

Improving perioperative efficiency in the management of surgical sets for trauma surgeries: the 4S approach.

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Abstract

Background

The perioperative management of the surgical instruments and implants that comprise sets for trauma surgeries has been identified as a complex and resource-intensive activity due to non-standardized inventories, redundant surgical instruments and unnecessary sterilization cycles. The 4S Intelligent Trauma Care program aims to improve process efficiency and thereby reduce environmental impact by utilizing standardized inventories, a sterile implant portfolio, a barcode that enables a digital safety certification, and a digitized restocking service.

Objective

The objective of this study was to investigate the impact of the introduction of the 4S program for the management of surgical sets in open reduction internal fixation (ORIF) trauma surgeries.

Methods

This was a single-center, prospective, comparative study of ORIF trauma surgeries undertaken pre- and post-implementation of the 4S program (30 pre- and 30 post-implementation procedures). The primary outcome was the proportion of procedures with fewer than two sterilization cycles. Secondary outcomes were the number of sterilization cycles per procedure, set processing time across departments, total set processing costs, number of missing or damaged implants, number of cleaning cycles per procedure, time taken to assemble containers for sterilization, number of containers entering the autoclave per procedure, environmental impact, number of baskets entering the cleaning machine per procedure, and staff satisfaction.

Results

Implementation of the 4S program resulted in a reduction in the mean number of sterilization cycles required from 2.1 to 1.0 ($p < 0.001$). Pre-implementation, only 30.0% of procedure sets were sterilized within one cycle, compared to 100.0% post-implementation ($p < 0.001$). A reduction in the mean set processing time of 24.1% in the OR and 35.3% in the sterilization department was observed. Mean set processing costs pre-implementation were €81.23, compared to €50.30 post-implementation. Furthermore, implementation was associated with significant reductions in water and electricity usage per procedure, and increased staff satisfaction.

Conclusions

This study demonstrates the substantial time and cost savings, positive environmental impact and staff satisfaction that can be achieved by streamlining surgical set management through the 4S program. To our knowledge, this is the first study of this type and our findings are anticipated to be generalizable to other hospitals and surgical specialties.

Introduction

The perioperative management of surgical instruments and implants has been identified as a complex and resource-intensive activity frequently associated with substantial administrative and financial burden.(1–4) In our experience, ahead of a traumatological surgical procedure, instruments and implants to be used in the operating room (OR) are placed inside trays which are then deposited in metal containers to create surgical sets. After surgery, all instruments and unused implants require reprocessing, which involves disassembly of instruments, cleaning, disinfection, inspection and functional testing, repackaging and sterilization. Contaminated instruments and clean but unused implants have to be cleaned separately from each other to avoid any potential contamination of implants. Following this, further sterilization cycles may be needed to add required implants to the trays.

Underutilization of instruments during surgery has been observed in multiple studies, likely resulting in unnecessary reprocessing of unused equipment.(1, 3–7) In one study investigating otolaryngology, plastic surgery, bariatric surgery and neurosurgery, the average instrument use per tray varied from 13–22%, demonstrating that the majority of included instruments were most often unnecessary.(4)

In traumatology, the inclusion of implants alongside instruments within surgical sets introduces additional complexity. In our experience, frequently, implants are added after the initial sterilization of instruments as they were not on site at the time of the first sterilization, resulting in the requirement for an additional sterilization cycle. EU Medical Device Regulations (MDR) enforce traceability requirements for all implants used.(8) Commonly used paper-based methods of registering and recording implant use can result in a substantial resource burden and the potential for human error. Furthermore, adding implants to surgical sets ahead of use as well as the reprocessing of implants as part of large sets means that it is not possible to track exactly which implants are ultimately used in a specific procedure using the batch numbers of individual items.

The absence of standardized inventories, the redundancy of and in surgical sets and unnecessary sterilization cycles all contribute to an increase in health resource utilization, and raise concerns over environmental impact and sustainability of these practices.(1–5, 7) This is anticipated to be particularly acute in trauma surgery due to the wide variation of specialized implants potentially required and because surgical sets for trauma surgeries traditionally include plates and screws alongside instruments. There is a clear need for a system that provides organized and immediately available instruments and implants for use in time-critical and often unscheduled procedures.

Previous studies have shown that the implementation of perioperative efficiency programs to the management of surgical sets have resulted in substantial cost and time savings related to the reduced level of instrument reprocessing.(5, 6, 9, 10) However, there are no known studies that assess the impact of the introduction of a program designed to increase the efficiency of surgical set management for trauma surgeries across all departments (OR, sterilization and purchasing departments). To this end, the 4S Intelligent Trauma Care (Johnson & Johnson Medical Devices, New Brunswick, New Jersey, USA; referred to herein as 4S) program has been devised to include the following four components:

1. **Standardized Inventory:** Surgical sets are standardized to create new lightweight versions that contain the instruments only, eliminating all implants (plates and screws). These smaller sets are designed to be used across a wide range of traumatological surgical indications, creating a simplified inventory and removing the need for procedure-specific sets.
2. **Sterile Portfolio:** Pre-sterilized, individually packed, ready-to-use, bar- and color-coded implants separate to the instrument sets are used.
3. **Safety Certification:** Implants can be traced from manufacturers to patients through the use of barcoding and a digital management system, resulting in clear and precise documentation.
4. **Service and Advanced Planning:** The program introduces digital management of restocking, reducing personnel time required.

The objective of this study was to investigate the impact of the introduction of the 4S program for the management of surgical sets in open reduction internal fixation (ORIF) surgeries. The first hypothesis was that the implementation of the 4S program would reduce the number of sterilization cycles of the required surgical sets, thereby reducing the environmental impact and increasing the sustainability of surgical set processing. It was further hypothesized that the 4S program would improve process efficiency by reducing staff and set turnover time, reduce hospital costs, and improve staff satisfaction for activities related to the management of surgical instruments and implants used in ORIF procedures.

Methods

Study Design

This was a single-center, prospective, comparative study of 60 trauma surgeries undertaken pre- and post-implementation of the 4S program from November 2019 to November 2020. Both cohorts consisted of 30 trauma procedures. There was no randomized comparison.

The study was conducted at a tertiary hospital in Spain, serving a population of around 250,000 people. In 2018, approximately 17,000 surgeries were performed, 2,000 of which were trauma surgeries.

Due to COVID-19 restrictions on external personnel access within the hospital, the study was paused for four months between March 2020 and July 2020.

Patients

All consecutive procedures for adult patients (aged 18 and older) undergoing ORIF surgeries with locking plates using the DePuy Synthes Small Fragment System were included. There were no exclusion criteria.

Intervention

The intervention was the implementation of the 4S program. Table 1 details the changes made for each of the four components. Photographs of the surgical sets pre- and post-4S program implementation are shown in Fig. 1, Fig. 2, Fig. 3 and Fig. 4.

Table 1
Summary of the implementation of the 4S program components.

Component	Pre-4S program implementation	Post-4S program implementation
Standardized Inventory	<p>Surgical sets included plates and screws.</p> <p>Six different surgical sets were utilized in ORIF surgeries (Small Fragments 1 and 2, Elbow, Ankle, PHILOS™ and Tibia [DePuy Synthes, a Johnson and Johnson company]).</p>	<p>One standardized surgical set (DePuy Synthes, a Johnson and Johnson company) to be used in ORIF surgeries was established with the number of instruments reduced to create a streamlined set.</p> <p>All implants (screws and plates) were removed from sets.</p>
Sterile Portfolio	<p>A non-sterile surgical set model was utilized in which all implants were non-sterile upon delivery to the hospital and sterilized prior to surgery.</p> <p>Unused implants would undergo reprocessing and re-sterilization.</p>	<p>All implants were provided in an individual pre-packaged and sterilized format.</p>
Safety Certification	<p>Traceability of individual implants relied on manual processing at the hospital.</p>	<p>All implants were sterilized by the manufacturer and labeled to allow traceability.</p>
Service and Advanced Planning	<p>Stock management involved manual processing of data.</p>	<p>Digital management of stock control was done by <i>in situ</i> barcode reading and the use of an advanced inventory management system to digitalize processes (eSIMS Advanced Inventory Management Solution).</p>

Study Endpoints

Data were collected through in-person direct observation by a trained investigator using a calibrated stopwatch. The investigator was trained on the definitions of each of the outcome measures. The investigator could not be blinded to the intervention due to the pre- and post-intervention cohort study design.

The primary outcome was the proportion of procedures with fewer than two sterilization cycles. The secondary outcomes were i) the number of sterilization cycles per procedure; ii) the set processing time in the OR; iii) the set processing time in the sterilization department; iv) the set processing time in the purchasing department; v) the total set processing time; vi) the total set processing costs (based on published unit costs and Hospital Universitario de La Ribera accounting costs [see the Supplementary Data]); vii) number of missing or damaged implants; viii) number of cleaning cycles per procedure; ix) time taken to assemble containers for sterilization; x) number of containers entering the autoclave per procedure; xi) water and electricity consumption of cleaning machines and steam autoclaves; xii) the

number of baskets going into the cleaning machine per procedure, and xiii) staff satisfaction. Staff satisfaction was evaluated through two methods; the NASA Task Load Index (NASA-TLX)(11) for staff with physically demanding work, and a questionnaire developed in The Netherlands to assess efficiency by changing processes.(12) For further details regarding the NASA-TLX and the definitions of the secondary outcomes, please see the Supplementary Data.

Statistical Analysis

The primary endpoint was powered to 80% based on (i) two-sided z-test, (ii) type 1 error = 0.05, (iii) 30 procedures per group and that (iv) 30% of the procedures prior to the 4S program would require less than two sterilization cycles and 70% after the 4S program. All study variables were analyzed descriptively. A two-sided z-test was used for the comparison for the primary endpoint. A p value < 0.05 was considered statistically significant. All other statistical comparisons that were conducted for the secondary endpoints were considered exploratory. Fisher's Exact test was used for categorical data and Kruskal-Wallis rank sum test was used for continuous data, unless otherwise specified. Analyses were conducted using R version 3.6.3.(13)

Results

Surgical Set and Procedure Characteristics

In total, 60 procedures were observed: 30 pre- and 30 post-implementation of the 4S program. Table 2 shows a comparison of the type of sets used throughout the study. In line with implementation of the 4S program, only a Small Fragment set (DePuy Synthes, a Johnson and Johnson company) was used following the intervention, as opposed to the use of various procedure-specific sets prior to introduction of the 4S program. Table 2 also shows a comparison of anatomical area of surgery pre- and post-4S program implementation. Prior to 4S program implementation, nearly half of the procedures (46.7%) were ankle procedures whereas post-4S program implementation, 26.7% of the procedures were ankle and 26.7% were clavicle (p=0.020). There were no cancellations of the planned procedures in the study.

Table 2

Procedure characteristics for the pre-4S and post-4S program implementation cohorts.

	Pre-4S program implementation (n=30)	Post-4S program implementation (n=30)
Set characteristics		
Ankle	5 (16.7%)	0 (0.0%)
Elbow	4 (13.3%)	0 (0.0%)
PHILOS™	4 (13.3%)	0 (0.0%)
Small Fragments	15 (50.0%)	29 (96.7%)
Proximal tibia	2 (6.7%)	0 (0.0%)
Missing data	0 (0.0%)	1 (3.3%)
Anatomical area		
Ankle	14 (46.7%)	8 (26.7%)
Carpus	2 (6.7%)	0 (0.0%)
Clavicle	1 (3.3%)	8 (26.7%)
Elbow	2 (6.7%)	1 (3.3%)
Foot	0 (0.0%)	1 (3.3%)
Radius	1 (3.3%)	0 (0.0%)
Shoulder	7 (23.3%)	6 (20.0%)
Tibia	3 (10.0%)	2 (6.7%)
Other	0 (0.0%)	4 (13.3%)

Primary Outcome

Prior to the introduction of the 4S program, only 30.0% of procedure sets were sterilized within one cycle, compared to 100.0% after implementation of the 4S program ($p < 0.001$).

Secondary Outcomes

Implementation of the 4S program resulted in a reduction in the mean number of sterilization cycles required per procedure from 2.1 to 1.0 ($p < 0.001$). The maximum number of sterilization cycles per procedure for a single set pre-implementation was 4, compared to 1 post-implementation.

Implementation of the 4S program resulted in a reduction in the mean set processing time of 24.1% in the OR (5.7 minutes, $p=0.040$) and 35.3% (5.3 minutes, $p=0.005$) in the sterilization department. No significant differences in the set processing time in the purchasing department were noted as a result of the intervention (Table 3). Overall, there was a significant difference in the total set processing time, with the overall mean turnover time for sets being reduced by 20.7% (10.5 minutes, $p=0.014$) following implementation of the 4S program.

Table 3

Set processing times for the pre-4S and post-4S program implementation cohorts.

Set processing time in minutes, median (range)	A: Pre-4S program implementation (n=30)	B: Post-4S program implementation (n=30)	p value ^a
Overall turnover time	48.6 (16.3–94.1)	39.4 (9.6–70.8)	0.014
In operating room	22.1 (3.9–49.4)	17.5 (6.4–28.0)	0.040
In sterilization department	12.3 (1.9–42.0)	8.4 (3.2–30.0)	0.005
In purchasing department	12.6 (0.0–23.9)	11.8 (0.0–31.5)	0.842

^aKruskal-Wallis rank sum test.

Pre-implementation of the 4S program, an implant was unavailable or damaged in 40% of procedures, compared to 3.3% post-implementation ($p=0.001$).

The mean number of baskets placed into the cleaning machines per procedure per cycle was numerically lower post-implementation of the 4S program compared to pre-implementation (5.17 versus 4.37, respectively, $p=0.121$). The mean number of cleaning cycles per procedure was similar pre- and post-4S program implementation (0.87 and 0.97, respectively; $p=0.165$). Implementation of the 4S program significantly reduced the mean assembly time of containers for sterilization per procedure by 43.3% (4.22 minutes, $p=0.001$). There was a significant difference in the mean number of containers entering the autoclave per procedure per cycle, which was reduced from 14.2 containers pre-4S program to 5.6 post-implementation ($p<0.001$).

Implementation of the 4S program was also associated with a reduction in processing costs, water consumption, and electricity consumption. The mean global set processing cost (OR, sterilization and purchase departments) per procedure prior to the 4S program was €81.23, compared to €50.30 post-implementation of the 4S program ($p<0.001$; Figure 5 and Supplementary Data).

Mean values for the water and electricity consumption of the cleaning machines and steam autoclaves were obtained and used to calculate water and electricity usage prior to, and following, implementation of the 4S program (see Supplementary Data for further details). Implementation was associated with

reductions in mean water and electricity usage per procedure of 320 L ($p < 0.001$) and 5.77 kW ($p < 0.001$), respectively. These translated into cost savings per procedure of €0.61 and €0.70, respectively.

The NASA-TLX results from five staff members showed that mental, physical and time demands, along with performance and frustration levels, were all significantly improved with the 4S program (all $p < 0.01$; Table 4). There was also a numerical improvement in the effort dimension following implementation ($p = 0.753$).

Table 4

Summary of results of NASA-TLX questionnaires: pre- versus post-4S program implementation.

NASA-TLX dimension, median score ^a (range)	Pre-4S program implementation (n=5)	Post-4S program implementation (n=5)	p value ^b
Mental challenge	65 (50–80)	15 (15–40)	0.008
Physical demand	65 (45–80)	15 (15–40)	0.008
Time requirements	80 (65–90)	15 (15–40)	0.008
Effort ^c	65 (35–75)	40 (15–90)	0.753
Performance ^d	85 (55–85)	30 (15–40)	0.007
Frustration level	70 (55–90)	15 (10–40)	0.009

^aMedian score measured on a scale of 0–100 (very low–very high); ^bWilcoxon rank sum test; ^cEffort is defined as the degree of mental and physical effort that the individual has to make to obtain their level of performance; ^dPerformance reflects the mental workload that an individual experienced to be satisfied with their performance.

The seven efficiency questionnaire respondents comprised three employees from the sterilization department, two from the OR and two from the purchasing department. Results showed that, prior to the 4S program, the three sterilization staff reported having to re-sterilize sets that had not been fully used in surgical procedures 3–6 times per week, compared to 1–2 times following the intervention. All three staff members felt that it was “very important” to both reduce the weight of surgical sets and optimize the number of instruments per set. Prior to the 4S program, the difficulty of implant traceability was noted as “extremely difficult” to “difficult”. Ease of traceability improved post-4S program implementation, with staff rating the difficulty level as “somewhat difficult” to “not difficult”.

Two staff members from the OR who completed the questionnaire both rated their current satisfaction levels with the overall process as “very satisfied” post-implementation compared to “dissatisfied” prior to the 4S program.

Staff in the purchasing department reported that human errors or misinterpretation in the OR report "often" led to subsequent administrative issues prior to the intervention, compared to "often" or "sometimes" after the implementation of the 4S program. Current satisfaction levels with the inventory management processes were reported to be "satisfied" and "neutral" post-implementation and "dissatisfied" and "neutral" pre-4S program.

Discussion

Process efficiency was increased based on the four pillars of the 4S program: 1) a standardized inventory, 2) a sterile implant portfolio, 3) a barcode system that enables a digital safety certification, and 4) a digital service for restocking. Its introduction in the perioperative process management of surgical sets for ORIF trauma surgeries resulted in a reduction in set processing times, number of sterilization cycles, and processing costs. Furthermore, post-implementation of the 4S program, staff satisfaction was increased and there was a positive sustainability effect due to the reduction in water and electricity usage.

A key improvement noted after the implementation of the 4S program was the increased speed of set processing. Post-4S program implementation, total time spent in the OR, sterilization and purchasing departments decreased by 10.5 minutes, freeing up staff to undertake other tasks. Over 1,000 surgeries, this equates to a time saving of 174 hours. The removal of all implants (screws and plates) from the sets leads to a reduction in size and variability of sets, thereby optimizing inventory management and allowing for the use of one central depository per OR. Surgeons may have concerns about the additional time burden of opening separately packaged implants, thus increasing OR time. However, a hospital in Germany assessed how the 4S program impacted surgical set management practices in trauma surgeries. It was reported that there was no significant difference in median incision-to-suture time after the change in surgical set management practice, and a numerical reduction of 4 minutes post-implementation, indicating that separately packaged implants and screws did not confer an additional time burden during surgery, contrary to the authors' initial expectations.⁽¹⁴⁾

The introduction of a stock management system and the digitalization of supply chain procedures such as consumption, purchasing and invoicing, aims to reduce the timings in the purchasing department. However, in this study, timings reported for the purchasing department were not significantly decreased post-implementation of the 4S program. Possible explanations for this were that one employee broke her hand after the 4S program was implemented, reducing her productivity and that the 4S stock management tool (eSims) was not fully integrated with the hospital's enterprise resource planning (ERP) system. This would have eliminated all manual transactions in the hospital's ERP system, since each report would have been automatically sent to the system instead of being sent via email to the responsible team.

The provision of pre-sterilized implants separately to the surgical instrument sets reduces the number of sterilization cycles required in the hospital and results in fewer containers requiring sterilization per

procedure, reducing the workload for sterilization staff. Sterilized surgical sets no longer need to be opened to add new or missing implants, thereby avoiding unnecessary reprocessing and further reducing the burden on hospital staff.

The combination of decreased set processing times and the requirement for fewer sterilization cycles translates into measurable cost savings. Analysis found that the whole process was €30.93 more expensive pre-4S program implementation compared to post-implementation (see the Supplementary Data for calculations). Over 1,000 procedures, the mean process cost saving was calculated to be €30,930. This may be of particular importance for healthcare systems, given the growing concern over the increasing rates of healthcare expenditure in Spain and other developed countries.(15)

Reduced environmental impact is another important outcome of the implementation of the 4S program. The United States healthcare system is responsible for 10% of the national total greenhouse gas emissions and other environmental pollutants.(16) Hospitals have a key role to play in addressing resource consumption levels and must find ways to reduce their carbon footprint.(17) Studies have shown that ORs are the most resource intensive area in the hospital, with surgical instruments being the main driver of the environmental impact of surgical procedures.(18-20) Several studies looking into ways to reduce waste and carbon footprint in hospitals and in the OR have found that simple changes can have a significant impact.(6, 21) For example, simply reducing the number of trays used in the OR, and thus the amount of tray wrapping used, leads to a reduction in waste.(6) In this study, the implementation of the 4S program reduced the number of sterilization cycles required by more than 50% and reduced the number of containers entering the autoclave per procedure, leading to a reduction in water and electricity consumption, resulting in a positive environmental impact in the sterilization department. Over 1,000 procedures, the water usage is calculated to be reduced by 320,000 L and electricity usage by 5,770 kW, resulting in potential cost savings of €608 and €701, respectively.

The final improvement observed was in staff satisfaction. The new standardized sets in the 4S program are much lighter than those typically used (6 kg versus ~12 kg), making them easier for OR personnel to transport and set up, and potentially reducing the risk of injury from transporting heavy sets. With the standardization of sets, there are fewer procedure-specific sets which simplifies the overall process. Carrying out inventory of every implant used is also easier, since surgical personnel only need to read the barcode label on the packaging. These improvements were captured in the results of the NASA-TLX and the efficiency questionnaire. Staff reported reduced physical and mental demands and an overall reduction in workload following implementation of the 4S program. They also noted that it was easier to trace implants following implementation of the program and that fewer administrative errors occurred in the purchasing department. The utilization of barcoding allows for tracking of implants, increases the ease with which hospitals can comply with MDR traceability requirements and simplifies the purchasing process as single items can be easily identified and reordered. Digitalization of the stock management results in the immediate flow of information from the OR to the administrative teams, with enhanced security compared to paper-based methods which are more easily damaged or lost.

The findings of our study are in line with published literature in that several studies have reported measurable improvements in efficiency when changes are made to the management of surgical sets. Implementation of a perioperative efficiency program for elective orthopedic surgeries, which involved the optimization of surgical tray contents, resulted in a reduction in instrument processing time and associated costs.(9) A review of surgical sets used in otolaryngology surgeries found that the removal of unused instruments could reduce set size by approximately 60%, thereby increasing process efficiency.(6) Moderate cost-savings have been reported in a cost-analysis study of the streamlining of instrument trays for otolaryngology procedures.(5) Resource savings have been shown to not be limited to adult surgeries. A systematic review of the standardization of surgical sets in pediatric surgical cases found costs were reduced, without an observable impact on OR time or safety.(10)

This study had some limitations. Lack of randomization may have impacted the results by introducing bias. Only procedure-related data were collected during the study, and no patient baseline characteristics were recorded, e.g. comorbidities. It was therefore not possible to control for potential confounders in the analyses. Additional confounding factors that may have influenced surgical set processing were not recorded but had the potential to have a significant impact on findings (e.g. the additional time required if one instrument was missing/damaged). In-person observation of OR staff may have influenced behavior and subsequent outcomes (e.g., via the Hawthorne effect).(22) Although the surgical procedures remained consistent throughout the study, patient outcomes were not recorded. In future studies, it would be valuable to collect data on surgical and safety endpoints for patients. Whilst the implementation described here is specific to DePuy Synthes Trauma (a subsidiary of Johnson & Johnson), it is our belief that the principles underpinning the 4S program are nonetheless transferable to other surgical specialties to realize similar benefits from the perspective of reduced resource use and costs, and improved sustainability of these procedures. Further research would be advisable to understand the potential benefits after a complete integration of the stock management tool.

Key strengths of this study include the prospective study design, broad patient inclusion criteria and standardized data collection instruments. The same hospital staff were present pre- and post-implementation of the 4S program, thereby reducing variability in potential confounding factors, despite the necessary pause of the study during the COVID-19 pandemic.

To our knowledge, this is the first study evaluating time efficiency, cost savings and the environmental impact of streamlining perioperative management of surgical sets via the 4S program in trauma surgery. Although this was a single-center study in Spain focusing on ORIF surgeries, the broad and comprehensive changes made to surgical set management within this approach, and subsequent positive impact, are anticipated to be generalizable to other surgical specialties across the world.

Conclusion

In conclusion, this study demonstrates the substantial time and cost savings that can be achieved by the implementation of the 4S program. Furthermore, the 4S program has a net positive environmental impact

and results in increased staff satisfaction. Implementation of a lean management program such as the 4S approach is of paramount importance, given the shift towards a value-based approach to management within healthcare systems and the necessity to minimize costs. Scaling the 4S program to other specialties and settings has the potential to improve the management of surgical instruments and implants, resulting in lower costs for hospitals, payers, and ultimately, patients.

Abbreviations

AEAS-AGA: Asociación Española de Abastecimientos de Agua y Saneamiento - Asociación Española de Empresas Gestoras de los Servicios de Agua Urbana

ERP: enterprise resource planning

MDR: Medical Device Regulations

NASA-TLX: NASA Task Load Index

OR: operating room

ORIF: open reduction internal fixation

Declarations

Ethics approval and consent to participate

The study was a hospital-based quality improvement project and was therefore considered exempt from ethical committee and patient consent requirements since no identifiable patient data were collected. The study was approved by the investigation committee of the Hospital Universitario de La Ribera. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon reasonable request. More details on Johnson & Johnson's commitment to transparency are available via the following link: <https://www.jnj.com/coronavirus/our-commitment-to-transparency/>.

Competing interests

JQ, TG, JN, CM, SB, EE are employees of Johnson & Johnson. JR declares receipt of speaking fees from Johnson & Johnson. BS declares no relevant disclosures. VC declares no relevant disclosures.

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Authors' contributions

Substantial contributions to study conception and design: JR, BS, VC, JQ, TG, CM, EE, JN; substantial contributions to analysis and interpretation of the data: JR, BS, VC, JQ, TG, CM, SB, JN; drafting the article or revising it critically for important intellectual content: JR, BS, VC, JQ, TG, CM, SB, JN; final approval of the version of the article to be published: JR, BS, VC, JQ, TG, CM, SB, JN.

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References

1. Farrelly JS, Clemons C, Witkins S, Hall W, Christison-Lagay ER, Ozgediz DE, et al. Surgical tray optimization as a simple means to decrease perioperative costs. *Journal of Surgical Research*. 2017;220:320-6.
2. Marchand KB, Taylor KB, Salem HS, Mont MA, Marchand RC. Surgical Tray Optimization and Efficiency: The Impact of a Novel Sealed Sterile Container and Instrument Tray Technology. *Surgical Technology International*. 2020;37.
3. Mhlaba JM, Stockert EW, Coronel M, Langerman AJ. Surgical instrumentation: the true cost of instrument trays and a potential strategy for optimization. *J Hosp Adm*. 2015;4(6):82-8.
4. Stockert EW, Langerman A. Assessing the magnitude and costs of intraoperative inefficiencies attributable to surgical instrument trays. *Journal of the American College of Surgeons*. 2014;219(4):646-55.

5. John-Baptiste A, Sowerby L, Chin C, Martin J, Rotenberg B. Comparing surgical trays with redundant instruments with trays with reduced instruments: a cost analysis. *CMAJ open*. 2016;4(3):E404.
6. Chin CJ, Sowerby LJ, John-Baptiste A, Rotenberg BW. Reducing otolaryngology surgical inefficiency via assessment of tray redundancy. *Journal of Otolaryngology-Head & Neck Surgery*. 2014;43(1):1-4.
7. Van Meter MM, Adam RA. Costs associated with instrument sterilization in gynecologic surgery. *American journal of obstetrics and gynecology*. 2016;215(5):652. e1-. e5.
8. Article 33: European database on medical devices. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424>. Accessed 7 December 2021.
9. Capra R, Bini SA, Bowden DE, Etter K, Callahan M, Smith RT, et al. Implementing a perioperative efficiency initiative for orthopedic surgery instrumentation at an academic center: A comparative before-and-after study. *Medicine*. 2019;98(7).
10. Dekonenko C, Oyetunji TA, Rentea RM. Surgical tray reduction for cost saving in pediatric surgical cases: A qualitative systematic review. *Journal of pediatric surgery*. 2020;55(11):2435-41.
11. Hart SG, Staveland LE. Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. *Advances in psychology*. 1988;52:139-83.
12. Kroes L. Creating more efficiency and patient safety by changing processes and contents of instrument trays: University of Twente; 2009.
13. R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. <http://www.R-project.org/>. Accessed 02 February 2022.
14. Meier, S et al. Modernes Implantat- und Instrumentenmanagement in der Unfallchirurgie. In: Current Congress, Deutscher Kongress für Orthopädie und Unfallchirurgie. DKOU 2017. https://www.thieme.de/statics/dokumente/thieme/final/de/dokumente/zw_current-congress/CC_DKOU_2017.pdf. Accessed 18 November 2021.
15. Blanco-Moreno Á, Urbanos-Garrido RM, Thuissard-Vasallo IJ. Public healthcare expenditure in Spain: measuring the impact of driving factors. *Health Policy*. 2013;111(1):34-42.
16. Eckelman MJ, Sherman J. Environmental impacts of the US health care system and effects on public health. *PloS one*. 2016;11(6):e0157014.
17. Thiel CL, Woods NC, Bilec MM. Strategies to Reduce Greenhouse Gas Emissions from Laparoscopic Surgery. *Am J Public Health*. 2018;108(S2):S158-s64.
18. Champion N, Thiel CL, DeBlois J, Woods NC, Landis AE, Bilec MM. Life cycle assessment perspectives on delivering an infant in the US. *Sci Total Environ*. 2012;425:191-8.
19. Thiel CL, Eckelman M, Guido R, Huddleston M, Landis AE, Sherman J, et al. Environmental impacts of surgical procedures: life cycle assessment of hysterectomy in the United States. *Environ Sci Technol*. 2015;49(3):1779-86.
20. Reprocessed medical devices. Practice Greenhealth. <https://practicegreenhealth.org/topics/greening-operating-room/reprocessed-medical-devices>. Accessed 19 November 2021.

21. Wormer BA, Augenstein VA, Carpenter CL, Burton PV, Yokeley WT, Prabhu AS, et al. The green operating room: simple changes to reduce cost and our carbon footprint. *Am Surg*. 2013;79(7):666-71.
22. McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. *Journal of clinical epidemiology*. 2014;67(3):267-77.
23. AEAS-AGA 2020 Study. <https://www.iagua.es/noticias/aeas/estudio-aeas-aga-2020-precio-medio-agua-uso-domestico-espana-es-190-eum3>. Accessed 09 December 2021.
24. FACUA. The price of kWh in 2020 has dropped by 14.5% compared to 2019. <https://www.facua.org/es/noticia.php?Id=16315>. Accessed 09 December 2021.
25. Colligan L, Potts HW, Finn CT, Sinkin RA. Cognitive workload changes for nurses transitioning from a legacy system with paper documentation to a commercial electronic health record. *International journal of medical informatics*. 2015;84(7):469-76.
26. Arellano J, Martinez J, Perez J, Alcaraz J. Relationship between Workload and Fatigue among Mexican Assembly. 2015.
27. Arellano JLH, Mejía GI, Pérez J, Alcaraz JLG, Brunette MJ. Construction of a survey to assess workload and fatigue among AMT operators in Mexico. *Work*. 2012;41(Supplement 1):1790-6.

Figures



Figure 1

Pre-4S program: Small Fragments set.

This encompasses a basic set for small fragment procedures in locations such as the ankle, with no anatomical plates included.

Key: purple box: basic plates; red box: screws; black box: instruments (38 in total).



Figure 2

Post-4S program: Small Fragments set.

This encompasses a set with all instruments related to small fragment surgeries (20 instruments), including those required for anatomical plates such as basic small fragment plates, anatomical ankle or fibula, elbow, clavicle, and distal tibia plates.



Figure 3

Post-4S program: Small Fragments implants (shown in cabinet drawers).

Separate pre-sterilized implants for use in conjunction with the Small Fragment set in Figure 2.



Figure 4

Post-4S program: cabinet containing implants.

This cabinet includes Small Fragments implants sets together with two distal radius implant sets.

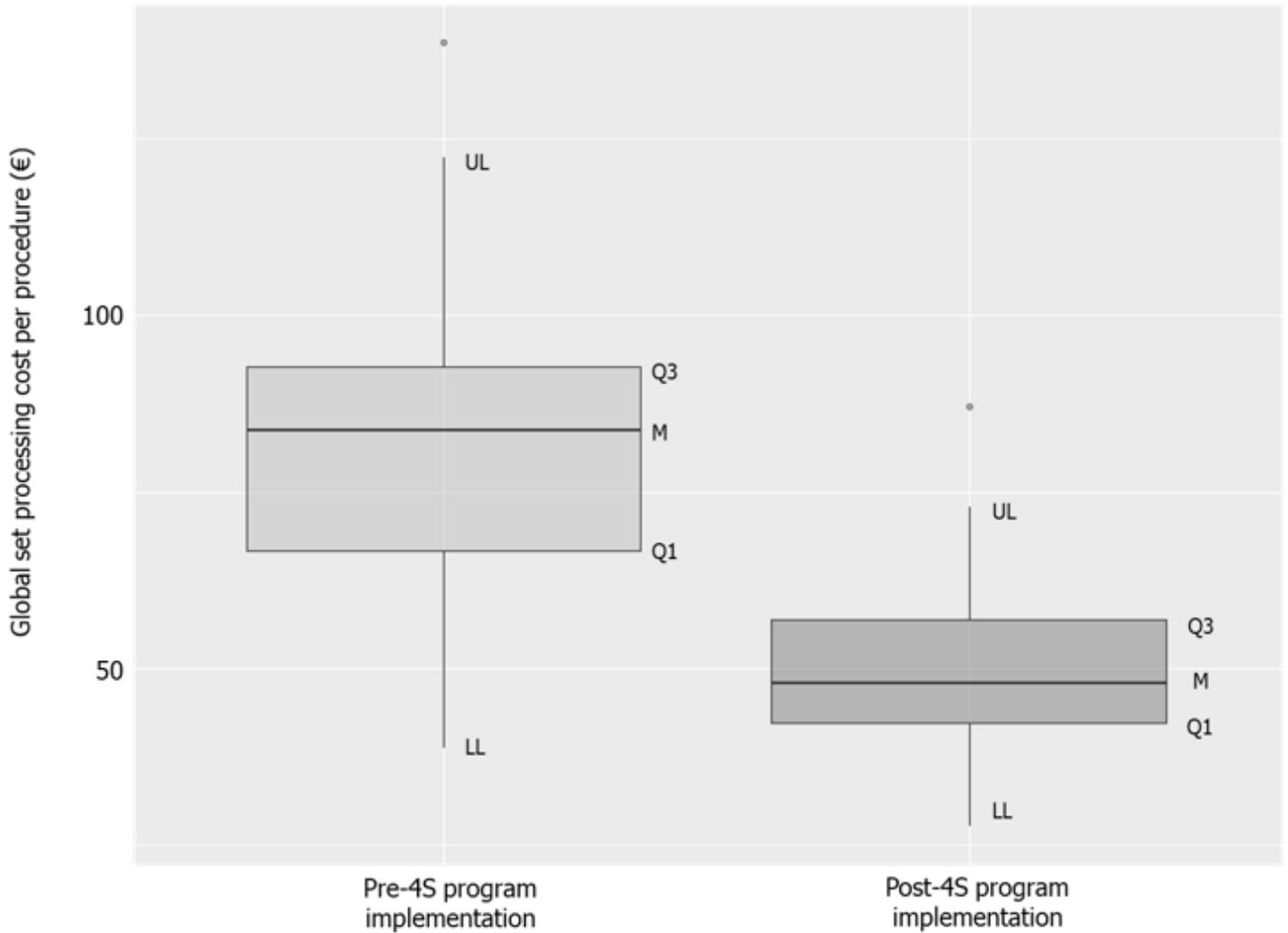


Figure 5

Global set processing costs pre-4S and post-4S program implementation.

Abbreviations: LL, lower limit; M, median; Q1, 25% quartile; Q3, 75% quartile; UL, upper limit. $Q3 + 1.5 \times IQR$ (UL) ; $Q1 - 1.5 \times IQR$ (LL). Points outside the box-and-whisker plot are outliers.

Supplementary Files

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