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EXECUTIVE SUMMARY OF THE THESIS

Design and commissioning of the new Day Surgery unit at Humanitas San Pio X Hospital

TESI MAGISTRALE IN CLINICAL ENGINEERING – INGEGNERIA CLINICA

AUTHOR: DAMIANO MARCHETTI

ADVISOR: VERONICA CIMOLIN

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1. Introduction

The general management of the Humanitas San Pio X (HSPX) hospital has defined the budget for the design and implementation of the new day surgery (DS) operating unit. The work started in July 2021, from the beginning of my internship dated September 13 until February 18, I was able to follow the development and design of the new operating unit, from the analysis of patient workflows and dirty/clean paths, to the acceptance and testing procedures of electromedical equipment, thanks to which it was possible to set up the DS.

The DS, or "one-day surgery", represents the clinical-organizational modality to perform surgery or invasive diagnostic and/or therapeutic procedures, in hospitalization limited to the hours of the day, under general, loco-regional or local anesthesia.

The new operating unit has been set up and prepared to the minimum plant, structural, and technological equipment requirements, which meet the Decree Law 14/01/1997. The DS since February 2022 is in accreditation phase supervised by the ATS, so that it can be accredited to the national health service and can start the operational activity.

The paper shows the functions carried out by the Clinical Engineering Service (SCI) of HSPX, which include the management of equipment throughout its life cycle (evaluation, purchase, testing, maintenance, decommissioning) and the associated risk. The structure of the spaces of the DS has been described and then have been illustrated the pivotal tasks carried out by the undersigned assisting the clinical engineer in the activities of acceptance and testing of medical equipment purchased for the new operating unit, describing the management of processes through the use of electromedical inventory and management software of the SIC.

At the same time as setting up the DS, it was possible to re-evaluate the functional status of the existing fleet of equipment, using a replacement priority index (IPS), extracted from the literature, as a tool to support the assessment of the state of obsolescence of the equipment. The IPS was applied on seven machines located in the operating rooms of the operating block, and allowed to reallocate these devices in DS, saving a part of the budget allocated to the setting up of DS, which was used to modernize in the operating block of HSPX by purchasing new machines to enhance the surgical activity.

The analyses carried out in the present work highlight the potential of the DS care regime, which makes it possible to reduce the number of ordinary hospitalizations and contain management costs.

2. Humanitas San Pio X: organization and functions of SIC

In most healthcare facilities, the SIC plays the role of the entity responsible for the safe management of the biomedical technology park and can assume different organizational models for the management of maintenance [1]:

- In-house type service: with this organizational model, a staff of Clinical Engineers and Biomedical Technicians perform the control and service of the equipment, as employees of the healthcare facility.
- Mixed service: in this case, control is entrusted to in-house clinical engineers while technical assistance is carried out by biomedical technicians employed by the healthcare facility and/or by specialized third-party companies and/or by stipulating maintenance contracts with manufacturers.
- Completely external service: the technical assistance of the technologies is completely entrusted to a single interlocutor external to the company, the Global Service companies.

The SIC of HSPX is an internal service and currently the staff is composed of a Clinical Engineering Service Manager, a Clinical Engineer and a Biomedical Technician. The SIC coordinates the management of testing, preventive/corrective maintenance and determines the formalization of maintenance and loaner agreements. It manages the inventory of equipment and all related technical documentation and follows the suppliers during the testing phases of the equipment that, for any reason, must be introduced in HSPX.

My role was to support the clinical engineer in daily activities, performing the following duties:

1. management of the inventory of electromedical devices, an inventory that is constantly compiled and updated, an extremely necessary and useful tool for keeping track of any information related to an electromedical device that is purchased and tested by the SIC.
2. acceptance and testing of devices: from the drafting of the machine book to the collection of the necessary documentation, as a basic requirement, the EC declaration of conformity and user manual in Italian.
3. monthly scheduling of preventive maintenance activities and performance checks, where necessary;
4. support to medical-nursing staff for the resolution of problems related to the use of the instrumentation, where necessary, and scheduling of education and training events to support staff.

In particular, when the device arrives at the facility, it is subjected to testing, which is a standard procedure coordinated by the clinical engineer and divided into the following phases:

- Visual inspection and collection of technical documentation;
- Verification of electrical safety;
- Performance verification;
- Coding, inventory and machine book compilation;
- Staff training.

3. Day Surgery: definition and plant-structural characteristics

As stated in the portal of the Ministry of Health, the DS represents:
"the clinical-organizational modality to perform surgical interventions or invasive diagnostic and/or therapeutic procedures, in a hospitalization regime limited to the hours of the day, under general, loco-regional or local anesthesia".
This model of organization and care is spreading widely in Western countries, because it responds to the need to reduce the costs of treatment, to optimize fixed resources, to intervene on the "hotel" expenditure related to hospitalization and incurred by health facilities, to reduce the time of inability of patients, and then also contain the social costs related to the delayed recovery of "job fitness".
The DS programmed and structured in HSPX represents an autonomous operating unit with dedicated inpatient units and independent operating rooms, in fact it has been set up with three operating rooms dedicated exclusively to the care of patients in day hospitalization who require surgery. This solution allows to carry out operations in day hospitalization in a new and separate unit compared to the operating block, which respects the minimum structural and plant requirements as indicated by the D.P.R. 14/1/1997 [2].
The operating unit designed within the DS, reflects to all intents and purposes the characteristics of a real operating block.
The operating rooms, in terms of plant engineering and design features, have been set up and programmed as operating rooms in all respects, which would allow not only to perform mini-invasive surgical interventions such as those carried out in the DS, but also interventions of greater caliber, carried out daily in a real operating block.
This choice not only ensures a perfect execution regime according to high standards, but in the future may allow the use of the three operating rooms of DS for more demanding interventions, converting the operating core.
In order to comply with the regulations in force, the operating center of DS meets specific technical and design requirements. Therefore are present both all the

common plants to the buildings destined to civil use, and specific plants that allow the use of some types of instrumentations such as:

- electrical system with dedicated safety power supplies (terminals under Uninterruptible Power Supply (UPS) and generating set);
- potential equalization for the connection of electro-medical equipment;
- medical compressed air system;
- oxygen system;
- vacuum system;
- system to remove the patient's breath.

3.1. Day Surgery composition

The DS is located on the second floor, sector A of the hospital, where 21 outpatient clinics were previously located.
The new operating unit can be divided into 3 macro-areas, as can be seen in Figure 1:

- Acceptance Unit;
- Inpatient Unit;
- Operating Unit.

Acceptance Unit represents the first functional nucleus of the DS, where patients are admitted to carry out the day procedure in the DS.
The DS hospitalization **Inpatient Unit** is the second functional unit, where the prolonged hospitalization of patients who need it takes place, but not longer than a day, and the patient is supervised by medical and paramedical staff.
The third and last functional nucleus is the **Operating Unit**, the nucleus where operations are actually carried out in the operating rooms and where patients are prepared and monitored in the post-operative phase.
The activities carried out in the DS in the three functional cores described, are summarized in Table 1.

3.2. Operating flows in day surgery

The study of the routes is an element of fundamental importance in the design of an operating unit. Within the DS, appropriately defining the paths of both personnel and dirty and clean material contributes significantly to safety, ensuring defense against contamination and increasing the functionality of the operating unit.
It is possible to identify two main categories of routes within the structure of an operating block:

1. patient path: the patient after finishing the bureaucratic phase of acceptance, enters the DS, passing first through the locker rooms. Then the patient will be examined for a check-up, he will be prepared and then he will be ready to perform the surgery. Post-operation will take place controlled awakening in the awakening room, and will temporarily stay in the inpatient rooms. In case of severity the patient can be transported to the intensive care unit in the hospital.

2. surgical iron/instrument pathway:
   The study of dirty-clean paths is traditionally relevant in the field of hospital design, being connected to complex problems of protecting the asepticity of the rooms crossed. In the case of a surgical unit of DS, it is possible to consider as generally preferable the solution to distributive prevalence with paths for dirty and clean physically separated, as it has been done for the DS in HSPX.
   The logistic path of the instrumentation is therefore, as previously illustrated, separated into two flows:
   - the flow of material defined as 'clean': this material, after being sterilized, is transported from the sterilization central unit to the clean depot in DS, through a dedicated path. From the clean depot it will be taken and distributed in the operating rooms.
   - The flow of material defined as 'dirty': the instrumentation after being used for the operation, is removed from the room through the dirty corridor, a dedicated path for septic material.
     The material is then conveyed to the 'dirty' room, from where it will be taken to the sterilization central unit.

4. Commissioning of the day surgery department

The Clinical Engineer in collaboration with the IC Manager, established the appropriate investments for the renewal of the technological park, planning the purchases of medical devices and equipment of the DS taking into account the multiple aspects involved such as workloads, interventional specialties that will operate in DS and obsolescence of technologies. The latter is an important issue that has been addressed for the reallocation of specific equipment in DS, for the modernization of the operating block.
In light of the evaluation for the DS design, the possibility of leveraging the available budget for two parallel purposes was defined:
1. Acquisition of fleet of equipment to equip the DS rooms;
2. Acquisition of specific electro-medical equipment for modernization of the Operating Block.

Following the initial considerations for the preparation of the DS, the reallocation of the following equipment already present in the Operating Block was evaluated and subsequently programmed:

- n.3 Operating Tables
- n.3 Anaesthesia equipment
- n.1 Electric Scalpel

This choice was supported and validated by the calculation of the Index of Priority of Replacement (IPS), a quantitative indicator that supports the clinical engineer in the evaluation of equipment obsolescence.

4.1. The management of acceptance and testing of electromedical equipment

In my experience at the HSPX facility, one of my primary roles was managing the electromedical inventory and performing the acceptance and testing procedure for electromedical equipment. Since joining the facility dated September 13, 2021, I have actively contributed to the inventory and subsequent testing of 146 devices: #39194 through #39340 respectively, referencing the inventory and coding number of the equipment. Of these 146 tested devices, 70 are those belonging to the DS area. The job that I have carried out and present in the elaborate one of thesis, has been that one to explicate the tasks of acceptance and test of the equipments acquired for the day surgery, describing in the detail the previewed procedures and dwelling me on the structure of the electromedical inventory used in the hospital HSPX.

The acceptance and testing process includes a series of procedures well defined by the SIC, summarized as follows:

- arrival of the order with delivery note: a document that attests to the contents of what has been delivered;
- delivery of the equipment to the warehouse;
- taking over by the SIC;
- order conformity check (number of correct components, correct models, correct specifications);
- documental verification: CE declaration of conformity, user manual as requested to suppliers and service manual, other valid certifications of the manufacturing company;
- visual inspection;
- test of compliance with CEI standards (CEI EN 62353 and updates): instrumental verification and subsequent functional verification;
- updating of computerized inventory of electromedical equipment;
- acceptance of the equipment and compilation of form (R/011-07): document identified as "machine book";
- Sharing of completed form "Medical equipment acceptance and testing form" (R011-07) with the Sanitary Management. (R011-07) with Health Management and RSPP;
- Organization of user training (where applicable);
- delivery of the equipment to the department.

For each device I explained what the management procedure was, showing the data entered in the inventory: master data, economic data and technical data of the devices.
Finally, data regarding periodic verifications are inserted, there are data regarding the Verification of Electric Safety (VSE), the Performance Verification (VP) and the Preventive Maintenance (MP).
These data allow the SIC to evaluate, one by one, the preventive maintenance carried out on a piece of equipment both with regard to the feasibility of carrying out the MP intervention internally and with regard to the maintenance periodicity according to its own risk assessment.
The DS equipment that requires preventive maintenance are: the biological refrigerator, the bed washer, the operating room cabinets, the operating lamps, the desflurane vaporizers, the electrified trolley and the acquisition module attached to the laparoscopy column.

The equipment was subsequently entered in the Asset Plus® equipment management software, reporting the plate, administrative, technical and maintenance data and attaching, where possible in electronic format, the documents provided during testing.
Afterwards, for each DS equipment tested, a summary of the master data ("Medical equipment acceptance and testing form") was compiled and printed, which constitutes the machine book and confirms the acceptance of the equipment.
The machine book summarizes the inventoried data, showing the registry and nameplate data of the device, the technical data, some economic data, and in particular the data related to the maintenance program for the equipment.

4.2. IPS selection and computation

The Replacement Priority Index (IPS) is a quantitative index developed since the 1990s and continuously innovated and reworked by clinical engineers over time, with the aim of providing a tool that could support the evaluation of electromedical equipment in the planning phase of investments, acquisition and renewal of the technological park.
Following a brief review of the literature, an IPS model was extracted that could be akin to the characteristics of the HSPX hospital and applicable based on the necessary information to be found for the computation of the index.
In agreement with the clinical engineer, it was decided to opt for a simple and effective model, whose use was

not too complex; a model balanced between technical-objective and clinical-subjective criteria.
The model taken into consideration is that of E.Milani et al. [3] , a linear model that represents the weighted sum of 10 parameters:

$$IPS = \sum_{i=1}^{10} p_i \cdot x_i$$

The index can assume a value between 0 and 10 depending on the individual values of the parameters that compose it. All the weights used in the model of E.Milani et al. have therefore been initialized equal to 1: to use the model with a critical approach I decided to re-evaluate the weights assigned diversifying them for some parameters, so as to highlight the technical and economic aspects, such as the existence of spare parts, the reliability of the equipment and the cost of maintenance.
Since the weights were varied, for convenience of reading and to obtain a final value with range [0,10] as in the original model of E.Milani et al. [3], the multiplicative factor 10 was used for the final calculation of the IPS.
The thresholds set by the model are equal to IPSmin=4 and IPSmax=7. If the calculated value of IPS is less than 4, replacement is not necessary; if IPS is between 4 and 7, replacement is deferable; if greater than 7, replacement is urgent. The model was applied for the 7 machines of the operating block, n.3 operating tables, n.3 anesthesia equipment and n.1 electrosurgical unit.
As can be seen from the results in table 2, five devices fall into the lower range, in which replacement of the equipment is not necessary, while two devices fall into the intermediate range for which replacement can be considered deferrable. Considering also that the IPS for the two anesthesia devices 37219 and 37220 slightly exceeds the minimum threshold value IPSmin =4 , the quantitative tool confirms the clinical opinion, noting that the devices are in a good state.
These results supported and confirmed the choice of the SIC to reallocate the equipment in the DS, as the clinical opinions are positive and the equipment has never presented major problems or endangered the safety of patients and operators. In light of the results, however, a re-evaluation was defined to be performed in 2 years to verify and evaluate the status of the equipment.

4.3. Day Surgery set up

After the acceptance and testing phase of the equipment purchased for the DS, we proceeded with the installation of the same, with the aim of progressively setting up the DS premises.
The first equipment to be installed is the 'fixed' equipment: the installation took place earlier than the 'mobile' equipment, as it requires wall installation and/or creation of appropriate connections to the electrical and/or water system and medical gas system where necessary.
The fixed equipment installed are operating room wall units, operating room lights, television monitors for bioimaging, bed head beams and a bed washer.
Subsequently, the 'mobile' equipment and technical furnishings necessary for DS activities were distributed and positioned, ready for use when the new O.U. starts up after the accreditation phase.
The mobile equipment includes: operating tables, electrosurgical scalpels, anaesthesia equipment, multi-parameter monitors, syringe pumps, a laparoscopy column, an ultrasound machine, desflurane vaporizers, defibrillators, a sick-pass system and a biological refrigerator.

In detail, in the thesis I have studied three types of equipment: operating room cabinets, operating lamps and operating tables.

5. Maintenance plan applied to day surgery

In order to meet DS accreditation requirements, ATS verifiers require that you provide the established routine maintenance schedule for equipment in the new operating unit. The routine maintenance plan takes into account the indications contained in both technical standards and service manuals and guarantees the necessary quality and safety requirements of the services provided. The routine maintenance plan is shown in the appropriate columns of the Inventory of electromedical equipment, and is based on the following assumptions:

- technical documentation accompanying the machine or system;
- possible existence of a service contract, to integrate the specifications of the service manuals;
- existing technical regulations.

The plan is then drawn up by extracting the necessary data, namely:

- Inventory number;
- Type of equipment, manufacturer, model and serial number;
- Risk class certified by the manufacturer according to 93/42 EEC or EU 2017/745 (I - IIa - IIb - III);
- Risk rating assigned by the SCI (low, medium, high);
- Periodicity of scheduled maintenance VSE (electrical safety check) and VP (performance check) according to manufacturer's instructions, if any;
- MP preventive maintenance data established by the SIC: these data are intended to objectify in advance the periodicity and type of

maintenance activities foreseen for that specific type of equipment and are the basis of the maintenance plan.

- Entities in charge of verifications and maintenance, as foreseen by the contract.

The plan therefore identifies the internal or external managers for the technical assistance procedures and for the conformity checks foreseen and is accompanied by the indications for the scheduled interventions.

6. Discussion and conclusion

The structuring of the new operational unit of DS at the Humanitas San Pio X hospital has allowed me to make some considerations and observations of a specific nature regarding the index of priority of replacement computed and of a general nature regarding the introduction of the care model of DS in the structure.

6.1. Replacement Priority Index Considerations

The proposed index represents a starting tool, modifiable on the basis of the characteristics of the hospital's fleet.
In my case, I have wanted to apply a modification of the weights associated to every parameter of the model, like described in paragraph 4.2.

The greater weights have been assigned to the parameters X3, X6, X10 that is the existence of the pieces of exchange, the reliability and the cost of maintenance.
The choice is motivated from evidences found also in literature, in how much in the developed pregresse models the greater weight is entrusted to technical and economic parameters. See the model developed by Fenningokh [4], in which the greatest weight is given to the parameters of cost and end of maintenance service by the manufacturer.
The total analysis has led to good values: only two devices, two anesthesia machines, report a higher value with an IPS equal to 4.70 value higher than the lower threshold IPSmin = 4 for which the replacement of the machinery is deferrable and can be considered in a multi-year renewal plan. All other machinery reported a value below the minimum threshold.

6.2. Conclusion

The DS is a model of care and organization that allows the treatment of patients, appropriately selected, according to a regime that provides a higher index of patient turnover [5].

In the HSPX structure, the introduction of DS was seized as an opportunity to carry out an internal re-evaluation: the machine park was reviewed, exploiting and maximizing internal resources, making possible the modernization of other hospital operating units.

The budget, as illustrated in chapter 3, has been exploited to purchase not only new assets to be allocated in the DS, but also new equipment of fundamental importance to be introduced in the operating rooms of the BO.

In summary, the study conducted on DS at the HSPX hospital thus allows three important observations to be developed:
1) The introduction of DS has simultaneously allowed the reorganization of existing technological resources previously employed in other departments and the possibility of modernizing the operating block, introducing new technologies to ensure a high standard of performance.

2) The introduction of this form of health organization will allow to carry out interventions previously carried out in the operating block in a new operating unit with an appropriate regime.
This will guarantee a considerable relief of the work carried out in the operating block, which will be more concentrated in the care of patients with serious surgical pathologies.

3) The DS will allow for a significant reduction in the length of stay, increasing the bed turnover rate, while guaranteeing good continuity of care with a significant reduction in costs for the healthcare company.

4) The DS at HSPX has been structured as an innovative operating unit, where operating rooms have been set up to perform any type of intervention. This flexibility is a key tool, as it could allow the department to be repurposed in the future depending on the needs of the facility.

7. Figures, Tables

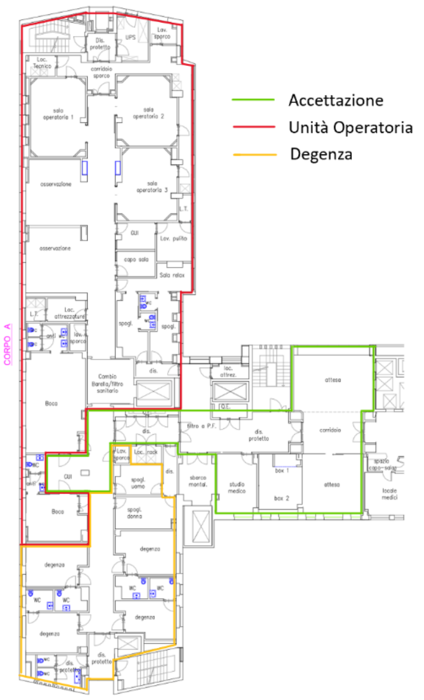

Figure 1. Planimetry of the DS in which the 3 macro areas of the new O.U. are highlighted. Operative nucleus in red, reception nucleus in green and inpatient nucleus in yellow.

Functional Core	Activities	Environmental units
Acceptance Unit	-Entrance, waiting for patients and companions -First check-up, preliminary checks -Administrative activities: filing of files, admission and discharge formalities	-Waiting space for patients/escorts -Medical examination room -GUI (nurse's station)
Operating Unit	-Patient preparation -Anesthesia -Physicians and nurses preparation -Surgical material preparation -Surgical intervention -Postoperative recovery and controlled patient awakening	- BOCA 4P, BOCA 8P -Filter area -Dirty Deposit -Clean Depot -Depot equipment -Dirty Workroom -Medical Locker Rooms and nurses -GUI -Chief nurse room -Relaxation room -Preparation area pre-operative -Wake-up area post-surgery -Operating rooms
Inpatient Unit	-Paramedic staff supervision and medical staff visits -Patient admission	-Patient locker rooms (men, women) -Houses: 2pl, 2pl, 1pl -Health services

Table 1. Activities performed in DS broken down by functional cores. The environmental units belonging to each DS core are specified.

N. Inv.	Medical Equipment Object	IPS value
34377	Apparecchio per Anestesia, mod. PRIMUS, DRAEGERWERK AG & CO. KGAA	**4,70**
37219	Apparecchio per Anestesia, mod. PRIMUS, DRAEGERWERK AG & CO. KGAA	**3,50**
37220	Apparecchio per Anestesia, mod. PRIMUS, DRAEGERWERK AG & CO. KGAA	**4,70**
38186	Tavolo Operatorio , mod. SE CC MODULO, NUOVA BN S.R.L.	**3,68**
38187	Tavolo Operatorio , mod. SE CC MODULO, NUOVA BN S.R.L.	**3,68**
38257	Tavolo Operatorio , mod. SE CC MODULO, NUOVA BN S.R.L.	**3,28**
36335	Elettrobisturi, mod. VIO 300D, ERBE ELEKTROMEDIZIN GMBH	**3,82**

Table 2. IPS values computed for the equipment examined.

8. References

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