Quality improvement efforts in the intensive care unit: development of a new heparin protocol

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Context: An ongoing process of identifying and implementing breakthrough projects to quickly improve patient outcomes and reduce costs in the intensive care unit.

Objective: To develop and test a new protocol for heparin administration in the intensive care unit, replacing the 5 existing protocols and ensuring compliance with the recommendations of the Fifth American College of Chest Physicians Consensus Conference on Antithrombotic Therapy.

Design: A pilot study comparing results of 58 patients on the 5 existing protocols with those of 10 patients on the new heparin protocol.

Setting: Baylor University Medical Center, a large tertiary hospital in Dallas, Texas, with 115 adult intensive care unit beds.

Interventions: Heparin dosing was based on a patient's weight, and anti-coagulation was monitored through the heparin assay.

Main outcome measures: In the control group treated according to the existing protocols, 5 patients (8.6%) received optimal bolus doses, and 2 patients (3.4%) received optimal infusion doses. In the pilot group treated according to the new protocols, 9 patients (90%) received optimal bolus doses, and all received optimal infusion doses.

Results: The implementation of the new heparin protocol resulted in better patient care, improved nursing efficiency, and reduced costs.

Conclusions: As shown in this example, a rapid breakthrough project following a plan-do-study-act cycle can apply best practices relatively quickly and lead to better patient outcomes.

In April 1997, the intensive care units (ICUs) of Baylor University Medical Center (BUMC) began a process of identifying and implementing breakthrough projects that would improve patient outcomes quickly and reduce costs (1). The initial impetus for this project came from Dr. John Anderson, senior vice president for clinical integration; Remy Tolentino, chief nursing officer; and myself. A team was formed consisting of the director of the ICU, hospital administrators, nurse administrators, pharmacists, dietitians, and information system professionals. The physician champions promoted evidence-based medicine, use of protocols, and best practices. The nursing champions promoted changes in bedside practice, continued evolution of work redesign, and appropriate staffing for patient needs. Administrative champions worked to remove or reduce barriers to change and to share the results within the hospital. The team internalized the following assumptions from the Institute for Healthcare Improvement: 1) we cannot settle for the status quo; 2) rapid change can occur; 3) we need to enlist the right people and find champions for each project; 4) work in small groups with regular meetings is very important to progress; and 5) measurements have to be made at each implementation point (2, 3).

The quality improvement team made use of the plan-do-study-act cycle to implement changes (4). This model states that, after a plan is created for a specific change, a small trial is implemented, sometimes consisting of only a handful of patients. The group studies the results by reviewing several key measurements that show success or failure and then acts on the results by implementing the change or beginning the process again (5). At BUMC, part of the plan was to streamline the approval process for changes: after results were in, approval was required only by

the ICU committee, the Pharmacy and Therapeutics Committee if the study involved a drug, and the medical staff officers.

This methodology for implementing changes to improve quality differs significantly from that for large research projects. In bringing about change, the aim is improvement, whereas in publishing research, the aim is new knowledge. Methods also differ: in care-improvement projects, tests are observable instead of blinded; bias is stabilized rather than eliminated; there are just enough data rather than extra data "just in case"; the study adapts with change rather than testing a fixed hypothesis; and sequential tests are used rather than one large test (6). Collecting data on small numbers of patients may not be sufficient to show statistical significance but does allow the team to achieve improvement, which is the designated goal.

The ICU Breakthrough Quality Improvement Committee has 11 ongoing projects; it has completed 12 projects (*Table 1*). This article focuses on one of those projects: the development of a new heparin protocol.

INTRODUCTION

The committee found that BUMC had 5 heparin protocols—and none was based on the most recent research and clinical guidelines. With the existing protocols, many patients were not reaching desired dosages and, if they were, they may have received subtherapeutic infusions for some time before reaching the optimum dose. It was clear that developing a new protocol would

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Table 1. Projects of the ICU Breakthrough Quality Improvement Committee

Current projects

Project Impact: data collection, data management, and benchmarking
ICU bed management/diversion
Monitoring and tracking in the ICU
Elevated intracranial pressure protocol
Multidisciplinary rounds for medical ICU patients
Diabetes inpatient management project
Chronic ventilator unit project
Deep vein thrombosis prophylaxis
Rapid ventilator wean protocol
Systemwide bed management project
Noninvasive positive pressure ventilation

Completed projects

Potassium protocol
Heparin protocol
Analgesia/sedation/neuromuscular blockade protocol
ICU admission criteria for gastrointestinal bleed patients
Intubation guidelines
Extubation protocol
Enteral feeding protocol
Intravenous insulin protocol
Hypoglycemia protocol
Subcutaneous insulin protocol
Ventilator withdrawal/end-of-life protocol
Chest tube protocol

standardize care and that a protocol based on evidence-based medicine could lead to improvements in patient outcomes.

A protocol development team was formed, consisting of 2 physicians (Robert Baird, MD, and Barry Cooper, MD), 2 nurses (Rita Krantz, RN, and Mary Ellen Savage, RN), and 1 pharmacist (Michelle Megellas, PharmD). Team members met every 1 to 2 weeks with the following objectives:

- To incorporate the findings of the Fifth American College of Chest Physicians Consensus Conference on Antithrombotic Therapy (7)
- To base dosages on patient weight
- To monitor anticoagulation through laboratory tests
- To assess laboratory data to determine therapeutic heparin level

The protocol was considered a work in progress. During the effort, for example, the infusion dose was changed from 18 to 14 U/kg/hr, since several patients on the higher dose had prolonged coagulation studies. In addition, 2 protocols were developed initially—one that used activated partial thromboplastin time (aPTT) and another that used the heparin assay. The literature supported use of both, and the team wanted physicians to be able to choose the one they were more comfortable with. However, further studies pointed to the benefit of the heparin assay, so the final protocol used only this test (Table 2).

METHODS

The team reviewed retrospective data on the 58 patients who were on the 5 physician-specific heparin protocols. Those data were compared with data from 10 patients on the new protocols

Table 2. Adult heparin protocol*

1. Patient weight: _____ kg (actual weight).
 2. STAT baseline CBC, PT, PTT.
 3. Heparin (1000 U/mL) 80 U/kg = _____ units IVP now x 1 bolus. (Round to the nearest 100 units if PT, PTT, and platelets are within normal limits. Not to exceed 10,000 units.)
- For venous thromboembolism, unstable angina, or myocardial infarction:*
4. (Premixed solution): Heparin 25,000 U/500 mL D5W to infuse at 14 U/kg/hr = _____ U/hr (round to nearest 100 units) via pump, until discontinued.
 5. STAT heparin assay 6 hours after start of heparin infusion (time: _____).
 6. Heparin dosing adjustments (MD to RN):
Laboratory value	Action
Heparin assay < 0.1 U/dL	Bolus 80 U/kg and increase rate by 4 U/kg/hr
Heparin assay = 0.1 U/dL	Bolus 40 U/kg and increase rate by 2 U/kg/hr
Heparin assay = 0.2–0.4 U/dL	No change
Heparin assay > 0.4 U/dL	Hold infusion for 1 hour and decrease rate by 2 U/kg/hr
7. Check heparin assay 6 hours after dosage rate change until 2 consecutive assays are therapeutic (0.2–0.4 U/dL). Start daily heparin assay at 0500 until heparin is discontinued.
 8. CBC every 3 days while on heparin therapy.
 9. Contact physician if patient exhibits signs of bleeding.

*Alterations to this protocol, with the exception of the bolus dose, render it inactive. Specific orders must be written separately on the physician order sheet.

CBC indicates complete blood cell count; D5W, dextrose 5% in water solution; IVP, intravenous push; PT, prothrombin time; PTT, partial thromboplastin time.

(the one using aPTT and the one using the heparin assay). The following data were gathered: bolus dose, infusion dose, time to anticoagulation, and duration of treatment. The optimal level for bolus dose was defined as 80 U/kg, and the optimal level for infusion dose was defined as 18 U/kg. Credit was given for optimal dosing if the dose was within 5% of the indicated amount. These definitions were based on recommendations of the Fifth American College of Chest Physicians Consensus Conference on Antithrombotic Therapy (7).

RESULTS

Of the 58 historical patients selected for review, 54 had complete data. The primary indications for heparin in these patients were unstable angina (16 patients) and deep vein thrombosis (12 patients). Other indications included myocardial infarction, venous-to-venous anastomosis, atrial fibrillation/flutter, thromboembolism, and ischemic disorders.

Of the 58 patients, 5 (8.6%) received optimal bolus doses and 2 (3.4%) received optimal infusion doses. Of the patients who received optimal bolus doses, none received optimal infusion doses. Of the patients who received optimal infusion doses, one did not receive a bolus dose and the other received a suboptimal bolus dose. The mean time to anticoagulation in this group was 63 ± 49 hours. The mean duration of treatment was 4.5 ± 2 days.

In contrast, among the 10 patients in the pilot trial for the new protocol, 9 (90%) received optimal bolus doses. The 10th

patient did not receive a bolus dose. All patients received optimal infusion doses. The mean time to anticoagulation was 34 hours, and the mean duration of treatment was 5.3 days.

DISCUSSION

Clearly, the standards in the new protocol differed from those in the previous protocols, as shown by the very different doses and the different mean time to anticoagulation (34 hours in the pilot group vs 63 hours in the historical group). The mean treatment times were similar because the literature has consistently supported use of heparin for 5 days before changing to oral anticoagulants.

The implementation of the new heparin protocols resulted in better patient care, improved nursing efficiency, and reduced costs. The patients received the proper loading dose, reached the therapeutic level of the drug more expeditiously, and were able to maintain the therapeutic level. In addition, anecdotal evidence suggests that with the new protocol there has been less recurrence of disease, less morbidity, fewer overcorrections, and fewer bleeding complaints. Nursing efficiency has improved since fewer dose changes and laboratory tests have been required. Finally, medication and laboratory costs have decreased, and costs have also been reduced by the decreased length of stay.

Several obstacles are associated with protocols. Some physicians have not accepted protocol use. They may oppose protocols because so many exist and because some aren't based on evidence. The development of the new protocol attempted to address these issues and increase physicians' confidence in this tool. The committee has also made it easier for physicians by producing these protocols as physicians' order forms. In addition, the champions have a role in announcing the project and showing enthusiasm for it, and nurses and pharmacists have a key role in ensuring that the protocol is used. The very process of devel-

oping protocols builds a collaborative environment and can bring about change in the hospital culture.

CONCLUSION

Over the past 3 years, with implementation of this project and others, we have created a management mindset for rapid-cycle changes in our ICU that has spread hospitalwide. Some cultural changes have a team concept, with physician and nursing champions using evidence-based medicine, protocols, and best practices. We have been able to remove or reduce barriers to change. The results have helped improve patient care. Secondarily, we have also reduced costs in some areas and have improved relationships along the way.

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Invited commentaries

The recently published Institute of Medicine report, *To Err Is Human: Building a Safer Health System*, documented that medication-related errors occur often, are costly, and frequently result in harm to patients. Designing systems at a local level that "make it hard for people to do the wrong thing and easy for people to do the right thing" can eliminate or at least minimize many of these errors. In this issue of *Proceedings*, Baird and colleagues describe their efforts to standardize one approach to anticoagulation at Baylor University Medical Center using a multidisciplinary team of critical care professionals and a rapid-cycle approach to quality improvement. Several points are worthy of emphasis.

ASSESSMENT OF CURRENT PRACTICE

This study focuses only on the intensive care unit administration of heparin, implying that further disparity in the use of

heparin may exist in other areas of the hospital. Dr. Baird describes a common scenario of 5 existing protocols for heparin administration. When multiple protocols exist, it is often because the original protocol has not been removed when updates are available or a new one is developed. Local "experts" create protocols unique to their practice situation and require the hospital and nursing staff to include them as a standard of care for their patients. Unfortunately, this support of individuality in practice creates an environment that ultimately results in less-than-optimal care and a greater potential for confusion at many points in the health care system. Dr. Baird did not go into detail with respect to the initial impetus for change, but his subsequent discussion of results reveals that his historical group representing practice prior to the protocol standardization effort had a mean time to anticoagulation of 63 hours, far below what would be considered an acceptable standard of care.