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Responding to patient safety incidents: the "seven pillars"

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ABSTRACT

Background Although acknowledged to be an ethical imperative for providers, disclosure following patient safety incidents remains the exception. The appropriate response to a patient safety incident and the disclosure of medical errors are neither easy nor obvious. An inadequate response to patient harm or an inappropriate disclosure may frustrate practitioners, dent their professional reputation, and alienate patients.

Methods The authors have presented a descriptive study on the comprehensive process for responding to patient safety incidents, including the disclosure of medical errors adopted at a large, urban tertiary care centre in the United States.

Results In the first two years post-implementation, the "seven pillars" process has led to more than 2,000 incident reports annually, prompted more than 100 investigations with root cause analysis, translated into close to 200 system improvements and served as the foundation of almost 106 disclosure conversations and 20 full disclosures of inappropriate or unreasonable care causing harm to patients.

Conclusions Adopting a policy of transparency represents a major shift in organisational focus and may take several years to implement. In our experience, the ability to rapidly learn from, respond to, and modify practices based on investigation to improve the safety and quality of patient care is grounded in transparency.

When patients suffer harm, most providers are ill-prepared to respond. Abandonment of care providers and patients is common.[1] The tendency to "shame and blame" often perpetuates the "wall of silence"[2] between providers and patients. Disclosure related to a patient safety incident, defined as "an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient",[3] is warranted out of consideration for patient autonomy. Disclosure and investigation can help providers learn about problems of care delivery, prompt system improvements and reduce future harmful incidents.[4]

Disclosure is a process requiring careful planning, preparation and coordination by providers and hospital administrators. Given its complexity, providers understandably fear that inadequate or poorly executed disclosure only frustrates practitioners, ruins the reputation of the organisation and practitioners involved in the incident and alienates patients.[5–8] Few published descriptions of processes responding to patient safety incidents are available.[9 10] To bridge this void, we describe the "seven pillars" that constitute a comprehensive process for responding to patient safety incidents, including full disclosure of harm-causing unreasonable care, that has been in operation at a large tertiary care medical centre in the Midwestern USA for under two years.

SITE

The University of Illinois Medical Center at Chicago (UIMCC) is a 450-bed academic affiliated tertiary care centre in Cook County, Illinois. UIMCC cares for >19 000 inpatients and 450 000 outpatients annually. In 2004, the UIMCC implemented a comprehensive process for responding to patient safety incidents resulting in patient harm. This evolved to include full disclosure in April 2006.

GUIDING PRINCIPLES

The process is grounded in five principles (table 1).

These closely follow the principled approach[11] adopted by the University of Michigan Health System[12] (principles 1–3), with two supplemental principles grounded in a "just culture" approach (principles 4 and 5). The process strives to hold blameless providers involved in systems-induced incidents but enforces a standard of corrective action for individuals demonstrating a reckless disregard for patient safety.[13] The comprehensive process for responding to patient safety incidents at the UIMCC (figure 1) diverges from other published programmes by providing a direct link between patient harm and improved patient care. We describe the "seven pillars" of a comprehensive process for responding to patient safety incidents.

THE "SEVEN PILLARS"

Patient safety incident reporting

Reporting is the first pillar and triggers the process. The UIMCC encourages professionals and even patients to report any patient safety incident to its safety and risk management department. Reports can be made by telephone, hand-written, and online (all can be anonymous), and in-person. A risk manager is available 24/7 to receive and respond to patient safety incidents. Staff who promptly report patient safety incidents are applauded and recognised in *Safe-Times*, the UIMCC's patient safety newsletter. On the other hand, clinical departments are financially penalised through medical malpractice premium allocations for failing to report patient safety incidents involving patient harm. After the institution of these efforts, the number of patient safety incident reports doubled. This first "pillar" supports the premise that risk management depends on a robust "reporting culture".[14]

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Table 1 Guiding principles of the comprehensive process for responding to patient safety incidents at the UIMCC

1. "We will seek to provide effective and honest communication to patients and families following patient safety incidents involving patient harm."
2. "We will apologise and provide rapid compensation when inappropriate or unreasonable medical care causes patient harm and defend vigorously care that we believe was appropriate."
3. "We will learn from our mistakes."
4. "Reckless behaviour will be subject to corrective action."
5. "We will provide support services for providers involved in patient safety incidents (the "second patient"(13))."

Investigation

Investigation is the second pillar. The risk manager on call conducts a preliminary review of the patient safety incident to ascertain if patient harm[3] has occurred (figure 1, decision 1). If "no", the incident information is entered into the database for future determination if the incident was a "near miss" and worthy of further analysis.[3] If harm has occurred, the Chair of the Medical Staff Review Board (MSRB), a committee of medical, professional, and administrative staff charged with oversight of the patient safety incident management process, convenes an investigation and appoints a rapid investigation team to collect information and perform a root-cause analysis (RCA) of the incident.

The rapid investigation team is charged with conducting a thorough multidisciplinary investigation with RCA within 72 h of the patient safety incident report to determine, inter alia, whether care was reasonable or not (figure 1, decision 2). The results of the investigation are presented to the MSRB for deliberation, determination of underlying cause and accountability, and for process and quality improvement recommendations. The MSRB use Reason's[15 16] algorithm of unsafe acts to guide its determination of personal culpability versus systems failures. Using a standardised approach to determine culpability is essential to promoting a fair and just culture.

Communication and disclosure

Communication, the third pillar, is the centerpiece of the process. The UIMCC maintains ongoing communication with the patient and family from report through investigation and resolution. Facts revealed during the investigation drive the communication (figure 1). In general, only the findings surrounding the incident that are reasonably certain and unlikely

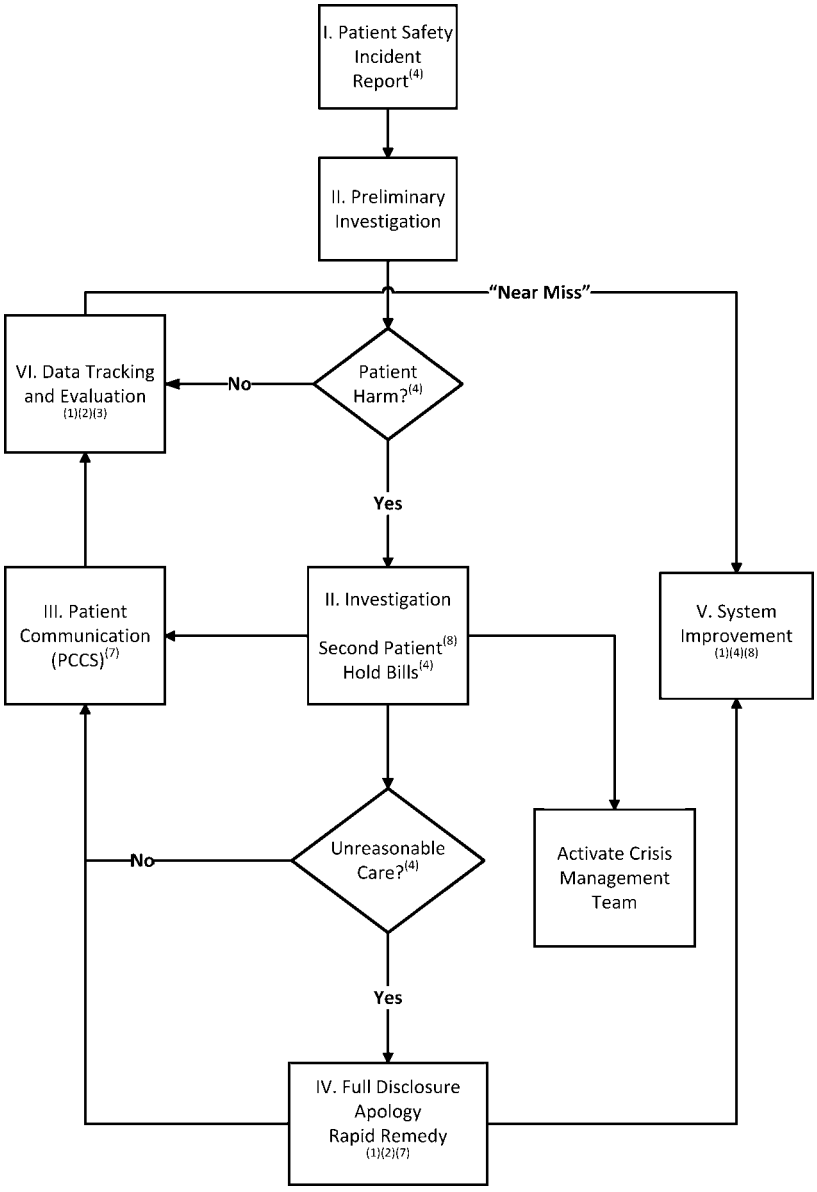

Figure 1 The comprehensive process for responding to patient safety incidents at the University of Illinois Medical Center at Chicago. National Quality Forum "Safe Practices" (19). 1—structures and systems; 2—culture measures and interventions; 3—team training and team interventions; 4—identification and mitigation of risks and hazards; 7—disclosure; 8—care for the care provider. PCCS, Patient Communication Consult Service.

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to change as the investigation proceeds are communicated to the patient. In all cases, the assessment of "reasonable" or "unreasonable" care, the process of determining "reasonableness" and the results of the RCA are communicated to the patient and family. If consensus on "reasonableness" cannot be reached, the patient and family are offered a third-party peer review. If, however, consensus deemed care "unreasonable", the team will move forward with a full disclosure of the unreasonable care and how harm was caused. In all cases, a patient liaison is assigned to address any subsequent concerns.

Full disclosure is a process, not an event. Communicating the details of a patient safety incident involves a series of meetings. In most cases, the responsible care provider is part of and often leads the disclosure and delivers the apology if an apology is indicated. The information provided to the patient at each step in the communication process is guided by Gallagher and Quinn's[8] "balance beam", which considers the facts of the case as they are revealed during the investigation and may ultimately involve an apology, admission of unreasonable care and accountability. This approach guides the timing and content of the disclosure discussions and "balances" the benefit of early disclosure against the risk of prematurely disclosing information and conclusions that may later turn out to be incorrect.

To facilitate conversations between the patient and provider, the UIMCC developed the Patient Communication Consult Service (PCCS). The PCCS is a group of volunteers composed of health care providers from every department within the UIMCC who have received training in the complex communications after patient safety incidents. PCCS members are available at the request of a provider to facilitate communication with a patient or family for any reason, and providers are expected to ask a PCCS member to be present during a full disclosure. PCCS members help to ensure that the disclosure includes "an apology for any unreasonable care, what happened, and the link between the unreasonable care and outcomes in a manner that is meaningful to the patient"[17] and to ensure the quality of the disclosure process.

Apology and remediation

Apology and remediation encompass the fourth pillar. In our experience, saying "we are sorry" without any subsequent action is inadequate because no remedy has been offered. Thus, when an investigation reveals that the patient harm resulted from unreasonable care, in addition to an apology, our process includes a mechanism to provide rapid remediation and an early offer of compensation, if warranted. Rapid remediation involves immediately holding and subsequently waiving hospital bills once consensus on the failure to provide reasonable care has been reached. Concurrently, a rapid settlement team works with the patient or their legal representative towards a swift resolution of financial claims or extends an early offer of compensation.

System improvement

The process does not end with full disclosure, apology, rapid remediation and early offer. Each investigation's findings are used to identify and implement system improvements—the fifth pillar. System improvements are aimed at preventing a recurrence of system breakdowns and identifying latent conditions. Patients and families are invited to actively participate in this process. The MSRB is responsible for evaluating the proposed system improvements, overseeing quality metrics for effectiveness and reporting progress to oversight committees. Risk management and quality specialists collect and analyse the data. Through this methodology, safety, risk management and quality experts become intertwined in the collaborative effort to improve patient safety.

Data tracking and performance evaluation

Data tracking and analysis are the sixth pillar. Data collected include type of patient safety incident, investigations, disclosures, financial, legal and public relations implications of the event, system improvements, and number and quality of PCCS encounters. These data are used for internal quality assurance, research, public outreach and dissemination. The safety and risk management department maintains the patient safety incident management database and reports medical malpractice and patient safety trend data to the UIMCC administration on a quarterly basis.

Education and training

To improve transparency, the UIMCC has established initial and continuing training requirements for professional, administrative and support staff—the seventh pillar. Educational requirements are met through annual competency assessments, monthly organisation-wide patient safety and PCCS educational programmes, grand rounds, unit-specific patient safety and disclosure training, and train-the-trainer programmes. The level of training ranges from didactic to experiential using standardised patients and role plays. Training modules are case-based, drawn from experiences within the UIMCC. In addition, risk management, departmental supervisors and PCCS staff are trained to identify the need for support and to refer providers to the second patient program. This programme includes peer—peer support, individual and group employee assistance and fitness-to-work assessments as needed. All care providers involved in an event associated with harm are encouraged to actively participate in the communication process and disclosure as part of their healing and learning processes.

LESSONS LEARNED

Since the inception of the process, the UIMCC has seen no increase in lawsuits and no increase in payouts from our self-insurance fund related to full disclosure. Although this conclusion is preliminary, the university's actuaries are encouraged that the financial "Armageddon" predicted by Studdert *et al*[18] has not occurred. Summaries of the outcome metrics for the first 2 years are presented in tables 2—4. The process requires significant institutional investment in risk management and an

Table 2 Summary of 2-year disclosure experiences

	2006—2007	2007—2008
Patient safety incident reports (n)	2069	2353
Patient harm	359	407
Full disclosure	6	13
System improvements	114	75
Patient communication consultations (n)	37	90

Table 3 Patient safety incident reports by provider reporting

	2006—2007 (n=2069)	2007—2008 (n=2353)
Physician	72	97
Nurse	1324	1447
Pharmacist	7	37
Applied health professional	201	171
Patient or family member	10	7
Anonymous/Other	455	594

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Table 4 Personnel resources

	Cost centre	Staff	n	Time
Risk managers	UIMCC	Nurse	5	FTE
		Informaticists	0.5	FTE
Patient communication consult service	Volunteer	Physicians	30	1—5 h/month
		Nurses	100	
		Administration	20	
Medical staff review board	Volunteer	Physicians	11	2—3 h/month
		Nurses		2
		Pharmacists		1
		Administrators		4
		Quality		1
		Safety		5
		Information systems		1
Patient safety committee	Volunteer	Physicians	4	2—3 h/month
		Nurses		2
		Administrators		2
		Researchers		2
		Quality		1
		Safety		5
		Information systems		1

FTE, full time equivalent.

organisational commitment to provide swift peer review support when called into action.

In addition, our experiences have yielded several valuable lessons generalisable to any organisation considering a transparent process for responding to patient safety incidents. First, the decision tree (figure 1) is continually evolving, influenced by each patient safety incident. The process and its seven essential components work harmoniously to meet 6 of the 34 National Quality Forum Safe Practices (19; figure 1) allowing for direct extrapolation from transparency to patient safety. Second, risk management has emerged central to the pursuit of safety in managing the risk of the institution and managing future patient risk through systems improvement. Risk managers are trained to recognise provider stress and direct them to peer support services, adding an essential front-line layer to improving safety by providing "care to the caregiver" (National Quality Forum Safe Practice 8: "Care of the Care Giver"[19]). Third, the timeliness of responding to any patient safety incident is crucial. Any delay in communication may be misconceived as subterfuge. Thus, the immediate communication with the family is essential to opening and maintaining the lines of communication, thereby engendering trust in the process and making the patient and family key partners in the process. Fourth, adoption of the patient safety incident response process including full disclosure has resulted in an organisation-wide shift towards a patient-safety rich culture.

SUMMARY

In the USA, the disclosure of medical errors to patients remains the exception. In this report, we describe the "seven pillars" that constitute the comprehensive patient safety incident response process at the University of Illinois Medical Center at Chicago. The pillars were designed to provide all members of the UIMCC with the confidence and resources to adopt a culture of safety, transparency, inquiry and medical error disclosure. Adopting a policy of transparency related to patient safety incidents represents a major shift in organisational focus and may take several years to implement. It requires strong and persistent endorsement by leadership. The ability to rapidly learn from, respond to and modify practices based on investigation to improve the safety and quality of patient care is grounded in transparency.

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REFERENCES

1. **Leape LL,** Berwick DM. Five years after *To Err Is Human*: what have we learned? *JAMA* 2005;**293**:2384—90.
2. **Gibson R,** Singh JP. *Wall of silence: the untold story of the medical mistakes that kill and injure millions of Americans* Lifeline Press, 2003.
3. WHO International Classification of Patient Safety. Technical Annex 2—Glossary of Patient Safety Concepts and References Version 1.1, January 2009. 14:45 CDT. http://www.who.int/patientsafety/taxonomy/icps_technical_annex2.pdf (accessed 5 Mar 2009).
4. **Leape LL,** Bates DW, Cullen DJ, *et al*. Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA* 1995;**274**:35—43.
5. **Hickson GB,** Federspiel CF, Pichert JW, *et al*. Patient complaints and malpractice risk. *JAMA* 2002;**287**:2951—7.
6. **Gallagher TH,** Studdert D, Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med* 2007;**356**:2713—19.
7. **Gallagher TH,** Garbutt JM, Waterman AD, *et al*. Choosing your words carefully: how physicians would disclose harmful medical errors to patients. *Arch Intern Med* 2006;**166**:1585—93.
8. **Gallagher TH,** Denham CR, Leape LL, Amori G, Levinson W. Disclosing Unanticipated Outcomes to Patients: The Art and Practice *J Patient Saf* 2007;**3**:158—165.
9. **Pichert JW,** Hickson GB, Vincent C. Communicating about unexpected outcomes and errors. In: Carayon P, ed. *Handbook of human factors and ergonomics in healthcare and patient safety*. Hillsdale (NJ): Erlbaum Associates, 2007:579—598.
10. **Kaldjian LC,** Jones EW, Wu BJ, *et al*. Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals. *Arch Intern Med* 2008;**168**:40—6.
11. **Kraman SS,** Hamm G. Risk management: extreme honesty may be the best policy. *Ann Intern Med* 1999;**131**:963—7.
12. **Boothman RC.** Apologies and a strong defense at the University of Michigan Health System. *Physician Exec* 2006;**32**:7—10.
13. **Wu AW.** Medical error: the second victim. *BMJ* 2000;**320**:726—7.
14. **Kohn LT,** Corrigan JM, Donaldson MS, eds. *Committee on quality of health care in America, Institute of Medicine. To err is human: Building a safer health system*. Washington, DC: National Academy Press, 2000.
15. **Reason J.** Human errors: models and management. *BMJ* 2000;**320**:768—70.
16. **Reason J.** *Managing the risks of organizational accidents*. Hampshire (England): Ashgate Publishing Limited, 1997.
17. **Fein SP,** Hilborne LH, Spiritus EM, *et al*. The many faces of error disclosure: a common set of elements and a definition. *J Gen Intern Med* 2007;**22**:755—61.
18. **Studdert DM,** Mello MM, Gawande AA, *et al*. Disclosure of medical injury to patients: an improbable risk management strategy. *Health Aff (Millwood)* 2007;**26**:215—26.
19. **National Quality Forum (NQF).** *Safe practices for better healthcare—2009 update: a consensus report*. Washington, DC: NQF, 2009.

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