



Striking A Balance: Who Is Accountable for Patient Safety?

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ILLUSTRATIVE CASE

An elderly patient develops acute pulmonary edema. The junior resident physician and nurse are providing urgent care. The physician asks for 2 mg of morphine to be given intravenously. The nurse selects a 10 mg ampoule, draws up the 10 mg dose, and gives it to the physician. The junior resident physician injects the entire dose. The patient quickly loses consciousness and develops a very slow respiratory rate. An antidote (naloxone) is given, and the patient recovers.

How should an organization manage this case from a safety perspective?

INTRODUCTION

The cornerstone of the patient safety movement is the systems approach, which is based on the theory that preventable adverse events are caused by the interaction between imperfectly designed systems and human error. Healthcare institutions that wish to enhance patient safety must strike an appropriate balance between focusing on the system of care and the individual members of the healthcare team. Our challenge was to understand the role and responsibilities of individual staff and our hospital as we tried to endorse and implement the systems approach.

STATEMENT OF THE PROBLEM

The role of individual staff in the systems approach must be carefully explored. One important element of the systems approach for individual staff is the concept of “non-punitive” or “blame-free” reporting of adverse events and incidents. These terms are intended to encourage voluntary staff reporting by removing the fear of punishment and blame.

We encountered two problems early in our attempts to share the systems approach within the hospital. First, some members of our senior leaders and board members expressed concern that a blame-free reporting policy suggested that the hospital was no longer being fully accountable for errors and patient safety in the care of the patients. If the individual healthcare provider was not accountable for safe care, who was? Second, we encountered some isolated events that suggested individual staff could misinterpret the intent of the systems approach. We heard of one student who stated that they had learned that “errors weren’t their fault, it was the hospital’s fault.” We also attended a committee meeting where a staff member was discussing an adverse event, and a similar sentiment was expressed.

(BEGINNING) OF A RESOLUTION TO THE PROBLEM

Other organizations had also begun to apply the systems approach, so we sought guidance and clarity from those

organizations. We learned three key concepts: balance, limited exclusion, and continuum. We learned the concept of balance at a local patient safety meeting in a presentation by a group from Toronto's Hospital for Sick Children. They talked of a "just" culture where the responsibilities of the individual are balanced with the responsibilities of the system. The systems approach shifts the balance of attention towards the system, but individuals must play an active role in system improvements, and there will be situations where individuals require remediation or discipline.

We learned the concept of limited exclusion from the Veteran's Administration National Centre for Patient Safety (NCPS) training program in June 2002. The NCPS staff generously shared their experience, knowledge and materials. Their algorithm for safety investigations states that certain events are outside of the scope of a safety review. These events could include episodes of deliberate harm, staff illness, patient abuse or practising outside one's scope of professional practice. A formal safety review could only occur once these issues had been screened out, and referred for institutional review, with possible remediation or discipline.¹

Finally, we learned the concept of continuum at the Institute for Health Care Improvement (IHI) Patient Safety Officer Training Program in September 2004. There was a very helpful discussion on managing "unsafe acts," with heavy reliance on the United Kingdom's National Health Service (NHS) experience. The NHS has developed a Decision Tree for Unsafe Acts and an accompanying reference guide.² (Figure 1) This extremely useful material describes a continuum of unsafe acts, from honest mistakes through deliberate deviations from established protocols to deliberate attempts to harm. It outlines steps to be taken at the level of the individual and the system for each type of event along the continuum.

Together, these experiences helped us to formulate the concept of "shared accountability" for patient safety. The concept of balance told us that the individual and the system share accountability for patient safety. For each unsafe act, the individuals involved and the system (hospital) have clear accountabilities. The nature of these accountabilities will depend on where the event falls along the continuum. The conceptual shift is that the majority of unsafe acts will represent honest mistakes within a complex and imperfect system of care. In this case, the individual's accountability includes: (i) taking necessary steps to mitigate harm to the patient, (ii) reporting the incident, (iii) disclosing the event to patient and family when appropriate, (iv) participating in system review, (v) participating in development and implementation of improvement, (vi) making use of staff support services when needed.

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The framework also addresses less common scenarios:

1. The event represents a significant deviation from accepted practice
2. The event involves a deliberate violation of an existing policy or protocol
3. The event involves a staff member suffering from illness that is affecting their ability to work safely
4. The event involves the intentional attempt to harm a patient

In these subsequent scenarios, the accountabilities of the system and individual are somewhat different. In each case, there is an assessment for mitigating factors, an evaluation of the availability and usability of existing protocols, an assessment of training and supervision. We expect that deficiencies in the design and implementation of protocols and procedures, training or supervision will often be uncovered. In some situations, however, there will be concerns for recklessness, incapacity or intentional harm, leading to additional responses focused on the individual.

POLICY DEVELOPMENT

Two of us (BJ and EE) drafted the initial policy, and had frequent consultation with the Executive Vice-President for Medical and Academic Affairs/Chief Medical Executive (BL), and the Director of Labour Relations (BM). We found it extremely helpful to gather input from a wide group. Most important, we sought input from occupational health, the Chief of Health Disciplines, the director of nursing and the vice-president for education and medical affairs. A draft policy was presented to several groups, including the senior leadership committee, the medical advisory committee, the nursing advisory committee and the professional advisory committee (representing the allied health professions). The policy was then presented to the quality subcommittee of the board for review. We did not encounter any significant concerns on this second "go-around." The concepts of balance, limited exclusion and continuum seemed to have addressed concerns that had previously been raised.

The policy was accepted in February 2005.

1. <http://www.patientsafety.gov/SafetyTopics/CogAids/triage/index.html>. Accessed July 5 2005.

2. http://www.npsa.nhs.uk/health/resources/incident_decision_tree. Accessed July 5 2005.

Figure 1: Individual and system accountabilities for different types of unsafe acts, based on the NHS framework. This is a sample framework and specific actions could vary from case to case.

	Individual	System
Honest mistake	<ul style="list-style-type: none"> • Report incident • Participate in systems review • Suggest remedial actions • Assist in development and testing of remedial actions 	<ul style="list-style-type: none"> • Safety alert within and beyond organization when appropriate • Systems review • Develop improvements • Implement improvements
Honest mistake but fails substitution test	<ul style="list-style-type: none"> • As above plus • Additional training • Mentoring program when available 	<ul style="list-style-type: none"> • As above • Search for mitigating factors such as training, supervision, workload
Deliberate violation of protocol	<ul style="list-style-type: none"> • As above plus • Consult with professional organization 	<ul style="list-style-type: none"> • As above • Internal investigation • Search for mitigating factors such as training, supervision, workload • Modification of duties when appropriate
Possible ill health of staff, including substance abuse	<ul style="list-style-type: none"> • As above, plus • Assessment and treatment based on human resources and occupational health policies and procedures 	<ul style="list-style-type: none"> • Internal investigation • Notify occupational health • Notify professional colleges when appropriate • Modification of duties when appropriate
Intentional harm or criminal act	<ul style="list-style-type: none"> • Seek counsel 	<ul style="list-style-type: none"> • Internal investigation • Notify VP professional affairs and service chief • Notify police when appropriate • Notify professional colleges when appropriate • Suspension if patients or staff are perceived to be at immediate risk

POLICY IMPLEMENTATION

We are now in the process of implementing the policy. (Figure 2). First, although we were pleased at the relatively smooth policy development, we were unsure about the existing staff beliefs regarding safety climate. We undertook a safety climate survey in May 2005. We achieved a 20% response rate, and we are currently analyzing the results. The results of the climate survey will help us develop proper resources for staff.

Second, we wanted to begin detailed discussions with staff who will be most affected by implementing the policy. We believe that front-line clinical staff will ultimately find the policy helpful and relatively undemanding. However, directors, managers, professional practice leaders and educators will experience new challenges. We will need the input and feedback from these groups as we implement the policy. As a starting point, we implemented “Safety Leadership Sessions” in April 2005. The purpose of these rounds is to communicate key safety developments within the organization to this target group, and to provide a forum for dialogue and discussion. Our CEO and Board Chair opened the first rounds in April 2005. All rounds

Key Issues


1. Ensuring climate is right for more detailed implementation
2. Identify needs of program directors and managers
3. Providing appropriate training and resources
4. Ensuring that existing safety mechanisms are in harmony with policy (especially e-reporting)
5. Ensuring that staff and management have proper tools to ensure responsiveness to reported incidents

were well-attended (average 40 attendees) and evaluations were uniformly positive.

Concurrently, we implemented Patient Safety Walk Arouns. The purpose and conduct of these rounds is described in a separate article in this journal. We believed that these rounds were an essential complement to the accountability policy; our senior leaders were demonstrating their accountability to patients and staff by learning about and acting on issues raised by unit staff.

Figure 2

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Patient Care Policy Manual

Title: **Accountability for Patient Safety**

Policy No: **I-P-2800**

POLICY STATEMENT:

It is a strategic goal of Sunnybrook and Women's to be the safest hospital in Canada.

To create a culture that will support this goal Sunnybrook and Women's has adopted the following principles about patient safety that will guide S&W employees, physicians, students, volunteers & agents of the hospital [these categories of individuals will be referred to collectively as 'staff' throughout this policy]:

1. The organization and each individual staff member share the accountability for ensuring the safest possible patient care and service.
2. Staff reports of errors, near misses and adverse events are a critical component of patient safety and must be reported diligently and without fear of reprisal by all staff.
3. The majority of errors, near misses and adverse events involve competent and caring staff interacting with complex systems. S&W responds to reports of errors, near misses and adverse events by carefully examining and improving the systems of care.
4. S&W needs and values the participation of staff and professionals in the investigation of the system of care, and in creating and testing improvements.
 - a. S&W will create and foster a supportive environment for all staff and professionals to report errors, near misses and adverse events.
 - b. S&W will track errors, near misses and adverse events, so that we can identify trends and patterns that require investigation and improvement.
5. S&W has a responsibility to address the actions of individual(s) when their actions fail to meet professional, patient care and/or service standards. These situations include:
 - a. Intentional acts meant to harm or deceive.
 - b. Physical or mental impairment of staff.
 - c. Substance abuse by staff.
 - d. Staff incompetence. If it becomes clear that a staff member cannot practice in a reliably safe manner, in spite of education and counseling, this situation will be treated as a staff competency issue in accordance with professional standards and Human Resource principles.

DEFINITION(S):

Error:
Any act of omission or commission that occurs in the planning or delivery of patient care or service.

Near Miss:
Any error or hazardous situation that was identified and resolved before any patient consequence occurred.

Adverse Events:
Negative patient outcomes that occur as a result of health care treatment and are not due to the patient's illness. They are often unanticipated and unintended outcomes of health care that do, or have the potential to, negatively impact a patient's health and quality of life. They include complications and side effects of treatment as well as errors in performance of health care duties. Adverse events are not necessarily markers of substandard care.

System:
The system of care, beginning with individual staff, and including teamwork, staffing, training, supervision, environment, equipment, procedures, policies, and resources.

The S&W Intranet version of this document is considered the most current

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Finally, a climate of safety will only be maintained by developing skills in conducting system reviews and implementing wise safety improvements. We will use the Safety Leadership Sessions as a forum for demonstrating principles and methods for system review. Our initial sessions focused on key elements of high reliability organizations, and basic principles of Human Factors. We will be providing a series of more detailed human factors training sessions over the summer of 2005.

ONGOING CHALLENGES

We were pleased at the uniform positive response for the policy. It seemed to set the proper balance between individual and system accountability. The challenge will be for supervisors, managers and directors to actually strike that balance when faced with incidents. We anticipate there will be difficult cases where the proper balance will be difficult to establish. The most difficult situations will involve extreme deviations from usual practice that test the meaning of “honest mistake,” and judging whether there are sufficient mitigating factors when there is a deliberate violation of existing protocol. However, these difficult situations exist currently. We believe that the new policy represents an advance, because the majority of events will almost certainly fall into the category of honest mistake, where the desired response will be to support the individuals involved and conduct a systems review. Staff will know what to expect when such an incident is reported, the hospital will be able to conduct a wise and efficient systems review and, ultimately, will be able to implement and test wise safety improvements.

BACK TO THE CASE

An elderly patient develops acute pulmonary edema. The junior resident physician and nurse are providing urgent care. The physician asks for 2 mg of morphine to be given intravenously. The nurse selects a 10 mg ampoule, draws up the 10 mg dose and gives it to the physician. The junior resident physician injects the entire dose. The patient quickly loses consciousness and develops a very slow respiratory rate. An antidote (naloxone) is given, and the patient recovers.

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MANAGEMENT

The nurse went back to check the narcotics drawer after the patient had improved. She recognized her error. She completed an incident report, notified her manager and the attending physician.

The manager quickly judged that this was an honest mistake. There was certainly no evidence of deliberate harm or staff illness. The nurse had followed all established protocols for ordering and dispensing of narcotics. Selecting the wrong drug during an emergency situation was an error that could

occur to any competent practitioner; in fact, a similar incident had occurred the week before with different staff caring for a different patient. The manager thanked the nurse for reporting the incident, and a systems review was undertaken with the active involvement of the nurse and physician. Important findings included:

- (i) the packaging for the 2 mg and 10 mg ampules had recently been changed
- (ii) there was a remarkable similarity in appearance in the external packaging between the 2 mg and 10 mg ampules

The finding was reported to the Institute for Safe Medication Practices-Canada. ISMP Canada worked closely with the manufacturer, and a new distinct design for the 10 mg package was introduced within months of the report. The staff involved in the incident received feedback regarding the change in packaging.

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