Near-miss event assessment in orthopedic surgery: Antimicrobial prophylaxis noncompliance

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**KEYWORDS**
Professional practice; Antimicrobial prophylaxis; Surgical check-list; Patient safety incident

**Summary**

**Introduction:** Antimicrobial prophylaxis is one of the main safety measures to be enforced when implanting any medical device; surveys of practice, however, have found poor compliance.

**Material and methods:** This study is based on analysis of 153 dedicated in-depth analysis forms sent to orthopedic surgeons who had reported an antimicrobial prophylaxis-related near-miss event (NME) during the year 2008 as part of their certification report to the official organization, Orthorisq (orthopaedic Patient safety risk management agency).

**Results:** Antimicrobial prophylaxis guidelines exist in 95% of French centers, but in 14% are not available in the right place. 88% of orthopedic surgeons consider them well-adapted to their practice. Most declarations follow fortuitous discovery by the surgeon of an immediate perioperative malfunction. Human causes were found in 92% of declarations, general organizational causes in 50% and material causes in 28%. Regarding corrective action, 65% of respondents reported implementing a second-order procedure, and only 20% were able to resume truly regular antimicrobial prophylaxis.

**Conclusion:** The main reason for poor or non-performance of antimicrobial prophylaxis was "omission by negligence or oversight", reported in 56% of declarations. Proposals for improvement were: revised antimicrobial prophylaxis guidelines specifying "who does what"; guideline awareness checks on new, temporary and locum-tenens staff; patient involvement in personal data collection; and implementation of a check-list in line with WHO and French Health Authority recommendations. These improvement proposals were taken on board in the antimicrobial prophylaxis consensus update currently being drawn up by the French Society for Anesthesia and Intensive Care.

**Level of evidence:** Level IV, Decision Analyses Study.

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Introduction

The first work on antimicrobial prophylaxis was by Altemeier, who in 1955 put forward the principles of systematic antibiotic therapy in surgery [1]. In 1961, John Burke demonstrated...
that the effectiveness of antibiotics depended on the timing of their administration with respect to surgery, but the issue was not raised again until 1992, by Classen et al. [2]. In France, the first work on the "rational practice of preventive antibiotic therapy" was by François Vachon, in 1986 [3]. There has since formed an international consensus that antimicrobial prophylaxis reduces the rate of postoperative infection, as was recently confirmed a meta-analysis of the literature for the period 1990–2006 [4]. The Infectious Diseases Society of America, however, reported that prescriber practice still needed assessment in terms of risk-benefit and cost-benefit analysis [5].

Above all, the evidence-based guidelines need to be known to and applied by the health professionals. Adherence is frequently imperfect, as well shown in a Canadian study of national practice, in which antimicrobial prophylaxis in line with recommendations was indeed implemented in 92.6% of cases of major surgery, but within the hour preceding the operation in only 55.7% and for the recommended duration in only 40.7% [6]. Non-adherence rates may reach worrying levels, even in specialties associated with high risk of mortality. A 2007 audit performed in one cardiac surgery department found 1.7% adherence to choice of molecule, 28% to dosage and 39.4% to duration [7]. Again in cardiac surgery, wide variations in prescription were found in a Canadian national audit [8]. Reasons for non-adherence include human negligence, but also organizational factors, especially in developing countries [7,9].

As of 1973, orthopedic surgeons made "antibiotic prophylaxis" a major concern, especially in France [10–12], but it was in 1992 that the French Society for Anesthesia and Intensive Care (Société française d'anesthésie et réanimation: SFAR) drew up the first guidelines, which have been regularly updated since. Although antimicrobial prophylaxis has been proven effective, the various surveys of practice in France found poor adherence unless targeted information programs were implemented [13,14], in which case adherence rose from 31% to 82% [15]. These findings were confirmed in a recent study by the Committee for Protection against Nosocomial Infection (centre de coordination pour le lutte contre les infections nosocomiales: CCLIN) of the Champagne-Ardenne area of France, in which a program of staff training and nosocomial infection monitoring raised adherence from 45 to 63%, and even 79% in the centers most actively involved [16]. Recommendation-compliant kits specific to each type of procedure have also met with a certain success [17].

The French orthopedic community set up a dedicated structure, Orthorisq, to manage risk associated with orthopedic surgery. Orthorisq has had official Health Authority approval since 2007, and collects anonymous declarations of near-miss events (NME), which by definition had no adverse effect on the patient. Data are processed and analyzed by orthopedic surgeons trained in risk management (appraisers), and recommendations intended to reduce the incidence and impact of at-risk situations are drawn up and communicated.

Various areas of assessment were chosen as critical, including antimicrobial prophylaxis, which was considered especially fundamental in ostearticular surgery, with a breakdown in consensus recommendations as highlighted in a meta-analysis [18]: guidelines in the field are widely published and officially recognized, but implementation is shaky, with wide variation and divergence due to a clear lack of consensus, especially in joint replacement surgery [19].

The present study differed from simple audits of practice or adherence, seeking to specify the respective roles of the various causal factors, based on feedback from Canadian colleagues working in both the private and the public sectors. It is an original analysis, shedding new light on the practice of antimicrobial prophylaxis and putting forward solutions to improve practice and prevent recurrence of potentially at-risk situations.

Material and methods

The present study was based on targeted “in-depth analysis” forms sent to orthopedic surgeons who had declared an NME relating to antimicrobial prophylaxis during the year 2008 as part of their certification report to Orthorisq. Poor input on the first 47 NME declarations, probably due to the novelty of this assessment procedure and the declaration methodology, led us to draw up what we hoped would be a more "accessible" questionnaire, replacing the in-depth analysis report recommended by the French Health Authority, which appraisers considered too general for purposes of effective analysis. The new questionnaire was originally under Microsoft Word, but this was converted to an Excel spreadsheet to facilitate data processing by the appraisers. Two open questions were added, allowing the circumstances of the incident and the actions (barriers or defenses) taken to avoid recurrence of the NME to be specified where applicable. The aim was to enable the essential information to be processed using Orthorisq’s database.

An assessment form was therefore systematically attached to all declarations made on the Health Authority’s website concerning malfunction in the practice of antimicrobial prophylaxis. Following a predefined procedure, the assessment form was sent as an attachment in the e-mail section of the declaration, in the form of a "requested complement", and in an e-mail sent directly to the declarant. The analysis of corrective action was integrated in the form only at a later stage, making it possible to record the solutions found by the declarant to try to correct the malfunction, thereby compiling a useful data-base for specialists.

The prime objective was to complete declarants’ information so as to improve the quality of the declaration, facilitating analysis and processing by the appraisers. The secondary objective was educational: on the one hand, the questionnaire provided a check-list of information and clarification to render the declaration more precise and to bring its vocabulary closer into line with the professional jargon; at the same time, it was intended as an initiation to "a-posteriori risk analysis", introducing the declarant to a systemic causal analysis approach.

The questionnaire items explore four areas directly concerning the circumstances and working environment underlying the declared malfunction in antimicrobial prophylaxis prescription or administration:
characteristics of the center’s antimicrobial prophylaxis guidelines;
• circumstances under which the declared event was discovered;
• search for human and organizational causes;
• corrective action, if any.

Results

Excel files (153) were analyzed by three appraisers, who examined all declarations of defective antimicrobial prophylaxis made to Orthorisq. Possible responses were intentionally limited to “Yes”, “No” and “Don’t know”. The results have no statistical or epidemiological value, as they are the declarants’ own expression and analysis of the malfunction: they represent feedback from orthopedic surgeons, the great majority of whom were discovering risk management processes for the first time.

The center’s antimicrobial prophylaxis guidelines

The first part of the form focused on the existence of antimicrobial prophylaxis guidelines, knowledge of them and their implementation in the center declaring the NME (Fig. 1). Five percent of centers had no written guidelines. Antimicrobial prophylaxis guidelines existed in the vast majority of centers, but were not available in the right places in 14% of them. Eighty-eight percent of orthopedic surgeons considered the guidelines well-adapted to their practice, but more than 10% did not know what they consisted of. Fifty-two percent of guidelines in force did not specify who should prescribe and who administer and when, or who should monitor implementation.

Circumstances of NME discovery

The second part of the form sought to specify and detail the circumstances under which the NME was discovered (Fig. 2). Eighty-eight percent of declarants discovered the NME themselves, usually fortuitously during an immediate perioperative dysfunction. Systematic prospective (checklist) or retrospective (audit) analysis was exceptional.

Search for causes

The third part of the form set out a typology of possible causes for the NME. The aim being to help the declarant’s reflection on the question, they were subdivided into material, human and organizational causes, even though these three are often intertwined and finally implicate organizational issues.

Material causes

Material causes were implicated in 28% of cases (Fig. 3). Ten percent concerned guideline inaccessibility, either in the operating theater (for anesthetists and anesthesia nurses) or on the ward (nurses), and which was a particular problem for replacement and temporary staff.

Human causes

Human causes were implicated in 92% of cases (Fig. 4). Nine percent of declarations implicated an allergic terrain, causing the anesthetist to abandon the guideline protocol at the last minute, either because they were imprecise or because of some information discovered (or not known) concerning the patient. The main cause (56%) of antimicrobial prophylaxis being not or badly implemented, however, was “non-administration by negligence or oversight”. This was explicitly imputed to the anesthesia team, and more especially to the anesthetist, as
being in charge of the prescription and administration of antibiotics in 95% of cases; but in 35% of cases the surgeon and surgical team shared responsibility, implicating a failure of communication between specialties (in 54% of cases, a "failure of oral communication"). Twelve percent of declarations reported a member of the anesthesia team being absent at the moment of a peroperative reinjection.

General organizational causes

General organizational causes were implicated in 50% of cases (Fig. 5). Predominantly (24%), this concerned "insufficient staff training", mainly of replacement or temporary staff, or "excessive work-load" associated with "inappropriate work allocation" (21%). Finally, although regulations provide for antimicrobial prophylaxis guideline implementation as of the anesthesia consultation, this was adhered to in only 18% of cases; our colleagues did not seem to be greatly concerned by this issue, 44% declaring that they had not taken the trouble to find out what the situation was in this regard in their center.

Corrective action

Corrective action was analyzed on the basis of only 49 responses (Fig. 6). Sixty-five percent of respondents reported implementing a second-order procedure, but only 20% were able to resume truly regular antimicrobial prophylaxis. Sixty-seven percent of NMEs were discovered peroperatively, after incision, and reinforced monitoring.
could be implemented. No second-order procedure being prescribed in the SFAR guidelines once surgery has begun, 43% of declarants made do with reinforced postoperative clinical or biological monitoring, and 16% revised the initial guideline protocol with respect to the type of molecule, dosage or duration of the prescription. Among declarants’ proposals for improvements, 40% recommended a checklist, either written or simply as an “oral step”, prior to incision. Participative measures (“posting the antimicrobial prophylaxis guidelines in the operating theater, ward and recovery room”, “improved communication between surgeon and anesthetist” and “systematic check-list before incision”) were frequently proposed, but the question of the systematic implication of the anesthetist in case of surgical nosocomial infection was also raised several times.

Discussion

Questionnaire limitations

The Excel format enabled the declarations to be processed as of reception of the first forms, which declarants returned systematically, as they appreciated the methodology. Unfortunately, imprecise formulation in some questions made certain responses unusable. For example, the idea of systematic or fortuitous discovery was not well understood, making answers unreliable. Furthermore, the option of answering “Don’t know” or of leaving boxes blank led too large a number of declarants not to think deeply enough...
about primary and fundamental causes and to fail to fully investigate certain of the criteria requested. Automatic mistake-proofing, obliging the declarant to answer "yes" or "no" to certain questions before confirmation and sending is one possible technical solution currently being looked into, and should improve feedback quality and provide more statistically reliable results. It could be reserved for certain sensitive key areas of orthopedic surgery practice.

**Results analysis**

Analysis of the questionnaires highlighted certain main lines for improvement.

**The role of the patient**

Discordant patient answers to questions asked by the anesthetists, surgeons and care staff during the hospital stay and in the operating theater are one cause of NMEs. Risk is increased when information recording methods are heterogeneous, as is frequently the case. The patient’s self-reports could be made more reliable by having him or her sign a paper collating history, pathology or pathologies and treatments requiring cooperation.

**Guideline availability**

The guidelines are insufficiently accessible at sensitive locations: operating theater, recovery room, ward. The recommendations contained in the 2010 version (V2010) of the Health Authority’s health-care establishment certification process should improve this situation. The guidelines are often not properly known, especially to replacement and temporary staff: all those usually concerned could be asked to confirm knowledge of the guidelines, for example by signing them. V2010 certification recommends including it in the booklet given to each new arrival working in the center’s surgical departments.

**Prescription**

The quality of the prescription, which is often terse, not meeting regulatory standards (e.g., failure to specify exact postoperative administration times), is a serious source of malfunction, especially on the wards. This is relevant to the lack of traceability of antimicrobial prophylaxis administration found on auditing of records. Systematic surveys based on criteria for quality and safety improvement in health (the so-called IPQASS process in the French health system) and antimicrobial prophylaxis audits in surveys of the rate of operative site infections (known as INCISO) should help improve this particular point.

**Administration**

The two main causes of declared NMEs were omission by negligence or oversight (61.4%) and lack of communication between anesthetist and surgeon at induction (58.5%). Although 38% of declarants considered the whole medico-surgical team to bear responsibility for any NME, it is the anesthetist that is deemed to be in charge of implementation and administration of antimicrobial prophylaxis in 95% of cases. In law, the job of the anesthetist is "to ensure that the surgery patient is anesthetized and to monitor the patient during the surgeon’s intervention and, after the operation, to monitor recovery of consciousness until this is complete” (Decree dated 4 December 1994, art. D 712-45). The anesthetist is in charge of the patient’s installation on the operating table (decision by the Paris District Court (Tribunal de Grande Instance), dated 18 March 1996) but no mention is made of the administration and prescription of antimicrobial prophylaxis.

Although they now come under the responsibility of the establishment, nosocomial infections remain the most frequent cause of complaints regarding orthopedic surgeons. As the degree of permanent partial invalidity seldom exceeds the 24% threshold for French “national solidarity” cover, nosocomial infections are generally covered by third-party insurance. Our proposals seek not to encourage systematic implication of the anesthetist in case of nosocomial infection (more than 50% of surgeons feel they share responsibility) but rather, in a participative approach, to highlight clearly and consensually the role of each agent, when center guidelines are up for revision. Who informs whom? Who prescribes? When are the various pre-, per- and post-operative administrations delivered? Traceability is mandatory, and a culture of assessment needs to be developed.

**Specificities of surgery**

Since the last update (2002) of the French antimicrobial prophylaxis consensus, new techniques (arthroscopic reconstruction surgery, minimally invasive surgery, etc.) and new materials and implantable devices (bio-resorbable, etc.) have been developed. These developments challenge the surgical criteria laid down by the SFAR for decision-making as to whether to perform antimicrobial prophylaxis. This presently gives rise to frequent disagreements between anesthetists and surgeons as to indications for antimicrobial prophylaxis, depending on specialty specificities and individual attitudes to the risk/benefit ratio which each specialty considers bound by to ensure patient safety. The typology of current interventions needs to be given greater precision in consensus up-dates, in close cooperation with surgical societies, the SFAR and infectious pathology societies.

Likewise, individual patient specificities (immunodepression, institutionalization, morbid obesity, etc.) need to be taken into account and discussed on a case-by-case basis by all those involved in antimicrobial prophylaxis, when not dealt with by the center’s guidelines.

**Corrective action**

Analysis of NMEs shows that effective corrective action enabling resumption of adapted antimicrobial prophylaxis is rare (20% of cases), as this presupposes that the NME be discovered ahead of incision. The drawing up of a check-list and its implementation as of January 2010, as recommended by the Health Authority, should largely remedy this. It further meets the wishes of the 40% of surgeons who suggested exactly this or had already drawn one up following a detected malfunction, either in the form of simple but systematic oral questions to the anesthetist or, more rarely, with a paper support. The declarants’ spontaneous proposals express the community’s greater maturity in risk management, holding out hope for a broad consensus in applying Heath Authority guidelines.
Finally, the declarations spotlight the difficulty of cor-
rective action when omission or error in antimicrobial pro-
phylaxis administration is discovered after the inci-
sion has been made. The wide variability in corrective ac-
tions described, whether simple surveillance, antibiotic-
therapy involving molecules and doses guided by no known
practice, or probabilistic antibiotherapy, indicates improvi-
sation. The learned societies concerned by this issue need
to react, so that the remedies on offer, even if not of high
efficacy, should at least do less harm than good.

Conclusion

The results of this survey clearly show the risks entailed
by the transversal nature of antimicrobial prophylaxis pres-
cription and administration and the limits of the guidelines
as they presently stand (failure to specify who does what)
and the responsibility of practitioners in case of nosoco-
rial infection. Thus "omission of antimicrobial prophylaxis
by negligence or oversight" remains the most frequently
attributed cause. NMEs are unpredictable events, revealing
the inadequacy of potential preventive organization. This
way of thinking is still new to the declartors. The lines for
improvement put forward are:

- revising antimicrobial prophylaxis guidelines, to specify
  who does what and define the role and function — and
  thus the responsibility — of each individual agent with
  respect to prescription, administration and monitoring of
  antimicrobial prophylaxis;
- checking awareness of antimicrobial prophylaxis guide-
  lines by newcomers, temporary staff and replacements;
- involving the patient in collecting the medical information
  concerning him or her;
- and setting up a check-list, in line with WHO and Health
  Authority guidelines.

The proposed actions directly target improvement in
practices in the implementation of antimicrobial prophyl-
axis guidelines. They should be taken account of when the
SFAR updates its antimicrobial prophylaxis consensus doc-
ument, which could gain Health Authority approval. They
could serve as quality criteria for compliance or practice
audits by the Good Practice Colleges being set up in each
specialty on advice from the Health Authority. Finally, they
should enable definition of different levels of quality and
the notion of evolutivity and progression currently lacking
in audit methodology but which are to be found in the 2010
version of the French health establishments certification
process.

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