


Digitalization of Healthcare Processes Through BPMN for Clinical Risk Monitoring and Management

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Abstract: Several recent studies have provided alarming data regarding the occurrence of errors in healthcare in all OECD (*Organization for Economic Co-operation and Development*) countries, including, to a significant extent, also Italy. Many of these errors seem to be largely due to failure to comply with company operating procedures, which are typically based on ministerial directives and international standards. In this context, the paper describes the work carried out in an Italian research project where a more structured approach to the healthcare sector has been proposed, focusing on clinical risk management. Clinical processes have been modelled by using BPMN (*Business Process Modelling and Notation*) standard notation and then interfaced with the hospital information system to monitor and manage clinical risks. Digitalization of operating procedures also allowed the definition and computation of several KPIs (*Key Performance Indicators*) for long-term monitoring. The work carried out in the experimental phase of the project, through the developed system, highlighted the areas most affected by operational non-conformities, to address actions aimed at safeguarding the patient's health and, indirectly, providing considerable economic savings.


1 INTRODUCTION


The rapid technological progress of recent years, accompanied by the growing use of information systems suitable for supporting their implementation in complex business and organizational contexts, has favoured the adoption of increasingly structured, safe, and standardized approaches for modern production processes, making them also more efficient and monitorable. Latest trends in business automation and digitalization, and the transformation of production contexts enabled by Industry 4.0, have also accelerated the adaptation process to new organizational requirements to cope with the global market, which requires products of ever-increasing quality, in a short timeframe and suited to the needs of the customer. In such a context any non-conformity translates into an enormous cost, both from an economic and image point of view. This need was not confined to the industrial production sector, but also has extended to the services market and operations, thanks above all to the ever-increasing diffusion of

the IoT and cloud computing, which make it possible to overcome the old infrastructural barriers that represented an obstacle to the high level of customization, scalability and resilience required by the clients.

The concept of *Smart Hospital* also fits into this promising context, thanks to the advent of modern technologies and IT infrastructures, a different approach in healthcare, guaranteeing more accurate results, the reduction of errors, as well as greater efficiency, speed, and agility of all medical procedures, necessary above all for clinical risk management. This also indirectly translates into a reduction of costs related to compensation for damage caused to patients who are victims of medical errors or medical malpractice, resulting in a higher quality of produced output, and therefore in greater patient trust.

This work was carried out within the Italian project “*Mo.Ri.San Monitoring and management of clinical risk in the social and health care sector*”, whose main objective was to provide useful tools for

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the reduction of clinical risk and *risk management*, using *Information Technology* and *process management* as enablers to guarantee patient safety and, indirectly, economic savings in the long term.

To reach these objectives a structured approach to a healthcare context was applied, which is strongly characterized by operations and human interactions, really difficult to control and standardize by their nature, with the aim of monitoring operational non-conformities within their processes.

Within the project, the basic approach was to adopt the *Business Process Management* methodology to build executable models of the care pathways provided within some healthcare facilities. More specifically the standard notation BPMN 2.0 was used to model structured and repeatable processes (OMG (2013)).

The results and the evaluations carried out in our study will be used by the private clinics partners of the project, concerned with implementing operations' restrictions or constraints within the software used, thus guaranteeing the adherence of the work of physicians and nurses to the medical and organizational operating procedures, according to the current legislative framework and the standards of reference.

The rest of the paper is organized as follows. Related work is reported in Section 2. In Section 3 the process modelling phase is described together with some details on a specific process. Then Section 4 reports the risk analysis performed, while system integration with the existing hospital information system is described in Section 5. Section 6 describes the experimental phase and discusses about the obtained results. Finally, we conclude the work in Section 7.

2 RELATED WORK

Clinical risk management, which is a requirement of current legislation in the healthcare sector, represents an important factor in modern healthcare systems. According to research conducted by Kohn et al. (2000), of the IOM - Institute of Medicine, clinical risk can be defined as the "*probability that a patient is victim of an adverse event, that is, suffers any damage or discomfort attributable, even if involuntarily, to treatment provided during the period of hospitalization, a worsening of health conditions or fatality*"; its inadequate management represents one of the main causes of legal actions against health structures in OECD countries, as well as, according to the *Institute for Healthcare Improvement*, has

become the third leading cause of death in the United States.

The ever greater technological, regulatory, and organizational changes in the healthcare sector have therefore required the adoption of increasingly in-depth analysis, aimed at identifying the causes of adverse events, and intervening even before they can occur. In this regard, Cagliano et al. (2011) demonstrated the advantages deriving from the application of a structured and systemic approach in identifying risks for the patient, by the Reason theory, within health contexts characterized, by their nature, by a strong variability linked to human decision-making processes.

Wingate (2003) highlighted the possible impact of computerized systems within healthcare and pharmaceutical companies, to support daily operations, evaluating regulatory compliance through IT validation systems.

In Crotti Junior et al. (2020) an Access Risk Knowledge (ARK) platform has been presented and used in clinical risk management. The ARK platform uses Semantic Web technologies to model, integrate, and classify risk and socio-technical system analysis information from both qualitative and quantitative data sources into a unified risk graph. A clinical safety management taxonomy to annotate qualitative risk data has been developed, in order to support automated analysis.

Furthermore, several recent studies have proposed the implementation of Business Process Management in the healthcare sector. Among these, Emanuele and Koetter (2007) analyzed a case study of integration between BPM (*Business Process Management*) and corporate information systems within a healthcare facility, highlighting the advantages related to the support it can give to processes.

A further study by Reichert (2011) analyzed the possibility of adopting PAIS (*Process Aware Information Systems*), which have healthcare business processes implemented within them, highlighting the need of flexibly to adapt them to the variability that characterizes the healthcare pathways, through all the decision-making processes of which they are composed.

Gomes et al. (2018) proposed a case of integration between models of healthcare processes, created using the BPMN 2.0 standard, and the electronic medical record.

However, it should be highlighted that, since modern health systems are highly interconnected and dependent on the large amount of data they generate, patient safety relies not only on the adoption of the

best medical practices and on the healthcare pathways, which are as standardized as possible and established by current and regional regulations but also from the correct treatment of personal data, which can guarantee privacy both during hospitalization phases and in subsequent periods.

In this regard, in recent years new frameworks mainly focused on ensuring patient cybersecurity have emerged, such as, for example, the CUREX conceptual model (Kougka et al., 2021), which offers a platform-independent integrated environment to execute cybersecurity and risk assessments, to verify the security and robustness of information systems containing sensitive data, as well as providing a useful tool for the correct exchange of patients' information between different healthcare facilities, through the adoption of technologies such as the blockchain and IoT (*Internet of Things*) devices.

Although the safety and privacy of patients have been strongly considered in the context of the proposed study, through the anonymization of the data provided and processed by the developed model, it is mainly focused on the analysis and monitoring of the critical issues related to the adoption of incorrect medical practices, which could lead to serious physical harms to patients.

From the preliminary research executed, therefore emerges the lack of a real-time monitoring system of the risks that may occur during healthcare pathways within health facilities, based on a structured and standardized approach, as proposed by the *OMG Healthcare Domain Taskforce (2020)*, which is the scope of the study.

As anticipated, the modern context, strongly influenced by *digital transformation*, together with the greater awareness and attention of the institutions towards the clinical risk, have provided the main input and the possibility of developing the project, thanks to the tools they make available, as well as the cultural changes taking place.

3 PROCESS MODELLING

Through the process models, the study aimed to create a digital representation of the healthcare procedures, which could be performed in background, through the recordings reported on Healthcare ERP software, with which they exchange data and information, allow to instantiate a new process, complete a certain task, or exchange messages necessary for their execution.

Through this approach, it was possible to trace daily operations performance, evaluating the

operational differences, also with respect to the procedures established by the companies, by a status code returned by the system.

To model the processes the *Signavio* platform was used. This tool allows you to create business process models using the BPMN 2.0 standard and allows different users to collaborate on the same process modeling in real time. By using this platform, it was possible to highlight all the decision-making processes, the involved actors, the documents, and information exchanged within the identified processes.

The built models can be traced back to Petri nets, in which a transition of the state associated with the system occurs upon predetermined conditions.

For the preliminary study phase, the operating procedures in use at the clinics involved were used, thanks to which it was possible to identify three main processes for the subsequent modeling and analysis phases:

- Laboratory analysis processes;
- Surgical room processes;
- Drug management and administration processes.

After the preliminary study phase and the collection of essential information and operating procedures by the healthcare facilities, a first version of the process models was created as closely as possible to the operations carried out by healthcare personnel within the companies.

For the surgical room processes, the following sub-processes were identified and built:

- Hospitalization phase, execution of the pre-operative medical examinations and planning of the surgical intervention.
- Pre-surgical phase, concerning the preparation of the patient and his transport and access to the surgical block, verification of the completeness of the documentation supplied with the patient.
- Surgical phase, including the records relating to the surgical and anaesthetic medical practices adopted.
- Post-surgical phase, concerning the recordings made on Healthcare ERP software concerning the monitoring of the patient's vital parameters in the phase immediately following the surgical operation.

The modelling of laboratory analysis processes involved the following sub-processes:

- Pre-analytical phase, which begins with the request for laboratory analysis by the physician, continuing with the preparation of the patient and the collection of the sample by the nursing staff,

- and with the subsequent sorting of the samples, identified and labelled, to the analysis laboratory.
- Analytical phase, in which the actual analysis of the samples provided by the department takes place, according to different paths for the examinations that can be performed with instrumentation interfaced with healthcare ERP software and those that can be performed manually or with non-interfaced instrumentation.
- Post-analytical phase, which concerns the communication of the results to the department and their reporting.

The models of drug management and administration processes have been divided into the following sub-processes:

- Phase of medical examination, during which the patient's condition is re-evaluated, then the therapy is prescribed or updated. In the case of first access, pharmacological recognition is also carried out, as well as the patient's anamnesis, to identify the therapies already in act, allergies, and pathologies of the patient that must be taken into consideration for subsequent prescriptions and administrations.
- Phase of preparation and administration of the drug, in which the nursing staff proceeds to the correct identification of the patient, preparation of the drug, and subsequent administration.
- Monitoring phase, in which any abnormalities or adverse reactions in patients due to administration are recorded.
- Pharmacological reconciliation, at the time of discharge, in which the medical staff delivers the SUT (*Single Therapy Card*) to the patient, providing him/her with the necessary information regarding the therapy to be followed after discharge.

The adherence of these models (*as-is configuration*) to the standards identified in the preliminary study phase and to the current legislation was considered, to evaluate a possible redesign and a *to-be configuration*.

As an example, the workflow concerning the patient's hospitalization booking sub-process is shown in Figure 1. In it, many of the elements that the BPMN 2.0 standard makes available for modelling have been used.

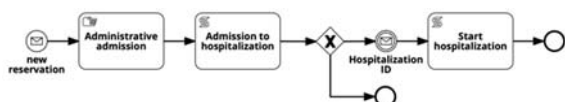


Figure 1: A simple process model representing the patient hospitalization booking.

The elements of the workflow represented through circles represent *start events*, *intermediate events* or *end events*, while the tasks, i.e. the elementary operations which compose the model, are represented through rectangles.

As shown in Listing 1, the initial start event, which represents the receipt of a new booking, is started as soon as the management software, through the prepared REST (*Representational State Transfer*) web-service, sends the JSON (*Javascript Object Notation*), containing all the booking information, to the appropriate endpoint.

```

{
  "key": "new-booking",
  "businessKey": "<booking ID>",
  "payload": {
    "initiator": "<user ID>"
  }
}
  
```

Listing 1: JSON for the *new-booking* request.

The system, in turn, sends a response to the management software, shown in Listing 2.

```

{
  "key": "new-booking",
  "businessKey": "<booking ID>",
  "correlation": object,
  "payload": {
    "started": [ {
      "processId": string,
      "businessKey": "<booking ID>",
      "initiator": "<user ID>"
    } ],
    "errors": [string]
  }
}
  
```

Listing 2: JSON for the new-booking response.

The JSON is addressed by the management software on an endpoint of type */ message / start*, which allows, upon receipt, to start a new instance of the process.

The next *manual task* is automatically performed by the process engine upon receiving the JSON shown.

The next task, created by a *script task*, contains a Groovy script which is executed by the process engine when the task itself is instantiated. Through this script, the execution variables of the "*Sanitary acceptance*" process are set with the value received through the JSON, while the "*initiator*", i.e. the user who started the process instance, is assigned to the "*evaluator*" variable.

The next gateway, of the XOR type, allows the flow to continue along only one of the outgoing branches. If the condition $\${SanitaryAcceptance == "hospitalization"}$ is verified, meaning that the patient's hospitalization has been arranged, then the

flow will continue towards the subsequent tasks, while it will be directed to an *end event* otherwise.

The flow will therefore await the receipt of the JSON corresponding to the subsequent user registration on the management software, containing the "key" field: "assignment-id-shelter", and a structure like the JSON previously illustrated. In each of the JSONs, there is the "businessKey" field, having the reservation ID as a unique value, through which it is possible to correlate all subsequent requests to the correct process instance.

The next script task, containing the Groovy script shown in Listing 3, is started and executed immediately upon receipt of the hospitalization ID assignment message.

```
def key = "sanitary acceptance";
def businessKey =

HospitalizationIdAssignment.get("HospitalizationId");
def payload = commonService.payloadBuilder().put
("initiator", execution.getVariable("evaluator")).build
();
def message = messageService.createMessage(key,
businessKey, null, payload);
messageService.start(message);
```

Listing 3: Example of a script task.

Through the previous script, *key*, *businessKey* and *payload* variables are defined, within which the values of the previously illustrated process variables are entered, such as *HospitalizationId* and *initiator*. Through the method *messageService.createMessage()*, to which the previously defined variables are passed as parameters, a message is created addressed to the subprocess shown below, allowing to start a new instance.

The message sent by the previous script task allows to start the *start event* of the hospitalization sub-process (shown in Figure 2), followed by a script task, with which the variable containing the information of the *initiator* of the process is set.

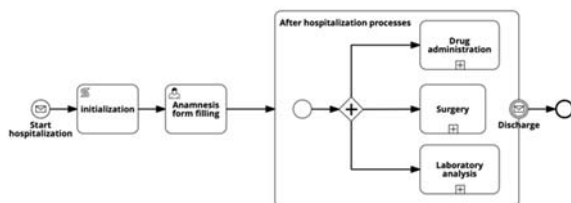


Figure 2 Start hospitalization subprocess.

The next *human task* is performed upon receipt, by the management software, of the respective JSON, in which the "key" field: "compilation-file-anamnesis" allows you to refer it to the correct task, while the "businessKey" field allows you to correlate

it the process instance of the patient for which registration on the software is being carried out. In this case, a /task/complete web-service REST was used to interface the two systems.

Downstream of the human task, the period of stay of the patient inside the structure was modelled through the use of a *subprocess*, through an AND gateway, which allows the process instance to continue on the three outgoing branches, for each of which a *collapsed subprocess has been inserted*, which refers to the relative models created for the processes of drug administration, surgery, and laboratory analysis.

The *boundary event* of receipt of the communication message is instantiated upon registration on the management software of the patient's discharge from the facility, entered by the physician or nurse, which corresponds to the sending of a JSON containing the "key": "Discharge", and with a structure like those previously illustrated. Upon receipt of the discharge message, the relative process instance is closed.

4 RISK ANALYSIS

After the modeling phase, a risk analysis was conducted with the H-FMEA methodology (*Healthcare Failure Mode and Effect Analysis*), reaching for each of them the identification of the risks and the calculation of the relative RPN (*Risk Priority Number*), the identification of possible consequential damages and the adopted prevention measures. To determine the RPN, the following parameters were used:

- S = Severity of the injury or damage that the patient may suffer.
- L = Likelihood or probability that the event happens.
- D = Detection, the ease and difficulty of detecting the error before it causes damage.

The calculated RPN made it possible to hypothesize an order of priority of intervention for the various risk factors, as well as to build statistics on the phases most affected by errors within the same process, also allowing the identification of causes and containment factors.

Based on the results of the H-FMEA analysis and the Ministerial evidence, a set of indicators was built referring to the processes that were modelled in the previous phases and suitably integrated with other indicators already in use in nursing homes.

This set has the purpose of monitoring the progress of the processes, the correct execution of the various phases, and avoiding errors related to the deviation from the company procedures established for the execution of the same. To do this, the indicators have been designed to be measured over different time horizons.

A subset of them, once implemented in respective digital dashboards, will provide constantly updated information, to promptly identify any anomalies with respect to what is established by the work plans or by the evaluation criteria, thus representing a tool capable of reducing the incidence or severity of the risk factors found within the processes in the previous stages.

The remaining part of the indicators has been designed to constitute medium to long-term monitoring, measuring and certifying the effective reduction of clinical risk resulting from the implementation of the project itself, which can be found in the reduction of significant events.

This set of indicators was used to create a new software module, made available to clinics, which allows you to extract its value based on the data contained in the respective databases, then evaluate its temporal trend, as well as any abnormal variation.

5 SYSTEM INTEGRATION

To interface the models created within the project to the management software in use at the facilities, as anticipated, three different types of REST web-services were used (as shown in Figure 3):

- *Message/start*, when received by the engine corresponds to the start of an instance of a specific process.
- *Message/send*, through which data is exchanged between the engine and management software.
- *Task/complete*, the receipt of which by the engine corresponds to the completion of a specific instance of a thread.

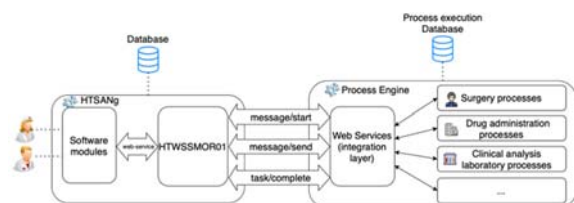


Figure 3: System integration.

The exchange of information between the process engine, which is responsible for executing the models of the developed processes, and the Healthcare ERP software the operators are interfaced with, allows to complete of certain tasks (elementary actions) belonging to the model created, therefore to be able to continue their execution, monitoring their status in real time, by triggering the specific task and instance connected to the sent message, elaborated by the Web Services (integrated layer) component of the Process Engine.

The implementation and interfacing with the process models have been designed in such a way as to operate in the background, resulting in minimal impact compared to the normal working conditions of the medical and nursing staff, and carried out in such a way as not to return alerts or error messages, ensuring the normal functioning of the software used by companies.

These implementations involved not only the development, digitalization and execution of the process models but also the revision of the software code used by the structures, in such a way as to provide for interfacing with the previously indicated cloud process engine.

Through the execution in the process engine, based on the messages exchanged with the ERP software, it was possible to collect information about the most critical processes with respect to the operating procedures established by the management of the structures involved, as well as to keep track of the major process non-conformities, whenever a different task than the one scheduled in the developed models has been performed, which could represent a risk for the patient during his stay in the clinics.

This execution information has been stored in a process execution Database.

The objective of the subsequent test phase was to ensure the correct functioning of the developed system, both limited to the workflows implemented, and as regards their interfacing with existing systems, as well as ensuring their stability over time and effective maintenance conditions of any overload of data transferred and communications exchanged.

After having validated the correct functioning and interfacing between the software and the developed processes and after having tested the reliability and stability of the updated system, the test environment was replicated within the servers of the two clinics, by updating the pre-existing software version within them and the installation and configuration of a new server exclusively dedicated to the BPMS (*Business Process Management Suite*) system.

6 EXPERIMENTAL PHASE AND RESULTS

After training the personnel involved, the last project phase concerned the final experimentation, which had the aim of collecting data on the actual functionality in the field of the new system interfaced with the process engine, operationally evaluating the adherence of the assistance activities provided within the clinics with the operating procedures and with the ministerial standards and directives, identifying any bottlenecks or discrepancies in their execution, which could represent a risk for the patient.

The experimental phase was then conducted on the job for all the processes and sub-processes identified, analyzed, and modelled in the previous phases of the project, through the normal registration operations on software by the medical and nursing staff of the clinics.

Downstream of the experimental phase, it was possible to extract the data stored in the appropriate process execution database, which recorded, for each process instance executed, a code relating to the state of completion of the same, as well as any error codes, which identify differences in execution with respect to the models prepared.

The distribution of the return codes for the process instances have been collected in the histogram shown in Figure 4, where *code 0* represents a communication error between software and the BPMS server, *code 1* represents the correct execution of the single process instance, while *code 100* represents discrepancies with respect to the operating procedures established by the companies.



Figure 4: Status code distribution.

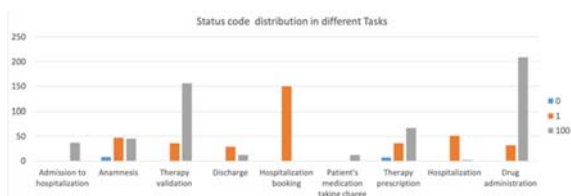


Figure 5: Status code distribution in different tasks.

This histogram was also replicated with reference to the individual sub-processes of each of the three main identified ones, of which, by way of example,

the data relating to the administration of drugs within the departments are reported in Figure 5.

The histogram in Figure 6, on the other hand, shows the distribution of status code 100, which therefore represents an operational difference, with respect to the different phases of the drug administration process, taken as an example.

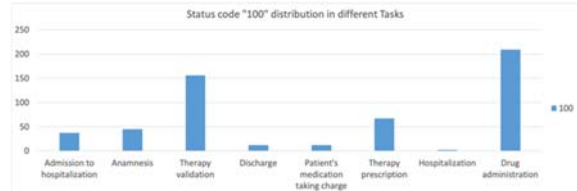


Figure 6: Distribution of status code 100.

This graph made it possible to focus attention on the sub-processes most affected by procedural errors, therefore potentially having the greatest impact on the success of the care pathways and the safety of the patient during the period of stay in the facility.

However, as shown in Figure 7, it is necessary to consider the percentage distribution of the onset of the status code 100 between the different phases, to have a clearer idea about the possible containment measures and the constraints that could be implemented in the future within the management software.

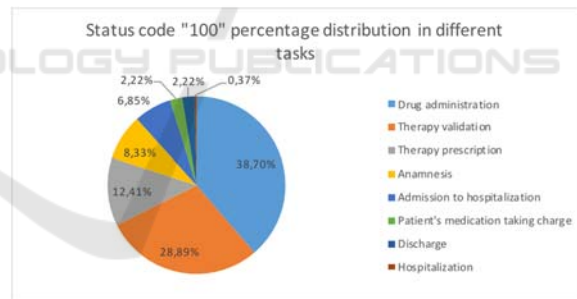


Figure 7: Status code "100" distribution in different tasks.

7 CONCLUSIONS

The use of a structured approach within a context strongly characterized by human work, therefore also by the decisions that the healthcare worker is called to make, has allowed to highlight all the discrepancies and anomalies that may emerge in the normal carrying out of the daily activities that characterize it.

BPM technology, and in this specific case the BPMN 2.0 notation, proved to be a valid choice to guarantee and monitor the compliance of processes with current legislation and international standards.

In particular, the integrated system developed appeared to be able to monitor all deviations from the operating procedures established at the company level, and based in turn on ministerial standards and recommendations, which may represent a risk factor for the patient, which could result in serious damage to the image and economic for the structure, as well as physical damage for the patient. The tool to calculate KPIs is also useful especially for medium and long-term monitoring, to evaluate any improvements following future implementation of constraints and alerts within the management software, which can instantly report the operational differences to the operator, in the same registration phase on the software in use.

Future development of the study could involve the introduction of constraints within the software, based on the structure of the process model in execution, which prevents the operator from completing the tasks for which the foreseen operations have not been performed upstream, or that return error messages in case of discrepancies with the operating procedures.

The modelling could also be extended to other fields of operational procedures, not directly reproducible digitally through the BPMN 2.0 standard, due to their unstructured nature, such as complex decision-making operations or unstructured procedures. The latter could be modelled using other Business Process Management tools, such as the Case Management Model and Notation (CMMN) for unstructured processes, and Decision Model and Notation (DMN) for decision-making processes.

Finally, once the effects of the proposed implementations have been assessed, should they prove useful for the objective of safeguarding the safety of the patient and the work of the healthcare personnel, it could be useful to extend this approach to all other healthcare processes that have not been subject of the present study. This would also make it possible to classify the latter based on their need for a more or less structured approach, adapting the models and systems developed to the cases analysed from time to time.

Furthermore, this approach would follow the latest trends and propensities of Industry 4.0, oriented towards the introduction of automated processes and innovative technologies, to improve working conditions in terms of productivity and safety.

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