Business process modelling in healthcare and compliance management: a logical framework

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Abstract

This work describes a methodological approach to investigate Compliance Management in healthcare based on a BPM perspective, exploring an application in an innovative hospital service. Firstly, we present a business process analysis by modeling the process with the adoption of a standard language. Secondly, we encode a set of rules in LegalRuleML, an XML formalism designed

to be a standard for representing the semantic and logical content of legal documents. The rules represent some provisions of the General Data Protection Regulation (GDPR) that are involved in the health process analyzed. Moreover, in order to perform the regulatory compliance check automatically, we converted the set of rules into Defeasible Deontic Logic format (DDL), readable by the Regorous compliance checker developed at CSIRO. Overall, the paper shows a methodology to automate regulatory compliance checking of a real hospital process with actual regulations and norms. The codes in the LegalRuleML and DDL formats used in the work are available online[1].

1 Introduction

One of the main research topics in Business Process Management (BPM) concerns regulatory or Compliance Management (CM), i.e. the analysis of compliance to norms [26; 60]. The necessity of satisfying regulations or laws forces organizations in redesign their internal processes, in the context of change management [40]. The increasing pressure from regulatory authorities to organizations led to the development and application of Compliance Management Frameworks (CMFs). In this context, CM can be addressed at the operational level by focusing on business processes, intended as the set of activities accomplishing a specific organizational goal.

Business process analysis usually introduces performance objectives to be considered in addition to constraints imposed by external pressures (e.g., regulatory issues). The investigation of undesirable events and norm violations adopted traditional techniques, e.g. root cause analysis (commonly used in manufacturing processes to improve performance). More recently, CMFs explore the relationship between the formal representation of a process model and the relevant regulations. There are many different adoptable CM strategies consisting in approaches to check whether a business process complies with the actual regulation automatically [35]. The goal is to ensure that such approaches properly model business processes as well as norms. Moreover, in the past decades many CM approaches in the context of digitization to automatize business processes have been proposed [50]. We describe here a CM approach to support regulatory compliance for healthcare business processes based on a compliance-by-design methodology [35] and using a business process compliance checker called Regorous [28]. In particular, this paper explores the adoption of a two-step pipeline introducing a CMF applied to an innovative hospital service. In a first step, business process analysis can be performed by adopting standard modeling language to investigate healthcare processes at operational level. In a second step, a regulatory CM is proposed on the top of the model by applying a logic-based

[1] See `https://github.com/liviorobaldo/BPMinHealthcare`

approach to automate checking whether the process complies with the new General Data Protection Regulation (GDPR).

The rest of this paper is structured as follows: background and related work, detail of the analysis of the case study on Business Process Management prospective and Regulatory Compliance prospective and finally, results and discussions on future work.

2 Framework and Related Work

2.1 Risk management and regulatory compliance

Risk is part of every business activity and therefore part of every business process [60; 39]. The occurrence of a risk may lead to loss of quality, increased costs, time delays, complaints, and legal problems [17] as well as, in healthcare, serious and permanent damages up to death. There are several types of risk, such as legal, procedural, economical, financial, etc. The Risk Management is the discipline that allows the management of these different kinds of risks thank to the application of some principles [51; 42; 36].

Regarding legal risks, it should be considered that the process has to be compliant to law, whereas norms and regulations are constantly evolving and new reorganizations must be implemented with the introduction of new procedures [40], i.e., for privacy control, AI technologies.

Compliance in healthcare considers the conformity of care processes with laws, regulations and standards related to patient safety, privacy of patient information and administrative practices [7; 44].

Ultimately, health compliance is about providing safe and high quality patient care. Healthcare organizations are also required to comply with strict standards, regulations and laws at regional and state level. Violations of these laws may result in legal action, heavy fines or loss of licenses.

It is possible to find several studies on compliance with laws, rules or regulations in the case of processes related to patient health [23; 48; 9; 5; 6].

The intensive use of ICT solutions to collect, share and digitize data of a health process, makes it necessary to prepare tools able to identify any possible risk scenario related to the use of computer systems and lack of awareness on the agents, as well as to facilitate the adoption of appropriate counter-measures. Previous research on IT in healthcare explored digitalization challenges for organization [Amantea et al., 2018]. These innovations may require the application of new regulations, such as the GDPR, without forgetting that the health sector is full of strict health regulations in constant evolution.

2.2 Business process compliance and logic

Regulatory compliance is the set of activities an enterprise undertakes to ensure that its core business does not violate relevant regulations, in the jurisdictions in which the business is situated, governing the (industry) sectors where the enterprise operates. The activities an organization undertakes to achieve its business objectives can be represented by the business processes of the company. On the other hand, a normative document (e.g., a code, a guide line, an act) can be understood as a set of clauses, and these clauses can be represented in an appropriate formal language.

2.2.1 Business process modeling

In order to analyse the use case hospital business processes, we exploit a Business Process Management (BPM) methodology. One of the central issues in BPM is change management [61; 1; 25]. Using a process-centric approach, in order to describe the diagram of the process, we will adopt the Business Process Model and Notations (BPMN) standard language [2]. Primarily, in the context of healthcare studies, BPMN standard language acquires a peculiar consideration [43; 8; 56].

The business process analysis aims to define and engineer a model to be verified and validated with system experts. One of the main output is the creation of visual models of processes (i.e., process map or flowchart). These diagrams depict the sequence of activities and various crossroads (gateways), which lead to different routes depending on choices made. A business process model is a self-contained, temporal and logical order in which a set of activities are expected to be executed to achieve a business goal. Typically, a process model describes what needs to be done and when (control flow), who is going to do what (resources), and on what it is working on (data). In this context, a possible execution, called process trace or simply trace, is a sequence of tasks and events respecting the order given by the connectors.

2.2.2 The automation of compliance

Business process compliance is a relationship between the formal representation of a process model and the formal representation of the relevant regulations [33]. Any approach to automatically check whether a business process complies with the regulation governing has to ensure that it is able to properly model business processes as well as norms. In the past decades many approaches to automatize business process compliance have been proposed [41; 16] and legal informatics is experiencing growth in activity [20; 18; 15; 59; 45].

However, a challenging research topic is the possibility of modeling standards in a conceptually valid, detailed and exhaustive way that can be used in practice for companies and, at the same time, have the ability to be used generically for any type of standard also taking into account the regulatory environment as a whole [28].

This shifts the focus to the adoption formalisms. Temporal logic and Event Calculus have been used in several frameworks. However, it has been shown that when norms are formalized in Linear Temporal Logic the evaluation whether a process is compliant produces results that are not compatible with the intuitive and most natural legal interpretation [38; 29]. Furthermore, it was argued that, while such logics can properly model norms, such formalizations would be completely useless from a process compliance point of view insofar they would require an external oracle to identify the compliant executions of the process, and build the formalization from the traces corresponding to the traces deemed legal by the oracle. This means that, there is no need for the formalization to determine if the process is compliant or not, since this is done by the oracle [29; 31]. Some studies had focused on the application of Natural Language Processing (NLP) methods to design legal document management system to assist legal professionals in navigate legislation and retrieving the information they are interested in [21; 22]. An example is Eunomos [19; 18]. These types of systems classify, index, and discover inter-links between legal documents, retrieved through Web-crawling tools, by exploiting NLP tools, such as parsers and statistical algorithms, and semantic knowledge bases, such as legal ontologies in Web Ontology Language (OWL)[2]. This is often done by transforming the source legal documents into XML standards and tagging the relevant information to allow queries and information retrieval from the XML files.

However, the overall usefulness of these systems are limited due to their focus on terminological issues and information retrieval while disregarding the specific semantic aspects, which allow for legal reasoning. Just as standard deontic logic mostly focused on the notion of obligation, subsequent developments in deontic logic also adopted an abstract view of law, with a very loose connection with the texts of regulations. For lawyers, the meaning of laws can be fully understood only within the rich expressiveness of natural language since âĂIJlike language generally, legal discourse can never escape its own textualityâĂİ [47].

There is thus a gap between a powerful reasoning mechanism on the formalization of law and the textuality of law, which can be addressed with solutions coming from the literature on Natural Language Semantics.

A new standardization initiative called LegalRuleML[3] [13; 14] tries to address

[2]See `https://www.w3.org/OWL`

[3]See `https://www.oasis-open.org/committees/legalruleml`

these issues. LegalRuleML is an XML format that extends the RuleML standard[4] to define a rule interchange language for the legal domain. While legal XML standards are used to tag the original textual content of the legal documents, LegalRuleML separately represents and stores the logical content of the provisions. Specifically, LegalRuleML allows to specify semantic/logical representations and associate them with both the structural elements of the documents or with tasks in a business process. LegalRuleML allows to encode RuleML representations of formulas[5] in Defeasible Deontic Logic (DDL) [30]. This is an extension of standard Defeasible Logic with deontic operators, and the operators for compensatory obligation [34]. Defeasible Logic is an efficient and simple rule based computationally oriented non-monotonic formalism, designed for handling exceptions in a natural way. According to the formalization proposed in [12], Defeasible Logic is a constructive logic with its proof theory and inference condition as its core. The logic exploits both positive proofs, where a conclusion has been constructively proved using the given rules and inference conditions (also called proof conditions), and negative proofs: showing a constructive and systematic failure of reaching particular conclusions, or in other terms, constructive refutations. The logic uses a simple language, that proved to be successful in many application area, due to its scalability and constructiveness. These elements are extremely important for normative reasoning, where an answer to a verdict is often nor enough, and full traceability is needed.

2.3 Legal reasoning and Defeasible Deontic Logic

Norms describe general cases and what behavior should be taken, or the consequences, if the real facts are similar to the general case described in the norm. Therefore, norms describe the conditions under which they are applicable and the normative effects they produce when applied. Simply put, the scope of norms is to regulate the behavior of their subjects and to define what is legal and what is illegal.

In a compliance perspective, the normative effects of importance are the deontic effects (also called normative positions). The basic and more important deontic effects are: obligation, prohibition and permission.

- **Obligation:** when there is a situation, an act, or a course of action to which a bearer is legally bound, and if it is not achieved or performed results in a

[4] See `http://wiki.ruleml.org`

[5] However, LegalRuleML is actually logic-neutral, i.e., it permits to encode formulae in other logics, even radically different from Defeasible Deontic Logic. For instance, [46] and [49] presents an ontology and a knowledge base of formulae that formalizes the norms in the GDPR. This knowledge base will be possibly considered in future works, because at present there is not a reasoner such as Regorous that works with reified I/O logic formulae.

violation.

- **Prohibition:** when there is a situation, an act, or a course of action which a bearer should avoid, and if it is achieved results in a violation.
- **Permission:** when something is permitted if the prohibition of it or the obligation to the contrary do not hold.

This gives rise to some considerations:

- Obligations and prohibitions are constraints that limit the space of action of processes.
- They can be violated, and a violation does not imply an inconsistency within a process with the consequent termination of or impossibility to continue the business process.
- Violations can be generally compensated for, and processes with compensated violations are still compliant [35; 32] (e.g. contracts typically contain compensatory clauses specifying penalties and other sanctions triggered by breaches of other contracts' clauses [27]).
- Not all violations are compensable, and uncompensated violations means that a process is not compliant.
- Permissions cannot be violated. They can be used (indirectly) to determine that there are no obligations or prohibitions to the contrary, or to derive other deontic effects.
- Legal reasoning and legal theory typically assume a strong relationship between obligations and prohibitions: the prohibition of A is the obligation of ÂňA (the opposite of A), and then if A is obligatory, then ÂňA is forbidden [53].

Taking in consideration the notion of obligation, compliance means to identify whether a process violates or not a set of obligations. Thus, the first step is to determine whether and when an obligation is in force. Hence, an important aspect of the study of obligations is to understand the lifespan of an obligation and its implications on the activities carried out in a process. A norm can specify if there is:

- **Punctual obligations:** an obligation is in force for a particular time point.

- **Persistent obligations:** a norm indicates when an obligation enters in force. An obligation remains in force until terminated or removed.
  - For persistent obligations we can ask if to fulfil an obligation we have to obey to it for all instants in the interval in which it is in force, **maintenance obligations**, or
  - Whether doing or achieving the content of the obligation at least once is enough to fulfil it, **achievement obligations**.
  - For achievement obligations another aspect to consider is whether the obligation could be fulfilled even before the obligation is actually in force. If this is admitted, then there is a **preemptive obligation**, otherwise the obligation is **non-preemptive**.
- **Termination of obligations:** norms can specify the interval in which an obligation is in force.

As said, what differentiates obligations from other constraints is that obligations can be violated.

- If we still have to comply with a violated obligation (the obligation persists after being violated) we speak of a **perdurant obligation**.
- Otherwise, we speak of a **non-perdurant obligation** [28].

3 The project CANP

Our work is collocated within CANP project[6] , which aims at using Artificial Intelligence to enhance e-Health procedures within the CittÃă della Salute e della Scienza di Torino[7], the biggest hospital complex in Europe [55]. A case study of the project is concerned with the application of innovative telemedicine technologies supporting the care of elderly patients in the context of a Hospital at Home (HaH). The use of communication systems in the remote management of the patient could improve treatment outcomes, increase access to care, and reduce health costs [24].

We show below how it is possible to model and integrate, within the HaH process, compliance checking via DDL and the Regorous reasoner. As mentioned above, we consider GDPR provisions to safeguard the personal data of the patients, but the approach is general enough to handle any kind of legal constraint involved in e-Health procedures.

[6] `http://casanelparco-project.it`

[7] `https://www.cittadellasalute.to.it`

3.1 Hospital at home (HaH)

For more then 30 years, the "CittÃă della Salute e della Scienza of Turin has operated the Hospital at Home (HaH). This is a home care service defined by Resolution DGR n. 85-13580 of 16 March 2010, as a form of health care hospital character, which provides for the organization of care in the home of patients suffering from acute diseases, but who do not require equipments with high technological complexity and intensive or invasive monitoring [54].

The service is composed by two main processes: the acceptance (in Fig. 1) and the tour visits in the patients' houses (in Fig. 2)[8].

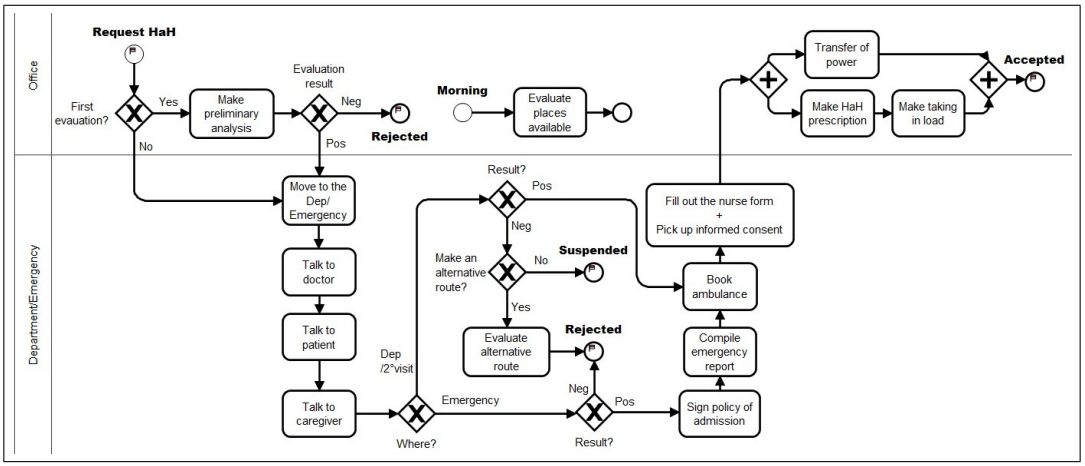

Figure 1: The patient registration process model of HaH service in standard language BPMN.

Requests for the activation of the HaH service are made by the emergency or regular departments and by general medical doctors. After that, each patient is evaluated by the team to establish the feasibility of hospitalization under HaH.

The service begin with the admission process shown in Fig. 1. It involves the Case Manager (CM), who has to evaluate all the requests. Each case refers to some guidelines to understand if the patient has some characteristics to take in charge to this type of hospitalization. At the end of this evaluation process, for the taking in charge of a patient, a real contract of collaboration is created.

The contract involves on one side the hospital, and in particular the staff of the department of HaH, and on the other side the patient with the caregiver and possibly

[8]For reasons of space in this article are illustrated only the salient features of the processes, for a more accurate description see [3; 10; 11].

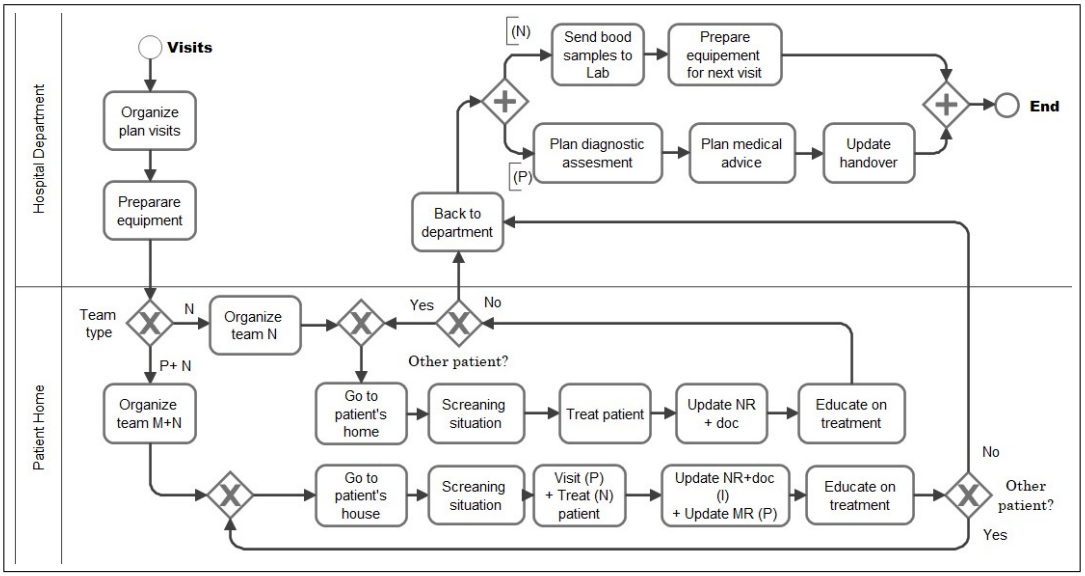

Figure 2: Hospital at home process model including Hospital Department and Patient Home lanes in BPMN.

with his/her family, which can coincide with the figure of the caregiver. Besides, it is important that this type of collaboration remains as initially established for the whole duration of the service. Otherwise, for instance, in case of missing caregiver or family exhaustion, the patient is immediately move to the hospital and hospitalized classically inside the hospital wall.

Firstly, the CM has to evaluate every morning the available number of possible posts (**Evaluation nÂř places available**), that correspond to the maximum number of patients that she could accept in this day. She has to evaluate the probable number of discharged patient, the available staff, how long each patients, they already have in charge, been (some patients have some pathology that requires more time than others, for example blood transfusions are longer than bandages that are longer than giving a medicine. The first type of patients occupies two slots, the second type of patients occupies one slot and an half and the third type occupies only one place).

This first evaluation determines the future workload of all the staff involved in the service. At the same time, input requests can arrive by telephone from the emergency department as well as from any other hospital department. The requests are made by the responsible doctors of the departments that made a first quick evaluation.

The arrival of a request by phone at the Hospital at Home (HaH) (generator **Request HaH**) implies an initial evaluation (gateway *First evaluation?*) by the doctor and the CM or the chief nursing (**Make preliminary analysis**). If there are features not complying with this type of hospitalization (gateway *Evaluation's result?*) the request is immediately rejected (end of the process **Rejected**). Otherwise, CM moves to the department to evaluate the patient (**Move to the Dep/Emergency**). At first, the CM talks to the requested doctor to evaluate clinical conditions (**Talk to doctor**). All patients are in acute disease but they must not be in state of bleeding or risk of reanimation. Then the CM talks to the patient to check if he/she is conscious and capable of understanding and willing (**Talk to patient**), as well as to the family and the caregiver (**Talk to caregiver**).

During this meeting the CM explains to the patient, if possible, and to the family the characteristics, organization and requirements of the service. On the other hand, she evaluates clinical, functional and cognitive aspects.

Through this structured interview of mutual knowledge, the CM attentively appraises the real availability to accept the cares in house, if it is possible to identify a caregiver, so the availability of taking in charge the patient in this type of hospitalization.

The requests could be forwarded both from each department of the hospital and from the emergency department. For both of them the activities already shown are always the same, but after having talked to all the interested parts, the decisional trial is different according to where they are (gateway *Where?*).

If they are in the emergency department there is an urgent need to free up beds. Any bed of the emergency department can be busy for more than 24 hours. Therefore, the evaluation result must be immediately positive or negative (gateway *Result?*). If it is negative the request is definitively rejected (**Rejected**). Probably the patient has not the requirement and he is transferred in a standard department. If the parts (CM-patient-caregiver-patient's family) reach the accord to hospitalize at home the CM signs the policy of admission (**Sign policy of admission**), the emergency department's doctor compiles the emergency report (**Compile emergency report**) and then the CM books the ambulance for the transport to the patient's domicile with the transport settled with the hospital (**Book ambulance**) and finally the CM fills out the nurse form asking dates to the patient/caregivers, collects some patient's information, gives to the patient and his/her family some information about the service including an âĂIJInformative CardâĂİ with information on the service and about organization of the next tasks, and at the end makes to sign and pick up informed consent to the patient, or to the caregiver if the patient is unable (**Fill out the nurse form + Pick up informed consent)**.

If the request came from a standard department of the hospital the result of the

evaluation (gateway *Result?*) could be:

- Positive: the patient is taken in charge, so the CM books the ambulance, gives and takes different information, fill out the nurse form and make sign the informed consent to the patient, like the previous process (**Book ambulance** and **Fill out the nurse form + Pick up informed consent**).
- Really negative: the CM suggests an alternative route to the patient (gateway *Make an alternative route?*) and the request for this type of hospitalization is definitively rejected (**Rejected**).
- Negative but actually Suspended: often the family needs time to organize themselves or to require medical products or it is necessary to talk also to the "real" caregiver that will actually stay with the patient or to other family members, so it is a temporary rejection (**Suspended**), but the CM takes another appointment.

To establish this contract of trust and collaboration among patient and hospital, it is essential that the CM talks to the whole family nucleus to establish a closer contact with the patient, that must take care and divide assignments and responsibility and finally with the caregiver, who might also be a relative or not. It is necessary that all these people are informed, aware and give the consent to the service, otherwise there could be severe consequences in terms of collaboration that could affect the patient's care.

In this case, the CM will have other tours (gateway *First evaluation* arrow 2Âř visit). These others visit are in average 1, 2, 3 or at most 4 in particular cases (e.g., if there is the need to wait some medical products that have to be ordered). These other visits are not made by a different doctor with other requests, but the CM takes the appointment on a case-by-case bases directly with the patients. The activities remain the same but need less time than the firsts. This second evaluation could exist only in the department (gateway *Where*, 2Âř visit), as has been already explained. In all these visits, it is possible both a taking in charge of the patient, or a rejection of the request, or a suspension of the request which will generate another visit, and the trial can be repeated until the patient will be taken in charge, or the service will be refused, or the patient will die or will be discharged.

In all cases in which the patent go at home in a different day from that of the request of the HaH, the CM autonomously goes to the patient before he goes away, with the purpose to make sure that all the information are clear. It imply the remake of the three activities already explain but in less time.

At the end of this trial with the patient the CM comes back to her department's office and makes the administrative tasks for the patients just taken in charge.

On the hospital's computer system the CM has to make the prescription of the Hospitalization at Home (**Make HaH prescription**) and the formal taking in charge in the department of the Hospitalization at Home (**Make taking in charge**). In the meantime, as soon as the doctors and the nurses arrive the CM informs them about the new patients (**Transfer of power**). At this time the request is also formally accepted and the patient is definitively in the workload of the department of the Hospital at Home (**Accepted**).

Fig. 2 shows the business process of the Hospital at Home service, in detail the organization of the tour visits of the staff (medical doctors and nurses) going to patient's home.

All patients receive home visits every morning; some patients with special conditions (politrasfused or antibiotic therapy) may also receive an afternoon visit.

At full workload, there are 7 nurses and 4 physicians in the morning, and there are 2 nurses and 1 physician in the afternoon involved in the shown process. This staff is then divided into teams to carry out tours. In the morning there are 6 teams: 4 teams composed of 1 physician (or 1 grad student) + 1 nurse and 2 teams made by 1 nurse. In the afternoon there are 2 teams: 1 team made by 1 physician + 1 nurse and 1 team of 1 nurse. Each team visits on average 4 patients.

In the morning, all the staff together analyze all the patient's situations according to four impact factors: medical and nursing complexity care, condition of the caregiver and geographical location of the house's patient (**Organize tour visits**). This allows to divide the whole amount of patients in balanced groups in terms of time to spend in visits and time to go from patient to patient; and assign to each group of patients an hospital team (gateway *Team type?* composed by one physician + one nurse, **Organize team PN**, or made by only one nurse, **Organize team N**). After that, each nurse prepares the medical equipment for each of his patients (**Prepare equipment**).

Once arrived at the patientâĂŹs home (**Move to home patient**), they analyze the current situation (**Screening situation**) and carry out the visit. If there is only the nurse, he treats the patient (**Treat patient**), updates both the nurse record and the other clinical and organizational documents (**Update NR + doc**) and educates the caregiver on treatment (**Educate on treatment**). If there are both physician and nurse, the physician visits the patient while the nurse treats him (**Visit (P) + Treat (N) patient**); after, the physician updates the medical record and the nurse compiles the nurse record and the other organizational documents (**Update NR+doc (N) + Update MR (P)** and, at the end, they educate the caregiver on treatment (**Educate on treatment**).

Once the visit is finished, if there is another patient to visit (gateway *Another patient?*), the team heads to the second patientâĂŹs house. The cycle resumes until

the assigned patients are not finished; only then the team will be back to the hospital (**Back to hospital**).

The morning shift staff completes some “administrative" tasks (**Plan diagnostic assessment, Plan medical advice, Update handover** for physicians and **Send blood samples to Laboratory, Prepare equipment for next visits** for nurses)

In the meanwhile, all the staff make the handover: the morning staff communicates the different patients' situation, one by one; and the afternoon staff receives any useful information to organize the future work. Subsequently, they **organize tour visits**, the nurses **Prepare equipment**, they decide the team composition and start the visit tour. All the activities are the same already explained for the morning.

3.2 Compliance check in HaH

Compliance checking not only refers to the tasks that an organization must perform to achieve its business goals, but also to their effects, i.e., how the activities in the tasks change the environment in which they operate, and the artefacts produced by the tasks (see discussion in [37]). To capture these aspects, process models are usually enriched with semantics annotations [52]. Each task in a process model can have attached to it a set of semantic annotations. Annotations are formal representations, e.g., formulae, giving a description of the environment in which a process operates. Then, it is possible to associate with each task in a trace a set of formulas corresponding to the state of the environment after the task has been executed in that particular trace. It is important to underline that different traces can result in different states, even if the tasks in the traces are the same. Moreover, even if the end states are the same, the intermediate states can be different. Finally, a trace uniquely determines the sequence of states obtained by executing the trace.

The business compliance checking tool Regorous [29] allows to enrich BPMN graphs with semantics annotations corresponding to DDL formulas.

As part of our research activity in the âĂIJCANPâĂİ project, we have enriched the BMPN graphs representing e-Health processes within the âĂIJCittÃă della Salute e della ScienzaâĂİ of Turin, such as the one shown above in Fig. 1, with selected GDPR legal constraints modeled in DDL and LegalRuleML. These constraints have been then implemented in Regorous in order to test and evaluate compliance checking with respect to different input configurations and scenarios. The LegalRuleML and Regorous formalizations of the GDPR norms that we considered are available online[9].

[9]See `https://github.com/liviorobaldo/BPMinHealthcare`

Regorous implements the sub-classes of obligations and permission seen above in the section âĂIJLegal reasoning and Defeasible Deontic LogicâĂİ via the following notations (atomic DDL formulas):

- **[P]p:** p is permitted.
- **[OM]p:** there is a maintenance obligation for p.
- **[OAPP]p:** there is an achievement preemptive and perdurant obligation for p.
- **[OAPNP]p:** there is an achievement preemptive and non-perdurant obligation for p.
- **[OANPP]p:** there is an achievement non preemptive and perdurant obligation for p.
- **[OANPNP]p:** there is an achievement non preemptive and non-perdurant obligation for p.

In the above notations, âĂIJpâĂİ is a predicate, called a âĂIJtermâĂİ in Regorous terminology. Regorous lists all terms used in a set of formalizations, together with their description, in a special XML tag `<vocabulary>`. Two terms used in the formalization of Art. 6 of GDPR are the following:

```
<vocabulary>
   <Term atom="Proc" description="Processing: means any
      operation or set of operations which is performed on
      personal data âĂę"/>
   <Term atom="GiveConsent" description="Consent given
      by the data subject means any freely given, specific,
      informed and unambiguous indication âĂę"/>
</vocabulary>
```

On the other hand, (part of) the formalization of Art. 6 is the following; note that we chose to formalize the processing of personal data as prohibited unless one of the legal basis is in place, e.g., unless the patient has given consent to the processing of personal data (see GDPR, Art.6.1(a)):

```
<Rule xmlns:xsi="âĂę" xsi:type="DflRuleType" ruleLabel="Art.6.0">
   <ControlObjective>Personal data processing
```

```
                                is prohibited.</ControlObjective>
   <FormalRepresentation>=>[OM]-Proc</FormalRepresentation>
</Rule>

<Rule xmlns:xsi="âĂę" xsi:type="DflRuleType" ruleLabel="Art.6.1a">
   <ControlObjective>Processing shall be lawful if the data
       subject has given consent to the processing of his or
       her personal data for one or more specific
       purposes.</ControlObjective>
   <FormalRepresentation>GiveConsent=>[P]Proc</FormalRepresentation>
</Rule>
```

"`-`" and "`=>`" are the standard propositional logic operators for negation and implication. Thus, the two formulas above can be rewritten in a more classical notation as "`=>[OM]-Proc`" and "`GiveConsent=>[P]Proc`".

Of course, the two formulas cannot hold together as the first entails that the processing is prohibited while the latter entails that it is permitted. In order to solve these conflicts, both LegalRuleML and DDL implement overriding relations between norms. In our example, the second formula will have to override the first one, in order to permit processing of personal data when consent is given.

In Regorous, overriding is implemented as âĂIJsuperiority relationsâĂİ, encoded via the homonym tag, in which the âĂIJsuperiorRuleLabelâĂİ overrides the âĂIJinferiorRuleLabelâĂİ. In the example under consideration we have:

```
   <SuperiorityRelation superiorRuleLabel="Art.6.1a"
                                inferiorRuleLabel="Art.6.0"/>
```

Given a set of well-formed rules and superiority relations encoded in the XML format briefly seen above, Regorous allows to check whether a Business Process in the BPMN standard is compliant with them.

Regorous is implemented as a plug-in of Eclipse[10]. The BPMN is uploaded in the platform together with a set of rules in Regorous XML format. Subsequently, in each task of the process it is possible to specify which terms of the vocabulary are true or false via special Eclipse windows provided by the plug-in. Of course, the truth value of these terms might be also asserted programmatically during the real-time execution of the Business Process; this is indeed how we plan to use Regorous in the future, when the service will be up and running. However, since at present we are still in the research and development phase, in our current activity we always executed

[10] `https://www.eclipse.org`

Regorous by manually identifying, setting, and testing different input configurations and scenarios.

Fig.3 shows a simple example of how Regorous performs compliance checking on the BPMN representation from Fig.1. The BPMN file is uploaded in Eclipse together with the ruleset formalizing the GDPR norms in Regorous XML format.

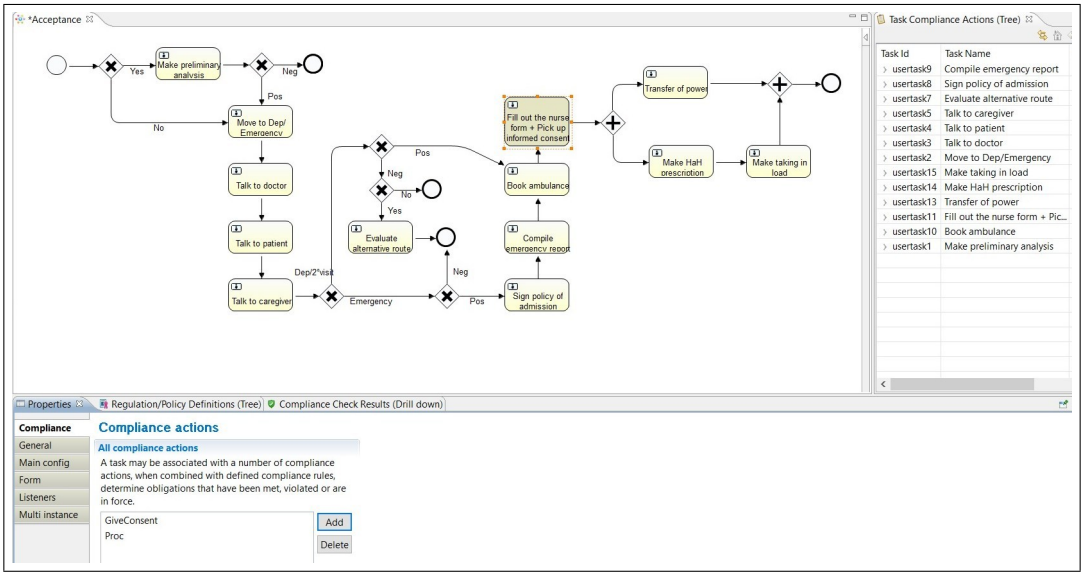

Figure 3: Regorous screenshot example for compliance checking.

The plug-in includes special tabs (shown on the bottom of Fig. 3) that allow to specify, for each task, the values of the terms. For instance, by specifying "`GiveConsent`" and "`Proc`" in the task âĂIJFill out the nurse form + Pick up informed consentâĂİ, Regorous infers that the process is compliant with the ruleset, as the superiority relation seen above will make the processing of personal data permitted. Conversely, by specifying the single action "`Proc`", Regorous infers that the process is not compliant with the ruleset because the rule with `ruleLabel="Art.6.0"` asserts the processing of personal data as prohibited and, contrary to the previous case, that prohibition is not overridden by a stronger permission.

After specifying the rules or checks performed in that task in the various activities, it is possible to run the Regorous check. Thank to the superiority rules and the BPMN, for the check Regorous will follow the flow of the process, in this way it is able not only to check if every rule is respected, but also if the sequence of them is compliant to the sequence imposed by law.

If the result of the compliance checking is positive it will appear a green screen

as in Fig. 4.

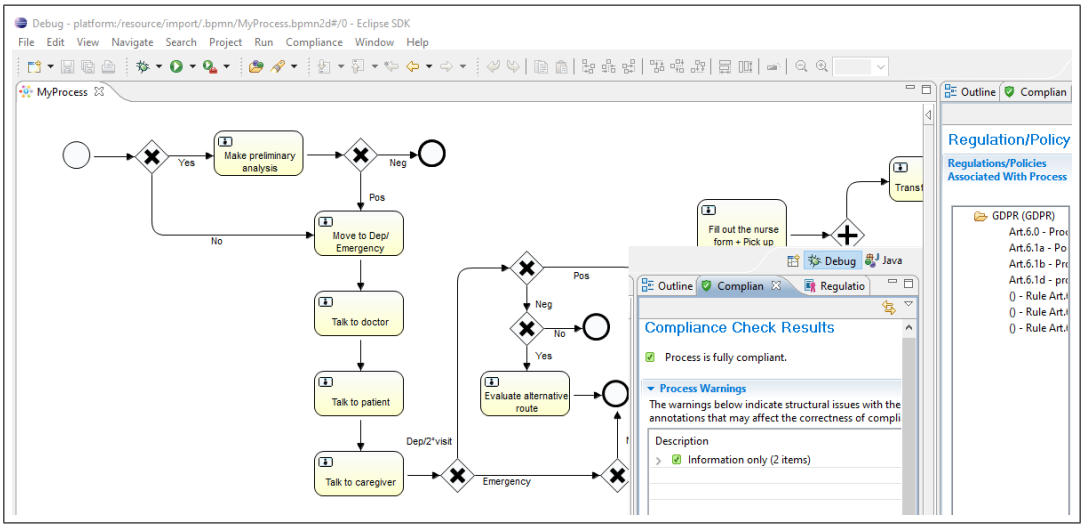

Figure 4: Regorous screen of compliance check results.

if the control detects non-conformities or anomalies, the same screen will appear but red or orange respectively, which will highlight in which areas the non-conformities were detected and with respect to which controls.

4 Conclusion and Future Works

The proposed pipeline addresses a specific risk management application in a selected healthcare process. However, of course further work is needed to formalize all the laws, regulations, and guidelines involved in all healthcare processes, in order to have a full exhaustive analysis on how legal compliance is handled in medical procedures. Although, as explained in Section 2, the DDL is currently one of the best logics for formalising legal rules, this formalisation still needs to be done by a legal expert, who has experience with the principles governing legal interpretation, both for formalize the rules and for establish the relations of superiority between them.

On the other hand, using this methodology, if changes are made over time, you can only change the impacted area, leaving the rest of the work intact:

- If the business process is changed, just modify the modified activities in the real process to check if the new process is still compliant (without changing the rest of the activities).

- Since the law is formalized in an XML file and then uploaded to Regorous:
  - If the legislation is changed, the XML file can be modified only in the parts modified by the legislator (without changing the rest of the corpus).
  - If we have a second process that must comply with a regulation already formalized, just add the XML file to the second BPMN (without having to remake the formalization already made for the first process).
  - If a new law is added in the field of our business, it will be enough to add a second XML file containing the new legislation. In this way, the compliance check will be carried out for both regulations (without changing the BPMN or the previous XML files).

In conclusion, the aim is to combine this compliance checking methodology in a context of re-organization and optimization of processes. Maintaining the already formalized norms as a background, the purpose is to obtain a methodology able to balance the managerial aspect with that of regulatory compliance.

Finally, the authors are also currently working on two branches of research. On one hand, in the context of the project âĂIJCANPâĂİ, on the development of a methodology to automatize or semi-automatize formalization of laws, that combines Defeasible Deontic Logic with NLP technologies, in order to make the whole process faster, simpler, and accessible to users who have little or no competence in law or in logical formalizations. On the other hand, the authors are working on the automation of the compliance checking process starting from a legal point of view, i.e., by seeking methodologies capable of reproducing the principles governing legal interpretation [4; 57; 58].

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[11] See `http://casanelparco-project.it`

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