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NAVIGATING COMPLEXITY: CHALLENGES IN DEVELOPING SIMULATION MODELS FOR STERILE PROCESSING

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ABSTRACT

The Sterile Processing Department (SPD) is an essential component of hospitals and healthcare facilities. It ensures the cleanliness, sterility, and proper functioning of medical instruments. A well-designed SPD workflow can improve productivity, reduce operating room (OR) delays, and enhance patient safety. Developing a simulation model for sterile processing is challenging because of the complex interactions between different units, such as decontamination, assembly, sterilization, storage, and case-cart preparation. Moreover, the dynamic nature of the surgical volume, tray requirements, and staffing dynamics further complicate the modeling process. Furthermore, missing instruments, bioburden, and nonfunctional instruments add another layer of complexity. Therefore, the additional tray request from OR personnel results in undue strain on the SPD's inventory of trays and its ability to process dirty trays and instruments. This study focuses on the following challenges: duplicate tray requests, replacement tray needs, tray representation, on-time start pressures, and staff shortages.

1 INTRODUCTION

Sterile processing, also called central sterile services or supplies, is an important aspect of hospitals. In SPD, sterilization and other tasks are conducted on the medical devices used in patient care (Swenson 2013). The basic functions of SPDs include decontamination, assembly, sterilization, storage, and case cart preparation. Good coordination among all of them can improve productivity and safety and reduce surgery delays. The decontamination, inspection, preparation, sterilization, storage, and distribution of sterile medical and surgical supplies, instruments, and equipment throughout the hospital fall under the purview of the SPD, which is responsible for ensuring infection prevention and control within the healthcare organization. The role of SPD is to organize medical and surgical instruments to prevent infections in patients and reduce risks to staff (Huber 2010). Adequate staffing is essential for ensuring the prompt and efficient processing of instrument trays (Bush 2019; Kusler-Jensen 2023). Many healthcare facilities struggle to maintain sufficient staffing levels because of budget constraints or difficulties in recruiting and retaining qualified personnel (Berg et al. 2015). Understaffing was a key contributor to increased processing times, as SPD technicians struggled to keep up with the demand for instrument sterilization (Swenson and Conklin 2016; Agarwal et al. 2018). Insufficient staffing or a high workload can result in backlogs, leading to delays in processing trays (Hionis 2023). In addition, SPD technicians rely on immediate-use sterilization or flash sterilization, which require the availability of trays for forthcoming treatments in emergent clinical situations. Flash sterilization can be used excessively or improperly to compensate for inadequate inventory, workflow inefficiencies, or worker convenience.

In addition to staffing issues, inadequate tray inventory can also contribute to instrument tray delays in

sterile processing (Hionis 2023). SPDs rely on specialized equipment and facilities for cleaning, sterilizing, and storing surgical instruments. Many healthcare facilities operate on tight budgets, forcing SPDs to prioritize trays to meet the growing demands of the OR. However, inadequate staff levels affect operational efficiency, delay tray turnaround times, and create additional bottlenecks in the SPD workflow. Staff absenteeism and machine failures also present significant challenges to the SPD workflow. Staff absenteeism places a burden on the remaining personnel, causing delays in critical steps such as cleaning, inspecting, assembling, and packaging. It also introduces skill gaps and disruptions, leading to potential errors as other staff members attempt to cover unfamiliar tasks. Machine failures, whether due to malfunctions or breakdowns, halt the automated processes. In all cases, these factors contribute to extended processing times, increased workload on the available staff, and increased possibility of making errors, making it harder for the SPD to maintain optimal standards of sterility and patient safety. Staff shortage and absenteeism, inadequate tray inventory level, machine downtime, and resource constraints directly affect different stages of SPD, such as cleaning, inspecting, assembling, and packaging surgical instruments. Furthermore, SPD process failures and tray processing delays not only compromise patient safety but also the hospital's budget and reputation. By understanding the impact of these factors on the SPD-OR workflow, healthcare facilities can implement targeted interventions to mitigate risks, optimize efficiency, and ensure the highest standards of patient care.

Sometimes, OR orders extra trays to reduce the risk of surgical delay (due to bioburden, missing instruments, or non-functional instruments). This increases the workload of the SPD-OR system. With less slack in the system, SPD staff rush or expedite tray preparation. Consequently, the possibility of errors increases. Trays may contain bioburden, missing instruments, or non-functional instruments. This cyclical behavior then increases/creates mistrust between the OR and SPD (Hionis 2023). The key components of the SPD workflow are trays, responsibilities in SPD units (i.e., decontamination, assembly, sterilization), SPD staff, and resources. We can build a simulation model that considers factors such as tray flow, resource allocation, and different sterilization modes. If, for instance, there is an increase in tray demand due to add-on cases, bioburden, missing, or contaminated instruments, the model would simulate how this affects tray processing times in different units in SPD. In addition, a decrease in capacity, perhaps owing to maintenance or equipment failures, would illustrate the ensuing effects on the system's performance. By incorporating such capacity dynamics and their interactions with other components of the SPD-OR system, simulation modeling provides a dynamic and comprehensive understanding of how changes in tray demands and capacity allocation impact the overall behavior of this complex system.

Simulation is widely used in the healthcare industry because of its flexibility and ability to manage uncertainty and variability (Milstein et al. 2010; Mielczarek and Zabawa 2016). A significant benefit of simulation can be obtained once it is properly integrated into daily healthcare operations (Barjis 2011). Simulations can be employed to manage SPD complexity caused by significant instrument heterogeneity and related reprocessing heterogeneity. Discrete event simulation (DES) is widely used in healthcare decision making at tactical or operational levels (Marshall et al. 2015). The healthcare sector effectively uses DES to manage hospital capacity, allocate resources, enhance patient or process flow, and assess scheduling (Hamrock et al. 2013).

A feasibility study also needs to be performed with the goal of determining how the DES of SPD operation can enhance the SPD workflow and its resource utilization (Haseeb 2020). The primary assumption of this research is that because the instrument sets are usually packed in baskets, the authors chose to simplify the simulation modeling by presenting only the flow of baskets rather than a list of individual instruments. The DES model can be applied to analyze different scenarios of usage of automated guided vehicles (AGVs) in SPD (Ghiyasinasab et al. 2020). Here, the simulation model offers the central sterilization department (CSD) a decision-making tool that guides judgments regarding the usage of AGVs, as well as its advantages, disadvantages, and interactions with other aspects. A simulation-based framework can also be used for forecasting reusable medical equipment (RME) inventory levels in surgical services to balance competing performances such as patient care quality, frequent RME shortages, surgery delays, and cancellations (Khaleghi et al. 2016). The DES can also be used to evaluate the effectiveness of management

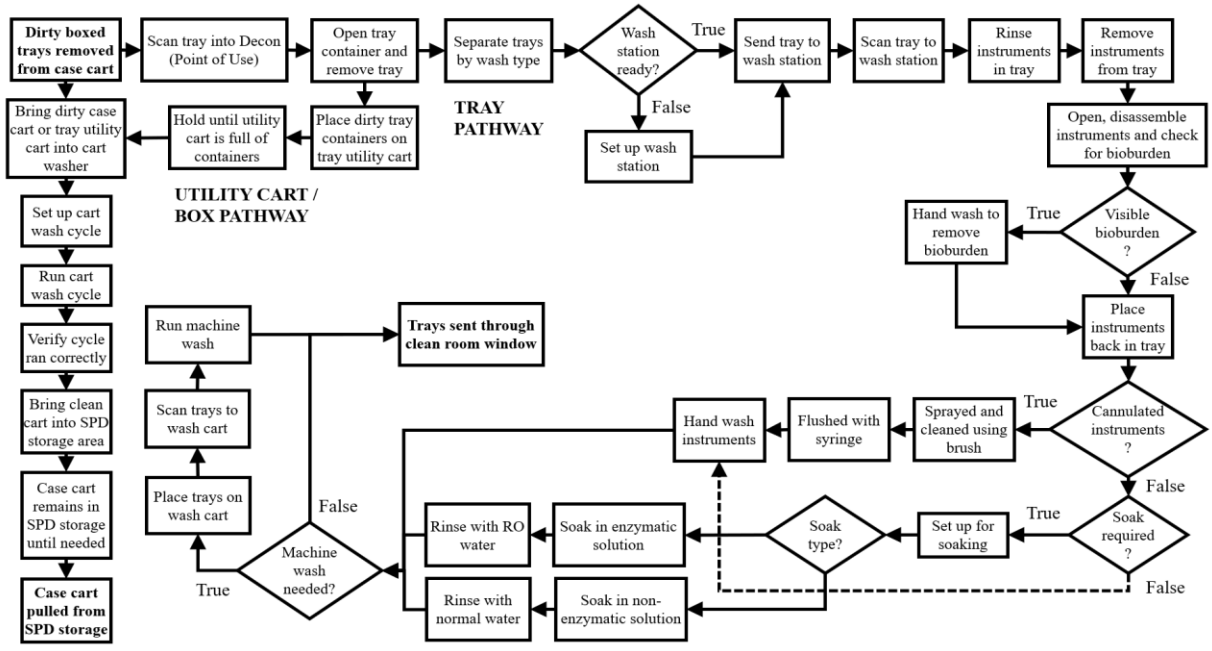
strategies in a private healthcare facility's radiology department using data on service time and arrival rates (Shakoor et al. 2021). To date, no quantitative research has addressed the nature of tray flow times across decontamination, assembly, and sterilization, which reflects the true dynamics of the SPD system. Our study aims to address a critical gap in the existing literature concerning the impact of extra tray requests, missing instruments, nonfunctional instruments, bioburden and tray flow dynamics within the SPD. To fill this void, an accurate tray representation for each surgical case is needed to develop a simulation model that can assess the impacts of these issues on SPD. Simulation modeling can be used as a novel approach to comprehensively assess and understand the repercussions of additional tray requests and tray flow dynamics in SPD operations. This study may provide a foundation for more in-depth research and interventions to improve SPD performance.

2 TRAY PROCESS FLOW

In our study, we are focusing on developing detailed process flows specifically for the decontamination and assembly departments within the SPD. These areas involve human staff and complex processes that are critical for ensuring the cleanliness, functionality, and safety of surgical instruments and equipment. By mapping out these process flows, we aim to gain a comprehensive understanding of each step involved in decontamination and assembly, including how tasks are performed, what resources are required, and where potential bottlenecks or inefficiencies may arise. While sterilization processes rely heavily on automated machines and are more straightforward, our focus on decontamination and assembly will provide valuable insights into optimizing these labor-intensive aspects of SPD operations.

2.1 Decontamination

Decontamination begins when dirty trays are transferred from the OR. The primary tasks performed by the decontamination staff are shown in Figure 1.



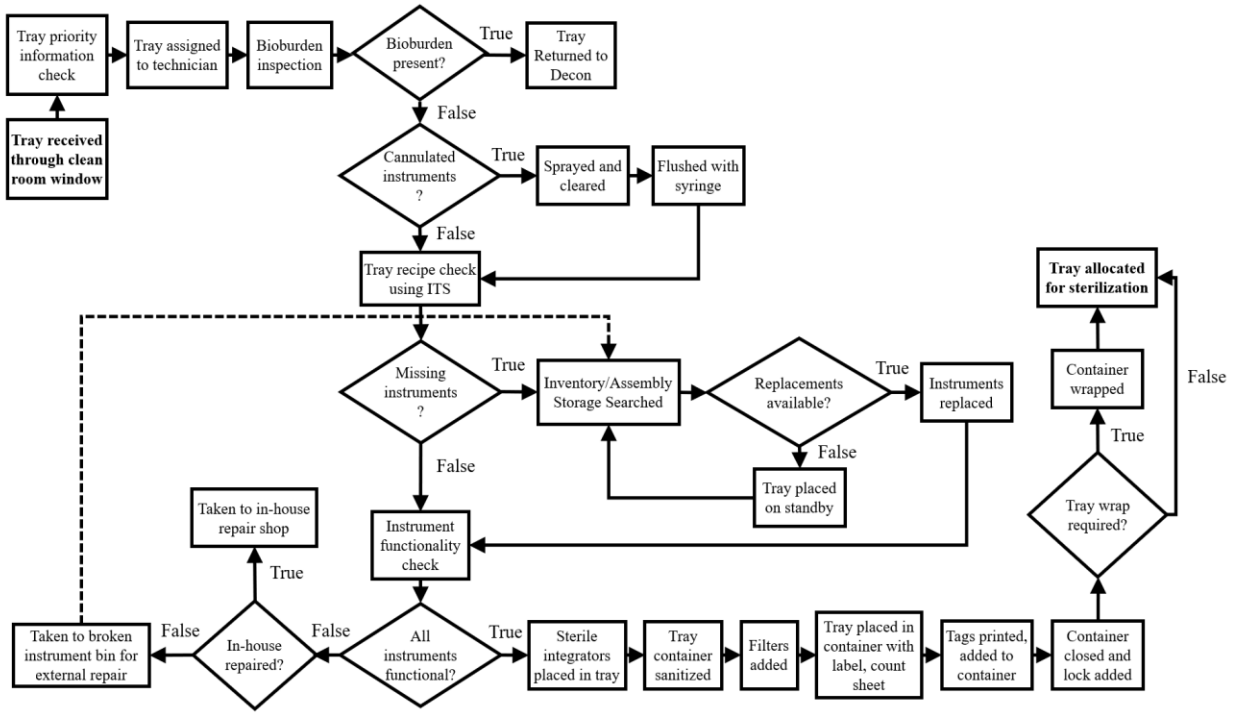
*RO = Reverse osmosis

Figure 1: Decontamination process flow.

Each tray is barcode scanned when it enters decontamination, and it is often placed in a holding room to wait for processing. More experienced decontamination staff members classify trays into categories representing various cleaning modes, specialties, and priorities. To decontaminate the surgical instruments, they were removed from their tray, examined, opened, disassembled, cleaned, and placed back into their tray. Decontamination workstations contain multiple sinks, several small cleaning tools, large magnifiers for examining instruments, dispensers for enzymatic or non-enzymatic fluids, and thermometers for measuring the water temperature. Several cleaning modes are employed, such as manual washing using brushes and syringes, soaking, ultrasonic cleaning, and machine washing using a washer-disinfectant. Following instrument cleaning, the trays were scanned out of the decontamination and moved into the "clean" room for assembly.

2.2 Assembly

Assembly begins when trays from decontamination are carried to the assembly area through a window or washer disinfector. The primary tasks performed by the assembly staff are shown in Figure 2. The list of instruments necessary for each tray was accessed using an instrument tracking system (ITS). The instruments were removed from the tray and visually examined for bioburden using a magnifier. Cannulated instruments were inspected using an air compressor. Contaminated instruments were returned for decontamination. The functionality of the instrument was assessed by using an instrument check sheet. Instrument maintenance technicians may promptly fix damaged instruments or take them out of circulation. Missing instruments were retrieved from a single instrument storage tray or another tray. If an instrument is missing and cannot be found, the tray is either taken out of circulation, or a label for the missing instrument is added.



*ITS = Instrument tracking software

Figure 2: Assembly process flow.

3 DATA

Research data were collected from a 700-bed academic hospital with two reprocessing facilities. Two types of data were required for this study: surgical and sterile processing microsystem (SPM) process data. Surgery data were obtained from a one-year historical query that included the date, start time, end time, specialty, and room number for each surgical procedure. The SPM process data included the number of trays per procedure, number of workstations, cycle times and capacities, processing time of each workstation, number of sterilizers and cycle time of several types of sterilization, and list of vendor trays. The SPM system does not have the processing time for all tasks performed in the SPD-OR workflow; therefore, these data were collected by direct observation and discussion with SPD personnel.

3.1 Surgery Schedule

Surgical coordinators usually develop surgery schedule to guarantee effective and safe use of ORs and resources. It contains data regarding the surgical team, patient, type of surgery, expected duration of surgery, and assigned room. Surgical data were collected at the Medical University of South Carolina (MUSC). From Figure 3, we see that most of the surgeries are scheduled in the morning. In the morning, medical staff - including surgeons, nurses, and support personnel, tend to be well-rested, which lowers the likelihood of errors. Moreover, starting surgeries early in the day provides a buffer against unforeseen delays or complications, allowing medical staff to resolve any concerns without affecting the entire day's schedule.

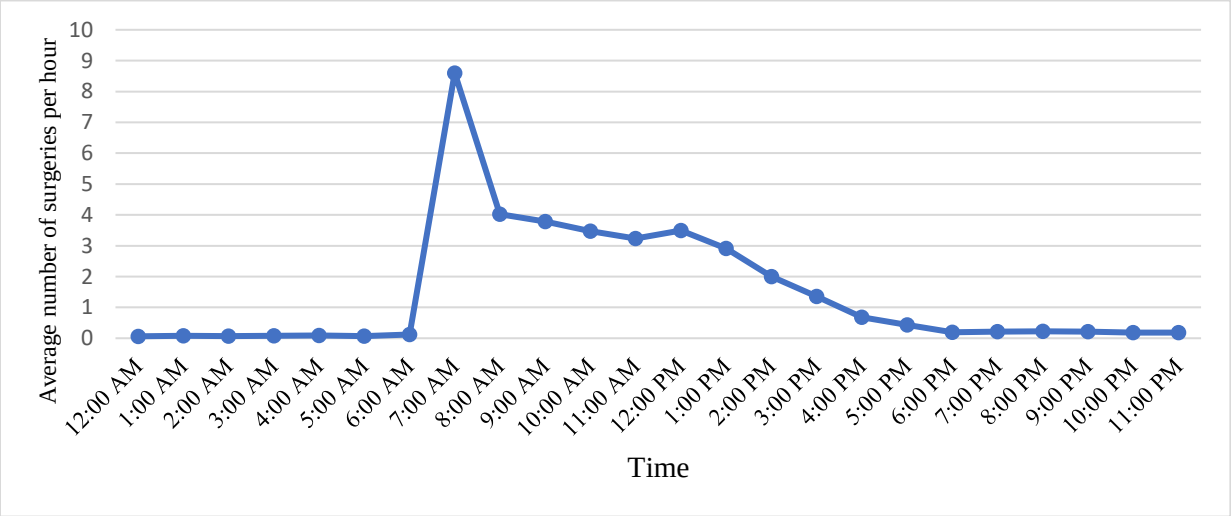


Figure 3: Average number of surgeries performed per hour (2022).

3.2 Extra Tray Requests

Occasionally, trays arrive to the OR with any of the following issues – instruments containing bioburden, missing instruments, and nonfunctional instruments. Table 1 illustrates a surgical case with the requested extra (duplicate) trays. We used a dummy number to replace the actual surgical case identifiers to protect data privacy. The actual tray requirement for this surgery was nine (9), but the OR personnel ordered two (2) extra trays for this surgery – Power Plastics Zimmer Air Dermatome and Set Gen Burn Skin Graft. Every month, the overall duplicate trays requested by OR personnel varied, on average, from 4% to 6%. The top four services were orthopedics (33%), neurology (21%), urology (11%), and general surgery (17%), containing 82% of all duplicate trays requested by the OR personnel. Orthopedics, Neurology, Urology and General surgeries contributed 33%, 21%, 11% and 17% duplicate trays respectively.

Table 1: Duplicate tray data example.

Case #	Service type	Instrument type
G0001	General surgery	Power Plastics Zimmer Air Dermatome Power Plastics Zimmer Air Dermatome Set Plastics Brennen Mesher 1/1 Set Plastics Brennen Mesher 2/1 Set Plastics Brennen Mesher 3/1 Set Gen Burn Skin Graft Set Gen Burn Skin Graft OR Metal Basin Power Stryker TPS Core Drill Set Gen Burn Guards and Handles Set Amalgatome Skin Graft & Wound Debridement System

The top five trays requested by OR personnel are presented in Table 2 which contribute 51% of the total duplicates in 2022.

Table 2: Top five duplicate trays requested by the OR personnel in 2022.

Tray name	Tray type	# of duplicates	Percentage (%)
Set Ortho Stryker System 7 Battery	11	910	14%
Set Urology R. Wolf Cystoscopy Rigid	6	902	14%
Power Plastics Zimmer Air Dermatome	5	519	8%
Set Gen Burn Skin Graft	1	491	8%
Set Stryker Small Battery for Drill	7	444	7%

Urology, Orthopedics, Gynecology and General surgeries are more prone to request extra trays from the SPD. Table 3 represents the extra tray requests data of all types of surgeries performed in 2022.

Table 3: Surgery cases with and without extra tray requests in 2022.

Surgery Type	# of cases without extra tray request	# of cases with extra tray request	Total	% of cases with extra tray request
Urology	899	1134	2033	56%
Orthopedics	1691	1202	2893	42%
Gynecology	687	311	998	31%
General	1393	571	1964	29%
Vascular	9	2	11	18%
Otolaryngology	1177	232	1409	16%
Plastic	52	9	61	15%
Transplant	711	114	825	14%
Neurosurgery	2127	295	2422	12%
Ophthalmology	42	5	47	11%
Oral	279	7	286	2%
Radiation Oncology	94	1	95	1%
Colorectal	5	0	5	0%

3.3 Historical Tray Flow Times

Typically, barcoding, RFID technology, and computerized inventory management systems are used to track the tray location and usage. Surgical tray turnover and the fluctuating frequency of specific surgical procedures add another layer of complexity. It is crucial to gather comprehensive data on the processing times at each stage, including tray arrival during decontamination, assembly, and sterilization. To gather tray flow time in SPD workflow, we use 'Step Timing Report' data from 01/01/2022 to 06/30/2023. The key points within the SPD workflow are decontamination receipt, decontamination clean, pack receipt, package set, sterilization receipt and sterilization cooling. Step timing report records the movement and progress of trays throughout the SPD workflow. This report ensured real-time understanding of the entire processing timeline. The collected data underwent thorough analysis, allowing for the identification of bottlenecks, or areas of improvement within the workflow. The average tray flow time of all the stages in SPD is very long as shown in Figure 4. In the SPD, various factors such as staff shortage, staff absenteeism, and machine failures can create a strain on the available workforce, potentially causing delays in handling and processing trays.

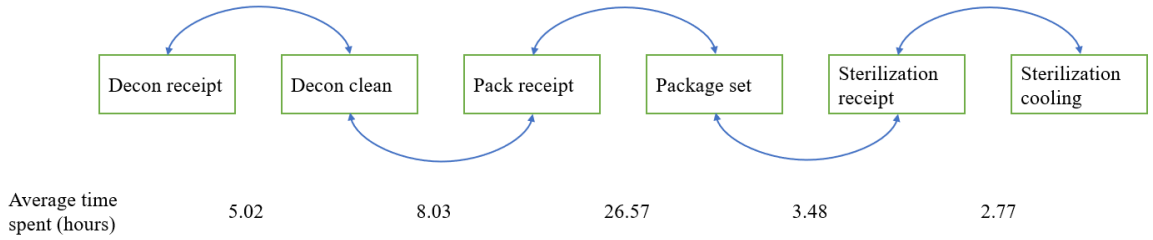


Figure 4: SPD process breakdown.

3.4 Influence on Tray Flow Times

The SPD technicians face the challenging task of managing tray processing to meet the ever-growing demands from the OR. As a result, there emerges a priority system where certain trays receive precedence over others, potentially leading to variations in processing times. Upon analyzing the 18 months data from 01/01/2022 to 06/31/2023, we identified longer tray flow times at different stages within the SPD workflow. This variation underscores the intricate relationship among different stages in the SPD workflow. Figure 5 illustrates the distribution of tray flow times from 'Decon receipt' to 'Decon clean'. 'Decon receipt' to 'Decon clean' presents the stage prior to decontamination.

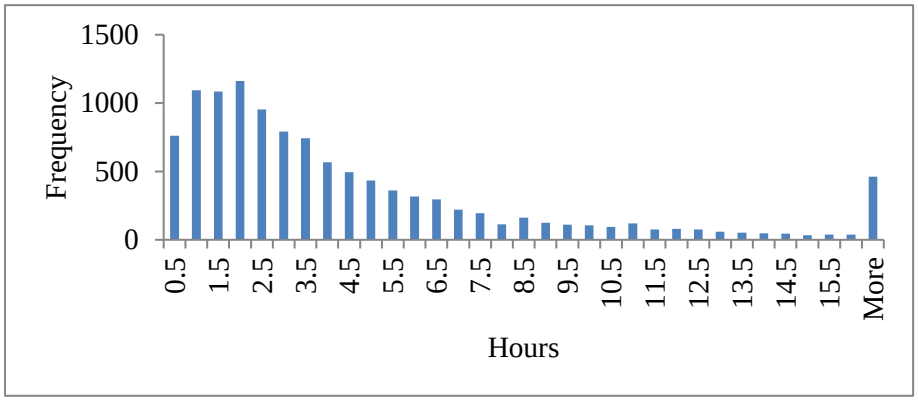


Figure 5: Tray flow time from Decon receipt to Decon clean.

The X-axis represents the tray flow time intervals, and the Y-axis represents the frequency of trays

processed within each interval. From the histogram, it can be observed that 52% of the trays were processed within 3 hours. However, there is also a noticeable tail towards longer tray flow times, indicating occasional instances of delays in this stage. For example, 7% of the trays required more than 12 hours. Figure 6 illustrates the distribution of tray flow times from 'pack receipt' to 'package set'. This stage is facing significant challenges due to staff shortages and absenteeism, resulting in longer tray flow times than what one might expect. However, often tray delays can be avoided by prioritizing the trays used and needed most. This is not uncommon across other SPDs in the U.S. (Schmitz 2023). With tray flow times reaching up to 3 hours for nearly 18% of the trays, whereas 53% of the trays required more than 12 hours. When the trays are received from the Decontamination department, the assembly team immediately begins the process of prioritization. This involves assessing each tray's utilization and inventory status. Trays that have been frequently used or are in high demand are given priority, ensuring that they are readily available for upcoming procedures. During this prioritization process, non-priority trays are temporarily sidelined on designated shelves, resulting in longer tray processing time. This approach allows the assembly department to efficiently manage tray flow, ensuring that critical instruments are always accessible despite the constraints imposed by staffing limitations.

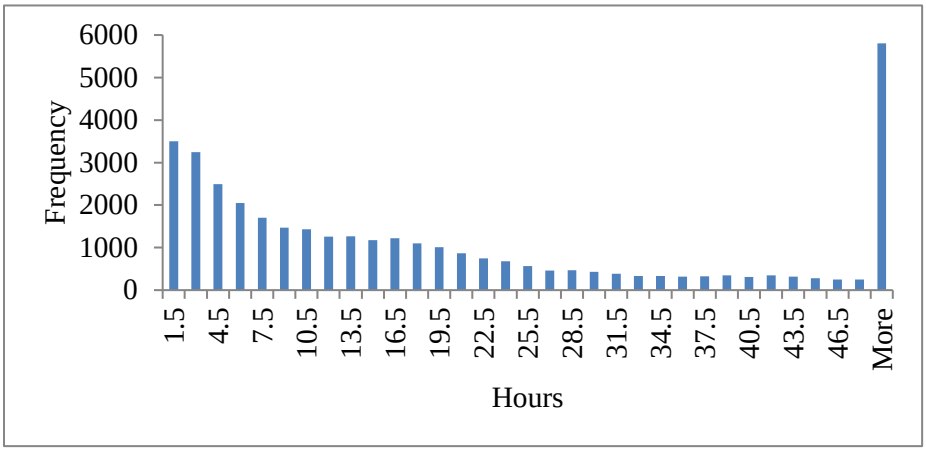


Figure 6: Tray flow time from Pack receipt to Package set.

4 TRAY REPRESENTATION

Simulation modeling in SPD involves establishing connections between different stages within a system that accurately represents the flow and dynamics of different tray types. Through an accurate representation of tray for each surgical cases, simulation modeling can be a powerful tool that enables healthcare facilities to simulate various scenarios and test different strategies in a risk-free environment. Top management needs to work on its strategic goals, overall facility design, and broader operational considerations, which may overshadow the detailed planning of every instrument. Because of the vast array of medical instruments and their specialties, top management finds it challenging to comprehensively plan all possible scenarios. In 2022, there were 1818 unique tray types used in MUSC. Developing a simulation model that considers every tray type is impractical and likely an overspecification of the process. Trays with a higher usage may be prioritized, ultimately requiring less processing time. The inherent urgency associated with the frequently used trays may prompt expedited processing. In contrast, lower-usage trays, receiving less priority, may experience longer processing times owing to potential delays associated with reduced workflow urgency, resource allocation, or scheduling considerations. Our hypothesis is as follows:

Hypothesis: The tray processing time in SPD is influenced by the usage frequency of trays, with higher-usage trays requiring less processing time than lower-usage trays.

All hospital-owned tray types were categorized based on tray utilization. All vendor trays were grouped into the single-tray category. Tray type 20 represents the vendor trays. Table 4 represents the tray categorization process based on frequency of tray usage per case.

Table 4: Tray types based on frequency of tray usage per case.

Tray Type	1	2	3	4	5	6	7	8	9	10
Frequency of trays/Case	>=0.19	0.18	0.17	0.16	0.15	0.14	0.13	0.12	0.11	0.1
Tray Type	11	12	13	14	15	16	17	18	19	20
Frequency of trays/Case	0.09	0.08	0.07	0.06	0.05	0.04	0.03	0.02	<0.02	Vendor

Tray type 1 presents the higher utilization trays and tray type 20 represent the lower utilization or infrequent trays. As the prioritization starts after the decontamination, we might get lower tray flow time for tray type 1 and longer tray flow time for tray type 20 in assembly (pack) stage. As the decontamination stage is less labor intensive and sterilization stage is fully automated, therefore we do not see any relationship between tray types and tray flow times. Figure 7 shows the tray prioritization dynamics in the assembly stage. Now, we aim to investigate the presence of a linear relationship between 'Decon clean to pack receipt' and 'Pack receipt to Prep set'. To accomplish this, we will employ the Pearson correlation coefficient to assess the strength and direction of a linear relationship between these stages. The Pearson correlation coefficient ranges from -1 to 1, where values closer to 1 indicate a strong positive linear relationship, values closer to -1 indicate a strong negative linear relationship, and values close to 0 suggest no linear relationship.

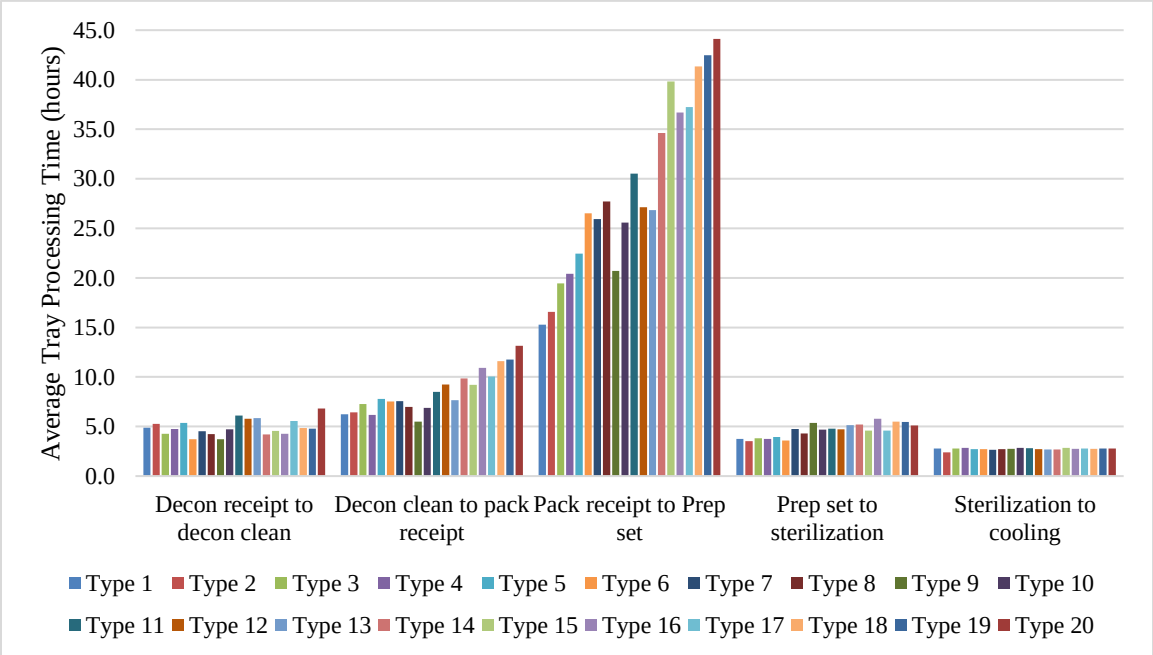


Figure 7: Average tray flow time of different tray types based on frequency of tray usage per case.

For performing a linear relationship test, we formulate the null and alternative hypotheses as follows:

H_0 = There is no linear association between 'Decon clean to pack receipt' and 'Pack receipt to Prep set'.
H_a = There is a linear association between 'Decon clean to pack receipt' and 'Pack receipt to Prep set'.
If p value < α (α = 0.05), Reject H_0 (i.e., There is a linear association)

else, fail to reject H_0 (i.e., No significant linear association found).
After conducting the Pearson correlation test, we find a p-value of every tray types less than the chosen significance level (0.05). Statistical results are presented in table 5.

Table 5: Pearson correlation test results of different tray types between Decon clean to Pack receipt and Pack receipt to Prep set.

Tray Type	1	2	3	4	5	6	7	8	9	10
P value	0.000	0.000	0.003	0.000	0.001	0.000	0.001	0.001	0.003	0.003
Tray Type	11	12	13	14	15	16	17	18	19	20
P value	0.003	0.000	0.000	0.008	0.000	0.000	0.002	0.000	0.000	0.000

We reject the null hypothesis and conclude that there is a statistically significant positive linear relationship between the 'Decon clean to pack receipt' and 'Pack receipt to Prep set'. In other words, as the amount of time spent in 'Decon clean to Pack receipt' increases, the tray flow time in 'Pack receipt to Prep set' tend to increase as well. Categorizing trays by frequency of use does have merit but it does not account for current inventory levels by tray types. For example, a frequently used tray type may have sufficiently large inventory such that tray availability is rarely an issue. With limited staffing in the SPD, trays are often prioritized for cleaning based on when they are needed next. This categorization method does not reflect fully the behavior of the actual SPD system. Therefore, a modified tray categorization method is required, which also considers the inventory level of the tray types.

5 CONCEPTUAL SIMULATION MODEL OF SPD

A DES model can be used to explore SPD performance in various ways. Figure 8 outlines the process of examining the different SPD scenarios within the model. Any element within the DES model may be altered to determine their effects on the output such as tray cycle time, tray time in SPD, case readiness time, time to prepare a case, etc. This option not only allows users to test a wide array of changes but also supports the development of new strategies for SPD. The specific objectives of DES in SPD include tray flow management, improving SPD workflow, managing OR capacity, scheduling surgical procedures, improving staff scheduling, and maximizing resource utilization (e.g., workstations for decontamination, assembly, and sterilization).

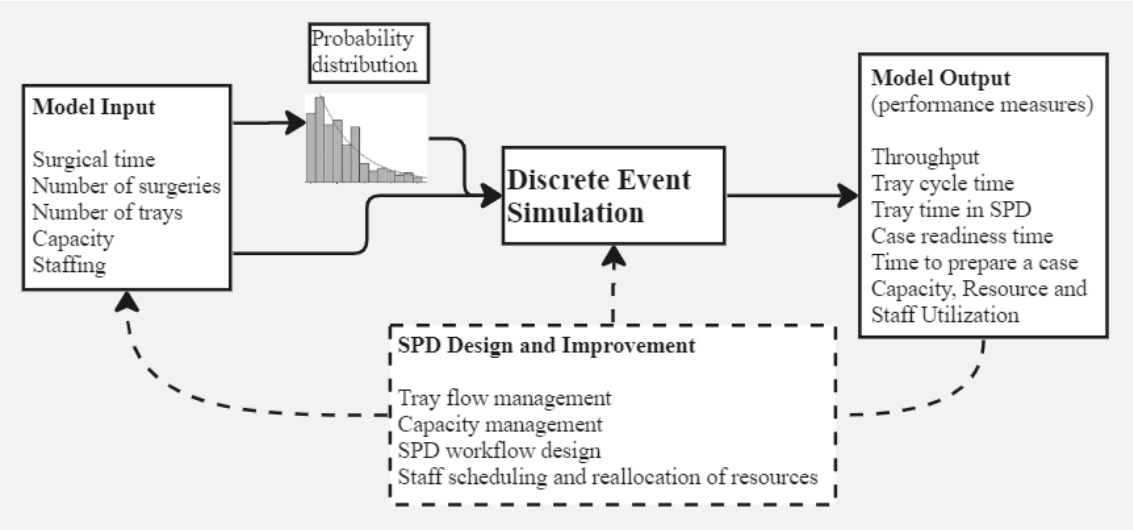


Figure 8: Conceptual DES model for SPD.

6 CONCLUSIONS AND FUTURE WORK

While simulation model development and calibration/validation continue, this study focuses on the interpretation of SPD data and how it can help define the structure of the base model. The simulation is dependent on the data we can obtain, its quality, and our interpretation of it, which relies on the level of robust integration of the instrument reporting software into the work system. Our study revealed that each month, OR personnel requested 4% - 6% of duplicate trays from the SPD. In addition, specialties such as Urology, Orthopedics, Gynecology, and General Surgery are more likely to request additional trays from the SPD. The duplicate tray requests from the OR put extra strain on the SPD personnel. To navigate these challenges, the assembly staff prioritized trays to efficiently manage tray flows, despite staffing issues. Furthermore, the tray categorization strategy based on tray utilization revealed the dynamic nature of the assembly stage within the SPD. Statistical analysis revealed a linear association between 'Decon clean to Pack receipt' and 'Pack receipt to Prep set'. Therefore, a tray prioritization strategy needs to be employed in the simulation model to mimic the operational dynamics of the SPD system.

The construction of this base model represents a significant advancement in our understanding of the complex dynamics involved in sterile processing. As we proceed to the validation phase, our focus is on establishing a robust framework that can effectively simulate and optimize sterile processing workflows. In the context of sterile processing, the challenges posed by duplicate tray requests, replacement needs, and various operational pressures present significant complexities. Additionally, dealing with missing instruments, bioburden, and nonfunctional instruments adds complexity and strain to SPD inventories. These issues make it difficult to clean and process dirty trays and instruments efficiently. To address these challenges, simulation modeling can be used to optimize tray management by providing insights into tray representation, on-time start pressures, and staff shortages. This study attempts to provide insights into the complexity of developing simulation models for sterile processing departments. This study is the first of its kind to address issues in simulation modeling, such as duplicate tray requests, replacement trays, bioburden, missing instruments, non-functional instruments and tray flow dynamics within SPD. In addition, we demonstrate the importance of accurately representing trays in the simulation model to realistically mimic tray processing workflows, including the cleaning, inspection, assembly, and sterilization processes. By incorporating tray data into the simulation, healthcare facilities can optimize resource allocation, streamline workflow management, and identify potential bottlenecks or inefficiencies. Furthermore, accurate tray representation enhances the model's ability to assess the impact of different issues, such as tray shortages, bioburden, or unexpected events, on SPD operations.

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