Budget Impact of Improved Perioperative Reprocessing of Surgical Sets used in Trauma Surgery in a Major German University Hospital

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Objective

The objective of this study was to assess the efficiency, financial and sustainability impact associated with the introduction of the 4S Intelligent Trauma Care program during post operative reprocessing of surgical sets for open reduction internal fixation (ORIF) surgeries within the Reprocessing Unit for Medical Devices (RUMED) of a major German trauma center.

Background

- Reprocessing of surgical instruments and implants is complex and costly, requiring many steps.[1]
- Previous work has shown that on average 13–22% of instruments per surgical set are utilized per procedure; however, once a surgical set container is opened all instruments within require reprocessing before reuse.[1]
- Reprocessing per instrument, including sterilization, varies depending on its complexity, but has been estimated to cost €0.47–€9.20 per instrument, not including overheads.[1]
- Improving reprocessing efficiency to optimize costs, resource use and sustainability requires the maintenance of patient safety and high-quality care.[2,3]
- In this study, the 4S Intelligent Trauma Care (4S) program was introduced, a lean management program designed to increase efficiency in the management of surgical sets (summarized in **Table 1**).

Methods

- This study comprised a single-center, retrospective pre-post 4S program implementation study conducted in the RUMED department, Ludwig Maximillian University Hospital, Munich, followed by a budget impact analysis (BIA).
- As no identifiable patient data were collected, the study was considered exempt from ethical committee and patient consent requirements.
- Data were collected between January 2017 and December 2017 to understand standard practice prior to 4S introduction ("pre-4S"); data were obtained between April 2018 and March 2019 post-4S introduction ("post-4S").
- The "partial 4S implementation" program standardized the following instruments and implants used for ORIF procedures:
  1. 'Base instrument sets' suitable for use across multiple procedures.
  2. 'Specialized instrument sets' for specific procedures.
  3. Removal of plate implants from surgical sets into pre-sterilized individual packaging.
  4. The creation of screw implant-only surgical sets with the complete range of screws required.
- A "full 4S implementation" scenario was also simulated, wherein points (1)–(3) above were implemented, while for (4) screws would be delivered pre-sterilized and individually packed, removing the screw surgical sets.
- Data collected included the number of unique surgical sets and instruments or implants per set, storage requirements, processing complexity, processing cycles, and water, electricity, and chemical consumption required during reprocessing to clean and disinfect ORIF surgical sets.
- Each individual instrument or implant was assigned complexity points based on the cost and resource use of reprocessing it in the RUMED department, with higher values representing greater processing complexity and cost. The total points for each set was calculated by summing the points assigned to each individual component. Reprocessing costs were estimated to be €0.14 per complexity point.
- Utilizing these data, a BIA was modelled from the perspective of the German healthcare system, over a one-year time horizon. All costs were calculated in 2022 Euros, with an accompanying probabilistic sensitivity analysis (PSA).
- The volume of ORIF procedures were considered pre-4S and post-"partial 4S implementation" and were adjusted to the pre-4S period in calculations.

Results

- A total of 653 procedures were conducted prior to the partial introduction of the 4S program, and 725 procedures following introduction of the program.
- The partial introduction of the 4S program resulted in a 55% reduction in the number of unique sets.
- The mean number of individual items (instruments or screw implants) per set reduced by 34%.
- The total volume of standard sterilization units (SSUs) required to store surgical sets was reduced by 16% (**Figure 1**).
- Though there was a 19% increase of sets requiring reprocessing per year, likely driven by the increased number of screw sets (47% of all sets) in partial 4S implementation, the number of cleaning and disinfecting machine loading units per year was reduced by 27%.
- As a result, water consumption reduced by 14,728 L, electricity consumption by 1,062 kWh and chemical consumption by 63 L.
- Greater reductions were anticipated in the scenario analysis of full 4S implementation versus the partial implementation (**Table 2**).
- Whilst the budget impact associated with the partial implementation was modest (€462), substantial savings were anticipated with the full 4S implementation scenario versus previous practice over a 1-year time horizon (€19,382; **Figure 2**).
- The PSA demonstrated that the full 4S program was cost-saving in 100% of simulations versus both previous practice and partial implementation.

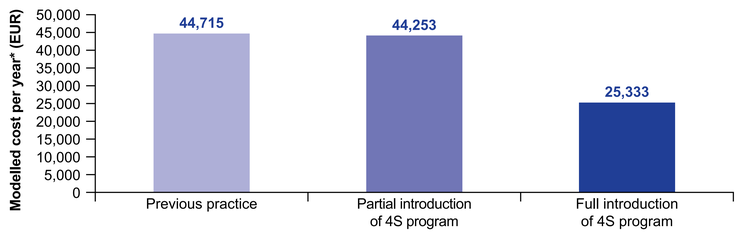
Table 1 • Overview of the 4S Intelligent Trauma Care program

4S Domain	Description
Standardized Inventory	Surgical sets are standardized to create new lightweight demand-driven versions. There are base instrument sets, that are suitable for use across multiple procedures, or specialized instrument sets, that are combined with the base instruments to conduct specialized procedures. All implants (bone screws and plates) are eliminated from the instrument sets. These smaller standardized 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. In addition, new instrument containers are introduced which can eliminate the requirement to take the instruments out of the surgical instrument trays for cleaning and disinfection, thereby removing the need for re-organization of clean instruments.
Sterile Portfolio	Pre-sterilized, individually packed, ready-to-use, bar- and color-coded plate and screw implants separate to the instrument sets are used.
Safety/Traceability	Individually packed plate and screw implants can be traced from manufacturers to patients using barcoding and a digital management system, resulting in clear and precise documentation. This is required for Class III implantable medical devices according to the new EU Medical Device Regulation.
Service and Advanced Planning	The program introduces digital management of restocking, reducing personnel time required.

Figure 1 • A representative example of a standard sterilization unit (SSU) container alongside smaller containers used post-introduction of the 4S program

(1x1 standard SSU) (5x0.75 SSU) (6x0.5 SSU) (5x0.25 SSU)

Figure 2 • Budget impact of the introduction of the 4S program



*Cost per year per surgical set type was calculated from the total complexity points per set, multiplied by the reprocessing cost per complexity point estimated to be €0.14 per complexity point

Table 2 • Outcomes with implementation of 4S program relative to previous practice

Outcome	Previous practice	Partial 4S introduction[a]	Full 4S introduction[b]
Total number of unique surgical sets (% change vs. pre-4S)	40 (NA)	18 (–55%)	13 (–68%)
Base instruments	NA	2	2
Specialized instruments	NA	11	11
Screw implants	NA	5	0
Total number of surgical sets (% change vs. pre-4S)	50 (NA)	63 (+26%) Base instruments 18 Specialized instruments 19 Screw implants 26	37 (–26%)
Total volume of standard sterilization containers (% change vs. pre-4S)	43.25 (NA)	36.25 (–16%)	23.25 (–46%)
Mean processing complexity per surgical set, points[c] (% change vs. pre-4S)	188 (NA)	160 (–15%) Base instruments 285 Specialized instruments 103 Screws implants 235	131 (–30%)
Total processing complexity of surgical sets per year, points[c] (% change vs. pre-4S)	319,393 (NA)	316,093 (–1%) Base instruments 184,110 Specialized instruments 16,795 Screws implants 150,040	180,953 (–43%)
Total volume of standard sterilization containers processed per year (% change vs. pre-4S)	836 (NA)	700 (–16%)	432 (–48%)
Cleaning and disinfecting machine loading units (% change vs. pre-4S)	3,466 (NA)	2,519 (–27%)	1,983 (–42%)
Total number of sets requiring sterilization per year (% change vs. pre-4S)	948 (NA)	1,129 (+19%)	594 (–37%)

[a]Partial sterile portfolio 4S introduction – only plate implants delivered separately; [b]Full sterile portfolio 4S introduction – plate implants and screws delivered separately; [c]Points were assigned to each instrument based on the individual reprocessing cost and resource use, and the complexity per set was calculated by summing the individual instrument points.

Conclusion

This study demonstrated the benefits of implementing the 4S program with standardization of surgical sets destined for use in ORIF procedures, and provision of separate individual pre-sterilized plate and screw implants. This resulted in clear improvements for "partial 4S implementation" in reprocessing efficiency; however, high reprocessing complexity remained. Most benefits are realized with "full 4S implementation" on reprocessing efficiency improvements and reduction in annual direct reprocessing costs. Environmental improvements at the hospital are linked to water, energy, and chemical usage.

References

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Abbreviations

4S: 4S Intelligent Trauma Care; **BIA:** budget impact analysis; **EUR:** Euros; **LMU:** Ludwig Maximillian University; **NA:** not applicable; **ORIF:** open reduction internal fixation; **PSA:** probabilistic sensitivity analysis; **RUMED:** Reprocessing Unit for Medical Devices; **SSU:** standard sterilization unit; **vs.**: versus.

Authors' contributions

Substantial contributions to study conception and design: **AF**, **CM**, **SB**, **JB**, **TG**, **GP**, **MH**; substantial contributions to analysis and interpretation of the data: **AF**, **CM**, **SB**, **JB**, **TG**, **GP**, **MH**; drafting the publication or revising it critically for important intellectual content: **AF**, **CM**, **SB**, **JB**, **TG**, **GP**, **MH**; final approval of the version of the publication to be published: **AF**, **CM**, **SB**, **JB**, **TG**, **GP**, **MH**.

Competing interests

CM, **SB**, **JB** and **TG** are employees of Johnson & Johnson. **AF** declares no relevant disclosures. **GP** declares no relevant disclosures. **MH** declares no relevant disclosures.

Acknowledgements

The authors thank the Costello Medical Creative team for design support. We also thank Alex Pashley, Costello Medical, for review and editorial assistance in the preparation of this poster.

Presented at ISPOR 2024 • May 5–8 • Atlanta, GA