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Through Engineering 4.0 the Safe Operating Block for Patients and Medical Staff

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***Abstract*— The Paper deals with the management of the operating block in its many activities. By a new approach and with innovative machinery specific several problems were thus studied and overcome, such as the control of hospital infections, the operations of washing and sterilization of surgical instruments, the planning of interventions, the tracking of drugs and medical devices entering the operating block, the management of stocks, the bed management, the monitoring of environmental parameters for patient comfort and safety, the monitoring of machines and the interlocking of doors, etc. Furthermore, it is proposed a wide use of the analytical tools to support decision making, extended to the most modern Cyber-Physical Systems and Digital Twin, alongside Machine Learning and Artificial Intelligence algorithms. Concluding with the new services that can be offered following the digital transformation 4.0 process of the operating block. Using the tools made available by the most advanced Engineering, an operating block was redesigned, safer for patients and medical staff and more efficient from a conduction point of view. This is done using an administration model that was first conceptualized, designed and then implemented adopting what is made available by Industry 4.0, as well as a series of Management Engineering methodologies aimed at an optimized government of complex systems. Through the data collected by appropriate sensors and translated by the software into usable information, there is an optimal use of the available resources, furthermore, the activities for which improvements can be made with the benefit of patients and structures are identified.**

***Index Terms*—Healthcare 4.0, operating block, operating rooms, Industry 4.0**

I. Introduction

THE study aims to transfer to the operating block, first, and then to the entire hosting facility, the advantages that Industry 4.0 has brought to industrial plants and, among these, the ability to monitor processes in real time and to control online in feedback, on the base of the parameters considered of primary importance for the correct functioning of the system. The system collects and centralizes peripheral data, from the process, to transform into usable information for the most diverse types of use. It should be emphasized that this takes place at any distance from the detection point and becomes accessible from any point of the globe, by an Internet connection, releasing the need of on-site operators.

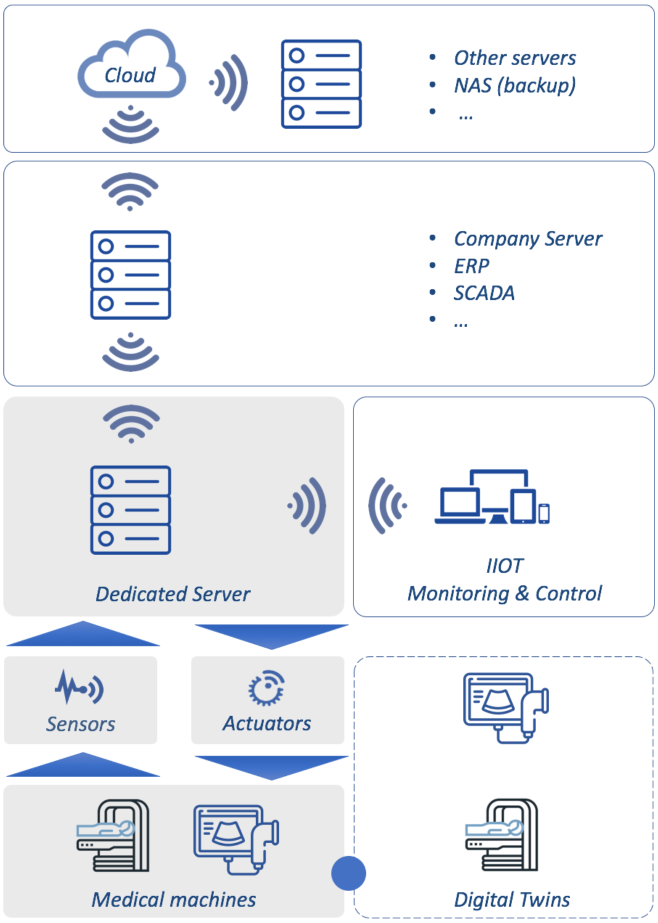

Fig. 1 System Architecture (Cyber Physical System)

The implementation process consists of 4 phases in series and 3 in parallel. The series phases allow to improve the knowledge of the machine park by a) centralizing the peripheral data, b) analyzing data, c) transforming data into information, d) making information available on any authorized device. The subsequent parallel phases allow the transition from monitoring to control and the extension to an advanced analytical phase by using the most modern simulation tools, such as Digital Twin and Cyber Physical System, to f) develop a superior knowledge of the process,

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g) improve performances, h) open the doors to new services. The core of the process, described above, is highlighted in grey (Fig. 1). It shows data collection, processing, and feedback control. The boxes surrounded by a solid line shows how the data, once centralized, can be shared with any authorized device and with the company server (note that the proposed system is totally independent, not to interfere with the IT architecture of the company). The local server will then make the data available for integration with the multiple platforms installed, such as ERP-Enterprise Resource Planning, MRP-Material Requirement Planning, CRM-Customer Relationship Management, and WMS-Warehouse Management System. If the hospital has a multi-site structure, the local server will share the collected data with any decentralized servers, to develop an aggregate vision and a detailed one, with the ability to monitor the whole hospital or any single point of collection. The box surrounded by a dashed line of Fig. 1 is reserved to Cyber Space, with the DT-Digital Twins of physical machinery, connected online and real-time. DTs have a totally independent life, but continuously learn from daily routines of the physical system, using Machine Learning algorithms. DTs allow both to improve knowledge of the system and to generate updated forecasts for resource management (personnel, infrastructure, stocks).

II. Identification of Risk Phases

Normally operating blocks hide unexpected risks for patients and operators, introducing more threats for safety than the surgery itself. From the literature it is known, in fact, that the hospitalized patients are, not infrequently, subject to aggression from viruses and bacteria, to heal which it is necessary to intervene with strong and complex treatments, due to the resistance developed by such pathogens to drugs. The direct consequence is the dangerous infections for the patients and the additional costs for the institution, which must provide appropriate treatment. The presence of insects, molds and even rodents is also a possible event, the solution of which is not trivial due to the impossibility of using common insecticides and rat killers, which would generate new phases of risk in a sterile environment. Another problem that is often seen, especially in periods of overload, is that a surgical tool escapes the control of the operators and is forgotten into the patient's body, with the need to repeat the surgery for its removal. It is easy to imagine the negative consequences for the patient and for the institution. Another point is about the safety of the operating-block-personnel assigned to washing the surgical equipment, arriving "dirty" from the operating rooms, which must be pre-treated before starting the sterilization cycle. It happens, non-infrequently, that they accidentally get cuts or punctures, aggravated by contact with the organic material of the patient, thus exposing the operators to serious risk of contamination.

III. Operational Criticalities

The management of an operating block (generally consisting of multiple operating rooms), then extended to the entire hospital or, even, to multi-site structures, presents non-banal complexities, with a 360-degree impact on efficiency, costs, and customer satisfaction. By way of example: a) the management of medical devices and drugs is normally difficult in terms of sizing, purchasing and traceability within the operating block; b) the consumption of technical gases is difficult to monitor in real time, with negative consequences on stocks and restocking; c) the upstream integration with suppliers is usually lacking and it is limited to contacts for ordering and for consultancy; d) the monitoring of patients in the recovery room, as in the departments, forces the management to make a heavy investment in staff for 24-hour control and, nevertheless, residual inefficiencies impact both on the safety and comfort of the patients; e) personnel and guest addressed to specific areas may be taking wrong paths, generating inconvenience, risks and impacting on flows; f) the preparation of the surgical kits for the interventions is complex because it is affected by great variability in planning (as described in bullet g); g) the processes of planning, scheduling and re-scheduling surgeries are extremely difficult, due to cancellations (patients' transfer, illness, death), insertions (urgent interventions), replacements (changes), unavailability (team, machinery, operating rooms) and the duration of the interventions (normal variability). This requires the head nurse and the staff significant efforts for re-scheduling in urgency, with implications on the system and stress of the staff. This approach makes impossible to optimize the agenda and provokes the reduction of the interventions that can be performed. The consequences are slippages, elongated lists (dangerous factor for health) and, also, the economic damage for the Organization.

IV. Identified Applications

Along the analysis phase of such problems, the authors identified several axes of intervention.

A. *Tracking*

Critical aspects for the operating block are certainly that of the traceability of incoming medical devices and drugs. The main reasons for this importance are: a) the need for a continuously updated image of the stock in the operating block; b) the inventory management (maintaining minimum stocks, while avoiding stock outages); c) the real-time control of obsolescence and reviews (of tooling) and deadlines (of drugs); d) the possibility of exact localization of tooling and drugs within the operating block; e) the possibility of associating the single product to the batch to which it belongs; f) the confirmation of actual use (difference between stored and consumed); g) the traceability, over the years, of drugs and prostheses administered to patients. The proposed technology, overcoming all these problems, is based on the application of 96bit-tags (in form of small labels) to each product entering the operating block, to be scanned in radio frequency by special antennas (or gates), suitably located in the layout. A dedicated server manages the flow of product data, organized by channels, into a database. The analytic designed provides the operator, by a friendly interface, the information necessary to improve management. Integrated systems such as "smart bins", positioned in each room, check actual consumption and waste in real time, thus providing up-to-date feedback to the tracking system.

B. *Sanitization*

According to the Sources consulted (hospital infections: elements of epidemiology and prevention 2004; healthcare-associated infections in intensive care units - Annual

Epidemiological Report for 2015) nosocomial infections are infectious diseases acquired in hospital or in healthcare settings (nursing homes, long-term hospitalizations, etc.) which affect between 5% and 10% of patients, causing 80 thousand deaths a year in the USA alone. Consequently, this issue was considered by the authors of particular importance as too often it was heard that a patient who entered the operating block for any type of surgery came out perfectly healed (from a surgical point of view), but struck by a viral or bacterial disease, sometimes even severe, there contracted. It was therefore decided to investigate this topic through the rigorous analysis of data. The solution elaborated and recommended consists in the adoption of a 4.0 machine, designed and developed directly by the authors, used to perform a 2 steps approach: a) between one patient and the next, to systematically intervene with a treatment, lasting only a few minutes, based on UVC rays, controlled in wavelength and frequency; b) at the end of each shift, to launch a radical treatment with gaseous Ozone, thus guaranteeing absolute sanitization against viruses, bacteria, insects, molds, spores. These procedures provide much greater safety guarantees compared to the current process, as scientifically recognized by the sector literature on a planetary level. This comes with negligible operating costs and with the advantage that the room can be readily resettled. None of the treatments described leave any residue in the environment, so cleaning is not required at the end of the cycle. Both the steps are conducted in the absence of personnel, therefore not exposing the operators to any risk. Gaseous ozone allows to sanitize the entire operating block automatically, by centralizing the operations according to the principles of Industry 4.0. For an in-depth analysis of the topic in question please refer to the full text of the paper presented by Marco Mosca at the Word Congress on Engineering, IAENG 2021, where the authors obtained the best paper award for the biology and bioengineering section [21]. The 2 proposed steps, of equal effectiveness, have different characteristics and applications: a) UVC rays act by proximity, in a few minutes and work by radiation (they do not cross surfaces, mattresses and sofas), therefore, they are suitable for quick sanitization between one patient and the next; b) gaseous ozone acts more slowly (according to the specific concentrations and timing of exposure, defined in literature by appropriate tables), with the difference that it can sanitize the entire operating block with a single treatment, because not stopping on the surfaces and deeply penetrating fabrics, mattresses and sofas. It is therefore suitable for a deep sanitization at the end of any shift. The main strengths of both proposed technologies consist in: a) dry sanitization without leaving residues (it does not require cleaning after treatment); b) procedure free of substances being harmful and permanent in the environment; c) frequent (part-time operator), fast and safe sanitization; d) compatibility with desks and bookcases (does not damage electronics, paper, and furnishings); e) low cost process, as it is cheaper than vaporized substances (which imply a daily expense) and the sanitation performed by external companies.

1) Sanitization of Access to the Operating Block

People (medical and nursing team, cleaning, and maintenance operators) and things (surgical equipment, drugs, machines, products, ...) have almost continuous access to the operating block. Such area has higher hygienic needs than the any other of the structure and, therefore, must be protected from pathogens, viruses, bacteria, molds, spores, insects, and rodents. Consequently, the access to the operating block is configured as a critical gateway to the hygienic preservation, which would require the sanitization of any entering element. For this purpose, it is proposed to intervene on people by restricting the transit to a sanitizing platform irradiating UVC rays and on things by conveying them through a tunnel, that they cross on a motorized belt, while being irradiated with UVC rays. [21]

2) Sanitization of the Filter Room

The access to the operating rooms is possible only through a small room in the front, called “filter”, characterized by two sliding doors (positioned upstream and downstream of the filter) with the purpose of separating the operating room from the upstream process phases. In the filter, in fact, the staff leaves clothes and shoes coming from outside and wears clean clothing. The identified risk consists in cross-contamination during the change shoes which, polluting the floor of the filter, may cause the clean shoes worn by the staff to lose sterility. Same for the clothes, stored in lockers which progressively get dirty. For this purpose, an almost continuous sanitization process is proposed to be performed on the filter by applying the approach described in the previous chapter: during normal activity, by means of UVC rays (in operation after each transit) and, at the end of each shift, by gaseous Ozone. [21]

3) Sanitization of the Operating Room

Here again, it is performed with a continuous sanitization process using UVC rays for quick sanitization at each use and Ozone for deep sanitization at the end of each shift. [21]

4) Sanitization of the Sterilization Room

The sterilization room is composed by 2 areas: the dirty one (washing, decontaminating, sterilizing) and the clean one (downstream to the autoclave). The dirty area presents an important phase of risk for the operator who, statistically, is subject to the likelihood of being punctured and cut with the surgical tools during the washing phase, with exposure to the danger of contracting diseases such as, for example, HIV and Hepatitis. For this purpose, this area is now protected with a "hand free" machine specially engineered by the authors, which is placed before the washing phase to execute a pre-sanitization of the surgical tools upstream of contact with the operator. The features of the machine are the direct loading of the tray coming the operating room, the rinsing of the irons without having to touch them, the high-pressure pre-wash and the final UVC treatment. However, the machine does not replace any of the current sterilization procedures, but it integrates the process.

5) Sanitization of the Air Conditioning System

The air conditioning system generates a risk phase for the spread of pathogen agents from one room to another of the operating block. Such pathogens tend to lurk in the ventilation ducts and, part of them, in its filters. The cleaning of the ventilation filters, again, presents more phases of risk such as an incorrect frequency or procedure of sanitization and the contact of operators with contaminated filtering material. According to a basic principle of resilience, it is proposed to convert this weakness into a strength, by using UVC rays to keep the HVAC (Heating, Ventilation and Air Conditioning) pipelines continuously sanitized, thus drastically reducing the opportunity for room-to-room contagion. The same ducts are used also as a vehicle for Ozone during rest shifts, to deeply sanitize the entire operating block eliminating the need to move bulky machines from one room to another. This approach keeps the HVAC filters continuously sanitized, with no need for intervention by the operators. The Ozone produced is then automatically disposed of before re-populating the treated rooms, according to the previously described procedures.

C. Surgical Equipment Counter

A serious and, unfortunately, not uncommon problem in the operating rooms is the possibility of stitching up the patient after the surgery, by forgetting surgical tools within the operating field. This eventuality is due to multiple and complex parameters to manage such as the stress, the speed imposed by the surgical requirements, the large number of irons and tools used, the fact that the team is made up of multiple members, as well as the wide range of standard surgeries, often considered as routine. With the aim to counter this problem, the authors first conceptualized and then developed an "intelligent" holder tray for surgical equipment, which allows for the recognition of the overlapping tools, regardless of their positioning on the surface. It works using combined technologies on a mechanical and optical level, such as to ensure cross-checking to redundant safety. The tray then “communicates” with the operator by remaining lit in red until it recognizes the presence of all the tools initially contained, condition in which it lights up green.

D. Bed Management

Bedridden patients are not infrequently subject to events that can have serious consequences for their safety. These are, for example, clumsy attempts to get out of bed. The act of climbing over the banks (bed protection bars) results in falls that may cause fractures of various kinds to the patient from the less severe but painful (limbs, cheekbones, ...) to those that are ruinous (femurs, pelvis, ...). To prevent any of these from happening, a 24-hour surveillance would be required, which is not always possible for all the critical beds of the structure. In this case also, using Industry 4.0, the authors created a system which, being integrated into each bed (so freeing the patients from wearable devices), detects any attempt of abandonment and real-time notifies the event to the control center, enabling sudden intervention and preventing the consequences. Other important parameters monitored are movement / stasis, vibrations (epileptic attacks), dry / wet bed (favoring the formation of pressure sores), weight trend, etc. [29]

E. Monitoring of Environmental Parameters (Comfort and Safety)

To improve patients and operators’ comfort (and to save energy at the same time), the ability to monitor and to control centrally and real-time parameters such as temperature and relative humidity plays a primary role. At this purpose environmental data are collected peripherally and analyzed centrally. The system allows the integration of the data collected for operating on different levels: an aggregated level, producing an overview of the whole structure, or a detailed one, where the operator can easily drill-down into floors or departments, aisles and rooms, with the possibility of zooming down to each sensor (e.g. corridors, kitchens, technical rooms, common areas, ...). The simplicity of extending the number of sensors, unlimitedly, allows the management to increase the parameters to monitor and to control in feedback, both in the operating block and in the entire structure, as well as in other connected structures. The same system, equipped with different sensors, can be used to monitor safety parameters like flooding, smoke, fire, gas and technical gases, a selection of bacteria and radiations. The greatest benefits consist in the prevention of disastrous events, thus preserving the safety of people and structure.

F. Monitoring and Control of Machines

The efficiency of the machines depends on multiple operational and maintenance factors. Along life cycle, the machines tend to progressively decrease efficiency, which can provoke a loss of performance, but can also shorten the duration of the same in case of maintenance deficiencies. The damage caused by a possible breakage is calculated, in addition to the extraordinary costs for repair, as downtime risks and costs. In fact, the unexpected unavailability of machine would be dangerous both for the patient (in terms of safety) and for the structure (in terms of reputation and cost). It is therefore proposed to intervene on the continuous monitoring of machines efficiency by affixing appropriate sensors and analyzing the data collected by means of statistical process control (Fig. 2). The definition of control limits makes it possible to anticipate, with traffic-light alarms, the reaching of preset thresholds, thus monitoring the health of the machinery. This method allows to maximize the efficiency and to minimize unexpected failures. For those failures that cannot be predicted in advance, such as the blown of a fuse (with a sudden transition from available to unavailable) the system provides, anyway, with a sudden central detection. The data collected is recorded on control cards, to map the performance and to monitor the efficiency.

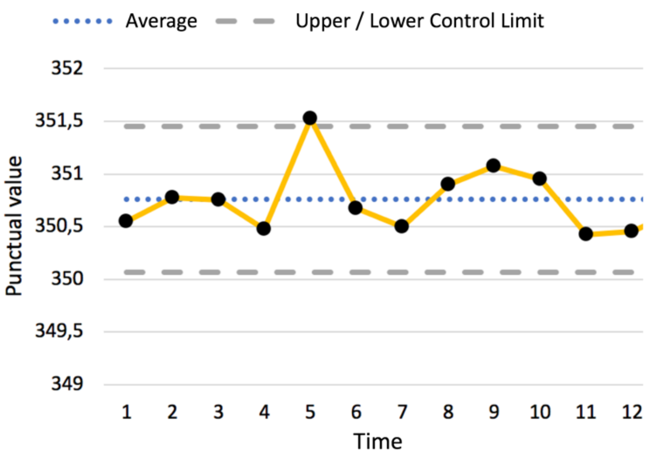

Fig. 2 Control card

1) UC (Utilization Coefficient)

By a constant surveillance the operating block in a 4.0 logic and using the IOT (Internet Of Things), the management can continuously control this important index and make real-time decisions. Non infrequently, in the healthcare sector, it happens that capital intensive machines

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end-up having a low utilization coefficient due to logistics problems in flow (upstream or downstream). This is due, for example, to the lack of personnel or to organizational deficiencies to support the services offered. Serious consequences may impact on the economics of the institution (facing a very long time for the return on investment) and on patients (enlarging waiting lists before examinations, that are sometimes essential for diagnostic purposes). From these considerations originated the attention of the authors in monitoring the UCs of the various components of the operating block, in the full conviction of providing, through constant monitoring of such indexes, strong support to the managers for an optimized administration in terms of care and costs.

2) OEE (Overall Equipment Effectiveness)

The analytic software also calculates the OEE (Overall Equipment Effectiveness) which allows the management to evaluate the performance of the machines with respect to the waste of direct operating time, attributable to the lack of availability, speed and quality.

G. Energy Monitoring and Energy Saving

Energy saving is a current issue and widespread problem for energy-consuming systems. It is considered as a critical factor that is worth keeping constantly monitored, especially if the structure is composed of different sites. In fact, sites are normally featured by similar needs and results, but may encounter significantly different consumptions. Therefore, a real-time system is designed by the authors to monitor and control utility consumption, lights, and climate, with the possibility of extending monitoring to the entire structure and to the other belonging sites. Such analytics is self-consolidating to autonomously build an overall vision, with the possibility of performing drill-down (progressive explosion down to the single sensor), of monitoring individual consumptions (surgeon, team, ...), of switching utilities on-off remotely. Therefore, it normally produces significant energy savings. Furthermore, if associated with a Digital Twin equipped with Artificial Intelligence it can define different scenarios, for improving, in parallel, even multiple objective functions.

H. Technical GAS Consumption Monitoring

Surgical interventions require the use of multiple technical gases. The actual consumption is not easy to monitor in rea-time in the whole operating block, especially in case of multi-site institutions. The detection and centralization of this information would produce benefits extended to several areas, as monitoring cylinder pressure and residual gas in the cylinders, cylinders consumption, real-time inventory monitoring, stock outage prevention and optimization of re-orders and inventory. The associated analytic also allows the possibility of comparing the consumption by structure and by team, so improving costing and pricing by intervention, as well as the definition and compliance with standard costs, therefore improving, at the same time, the knowledge of the process.

I. Warehouse Picking 4.0 and Surgical KITs Preparation

The packaging of surgical kits could be professionalized and streamlined by means of an automated central picking system, which autonomously collects wrapped and self-clawed irons, medical tools, and drugs. This small infrastructure would replace the stock warehouses in the operating block, with substantial differences in productivity and safety. In relation to productivity: a) the image of the warehouse is continuously updated; b) the stocks is kept to a minimum (in consideration of seasonality and lead times); c) the risk of stock out is prevented; d) the mistakes are eliminated (wrong product or forgotten product); e) the preparation of daily surgical kits is automatic, on input of the connected scheduler; f) any stock obsolescence is anticipated and alerted; g) the time saving of operators and office staff is continuously achieved. About safety: the self-sanitization of the warehouse and contents by UVC rays (prevention of molds, viruses, bacteria, insects and rodents) is automatically performed after any opening. The proposed system was conceptualized and developed by the authors, in 2019, for small and medium-sized enterprises operating in the pharmaceutical, beauty and cosmetics sectors cit. [22]. Such system is perfectly suited to meet the needs described above for the operating block.

J. "Hands Free" Voice Control

The operating rooms, although exposed to continuous sanitization processes, still presents residual issues of cross-contamination, which can be critical for safety. For this purpose, the manual controls of machinery are normally operated by means of touch screen interfaces, which are suitable for quick sanitizing by using liquids. The next step consists in the possibility of controlling any utility by voice control. A simple library of standard vocal commands is provided by the authors to the medical staff; therefore, no voice training is required.

K. Digital Supply Chain and VMI (Vendor Managed Inventory)

The concept of 4.0 digital supply chain can be applied to the operating block, offering significant advantages using the cloud and IOT. By giving to the qualified suppliers constant visibility on the level of stocks of each item, based on the actual demand from the warehouse and from the internal pharmacy for delivery by a certain date, it is possible to give the supplier the responsibility of maintaining the right level of stock for each product (drugs, devices, tools, consumables for cleaning, ...). This level (re-order point) is set, item by item, according to the theory of stocks, frequency of consumption, lead times, seasonality, and any trends; the image of each level is always updated in real time. Upon reaching this point, the supplier, automatically delivers and invoices an appropriately calculated quantity (EOQ, Economic Order Quantity) of the item under stock. As per theory, re-order point and EOQ are calculated in such a way as to minimize the cost of stock but, at the same time, to prevent possible stock outages. By operating in this way, the management eliminates the risk of going under stock, which is essential for important drugs or tools, as well as of going over-stock, with the related costs and the risk of disposal for expiration. By acting in this way, several internal operational steps will be avoided (as inventory control or order issuance to the supplier, ...), with a significant saving of time by the warehouse and purchasing operators and related costs. For each shipment by the supplier, appropriate automated control procedures will evaluate the correctness of the same in terms of re-order point and EOQ and, in case of full compliance, the hospital offices will confirm the payment for the invoice received. In

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accordance with the practice of VMI (Vendor Managed Inventory), following a supply agreement between the partners (hospital and suppliers) and a selection of qualified suppliers, the structure is released from problems like inefficiencies and sourcing costs.

L. Reporting Analytics

Starting from the assumption that “what cannot be measured cannot be controlled nor improved”, great attention was paid to the data provided by the sensors applied. However, the data, unless properly analyzed, do not constitute information, because its volume and variety make it not intelligible to the operators. Therefore, the software developed transforms the data into usable information, in the form of reports with graphs and tables, thus developing a deep knowledge of the care and management processes. These reports make it is possible to improve the knowledge of the process and to act on the process in feedback. The objectives are to improve the process performance, to develop best practices that can be replicated into other processes (for example in other structures), to automate some process phases and to extrapolate information through simulation.

1) Crystal Report

The performance measures are multiple and different from each other, for this reason they can be presented and analyzed at different levels of aggregation. The more aggregated they are, the more they take on a strategic value; the more detailed they are, the more they take on an operational value. Therefore, focusing on traditional performance measures such as quality, reliability, speed, flexibility and cost, composite measures are created that allow the management to generate an overview of one or more structures, with the possibility of progressively breaking them to lower levels, down to the individual KPIs. Such measures become more intelligible and usable once automatically organized in crystal reports by the implemented software.

2) Operational Times Analysis

Following the classical theory, the software allows supervisors to detect the running time RT, the operating time OT and the non-operating time NOT. The ratio between the OT and the RT is the availability index, which classifies the time in which the machine is available for use. The OT is then divided into directly operational time DOT (effective use), and non-directly operational time NDOT (plant stopped due to delays caused by inadequate scheduling). Then the ratio between the DOT and the OT is the rate of performance, which distinguishes the time in which the machine works at full speed from the time in which the machine faces a stop. In case of quality unconformity during the time in which the machine performs a useful work, it is registered a waste of time (need for rework).

3) KPI (Key Performance Indicators)

KPIs are indexes used to evaluate a certain magnitude or trend with the scope to quickly obtain knowledge from the data collected. They can be consolidated, based on the specific needs of supervisors. By increasing the level of detail, it is possible to investigate the root causes of problems so to identify possible solutions. In the case of operating block 4.0, more indicators are identified such as, for example, the percentages of unsuccessful interventions or the hospital infections contracted for surgery, or deaths that have occurred due to infections contracted, etc. Furthermore, KPIs can be created to measure the time spent by patients waiting for hospitalization and compare them with those required by law. The KPIs can be reported in a dashboard that allows, by clicking on a graph, to easily navigate aggregate information down to specific data.

4) Balanced Scorecards

It is a tool that allows the management to integrate, in a single dashboard, indicators of different nature, in the short and long term, financial and operational. To create a balanced scorecard, in healthcare, it is necessary to answer 4 questions: "How do the lenders see the structure in terms of managing the capital transferred to it?" (financial indicators), "How do patients see the structure?" (satisfaction indicators), "What should the structure excel at?" (operational indicators), "Where do the structure need to improve?" (growth indicators).

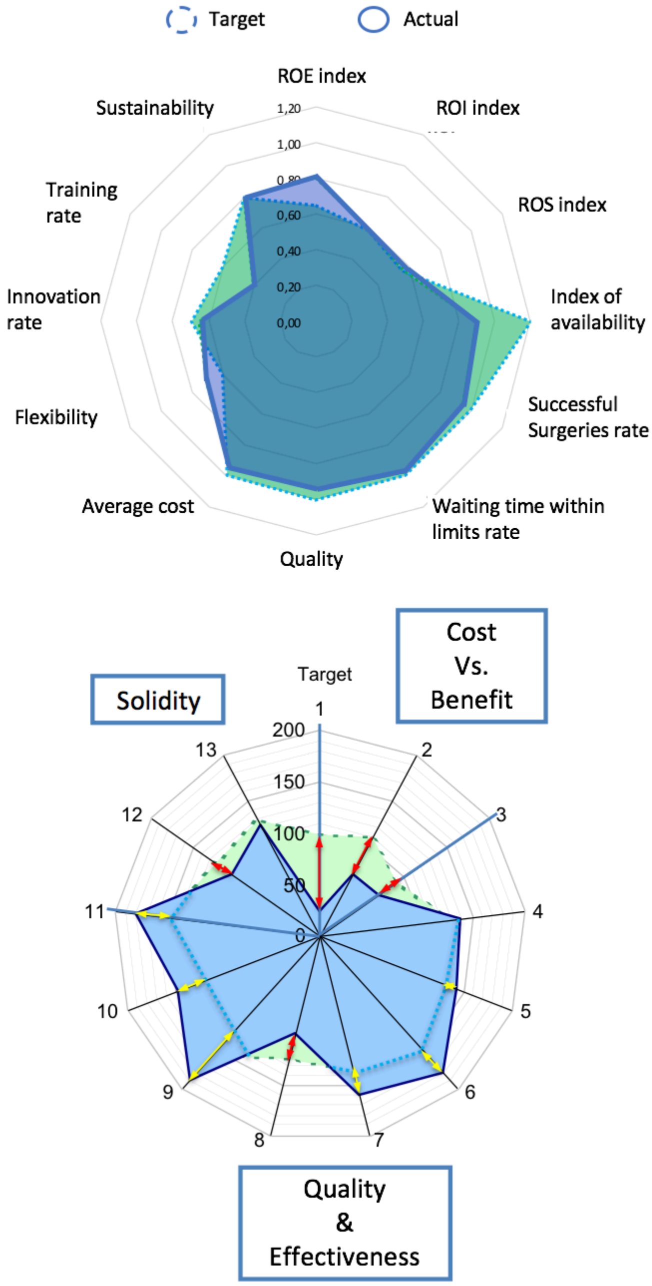

Fig. 3 Balanced Scorecard

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These indicators can be monitored by radar diagrams for a clear comparison with the objectives set or with the sector average, thus highlighting, in a simple and intuitive way, the areas of under-qualification (to be strengthened) and the areas of over qualification (in which an excess of flexibility causes a bad performance on costs, which can be identified and traced back to savings). As illustrated in the example graph (Fig. 3), a varied series of indexes can be evaluated, according to the specific needs and easily compared with the targets. The areas surrounded by a dashed line represents the goal, while the areas surrounded by a solid line is the actual result. Where the solid line area exceeds the dashed one, the intended objectives have been achieved and even exceeded. This means that the structure was particularly effective in that area but can incur in waste, by performing more than needed. The distance between the two areas also gives information on the magnitude of the deviation. In case the dashed line area exceeds the solid line one, it means the performances achieved by the structure are lower than the target, providing a clear information of where to intervene, by investigating the causes provoking such deviations.

5) Data Log and Statistics

It is possible to conduct statistics on the collected data to facilitate the understanding of the trends of certain quantities and the level of compliance with the target. Once data has been gathered through a specific collection sheet, it is inserted into the database. At this point, basic analysis can be carried out, such as the evaluation of the type of statistical distribution of the quantity in question. It can be observed, for example, when the process is running out of tolerance. Therefore, it becomes important to analyze the causes of these results. Other statistical analysis refers to trends and seasonality. For example, it is highlighted the seasonality of hospitalizations and evaluated the trend over the years, in this way making visible information otherwise hidden, which are necessary for demand forecasting and, consequently, for demand planning.

6) Statistical Process Control

Statistics can be used to check whether the process is in a statistical control regime or not. In the first case, deviation from the average is due exclusively to common causes (which cannot be eliminated because they are inherent in the process); in the second case it can be expected to find special causes (which can be eliminated as such as errors, wear of the tools used, maintenance deficiencies, etc.). Once data are collected, control charts can be implemented, as graphic tools capable of providing a series of information on the presence and type of special causes affecting the system.

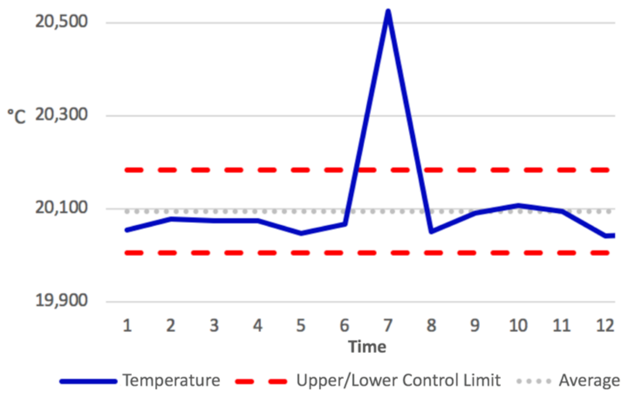

Fig. 4. X-Average Control Chart for Temperature

There are available various types of charts in dependance of the process under consideration. With them it is possible to monitor several quantities, such as the number of corrected interventions on the total and the various environmental parameters compared to the target range, such as the temperature or the humidity (Figure 4).
Clearly, the control charts highlight possible outliers briefly. An example of a graph of this type is the scatter plot reported in Fig. 5. Here, it can be observed an outlier in the mean value of the sample. We then move on to analyze the situation to investigate the root causes. Therefore, possible factors affecting the system are evaluated and, only at this point, correlations between the measured data and the possible cause are identified.

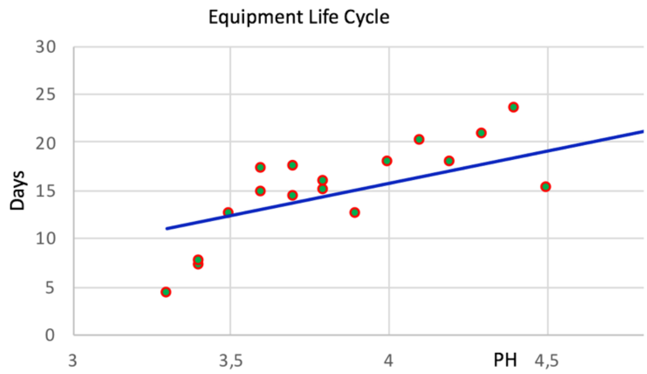

Fig. 5 Scatter plot on the useful life instrument / pH correlation

This example shows how the life cycle of an instrument (measured in days) is correlated to the PH of the substance with which it comes into contact. By adjusting the same, therefore, the duration of use of such instruments can be increased. Following, a Pareto curve ranks and sorts the causes affecting the system, which can be multiple (normally it is not possible to intervene on all of them at the same time quickly and with low costs), so providing a clear indication on priorities.

M. Analytics and Tools to Support the Interventions

1) Scheduler

In all operating blocks visited by the authors, the scheduling process of the interventions follows a standardized process based, normally, on the following phases: a) Planning (rough scheduling performed every 15 days based on the information available); b) Scheduling (review of the planning performed every 7 days on the basis of updated information and any changes; c) Re-Scheduling (review of the surgical day-plan carried out the morning of the interventions in consideration of specific constraints such as: insertion of urgent interventions, cancellations due to illness, health, abandonment, death, replacements for patient change, unavailability of teams, machinery or rooms); d) re-scheduling review (adjustment of the re-scheduling, carried out in progress along the operating day itself, in consideration of specific constraints such as: accumulated delays on interventions due to the normal variability of their duration, last minute events such as any new entries, cancellations, replacements or unavailability). In consideration of this, the authors decided to propose the management of the operating block 4.0 highly effective tools to support the programming of surgical interventions. The scope is minimizing the under-use of the operating

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rooms and related teams, generated by the last-minute changes due to patients (on the list for the intervention) which must be cancelled or added for the most diverse causes (cited above) with the consequent need for re-scheduling. Such task is carried out normally by the institution nurse (which is expert in surgical procedures but not in management) who must strive under pressure to re-schedule the surgeries in the best possible way, knowing in advance that the result will not be able to optimize the use of resources, with a clear economic damage for the structure. Using the tool made available by the authors (a Scheduler in this case), the medium-term planning, as well as the short-term planning and re-scheduling of the surgeries are continuously updated. This comes from a specific algorithm, which has the goal of keeping the resources optimized, in the occurrence of any disturbance events. Such Scheduler, in an agile way, allows the generation of alternative scenarios in consideration of constraints (which can be easily inserted, from time to time, by the institution nurse). Combined with other tools such as Digital Twin, Machine Learning and Artificial Intelligence, it allows the institution nurse (with a minimal training) to refine scheduling on variable parameters (like preferences / habits of certain surgical teams or the variability of specific surgeries). By acting in this way, the Scheduler allows the institution nurse to choose, according to the scenarios offered, which of the objective functions to optimize (e.g., maximum number of interventions, less waste of time, minimization of waiting lists, ...). It is also possible to relaunch the Scheduler in progress at any time, if cancellations, insertions, or variations of the surgical times should occur in the working day. Finally, where several teams intervene (surgeon-anesthetist, nurses, operators, cleaning staff, maintenance workers, …) the Scheduler is able to distinguish the different types of activities to proceed to parallelize the operations, thus allowing to increase significantly the coefficient of utilization and, therefore, the surgeries that can be carried out, shortening the waiting lists and improving the level of service at the same time.

2) Analysis of Surgical Kits (Equipment, Tools, Drugs)

The appropriate scheduling of the surgeries allows for the optimization of the use of infrastructures (availability of the rooms) and of the teams (medical, nursing and re-set / cleaning of the operating rooms). To optimize the management of operational resources (surgical irons, medical devices, drugs, ...) it is proposed to integrate the Scheduler with an ad hoc process of preparation of the interventions, which consists of the phases of defining the operating kits, sizing, and controlling the stock. This information is then provided in feedback to the procurement department. The definition of the kits consists in configuring the Scheduler with standardized kits for each type of surgery, so that the software, in consideration of the interventions scheduled for the day, can check the availability of any operational resources, and validate the surgical plan. The Scheduler considers, also, the sterilization performance between one surgery and the next, to minimize the need for sourcing new equipment. The definition of the kits, with consequent proposal to the operators, allows an accurate preparation of the operating day, reduces the stress of the operators, and prevents possible errors. The sizing and control of stocks consist in the continuous and automated comparison of the kits defined with actual consumption. It allows to substantially improve the control and management of stocks, thus avoiding the common problems of shortage and the costs provoked by precautionary contingencies. Feedback to the procurement department allows the purchasing operators to improve ordering performance, avoid errors and reduce office times. As already mentioned, this phase can be further improved in performance and speeded up by switching to a VMI-Vendor Managed Inventory logic. In this way, the information is automatically transmitted to the supplier of medical devices and drugs, who provides to refill autonomously. The role of purchasing, instead, is limited to the negotiation of prices and approval of the outgoing orders, automatically generated by the system.

3) Digital Twin

Simulation plays a central role in Industry 4.0 because, when properly developed, it can increase the knowledge of both process and business. The “Digital Twin” of a machine or system, connected online and real time, lives an autonomous life, parallel to its physical twin and continuously learns from the evolution of the system, without exposing reality to any risk. Once the performance of the Digital Twin has been tested, it is able to project virtual operations over various time horizons, allowing the management to analyze the performance in the future. This tool allows, for example, to prevent problems, to react to changes in status, to maximize availability, to optimize the stock, to make accurate forecasting, to shorten waiting lists, to improve maintenance performance, etc. It is able, also, to predict trends, cyclicality and seasonality based on Machine Learning algorithms, and to dialog with the Scheduler to improve the coefficient of utilization of the rooms and of resources. As well, it can have quite a strong impact on the OEE of the machines, and automatically return inputs to the Scheduler, for example in case of delays in the operating rooms, so maximizing the number of sustainable surgeries (perfect parallelization of teams, surgeon-anesthetist, responsible of equipment, cleaning operators, …). By learning from reality and projecting in future, as described above, the life of the system, the Digital Twin is capable to continuously develop and propose multiple improvement scenarios (that can be further evaluated and improved by a simple use of Artificial Intelligence algorithms).

4) Cyber Physical System

The CPS-Cyber Physical System is the broadest and most important concept of Industry 4.0. It consists in the continuous comparison of the real world with a cyber world (made of the Digital Twins of the subsystems). Such comparison can anticipate problems and much improve overall performance. It is, in fact, a larger connected simulator, online and real time, which allows, through Artificial Intelligence and Machine Learning algorithms, to make autonomous and decentralized decisions. CPS continuously propose improvement scenarios to operators on a circumstantial basis. It makes the system self-configuring and adaptive, according to the happening situations that arise daily.

5) Machine Learning and Artificial Intelligence

As previously anticipated, the final and integral step in the adoption of Digital Twin and Cyber Physical System is

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the extension of these technologies through Machine Learning and Artificial Intelligence. It consists of a second level analytics that is particularly effective in managing the natural stochasticity of the systems, such as to minimize the variability, which is a sworn enemy of any process performance.

N. Dematerialization and Digitization of Documents

In compliance with the current trend on the dematerialization of documents, it is possible to implement the process in the two phases of scanning the existing documents (after identifying the documents which can be dematerialized, according to law) and creating a digital archiving system. As well, new documents will be created and managed digitally, without the need for producing any paper output.

O. Interlock of Doors

Sterile environments, such as operating rooms, require access point control such that only one door is open for each room at a time. This applies to multi-door rooms, pass-through lockers, and patient passes. In this regard, the authors have developed an interlocking system suitable for any type of door of the operating rooms (automatic sliding, automatic swing, lockers, and patient pass). The software, in a system with 2 or more doors, allows the management to define the opening logic (e.g., permission to open one door at a time). It prevents accidental or distracting opening of a door when it shall remain closed (Poka-Yoke effect which does not allow the operator to commit a specific mistake), avoids accidents from unexpected opening, etc. Among the obvious benefits it frees the structure from costs for restoring problems caused by opening conflicts.

P. Service 4.0

From the application of the technologies made available by Industry 4.0, many innovative services emerge. By way of example, consider the opportunity to classify patients and to assist selected patients at home, for chronic diseases or for temporary saturation of the structures, being able to monitor them, in real time, according to the most modern IOMT systems (Internet of Medical Things). This is the case of Bed Management, previously described, of monitoring and delivery drugs, with prompt intervention in case of need. The service can be extended to assistance and maintenance of the installed systems, trusting in the self-diagnostics and, where expressly requested by the company, of remote data management by the cloud, in full compliance with cyber security, and subsequent integration with the structure installed management systems (ERP, WMS, …).

V. Conclusions

A widespread worldwide diffusion of the operating block 4.0 will allow doctors, surgeons, and nurses to carry out their irreplaceable activity in conditions of higher safety for themselves and for the patients. The result is safeguarding the integrity of tens of thousands of patients who, currently (for exogenous causes), they lose their lives in the operating blocks. In addition, an optimized structure-management will produce significant advantages in terms of better use of staff, machinery, and systems with a consequent reduction in waiting lists, less stress for the personnel, optimal use of the systems and, therefore, maximal impact of any connected investment.

With a moderate cost increase (on average between 10% and 20% of the value of the initial investment, depending from the solutions adopted) the operating room is subject to digital transformation 4.0, without altering any balance, or ergonomics, or layout of the original operating room, as it is shown in figure 6.

Fig. 6, operating room, 3D model

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