

# Healthcare Safety: The Impact of Disabling “Safety” Protocols

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**Abstract**—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 a focus group of seven operating room nurses and an observational study of nine complex operations, we show that the count protocol has 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 in assessing its potential benefits to patient safety.

**Index Terms**—Adverse events, human performance, medical error, protocols, risk, system safety, task analysis.

## I. 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 the risk of harm to patients. Examples of some of the more widely implemented protocols include the Universal Protocol endorsed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) [1], power injection protocols for contrast media and blood-product ordering protocols. While treatment protocols tend to be research-based (i.e., they are the product of research that demonstrates efficacy), protocols intended to improve safety through processes and procedures (“safety protocols”) have in many cases been applied without the benefit of formal evaluation or review. Several researchers from the field of cognitive engineering have described the potential for unintended consequences when new devices or technologies are introduced into a clinical environment, and

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have argued for formal evaluation during the implementation phase [2], [3]. Introduction and implementation of new procedures or protocols may have the same potential to introduce complexity, disrupt normative work routines, and perhaps even fail in their intended goals. For this reason, when a new safety protocol is introduced into the clinical environment, it is essential to assess the extent to which the protocol achieves the objective it was designed for, identify limits to the utility or effectiveness of the protocol, and most importantly, determine whether there are any unintended negative “side-effect” consequences produced by the “safety-protocol.”

In this paper, we perform a detailed analysis of a specific clinical safety protocol, the perioperative needle, sponge, and instrument count, that was originally designed to improve patient safety during surgical procedures. The analysis reveals that under some system conditions, use of this particular “safety protocol” produces 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 [4]. In the 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’s body cavity. This protocol was designed and endorsed by the Association of Operating Room Nurses (AORN) and widely used in hospitals and free-standing surgical centers in the United States [5]. Recent retrospective reviews of institutional data had suggested that the counting process was potentially unreliable [6], so we were initially interested in assessing the reliability of the count—i.e., how successfully it achieved its stated goal—under standard system conditions. We expanded the scope of the analysis to also assess the extent to which the protocol increased complexity, workload, and the risk of injury to patient and provider. The results reported here have significant implications for the future design and evaluation of safety interventions in medicine.

## II. METHODS

Two converging approaches were used to examine issues relating to the “counting protocol” during surgical procedures. We

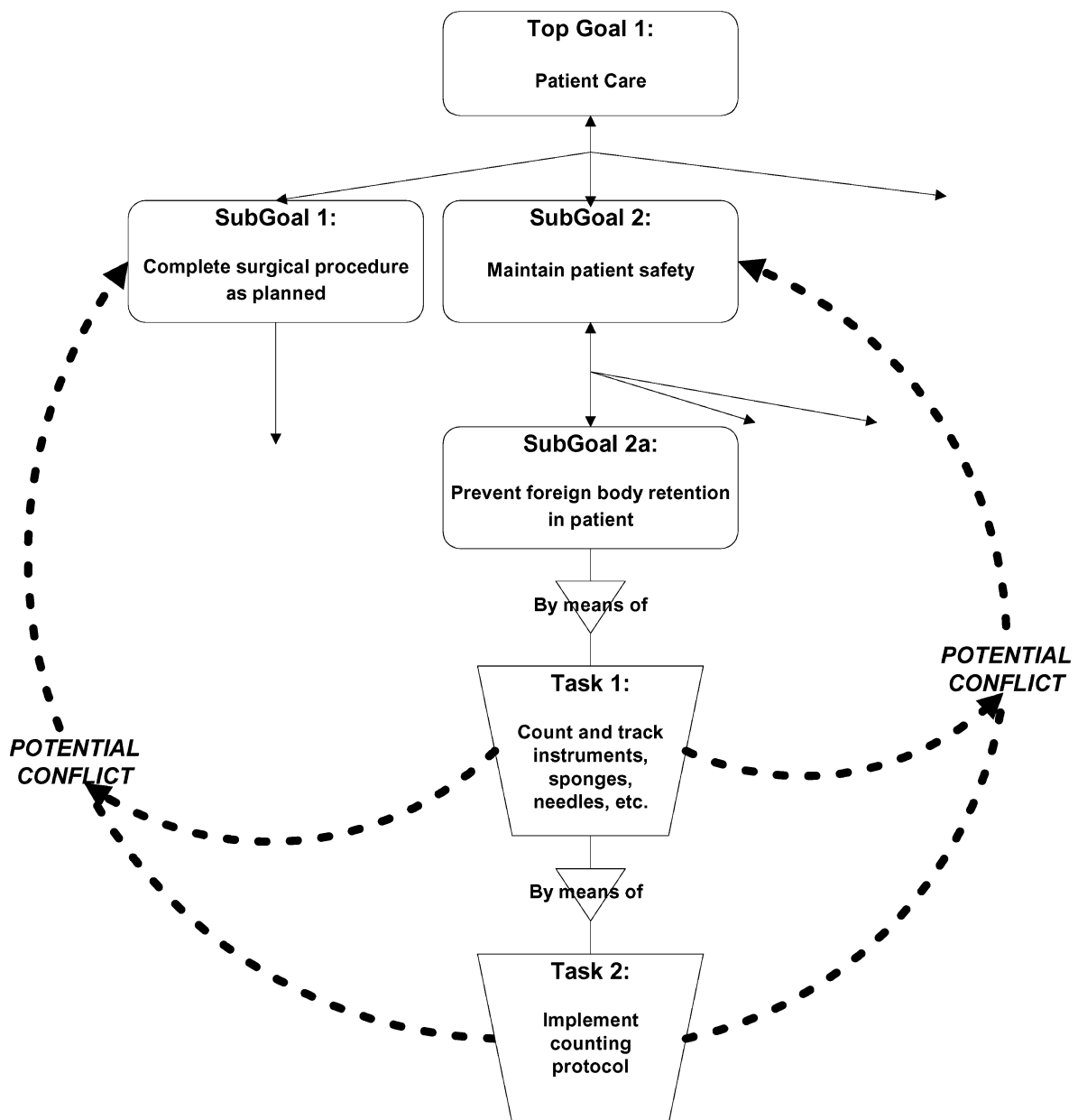


Fig. 1. Fragment of the task analysis, illustrating the top-level goal, and its decomposition into subgoals 1, 2, and 2a. Additional subgoals are truncated in this diagram. Subgoal 2a, (i.e., preventing a foreign body retention in the patient) is achieved through a task of counting and documenting the location or status of instruments, sponges and needles that are in use. This task, in turn, is achieved through the use or execution of a specific counting protocol designed and endorsed by AORN and widely used in hospitals and free-standing surgical centers in the United States. Results of this study demonstrate potential conflicts between different goals and within a specific goal–subgoal structure.

began by conducting a focus group interview with operating room nurses to identify factors that they perceive can influence their ability to perform the protocol-based task of counting. This included perceptions of factors that complicate counts and increase the possibility that a surgical object would be left in the patient (referred to as a “retained foreign body”). The objective was to better understand the sources of complications that contribute to the risk of a retained foreign object and the skills and strategies that experienced nurses have developed to reduce this risk.

The interviews were followed by an observational field study of nine complex operations from the point at which the patient entered the preoperation holding area to the point at which the patient was wheeled to the recovery room.

Both of these methods were informed by a preliminary task analysis, in which the larger process of surgical patient care was decomposed into goals, subgoals, and tasks including the specific counting tasks and count protocol execution. The preliminary task analysis was based on a review of existing guidelines and process (e.g., the count protocol used at the hospital) as well as the clinical knowledge of the surgeons on the research team. Fig. 1 reveals a fragment of the task analysis, focusing on the top-level goal, subgoals, and tasks executed to achieve the goal. Goals and subgoals are achieved by means of specific tasks, with the normative flow of control depicted using solid lines. Through the interviews and direct observations, we attempted to assess the extent to which the counting tasks and protocol by

which the tasks are executed conflicted with higher level goals of maintaining patient safety and completing the primary surgical procedure.

### III. FOCUS-GROUP INTERVIEW

Six operating room (OR) nurses and one technician at a major academic center participated in the focus group. The nurses and technician came from a variety of surgical areas. Their years of experience ranged from 2 to 27 years, with a mean of 18 years. The focus group lasted 1 h and 15 min and covered three main topics: 1) What makes it difficult to perform this task? 2) What contributes to close calls? and 3) What skills and strategies have you developed to improve count accuracy and minimize the possibility of a retained foreign body?

#### A. *Observational Study*

Nine complex general surgery cases were observed at the same academic hospital where the focus group took place. 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 preoperative holding area where the patient was brought. 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 handwritten 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 and 2) a quantitative analysis of duration (raw time and percentage of operating time where nurses were engaged in counting activities) and concurrent activities.

## IV. RESULTS

#### A. *Focus-Group Interview*

The results of the focus group made it clear that while a retained foreign body in a patient is a rare event, nurses perceived the risk as significant and felt responsible for preventing such occurrences. The nurses felt that the protocol and procedures required to maintain an accurate count were demanding and the nurses recalled a number of “close calls.”

Nurses perceived several factors contributing to count difficulty. Among factors they mentioned were production pressure (the need to complete the current surgical case and proceed to the next case) leading to high workload and time pressure to complete the counting and other tasks. Another factor mentioned was the lack of standardization and variation in conventions for actual implementation of the counting protocol and documenting the results of the process. Nurses felt that this variation at the implementation end of the protocol introduced uncertainty, particularly in cases where one nurse performs the baseline counting activities at the beginning of the case and a different nurse performs the final counting activities at the end of the case (e.g., due to shift change). For example, while the

counting protocol specifies that all sponges and instruments are counted, the definition of other “countable” objects is left to the discretion of the scrub and circulating nurse. Objects excluded from the baseline count by one nurse may be deemed worthy of counting and documenting by a new nurse at the end of the case. They noted that communication breakdowns at “hand offs” could contribute to count problems. Such problems included uncertainty with respect to what had already been counted and uncertainty about what objects (e.g., small sponges) were placed in the body cavity and needed to be removed. Other sources of complexity mentioned included interruptions and distractions (e.g., the need to interrupt the count to perform another task) and the fact that sometimes instrument packs are incomplete or supplemental instruments are introduced into the field after the “official” count had been completed. The perception was that all of these factors contributed to inconsistencies between the initial and final counts. Inconsistencies required a recount to reconcile the two counts and created new opportunities for additional count discrepancies. The nurses thought that these offered reasonable explanations for cases in which the count is declared “correct,” in spite of the fact that a foreign body is left in the patient body cavity (cf. Gwande *et al.* 2003).

#### B. *Observational Field Study*

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” and activities associated with handoffs proved to be some of the most demanding of these auxiliary tasks. They occurred frequently, consumed significant time and cognitive resources, and influenced their ability to attend to primary patient-centered activities.

Nurses devoted an average of 35.9 min to counting activities after the patient entered the room and 29.8 min after the incision was made (the window of vulnerability for a retained foreign body). On average, this represents 12.9% of the total procedural time and 14.5% of the total incision time for these cases. Hence, the process of counting conflicted with the subgoal of completing the primary surgical procedure in a timely and efficient manner. 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 (a predictable side-effect of prolonged or technically demanding cases) triggered a mandatory repeat of the count or a prolonged search for the source of the inconsistency. Of the nine cases on which observations were made, six had some problem in the count that required a search for the missing item and/or a recount in an effort to reconcile a count discrepancy. In two of those six cases, there was sufficient residual uncertainty in the reliability of the count that a radiographic imaging study was performed to insure that there was no retained foreign body in the patient. 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,

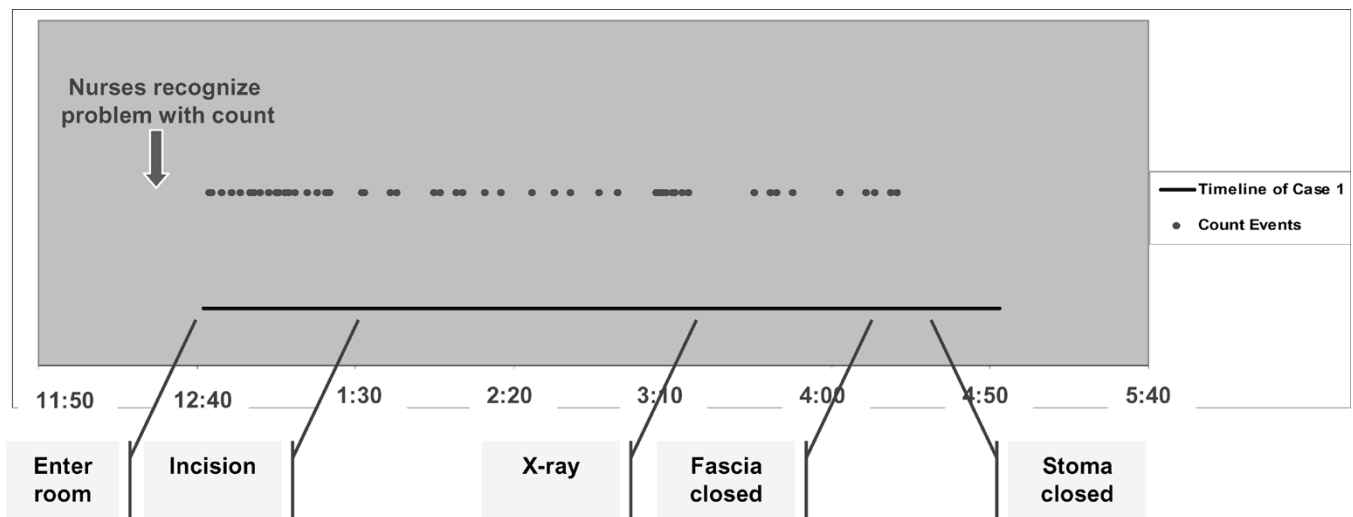


Fig. 2. Illustrative case of how the count protocol can become counterproductive. Time line and major-event markers are shown at the bottom. Dots represent counting events. Due to a delay in preoperative preparation, two different nursing teams participated in the setup of the room. The case was complex, 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.

nurses spent a significant fraction of the case time performing some type of counting activity. Fig. 2 illustrates this point.

Fig. 2 graphically illustrates how the count protocol, which is intended to increase patient safety could inadvertently become counterproductive. Due to a delay in preoperative 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 protocol 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. Since in this instance, the discrepancy in the count occurred and was recognized even before the patient entered the room, it was common knowledge that the count discrepancy could not be the result of an instrument being inadvertently left in the patient. Nevertheless, 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.

## V. INFLUENCE ON OTHER ACTIVITIES AND RESPONSIBILITIES

To a great extent, 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 delayed progress and disrupted the flow of the case, ultimately resulting in a prolongation of total anesthetic and procedural time. We also observed a case in which preoccupation with a count discrepancy appeared to contribute to a safety-compromising event. In this specific instance, the nurses were engaged in a complex count during the terminal phases of a surgical case, but attempting to attend to ongoing primary tasks as the surgeons continued the operation (see Fig. 3 for graphical illustration). Before the counting procedure began, the surgeon and chief resident request and receive instruments promptly. After the counting protocol begins, there are significant delays, noted by the shading between black and hash marks in Fig. 3, before each request is filled. Moreover, during the counting procedure, the primary scrub and circulating team handed off the case to a second team in order to take a schedule break. When the counting activity was resumed, an inconsistency was encountered. Finally, one of the nurses engaged in the counting activities inadvertently handed a surgeon contaminated irrigation fluid. This slip was identified readily by the surgeon who discarded the contaminated irrigation device before the patient was harmed.

## VI. DISCUSSION

In this paper, we performed a detailed analysis of one of the safety protocols currently in use in the operating-room environment. Our objective was to assess the extent to which a protocol that is designed to enhance patient safety can conflict with other system goals, and, under certain circumstances increase the risk of certain adverse events. In the case of the count protocol, our observations suggest that while the manual counting activities prescribed by the protocol are intended to serve an important safety function—i.e., to insure that the number of needles, sponges and

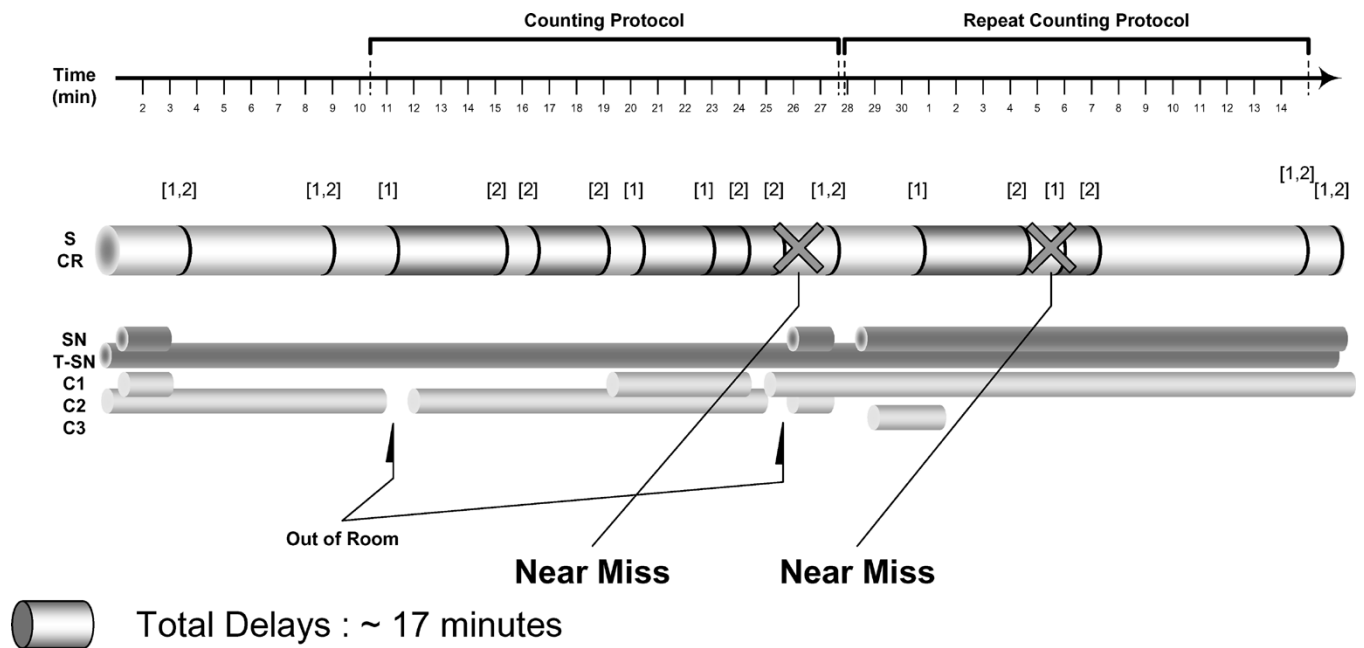


Fig. 3. Illustrative case of unanticipated negative consequences of the counting protocol. The time course of the case is noted at the top. The thick bar represents the progress and activities of the attending surgeon (S) and surgical chief resident (CR) who is assisting him. Each black vertical line on this surgeon’s activity bar signifies a request for an instrument with [1] indicating the request, and [2] indicating the receipt of the instrument. The thin bars below this represent the progress and activities of scrub nurses (SN), the scrub nurse trainee (T-SN), and the circulating nurses (CN). During this time interval, the primary scrub and circulating team handed off the case to a second team in order to take a scheduled break. Before the counting procedure began, the surgeon and chief resident request and receive instruments promptly. After the counting protocol begins, there are significant delays, noted by the shading between black hash marks, before the requests are filled. The counting activities contributed to two near-misses, each involving a nurse passing a contaminated instrument to the sterile surgeon. In both instances, the contamination was recognized immediately. Moreover, during the counting procedure, an inconsistency was encountered by the secondary team of nurses, and the count needed to be repeated when the primary team returned from break.

instruments put out at the start of the case are accounted for at the end of the case, and prevent the retention of an object in the patient’s body cavity—there are many system and human factors that impact the ability of the protocol to meet this goal.

The inherent reliability of the human in performing manual counts of a large number of instruments and objects has never been formally tested under either ideal or degraded conditions. Prior work in the field of cognitive science suggests that under ideal conditions, performance on straightforward repetitive tasks can vary widely, and is influenced by training style and the mental task representation of the operator [7]. A recent cognitive analysis of the mental processing and memory demands required in performing the counting protocol during surgical cases identified a number of cognitive processing factors that could contribute to error [8]. Our work suggested that various conditions under which this task is commonly performed can further degrade performance. In particular, the counting activity is subject to many interruptions, scheduling cycles require different nurses to participate in different phases of the formal counting protocol, and while performing the counting, nurses often attempt to allocate attention to other tasks. All of these factors are likely to reduce the reliability of the task to achieve its intended goal.

Further, our observations suggest that the count protocol has unanticipated negative consequences that need to be considered in evaluating the net positive value of enforcing the protocol to promote patient safety. In particular, we found that the need to reconcile inconsistencies in the count can consume much of the nurses’ attention and can impair their ability to support ongoing patient-centered tasks during the surgical procedure. Perhaps more importantly, when the counting protocol is executed

at high-risk, technically demanding phases of the case, it can degrade performance in other patient-centered activities and produce unintended consequences for safety and performance, including prolongation of the surgical procedure, and slips as evidenced in the near-contamination event. Finally, as is illustrated by Fig. 2, 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. Similar unanticipated negative side effects have been observed in other industries that have attempted to impose rigid procedures intended to be followed “verbatim” [9]–[11].

While awaiting an alternate, more reliable method for tracking surgical instruments and materials, one interim modification to the protocol might be clear guidelines on suspension of the protocol when the task becomes excessively complex (e.g., with large numbers of instruments, and frequent additions of instruments to the surgical field), or when system factors have the potential to significantly degrade performance (e.g., when there have been many changes in personnel throughout the surgical case).

This study highlights several important issues relating 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. There may be barriers in the actual environment to which they are applied that render them ineffective or unusable [12]. Even if they are effective in achieving their intended goal, there may be specific cases in which the protocol has unintended consequences for patient safety. 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 prospec-

tive field observations to assess utility and safety, and develop recommendations for modification or suspension of the protocols in circumstances where they become “disabling.”

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