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Original article

Can the number of surgery delays and postponements due to unavailable instrumentation be reduced? Evaluating the benefits of enhanced collaboration between the sterilization and orthopedic surgery units

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ABSTRACT

Introduction

The development of outpatient surgery, cost-reduction pressures and instrumentation storage limitations have led to their use “just-in-time”. A recent study showed that stoppage of surgical procedures immediately before the incision (No-Go) was often due to the management of supplies and implantable medical devices. To our knowledge, since the development of outpatient surgery and the shortening of hospital stays, managing the flow of instrumentation has not been optimized. At our hospital, we used a two-prong approach consisting of a tool to manage instrumentation and working group from the sterilization and orthopedic surgery units. The aims of this study were to 1) evaluate whether this approach led to better notification of the risk of supply shortage for instrumentation and 2) determine whether it could reduce by at least half operating room disruptions such as delays or cancellation of surgical procedures.

Hypothesis

This approach results in better notification of the risk of supply shortage for instrumentation and reduces by at least half operating room disruptions such as delays or cancellation of surgical procedures.

Material and Methods

A tool was developed to manage instrumentation flow based on a retrospective analysis of data from 2015. This tool consisted of (1) a list of instrumentation needed for each surgical procedure from an analysis of the surgical schedule and verification of traceability labels of the instrumentation actually used, (2) a list of reasons for supply shortage identified from an analysis of non-conformities occurring in the sterilization process of instrumentation kits. These analyses resulted in the development of check-lists for instrument sets for each procedure, while identifying those with a high risk of shortage. In 2017, a working group

focused on instrumentation was set up with personnel from the sterilization unit and the orthopedic surgery unit. Based on the check-lists and the schedule 24 hours before the surgery, the sterilization unit alerted the surgery unit by email of the risk of material shortage; the surgery ward replied with potential changes to the material or the surgery planning. This approach (instrumentation management tool and working group) was named just-in-time (JIT). The main outcome was the number of notifications of potential supply shortage with and without JIT over a 10-week period. The secondary outcomes were the number of notifications resolved in time and the occurrence of operating room disruptions (delay > 30 min or postponement of surgery) related to unavailable instrumentation.

Results

Nine reasons for potential supply shortage were identified such as instrumentation kits used for several types of procedures, those with fast rotation and low stock, or in double pathways (on loan and on deposit). The working group reported 163 potential shortages with JIT versus 41 without ($p < 10^{-5}$), of which 150 (92.5%) were resolved. Thirteen operating room disruptions occurred; only one was not detected by the JIT approach.

Conclusion

Our JIT approach (instrumentation management tool and working group) is effective at preventing instrumentation supply shortages.

Level of evidence: III, prospective comparative study

Keywords: Instrumentation, postponements of surgery, sterilization, securing

1. Introduction

In France, the sterilization of sterile reusable medical devices is centralized and entrusted by decree to the hospital pharmacy [1]. According to Coudane et al. [2], 52.5% of stoppages of a surgical procedure immediately before the incision (No-Go) were related to management of supplies and implantable medical devices.

Delays in the availability of instrumentation are a recurrent source of disorganization in hospital facilities [3]. This requires a complex process [4] and close collaboration between central sterilization and the operating room staff [5,6]. There are certain constraints, some of which cannot be altered such as the wide range of instrumentation kits, sterility requirements [1,6], fixed time for instrumentation sterilization [7] and the available stock [8]. However, other scenarios of supply shortage appear to be rectifiable: use of different terminology between the two units to designate the various elements of the instrumentation [9], potential mismatch between the surgical procedure and the prepared instrumentation [10], lack of prioritization for processing of materials by the sterilization unit, and changes in the instrumentation needs following the cancellation or addition of surgical procedures [11]. The current management of instrumentation needs is not optimal. The management group of the operating suite does not always include staff from the sterilization unit. While the surgical staff may notify the sterilization unit of potential supply shortages, this often occurs too late and is not standardized. Consequently, it is not always possible to find a suitable solution in the desired time frame. To our knowledge, since the development of outpatient surgery and the shortening of hospital stays, managing the flow of instrumentation between these two units has not been optimized [12].

At our hospital, we used a two-prong approach consisting of a tool to manage instrumentation and an orthopedic instrument sterilization working group. The aims of this study were to 1) evaluate whether this approach led to better notification of the risk of supply shortage for

instrumentation and 2) determine whether it could reduce by at least half operating room disruptions such as delays or cancellation of surgical procedures. We hypothesized that this approach results in better notification of the risk of supply shortage for instrumentation and reduces by at least half operating room disruptions such as delays or cancellation of surgical procedures.

2. Material and Methods

Figure 1 summarizes our study's procedures.

2.1 Development of an instrumentation management tool

The aim of this instrumentation management tool was the develop check-lists for instrumentation kits corresponding to each procedure while identifying those at risk of shortage. This analysis was carried out collaboratively by the sterilization unit and the orthopedic surgery unit. At our hospital, sterilization is centralized and performed in-house. Typically, 8 hours is required from the time an instrumentation set arrives at central sterilization to when it is available for pick-up. This tool captured:

1. A list of reasons for shortage identified based on a retrospective analysis of non-conformities [13] that occurred in the instrumentation sterilization process during the second half of 2015 and that led to the orthopedic surgery unit filing a complaint with the sterilization unit. Only those resulting in a delay or postponement of a surgical procedure were taken into account.
2. A list of instrumentation sets (checklist) needed for each procedure. This list was based on a prospective analysis of the surgery schedule (IPOPTM module, Cristal-Net software, Hospices Civils de Lyon, France) then OrbisTM Bloc (AGFA Healthcare, Ivry-sur-Seine, France) and verification of traceability labels on the materials (OptimTM SPM sterilization software, Nexus AG, Grenoble, France) attached to the sterilization-

to-surgery tracking sheet which accompanies the material returned to the washing facility after each procedure. The names of the various instrumentation kits were standardized between the two teams. This analysis was carried out over a 6-week period.

The checklists were then cross-referenced with the available stock of instrumentation and the identified causes of shortage to select the instrumentation having the highest risk of shortage. In all, the development of this tool took 6 months.

2.2 Working group focused on instrumentation

In 2017, a prospective study was carried out. An orthopedic instrument sterilization working group was set up [14]. It consisted of 11 members: pharmacist and intern from the sterilization unit, managers of the sterilization unit, sterilization agent, manager of the orthopedic surgery unit, operating room nurse responsible for orthopedic surgery scheduling, nurse and nursing assistant from the surgery unit. The implementation of this group required 2 months of meetings. The operating room staff and the sterilization staff worked together to plan the instrumentation needs based on the surgery schedule [5]. Based on the checklists developed previously and the surgery schedule over the next 24 hours, the sterilization unit notified the surgery unit by email of potential supply shortages. The surgery unit responded with a possible modification in the materials needed or the surgery schedule. Daily monitoring of the planning by the sterilization unit and the orthopedics surgery unit and required about 1 hour per day (Fig. 2). This approach (instrumentation management tool and working group) was named just-in-time (JIT). The notifications of potential supply shortage were carried out in the same patient group with JIT and without JIT according to the typical procedure used before this study (surgery staff to sterilization unit).

2.3 Outcomes

The primary outcome was the number of notifications of potential shortage with and without JIT over a 10-week period (January 26 to April 14, 2017). These are the same patients for which we applied the JIT or not to measure its effectiveness in the same situations. The secondary outcomes were the number of notifications resolved in time and the occurrence of operating room disruptions (delay > 30 min or postponement of surgery) related to unavailable instrumentation.

2.4 Statistical analysis

The quantitative variables were analyzed using Student's *t*-test for paired samples. All the correlations were tested using Pearson's correlation coefficient. The correlation was considered as "strong" ($r > 0.5$), "average" ($0.5 > r > 0.3$) or "low" ($0.3 > r > 0.1$). The agreement between the two methods (with and without JIT) was evaluated using the interclass correlation (ICC) coefficient. The agreement was considered "excellent" ($ICC > 0.75$), "good" ($ICC 0.40$ to 0.75) or "poor" ($ICC < 0.40$). A *P* value of less than 0.05 was considered statistically significant.

3. Results

3.1 Instrumentation management tool

3.1.1 Non-conformities related to instrumentation and identification of sets with high risk of shortage

During the second half of 2015, 81 non-conformities led to a complaint by the orthopedic surgery unit, of which 54 (67%) were related to surgical instrumentation (Fig. 3). Nine reasons for supply shortages were identified, allowing us to identify the instrumentation sets with the highest risk of shortage due to equipment breakdown (autoclave or washer) or environment-related problems (i.e. water or electricity). The risk was highest for instrumentation (1) used in several types of procedures, (2) with fast rotation and low stock,

(3) double pathways (on loan and on deposit), (4) that require simultaneous washing, requiring both a washer and an autoclave, (5) used in both scheduled and emergency procedures, (6) packaged in very heavy containers or in non-woven wrapping (increased risk of residual humidity or piercing upon autoclave exit, thus requiring reprocessing) [15], (7) fragile material with risk of failure (such as powered surgery tools) that may require manual washing, (8) used more than once in 24 hours and only one unit available, and (9) loaner arriving less than 48 hours before the scheduled start of the procedure [16].

3.1.2 Development of equipment checklists

In the 6-week monitoring period (November 2 to December 22, 2015), 629 surgical procedures were analyzed. This analysis allowed us to create a map of the 28 types of surgical procedures performed for which the composition of the instrumentation can be planned. Of the 200 instrumentation sets packaged in containers or non-woven wrapping available in the orthopedic surgery suite, 96 sets (48%) were identified as having the highest risk of being involved in delays in the availability of sterile operating materials. To make it easier to use the map during the scheduling analysis, a four-part checklist was developed for the main surgical activities in our orthopedic surgery department (shoulder, knee, hip/foot and fracture).

3.2 Number of at-risk instrumentation sets with and without JIT

During the study period (10 weeks), 1071 surgical procedures were analyzed, of which 968 (90.4%) used instrumentation sets that could be planned. The JIT approach resulted in notifications for 163/968 (16.8%) instances of risk of shortage versus 41/968 (4.2%) without JIT ($p < 10^{-5}$), thus four times more. The number of potential shortages identified daily without (0.7 ± 0.6) and with JIT (2.8 ± 1.9) were moderately and significantly correlated ($r=0.46$ and $p=0.0003$) but the ICC was nil, evidence of a lack of agreement between the two methods.

3.3 Reasons for potential shortage notifications

Of the 163 instances of potential shortage reported by the JIT, 51 (31.3%) were due to rapid rotation and low stock, while 25 (15.3%) were due to the instrumentation being used more than once in 24 hours (Fig. 4). Powered surgical instruments were most often the subject of notification (59 or 36%). The most impacted surgical procedures (481 or 49.7%) were percutaneous hallux valgus and Chevron osteotomy, humeral and pertrochanteric fracture fixation, and total hip arthroplasty, which corresponded to the primary activities of our orthopedic surgery department used to establish the instrumentation checklists needed for each procedure.

3.4 Number of notifications resolved in time and occurrence of operating suite disruptions

Of the 163 potential shortage notifications by the JIT, 150 (92%) were resolved in time. Among the 13 instrumentation-related problems, one was not detected by the JIT approach (7.7%) and 12 were detected but could not be resolved in time and required that the procedure be delayed to later that day or postponed to the following day. The potential shortage notifications related to these 13 events were due to “rapid rotation and low stock” in 6 cases, “loaner instrumentation arriving less than 48 hours before scheduled procedure” in 5 cases, “fragile material” in 1 case and “instrumentation used more than once in 24 hours” in 1 case.

4. Discussion

This study allowed us to propose a methodology to develop an instrumentation management tool by identifying the reasons for disruption in the sterilization pathway and the instrumentation sets with the highest risk of shortage. It also showed that close collaboration between the sterilization unit and the orthopedics surgery unit while using this tool (just-in-time approach) helped to quadruple the number of preoperative notifications of potential stock

shortage and to reduce the number of operating suite disruptions related to unavailable instrumentation by providing an appropriate solution in the right time frame for 92% of notifications. The main reason for potential shortage notification was rapid rotation of instrumentation and low stock.

Coudane et al. [2] described the reasons for “No-Go”, which is a stoppage in the patient’s treatment upon entry in the operating suite and before the incision is made. Of the 101 No-Go events declared by Orthorisq (French orthopedic surgeon risk accreditation agency) participants, or 5.7% of the healthcare-associated adverse events, 53 (52.5%) were due to problems managing the implants and instrumentation. In our study, we chose to address this question solely by looking at the availability of instrumentation and the disruptions that can ensue in the operating suite such as delays or cancellations. While the management of implants and instrumentation is the responsibility of the hospital pharmacy department, their processing pathways differ and often involve other parties, thus we felt it was most appropriate to analyze the two pathways separately. Also, our study evaluated a model to manage instrumentation on deposit or on loan relative to scheduling and allocations and involving the pharmacy and sterilization unit.

To our knowledge, there are no other published studies describing a well-standardized approach for managing instrumentation between the surgery unit and sterilization unit. Seavey [12] recommended strategies to avoid errors and misunderstandings between the two units. These strategies must reduce the errors in the instrumentation composition, foster harmony and reinforce the collaboration and communication between the two units. Eder [14] recommended changing habits based on two pillars: standardization and organization.

This organization required a strong involvement of the sterilization unit and the orthopedic surgery unit to monitor the scheduling and material planning. Feedback from the sterilization team showed a reduction in the requests from the surgery unit to urgently look for materials.

These are communicated at the sterilization transmission meeting and a copy of the daily JIT email is posted in the production area to allow fast response for the progression of a material flagged as urgent. The surgery unit observed better responsiveness when the JIT approach allowed members of the working group to harmonize the names of the instrumentation sets and to agree on the day's priorities in case of unplanned events. The JIT approach notifies the orthopedic surgery unit at the end of the day before the last autoclave cycle is started. The aim is to avoid a patient being admitted to the operating suite when the necessary surgery material is not available.

The long-term success of the JIT approach mainly rests on the adoption of the checklist tool by the sterilization unit. Regular training sessions on how to analyze the surgery schedule are planned for the sterilization staff in order to improve the relevance of the alerts to the surgery unit. This is a technical and complex exercise given the wide range of materials used. Regular updating of the checklists based on changes in the surgery procedures is also needed. The consistent presence of an orthopedic surgeon in the working group would enhance the process and the ability to come up with alternative compositions when a shortage occurs despite the warning.

However, our approach has some limitations as evidenced by the problems that still occurred. Improvements can be made. Computerized support could be a powerful lever in the flow management process. A request has been made to interface the Optim SPM™ module (sterilization traceability software) with Orbis bloc™ (software used to manage surgical procedure scheduling). This common interface for the sterilization and surgery units would allow better management of allocations and allow the surgery staff to view the status of instrumentation sets as they progress in the sterilization cycle.

The main limitation of this study is that it was performed at a single center. The surgical procedures most likely to be affected by material shortage reflect the surgical activity of the

orthopedic department at our hospital. However, the reasons for shortage identified here can be transposed to other hospitals because most stem from how the instrument sterilization is organized. Conversely, this method must be validated in larger facilities with more orthopedic and trauma surgery subspecializations, especially a larger number of emergency cases, and in case of third-party sterilization (in which case the analysis would have to be done 48 or even 72 hours beforehand, whereas our time frame was 8 hours for the return of instruments sterilized in-house). Nevertheless, the methods proposed to develop an instrumentation management tool and the make-up of the working group can also be easily generalized to other hospitals. The implementation of this operational structure required 8 months of work and 1 hour of on-going work daily. Lastly, we used the same patients to measure the effectiveness of this approach (simulation with and without JIT), thus a real-time in vivo prospective validation with before or after data, or parallel arms is justified.

5. Conclusion

The implementation of an orthopedic instrument sterilization working group along with an instrumentation management tool, or a just-in-time approach, has helped to reduce the number of operating suite disruptions related to unavailable instrumentation. Since this study was performed, the working group continues to operate and has become integrated into the activities of the sterilization and surgical units. This organization allows the sterilization unit to be involved in the coordination of the surgery unit's logistics, which is especially important in the context of a growing emphasis on outpatient surgery.

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Contributions: Ethel Huynh: design of the instrumentation management tool and the working group, data collection, development of check-lists, cowriting of the article. Shahnaz Klouche: study methodology, statistical analysis, cowriting of the article. Claudine Martinet: monitoring and notification of problems. Franck Le Mercier: consultant pharmacist for the study. Thomas Bauer: consultant orthopedic surgeon for the study. Anne Lecoeur: design of the instrumentation management tool and the working group, project oversight

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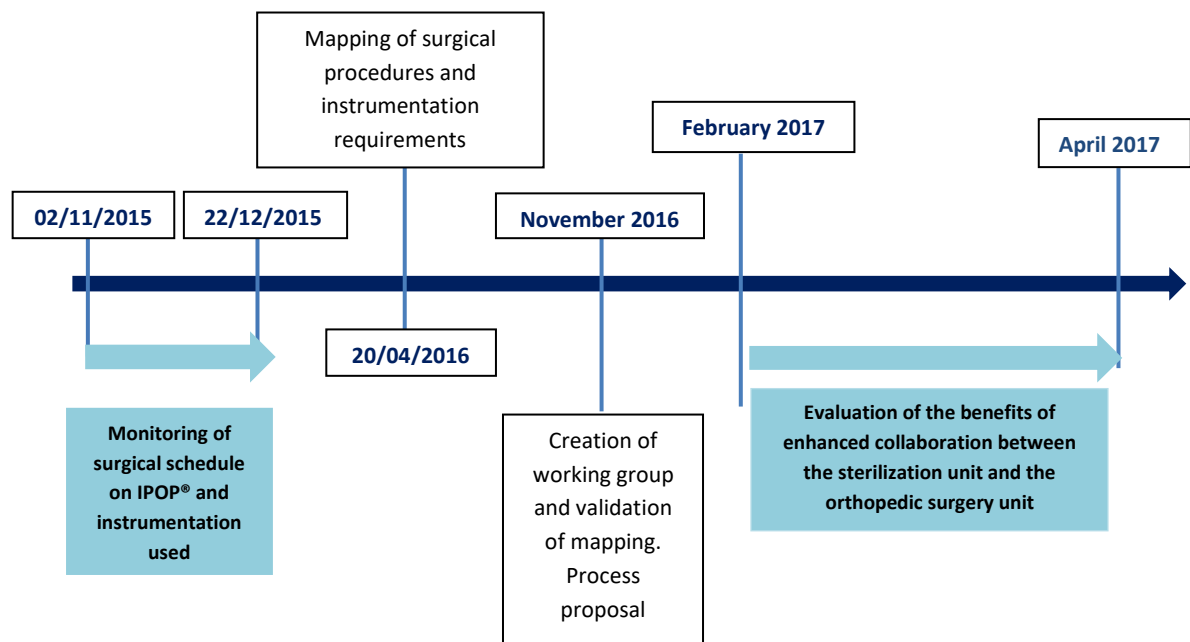
FIGURE LEGENDS

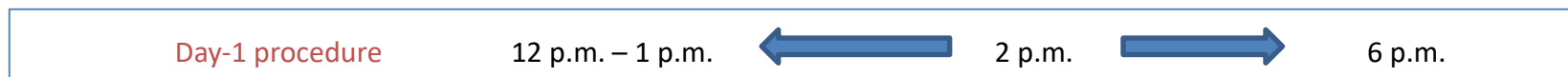
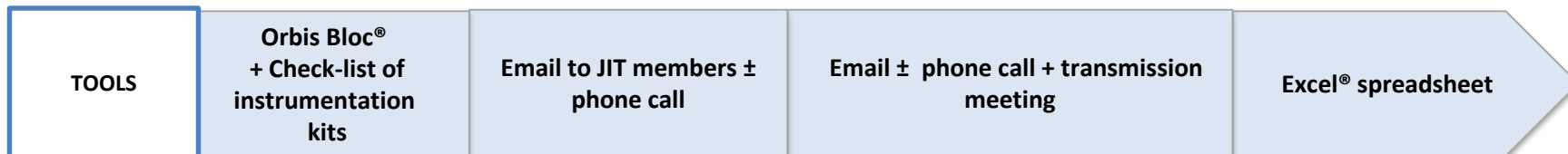
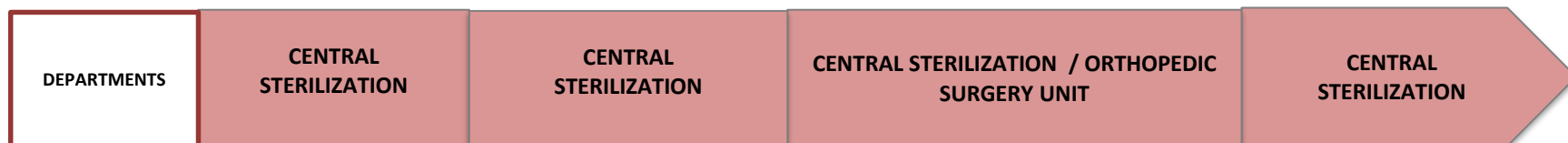
Figure 1: Study timeline

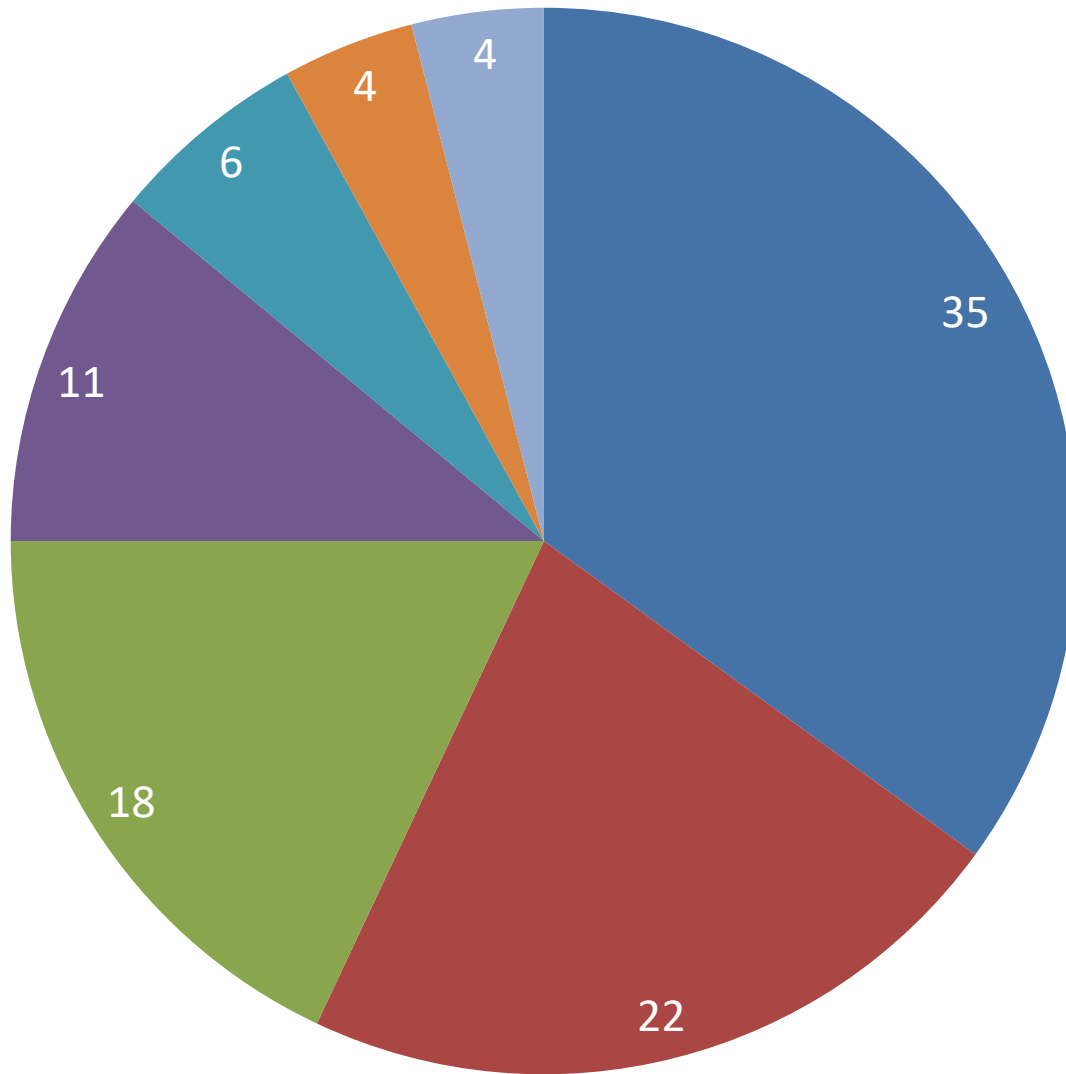
Figure 2: Monitoring procedures for instrumentation sets used by the orthopedic instrument sterilization working group.

Figure 3: Distribution of the non-conformities related to instrumentation.

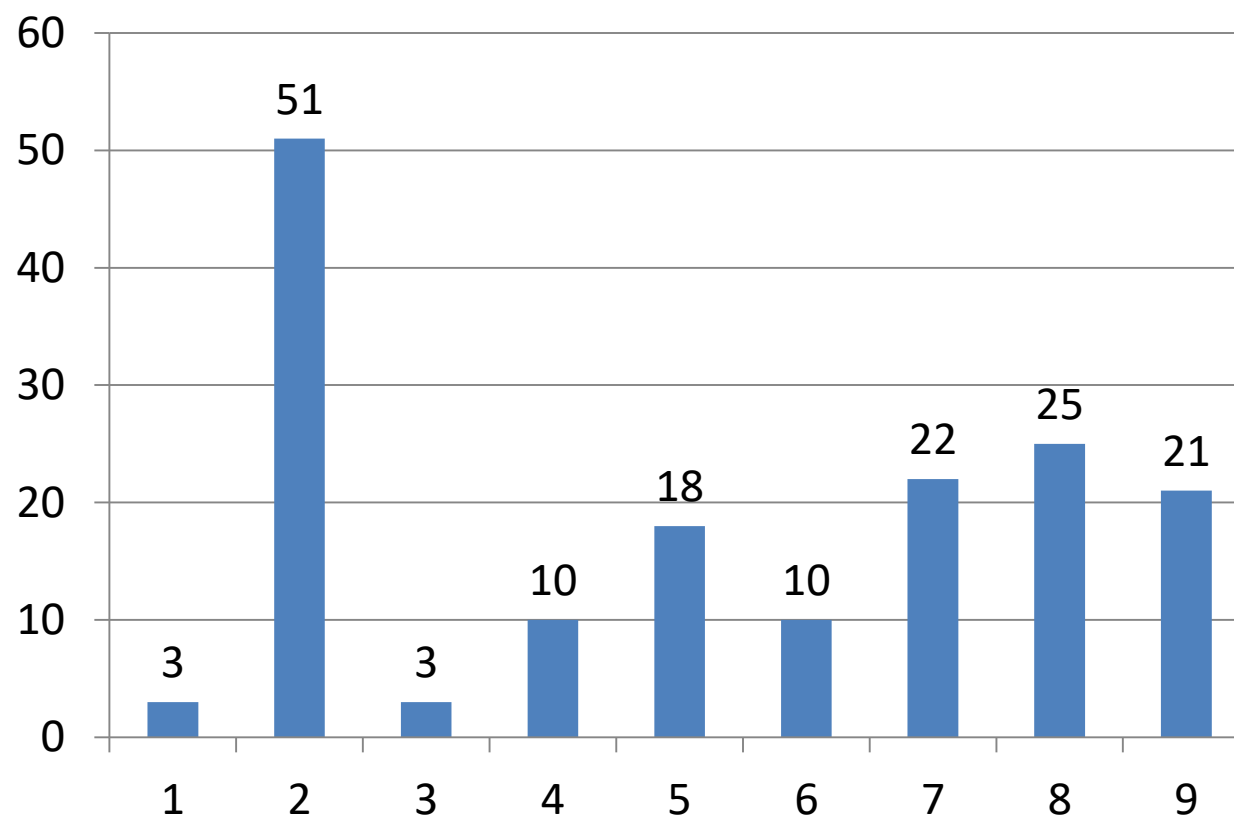
Figure 4: Reasons for notification of potential shortage using our just-in-time approach.







- Residual humidity or breach in non-woven wrapping
- Technical sterilization problem
- Name-related problems
- Fragile instrument or being repaired
- Fast rotation + low stock
- Loaner arriving less than 48 hours before surgery
- Incomplete instrumentation set



- 1: Used in several types of procedures
- 2: Fast rotation – low stock
- 3: Double circuit: deposit + loaner
- 4: Requires simultaneous washing: washer and autoclave together
- 5: Used in both scheduled and emergency procedures
- 6: Packaged in very heavy containers or non-woven wrapping
- 7: Fragile material that often requires repair
- 8: Used more than once in 24 hours
- 9: Loaner arriving less than 48 hours before start of procedure