

A decision-support tool for outsourcing the reprocessing service of surgical instruments: a preliminary model

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Abstract: This work aims at providing a decision support tool for the choice among the in-house and the outsourced reprocessing process of surgical instruments. The decision parameters is the total cost of a surgical instruments kit. The surgical instruments reprocessing service is a time consuming process. Operating Theatre (OT) usually manages this process in-house inside its own Central Sterilization Service Department (CSSD). This duty is often performed by nurses who usually are diverted from their welfare task. Actually few enterprises offer the rental of surgical instruments and the outsourcing reconditioning service. Among the advantages related to this outsourced service, there is the possibility to achieve savings on the total expenditure related to the OT. Indeed, to make a choice the hospital facility should be able to calculate the costs involved in the process performed in-house, and to compare it with outsourcing offers. The costs involved in this process are numerous and are affected by a great number of variables. Parameters, variables and unknown quantity are analysed. Input data are the number of surgeries per year and the index percentages related to the type of surgeries on which depends the container and the surgical instruments to be used. These data, entered in the model, allows deriving an average cost per kit of surgical instrument or a cost per kit depending on the type of surgeries that can be used as a basis for comparison with the price proposed by the outsourcer in order to make a choice.

Keywords: cost evaluation, surgical instruments, reprocessing service

1. Introduction

Modernization of hospitals has a two-fold objective: improving quality of care and reducing health care costs ([Reymondon et al., 2008](#)). Costs related to the Operating Theatre are a relevant part of the whole hospital costs. Among them there are those related to the reprocessing service. This service greatly affects the annual total expenditure of a hospital and requires high quality procedures in order to ensure the sterility of every single device. The more widely used industrial medical devices sterilization technologies are steam, ethylene oxide, and γ and electron beam irradiation ([Mendes et al., 2007](#)). Actually few innovative enterprises offer the outsourced reprocessing process and kits of Reusable Devices rental. To make decision among the in-house service or the outsourced solution it is necessary to evaluate the cost of the process performed in-house in order to compare it with the price proposed by the outsourcer.

The paper is organized as follows: in Section 2 a brief literature review on the issue of the reprocessing process is drawn. In Section 3 the reprocessing process is described. After the notation (Section 4), costs formulation is proposed in Section 5 and in Section 6, variables are defined. In Section 7 the numerical analysis is drawn. Results are illustrated in Section 8, then a sensibility analysis on the input parameter is performed in Section 9 and finally, conclusion are in Section 10.

2. Literature Review

Reviewing the literature on this issue there are many papers in which the economic and environmental analysis is performed on a single item for both Single Use Devices

and Reusable Devices (RDs). [Jacobs et al. \(2008\)](#) outlined a literature review on the issue of the Single Use Devices reprocessing process. Other authors compared in economic terms RDs and Single Use Devices considering a time line equal to the RDs life. In this analysis they considered among the costs related to RDs life, not only those related to the reprocessing process but also those related to maintenance ([Adler et al., 2005](#)). [Prat et al. \(2004\)](#) conducted an analysis both on the economic and on the reliability perspective considering only three types of endoscopic Single Use and Reusable Devices.

Reusable Devices are preferable with respect to Single Use Devices because by reprocessing it is possible to save every years a lot of tons of wastes ([Kwakye et al., 2010](#)). By reprocessing Single Use Devices, as evidenced by many authors, it is possible to achieve savings but on the contrary sterility may be not insured and on a legal perspective, they cannot be utilized more than one time. RDs are surgical instruments generally made from high-quality stainless steel; they can be used and sterilised for several years ([Ibbotson et al., 2013](#)) and they are generally stored in containers (i.e. steel boxes that permit the autoclave steam sterilization); a kit is a container in which surgical instruments are stored. Kits surgical instruments composition is designed for each specific surgery.

[Di Mascolo and Gouin \(2013\)](#) conducted a discrete event simulation on this process in order to evaluate the performances of a sterilization service. Actually only few authors studied this issue on the economic perspective. [Reymondon et al. \(2008\)](#) proposed a methodology enabling new grouping choices of RDs into packages. They exploit an innovative sharing strategy, with the final goal to minimize the objective function corresponding to

process and storage costs of the sterilization activity. van de Klundert et al. (2008) studied how to reduce storage cost of surgical instruments at the Operating Theatre. They analysed several scenarios. Among them, the authors proposed two extreme cases in two notable scenarios. The first presents the case in which each surgical instrument is packed singularly. In the second, all the instruments that may be used during a surgery are stored in a single container. Intermediate scenarios propose some instrument specific for a surgical discipline stored in a container and other instruments that can be used by different surgical discipline packed in other containers or other envelopes.

3. The reprocessing process

The reprocessing service is mainly a manual activity that involves many operators. This circular process is composed by 9 steps. It starts with the utilization of the sterile equipment. After the use, all the surgical instruments, both they were utilized and they weren't, are pre-disinfected in the Operating Theatre by a nurse in order to avoid the risk of operator's contamination. After this phase that lasts about half an hour, Reusable Devices are transferred to the Central Sterilization Service Department (CSSD). Inside the CSSD that may be, inside the Operating Theatre or near it, the reprocessing process takes place. This process involves operators that can carry out all the manual operations, machines setup, load and unload; this process concerns also three kinds of machines: washing machine, autoclave and ultrasounds sterilizer. RDs are firstly manually rinsed by an operator that, later disassembles all the instruments that have harshness in order to avoid some bacteria may not be removed. After the manual washing, the operator divides instruments into two groups: critical and non-critical items. Non-critical RDs are made of stainless steel and can be sterilized by a steam sterilizer (autoclave). Critical RDs are for example those related to Video Laparoscopy surgeries; they are heat-labile instruments and, for this reason, they cannot be sterilized inside an autoclave. In that case, they are reprocessed by washing them inside an ultrasound machine and packed individually in special single-use envelopes. The second phase of the washing process is performed by a washing machine. If instruments are made by steel, they follow the traditional reconditioning process. After the washing step, steel surgical instruments are first checked in order to identify damaged instruments. Each instrument that does not respect quality standards is either dismissed or repaired by sending it to a service centre. After this manual process, every single container is recomposed with all its specific instruments respecting weight limits in order to avoid condensation formation inside the container during the sterilization step. This way it is ready to a sterilization cycle in autoclave where bacteria are heat-killed. Condensation presence reveal a fail in the sterilization process; a container in which there is condensation cannot be used. RDs after autoclave sterilization can be stored inside the Operating Theatre waiting to be used again.

Actually, a cost analysis for all the RDs of a single surgery container is not yet present in the literature.

4. Notation

Indexes

- j different surgical disciplines performed inside the Operating Theatre
- k different types of machines
- q different types of resources

Variables

- R_j Number of operating rooms required for the j th surgery
- d_j replicas number of the j th kit [unit]
- N_j lifetime of a Reusable Device for surgical discipline j [years]
- F Central Sterilization Service Department surface [m²]
- P number of operators required
- G_k maximum number of machines of type k an operator can supervise [machines/operator]
- M_k number of machines of type k required [machine]

Input parameter

- O_j number of surgeries j th per year [surgeries/year]

RDs parameters

- t_j Average duration of the j th surgery [hours/surgery]
- s_j average cost of a Reusable Device for surgical discipline j [€/unit]
- I_j average number of Reusable Devices per kit for surgical discipline j [unit/container]
- K_j average number of container per single j th surgery [unit]
- k_l cost per single j th container [€/unit]
- u_j number of sterile units per kit j th [sterile unit]
- V number of cycles in the lifetime of a Reusable Device [cycles/life]
- w cleaning products average cost per single Reusable Device [€/unit]
- v number of cycles between two Reusable Devices maintenance works
- SI average number of Reusable Device maintenance works per year [unit/year]
- CI average cost of maintenance work per single Reusable Device [€/unit]

Machines parameters

- m_k purchasing cost of a machine of type k [€/machine]
- A_k setup, upload and unload time of a machine of type k [hours]
- uM_k lifetime of a machine of type k [years]
- CM_k average cost of a machine of type k maintenance work [€/machine]
- SM_k average annual number of maintenance work per machine of type k [unit/year]
- C_k capacity of a machine of type k [sterile unit/cycle]
- η_k utilization coefficient of a machine of type k machine
- q_q unitary resource cost [€/resource unit]
- Q_{qk} resource per time unit of resource q when a machine of type k is running [resource unit/time unit]

T_k duration of a cycle of a machine of type k [hours/year]

Operators and Central Sterilization Service Department (CSSD) parameters

r average cost of CSSD construction [€/m²]

Y CSSD lifetime [year]

E CSSD working days per year [days/year]

D_j working days in a year of surgical discipline of type j [days/year]

CL average annual cost for the CSSD cleaning [€/m²]

H duration of a surgery session [time unit/day]

X duration of a daily reprocessing turn [time unit/day]

W duration of a manual washing cycle [time unit/cycle]

P number of operators required

p cost of an operator [€/time unit]

i annual interest rate

5. Costs Definition

In order to outline from the tool the hospital total annual cost related to the reprocessing service it is necessary to define the entire cost elements involved in the model. In this work all the costs related to a specific process are calculated on an annual base. The total annual costs related to the reprocessing service performed inside a hospital are essentially 8:

IP Total surgical instrument purchasing; [€/year]

O Total CSSD operators cost per year; [€/year]

MP Total CSSD machine purchasing cost [€/year];

CP annual cost for cleaning products [€/year];

CQ annual cost for resources consumption [€/year];

Se annual cost for ordinary maintenance work related to RDs and machines [€/year];

CC annual cost for the CSSD cleaning [€/year];

DC annual cost related to the construction of the CSSD [€/year].

The total annual cost TCY incurred by the hospital to provide in-house the reprocessing service of the surgical instruments is the following:

$$TCY = IP + O + MP + CP + CQ + Se + CC + DC \quad (1)$$

The input parameter on which each cost depends is the total number of surgeries O . Each surgeries requires an average of one container containing about 250 RDs. To reprocess in a single day all the RDs utilised in a surgery session, it is necessary an adequate number of machines and operators. For this reason, it is compulsory to first define all the parameters and constraints involved in the model by a punctual definition of each cost line. Through variables definition, it is also possible to verify if the hospital CSSD is well dimensioned.

IP – Total cost of surgical instruments purchasing

This cost is composed of two different contributions. The first is related to Reusable Devices purchasing, the second to containers purchasing. The cost of each RD s_j , the number of surgical instrument per j th container I_j and the type of the container depend on the surgery it is designed for. Indeed the type of container (i.e. the number K_j , the size and their cost k_j) depends on the surgical discipline. The dimension of a container is provided in sterile units

(u) which correspond to a container, sized 30 cm x 30 cm x 60 cm. As an example, we can take into account a set of RDs related to an ophthalmology (0.25 u – 25 RDs) and one related to orthopaedic surgery (0.8 u – 100 RDs).

$$IP = \sum_j d_j (I_j s_j + K_j k_j) \cdot A/P(i, N_j) \quad (2)$$

where $A/P(i, N_j)$ is a coefficient that shares the total expenditure in annual payments.

O – Total cost of operator

The total cost of the operator can be calculated considering the number of the operators P , their cost per hour p and the annual hours of activity $b \cdot E$.

$$O = P \cdot p \cdot X \cdot E \quad (3)$$

MP – Total cost of machine purchasing

This annual cost correspond to the annual payment related to the total investment of machines purchasing $\sum_k M_k m_k$.

$$MP = \sum_k M_k m_k A/P(i, u_{M_k}) \quad (4)$$

where $A/P(i, u_{M_k})$ is a coefficient that shares the total expenditure in annual payments.

CP – Total cost of cleaning products used

To evaluate the total cost of cleaning product, first an average cost of products used for the cleaning of a single instrument has been supposed. After that, it is possible to evaluate this cost by multiplying the total number of Reusable Devices processed in a year $K_j S_j O_j$ and their unitary cleaning cost w .

$$CP = w \sum_j K_j S_j O_j \quad (5)$$

C – Total cost of resources

This cost depends on the type of resource q and on the type of machine k . It is the product of the q th resource quantity per time unit related to the k th machine Q_{qk}/η_k and the time of activity T_{qk} , and the cost per q th resource

unit q_q . The value $\sum_k \sum_q \frac{Q_{qk} q_q T_k}{\eta_k}$ is the cost per cycle that

has to be multiplied for the number of cycles per year $\left(\sum_j \frac{O_j u_j}{C_k} \right)$.

$$CQ = \sum_k \sum_q \frac{Q_{qk} q_q T_k}{\eta_k} \cdot \left(\sum_j \frac{O_j u_j}{C_k} \right) \quad (6)$$

Se – Total cost of servicing

Services are provided to both RDs and machines. The total cost related to services is the sum of these two contributions. The first is that related to RDs and is the product among the average cost C_l per RD maintenance,

the number of maintenance per year S_l and the total number of RDs utilized in a year $d_j S_j K_j$. The second term is related to machines maintenance; it is the product of the cost per maintenance C_{M_k} and the annual number of maintenance work S_{M_k} and the total number of k th machines M_k .

$$Se = C_l \cdot S_l \sum_j d_j S_j K_j + \sum_k C_{M_k} S_{M_k} M_k \quad (7)$$

CC– Total Cleaning cost

A CSSD is a place in which sterility is compulsory. For this reason, it is necessary an adequate cleaning service that is usually performed by outsourcing it to an external company. That cost line mainly depends on the total surface of the CSSD F and the average cost of cleaning per surface unit C_l .

$$CC = C_l \cdot F \quad (8)$$

DC– Total Construction cost

This cost can be evaluated considering an average cost per surface unit r and the total surface of the CSSD F and multiplying it for a coefficient $A/P(i, Y)$ that share this cost in annual payments considering an average lifetime for the CSSD equal to Y years.

$$DC = r \cdot F \cdot A/P(i, Y) \quad (9)$$

6. Variables definition

Number of operating rooms

The minimum number of operating rooms required inside a hospital depends on the annual number of hours required for surgeries of type j (O_j) and on the annual number of hours available in a single OR for the j th surgical discipline $D_j H$.

$$R = \max \left(\left\lceil \sum_j R_j \right\rceil, 2 \right) = \max \left(\left\lceil \sum_j \frac{O_j \cdot t_j}{D_j H} \right\rceil, 2 \right) \quad (10)$$

If R is less than 2 Operating rooms, it is in any case necessary to have almost 2 operating rooms. This is due to the necessity to have always almost one room available for emergency surgeries.

Minimum Central Sterilization Service Department surface required

As described before, the CSSD surface is a fundamental variable for costs evaluation. It is possible to evaluate the minimum CSSD surface required by respecting the DPR 14/01/1997 requirements, SIAARTI and national guidelines using the following assumption.

$$F = \begin{cases} 25R & R \leq 4 \\ 20R & R \leq 12 \\ 15R & R > 12 \end{cases} \quad (11)$$

Container replicas number

The number of container replicas depends on the number of surgeries that requires the same container to be

performed. Each container of Reusable Devices requires a day to be reprocessed. For this reason, the lower bound has been defined considering the minimum number of surgeries per type O_j/D_j that can be performed in a single surgery session. The upper bound has been defined considering the maximum number of j th surgeries (i.e. the surgery type that requires the minimum surgical time) that can be performed in a single surgery session utilizing all the Operating Rooms available for the j th surgical discipline $H \cdot R_j / \min \{t_j\}$.

$$\left[\frac{O_j}{D_j} \right] \leq d_j \leq \left[\frac{H \cdot R_j}{\min \{t_j\}} \right] \quad (12)$$

Maximum life of surgical instruments

This variable is the ratio between the numbers of uses in the whole lifetime of all the hospital Reusable Devices $V \cdot d_j$ and the number of annual use of each RD O_j .

$$N_j = \frac{V \cdot d_j}{O_j} \quad (13)$$

Number of annual Reusable Devices service

This number is the ratio between the numbers of annual use of the j th container O_j/d_j , and the average number of use between two-maintenance works.

$$S_l = \frac{O_j/d_j}{v} \quad (14)$$

Number of machines

That relation provides the minimum number of machines k th required to process all the Reusable Devices used in a daily surgery session. The sterile unit previously described is the capacity unit of measure C_k of each k th machine. This number is the ratio between the total time required to process in a year the entire sterile unit utilized (i.e. the time per machine cycle T_k and the number of cycle per year $\sum_j O_j u_j / C_k$), and the time available for a single

machine in a year $E \cdot X$. For this reason to evaluate the minimum number of k th machine required it is necessary to calculate the ratio between the total number of sterile unit used in a year and the maximum number of sterile unit a single machine can process.

$$M_k = \left\lceil M'_k \right\rceil \geq \left\lceil \frac{T_k \left(\sum_j O_j u_j / C_k \right)}{E \cdot X} \right\rceil \quad (15)$$

Number of machine an operator can supervise

It is the ratio between the time per cycle required by the k th machine $A_k + T_k$ and the time required by an operator to perform its manual tasks $A_k + W$

$$G_k = \frac{A_k + T_k}{A_k + W} \quad (16)$$

Number of operators

The minimum number of operators is the ratio between the total number of machines and the maximum number of machine an operator can supervise.

$$P \geq \left\lceil \sum_k \frac{M'_k}{G_k} \right\rceil \quad (17)$$

That ratio represents exactly the minimum number of operators. It is noteworthy that by this equation how it is possible to optimize the number of operators because it is possible for an operator to supervise also different type of machines and not only the same type k .

7. Numerical analysis

To complete this evaluation tool it is necessary to provide it with the real value of each parameter involved in the costs calculation. All the value utilized in this model have been derived from a one-week survey in the Operating Theatre of an Umbrian hospital and from machines technical files. In that period, all the surgery types, their duration, the number of kits involved etc. were reported in order to collect the necessary input parameters for this model. This hospital performs an average of 3000 surgeries O per year. The Operating Theatre is composed by 4 Operating Rooms R . Only 3 of them are utilized, one of them is free for emergency surgeries. In order to maximize the utilization of the Operating Rooms, surgeons and nurses works following a chessboard scheduling. The different surgical discipline performed inside the hospital are essentially 6 (Table 1).

Table 1: Indexes values

Surgical discipline		Machine	
$j=1$	Surgery	$k=1$	Washing machine
$j=2$	Abdominal surgery	$k=2$	Autoclave
$j=3$	Orthopaedics	$k=3$	Ultrasound machine
$j=4$	Urology	Resource	
$j=5$	Genecology	$q=1$	Electricity
$j=6$	Ophthalmology	$q=2$	Water

Value related to Central Sterilization Service Department machines are reported in Table 2; those related to the hospital CSSD are in Table 3. Table 4 and Table 5 show data related to surgeries and their Reusable Devices.

Table 2: Machines parameters

	Autoclave	Washer	Ultrasound washer
T_k [hours]	2	1.5	1.5
C_k [unit/cycle]	10	4	1.50
A_k [hours]	0.5	0.5	1
Q_{1k} [kWh]	6.3	6.3	6
Q_{2k} [m3/h]	1.1	0.4	0.02
SM_k [€]	3.660	3.660	3.660
m_k [€]	73.200	46.360	46.360

Table 3: Data related to Central Sterilization Service Department

Central Sterilization Service Department	
Construction cost per surface unit R [€/m2]	5000
Cleaning cost per surface unit C_L [€/m2]	100
Cost per time unit of an operator p [€/hours]	20
Duration of a CSSD turn b [hours/turn]	6
CSSD working days per year E [days]	250
Manual washing cycle duration W [hours]	1.5
(Resource 1, electricity) q_1 [€/kWh]	0.2
(Resource 2, water) q_2 [€/m3]	1.5

Table 4: Data related to Reusable Devices

	Surgery	Abdominal surgery	Orthopaedics
t_j	0.75	2.2	4
D_j	250	250	250
s_j	250	250	300
K_j	265	410	595
k_j	1	1	3
S_j	60	80	100
u_j	0.25	0.8	0.8

Table 5: Data related to Reusable Devices

	Urology	Genecology	Ophthalmology
t_j	1.5	2	0.5
D_j	52	52	52
s_j	250	250	250
K_j	390	390	265
k_j	1	1	1
S_j	60	60	25
u_j	0.4	0.4	0.25

8. Results

Results are obtained by calculating all the variables following the specific order (10)-(17) given in Section 6. In this work, all the variables that can range into an interval are considered to assume a value equal to the average between the lower and the upper bound, or the minimum value when the unbound interval. After variables calculations and parameters definition, the model is ready for the costs evaluation. All the costs defined in Section 5 can be calculated simply utilizing equations (2)-(9).

Table 6: Annual costs line

Total costs per year [€/year]	
IP - Instruments Purchasing	179.275
O - Operators cost	120.000
MP - Machines purchasing	21.228
CP - Cleaning products cost	141.750
C - Resources cost	4.684
Se - Servicing cost	11.070
CC - CSSD cleaning cost	18.333
DC - Construction cost	10.000
TCY - Total Cost per Year	506.341

Results related to each cost line are reported in Table 6. It is evident how the cost line that mostly affects that process is the Instrument Purchasing IP . It is also possible to derive the average cost per kit. The outsourcer may propose the price by adopting three different cost unit. In

Table 7 for this reason costs are reported following the different solutions an outsourcer may adopt: average cost per kit (Solution A, considering the number of kits), the average cost per sterile unit processed (Solution B) or considering the cost per kit varying the j th surgical discipline (Solutions C).

Table 7: Average cost per kit

Type of solution	Cost per solution	
Solution A	Average cost per kit	170.79
Solution B	Average cost per sterile unit	206.39
Solution C	Average cost per kit 1	51.60
	Average cost per kit 2	165.11
	Average cost per kit 3	495.34
	Average cost per kit 4	82.56
	Average cost per kit 5	82.56
	Average cost per kit 6	51.60

9. Sensibility analysis

In order to comprehend how the cost per kit (Solution A) varies on the total number of surgeries O , a sensibility analysis on this input parameter has been performed. In this analysis, we maintain the same ratio O_j/O of the case study.

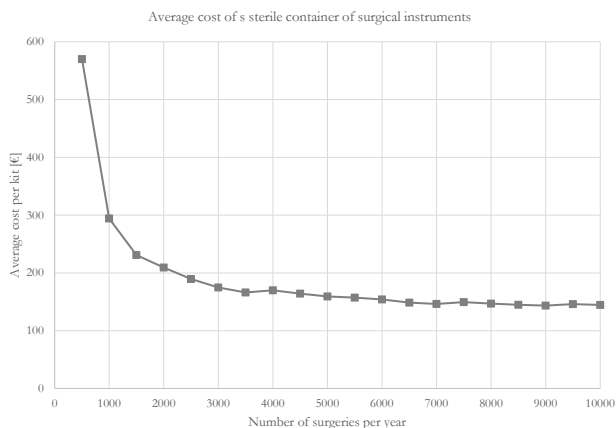


Figure 1: Average cost per sterile container

From Figure 1, it is evident how the total cost per kit quickly decreases in the interval $0 < O < 2000$. Considering $O \geq 2000$ the cost decreases more slowly. Increasing the number of surgeries per year, also the number of machines, operators and the number of containers increase, so that it is easier to increase the utilization coefficient of these resources. Therefore, the total cost per kit does not vary very much. It is also noteworthy that the function is not properly convex; this is due to variables definition. Most of them are defined as integer and are derived by rounding to the higher integer (see as example(15)). The total cost function is therefore the sum of a plurality of jump functions.

10. Conclusion

This tool provides an average cost per kit of Reusable Devices reprocessed in a well-dimensioned hospital Central Sterilization Service Department. In a design

phase, this tool may support in the preliminary design of a CSSD.

This tool allows hospital facility to make decisions among the in-house reprocessing service or the outsourced one. In addition to economic enhancement a hospital may achieve by outsourcing this service, there are also other advantages such as the relocation of the patient safety responsibility on the outsourcer. The need to respect new law requirements or to renew machines are now making hospitals paying attention at this issue.

Further improvement of this model is the integration of Se (Cost of maintenance services) with costs related to unexpected maintenance works. Other integration is to consider also each different type of surgical instruments without assuming all the RDs parameters equal for each j th surgical discipline.

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