Issues in Patient Safety

Report to the Wyoming Health Care Commission
Medical Errors Subcommittee

Prepared by Fran Cadez, J.D., M.B.A.
December 31, 2006

The following report addresses issues related to patient safety and alternative systems to compensate those injured through errors in medical treatment, as they relate to Wyoming's efforts in this area. The report relies on current empirical research in the study of patient safety and medical errors, as well as limited interviews with individuals engaged in these activities, both nationally and within the state.

Overview

Like many states, Wyoming has begun to approach the numerous issues related to patient safety from a variety of perspectives. Development of a state-wide reporting system and patient safety activities are underway.[1] Legislation protecting statements of apology from health care providers involved in adverse events[2] and establishing a medical review panel for initial review of malpractice claims have been implemented.[3] Yet questions remain concerning the most effective methods to improve the safety of care and compensate those who are adversely affected when errors occur. Six years following the Institute of Medicine's report on medical errors, progress on improving patient care in Wyoming and throughout the U.S. "is slow, results in general are modest and the gap between the best possible care and actual care remains large."[4]

Patient Safety Event Reporting

Recommendation #1:

The Wyoming legislature should amend W.S. §35-2-912 to include the newly revised NQF List of Serious Reportable Events and subsequent revisions, and provide appropriate funding for state-wide training and education to health care facilities regarding interpretation of patient safety events and compliance with reporting requirements. To enhance consistency in reporting, the Wyoming Department of

[1] Wyo. Stat. Ann. §35-2-912 (2005).
[2] Wyo. Stat. Ann. §1-1-130 (2005).
[3] Wyo. Stat. Ann. §9-2-1513 through 1523 (2005).
[4] Health Grades Quality Study, Third Annual Patient Safety in American Hospitals Study, April 2006; Larkin C, Gaps Growing Between Best and Worst Hospitals, *Philadelphia Inquirer*, Oct. 17, 2006.

Health should adopt by rule the implementation guidelines associated with the NQF events.

Patient safety reporting systems elicit information about defined classes of "adverse events," or injuries that are believed to be related to medical management. The objective of such systems is to provide data about preventable injuries and the subset of preventable injuries that are attributable to medical errors. Issues surrounding the role of patient safety reporting systems have raised many concerns. Lack of standardization and coordination regarding what is reported and lack of analysis and feedback to reporters is common. Variability in how adverse events are described and classified limits meaningful comparisons of data across systems. Questions regarding the extent to which reported adverse events are representative of all injuries and all errors, and issues of underreporting, exist as well.[5] The proliferation of reporting systems by entities such as the Joint Commission for Accreditation of Hospital Organizations (JCAHO), Federal Drug Administration (FDA), liability insurers and facility risk managers to name a few, create reporting fatigue in institutions required to comply.

Patient Safety Event Reporting in Wyoming

Last year, Wyoming implemented a mandatory system requiring every licensed health care facility within the state to report patient safety events causing serious injury, death or the risk thereof.[6] The Wyoming Department of Health, Division of Preventive Health and Safety (Division) manages the reporting system. Three hundred Wyoming facilities have been required by statute to report patient safety events to the Division since October 2005. Facilities have expressed uncertainty and confusion concerning reporting requirements and sought clarification from the Division.[7] Some Wyoming health care facilities were slow to designate a Patient Safety Officer, a requirement under the statute, and most of the event data reported has come from a small number of institutions.[8] The Division speculates the institutions which are making reports to the state may have better-developed internal systems for reporting adverse events and/or been engaged in the process of doing so longer than those who do not report as frequently or at all. Funds to support education and training regarding reporting requirements were not designated in W.S. §35-2-912. The Division recently created an on-line reporting portal to receive electronic submissions which may improve the frequency of reporting.

The Division expects to issue its first aggregate report of data collected under the mandatory system in December 2006. The data may provide baseline information

---

[5] Mello, M. *Medical Error Prevention: Where Are We Now?* Presentation made to: Medical Errors: The Telehealth Prescription, a conference in Cheyenne, WY, April 12, 2006.

[6] A detailed review and analysis of the system's elements was previously undertaken and can be found in *Report on Medical Errors and Medical Injury Compensation*, submitted to the Wyoming Health Care Commission by the Subcommittee on Medical Errors, October, 2005, found at: **http://www.wyominghealthcarecommission.org/reports.html**

[7] Conversation with Clay Van Houten, epidemiologist, Wyoming Department of Health, Division of Preventive Health and Safety, June 23, 2006.

[8] *Id.*

regarding the rate of medical injuries in Wyoming, or perhaps only reflect the rate at which Wyoming facilities report adverse events at this time. In order for the data to be meaningful, some comparison should be made to national data to determine whether the frequency and severity of adverse events reported in Wyoming are similar to what would be expected for a rural western state. One way to provide this perspective may be to compare Wyoming data with estimates of the prevalence of injuries at various severity levels found in a previous study of Utah and Colorado hospitals.[9]

The National Quality Forum List of Serious Reportable Events

Wyoming is one of eleven states to base its reporting system on the National Quality Forum's List of Serious Reportable Events, issued in 2002.[10] The National Quality Forum (NQF) list of "never events" was intended to identify adverse events that are serious, largely preventable, and of concern to both the public and healthcare providers for the purpose of public accountability. The events are meant to be clearly identifiable and measurable, with specifications and definitions enabling state-wide reporting. The NQF events were thought to be of "a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility" but were not meant to be static, nor to capture all events that might be considered useful to report.[11]

NQF has since sought to reassess the original list for additions, deletions and modifications. The list is currently in the review process and is expected to include one new event related to artificial insemination, while modifications are recommended for six previously endorsed events. In addition, for the first time implementation guidance is proposed to accompany the patient safety events and facilitate consistent reporting.[12] On October 13, 2006 the NQF Board endorsed revisions to the list and solicited additional review by its membership. The NQF is expected to publish the revised List of Serious Reportable Events and corresponding implementation guidelines by the end of 2006.

Healthcare standards and measures are only useful as long as they reflect current knowledge and remain appropriate. However, the interest in being up-to-date with current knowledge in patient safety must be balanced with the benefit of being able to compare the same types of events over time and with other health care facilities. As the NQF continues to advocate its list of events as a voluntary standard for patient safety reporting, more states may adopt this system. If this trend continues, the NQF List of Serious Reportable Events may provide the best opportunity for Wyoming to compare our state's efforts with other states and health care facilities collecting data on the same patient safety events. In that regard, the Wyoming legislature should consider amending Wyoming Statute §35-2-912 to reflect the current state of knowledge in adverse event reporting, as determined by research and evaluation, giving specific consideration to replacing the

---

[9] Communication with Michelle M. Mello, J.D., Ph.D., C. Boyden Gray Associate Professor of Health Policy and Law, Department of Health Policy and Management, Harvard School of Public Health, March 16, 2006, referencing Studdert, DM, et al., Negligent Care and Malpractice Claiming Behavior in Utah and Colorado, *Medical Care*, 38:3, 250-260, 2000.

[10] http://www.qualityforum.org/

[11] NQF Member Memo, May 9, 2006.

[12] *Id.*

current NQF events with the revised list due for release by the end of 2006 and any subsequent revisions.

These same issues regarding the research basis and comparability of reported events are being discussed at the national level. The Federal Patient Safety and Quality Improvement Act of 2005 provides for recognition and qualification of patient safety organizations by the Department of Health and Human Services and creates a national network of patient safety databases.[13] The Agency for Healthcare Research and Quality (AHRQ) will manage implementation of the act and is conducting an inventory of every reporting system in operation to determine whether the events are evidence-based and the extent of acceptance of particular reportable events. The investigation so far has shown enormous variation in the definitions used in reporting systems throughout the country.[14]

Legal Concerns Surrounding Patient Safety Reporting

Recommendation #2:

An assessment of Wyoming's current patient safety activities should be conducted to determine changes required to qualify for certification under the federal Patient Safety and Quality Improvement Reporting Act. Wyoming should closely follow the progress of rule promulgation for the federal act and apply for certification as a Patient Safety Organization and federal protections for reporting patient safety events under the act.

Perception, Precedent and Potential Protection

Fear regarding legal exposure can undermine the effectiveness of patient safety reporting systems, resulting in underreporting of adverse events, which undercuts efforts to analyze and learn from these data.[15] Failure to disclose and report possible medical errors may deprive a patient of the opportunity to seek appropriate treatment and lead to greater liability exposure if the injury was due to negligence and the patient's condition continues to worsen.[16] Research efforts to determine prevalence and cause of errors are hampered when errors are not reported.[17]

---

[13] The act has yet to be implemented, though rules are currently being drafted with final rules expected in 2007. Communication with Bill Munier, Acting Director, Patient Safety and Quality Improvement Center, AHRQ, August 29, 2006.

[14] *Id.* The agency has recognized that clinical definitions of reportable events will need to be constantly refined and updated and should be developed through a public-private partnership, as opposed to generated by government regulation. This has led agency leaders to decide at this time to exclude definitions of reportable events from the final rules.

[15] Rosenthal, J, Riley, T, Booth, M. State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey. Portland, ME: National Academy of State Health Policy, April 2000.

[16] Sato, L, et al. Legal Liability and Protection of Patient Safety Data, commissioned paper for the Institute of Medicine Committee on Patient Safety Data Standards, February 2003.

[17] Kapp, MB. Legal Anxieties and Medical Mistakes: Barriers and Pretexts. *Journal of General Internal Medicine,* 1997; 12:787-788.

Surveys have shown physicians believe overwhelmingly that fear of malpractice is a barrier to patient safety event reporting.[18] Although empirical research has not been conducted to determine the extent to which event reporting truly increases malpractice exposure or whether reporting system data are being used in malpractice litigation, the perception of physicians is very important. If physicians feel reporting patient safety events will increase malpractice risk, they will undoubtedly be hesitant to do so. No attempt has yet been made to survey the perceptions of Wyoming's physicians regarding the state's patient safety reporting statute. However, the Wyoming Medical Society believes Wyoming case law permitting disclosure of privileged peer review information to further malpractice litigation has created an atmosphere of uncertainty and risk of exposure.[19] A look at case law and the legal process protections provided by the patient safety reporting statute may be helpful in understanding these opinions and physicians' perceptions.

Review of Wierdsma, Harston and Nalder.

Whether information protected by privilege should be disclosed and what situations would warrant disclosure have been addressed in several Wyoming Supreme court opinions. In *Greenwood v. Wierdsma and Memorial Hospital of Sweetwater County,* 742 P.2d 1079 (Wyo. 1987), the plaintiff alleged the hospital failed to properly investigate, certify or review Dr. Wierdsma's skills and negligently permitted him to perform surgical procedures. In order to prove negligence by the hospital, the court recognized the plaintiff's need to access information concerning the physician's performance, information that was likely available to the hospital's medical staff committee as defined in W.S. §35-2-604 (now W.S. §35-2-605(2005)). Noting "causes of action are encompassed and protected" under Article 1, §8 of the Wyoming Constitution, the court determined the legislature did not intend for the statutory privilege prohibiting disclosure of this information to abrogate the plaintiff's right to recover for the hospital's negligence.[20]

Finding additional support in Article 10, §4 of Wyoming's Constitution the court stated, "The continued availability and vitality of such causes of action serve an important public policy – the preservation of quality health care for the citizens of this state."[21] The *Wierdsma* court determined privileged data under the statutes included only the documents produced by the committee as notes, reports and findings in the review process, and not the materials reviewed by a medical staff committee. Recognizing that

[18] Blendon, RJ, DesRoches CM, Brodie M et al. Views of Practicing Physicians and the Public on Medical Errors. *N Eng J Med* 2002; 347:1933-1940; Robinson AR, Hohmann KB, Rifkin JI et al. Physician and Public Opinions on Quality of Health Care and the Problem of Medical Errors. *Arch Intern Med* 2002:162:2186-90.

[19] Discussion with Susie Pouliot, Executive Director and Richard Rideout, General Counsel for Wyoming Medical Society, August 31, 2006.

[20] Article 1, § 8 of the Wyoming Constitution states in part: "All courts shall be open and every person for an injury done to person, reputation or property shall have justice administered without sale, denial or delay."

[21] *Wierdsma,* 742 P.2d at 1088; Article 10, § 4 of the Wyoming Constitution states: "No law shall be enacted limiting the amount of damages to be recovered for causing the injury or death of any person."

admissibility of the committee's activities would be tantamount to the "committee providing an expert opinion on the ultimate issue of negligence" the court decided a broad application of the privilege would be improper.[22] However, the *Wierdsma* court concluded the "statute was not intended to except from discovery all relevant information and thereby preclude the possibility of proving negligence."[23]

Almost ten years later, the court again reviewed the application of privilege to requests for discovery in a medical malpractice case. In *Harston v. Campbell County Memorial Hospital*, 1996 WY 50, 913 P.2d 870 (Wyo. 1996), the court considered whether denying plaintiff Harston, access to the records of Campbell County Memorial Hospital regarding the privileging and credentialing processes of a physician constituted an abuse of discretion. Defendant hospital argued the previous decision in *Wierdsma* was overruled by the legislature's subsequent statutory amendment following the court's decision in that case. Even though W.S. §35-2-601 to 604 were repealed after *Wierdsma* and replaced with W.S. §35-2-605 to 617, the *Harston* court declared the new statute to be quite similar to the prior statute and held there was no legislative intent to overrule *Wierdsma* in that regard.[24]

The *Harston* court found the essence of the *Wierdsma* decision in language relating to professional standard review organizations addressed in W.S. §35-17-105(1994).[25] Noting the continued validity of *Wierdsma*, the court repeated that absolute protection from discovery could not be found in statutes relating to professional standard review organizations and hospital records.

The *Harston* court resolved the issue relating to the plaintiff's discovery requests for credentialing, peer review and quality assurance documents regarding defendant hospital's staff physician through analysis of W.S. 35-2-610(a)(ix) which states in pertinent part:

> (a) Health care information shall not be disclosed by a hospital pursuant to compulsory legal process or discovery in any judicial, legislative or administrative proceeding unless:

---

[22] *Wierdsma* 742 P.2d at 1089.

[23] *Wierdsma*, 742 P.2d at 1090.

[24] Specifically, W.S. §35-2-609(d)(2005) declares confidential and privileged "all reports, findings, proceedings and data of medical staff committees" and provides protection from suit for medical staff members or employees regarding actions taken to deny, suspend, or engage in expulsion, restriction or other disciplinary action against any medical staff.

[25] W.S. §35-17-105 provides: "All reports, findings, proceedings and data of the professional standard review organizations is confidential and privileged, and is not subject to discovery or introduction into evidence in any civil action, and no person who is in attendance at a meeting of the organization shall be permitted or required to testify in any civil action as to any evidence or other matters produced or presented during the proceedings of the organization or as to any findings, recommendations, evaluations, opinions or other actions of the organization or any members thereof. However, information, documents or other records otherwise available from original sources are not to be construed as immune from discovery or use in any civil action merely because they were presented during proceedings of the organization, nor should any person who testifies before the organization or who is a member of the organization be prevented from testifying as to matters within his knowledge, but that witness cannot be asked about his testimony before the organization or opinions formed by him as a result of proceedings of the organization."

. . .

> (ix) A court has determined that particular health care information is subject to compulsory legal process or discovery because the party seeking the information has demonstrated that the interest in access outweighs the patient's privacy interest.

The *Harston* court held the trial court was obliged to hold an *in camera* inspection to weigh the interest of the party seeking access against the privacy interest of the patient whose records may be relevant to the disclosure. In dicta, the court discussed the application of Article 1, §8 of the Wyoming Constitution, noting "the constitutional issue, were it posed, might well reach the question of 'denial' of justice to Harston or perhaps even whether justice was administered."[26]

More recently, in *Nalder v. West Park Hospital*, 254 F.3d 1168 (10th Cir. 2001), plaintiff claimed malpractice after her son suffered brain damage, seeking disclosure of notes produced by the hospital's director of nursing following the child's birth. The district court provided an *in camera* review of the notes, initially ruling the notes were not privileged. However, after testimony by the nurse outside the presence of the jury, the district court denied disclosure under W.S. §35-17-105 and determined the notes had been created pursuant to an investigation, for supervision of the hospital's nurses and to prepare a formal report to the hospital department's committee to improve patient care. Noting the trial court had conducted an *in camera* inspection, as required by *Harston*, the *Nalder* court determined the notes "fit squarely within the privilege" created by W.S. §35-17-101,[27] and upheld the privilege, denying disclosure to plaintiff.

Potential implications for W.S. §35-2-912 (2005)

States operating adverse event reporting systems have chosen to protect data either by invoking peer review protections or creating statutory protections specific to patient safety reporting systems.[28] Wyoming has done both.

Currently, there is little legal precedent concerning how peer review protections may apply to patient safety reporting systems.[29] Generally, privileges limiting the scope of discovery are narrowly interpreted and Wyoming courts have consistently followed this trend.[30] The tendency to view peer review protections as an exception, rather than the rule, significantly impacts their strength and predictability since courts are asked to determine the confidentiality of materials on a case-by-case basis. In doing so, judges are called upon to "reconcile the significant public policies underlying peer review statutes

---

[26] *Harston* 1996 WY 50 at ¶22.
[27] W.S. §35-17-101 defines a professional standard review organization
[28] Flowers L, Riley T. State-Based Mandatory Reporting of Medical Errors: An Analysis of the Legal and Policy Issues. Portland, ME: *National Academy for State Health Policy*: 21. March 2001.
[29] Sato, *supra* note 16.
[30] *Id.*; *Greenwood v. Wierdsma and Memorial Hospital of Sweetwater County*, 742 P.2d 1079 (Wyo. 1987); *Harston v. Campbell County Memorial Hospital*, 913 P.2d 870 (Wyo. 1996)

with the equally powerful common law principle that 'the public . . . has a right to every man's evidence.' " [31]

Many questions remain. How would the denial of a request for disclosure of information from the state reporting system be reviewed by the Wyoming Supreme Court? Would the court expand on the constitutional argument alluded to in *Harston*? Would a reporting system designed to count adverse events and provide annual aggregate feedback be recognized as preserving quality health care, enough to tip the scales towards protection from disclosure? These questions of judicial interpretation are largely unknown, though the Wyoming Supreme Court's decisions in *Wierdsma* and *Harston* may offer some insight. If information collected for patient safety reporting serves a dual purpose as material relevant to review of a physician's performance, even if the review is conducted by a hospital's medical staff committee, in a suit for negligent credentialing against a hospital, *Wierdsma* and *Harston* indicate the information may at the very least, be subject to an *in camera* inspection. If an issue is raised under Article 1, §8 of the Wyoming Constitution claiming failure to disclose protected information to a plaintiff would amount to a denial of justice, according to *Harston*, the court may be inclined to issue a far more reaching decision.

The state reporting act also invokes the protections of W.S. §35-2-910(a) for quality management functions, which deems information confidential that relates to the evaluation or improvement of the quality of health care.[32] Wyoming's patient safety reporting statute, however, imposes no requirement for health care facilities to utilize reported patient safety information for quality management, nor instructs facilities to do anything other than report. Even assuming that reporting patient safety events can be equated with "functions of a quality management program" (which remains undefined in Wyoming statutes) the immunity provided by W.S. §35-2-910(a) excepts "omissions in the provision of care."[33] Arguably, some of the patient safety events for which reporting is required under W.S. §35-2-912, describe scenarios in which an omission in the provision of care may have taken place.[34]

A pattern of practice of negligent care on the part of a physician, or claim against a hospital for negligent credentialing of a physician, might find support by discovering the manner in which an injury was handled by the institution or physician. "Health care information," as defined by Wyoming statutes, includes "any record of disclosures of that

---

[31] Sato, *supra* note 16, quoting *University of Pennsylvania v. Equal Employment Opportunity Commission*, 493 U.S. 182 (1990).

[32] W.S. §35-2-912(g) states, "Any act authorized or required by this section shall be subject to the confidentiality, immunity and whistle blowing provisions of W.S. 35-2-910(a) and (b)."

[33] W.S. §53-2-910(a) states in part: "Any person who in good faith and within the scope of the functions of a quality management program participates in the reporting, collection, evaluation, or use of quality management information or performs other functions as part of a quality management program with regard to a specific circumstance shall be immune from suit in any civil action based on such functions brought by a health care provider or person to whom the quality information pertains. In no event shall this immunity apply to any negligent or intentional act or omission in the provision of care."

[34] W.S. §35-2-912(a)(i) through (vi).

information."[35] Would this record of disclosures include report of a patient safety event to the state agency, even if the information reported was first de-identified? If so, a plaintiff's request for disclosure of health care information might include the health care facility's act of reporting the patient safety event to the state reporting system.

Wyoming's patient safety reporting act also seeks immunity protection for the Department of Health by electing coverage under the federal Health Care Quality Improvement Act of 1986, P.L. 99-660, Title IV.[36] Congress enacted Chapter 117 of the Health Care Quality Improvement Act (HCQIA) for the express purpose of "provid[ing] incentive and protection for physicians engaging in effective professional peer review."[37] It specifically provides immunity from monetary damages for professional review bodies and to any person "providing information to a professional review body."[38] HCQIA confers immunity upon peer review participants but does not provide privilege against disclosure for peer review materials.[39]

It is unlikely HCQIA will provide any additional immunity protections for duties and responsibilities undertaken by the Department of Health in conformance with W.S. §35-2-912. Wyoming's patient safety reporting statute takes no action towards a physician involved in a patient safety event. Though the reporting health care facility is identified, all identifying information related to health care professionals, employees and patients is excluded from the report[40] The reporting statute does not provide for peer review action as defined by HCQIA, nor does the Department of Health engage in professional review of physicians.

Although the Tenth Circuit looked to Wyoming case law to determine the merits of the disclosure request in *Nalder*, the court may not always be required to do so. Where a federal claim is asserted together with a state claim, the court will be required to consider the federal privilege law, HCQIA, as governing the case. In that instance, a federal court may be persuaded not to apply a peer review privilege, since Congress in enacting HCQIA had the opportunity to create a privilege for medical review documents but chose not to do so.[41]

Given the propensity of the courts to make determinations in favor of disclosure, relying only on peer review statutes for protection of patient safety reporting data may be

---

[35] W.S. §35-2-605(a)(vii) " Health care information" means any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and relates to the patient's health care, **and includes any record of disclosures of that information**. (emphasis added). *Wierdsma* and *Harston* suggest any request for health care information requires a court to consider and weigh the request under the provisions of W.S. 35-2-610(a)(ix).

[36] 42 U.S.C. § 11101-11152; W.S.§35-2-912(j) states, "The state of Wyoming elects to be covered as of April 1, 2005, by the immunity granted by the Health Care Quality Improvement Act of 1986, P.L. 99-660, Title IV adopted by Congress in 1986, to the extent authorized, for the department with respect to its duties and responsibilities under this section."

[37] 42 U.S.C. § 11101(5).

[38] *Id*. at § 11111(a)(1).

[39] Sato, *supra* note 16.

[40] W.S. § 35-2-912(c).

[41] Sato, *supra* note 16.

"tenuous" at best.[42] Wisely, the Wyoming legislature crafted protections specific to the reporting system in addition to relying on peer review protections. Wyoming's patient safety reporting system W.S.§ 35-2-912(e) seeks to protect "any notice, report, document and any other information compiled or disseminated" in the process of reporting patient safety events as confidential, inadmissible and undiscoverable in any administrative or legal proceeding in this state.[43] Wyoming's statute also places restrictions on the information reported by requiring the reporting facility to exclude identifying information regarding "health care professionals, facility employees or patients" involved in the reportable event.[44] The Department of Health is permitted to issue an annual report only of aggregate information "so as not to reveal the identity of any specific person or health care facility." [45] Finally, Wyoming has declared, "any notice, report, document and any other information compiled or disseminated" under the act confidential and "not discoverable or admissible in evidence in any administrative or legal proceeding."[46]

Until this law is tested in Wyoming courts, speculation regarding how it will be interpreted will continue, fostering anxiety and apprehension among some providers. If fear of disclosure prevails, reporting can expect to be stymied. However, the recent passage of a federal patient safety reporting act may offer the kind of assurance perceived to be lacking in Wyoming laws.

Federal Patient Safety and Quality Improvement Act

The federal Patient Safety and Quality Improvement Act (Act) was signed into law in 2005.[47] Generally, the Act provides legal privilege and confidentiality protections for "patient safety work products" assembled or developed "by a provider for reporting to a patient safety organization" or "by a patient safety organization for the conduct of patient safety activities."[48] To be covered under the Act, a patient safety organization must be certified by the Secretary of Health and Human Services and have policies and procedures in place to perform the patient safety activities described in the Act.[49] Among those activities listed is a requirement for the "utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk."[50]

---

[42] Liang, BA. Risks of Reporting Sentinel Events. *Health Affairs* 2000;19:112-120.

[43] W.S. §35-2-912(e) states in part, "Any notice, report, document and any other information compiled or disseminated pursuant to the provisions of this section is confidential, is not discoverable or admissible in evidence in any administrative or legal proceeding conducted in this state and is not a public record. No contractor, employee or other member of the department who receives any notice, report, document or any other information compiled or disseminated pursuant to the provisions of this section shall be permitted or required to testify in any civil action as to any evidence or any other matters presented to the department or as to any findings, recommendations, evaluations, opinions or other actions of the department or any contractors, employees or other members thereof."

[44] W.S. 35-2-912(c)

[45] W.S. 35-2-912(f)

[46] W.S. 35-2-912(e)

[47] *See*, Appendix A. Public Health Service Act, 42 U.S.C. § 299 et seq.

[48] 42 U.S.C §§ 921(7)(A)(i)(I) and (II).

[49] 42 U.S.C. § 924(a)(1)(A) (referencing §§ 921(5)(A) through (H)).

[50] 42 U.S.C. § 921(5)(D).

The Act also prohibits an employer from taking an adverse employment action against a provider, including an "adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of an individual," for having reported information in good faith to a patient safety organization.[51] The Act promotes the creation of a network of patient safety databases that "provide an interactive evidence-based management resource for providers, patient safety organizations and other entities."[52]

The Act confers federal privilege and confidentiality protections for patient safety work product, essentially information assembled or developed by a provider for reporting to a patient safety organization or conducting patient safety activities.[53] Where questions and apprehension may exist regarding the possible interpretation of protections afforded under Wyoming's reporting statute, the Act would provide a layer of federal protections for patient safety work product and those who report to patient safety organizations. However, these same confidentiality and privilege provisions that offer promise to alleviate the reporting concerns of Wyoming providers have also made the development of rules for the Act's implementation difficult.[54] Though it became law in 2005, the Act has yet to be implemented. Public hearings have been held and draft rules may be published by the end of 2006 with final rules expected in 2007.[55]

In order to receive federal privilege and confidentiality protections, the Act requires a patient safety organization seeking certification to engage in very specific activities, including:

1) efforts to improve patient safety and the quality of health care delivery;

2) collection and analysis of patient safety work product;

3) development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;

4) utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;

5) maintenance of procedures to preserve confidentiality with respect to patient safety work product;

6) provision of appropriate security measures with respect to patient safety work product; and

---

[51] 42 U.S.C. § 922(e).
[52] 42 U.S.C. § 923.
[53] 42 U.S.C. §922
[54] Communication with Bill Munier, Acting Director, Patient Safety and Quality Improvement Center, AHRQ, August 29, 2006.
[55] *Id.*

7) activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

The Wyoming Department of Health, currently designated by statute as the state's patient safety entity, would have difficulty meeting these requirements to qualify for certification under the federal act. Wyoming's patient safety reporting statute is structured primarily for surveillance and does not provide direct feedback, recommendations, protocols or information regarding best practices. Rather, Wyoming's statute provides only for the collection of data and the publication of an annual aggregate report.

Patient Safety Centers

Recommendation # 3

The Wyoming legislature should authorize and fund a Patient Safety Center to coordinate activities related to medical error reduction, including receiving reports of patient safety events, training and education of providers and patients, and integration of medical error data from numerous state sources. The Patient Safety Center will act as the Patient Safety Organization for purposes of participation in the federal Patient Safety and Quality Improvement Act.

At least six states, Florida, Massachusetts, Maryland, Pennsylvania, Oregon and New York, have enacted legislation to support creation of a state patient safety center to address medical errors.[56] All centers have been designed to coordinate statewide patient safety activities, including:

- education of health care providers and consumers regarding how to reduce adverse events;
- adverse event and near-miss data reporting, collection and analysis and dissemination of findings to improve care;
- fostering creation of safety cultures to identify causes of errors;
- serving as a clearinghouse for evaluation and dissemination of best practices;
- promoting on-going collaboration between public and private sectors, and
- coordinating state initiatives.

All six centers are legislatively authorized or endorsed and include as their mission improving, ensuring or promoting patient safety. Most centers are governed by a board of directors, some appointed by the governor or legislature and several also have advisory councils that support their work. Four of the state centers are housed within state government, though Pennsylvania and Oregon have created their centers as semi-independent or independent state agencies. Florida's center is a not-for-profit entity and

[56]The discussion in this section is taken from, Rosenthal, J and Booth, M. The Flood Tide Forum: State Patient Safety Centers: A New Approach to Promote Patient Safety, *National Academy for State Health Policy*, Oct. 2004.

Maryland chose to develop a joint enterprise with the Maryland Hospital Association and a medical foundation.

Funding to support the centers' activities comes from a number of sources. Legislative appropriations support the centers in New York and Florida, while Oregon and Pennsylvania assess fees. Pennsylvania established a Patient Safety Trust Fund supported through an annual surcharge on licensing fees from facilities required to report medical errors. This independent funding stream has enabled Pennsylvania to create, implement and maintain a sophisticated medical error data collection and analysis system.

Activities among the centers are varied, but all focus on educating providers and consumers and promoting collaboration between public and private sectors. Maryland intends to provide training in root cause analysis, failure mode and effects analysis and develop learning collaboratives for specific process improvements. Massachusetts plans to offer an annual patient safety symposium and Pennsylvania issues a quarterly newsletter featuring in-depth clinical analysis of data from its reporting system. New York is working with medical schools to integrate patient safety training into residency programs.

Such centers provide an opportunity to integrate data important to understanding medical errors and medical malpractice in one location. For example, the Florida center will analyze medical malpractice closed claims data as well as data from the state mandatory adverse events reporting system, voluntarily reported near-miss data, hospital discharge data and vital statistics.

Centers have also developed methods to reward improved care and reduction in medical injuries. Florida is looking at provider rewards for implementing evidence-based practice; New York will recognize patient safety leaders; and Pennsylvania provides a discount in medical malpractice liability insurance premiums for facilities demonstrating a reduction in serious events as a result of implementing safety recommendations.

Though all these centers are relatively new and their activities are just beginning to take shape, some lessons are already evident. States considering the development of a patient safety center are advised to: 1) develop the concept through the legislative process to create a public mandate for their mission; 2) develop clear and consistent authorizing legislation, and 3) establish a funding stream through legislative appropriation.

The potential for establishment of a patient safety center in Wyoming is great. A patient safety center could re-focus state efforts from merely counting patient safety events to providing resources to understand why they happen and how to correct systems that lead to error. Education and training of providers to foster improvement and recognition of those who have realized improvement as a result of creating a culture of safety could all be fostered through patient safety center activities. A center would be a logical choice to serve as the state's Patient Safety Organization for implementation of the federal Patient Safety and Quality Improvement Act. More importantly, a patient safety center in Wyoming would be able to integrate Wyoming data from medical malpractice claims

reported under W.S. §26-3-124, patient safety reporting, and other health care quality information to provide an unprecedented view of these issues in our state.

Patient Safety Reporting: System Evaluation

Recommendation # 4

The Wyoming legislature should require an on-going evaluation of Wyoming's Patient Safety Reporting system to determine the significance of legal protections, extent and reasons for underreporting, if found to exist, and whether reported data has effectively reduced medical errors and preventable injuries.

Although Wyoming's patient safety reporting statute will sunset in 2010 and might possibly be assessed at that time, no provision is made for an on-going evaluation of the reporting system while in effect.[57] A reporting system like Wyoming's, which encourages reporting by providing legal protections for the anonymous reporting of de-identified information for distribution through aggregate data reports, does so at the cost of limiting the ability of quality management personnel and researchers to determine the source and prevalence of errors and maximize the use of reported data. Acknowledging this fundamental tradeoff, Wyoming's reporting system should consider three areas for evaluation:

1) The scope of agency authority to protect reported information: Are the legal protections sufficient to permit reporting health care facilities and the Wyoming Department of Health to deny disclosure or discovery of reported information? What is the likelihood such a determination would be upheld in court? Answers to these questions may await a legal challenge in Wyoming's courts.

2) Issues related to underreporting: To what extent does underreporting occur? How secure do physicians/reporters feel that information reported will not be disclosed? Matching reported adverse events to a review of patient records or comparing the frequency of reports to the expected frequency and types of injuries at the reporting facilities (based on data from similar hospitals) may indicate whether the system is fulfilling its legislative intent.

3) Utility of reported data: How useful are the reported data? Has the information been used to create change in the reporting health care facilities and reduce medical errors?[58] If not, what do patient safety researchers and administrators with responsibility for patient safety in hospitals report as the main barriers to making better use of collected data?

[57] W.S. § 35-2-912(k).
[58] Sato, *supra* note 16.

Underreporting of patient safety events is one of the greatest concerns of states with mandatory reporting systems.[59] To date, data reporting in Wyoming does not appear to be robust. If the Wyoming Department of Health's annual aggregate analysis of reported data determines underreporting to be an issue, several factors should be considered. First, education and training of personnel in health care facilities, regarding the importance of reporting, what to report and how to classify events was not considered in creating the initial reporting statute. Feedback to the Division from reporting facilities indicates this has been an issue and clarification is in order.[60] Second, the perceptions of Wyoming physicians and health care providers regarding protections under the law and whether there is reluctance to report should be investigated. Unfortunately, if reporting is perceived as heightening exposure to liability, until the reporting statute is challenged in Wyoming courts, this perception may be neither confirmed nor dismissed. Applying for certification under the federal Patient Safety and Quality Improvement Act would provide federal privilege and confidentiality for patient safety reporting and may alleviate this concern. Once an environment is created in which providers feel safe to report, noncompliance or underreporting then becomes difficult to justify or tolerate.

A larger question, however, is whether the reporting of errors has led to a change in practices and enhancement of patient safety. The ultimate benchmarks of an effective reporting system are measurable progress in four domains: (1) identifying errors and their causes, (2) identifying changes in patient care that address the causes of errors, (3) spurring implementation of those changes by health care providers, and (4) actually impacting error rates. Whether Wyoming's reporting system is an efficacious and cost-effective method to improve patient outcomes is important and should be systematically studied over time.

Preventing Medical Errors and Improving Patient Safety

Recommendation #5:

Wyoming should adopt the NQF Patient Safety Event Taxonomy for reporting and classifying patient safety event data.

A Common Taxonomy

In order to understand, document and examine trends in errors, discussion surrounding them must use a common vocabulary. How we talk about errors and what language we use to describe them requires a common taxonomy. A taxonomy is not a reporting system, but a tool for organizing and classifying data collected from error reporting systems, enabling the information about patient safety to be organized and analyzed, with the intent of supporting better decision-making.[61] For every patient safety reporting system, an underlying structure determines how events are labeled, grouped, defined and

[59] Rosenthal, et al., *supra* note 15.
[60] Discussions with Linda Chasson, Manager, Wyoming Department of Health, Division of Preventative Health and Safety
[61] National Quality Forum Standardizing a Patient Safety Taxonomy, A Consensus Report, 2006

coded. Currently, no standardized system for classifying patient safety data is embraced by all reporting systems, creating a major barrier to understanding how and where patient safety events, health care errors and system failures occur.[62] With a common taxonomy, analyses of patient safety events would not be limited to the internal analysis of reporting systems, but could begin to answer questions that run across systems, such as the pervasiveness of the problem, most common types of errors and adverse events, how errors are discovered and how can they be prevented.[63]

The National Quality Forum's proposed Patient Safety Event Taxonomy (PSET) was developed by JCAHO with assistance from providers, health professional organizations and federal researchers.[64] The taxonomy focuses on initial information about the event and information relevant to follow-up activities and causal analysis.[65] As a tool, the taxonomy is envisioned to accommodate the needs of "interface users," those who initially report events; "analyzers," those who analyze the data; and "end users" who include providers, policymakers and consumers.[66]

The NQF seeks to establish a national voluntary consensus standard to include a classification structure and set of terms and definitions associated with clearly defined domains. For example, the taxonomy contains five primary classifications for reported information:

1. **Impact** – the outcomes or effects of medical error and systems failures, commonly referred to as harm to the patient.
2. **Type** – the implied or visible processes that were faulty or failed.
3. **Domain** – the characteristics of the setting in which an incident occurred and the type of individuals involved
4. **Cause** – the factors and agents that led to an incident
5. **Prevention and Mitigation** – the measures taken or proposed to reduce the incidence and effects of adverse occurrences.[67]

Within each of these classifications, specific information is requested to provide detail regarding the patient safety event.

---

[62] *Id.*
[63] *Id.* A taxonomy is "the science of classification according to a predetermined system, with the resulting schema used to provide a conceptual framework for discussion, analysis or information retrieval." Patient safety taxonomies have three basic components: nomenclature, or common definitions; classification structure and related algorithms, representing the relationships and shared characteristics among patient safety concepts and; coding, assigning symbols (usually numbers) to facilitate the collection of data and utilize information technology.
[64] *Id*. Participants in the development of the PSET are the American Dental Association, American Medical Association, American Hospital Association, American College of Physicians, American College of Surgeons and Agency for Healthcare Research and Quality.
[65] *Id.* Implementation of a standardized taxonomy, such as the PSET, will require testing, periodic reconsideration, and a core group committed to maintain the taxonomy and continually make improvements. NQF intends to convene the Patient Safety Taxonomy Consensus Standards maintenance Committee to accomplish this purpose.
[66] *Id*.
[67] *Id.*

The standardized taxonomy offers the potential to be more systematic in classifying the reported information and would provide a better opportunity to dissect the specific factors attributable to error. The taxonomy provides for the integration of more extensive information surrounding adverse events and near misses than currently asked for by the Division. Given these considerations, as the Division seeks to refine Wyoming's patient safety reporting system, particularly with creation of an electronic reporting system, the PSET should be given a close look. A taxonomy would provide better guidance to reporters regarding how to consider patient safety information and provide the Division with a better means to analyze this data in the future. The ability at some point to reach congruence with all the information reported about near misses, adverse events and medical errors would allow meaningful comparisons of data.

The vision of a standard taxonomy is to become a core part of the national health information infrastructure, where all reporting systems in place will map to a standard classification, allowing aggregate data analysis to improve patient safety at the point of care. Coordination of the taxonomy with the NQF's List of Serious Reportable Events will ensure future modifications of the events can continue to be adequately described in the integrated taxonomy. Since Wyoming already employs the NQF's reportable events, this data collection tool would seem a natural accompaniment.

Issues in Ambulatory Care

Recommendation # 6

Wyoming should work with medical malpractice insurers to encourage and support an assessment of current patient safety practices and identify best practices among ambulatory care providers. A Patient Safety Center should coordinate data collection and provide resources to assist ambulatory care physicians to improve awareness and knowledge to address systems and process issues that affect patient safety.

Medical Errors in Ambulatory Care

Although efforts are underway in Wyoming to identify the level of patient safety and patient safety consciousness within healthcare institutions, no similar effort exists in the state to determine patient safety awareness in ambulatory care (e.g., physician offices, hospital outpatient clinics, and freestanding ambulatory surgery centers). At this time, no information is available regarding the extent of patient safety measures in the offices of Wyoming's health care providers. More than three quarters of all medical procedures are performed in ambulatory settings.[68] While most ambulatory care is less technically complex than inpatient care, it is often more logistically complicated with many players, many sites for care and substantial responsibility on the patient and the patient's family to

[68] Hammons T, Piland NF, et al. Ambulatory patient safety: What we know and need to know, *Journal of Ambulatory Care Management*, 26(1): 63-83, 2003.

coordinate care.[69] Many opportunities exist for errors in ambulatory care, such as drug complications, prescription errors, failure to provide appropriate follow-up care, or failure to obtain appropriate information from patient referrals.[70] In particular, physician practices are the setting of many missed/delayed-diagnosis errors, such as delayed detection of cancer, which are among the most serious medical errors and the most costly malpractice claims.

Ambulatory care frequently involves coordination among a number of clinicians and several different sites, involving handoffs and transitions over time. The risk of "dropped balls" and information falling through the cracks abounds. Communication breakdowns are cited as major factors in 80% of medical malpractice suits.[71] Clear lines of communication and responsibility among treating physicians must be established. Otherwise, handoffs may lead a physician to assume someone else will follow-up on a test result.[72]

Failure to make a timely diagnosis has become the fastest growing area of malpractice litigation.[73] Approximately twenty-five percent of diagnosis-related malpractice cases involve follow-up system failures.[74] Failure to notify patients of normal or even abnormal test results is common, highlighting the need to examine how test results are managed. A study, which specifically considered missed or delayed diagnoses in ambulatory care settings found 89% of these errors resulted in significant physical adverse outcomes or death.[75] Errors occurred most often in physician's offices and involved primary care providers. In more than half the errors, cancer, primarily breast, colorectal and skin cancer was misdiagnosed and most likely involved diagnostic tests performed or interpreted incorrectly.[76] The difference between when a diagnosis should have been made and the actual occurrence averaged more than a year.[77] Process breakdowns resulting in error included failure to order appropriate diagnostic or laboratory tests, obtain

---

[69] *Id*.
[70] Poon, Eric *Using Information Technology to Improve Patient Safety in the Ambulatory Setting: Lessons from the trenches*, presentation made to: Medical Errors: The Telehealth Prescription, a conference in Cheyenne, WY, April 12, 2006.
[71] Gandhi TK. Fumbled Handoffs: One Dropped Ball after Another, *Ann of Intern Med*, 2005; 142:5. 352-358.
[72] *Id*.
[73] Poon, Eric G, et al., I Wish I had Seen this Test Result Earlier! Dissatisfaction with test result management systems in primary care, *Arch Intern Med*, 2004; 164: 2223-2228.
[74] *Id*. Citing Boonhaker, EA, et al., Patient notification and follow-up of abnormal test results: A physician survey. *Arch Intern Med.* 1996; 156: 327-331.
[75] Gandhi, TK, Kachalia, A, et. al, Missed and Delayed Diagnoses in the Ambulatory Setting: A Study of Closed Malpractice Claims, *Ann. Intern. Med*. 2006; 145:488-496. The study reviewed closed malpractice claims from four insurance carriers across the country which insured 21,000 physicians and 390 outpatient facilities. Of 429 claims meeting the study criteria (alleging an error in diagnosis or testing that caused a delay in appropriate treatment or failure to act or follow up on test results), 181 occurred in ambulatory settings, led to adverse outcomes and became the subject of further inquiry. Ambulatory settings included physician's office, ambulatory surgery, pathology, laboratory, or radiology suites.
[76] *Id*. at 491. Non-cancer missed diagnoses were mainly infections, fractures and myocardial infarctions and were more likely to involve delays by patients seeking care, inadequate history or physician examination and failure to refer the patient.
[77] *Id.* at 490-491.

an adequate medical history or physical exam and inappropriate or inadequate follow-up plans.[78] Seventy-nine percent of errors were attributed to failures in judgment, with failures in vigilance or memory, knowledge and handoffs noted as well.[79]

Diagnostic errors are complex, frequently involving multiple physicians and multiple breakdowns in communication.[80] What can be done to address these errors? Focusing first on the weak links identified by researchers, specifically, test ordering decisions, interpretation and follow-up is a reasonable place to start. The use of tools to improve performance such as decision support software, which forces consideration of alternative diagnostic plans or second opinions and improved test result tracking systems that reduce reliance on memory are systems interventions that should be employed.[81]

Managing test results is difficult and delays are common. Numerous factors contribute to this problem: Primary care physicians typically have large volumes of data to review weekly; test results become available anywhere from hours to weeks after tests are ordered, making it easy to forget; paper test results are prone to misfiling and delay; and, specialists performing tests often lack clinical information about why a test was ordered, or whether a result warrants a phone call to the provider. [82]

Even providers using electronic health records systems have difficulty managing test results. Management practices were reviewed in a survey of internal medicine physicians practicing in primary care where all physicians had electronic medical record systems providing full access to results of testing. [83] Despite spending more than 70 minutes per clinical day managing test results, more than half of the physicians were dissatisfied with how results were managed and 83% reported at least one delay in reviewing results during the previous two months. Improvement in test result management will require the commitment of physicians in ambulatory care and radiology, laboratory and cardiology departments. Fail-safe mechanisms for communicating results and explicit criteria to determine results requiring immediate notice to the ordering physician must be developed.[84]

Patient Safety Initiatives in Ambulatory Care

By focusing exclusively on identifying the frequency and severity of medical errors in the inpatient setting, a very large segment of care is excluded. An assessment tool created to determine the level of patient safety awareness as well as current patient safety practices

---

[78] *Id.* at 492.
[79] *Id*.
[80] *Id*. at 492-493. Agreement among the study's physician reviewers was only fair, which the authors deemed reflective of "how difficult and subjective clinical judgments regarding missed diagnoses are."
[81] *Id*. at 495.
[82] Gandhi, *supra* note 71.
[83] Poon, *supra* note 73. Practices differed in policies and procedures regarding who held test result review responsibility and the method of review. In some practices the ordering clinician was responsible for test result review, while in others this task was delegated to support staff. Some practices reviewed the results online, while others used paper printouts of the results.
[84] Gandhi, *supra* note 71.

in the ambulatory care setting has been developed for this purpose by the Medical Group Management Association.[85] The Physician Practice Patient Safety Assessment Project (PPPSA) contains approximately 80 individual assessment questions on safe practices, covering six domains: 1) medications; 2) handoffs and transitions; 3) surgery, anesthesia and sedation and invasive procedures; 4) personnel qualifications; 5) practice management and culture and; 6) patient education and communication.[86] A team of personnel, including nurses, laboratory technicians and the ambulatory care physician are required to complete the survey. The comprehensive assessment requires in-depth discussions of processes used in the physician's office and may take up to four hours to complete.

Medical malpractice insurers in Wyoming have focused on some of these issues, albeit from the perspective of decreasing the malpractice risk of their insureds. The Doctors Company, which provides malpractice insurance to Wyoming physicians, supports a patient safety department which assists its insureds with risk management. In Nevada, where risk management is mandated by the state, The Doctors Company offers a risk management program and awards a 5% credit on malpractice premiums to physicians who participate. No plan is underway to institute a similar program and discount in Wyoming.[87] The Utah Medical Insurance Association (UMIA), which also provides medical malpractice insurance in Wyoming, offers five-hour seminars on risk management directed at the underlying causes of malpractice claims, including communication between physicians and patients. Those physicians who participate in Wyoming receive a 7.5 percent discount on malpractice rates for a three year period. Approximately two thirds of Wyoming physicians insured by UMIA have attended a risk management seminar in either Casper or Jackson.[88] UMIA reports claims data have shown a decrease across all types of claims as a result of this training.[89] The risk management efforts of The Doctors Company and UMIA are focused primarily on averting lawsuits and not necessarily the types of activities which would reduce medical injuries.

Efforts by medical malpractice insurers to reduce the liability of ambulatory care physicians are a step in the right direction, but do not go far enough. A thorough assessment identifying current patient safety practices in ambulatory care is needed to achieve a complete picture of systems and processes in use and highlight areas for education, training and improvement. This activity would seem complementary to the work already underway by medical malpractice insurers in Wyoming. Partnering with insurers would help support the state's goal of improving patient safety and provide incentive for physicians to participate. Reduction in premium rates as a result of completing an assessment of patient safety practices may motivate physicians to undertake this activity and provide a baseline of information regarding safety practices in

[85] MGMA at: www.mgma.com
[86] Physician Practice Patient Safety Assessment Project, Medical Group Management Association, 2005
[87] Communication from Ken Vines, Wyoming Insurance Commissioner, June 26, 2006, regarding a discussion with Mike O'Donahue, The Doctors Company.
[88] Marty Oslowski, President, UMIA.
[89] Communication with Jeri James, UMIA Risk Management, Nov. 21, 2006.

ambulatory care.[90] The Doctors Company has acknowledged interest in the MGMA assessment tool, recognizing the significant educational benefit for physicians completing the assessment. However, The Doctors Company's interest exceeds merely conducting a survey and extends to utilizing survey results to foster behavior change in physician offices.[91] The Obstetrics Risk Reduction Program, a voluntary program launched by a medical malpractice insurer in 2003 for obstetricians, midwives and family practitioners working in Harvard-affiliated hospitals, rewards specific patient safety activities with a malpractice premium discount and has seen good participation by its insureds.[92] Programs such as these indicate physicians will be willing to participate with proper incentives and provide models to consider in creating a Wyoming program.

Electronic Health Records: Adoption in Ambulatory Care

Recommendation #7

Establishment of interoperability standards for electronic health records is critical to widespread adoption. Wyoming should closely follow the progress of federal bills proposed to address this problem. Until agreement on universal standards is reached, Wyoming should focus on medical information technology applications not dependent on interoperability. Development and utilization of electronic prescribing and access to Internet-based decision support tools should be encouraged and supported.

The coordination, management and communication of the many activities in ambulatory care are difficult for patients and physicians alike, and often the infrastructure available is not up to the task.[93] Information technology offers promise to improve ambulatory care by providing clinical information at the point of care, as well as improving medication safety, test result follow-up, transitions in care and communication with patients and between providers.[94]

Discussions of information technology usually focus on computerized physician order entry (CPOE) systems and electronic health records (EHR) both of which may be helpful in improving patient safety in ambulatory care settings. CPOE is an application that is used to electronically write physician orders either in the hospital or in the outpatient setting and is linked with clinical decision support. Ideally, these systems would be integrated, allowing information on contraindications from a patient's EHR, for example, to be displayed on the CPOE system at the time a medication is ordered. However, with increasing implementation of CPOE systems in various settings of care has come evidence

[90] Comment from Michelle M. Mello, J.D., Ph.D, regarding the effect of premium reductions for survey completion on physicians associated with Harvard hospitals.
[91] Communication with Robin Diamond, V.P. of Patient Safety, The Doctors Company, Nov. 30, 2006.
[92] http://www.rmf.harvard.edu/high-risk-areas/obstetrics/ob-risk-reduction-program/general-information.aspx.
[93] Gans, David N., *Patient Safety In Physician Practices: Will IT Save the Day?* MGMA Center for Research, Presentation made to: Medical Errors: The Telehealth Prescription, a conference in Cheyenne, WY, April 12, 2006.
[94] Poon, *supra* note 70.

that some implementation approaches may actually cause new errors or even harm.[95] In a study of inpatient pediatric admissions, computer-related medication errors though found to be uncommon, introduced new pediatric medication errors not typically seen in a paper ordering system.[96] As CPOE systems are implemented, practitioners must be aware of the potential for CPOE facilitated medication errors, as well as the errors these systems prevent.[97]

Though holding great potential, electronic health record EHR systems present no panacea but will require coordination and management to be effective. Teamwork, communication and decision support can be improved through information technology (IT) applications, but at the same time interject new processes into the delivery of care, creating new opportunities for error.[98] Most technology applications available off the shelf still need to be customized for use in medicine. The change in workflow patterns that IT utilization will create can be very difficult and overwhelming to providers. Therefore, it may be best to start small with IT implementation. The strong support and vision of physician leaders, focus on workflow, letting the clinical processes dictate the IT development as well as provision of ample and on-going IT training and support will all be very important to successful creation and use of IT systems.[99]

The rate of adoption of electronic health records as well as other clinical support information technology is more complicated and proceeding more slowly than expected, especially among small physician practices.[100] As of 2005, about 24% of physicians nationally in ambulatory settings made use of an EHR to some extent.[101] Adoption rates remain low due to four factors: 1) financial barriers, including the high cost of implementing an EHR and uncertainty regarding the provider's return on investment; 2) technical barriers, including the ease of use and expected obsolescence of systems; 3) organizational barriers, including small practice size, payer mix and leadership; and 4) legal barriers, including perceptions regarding new potential liabilities and security and privacy regulatory compliance.[102] These barriers, whether real or perceived, provide opportunities for policy interventions to spur adoption. Wyoming is currently studying privacy and security issues specifically related to electronic health record adoption

[95] Classen D, Avery AJ, Bates DW. Evaluation and Certification of Computerized Physician Order Entry Systems *J Am Med Inform Assoc*.2006; 0: M2248v1

[96] Walsh K, et al., Medication Errors Related to Computerized Order Entry for Children, *Pediatrics*, 118:5 (2006) 1872-1879.

[97] Koppel R, et al., Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors, *JAMA*, 293:10 (2005), 1197-1203.

[98] *Id*.

[99] *Id*.

[100] Jha AK, Ferris TG, Conelan K, DesRoches C, Shields A, Rosenbaum S, and Blumenthal D. How Common Are Electronic Health Records in the United States? A Summary of the Evidence, *Health Affairs*, 25 (2006): w496-w507; web exclusive found at 10.1377/hlthaff.25.w496. EHR use among health care providers serving vulnerable populations appears to lag behind as those providers who treat fewer Medicaid patients are more likely to use an EHR than providers with a larger share of Medicaid patients.

[101] *Id*. The study reviewed 36 surveys conducted over a nine year period and also determined only 5% of hospitals had computerized physician order entry systems.

[102] *Id*.

through the Health Information Security and Privacy Collaboration.[103] One of thirty-four states and territories engaged in these activities, Wyoming stakeholders will determine the state's current health care information exchange practices and legal barriers and identify solutions and implementation specifics to resolve these issues. Information from all participants will be assimilated to present a national perspective on EHR readiness.

A major area of concern among ambulatory care providers and health care facilities regarding EHR adoption is the lack of technology standardization, raising issues about whether electronic medical systems will be able to communicate with each other once established. [104] Two bills in Congress currently address adoption of health information technology. The House bill (HR4157) would develop a permanent structure to govern national interoperability standards and apply medical privacy laws to data stored or transmitted electronically. It also includes an exemption to the Stark anti-kickback laws that would permit hospitals to provide health care IT hardware and software to individual physicians. Under the House bill, the Secretary of the Department of Health and Human Services (HHS) would be required to propose to Congress a privacy standard to reconcile differences between federal and state laws. The Senate version, Wired for Health Care Quality Act (S1418), approved by the Senate in 2005, establishes an American Health Information Collaborative to advise the Secretary of HHS on content, communication and security standards for the electronic exchange of information; creates implementation and certification of health information standards; provides grants to facilitate wide-spread adoption of health information technology; and provides for demonstration grants to develop academic curricula integrating qualified health information technology systems into clinical education. These bills have yet to be reconciled and it remains to be seen whether differences will be resolved in the current lame-duck session of Congress or addressed when the new Congress is seated in January, 2007.

The former National Coordinator for Health Information Technology, David Brailer, warns portability of technology is the "key to digital medicine" and Congress may miss this most fundamental issue in reconciling the two competing versions of the bill. According to Brailer, "opposition to portable health information is, by definition, support for proprietary health information." Brailer notes, "As the era of digital medicine begins, we have one chance to get it right, and that means making portable health information our priority." [105]

---

[103] The project is managed by RTI in cooperation with the National Governors Association under a contract from the Department of Health and Human Services (HHS), Agency for Healthcare Research and Quality. The project is a national collaboration created to address privacy and security policy questions affecting the exchange of health information. More information may be found at: http://www.rti.org/page.cfm?nav=7&objectid=6D0A81F4-6A6D-44A5-BD5E14B2A7077ED6

[104] Gans, D, Kralewski, J, et al., Medical Groups' Adoption of Electronic Health Records and Information Systems, *Health Affairs*, 24 (5): 1323-33, 2005. The lack of standardization in technology systems is often seen as a barrier to adoption.

[105] Health Information Technology Legislation Should Allow Portability for Electronic Health Records, Former HHS Official Brailer Says, Kaiser Daily Health Report, citing *New York Times*, Sept. 19, 2006, found at http://www.kaisernetwork.org

Aware of the importance and problems of interoperability, federal health care providers have proposed a solution to assist federal health care facilities who share these concerns. Recently, the Department of Defense and Indian Health Services announced adoption of VistA, the Veterans Administration's medical imaging system, to integrate clinical images and scanned documents into a patient's electronic health record. This appears to be a move by federal health services toward standardizing electronic record keeping with the VA's current system.[106]

The eventual adoption of computerized prescribing may play a large part in improving patient safety and state leaders are beginning to recognize this potential.[107] New Hampshire's governor has set a goal for all health care providers to begin e-prescribing in the next two years, with primary care physicians encouraged to comply by 2007.[108] The governor's policy recognizes e-prescribing does not require an expensive electronic health records system to be in place, but can be accomplished through use of a "Blackberry," or personal digital assistant (PDA).

Wyoming is also utilizing existing technology to improve decision support capability and the delivery of care. A free on-line subscription to evidence-based medical resources is currently available on the desktop computer and PDA of every health care provider in the state. Every hospital and clinic in Wyoming, as well as any health care provider practicing in these institutions, has access to this information provided through the Wyoming Network for Telehealth.[109] Feedback from users indicates strong support for access to these digital resources and recognition of the value of online evidence-based resources as an aid in physician recruitment.[110]

Improving Patient Safety

Research Problems

Recommendation # 8

Wyoming would benefit from a coordinated approach to improving patient safety in health care facilities. A Patient Safety Center would provide a state resource for evidence-based medical practice, dissemination of information, education and training in root cause analysis and proven patient safety techniques, as well as provide facilitation for collaborations among facilities focusing on the same problems and issues.

---

[106] Brewin, Bob. Federal health services choose VA imaging standard; The major federal health services may standardize on the VA's VistA system. *Government Health IT*, July 10, 2006. accessed at http://www.govhealthit.com/article95198-07-10-06

[107] Gandi, TK, Wiengart, SN, et al., Outpatient prescribing errors and the impact of computerized prescribing, *J Gen Intern Med*, 20:837-41, 2005.

[108] Landrigan, K "Lynch's goal: E-prescribing by 2008." *The Nashua Telegraph* Oct. 20, 2006 found at: http://www.nashuatelegraph.com/apps/pbcs.dll/article?AID=/20061020/NEWS02/110200214

[109] Wyoming Department of Health, Office of Telemedicine, Wyoming Network for Telehealth currently provides free on line access to MD Consult, Nursing Consult and First Consult.

[110] Communication with the Wyoming Department of Health , Office of Telemedicine

As governmental and nongovernmental regulators pressure the leaders of health care organizations to improve patient safety, programs designed to prevent medical errors are beginning to proliferate. Many are not being rigorously evaluated or studied by academicians, although reviewing their progress may provide insight into where the safety field is heading and where barriers to improvement lie.[111]

Medical error prevention is a relatively young science and presents a number of challenges to typical research methods. Many patient safety practices are difficult to research. For example, the introduction of computerized physician order entry systems or modification of nurse staffing levels is not subject to double-blind studies because use of these methods is evident to participants.[112] Capturing all relevant outcomes, such as "near misses," is often very difficult and many effective safety practices are multidimensional, so that sorting out precisely which part of the intervention works is often quite complex. In addition, patient safety problems that generate the most concern, like wrong-site surgery, are fairly uncommon, making it difficult to statistically detect a successful safety practice with respect to outcomes. Because of Wyoming's small population numbers, these research challenges may make it difficult to determine the statistical significance of patient safety interventions in the state.

Establishing firm epidemiologic links between presumed causes and those that have previously been accepted as a cause and specific adverse events is critical to the science of patient safety.[113] Often what has been presumed and accepted as a cause of patient error is difficult to prove. The movement to improve patient safety has long focused on health care systems as a major source of error, though empirical evidence relating to this assertion is only now beginning to emerge.[114] Ambiguity about what defines a system and where individual errors begin and end makes these inquiries complicated.

While it is important to acknowledge and address the role of systems in mistakes, it is also critical to hold individual health care providers and facilities accountable for violations of well known, widely accepted, straightforward standards of care affecting patient safety.[115] Low-profile mistakes, such as a provider's failure to wash hands between treating patients, should be documented, yet generally are not within the purview of adverse event

---

[111] McCarthy, D. Blumenthal, D. Stories from the Sharp End: Case Studies in Safety Improvement, *The Milbank Quarterly*, Vol. 84, No.1, 2006, 165-200. This is an excerpt from Committed to Safety: Ten Case Studies on Reducing Harm to Patients, funded by the Commonwealth Fund and found at: www.cmwf.org

[112] Making Health Care Safer: A Critical Analysis of Patient Safety Practices, AHRQ Publication 01-E058, July 20, 2001. Accessed at http://www.ahcpr.gov/clinic/ptsafety/summrpt.htm

[113] *Id.* The AHRQ study provides the following example: " For instance, in studying an intuitively plausible "risk factor" for errors, such as "fatigue," analyses of errors commonly reveal the presence of fatigued providers (because many health care providers work long hours and/or late at night). The question is whether or not fatigue is over-represented among situations that lead to errors. The point is not that the problem of long work-hours should be ignored, but rather that strong epidemiologic methods need to be applied before concluding that an intuitive cause of errors is, in fact, causal."

[114] Mello, *supra* note 5.

[115] Goldman, D. System Failure Versus Personal Accountability – The Case for Clean Hands, *N Eng J Med*, 355(2): 121-123, July 13, 2006.

reporting systems unless they clearly lead to serious injury.[116] In most health care institutions, compliance with good hand washing procedures happens half of the time or less.[117] To ensure this small but important procedure is always undertaken, the system must promote its importance as well as provide health care workers with ample time to perform the act, reliable access to antiseptic wash and education on proper technique.

Progress in Patient Safety Improvement

Despite questions about systems verses individual behaviors and the research challenges described, the AHRQ evaluated and rated 79 patient safety practices, finding eleven of sufficient evidentiary weight to support more widespread implementation by other health care institutions. Most of these identified practices apply to the care of those who are very ill.[118]

The Division, along with Mountain Pacific Quality Health Foundation, Wyoming Medical Center and Campbell County Memorial Hospital, is participating in the Patient Safety Improvement Corp (PSIC), a project sponsored by the Agency for Healthcare Research and Quality and the Veterans Administration National Center for Patient Safety.[119] The project's focus is to improve patient safety by providing knowledge and skills to teams of state field staff and hospital partners selected by the state.[120] To advance these goals, the Wyoming PSIC group sponsored four days of training throughout the state in April, 2006 to discuss the objectives of the project, the state patient safety reporting system, aspects of safety culture and root cause analysis of medical errors.

The Wyoming's PSIC group issued a survey to assess the safety culture of five Wyoming hospitals with plans to tabulate the results at a later date.[121] This effort to bring institutional awareness of patient safety issues seems to compliment the on-going work of at least one Wyoming liability insurer. In 2003, hospitals from Wyoming, Idaho and Montana banded together to create the Yellowstone Insurance Exchange, a hospital

---

[116] *Id.*

[117] *Id.* citing Pittet D. et al., Compliance with hand washing in a teaching hospital. *Ann Intern Med* 1999; 130:126-130 and Lankford, MG, et al., Influence of role models and hospital design on hand hygiene of healthcare workers. *Emerg Infect Dis* 2003; 9:217-233.

[118] *See* Appendix B: Making Health Care Safer: A Critical Analysis of Patient Safety Practices, AHRQ Publication 01-E058, July 20, 2001. Accessed at http://www.ahcpr.gov/clinic/ptsafety/summrpt.htm

[119] http://www.patientsafety.gov/psic/index.html

[120] *Id.* Specifically, the project seeks to: 1) conduct effective investigations of reports of medical errors (e.g. close calls, errors with and without patient injury) by identifying their root causes with an emphasis on underlying system causes; 2) Prepare meaningful reports on the findings; 3) Develop and implement sustainable system interventions based on report findings; 3) Measure and evaluate the impact of the safety intervention (i.e., that will mitigate, reduce, or eliminate the opportunity for error and patient injury); 4) Ensure the sustainability of effective safety interventions by transforming them into standard clinical practice.

[121] Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture, found at: http://www.ahrq.gov/qual/hospculture/hospcult.pdf

liability risk retention pool.[122] Yellowstone requires any hospital seeking membership in the pool to complete a facility risk assessment and provides its members with risk management educational opportunities and quarterly risk management visits.[123]

Notable National and State Efforts in Patient Safety

This section of the report examines the key accomplishments in patient safety and culture change accomplished by the state of Minnesota and two leading hospital organizations, the U.S. Department of Veteran Affairs (VA), National Center for Patient Safety and Kaiser Permanente (KP). A recent survey of U.S. hospitals found the state of Minnesota leading the nation in patient safety efforts.[124] Both the VA and KP determined organizational culture change to be a critical component in making patients safer and have acknowledged cultural attributes identified with supporting patient safety.[125] Both are also currently using web-based decision support tools to reduce errors and malpractice claims by targeting "the most common lapses in the diagnostic process."[126]

U.S. Department of Veteran Affairs (VA), National Center for Patient Safety, Ann Arbor, Michigan[127]

As part of a broad organizational transformation undertaken in response to public and congressional concerns about quality of care, the VA established a National Center for Patient Safety in 1999 to create a culture change program to empower local facilities and frontline staff with proven tools, methods, and initiatives to improve patient safety. To accomplish this task, the VA used human factor principles and the experience and lessons from aviation and nuclear power industries, known for their high-reliability measures. The main components of the VA safety program include creating a non-punitive approach to patient safety, encouraging reporting of adverse events, engaging in analysis of errors and reviewing systems for vulnerability. [128]

In creating a non-punitive approach to patient safety, the VA distinguished between unintended errors and blameworthy acts and protected the confidentiality of those

---

[122] Fashek, Allison, Rural hospitals create own insurance company: The Yellowstone Insurance Exchange was formed to keep premiums low, *Wyoming Tribune-Eagle*, December 22, 2003.

[123] Communication with Robert Kidd, President, Wyoming Hospital Association, June 27, 2006.

[124] HealthGrades Quality Study: Third Annual Patient Safety in American Hospitals Study, April 2006.

[125] *See* Appendix C: Five Attributes of a Safety Culture**.** Reason, J. 1997. *Managing the Risks of Organizational Accidents.* Bulington, Vt.: Ashgate.

[126] Web-based Tools Can Help Prevent Diagnostic Errors, California Healthcare Foundation, iHealth Beat, Nov. 29, 2006 found at: http://www.ihealthbeat.org

[127] U.S. Department of Veteran Affairs (VA), National Center for Patient Safety, Ann Arbor, Michigan http://www.patientsafety.gov/contact.html James Bagian, M.D., Director

[128] *See* Appendix D: Definition of Key Terms.

reporting unintended errors.[129] The VA encourages the reporting of adverse events and close calls by offering two avenues for reporting events: reporting to the institution's internal patient safety manager or an external reporting system. The identity of the individual who reports internally is known to the patient safety manager, allowing the employee to get feedback on the findings of a root cause analysis and an opportunity to comment. The external reporting system created in 2002, exists for those who are uncomfortable reporting internally. These reports go to a system operated by the NASA Ames Research Center and is modeled on the Aviation Safety Reporting System, which NASA operates for the Federal Aviation Administration. Once the necessary information regarding the adverse event has been collected, the report is de-identified to maintain the confidentiality of the reporter.

Computer-aided root cause analysis tools assist multidisciplinary teams in the analysis of events that are reported in each VA facility. The tools are easy-to-use and training is provided. The National Center for Patient Safety also provides a central analysis of adverse events to determine how to address common issues throughout the VA system. The VA utilizes an adaptation of a systems engineering tool called "failure modes and effects analysis" to aid discovery of critical system vulnerabilities within its health care facilities and design improvements to prevent and reduce harm.

The VA's patient safety efforts have shown promising results. After ten months of operating the internal reporting system, the rate of adverse events reported was 30 times greater than the reporting rate prior to implementing the system. Hundreds of thousands of reports have been made by identified reporters to the internal reporting system, compared to less than 4,000 submitted anonymously to the external system. This seems to indicate that in a non-punitive reporting environment, health care providers will willingly report errors, even if their identity is known to the reporting entity. The VA experience shows a non-punitive system is critical to facilitate reporting, even more so than providing anonymity for the reporter. In contrast, Wyoming's reporting system protects the identity of the reporter but is perceived by some as unable to guarantee the report will be protected from a punitive environment.

With better training and computer assisted analysis in the VA system, nearly all the root cause analyses are now able to recommend a solution to a specific patient safety problem, where before, about half failed to do so. Causes identified have shifted from patient's behavior and professional training to human factors and systems issues. Multidisciplinary teams now seem to view the circumstances creating errors as amenable to change. Using these techniques, VA personnel hope to set and achieve safety goals that exceed JCAHO's requirements.

Veterans Administrative Hospital, Cheyenne, Wyoming

[129] Blameworthy acts are defined as a criminal act; an act related to alcohol or substance abuse or patient abuse; or intentionally unsafe act that was known to be unsafe. Blameworthy acts are reported to and investigated by the VA administration and can possibly result in disciplinary action.

At the Cheyenne VA Hospital, reports of adverse events and near misses are recorded on a template in the patient's electronic medical record, transmitted to the patient safety officer, then reported to the National Center for Patient Safety and the central office of the Veterans Integrated Service Network (VISN) 19.[130] The electronic report of error triggers a preliminary investigation by the patient safety officer. Each error is scored to determine its severity and multidisciplinary teams meet to conduct a root cause analysis and action plan to correct the problem. The facility director, assisted by the patient safety officer, reviews the root cause analysis and action plan, orders implementation of the plan and subsequently looks for evidence in the facility that the plan has been implemented.

Any adverse event that causes an injury must be disclosed to the patient. The most frequent errors seem to be medication errors or patient falls.[131] A behavior that does not result in injury, such as the untimely distribution of medication, is not disclosed to the patient. According to the patient safety officer, the adverse event reporting program has enabled the Cheyenne VA hospital to make specific improvements in systems of care. For example, problems with medication errors led the hospital to provide a medication dispensing unit, bar code reader and laptop at every patient's bedside. Because health care providers can see visible change as a result of their reporting efforts, reports seem to be made more frequently.

In contrast, Wyoming's state patient safety reporting system does not require the reporting health care institution to conduct a root cause analysis of the error, nor make improvements or changes to the care process as a result. The reinforcement for error reporting found through facilitating change to prevent a recurrence of error is missing.

Kaiser Permanente

Kaiser Permanente (KP) is a group-model health maintenance organization serving 8.2 million people in nine states and Washington, DC. KP instituted a program of organizational learning in 2002 to promote teamwork and communication in high-risk areas, such as surgery, labor and delivery. Clinical leaders were taught safety-oriented principles and techniques adapted from U. S. Navy and airline crew resource management training. Dr. Michael Leonard, an anesthesiologist and physician leader for patient safety at KP, and his colleagues have collaborated with the Human Factors Research Project at the University of Texas, Austin to explore how lessons of the aviation industry can be applied to medicine. KP also adapted research on high-reliability prenatal care developed at the University of Minnesota. A multidisciplinary team led by a KP anesthesiologist developed simulation-based perinatal critical event team training drawing on the work of the Stanford Center for Advanced Pediatric Education.[132]

[130] Interview with Larry Rayburn, Patient Safety Officer, Cheyenne VA Hospital, June 22, 2006.
[131] Mr. Rayburn reports one quarter of the errors reported are attempted suicides and medication errors; one half are falls and patient elopement.
[132] McCarthy ,et al., *supra* note 108.

A corps of techniques is employed in these clinical situations based on the following elements of interaction:

1. ***Briefing:*** A structured type of interaction used to attain clear and effective communication in a timely manner, conducted periodically or on a situational basis, depending on need (such as at the beginning of each shift, before surgery, or situations requiring a physician's immediate attention).

2. ***Appropriate Assertion:*** Teaching health care workers to politely assert themselves in the name of safety; using critical language that ensures the concerns are not shrugged off.

3. ***Structured communication:*** Situation-Background-Assessment-Recommendation (SBAR) adapted from the U.S. Navy facilitates critical thinking and responsiveness by structuring communication in a logical sequence that clearly defines the patient's current situation and clinical status, short term assessment of the problem and recommended action.

4. ***Structured Awareness:*** Team members share understanding of the situation at hand, what happens next and a contingency plan, cross-monitoring each other's performance to mitigate errors and deficiencies and recover from unexpected events.

5. ***Debriefing:*** After an event or activity, questions are asked: What did we do well? What did we learn? What could we do better? What systems need correcting? Who is responsible for follow-up? The quality of the final debriefing is dependent on the quality of the initial briefing.

In February 2002, a multidisciplinary design was launched for surgical operations at the KP facility in Anaheim, CA. In the surgical arena, two important elements that predict successful teamwork are sharing a common understanding of the situation so there are no surprises and "setting the stage" through team leadership. Physicians have a profound influence in setting the tone and whether and how members feel comfortable about discussing safety. Surgical teams employed a preoperative safety briefing to enhance basic patient safety practices, such as time out to verify surgical sites. Initially, these briefings were conducted while the patient was under anesthesia, though recently, surgical teams have begun to conduct preoperative safety briefings in the presence of a fully awake patient. Patient feedback has been positive, with many reporting they favor the process conducted in their presence. A one page checklist is used to prepare the surgical team for cases and operating room personnel are trained in human factors principles, with a self-assessment component.[133]

Six months following the initiation of these safety procedures, no wrong-site surgeries have taken place, while three such cases were reported the year before. Other error

[133] Human factor principles involve the study of the interrelationships among humans, the tools they use, and the environment in which they live and work.

management behaviors increased, such as the willingness to speak up about safety concerns and report and discuss mistakes, which suggests some situational awareness of safety issues has been instilled in these employees. Turnover rate for nurses fell by two-thirds, from 23% to 7%, and has been sustained at a lower level than other comparison hospitals.[134]

Based on the Texas Safety Attitudes Questionnaire, operating room staff perceived an improvement in safety culture and teamwork following implementation of the safety project. Briefings were seen as a powerful way to change the way people think and practice teamwork. Explicit communication helped team members focus on the common task at hand, while bridging cognitive gaps in training and experience levels among team members, thus avoiding unjustified assumptions about other team members' knowledge.

In 2002, four northern California KP medical centers piloted perinatal patient safety projects (PPSP) and provided comprehensive training for labor and delivery staff on safety science, accident causation, high-reliability theory and communication skills. The following safety interventions were implemented: 1) multidisciplinary patient rounds to ensure a patient's care plan is understood; 2) assertive and structured communication techniques to promote accurate situational briefings; 3) communication escalation policy to avoid delays in responding to critical events and; 4) team briefings before and debriefings after procedures.

Multidisciplinary teams created critical-event team training to practice teamwork and communication skills in simulated crisis situations using computerized mannequins. These training sessions present complex scenarios that force the team to recover from errors and allow for debriefing from videotaped sessions. One year following implementation of PPSP, the labor and delivery staff rated safety culture higher than before the intervention. However, at that time, not enough data were available to measure the direct effect on perinatal events.

KP has implemented similar patient safety improvements as part of a national best practice transfer program at thirty KP sites. Applications of these principles have been made in radiology, procedural sedation, and patient transfers, with plans to embed high-reliability surgery techniques into outpatient surgery settings.

Improving team communication requires cultural change. According to Dr. Michael Leonard, KP's physician leader for patient safety, effective change requires a bottom-up approach that empowers frontline staff to take responsibility for safety with the support and involvement of administrative leadership and physicians.[135] Explicit communication among team members helps to bridge and identify cognitive gaps in training and experience levels, so that assumptions are not made about what a team member knows. Safety principles and techniques from other industries offer valuable lessons but must be modified to achieve the right cultural fit for medicine and be embedded in broader culture change efforts that involve teamwork and process improvements. The SBAR technique

[134] McCarthy, et al., *supra* note 108.
[135] *Id.*

employed by KP has been recognized by the Institute for Healthcare Improvement, which now promotes it as a safety measure.

Both the VA and KP identified organizational culture change as critical to making patients safer. The goal of both has been a safety culture that promotes continual innovation and improvement and which transcends whatever particular safety methodology is employed.[136] Since there is currently no proven formula for creating cultural change in health care organizations, nor model of what health care institutions should strive to achieve in their own safety environment, culture change presents difficult goals for hospital leadership to tackle.

A Wyoming Patient Safety Center would be a vehicle for promoting successful patient safety techniques throughout all Wyoming health care facilities. Techniques such as the SBAR approach, briefing and debriefing protocols and assertive communication training would provide specific skills to health care staff and engage all personnel in the goal to improve the safety of care. Drawing from current research and lessons learned, a Patient Safety Center would be a central conduit for up-to-date information and methods of application for the latest techniques shown to improve patient safety.

Closer to Home

The Institute for Healthcare Improvement's 100,000 Lives Campaign (IHI) promotes six specific hospital interventions to improve hospital safety and save lives.[137] The campaign began in December, 2004 with the goal of enrolling 2,000 hospitals in this effort and saving 100,000 lives by June 14, 2006. Eighteen months later, over 3,000 hospitals have committed to full participation in the effort and an estimated 122,300 lives have been saved by implementing these specific interventions.

Eight Wyoming hospitals are participating in the IHI campaign.[138] The experiences of two hospitals, Platte County Memorial Hospital and Wyoming Medical Center, are particularly instructive. Platte County worked to reduce adverse drug events by improving medication reconciliation of patients brought into the hospital[139] A baseline

---

[136] *Id*. McCarthy and Blumenthal's evaluation of the VA, KP and eight other hospitals did not examine expensive high-technology innovations, like computerized physician order entry (CPOE), because they wanted to look at approaches that would be broadly applicable across institutions, regardless of any institution's ability to make big money investments. This may be particularly meaningful to Wyoming, as most hospitals are small in size with relatively meager budgets.

[137] www.ihi.org The specific safety interventions include: 1) rapid response teams; 2) evidence-based care for myocardial infarction; 3) preventing adverse drug events; 4) eliminating ventilator associated pneumonia; 5) eliminating surgical site infection; 6) eliminating central line infections.

[138] Campbell County Memorial Hospital, Community Hospital of Torrington, Memorial Hospital of Converse County, Platt County Memorial, United Medical Center, Washakie Memorial Hospital, West Park Hospital and Wyoming Medical Center.

[139] Medication reconciliation is defined as a formal process of obtaining a complete and accurate list of each patient's current home medications—including name, dosage, frequency, and route—and comparing the physician's admission, transfer and/or discharge orders to that list. Discrepancies are brought to the attention of the prescriber and if appropriate, changes are made to the orders. Any resulting changes in orders are documented. www.ihi.org

showed that 75% of patients admitted to the hospital did not have their medications reconciled upon transfer. Following implementation of the IHI campaign, in January and February, 2006, 18 of 19 patients underwent medication reconciliation.[140] Staff at Wyoming Medical Center marshaled administrative backing to implement a rapid response team to respond to patients whose condition is progressively deteriorating but who are not in the intensive care unit. Wyoming Medical Center uses mock response calls for training staff to respond, displays posters and holds team meetings to support the effort. Still, some resistance towards complete adoption remains, indicating that change, particularly institutional culture change, is difficult.

Minnesota

Minnesota is the first state to develop a state reporting system around adoption of the National Quality Forum's List of Serious Reportable Events.[141] Mandatory reporting began in 2003, with the first public report of findings released in January, 2005. Minnesota requires the reporting hospital to include a root cause analysis and corrective action plan in reports to the Health Commissioner.[142] Identifying information concerning providers, employees and patients is excluded. Though the intent is for surveillance, the Commissioner may issue sanctions for failure to report. If the facility fails to develop and implement a corrective action plan or report why one is not needed, the commissioner has authority to suspend, revoke, fail to renew or place conditions on the facility's license.[143] Following implementation of the reporting system, one large health plan announced intentions to withhold reimbursement from hospitals for any of the NQF events reported.[144]

Minnesota's experience implementing the NQF events has not been without some problems. Health care facilities have reported confusion over definitions of events and determining what to report.[145] Despite these issues, Minnesota's efforts in patient safety have been recognized as the most progressive in the nation.[146] Ten hospital systems in the Twin Cities and Rochester, which collectively include 23 hospitals, have banded together to improve patient safety by sharing and learning from aggregate experiences of all group members, despite fierce market competition among them.[147] This initiative, called "Safest in America," requires members to commit time and money to patient safety improvement.[148] Each institution pays $10,000 per year to support staffing, goal setting and operational changes. Hospital teams meet monthly to report data and discuss best practices, while their CEOs meet quarterly to ensure adequate resources are allocated for

---

[140] Teleconference on results of the IHI campaign, April 27, 2006
[141] News release from the Minnesota Hospital Association, June 6, 2003.
[142] Minnesota Adverse Health Care Events Reporting Act of 2003, §144.706 to 144.7069
[143] §144.7067(b)
[144] Kazel, R. Minnesota insurer won't pay hospitals for "never events." Nov. 8, 2004. Amednews.com found at: http://www.ama-assn.org/amednews/2004/11/08/bisd1108.htm
[145] Conversation with Bill Munier, Acting Director, Patient Safety and Quality Improvement Center, AHRQ, August 29, 2006.
[146] Health Grades Quality Study, Third Annual Patient Safety in American Hospitals Study, April 2006
[147] *Id.*
[148] www.safestinamerica.org

projects. Direction is set by clinical and patient safety leaders who meet every six months. Together these groups share data, highlight best practices and implement evidence-based, community-tested solutions. Quarterly newsletters highlight accomplishments and current initiatives.

So far, Safest in America has instituted directives for writing prescriptions and standardized surgery site markings.[149] Recognizing the success of crew resource management theory in building a culture of safety, the group's focus is now on creating community agreement on behaviors and expectations that would support a safety culture among hospital members. Part of this effort will include creating a series of mandatory safety sessions for all health care disciplines as part of continuing education and competency requirements, new employees training and privileging.

Work groups and data analysis for Safest in America members are managed by the Institute for Clinical Systems Improvement.[150] Although competition might have kept them apart, peer pressure keeps the coalition goal oriented since "none of the members want to look bad, so they go home and see that things get done."[151]

With this type of commitment to improve patient safety, it is no surprise that Minnesota tops the nation in this effort. Four hospitals in this collaborative have been ranked as Distinguished Hospitals for Patient Safety.[152] Of the 239 hospitals noted nationally for this achievement, no hospital in Wyoming was recognized. Distinguished hospital determinations were based on a review of three years of Medicare data (2002-2004) for evidence of the AHRQ's Patient Safety Indicators.[153] The indicators are used to identify potentially preventable patient safety incidents from hospital discharge data. Data review of all 50 states and the District of Columbia revealed over one million patient safety incidents occurred in 40 million hospitalizations of Medicare patients, resulting in $9.3 billion in excess cost. Patient safety indicators with the highest rates were failure to rescue, decubitus ulcer and post-operative sepsis. One in four Medicare patients who experienced a patient safety incident during the study period died. Data revealed a 9% increase in patient safety indicators from a previous study in 2004.

The Minnesota experience reveals how quality of care can be improved across health care systems when patient safety is the common focus and hospitals share and learn from the aggregate experiences of all health care facilities. Other states are moving towards more public disclosure of patient safety issues to improve care across systems. This trend toward public openness regarding quality of care issues reached a new level with the

---

[149] *Id.*

[150] Institute for Clinical Systems Improvement is an independent, non-profit organization that facilitates collaboration on health care quality improvement by medical groups, hospitals and health plans that provide health care services to people who live and work in Minnesota and in adjacent areas of surrounding states. ICSI has 56 members and is funded by all six Minnesota health plans. The combined medical groups and hospital systems represent more than 7,600 physicians. Information found at: http://www.icsi.org/index.asp

[151] Gordon Mosser, M.S., Executive Director of the Institute for Clinical Systems Improvement.

[152] Health Grades Quality Study, Third Annual Patient Safety in American Hospitals Study, April 2006

[153] Patient Safety Indicators, Version 2.1, Revision 3a. February 2005. Agency for Healthcare Research and Quality, Rockville, MD. http://www.qualityindicators.ahrq.gov/data/hcup/psi.htm

Pennsylvania Health Care Cost Containment Council's publication of hospital-acquired infection rates.[154] Pennsylvania is the first state to issue a hospital-specific report regarding hospital-acquired infections. Hospitals are required by law to report infections in four categories: surgical site, urinary tract, pneumonia and blood stream. The Pennsylvania Council reviewed data for over 1.5 million patients in 168 hospitals and determined that hospital infections were not linked to the severity of illness or risk, but to the processes of care and hygiene followed by the hospital in treating patients. The health and economic impacts of these infections are staggering. Patients with acquired infections cost $1 billion to treat and had an increased length of hospital stay of 18 days. Nearly 2,500 patients with acquired infections died during their hospital stay; the rate of death for these patients was almost 13% compared to over 2% for patients without infections. Because some insurers, including Medicare, pay hospitals on a per-diagnosis rather than per-diem basis, hospitals are often unable to recoup the costs of extra care necessitated by nosocomial infections. As a result, Pennsylvania hospitals experienced a net loss per infected patient of over $26,000.[155] The Pennsylvania Council concluded that standardizing routine processes in the treatment of patients would eliminate variation and greatly decrease infection rates.

Wyoming Medical Malpractice Claims Data

Recommendation #9

The Wyoming Insurance Department should publicly report specific information regarding the amount of payments made to claimants by type of claim and medical specialty area; the reason a claim was denied, withdrawn or closed; and the amount of time elapsed from filing a claim to final resolution (most easily indicated by reporting the date of the alleged incident and the data of claim closure). Consideration should be given to levying penalties under W.S. §26-1-107(2005) against insurance companies failing to comply with reporting requirements. The Wyoming legislature should require the reporting of claimant's attorney fees, costs and expenses for medical malpractice claims.

The Wyoming Insurance Department's Annual Report for 2006 contains detailed claims data from health care malpractice insurers practicing in Wyoming, as required by recent revisions to W.S. § 26-3-124 (2005).[156] Though medical malpractice claims data had

---

[154] Pennsylvania First State To Report Hospital-Acquired Infection Rates, 11/15/2006, *Kaiser Daily Health Policy Report*, found at http://www.kaisernetwork.org

[155] *Id.*

[156] W.S. §26-3-124(2005) provides in part:

(a) Any insurer writing coverage for health care malpractice in this state, by March 1 of each year, shall file with the commissioner a report of all claims against a health care provider and a report of all awards or settlements given in cases against health care providers. The report shall contain the following information only for the preceding calendar year:

(i) The number and categories of all health care providers the company insures for professional liability;

(ii) The number of claims for which a reserve has been established made against covered health care providers, including those claims in which no suit was filed;

been previously collected by the department, this is the first time that year-specific, detailed information has been required by statute.

Summary data utilized in this discussion are available in the Wyoming Insurance Department Annual Report 2006. (No raw data from the Wyoming Insurance Department were reviewed for this analysis.) Thirty-eight of forty-four medical malpractice insurance companies (over 80%) insuring 3,126 health care providers in Wyoming, submitted reports of activity for 2005, as illustrated in **Appendix E, Table 1**.[157] Health care providers included nurses, doctors, surgeons, dentists, chiropractors, hospitals and clinics. The Doctors Company (TDC), which insured 293 health care providers, the OHIC Insurance Company, which insured 23 hospitals and 39 physicians, and the Utah Medical Insurance Association (UMIA) which insured 352 health care providers, all complied with reporting requirements as noted in **Table 2**. Risk retention groups (which generally insure hospitals, not health care providers) are not subject to state regulatory requirements but are instead organized under a federal statute.

Medical malpractice insurance companies reported information as aggregate data and also as individual claims and discrepancies between the two levels of reporting were observed.[158] Aggregate reports noted 154 malpractice claims, while individual reports of claims reflected a total of 165. Aggregate reports showed total claims paid of $9,865,282 while individual report forms showed $7,628,804 in total claims paid. Because of these discrepancies, aggregate data and data from individual report forms are difficult to analyze. However, the comprehensive data reported by TDC, OHIC and UMIA are sufficient for analysis. The data from these three companies represent the vast majority of claims paid by medical malpractice insurers and provide meaningful information regarding claims experience in Wyoming. TDC, OHIC and UMIA reported $7,546,506 in claims paid, representing 76% of aggregate claims paid ($9,865,282).

Malpractice claims were reported by provider type and clinical specialty. The largest number of claims were found in the following categories: 33 claims against hospitals; 20 related to clinics/corporate-group practices/entities; 18 in gynecology/obstetrics; 14 in general surgery; 14 in orthopedic surgery; 10 in family practice; and 9 in internal

---

(iii)The awards and settlements on health care professional liability claims, including the costs of defense;
(iv)For each claim:
(A) Specialty coverage of the insured;
(B) Nature and substance of the claim;
(C) Age of the claimant or plaintiff;
(D) After the final disposition of the claim, the date and manner of disposition, whether by judgment, settlement, arbitration or otherwise, and an itemization of the amounts paid, if any, if reported separately or can be reasonably segregated or identified for:
(I) Medical and prescription costs;
(II) Economic damages;
(III) Noneconomic damages;
(IV) Defense attorneys fees, costs and expenses.

[157] *See* Appendix E for Tables 1-11 addressing data discussed in this section.
[158] Wyoming Insurance Department Annual Report 2006.

medicine. *See* **Table 3**. Malpractice claims included the following types: 66 mistakes in performance/improperly performed procedure; 20 claims for failure to diagnose; 12 claims for failure to prevent harm; and 11 delayed treatments. *See* **Table 4**. Forty-two deaths were reported. Types of injuries noted in order of frequency were infections, bone damage, non-physical injuries, diminished use/loss of use, prolonged recovery/care and diminished life expectancy and organ injuries. *See* **Table 5**. Individuals between 31 and 60 years of age were the most frequent claimants. Additional information regarding the age of claimants is found in **Table 6**.

Aggregate data from individual report forms revealed the following information, as described in **Tables 7 and 8**: Total claims paid of more than $7.6 million and medical and prescription costs of nearly $1 million were reported. Payment for economic damages exceeded $2 million, but may also have included some medical and prescription costs, while payment for non-economic damages was nearly twice that amount, or $3.9 million. $1.6 million in payment to claimants were not specified as either economic or non-economic damages. The insurance companies paid over $2.2 million in attorney fees and additional costs and expenses accounted for another $1.5 million.[159]

Analysis of data from TDC, OHIC and UMIA

In 2005, TDC reported 56 claims filed, OHIC had reported 51 claims filed, while UMIA had 10 claims filed.[160] Of the claims reported, two resulted in jury awards of $1.175 million while 26 claims settled without trial totaled $6,371,506 including medical and prescription costs. *See* **Table 9.**

TDC, OHIC and UMIA spent $3,230,618 to defend claims, including attorney fees, costs and expenses, as described in **Table 10**. $7,546,506 was paid out in economic, non-economic, unspecified and medical/prescription costs. *See* **Table 9**. For every $1 paid to claimants, these three insurance companies spent 43 cents defending the claim.

Claimants' attorney fees are not provided but can be estimated, conservatively, at thirty-three and a third percent of the economic and non-economic payments, or a total of $2.5 million. *See* **Table 11**.[161] Together, defense costs and expenses plus attorney fees for both parties can be estimated at $5.7 million. Net payment to claimants is approximately $5 million (total claims paid of $7.5 million, minus estimated claimants' attorney fees of $2.5 million). *See* **Tables 9, 10 and 11**.

---

[159] *Id.*

[160] The Wyoming Department of Insurance Annual Report 2006 reports the number of claims "filed" against these three companies. Wyoming Insurance Commissioner Ken Vines notes these may actually reflect claims "open" in the reporting year, as opposed to "filed" within the reporting year against the companies.

[161] Rule 5(a), Rules Governing Contingent Fees for Members of the Wyoming State Bar, notes a contingency fee of thirty-three and one third is a common contingent fee in casualty and wrongful death cases, although rates of 40% could be considered reasonable under some circumstances. Even more latitude may exist as "The provisions of the rule are not intended to abridge the freedom of the attorneys and clients to contract for different percentages." Rule 5(c)

Claimants' costs and expenses are not included in the above data, but represent an additional real expense that must also be calculated. If claimants' costs are estimated to be at least the same ratio as those reported by the insurance companies, another $1.4 million should be added to the costs of the system. *See* **Table 11.** The total expense of litigating this group of medical malpractice claims in Wyoming then becomes $7.1 million, compared to $5 million in net payments to claimants. *See* **Table 9, 10 and 11**. The exact expenditures incurred by claimants, including attorney fees, costs and expenses, is unknown. In order to have an accurate picture of all medical malpractice litigation in Wyoming, claimants' attorney fees, costs and expenses must also be reported and analyzed.

Wyoming malpractice claims data permit some comparison to national data on malpractice. The National Practitioner Data Bank, the most representative national and publicly available database on physician malpractice payments, has collected information since 1990.[162] The National Practitioner Data Bank claims data for 2005 ranks Wyoming third highest of all states in the number of paid medical malpractice claims per 1000 active nonfederal physicians.[163] The Data Bank does not collect information on claims that did not result in a payment to the claimant.

A review of medical malpractice data in the National Practitioner Data Bank from 1991 to 2003 showed that trial verdicts accounted for less than 4% of all payments, but had monetary awards almost twice as large as settlements. In Wyoming, jury awards for plaintiffs accounted for 7% of all payments and resulted in payments more than twice the amount received through settlements. A total of 26 settlements without trial were reported for TDC, OHIC and UMIA, averaging $245,057 per claim. OHIC had two judgments against it, which averaged $587,550 per claim and was the only company of the three insurance companies to have any judgments for plaintiffs. Nationally, obstetric claims received the highest payments but accounted for only 15% of total malpractice payments.[164] Wyoming data indicate that gynecology/obstetrics claims were about 11% of all claims, although the data do not reveal the amount of malpractice payments associated with this group or any other. Nationally, failure to diagnose is a growing area of malpractice and was the second most frequent type of malpractice claim reported in Wyoming.[165]

A recent study of medical malpractice claims data provides information for comparison. Over 1400 closed malpractice claims from five liability insurers throughout the country were reviewed along with the associated medical records to determine whether a medical injury had occurred, whether it was due to medical error and the litigation outcome of the

[162] The federal Health Care Quality Improvement Act of 1986 requires all malpractice payments made on behalf of a licensed health care provider to be reported to the National Practitioner Data Bank.
[163] Kaiser Family Foundation, Number of Paid Medical Malpractice Claims, 2005 found at: http://www.stateheatlhfacts.org
[164] Chandra A, Nundy S, and Seabury S, The Growth of Physician Medical Malpractice Payments: Evidence from the National Practitioner Data Bank, *Health Affairs*, 5 (2005): W5-240 to W5-249; found at: 10.1377/hlthaff.W5.240.
[165] The category of "mistake in performance/improperly performed" gathered 66 claims, the highest number reported. Wyoming Insurance Department Annual Report 2006

claim.[166] The study data showed defense costs and standard contingency fees charged by plaintiffs' attorneys brought the total costs of litigating the claims to 54% of the compensation paid to plaintiffs.[167] Not only did the litigation process reveal "exorbitant" overhead costs, the process was lengthy. The average time between injury and resolution was five years, and some cases took six or more.[168] The study found a medical injury could not be identified in only 3% of malpractice claims. A larger group, 37%, did not involve a medical error. About three quarters of "frivolous" claims—those lacking evidence of both medical injury and error—did not result in compensation to the patient.[169] The study authors concluded the current tort litigation system did a reasonably good job of distinguishing between meritorious and nonmeritorious claims, although it had far from perfect accuracy. Meritorious claims which received no payment occurred at 26%. Overall, one in six claims involved errors but received no compensation.

How many meritorious claims in Wyoming went unpaid, or how many patients suffered a negligent injury and did not file a claim, cannot be estimated from this data. However, the prevalence of negligent injury in Wyoming could be estimated by multiplying the number of hospital admissions or discharges in Wyoming in 2005 by 1%, which is the prevalence of negligent injury determined through the Harvard Medical Practice Study and the Utah-Colorado Medical Practice Study.[170] Information regarding the length of time between filing a claim and resolution in Wyoming is not available for comparison.

The Wyoming Insurance Department's first attempt to assimilate detailed medical malpractice claims data is laudable and has provided useful information relevant to patient safety, types of claims and costs. The database collects a more comprehensive range of claims information than other state closed-claims databases, which will facilitate a broader range of analyses. A more thorough analysis of the data categories reported by the medical malpractice insurance companies would provide a more complete picture of malpractice claims in the state and provide additional useful information. The department acknowledges the first year of collecting detailed data under the revised statute was a learning experience.[171] The department intends to review its reporting form to increase reporting consistency and become more aggressive with non-complying insurers.[172] Although 80% of insurers complied with the report requirements, the department sent reminders to several and still did not achieve full compliance. W.S. §26-1-107(2005) provides penalties, including monetary penalties, for failure to comply with provisions of

[166] Studdert DM, Mello MM, Gawande A, Gandhi T, Kachalia A, Yoon C, Puopolo AL, Brennan TA, Claims, Errors and Compensation Payments in Medical Malpractice Litigation, *N. Eng.J.Med*., 354:19 May 11, 2006, 2024-2033.
[167] *Id.*
[168] *Id.*
[169] *Id.*
[170] Communication with Michelle M. Mello, J.D., Ph.D., C. Boyden Gray Associate Professor of Health Policy and Law, Department of Health Policy and Management, Harvard School of Public Health, March 16, 2006, referencing Studdert, DM, et al., Negligent Care and Malpractice Claiming Behavior in Utah and Colorado, *Medical Care*, 38:3, 250-260, 2000; Brennan TA, et al., Incidence of Adverse Events and Negligence in Hospitalized Patients, *New Engl. J. of Med*. 324:370 (1991).
[171] Communication with Wyoming Insurance Commissioner Ken Vines, November 28, 2006.
[172] *Id.*

the insurance code. Consideration should be given to levying penalties against insurers failing to comply with reporting requirements in the future.

Alternative Process Designs

Recommendation # 10

The Wyoming legislature should propose funding for a health court demonstration project to promote disclosure of medical adverse events to patients, establish consistent and efficient compensation for medical injuries, and create a repository for information regarding occurrence and prevention of medical injuries.

Interest in medical malpractice reform persists throughout the country. Conventional reform measures continue to be proposed, but seem to often meet with resistance. In his 2006 State of the Union address, President Bush expressed interest in medical liability reform, including limits on non-economic damages, establishing statutes of limitations on malpractice claims and judgments allocated in proportion to fault.[173] This spring, however, Congress defeated a bill providing a federal cap on medical malpractice damage awards. Wyoming voters have also declined to support a proposed state constitutional amendment that would permit malpractice damage caps to be considered. Instead, a medical review panel, providing administrative screening of medical malpractice claims at an early stage was approved and initiated.[174]

Early Offers

Sidestepping the traditional and continuing debate on malpractice litigation reform, interest in developing alternative processes for medical injury compensation is growing both nationally and among the states. Pragmatic thinking about the problems of lengthy litigation and delays in patients receiving compensation prompted a federal agency to initiate a pilot program in an attempt to alleviate these issues. The Department of Health and Human Services Early Offers Pilot Program may be a "promising approach for fairly and promptly compensating patients injured by negligence without requiring them to go through time-consuming and expensive litigation."[175] The pilot would apply to all medical negligence tort claims under the Federal Tort Claims Act. To foster more rapid resolution of medical negligence claims, the project utilizes an early offer arrangement through submissions of acceptance and offer to a third party "settlement depository" with provisions against admissibility of either in any subsequent litigation.[176] Analysis of the pilot program indicates that early offers are likely to generate significant insurer savings

[173] President George W. Bush, State of the Union Address, January, 2006.
[174] Since its inception, 44 medical malpractice cases have been referred to the medical review panel. Of these cases, 17 waived review by the parties. Four cases went through the review panel process, and twelve cases are still pending. Frazer, J. Medical review panel ignored: Group approved by voters has heard only four out of 44 cases, *Wyoming Tribune Eagle*, Nov. 13, 2006.
[175] Federal Register, 69:185, 57294-57297, September 24, 2004.
[176] *Id.*

through reduced payments for noneconomic damage, while also reducing attorneys' fees for both parties.[177] If these savings would allow insurers to reduce premiums for malpractice insurance and perhaps enable health care providers to reduce their fees, consumers, employers, and governments may benefit from reduced health insurance premiums and the reduced cost of care.[178]

Other reform proposals have focused on error disclosure to improve patient safety. The National Medical Error Disclosure and Compensation Act (MEDiC) seems closely aligned with early offers programs and would promote confidential disclosure of medical errors to patients in an effort to improve patient-safety systems.[179] As proposed by Senators Clinton and Obama, MEDiC would provide federal grant support and technical assistance to physicians, hospitals and health systems that disclose medical errors and problems with patient safety and offer fair compensation for injuries. Errors resulting in harm would be disclosed to the patient, compensation negotiations would be held, with terms of the negotiation, as well as any apology by the provider, kept confidential and inadmissible in any subsequent legal proceedings. A percentage of savings from lowered administrative and legal costs would be applied to reduce malpractice premiums and support patient safety initiatives, such as training to improve provider communication and technology to improve reporting and collection of patient safety data. The act would create a federal Office of Patient Safety and Health Care Quality. The office would conduct annual studies to determine performance and systems standards, safety tools and best practices; analyze the medical liability insurance market to determine historical and current legal costs related to medical liability; and create a database of case studies of unsuccessful negotiations to determine reasons, trends and effects of such outcomes.[180]

In 2005, Illinois passed a comprehensive health care reform package combining conventional reform elements and alternative processes. Traditional reform measures include a requirement that a medical malpractice claim be accompanied by attestation from a medical expert that the claim is reasonable and meritorious or risk dismissal of the claim.[181] Malpractice damage awards for non-economic damages are capped at $1 million against a hospital and $500,000 for claims against a physician.[182]

An alternative and less traditional method of reform, the Illinois act also provides opportunity for one Illinois hospital to focus on error disclosure through participation in a Sorry Works! pilot project. Opportunity for participation by an additional hospital would be added in second year.[183] Participant hospitals and physicians are required to promptly

---

[177] Hersch J, O'Connell J, Viscusi W. *Evaluation of Early Offer Reform of Medical Malpractice Claims: Final Report* found at: http://aspe.hhs.gov/daltcp/reports/2006/medmalcl.pdf
[178] *Id.*
[179] Clinton HR, Obama B, Making Patient Safety the Centerpiece of Medical Liability Reform, *N.Eng.J.Med.*, 354:21, May 25, 2006.
[180] *Id.*
[181] Illinois Medical Liability Reform Public Act 094-0677
[182] Sec. 2-1706.5
[183] Sec. 401; Sorry Works! is a coalition of stakeholders and interested parties in the medical malpractice crisis, including doctors, insurance executives, lawyers, hospital administrators, legislators, patients,

acknowledge, apologize and offer fair settlement for mistakes in patient care. Patients will be encouraged to retain legal counsel. Prior to inception of the Sorry Works! project, an average cost of malpractice verdicts, settlements and defense litigation for the preceding five years will be determined for participating hospitals. If the cost of cases handled under the Sorry Works! pilot project is found to exceed the previous average costs determined for traditional disposition of malpractice cases, the facility may apply for a grant from a special state fund for the difference between the two amounts. Payment from the fund is capped at $2 million per hospital per year or the total amount in the fund, which ever is less.[184]

Disclosure

All these initiatives share one common ingredient, the early disclosure of medical errors to promote quick compensation and cultivate a climate of patient safety. The power of meaningful disclosure has been identified as a key in the resolution of mistakes and continuation of the healing process for both patient and health care provider. Some entities have supported this concept through changes in administrative procedures. The Veterans Health Administration, as previously described in this report, identified through policy, an obligation to disclose adverse events related to clinical care to patients or their representatives.[185]

Probably the best example of the power of disclosure outside federal systems is found in the COPIC experience. Based in Colorado, the COPIC Insurance Company provides medical professional liability insurance and offers a program known as the 3Rs.[186] The hallmark of the program is disclosure of "unanticipated medical outcomes" by recognizing the event, responding to it and resolving the incident with the patient.[187] Since its inception in the year 2000, over 2,800 physicians have participated in the program and over 3,000 disclosure discussions have taken place. The program stresses communication, continued involvement and concern for the patient as paramount in maintaining the physician/patient relationship following an adverse event. COPIC coaches the provider to work through the event and can offer the patient compensation for loss of time and out-of-pocket expenses. The patient retains the right to bring a malpractice action if desired and program benefits are not conditioned on a waiver of these rights.[188] As of September 30, 2006, over 2,500 cases have been closed without payment and only sixteen suits have been filed. The average payment was $5,300 with payments ranging from $5,000 to

---

researchers, and concerned citizens. Information regarding the involvement of Sorry Works! in the Illinois act can be found at: http://www.sorryworks.net/media20.phtml

[184] The development, oversight and implementation of the Sorry Works! pilot project will be the duty of a committee of nine to include four state legislators in leadership positions, each who appoint one additional committee member and the Secretary of Financial and Professional Regulation, a position which seems to combine the duties of insurance commissioner as it applies to medical malpractice insurance and the board of medicine for professional disciplinary purposes.

[185] Department of Veterans Affairs, Veterans Health Administration, VHA DIRECTIVE 2005-049, October 27, 2005.

[186] COPIC Insurance Company found at: http://callcopic.com/publications/3rs/3rs_newsletter.htm

[187] *Id.*

[188] *Id.*

$40,000.[189] These modest compensation amounts reflect the program's focus on minor injuries that do not appear to involve error or substandard care. Other insurance companies across the country, as well as groups like Kaiser Permanente, have expressed interest in the COPIC experience and are investigating similar disclosure and early intervention programs.[190]

In situations where disclosure is not required by law or policy, how do physicians and surgeons feel about disclosing medical errors? Not surprisingly, a survey of U.S. and Canadian physicians found they were more likely to disclose errors if the errors were apparent than if they were not.[191] Canadian physicians, subject to a less aggressive malpractice environment than U.S. physicians, indicated willingness to disclose more information than doctors in the United States. Disclosure was also influenced by perceived severity and responsibility for the error, prior experience with disclosure and general disclosure attitudes.[192]

The Wyoming legislature has given health care providers a tool to express sympathy and apology for adverse events without fear such statements will be used in subsequent litigation by an injured patient.[193] At this time, no data exist to indicate whether providers are making disclosures of errors under these protections or the effect of the statute on malpractice litigation. No feedback is available from physicians regarding the usefulness of this tool, or the reaction of patients who may have received an apology.

COPIC has recognized disclosure can be a powerful tool in facilitating reasonable and efficient compensation for medical injury and provides strong support to physicians participating in disclosure discussions. The COPIC experience illustrates the significant potential of early intervention and disclosure to patients. Research indicates willingness to disclose is influenced by prior experience with disclosure and physician attitude. Absent any requirement to engage in disclosure discussions with patients and lacking education and guidance in the process of disclosure, it seems unlikely Wyoming will achieve the benefits realized by institutions like COPIC which have completely committed to the disclosure process.

Health Courts: Characteristics

An in-depth analysis of the special features of a health court, including how one would operate was provided in detail in the first Wyoming Health Care Commission Report on

---

[189] George Kikeou, Legislative Consultant, COPIC Insurance Co., presentation at Health Courts, Administrative Compensation, and Patient Safety, Nov. 8, 2006, Washington, D.C.
[190] COPIC, *supra*, note 182.
[191] Gallagher, TE, Garbutt, JM, Waterman, AD, Flum, DR, Larson, EB, Waterman, BM, Dunagan, WC, Fraser, VJ and Levinson, W. Choosing Your Words Carefully: How Physicians Would Disclose Harmful Medical Errors to Patients, *Arch Intern Med*. 2006,166:1585-1593, at 1591. But wide variation was found to exist in how disclosures would be made. The authors speculate this variation "likely reflects competing pressures physicians face regarding disclosure, because ethicists and patient advocates promote full disclosure while risk managers and malpractice insurers often urge restraint."
[192] *Id.* at 1592.
[193] W.S. §1-1-130(2005)

Medical Errors and Medical Injury Compensation.[194] Generally, a health court routes medical injury compensation claims to an administrative system, rather than the courts, and would increase the pool of injured patients eligible for compensation by including all patients whose injury was avoidable, not just the subset injured by negligence.[195] Avoidability refers to a type of injury caused by treatment or omission of treatment which should rarely if ever occur if care is provided according to best practice.[196] Compensation would be determined based on application of this general definition of avoidability as well as specific lists of "accelerated-compensation events" which are types of medical events resulting in injury that have been determined by an expert consensus process to be presumptively avoidable and therefore compensable. Compensation criteria would be "evidence-based" in the sense that they would be grounded in experts' interpretations of the scientific literature. This knowledge and the precedent of decisions rendered become decision aids that would permit efficient compensation decisions. *Ex ante* guidelines would help determine how much economic and non-economic damages should be awarded.

The occurrence of an adverse event would require the hospital to determine whether it fell within the class of events covered by the system. The insurer would be notified about the occurrence and the patient would be notified about her right to seek compensation under the program. Disclosure would follow a process similar to that of the COPIC risk management early intervention program. Failure to make a timely disclosure could trigger imposition of a fine by the insurer on the clinician or facility, if the insurer learned of the event from the patient prior to disclosure by the provider.

Patients seeking compensation would complete a simple claim form describing the event. In straightforward cases, patients could bring claims without engaging legal counsel, though they would have the right to do so. In the tort system, patients with low-value injury claims may be unable to find an attorney willing to take the case and therefore effectively be denied access to compensation, since the system is too complex to navigate without assistance of counsel. In a health court, patients with low-value claims would enjoy procedural accessibility to compensation.

The insurer or hospital would undertake the first level of review, which is designed not as a neutral adjudication so much as a mechanism to encourage expeditious settlement, using the decision aids previously mentioned. A patient unsatisfied with the decision at this level could request review by a health court, where a formally appointed administrative law judge specializing in health court adjudication would render a decision. The health court judge would review the claim *de novo*, and if necessary confer with court-appointed,

---

[194] *See*, *Report on Medical Errors and Medical Injury Compensation*, submitted to the Wyoming Health Care Commission by the Subcommittee on Medical Errors, October, 2005 at:http://www.wyominghealthcarecommission.org/reports.html

[195] Mello, MM, Studdert, DM, Kachalia, AB, and Brennan, TA, "Health Courts" and Accountability for Patient Safety, *The Milbank Quarterly*, 84:3, September, 2006, found at http://www.milbank.org/quarterly/8430feat.html

[196] *Id.* at 7

neutral medical experts in the relevant clinical area of the claim. Further appeal could be taken to a higher-level administrative tribunal, or directly to a state judicial court.

Health courts would have advantages for patient safety. Since the Institute of Medicine's report on medical error was released in 2000, there has been general agreement regarding the importance of building a culture of safety to reduce medical errors. Paramount to creating and maintaining a safety culture is disclosing information about errors to patients and sharing this information with entities that can facilitate analysis and learning among all health care institutions. Centralized reporting is crucial in building an evidence base to determine why errors occur and how they can be prevented. Tort litigation works at cross-purposes to promoting a safety culture based on open, honest disclosure. The litigation system encourages little or no disclosure to patients and once accused of negligence, physicians are reluctant to share information learned from the experience that would be beneficial to the safe practice of medicine.

Presently, only a small proportion of negligent injuries result in malpractice claims. Although these claims generate a tremendous amount of anxiety among providers, the system does not send the kind of consistent signal needed to spur changes in providers' behavior that result in improved safety.[197] Under a health court model, a greater proportion of injured patients would bring claims and the outcomes of those claims would be more predictable to providers. This should improve the "deterrence" of medical errors currently lacking in the tort litigation system, by increasing the certainty that negligent care will result in a claim and compensation. Of course, the fact that a greater proportion of avoidably injured patients will receive compensation under a health court model is an advantage in and of itself.

A health court would make the malpractice claiming process less adversarial and punitive than claims under the tort system. The tort liability system, particularly in these times of malpractice "crisis," creates an environment of care that is marred by mutual distrust in the physician/patient relationship, lack of candor about adverse events, an atmosphere of fear among physicians and stigmatization associated with making errors. Moving to a health court model would involve the replacement of the concept of negligence, which is individualistic and punitive in orientation, with the more systems-oriented concept of avoidability. Hopefully, a lessened degree of stigma would foster a greater willingness among health care providers to discuss preventable adverse events among themselves and with affected patients and a willingness to assist patients in filing claims for compensation rather than fighting such efforts

Patients would have less reason to believe that providers will "cover up" errors where they occur and physicians would have less reason to view every patient as presenting the potential for a devastating malpractice lawsuit. Describing classes of injuries through accelerated-compensation events and making that information available to the public should improve public awareness that medical care often involves bad outcomes; that some are preventable and some are not; and that there is a kind of social contract in place,

[197] Mello MM, Brennan TA. Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform, 80 *Tex. L. Rev*. 1595 (2002).

in which providers pledge that preventable injuries will be disclosed and compensated. All of these dynamics should result in an improved physician/patient relationship and environment of care.

The New Zealand Experience

A health court system is expected to offer faster, more reliable decisions and reduced uncertainty for providers and insurers regarding their liability exposure and the conduct required under the law. Some of these benefits are evident in the New Zealand system of compensation. In New Zealand, a government-funded compensation system has replaced a tort-based system of litigating malpractice claims. In place since 1974, the system is operated by the Accident Compensation Corporation (ACC).[198] Following several modifications, the system now provides compensation for all "treatment injuries" defined as "all personal injuries suffered while receiving treatment from health professionals."[199] Based on information provided by patients, their providers and advice from independent clinical advisers, simple claims can be processed in weeks and all compensation decisions must be made by the ACC within nine months.

New Zealand compensation awards can include payments for: **1) treatment and rehabilitation** (cost of pharmaceuticals, disability aides, child care, home modifications and vocational training; health care treatment is already provided); **2) compensation for loss of earnings** (includes weekly compensation of 80% of the claimant's earnings at the time of injury); **3) lump-sum compensation** (one time payment of up to $70,000 for permanent impairment); and **4) support for dependents**.

Overhead costs of compensating patients with treatment injuries in the New Zealand compensation system average less than 10% of the total cost of the system.[200] Wyoming's preliminary medical malpractice litigation data for 2005 suggests overhead costs of more than 50%. National study findings determined overhead costs of 54% for tort litigation.[201] While ACC compensation payments average $30,000, low by U.S. standards, this figure does not include most medical expenses, which New Zealanders receive through the country's universal health care system. Injured patients are offered "reasonable assistance, quickly and without rancor."[202] An interagency review of the New Zealand system in 2002 concluded "even an imperfect administrative compensation system [is] an improvement over the . . . medical malpractice system."[203]

Health Court Proposals in U.S. Legislatures

[198] Bismark M, Paterson R. No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability and Patient Safety, *Health Affairs*, 25:1, Jan/Feb 2006, 278-283.
[199] *Id.* at 280
[200] *Id.* at 281
[201] Studdert, *supra* note 163
[202] *Id*. at 282
[203] *Id*. at 280

Wyoming Senator Mike Enzi and Montana Senator Max Baucus have introduced legislation to create special health courts on a pilot project basis.[204] The bill known as the Fair and Reliable Medical Justice Act was first introduced in June 2005. The bill would foster alternatives to current medical tort litigation by promoting early disclosure of health care errors and prompt fair and reasonable compensation to injured patients, as well as promote patient safety and support and assist states in developing these alternatives.[205] States could choose to participate in specific model projects, including:

1) Early Disclosure and Compensation: A state would provide health care providers and organizations with immunity from suit if an error was disclosed and a timely offer made to compensate an injured patient for actual net economic loss, plus a defined and scheduled payment for pain and suffering if appropriate;

2) Administrative Determination of Compensation: A state would set up classes of avoidable injuries and establish an administrative board to resolve injury-related claims and develop a schedule of compensation to include payment for the patient's actual net economic loss, plus a defined and scheduled payment for pain and suffering if appropriate;

3) Special Health Care Court: A state would establish a special court for adjudication of disputes over injuries allegedly caused by health care providers and organizations, ensuring the presiding judges have expertise in and understanding of health care.[206]

In June 2006, the U.S. Senate Committee on Health, Education, Labor and Pensions held hearings on the bill and six prominent hospitals and academic medical centers have expressed strong interest in serving as a pilot project for a special health court.[207] The bill still lingers in Congress and may be addressed in the 2007 congressional session.

The Need for Demonstration Projects

Collecting detailed medical malpractice claims data is an important first step in understanding the complex relationships between medical errors, claiming behavior and the effects of malpractice reforms over time. However, the current data available from Wyoming and the few other states that require insurers to report basic information about closed claims focus on negligent care and thus provide only a relatively small view of the entire spectrum of avoidable injuries. Because most injuries due to negligence do not result in a malpractice claim and many injuries that are not due to negligence do become

[204] Senate File 1337, The Fair and Reliable Medical Justice Act, June 2006.
[205] *Id.*
[206] News release from Senator Mike Enzi's office, July 11, 2005.
[207] The hospitals include: Duke University School of Medicine and Health System, Durham, NC; Emory Healthcare, Atlanta, GA; Jackson Health System/University of Miami Leonard M. Miller School of Medicine, Miami, FL; Johns Hopkins Medicine, Baltimore, MD; New York-Presbyterian. The University Hospital of Columbia and Cornell, New York, NY and; Yale-New Haven Hospital/Yale Medical Group, New Haven, CT, Common Good news release, June 23, 2006.

claims, Wyoming's malpractice data will never truly reflect a complete picture of the state's frequency of medical adverse events.[208]

Initiatives aimed at encouraging disclosure and reporting of adverse events have experienced difficulties, partially due to the "dissonance between the culture of tort and the culture of disclosure" and fear of litigation.[209] Mandatory state reporting systems have experienced serious underreporting problems and hospitals seem to frequently fail to inform patients of unanticipated outcomes of care as required by JCAHO.[210] Health courts offer the promise of greater transparency by focusing on avoidable events resulting in suboptimal outcomes, which are far less stigmatizing to providers than negligent acts.

Small-scale demonstration projects are suggested by researchers who have studied these issues in-depth.[211] Initial demonstrations and compensation would be limited to clinical areas, such as obstetrics or anesthesia, in which types, range and causes of adverse outcomes are relatively well understood and which offer ample opportunity to obtain patient consent to participation in the pilot. As a matter of course, hospitals would conduct root-cause analysis of the injury, not only to determine compensability, but to improve care. A repository of information regarding patient safety could be established in the health court to serve as a source of precedent for adjudicators and a database to assist on-going research efforts in patient safety.[212] A feedback loop of detailed information from the health court to hospitals would assist hospitals in identifying quality problems and perhaps physician competency issues.[213]

A demonstration project would focus on covering a single liability insurer, or single institution in an enterprise liability model. Enterprise liability focuses on shifting malpractice liability from individual providers to healthcare enterprises such as hospitals and group practices, recognizing that the organizational unit responsible for efficient

---

[208] Mello MM. Medical malpractice: Impact of the crisis and effect of state tort reforms. May 2006 *Robert Wood Johnson Foundation* Research Synthesis Report No. 10.

[209] Mello, MM, Studdert, DM, Kachalia, AB, and Brennan, TA, "Health Courts" and Accountability for Patient Safety, *The Milbank Quarterly*, 84:3, September, 2006, found at http://www.milbank.org/quarterly/8430feat.html, citing Lamb, et al. 2003. Hospital Disclosure Practices: Results of a National Survey. *Health Affairs* 22(2):73-83.

[210] *Id.*, citing, Rosenthal, J, Riley, T and Booth M. 2000. *State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey.* Portland, Maine: National Academy for State Health Policy and Lamb, et al., *supra*, note 204.

[211] Corrigan, J.M., A. Griener, and S. M. Erikson. 2002. *Fostering Rapid Advances in Health Care: Learning for System Demonstrations.* Washington D.C.: National Academies Press. In January 2003, an Institute of Medicine committee endorsed experiments with administrative compensation in the form of either statewide systems or voluntary demonstration projects based at the level of individual liability insurers.

[212] Mello, et al., *supra* note 204

[213] *Id.* The authors suggest two reasons for referring quality problems identified through a health court system to hospitals instead of disciplinary boards: 1) experiences with other countries which implement a type of health court reveals physician participation, which is critical to the health court system, will not occur if the health court compensation process is enmeshed with discipline and; 2) following the national focus on medical errors, hospitals generally have demonstrated a "unprecedented commitment to patient safety."

health care delivery should also share the financial risk of medical errors.[214] Insurers or institutions and the patients they serve would participate in the demonstration project on a voluntary basis. Pennsylvania, which recently experienced a medical malpractice insurance crisis, has drafted a bill expected to be introduced in January, 2007, to create an administrative medical liability system demonstration project.[215] Demonstration grants for up to five years would be available to hospitals and physicians with hospital privileges for the development, implementation and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by hospitals or physicians. Projects will develop a uniform schedule for compensation, engage in early offers and provide for claim review by an independent panel, consulting with qualified medical experts.[216]

Research suggests a health court system would realize significant savings on the administrative and overhead costs of the current tort system, allowing more patients to be compensated, although at more modest levels.[217] More importantly, health courts may offer an important link to prevention of medical errors largely missing from today's tort system. By applying evidence-based decision guidelines and precedent in decision-making to a broader range of injured patients, a health court would increase understanding of the standard of care and the opportunity for suboptimal care to be recognized and foster improvement.[218]

Small-scale health court demonstration projects are advocated by Senator Enzi and health policy researchers who believe these systems will improve patient safety in ways tort litigation never can. A pilot project would provide an opportunity to determine whether the projected benefits of this type of compensation system will occur and address questions of fairness, corrective justice and cost.

---

[214] Sage WM, Hastings KE, and Berenson RA. Enterprise Liability for Medical Malpractice and Health Care Quality Improvement, *Am. J.L. and Med.* 20:1 (1994); Sage WM and Jorling JM. A World That Won't Stand Still: Enterprise Liability by Private Contract, *43 DePaul L. Rev.* 1007 (1993). Enterprise liability is more than theoretical and already exists in some healthcare delivery systems. Liability for negligent acts of physicians is expressly assumed by Kaiser-Permanente, the Veterans Administration, Indian Health Services, and the Public Health Service.

[215] General Assembly of Pennsylvania Senate Bill 1231.

[216] *See* Appendix F.

[217] Mello, et al., *supra* note 204.

[218] *Id.*