

## IT & MEDICAL DEVICE

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The IOR (Rizzoli Orthopaedic Institute) specialises in orthopaedic and traumatology surgery and makes use of eleven operating rooms, divided into two distinct sections designed to differentiate routine surgery from day surgery. These facilities have been radically reorganised during the past two years. Doctors at the Rizzoli Hospital tell us what has changed and why.

### **Computerising the Surgical Block at the Scientific Institute for Hospitalisation and Healthcare, "Rizzoli Orthopaedic Institute" Bologna**

The Surgical Block is one of the main expressions of a hospital's performance, and its success is of the utmost importance for the facility's progress. Its management entails a considerable financial burden as surgical procedures are daily becoming more complex and technologically demanding.

Streamlined clinical, managerial and economic efficiency in the Surgical Block has a strategic effect especially on facilities, whose core-business is surgical activity.

Launching the Computerisation Project in the Surgical Block of the Rizzoli Orthopaedic Institute (IOR) required project managers to decide how to structure it, whom to involve in the product analysis and adaptation process, how to implement its use, and how to retain control of potential risks. This is achieved by effectively meeting the Hospital Management's request to maintain the volume of activities performed unaltered, while informing the operators involved and ensuring safe working procedures.

### **THE IOR AND COMPUTERISATION**

The IOR specialises in orthopaedic and traumatology surgery, which is carried out in 11 operating rooms that have been completely renovated in recent years. The facility is divided into two distinct surgical blocks that are situated in different areas to differentiate routine surgery from day surgery.

The Rizzoli Hospital's current IT system (SIR) was first studied in 2000 with the immediate goal of integrating patient management into the hospital's workflow. Since then we have witnessed the development and implementation of forms for the Emergency Room, Outpatient Services, Waiting List and Admissions Management, Management of Physiotherapy Cycles, Medical Mobility and Management of the Medical Records Archive. 2008 marked a change when the electronic medical record was implemented in all departments, shared with healthcare professionals and linked up to the existing software of transversal services (laboratory of analyses and pathological anatomy, imaging diagnostics) in client-server mode. Every new implementation led to the progressive enrichment of both the hospital's repository and the regional Electronic Healthcare Folder.

The operating room and related processes were an important missing link in this setting of progressive computerisation of the healthcare area. The presence of a non-encoded

surgical list common to all hospital units, hard copy management of implantable materials required for surgery and the purchase of new stocks, and the lack of data flow regarding Operating Room schedule and activities have generated the need for a computerised system that would include all the main and secondary aspects of surgery, while allowing the use of devices designed to manage the clinical risk.

The analysis of the organisational context also revealed some critical factors, whose containment demanded the organisation's special attention. Said factors included the issue that healthcare staff were not accustomed to using IT systems, the fear of negative changes in working procedures, and mistrust towards a potential activity control system.

This led to the definition of a project implementation strategy focused on constant participation and information sharing with the staff.

Hence, the Hospital Management decided to invest considerable economic resources to face this important additional challenge.

## **COMPUTERISING THE SURGICAL BLOCK**

Drawing up the specifications of the tender in 2009 was an important moment as it required processes to be described and the needs to be met by the IT system to be defined. To increase patient safety in the Surgical Block, while optimising the way Operating Room time is used, reduce the time doctors spend drawing up documents by enhancing efficient cost and distribution management of dedicated resources and, finally, make the necessary information accessible to transversal services and for analysis by creating an operative and managerial dashboard were the main goals defined by the Management.

While drawing up the specifications, a select group of representatives of in-house services performed some on-site visits to Italian hospitals to gain knowledge and assessments of experiences regarding the use of IT products in the Surgical Block. Following the outcome of the tender process in late 2010—the company UMS was awarded the contract for the product 'DIGIStat'- the Hospital Management organised a general presentation of the project for all the staff.

Then a team of clinical and caregiving professionals from every Hospital Unit and from the services involved defined and followed the implementation stages of the project with the assistance of the Hospital's Management.

The processes managed by the IT system proposed develop in various forms that follow the patient's path and the materials used, as specified below.

- **Surgical planning.** From completing the hard copy version of the surgical list drawn up by the department secretary as indicated by the surgeon, we have moved on to the computerised draft of the same by the surgeon himself. Implementation of a common encoded nomenclature for diagnoses and surgical procedures, shared by the surgical team, was the starting point that converged planning the surgical schedule, implanted materials, surgical instruments and other associated devices.

Some additional requirements can be entered during the planning phase of surgery, such as the type of surgical bed, the need for blood and blood derivatives or for biological components for implants, the presence of mobile radiological devices or of custom-made surgical instruments. This is a sort of resource “booking” procedure. The surgical operation thus planned is placed in a common waiting area or directly in a daily time interval defined slot, which is assigned to the hospital unit. The daily surgical list is validated by the surgeon by entering a “booking” that can, anyhow, be changed if required, and which immediately and automatically informs all the services concerned. This allows short-term, medium and long-term planning, and ensures that crucial information is transmitted to transversal services, allowing all the envisaged activities and materials to be arranged.

Figure 1a. Check-list Sign-in

Figure 1b. Check-list Time Out

- **The pre-operative and intra-operative anaesthesiological record.** From the use of a common hard copy form both for the pre-operative and intra-operative phases, we have moved on to a form that has been jointly defined by all for case history taking and the pre-operative assessment. It presents mandatory application fields with automated entry of the patient's anagraphic data and the possibility of recording all tests that are prescribed and being assessed, allowing constant topical monitoring of the patient's clinical picture.

The implementation of an intra-operative form for automated acquisition of monitoring and ventilation data is being studied at present.

- **Surgical track management.** The surgical track unfolds from the moment the patient enters the Surgical Block until he or she leaves either the Surgical Block or the Recovery Room. From manual management of the hard copy version on the part of operating room staff, we have shifted to management based on temporal and binding markers depending on the activities, which allow to trace the patient's entire path in the Operating Room. Starting from the moment the patient enters the Surgical Block, the markers are gradually recorded by the medical staff involved through the touchscreen display or by reading a barcode placed on the patient's bracelet.

- **Managing materials and instruments.** The need to monitor the instruments and prosthetic systems has been met by creating a series of forms for supplies management and to delete materials implanted in the patient; the latter are directly deleted from the supplies list in real time from the Operating Room. This enables us to replenish and record prosthetic materials and to access the history of the movements of all stocked devices.

A preliminary inventory and census of all supplies present in the Pharmacy, Storeroom and Operating Rooms has been drawn up to enable materials implanted and used for surgery to be traced. Real time information of the individual lots implanted in the patient facilitates the patient identification process in the event of a recall of Medical Devices. It is also useful to calculate the cost of materials of each operation in order to ensure precise management of supplies, particularly of material on consignment.

- **The surgical register.** Initially present in the hospital's IT system only as the surgeon's description of surgery, the Surgical Register was later integrated into the Operating Room system by automatically entering data on the room used, duration of surgery, diagnosis and surgical procedure. The surgeon, who is the only person authorised to do this, completes the report with all the details of the operation and with postoperative indications, and finally validates it, allowing the same to be submitted in PDF format to the patient's hospital repository.

- Each of these processes, as already mentioned, issues from several meetings of the dedicated working groups. Hence, the various forms were shared in order to make the system familiar for operators to use, and adapting the software to meet their operative needs. Moreover, before a new electronic form is introduced, the staff involved was appropriately trained with simulations in the IT room, which is equipped with a computer and supported by ongoing constant tutoring in the field, and also by specific operative manuals.

Our goals include enhancing patient safety in the Surgical Block, while optimising the way Operating Room time is used and reducing the time doctors spend drawing up documents by enhancing efficient cost and distribution management of dedicated resources.

## PROCEDURAL SAFETY

Starting from the Operating Room Safety Manual that was published in 2009 by the Ministry of Health, based on Guidelines issued by the WHO, the IOR has acquired dedicated hard copy operative instruments for clinical risk management (e.g. checklists to identify the surgical patient, the side and site of surgery, gauze and materials count sheet). Moreover, since 2010 the IOR has participated in project SOS.net (*Safe Operating Rooms*) organised by the Emilia-Romagna Health Authority. It envisages the use of a Surgical Safety Checklist (SSCL) to verify the safety checks performed on the surgical patient.

In this regard, in order to enhance patient safety, some “checks” and instruments have been introduced in the development of the IT system for surgical procedures.

The safety of the patient's surgical path is especially underpinned by the presence of the computerised bracelet that, placed on the patient's wrist or ankle at the time of admission, allows to trace his or her transit along all the hospitalisation phases by means of univocal and correct identification.

Moreover, some essential tools, such as the “Pre-operative sheet to verify correct identification of the patient and of the surgical and procedural site,” the “Operating Room Safety Checklist” and the “Gauze and Materials Count Sheet,” which were already used in hard copy format, have been entered in the IT operative flow.

Regarding the “Operating Room Safety Checklist,” it entails the performance of safety checks during the three essential phases of surgery, namely before starting the anaesthesiological manoeuvres on the patient (sign-in), before incising the skin (time-out) and, finally, before suturing the surgical wound (sign-out). The computerisation process has allowed certain predefined items to be integrated into the three checklists to detect deviations from the standard that can occur during the individual steps, thus placing the checks and corresponding non-compliance issues in a single screen in order to facilitate completion by the operator using the touchscreen (Figures 1a, 1b, 1c). This has allowed to define prearranged, systematic reports, which are useful to analyse the most frequent deviations observed in the Operating Room.

*Figure 1c. Checklist Sign-out*

## CONCLUSIONS

The process described so far has still to be completed. The Hospital is a “living” facility and, as such, is the focus of an ongoing remodelling and reorganisation effort resulting from the changing needs of patients and clinicians and the technologies available to support medicine. After the structural part and management of the overall surgical path has been organised, the Computerisation Project for the Surgical Block envisages additional stages that will be gradually implemented. The acquisition of data from anaesthesiological ventilation and monitoring devices to be entered in the Intra-operative Anaesthesiological Record will be another important goal that will be implemented this year. This will be accompanied by the addition of the Recovery Room Record, which is still in hard copy format, and will ensure continuous recording of post-operative monitoring and treatment. The crucial Computerisation Project for the Surgical Block has entailed a massive effort both on the part of the hospital and also on the part of the various professionals involved. Some results can already be noticed two years after the start-up phase, and have already yielded doubtless benefits in terms of operative and administrative efficiency and patient safety. We expect additional positive effects from the process, which is still unfolding, not least of all the considerable quantity of data and information that will be precious for both management decisions and scientific research.

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But the process described has still to be completed. After the structural part and management of the overall surgical path has been organised, the Computerisation Project for the Surgical Block envisages additional stages that will be gradually implemented. Not least of all, the optimal use of information that will be placed at the disposal of scientific research.