

The Joint Commission

# Journal on Quality and Patient Safety®

Improvement from  
Front Office to Front Line

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## The Anatomy of a Hospitalwide Quality Improvement Initiative

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*“The decision to implement hospitalwide QI initiatives requires a huge practice change in most institutions, particularly in large hospitals.”*

—Horst et al. (p. 291)



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## Performance Improvement

# A Tight Glycemic Control Initiative in a Surgical Intensive Care Unit and Hospitalwide

H. Mathilda Horst, M.D.; Ilan Rubinfeld, M.D.; Mark Mlynarek, R.Ph., B.C.P.S.; Mary-Margaret Brandt, M.D.; Gail Boleski, M.S.N., R.N., C.C.R.N., A.C.N.S.-B.C.; Jack Jordan, M.S.; Gwen Gnam, M.S.N.; William Conway, M.D.

Quality improvement (QI) initiatives, many involving clinical interventions, entail a cultural journey that institutions must undergo to achieve effective and lasting practice change.

In the area of glycemic control, Murphy et al.<sup>1</sup> recently reported on a hospitalwide QI initiative for blood glucose control, and Lipshutz et al.<sup>2</sup> highlighted the application of the Plan-Do-Study-Act (PDSA) model to implement change in their own tight glycemic control (TGC) initiative. In this article, we review implementation of TGC in a 40-bed surgical intensive care unit (SICU) throughout a large hospital, which involved modification of the target ranges in the TGC protocols in response to changing evidence. We also discuss how we addressed cultural and other organizational barriers during QI project planning and implementation.

## Planning for Practice Change

The decision to implement hospitalwide QI initiatives requires a huge practice change in most institutions, particularly in large hospitals. Physicians, nurses, pharmacists, executive- and local-level administrators, and other health care professionals all bring their individual, professional group-, and organizational unit-level cultural and behavior patterns to a QI team initiative. For intensive care clinical practice, teams of physicians, nurses, pharmacists, and others are required to implement the change at the bedside. Multidisciplinary team barriers to adoption of new practice change include the following:

- **Cultural-historical:** Care traditions and training may directly contradict the new approach to patient care.
- **Communications and teaming:** Multiprofessional communication always comes with increased complexity, communications needs, and frictional losses.
- **Resources:** Although quality initiatives are intended to save lives and may prove to reduce health care expenses in the long run, resources and increases in time and expense are potent barriers to change.

## Article-at-a-Glance

**Background:** In 2002, tight glycemic control (TGC) was mandated at Henry Ford Hospital (Detroit) to reduce surgical site infections (SSIs).

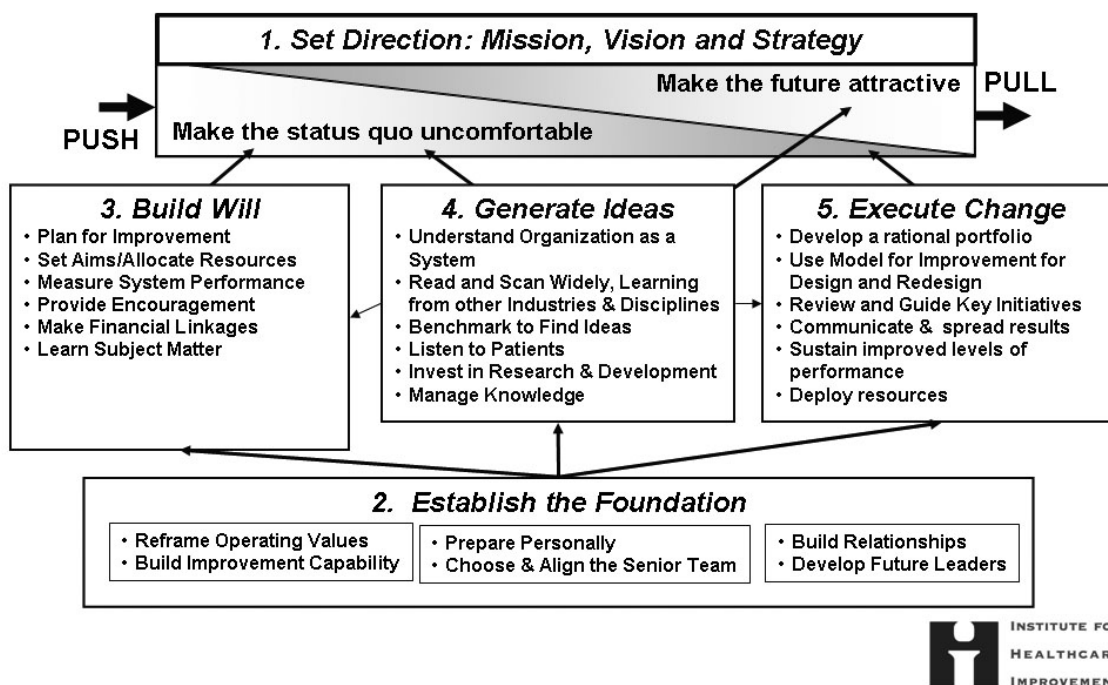
**The Five Steps for Improvement:** The TGC initiative was developed in terms of the five primary steps of the Institute for Healthcare Improvement (IHI) framework for leadership for improvement to drive practice change and maintain continuous improvement. In terms of Steps 1–3 (set direction, establish the foundation, and build will), in April 2002 the chief executive officer of the Henry Ford Hospital (Detroit) announced a hospitalwide initiative to reduce SSIs. For steps 4 and 5 (generate ideas and execute change), the 40-bed surgical intensive care unit (SICU) was designated the practice-change setting. TGC protocols were implemented in cardiothoracic patients, followed by all SICU patients, with target glucose ranges moving from the initial < 150 mg/dL to 80–110 mg/dL. Results showed decreases in SSIs and mortality. The project's success led to initiation of hospitalwide TGC in the next two years.

**Responding to a Changing Evidence Base:** In 2009, as studies began to show that the recommended glucose target of 80–110 mg/dL was not associated with clinical improvement in ICU patients and perhaps may cause harm (increased mortality), the target ranges were modified.

**Lessons Learned:** Barriers to adoption of new practice change must be integrated into the planning process. Leadership champions are required across multiple levels of the organization to drive change to the bedside for effective and lasting improvement.

**Conclusions:** A universal TGC protocol continues to be used throughout the hospital, with modifications and next-generation improvements occurring as evidence arises.

The Institute for Healthcare Improvement Framework for Leadership for Improvement



**Figure 1.** The tight glycemic control initiative followed the five primary steps of the Institute for Healthcare Improvement (IHI) framework for leadership for improvement to drive practice change and maintain continuous improvement. Reprinted with permission from Reinertsen J.L., Bisognano M., Pugh M.D.: Seven Leadership Leverage Points for Organization-Level Improvement in Health Care (Second Edition). IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement, 2008. <http://www.ihc.org/IHI/Results/WhitePapers/SevenLeadershipLeveragePointsWhitePaper.htm> (last accessed May 18, 2010).

■ Data: Perceptions generally are more potent persuaders than inconsistent data, and the lack of data leads to universal adoption of assumptions based on perceptions. Changing the mind-set to the pursuit of data reporting and quality metrics presents an enormous barrier to change and improvement.

Each of these cultural and organizational factors must be addressed and integrated into the QI planning process. For implementation of TGC at our institution, multiple teams of multidisciplinary leaders were essential to drive change at the various points of bedside care, such as from the operating room (OR) to SICU to inpatient ward, during a patient’s hospitalization.

**The Five Steps for Improvement**

The TGC initiative illustrates the use of the five primary steps of the Institute for Healthcare Improvement (IHI) framework for leadership for improvement<sup>3</sup> (Figure 1, above) to drive practice change and maintain continuous improvement. These five steps were followed as shown in the time line (Figure 2, page 293).

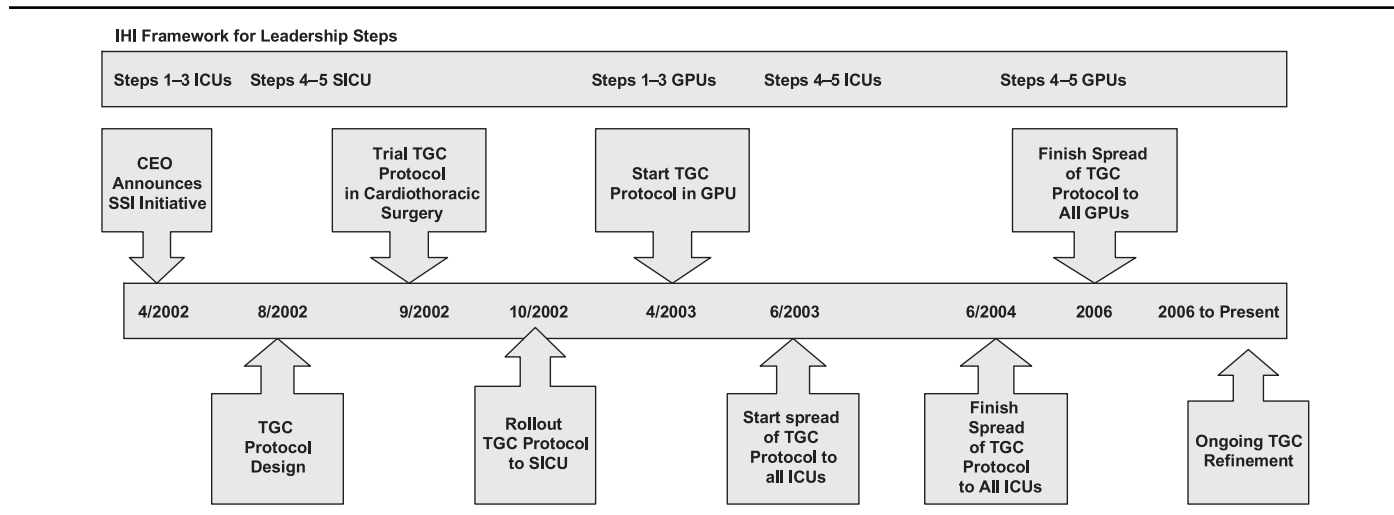
**IMPROVEMENT STEPS 1–3: SET DIRECTION, ESTABLISH THE FOUNDATION, AND BUILD WILL**

In April 2002, the chief executive officer (CEO) of the Henry Ford Hospital (Detroit), a 900-bed, urban tertiary hospital, announced a hospitalwide initiative to reduce surgical site infections (SSIs). The hospital’s administrative vice president, who was designated the project’s champion, organized an executive steering committee (“executive committee”), which included high-level stakeholders tasked by and accountable to the committee. The initiative’s goal to reduce SSIs was made clear to all hospital employees.

A portfolio of projects selected by the executive committee to reduce SSIs included TGC in surgical patients. The evidence base for TGC had increased dramatically in the late 1990s, with hyperglycemia considered a contributing factor to increased morbidity and mortality in the critically ill.<sup>4-7</sup> One of the executive committee’s physician administrative leaders [W.C.] accepted responsibility as the TGC project champion.

The TGC champion formed a TGC committee, which was composed of high-level stakeholders, including the medical

## Institute for Healthcare Improvement Framework for Leadership for Improvement Steps in Relation to Time Line of Hospitalwide Implementation of the Tight Glycemic Control Protocol



**Figure 2.** The time line shows the sequence of actions taken in the tight glycemic control (TGC) initiative in correspondence with the Institute for Healthcare Improvement framework for leadership for improvement. ICU, intensive care unit; SICU, surgical intensive care unit; GPU, general practice unit. SSI, surgical site infection.

directors of all ICUs [including H.M.H.], OR directors, and inpatient floor unit directors, as well as pharmacy and nurse leaders [M.M., G.G.], data analysts, and QI experts [J.J.]. The institution's metabolism expert served as a consultant to the TGC committee. At the first committee meeting, the TGC champion presented the SSI initiative, along with background data on infections at our institution. The entire project was outlined, along with the results that other process changes, such as on-time administration of antibiotics for surgery (see page 297), had already achieved. To introduce the TGC project, the metabolism expert presented the evidence-based literature, as well as data revealing the presence of marked hyperglycemia in our institution's ICU patients, 15% of whom had glucose readings > 250 mg/dL.

**Push for Change.** Existing perceptions of the ICU physicians held that patients' blood glucose levels were being well controlled. However, the data showed that 65% of readings were > 150 mg/dL (Figure 3, page 294). Vigorous discussion ensued, with comments typical of resistance to change: "We cannot possibly do this." "We have too much else to do." "Who is going to collect all the data?" "This does not apply to us; the literature only cites surgical patients." "It will never work." The TGC champion remained steadfast to the vision and insisted on development of a plan to address hyperglycemia.

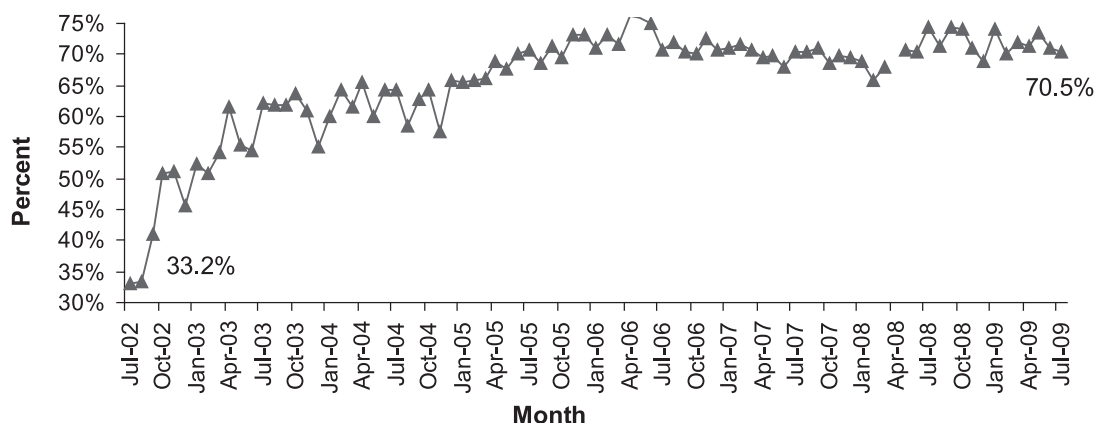
At the second TGC committee meeting, naysayers were well

prepared with good arguments on the various insurmountable barriers and presented plans to address what others, and not themselves, should do for the initiative. The TGC champion, similarly well prepared, refocused the group on the importance of controlling glucose to reduce SSIs by presenting data and suggestions from other institutions that had undertaken the practice change. The TGC champion divided the project into separate components, assigning responsibility for process changes in the ICU complex, OR, and inpatient surgical wards. Leadership assured the group that resources would materialize for data collection and analysis. In assigning responsibility, the TGC champion made it clear that this project was a requirement of everyone's job. Success or failure was ours to determine.

TGC committee members each became responsible for introduction and implementation of the TGC project components at the unit levels. For the 124-bed ICU complex, the ICU executive committee (which was composed of ICU medical directors) was made responsible for TGC process planning. The SICU medical director and existing SICU Committee were to be responsible for developing the TGC protocol and pilot study.

SICU team discussions mirrored those at the upper-level committee meetings: "Why can't someone else do this?" "The surgeons will not like it and the nurses will not do it." "It's too

Percent Blood Glucose Readings 80–150 mg/dL, 2002–2009 (N = 90,000 Patients)



**Figure 3.** Blood glucose readings are displayed over time from 2002 to 2009. Glucose readings from July to October 2002 are pre-protocol and serve as baseline or historic controls. With implementation of the tight glycemic control protocol, fewer hyperglycemia and more glucose readings in the target range of 80–150 mg/dL occurred.

big.” The SICU committee listened to the team’s comments and reviewed the data and the literature with the team, at which point the team agreed, with many misgivings, to give the initiative a try.

**Comments.** Although decision making for clinical change may be driven by scientific evidence, process changes often occur as part of QI or in response to initiatives from internal or external agencies. Whether a grassroots effort or an institutional imperative, process change requires an enthusiastic champion—preferably several leaders across organizational levels—with a steadfast vision of the end product.

The TGC project became part of the institutional imperative for SSI reduction as directed by the CEO, with the hospital’s administrative nurse vice president, chief medical officer/chief quality officer, chief of surgery, and chief of anesthesiology as the high-level leaders serving on the executive committee who endorsed the project. These champions had existing responsibility and ability to direct the major professional groups, including physicians and nurses. The TGC project champion, in a dual role as both chief medical officer and chief quality officer, drove practice change across the hospital, down management levels, and recruited QI expertise and resources. This structure for team leadership and project champions was duplicated at each management level—from executive committee to TGC committee to ICU committee to SICU committee. The structure allowed cultural and behavioral barriers to be addressed via ongoing team discussions at every committee level, with project champions at each level serving to set

direction, focus the group on project goals, and assign responsibility for champions of change at subsequent levels, right to the patient’s bedside. As shown in Table 1 (page 295), this QI leadership structure across and down organizational levels requires overlap at every level of project component responsibility to help create a seamless process to propel change forward.

Existing practice evidence became the critical component in creating the push for change by confronting popular perception with the reality of patient data. The preexisting mind-set that blood glucose was well controlled became debatable in the face of reliable patient data to the contrary. The debate then enabled practice change, keeping the project moving forward.

**IMPROVEMENT STEPS 4 AND 5: GENERATE IDEAS AND EXECUTE CHANGE**

**TGC Practice Change Setting.** The 40-bed SICU, an open unit for surgical patients, has many admitting surgeons, with approximately 3,400 patients annually. The two SICU services are composed of residents, fellows, and attending intensivists, most of whom are surgeons. The SICU attending physicians rotate weekly, whereas the residents rotate monthly. The nursing-to-patient ratio ranges from 1:2 to 1:3, with two clinical nurse specialists for clinical and educational support. The nursing administrative staff includes a nursing director and several charge nurses. One clinical pharmacist and several technicians are assigned to the unit. In 2002, when we did not have an electronic medical record or medication ordering system, protocols were already in use for electrolyte replacement, seda-

Table 1. Leadership Structure Driving Hospitalwide Tight Glycemic Control (TGC)\*

Project	Resources and Responsibilities		
Leadership Levels Driving Change	Senior Sponsor	Lead	Driver
<i>Level 1</i> SSI Reduction Hospitalwide	Hospital CEO	Hospital VP administration	SSI executive committee: VP hospital administration Chief of surgery Chief of anesthesiology CMO/CQO
<i>Level 2</i> TGC All Surgical Patients	SSI executive committee	CMO/CQO	TGC committee: CMO/CQO ICU MD Directors IPD unit Directors OR directors Pharmacy leaders Nurse leaders QI experts Metabolism MD (consultant)
<i>Level 3</i> TGC Operating Room	TGC committee	Chief, anesthesiology Chief, surgery	OR director, MDs, RNs
<i>Level 3</i> TGC IPD Surgical Units	TGC committee	Chief, surgery Surgical MD directors	IPD medical directors, nurse directors
<i>Level 3</i> TGC ICU Complex	TGC committee	ICU executive committee (all unit directors)	SICU medical director and SICU committee
<i>Level 4</i> TGC SICU Protocol Development	TGC committee and ICU executive committee	SICU medical director and SICU committee	SICU pharmacist with MDs, RNs
<i>Level 4</i> TGC SICU Pilot, Phase 1, Phase 2	SICU committee	SICU medical director, nursing director, pharmacist, clinical nurse specialists	RNs at the bedside
<i>Level 3</i> TGC ICU Rollout	ICU executive committee	ICU unit directors, MDs, RN leaders	RNs at the bedside
<i>Level 2</i> TGC Hospitalwide	TGC committee	GPU medical directors, nursing directors, pharmacist	RNs at the bedside, unit by unit

\* SSI, surgical site infection; CEO, chief executive officer; VP, vice president; CMO, chief medical officer; CQO, chief quality officer; ICU, intensive care unit; IPD, name of ward; OR, operating room; QI, quality improvement; MD, physician; RN, registered nurse; SICU, surgical ICU; GPU, general practice unit.

tion, ventilator weaning, and transfusion.

**TGC Protocol Design.** The SICU committee assigned the clinical pharmacist to develop the glycemic control protocol in conjunction with input from a multidisciplinary team. Practice regarding glycemic control in SICU patients had been inconsistent, with either subcutaneous or intravenous (IV) insulin administered when blood glucose values exceeded 150–200 mg/dL. In developing the new protocol, a start-treatment point

several values above 150 mg/dL was chosen, with the goal to maintain blood glucose < 150 mg/dL. We chose the 150 mg/dL value as the initial control point because of its familiarity to the nursing staff.

**TGC Pilot Study Population.** The SICU committee evaluated evidence to select a trial population for the TGC protocol. The Diabetes Mellitus, Insulin Glucose Infusion in Acute Myocardial Infarction (DIAGMI) trial had reported increased



and sustained improvement in mortality rates when glucose was controlled.<sup>8,9</sup> Deep sternal wound infection rates after bypass surgery were shown to be reduced in patients with and without diabetes when instituting tight glucose control. Van den Berghe et al.<sup>6</sup> had reported adverse clinical outcomes in critically ill patients with elevated blood glucose levels. Increases in length of stay, nosocomial infections, and mortality were reported in trauma patients with hyperglycemia.<sup>10</sup>

The SICU committee elected to start the glycemic protocol with cardiothoracic surgery patients because of the specific literature to justify TGC in these patients, who, in addition, constituted a steady source of complex patients in the SICU. The SICU committee discussed the protocol with the cardiothoracic surgeons, who were supportive and wondered why a TGC protocol had not been previously implemented.

**TGC Pilot with Rapid-Cycle PDSA.** Use of the new IV insulin protocol, based on the nomogram of Brown and Dodek,<sup>11</sup> began in the SICU in September 2002. We decided to trial the protocol on several patients and make modifications as needed. This method of introducing a protocol followed by rapid-cycle improvement, as advocated by IHI,<sup>12</sup> had proved successful when we had implemented the ventilator-weaning protocol a few years previously.<sup>13</sup>

Just-in-time teaching was provided for the nursing staff, and several patients were selected for the glycemic protocol. The pharmacist was available for questions and tracked the results. Nursing input indicated that (1) immediate modification of the protocol was required for patients who were taken off vasoactive agents and (2) the glucose monitoring and recording required additional nursing time. Although we thought the protocol was clearly written, multiple questions arose. We revised the protocol and tried it again on several more patients. We then conducted several more trials, making modifications to the protocol after each trial. In the course of these initial trials, which took approximately six weeks, we proved to ourselves and to the physician and nursing staff via documented measures that continuous infusion of insulin did achieve glycemic control. We presented the protocol and the associated results to the TGC committee, incorporating several suggestions from the metabolism expert into the protocol.

**Phase 1 TGC Implementation.** To place all cardiothoracic surgery patients on the glycemic protocol, nurses required education about the protocol, and the implementation required refinement. During this process, we discovered that the bedside glucose-monitoring devices were in short supply. These devices allowed data to be downloaded into the laboratory computer system, freeing nurses from the time-consuming task of chart-

ing the results. Consequently, the nurses spent considerable time hunting for them and recording the results. These issues were discussed with hospital administration, and more devices were purchased. The bedside nurses were taught and tested on the protocol as well as on the use of the device.

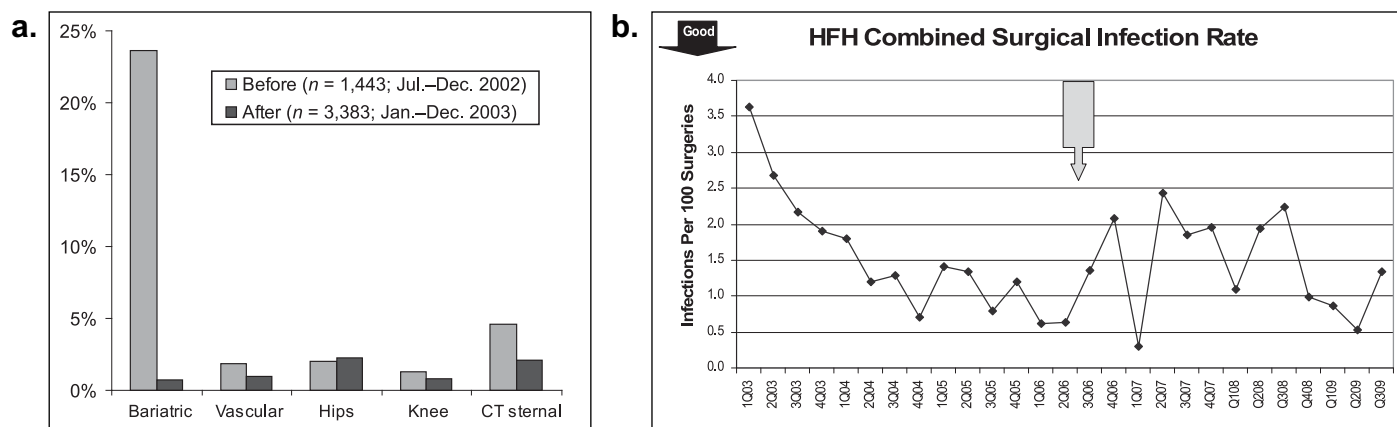
The protocol was instituted for all cardiothoracic SICU patients. The pharmacist continued to collect data and answer questions. Individual bedside education was provided by the clinical nurse specialists or the pharmacist when nurses had questions or a protocol violation occurred. As more patients were treated on the protocol, it became apparent that improved glucose control in the OR setting required refinement and that we needed to address transitioning patients from the continuous insulin in the SICU to subcutaneous insulin when they were transferred to the inpatient wards. These issues were presented to the TGC committee, which created two task forces to address them. Glucose was controlled on the ward with multiple subcutaneous-insulin protocols, prompting concern that continuous insulin infusions could not be monitored closely enough to prevent hypoglycemia.

The data-collection and analysis demands began to exceed the limits of the pharmacist's time, which was addressed by the electronic reporting of the data as collected by the bedside glucose-monitoring device. The SICU received a monthly dashboard from data pulled from the administrative database. This dashboard was shared with hospital administration, the SICU committee, and the bedside nurses and physicians. In addition, the dashboard data were posted in employee break rooms for all to see the results and progress each month.

During the next several months, the number of glucose values outside the target goal of 80–150 mg/dL decreased (Figure 3). Satisfied that the first phase of the protocol was successful, we further modified the protocol to decrease the target glucose range to 80–110 mg/dL in the cardiothoracic SICU patients. In addition, we modified the dashboard, as defined earlier, for ready availability to nurses.

**Phase 2 TGC Implementation.** With several months of success in working with the TGC protocol in cardiothoracic surgery patients,<sup>14</sup> we extended its use to all SICU patients. The same small steps were taken to ensure compliance and integration of the protocol and patient safety. A monthly education session was implemented for the residents and nurses. As the TGC protocol became widely used in the SICU, we developed standardized order sets, with glucose control becoming an opt-out order according to individual patient requirements. Hypoglycemia was identified as one issue to be monitored because it occurs in patients with renal failure, liver

## Rates of Surgical Site Infections



**Figure 4.** The rates of surgical site infection before and after implementation of the tight glycemic control protocol are shown in the surgical intensive care unit by patient population (4a) and hospitalwide (4b) over time. In Figure 4b, the arrow marks the completion of spread of the protocol to all medical general practice units (September 2006); the reporting method changed after September 2009. CT sternal, cardiothoracic sternal incision; HFH, Henry Ford Hospital; Q, quarter.

failure/resection, and solid-organ transplants more frequently than in other patients.

**Comments.** After the team leadership structure successfully drove the TGC project to design change at the SICU patients' bedside, the critical steps of generating ideas for practice change ranged from protocol development to selection of the trial population, as well as use of rapid-cycle PDSA to continually refine the protocol and spread practice change. The multilevel leadership structure (Table 1) became a critical part of the process to move up, down, and across chains of command for prompt resolution of problems as new clinical issues arose and resources became required.

In terms of the TGC protocol's initial goal, our results showed a decrease in SSIs for cardiothoracic and bariatric patients (Figure 4, above) who were cared for in the SICU. As stated, the TGC project was just one of several projects in the portfolio of initiatives aimed at reducing SSIs. These other projects, each of which was led by its own team, were as follows:

- Administration of prophylactic antibiotics within one hour of surgical incision
- Selection of appropriate antibiotics
- Appropriate stop time of antibiotics
- Administration of glucose at 6:00 A.M. [6:00] for cardiac patients
- Use of hair clippers instead of shavers for hair removal
- Maintenance of normothermia in colectomy patients

Together, these projects resulted in an overall reduction in SSIs at our institution.

### Continuing the Cycle for Improvement

The TGC project underwent clinical practice changes over the course of several years. For the critically ill, what started as a small trial of protocol change in select cardiothoracic SICU patients in September 2002 became fully implemented in the 124-bed ICU complex in 2004. Parallel project components for TGC in surgical patients in the OR and on inpatient surgical wards were completed alongside the SICU project. Evidence documenting this widespread success prompted executive leaders to set direction for TGC in all hospitalized patients, a new change process for the medical general practice units (GPUs). The glucose goal for the GPUs aimed to treat with correctional sliding-scale insulin if the glucose was > 120 mg/dL. Basal insulin had to be ordered by the physician and was not part of the protocol. Full implementation of TGC in the hospital was completed by 2006 (Figure 2).

### TGC FOR SPECIAL POPULATIONS

It is often found that each care team believes that its patients are the sickest and least like any other patient population in the hospital. This internal cultural bias leads to attempts to seek special status, exemptions, and custom protocols, leading to overall protocol and process instability. Yet, the next generation of change must be able to acknowledge true differences and handle the subtlety of special populations. Protocols should be simple but must first be safe. We began the next generation of TGC refinement in 2006, partnering with subspecialists to assure use of their patients' data to guide improvement and

refinement. In this process we favored changes that related to different starting points on a universal protocol rather than new and different protocols. For example, as we monitored patient data for special populations, we found that bariatric-surgery patients were not adequately controlled on the initial starting point for the TGC protocol. We then initiated a process change whereby all bariatric patients began at a higher level of insulin on the standard protocol, and we continued to monitor these patients' glycemic control. Improvement was clear and enduring, and a new or custom protocol for this special population was not necessary.<sup>15</sup>

### **Responding to a Changing Evidence Base**

As evidence in the late 1990s grew to support TGC in the critically ill, many hospitals implemented glycemic control in the ICU or hospitalwide. In 2005, evidence suggested that even one glucose reading > 150 mg/dL may increase the chance of SSI.<sup>16</sup> Infectious complications and poor wound healing, skin graft failure, increased risk of congestive heart failure and cardiogenic shock, decreased neurologic outcome, and higher mortality were reported to be associated with blood glucose levels > 110 mg/dL.<sup>17</sup> Pneumonia and mortality rates were reported to increase in trauma patients with blood glucose > 150 mg/dL.<sup>16</sup>

Specific studies of the relationship between hyperglycemia and SSIs are uncommon. SSIs account for 15% of nosocomial infections and additional length of stay, rehospitalizations, operations, and impaired surgical site healing. Single center retrospective studies from the Seattle group showed a decrease in deep sternal wound infections in cardiac patients with glucose control compared with historical controls.<sup>4</sup> A private practice cardiac group in Maine that initiated TGC reported an SSI rate of 1% in 1,388 patients compared with 2.6% in its historical controls ( $p < .001$ ).<sup>18</sup> Reduction of SSI with glycemic control has been shown in other surgical patients. In a prospective randomized controlled trial of 61 critically ill surgical patients, the SSI rate decreased from 30% to < 10% ( $p < .05$ ).<sup>19</sup> In a retrospective review of 995 general surgery and vascular patients, Ramos et al<sup>20</sup> found a 30% risk of postoperative infections with every 40 mg/dL increase in glucose above 110 mg/dL. Elevated glucose levels were an independent risk factor for SSI in patients with mastectomy.<sup>21</sup> Trauma patients with glucose > 200 mg/dL had increased infections with skin and wound at 6% ( $p = .04$ ).<sup>22</sup> However, controversy still exists. A Cochrane review in 2008 identified five randomized controlled trials, which differed in glucose targets, methods of control, and patient characteristics.<sup>23</sup> Some of these trials were underpowered or did not

mention SSI as an outcome. The authors recommended large randomized studies to answer the question of the relation between SSI and glucose control.

In 2008 and 2009, studies began to show that the recommended glucose target of 80–110 mg/dL was not associated with clinical improvement in ICU patients and perhaps may cause harm (increased mortality). Meta-analysis evidence pooled from 27 randomized trials suggested that TGC in the critically ill does not lead to reduced in-hospital mortality and increases the risk of hypoglycemia in these patients.<sup>24</sup> The NICE-SUGAR study<sup>25</sup> and the Cochrane review<sup>23</sup> have created doubts about the benefits of TGC. At our institution, the TGC committee reviewed these studies, and we modified our target ranges in June 2009. A summary of the changes made to TGC protocols is provided in Table 2 (page 299), and the modified TGC protocol is provided in the Appendix (available in online article). The new basal-prandial protocol changed the goal to a premeal glucose of < 140 mg/dL. This basal-prandial protocol will assess insulin needs with correctional insulin, and if diabetes is suspected the physician will have the opportunity and direction to order basal insulin with prandial (with meals) insulin on the new order form. The American Association of Clinical Endocrinologists and the American Diabetes Association jointly issued a new guideline in 2009 for inpatient glucose control.<sup>26</sup>

Data from our ongoing experience show minimal episodes of hypoglycemia. Review of these data failed to identify uniform predictors of at-risk patients. Hypoglycemic episodes, although uncommon, were treated with D<sub>50</sub> (dextrose 50%) and a reduced insulin-drip rate. In developing our initial protocols, we developed an insulin-sensitive protocol for renal and liver failure/transplant patients because of the hypoglycemia concerns. Specific patient populations have been reviewed. In 2,286 neurologically compromised patients, hypoglycemic episodes increased with glucose control < 110 mg/dL. In this patient population, age, diabetes mellitus, African-American race, positive cultures, and longer ICU length of stay were associated with hypoglycemic events. Hypoglycemic patients were 4.61 times more likely to die than those without hypoglycemia (95% confidence interval [CI], 2.54–8.35).<sup>27</sup> Multiple hypoglycemic events were identified in 53 of 12,901 patients in the SICU. Diabetes mellitus was protective in the ICU but not on the floor. Age, gender, race, chronic kidney disease, and length of stay were not predictive of these multiple episodes of hypoglycemia.<sup>28</sup>

By implementing TGC in small steps, we were able to identify in early implementation phases those patients in our SICU

Table 2. Summary of Tight Glycemic Control Protocol Changes for All Intensive Care Units (ICUs)\*

Protocol Change	Surgical and Neuro ICU Patients	Medical and Cardiac ICU Patients
Glucose goal	< 130 mg/dL	< 180 mg/dL
Insulin drip glucose goal	100–130 mg/dL	140–180 mg/dL
Every 4-hour glucose checks on admission	Yes	Yes
Start insulin drip for first glucose	> 150 mg/dL	> 180 mg/dL
When checking glucose every 4 hours on admission, do not give IV push insulin for initial glucose values	≤ 150 mg/dL	≤ 180 mg/dL
Stop every 4- hour glucose checks for initial 3-in-a-row glucose values	≤ 130 mg/dL	≤ 180 mg/dL

\*Neuro, neurological; IV, intravenous.

who were at higher risk for hypoglycemia. We continue to use the modified TGC protocol in our large ICU complex and hospitalwide, with ongoing monitoring and education for patient safety.

### Lessons Learned

Although we were able to translate evidence-based practice change requirements into daily patient SICU care processes in the course of 16 months, the success of the TGC protocol required several critical components, including hospital administrative and physician leadership endorsement and resource support; substantial time commitment across the full range of health care providers, especially the pharmacy and nursing staff; and, as described, accommodation to a rapidly changing evidence base.

■ **Leadership Champions.** Hospital administrative support was crucial. The administrative project champion articulated clear vision with concrete goals from the outset. We were allowed to react to the idea of the project but were also required to accept specific responsibility to carry the project to the level of the bedside and implement the practice change. Without hospital administrative and physician leadership support, this project would have failed.

■ **Resources.** Resources in terms of personnel, equipment, data management, and ongoing education are significant cost issues that present barriers to change. As a vertically integrated health system and with salaried physicians in the large medical group that services our urban hospital, our institution supports a dedicated quality office with an annual budget and various professionals to assist in the implementation of QI projects. Although we did not measure costs across the TGC implementation hospitalwide, our institution has tracked mortality rates as one outcome summarizing the impact of the totality of QI efforts across time. In the same four-year period in which the

TGC project was one of many QI initiatives, hospital mortality was shown to decrease by more than 25%.

■ **Team Commitment.** During the initial phases, the team members each spent about 8–10 hours per week beyond their regular daily duties. Nursing work flow and processes changed, and nurses spent about 6 hours in learning and carrying out the protocol. We learned never to underestimate the importance of education, and today we continue to provide monthly education conferences on the glycemic control protocol. Given the salaried status of our medical group physicians, additional costs or reimbursement for physician time were not a factor for consideration at our institution.

■ **Project Cycle Method.** Dividing the project into component pieces with defined responsibilities and expectations made each step possible. The technique of rapid-cycle change, which had previously worked for the SICU, again proved critical in making the project smaller in scope and then building on the success or failure of each small cycle. This process allows small changes to build toward the end result while simultaneously allowing near immediate alteration for required change.

■ **Communication of Results.** Measuring and communicating the results in a consistent time frame allow the team to see actual, not perceived, impact of its efforts on daily patient care. Communication of results also provides information flow up and down the chain of command for continuous support, both verbal and material, and for encouragement of ongoing improvement.

■ **Continuing Improvement.** Once one small success occurs, the process can be replicated in small steps in other areas over time. We required six weeks of protocol design and refinement in select patients before implementing glucose control to all cardiothoracic surgery patients and then another 11 months before extending implementation to all SICU patients. In addition, we started with one glucose protocol, waiting for process

change and success, before implementing the final TGC protocol of 80–110 mg/dL now used in our SICU. This same process, step by step, was repeated across the entire 124-bed ICU complex and throughout our institution over the next several years.

## Conclusions

A universal TGC protocol continues to be used throughout the hospital, with modifications and next-generation improvements occurring as evidence arises. ■

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## Online-Only Content

See the online version of this article for

Appendix. Modified Tight Glycemic Control Protocol

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## Appendix. Modified Tight Glycemic Control Protocol

### SURGERY AND NEURO INTENSIVE CARE GLYCEMIC CONTROL INSULIN NOMOGRAM 100-130

**GOAL:** Glucose levels between 100-130 mg/dL. Start insulin infusion for 1st value greater than 150 mg/dL.

**MONITORING:** Check glucose Q2h, (either capillary or blood) If Glucose less than 100mg/dL check every hour. Restart Q 2 hr blood glucose checks when glucose is greater than 99mg/dL. Document all glucose values and Insulin dosing in ICU Electronic Documentation System

**Guidelines:** All Insulin Doses are Regular Insulin IV

1. Intubated Patients, Not Intubated and NPO, any patient on tube feedings or receiving TPN-Start insulin infusion for 1st value >150 mg/DL.
2. If insulin drip held for glucose less than 100, restart insulin drip when glucose greater than 100 according to protocol
3. **Continue Insulin Infusion Protocol until preparing for discharge or otherwise directed by physician.**
4. Consult physician for starting long acting insulin (basal) - glargine (Lantus) Collaborate with physician or pharmacist about dose.
5. Consult physician to start tube feeding, TPN, or D5W for caloric source and to prevent hypoglycemia. Continue insulin drip protocol
6. All peritoneal dialysis patients check blood glucose in lab before starting protocol. Make sure blood glucose matches chemstick glucose.
7. If tube feedings are discontinued or held - stop the insulin drip- check glucose q2hr -restart glycemic control protocol from beginning
8. Any patient traveling off of the unit decrease the insulin drip by 50%. Check the glucose on return to the ICU and restart nomogram.

#### STARTING INSULIN INFUSION

Glucose	151-219mg/dL	>220 mg/dL
Starting Insulin Dose	Give 2 units Regular insulin IVP and start 2 units/hr If Renal Failure (creatinine >2), Liver Failure, Liver Transplant or Kidney Transplant start at 1 unit/hour	Give 4 units Regular insulin IVP and start 4 units/hr If Renal Failure (creatinine >2), Liver Failure, Liver Transplant, or Kidney Transplant start at 2 units/hour

#### Maintenance Insulin Drip

Glucose Level	Insulin Rate 1-3 units/hr	Insulin Rate > 3 units/hr
<41mg/dL	D/C infusion. Give 1 amp Dextrose 50% IVP-Notify Physician. Check glucose hourly until glucose greater than 80, then every 2 hours. When 2 in a row every 2 hour glucose checks are greater than 100 restart drip at 0.5 unit/hour and use the insulin sensitive nomogram. Notify physician when glucose greater than 80	D/C infusion. Give 1 amp Dextrose 50% IVP-Notify Physician. Check glucose hourly until glucose greater than 80, then every 2 hours. When 2 in a row every 2 hour glucose checks are greater than 100 restart drip but reduce rate by 50% and use insulin sensitive nomogram. Notify Physician when glucose greater than 80
41-60mg/dL	D/C infusion. Give 1/2 amp Dextrose 50% IVP-Notify Physician. Check glucose hourly until glucose greater than 80, then every 2 hours. When 2 in a row every 2 hour glucose checks are greater than 100 restart drip at 0.5 unit/hour and use the insulin sensitive nomogram. Notify physician when glucose greater than 80	D/C infusion. Give 1/2 amp Dextrose 50% IVP-Notify Physician. Check glucose hourly until glucose greater than 80, then every 2 hours. When 2 in a row every 2 hour glucose checks are greater than 100 restart drip but reduce rate by 50% and use insulin sensitive nomogram. Notify Physician when glucose greater than 80
	Insulin Rate 1-3 units/hr	Insulin Rate > 3 units/hr
61-99mg/dL	D/C Infusion: Recheck glucose EVERY HOUR for glucose 61-80 or every 2 hours for glucose 81-99 <b>When glucose greater than 99 restart drip at 1 unit/hr</b>	D/C Infusion: Re-Check glucose EVERY HOUR for glucose 61-80 or every 2 hours for glucose 81-99. <b>When glucose greater than 99 restart insulin infusion, but decrease dose rate 50%</b>
If insulin drip turned off for glucose less than 100 (but greater than 60) check every hour until greater than 80 then every 2 hours. If 3 in a row every 2 hour checks are less than 100 restart protocol from beginning. Change glucose check to q4h and start insulin drip for first glucose greater than 150 mg/dL.		
	Insulin Rate 1-3 units/hr	Insulin Rate > 3 units/hr
100-130mg/dL	No Change unless: If previous glucoses higher Reduce drip by 1 unit/hr (If current dose 1 unit / hour do not change)	No Change unless: If previous glucose higher then reduce per below: <u>Infusion Rate</u> <u>Decrease Dose by:</u> 4 – 7 units/hr                      1 unit/hr 8 – 12 units/hr                      2 units/hr 13 – 17 units/hr                      3 units/hr 18 – 22 units/hr                      4 units/hr >22 units/hr                          5 units/hr

#### STANDARD INSULIN NOMOGRAM

Glucose	Insulin Dosage All Others
131-150 mg/dL	Increase Drip Rate by 0.5 unit/h (no bolus) Continue same rate if Last glucose was higher value
151-200 mg/dL	Give 2 units Regular insulin IVP and Increase drip rate by 1 u/h
201-250 mg/dL	Give 4 units Regular insulin IVP and Increase drip rate by 1 u/h
251-300 mg/dL	Give 6 units Regular insulin IVP and Increase drip rate by 1 u/h
301-400 mg/dL	Give 8 units Regular insulin IVP and Increase drip rate by 1 u/h
>400 mg/dL	Call MD for New Order

#### INSULIN SENSITIVE INFUSION NOMOGRAM

Glucose	Insulin Dosage for: Renal failure-(creatinine > 2), Liver Failure Liver or Kidney Transplant, or one glucose less than 61 mg/dl
131-150 mg/dL	No Change
151-200 mg/dL	Give 2 units Regular insulin IVP and Increase drip rate by 0.5 u/h
201-250 mg/dL	Give 4 units Regular insulin IVP and Increase drip rate by 0.5 u/h
251-300 mg/dL	Give 6 units Regular insulin IVP and Increase drip rate by 0.5 u/h
301-400 mg/dL	Give 8 units Regular insulin IVP and Increase drip rate by 0.5 u/h
>400 mg/dL	Call MD for New Order

This protocol was last revised in June 2009. Q2h, every 2 hours; IV, intravenous; NPO, nothing by mouth; TPN, total parenteral nutrition; D5W, 5% dextrose in water; IVP, intravenous push; D/C, discontinue; amp, ampule; Q4h, every 4 hours; u/h, unit/hour; MD, physician.

## Performance Measures

# Community Hospital Participation in a Pilot Project for Venous Thromboembolism Quality Measures: Learning, Collaboration, and Early Improvement

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More than 900,000 persons in the United States suffer from venous thromboembolism (VTE) each year, resulting in 300,000 deaths.<sup>1</sup> Two thirds of these deaths occur in hospitals and most of them are considered preventable,<sup>2,3</sup> yet fewer than 50% of hospitalized patients receive adequate VTE prophylaxis.<sup>4,5</sup> VTE significantly contributes to health care costs, with estimates as high as \$15.5 billion per year.<sup>6</sup>

To decrease the morbidity, mortality, and costs associated with VTE, the American College of Chest Physicians (ACCP)<sup>7</sup> and other professional societies recommended that hospitals develop formal strategies that address the prevention of thromboembolic complications. As part of such strategies, physicians must identify patients at risk for developing thromboembolic complications. In a review of 1,231 consecutive patients treated for VTE, 96% had at least one recognized risk factor. The risk increases in proportion to the number of predisposing factors.<sup>8</sup> Heit et al. concluded that VTE is a disease of hospitalized and recently hospitalized patients.<sup>9</sup> Yet, no national quality measures have been available to demonstrate that the ACCP's evidence-based guidelines were being practiced consistently to reduce and prevent VTE.

Objective measurement of guideline adherence and related patient outcomes is a quality/patient safety imperative. In addition, national and state agencies are increasingly requiring hospitals to become more transparent with quality measures. Since 2007, the U.S. Centers for Medicare & Medicaid Services (CMS) has tied a portion of a hospital's Medicare Annual Payment Update to reporting of the two VTE quality measures for patients undergoing select surgical procedures.<sup>10</sup> Recently, VTE prevention and treatment measures were included in a CMS final ruling effective for fiscal year 2010.<sup>11</sup>

In 2005, the National Quality Forum (NQF) formally launched a project to develop a set of voluntary consensus standards composed of organizational policies and preferred practices and subcontracted with The Joint Commission to develop performance measures for prevention and care of VTE. As

## Article-at-a-Glance

**Background:** Participation in national demonstration projects by hospitals provides opportunities for learning, collaboration, and early improvement. A community teaching hospital, Overlook Hospital, part of the two-hospital Atlantic Health system, participated in a pilot project in the United States with The Joint Commission to develop quality measures for venous thromboembolism (VTE) prevention and management.

**The Pilot Project:** The VTE project formally began in January 2005, and by January 2007, on the basis of alpha testing to assess face validity and data-collection issues, eight measures were selected for pilot testing. The hospitals tested the quality measures from January through June 2007; data collected included discharges from October 2006 through March 2007. During the pilot, Overlook achieved significant improvements in VTE prevention and management. As a result, in Summer 2007, Atlantic Health developed an organizationwide initiative to improve VTE prevention and treatment.

**Discussion:** In 2008, the Joint Commission recommended that the VTE measures become a core measure set and be aligned with the Centers for Medicare & Medicaid Services quality measures. Following successful implementation of multiple quality improvement innovations that arose from the pilot project participation, Atlantic Health sustained and expanded its efforts in 2009 to improve performance on eight VTE quality measures.

**Conclusions:** Participation of a broad range of hospitals, including academic medical centers and community hospitals, in a national pilot project to develop quality measures is critical to ensure that differences in environment, resources, staffing, and patient acuity are accounted for, particularly when the measures are used for public reporting.

Bratzler<sup>12</sup> has described, a technical advisory panel was created to evaluate the technical aspects of all candidate policies and procedures and to assist the Joint Commission in developing and testing the performance measures with hospitals participating in the project. Overlook Hospital, a community teaching hospital within the Atlantic Health health care system, identified this as an opportunity to directly influence the development of measures that would be applicable in this practice setting and to meaningfully evaluate current practices related to VTE risk assessment and prevention. Participation in national demonstration projects by hospitals provides opportunities for learning, collaboration, and early improvement. In this article, we describe Overlook's experience in participating in the VTE project. We present the specifics of project requirements and challenges of meeting these requirements, describe insights gained and shared potentially to refine and shape the pilot measures, and discuss our efforts in assessing and improving performance related to VTE prevention and management during and after the pilot project.

## The Pilot Project

### SETTING

Atlantic Health is a two-hospital health care system in north central New Jersey (Overlook Hospital in Summit and Morristown Memorial in Morristown), with a total of 1,133 acute inpatient beds and 62,581 inpatient admissions in 2008. With 9,700 employees, 250 residents in training, and 2,200 physicians on staff, the hospitals also provide more than half a million outpatient visits per year.

### RATIONALE FOR JOINING THE PROJECT

Before 2007, Atlantic Health did not have consistent systems in place to promote VTE screening, risk assessment, prophylaxis, or anticoagulation-related education during discharge planning. In 2006, Overlook, as part of Atlantic Health, was an active NQF member and regularly responded to calls for public comments on proposed indicators. Along with many community hospitals, our quality staff responsible for chart abstraction and reporting regarding national quality measures had some concerns and frustration related to the specifications and abstraction guidelines for some of the indicators. In addition, physicians and clinical staff regularly questioned the data, which they perceived to reflect inappropriate inclusion/exclusion criteria as well as, at times, questionable abstraction guidelines. We recognized the importance of systematically evaluating care related to preventing and treating VTE and were immediately interested when The Joint Commission

asked for volunteers to pilot test the VTE metrics. Although all the details of what would be required were not yet available, we responded to the call for volunteers and were accepted to join the pilot.

### PROGRESS OF THE PILOT PROJECT

*Pilot Project Begins.* The VTE project formally began in January 2005, when the Joint Commission and NQF issued a call for nominations for the steering committee, technical advisory panel (TAP), measures, preferred practices, and model Organizational Policies.<sup>13</sup> After significant work by the steering committee and TAP, and an additional call for measures in August 2005 and a public comment period in January 2006, 10 of the 19 proposed measures were modified for testing. On the basis of subsequent alpha testing to assess face validity and data-collection issues, 8 of the measures were selected for pilot testing,<sup>12</sup> as follows:

- VTE risk assessment/prophylaxis within 24 hours of hospital admission
- VTE risk assessment/prophylaxis within 24 hours of transfer to ICU
- Documentation of inferior vena cava filter indications
- VTE patients with overlap therapy
- VTE patients receiving unfractionated heparin with platelet count monitoring
- VTE patients receiving unfractionated heparin management by nomogram/protocol
- VTE discharge instructions
- Incidence of potentially preventable hospital-acquired VTE

Objectives for pilot testing, as specified in the project specifications manual, were as follows:

- Evaluation of the reliability of the individual measures and associated data elements
- Enhancement of measure specifications, including definition, abstraction guidelines, and identification of contraindications to specific processes
- Assessment of sampling strategies
- Assessment of data-collection effort, including abstraction time and estimated cost

Thus, in early 2007, Overlook volunteered, along with 54 other hospitals across the United States, for a six-month pilot project sponsored by the Joint Commission to identify and develop a set of standardized, inpatient measures that would eventually be used to evaluate health care practices for prevention and management of VTE.<sup>14</sup> Some 37 participants completed the project. The hospitals tested the quality measures from



January through June 2007, and data collected included discharges from October 2006 through March 2007.

Getting the pilot database up and running proved challenging—it involved significant work by our information technology (IT) department and our quality department's systems and data coordinator. Specifically, the pilot database required the development of electronic links to patient information for the repopulation of database fields such as patient demographics, diagnoses with codes, admission date, and discharge source, as well as IT challenges associated with “downloading” the abstracted records in the database to the Joint Commission. After the database was functioning efficiently, the majority of the time required for the project was devoted to chart abstraction and data entry through the provided database—which took about 10 hours per month for an experienced nurse abstractor. Additional time, estimated at 10 hours per month, was required for data summaries, analyses, and communication with and facilitation of the related work groups.

**Conference Calls and Webinars.** The pilot project included regular conference calls with the other hospital participants, led by the Joint Commission project coordinator. Along with detailed written documentation, these calls addressed initial orientation to the project, as well as ongoing discussion of participants' questions, concerns, and issues. These calls and related written documentation proved to be invaluable in clarifying some details of the specifications and abstraction guidelines and reinforced our sense that we were on track with the project, given that our experience was consistent with that of others. We also benefitted significantly from Webinars addressing successful VTE work under way at hospitals in the United States and Canada. The Webinars highlighted effective strategies to increase appropriate assessment of VTE risk and support-related interventions. For example, one in-depth discussion concerned the use of various VTE risk-screening tools, including the benefits of a physician-based versus a nurse-based risk assessment. Another important shared strategy, which addressed education and practices, was designed to shift the focus away from the use of mechanical devices (for example, intermittent pneumatic compression) to the use of pharmacologic interventions for prophylaxis.

**Improvement Opportunities.** After the first month of data (October 2006) were entered and summarized in January 2007, Overlook's newly convened, multidisciplinary VTE work group (composed of physicians, nurses, pharmacists, nutritionists, and quality staff), working with the nurse abstractor (who acted as both a resource and facilitator), began to analyze the results. It was clear that we had improvement opportunities for

all of the pilot quality measures. The group began to explore related evidence-based practices provided to pilot participants by contacting best practice organizations and conducting literature reviews. In addition, a major education program was launched for physicians and nurses regarding VTE as the number-one cause of preventable deaths in hospitalized patients. Although the surgical teams had processes in place to ensure that VTE prophylaxis was provided for patients undergoing surgery, incorporating this practice into processes for most hospitalized medical patients proved a greater challenge. Interventions targeting medical patients included updating the admission order packet to include a VTE risk assessment and related prophylaxis order set. Physician education on the evidence of risk of deep vein thrombosis (DVT)/pulmonary embolism (PE) in the medical population was necessary, along with data demonstrating that increased use of prophylaxis would not increase the risk of bleeding. In addition, education on the criteria for overlap therapy was provided.

**Accomplishments.** As a result of work done on this project, by January 2008 Overlook's accomplishments were as follows:

- Extensive physician education regarding VTE risk assessment and prophylaxis based on the ACCP's guidelines
- Development and implementation of a VTE risk assessment and prophylaxis order form
- Extensive nursing education regarding VTE risk, including pathophysiology that causes 90% of hospitalized patients to be at moderate or high risk, and implementation of the prophylaxis order set
- Inclusion of status regarding risk assessment and prophylaxis for newly admitted patients in multidisciplinary rounds and shift handoffs

**VTE Quality Measure Recommendations.** On the basis of the pilot project, Overlook recommended to NQF (1) modification of the data definition for VTE discharge instructions and (2) streamlining of the abstraction requirements.

## **Learning from the Pilot Project**

### **TAKING ACTION ACROSS ATLANTIC HEALTH**

**Creating an Organizationwide Initiative.** During the pilot, Overlook achieved significant improvements in VTE prevention and management. As a result, in Summer 2007, Atlantic Health also formed a multidisciplinary, multihospital team to develop an organizationwide initiative designed to improve VTE prevention and treatment on the basis of existing ACCP evidence-based guidelines<sup>7</sup> and evolving NQF performance measures. The team, which included physicians from numerous specialties, nurses, pharmacists, residents, quality improvement

(QI) experts, and information system scientists, was fully supported by Atlantic Health's chief medical officer. To gain additional insights to further advance its implementation strategies, Atlantic Health participated in the final discussions of the NQF VTE quality measure steering committee in December 2007.

As part of this systemwide initiative, Overlook, along with its sister hospital, Morristown Memorial Hospital, a 660-bed regional trauma center, engaged multidisciplinary teams in efforts to understand the VTE quality measures in development and their significance and to improve related processes and documentation. On the basis of this early experience, the Atlantic Health QI council and board quality committee agreed to fully implement the NQF-endorsed VTE consensus standards in all inpatient units beginning January 2008. (This initiative was also endorsed by the Atlantic Health board of trustees, the senior management team, the Atlantic Health physician quality committee, and the quality and patient safety committees of both hospitals.)

**Setting Quality Goals.** As early as July 2007, the Atlantic Health chief medical officer, along with the quality directors, began packaging these measures as systemwide organizational quality goals for 2008. Proposed achievement targets for each measure were set, and a VTE prevention and management scorecard was designed and populated. The consensus of these committees and the board was to approve a composite measure that included five of the eight VTE quality measures as part of Atlantic Health's 2008 leadership performance incentive program.

The VTE quality composite measure consisted of the two nationally endorsed Surgical Care Improvement Project (SCIP) VTE quality measures and the piloted quality measures, including VTE prophylaxis in medical and other surgical patients, nomogram use for those patients receiving anticoagulation therapy, and comprehensive anticoagulation instructions for patients discharged on this therapy. Although the goal for the composite VTE quality measure was to achieve specified performance goals for three of the five individual measures during 2008, the team focused on achieving all five. The individual measures and their goals are shown in Table 1 (page 305). In May 2008, NQF endorsed six VTE quality measures, which included the five that Atlantic Health had selected for evaluation of its 2008 organizational VTE quality goals. The other two Atlantic Health measures (SCIP-VTE-1, SCIP-VTE-2) had been previously endorsed.<sup>15</sup>

**Pursuing Tools and Interventions.** At Overlook, aggressive pursuit of tools and processes that would support consistent

VTE risk assessment and prophylaxis continued. At the other, nonpilot hospital, the quality director and physician champion initiated a VTE quality work group that included representatives from pharmacy, nursing, residents, QI experts, and information system scientists, while the Atlantic Health chief medical officer convened a systemwide work group. The charge of these two new work groups was, at the hospital or systemwide level, to review the data, identify opportunities for improvement, and develop interventions that would drive ideal VTE prevention and management, much as Overlook's VTE quality work group had done.

Overlook's VTE quality work group's experience and lessons learned were rapidly shared through this structure of work groups, given the organizationwide focus on VTE prevention and management as a quality goal for 2008. Standardized organizational interventions and tools were developed, along with hospital-specific interventions to accommodate areas where the site cultures and/or processes naturally varied. For example, while the process for triggering the nutritional consult or processes and documentation forms for patient education varied, the educational brochure was standardized across the entire system.

In addition to drawing on the lessons learned from the pilot experience, the teams identified—and modified—tools and interventions from other organizations that successfully implemented these guidelines. For example, a risk assessment form combined with an order set was modeled after a form provided by the University of Washington. When such tools or interventions could not be identified, the implementation teams at the clinical unit levels tested their ideas and modified them in accordance with effectiveness through Plan-Do-Study-Act (PDSA) cycles, much as Overlook had done during the pilot project. For example, pharmacy, QI, dietary, medicine, home care, rehabilitation, and public relations all collaborated to develop a comprehensive patient education brochure that was used to discuss safe, effective anticoagulation management with all Atlantic Health patients discharged on anticoagulation therapy.

## **Continuing VTE Prevention and Management Efforts**

### **RESETTING OF MEASURES**

In July 2008, Atlantic Health's chief medical officer began the organizational process for determining the 2009 quality goals by asking the VTE work groups to review all six of the newly endorsed VTE quality measures. The teams were asked to determine if these measures, along with SCIP-VTE-1 and

**Table 1. Atlantic Health 2008–2009 Venous Thromboembolism (VTE) Prevention and Management Quality Measures and Goals**

Measure Name	Measure Description	AH 2008 Data	2008 Goal	AH 2009 Data	2009 Goal
SCIP-VTE-1	Surgical pts w/ VTE prophylaxis ordered	98%	95%	98%	99%
SCIP-VTE-2	Surgical pts receiving VTE prophylaxis w/in 24 hours prior to 24 hours after surgery	94%	95%	97%	99%
VTE-1 Prophylaxis	VTE risk assessment/prophylaxis within 24 hours of hospital admission or surgery end time	69%	75%	70%	95%
VTE-2 ICU VTE Prophylaxis	VTE risk assessment/prophylaxis within 24 hours after the initial admission (or transfer) to the ICU or surgery end time	n/a	n/a	95%	75%
VTE-3 Anticoagulation Overlap Therapy	Pts diagnosed with VTE who received parenteral and warfarin therapy for at least five days with an international normalized ratio (INR) greater than or equal to 2 prior to discontinuation of parenteral therapy or discharged in less than five days on both medications	n/a	n/a	79%	75%
VTE-4 UFH Monitoring	VTE pts receiving IV unfractionated heparin (UFH) therapy with documentation that the dosages and platelet counts are monitored by nomogram/protocol	100%	95%	100%	Maintain 100%
VTE-5 VTE Discharge Instructions	VTE pts that are discharged home, home care, or home hospice on warfarin with written discharge instructions that address all four criteria: follow-up monitoring, compliance issues, dietary restrictions, and potential adverse drug reactions/interactions	59%	75%	77%	95%
VTE-6 Incidence of Potentially Preventable VTE	Pts diagnosed with VTE during hospitalization (not POA) that did <u>not</u> receive VTE prophylaxis	n/a	n/a	0%	< 10%

Pts, patients; SCIP, Surgical Care Improvement Project; ICU, intensive care unit; POA, present on admission; AH, Atlantic Health; n/a, nonapplicable.

SCIP-VTE-2, afforded sufficient opportunity to continue VTE prevention and treatment as an organizationwide initiative. The work groups concluded that, although some of the measures could be moved to a “maintenance phase,” one year was not sufficient to address all opportunities in each of the areas of care represented by the eight VTE quality measures. So, by the end of 2008, Atlantic Health had approved a revised composite VTE quality measure, which consisted of the following four measures, with a commitment to continue monitoring the other four:

1. VTE prophylaxis in medical and “non–SCIP” surgical patients
2. VTE prophylaxis in the ICU
3. Overlap therapy
4. Comprehensive discharge instructions for patients receiving anticoagulation therapy

Again, goals for each individual measure were established and endorsed by the various quality committees and the board (Table 1). In 2009, the VTE prevention and management quality scorecard was updated (Figure 1, page 306).

#### ABSTRACTION OF VTE DATA

A new challenge was how to abstract VTE data more effi-

ciently for these measures while the clinical information systems, such as computerized provider order management (CPOM) and electronic health records, which capture information such as contraindications to prophylaxis, were not fully functional. Partnering with the clinical data management department, the VTE work groups were able to streamline abstraction by culling billing data in accordance with the measure specifications, minimizing the review of charts to reliably identify cases meeting inclusion criteria. While nurse abstraction times remained substantial, a relevant, random, hospital-wide sample was available.

#### CONDUCTING SUCCESSFUL INTERVENTIONS

Standardized order sets, audit and feedback of results, and electronic reminders (including those provided through CPOM systems) have all helped improve VTE prophylaxis.<sup>16–20</sup> The following interventions, reflecting almost four years of experience at Atlantic Health, have helped us to meet our quality measure goals (see “Results”):

- Implemented a risk assessment/order set for all medical and surgical patients, which has been adopted systemwide and has recently been integrated into CPOM (Figure 2, page 307; full-size form available in online article)

Venous Thromboembolism (VTE) Prevention and Management Quality Scorecard

Legend				
Achieves National Excellence	Meets or Exceeds Target	Approaching Target	Not On Target	
Atlantic Health Quality Organizational Goals for 2009			No Data Available	
Performance Measure	2009 Target	Morristown Memorial Hospital	Overlook Hospital	Atlantic Health
Prevent Venous Thromboembolism (VTE) # At or Above Benchmark of 4 VTE Measures	3 of 4 Measures at Benchmark	2 of 4	2 of 4	2 of 4
VTE 1: VTE Prophylaxis in Medical / Surgical Patients	95%	76%	64%	70%
VTE 2: VTE Prophylaxis in ICU Patients	75%	95%	94%	95%
VTE 3: VTE Patients with Overlap of Anticoagulation Therapy	75%	81%	77%	79%
VTE 5: VTE Discharge Instructions (composite of 4 instructional topics including follow-up monitoring, compliance issues, dietary restrictions, potential for adverse drug reaction/interaction)	95%	73%	83%	77%
SCIP VTE 1: Surgical Patients with VTE Prophylaxis Ordered	Top US 10%	96%	100%	98%
SCIP VTE 2: Surg Pts Receiving VTE Prophyl w/in 24 Hrs Bef or 24 Hrs Aft Surg	Top US 10%	96%	98%	97%
VTE 4: VTE Patients Receiving Heparin, Managed by Nomogram	>95%	100%	100%	100%
VTE 6: Incidence of Potentially Preventable VTE	<10%	0%	0%	0%

\* Top US 10% is 99% for these individual SCIP VTE measures based upon the National Q2 2008 Benchmarks report.

Figure 1. Draft preliminary rolling-quarter (October–December) 2009 results are shown. ICU, intensive care unit.

- Developed a daily unit report to alert physicians to medical patients on a unit/floor who have not yet received VTE prophylaxis; this is currently being replaced by a CPOM system requiring VTE prophylaxis orders or documentation of contraindication (Figure 3, page 308).

- Designed a comprehensive patient education booklet for patients discharged on anticoagulation therapy—used across the health care system

- Developed trigger systems for the nutrition department to ensure that patients receiving warfarin receive a consult before discharge

- Developed/modified and implemented heparin and warfarin nomograms

- Established a systemwide anticoagulation task force

- Established a timely follow-up process with individual nursing units when documentation of written warfarin education is not present in the medical record

- Established a timely process by which to send letters to

department chairs and responsible physicians regarding failure to meet the standard when prophylaxis was not provided

### Results

Summary reports from the pilot project, although imperfect because of modifications in the measure specifications, indicated opportunity for improvement in all tested quality measures. As described previously, the organization adopted quality goals encompassing five VTE quality measures in 2008. Atlantic Health achieved three of the five individual goals set for these measures, as shown in Table 1.

For 2009, Atlantic Health's quality goals, as stated, included four of the eight VTE quality measures and reflected a commitment to continued monitoring of the remaining four quality measures. In addition, for the quality measures that carried over from 2008, the individual targets were raised from 75% to 95%. The 2009 results are also shown in Table 1.

## Discussion

We celebrate our achievements in VTE prophylaxis for ICU patients (95%) and reliable use of nomograms (100%) for medication administration in patients with DVT/PEs. Our performance on the SCIP-VTE measures has been nearly perfect, with only one case missed per quarter; however, we continue to strive to achieve 100% consistently. We continue to focus on VTE prophylaxis in the medical patient population; for patients with DVT/PEs, we continue to strive to reach 95% compliance for appropriate overlap therapy and documentation of comprehensive discharge instructions.



As expected with newly endorsed quality measures, frequent modifications or multiple iterations of measure specifications follow—for years, in some cases. In 2008, the Joint Commission recommended that the VTE measures become a core measure set and be aligned with the CMS quality measures. (The specifications are located at CMS or Joint Commission<sup>21</sup> Web sites.)\*

The VTE measures are one of the first sets to be “retooled” for retrieval from an electronic health record and have been mentioned in the American Recovery and Investment Act of 2009 legislation as a potential measure set that hospitals could use in the future to abstract data “electronically.”<sup>22</sup>

In its work to build effective VTE prevention and management practices, Atlantic Health relied heavily on well-established and widely known clinical practice guidelines, including those from the ACCP, the American Heart Association (AHA), the American College of Cardiology (ACC), and the American Society of Health-System Pharmacists (ASHP).<sup>7,23,24</sup> A systemwide VTE steering committee was established to prevent VTE in hospitalized patients. Clinical and quality leaders from both Atlantic Health hospitals met together throughout 2008 to develop and implement order sets, patient information materials, and discharge instruction tools to achieve effective prevention and treatment of VTE as assessed by the VTE measures. Actions also included working collaboratively with patients with VTE and their families to ensure successful management of anticoagulation therapy. Following successful implementation of multiple QI

\*Specifications have been available since April 2009, for use beginning with October 2009 discharges.

## Venous Thromboembolism (VTE) Prophylaxis Medical Admission Orders



FINAL

**Venous Thromboembolism  
Prophylaxis Medical Admission  
Orders**

PATIENT ID  
HERE

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Allergies: \_\_\_\_\_

VTE RISK STRATIFICATION		
Low Risk	Intermediate Risk	High Risk
0 risk factors (or expected LOS less than or equal to 2 days), plus patient ambulatory.	1 risk factor below. <b>Pharmacologic prophylaxis preferred over mechanical unless Contraindicated</b>	2 or more risk factors below. <b>Enoxaparin, fondaparinux</b>

VTE RISK FACTORS		
Patient Circumstances	Medical or Surgical Conditions	
<ul style="list-style-type: none"> <li>• Age greater than 40 years</li> <li>• Hospitalization for surgery or acute illness</li> <li>• Critical Care Unit admission</li> <li>• Obesity (BMI greater than or equal to 30)</li> <li>• Immobility (confined to bed or chair) greater than or equal to 72 hours</li> <li>• Central venous catheter</li> <li>• Recent major surgery (less than or equal to 3 months)</li> </ul>	<ul style="list-style-type: none"> <li>• <i>CV</i> Myocardial Infarction (less than 3 months) CHF (NYHA Class III or IV) Venous stasis / varicose veins</li> <li>• <i>Pulm</i> Lung disease (acute or chronic)</li> <li>• <i>Renal</i> Dehydration, severe (greater than 10% weight) Nephrotic syndrome Inflammatory bowel disease</li> <li>• <i>GI</i> Acute ischemic stroke</li> <li>• <i>Neuro</i> Spinal cord injury (less than 1 month) Previous ischemic stroke with paresis</li> <li>• <i>ID</i> Acute infection</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Heme</i> Hypercoagulable state History of DVT or PE Family history DVT or PE (1<sup>st</sup> relative) Sickle cell disease</li> <li>• <i>Onc</i> Malignancy (active) Myeloproliferative disorder</li> <li>• <i>Rheum</i> Rheumatologic disease (active)</li> <li>• <i>Ortho</i> Elective hip or knee arthroplasty Fractured hip, pelvis, femur, or leg</li> <li>• <i>Gyn</i> Pregnancy or post-partum (less than 1 month) Estrogen-based therapy (OCP, HRT) Pelvic Floor Surgery (less than 1 month)</li> </ul>

CONTRAINDICATIONS TO PHARMACOLOGIC VTE PROPHYLAXIS

<p><b>ABSOLUTE</b></p> <ul style="list-style-type: none"> <li>• Active hemorrhage</li> <li>• Hemorrhage from severe trauma to head or spinal cord (less than 1 month)</li> <li>• Immune mediated heparin induced thrombocytopenia (HIT) [See Argatroban protocol]</li> <li>• Epidural catheter presence is an absolute contraindication for Enoxaparin/Fondaparinux</li> </ul>	<p><b>RELATIVE</b></p> <ul style="list-style-type: none"> <li>• Intracranial hemorrhage <b>within</b> 1 year</li> <li>• GI hemorrhage <b>within</b> 1 month</li> <li>• GU hemorrhage <b>within</b> 1 month</li> <li>• Intraocular surgery <b>within</b> 2 weeks</li> <li>• Epidural catheter removal <b>within</b> 12 hours</li> <li>• Post-operative bleeding concerns <b>within</b> 4 hours</li> <li>• Active intracranial lesions/aneurysm</li> <li>• Hypertensive urgency/emergency</li> <li>• Thrombocytopenia (less than 50 platelets/mL) or falling platelet count</li> <li>• Coagulopathy (INR greater than 2)</li> <li>• End stage liver disease</li> </ul>
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**VTE prophylaxis - Patient at intermediate or high risk (see risk stratification)**

Enoxaparin (Lovenox) 40 mg subcutaneously once daily (if creatinine clearance greater than 30 mL/min.)

Enoxaparin (Lovenox) 30 mg subcutaneously once daily (if creatinine clearance greater than 20 mL/min and less than 30 mL/min.)

Fondaparinux (Arixtra) 2.5 mg subcutaneously once daily (if creatinine clearance greater than 30 mL/min & wt. greater than 50 kg)

Unfractionated Heparin 5000 units subcutaneously  every 8 hours  every 12 hours (for patients 75 or older)

Other: \_\_\_\_\_

Intermittent Pneumatic Compression Boots while in bed

**VTE prophylaxis not ordered because**  Patient at low risk  On anticoagulation  Contraindicated Reason \_\_\_\_\_

\*Sign, Date and Time each page of Orders

Physician Signature \_\_\_\_\_ Contact Number \_\_\_\_\_ Time/Date \_\_\_\_\_

WHITE - CHART COPY      YELLOW - PHARMACY COPY      PINK - NURSING COPY

A4H903378 (07/09)

**Figure 2.** The risk assessment/order set for all medical and surgical patients was adopted systemwide and was integrated into the computerized provider order management system. This form is currently being revised to exclude “Epidural Catheter Presence is an absolute contraindication for Enoxaparin/Fondaparinux.” LOS, length of stay; BMI, body mass index; CHF, congestive heart failure; NYHA, New York Heart Association; DVT, deep vein thrombosis; PE, pulmonary embolism; CV, cardiovascular; Pulm, pulmonary; GI, gastrointestinal; Neuro, neurologic; ID, infectious disease; Heme, hematologic; Onc, oncologic; Rheum, rheumatologic; Ortho, orthopedic; Gyn, gynecologic; OCP, oral contraceptive pill; HRT, hormone replacement therapy; GU, genitourinary; INR, international normalized ratio.

innovations that arose from our community hospital’s pilot project participation in 2006, Atlantic Health sustained and expanded its efforts in 2009 to improve performance on all eight NQF–endorsed VTE quality measures for the entire health system. This focus, with refinements based on previous successes and identification of continued improvement oppor-

Daily Room Report for Venous Thromboembolism (VTE) Prophylaxis

Daily Room Report: VTE Prophylaxis									
Room #	21-Jan-08	22-Jan-08	23-Jan-08	24-Jan-08	25-Jan-08	28-Jan-08	29-Jan-08	30-Jan-08	31-Jan-08
11	xxxxx	0	0	xxxxx	xxxxx	0	0		
15	0	xxxxx	enoxaparin 30 mg qd	enoxaparin 30mg qd	enoxaparin 30mg qd	enoxaparin 30 mg qd	xxxxx		
17-1	q8h heparin	q8h heparin	q8h heparin	q8h heparin	q8h heparin	0	xxxxx		
17-2	q8h heparin	q8h heparin	q8h heparin	q8h heparin	xxxxx	0	q8h heparin		
18-1	0	0	0	xxxxx	0	0	0		
18-2	0	warfarin	0	0	0	0	0		
19-1	0	0	0	0	0	xxxxx	0		
19-2	0	0	0	0	q8h heparin	q8h heparin	q8h heparin		

Legend: 0 = outlier (i.e. no prophylaxis)      xxxxx = empty room

Summary Statistics

	21-Jan-08	22-Jan-08	23-Jan-08	24-Jan-08	25-Jan-08	28-Jan-08	29-Jan-08	30-Jan-08	31-Jan-08
Pts Rec'ing VTE Prophylaxis	18	20	13	19	18	18	20		
Outliers	27	27	24	21	27	32	26		
Total Patients	45	47	37	40	45	50	46		
% Prophylaxed	<b>40%</b>	<b>43%</b>	<b>35.1%</b>	<b>47.5%</b>	<b>40%</b>	<b>36%</b>	<b>43.5%</b>		

Figure 3. The daily unit report to alert physicians to medical patients on a unit/floor who have not yet received VTE prophylaxis is being replaced by a computerized provider order management system requiring VTE prophylaxis orders or documentation of contraindication. q8h, every 8 hours; Qd, every day; Pts, patients; Rec'ing, receiving.

tunities, continues into 2010.

Bratzler and others have published several studies that describe less than adequate practice of VTE prophylaxis in at-risk medical and surgical patient populations.<sup>16,25-30</sup> Although we have greatly increased the consistent use of VTE prophylaxis in surgical and stroke patients, we continue to work with our medical staff to identify system changes and technology applications—such as efforts to include VTE-related risk assessment and ordering processes in Atlantic Health's CPOM system—that will further support their efforts to prevent DVT/PE. In addition, we remain focused on the comprehensive, effective education of our patients on anticoagulation therapy and, equally important, on understanding and addressing any challenges the patients have in following the recommendations made at discharge.

Atlantic Health continues to assess its performance in accordance with the 2009 NQF Safe Practice 28 for VTE Prevention<sup>31</sup> as a participant in the Leapfrog Hospital Survey

(sponsored by Horizon Blue Cross of New Jersey, as part of its “Hospital Rewards” pay-for-performance program), achieving all points for this safe practice at both hospitals. In addition, both hospitals participate in the American Stroke Association/AHA Get With The Guidelines®–Stroke program, which includes VTE prophylaxis as one of the quality indicators.<sup>32</sup> Finally, Atlantic Health is an active member of the Coalition to Prevent Deep Vein Thrombosis, whose goal is to raise awareness of patients, caregivers, and policymakers of the risk factors, signs, and symptoms of VTE.<sup>33</sup>

Conclusion

Participation of a broad range of hospitals, including academic medical centers and community hospitals, in a national pilot project to develop quality measures is critical to ensure that differences in environment, resources, staffing, and patient acuity are accounted for, particularly when the measures are intended to be used for public reporting. A hospital's participation pro-

vides a detailed understanding and valuable insights on the topic area and measures, creates a feeling of collaboration and shared investment in the measures, and provides opportunities to assess and improve performance well in advance of the actual launch of the measures. **J**

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Venous Thromboembolism (VTE) Prophylaxis Medical Admission Orders



**Venous Thromboembolism  
Prophylaxis Medical Admission  
Orders**



DT1400

**FINAL**

PATIENT ID  
HERE

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Allergies: \_\_\_\_\_

VTE RISK STRATIFICATION		
Low Risk	Intermediate Risk	High Risk
<b>0 risk factors</b> (or expected LOS less than or equal to 2 days), plus patient ambulatory.	<b>1 risk factor</b> below. <i>Pharmacologic prophylaxis preferred over mechanical unless Contraindicated</i>	<b>2 or more risk factors</b> below. <i>Enoxaparin, fondaparinux</i>

VTE RISK FACTORS			
Patient Circumstances	Medical or Surgical Conditions		
<ul style="list-style-type: none"> <li>• Age greater than 40 years</li> <li>• Hospitalization for surgery or acute illness</li> <li>• Critical Care Unit admission</li> <li>• Obesity (BMI greater than or equal to 30)</li> <li>• Immobility (confined to bed or chair) greater than or equal to 72 hours</li> <li>• Central venous catheter</li> <li>• Recent major surgery (less than or equal to 3 months)</li> </ul>	<ul style="list-style-type: none"> <li>• <i>CV</i> Myocardial Infarction (less than 3 months) CHF (NYHA Class III or IV) Venous stasis / varicose veins</li> <li>• <i>Pulm</i> Lung disease (acute or chronic)</li> <li>• <i>Renal</i> Dehydration, severe (greater than 10% weight) Nephrotic syndrome</li> <li>• <i>GI</i> Inflammatory bowel disease</li> <li>• <i>Neuro</i> Acute ischemic stroke Spinal cord injury (less than 1 month) Previous ischemic stroke with paresis</li> <li>• <i>ID</i> Acute infection</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Heme</i> Hypercoagulable state History of DVT or PE Family history DVT or PE (1° relative)</li> <li>• <i>Onc</i> Sickle cell disease Malignancy (active) Myeloproliferative disorder</li> <li>• <i>Rheum</i> Rheumatologic disease (active)</li> <li>• <i>Ortho</i> Elective hip or knee arthroplasty Fractured hip, pelvis, femur, or leg</li> <li>• <i>Gyn</i> Pregnancy or post-partum (less than 1 month) Estrogen-based therapy (OCP, HRT) Pelvic Floor Surgery (less than 1 month)</li> </ul>	

CONTRAINDICATIONS TO PHARMACOLOGIC VTE PROPHYLAXIS	
<p><b>ABSOLUTE</b></p> <ul style="list-style-type: none"> <li>• Active hemorrhage</li> <li>• Hemorrhage from severe trauma to head or spinal cord (less than 1 month)</li> <li>• Immune mediated heparin induced thrombocytopenia (HIT) [See Argatroban protocol]</li> <li>• Epidural catheter presence is an absolute contraindication for Enoxaparin/Fondaparinux</li> </ul>	<p><b>RELATIVE</b></p> <ul style="list-style-type: none"> <li>• Intracranial hemorrhage <b>within</b> 1 year</li> <li>• GI hemorrhage <b>within</b> 1 month</li> <li>• GU hemorrhage <b>within</b> 1 month</li> <li>• Intraocular surgery <b>within</b> 2 weeks</li> <li>• Epidural catheter removal <b>within</b> 12 hours</li> <li>• Post-operative bleeding concerns <b>within</b> 4 hours</li> <li>• Active intracranial lesions/neoplasm</li> <li>• Hypertensive urgency/emergency</li> <li>• Thrombocytopenia (less than 50 platelets/mL) or falling platelet count</li> <li>• Coagulopathy (INR greater than 2)</li> <li>• End stage liver disease</li> </ul>

**VTE prophylaxis - Patient at intermediate or high risk (see risk stratification)**

Enoxaparin (Lovenox) 40 mg subcutaneously once daily (If creatinine clearance greater than 30 mL/min.)

Enoxaparin (Lovenox) 30 mg subcutaneously once daily (If creatinine clearance greater than 20 mL/min and less than 30 mL/min.)

Fondaparinux (Arixtra) 2.5 mg subcutaneously once daily (If creatinine clearance greater than 30 mL/min & wt. greater than 50 kg)

Unfractionated Heparin 5000 units subcutaneously  every 8 hours  every 12 hours (for patients 75 or older)

Other: \_\_\_\_\_

Intermittent Pneumatic Compression Boots while in bed

**VTE prophylaxis not ordered because**  Patient at low risk  On anticoagulation  Contraindicated Reason \_\_\_\_\_

*Sign, Date and Time each page of Orders*

Physician Signature \_\_\_\_\_ Contact Number \_\_\_\_\_ Time/Date \_\_\_\_\_

**WHITE - CHART COPY**
**YELLOW - PHARMACY COPY**
**PINK - NURSING COPY**

AH9903378 (07/09)

Figure 2. The risk assessment/order set for all medical and surgical patients was adopted systemwide and was integrated into the computerized provider order management system. This form is currently being revised to exclude "Epidural Catheter Presence is an absolute contraindication for Enoxaparin/Fondaparinux." LOS, length of stay; BMI, body mass index; CHF, congestive heart failure; NYHA, New York Heart Association; DVT, deep vein thrombosis; PE, pulmonary embolism; CV, cardiovascular; Pulm, pulmonary; GI, gastrointestinal; Neuro, neurologic; ID, infectious disease; Heme, hematologic; Onc, oncologic; Rheum, rheumatologic; Ortho, orthopedic; Gyn, gynecologic; OCP, oral contraceptive pill; HRT, hormone replacement therapy; GU, genitourinary; INR, international normalized ratio.



## Patient and Family Involvement

# Best Practices for Basic and Advanced Skills in Health Care Service Recovery: A Case Study of a Re-admitted Patient

Anna C. Hayden; James W. Pichert, Ph.D.; Jodi Fawcett; Ilene N. Moore, M.D., J.D.; Gerald B. Hickson, M.D.

*Patient relations representative Ms. Heard receives a call from the nurse manager of the inpatient gynecology service, asking her to talk with a patient. B.W., a 58-year-old woman, was discharged five days earlier but has been re-admitted for abdominal pain and fever. The manager reports that B.W. complained, "I'm not sure my doctor knows or cares what's going on." Ms. Heard responds that she will come to the floor to talk with B.W.\**

The Joint Commission encourages patient and family reporting of concerns about their experiences as one way to promote quality and safety.<sup>1</sup> Inviting, responding to, and following up on patient complaints are important to provider organizations.<sup>2,3</sup> Various terms in the literature, the more common references include *service recovery*, *complaint management*, and variants such as *complaint handling*, *service marketing*, or *service recovery marketing*.<sup>4-6</sup>

*Complaint management* and *service recovery* sometimes are used to connote different aspects of a unified process. *Complaint management* may refer to behind-the-scenes policies, procedures, and standards for inviting and evaluating complaints and dealing fairly and consistently with "customers."<sup>2,7-9</sup> In comparison, *service recovery* following a service failure may mean customer recovery, that is, working directly with an unhappy customer to earn back satisfaction, trust, and willingness to return for future services. *Complaint management* and *service recovery* are sometimes used interchangeably, while *service recovery* can also be viewed as a tool within a complaint management plan, such as dispensing parking vouchers for delays in service.<sup>10-15</sup>

Our use of the term *service recovery* refers to the organization's entire process for facilitating resolution of dissatisfactions, whether or not visible to patients and families. In this usage, *service recovery* is "the systematic approach to proactively solicit . . . feedback while responding to complaints in a manner that

### Article-at-a-Glance

**Background:** *Service recovery* refers to an organization's entire process for facilitating resolution of dissatisfactions, whether or not visible to patients and families. Patients are an important resource for reporting miscommunications, provider inattention, rudeness, or delays, especially if they perceive a connection to misdiagnosis or failed treatment. Health systems that encourage patients to be "the eyes and ears" of individual and team performance capitalize on a rich source of data for quality improvement and risk prevention. Effective service recovery requires organizations (1) to learn about negative perceptions and experiences and (2) to create an infrastructure that supports staff's ability to respond. Service recovery requires the exercise of both basic and advanced skills. We term certain skills as *advanced* because of the significant variation in their use or endorsement among 30 health care organizations in the United States.

**Best Practices for Basic Service Recovery:** On the basis of our work with the 30 organizations, a mnemonic, HEARD, incorporates best practices for basic service recovery processes: Hearing the person's concern; Empathizing with the person raising the issue; Acknowledging, expressing Appreciation to the person for sharing, and Apologizing when warranted; Responding to the problem, setting time lines and expectations for follow-up; and Documenting or Delegating the documentation to the appropriate person.

**Best Practices for Advanced Service Recovery:** Impartiality, chain of command, setting boundaries, and documentation represent four advanced service recovery skills critical for addressing challenging situations.

**Conclusion:** Using best practices in service recovery enables the organization to do its best to make right what patients and family members experience as wrong.

\*The case study is a composite, drawing on the records of a number of patients.

creates loyalty and utilizes information to make system improvement.” It “entails...taking a negative experience and turning it into a positive and memorable one.”<sup>2</sup> Put simply, service recovery is the process by which organizations attempt to “make right” what went wrong for patients and families.

Effective service recovery requires organizations (1) to learn about negative perceptions and experiences and (2) to create an infrastructure that supports staff’s ability to respond. Even when patients’ expectations appear unrealistic, expressed dissatisfactions deserve consideration because they suggest opportunities to improve communication. These individually recorded comments, concerns, complaints, issues, and observations (collectively, *complaints* or *concerns*) can later be aggregated and analyzed to identify ongoing issues and trends.

Service recovery requires the exercise of both basic and advanced skills. In this article, we first describe models for service recovery and then review commonly accepted best practices in basic service recovery.<sup>15</sup> Next, we discuss best practices in advanced service recovery derived from our working relationships with patient advocates at 30 health care organizations in the United States. We term the skills discussed as *advanced* because we have noted significant variation in their use or endorsement among those organizations. Finally, we (1) identify how leading organizations increase identification of dissatisfied patients/families and (2) explore how advanced service recovery practices benefit organizations that use aggregate complaint data to track, trend, and provide feedback.<sup>1-3,7</sup>

## Why Do Service Recovery?

Although external regulations, such as those reflected in Centers for Medicare & Medicaid Services (CMS) requirements, may motivate organizations to address complaints,<sup>16</sup> the best programs are driven by three internal motivators. Specifically, service recovery:

1. Aims to “do the right thing,” showing the organization’s and staff’s commitment to deliver safe, compassionate, quality care (moral motivation)
2. Rebuilds confidence, retains patient loyalty, distinguishes the organization from competitors, and reduces the risk that patients will be lost to follow-up or leave the practice (marketing motivation)
3. May reduce revenue loss and risk associated with dissatisfied patients and families to improve an organization’s bottom line<sup>8,17,18</sup> (money and margin motivation)

To these we add one more reason that organizations should highlight service recovery. In our experience, patients and families routinely report missed opportunities and errors. As close

and continuous observers, patients are an important resource for reporting miscommunications, provider inattention, rudeness, or delays, especially if they perceive a connection to misdiagnosis or failed treatment. Health systems that encourage patients to be “the eyes and ears” of individual and team performance capitalize on a rich source of data for quality risk prevention.<sup>17</sup>

## Service Recovery Processes

service recovery processes (Figure 1, page 312) and models vary. Many organizations employ a three- or four-level service recovery model (Table 1, page 313). At Level 1, organizations encourage patients to report concerns or unmet expectations and empower frontline staff to address issues “in-the-moment” at the point of service. Failure to resolve a complaint, persistent dissatisfaction, or the need for more resources to address the concern may require managerial assistance—Level 2. Level 3 involves referrals to a patient relations representative or advocate in the organization’s office of patient relations (sometimes called *patient/guest services*, *patient affairs*, *patient advocates*, or *ombudsmen*). At Level 4, patient relations representatives refer the complaint to others for input or resolution.

Many complaints handled at Levels 1 and 2 are relatively minor. As a result, many complaints go no further. However, select categories of complaints should be reported to patient relations even if successful in-the-moment service recovery has occurred, permitting identification of important and/or recurring problems (Table 2, page 313).

On notification, patient relations representatives have five options for handling complaints, as follows:

1. Recommend that resolution be attempted by (and coach if needed) the person who referred the patient/family.
2. Resolve the complaint without further consultation or referral.
3. Guide the complaint to the right person/department/office for review or resolution (for example, manager, physician or other associated provider, quality and safety, risk management, privacy, security).
4. Refer to an appropriate leader when the complaint suggests a concerning pattern.
5. Document only.

Whichever option (or combination of options) advocates choose, all communications and actions are documented.

## Best Practices for Basic Service Recovery

Health care organizations employ various mnemonics for guiding their basic service recovery processes. Some use EXCELL

Basic and Advanced Skills in Evaluating and Resolving Patient and Family Concerns

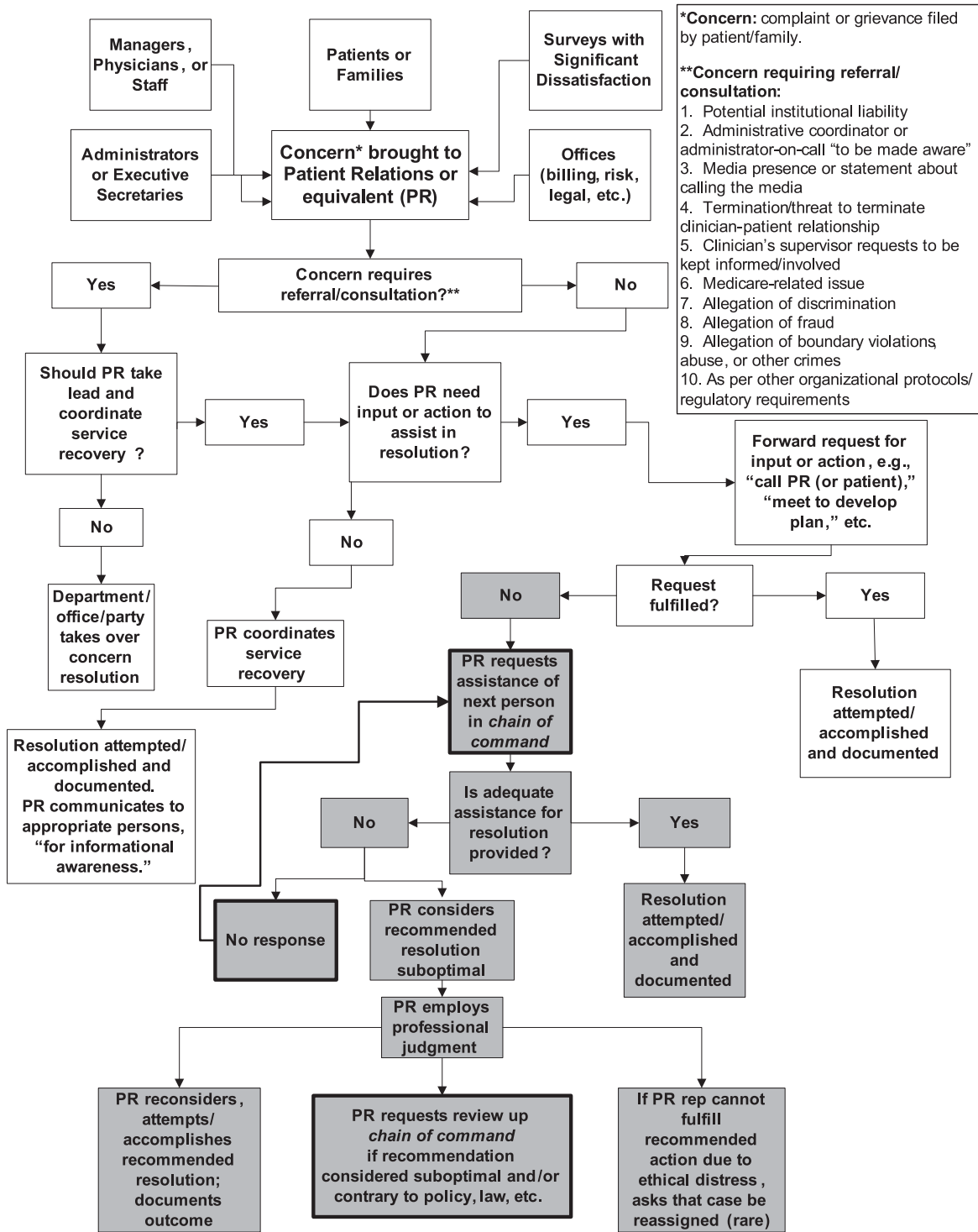


Figure 1. The processes for basic skills in evaluating and resolving patient and family concerns (white boxes) and for advanced skills in evaluating and resolving patient and family concerns (gray boxes) are shown.

Table 1. A Service Recovery Model\*

Level	Description
Level 1	Complaints are addressed immediately by employee on site.
Level 2	Complaints are addressed by manager on site.
Level 3	Manager/physician/staff refer patient or family to patient relations to facilitate complaint resolution. When appropriate, patient relations also initiates the grievance process in accordance with CMS guidelines.
Level 4	Patient relations personnel refer complaint up the chain of command for resolution or to another office within the organization with jurisdiction over the type of issue.

\*CMS, Centers for Medicare & Medicaid Services.

Table 2. Complaints to Refer to Patient Relations

Refer to patient relations complaints that:

1. Remain unresolved at the point of service
2. Are repeat concerns
3. Involve several departments or health care professionals
4. Involve physicians
5. Involve quality-of-care issues
6. Allege malpractice or involve an adverse event
7. Involve threats to call the media or regulatory bodies
8. Involve patient request to terminate a provider relationship
9. Allege abuse or boundary issues
10. Concern issues of privacy or confidentiality
11. Involve injury on the premises

(Empathize, eXplain, Communicate, Empower, Listen, and Learn),<sup>19</sup> while others use HEAT (Hear, Empathize, Apologize, Thank)<sup>20</sup> or HEART (Hear, Empathize, Apologize, Respond, Thank).<sup>2,21</sup> On the basis of our work with 30 leading health care organizations, we teach a fourth mnemonic, HEARD, which incorporates best practices for basic service recovery processes:

- Hearing the person’s concern
- Empathizing with the person raising the issue
- Acknowledging, expressing Appreciation to the person for sharing, and Apologizing when warranted
- Responding to the problem, setting time lines and expectations for follow-up
- Documenting or Delegating the documentation to the appropriate person

Although crucial for tracking and trending, documentation of patient/family complaints is not often discussed in the health care literature. However, we consider it an advanced skill and address it later in this article.

In summary, HEARD requires listening, communication, and problem-solving skills.<sup>2,3,19–21</sup> HEARD also suggests that patient relations representatives must be adept at unbiased and compassionate information gathering, identifying and managing expectations, drawing on a variety of resources, and documenting both complaints and their resolution, as illustrated in the continuing scenario regarding the patient B.W.:

Ms. Heard meets B.W., who explains that she went home five days after a laparoscopic procedure to remove her uterus and ovaries for early cancer. Two days later, she called her doctor, Dr. GYN, to report severe abdominal pain. B.W. was hospitalized and underwent tests, including computerized tomography (CT) of her abdomen and pelvis and a urinary tract x-ray (intravenous pyelogram [IVP]). During this admission, B.W. was told that the studies showed only “nor-

mal postoperative change” and was treated with intravenous (IV) antibiotics for an “infection.”

Three days after discharge, B.W. returns to the emergency department with continued abdominal pain and fever and was re-admitted. She states that she is upset because her doctor has not yet been in to see her and that she feels frustrated about this third admission because she is “not sure they really know or care about what’s happening.”

Ms. Heard listens to B.W.’s concerns, that is, she Hears, Empathizes, Acknowledges, and expresses Appreciation, and then begins the Resolution process by contacting Dr. GYN. Immediately after meeting with B.W., Ms. Heard Documents the specifics of B.W.’s concerns and Dr. GYN’s stated plan to visit B.W. the same day.

## Best Practices for Advanced Service Recovery

In this section, we discuss the four advanced service recovery skills critical for addressing challenging situations: (1) maintaining impartiality while reviewing allegations, (2) appropriately using the organizational chain of command to achieve complaint resolution, (3) navigating communication challenges with other members of the team related to service recovery attempts, and (4) documenting what patients and families say and the organization’s response.

### IMPARTIALITY

Maintaining impartiality is an important advanced skill. As patient advocates mediate between patients, families, providers and/or organizational leaders during the *H*, *E* and *A* stages, they refrain from forming, declaring, or speculating aloud about conclusions until a review and assessment of the facts have been completed. An advocate’s goal during the assessment phase is to

thoughtfully, respectfully, and skillfully acknowledge parties' questions and assertions without providing definitive answers and without prejudging outcomes. Maintaining impartiality can be difficult when plausible but diametrically opposed stories are told or when one story on its face is more believable. Projecting an objective, unbiased, and caring manner during the fact-finding review complies with the Society for Healthcare Consumer Advocacy Code of Ethics.<sup>3</sup> It also serves to minimize the potential for health care professionals to view advocates as "always taking the patient's side," or for patients to feel that advocates "just defend doctors and staff."

Consistently employing objective processes for complaint investigation and resolution promotes impartiality. Advocates demonstrate impartiality by team-oriented problem solving, an approach that signals and reassures all that advocates respect and value multiple inputs. For example, the process at the Vanderbilt University Medical Center is to (1) record the narrative text of the concern, (2) identify organizational personnel who can assist and can help resolve the concern, (3) ensure follow-up with the patient/family and involved health care professionals, and (4) document actions taken and the resolution.

To maintain impartiality, advocates should refrain from declaring what the organization or provider "should" do while an allegation remains unsubstantiated or when the assessment is inconclusive or complicated. After assessments are complete, however, patient relations representatives should solicit and advocate for the best resolution (the **R** stage) for all parties, thereby maintaining the balanced, team-oriented approach. If asked to propose a resolution, advocates find it useful to employ such phrases as "I don't know, but could we define a few alternatives?" or "It would seem we have several choices." For example, a provider might state, "I'm frustrated because that family called my office six times about the same thing—what was I supposed to do?" The response might be, "I don't know, but I wonder why they kept calling. Perhaps they didn't understand that you were waiting for important test results."

Ms. Heard maintains follow-up contact with B.W. during her inpatient stay. On hospital day 3, B.W. expresses her continued frustration to Ms. Heard, stating that her physician is not listening to her, and adds that she is certain the team missed something, now resulting in this third hospital stay.

Ms. Heard, maintaining impartiality, responds, "Your concerns are important. I will contact your doctor to learn more." Ms. Heard contacts Dr. GYN again and shares the concern. Dr. GYN assures Ms. Heard that none of the tests revealed anything amiss and adds that B.W. is "difficult."

Although he states there is nothing more to be gained from conversations with B.W., he agrees to stop by her room and reassure her.

Ms. Heard tells B.W. that she spoke with Dr. GYN about her concerns and relays his plan to visit her. The next day, Ms. Heard learns that B.W. is in the operating room to have fluid drained from her abdomen. Ms. Heard visits her before discharge to make sure she has her contact information.

## CHAIN OF COMMAND

To promote consistency, best-practice organizations support advocates by establishing service recovery policies and processes, including use of the chain of command in the face of particularly challenging circumstances (Figure 1, process outlined in bold). When a health care professional has not responded adequately (or at all) to an advocate's request for assistance resolving a complaint or refuses to do more, the chain of command should be used. The second advanced skill, then, is to know how, to whom, and when one should take an issue up the chain. Deferring to organizational authorities promotes the advocate's credibility with patients and families and, in most cases, providers. Using the chain of command also permits advocates to maintain impartiality while still advocating for the patient's complaint to be reviewed, resolved, and responded to (the **R** stage). If the organization has adopted a standard technique for patient-related communications, advocates may wish to employ it.<sup>22</sup>

Three days after her last hospital discharge, B.W. calls Ms. Heard: "I am in pain, I am still swollen, and I left a message but haven't received a call back from my doctor's office." Ms. Heard contacts Dr. GYN, who remarks, "B.W. is just impatient. It's going to take time. Tell her to take her pain medication and to call the office tomorrow." Ms. Heard responds that in her role she cannot provide medical instructions. Dr. GYN tells her, "We've given this patient the necessary information and we just don't have time to continue calling back." The phone clicks off.

Ms. Heard, assessing the attending physician's response and the nature of B.W.'s concerns, decides to contact the medical director of the GYN service. She respectfully and efficiently communicates the situation ("Patient states she's had continuing symptoms since her surgery and feels 'something has been missed'"), provides a brief background ("Patient states Dr. GYN is not listening"), describes her assessment ("Based on my communications with the patient and Dr. GYN, I am concerned for her"), and makes a specific recommendation/request ("I am calling to ask if you would review the case today or refer to someone who can review quickly").

Reporting through the chain of command can pose challenges. For example, consider a case in which an advocate refers a complaint up the chain for resolution but finds the supervisor's recommended resolution suboptimal, inadequate, illegal, contrary to policy, or unethical. To achieve resolution, advocates must first reconsider their own view, then use professional judgment to do one or more of the following (Figure 1):

■ Facilitate the recommended resolution/service recovery and document the outcome.

■ Take the concern to the next level in the chain of command for review.

■ Request case reassignment in the rare circumstance in which ethical distress may interfere with the advocate's ability to facilitate resolution.

A variant of the chain of command is referral to another person or department, such as a risk manager or quality/safety officer, who is empowered to review and bring parties together.

The medical director calls Dr. GYN to discuss B.W.'s case and then asks the organization's risk manager to coordinate a medical review. The medical review reveals that a leak of contrast material on B.W.'s urinary tract x-ray (IVP), indicating an injury to the ureter, was missed during the patient's first re-admission. Dr. GYN suspects that urine has been leaking into the abdomen since the original procedure. He orders a urology consult to prepare for surgical repair of the ureter.

## SETTING BOUNDARIES

The third advanced skill requires communicating well in circumstances where patients and families have questions about unanticipated outcomes or medical errors, assert that the organization is biased, or share concerns about unprofessional behavior. To the extent possible, advocates should promote patients' confidence in their providers and the organization and simultaneously be diligent in helping professionals "do the right thing" by patients. Advocates should not bear responsibility for assessing allegations of bias or unprofessional behavior, nor for disclosing adverse outcomes or errors, and should decline to do so.

Unfortunately, advocates may be caught between patients and families who want immediate answers and professionals who may appear unresponsive. If an advocate suspects, for example, that an error was not disclosed, the advocate must know how to proceed within the organization. If during service recovery efforts the attending does not respond or follow through, patient relations representatives employ the chain of command to share the relevant information and seek assistance.

This skill, then, helps the right people present patients and families with the right responses at the right time (Figure 1).

Policies, common language, and common training increase the reliability of timely, appropriate, and effective disclosure. At Vanderbilt, organizational policy, for example, places on the patient's attending clinician primary responsibility for coordinating a plan to share information concerning unanticipated outcomes, whether related to the patient's illness, complications of treatment, or medical error.

All Vanderbilt clinicians; patient relations representatives; risk managers; nursing, medical, and administrative leadership; and medical students undergo training in disclosure of known or suspected medical error. They learn to recognize the four most common scenarios—obvious error with obvious harm, a poor outcome but uncertainty as to whether error is involved, apparent error by a previously treating professional or medical team, and a bad outcome that the patient or family believes resulted from an error but did not—and associated issues.<sup>23</sup> Training on the "how and when" of disclosure has been disseminated organizationwide. After certification through a "train the trainer" program, individuals from each department train the other members of their department.

As the attending responsible for sharing with B.W. information about the ureteral injury and delayed recognition, Dr. GYN reviews with Ms. Heard their disclosure training for "obvious error with obvious harm" situations. They anticipate B.W.'s likely questions: How did this happen? Why didn't you know sooner? What will be the long-term effect? Will it affect my cancer? How will you stop this from happening to anyone else? Who's going to pay for the extra surgeries and medical costs? Dr. GYN considers how best to respond.

Because of Ms. Heard's good relationship with B.W., Dr. GYN asks if she would agree to be present when he speaks with B.W. In a private setting, B.W. shares her frustration and disappointment with her care and how she was treated. Dr. GYN discloses the errors and acknowledges his role in her mounting frustration. He apologizes. He remains in the meeting until B.W. feels confirmed that he has answered all her questions. B.W. voices her appreciation for Dr. GYN's candor and apology. She also thanks Ms. Heard for advocating on her behalf. B.W. states that although she does not relish the idea of another surgery, she feels that they're now on the right track and that the problem will finally be resolved.

**Table 3. What Should Be Documented When a Patient or Family Member Complains?**

1. Unique identification (ID code) for the complaint
2. Date of first contact with patient relations or organizational designee
3. Method of patient or family contact (visit, call, etc.)
4. Person contacting patient relations or organizational designee
5. Person's relationship to patient
6. Patient's name
7. Any additional information on the patient
8. Date of incident
9. Location where the incident occurred
10. Detailed but succinct narrative of the concern(s) being raised (include quotes)
11. First and last name(s) and type(s) of professionals associated with the concern(s)
12. Any attachment(s) of original documentation
13. Names of involved person(s) with whom complaint report was shared
14. Resolution or result of the complaint
15. Whether follow-up is required

## DOCUMENTATION

Only the HEARD mnemonic emphasizes the importance of documenting patient complaints, the fourth advanced skill. Most advocates keep notes, and many organizations use advocates' reports. Furthermore, CMS regulations require organizations to provide written responses to filed grievances.<sup>16</sup> In our experience, however, documentation practices vary widely.

Key practices for documentation involve (1) the types of patient/family concerns that need to be documented, (2) the elements that need to be captured, and (3) identifying whose responsibility it is to document.

Table 2 lists the types of concerns that, in our experience, should always be documented, even if "in-the-moment" service recovery has been successful. These types of concerns often correlate with regulatory requirements, quality, and risk issues, and thus are critical to capture, track, and trend. Table 3 (above) outlines the elements of best-practice documentation.

At least four groups of individuals usually document complaints (Table 4, page 317): (1) the staff member or provider who first learns about the concern, (2) the patient or family member, (3) the practice/unit manager, or (4) the patient relations representative. Advantages and disadvantages are associated with each group.

**Staff Member or Provider.** The advantages are that more complaints will be captured if an organization's entire staff can document, and information may be more accurate if contem-

poraneously recorded. The disadvantages include competing priorities for time, which inhibit staff's ability both to respond and to document in a reasonable time frame; inconsistency in report content and detail; the potential for personal defensiveness and bias; and the risk of inconsistent follow-up and decision making.

**Patient or Family Member.** Some organizations use videos, signage, and/or tent cards to encourage patients and families with concerns to contact or visit the patient relations office. In other cases, organizations rely on staff members or hospital volunteers to distribute comment cards or refer patients to an advocate. Comment cards and surveys, which can be helpful if placed in all units, provide the advantages of greater convenience than visiting an advocate and allowing a quick way to communicate disappointments and positive impressions. The disadvantages include the potential for limited detail, poor-quality documentation, and variable patient/family literacy; omissions such as follow-up contact information; and, in some cases, failure of some patients to follow through and make the report.

**The Manager.** The advantages include consistency in documentation of concerns and on-site resolutions and the ability of managers who are familiar with the complaint to take steps to reduce the likelihood of a recurrence. The disadvantages include competing priorities for time, a potentially defensive manager, and—in large organizations with many practices, clinics, or units—inconsistency in documentation and follow-up toward resolution.

**The Patient Relations Representative.** Employing trained, skilled patient relations professionals to document concerns and assist with assessment and resolution has clear advantages. Service recovery is their priority, and they are empowered to deliver it. In addition, they are in the strongest position to consistently provide best-practice documentation and yield a return on investment. The disadvantages include salary and benefit costs and unnecessary referral of matters that might have been resolved in the moment by frontline staff.

From the first report from the nurse manager, Ms. Heard contemporaneously documented in the organization's complaint database details of B.W.'s complaint, service recovery efforts, and the ultimate resolution.

## Organizational Infrastructure for Service Recovery Programs

How do you know whether an organization's service recovery program is adequately supported? Best practices for advanced

**Table 4. Who Documents Complaints?**

1. Person who first becomes aware of the concern or complaint
2. Patient or family member
3. Practice/unit manager
4. Patient relations representative

service recovery include the following:

1. Leadership committed to complaint capture and service recovery
2. Supportive organizational policies and service recovery procedures
3. A model to guide levels of service recovery
4. Clear communication to patients that “we want to hear” (for example, visible and well-located tent cards, signs, comment cards, videos)
5. Surveillance systems that use dedicated personnel and software systems to record and document complaint data
6. Data aggregation and trending for review and thoughtful action by administrators and managers
7. Multilevel professional and cross-disciplinary training in service recovery skills
8. Leaders trained to intervene effectively with providers/staff and service units associated with disproportionate shares of complaints and recurring issues<sup>24</sup>

Within a supportive infrastructure, service recovery efforts allow organizations to use aggregated patient complaint data to achieve desired quality, safety, and risk management outcomes.

### Increasing Complaint Capture

In our view, complaints are gifts of information that organizations cannot get from any other source. Although health care organizations never want patients to have reason to complain, dissatisfactions do occur. Recorded complaints, however, represent only the “tip of the iceberg” of dissatisfied patients and families; for every person who complains, as many as 11–90 with similar concerns do not.<sup>25,26</sup> Each complainant, then, represents many more unhappy individuals who may choose instead to recount their negative experiences to friends, family, and others in their community.

So therein lies the paradox of recorded patient complaints. Although complaints may seem “bad,” they are “good” when voiced so the organization has an opportunity to respond. In addition, complaints serve as a sensitive surveillance system for detecting errors and substandard practices. As observers with the most to gain or lose from health care encounters, patients’

and families’ instincts and insights must be seriously considered—they provide valuable feedback to organizations about the quality of communications, services, and care.

Systematic use of aggregated complaints offers opportunities for reducing costs associated with patient dissatisfaction.<sup>8,17,27</sup> However, organizations cannot prevent future dissatisfaction and address underlying issues unless they are aware of patterns that increase risk for some professionals and units. A complaint provides a window into individual patients’ experiences, but analyzing, tracking, and trending aggregate data enlarges that window to reveal patterns and trends that can help thoughtful leaders better understand their organization and facilitate decision making. After all, complaints are *not* randomly distributed. Assuming sufficient data, aggregated complaints have been used successfully to identify, intervene with, and reduce complaints associated with high-complaint physicians<sup>17,27–29</sup> and service units with quality and service issues.<sup>30,31</sup> Exploring complaint data may reveal, for example, individual deficiencies, maladaptive policies, and/or systems inefficiencies.

If complaint capture is good, how do organizations go about increasing it? In our experience, the most successful organizations establish a centralized repository and record all reports (inpatient and outpatient) in one electronic database. Complaints may come to an organization through different venues, such as the billing office, patient surveys, compliance lines, clinic managers, and administrators. Encouraging all areas to forward patient complaints (or copies) to a central location increases the reliability of tracking/trending data (Figure 1). Best-practice organizations also set clear goals to increase and track complaint capture.

Achieving robust complaint data requires regular communication to patients and staff that their observations are valued and how and where to report them.<sup>32</sup> Best practices also include creating staff awareness of patient relations services by disseminating information at multiple venues and events, such as employee orientation.

Organizations that employ basic service recovery skills can reap benefits. Yet, organizations that also employ the advanced service recovery skills described in this article are best positioned to get the most from their investment in their service recovery program. Encouraging patients to voice their concerns, documenting those concerns, and then analyzing and using complaint data to inform and complement other organizational initiatives can help improve patient care, quality, safety, and risk management outcomes<sup>17</sup>; help meet regulatory<sup>16</sup> and accreditation standards<sup>24,33</sup>; and yield a positive return on investment.<sup>8</sup>



## Conclusion

Using best practices in service recovery enables the organization to do its best to make right what patients and family members experience as wrong. Responding to patient/family concerns decreases dissatisfaction and attendant cost burdens, while increasing patient/family loyalty and distinguishing the organization as a provider of high-quality and caring service. ■

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## Organizational Change and Learning

# Patient Safety Climate in Hospitals: Act Locally on Variation Across Units

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**K**ey components of a positive patient safety climate include strong leadership commitment to patient safety, open discussion of errors, and a habit of learning from mistakes.<sup>1</sup> Historically, the medical profession and health care organizations have not fully exemplified these values.<sup>2</sup>

In recent years, hospitals have made progress in addressing these issues, although studies of current caregiver attitudes related to patient safety suggest that more work is needed.<sup>3</sup> Regulators and patient safety organizations have identified assessing and improving safety climate as important goals for hospitals. Since 2007 The Joint Commission has required a periodic assessment of safety climate,<sup>4\*</sup> a socially enacted concept that emerges through interactions with members of the same work group in which shared perceptions develop about the true or actual priorities in the workplace.<sup>5</sup>

To facilitate assessments, the U.S. Agency for Healthcare Research and Quality (AHRQ) has developed the Hospital Survey on Patient Safety (HSOPS), which is designed to allow hospitals to assess their patient safety climate and benchmark it against the patient safety climates of other hospitals in a national database.<sup>6</sup>

Growing numbers of hospitals are measuring safety climate, with much of the analyses examining aggregations of attitudes by broad staff or work-area categories or simply reporting the results for the entire hospital. This approach, however, fails to recognize that hospitals are generally composed of discrete clinical areas or “clinical microsystems,” such as emergency departments (EDs), operating rooms (ORs), individual medical or surgical wards, and intensive care units (ICUs).<sup>7</sup> Focusing climate assessments on broad work area or staff categories (such as physicians and nurses, or surgeons and nonsurgical physicians) can obscure important differences that exist at more local levels. Units differ by types of patients, acuity, nature and pacing

\* Standard LD.03.01.01: “Leaders create and maintain a culture of safety and quality throughout the hospital.” Element of Performance 1: “Leaders regularly evaluate the culture of safety and quality using valid and reliable tools.” (p. LD-16)

### Article-at-a-Glance

**Background:** An appreciation of how human factors affect patient safety has led to development of safety climate surveys and recommendations that hospitals regularly assess safety attitudes among caregivers. A better understanding of variation in patient safety climate across units within hospitals would facilitate internal efforts to improve safety climate. A study was conducted to assess the extent and nature of variation in safety climate across units within an academic medical center.

**Methods:** The Agency for Healthcare Research and Quality (AHRQ) Hospital Survey of Patient Safety was administered in 2008 to all nurses and attending physicians ( $N = 4,283$ ) in a 900-bed acute care hospital (overall response rate, 69% [ $n = 2,961$ ]). Responses were analyzed from the 2,163 physicians and nurses (73% of respondents) who could be assigned to one specific clinical unit. Results were examined for 57 units, categorized into six types.

**Results:** Ratings of various safety climate domains differed markedly across the 57 units, with the percentage reporting a safety grade of excellent ranging from 0% to 50%. The overall percentage of positive ratings was lower for the operating and emergency unit types than for inpatient medical and other clinical units. Even within the six unit types, substantial variation across individual units was evident. Unlike previous findings, physicians reported more negative ratings than nurses for some safety climate dimensions.

**Conclusions:** Safety climate may vary markedly within hospitals. Assessments of safety climate and educational and other interventions should anticipate considerable variation across units within individual hospitals. Furthermore, clinicians at individual hospitals may offer different relative perceptions of the safety climate than their professional peers at other hospitals.

of clinical care activities, and work load, as well as by staff composition, local leadership, and organizational structure. These factors all have the potential to influence patient safety climate in a hospital.<sup>3</sup>

We hypothesized that examining safety climate at the unit level would reveal significant variations in climate within a single hospital. Hospitals that identify substantial differences across units can use this information to help hospital leaders prioritize areas in particular need of assistance and tailor interventions to the specific needs of individual units. To investigate our hypothesis, we undertook a unit-based analysis of safety climate among physicians and nurses at Massachusetts General Hospital (MGH), a 900-bed tertiary care facility, using the AHRQ HSOPS assessment tool. Because previous studies have demonstrated differences in perceptions of safety climate between physicians and nurses,<sup>8-16</sup> with physicians displaying, overall, more favorable perceptions than nurses, we also sought to compare safety climate perceptions of physicians and nurses.

## Methods

The MGH Institutional Review Board approved this study.

### SURVEY INSTRUMENT

We assessed safety climate using the HSOPS, a publicly available instrument developed by AHRQ, which has been administered in more than 500 hospitals in the United States.<sup>17,18</sup>

### STUDY VARIABLES

The HSOPS assesses the different dimensions of patient safety as follows:

1. Supervisor/Manager Expectations and Actions Promoting Safety
2. Organizational Learning and Continuous Improvement
3. Communication Openness
4. Feedback and Communication About Errors
5. Teamwork Within Units
6. Nonpunitive Response to Error
7. Staffing
8. Hospital Management Support for Safety
9. Teamwork Across Units
10. Hospital Handoffs and Transitions

The HSOPS also includes items that address (1) Overall Perceptions of Safety, (2) Frequency of Event Reporting, and (3) Patient Safety Grade. Most dimensions are assessed using three to five individual survey items. Rating options are gener-

ally either 5-point Likert or 5-point frequency scales. The HSOPS dimensions have been previously validated.<sup>19</sup>

### STUDY POPULATION

With assistance from MGH leadership, we identified all clinically active attending physicians considered by the hospital to have a “core” presence at the hospital and all registered nurses working 20 or more hours per week at MGH. Core presence was defined as meeting at least one of the following two criteria:

1. A minimum level of clinical productivity that had been previously established by the MGH physician organization as indicating that the physician engaged in substantial clinical activities at MGH: at least 50 work relative value units in the preceding six months (ending in December 2007)

2. Listing on a hospital unit’s call schedule as an active participant in that specific hospital unit during the previous year

We identified nurses on the basis of work hours reported by the hospital’s patient care services department.

### UNIT ASSIGNMENT

This study concentrated on inpatient and specific outpatient procedural or specialty units, not the routine ambulatory care clinics within MGH. We defined a hospital unit as any inpatient or procedural unit or hospital work area, including inpatient medical and surgical units, ICUs, EDs, cardiac catheterization laboratory, the main and same-day ORs, outpatient chemotherapy infusion center, and the anticoagulation unit.

We prospectively assigned physicians and nurses to a specific hospital unit. We sent the survey with a cover letter indicating their unit assignment and asking them to answer the HSOPS considering that unit. Nurses were assigned to a unit on the basis of their respective cost centers. Physicians were assigned to a unit in one of two ways: (1) listed on the unit’s call schedule or roster as working in the specified clinical area currently or over the previous year or (2) identified by administrative data as having discharged at least 12 patients from a specific inpatient unit in the previous 12 months. We instructed physicians and nurses who could not be assigned to a specific unit on the basis of these criteria to pick the unit where they had spent most of their time during the preceding year.

Sixty-one distinct units met our specifications. For this analysis, we considered only the 57 units that had 10 or more respondents. We categorized the units into one of six types, as follows:

1. Critical care (ICUs, including the neonatal and pediatric ICUs)
2. Emergency (ED and ED observation unit)
3. Operating units (main ORs, day-surgery unit, preadmis-

sion testing unit, and postanesthesia care unit)

4. Medical inpatient (nonsurgical inpatient units, including pediatrics units)

5. Surgical inpatient (including obstetrics)

6. Other units (chemotherapy infusion, anticoagulation unit, interventional radiology, and electrophysiology and cardiac catheterization units)

## SURVEY ADMINISTRATION

Between March and May 2008, all eligible physicians and nurses ( $N = 4,283$ ) at MGH were asked to complete the survey either electronically or on paper. Initially, an e-mail was sent with a link to a Web site for completing the survey. Nonrespondents were contacted by subsequent e-mails and were encouraged to complete the survey. Approximately one week after the initial e-mail, we mailed nonresponders a paper copy of the survey through the hospital's internal mail system. Both e-mail and paper administration methods allowed respondents to complete the survey anonymously.

Our overall response rate was 69% ( $n = 2,961$ ), with a response rate of 57% ( $n = 881$ ) for physicians and 76% ( $n = 2,080$ ) for nurses. For the purposes of the present analysis, we excluded those nurses ( $n = 347$ ) and physicians ( $n = 430$ ) who were not assigned to a unit and did not self-identify a specific unit as their predominant work area or who were from a unit with fewer than 10 respondents. The final population analyzed included 1,733 nurses and 451 physicians from 57 units.

## ANALYSIS

For each item, we considered ratings to be positive if they indicated "Strongly agree"/"agree" or "Most of the time"/"always" for items that were positively worded. For negatively worded items, a positive rating was disagreement in the form of "Strongly disagree"/"disagree" or "Never"/"rarely." For example, disagreement with the statement "Important patient care information is often lost during shift changes" was coded as a positive rating. Following the analytic approach recommended by AHRQ, we calculated one overall frequency for each dimension by creating a composite frequency of the total percentage of positive ratings for each safety climate dimension. We calculated the percent positive for a particular dimension, termed the *average percent of positive ratings*, as the total number of positive ratings for all of the items in that dimension divided by the total number of responses for that dimension. In calculating the average percent of positive ratings, we weighted each item in a dimension equally. For comparisons across units, we calculated the average percent of positive ratings for each dimension from

all physician and nurse respondents for each unit. We also generated what we termed an *overall average percent of positive responses* by averaging the percent of positive responses for each of the safety climate dimensions, which were weighted equally. We excluded from the overall average the "outcome" dimensions of overall perceptions of safety and patient safety grade.

We compared MGH results to those in the publicly available AHRQ Comparative Database 2008 Report.<sup>17</sup> In doing so, and in comparing results across unit types and individual units within MGH, we followed the AHRQ's guideline of considering an absolute difference of  $\geq 5\%$  in the proportion of positive ratings as potentially indicating a meaningful difference. Because we included all physicians and nurses who met the study criteria rather than a sample of these individuals and because we are not trying to, and cannot, generalize to any other hospital or group of physicians or nurses other than those at MGH, no tests of statistical significance are necessary.<sup>20</sup> However, we recognize that some in the biostatistics community may hold different views on this issue.

## Results

### CHARACTERISTICS OF RESPONDENTS

Table 1 (page 322) shows the characteristics of respondents. Of the 2,163 respondents included in the analysis, 80% were nurses and 20% were physicians. Almost all respondents (92%) had worked in their unit for at least one year. Slightly more than half of all respondents worked between 20 and 39 hours per week. The distribution of respondents across work areas was as follows: 18% were in critical care units; 32% in inpatient medical units; 23% in inpatient surgical units; 14% in OR units; 7% in ED units; and 8% in other clinical units.

### HOSPITAL-LEVEL RESULTS

For the hospital as a whole, the average percentage of positive ratings varied across the dimensions assessed by the safety climate survey. As shown in Figure 1 (page 323), the highest percentages of positive ratings were for teamwork within units (85% reporting positive rating), supervisor/manager support for safety (74%), hospital management support for safety (72%), and organizational learning (70%). The lowest percentages of positive ratings were for handoffs and transitions (45%), event reporting (49%), nonpunitive response to error (54%), feedback and communication about errors (51%), and teamwork and transitions across units (55%).

For the vast majority of the dimensions, the percentages of positive ratings for MGH were similar to the means for the AHRQ benchmark hospitals. MGH had a higher percentage

Table 1. Respondent Characteristics\*

	RNs N = 1,733	MDs N = 430	All Clinicians N = 2,163
<i>How long have you worked in this hospital?</i>			
Less than 1 year	6.9%	1.6%	5.8%
1 to 5 years	32.7%	17.3%	30.0%
6 to 10 years	20.7%	29.4%	22.4%
11 to 15 years	7.6%	18.5%	9.8%
16 to 20 years	8.0%	9.3%	8.3%
21 years or more	24.1%	23.8%	24.0%
<i>How long have you worked in your current hospital work area/unit?</i>			
Less than 1 year	9.6%	3.3%	8.3%
1 to 5 years	38.5%	25.6%	36.0%
6 to 10 years	23.1%	31.1%	24.7%
11 to 15 years	9.6%	15.8%	10.8%
16 to 20 years	8.7%	7.8%	8.5%
21 years or more	10.6%	16.5%	11.8%
<i>Typically how many hours per week do you work in this hospital?</i>			
Less than 20 hours per week	0.1%	11.4%	2.3%
20 to 39 hours per week	64.6%	11.2%	54.0%
40 to 59 hours per week	35.3%	37.1%	35.7%
60 to 79 hours per week	0.1%	32.4%	6.5%
80 to 99 hours per week	0.0%	5.6%	1.1%
100 hours per week or more	0.0%	2.3%	0.5%
<i>How long have you worked in your current specialty or profession?</i>			
Less than 1 year	5.0%	0.9%	4.2%
1 to 5 years	24.5%	12.8%	22.2%
6 to 10 years	16.4%	21.9%	17.5%
11 to 15 years	11.5%	17.9%	12.8%
16 to 20 years	10.5%	11.6%	10.7%
21 years or more	32.1%	34.9%	32.7%
<i>Unit Type</i>			
Critical Care	19.0%	11.6%	17.6%
Emergency Department	6.6%	6.3%	6.6%
Inpatient-Medical	30.0%	39.5%	31.9%
OR/Pre-op/Post-op	13.6%	15.1%	13.9%
Other Clinical	7.0%	9.8%	7.6%
Inpatient-Surgical	23.7%	17.7%	22.5%

\*RN, registered nurse; MD, physician; OR, operating room; Pre-op, pre-operative; Post-op, postoperative.

positive (by 5%) than the benchmark average for teamwork within units, staffing, and nonpunitive response and a lower percentage positive for overall perceptions of safety, event reporting, and feedback and communication about error. Similar percentages of respondents rated safety of the care provided in their clinical area as excellent (21% of MGH respondents versus 24% in the AHRQ database).

#### VARIATION ACROSS STAFF CATEGORIES

The percentage of positive ratings differed between physicians and nurses for several dimensions (Figure 2, page 323). The average percent positive was lower for physicians than nurses by nearly 10% or more for organizational learning (60% for physicians versus 72% for nurses), frequency of event

reporting (35% versus 53%), staffing (58% versus 71%), hand-offs and transitions (31% versus 49%), and nonpunitive response to error (45% versus 56%). In other domains, the ratings from physicians and nurses were comparable.

#### VARIATION ACROSS UNITS

We found substantial variation across individual units in the percentage of positive ratings. Unit-level variation occurred for each safety climate dimension. For example, the range in percentage of positive ratings for individual units varied by more than 60 percentage points regarding nonpunitive response to error, by 54 percentage points for feedback and communication about errors, and by 50 percentage points for organizational learning and continuous improvement. For items that

addressed overall assessments of patient safety and patient safety grade, the proportion of respondents assigning their unit a patient safety grade of excellent ranged from 0% to 50%.

Figure 3 (page 325) shows the overall average percent of positive ratings for each of the units. We found similar unit-level variation when we examined, for each of the units, ratings from both physicians and nurses and from nurses only.

The percentage of positive ratings also varied across the six unit types within the hospital (Table 2, page 324). The overall percentage of positive ratings was lower for the OR and ED unit types than for inpatient medical and other clinical units. Even within the unit types, we found substantial variation across units, with marked differences, for each of the unit types, between the units with the highest percentage of positive ratings and those with the lowest. For example, the percentage of respondents giving their unit an overall safety grade of excellent ranged from 3% to 50% for the inpatient medical units and from 0% to 29% for the critical care units.

## Discussion

At least for this academic medical center, patient safety climate was intensely local. As measured using the HSOPS, patient safety climate varied markedly across individual patient care units and unit types. Even within types of patient care units, aspects of patient safety climate differed substantially. In contrast to a number of previous studies that had examined differences by clinical discipline, physicians offered somewhat more negative perceptions of safety than did nurses.<sup>3,8-16</sup>

Other studies have also described variation in safety climate by unit type across hospitals.<sup>21,22</sup> Huang and colleagues noted variation among ICUs at a single institution.<sup>13</sup> However, research has yet to focus within hospitals across the full spectrum of clinical units to understand variation across units within the hospital and within unit types. Our results suggest that striking variation, far greater than has been previously reported, may occur at the unit level.

We did not investigate reasons for the variation across clinical units within this single hospital. Although physicians provided more negative ratings than nurses, the variation across units in the proportion of respondents who were physicians did not explain unit-level differences in safety climate ratings. When looking at nurses' ratings only (data not shown), we found similarly wide variation in perceptions of safety climate. Units may differ from one another in various factors that are conceivably linked to various dimensions of safety climate, including the unit's management, leadership, and organizational structure; staffing levels, specialty mix, and the extent to

## Percentage of Positive Ratings by Dimension of Safety Climate

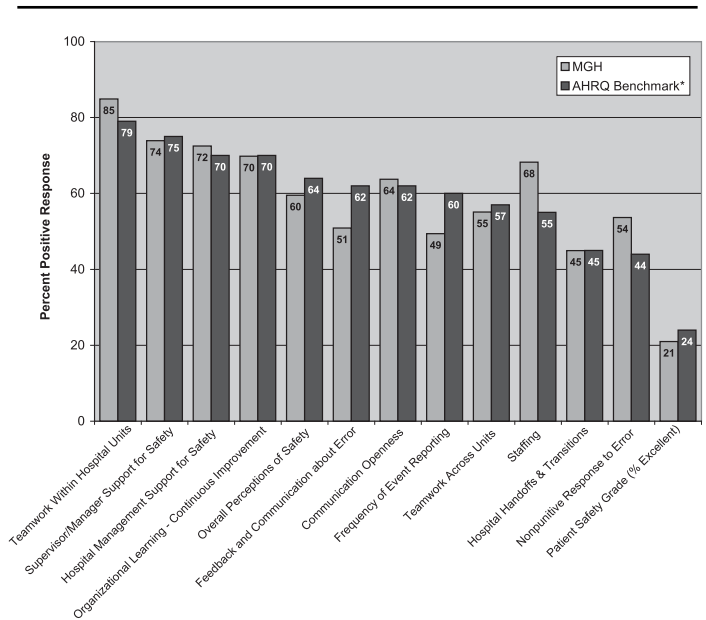


Figure 1. The average percentage of positive ratings varied across the dimensions assessed by the safety climate survey. MGH, Massachusetts General Hospital. For AHRQ benchmark, see Agency for Healthcare Research and Quality (AHRQ): Hospital Survey on Patient Safety Culture: 2009 Comparative Database Report. <http://www.ahrq.gov/QUAL/hospsurvey09/> (last accessed May 27, 2010).

## Percentage of Positive Ratings by Dimension of Safety Climate for Nurses and Physicians

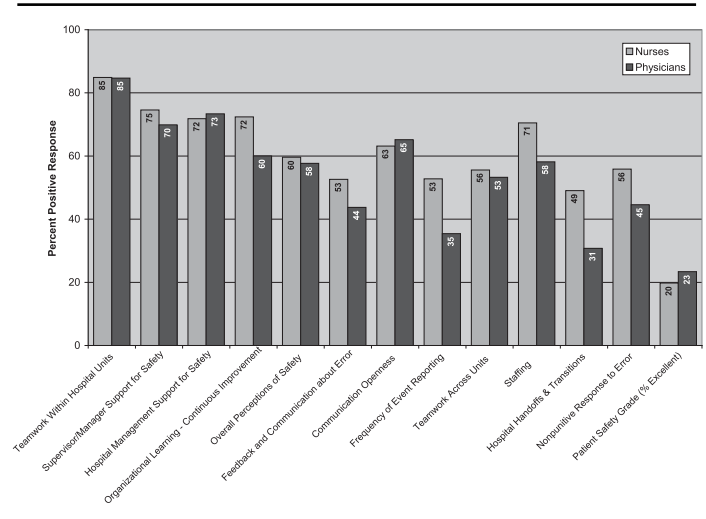


Figure 2. The percentage of positive ratings differed between physicians and nurses for several dimensions.

Table 2. Average Percentage of Positive Ratings by Dimension of Safety Climate for each Unit Type\*

Unit Type	Number of Units		Teamwork Within Hospital Units	Supervisor/Manager Support for Safety	Hospital Management Support for Safety	Organizational Learning—Continuous Improvement	Overall Perceptions of Safety	Feedback and Communication About Error	Communication Openness	Frequency of Event Reporting	Teamwork Across Units	Staffing	Hospital Handoffs & Transitions	Nonpunitive Response to Error
Critical Care	8	Average	91	73	69	73	61	54	69	46	57	68	52	51
		(High, Low)	(97, 80)	(83, 35)	(75, 44)	(82, 53)	(71, 40)	(71, 26)	(77, 43)	(55, 40)	(72, 45)	(80, 42)	(67, 37)	(64, 39)
Emergency	2	Average	69	70	62	64	36	37	51	38	32	46	31	47
		(High, Low)	(85, 67)	(70, 68)	(64, 49)	(67, 39)	(48, 34)	(41, 36)	(76, 48)	(40, 17)	(32, 32)	(64, 43)	(33, 20)	(47, 47)
Medical Inpatient	17	Average	88	77	79	72	63	54	69	54	56	73	44	57
		(High, Low)	(97, 74)	(90, 63)	(92, 71)	(89, 60)	(79, 51)	(77, 37)	(84, 50)	(64, 38)	(68, 39)	(95, 52)	(58, 29)	(79, 35)
OR/Pre-op/Post-op	10	Average	73	72	64	64	55	41	51	43	46	65	35	49
		(High, Low)	(87, 38)	(83, 50)	(78, 42)	(79, 37)	(67, 36)	(56, 19)	(67, 14)	(69, 22)	(51, 36)	(83, 42)	(49, 11)	(85, 19)
Other Clinical	7	Average	88	77	79	74	68	65	72	54	64	69	46	61
		(High, Low)	(93, 74)	(88, 28)	(91, 61)	(88, 36)	(89, 29)	(82, 23)	(84, 36)	(76, 19)	(75, 53)	(86, 12)	(58, 30)	(76, 17)
Surgical Inpatient	13	Average	87	72	72	67	60	49	60	51	61	70	50	52
		(High, Low)	(96, 75)	(86, 53)	(88, 44)	(83, 43)	(78, 39)	(74, 26)	(73, 35)	(65, 30)	(78, 47)	(86, 46)	(67, 37)	(68, 36)

\*OR, operating room; Pre-op, pre-operative; Post-op, postoperative.

which the staff are knowledgeable about or have received training in patient safety; patient factors such as severity, complexity, acuity of illness, and rate of patient turnover; and production factors, such as the pace and technological complexity of the services delivered. Further research should consider these factors, although it is worth noting that our finding of variation within general unit types suggests that influences other than patient factors are likely to be important.

Our finding that physicians were less positive than nurses in certain dimensions differs from results of other studies,<sup>14-16</sup> as well as those available through the AHRQ HSOPS comparative database.<sup>17</sup> While others have demonstrated differences in attitudes by discipline, and it is widely noted that physicians are less likely to report errors or adverse events,<sup>23,24</sup> we also found that the average percent positive was lower for physicians than nurses for organizational learning, feedback and communication about error, nonpunitive environment, and staffing. Although the differences between nurses and physicians in these domains may reflect differences distinctive to our hospital, the reasons are unclear. Nursing leadership at MGH has long addressed the nursing work environment, including perceptions about adequacy of staffing, as evidenced by its designation as a Magnet hospital (American Nurses Credentialing Center's Magnet Recognition Program®) through 2012, but the contribution of Magnet designation and other factors to differences in staff perceptions warrants further investigation.

A key implication of our findings, which represents a clear advancement of the field, is that safety climate surveys conducted in hospitals should ideally be done in a manner that allows for unit-based examination of variation in safety climate. This is important for several reasons, with implications for setting priorities about educational and other interventions for improving safety climate. Measurement strategies that acknowledge the likelihood of variation across hospital units will reduce the chance of making incorrect assumptions on the basis of the average ratings across the hospital about the needs of a particular unit. Second, unit-level assessments allow the hospital to prioritize its actions, perhaps focusing initially on those units with the greatest need. For example, a hospital that identifies certain units as particularly problematic with regards to attitudes about hospital leadership's support for patient safety could institute leadership walk-arounds in those units, assigning an executive sponsor to take ownership over walk-arounds in that arena. Third, knowing about inter-unit variation might facilitate learning among units within the hospital. Those units with a particularly positive safety climate may offer lessons that could be applied in other units and serve as a resource for other units' improvement efforts. Initiatives resulting in raising safety climate perceptions among below-average units to even average levels of safety climate could substantially improve patient safety.<sup>25</sup> Our findings suggest that summarizing overall safety climate ratings across an entire hospital, staff category, or even

### Variation in Average Percent of Positive Ratings for All Dimensions of Safety Climate (Excluding Overall Assessment and Patient Safety Grade) by Unit

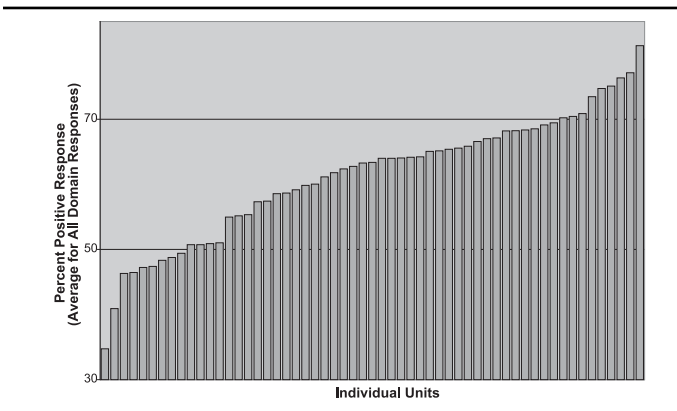


Figure 3. The variation across individual units in the percentage of positive ratings was evident.

department may mask differences at the unit level and fail to provide an adequate road map for improvement initiatives.

#### METHODOLOGIC CHALLENGES AND LIMITATIONS

It is important to note methodologic challenges to assessing climate at the unit level. The survey that yielded these results was part of a larger survey effort in which all MGH staff, including nonclinical staff such as housekeeping, nutrition services, and security, were asked to complete the HSOPS survey. MGH leadership believed it was important that everyone be given a voice about what they viewed as an organizationwide goal of improving patient safety. Although this message is laudable and may be important, conducting the survey hospitalwide is challenging, in part because the language of most patient safety climate surveys is clinically oriented and fits the nonclinical environments less well. In addition, most staff in the nonclinical departments are not organized in units that correspond to the hospital’s patient care units. With that said, we acknowledge that certain employees who are not nurses and physicians but who spend considerable time in the various hospital settings, such as housekeepers or patient escorts, may have important and legitimate views of patient safety climate and could be considered valuable informants in other studies.

Further, the process of linking even physicians to units for the purposes of completing a safety climate survey can be labor intensive and complex. Physicians are typically organized into clinical departments on the basis of specialty rather than the inpatient care units in which they provide care. In addition, they

may see patients in more than a single area of the hospital. Therefore, surveys that include physicians’ perceptions of unit-level climate must explicitly instruct physicians to respond based on experiences with a specific unit (for example, a specific ICU, OR, or inpatient floor). This may be hard to do, especially for physicians who see some patients on multiple medical floors, for example. The organization of physicians by departments rather than units also complicates feedback of unit-based assessments to physicians because many units do not have specific physicians with clear leadership responsibility for that unit.

Although overall response rates for hospitals are important, analysis of patient safety climate at the unit level requires that response rates be high for each of the units being assessed to lessen the likelihood of response bias. Tracking and ensuring high individual unit response rates adds to the burden associated with conducting the survey.

We excluded from the analyses a large number of respondents ( $n = 777$ ) who were not assigned to a unit and did not self-identify a specific unit as their predominant work area or who were from a unit with fewer than 10 respondents. These exclusions were necessary, given our focus on capturing unit-level perceptions and the need to protect confidentiality of respondents from very small units. Although necessary, this exclusion may result in less stable estimates for units with high numbers of excluded respondents. We acknowledge that this study was conducted to describe individual-level perceptions of work-group members who were stratified by unit-type. These perceptions may not be shared by all members of any given work group.

Finally, the process of unit-level analysis, review, feedback, and action can be much more time intensive than one in which results are only examined at the hospital level, by staff type, or by broad categories of units. Like MGH, large hospitals will have dozens of units that need to receive feedback on their survey results, many of which may warrant interventions designed to address dimensions of safety climate where there are opportunities for improvement. On the positive side, hospitals may find, as MGH has found, that in this era of increasingly stretched resources the opportunity to target interventions to those units most in need of help offsets some of the additional burdens associated with unit-level assessments.

Our study has other limitations. First, respondents may have underreported their concerns about safety in their area as a result of social-desirability bias. This possibility was lessened by the anonymous nature of the survey. In addition, because we have no reason to believe that underreporting would have varied by unit, it is unlikely to explain the variation in climate



across units that we observed. Second, nonrespondents could have differed from respondents, thus producing bias in our findings. Third, as a large, technologically sophisticated, highly research-intensive medical center in Boston, MGH differs in important ways from smaller teaching and nonteaching hospitals nationally, as well as from other large academic hospitals even within Boston (for example, Brigham and Women's Hospital). As a result, we should be cautious in generalizing the results of our study to other hospitals. Although MGH has actively pursued several efforts designed to address safety, our overall hospital results for safety climate are similar to those in the AHRQ's national database for hospitals submitting HSOPS findings. In addition, factors that contribute to unit-level variation in climate also vary in other hospitals, particularly those of similar size and organizational complexity.

## Conclusions

Our findings offer important new insights for understanding safety climate in hospitals. Although our approach to assessing safety climate required designing a method for assigning physicians to individual units, our findings suggest that safety climate in hospitals should be assessed in a way that permits unit-level examination of results. The variation that we observed across units suggests that efforts to address problems with patient safety in hospitals may benefit from a focus on the individual units that collectively provide care for patients in hospitals rather than more macro levels of analysis such as the hospital level. We found, in contrast to previous work, that physicians were less positive than nurses on a number of dimensions, suggesting that patterns of differences in attitudes by staff categories may differ across hospitals. Finally, the findings suggest that unit-level variation within unit types may provide hospitals with a rich source of learning, even without conducting extensive comparisons beyond their institutional borders. **J**

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## Adverse Events

# Addressing In-Hospital “Falls” of Newborn Infants

Linda Helsley, R.N., C.N.S.; John V. McDonald, M.D.; Valerie T. Stewart, Ph.D.

During postpartum hospitalization, close physical interactions between mother and newborn facilitate attachment, breastfeeding, and relationship competence. The challenge during this time is to support these important interactions in the hospital while ensuring the safety of the newborn. A literature review indicated that newborn “falls” and drops—referred to collectively as *falls* for the purpose of this article—in the hospital remains largely unaddressed, with the exception of a report by Monson et al. in 2008.<sup>1</sup>

A report from the Royal College of Midwives (RCM) in the United Kingdom described a nationwide audit of 100 maternity units in 2004 to identify “bed/sharing incidents.”<sup>2</sup> This work was initiated following the high-profile media report of the death from a fall of a well baby in a British hospital linked to maternal sleeping during bed sharing. A project involving the RCM, the World Health Organization (WHO), the United Nations Children’s Fund (UNICEF), and the Baby-Friendly Initiative (<http://www.babyfriendlyusa.org/eng>) resulted in the development of “guidelines for assessing the level of risk for mothers and babies when they are sharing a bed in the hospital” and a delineation of the levels of supervision required on the basis of risk-assessment results.<sup>3</sup> Queries to the Council of Women’s and Infants’ Specialty Hospitals (<http://www.cwish.org>) and the Vermont Oxford Network (<http://www.vtoxford.org>) resulted in little information about newborn falls in the hospital.

Given the limited extent of available information on this topic, it is important to report rates in other hospital systems and to identify possible guidelines for assessing and improving safety of the hospitalized newborn.

This report summarizes the experiences of a seven-hospital system in Oregon and offers a template for understanding how and why infant falls occur in hospitals with the intent of helping others address this issue and work to eliminate the risk of fall-related harm to newborns.

### Article-at-a-Glance

**Background:** During postpartum hospitalization, close physical interactions between mother and newborn facilitate attachment, breastfeeding, and relationship competence. The challenge during this time is to support these important interactions in the hospital while ensuring the safety of the newborn. A literature review indicated that newborn “falls” and drops—collectively referred to as *falls*—remains largely unaddressed. Experience of a seven-hospital system in Oregon offers a template for understanding how and why infant falls occur in hospitals and how to address the issue.

**Identifying the Problem:** For a two-year period (January 2006–December 2007), a query of a live voluntary event database yielded 9 cases of newborn falls (from 22,866 births), for a rate of 3.94 falls per 10,000 births.

**Responding to Newborn Falls:** A newborn falls committee made preliminary recommendations for interventions to reduce newborn falls, including (1) expanding the patient safety contract, (2) monitoring mothers more closely, (3) improving equipment safety, and (4) spreading information about newborn falls within the state and throughout the hospital system. For example, staff use the patient safety contract to improve awareness and prevention of falls. The mothers and significant family members are asked to review the safety information and sign the contract.

**Conclusion:** Newborns experience in-hospital falls at a rate of approximately 1.6–4.14/10,000 live births, resulting in an estimated 600–1,600 falls per year in the United States. Additional reports of rates of newborn falls are urgently needed to determine the true prevalence of this historically underreported event. Standardized evaluation and management guidelines need to be developed to aid the clinician in the appropriate care of newborns experiencing this infrequent event.

## Identifying the Problem

### SETTING

Providence Health & Services, a not-for-profit health system based in Renton, Washington, and active across five states (Alaska, Washington, Montana, Oregon, and California), includes 27 hospitals, more than 35 nonacute facilities, physician clinics, and a health plan, among other health services.

### REPORTED EVENTS

Since May 2001, a voluntary event-reporting system has existed in the system's hospitals to capture unusual events in patient care not necessarily rising to the level of harm or death. Previous analyses for the three Portland hospitals of the total of seven in Oregon indicated a count of approximately 30,000 events reported during a two-year period (April 1, 2002–April 30, 2004), 9% of which were categorized as falls. Further analyses showed that cases with reported events were 17% more expensive than case controls and had a length of stay 22% longer.<sup>4</sup> To increase likelihood of use, all reports were, and continue to be, anonymous.

We sought to identify the newborn events within the falls category. For a more recent 24-month period (January 2006–December 2007), we queried the live voluntary event database for any nonvisitor falls occurring on obstetrics (OB)/maternity units. Because there was no field in the database that specifically identified a fall as involving a newborn, we cast a wide net at the first stage to pick up any falls on units identified as locations where newborns and mothers were admitted. The query output produced key fields from the voluntary event database: fall date and time, location of the fall, observer's narrative, and manager comments. The most important field was the observer's narrative. The narrative explained in detail how the event occurred, what person fell, and why the observer thought it happened. This information was then categorized into one of three types of falls: infant fall, mother fall, or other. "Other" was often a family member who fell on the maternity unit.

The most important aspect of this query was to first determine for every hospital the units where mothers and newborns could possibly be admitted for the study time period. Next most important was review of the descriptive narratives to determine which of the three types of falls had occurred (newborn, mother, or other). After we completed this retrospective procedure, we began to track events in real time. It is not possible to know whether infant falls were underreported in this event registry during the study period.

### Sidebar 1. Sample Cases of Newborn Falls

#### Case 1. A Newborn Dropped from the Arms of an Adult Falling Asleep

Several hours following birth, a mother in the postpartum unit fell asleep in her hospital bed while holding her newborn. She awakened some time later to the sound of crying. She discovered that her newborn had apparently slipped between the rails at the side of the bed and fallen onto the floor.

#### Case 2. A Fall During Repositioning or Transferring of the Mother or Newborn

A mother had just completed breastfeeding her twins using a circular nursing pillow to support positioning. She placed the pillow on the surface of a counter in her room, and while transferring one of the newborns to a bassinet, the other fell to the floor, incurring a skull fracture.

#### Case 3. A Fall in Conjunction with Another Person Who Falls or Trips

A mother carrying her newborn tripped on her intravenous line tubing while walking across her room. In the process, she dropped the newborn, who struck its head on a metal portion of the bed, resulting in a skull fracture.

### CASE REPORTS OF THE NINE FALLS

For the two-year period, newborn falls and drops were monitored in the seven system hospitals in Oregon. During this period, 22,866 babies were born, and 9 newborn falls were reported, for a rate of 3.94 falls per 10,000 births. This rate was higher than expected on the basis of the sole previously published report of 1.6 falls per 10,000 births.<sup>1</sup> We do not know if these higher rates are due to more incidents, a higher reporting rate, or some other cause. We collected qualitative comments about each event.

Three sample cases illustrating the typical circumstances reported are provided in Sidebar 1 (above). Outcomes for the nine newborns that fell during this time period are shown in Table 1 (page 329). Of the nine falls, two experienced skull fractures (Cases 2 and 3, Sidebar 1), whereas the remainder had bumps, bruises, or no apparent injury. Figure 1 (page 330) shows the distribution of occurrence by time of day; more than half of newborn falls occurred in the early morning hours.

Many of the case narratives reflect parental reluctance to report the newborn fall. One case narrative quoted a mother as saying she was not going to tell anyone about the fall because when she jumped out of bed and picked him up off the floor, she thought he was "just fine" (Table 1, Patient 6). The mother only reported the fall to her nurse when the baby suddenly stopped crying and became very quiet, which increased the mother's anxiety about a potential injury. Family members

Table 1. The Nine Cases of Newborn Falls

Case	Explanation of Fall	Fall Reported by	Time of Day of Fall	Physical Exam	Diagnostic Workup
1	Mother fell asleep in her bed with newborn in her arms—fell to the floor	RN after hearing the mother scream	23:00	No apparent injury	None
2	Mother fell asleep in her bed with newborn in her arms—fell to the floor	Mother reported to nurse she woke up with infant crying on the floor	07:45	No apparent injury	None
3	Mother fell asleep in her bed with newborn in her arms—fell to the floor	Pediatrician was told on entry to the room by the crying mother	07:30	No apparent injury	Head CT scan—normal
4	Mother fell asleep breastfeeding and woke up when she heard the newborn crying on the floor	Mother called RN to report fall	23:50	No apparent injury	Head CT scan ordered for behavior change or head trauma—none
5	Mother had twins on a nursing pillow—turned partially to place one twin back in the bassinet—the other twin rolled off the pillow to the floor	Nurse heard mother gasp and state she had dropped her	17:00	Head trauma	Head CT scan—skull fracture
6	Mother fell asleep in her bed with newborn in her arms—fell to the floor	Mother told the nurse after a period of time—stated she wasn't going to report it initially	02:35	No apparent injury	None
7	Father holding newborn on the couch and fell asleep—newborn fell to the floor	Father told the mother that the baby had fallen to the floor—denied it to the nurse initially—then confirmed the fall	06:00	No apparent injury	None
8	Mother got out of her bed with newborn in her arms and tripped—baby's head hit metal bar on the hospital bed	Mother reported to the RN at the time of the incident	05:00	Quarter-size lump on side of head	Head CT scan—skull fracture
9	Mother breastfeeding in her bed—while adjusting her pillows the newborn fell to the floor	Mother called RN at time of fall	15:00	No apparent injury	Head CT scan—normal

\*RN, registered nurse; CT, computerized tomography.

speak of being extremely upset at the event and ashamed that it happened. Only in the face of increasing concern about inflicted injury reflected by their newborn's behavior do they tend to report the event. This was true for mothers and fathers.

Reluctance to report is a major challenge in determining the true incidence of these events, which are commonly not observed by members of the health care team.

### Responding to Newborn Falls

The newborn falls committee was established [co-chairs, J.V.McD. & L.H.], consisting of members from all of the system's hospitals in the state—including a neonatologist, a quality/safety nurse, a hospital educator, perinatal unit registered nurse (R.N.) representatives, a material services member, a lac-

tation consultant, and a computer services member. The committee's charter was to evaluate previous events, come to a greater understanding of the problem, and make preliminary recommendations for interventions to reduce newborn falls. The committee's initial approach to intervention has entailed (1) expanding the patient safety contract, (2) monitoring mothers more closely, (3) improving equipment safety, and (4) spreading information about newborn falls within the state and throughout the system. These interventions are described in detail, along with their respective challenges, in the following section.

### INITIAL INTERVENTIONS

*Safety Contract.* To improve awareness and prevention of

falls, staff use a “safety contract” on admission—referred to as the Newborn Safety Information for Parents (Appendix 1, available in online article). The contract outlines the risk factors that appear to increase the risk of a newborn fall during the postpartum period. These risk factors include marked maternal fatigue from the labor and delivery process, postpartum administration of pain medications, and the characteristics of hospital beds compared to beds at home. The mothers and significant family members are asked to review the safety information and sign the contract.

Challenges with the patient safety contract have to do with the sheer amount of information presented to patients on their arrival—at an emotionally exciting time. Although a signature is obtained, it does not ensure that the information has been processed or understood. During hospitalization, the nurses are asked to remind the patient and family members about the risks of newborn falls, but our approach is not standardized across staff and we do not know whether new parents understand the significance of the information provided to them. We currently are assessing the effectiveness of the communication of this information during the admission process and subsequent hospitalization.

**Monitoring.** The nursing staff was educated about the need for vigilance when newborns are placed in the maternal bed. This content was incorporated into the nursing practice guidelines for newborn care. A “no co-sleeping” policy was introduced to help ensure that the newborn was moved back to the bassinet by the mother, family members in the room, or nursing staff when the mother was preparing for sleep, was becoming drowsy, or had fallen asleep.

There are challenges associated with closer monitoring of the mother. Nursing staff are asked to separate mother and infant when mother is sleeping. When checked, a mother may seem alert and then drift off to sleep shortly after the observation. Staff and families often voice concern that separating the mother from her newborn may reduce success in establishing breastfeeding. We are developing individualized newborn fall-prevention plans by adjusting the amount of nurse observation time as deemed necessary given results from a maternal clinical assessment tool of risk of newborn fall. A recommendation that an awake adult monitor the newborn while he or she is in the maternal hospital bed with its mother may depend on the mother’s risk status.

**Equipment Safety.** The fact that for a number of the cases of newborn falls, the mother fell asleep in the maternal hospital bed while holding the newborn in her arms, only to wake up to the newborn crying on the floor next to the bed, led to an eval-

### Time of Fall for the Nine Cases

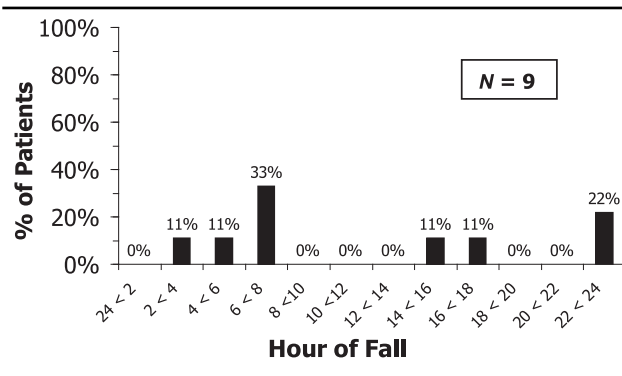


Figure 1. The figure shows the distribution of occurrence by time of day; more than half of the newborn falls occurred in the early-morning hours.

uation of the bed’s design. Most manufactured hospital beds seem to have similar upper and lower side rails; a space between the two sets of side rails allows the head of the bed to be elevated. When the head of the bed is elevated by 45 degrees, which is frequently the case, an opening on each side of the bed is thereby created at the mother’s hip level which is more than ample for the newborn to fall through. Many of the bed models also have openings within the side rails which are large enough for the newborn to accidentally fall through. As the mother falls asleep and her arms relax, the newborn falls to the floor through the openings.

In the United States, the bassinet is designed as a separate and independent unit frequently placed some distance from the mother’s bed, which discourages the mother from using it. In contrast, in the United Kingdom the bassinet is integrated into the design of the maternal hospital bed and attached parallel to one side of the bed.<sup>5</sup>

The newborn’s location in a hospital room creates potential for engineering design with greater attention to newborn safety considerations, including guardrail construction that eliminates all gaps, attention to the space between the mattress and the rails, and integration of a newborn crib with the mother’s bed. We are initiating a safe medical device reporting process to bring focused attention to the bed design relative to newborn safety issues. We are also working with our system’s leadership and manufacturing partners to develop safer mother/baby beds.

**Spreading Our Learnings.** To educate clinicians, the rates of newborn falls and the analyses and summaries of cases are now regularly reported to nursing and medical staff. We are developing our collection tools to improve our understanding of these events. A newborn fall debrief form (Figure 2, page 331; full-size version available in online article) was designed to capture

Newborn Fall Unusual Occurrence Report (UOR) Debrief Form Postevent

The image shows two pages of a 'Newborn Fall UOR Debrief Form'. Page 1 (left) contains sections for 'Demographics' (Date of Event, Time, Reported Location), 'Situation (Describe the event)' (Who was involved, Maternal medications, Documented maternal history of substance abuse, Other adults in the room, Estimated times), and 'Type of Newborn Fall Involving Mother of Newborn' (From Maternal Hospital Bed, Ambulation, Mother in Rocking Chair or Room Chair, Other event leading to fall or drop of the newborn). Page 2 (right) contains 'Type of Newborn Fall involving partner, family or visitor' (Ambulation, Partner, family member, visitor, Other event leading to fall or drop of the newborn) and 'Complete the following sections for all newborn fall types' (Identification that newborn had fallen, Did fall occur from isolette or warmer?, Immediate parental report to nursing staff?, Newborn injuries identified?, Estimated distance newborn fell?, Newborn provider notified?, Newborn on frequent observation?, Newborn moved to Nursery/NICU?, Were there any diagnostic tests completed?, Newborn safety contract reviewed and signed on admission?, No co-sleeping policy verbally reinforced by nursing staff for mother and family members?, Visual reminders of no co-sleeping policy in the maternal hospital room?, Fall appropriately documented in the medical record (event, physical exam, interventions, MD notification, no reference to a UOR)).

Figure 2. A newborn fall debrief form, reported online, was designed to capture additional details for continued evaluation of factors involved in the event. PSVMC, Providence St. Vincent Medical Center; NICU, neonatal intensive care unit; L&D, labor and delivery; MD, physician.

additional details for continued evaluation of factors involved in the event. A newborn fall must now be reported using an online version of this form, which ensures that additional objective information will be captured above and beyond qualitative observations. Analysis of data from the form is pending.

The Oregon Patient Safety Commission collects voluntary information about all sentinel events that occur in participating hospitals within the state. Because Providence Health & Services–Oregon is a participating member, we supported a statewide alert to all hospitals about the risk of newborn falls in perinatal units.<sup>6</sup> Moreover, the seven Oregon hospitals alerted the five-state system about the possibility of newborn falls via a systemwide safety alert so that all hospitals affiliated with our organization could take action to reduce the risk of newborn falls.

STANDARDIZING WORKUP FOR NEWBORN FALLS

As the committee reviewed all newborn fall reports, it dis-

covered a significant variability in the diagnostic workup among pediatric providers. For example, in Case 8 (Table 1), a provider was not inclined to order diagnostic testing in the face of a normal physical examination. When pressed by nursing staff concerns, he ordered a head computerized tomography (CT) scan, which led to identification of a skull fracture. Because of the lack of literature on in-hospital newborn falls, there is little guidance on the evaluation and management of the newborn who falls.

As a result, in February 2010 we convened a work group of physicians (emergency department pediatric provider, pediatric hospitalist/medical director, pediatric radiologist, and neonatologist) from the largest Oregon hospital with an NICU to develop a standardized algorithm for evaluation and management of the newborn who falls. The workup being developed focuses on a physical examination by the provider; a 12-hour observation period with neurologic checks; and, if criteria for clinical symptoms are present, a CT scan of the head.<sup>7</sup> Criteria

### Number of Newborn Falls Across Seven Oregon Hospitals, 2006–2009, by Quarters

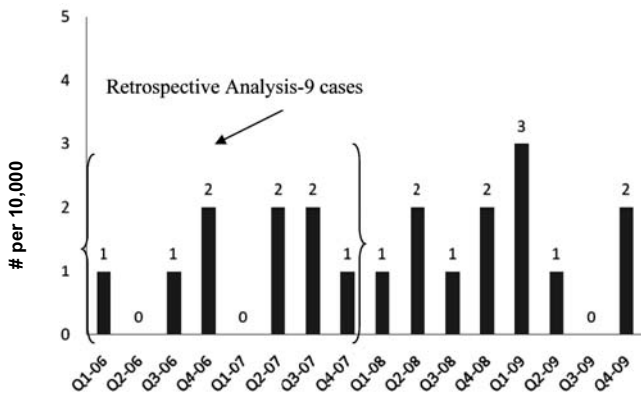


Figure 3. Data from the seven hospitals in Oregon yields a rate of 3.94 falls/10,000 live births.

for the CT scan will likely include loss of consciousness of any time duration, abnormal behavior per parental opinion, and vomiting.

### Trends in Rates of Newborn Falls

We have engaged our system in looking more widely at the problem of newborn falls. With recent reporting from 22 of these hospitals, we have observed a rate of 4.14 falls/10,000 live births (Figure 4, right), which is remarkably similar to our initial data from our 7 hospitals in Oregon—3.94 falls/10,000 live births (Figure 3, above). Extrapolating a range of 1.6<sup>1</sup>–4.1 falls/10,000 births across the United States would suggest that 600 to 1,600 newborns are experiencing an in-hospital fall every year.

### Discussion

After implementing the interventions and spreading information about newborn falls, we have continued to document incidents. We have recently begun to use a new analytical database to store the post-falls debrief information, including results of the standardized workup. Fortunately, these events are very rare, which however makes comparative statistical analyses impossible for several years unless large geographical data sets are used (which may be a possibility in the future). On the basis of observations of what has happened since we educated staff, we have decided to adopt reporting practices from quality improvement studies of rare events.<sup>8</sup>

We plan to begin reporting for each hospital in Providence Health & Services—Oregon the “number of days since last new-

### Five States’ Hospitals Event Frequency per 10,000 Live Births per Month, January 2008–February 2010 (26 Months)

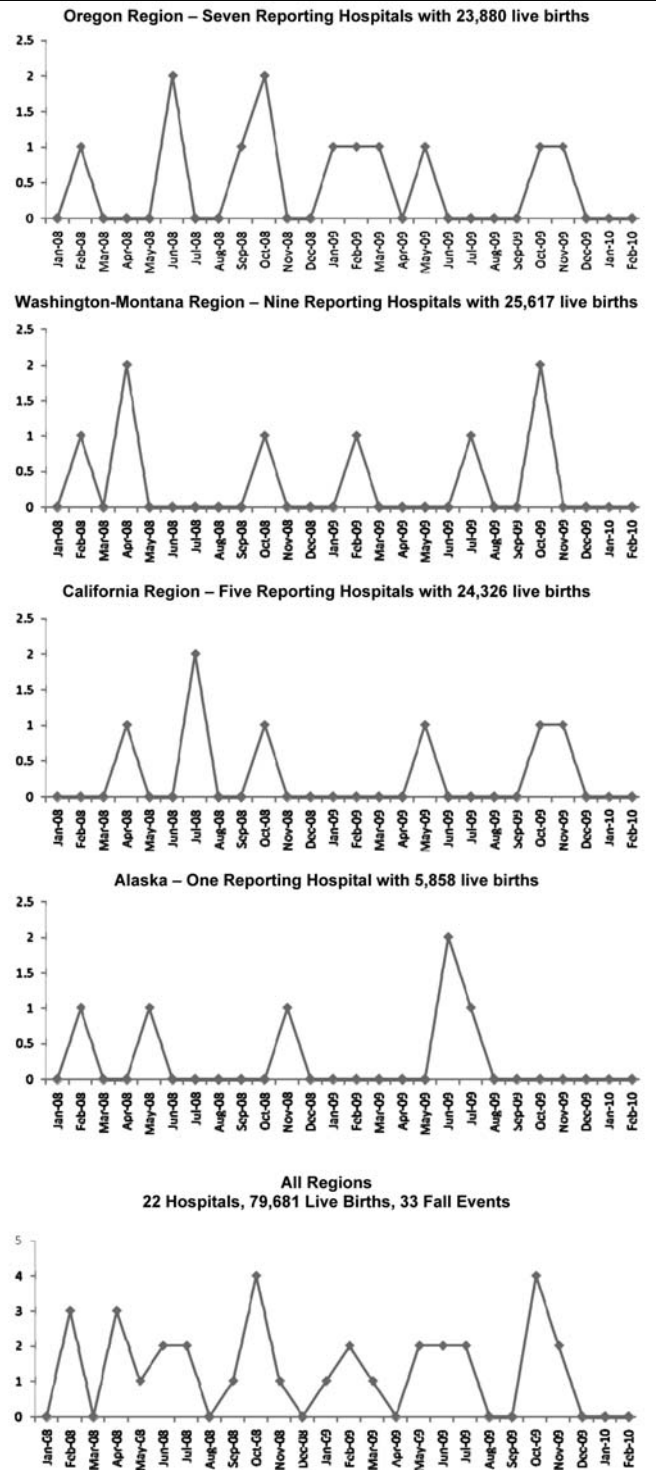


Figure 4. Reporting from 22 hospitals in five states yields a rate of 4.14 falls/10,000 live births.

Table 2. Failure Mode and Events Analysis, with Error Events in Order of Criticality

Error Event	Criticality Score
Newborn fell from side of maternal hospital bed while being breast fed; fell between upper and lower railings	378
Mother physically tired after delivery	360
Mother sleeping in bed with newborn at her side at night	336
Mother turns while sleeping and knocks infant to the floor	336
Mother in rocking chair and falls asleep holding newborn, who falls to the floor	324
Mother has urgent need to use restroom and abruptly leaves newborn in the bed	288
Mother using pillows for breastfeeding and as support for neonate	270
Mother does not place newborn in bassinet while sleeping	270
Father swaddling neonate on the end of the maternal hospital bed; father misjudges the end of the bed due to bedding and the newborn falls to the floor	240

born fall.” We also plan to begin analysis of events using geometric distributions, or g-charts, in consultation with computing experts who can advise on mining our large databases over time on a regular basis. For example, we may be able to learn whether factors such as the number of deliveries affect the probability of falls.

We have recently performed a Failure Mode and Effects Analysis, in which we considered 68 possible events along three dimensions—(1) frequency of occurrence, (2) ability to detect these situations, and (3) severity of outcome. A team of risk and nurse specialists rated these 68 events as a group, scoring them for each dimension on a scale of 0 to 10. Multiplication of all three values yielded a possible range of 0 to 1,000. Events with the highest criticality for attention were revealed by using a cut-off score of over 240 points from all three dimensions. Table 2 (above) shows the nine situations that result in the highest risk of infant falls. We are also using cause mapping<sup>9</sup> to design effective and targeted actions to this problem.

### Conclusion

Newborns experience in-hospital falls at a rate of approximately 1.6–4.14/10,000 live births, resulting in an estimated 600–1600 falls per year in the United States. Additional reports of rates of newborn falls are urgently needed to determine the true prevalence of this historically underreported event. We are implementing several strategies in our attempt to eliminate the risk of harm to newborns during their initial hospitalization and will continue to measure the rates of falls to see if we have been able to decrease their incidence. Standardized evaluation and management guidelines need to be developed to aid the clinician in the appropriate care of newborns experiencing this infrequent event. We call on others to measure their rate of newborn falls and work with us to call for the development of safer mother/baby beds in our hospitals. **I**

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### Online-Only Content

See the online version of this article for  
 Appendix 1. Newborn Safety Information for Parents Form  
 Figure 2. Newborn Fall Unusual Occurrence Report (UOR) Debrief Form Postevent

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# NEWBORN SAFETY INFORMATION FOR PARENTS

PATIENT IMPRINT

For your Baby's Safety:

We want this to be a safe environment for you and your baby. Parents, staff, and visitors all play an important part in helping us reach this goal. To help ensure you and your baby have a safe and enjoyable stay with us, here is a list of some of the security measures we use on our unit:

- Specialized training for staff in maintaining a secure and safe environment
- Security doors and video cameras throughout the Family Maternity Center
- Cards with a sample of your baby's cord blood which contains your baby's DNA
  - We do not keep a copy of this card; you have the only one
  - Store this card in a cool, dark safe place and in the provided glassine envelope
  - DNA samples are more reliable than foot or finger printing for identification purposes and in case of your child's disappearance, this safety precaution will help with identification
- Bracelets with matching numbers for you, your baby, and your primary support person
  - You and your baby's band numbers will be checked whenever your baby is separated from you and again when your baby is returned
- Do not sleep with your baby in your bed or while relaxing on the couch or chair
  - When you feel sleepy or plan on sleeping, place the baby in the bassinet
  - If you should fall asleep with your baby in your bed or arms, your nurse will move the baby to the bassinet
  - Accidental infant falls happen because of unfamiliar surroundings, the effects of medication and design of the hospital bed, couch, or chair
  - Obtain information regarding co-bedding at home from your newborn's care provider.
- Babies are moved to and from the nursery or any other procedure area in their bassinet and may not be carried in the hallways
  - Only staff, you or your primary support person may have your baby outside your room
- Babies must remain in the Family Maternity Center at all times
- We will teach you steps you can take to keep your baby safe
  - Do not give your baby to anyone who is not wearing a Providence photo name badge and additional Family Maternity bright pink identification. Be sure the photo matches the person wearing the badge
  - Do not leave your baby alone in the room while you shower or go for a walk. A family member may watch the baby or you may discuss options with your nurse
  - If in doubt about anyone in your room, immediately call for your nurse
  - We encourage you to accompany your baby to and from any procedure

***I have read and understand the above information.***

\_\_\_\_\_  
Parent

\_\_\_\_\_  
Family Maternity RN

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time



58842

# Newborn Fall UOR Debrief Form

## Demographics

Date of Event (MM/DD/YY) <input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="radio"/> Medford <input type="radio"/> Milwaukie <input type="radio"/> Newberg <input type="radio"/> Portland <input type="radio"/> Seaside <input type="radio"/> St. Vincent <input type="radio"/> Willamette Falls	Patient Sticker (Account # and Medical Record #)
Time (24-Hour) <input type="text"/> : <input type="text"/>		
Reported Location <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

## Situation (Describe the event)

Who was involved in the newborn fall?  Mother  Partner/family/visitor  Staff

**Newborn fall involving the mother:**

Type of Delivery:  Vaginal  Cesarean Section

Maternal medications at the time of the fall:  None  Narcotics  Epidural  Ambien, other "sleeper"  Magnesium  Other medication: List: \_\_\_\_\_

Time medication last administered prior to newborn fall Time (24-Hour)  :   Not Applicable, if none checked above

Documented maternal history of substance abuse  Yes  No If yes,  Pt history  Positive UDS

Other adults in the room at the time of the fall?  Yes  No

Other adults awake?  Yes  No

Estimated time between newborn being placed in the maternal bed and nursing staff coming back in the room on rounds? In Minutes

Estimated time between newborn being placed in the maternal bed and the fall/drop? In minutes

Estimated time out of line of vision (i.e. behind privacy screens, etc.) (PSVMC NICU ONLY) In minutes

### Type of Newborn Fall Involving Mother of Newborn (Choose one)

<input type="radio"/> <b>From Maternal Hospital Bed</b>	<input type="checkbox"/> Mother fell asleep, newborn fell off bed onto the floor <input type="checkbox"/> Mother awake, newborn fell off bed onto the floor	<b>Bed detail</b> <b>Bed model:</b> <input type="checkbox"/> Stryker L & D Bed <input type="checkbox"/> Stryker Postpartum Bed <input type="checkbox"/> Hill Rom L & D Bed <input type="checkbox"/> Hill Rom Postpartum Bed <b>Side rails up</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b>Bed height</b> <input type="checkbox"/> Low position <input type="checkbox"/> High position <b>Head of Bed Elevated</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b>Pillows lining bed rails</b> <input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="radio"/> <b>Ambulation</b>	<input type="checkbox"/> Mother ambulating with newborn and fell/tripped with newborn	<b>Factors in ambulation fall/drops:</b> <input type="checkbox"/> Equipment (IV lines, phone cord, call light cord, etc) <input type="checkbox"/> Room conditions (Fluids on floor, furniture in the way, bedding on the floor, etc)
<input type="radio"/> <b>Mother in Rocking Chair or Room Chair, fell asleep &amp; newborn fell to floor</b>	<input type="checkbox"/> Rocking Chair <input type="checkbox"/> Room Chair <input type="checkbox"/> Other	
<input type="radio"/> <b>Other event leading to fall or drop of the newborn</b>		Comments <input style="width: 100%; height: 20px;" type="text"/> <input style="width: 100%; height: 20px;" type="text"/>



58842

Type of Newborn Fall involving partner, family or visitor (Choose one)

Ambulation

Family member/visitor walking with newborn & fell/tripped with newborn

Factors in ambulation fall/drops:

- Equipment (IV lines, phone cord, call light cord, etc)
- Room conditions (Fluids on floor, furniture in the way, bedding on the floor, etc)

Partner, family member, visitor in Rocking Chair or Room Chair, fell asleep & newborn fell to floor

Cot  
 Rocking Chair  
 Room Chair

Other event leading to fall or drop of the newborn

Comments:

[Empty text box for comments]

Complete the following sections for all newborn fall types

Identification that newborn had fallen:

- Mother awake or woke up when newborn fell
- Nursing staff came in the room and identified the newborn had fallen
- Other identification of newborn fall

Comments: [Empty text box]

Did fall occur from isolette or warmer?

Yes  No

Immediate parental report to nursing staff?

Yes  No  Unknown

Newborn injuries identified?

Yes  No If yes,  Describe injury:

[Empty text box for injury description]

Estimated distance newborn fell:

Inches: [ ] OR Feet: [ ]

Newborn provider notified?

Yes  No Care Provider Name

[Empty text box for care provider name]

Date (MM/DD/YY)

[ ] / [ ] / [ ]

Newborn on frequent observation?

Yes  No

Time (24-Hour)

[ ] : [ ]

Newborn moved to Nursery/NICU?

Yes  No

Were there any diagnostic tests completed?

Yes  No

List tests:

[Empty text box for list of tests]

Newborn safety contract reviewed and signed on admission??

Yes  No

No co-sleeping policy verbally reinforced by nursing staff to mother and family members?

Yes  No

Visual reminders of no co-sleeping policy in the maternal hospital room

Yes  No

Fall appropriately documented in the medical record (event, physical exam, interventions, MD notification, no reference to a UOR)

Yes  No

Bedside RN (Please Print)

[Empty text box for bedside RN name]

Charge RN (Please Print)

[Empty text box for charge RN name]

## Rapid Response Systems: The Stories

# How I Nearly MET My Maker: A Story of Clinical Futile Cycles and Survival

**Department Editors:** Michael A. DeVita, M.D.; Rinaldo Bellomo, M.D.; Kenneth Hillman, M.D. Readers are invited to submit inquiries regarding their own case studies on rapid response teams (also called medical emergency teams) to Steven Berman (sberman@jcrinc.com) or Michael DeVita (mdevpgh@yahoo.com).

*Michael D. Buist, M.B., Ch.B.*

*In this series, the articles have highlighted a variety of implementation methods and uses of rapid response systems (RRSs). They have described how RRSs have been uniquely tailored to the organizations' culture and clinical environments, with largely positive results following implementation. In this article, Dr. Buist tells a somewhat different story, a highly personal one, which focuses on his own critical decompensation after surgery at his own hospital. The RRS (in this case, a medical emergency team was the efferent arm) at first successfully intervened, only to make a near-tragic error. Yet, as Dr. Buist, one of the leading proponents of RRSs worldwide, argues, the RRS—like any system—has the potential to err. He reminds us that*

*even safety nets can require safety nets. So this story is also a cautionary tale: Just because your hospital has implemented an RRS, it does not mean (1) that the system is perfect or (2) that all preventable deaths are averted. To meet the goal of eliminating all preventable deaths in hospitals, an RRS requires continuous surveillance and adjustment. Furthermore, it must be implemented and operated in the context of the hospital's organizational culture. Although the administrative and quality improvement arms of the RRS are often underemphasized, this story exemplifies their importance—not just for RRSs but indeed for all hospital systems.*

—Michael A. DeVita, M.D.

## A Final Attack of Appendicitis

In October 2008 I had what was to be my final appendicitis attack. I had had chronic appendicitis for about a decade, which never really gave me much trouble. About twice a year I developed the classic symptoms, but the pain would subside after a few hours. In 2004 I had consulted a surgeon, who confirmed the diagnosis and told me that the only treatment option was appendectomy. I was reluctant to have any elective procedure on the basis of my experience as an intensivist, in which I often found myself treating patients for postsurgical complications.

It was a Sunday, and I was a passenger on the red-eye flight from Singapore to Melbourne. When the pain was still present many hours after I got home, at approximately 2:00 P.M. (14:00) I phoned a surgeon. The only hospital with any free operating time before midnight was the one that I was rostered to cover as an intensivist for the week starting the next day. And so, I was admitted to the hospital approximately two hours later.

## Calling in the Medical Emergency Team (MET)

The laparoscopic appendectomy was apparently uneventful,

and I was allowed to recover routinely. I briefly awoke sometime in the early morning hours to go to the bathroom. I recall that blissful postanesthetic state with the pain gone, but I also felt very light-headed on standing, which I attributed to the drugs, and got myself back to bed. In the morning I felt dreadful. I told the surgeon that there was no way that I could go home that morning. The surgeon agreed, and with that settled, I arranged for a colleague to cover my scheduled ICU work. Next, the nurse came to assess my vital signs. As she took my blood pressure, I could see the concern on her face. I asked her what the reading was and she replied “60.” For a moment we just looked at each other. She knew that I was the physician who drove the whole MET process and that I had a reputation for getting cross when the staff did not call the MET. So she called the MET. I was aware of the irony of the situation: I have published numerous times on METs,<sup>1,2</sup> and there I was, a patient in my own hospital and waiting for the MET (which consisted of an emergency medicine specialist, an intensive care nurse, and the hospital nurse coordinator) to arrive.

The MET responded quickly and competently assessed the situation. The team members sited a second intravenous line and gave me a bolus of fluid. Blood was taken and tests ordered.

Finally, an electrocardiogram (ECG) was done. There was a palpable silence before the team leader asked a nurse for 300 mg of aspirin and 5000 units of heparin. He showed me the ECG. He had circled the obvious ST-segment elevation in chest leads V2 to V4. He told me that I was having an anterior infarct. I got worried—real worried—and said that I was not experiencing chest pain and that I ran and swam laps regularly without angina. He said that he didn't care. He told me to stop being the intensivist and that he was now the doctor. I swallowed the aspirin, the heparin was injected, and I was wheeled to the cardiac catheterization laboratory. I had asked that my old ECG get faxed over from my office. I was pleased to discover that the interventional cardiologist was someone I knew—and respected—and that he had received the old ECG. Looking at me and the ECGs, he stated that he was not so sure that the ST-segment elevation was acute, and he ordered instead an urgent echocardiogram to look for regional wall motion abnormality. I was put in an adjacent coronary care unit (CCU) bed. But I still felt dreadful. No one had repeated my vitals. The echocardiogram confirmed what my exercise capacity had always told me, namely, that I have a “fantastic” heart without regional abnormalities consistent with the abnormal ECG. The surgeon came back, stating that he was unsure about what was transpiring and what was causing my discomfort. On re-examining my abdomen, he stated that he didn't think that I was bleeding because I didn't have a tachycardia (in fact I was bradycardiac, with a heart rate of 55 beats per minute), but nevertheless he ordered a computerized tomography (CT) scan of my abdomen and pelvis.

My wife arrived. She had been notified by the MET to come to the hospital but not to get panicked as everything was okay. On entering the CCU room, she said that she had been on the phone with my brother, an obstetrician in Sydney, discussing my symptoms. He thought that I was bleeding and should not have a CT scan. Nevertheless, I tried to reach up from my supine position to take a sip of the contrast media. My wife reiterated my brother's insistence that I not have a CT scan. I looked at my abdomen, which was distending before my very eyes. I looked at my palmar creases, they were white. The penny dropped—I knew I was bleeding.

### **“I Am Bleeding, Get the Surgeon”**

I was worried. I did not want to die in the CT scanner, vomiting and then aspirating contrast media in a difficult-to-resuscitate location, a scenario with which I was all too familiar.

In addition, I was sensitized to “not being heard” by health care workers. My wife and I had lost a baby girl at 26 weeks'

gestation just two months before all this. We blamed ourselves for not pushing the obstetric team hard enough on reasons for why the baby was not moving. Our cries for care then went unheard, despite my being a respected senior medical specialist. That experience steeled me now. I said to the bedside nurse, “I am bleeding, get the surgeon.” The nurse walked over to me and touched my lips she then said, “your lips are still pink, don't panic.” I then started to panic, using the only “forcing” function I knew, namely, a common curse word, as I ordered the nurse to get the surgeon. The nurse then called the surgeon. The rest was a blur; I remember the surgeon's hovering over me (and himself looking pale), saying that “everything would be okay.” I remember going to the operating room. I remember the anesthetist arriving in street clothes looking panicked as well. Then I went into that oblivion of anesthesia.

I didn't really wake up. I just became cognizant of a claustrophobic sensation in my face. There was light. There were people talking around me. I was intubated. Next, I was gagging. Then it was over, and the tube came out. I had needed massive resuscitation for 3 liters of blood in my abdomen. As it turned out, I was bleeding from an epigastric artery and also from an area where I had had adhesions. I had nearly died—the MET had initially “saved” me during an initial brief fluid resuscitation and evaluation, but it had also caused me a bit of trouble by delaying the real diagnosis.

### **Reflections**

As a practicing internist and intensivist, and as an investigator who has made an academic career out of researching unexpected deaths in hospital, I reflected on my situation during my convalescence. I have written about patients who die in circumstances similar to the ones that I had encountered.<sup>3</sup> So what insights did this experience give me? First, the James Reason Swiss Cheese model<sup>4</sup> of adverse events, while applicable in industrial accidents, does not always apply to what happens to patients when they die unexpectedly in the hospital. The model most easily provides a useful framework for discrete adverse events, such as falls, medication errors, and infection control issues. Although the “hole in the cheese” was the clinicians' failure to pursue the highest-probability complication for hypotension after a surgical procedure (that is, bleeding), the situation was indeed complex. Complex cases with potentially several etiologies (both coronary ischemia and bleeding) or “red herrings” (like my ECG) that confuse the people in the intervention may make using this method to explain error difficult. Perhaps my “close call” and adverse events that I write about are better explained by a different model that I have called “clinical futile

cycles.”<sup>2</sup> A *clinical futile cycle* refers to a situation in which clinical staff, presented with a patient, just go round and round the problem without moving the problem to another person, area, or space and toward resolution. In my case, the fact that the ECG ordered by the MET supported the diagnosis of an acute anterior myocardial infarct had all the attending nurses and physicians, and even myself, focused on that one issue, neglecting all others. The concept of “premature closure,” widely recognized in simulation education and clinical practice,<sup>5-8</sup> can be difficult to overcome in real time. So rather than someone thinking, “Day 1 postop, hypotension, what are *all* the possibilities here?” everyone focused on the one issue at hand—my ECG. With the benefit of hindsight, that line of thinking may initially appear to be implausible. However, our brains, particularly when we are stressed, are not very good at critically, rationally, and quickly assessing data and coming up with a plan or sequence of steps to solve the problem.

I encounter clinical futile cycles every day I go to work. I ask my resident to get a surgical consult on a patient and to phone with that opinion before he or she finishes work. I get no phone call. I phone the resident, who proceeds to cite many attempts all day to get hold of the surgical fellow but without success. I then phone the surgical consultant and get the opinion that I am after for my patient.

My second insight concerns the concept of the “good patient.” I was constantly reminded by colleagues to be a good patient and to stop being a doctor. If the good patient conforms with the health care system and is compliant with recommendations, I was a “bad patient.” In addition to demanding a surgeon in a crude manner, I also told the staff to get my central line out when the dressing came undone and was not promptly replaced. I stopped taking the oral antibiotics when I started to gag on them because of the smell. I refused another drip after five days’ consecutive infusions of normal saline at a rate of 3 liters per day. I could just feel the edema. Most importantly, I demanded the surgery that ultimately saved my life. I want to start a patient-centered movement called the “BAD” Patient, where *B* stands for better informed, *A* stands for asks questions, and *D* stands for discerning. This is consistent with The Joint Commission’s Speak Up!<sup>TM</sup> campaign.<sup>9</sup>

My third insight is that if the surgeon had not answered that phone call I would most likely be dead. However, he did answer the phone. He came straight back to the hospital, took one look at me, and operated. Perhaps the ability to contact the surgeon was just luck. If so, that is a scary thought. For some years, along with the development of my concepts of clinical futile cycles, I have been involved in developing information commu-

nication technology systems that enable the doctor to be constantly in touch with patients’ statuses, in which “alert logic” is activated in the event of delayed or even absent clinical responses to alerts. Yet, there has so far been little interest in the marketplace for such systems, in spite of ample evidence that needed calls to provide support are not initiated. Perhaps the thinking is that clinicians only “need to do their jobs properly.” Obviously, this is a thought process that blames the individual instead of the system that repeatedly allows the error.

My final insight is that because of the complexity and severity of illnesses that patients now exhibit, health care and hospitals in particular are dangerous places. Why do we not warn our patients of this and give them advice on how best to minimize the risks and effects of adverse events? Further, staff education is needed to improve their ability to “hear” the patient. Efforts to improve patient education and involvement must be increased, as advocated in burgeoning literature,<sup>10,11</sup> and allowing patients and their families the opportunity to activate the hospital’s rapid response system must be mandated. **J**

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*Hélène Faye, A. Joy Rivera, Ben-Tzion Karsh, Ann Schoofs Hundt, Christine Baker, Pascale Carayon*

Use of a proactive risk assessment method to identify failure modes in medication management suggests that organizations can categorize and evaluate failures modes in a variety of ways, such as focusing on a particular step in the process.

### A Practical Guide to Carrying Out Failure Mode and Effects Analysis: Creating the Team and Planning Meetings

*Laura Ashley, Gerry Armitage, Maria Neary, Gillian Hollingsworth*

On the basis of the literature and the lessons learned from conducting their own FMEAs, the authors provide instructions and recommendations for team formation and meeting planning.

### Tool Tutorial: Code Debriefing from VA Medical Team Training Program Improves the Cardiopulmonary Resuscitation Code Process

*Katherine B. Percarpio, Fonda S. Harris, Betty Ann Hatfield, Barbara Dunlap, Walter E. Diekroger, Pamela D. Nichols, Lisa M. Mazzia, Peter D. Mills, Julia B. Neily*

A Department of Veterans Affairs (VA) medical center developed a brief questionnaire to support the identification of issues and the continuous improvement of the CPR process and its outcomes.

### Pediatric HIVQUAL-T: An Innovative Approach to Measuring and Improving the Quality of Pediatric HIV Care in Thailand, 2005–2007

*Rangsima Lolekha, Suchin Chunwimaleung, Rawiwan Hansudewechakul, Pimsiri Leawsrisook, Wasana Prasitsuebsa, Pramote Srisamaun, Jurai Wongsawat, Worawan Faikratok, Sarika Pattanasin, Bruce D. Agins, Kimberley A. Fox, Michelle S. McConnell*

For the five participating hospitals in Thailand, the pediatric HIVQUAL-T model for performance measurement and quality improvement of care facilitated use of hospital data for care improvement.