

Introduction to the Operation Room Management technology: Interrupted Time Series analysis in an urban acute care hospital facility in Rome, Italy

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Parole chiave: Management Sanitario; Blocco operatorio; Chirurgia; Serie temporale; Health Technology Assessment

Abstract

Background. The surgical pathway represents a fundamental process in hospital productivity, and its digitalization is a major focus for hospital management. ASL Roma 1 health authority has taken up this digitalization challenge by introducing an Operation Room Management (ORM) system within the operating block of one of its hospital facilities in 2022.

Study Design. Interrupted Time Series analysis.

Methods. To evaluate the impact of Operation Room Management system adoption, data on surgery were collected from all interventions performed during two periods: January-June 2019 and January-June 2023. Analysis of the Operation Room Management system utilization rate since its introduction was performed, to estimate staff adaptation to the new software.

Results. As of June 2023, paper-registered interventions were 9%, nearing 100% for elective procedures only. The difference between the average intervention times was significantly in favor of the Operation Room Management cohort when restricting the analysis to Orthopedics (-9.02 minutes, $p=0.006$) and Surgery (8.47 min, $p = 0.03$). There was a modest but significant impact of Operation Room Management on the 'entering Operation Room to Incision' time (5 min, $p < 0.01$).

Conclusion. Overall, the adoption of the Operation Room Management did not worsen process outcomes. Operation Room Management offers advantages in real-time data quality, integrated with territorial and hospital platforms, contributing to a favorable cost-benefit assessment of digitalization.

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Introduction

In 2005, the United Nations' World Health Assembly, in its resolution WHA58.28 concerning eHealth, called upon Member States "to consider drawing up a long-term strategic plan for developing and implementing eHealth services". Over 120 member states, including low- and middle-income countries, have joined (1). The recent COVID-19 pandemic has accelerated, in the healthcare world, several processes that were already in place, such as the need for greater proximity of care, environmental sustainability, and the digitalization of healthcare (2-5). The latter point in particular, initially driven by the lockdown and restrictions on mobility, then by the increased digital literacy of the population and the diffusion of "smart" devices, has rapidly become a goal embraced by governments, institutions, and companies (6). Improvement of the Operating Rooms (ORs) efficiency is also an important objective, since they absorb up to 40% of total hospital costs, but represent a major source of revenue (7). Their adequate management is paramount in guaranteeing the most optimal usage of available resources, in terms of personnel, time, and money. For public services, this is the main way to consistently deliver sustainable and high-quality health services to the population, while for private facilities this represents a major focus for marginal profit income (8-11). In recent years, hospital facilities have faced a significant increase in the cost-per-treated patient, particularly for public healthcare systems. Nevertheless, this rise in costs is not proportionate to the overall healthcare expenditure (12). Demographic trends, with an aging population as a well-established tendency (13), and macroeconomic conditions, with a global inflation rate well above the average of the last two decades, are also noteworthy factors (14).

Availability of ORs is also a must in any structure with associated Emergency Department (ED), as its availability represents a necessity for ED functioning, regardless of actual usage. This, on the other hand, means that at least a surgical équipe has to be available 24/7, and as such it is hardly sustainable without an associated surgical ward performing elective procedures. This means that, especially for low-volume centres, even clinical results may be suboptimal. Experiences such as itinerant équipes and partnerships between high- and low- volume centres are still few, but seem overall promising, at least under a clinical perspective, while management should do its best to guaranteeing them to be most effective. (15)

Overall, ORs can be seen as a core function of any hospital facility, even if medically-oriented, to the point that other hospital functions may be impacted (spatially or functionally) by its localization. Moreover, patient inflow and outflow from ORs can also impact on ED and wards performance, representing a factor in beds availability organization. Also, surgical wards may be organized towards day surgery\ week surgery regimens, impacting on personnel allocation and turnation. (16)

Local background

The Local Health Authority (ASL) Roma 1 is the Public Health Authority in charge of the Historical Centre and the Northwestern area of the Metropolitan city of Rome, Italy. It has a resident population of over 1 million, extending on an area of 524.0 km², which is almost 40% of the metropolitan city of Rome (17,18). It hosts 13 hospital structures with operating EDs out of a total of 22 in the Rome metropolitan area (19). It directly manages 3 large hospital structures (Santo Spirito Hospital, San Filippo Neri Hospital, Ophthalmologic Hospital) and two lesser centers for day hospital/day surgery activity (Nuovo Regina Margherita facility, and S. Anna gynecologic center). Three University Hospitals (Policlinico Umberto I, Policlinico Gemelli and Policlinico S Andrea, under a special cooperative management Region Lazio – Universities, all of them with ED, must be added.

Efficient resource management is a key focus, reflected in the integrated organization of various structures. All the Departments and Coordination Areas for related functions (except for EDs) are transversal within the whole Health Authority, and so are many operating units across the several hospital facilities. This transversal approach also includes hospitals staff.

In 2022, ASL Roma 1 decided to fully digitalize operating room functioning, using an Operation Room Management (ORM) software to enable the acquisition and accessibility of data that were difficult, if not impossible, to obtain with traditional paper records. This allows the implementation of a data-driven system capable of collecting field data to provide valuable information, which can implement continuous improvement in the management processes. In this specific case, the ORM software delivers data to clinical staff and administrators related to each surgical procedure, supporting the entire surgical process: planning, preparation, execution, and analysis. Moreover, all elective interventions are performed within assigned "slots" with a scheduled start and

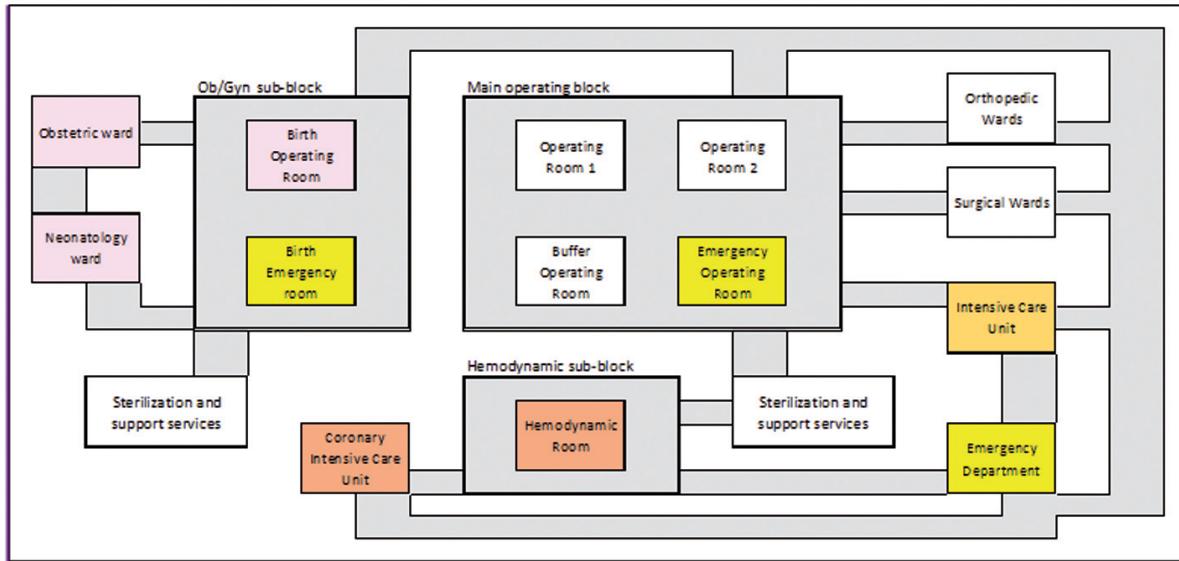


Figure 1 - Hospital Operating rooms functional organization.

end time, distributed among the surgical specialties depending on the volume of patients, and estimated intervention duration. Nursing and Anesthesiology coordinators were crucial in OR slot governance.

In the hospital facility chosen for ORM software implementation, the main operating block has two birth ORs, one hemodynamic OR, and four main ORs, of which one is dedicated to emergency-urgency activities, two to elective surgical activities, and a last one working as “buffer” room (Figure 1).

As for the intra-operative layout, each OR has two panel PCs: one installed on the wall, and one associated with the anesthesia machine. Nursing staff use the wall-mounted panel PC for completing application modules, gauze counts, and nursing checklists. The panel PC connected to the anesthesia machine is used by the anesthetist to record vital parameters and intervention phases. The surgical report is completed by the surgeon on the PC workstation in the operating block immediately after the intervention. Input for ORM may come from both Patient Data Management Systems (PDMS) and Electronic Medical Records (EMR) and integrated systems, such as wearable devices or connected electro-medical machinery (such as Anesthesiology monitors or defibrillators).

The ORM system is not only used for managing patients in the OR but also for preoperative intervention planning. The planning process involves two stages: the creation of operating sessions and their filling. The first phase, which is under the responsibility of the anesthesiologist and the nursing coordinator, defines the

times of the operating slots and the assigned surgical specialty. The second phase, for which the Head of the Operational Unit is responsible, involves inserting patients into the slot of their specialty, defining each day's operating list.

Study objectives

The aim of this study was to describe and evaluate the impact of the introduction of the new ORM system in the ORs of a single acute care hospital in an urban area.

Primary end-points were:

- Technical effectiveness, as per intervention duration;
- Operators' compliance, as per number of interventions correctly registered using the ORM software instead of paper support;

Secondary end-points were:

- Saturation of operating slots;
- Delay in first patient admission to the OR.

Details on end-points and their measurement strategies are shown in Table 1.

Materials and Methods

Study design

This study was conducted as an Interrupted Time Series Analysis using routinely collected data. The analysis was conducted on all surgical activity of the hospital ORs, from January to June 2019, and from

Table 1 - Study end-points and their measurement strategies.

End point	Definition	Measurement
Primary endpoints	Technical efficacy	Intervention duration is equal or less than paper-based recording
	Operators compliance	Attitude to use ORM instead of paper-based recording
Secondary endpoints	Slots saturation	Saturation of operating slots
	Start-time tardiness	Delay in first patient admission to the OR.

January to June 2023. The 2020-2021 period was excluded due to the COVID pandemic having impacted on hospital activity (20-26). Since operators' ORM training began in January 2022, the said year was excluded as any comparison would have been inherently biased.

The data from January to June 2019, pre-dating the introduction of the ORM system, were extracted from the internal database managed by the Nurse Coordinator of the operating block. This database, faithful to the paper registry, requires manual data entry at the end of each working day and contains information for each intervention, including patient demographics, intervention setting (urgent or elective), intervention type, intervention date and progressive number, OR number, and timing details of various phases. This registry was also used as a rescue source, collecting data on interventions that, for some reason, were not recorded via ORM software (usually emergency ones). Intervention types were coded as per the International Classification of Diseases v. 9 – Clinical Modification (ICD9-CM).

From the ORM interventions database, the following information were retrieved:

- Intervention start time;
- Intervention end time;
- OR location;
- Intervention specialty type;
- Intervention assigned slot;
- Slot total duration.

From these variables, the percentage of ORs saturation per operational unit (OU), intervention duration (time from the first incision to the last suture), and time from entering the OR to the actual beginning of the procedure were calculated. Slot saturation, defined, for each specialty/type, as the ratio between total actual OR usage and total duration of assigned slots, represents a good indication of efficiency for that particular specialty or type of intervention. This

value is usually considered acceptable when around 80% (27).

Statistical Analysis

Statistical analysis was performed using Stata v. 17.0 (StataCorp. College Station, TX, USA; <https://www.stata.com>; 2021). Descriptive analysis was conducted for quantitative variables by calculating mean and standard deviation (SD) and providing relevant graphical representations. Welsh t-test was used to test the association between certain variables when comparing two samples with potentially unequal variances and sample sizes. A time series analysis on intervention durations in the two different periods considered was conducted using a linear regression model to highlight potential differences in the temporal trend. The same procedure was used to verify potential differences in the time interval between entering the operating room and starting the intervention.

For the 2019 surgery group, interventions that were not performed (n=2), interventions with missing room exit time (n=4), those with missing incision start time (n=7), and interventions with missing entry room time (n=4) were excluded. The intervention time analysis was conducted on three groups: the first group included all interventions from the first semester of 2019 and the first semester of 2023 (TOT), while the second and third groups included interventions only for orthopedics (ORT) and surgery (CHIR) specialties, respectively, within the same time frame.

To assess the impact of using the ORM software on intervention duration concerning individual operational units, a multivariate linear regression model was employed, using individual operational units as covariates and intervention duration as the independent variable. The null hypothesis was that there was no difference between the paper-based group and the ORM group.

The STROBE guideline was used for study

reporting (28). Statistical significance level was set at $\alpha=0.05$ for all inferential analysis.

Results

Primary endpoints

During the first six months of 2019, 1,373 interventions were performed, of which 316 (23%) were urgent. In the same period in 2022, 1,294 interventions were performed, of which 281 were urgent (22%). Details on the interventions, divided by subspecialty, are available in Table 2. Pearson's χ^2 test shows no significant difference between the intervention volumes ($p = 0.227$). Figure 2 represents interventions timing pre- and post- ORM introduction, by specialty.

The results of the analysis are described in **Table 3**. Overall, there are no statistically significant differences in intervention times between the first semester of 2019 (paper) and the first semester of 2023 (ORM); the average for each intervention is approximately 83 minutes. Intervention times for all specialties are represented in Figure 1. Focusing the analysis on the units producing higher volumes (Orthopedics and General Surgery, responsible for 57% of all interventions), an average reduction of 9.02 minutes (95% CI 1.96 – 16.08) for Orthopedics and 8.47 minutes (95% CI -0.31 – 17.25) for General Surgery was found.

Table 2 - Intervention numbers during the study period, by specialty type (wards indicated with * closed after 2019).

Specialty	2019	%	2023	%	Total	%
Anesthesiology	60	4,37	89	6,88	149	5,59
Cardiology	101	7,36	142	10,97	243	9,11
Gen. Surgery	320	23,31	303	23,42	623	23,36
Gastroenterology*	8	0,58	-	-	8	0,30
Gynecology	142	10,34	102	7,88	244	9,15
Orthopedics	438	31,90	452	34,93	890	33,37
Obstetrics*	79	5,75	-	-	79	2,96
Plastic Surgery	28	2,04	27	2,09	55	2,06
Breast Surgery	197	14,35	179	13,83	376	14,10
Total	1373		1294		2667	

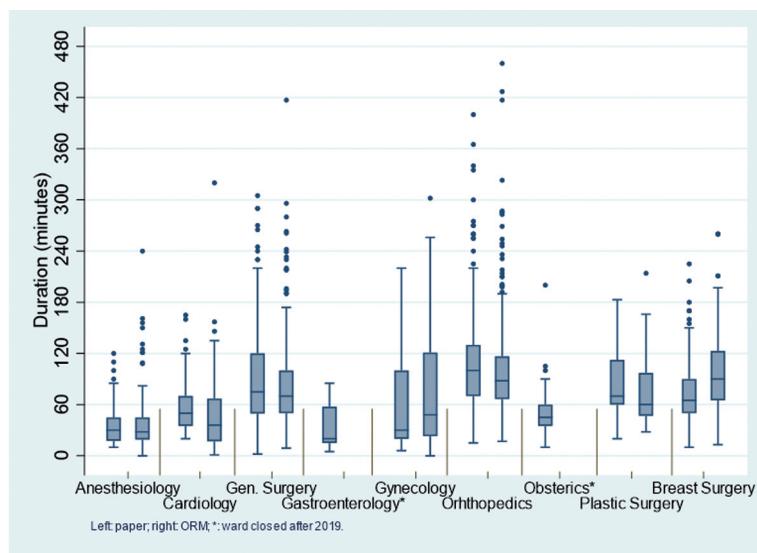


Figure 2 - Box plot of intervention times by specialty. Left: paper-based. Right: ORM based.

Table 3 - Mean of interventions duration, overall and for Orthopedics and General Surgery.

Overall:	N	Mean (min)	SD (min)	95%CI (Min)
Paper	1373	82.72	53.25	79.90 – 85.54
ORM	1294	83.09	55.04	80.09 – 86.09
DELTA	79	-0,37		-4.49 – 3.74 (p=0.570)
Orthopedics:	N	Mean (min)	SD (min)	95%CI (Min)
Paper	438	107.82	53.36	102.81 – 112.83
ORM	452	98.80	53.91	93.81 – 103.78
DELTA	14	9,02		1.96 – 16.08 (p=0.006)
General Surgery	N	Mean (min)	SD (min)	95%CI (Min)
Paper	320	91.40	58.79	84.93 – 97.86
ORM	303	82.93	52.80	76.96 – 88.90
DELTA	17	8.47		-0.31 – 17.25 (p=0.029)

A multiple regression analysis was then conducted between all paper-based interventions (2019) and all OMR-based interventions (2023), considering the intervention times of individual units (Table 3). Multivariable analysis did not reveal differences in intervention times between paper-based and OMR-based interventions.

Regarding operators' compliance, **Figure 3** represents ORM adoption trend within the operating block. It is evident that the majority of interventions still registered on paper in the first semester of 2023 regards urgent activities (n=96), while the use of ORM software for elective activities was close to 100%.

The timeframe between the entry time into the OR and the start of the surgery for the 2019 intervention group was analyzed compared to that of 2023 to assess the impact of ORM on pre-incision activities. In this analysis, operative units were not considered as the different types of intervention do not influence preoperative activities, performed by block personnel and not by operative unit personnel. A modest but statistically significant impact of the ORM system in the pre-incision phase was found, with an increase of approximately 5 min of phase duration ($p < 0.001$).

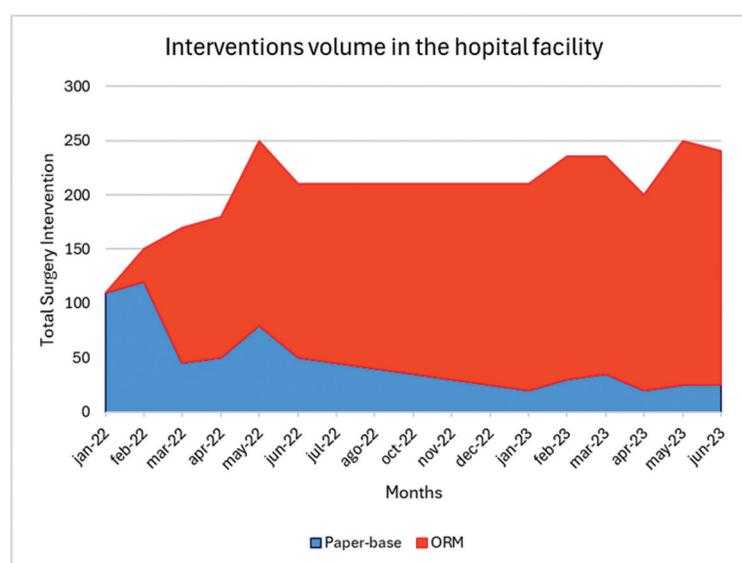


Figure 3 - Interventions volume in the hospital facility since January 1st, 2022. Blue: paper-recorded procedures. Red: ORM-recorded procedures.

Secondary endpoints

Data on the total intervention duration and the total assigned slot time were retrieved from the ORM system, by operating unit. The saturation percentage (sum of intervention times/total assigned slot duration) was then calculated. Unfortunately, this data was available only for 2023 since it was not recorded before ORM adoption. The results are synthesized in Table 4.

The Start-time delay represents the average time-frame between the time of entry into the OR of the first patient and the scheduled start time of the session. Its recorded values data are illustrated in Table 5, divided by surgical specialty. Again, this data was available only for 2023 since it was not recorded before ORM adoption.

Discussion and conclusions

Main Findings

After one-year since the adoption of the ORM system, the percentage of paper-based interventions has dropped below 10%, approaching 0% for elective procedures. However, some challenges persist in emergency/urgency activities, characterized by tighter timelines and inherently more hectic activity. Indeed,

in emergency OR activities one-third of interventions still miss digital record. Nonetheless, the remarkable increasing of the ORM software usage, one year after its implementation, even for emergency/urgency interventions, highlights the critical role of personnel training in introducing new technologies and tools. This trend also suggests the potential for a complete digitalization of operating room processes, in line with eHealth transition.

In addition, the ORM system adoption had a marginal and non-detrimental impact on OR timings. This result is confirmed by multivariate analysis in an organization that, as indicated by the distribution of the number of interventions per operating unit, has remained unchanged. The analysis of intervention duration in the two units with higher surgical activity and complexity in the operating block (Orthopedics and General Surgery) has shown a slight improvement in intervention times (Table 3). The analysis of the intervening period between entry time to the OR and the start of surgery, less dependent on the type of surgery performed, shows a small difference in the pre-incision phase between the ORM group and the paper-based group. This result reinforces the concept that healthcare professionals require continuous and regular training to maximize the efficiency of the digital process (29).

Table 4. -Saturation rate of the operating block between January and June 2023, divided by specialty type.

Specialty	Scheduled slot Duration (min)	Total intervention Duration (min)	Saturation
Anesthesiology	7,200	4,295	59.65%
Cardiology	13,675	6,912	50.54%
General surgery	34,499	29,916	86.72%
Plastic surgery	4,075	2,904	71.26%
Breast surgery	23,676	15,807	66.76%
Gynecology	14,880	10,311	69.29%
Orthopedics	75,946	65,574	86.34%

Table 5 - Average start-time delay between January and June 2023, by specialty type.

Specialty	Average start-time delay	St.Dev.	N
Anesthesiology	48.26	13.44	19
Cardiology	44.87	33.34	38
General surgery	59.86	30.52	56
Plastic surgery	129.10	73.00	10
Breast surgery	75.11	61.92	46
Gynaecology	51.74	12.19	23
Orthopedics	53.07	28.50	122

The introduction of the ORM software does not seem to have brought a concrete alteration to intraoperative times. However, cost-benefit considerations cannot be limited to the intraoperative phase. The patient's surgical pathway is far from the "first come, first served" concept, as it is influenced by numerous clinical and organizational variables that impact times and outcomes (30,31). Additionally, the impact of the ORM software cannot be overlooked from a management perspective. The availability and standardization of data enable a quantitative evaluation of the impacts of organizational measures on the OR ecosystem, better management of operating slots, and more effective identification of process criticalities (missed interventions, unsaturated sessions).

Conclusions

This is among the few studies that investigate the effects of organizational changes in an operating room using real-world data. One of the study limitations is the impossibility, due to the nature of non-standardized 2019 data, to adjust the analysis for the type of surgical intervention according to the ICD9-CM code. Attempts were made to mitigate the bias by adjusting the data for individual operating units, assuming that similar types of interventions were performed within the same operating unit during both periods. Secondly, the 2019 data, generated through periodic manual data entry, is inherently of lower quality compared to ORM data, and are therefore more prone to random errors.

Another correction that cannot be applied is related to the intervention's regime (urgent, emergency, and elective) for saturation calculation, as the mixed nature of the organization of the ORs in the hospital does not allow for a correct estimation of the denominator in case of excluding urgent interventions. For the same reason, it was not possible to compare the 2019 saturation with the 2023 saturation, as the 2019 denominator data is exclusively based on elective activities. The specific distribution of surgical activities in the operating block, with a mix of urgent and elective interventions in the same room and shared rooms across multiple specialties, would have made room saturation monitoring and identifying criticalities impractical. Saturation is thus an indicator that cannot be abstracted from the surgical pathway context.

Access to high-quality, real-time data integrated across all territorial and hospital platforms is a linchpin in governing healthcare processes to meet the

population's health needs (32). Increasing efficiency is essential for the future sustainability of any healthcare system, particularly the Italian National Health Service. An ORM system is a versatile and crucial tool in healthcare management, serving both the medical-nursing component to improve the quality of care, and the management component for processing analysis, identifying critical issues, and assessing the impact of adopted solutions. Ideally, once the software is integrated with an electronic clinical record, OR risk related to clinical conditions or ongoing therapy can be further monitored and, hopefully, reduced (33-35).

On the other hand, it should not be overlooked that digitalization inevitably creates a new critical node within the process, consisting of the combination of software and hardware. This requires a dedicated and cross-cutting approach in both training and organizing the entire structure. Services that were initially auxiliary in the organization, such as ICT, start to play a central and fundamental role in even the most basic care functions. Nevertheless, any new hardware and/or software introduction brings also multi-faced challenges, such as network malfunctions and program crashes/malfunctions which cause delays in the procedures and require extraordinary maintenance and support interventions. Adjustments to the presence of the new tool in established procedures also demanded modifications to the program and considerable organizational efforts. One of the main challenges that may arise with the introduction of a new digital tool, especially if the digitalization is entirely new and starts from an analog (paper-based) process, is the potential resistance from staff toward adopting new technologies, especially for non "digital natives," who might experience additional stress from using electronic devices. However, studies have shown that the ability to use digital and computer tools does not necessarily depend on the degree of digital literacy (29). Looking towards the future, we expect technology to play a more significant role in operating room scheduling and optimization, just as it is currently impacting on physicians' activity in both intra- and extra- hospital settings (36,37). Advanced software solutions, predictive analytics, and artificial intelligence will likely streamline the process further, enabling more precise and efficient scheduling. Additionally, healthcare facilities will continue to explore innovative ways to maximize resource utilization and deliver high-quality surgical care to an increasingly diverse patients' population.

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Conflicts of Interest: The authors declare no conflicts of interest.

Riassunto

Introduzione alla tecnologia di gestione digitale della sala operatoria: Serie temporale interrotta in un ospedale per acuti di Roma

Premessa. Il percorso chirurgico rappresenta un processo fondamentale nella produttività ospedaliera e la sua digitalizzazione è un obiettivo importante per la gestione ospedaliera. L'ASL Roma 1 ha affrontato questa sfida introducendo un sistema di Operation Room Management nel blocco operatorio di una delle sue strutture ospedaliere nel 2022.

Disegno dello studio. Analisi delle Serie Temporali Interrotte.

Metodi. Per valutare l'impatto dell'adozione del sistema Operation Room Management, sono stati raccolti dati sugli interventi chirurgici eseguiti durante due periodi: gennaio-giugno 2019 e gennaio-giugno 2023. È stata eseguita un'analisi del tasso di utilizzo del sistema Operation Room Management dalla sua introduzione per stimare l'adattamento del personale al nuovo software.

Risultati. A giugno 2023, gli interventi registrati su carta erano il 9%, raggiungendo quasi il 100% per le sole procedure elettive. La differenza tra i tempi medi degli interventi è risultata significativamente a favore del gruppo Operation Room Management quando l'analisi è stata ristretta a Ortopedia (-9,02 minuti, p=0,006) e Chirurgia (8,47 minuti, p=0,03). L' Operation Room Management ha avuto un impatto modesto ma significativo sul tempo "ingresso in

sala -incisione" (5 minuti, p < 0,01).

Conclusione. Complessivamente, l'adozione dell'Operation Room Management non ha peggiorato i risultati del processo. L'Operation Room Management offre vantaggi in termini di qualità dei dati in tempo reale, integrati con le piattaforme territoriali e ospedaliere, contribuendo a una valutazione costo-beneficio favorevole della digitalizzazione.

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