Health economic evaluation of a clinical pharmacist's intervention on the appropriate use of devices and cost savings: A pilot study

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Health Economic Evaluation

Health economic evaluation of a clinical pharmacist's intervention on the appropriate use of devices and cost savings: A pilot study

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ABSTRACT

Background: Good management of disposable and reusable supplies may improve surgical efficiency in the operating room (OR) and also corresponds to the best eco-responsible approach. The purpose of this study was to assess the impact of a clinical pharmacist's intervention in the OR on the non-compliant use of medical devices. We also assessed the economic impact of the pharmaceutical intervention.

Materials and methods: We conducted a monocentric prospective study in the OR of a University hospital over one year. Three surgical specialties: urologic, digestive and gynecologic were audited after a preparatory phase to optimize usage of medical devices used for surgeries. The supply costs concerning the three specialties were compared before and after the pharmacist intervention.

Results: One hundred and fifty surgical procedures were audited in digestive (33.3%, n = 50), gynecologic (32%, n = 48) and urologic (34.7%, n = 52) surgeries. With the pharmacist in OR, 51 procedures (34% CI95%[26.4%; 41.6%]) with a non-compliance concerning at least one medical device were found compared to the 50% rate without the pharmacist reported previously (P < .0001). Eighteen percent of surgical procedures had at least one circulator retrieval for the reason "incomplete case cart despite device listed on the case cart list" versus 29.1% before pharmacist intervention (P = .0028). A €33 014 saving associated with the presence of the pharmacist in OR was observed.

Conclusions: This prospective interventional study showed that the intervention of a pharmacist specialized in the medical device field could significantly reduce non-compliances in medical device use and reduce costs in OR.

1. Introduction

The operating room (OR) is a major source of hospital expenditure, responsible for about 60% of total hospital cost [1]. After staff, equipment and premises cost, medical supplies represent a significant proportion of expenditures. The continual launch of new technologies contributes to increase healthcare cost. Moreover, as the medical device market is in constant evolution, on-going operator training is essential to ensure the correct use of devices and patient safety.

Several strategies have been developed to reduce OR expenditure, such as standardization of the operative equipment, which would lead to a 20%–32% average reduction in supply cost [2,3]. This strategy depends upon all surgeons agreeing to use the same supplies. Another strategy consists of changing physician behavior through cost transparency efforts by presenting cost feedback to surgeons [4–6]. Zygourakis et al. showed that cost feedback combined with a departmental financial incentive significantly reduced surgical supply costs (9.95% decrease in the intervention group (95% CI, 3.55%–15.93%; P = .003)),

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without negatively affecting patient outcomes (30-day readmission, 30-day mortality, and discharge status) [7].

Nurses should not waste valuable time during surgery outside the OR. Indeed, lack of available supplies requires emergency retrieval that causes additional labor costs, delays in patient treatment and potentially life-threatening situations. Missing products can cause the circulator to spend almost 27% of the operating time outside the OR locating supplies [8].

Good management of disposable and reusable supplies could improve surgical efficiency in the OR and offers the best eco-responsible approach. The increasing number of publications on the management of surgical supplies reflects the growing interest of researchers in this issue [9].

In French hospitals, one of the pharmaceutical roles is to manage, supply, control and dispense medical devices. Pharmacists are heavily involved in all actions concerning the appropriate use of sterile medical devices [10]. It would therefore be appropriate for the pharmacist to work more closely with operators in the field. We hypothesized that the presence of a clinical pharmacist specialized in medical devices in the OR would improve appropriate use, rationalize consumption and optimize surgical cost. The purpose of this pilot study was to perform a preliminary assessment of the health economic impact of a clinical pharmacist's intervention in the OR.

The main objective was to evaluate the benefit of a clinical pharmacist's intervention on the quality of medical device management in the OR. The second objectives were to assess the economic impact of the pharmaceutical intervention and staff satisfaction.

2. Methods

2.1. Study design

We conducted a monocentric prospective pilot study in the OR from November 2017 to October 2018. This study was approved by the Institutional Review Board of the University Hospital (N° 18.06.04). This study has been reported in line with the CHEERS criteria.

Three surgical specialties were selected due to their high volume of surgical activity (42% of the total surgical activity of the hospital): urologic, digestive and gynecologic (UDG) surgeries. Surgical procedures investigated were those with the highest frequency. An extraction of the most frequent surgical procedures of UDG surgeries was performed with the OR software (OPERA® v5.1).

2.1.1. Preparatory phase

The study started with a five-month preparatory phase between November 2017 and March 2018. For each surgical procedure investigated, the pharmacist created/updated the case card list through meetings with nurses, the healthcare executive and surgeons. The purpose was to create a unique exhaustive file that could be used by any nurse to prepare/assist the surgical procedure in the best conditions. All the device names were recorded using the hospital supply catalog (not brand name) to improve the device order process. Once a consensus was obtained on the devices used, each case card list was first tested during a surgery with nurses and surgeons independent from those involved in creating/updating the list. Consumption of some devices was analyzed to optimize the stocking in OR and thus costs. Protocols were drafted to ensure the best use of some devices according to national or supplier recommendations, as appropriate.

The specific actions of the preparatory phase were to create/update institutional documents based on medical device needs and their use in surgery. Other actions, such as feasibility of switching from a reusable to a single use device, daily traceability checking of implantable devices, or management of supply disruptions, were common to both the preparatory and interventional phases.

2.1.2. Interventional phase

The seven-month interventional phase between April to October 2018 consisted of evaluating the measures and actions taken during preparatory phase by auditing surgeries. Thus, the pharmacist was present in the OR to audit surgeries with a new case card list or protocol and record data for the primary objective of the study.

Both phases of pharmaceutical interventions are described in Table 1.

2.2. Outcomes

The primary outcome was to assess the non-compliance in the use of medical devices. Surgical procedures were considered non-compliant in the event of at least one of the following criteria: traceability error of an implantable medical device; absence of supplies in OR during surgery; lack of information concerning the medical supplies (e.g. supply disruptions); or a non-respect of good practice guidelines for the medical devices concerned. Retrievals for supply reasons were standardized as follows: incomplete case cart; additional demand from the surgeon due to clinical/anatomical hazard; aseptic mistake; defective or incomplete supplies; need for a new implant due to a size error or implant placement failure; and other reason. The non-sterile supplies and the supplies used by the anesthetists were not included within the scope of the audit. At the end of the study, the number of surgical procedures where the circulator had to exit the OR to retrieve a product at least once due to incomplete case cart was compared against our earlier study (prior to pharmacist intervention) [8].

Secondary outcomes were the cost of overall consumption of sterile medical devices used in UDG surgeries before and after the pharmaceutical intervention from the perspective of the hospital. The supply costs concerning the three specialties involved from November 2016 to October 2017 (before the clinical pharmacist intervention) were compared to those from November 2017 to October 2018 (clinical pharmacist presence in the OR).

At the completion of the study, all UDG surgeons and nurses were asked to complete an anonymous survey of eight questions regarding

Table 1
Pharmacist's interventions in OR.

Type	Task
Surgery preparation	Update/create case cart lists for surgical procedures through multidisciplinary interactions with nurses and surgeons (including new medical devices based on market and technology changes)
Database and traceability	Update/create institutional guidelines through multidisciplinary interactions with nurses and surgeons (including health authority or institutional recommendations)
	Daily traceability checking of implantable medical devices
New devices or change in use	Analysis of each new device needed (technical/price analysis, tests, referencing strategy)
	Feasibility study (technical, logistical, economical) when surgeons wanted to modify the use of a medical device (*i.e* single use to reusable medical device)
	Staff support in OR during medical device tests throughout tender procedures
	Ensure compliance of utilization criteria of specific innovative medical device as they were validated in institutional commission (i.e hospital stay coding)
	Communication with staff and training in the use of new medical devices
	Suggest ways of optimizing the use of medical devices
Contact central pharmacy	Management of supply disruptions (information, alternative solution)
	Provide a direct link with the Sterile Processing Department
Rationalization	Rationalization of the number of medical devices based on a consumption analysis
	Raise the awareness of medical staff about medical device prices and waste

their perceptions about the presence of the clinical pharmacist and the actions taken for the medical device use.

2.3. Data collection

For the audited procedures, data were collected through direct observation by a trained pharmacist independent from the pharmacist who performed the preparatory phase. To limit observation bias, only the department heads were aware of the data collection and the purpose of the study. The audited surgeries were non-selected: each day the auditor observed the maximum number of surgeries according to the schedule available the day before on the OR software. As only one pharmacist was present, the audited surgeries for each surgical specialty were not consecutive. The observer was present from the entrance of the patient into the OR until their exit after surgery. The observer recorded the non-compliance in use of medical devices and the circulator's retrievals.

To avoid bias, the supply costs were provided from the institution supply catalog, which reflects negotiated prices in 2018. The extraction of the ordering devices and their related costs was performed with CPAGE® v208.000. All the devices used specifically by the three surgical specialties involved in the study were included. For supplies used by all specialties (*e.g* surgical drapes), we applied a rate of 42% to collect the data, which reflected the frequency of the UDG surgery activity in the hospital. The costs of some devices were not included due to their specific method of financing (e.g. innovation funding or specific reimbursement by the health insurance). Economic data were measured against the surgical activity from both periods.

The satisfaction survey was created by five pharmacists and then validated by a surgeon and a healthcare executive both independent from the UDG services. The survey was completed at the end of the study to avoid contamination bias. Surgeons and nurses were asked to provide information including satisfaction about the way the pharmacist helped the medical device management, about the updated case cart lists, and about the information improvement on the medical devices. Finally, they were asked if they wanted to maintain the intervention of the clinical pharmacist in the OR.

2.3.1. Study size

Based on our previous pilot study, we assumed that in routine surgical practices without the pharmacist in the OR, the rate of non-compliance with medical device use would be 50% [8]. To detect an absolute reduction of 25%, with a two-sided test, an alpha risk of 5% and a precision of 7%, the number of procedures audited would be 147. Sample size calculation was performed using RCoreTeam® v3.4.3.

2.3.2. Data analysis

Statistical analysis was performed with SAS® institute software, Cary, NC, USA v9.3. The distribution of surgery type is reported as counts and percentages. The rate with 95% CI of non-compliance in the use of medical devices was estimated among the audited procedures. This rate was compared to the 50% estimated rate without pharmacist intervention with a Chi-square test. We estimated the total cost with and without pharmacist intervention and the difference between groups. The total cost was related to activity to estimate a cost per procedure. The satisfaction survey was described with counts and percentages. P-values less than 0.05 were interpreted as statistically significant for two-sided tests.

3. Results

3.1. Non-compliance of medical device usage

One hundred and fifty surgical procedures were observed between April to October 2018 in digestive (33.3%, n = 50), gynecologic (32%, n = 48) and urologic (34.7%, n = 52) surgeries. Of these, 51 procedures (34%; 95%CI[26.4%; 41.6%]) had one non-compliance concerning at least one medical device. This is significantly less than the 50% rate estimated without the pharmacist in the OR (P < .0001) (Table 2).

Among the 51 non-compliant procedures, no "traceability error of an implantable medical device" was observed. Two "lack of information" concerning the medical device (3.9%) and one "non-respect of good practice guidelines" (2%) for the medical devices concerned were observed. The 48 remaining non-compliant procedures (94.1%) concerned an "absence of medical device in OR" and led to 72 circulator's retrievals. Most (66.7%) required only one exit, but nine (18.7%) required two exits, six (12.5%) required three exits and one (2.1%) required four exits. The reasons of these retrievals were: incomplete case cart (n = 33, 45.8%), additional demand from the surgeon due to clinical/anatomical hazard (n = 16, 22.2%), defective or incomplete supplies (n = 11, 15.3%), aseptic mistake (n = 4, 5.6%), need for new implant due to a size error or implant placement failure (n = 6, 8.3%) and other reason (n = 2, 2.8%) (Fig. 1).

There were 27 (18%) surgical procedures with at least one circulator retrieval for the reason "incomplete case cart despite listed on the case cart list". This is a significant reduction in comparison to our first study, which showed that of the 55 procedures audited, 16 procedures (29.1%) were for this motif (P=.0028) (Table 2).

3.2. Economics data

From November 2016 to October 2017, prior to the presence of the pharmacist in the OR, the total cost of medical devices bought for UDG surgeries was €2 982 765. From November 2017 to October 2018, the total cost of medical devices was €2 949 751, representing a €33 014 saving during the presence of the pharmacist in OR. Thus, the mean cost per procedure was €350.95 before *vs* €342.52 after (decrease of 2.4%).

Table 2
Non-compliances of medical device usage.

	Before pharmacist intervention[a] N = 55 procedures	After pharmacist intervention N = 150 procedures	P value
Non-compliances	**n=35**	**n= 51**	
Traceability error	2 (3.6%)	0	
Lack of information on the medical device	2 (3.6%)	2 (1.3%)	
Non-respect of the good use guidelines	3 (5.5%)	1 (0.7%)	
Absence of medical device in operating room	28 (50.9%)	48 (32%)	
Non-compliance rate	63.6%	51 (34%)	
Rate of surgery with at least one non-compliance[b]	50%	51 (34%)	**<0.0001**
Institutional recorded undesirable event linked to medical device management (over one year)	**6**	**1**	
Surgical procedures with at least one circulator retrieval for the reason "incomplete case cart despite listed on the case cart list"	16 (29.1%)	27 (18%)	**0.0028**

[a] From https://doi.org/10.1016/j.ijsu.2018.02.004.
[b] The "before" period did not evaluate the number of surgeries with at least one non-compliance. The 50% rate corresponds to the hypothesis used for sample size estimation. During the "after" period, a procedure could have multiple non-compliances.

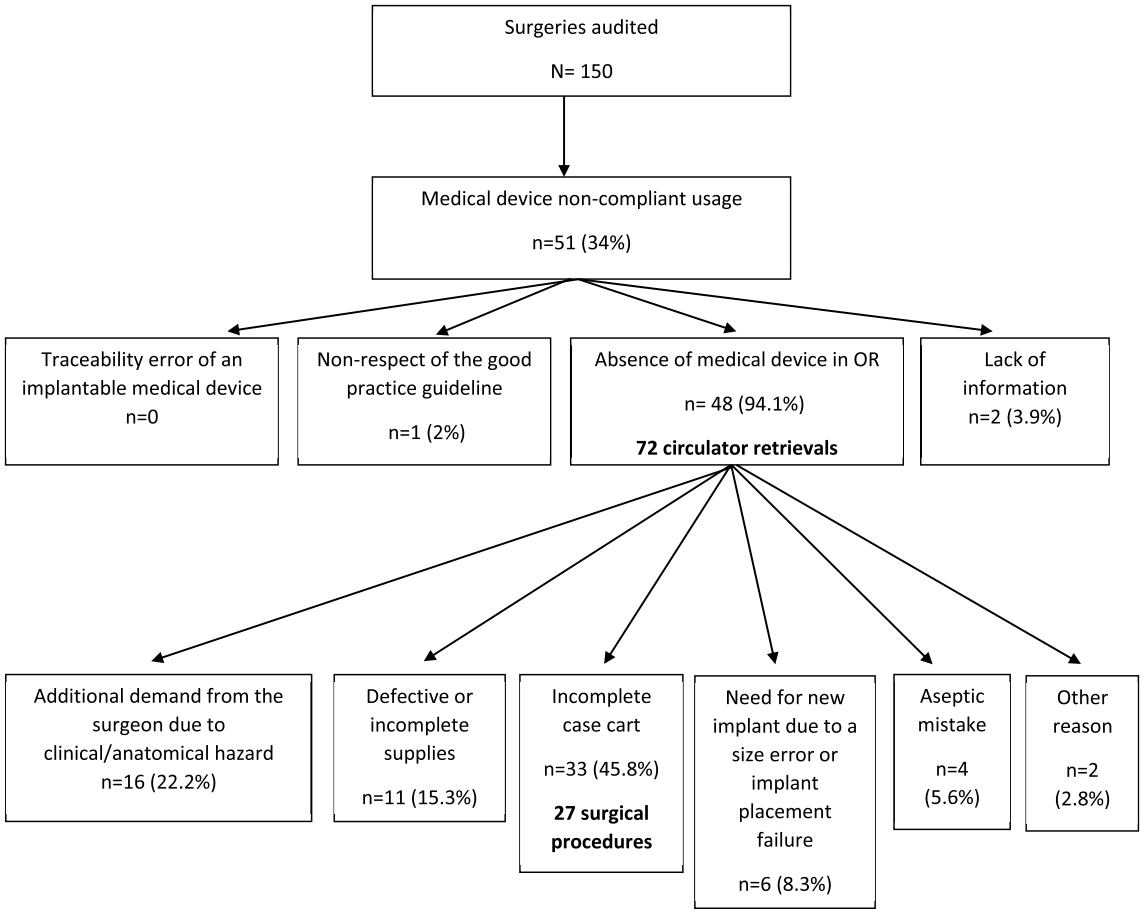

Fig. 1. Non-compliant use of medical devices and reasons for circulator's retrievals.

3.3. Satisfaction survey

Of the 32 participants surveyed, 22 (68.8%: 12/15 nurses, 9/16 surgeons, 1/1 healthcare executive) responded to the survey (Table 3). Of the total respondents, 55% were nurses, 41% were surgeons and 4% was the healthcare executive. To the question "are you satisfied with the management help of medical devices by the pharmacist in OR?" most of the participants (n = 19, 95%) replied "very satisfied" or "satisfied". Most of the participants agreed that the pharmacist in OR improved the accessibility to medical device information for the nurses (n = 22, 100%) and for the surgeons (n = 21, 95%). Twenty-one (95%) participants thought that the presence of a pharmacist in OR improved the quality of patient care. All responders answered positively (n = 19, 100%; 3 missing answers) to the question "do you want the pharmacist intervention in the OR to be maintained?".

4. Discussion

Our study showed that the intervention of a pharmacist in the OR for one year was associated with a significant reduction in the number of procedural non-compliances for medical devices, including traceability errors of an implantable medical device, absence of supplies in OR, lack of information concerning the medical supplies or a non-respect of the good practice guidelines for the medical devices. It also showed that creating/updating multidisciplinary case cart lists was associated with a significant reduction of circulator retrievals during surgeries. The intervention of a pharmacist reduced medical device expenditure in the OR. Although the percentage decrease per case was small (−2.4%), it led to substantial savings of €33 014 for one year in three surgical departments.

Regarding the procedural non-compliances for medical devices, no traceability errors of implantable device were observed during the audited surgeries, demonstrating how avoidable regulatory failures (health, financial and procurement risks) are. Detected traceability errors imply additional labor costs; undetected traceability errors carry serious consequences for both the patient (in case of quality error, batch recall) and the hospital (logistic and financial issues). The low rate of "lack of information on the medical device in OR" reports (*i.e* new devices due to market and technology change or stock shortage) showed that intervention by a medical device specialist improved the communication between the surgeons and nurses. It is important for OR staff to know how to use a new device to prevent wasted time and unnecessary risk for the patient. Similarly, multidisciplinary work with surgeons, nurses and a pharmacist ensured that institutional good practice guidelines were followed in OR by the staff.

The most frequent non-compliance observed was the absence of the medical device in OR (94%). The errors "additional demand from the surgeon due to clinical hazard" (22.2%) or "size error or implant placement failure" (8.3%) are unpredictable and difficult to reduce. However, it is possible to prevent "incomplete case cart" (45.8%), "defective or incomplete supplies" (15.3%) (most commonly corresponding to trays from the sterile processing department) or "aseptic mistake" (5.6%) by regular reminders to the staff. Diffusion of standardized case care lists would significantly reduce the lack of available supplies in OR during surgery, as shown by our significant improvements compared to our first study [8]. Indeed, the potential adverse outcome of a lack of available supplies in OR requires quick rectification, increasing labor costs, delays in patient treatment and potentially life-threatening situations for the patient.

Preference cards are lists including the quantity of all items required

Table 3
OR staff perception survey.

	Total	Surgeons	Nurses and healthcare executive
	(n = 22)	(n = 9)	(n = 13)
Are you satisfied with the management help of medical devices by the pharmacist in OR?			
Very satisfied	15 (75%)	8 (89%)	7 (64%)
Satisfied	4 (20%)	1 (11%)	3 (27%)
Not really satisfied	1 (5%)	0	1(9%)
Not at all satisfied	0	0	0
No response	2	0	2
Does the presence of a pharmacist in OR improved the quality of patient care?			
Yes, a lot	15 (68%)	7 (78%)	8 (62%)
Yes, a bit	6 (27%)	2 (22%)	4 (30%)
No, not at all	1 (5%)	0	1 (8%)
Does a pharmacist in OR improve the accessibility to the medical devices information for the nurses?			
Yes, a lot	17 (77%)	9 (100%)	8 (62%)
Yes, a bit	5 (23%)	0	5 (38%)
No, not at all	0	0	0
Does a pharmacist in OR improve the accessibility to the medical devices information for the surgeons?			
Yes, a lot	15 (68%)	8 (89%)	7 (54%)
Yes, a bit	6 (27%)	1 (11%)	5 (38%)
No, not at all	1 (5%)	0	1 (8%)
Does a pharmacist in OR improved the communication between the OR and the sterile processing department?			
Yes, a lot	12 (55%)	6 (67%)	6 (46%)
Yes, a bit	6 (27%)	3 (33%)	3 (23%)
No, not at all	4 (18%)	0	4 (31%)
Are you satisfied with the case card lists' improvements?			
Very satisfied	11 (50%)	3 (33%)	8 (62%)
Satisfied	11 (50%)	6 (67%)	5 (38%)
Not really satisfied	0	0	0
Not at all satisfied	0	0	0
Does the presence of a pharmacist in OR improved the security of the medical device circuit?			
Yes, a lot	13 (59%)	7 (78%)	6 (46%)
Yes, a bit	9 (41%)	2 (22%)	7 (54%)
No, not at all	0	0	0
Do you want the pharmacist intervention in the OR to be maintained?			
Yes	19 (100%)	9(100%)	10 (100%)
No	0	0	0
No response	3	0	3

by the surgeon in the OR for a given procedure. Our center does not use preference cards, instead using standardized case cart lists. Preference cards gather the devices for one surgeon, whereas case cart lists gather the devices for one surgery. For each surgical procedure, the case card list includes an illustration of the patient position on the operating table, and the name, quantity and localization of each device in the different OR stores. All devices are described using the generic name corresponding to the institutional names that can be found by all the staff involved in the supply chain (logistic, pharmacy, nurses and surgeons) and for the traceability. As market changes occur every three years, generic names in case card lists avoid the need to update lists. These case card lists require all the surgeons to agree to operate with the same medical devices, which can be difficult, especially for high numbers of surgeons within a specialty. However, our case card lists can be flexible as we can add some surgeons' specificities (e.g. position of the patient or specific device). One of the reasons for the lower cost reduction than described in the literature is that the existing case cart lists were already standardized by procedure and not by surgeon. The creation or updating of the case card lists did not lead to removal of many disposable supplies. Harvey et al. showed in their study that 14 surgeons revising 39 preference cards of frequently performed procedures led to the removal of 109 disposable supplies for a total cost saving of only $767.67 [11]. It is important to keep in mind that prices of the medical devices decreased due to a high level of competition between companies and the continual emergence of new devices. Whilst our costs savings showed a decrease of €33 014, it did not reflect the real impact of all the actions pioneered by the pharmacist during the year in OR. Indeed, several specific actions started six or eight months after the beginning of the study and their financial impact has not been evaluated yet. For example, it was very common to open sterile surgical gowns for thermal comfort in OR. The introduction of new non-sterile jackets led to savings of €15 000 per year. Similarly, in bariatric surgery, the replacement of three medical devices (a trocar, a stapler and a glue applicator) will have an expected saving of €21 000 per year. Some savings came from elimination of medical devices that surgeons agreed to not use anymore, for example discontinuation of a surgical stapler in digestive surgery saved €4200 in logistics management alone.

Our perception survey showed general satisfaction of the staff (surgeons and nurses) for the pharmacist's presence and interventions in the OR that encourage the maintenance of the pharmacist in OR. It would have been interesting to assess the impact of the pharmacist's intervention on the sale representatives. Most of them highlighted the improvement of quality exchanges and availability of medical devices (e.g. tests in the OR).

4.1. Limitations

One study limitation is that it was led in one center in three surgical departments. It would have been interesting to extend the study to all the surgical departments, but substantial manpower is needed to perform direct observation of every surgical case. To verify the repeatability of these results, further study is needed in several centers. The necessity of informing heads of departments of the purpose of the study could have introduced bias, as occasionally they performed the surgeries being audited. However, as the rate of audited surgeries where the operator was the head of the department was small (less than 6%), the bias was limited and preferable to not including the surgeries performed by the head of the department, which would have introduced a new bias.

We did not assess the potential effect of outcomes like operative times, length of stay, 30-day readmission, 30-day mortality, or discharge status. It could be interesting in a further study to show the pharmacist intervention on medical devices did not have a negative effect on clinical outcomes.

As some of actions started towards the end of the study, the cost reduction underestimated the reality and more long-term savings are expected. Another limitation is that the cost of the medical devices in UDG reflected the ordered devices and not the used devices. The objective was to evaluate if the actions led by the pharmacist could have an impact on the cost of medical devices as a whole on three specialties. We decided to not assess only the cost of the audited surgeries because some of the general actions led by the pharmacist had an economic impact on every surgery.

5. Conclusion

This prospective interventional study showed that the intervention of a pharmacist specialized in the medical device field could significantly reduce non-compliances in medical device use and reduce costs in OR. The presence of a pharmacist in the OR fostered cooperation and communication among healthcare professionals, providers and users, and improved care quality.

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Ethical approval

This study was approved by the Institutional Review Board of the University Hospital (N° 18.06.04).

Research registration unique identifying number (UIN)

Please enter the name of the registry, the hyperlink to the registration and the unique identifying number of the study. You can register your research at http://www.researchregistry.com to obtain your UIN if you have not already registered your study. This is mandatory for human studies only.

ClinicalTrials.gov
https://clinicaltrials.gov/ct2/results?term=NCT04423250&Search = Search.

ClinicalTrials.gov ID: NCT04423250.

Author contribution

Please specify the contribution of each author to the paper, e.g. study design, data collections, data analysis, writing. Others, who have contributed in other ways should be listed as contributors.

Virginie Chasseigne: conception and design of the study, acquisition of data, drafting the article.

Sophie Bouvet: analysis and interpretation of data, revising the article.

Sihame Chkair: analysis and interpretation of data, revising the article.

Marlène Buisson: acquisition of data.

Marie Richard: acquisition of data.

Renaud de Tayrac: revising the article.

Martin Marie Bertrand: revising the article.

Christel Castelli: conception and design of the study.

Jean-Marie Kinowski: conception and design of the study, revising the article.

Géraldine Leguelinel-Blache: conception and design of the study, revising the article.

Guarantor

The Guarantor is the one or more people who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish. Please note that providing a guarantor is compulsory.

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Data statement

Data are available if needed by contacting the corresponding author.

CRediT authorship contribution statement

Virginie Chasseigne: Conceptualization, Funding acquisition, Writing - original draft. **Sophie Bouvet:** Formal analysis, Data curation. **Sihame Chkair:** Formal analysis, Data curation. **Marlène Buisson:** Funding acquisition, Funding acquisition. **Martin Marie Bertrand:** Conceptualization. **Christel Castelli:** Conceptualization. **Jean-Marie Kinowski:** Conceptualization.

Declaration of competing interest

None.

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