registry's value, like all successful databases and registries, depends on the frequency of use. Certainly, anyone interested in designing and redesigning processes and systems to make patient care safer can find interesting data in the Registry. Clinicians of all disciplines, information managers, administrative managers, and others will find material that can be used to improve patient safety. The Office of Special Project's Virtual Learning Center is available for communicating adverse events and their root cause analyses as *Lessons Learned*.³⁰

Of the 2,927 events reported in the 19-month period, there were 2,497 (85%) facility-generated analyses submitted to VHA Headquarters. The Patient Safety Improvement Oversight Committee (PSIOC) reviewed 431 analyses of adverse events during the same 19-month interval. The committee also developed themes (root causes) that might be used by facilities to change and adjust processes and systems. Finally, the committee recommended financial awards for outstanding designs or redesigns of patient care processes and systems submitted by facilities to prevent (or decrease the likelihood of) future similar events. The true value of the Registry, however, rests on its usefulness to the caregiver in improving patient safety.

²⁹ Lempe LL, Woods DD, Hartle MJ, Kizer KW, Schroeder SA, Lundberg GD. Editorial: Promoting patient safety by preventing medical error. JAMA 1998;280:1444-1447.

³⁰ Director, VHA Office of Special Projects. Comments in Response to Draft Report of the Summary Analysis of the VA Patient Safety Event Registry, June 11, 1999.

Patient Safety Event Registry data were submitted by staff from 22 VISNs, all having equal access of entry into the centralized reporting system. As shown in Illustration 3 on page 6, the number of VISN entries ranged from 37 to 320 during the review period. There was no correlation with the demographic location of the facilities within the VISN or with the size of the facilities.

This review of the Registry did not evaluate the reasons for the wide variation in the reporting and analyzing of adverse events. The disparity may be due to the lack of identification or knowledge of reportable adverse events, to staffing constraints, to the unwillingness to adhere to the reporting requirements, or to the presence of competing data base systems. A recent study, sponsored by the Department of Veterans Affairs,³¹ indicates that employees: 1) fear how the information will be used, 2) feel that there is too much paperwork, and that it (data entry) takes time away from what they believe is really important work, and 3) believe that reporting does not seem to accomplish anything. Patient Safety and Risk managers and VISN management should meet regularly with the clinical staff to encourage discussion of these and other reasons. If the validity and accuracy of the reporting requirements in the Patient Safety Handbook are in doubt anywhere in the VHA system, top management should clarify such doubtful areas and re-emphasize the importance of reporting to all involved personnel.³²

The integrity of the Registry is dependent upon clear definitions and adherence to identification of reportable adverse events at the facility level, consistent entry of required data into the Registry, submission of thorough analyses, guidance from the respective VISN, and responsible and consistent oversight, maintenance and feedback from the National Center for Patient Safety.

Areas for improvement still remain. Feedback to facilities was sporadic and irregular. The oversight committee did not keep up with its charge to review all submitted facility reviews (17%),³³ and the Registry was frequently not maintained with entry of additional data about previously entered events.

Reports of sentinel events, events generating substantial negative publicity, and unplanned clinical occurrences were to be transmitted to each respective VISN within 24 hours of identification. The VISN Office was then to notify VHA Headquarters within the next 24 hours through the CNO. The actual documented reporting times varied from 24 hours to no information. Appropriate VHA, VISN and facility staff members need to re-evaluate the reporting time frames to assure that the current ones are valid. Once the reporting time frames have been evaluated, delays in reporting the events (or absence of reporting) should result in appropriate action.

³¹ Adelson R, Bisber J, Blum L, Casey MA, Flint K, Graham S, et al. Patient Safety: Listening to healthcare employees. Veterans Health Administration, CareGroup, Kaiser Permanente, National Patient Safety Foundation, December 1998.

³² The Patient Safety Handbook is undergoing revision.

³³ Changes to the requirement that PSIOC review all analyses of reported adverse events are in progress.

The Patient Safety Handbook specifies that disciplinary actions would be taken for infractions of the reporting requirements. The warning in the Patient Safety Handbook of disciplinary action to be taken concerning such delays or absence of reporting of adverse events should be replaced by appropriate education and training (Recommendation 2 on page 28).

Regular periodic reviews of the number and quality of the data entry fields in the Registry should be carried out to assure their usefulness and prevent a burdensome entry process. Additional data in several Registry fields would improve the analysis of the data. For example, the data concerning *Falls* would be enhanced if the data entry field requested restraint data.

The 2,927 adverse events were distributed among 17 categories. Nearly 80% of all events reported were grouped into seven of these categories. Attention to these seven categories would appear to be warranted.

The large number of *Suicides* and *Attempted Suicides* adds support to previously published information that the VA has a large population of suicide-prone veterans.^{34,35} Suicide prevention in many patients has been linked to the appropriate treatment of depression. This most difficult and challenging combination is heightened by the unpredictability of the act, the location of suicides (many occurred in the home), the significance of attempted suicide, and the many innovative methods of suicide and attempted suicide employed. Tracking and trending the data in the Registry might be helpful in detecting upward and downward trends, geographic differences and the effects of new technology, therapy and knowledge.

³⁴ Lambert MT, Fowler DR. Suicide risk factors among veterans: risk management in the changing culture of the Department of Veterans Affairs. *J Ment Health Adm* 1997;24(3):350-8.

³⁵ Bullman TA, Kang HK. The risk of suicide among wounded Vietnam veterans. *Am J Public Health* 1996;86(5):662-7.

VL Conclusions

The VA has been moving toward primary ambulatory care with a corresponding reduction in the number of unoccupied inpatient beds and a reduction in lengths of stay of hospitalized patients in acute care facilities. As this transition proceeds, it is imperative that VHA track and trend serious adverse events in order to assure the veteran population, their families and significant others, and the general public, that the quality of care has not diminished and that patient safety is of the highest priority. VHA must be pro-active in planning oversight and accountability of healthcare outcomes. This can only be accomplished by assessing accurate and complete data regarding the care provided. The VA Patient Safety Event Registry represents one important feature of that oversight and accountability function. The reliability of the Registry is dependent upon timely, complete and valid data entry and careful maintenance. The value to the VA and veterans will be determined by the quality of the reviews and the frequency of use. We are reminded by Leape and others (see footnote 29 on page 23) that "early identification of risk is the key to preventing patient injuries, and this depends on maintaining a culture of trust, honesty, integrity, and open communication among patients and providers in the healthcare system."

1. After an analysis and review of the contents of the first 19 months of the VA Patient Safety Event Registry, the OMI concludes that a central trending and tracking mechanism for adverse events is a valuable and useful tool. It provides VHA additional data upon which to act to improve patient safety system-wide.
2. The reporting and analysis requirements contained in the VHA Handbook on Patient Safety Improvement are clear and concise. The wide variation in the reporting of adverse events from VHA facilities and their respective VISNs indicates a need to educate and train appropriate staff in identifying and reporting adverse events that meet the intent of the reporting requirements.
3. The number of adverse events actually reported to the Joint Commission (29 in 19 months) is low compared to the number of events that are "subject to review" by the Joint Commission.
4. There is a need to accurately define each of the data entry fields in the Registry in order to obtain more uniform and reliable data.
5. The 38 data entry fields should be reviewed periodically to assess their usefulness. Additional demographic and event-specific data fields are recommended to provide maximum benefit from the Registry.
6. There was a lack of documentation that VISNs and facilities received feedback about the quality and the timeliness of their entries from appropriate staff at VHA Headquarters.

7. Patient outcomes were not routinely recorded following the report of adverse events. A specified follow-up period should be required for applicable adverse events, for example, 30 days following a serious fall.
8. The Patient Safety Improvement Oversight Committee (PSIOC), as required, did not review all submitted analyses of the adverse events.³⁶ The Registry did not contain documented recommendations from PSIOC regarding adverse event reviews that the committee did discuss.
9. The 2,927 adverse events reported in the first 19 months of the Registry's operation offer useful data and information that can contribute to improving patient safety throughout the VHA system and can be used in applicable performance improvement activities. Nearly 80% of the events reported could be grouped into seven categories (see pages 5-6). Falls accounted for the most frequently reported events.
10. Regional differences in occurrence of adverse events may be detected by a periodic (annual) evaluation of each of the 22 VISNs input into the VA Patient Safety Event Registry.
11. Ongoing maintenance and oversight of the Registry are necessary in order for it to earn facility and VISN acceptance as a reliable and useful patient safety improvement tool. An adequate, trained staff is required for its maintenance.

³⁶ Changes to the requirement that PSIOC review all analyses of reported adverse events are in progress.

VII. Recommendations

1. Staff at the National Center for Patient Safety (NCPS) and appropriate staff at VISNs and facilities should develop and conduct ongoing educational programs for Risk Managers, designees, VISN Quality Managers, and others in identifying and entering adverse events into the Patient Safety Event Registry.
2. The identification and reporting of significant adverse events should be part of new employee orientation and training should be added to the annual performance plans of applicable employees. The annual performance plan of applicable employees should include evaluations of how well this function is performed.
3. VHA leaders should determine the appropriateness and usefulness of reporting all "subject to review" adverse events to the Joint Commission. A VHA Directive containing the determination should be issued.
4. Medical center and VISN policies, directives and procedures should be reviewed to determine if appropriate reporting and analyses of adverse events and sentinel events are adequately addressed and implemented. The Director, NCPS, should monitor compliance and recommend action, as needed. The action should be in the form of further education and training.
5. All data entry fields should be accurately defined so that all participants enter reliable and valid data. Training sessions should be provided to assure uniformity.
6. Registry fields should be reviewed periodically for their usefulness. Consideration should be given to adding the following:
 - Gender
 - The age of the patient
 - The admitting diagnosis
 - Mandatory fields for the first initial of the first name and first initial of the last name and the last four numbers of the patient's Social Security number as the patient identifier
 - Preparation for the year 2000 using four-digit year inputs
 - A field for a follow-up period of not less than 30 days after the occurrence of applicable adverse events to register patient outcomes
 - In registering Falls, add whether restraints were used at the time
7. More uniform data should be entered for Field 10, *Brief Description of the Incident* and Field 11, *Extended Description of the Incident* to include taxonomy subheadings, for example, when, where, how and what.
8. Appropriate VISN and Registry staff should be accountable for updating the entries in the Registry when new data become available.

9. Appropriate Registry staff should provide timely feedback to the VISN and facility as to the quality and degree of documentation of Registry entries.
10. There should be a new field for *Recommendations* that contains either *Actions Taken* or *Closed Status* for each case presented to PSIOC.
11. Appropriate VISN and Registry staff should track corrective actions based on the oversight committee's recommendations that are entered into the Registry.
12. Appropriate facility, VISN and Registry staff should evaluate and prioritize the most prevalent adverse events and develop and implement action plans (best practices). It was noted that seven categories accounted for nearly 80% of all of the adverse events reported. Attention to these seven categories would appear to be warranted. If action plans or initiatives are already in place, they should be reviewed for possible revisions.
13. VHA should consider requiring each VISN to submit an annual evaluation of their reported adverse events identifying potential areas for performance improvement and any applicable action plans addressing them.
14. VHA should provide adequate staffing to operate the Registry's reporting, analyses, follow-up, feedback, maintenance and oversight functions.

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