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## Efficacy of surgical safety checklist: Assessing orthopaedic surgical implant readiness

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### ABSTRACT

**Introduction:** Our institution employs a Surgical Universal Protocol Preoperative Checklist in accordance with World Health Organization guidelines to promote patient safety. It is used in part to evaluate orthopaedic surgical equipment and implant readiness prior to the initiation of each surgical case. Our goal is to measure the preoperative checklist's efficacy in assessing orthopaedic equipment readiness preoperatively and its ability to prevent orthopaedic equipment failures (OEF). Our study focused on orthopaedic surgery cases as they require a large volume of equipment and implants for successful completion. These cases therefore present an appropriate medium to identify potential weakness in our institution's current surgical safety checklist (SSC).

**Methods:** Data was collected over a 6 month period of time, broken into 2 distinct periods. The goal during the first 3 months was to observe compliance with the SSC. And during this time, we observed how often the SSC identified an implant or equipment deficiency at the outset of the case. The goal during the second 3 months was to record if orthopaedic surgical equipment issues were occurring that should have been identified by the SSC. During the second 3 months, we continued to utilize the SSC but also added a postsurgical review at the end of each surgical case. The postsurgical review was a one page questionnaire aimed at identifying any orthopaedic equipment failures that had occurred during the surgical case. For the purposes of this study, we defined an intraoperative orthopaedic equipment failure (OEF) as any one of the 6 following categories: (1) surgery delayed due to missing equipment, (2) lack of sterility of equipment, (3) equipment not available, (4) equipment malfunction, and (5) equipment sets incomplete, or (6) additional equipment brought into room necessary for completion of case. The data was collected at a postsurgical review that was performed by the physicians, nurses, and technicians from the surgical team in a nonthreatening manner. We also attempted to quantify the impact that the OEF had upon the surgical case.

**Results:** During the first 3 months of the study (phase 1), we confirmed that our institutional SSCs were completed for all orthopaedic cases, including the specific questions related to implants and equipment. During phase 1, using the SSC alone, no orthopaedic equipment failures were identified. During phase 2, 33% of the reported surgical cases were identified as having started without essential equipment available or operational (defined as an orthopaedic equipment failure) in the operating room. The most common negative impact upon the surgical case was additional time requirement.

**Conclusion:** Our institution's current SSC fails to prevent OEF in our operating rooms. These checklist failures and intraoperative equipment deficiencies have measureable negative patient safety and institutional cost implications.

**Implications:** While the SSC is an effective tool it cannot be used alone to prepare for orthopaedic surgical cases. In order to improve patient safety and decrease hospital losses, further research is necessary to implement an effective communication network between surgeons, administrators, operating room nursing and sterile processing to eliminate OEF.

**Level of evidence:** Level IV.

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## 1. Introduction

In response to the Institute of Medicine's (1999) report regarding medical errors and their impact on patient outcomes,<sup>1</sup> the health care community has made efforts to improve patient safety. The World Health Organization (WHO) recommended the global implementation of the Surgical Safety Checklist (SSC) several years ago which was developed in an effort to reduce errors in patient care and resultant complications by standardizing certain aspects of a patient's perioperative care.<sup>2</sup> The SSC has 3 sections. The first is to be completed before the patient receives any anaesthesia or medications that would alter the patient's consciousness. This includes confirmation of the patient's name, location of surgery, correct side for surgery, any medical allergies, and making sure the anaesthesia needs have been met. The second phase is completed in the operating room (with or without the patient asleep under anaesthesia). This phase includes: confirming the patient's name, relevant information about the surgery, an opportunity for surgical team introductions, documentation of antibiotic administration, and a discussion about the surgical plan. The third phase is performed at the conclusion of the surgery prior to closing the skin, awakening the patient, and leaving the operating room. In this phase the operating room team discusses the challenges of the case, ensures all equipment and/or sponges are removed from the patient, and identifies any issues that may need to be addressed as the patient awakes from anaesthesia. Although evidence of improvement in overall surgical complications and patient mortality has been documented with the use of the SSC,<sup>3-6</sup> some questions remain whether the current preoperative checklist is itself enough to protect the patient's safety in the operating room.<sup>7</sup> Analogies to aviation pre and post-flight checklists have suggested that medical errors could be reduced if a more thorough post-operative evaluation was performed rather than just focusing on the immediate surgical time concerns (ie retrieving the missing equipment to perform the case and not reporting that it was missing when needed).<sup>11</sup>

Orthopaedic surgery is a high-volume, technically complex specialty using medical plates, screws, and rods to fix fractured bones.<sup>8</sup> For joint replacement surgery there are specific implants for each side of the arthritic bone replaced. In addition, sports surgery or arthroscopy surgery requires various combinations of suture and bone anchors/screws, and tendon and ligament grafts from cadavers that are used in complex reconstructions. Furthermore, because there is the possibility of operating on the wrong arm or leg, the SSC is a valuable tool to prevent wrong-sided orthopaedic surgery.<sup>8</sup> Fortunately, training and implementation of the SSC has increased in frequency among orthopaedic surgeons.<sup>9</sup> As technology advances, so do the equipment and implant demands of surgery, particularly in orthopaedic surgery (ie using different metals that patients are not allergic to for knee replacements, and smaller stronger plates to fix fractures so that patients are not bothered by them under the skin). Because of heavy surgical equipment demands to complete orthopaedic surgical cases such as repairing fractures, replacing arthritic joints, reconstructing ligaments and more, we believe it is no surprise that failure (as defined above) of either equipment (drills, saws, and screw drivers) or implants (plates, screws, metal knee replacements) may be common.<sup>4</sup> The SSC has two general questions which focus on surgical equipment. The SSC is important to patient care and safety. Unfortunately its ability to prevent surgical equipment failures is not well-studied.

In an effort to understand how well the SSC works for our institution we sought to evaluate the SSC's efficacy in identifying equipment and implant deficiencies at the onset of orthopaedic surgical procedures. Our hypothesis is that our institution's current preoperative SSC, adapted to fit local practice and conditions,

is an inadequate method of evaluating and detecting specific orthopaedic surgical equipment failures. We studied orthopaedic surgical cases because the high volume of equipment and implant needs would likely reveal any weakness in our current SSC's capacity to adequately prepare for orthopaedic procedures.

## 2. Materials and methods

This performance improvement initiative was completed at an urban, university hospital that is a Level 1 trauma centre. The project was performed as a patient safety initiative without patient identifiers and thus institutional review board approval was waived. A comprehensive SSC had been instituted 2 years previously at our institution that addressed multiple areas consistent with the WHO Surgical Safety Checklist.<sup>2</sup> The SSC requires signatures from the surgeon, anesthesiologists, and operating room nurse. The WHO recommended SSC questions about equipment readiness must be addressed prior to anaesthesia induction.<sup>2</sup> The SSC questions specific to equipment query if "the required implants or special equipment for the procedure are available" and has "sterility been confirmed." It is a requirement of the operating room nurse to sign off on these items before the patient can be brought into the operating suite. SSC questions are specific that available equipment is in the operating room or immediately available just outside the room.

Data was collected over a 6 month period of time, broken into 2 distinct periods. The goal during the first 3 months was to observe compliance with the SSC. During this time, we also observed how often "implant or special equipment" issues for the procedure were identified. There was no knowledge of the initiative among surgical team members during the first 3 month phase.

The goal during the second 3 months was to record if equipment issues were occurring that should have been identified by the SSC by performing a postsurgical review at the conclusion of each case.

During this second 3 month period, we continued to utilize the identical SSC employed by our hospital, but also added a postsurgical review at the end of each surgical case. The postsurgical review was a one page questionnaire aimed at identifying any equipment failures or deficiencies that had occurred during the surgical case. The postsurgical review was performed by the physicians, nurses, and technicians from the surgical team in a nonthreatening manner (comments were encouraged without fear of retaliation). During the second 3 months of data collection, the surgical team was aware that orthopaedic equipment failures would be reviewed at the completion of each surgical case.

On the postsurgical review, an intraoperative orthopaedic equipment failure (OEF) was defined as one or more of the following: (1) surgery delayed due to missing equipment, (2) lack of sterility of equipment, (3) equipment not available, (4) equipment malfunction, (5) equipment sets incomplete, or (6) additional equipment brought into the room necessary for completion of case (a technique related problem such as a surgeon breaking a drill bit was not considered an OEF). The postsurgical review also included case demographics, an assessment of root cause, and impact measures. Root cause was defined as the operating room team's postoperative assessment of the origin of the OEF. Root causes of failures were divided into 4 domains: failure of delivery, failure of setup, failure of communication, or failure to know need. Impact measures included the following: additional time required, alternative implants used, the circulator nurse was unable to perform functions in room due to absence, no impact, and procedure cancellation.

Data was analysed utilizing Persons chi-square test. As patients were not allowed to enter the operating room without a signed

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