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Original article

No-go decision: A newly identified adverse event in orthopaedic surgery – causes and medico-legal implications

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ABSTRACT

Background: No-go designates a decision not to perform surgery when it becomes apparent that safety and/or feasibility requirements are not met. No-go decisions can occur at any time between patient admission to a hospital department and immediately before the first incision. The primary objective of this study was to assess the causes of no-go decisions reported as healthcare-associated adverse events (HAAEs).
Hypothesis: Most no-go decisions in orthopaedic surgery are related to problems with medical devices.
Material and methods: A preliminary retrospective study assessed HAAEs reported over the 1-year period from 1st October 2014 to 30th September 2015, using the risk-management tool ALARM. A prospective survey was then performed by emailing a 15-item questionnaire to the 1828 members of Orthorisq (the French orthopaedic surgeon accreditation agency). Responses were either yes/no or open. Statistical comparisons were performed, using the paired Wilcoxon signed-rank test to estimate p values.
Results: Among reported HAAEs, 5.6% were no-go decisions. Of the 101 reported no-go decisions, 43.5% and 45.2% were due to problems with managing implantable medical devices in the retrospective and prospective assessments, respectively. In over 85% of cases, surgery was cancelled or postponed. Over half the no-go decisions were associated with unnecessary anaesthesia. Checklist completion was performed in only half the cases and was not associated with no-go decisions ($p > 0.8$).
Discussion: This study provides descriptive data on no-go decisions in orthopaedic surgery. Healthcare professionals use many methods to enhance patient safety by preventing adverse events or diminishing their impact. Errors in managing implantable medical devices are the leading cause of no-go decisions. The current checklist is not appropriate for managing implantable medical devices in orthopaedic surgery, in part because it does not include checking devices upon receipt. Before surgery, patients should be informed of the risk of a no-go decision, since unnecessary anaesthesia occurs in over half the cases.
Level of evidence: IV, prospective study.

1. Introduction

No-go is a term used in aviation to designate a decision not to go forward with a planned flight when it becomes apparent that safety and/or feasibility requirements are not met. Use of the term has extended to decisions not to perform surgery in patients who are in the operating room but have not yet had the first incision.

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Table 1
Analysis of reported healthcare-associated adverse events–causes of no-go decisions related to management of material ($n = 53$).

Causes	Number of cases Total, $n = 53$
Errors in overall management of implants and instrumentation kits	$n = 37$: material from outside sources: $n = 22$; material from in-hospital stores: $n = 15$
Errors in sterilisation and packaging	$n = 16$: breached paper packaging: $n = 9$; container incidents: $n = 7$

The French orthopaedic surgeon accreditation agency Orthorisq has recorded an increase in no-go decisions reported spontaneously by its members between 1st October 2014 and 30th September 2015. Thus, no-go decisions are emerging as a heretofore unreported healthcare-associated adverse event (HAAE). Evaluating the causes of no-go decisions and associated mitigation barriers (protocols designed to minimise adverse events) was therefore timely.

The primary objective of this study was to identify the causes of no-go decisions in orthopaedic surgery. The secondary objectives were to determine the frequency of no-go decisions reported among HAAEs, to assess the role for mitigation barriers, and to describe the medico-legal implications. The working hypothesis was that most no-go decisions are due to problems with medical devices.

2. Material and methods

Of the 1778 HAAEs reported by Orthorisq members over the 1-year period from 1st October 2014 to 30th September 2015, 101 met the definition of no-go decisions. Orthorisq experts whose role is to review all HAAEs as part of the accreditation procedure analysed the no-go decisions using the tool developed by the Association of Litigation and Risk Management (ALARM) [1]. In addition, a simple anonymous survey was conducted using a list of 15 yes/no or open questions. The questionnaire was emailed to the 1828 Orthorisq members between 8th March and 20th July 2015.

Statistical analyses were run using StatView (SAS Institute, Cary, NC, USA). Yates' correction was performed when appropriate. Comparisons were with the paired Wilcoxon rank-sum test. Values of p below 0.05 were taken to indicate significant differences.

3. Results

3.1. Reported healthcare-associated adverse events (HAAEs)

Of the 1778 reported HAAEs, 101 (5.7%) were no-go decisions. Of the 101 no-go decisions, 44 (43.5%) were taken before anaesthesia and 57 (56.5%) after anaesthesia but before the first incision. Hospital admission was conventional in 78% and day-case in 22% of patients. Neither admission modality nor proper checklist completion correlated with the occurrence of no-go decisions ($p > 0.8$).

Problems with the management of material or implantable medical devices (IMDs) were the leading cause of no-go decisions, with 53 (52.5%) cases (Table 1). In 37 cases, the material and/or IMD were lacking or unsuitable (ordering mistakes, poor inventory management with tardy resupply or IMDs beyond their expiry date). The IMD supply modality (in-house stores vs. outside supplier) correlated with no-go decisions, which were more common when IMDs were obtained from outside sources ($p < 0.01$). For 16 no-go decisions, the cause was an overall sterilisation deficiency with breaching of paper package integrity ($n = 9$), container incidents ($n = 7$, including unclipped filters in 3 cases), or moisture within instrument boxes ($n = 4$).

The other causes of no-go decisions ($n = 48$) were as follows: anticoagulant treatment management errors, $n = 13$; skin problems suggesting possible focal infection near the surgical site, $n = 11$; serious complications of anaesthesia, $n = 4$; absence of a surgical aid, $n = 3$; unavailable imaging studies, $n = 3$; absence of written informed consent by the patient, $n = 2$; allergies, $n = 2$; unforeseen change in the side to be operated on, $n = 2$; and miscellaneous reasons, $n = 8$.

The no-go decision was made by the surgeon in 76 (75.2%) cases, the anaesthesiologist in 20 (19.8%) cases, and both in 5 (5.0%) cases. The consequence of the no-go decision was postponement of the surgical procedure in 87 (86.1%) cases, performance of the procedure later on the same day to allow re-sterilisation of the material or material procurement from a neighbouring facility in 11 (10.9%) cases, and definitive cancelling of the surgery in 3 (3.0%) cases. In 11 (10.9%) cases, no corrective protocol was implemented after the no-go decision. Of the 101 patients, 6 (5.9%) took legal action because of the no-go decision.

3.2. Prospective survey among orthopaedic surgeons

The survey of 1828 Orthorisq members provided a mean of 663 (35.9%) answers per item (range, 338 [18.5%] to 722 [39.5%]). Tables 2–4 report the results of the answers to the 15 items. Among the responders, 72.6% had experienced at least one and 19.3% at least two no-go decisions during their career.

Problems with managing the material and IMDs were the most common cause of no-go decisions (Table 3). The check list was completed properly in over half the cases. However, checklist completion failed to prevent no-go decisions (Table 4). No-go decisions resulted in unnecessary anaesthesia and postponement of surgery in over half the cases. No corrective action was taken in 17% of cases (Table 5). Finally, 5% of patients engaged in malpractice litigation because of the no-go decision (Table 6).

4. Discussion

This work describes an HAAE previously reported only in a 2016 preliminary study by our group [2]. The results indicate that the main causes of no-go decisions (primary study objective) were errors in managing medical material, which accounted for over half the cases reported to Orthorisq and 46.5% of cases identified by the prospective survey. The working hypothesis is therefore confirmed. In over 80% of cases, patient information before surgery does not include the possibility of a no-go decision, providing patients with grounds for engaging in civil litigation to obtain reparation. Data on patient safety published over the last 15 years [3] highlight the importance of medical risks within hospital facilities. In France, the 2004 ENEIS study [4] showed that 350,000 to 460,000 serious events occurred annually, including 120,000 to 190,000 that were potentially preventable. Human factors are often identified as the proximate cause of adverse events [5]. Over two decades ago, the risk management culture was founded on assigning responsibility to those who committed errors. Starting in 1990, Reason [6] developed a new risk management approach in which human error is deemed unavoidable: "Countermeasures are based on the assumption that though we cannot change the human condition, we can change the conditions under which humans work. [...] Errors are seen as consequences rather than causes" In this systems approach, errors are analysed as failures of complex systems. Work by Berwick [7,8] supports the systems approach by showing that only 2% to 3% of clinical errors are ascribable to incompetence, imprudence, sabotage, or serious negligence. Thus, 97% to 98% of errors are related to problems embedded within the organisation of the healthcare system.