

Recommendations

These recommendations take into consideration testimony originally coded to 03 (MandRpt)¹, 04 (VolRpt)², 05 (ShareInfo)³, and 29 (PSRpt)⁴, as well as other sources, as noted.

- K1. The Michigan legislature should establish and fund a statewide, confidential, peer-protected, non-punitive, voluntary error reporting system.
 - o K1a. Guarantee sufficient, reliable, ongoing funding for the reporting system.
 - o K1b. Authorize the Michigan Partnership for Safe Health Care to design, implement, manage and maintain the reporting system. These responsibilities would include collecting and analyzing the data, as well as disseminating important findings to improve health-care safety.
 - o K1c. Authorize the Partnership to sub-contract functions related to the reporting system, as appropriate.
 - o K1d. Require that the system complement, to the extent possible, existing reporting initiatives sponsored by Michigan health-care organizations and emerging national error definitions and measurement criteria.
 - o K1e. Ensure that the reporting system's data, sources, and users are protected, as described in Recommendation J1 (Safeguard Data and Sources).
 - o K1f. Require an evaluation of the success of the voluntary reporting system within three years of implementation, with a stipulation that if the voluntary system is not successful, a mandatory system will be considered.
- K2. Charge the Partnerships with designing the system's specifications in consultation with reporting system experts and a broad array of health-care stakeholders, including consumers. The reporting system should be designed to:
 - o K2a. Define and require use of standardized data collection tools and methods.
 - o K2b. Collect adverse events.
 - o K2c. Collect "near miss" reports.
 - o K2d. Collect data from health-care organizations across the continuum of care.
 - o K2e. Accommodate information submitted by patients, families and consumers.
- K3. The Partnership should analyze aggregated, de-identified data to identify trends; system failures and contributing human factors; and persistent safety issues in need of intensive analysis or broad response.
- K4. The Partnership should disseminate important findings to improve health-care safety.
 - o K4a. Return detailed, de-identified data to reporting organizations in a timely and useful format.
 - o K4b. Disseminate aggregated findings to reporting organizations and, when appropriate, to the public in a timely and useful format.
 - o K4c. Communicate regularly with and convene stakeholders to facilitate sharing of error-based lessons learned and best practices.
 - o K4d. Develop or identify sources of expertise to help reporting organizations study error events and arrive at appropriate conclusions and good solutions.
 - o K4e. Disseminate solutions and successes of projects and patient safety initiatives to providers and the public.

- K5. The Partnership should consult with reporting system experts and a broad array of health-care stakeholders, including consumers, to recommend Incentives, financial and otherwise, to encourage participation in the reporting system.

Rationale

Given the right set of circumstances, even the most conscientious health-care professional will err. Sometimes those errors will result in serious harm to the patient. The goal of the proposed voluntary, non-punitive error reporting system is prevention: to learn from past errors, whether they reached the patient or not.

To reduce the potential for patient harm, errors and “close calls” or “near misses” must be identified, recorded, and analyzed. Near misses occur 100-300 times more frequently than do actual adverse events; improving analysis and trending capabilities related to near misses is critical.⁵ A large dataset with sufficient analytical power would permit rapid detection of rare events and trends. Information must be returned to those who provided the data and systems of care must be changed in ways that reduce the likelihood of future occurrences. Other high-risk industries, including aviation and nuclear power, use similar methods to provide services safely.

Reporting is not a new activity for health-care organizations⁶. For the most part, reporting has been associated with blame and fear of litigation. To make progress, this emphasis on punishment must change. The potential to learn from errors is greatly enhanced by collecting error reports from many organizations, then compiling, aggregating and analyzing the data in ways that make it possible to detect trends, especially for rare events. Collecting and aggregating information across unaffiliated health-care organizations requires that a statewide system be in place. Such a system would enhance learning opportunities for all participants by facilitating the sharing of de-identified data, lessons learned, and best practices with a broad group of health-care providers so all organizations have an opportunity to develop, implement and evaluate their own error prevention programs. A statewide reporting system would also facilitate communication with the public about which health-care organizations are working to improve care by participating in error reporting and monitoring activities.

Evidence for harm reduction

Although it seems logical to expect that voluntary reporting of errors and near misses, combined with improving systems of care, would result in a reduction in patient harm, few studies establish such a link. What is known is that, under the right circumstances, voluntary reporting systems generate reports, as demonstrated in the following examples.

- The U.S. Pharmacopoeia and the Institute for Safe Medication Practices operate the **Medication Errors Reporting Program**. This program is non-punitive and voluntary. As of 2000, it was receiving about 1,000 high-quality, detailed reports per year. The reports have prompted drug companies and federal regulatory bodies to issue safety warnings and to make changes to the way potentially harmful drugs are packaged and labeled, making it more difficult for a health-care professional to make a mistake.
- The **Veterans Affairs (VA) Patient Safety Reporting System (PSRS)** was developed by the VA in consultation with the National Aeronautics and Space Administration (NASA) and modeled after the Aviation Safety Reporting System (ASRS).⁷ PSRS has been active since 2000 and is a voluntary, confidential, and non-punitive reporting system. PSRS is managed by NASA, which is not involved in the regulation of VA health systems. PSRS collects close calls, unexpected serious injuries or death, lessons learned and safety ideas. As of 2004, PSRS had collected over 400 reports and issued 10 bulletins used to prioritize issues and improve awareness, safety systems, and operations.⁸ The VA also operates a voluntary, confidential and non-punitive internal

reporting system that has collected over 140,000 reports in the first five years of operation.

- **Trinity Health's** program, Potential Error/Event Reporting System (PEERS), is a voluntary, online reporting effort designed to reduce errors in clinical care. PEERS generates about 1,700 reports per month. PEERS findings have prompted local and system-level changes in health-care system structures and processes.⁹
- The Vermont Oxford Network sponsors the **Neonatal Intensive Care Quality Project**, a collaboration of 54 of its 400 hospital members.¹⁰ The system is Internet-based and anonymous. It used to collect errors, near misses and adverse events. In the first 27 months of operation 1,256 reports from 739 health-care professionals were submitted. The information was used to determine the causes of errors and change systems in ways that should reduce future harm to patients.

Assessment

Advantages

- Committing State resources for patient safety improvement through data collection and analysis for prevention, not punishment, demonstrates the State's commitment to building a culture of safety and creating a learning environment.
- A state-level reporting system would permit pooling of knowledge and resources across organizations and professions to analyze problems and develop solutions.
- A state-level reporting system could identify system vulnerabilities before a harmful event occurs.
- Hospital-based voluntary reporting is already occurring in Michigan, at VA hospitals and Trinity Health. Michigan hospitals have also voluntarily reported quality indicators, clinical events and medical procedures to the Michigan Health & Hospital Association since 1966.
- A patient safety incentive program for Michigan hospitals contracting with Blue Cross Blue Shield of Michigan is already in place. This program could serve as a catalyst for other third-party payers and could be expanded to include incentives for participating in a voluntary error-reporting program.
- Michigan is home to several national experts from the VA National Center for Patient Safety and the Trinity Health System.

Barriers

- The federal government has provided little support to states in the form of funding or technical assistance for reporting system design or analysis and solution-dissemination activities.
- The federal government has provided little support in terms of legal protection for error data or analyses reported to a third party. The question of legal protection may change in the near future if Congress passes proposed patient safety legislation that includes such protection.¹¹
- Unless peer protection is enacted, the reporting system is likely to fail because of fears of repercussion, incorrect assumptions that equate errors with competency, and the potential for legal discovery of reports.¹² Fear of malpractice litigation is also a potential barrier.
- As noted elsewhere, barriers to success in other programs have included: a lack of organized data collection methods;¹³ the lack of an organized approach to analyze root

causes;¹⁴ failure in the past to focus on system defects;¹⁵ and the absence of a way to share lessons learned.¹⁶

- Insufficient funding and resources are considerable potential barriers. Many states with reporting systems struggle to secure the resources necessary for analysis and dissemination of lessons learned.
- Concerns about the data—inadequacy, incompleteness, underreporting, variability, insufficient standardization of data elements—can lead to questions of accuracy and validity regarding the data and any conclusions drawn from the data.
- Inadequate information will reach the public without interpretation or context.

Implementation

Further research

State and federal agencies are funding a variety of research projects studying virtually every aspect of reporting, including:

- What type of technology works best under what type of conditions.
- Validation of definitions and measurement criteria.
- Best methods to aggregate data and provide feedback to reporters.
- Assessment of efficiency and effectiveness especially as it relates to reduction of harm.

Legislation and/or administrative rules

- Amend the Public Health Code to establish and fund a statewide voluntary error reporting system as specified in these recommendations.

Resources

- Substantial resources will be needed to operate a voluntary reporting system. Requests for funding should be bundled with budget requests for the Michigan Partnership for Safe Health Care.
- Federal grants should be pursued. In 2001 the federal Agency for Healthcare Research and Quality (AHRQ) awarded \$23 million to 16 three-year error reporting demonstration projects.¹⁷

Incentives

- Third-party payers, purchasers and others should reward health-care organizations that participate in the voluntary reporting system.
- Purchasers of care could assist hospitals by helping to subsidize data-gathering efforts through reimbursement or subsidies.¹⁸

Specific steps and target dates

Following adoption of these recommendations, the following steps will take place.

- Within 9 months, the Michigan Partnership for Safe Health Care will convene a panel of reporting experts to evaluate broad-scale applicability of existing systems and how such systems might align with efforts that unfold at the national level. The panel, in consultation with stakeholder groups, should:
 - o Within 24 months, determine the design and specifications of the reporting system in addition to measures, measurement criteria, operational processes and analytical methods.
 - o Within 26 months, present its recommendations for moving forward in a white paper presented to the citizens of Michigan.¹⁹
- Within 36 months, the Michigan Partnership for Safe Health Care will begin to phase in data collection, analysis and learning strategies for different types of organizations, beginning with hospitals and moving to other settings of care as capacity permits.

Testimony overview

Summary

27 informants representing hospitals (4), practitioners (4), educators (1), consumers (5), employers (2), insurers (2), professional societies (6), and others (3) submitted a total of 47 recommendations related to reporting. An additional 7 informants provided recommendations related to sharing and disseminating error system findings.

Key findings

- All informants indicated support for an error reporting system. There was more support for a voluntary reporting system than for a mandatory system. Of the 27 submissions, 11 requested creation of an exclusively voluntary system, 5 requested creation of an exclusively mandatory system, 2 requested a mixed voluntary/mandatory system, and 9 requested reporting systems but did not specify mandatory or voluntary.
- Almost all of the recommendations indicated that “the state” or “State of Michigan” or some aspect of the state (legislature, administration, or a state-level patient safety center) be responsible for setting up and administering a reporting system.
- Informants, regardless of the type of system they recommended, tended to recommend that the error reporting system be statewide, non-punitive, and protect the identity of the reporter (confidential, anonymous, de-identified, protected); use a standardized format consistent with various national standards; and provide some public reporting of trends and facility/organization-specific reports.
- There was less agreement among informants regarding particular aspects of a reporting system such as its data elements, reportable events, uses of the information, data collection methods, types of reporters, control and housing of the reporting system, contingencies and other issues.
- There was strong agreement that the primary purpose of analyzing data and conducting follow-up action with regard to data contributed to the error reporting system is to share lessons learned.

Summary of additional research

As evidenced by the work of the Institute of Medicine (IOM) and a number of state-based patient safety coalitions, there is support for error reporting systems.²⁰ Specifically, the IOM (1999) recommended creating reporting systems that would allow for the identification and prevention of errors. They suggested two types of systems to serve the purpose of identifying errors. First, mandatory reporting systems were cited as a way to hold providers accountable.²¹ Such systems, typically housed within a state agency, improve public confidence and allow the public to be aware of unsafe conditions. Second, voluntary reporting systems were identified as a way of detecting weakness before serious harm occurs. Voluntary systems were viewed as confidential and not necessarily run by the state. Their purpose is to improve patient safety and quality. Even though most states have implemented mandatory reporting systems (described below), there are compelling reasons to opt for a voluntary reporting system. The purposes of voluntary and mandatory error reporting systems are quite different. Essentially, mandatory systems punish “bad” professionals and organizations. Even when mandatory reporting systems offer amnesty or immunity, the system punishes those who fail to report.

In its 2000 report, the IOM made it clear that “the goal of reporting programs is not to count the number of reports. 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.”²² Five years later, in his assessment of the progress made since the IOM report on patient safety, Wachter reiterates the need to pay attention to what happens to data from reporting systems once it’s collected. He calls this “the Achilles heel of error-reporting systems: the flawed notion that reporting has any intrinsic value in and of itself.”²³ Though error-reporting systems are one of the five major areas of activity in patient safety over the past five years, he grades these efforts a ‘C’, because not enough has been done with data from these systems. He calls for new reporting models and “far greater resources devoted to translating submissions into action.”²⁴

As of 2003, the National Academy for State Health Policy (NASHP) reported that 21 states had adopted mandatory reporting systems.²⁵ All 21 states offer some level of information to the public regarding complaints they receive and poor decisions made. Nine of the 21 publicly release aggregate data in periodic reports and 11 have protected confidential information, meaning they do not offer the facility’s name. Ten states do disclose the name of the facility and of these only seven release incident-specific information.²⁶

Since the NASHP report was released, Oregon has passed legislation instituting a statewide voluntary error reporting system. The system will be reviewed in 2007 and, based on its performance, may be converted to a mandatory system. The Oregon system will collect serious adverse events with root cause analyses, action plans, and safety procedures and protocols. The Oregon system will not collect “near misses.”

The NASHP reports contain, for most states, some description of the reporting system, definitions of reportable events, and various statistics on the frequencies and rates of incidents. Half or fewer, however, include any recommendations or plans to improve the system, examples of how data has led to patient safety improvements, or interpretive information. None of the states provided analysis or discussed implications. In its conclusions, NASHP noted “patient safety event data require careful analysis and interpretation before they are useful to the public,”²⁷ but highlighted the current lack of funding and resources to support the development of reporting systems that incorporate both collection and learning components. Similarly, Rosenthal and Booth (2003) found that these systems are not supplying the public with consistent information about the release of adverse events and medical errors. Marchev et al (2003) believe that the question remains how to best present the data.

Review Panel Round One

Scoring summary

In Round One, the Review Panel was asked to score each recommendation area on a scale of 1 to 5, where 5=extremely viable, 4=very viable, 3=somewhat viable, 2=potentially viable with changes, and 1=not viable for this project. Average scores for relevant recommendations considered in Round One:

- Mandatory Reporting, Voluntary Reporting, Patient Safety Reporting (presented together): 4.1 (range, 3 to 5)
- Share Information: 3.7 (range, 2 to 5)

Notes

- There was strong and uniform support for a voluntary reporting system across the continuum of care that would be evaluated 3-5 years after implementation. A mandatory system was only supported in the event that a voluntary system failed.
- There was strong support for focusing the reporting system on near misses. The Review Panel suggested that care should be taken to collect patient safety data, not quality improvement data.
- Support for a reporting system was contingent upon having confidentiality and peer protections in place.
- A strong preference for the identification and funding of a single, central patient safety organization emerged, with the caveat that such an organization should have the flexibility to sub-contract specific tasks, as appropriate. Similarly, it was recommended that a single patient safety organization with separate divisions be developed to manage the patient safety analysis and education across various settings of care and health professions.
- The Panel recommended that functions of the system include collecting reports, aggregating data and disseminating detailed as well as trended de-identified data back to the field. To effectively share information back to reporters, staff with expertise in patient safety education would be needed.
- There was general agreement about the importance of sharing information back to reporters in ways that are meaningful and that are packaged to capture and share best practices, improvement strategies and toolkits.
- The Review Panel saw value in having a statewide patient safety clearinghouse.
- The Panel noted that a reliable source of funding is crucial to the success of the system. It was suggested that the system could be funded buy adding a surcharge on patient records of \$1 or \$2 and could also suggested that a surcharge on malpractice premiums could be used.
- It was also noted that financial and other incentives, such as liability protection and resources (training, funding, and support), would be needed to ensure robust reporting among health-care organizations and professionals.
- Recommendations from the testimony that requested public release of hospital-specific information were determined to be a disincentive to participating in the program.

Endnotes

¹ Code 03 (Mandatory Reporting) was used to identify testimony recommending use of a mandatory reporting system related to preventable adverse health events.

2 Code 04 (Voluntary Reporting) was used to identify testimony recommending use of a voluntary reporting system related to preventable adverse health events.

3 Code 05 (Sharing Information) was used to identify testimony recommending development of programs where standardized data elements are shared across health-care organizations and/or between health-care professionals for the purpose of joint problem-solving.

4 Code 29 (Patient Safety Reporting) was used to identify testimony recommending use of reporting system related to patient safety data but does not specify mandatory or voluntary.

⁵VA National Center for Patient Safety. *Challenge and Achievement*, retrieved 7.13.05 at http://www.patientsafety.gov/NEWS/NCPSBg/bg_NCPSChallenges_040904.doc

⁶ Reporting of some types of errors and other events are activities already performed in Michigan hospitals and other healthcare organizations. The Michigan Health & Hospital Association (MHA) has indicated that Michigan hospitals report various “events” to the Centers for Medicare and Medicaid Services (CMS), the Department of Community Health, the Hospital Quality Alliance (HQA), the Food and Drug Administration (FDA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Michigan Health and Safety Coalition (MHSC) and Leapfrog Group. In particular, hospitals, as a condition or participation, report to CMS; provide mortalities, communicable and occupational disease statistics to the Department of Community Health; provide data for the National Quality Measures program within the Hospital Quality Alliance; medical device failures to the FDA, data related to “core measures” to JCAHO; and procedure and practice volumes and other data for the annual survey fielded by the MHSC and Leapfrog Group. Some aspects of data reported to HQA, JCAHO, MHSC and the Leapfrog Groups are reported and released to the public.

⁷ Veterans Affairs. Patient Safety Reporting System, retrieved 7.10.05 at <http://psrs.arc.nasa.gov/>

⁸ The Commonwealth Fund, Case Study: NASA/VA Patient Safety Reporting System, retrieved 7.13.05 at http://www.cmwf.org/tools/tools_show.htm?doc_id=257033

⁹ Conlon, P. Innovations in Patient Safety, Trinity Health, retrieved 7.13.05 at <http://www.mihealthandsafety.org/presentations/conlon.ppt#13>

¹⁰ Suresh G, Horbar JD, Plsek P. et al. (2005). Voluntary anonymous reporting of medical errors for neonatal intensive care. *Pediatrics*, 113:1609-1618.

¹¹ JCAHO, op cit., p. 11.

¹² Cohen MR. (2000). Why error reporting systems should be voluntary. *BMJ*, 320:728-729.

¹³ Testimony 106W:38-43.

¹⁴ Testimony 106W:38-43

¹⁵ Testimony 106W:38-43

¹⁶ Testimony 205W:173-175

¹⁷ Agency for Health Care Quality and Research. AHRQ’s Patient Safety Initiative: Building Foundations, Reducing Risk, retrieved 4.28.05 at <http://www.ahrq.gov/qual/pscongrpt/psini1.html>

¹⁸ Testimony 110W:55-56, 70-71.

¹⁹ Testimony 608W:172-177.

²⁰ Kohn LT, Corrigan JM and Donaldson M (eds.). (2000). *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press.

²¹ Marchev M, Rosenthal J, & Booth M. (2003). *How states report medical errors to the public: Issues and barriers*. National Academy for State Health Policy: ME. (Colorado, Florida, Kansas, New York, California, Ohio, Massachusetts, New Jersey, Rhode Island, South Carolina, South Dakota, Washington, Connecticut, Georgia, Maine, Minnesota, Nevada, Pennsylvania, Tennessee, Texas, Utah).

²² Kohn, op cit., pg. 100.

²³ Wachter RM. (2004). The end of the beginning: Patient safety five years after ‘*To Err is Human*’. *Health Affairs – Web Exclusive*, W4-534—W4-545.

²⁴ Wachter, op.cit., pg. 539.

²⁵ Marchev, op cit.

²⁶ Marchev, *ibid*.

²⁷ Marchev, *ibid*., pg. 32.