HEALTHCARE SAFETY: THE IMPACT OF DISABLING 'SAFETY' PROTOCOLS

M. M. Dierks[1], C. K. Christian[2], E. M. Roth[3], T. B. Sheridan[4], K. Dwyer[5], T. K. Gandhi[2], M. Gustafson[2], M. J. Zinner[2]
[1]Harvard-MIT Division of Health Sciences and Technology and Beth Israel Deaconess Medical Center, Boston, MA;[2]Brigham and Women's Hospital, Boston, MA; [3]Roth Cognitive Engineering, Brookline, MA; [4]Massachusetts Institute of Technology, Cambridge, MA; [5]Risk Management Foundation of the Harvard Medical Institutions, Cambridge MA

With increasing attention to patient safety, hospitals and other clinical facilities are developing practice guidelines and protocols with the specific intent of reducing harm to patients. However, the introduction of these protocols can have unanticipated negative consequences and if followed rigidly can become 'disabling'. We use the manual count procedure that was designed to improve patient safety by reducing the likelihood of leaving an object (e.g., needle, sponge or instrument) inside a patient body cavity during a surgical procedure to illustrate this point. Using results from an observational study of nine complex operations we show that the count protocol can have unanticipated negative consequences that need to be considered in evaluating the net positive gain in patient safety. The study highlights the importance of evaluating the overall impact of proposed protocols when assessing their potential benefits to patient safety.

INTRODUCTION

With increasing attention to patient safety, hospitals and other clinical facilities are beginning to develop and implement practice guidelines and protocols with the specific intent of reducing harm to patients. While treatment protocols tend to be research-based (i.e., they are the product of research that demonstrates efficacy), in many cases protocols intended to improve safety through processes and procedures ('safety protocols') have been applied without the benefit of similar evaluation. It is important to assess whether the introduction of a new safety protocol achieves the objective it was designed for, as well as to check whether there are any unintended negative 'side-effect' consequences of the introduction of the new 'safety-protocol' (Patterson, Cook and Render, 2002; Woods and Dekker, 2002).

In this paper we provide an example of a protocol, the peri-operative needle, sponge and instrument count, that was designed to improve patient safety during surgical procedures, but has unintended and potentially negative consequences for patient safety. The findings reported here are from a comprehensive study of practices and processes in the operating room of a large academic medical center. In this larger study, our goals were to identify specific but previously unrecognized features of the system – including protocols and procedures – that contributed to system complexity and influenced safety and performance. In particular, we wanted to know what features of the system contribute to or propagate adverse events, and what features prevent or reduce the severity of adverse events.

Among the specific procedures that we reviewed was the 'counting protocol' performed by the nurses during an operation to monitor inventory and reduce the likelihood of leaving a surgical object (e.g., needle, sponge or instrument) inside a patient body cavity. Retrospective reviews of claims data suggested that the counting process was potentially unreliable (Gawande et al., 2003), so we were initially interested in monitoring the reliability of the count – i.e., how successfully it achieved its

stated goal. While the study did provide insight into the reliability of the count and the factors that contribute to problems in counts, to our surprise we also discovered that there were 'costs' associated with the count protocol in terms of attention demands on the nurses, with potential safety implications. Our findings, and their implications for design and evaluation of safety interventions more generally are described below.

METHODS

Nine complex general surgery cases were observed in a large academic hospital.

A multidisciplinary observation team consisting of a surgeon and a human factors engineer observed each case. At the start of the case one observer was located in the pre-operative holding area where the patient initially presents. The second observer was placed in the operating room so as to be able to observe the equipment and instrument set up activities prior to patient entry. Observers took hand-written notes during the case documenting communications, information flow, and task execution and the time at which they occurred.

The data were entered into a database that allowed for coding and reconstruction of the case. For this analysis we searched for all instances involving the counting activity. We performed two analyses of the problems associated with the counts: (1) a qualitative analysis looking for illustrative incidents and trends across cases; (2) a quantitative analysis of duration (raw time and percentage of operating time where nurses were engaged in counting activities).

A more complete description of the study methodology is provided in Roth, Christian, Gustafson, Sheridan, Dwyer, Gandhi, Zinner, and Dierks (in press).

RESULTS

In the nine cases observed, nurses had an identifiable set of primary tasks (generally patient-centered activities), as well as many auxiliary tasks that they were required to perform. The execution of the required 'counting protocol' proved to be among the most demanding of these auxiliary tasks. They occurred frequently, consumed significant time and cognitive resources, and influenced the nurses' ability to attend to primary patient-centered activities.

While nurses have developed effective strategies for balancing the multiple demands placed on them, occasions arose where the need to follow the required counting protocol reduced their ability to support the ongoing flow of the surgery.

Workload Associated with the Count Protocol

Nurses devoted an average of 35.9 minutes to counting activities after the patient entered the room and 29.8 minutes after the incision was made (the window of vulnerability for a retained foreign body). This represents 12.9% of the total procedural time and 14.5% of the total incision time.

One reason for ongoing and repetitive counts was the frequent need for the circulating nurse to add new (and countable) resources to the operative field after the start of the case. As a case became prolonged or technically demanding, the counting protocol itself became increasingly complicated and time consuming. Moreover inconsistencies in the count triggered a mandatory repeat of the count or a prolonged search for the source of the inconsistency.

Problems Encountered

Of the nine cases we observed, six had some problem in the count that required search for a missing item and/or a recount to reconcile a count discrepancy. In two of those six cases there was sufficient uncertainty in the count that an x-ray was required to insure that there was no retained foreign body in the patient.

Observation during the surgeries as well as informal interviews with nurses provided some insight into why the counting protocol was cognitively demanding and vulnerable to error. First, a manual counting procedure is fundamentally error prone. Small distractions can lead to inadvertently skipping over an item or counting an

item twice. Similarly interruptions can cause nurses to forget to document an item added to the surgical field (Levy, Gopher and Donchin, 2002).

Other sources of complexity include the fact that there can be ambiguity in how to classify an item for the purposes of the count. For example nurses were observed to discuss whether a 'purple clip' should be considered to be an instrument for purposes of the count. Ambiguity in counting convention can introduce uncertainty in the count, particularly in cases where one nurse does the count at the beginning of the case and a different nurse does the count at the end of the case (e.g., due to shift change).

More generally communication breakdowns at 'hand offs' (e.g., for lunch breaks or shift-turnovers) can contribute to count problems. Such problems include uncertainty with respect to what has already been counted and uncertainty about what objects (e.g., small sponges) were placed in the body cavity and need to be removed. In one of the nine cases we observed, a communication breakdown at a hand off contributed to a perceived count discrepancy and a need for a complete recount.

Another source of complexity is that sometimes instrument packs that are opened at the start of a case are incomplete or supplemental instruments are introduced into the field after the 'official' count has been completed. There were two instances in the nine cases we observed where there was uncertainty as to whether an instrument pack contained all the instruments it was supposed to, which contributed to uncertainty in the count.

All these factors combined help explain why the manual count can be unreliable. It makes less mysterious why cases can occur where the count is declared 'correct' in spite of the fact that a foreign body is left in the patient body cavity (c.f. Gwande, Studdert, Orav, Brennan and Zinner, 2003).

An Illustrative Case

Since there was no clear guideline for handling recurrent or unresolved inconsistencies, and no guideline for suspending the count when its complexity increased beyond a certain threshold, in some cases, the counting activity became unproductive, drawing attention away from the primary task of supporting the surgical flow.

Figure 1 provides an illustrative case of how the count protocol, which is intended to increase patient

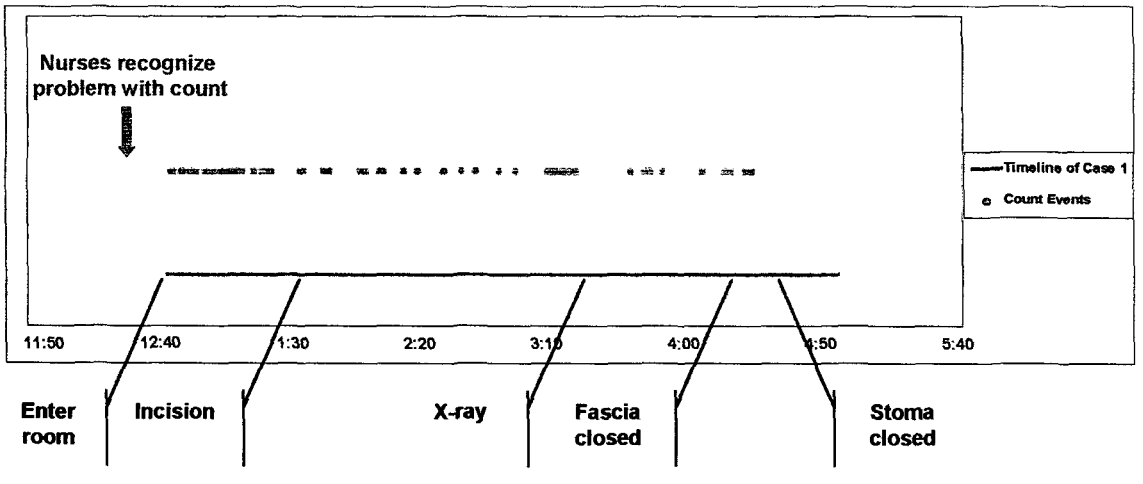

Figure 1: An illustrative case of how the count protocol can inadvertently become counter-productive. Time line and major event markers are show at the bottom. Due to a delay in pre-operative preparation, two different nursing teams participated in the setup of the room. The case was complex, and involved a large number of different instruments from many different kits. The team who opened the kits and laid out the instruments performed the initial counts of > 200 different instruments, and documented a count. Prior to the patient entering the room, a discrepancy was noted between the documentation and the actual number of instruments present on the tables. The patient entered the room and the incision was made before the source of the discrepancy could be identified and resolved. With the case proceeding, additional kits and instruments were added to the field as needed, while the nurses attempted to resolve the inconsistency. Since the nursing team was compelled by policy to identify the source of the discrepancy, and given the complexity of the case, a significant portion of the nurses' attention was consumed by counting activities.

safety, could inadvertently become counter-productive. In this instance, a discrepancy in the count occurred and was recognized, even before the patient entered the room. So, it was common knowledge that the count discrepancy could not be the result of an instrument being inadvertently left in the patient. Never-the-less the nurses continued to be engaged in counts throughout the case as required by policy. This continued even after a decision was made to perform an X-ray on the patient to be sure that there were no retained foreign bodies. The fact that they were engaged in the counts reduced their capacity to attend to and support the ongoing case.

Influence on Other Activities

While observations suggested that nurses have developed effective strategies for managing the multiple demands placed upon them, time spent counting is necessarily time spent away from the actual patient-centered events. We observed a number of instances, in this and other cases, where surgeons needed to repeat requests for instruments several times before a nurse responded because the nurses were engaged in the count. This could result in disruption and delay in the flow of the case, which can in turn impact patient safety. We also observed a case in which preoccupation with a count discrepancy appeared to contribute to a safety-compromising event. In that case, one of the nurses engaged in resolving a count discrepancy inadvertently handed a surgeon a contaminated irrigation fluid. Fortunately, this was identified readily by the surgeon and not used on the patient.

DISCUSSION

In this paper we used the count protocol to illustrate the fact that a protocol that is put into place to enhance patient safety can under certain circumstances become counter-productive. In the case of the count protocol, our observations suggest that while counts are intended to serve an important safety function – to insure that the number of needles, sponges and instruments put out at the start of the case are accounted for at the end of the case – there are many factors that combine to make the count activity inherently unreliable. Further, our observations suggest that the count protocol has unanticipated negative consequences that need to be considered in evaluating the net positive gain in patient safety. In particular we found that the need to reconcile the count could capture nurses' attention, reducing their ability to support the patient centered activities during the surgical procedure. Finally, as is illustrated by Figure 1, safety protocols that are useful under many circumstances, can become 'disabling' if followed rigidly even in circumstances where they no longer serve a productive use.

The study highlighted vulnerabilities in the count procedure as a means of preventing retained foreign bodies and suggested a number of directions for improving the reliability of the process. Options range from improvements to the count protocol itself (e.g., greater standardization in counting conventions to minimize opportunities for communication breakdowns and ambiguities in the count), to development of guidelines for when the count protocol should be suspended and x-rays used instead, to exploration of technological solutions that completely eliminate the need for a manual count (e.g., bar code readers). These options are currently being explored by the medical institution.

More generally, the study highlights several important issues related to the introduction of protocols intended to improve healthcare safety. Newly proposed safety protocols may be unreliable or ineffective in meeting their intended safety goals. Even if they are effective, there may be specific cases in which the protocol has unintended consequences to patient safety that are not anticipated. In high risk medical settings, the overall impact of proposed protocols should be evaluated. These can be studied using a combination of focused interviews of end-users and prospective field observations to assess utility and safety (Roth and Patterson, in press). The results can be used to develop recommendations for modification or suspension of the protocols in circumstances where they become 'disabling'.

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