UNIVERSITÉ DU LUXEMBOURG

ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

PhD-FSTM-2022-071
The Faculty of Science, Technology and Medicine

The Department of Legal Studies

DISSERTATION

Defence held on 16/06/2022 in Bologna

to obtain the degree of

DOCTEUR DE L'UNIVERSITÉ DU LUXEMBOURG

EN INFORMATIQUE

AND

DOTTORESSA DI RICERCA

IN LAW, SCIENCE AND TECHNOLOGY

by

Ilaria Angela AMANTEA

Born on 10 February 1988 in Venaria Reale (TO) (Italy)

METHODS AND TOOLS FOR ANALYSIS AND MANAGEMENT OF RISKS AND REGULATORY COMPLIANCE IN THE HEALTHCARE SECTOR: THE HOSPITAL AT HOME – HAH

Dissertation defence committee

Prof. Emilio Sulis, dissertation co-supervisor
Professor, Università degli Studi di Torino

Prof. Sjouke Mauw, dissertation co-supervisor
Professor, Université du Luxembourg

Prof. Monica Palmirani, dissertation co-supervisor
Professor, Alma Mater Studiorum – Università di Bologna

Prof. Andrea Marrella
Professor, Sapienza Università di Roma

Prof. Niels Martin
Professor, Hasselt University

Prof. Barbara Re
Professor, Università di Camerino

Alma Mater Studiorum - Università di Bologna

DOTTORATO DI RICERCA IN

LAW, SCIENCE AND TECHNOLOGY

Ciclo 34

Settore Concorsuale: 01/B1 - INFORMATICA

Settore Scientifico Disciplinare: INF/01 - INFORMATICA

METHODS AND TOOLS FOR ANALYSIS AND MANAGEMENT OF RISKS AND REGULATORY COMPLIANCE IN THE HEALTHCARE SECTOR: THE HOSPITAL AT HOME – HAH

Presentata da: Ilaria Angela Amantea

Coordinatore Dottorato

Monica Palmirani

Supervisore

Guido Boella

Co-supervisore

Leendert Willem Nicolaas Van Der Torre
Sjouke Mauw
Emilio Sulis

Esame finale anno 2022

Methods and Tools for Analysis and Management of Risks and Regulatory Compliance in the healthcare sector: the Hospital at Home – HaH

Ilaria Angela Amantea

2022

Abstract

Changing or creating a new organisation means creating a new process. Each process involves many risks that need to be identified and managed. The main risks considered here are procedural risks and legal risks. The former are related to the risks of errors that may occur during processes, while the latter are related to the compliance of processes with regulations. Therefore, managing the risks implies proposing changes to the processes that allow the desired result: an optimised process.

In order to manage a company and optimise it in the best possible way, not only should the organisational aspect, risk management and legal compliance be taken into account, but it is important that they are all analysed simultaneously with the aim of finding the right balance that satisfies them all. This is exactly the aim of this thesis, to provide methods and tools to balance these three characteristics, and to enable this type of optimisation, ICT support is used.

This work is not intended to be a computer science or law thesis but an interdisciplinary thesis. Most of the work done so far is vertical and in a specific domain. The particularity and aim of this thesis is not so much to carry out an in-depth analysis of a particular aspect, but rather to combine several important aspects, normally analysed separately, which however have an impact on each other and influence each other. In order to carry out this kind of interdisciplinary analysis, the knowledge base of both areas was involved and the combination and collaboration of different experts in the various fields was necessary.

Although the methodology described is generic and can be applied to all sectors, a particular use case was chosen to show its application. The case study considered is a new type of healthcare service that allows patients in acute disease to be hospitalised to their home. This provide the possibility to perform experiments using real hospital database.

Contents

Acronyms

ABOS: Agent-Based Organisational Simulation

ABS: Agent-Based Simulations

AHRQ: Agency for Healthcare Research and Quality

AI: Artificial Intelligence

ALS: Amyotrophic Lateral Sclerosis

AOU: Azienda Ospedaliera Universitaria - Hospital and University Company

B2B: Business-to-Busines

BB: Blood Bank

BMM: Business Motivation Model

BoN: Bag-of-Ngrams

BPD: Business Process Diagram

BPM: Business Process Management

BP-M*: Business Process Management star

BPMN: Business Process Management Notation

BPMSR: Process Modelling Simulation and Re-engineering

BVA: Business Value Added

CM: Case Manager

CMF: Compliance Management Frameworks

CN: Co-occurrence Network

COM: Communication from the Commission (EU)

COPD: Chronic Obstructive Pulmonary Disease

COSO: Committee of Sponsoring Organizations of the Treadway Commission

CTO: Centro Traumatologico e Ortopedico - Trauma and Orthopedic Centre

DDL: Defeasible Deontic Logic

DES: Discrete Event Simulation

DL: Defeasible Logic

DSS: Decision Support Systems

DT: Decision Tree

DU: Dummy

EC: European Council

ECJ: European Court of Justice

ED: Emergency Department

ER: Emergency Room

EU: European Union

FMEA: Failure Model and Effects Analysis

FMECA: Failure Mode and Critical Effect Analysis

FRBR: Requirements for Bibliographic Record

GATT: General Agreement on Tariffs and Trade

GDPR: General Data Protection Regulation

GP: General Practitioner

GU: Gazzetta Ufficiale - Official Journal

HaH: Hospital at Home

HIS: Health Information Systems

HR: Human Resources

ICT: Information Communication Technology

ILC: International Law Commission

ILSA: Italian Longitudinal Study on Aging

IoT: Internet of Things

IRV: Istituto per il Ricovero della Vecchiaia - Institute for Hospitalisation of Elderly

IS: Information Systems

ISMB: Istituto Superiore Mario Boella - Superior Institute Mario Boella

IT: Information Technology

JCAHO: Joint Commission on Accreditation of Healthcare Organizations

kNN: k-Nearest Neighbors

KPI: Key Performance Indicators

LDA: Linear Discriminant Analysis

LKIF: Legal Knowledge Interchange Format

LR: Logistic Regression

MDE: Multidimensional Evaluation

NASA-TXL: National Aeronautics and Space Administration - Task Load Index

NB: Naive Baye

NGO: Non-Governmental Organizations

NLP: Natural Language Processing

NLTK: Natural Language Toolkit

NVA: Non Value Added

OAD: Ospedalizzazione A Domicilio - Hospitalisation At Domicile

OMG: Object Management Group

OWL: Web Ontology Language

PICC: Peripherally Inserted Central Catheter

PM: Process Mining

POS: Parts Of Speech

R&D: Research and Development

RCA: Root Cause Analysis

RPN: Risk Priority Number

RSA: Residenza Socio-Assistenziale - Social Assistance Residences

SAUB: Struttura amministrativa Unificata di Base - Unified Basic Administrative Structure

SD: System Dynamics

SNG: Sondino Nasogastrico - Nose-Gastric Tube

SVM: Support-Vector Machines

TAO: Terapia Anticoagulante Orale - Oral Anticoagulant Therapy

TEU: Treaty on European Union

TFEU: Treaty on the Functioning of the European Union

TF-IDF: Term Frequency–Inverse Document Frequency

TI: Telecom Italia - Italian Telecomunication

TM: Telemedicine

TOI: Text of Interest

UML: Unified Modeling Language

VA: Value Added

VCLT: Vienna Convention on the Law of Treaties

WHO: World Health Organization

XES: Extensible Event Stream

XML: Extensible Markup Language

Chapter 1

Introduction

1.1 Notes on research context and motivation

In recent years, increasing attention is focused on integrating the typical hospital service model with alternatives care due to the growing ageing population. This leads to the relevance of home care models and focuses on the needs of patients often suffering from multiple chronic diseases [95, 280, 13]. Home care model supported by technological solutions has demonstrated a positive impact on health, well-being and quality of life [299, 161, 14]. In particular, assistive technologies focus on the concepts of patient-centered care, which is currently recognised worldwide as an essential dimension of quality care, as well as the so-called patient empowerment. A recent review of the literature on the topic reveals how a great amount of articles focuses on technology applications to all knowledge areas of health, as in the case of patient education [76, 11] or medical information management [288, 291, 294].

Creating a new type of hospitalisation, outside the hospital walls, means creating a new type of organisation (dedicated specialised resources, new emergency procedures, new material resources such as cars, etc.), so new processes. Every process involves risks that have to be identified and managed. Many risks can occur in an enterprise. The main risks considered here, and the most important for an hospital, are procedural and legal risks. The former are related to the risks of errors that might occur during the processes, while the latter are related to the compliance of the processes with norms. Managing risks means identifying risks and deciding whether to accept, transfer, reduce or eliminate them. For the last three cases,risk management also involves proposing changes to processes that enable the desired outcome [292]. The desired result may be a sequence of activities that allows fewer errors to occur during the process (as regards procedural errors), or avoidance of sanctions (as regards legal non-conformities). Moreover, it is not said that these two aspects cannot be linked: a rule may regulate a procedure (e.g. the guidelines for the blood sampling procedure), not having a proper process may leads to procedural errors (e.g.

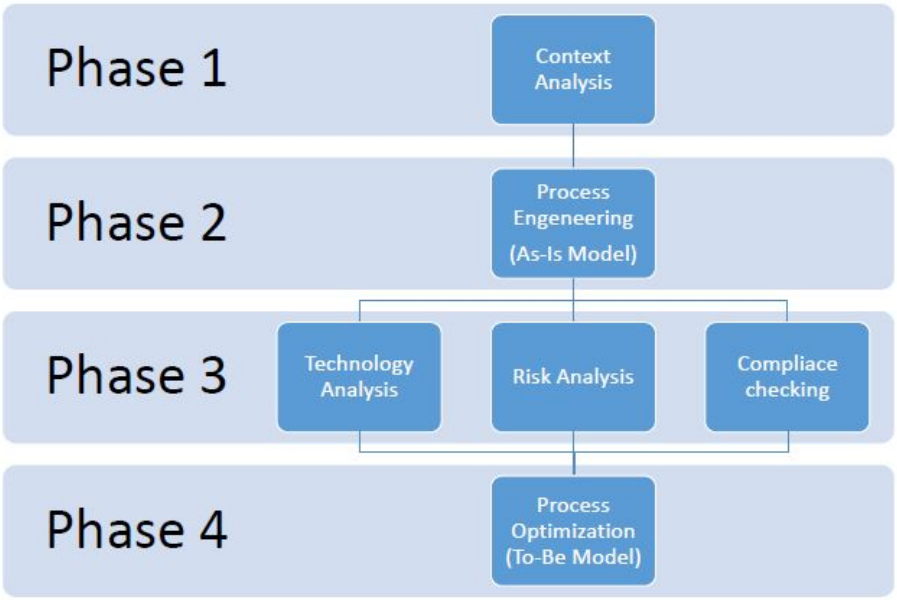

Figure 1.1: Phases of Business Process Management methodology.

taking blood from the wrong patient) but this also implies that legislation has not been complied with and, therefore, administrative, civil or even criminal sanctions may be incurred.

Moreover, these new processes are often supported by some technologies (telemedicine devices for remote monitoring, or information systems that also work outside the hospital walls but that guarantee data privacy). The introduction of technologies in a business process is likely to imply the consideration of other legislation and the management of new risks [223]. [224]. From the point of view of law, in health sector, it implies the creation and approval of a clinical trial by an ethics committee to introduce technologies into the care process. It means taking into account regulations concerning the specific technology, in the already enormous network of healthcare regulations[1]. Moreover, taking into account new regulations also means taking into account new risks during trials.

This reasoning shows that these three aspects (organisation, risk management and management of compliance of the process with the law) are not separate from each other and that, if you want to improve even one of these three aspects, you can not consider also the other two.

To support this new type of organisation and the optimisation of these new

[1]One is the new European Regulation (GDPR): Regulation (EU) 2016/679 of the European Parliament and of the Council, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), 27 April 2016.

processes, it is useful to adopt the perspective of Business Processes Management (BPM), which is a specific discipline to support the management of business [315]. It enables healthcare managers to better allocate appropriate resources, to improve the responsiveness of patient care, to manage the risks, and to support regulatory compliance monitoring [288].

This thesis is based on the BPM methodology [109]. There are four main phases and they are shown in Figure 4.1[2]. The first phase is the context analysis, which in this case is focused on some healthcare services and departments. The second phase consists of process engineering, the creation of the As-Is model and some simulations. In this case, the creation of the current model of the business processes of health services is in the Business Process Management Notation (BPMN) standard language [220]. Moreover, thanks to the simulations, it is possible to have an overview of the whole process, the interconnection between the activities and the problems (such as the bottlenecks); it is possible to make analysis of the data log (or generators) and last but not least, it is useful for the validation of the model [3].

Based on the objectives or direct requests addressed in Phase 1, or the problems encountered in Phase 2, research is carried out in Phase 3 to improve and optimise the process and, finally, to propose one or more solutions in the final Phase 4. In general, optimisations are of two types: organisational or risk management. Of the first type, we can have purely reorganisation improvements of existing resources, but more often they are at technological level, such as the implementation of an information system, a workflow, or AI, IoT tools. The aim may also be to improve risk management. There are many types of risks, but the ones most managed with this methodology are procedural ones, i.e. related to the performance of individual activities, and the legal ones, i.e. the compliance of the process with all laws, regulations, guidelines related to those business activities [198]. Although compliance verification is part of risk management, it can be considered as a macro-category in its own right, both because it encompasses several factors (e.g. it requires the intervention of specific resources such as legal experts) and because, depending on the resources and skills required, it is often decentralised and entrusted to external experts [154].

Phase 4 aims to provide an optimisation solution which, depending on the needs of the company being analysed, may concern only one of the aspects but also, and above all, a solution that may involve the integration of all these aspects. In other words, when proposing an organisational improvement, account is also taken of the fact that new risks may arise and therefore have to be reiterated because new rules may have to be complied with [201].

The objective of this thesis is to propose methods and tools for risk analysis and management and regulatory compliance in the healthcare sector to support management optimisation. The aim is to bring together and balance aspects of organisational optimisation, with procedural and automated legal risk management techniques and, as business management can be costly, ICT support is

[2]The details of each phase will be explained in Chapter 1.

required.

1.2 Research objectives

The objective of this thesis is introducing ICT tools to create, within the BPM methodology, a methodology to balance, in the context of a business, organisational management with risk management and regulatory compliance.

The majority of the works done so far are related either to legal aspects [117, 267] or to IT aspects [81] and is mostly vertical. Performing a horizontal analysis means considering practically (and not only theoretically) both these aspects and finding the right balance between them. This kind of work is not easy because it implies an interdisciplinary analysis, a basic knowledge of both areas and requires the union and collaboration of different experts in the various fields [108, 209].

Therefore, the peculiarity and objective of this thesis is not so much to perform an in-depth analysis of a particular aspect, but rather to combine several important aspects, normally analysed analysed separately, that have a mutual impact and influence each other. In order to simultaneously analyse both the organisational and risk management aspects, as well as the compliance of processes with legislation, ICT support is required to enable the adoption of BPM. As a case study we focus on the health sector, but it is a general methodology that can be applied to other sectors[3].

In particular, we address the following research questions:

- How BPM methodology could be applied to healthcare sector.
- How to support process optimisation when new technologies are introduced.
- How to support the reconstruction of processes from data.
- How to support the procedural risks management.
- How to semi-automatize the regulatory compliance checking.

For each research question, the problems are explained below, and in the next section it is explained what the research contribution is for each of them. Finally, the same pattern is followed to illustrate the conclusions.

[3]This thesis is focus on healthcare sector, as also stated in the title. But this methodology (or some steps of it) was applied also in other field, some example of our works are: [103] in the context of a growing small-medium manufacturing industry, [225] in which we consider a start-up of bitcoin exchange. Finally, we are working on a new project "Next Generation UPP" in which we are applying this methodology in order to optimise the workflow process in the tribunals of northern Italy.

BPM methodology applied to healthcare. In healthcare, it is not only the quantitative optimisation of processes that is important, but also the qualitative variables. Medical practice is not an assembly line with all the same steps. In relation to people, unfortunately sick people, it must be taken into account that each of them has its own peculiarities. Unforeseen events that lead to a deviation from the established path is the norm. In addition, each department has its own objectives and resources. There is no a single type of optimisation, but a different type for each department and for each objective.

Supporting process optimisation when introducing new technologies. Introducing a new technology often means changing more than one activity; perhaps it means changing half the process, or an entire process, merging two existing processes.

As a result, resources (material or humane) often have to be reallocated or acquired; human resources have to be trained; people are often reluctant to change so it may take some time to assimilate the new procedure; space may need to be reorganised. Major changes to the initial process should only be made if it is guaranteed (or if it is fairly convinced) that the new process is more optimal than the old one. It would be unlikely and dangerous to stop the production of a company (or to stop a hospital department) to change a process, reallocate space, train new resources, and then find that the old process was better in terms of working time, bottlenecks, available resources. And even more far-fetched is to decide to "go back" to the old process and the old allocation of resources, because maybe the resources are no longer available, expenses have been made, maybe the budget does not allow it, etc. In conclusion, it is necessary to have a support that helps to understand how the process will change once the new technology is introduced.

Supporting the reconstruction of processes from data. Using computer techniques it is possible to automatically reconstruct processes from databases. This is an important analysis because it can show the implicit knowledge contained in databases, knowledge that is normally precluded if only manual analysis is done. Such an analysis could show paths within processes that are difficult to detect because they arise from the simultaneous analysis of a large amount of data that cannot be processed simultaneously by the human mind alone. These results are of great value in optimising the process itself. The most used techniques for this purpose are those of process mining and among them the technique of process discovery [306, 201]. Since the case study concerns healthcare, it will be shown to apply these techniques only to the healthcare sector.

Support for the management of procedural risks. Procedural risks are the most likely to occur and therefore the highest risk. The medical field is full of highly detailed procedures with guidelines, best practices and regulations at various levels. Each high-risk practice has its own legislation establishing a procedure: a blood sample, the preparation of a medical record, a surgical

intervention. The medical field is among those with the highest procedural risks.

Managing regulatory compliance. The healthcare sector is one of the most regulated sector. For every organisation and company there are many regulations at various levels to comply with. The higher the level of regulations, the more general and difficult they are to interpret and contextualise. Guidelines regulating certain procedures in detail are checklists to be executed, easy to interpret and contextualise. But, a national or European law must necessarily establish only principles and objectives to be achieved, and the way is then left to regulations of a lower source. This leads to the problem of interpretation of laws. Interpreting a law is not easy. People who working in legal disciplines learn during their university years how to do interpretation. Therefore, there are two main problems:

- There are many regulations to comply with, so far the compliance of the processes has been checked by hand but this is a huge job.
- Having technological support to do this work means training machines to interpret the law, a task which, at present, can only be done efficiently and fully correctly taking into account all the key factors by a human.

1.3 Research contribution

This work is not intended to be a computer science or law thesis, but an interdisciplinary one.

Thus, this research has a horizontal rather than vertical structure. The aim is to consider some critical issues in management of health systems and to consider their correlation.

In doing this research, I had to bring together people with different skills, technicians in their fields. By bringing together medical technicians, computer scientists, logicians, process experts and lawyers, I have created a work to merge and balance many different aspects and points of view. The aim is to create research that touches on different aspects but in a transversal way in order to have a more complete view, rather than an in-depth examination of a single specific aspect.

It must be stressed that in order to manage a company and optimise it in the best possible way, it is not only necessary to consider the organisational, risk management and legal compliance aspects, but it is important that these three aspects are taken into account at the same time in order to find the right balance that satisfies them all. ICT supports is needed to enable this kind of optimisation to take place. To achieve this, we have answered the above questions in this way:

- A formal analysis of three hospital processes is made.

- Simulation and optimisation processes and To-Be models of these processes are created to prepare for the introduction of new health technologies.
- We show how a process can be automatically reconstructed from data logs.
- We show how simulations can support risk analysis.
- We introduce a way to perform a semi-automatic check of regulatory compliance.

Formal analysis of hospital processes. Following the BPM methodology, the analysis of three hospital process departments is carried out. Context analysis, As-Is models and simulations are created. Subsequent data considerations are carried out.

To-Be models. In order to improve some hospital processes with the introduction of different technologies, some process simulations are made to show how the process will be once the new technology is introduced. The aim is to provide some To-Be models that show specifically which activities will be changed and in what terms, what will be the changes in terms of human and material resources needed, what will be the differences in terms of the timing of individual activities, of the whole process, and how will the situation change with regard to queues and bottlenecks.

Process discovery. Using process discovery, a particular process mining technique, an automatic reconstruction of a healthcare process from real data logs is shown. The advantage of using these techniques is highlighted and it is shown how these techniques can help to improve change, including combining the results of these analyses with the results of these analysis with the results of process modelling and simulation using the BPM methodology.

Risks analysis. An analysis of a hospital department is made, taking into account procedural risks, the analysis of what the regulations say about a specific process and the analysis of what management is adopted by the hospital to avoid risks. It is shown how process modeling and simulations support risk management in order to identify, count and reduce risks.

Checking regulatory compliance. Linked to management of risks, an initial compliance check of a hospital department is done by hand. A semi-automatic regulatory compliance check of other hospital services is done with the support of logic languages. A final analysis is proposed on the basis of the principles of legal interpretation to develop a model capable of automating the compliance check.

The last part focuses on a new "in progress" perspective. The aim is to find a new methodology for automatic or semi-automatic compliance checking from

a legal point of view. It is precisely the point of view that is the innovative aspect. In fact, most of the tools for checking regulatory compliance are made by computer scientists and based on an IT point of view. The problem is that sometimes there are inconsistencies between the results provided by regulatory compliance tools and the principles of legal interpretation because the tools are set up with certain limitations (they are mostly based only on detecting semantic similarities) without taking into account other important factors such as the hierarchy of the source, the balance of principles, the time of entry into force of the law, repeals, etc.

1.4 Use case: Hospital at Home

The use case analysed is Hospital at Home (HaH). It is a type of home care, by hospitalising at their home patients, mostly geriatric, provided by the City of Health and Science of Turin, Italy[4], one of the largest complex hospital at national and European level. It has about twelve thousand employees and guarantees third level diagnosis and care in multiple care pathways, favouring multidisciplinary approaches that ensure highly qualified appropriate care to better meet patients' needs. The amalgamation of a number of regional reference hospitals allows the City of Health and Science, together with the Faculty of Medicine and Surgery of Turin, to be a competitive company in Europe. These hospitals are: Molinette Hospital, Dermatological San Lazzaro, San Giovanni, CTO Trauma and Orthopedic Centre, Regina Margherita Children's Hospital and the Sant'Anna Obstetric and Gynecological Hospital.

1.4.1 Historical introduction

Demographic and economic changes in recent decades, together with the availability of easily transportable technologies, have fostered a growing interest in alternative care settings to hospitalisation [12].

The elderly population in Italy is constantly growing. The group that is increasing most is made up of older people. Aging, although not synonymous with disease, is associated with an increased prevalence of chronic, often disabling diseases, as well as a progressive extension of life expectancy in conditions of chronicity and disability [206, 300].

Scientific literature and operational experience in the field of home care have highlighted the particular usefulness and effectiveness of this type of health intervention. In particular, in the geriatric and oncological area, also recognising the function of making the hospital structure more flexible and encouraging hospital-territory integration [12].

The Italian Longitudinal Study on Aging (ILSA) [99] has shown how comorbidity, disability (especially severe), and exacerbations of multiple chronic diseases represent a very common reality in the elderly population that is associated with an increasing recourse to medical care and hospitalisation [206].

[4]Città della Salute e della Scienza di Torino.

In the geriatric field, it is also known that prolonged hospitalisation, the loss of environmental and relational reference points, can be associated, especially for the frailest patients, with an increased risk of loss of functional autonomy, mental disorders with episodes of delirium, greater exposure to the risk of iatrogenic complications linked to the hospital environment and removal from one's usual living context [206, 300].

The above-mentioned Hospital at Home of City of Health and Science of Turin is a "*physician-led unit*" defined internationally as a *service that provides active treatment by health professionals, at the patient's home, for a condition that would otherwise require acute hospitalisation, and always for a limited period of time* [279].

Over the last 20-25 years, this model of care has aroused strong interest in the scientific community. The result is the implementation of home hospitalisation projects in Australia, New Zealand, North America, Israel, Spain, the United Kingdom and Italy, and the subsequent analysis of the advantages and limitations of this care approach in the context of randomised clinical trials.

Studies have identified five key points that can foster the development of home care: [183]

- The increasing age of the population.
- The increase in chronic diseases and their exacerbation.
- Advances in technology.
- The high consumption of healthcare resources and the need to contain costs.

It was pointed out that technological evolution continues to develop tools that can monitor the health status of patients at home. The home would represent an increasingly important place of care in the future, where physicians could combine old-fashioned and caring sensibilities with the application of new [286] technologies.

Already more than 20 years ago, in San Diego, California, physicians were able to use mobile devices at home to take X-rays and instruments to perform more than 20 laboratory tests. Massachusetts General Hospital in Boston was experimenting with a videoconferencing system for virtual visits at home.

In Spain, there were more than 70 home hospitalisation units (the so-called Unidad de hospitalización a domicilio) distributed in the main hospitals of the country, with specialised hospital medical and nursing staff [252, 150].

Similarly, home hospitalisation services have spread to other European countries. The experiences in England are significant: at the beginning of the 2000s, 139 home hospitalisation services were in operation and more than 100 were planned (some evolution in time are [226, 319, 168, 183]).

Established models are popular in Australia, New Zealand, Canada, Israel and USA (see respectively [78, 222, 249, 285, 192, 183]).

In Italy, in Turin, home hospitalisation is a well-defined model of care at organisational level and has been active for more than 25 years [206][5]. Hospital at Home (HaH) is a service based on the geriatrics department of OAD[6] and supported by the R@dhome radiology home department.

In March 2010, the Piedmont Regional Council produced the Resolution n. 85-13580 [7]. It defined *home hospitalisation* as *a form of hospital-type based health care, which provides for the organisation of home care for patients suffering from diseases in an acute phase, but who do not require highly complex technological equipment, intensive/invasive monitoring, as an alternative to hospitalisation. It is characterised by the total clinical care of the patient by a hospital structure*[8]*, by health personnel specifically trained and with documented experience in the management of the patient in the acute phase, outside the strict hospital context.* This definition is in line with what has been established in the scientific literature, which identifies *home hospitalisation as the modality by which hospitals, in view of specific evaluations, follow with their staff, directly at home, patients who require services of particular complexity, such as to require a hospital-level care process* [278]. This regional deliberative act represented a fundamental instrument for the development and diffusion of this model of care [206].

1.4.2 Numbers and results of HaH research over time

Over the years, the increased skills acquired by medical and nursing staff and the growing availability of equipment and technology that can be transferred to the home, has enabled an expansion of services that can be provided at home.

During the service's thirty years of activity, a number of clinical studies have been conducted to evaluate the results of this organisational model in terms of feasibility, effectiveness and costs. An analysis of direct costs carried out by the hospital calculated a cost per patient, per day of hospitalisation in the OAD, of approximately 160 euros compared to an average of 750 euros for of traditional hospitalisation. This includes the cost of medical, nursing, rehabilitation and administrative staff and costs of drugs, medical and non-medical supplies, non-medical services, depreciation, car fleet and ambulance transport [206].

Many studies have shown how HaH services for elderly and frail patients, affected by different acute pathologies, admitted in ED (Emergency Department), can help to reduce hospital stays, hospitalisation and institutionalization rates,

[5]Representative articles show that this service is used for elderly and frail patients and it is especially helpful in the presence of severe pathologies such as acute decompensation of chronic heart failure [299], exacerbations of chronic obstructive pulmonary disease [13], acute uncomplicated first ischemic stroke [246], hematological patients requiring hospital admission [162], and elderly delirium [161] and dementia and relatively caregiver's stress [296].

[6]Literally Ospedalizzazione A Domicilio: hospitalisation at domicile.

[7]Delibera della Giunta della Regione Piemonte del 16 marzo 2010, n. 85-13580, "Attività di continuità assistenziale: organizzazione e remunerazione delle attività di assistenza specialistica di ospedalizzazione domiciliare". http://www.cittadellasalute.to.it.

[8]In Italy, the health system is totally public. A characteristic of this service, different from other countries, is that it is also totally paid for by the National Health System.

and improve functional status and quality of life, as well as reduce costs [13, 245, 246, 78, 190, 222, 285, 299]. There are several publications that have analysed the advantages and limitations of HaH[9]. It has been confirmed that a comprehensive post-discharge care programme, which combines traditional treatment with education of patients and their caregivers, cardiological, dietary and social counselling and appropriate follow-up, reduce re-hospitalisations and the overall costs of managing frail patients [248, 56]. In order to optimise the management of frail patients, it is essential to create an integrated network of services between the hospital and the territory to ensure adequate continuity of care [12][10].

[9] In 2009, a meta-analysis was conducted by evaluating the results of 10 international clinical trials and published in the Canadian Medical Association Journal under the title "Avoiding hospital admission through provision of hospital care at home" [280]. This study evaluated the results of 2187 randomized clinical trials. Of these, 10 studies were considered eligible, two of which were conduct in Italy at the OAD service and the others in Australia, New Zealand and Great Britain. A total of 1333 patients suffering from different pathologies such as acute COPD (Chronic Obstructive Pulmonary Disease), uncomplicated stroke, pneumonia, dementia with acute internal disease were involved. The conclusion was that home hospitalisation may represent a "safe" alternative to hospitalisation for selected elderly patients. At three months there was no difference in mortality, which was even reduced at the six-month follow-up, with a high degree of satisfaction among patients and their families and a reduction in direct healthcare costs. [279, 206]. Subsequently, it was conduct a randomised clinical trial with six-month follow-up on elderly patients with exacerbated COPD admitted to the hospital ED, to assess the feasibility and usefulness of admission to OAD compared to traditional hospital wards. These patients are very elderly, multi-pathological, not self-sufficient in the performance of daily activities. The results did not reveal statistically significant differences in mortality and functional status in the two different care settings, however, a lower development of complications (especially infectious), the number of re-admissions to hospital was observed, with positive repercussions on the patients' mood and quality of life, the caregiver's level of emotional tension and also on costs in patients treated at home [13, 206]. Similarly, in collaboration with the University Division of Cardiology, a study was conducted on the home treatment of elderly patients with exacerbation chronic heart failure who arrived at the hospital ED. Heart failure is the leading cause of hospitalisation in the elderly [12]. Despite the progressive decline in mortality from coronary artery disease and hypertensive heart disease, there has actually been an increase in the incidence and prevalence of heart failure, mainly attributable to the progressive increase in the average age of the population and the increasing prevalence of cardiovascular disease [12]. More than 50% of patients with heart failure are over 75 years of age; therefore, heart failure, defined by Michael Rich as "cardiogeriatric syndrome", represents a public health problem that is likely to increase in the coming years [247, 12].

[10] A study was conducted on elderly dementia patients attending hospital emergency room for acute internal illness. It shows that treatment at home, compared to admission to the traditional hospital ward, significantly reduces the occurrence of behavioral disorders, use of antipsychotic drugs, caregiver stress and resources to institutionalization. Reassessing the patients who survived 2 years later, it was found that 88% of patients still lived at home, despite the high level of caregiver stress. This study confirms that where there is effective formal support, the family is able to provide comprehensive care for their loved ones with dementia, especially in the more advanced stages of disease [296]. Similar results emerged in the study conducted by the OAD department, published in Archives of Internal Medicine [299]. Treatment in HaH of elderly patients with acute heart failure was compared with treatment in the hospital ward. No difference was observed in mortality, which was 15% at six-month follow-up. Only in patients hospitalised at home was there an improvement in mood, nutritional status, quality of life and significantly longer hospital readmission times [12, 206]. Similarly, in collaboration with the ED and ED Neurology Service, a randomised clinical

1.4.3 Technological progress and telemedicine

In order to achieve all the clinical and quality-of- life goals derived from HaH, new biomedical and information technologies are increasingly used in various fields to support to clinical practice [300].

In the United States, according to a study by Manhattan Research [89], two-thirds of doctors use a smartphone and about 30% a tablet for their practice, thanks to a series of applications that allow not only to quick access to the pharmaceutical manual or other educational material, but also the possibility to monitor clinical parameters or perform diagnostic investigations [300].

New technological tools, such as the iPad, allow the doctor to consult the medical record while visiting patients. It allows new patient data to be entered into the healthcare database, to request analyses, medical services and certificates in real time, and to use the tool to improve patient communication [300].

The rapid development of automated diagnostic tools could address the need for more widespread screening and follow-up without directly engaging specialised medical resources on the ground[11].

In recent years, robotics and domotics have undergone great development and many applications in the medical and care field. One of the objectives of the European Union's Ambient Assisted Living Joint Program 2008-2013 is to improve the quality of life of elderly people, partly through the use of technologies that can help them to remain indipendent and safe at home. To this end, several projects have been implemented in recent years that envisage the presence of robots at home to remotely monitor the health and safety of the elderly[12].

Even smart homes, an innovative concept that integrates technology into the home environment with the aim of maintaining or possibly improving functional status, safety and quality of life, are currently largely experimental, with no firm scientific evidence to support their large-scale use [211, 300].

---

trial was conducted to test the feasibility of home treatment of elderly patients over 75 with acute ischemic stroke as an alternative to hospitalisation. With equal mortality and functional and neurological recovery, there was a more significant positive change in mood in patients treated at home compared to hospitalised patients [279, 206]. A prospective observational study conducted in patients at medium-high risk of delirium according to the Inouye criteria [159] showed that home care reduces the risk of developing a confusional state [161, 12]. In addition, for patients with acute cerebral ischaemic stroke or advanced dementia, OAD has been shown to be protective against the development of complications such as delirium and associated with a lower rates of return to hospital and institutionalisation and higher quality of life level for patients, as well as lower mortality [245, 246, 297, 296].

[11] The Pit2011 report, published by Cittadinanzattiva (See www.cittadinanzattiva.it), states that in Italy long waiting lists for diagnostic examinations are perceived by patients as one of the main problems for the protection of our National Health System. This aspect can only underline the need on the part of users for easier access to diagnostic technologies [300].

[12] Companion Able (2008-2012), SRS (Multi-Role Shadow Robotic System for Independent Living, 2010-2013) and RobotEra (2012-2016), to name a few. However, even if the developments are very promising from the point of view of technology and improvement of individuals' living conditions, there are problems with implementation of their use by users, especially the elderly, due in particular to the difficulties of interacting with the robot in their usual living context [300].

Technological development has made it possible to transfer many typically hospital-based practices to the home. It is available to treat even acutely ill patients, often complex ones, using instruments that are lighter and easier to handle or that offer clinical advantages to both patients and healthcare professionals but are still reliable [211, 12, 206].

One of the innovative methods that is having a positive impact on both health and quality of life is *telemedicine*, defined by the World Health Organization (WHO) as *an integral part of telecommunications systems in the promotion of public health* [300].

The term originated in the late 1960s as a result of NASA's need to monitor the physiological parameters of astronauts. Initially it served to denote mainly teleconsultation services, acquiring in the later years an increasingly broader meaning that now includes the application of information and telecommunications technologies to medicine, in order to guarantee remote health services and the real-time transmission of clinical information and images between doctor and patient or between professionals.

In the literature there are many definitions of the term telemedicine, more or less similar to each other. The most cited definition is the one proposed by an expert commission appointed by the European Union, which defined telemedicine as "*the investigation, monitoring and management of patients and education of patients and staff using systems which allow ready access to expert advice and patient information, no matter where the patient or relevant information is located*"[13] [300].

Telemedicine encompasses many areas. It includes telemonitoring, telediagnostics (teleradiology, telepathology, teleophthalmology, teledermatology, etc.), teleconsultation (teleconferencing between specialist doctors, general practitioners and possibly patients), remote management of procedures (e.g. telesurgery), and telerehabilitation. Telemonitoring, in particular, is an advanced service that provides for the possibility of providing assistance to patients in their own homes, through the telematic assessment of clinical parameters collected remotely using special tool kits. Data collection can be done either automatically, through personal health monitoring devices (portable, worn or implanted), or through the active collaboration of the patient (web-based input of physiological parameter measurements) [300].

Initially, telemedicine was applied to the treatment and surveillance of heart failure, diabetes and COPD with good results both in terms of reducing rehospitalisations and in terms of reducing costs and improving the quality of life of the elderly patient who has been discharged or recently hospitalised [164, 205, 237, 308].

In November 2008, an initial trial was carried out on patients admitted to the OAD[14]. The aim of the study was to assess the feasibility and usefulness of

[13] COM(2008)689, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, on telemedicine for the benefit of patients, healthcare systems and society. Bruxelles, 4 November 2008.

[14] MyDoctor@Home: a collaboration between Telecom Italia (TI), the Azienda Ospedaliera

a system enabling patients to measure certain physiological parameters (body weight, blood pressure, heart rate, oxygen saturation in the blood, spirometry and electrocardiogram) directly from home, using simple devices that automatically send the measurements in real time to a server that can be consulted by a hospital platform via a special Bluetooth connection. Doctors will be able to evaluate the measures received, be promptly alerted by automatic notifications if the measurements exceed the thresholds limits and, if necessary, interact with the patient himself, modifying the treatment protocol or drug therapy. Preliminary results show that this method is appreciated by patients, contributes to the patient's well-being and to reducion of cargiver's stress [12, 206, 300].

Another preliminary randomised trial was conducted between April 2009 and May 2010 to assess the feasibility and effectiveness of a clinical telemonitoring system applied to elderly patients with acute heart failure or exacerbated COPD admitted to the OAD [12, 206, 300].

The Piedmont Region subsequently presented a project to the evaluate the effectiveness of telemedicine. The results of these studies showed that this type of device is easy to use by patients and their caregivers and that telemonitoring has a reassuring function, significantly improving patients' mood and reducing caregiver stress. Indeed, real-time data visualisation can help to reduce the number of physician-nurse visits, thereby optimising the use of healthcare resources [12, 237, 300, 206].

1.4.4 Telemedicine and regulations

The European Commission, having recognised the potential of ICT, e-Health and telemedicine, has been funding research and development in this field for years. In 2008, the European Commission has identified a series of actions involving all levels of government, both within the Community and in individual Member States, aimed at providing greater integration of telemedicine services into clinical practice, removing the main barriers to their full and effective implementation[15]

The Italian Ministry of Health has created in 2007 a permanent national Observatory for the evaluation and monitoring of e-Care applications, in which the Regions Lombardy, Veneto, Tuscany, Liguria, Marche, Campania and Sicily participate, and has launched several telemedicine initiatives[16]. These experiences are scattered on the territory and on a small scale, but they represent the

Universitaria San Giovanni Battista (AOU) of Turin and the Istituto Superiore Mario Boella (ISMB).

[15] COM(2008)689, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, on telemedicine for the benefit of patients, healthcare systems and society. Bruxelles, 4 November 2008.

[16] Some examples are: Rare Tumors Network (collaboration between Italian oncology facilities), Telemedicine in small municipalities of Lombardy (TELEMACO: ensuring local healthcare for chronic patients), Broadband network for IRCCS (telemedicine-teleconsultation-telediagnosis-teleassistance) and, Telemedicine in the Aeolian archipelago (healthcare in disadvantaged areas in order to reduce travel).

starting point for a future implementation on a national scale [300].

Recently, In Italy, telemedicine has become a fully-fledged part of the National Health Service. The Italian Ministry of Health, in collaboration with the Regions, has created guidelines for the adoption at national level for the provision of some telemedicine services[17] such as televisiting, medical and health teleconsultation, teleassistance of health professions, and telereferencing. The aim is to guarantee that telemedicine services represent a concrete element of organisational innovation in the care process. Until now, at least in Italy, telemedicine was used but only in certain contexts and very often in fragmentary situations or dictated by the utility of the moment. From now on, telemedicine services will officially become recognised health services (although, obviously,it will always be the doctor who decides whether to use them or not). The document states: in this essential historical moment, an organisational and cultural renewal aimed at a widespread and uniform operational translation of the principles of primary healthcare recommended by the WHO and the reorganisation of health, clinical assistance and rehabilitation activities must be able to guarantee, at the same time,the maximum continuity of care and patient empowerment, with the minimum risk of spreading the virus to users, operators and families. The indications contained in this document will be periodically updated, also in relation to the evolution of technologies, and other documents similar to this one will follow, concerning further telemedicine services, in order to guarantee a progressive extension and application in all care settings where it can contribute to improve the quality of care[18].

Telemedicine has the great potential advantage of eliminating a number of barriers and making access to some health services more equitable for people disadvantaged by frailty, logistics (remote rural areas), or complex family-work situations. Equity of access to health services - as we learned during the pandemic - is one of the modern and essential dimensions through which the quality of a health service is defined.

Obviously, the introduction of these innovations leads to the need to make new considerations also in the ethical and regulatory field. Starting from the assumption that in Italy the introduction of any new drug or instrument in clinical trial is subject to prior approval by an Ethics Committee, i.e. an independent body, made up of healthcare and non-healthcare personnel, responsible for ensuring the protection of the rights, safety and well-being of the trial subjects. The activities on the citizens' personal and health data necessary for the provision of telemedicine services are part of the processing of sensitive data carried out with electronic instruments, which are governed by the European GDPR Regulation and the provisions of Legislative Decree 196/2003. The methods and

[17]See guide line "Telemedicina. Linee di indirizzo nazionale", Ministero della Salute, in www.salute.gov.it and "Avviso pubblico per la selezione degli interventi da realizzare nell'ambito della Traiettoria 2 "E-Health, diagnostica avanzata, medical devices e mini invasività", Azione 2.1 "Creazione di una rete nazionale per le malattie ad alto impatto" del Piano operativo salute - Fondo sviluppo e coesione 2014-2020. (21A01133)", Ministero della Salute, in G.U. Serie Generale , n. 46 del 24 febbraio 2021, in www.salute.gov.it

[18]See Telemedicina. Linee di indirizzo nazionale. Ministero della Salute, in www.salute.gov.it

solutions necessary to guarantee the confidentiality, integrity and availability of the data must, therefore, in any case be adopted in compliance with these security measures expressly provided for by the regulations. In terms of obligations towards patients, of particular importance, also in line with the ethical aspects, are the information on processing (examination, remote transmission, use, etc.); on their purposes/guarantees, and, in the case of specific therapeutic diagnostic paths, on protocols; on patients' informed consent and on their rights over their personal data.

Telemedicine has considerable repercussions in the sensitive ethical sphere, being a different way of managing interaction and communication between the patient and the doctor. It is necessary to ensure that the doctor-patient relationship bond of trust can also develop in this new context, including by taking the time necessary to meet the patient's information needs well beyond informed consent, which today is sometimes interpreted in a defensive manner and not in terms of dialogue and sharing with the patient. Interesting prospects are opening up from the point of view of the so-called "ethical certification" of the quality and professionalism of doctors and care facilities (public and private), which is still under way.

In conclusion, the introduction of telemedicine, which is based on AI tools, will lead to major changes on the current organisation. Both in terms of hospital processes and in terms of legislation and ethics.

1.5 Thesis outline

This research has a particular structure. This is intended to guide the reader in the exposition of the various aspects and the interconnection between them. As mentioned in Section 1.2, it is a horizontal analysis that examines different areas and tries to combine them in the right balance.

For this reason, the thesis is divided into two main symmetrical parts, as shown in Figure 1.2.

It starts with a presentation of the background of the management part of the organisation and then moves on to implementation on case studies.

Afterwards, a part of the background starts on risk management and regulatory compliance and then the application of these topics in the use case and the integration with the first part is shown.

Finally, the last chapter focuses on a new perspective "in progress" research. The aim is to find a new methodology for automatic or semi-automatic compliance checking based on the point of view of legal interpretation.

Chapter 3, Chapter 5 and partly Chapter 6 are the chapters containing the tasks of the practical cases. Therefore, in each of them there are one or several phases of the methodology of Figure 4.1.

Figure 1.3 shows for each chapter, which phases are analysed within. In Chapter 3 all phases have been analysed from an organisational point of view, so with respect to Phase 3 only the aspect of analysing and selecting technologies to improve the business process at an organisational level has been analysed.

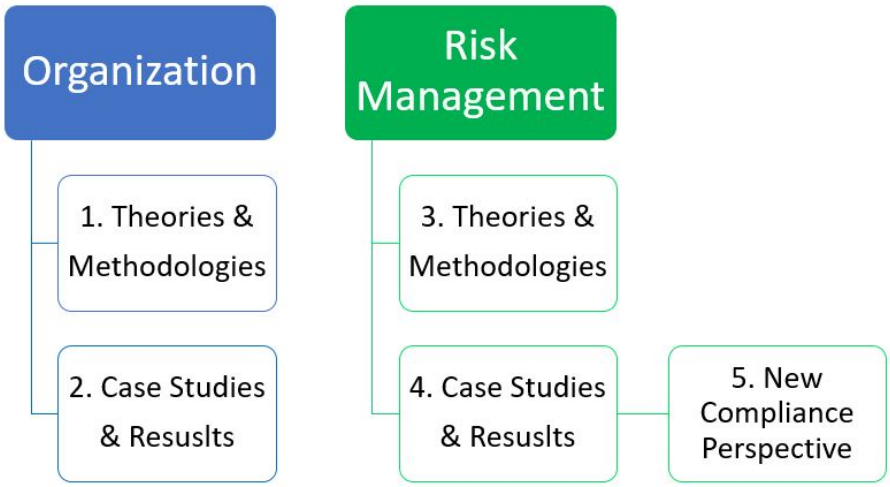

Figure 1.2: Structure of the thesis.

Chapter 5 focuses on Phase 3 with regard to both aspect of risk management and regulatory compliance monitoring. The results are shown in phase 4. Finally, Chapter 6 shows only a new perspective approach to automate regulatory compliance control, thus referring to a single detailed aspect of Phase 3.

1.6 Publications

This thesis work is a fusion of the results published in a number of articles written by myself and other co-authors in recent years. Since all these articles are the result of cooperation, my part of the work in each of them has been in the fieldwork. So I spent some time physically in the departments and in contact with the medical staff in order to understand the context, create models and collect data for the creation of simulation inputs and future analysis of results. In these articles there are the results achieved step by step. Therefore, part of this thesis has appeared in the following publications:

- Ilaria Angela Amantea, Emilio Sulis, Guido Boella, Renata Marinello, Marco Grosso, Andrea Crespo. (2020). **A Modeling Framework for an Innovative e-Health Service: The Hospital at Home.** In International Conference on Simulation and Modeling Methodologies, Technologies and Applications. Springer, Cham.
  This article presents As-Is and To-Be models of the main care process of the OAD tour visits used as a case study. The aim of this article is to show how to proceed for optimise a process by introducing some technologies. This is the book publication of the following paper [26].

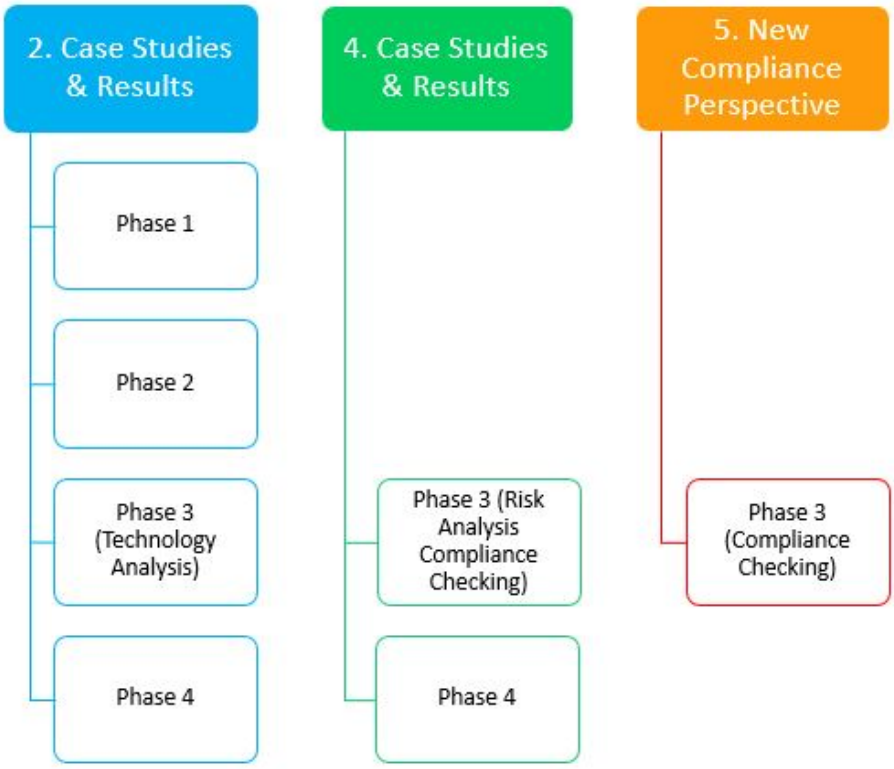

Figure 1.3: Structure of the thesis.

- Ilaria Angela Amantea, Emilio Sulis, Guido Boella, Andrea Crespo, Dario Bianca, Enrico Brunetti, Renata Marinello, Marco Grosso, Jan-Christoph Zoels, Michele Visciola, Elena Guidorzi, Luisa Miolano, Giorgio Ratti, Tommaso Mazzoni, Ermes Zani, Serena Ambrosini. (2020). **Adopting Technological Devices in Hospital at Home: A Modelling and Simulation Perspective.** In SIMULTECH 2020.
  This article presents As-Is and To-Be models of the main care process of the OAD tour visits used as a case study. The aim of this article is to show how to proceed for optimise a process by introducing some technologies. This is the proceeding publication of the previous paper [28].

- Ilaria Angela Amantea, Marzia Arnone, Antonio Di Leva, Emilio Sulis, Dario Bianca, Enrico Brunetti, Renata Marinello. (2019). **Modeling and Simulation of the Hospital-at-Home Service Admission Process.** In SIMULTECH.
  This article presents the As-Is model of OAD hospital service acceptance used as a case study and some analysis of the real data possible with this first model [29].

- Ilaria Angela Amantea, Emilio Sulis, Marco Grosso, Renata Marinello, Matteo Scardino, Stefano Cerutti, Antonio Guida, Gabriele Maffucci, Stefano Tibaldi. (2019). **X-ray at your home: the Business Process analysis of R@dhome service**. In ITAIS AND MCIS 2019: the 13th Mediterranean Conference on Information Systems and the 16th Conference of the Italian Chapter of AIS.
  This article presents the As-Is model of the R@dhome service, simulations and analysis of real data [32].

These four documents are used to show the BPM methodology, modelling and simulations. The results are part of Chapter 2 and Chapter 3.

- Jorge Munoz-Gama, Niels Martin, Carlos Fernandez-Llatas, Owen A. Johnson, Marcos Sepulveda, Emmanuel Helm, Victor Galvez-Yanjari, Eric Rojas, Antonio Martinez-Millana, Davide Aloini, Ilaria Angela Amantea, Robert Andrews, Michael Arias, Iris Beerepoot, Elisabetta Benevento, Andrea Burattin, Daniel Capurro, Josep Carmona, Marco Comuzzi, Benjamin Dalmas, Rene de la Fuente, Chiara di Francescomarino, Claudio di Ciccio, Roberto Gatta, Chiara Ghidini, Fernanda Gonzalez-Lopez, Gema Ibanez-Sanchez, Hilda B. Klasky, Angelina Prima Kurniati, Xixi Lu, Felix Mannhardt, Ronny Mans, Mar Marcos, Renata Medeiros de Carvalho, Marco Pegoraro, Simon K. Poon, Luise Pufahl, Hajo A. Reijers, Simon Remy, Stefanie Rinderle-Ma, Lucia Sacchi, Fernando Seoane, Minseok Song, Alessandro Stefanini, Emilio Sulis, Arthur H. M. ter Hofstede, Pieter J. Toussaint, Vicente Traver, Zoe Valero-Ramon, Inge van de Weerd, Wil M.P. van der Aalst, Rob Vanwersch, Mathias Weske, Moe Thandar Wynn, Francesca Zerbato. (2022). **Process Mining for Healthcare: Characteristics and Challenges (a.k.a. PM4H Manifesto)**. In Journal

of Biomedical Informatics, 127.
This article is a Manifesto regarding process mining in healthcare. It is a fusion of knowledge and competence of important authors specialised in the field of process mining and healthcare. It is used in particular in Chapter 2 [224].

- Ilaria Angela Amantea, Emilio Sulis, Guido Boella, Renata Marinello, Dario Bianca, Enrico Brunetti, Mario Bo, Carlos Fernandez-Llatas. (2020). **A Process Mining Application for the Analysis of Hospital-at-Home Admissions**. In Studies in health technology and informatics.
This article is realised thanks to the collaboration with the ITACA-SABIEN-PM4H Lab group of the Universidad Politecnica de Valencia [27].

The aim is to introduce process mining techniques and show some applications in the health sector in Chapter 2 and Chapter 3.

- Ilaria Angela Amantea, Antonio Di Leva, Emilio Sulis. (2018).
A Simulation-driven Approach in Risk-aware Business Process Management: A Case Study in Healthcare. In SIMULTECH 2018.
This aricle is the proceeding publication of the following article [18].

- Ilaria Angela Amantea, Antonio Di Leva, Emilio Sulis. (2018).
A simulation-driven approach in risk-aware business process management: A case study in healthcare. In Proceedings of 8th International Conference on Simulation and Modeling Methodologies, Technologies and Applications. Vol. 1. SciTePress. 2018.
This article is the book publication of the previous article [19].

- Ilaria Angela Amantea, Antonio Di Leva, Emilio Sulis. (2019-2020). **A Simulation-Driven Approach to Decision Support in Process Reorganization: A Case Study**. In Exploring Digital Ecosystems: Organizational and Human Challenges 33 (2019) and in Exploring Digital Ecosystems. Springer, 2020 [20, 22].

- Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. (2018). **A Simulation-driven Approach to Decision Support in Process Reorganization: a case study in healthcare**. In Proceedings of the 15th Conference of the Italian Chapter of AIS. Vol. 1. ITAIS. 2018 [21].

- Ilaria Angela Amantea, Antonio Di Leva, Emilio Sulis. (2019). **Risk-aware business process management: a case study in healthcare**. In The Future of Risk Management, Volume I. Springer, 2019.
This paper has also won the best paper award in the *International Conference of Risk Management* [23].

- Ilaria Angela Amantea, Antonio Di Leva, Emilio Sulis. (2018). **Using Simulation in Business Process Analysis and Risk Management: The Blood Bank Case Study**. In International Conference on

Simulation and Modeling Methodologies, Technologies and Applications. Springer. 2018 [24].

- Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. (2018). **A Simulation-driven Approach in Risk-aware Business Process Management: A Case Study in Healthcare**. In Proceedings of 8th International Conference on Simulation and Modeling Methodologies, Technologies and Applications - Volume 1: SIMULTECH, INSTICC. SciTePress, 2018 [25].

These seven documents are used to show both risk management of risks and manual control of regulatory compliance. The results are part of Chapter 4 and Chapter 5.

- Ilaria Angela Amantea, Livio Robaldo, Emilio Sulis, Guido Boella, Guido Governatori. (2021). **Semi-automated checking for regulatory compliance in e-Health**. In 2021 IEEE 25th International Enterprise Distributed Object Computing Workshop (EDOCW). IEEE [31].

This article is used to show the semi-automatic control of regulatory compliance, also in Chapter 4 and Chapter 5.

- Ilaria Angela Amantea, Luigi Di Caro, Llio Humphreys, Rohan Nanda, Emilio Sulis. (2019). **Modelling Norm Types and their Interrelationships in EU Directives.** In ASAIL@ ICAIL.
  This article was the first work from which the idea of this perspective was born and from which the following articles were developed [30].

- Ilaria Angela Amantea and Silvano Colombo Tosatto. (2020). **Formalising Legal Interpretation: Decoupling Methodologies and Abstract Semantics**. In JuL.IA-1st International Workshop on Artificial Intelligence in JUrisdictional Logistics.
  This article is a semantic and abstract evolution of the classifications made in the previous srticle [17].

- Emilio Sulis, LLio Humphreys, Fabiana Vernero, Ilaria Angela Amantea, Davide Audrito, Luigi Di Caro. (2020). **Exploring Network Analysis in a Corpus-Based Approach to Legal Texts: A Case Study**. In COUrT@ CAiSE.
  In this document there are some practical experiments. [290].

- Emilio Sulis, LLio Humphreys, Fabiana Vernero, Ilaria Angela Amantea, Davide Audrito, Luigi Di Caro. (2021). **Exploiting co-occurrence networks for classification of implicit inter-relationships in legal texts.** Information Systems, 101821.
  This article contains some practical experiments from the previous article [289].

These four documents are used to show the new perspective based on legal interpretation to verify regulatory compliance in Chapter 6.

Chapter 2

Methodologies for organisational analysis

2.1 Introduction

The focus of this thesis is to discuss how to merge and balance the organisation and the reorganisation with risk management and regulatory compliance. Therefore, these initial chapters will describe the theory and practice of analysing an enterprise from a business management perspective. The following three chapters will then be on the theory and practice of risk management and regulatory compliance.

In this first chapter we will show some methodologies, tools and means to analyse a company from an organisational point of view. In this part we will consider some business aspects from the perspective of activities, time, costs and resources. In Chapter 3 we will show how to apply these methodologies to some concrete cases.

The chapter begins with an overview of the state of the art and an explanation of the Business Process Management (BPM): definition, evolution over time, what a process is, why to use BPM and what its objectives are. Finally, we will demostrate BPM and its methodology. The next sub-chapter will analyse the languages and in particular the BPMN standard language.

The next step is to explain what simulation is and how to use it to validate the process model. I will show what the different types of simulation are, and then focus on discrete event simulation, the one I will apply in the use case.

Eventually, I will investigate the technique of process mining as another way of doing analysis on a company.

2.1.1 Related works

In the context of Business Process Management (BPM) [108], a great deal of attention has been given to the events, activities and decisions that affect an

organisation's process.

Several techniques have been developed on the analysis of the current situation (As-Is) of the organisation's processes, as well as on the re-engineering phase leading to restructured processes (To-Be).

Several research areas have already used simulation techniques, for example, computational social science [189], geography [231] or sociology [123]. Although several simulation techniques have been involved in business processes, their application in the field of BPM has not yet been developed as it deserves [6, 144]. However, planning, management and decision-making would benefit greatly from the analysing the results of simulated scenarios. Simulation results make it possible to detect inefficiencies, bottlenecks, constraints and risks, as well as to estimate the performance of the system when changes to the process, such as new strategies or increased workload, need to be applied. Among the existing techniques, computer-based Discrete Event Simulation (DES) [116] is one of the most widely used analysis approaches.

Business process analysis usually refers to methods, techniques and software used to support the management of an organisation [107]. A great deal of attention is focused on procedures concerning the design, control and analysis of operational tasks involving humans, documents, organisations or applications [108].

The adoption of computer-based simulations in business process analysis and modeling was first applied in industrial re-engineering [103, 243, 273]. In the public sector, studies have modelled public policy [193], services [140], public administration processes [178], political decision-making [255], private affairs (such as phone calls [122, 217], and to contact centers [195], dealing with more complex cases of user requests [177]), as well as care processes in the medical field [102].

In addition to statistical approaches (i.e. workforce planning [275], resource optimisation [68], queue modelling [176]), discrete event simulations have emerged as an alternative method of modelling business [275]. More recently, Agent-Based Simulations (ABS) modelling techniques have been applied [287, 196, 63].

In recent research, computer-based Decision Support Systems (DSS) have provided effective and efficient workforce planning and performance reporting in call centers [276]. In a similar study, a flexible Business Process Modelling, Simulation and Re-engineering (BPMSR) approach was presented [105]. Scenario analysis (or "What-If" analysis) was applied to explore different options for restructuring an existing process [181] before any changes were actually made.

2.2 Business process management

Starting with a definition, *Business Process Management (BPM) is a management discipline that uses a systematic and structured approach to support the explicit management of a business process using methods, techniques and tools. These involve human beings, organisations, applications, documents and other*

sources of information, with the aim of achieving the organisation's business objectives by aligning business processes with these objectives[1].

BPM is the management of a company through the processes it puts in place to achieve its objectives. There is a growing consensus that it is only by going through processes that it is possible to keep up with increasingly rapid changes. A company's flexibility and adaptability to change become the critical factors for progress or even simply for survival in times of deep economic crisis. To achieve this, the company must:

- Aligns its processes with the company's strategies and objectives.
- Describes and documents its processes in an unambiguous manner and in such a way as to ensure their proper execution in compliance with internal rules and national and EU laws.
- Makes it possible to monitor and measure these processes in real time to detect internal and external changes quickly.
- Makes it possible to modify and continuously improve these processes in order to adapt them to customers' expectations, ensuring that the company's objectives are achieved [107].

2.2.1 Evolution of vision over time

The shift from a functional to a process-based view of the company, the management of change as a necessity to stay on the market and the restructuring of processes to improve company performance have led, especially in recent years, to a focus on the analysis, diagnosis and restructuring of business processes, giving these concepts greater importance.

Continuous change leads the company to constantly evaluate its position in the market, to look for new strategies and technologies to renew itself in order to gain a competitive advantage over other companies and to stay in the market.

The context of change can be both external to the company (suppliers, customers, competitors, market dynamics, laws, EU regulations, etc.) and internal (increasing the efficiency of individual company activities, and in their control and coordination, in order to optimise the company as a whole by enabling it to achieve its objectives).

The corporate "system" can be defined as:

- Complex: i.e. characterised by a large number of components (structures, activities, products, actors, resources, ...).
- Distributed: i.e. based on heterogeneous and geographically dispersed networks.

[1] This definition is the result of a combination of definitions given over time by important authors [316, 110, 318].

- Stochastic: frequent and unpredictable events, both external (markets, stock exchanges, regulations, laws, ...) and internal (failures, accidents, resignations, ...) [100, 107].

The following paragraphs describe the main features of functional and process models.

- **Functional organisation:**

With the introduction of the concept of value, the company can be "read" from a perspective called Porter's value chain. The company is seen as a system of activities that generate value, defined as the price that consumer is willing to pay for the product that fully satisfies his/her needs.

The concept of value leads to a classification of business activities:

- VA (Value Added) - The activity is required and contributes to the creation or provision of a product or service.
- BVA (Business Value Added) - The activity is required by the business, but the task does not directly contribute to a product or service.
- NVA (Non Value Added) - The activity is not required to create or provide a product or service.

Primary activities can be related to:

- The product (activities that add value to the product or service provided to the customer)[2].
- The market (activities deal with the management of finished products from production units to customers)[3].

[2]The activities are:

- Inbound logistics: activities related to the receipt of raw materials, components, semi-finished products that the company buy from its suppliers and include inbound controls, sorting, storage in warehouses and preparation for further processing.
- Operations: activities directly related to the production of products or the provision of services to customers, controls, packaging of products, operation of facilities, etc.
- Services: activities related to customer care and "after-sales", such as those related to the management of maintenance and repairs, upgrades, customer training. etc.

[3]The activities are:

- Outbound logistics: includes products sorting and outbound warehouse management, order processing, shipment planning, transport and distribution to customers.
- Marketing and sales: these include the study of customer behavior, the choice of products, pricing, the choice and management of sales channels (use of wholesalers and re-sellers, own sales outlets, large-scale distribution, via the Internet, ...), advertising, promotions, etc.

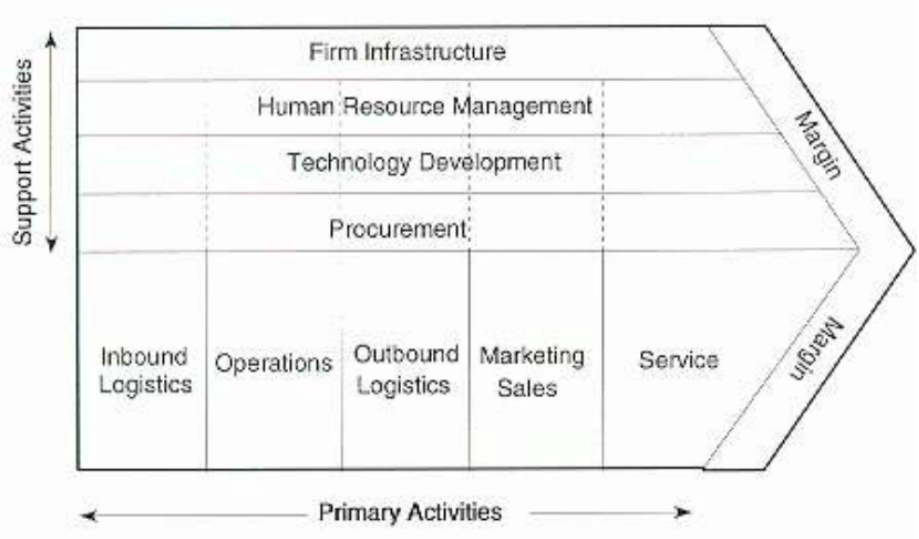

Figure 2.1: The value chain of Porter. (Source: Porter, 1985).

Supporting activities include all those activities that the company must carry out to ensure that the primary activities can be completed in the best possible way[4]. Value-generating activities produce the company's revenues and require resources to perform, so they also determine costs.

As shown in Figure 2.1, the company's margin is the difference between revenues and costs.

Therefore, the functional model (Figure 2.2) groups activities by organisational units (blue boxes). This means that it aggregates people and tools with similar competences that use the same type of resources and technologies to perform the same activities. Each unit has its own budget, its own objectives and is responsible for managing the activities to which it allocates the neces-

[4]The activities are:

- Purchasing: activities linked to the search for and purchase of goods (raw materials, components, semi-finished products, services) that will be transformed into finished products, at the best conditions for the company (in terms of cost, delivery times, quality, etc.).
- Technology management: research and development initiatives for new products, new materials, new production processes, production automation, optimisation and so on.
- Resource management: such as skills research, recruitment, career planning, incentive policies, training, retraining and so on.
- Infrastructure: everything related to general management, organisation, IT management, administration, finance, legal affairs, relations with public bodies and quality management.

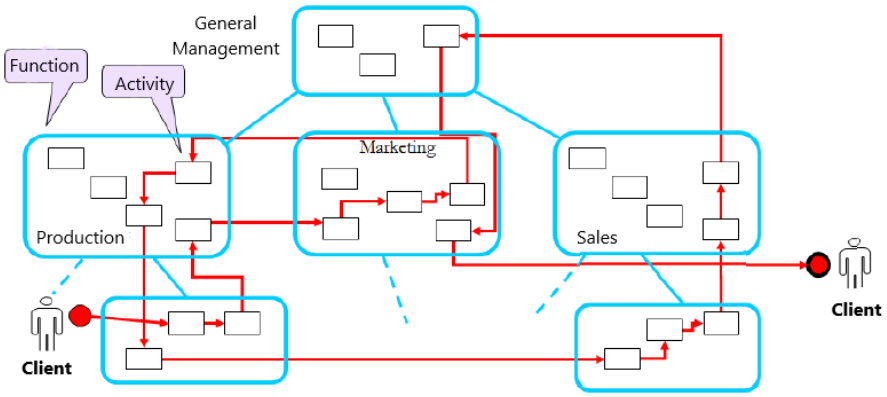

Figure 2.2: Functional model.

sary resources[5]. It is a very bureaucratic structure, resulting in cross-functional barriers and rather rigid lines of command and control. This organisation does not allow the identification of responsibilities towards the final customer. It has a narrow, internally focused vision, so communication with other functions is often not fully satisfactory, and there is a lack of necessary coordination between business activities. Finally, improvement is applied to those activities that the function manages, for which it is limited, and may have negative effects at a global level [100, 107].

The purpose of evaluating these activities is that the ultimate goal of every activity carried out by the company should be to create products that satisfy the wishes of customers, thus creating value for the customer.

Obviously, not all activities of a company can create a value that can be perceive by the customer[6], and therefore those that do create such value deserve special attention.

- **Process organisation.**

In order to overcome these problems, there has been a move towards an organisation by processes. They are called end-to-end processes: they start from an event outside the company (e.g. "an order arrives"), and produce an output (e.g. "sends the product"), often passing through several functions within the company itself (as shown in the red path of Figure 2.2).

A process view obviates the functional problems of a hierarchical organisation in which each function is limited to itself, reducing the improvement and optimisation of the company as a whole.

[5]The typical breakdown by function is: production, production management, quality, marketing and sales, general management, accounting and finance, R&D, HR.

[6]For example, the maintenance of equipment does not directly concern the customer.

Understanding how the company actually works means analysing its processes and building models that facilitate their analysis and improvement [100].

2.2.2 The process

A process is defined as a set of interrelated activities (decisions and actions) to achieve a defined and measurable result (the internal or external product/service) that transfers value to the customer [100, 107, 108].

A process in the company is characterized by the following set of properties:

- *It must respond to an external event by performing activities.* It should be seen as the response that the enterprise make when something happens in the external world. The way the company reacts is precisely a set of activities performed in a certain order[7].
- *It must achieve certain objectives.* The process is the instrument with which the company pursues its objectives[8].
- *It has to provide a result.* Clearly identifiable for the customer (this implies identifying the customers of the process) and measurable (e.g. in terms of objects produced or services provided in a certain time). It is possible to have several "customers" in a process (external and/or internal) but must receive a result.
- *It consumes the company's resources.* Resource in the sense of something that costs the company money: employee' time (which is charged on an hourly basis), materials, energy, maintenance services and so on; hence the need to evaluate costs in order to determine the price of the goods produced.
- *It has to meet customers' requirements.* Customers choose a product on the based of certain quality requirements they have in mind, so the process has to adapt as much as possible to these requirements (which may change over time) by trying to continuously improve current products and (possibly) pre-dictate the type and quality of goods or services the customer may require in the future. This leads to customer loyalty.
- *It is bound by internal*[9] *and external*[10] *rules that cannot be violated and can therefore lead to the execution of certain processes.*

[7] For example "an order arrives". At time t an order arrives from customer X, the company reacts with the first activity of the Manage Orders process which ends at time t' with the conclusion of the last activity "Deliver the package". Since the customer expects to receive the ordered items "as soon as possible", the time between t and t' is an important parameter, usually called cycle time, hence the need to measure and reduce it as much as possible.

[8] For example, covering 30% of the market per year. Hence the need to measure the gap between the final target and the current situation which might suggest, for example, a promotional campaign in the last quarter.

[9] E.g. in a bank "the cashier may not hand over to a customer a sum greater than that covered by the money deposited in the account and the credit available to the customer".

[10] External rules are laws, EU regulations, national labour contracts and so on. For example, "to rent a car the customer must have a valid driving licence".

- *It generally has a global manager (the so-called "Process Owner").* He/She operates across functions, manages and monitors the process, checking implementation times and intermediate and final outputs.

To construct a model of the process, these properties must therefore be fully specified[11]:

- *Time:* duration of the activities (average times and variability), both to carry out the simulation and because the shorter the cycle time, the "happier" the customer.
- *Deviation from corporate strategy:* KPIs - Key Performance Indicators.
- *Resource consumption:* specify how resources are used by activities.
- *Process improvement:* "better" processes produce "better" products.
- *Complex control policies:* messages, signals, exceptions, ...

It is important to emphasise, however, that the model cannot be limited to the process map (flow chart), as the actual model is much more complex than the map, so **the map is not the model.**

Moreover, "pseudo-processes" are often mistakenly analysed instead of considering the actual end-to-end process. *A single activity or a limited set of activities within an organisational function, a set of interrelated processes, interrelated activities but within a single function, or sub-processes within an end-to-end process are just "pseudo-processes".* Understanding the difference between end-to-end process and "pseudo-processes" is important in order to undertake optimisation actions of these "pseudo-processes". In fact, it is well known that local optimisations, of a single sub-process or pseudo-process, can have negative consequences on global processes. This leads to an understanding of the fundamental role that processes play in the company. Even if, traditionally, the company continues to be divided into functions, all considerations regarding the improvement of company performance should be based on how work actually takes place within the company and, therefore, on its processes [100].

2.2.3 Process-based organisation and management: why use BPM?

The evolution of the last fifty years that has brought together methods, techniques and tools from three different strands for business management by processes is the so-called Business Process Management or BPM [3]. These strands are:

- **Business management.** It is based on a philosophy and methodology to manage the company by organising it "around" its operational processes,

[11] These are the once that will be assimilated into the attributes in the tool of our practical case.

involving the company (its functions and resources) with customers, suppliers and partners[12]. Business management is driven by the manager, who needs tools to:

  - Control the execution of processes, directly managing the activation of applications and access to pre-existing data (e.g. data inherited from pre-existing applications).
  - Reduce risks and ensure compliance with laws and regulations.
  - Distributing documents, data and tasks for company's resources, providing the right information in good time and at the required location.

- **Quality control.** It comprises a set of (statistical) techniques aimed at improving the quality of products (or services) by analysing their variability and that of their production (or supply) processes. This trend belongs to the Quality Manager, who needs tools to control the quality of products/services provided to the customer from the quality of the related processes (assessable in terms of defects, reworking, delays, ...) and the quality of components and raw materials purchased from suppliers.

- **ICT.** A set of techniques and tools to design, analyse, control, execute and restructure the company's operational processes[13]. ICT is the responsibility of the BPM designer who uses models, languages and methodologies to describe, design and simulate business processes in order to support the company's strategy in pursuing its objectives as efficiently and effectively as possible. Process models must allow the analysis of times, cost and quality of the production (or delivery) processes of the products (or services) supplied to the customer.

The use of a "common language", comprehensible to all, to build a specification of business processes that can be easily understood by all business roles involved in the processes is of paramount importance[14].

2.2.4 BPM objectives

The Business Process Management discipline has the following objectives:

- Facilitating the alignment of management and production processes with the company's strategic objectives (improving productivity, resource management and quality).

[12] One of the tools used in this evolution is for example Porter's value chain.

[13] The tools and methods that have led to the evolution in this field are for example software methodologies, languages such as UML and BPMN, process simulators, workflow engines.

[14] The language that will be analysed and described is currently the international standard for the specification of processes, called BPMN (Business Process Management and Notation - version 2) and was released by the international standardisation group OMG (Object Management Group) together with other languages such as the Business Motivation Model (BMM) and the UML (Unified Modeling Language) [100].

- Optimising the company's "internal" processes by creating a corporate culture and a context in which it is possible to apply methodologies and tools capable of managing continuous process improvement activities, in parallel with radical improvement phases, which may become indispensable at critical moments when innovation initiatives need to be introduced in the company. The ultimate goal must always be to improve quality and efficiency. It is therefore necessary to be able to identify which steps are really necessary and who should carry them out, how they should be carried out and what skills they require, what the expected results are and how to evaluate them, and how to eliminate waste along the way. The graph in the Figure 2.3 shows the curve of improvement in efficiency and innovation over time.

- To automate the flow of control and documents internally (through a workflow engine).

- Analyse, model and measure the process by introducing Key Performance Indicators (KPIs) to identify critical points.

- Use the model to make predictions ("what if" analysis) in order to improve the working environment by eliminating repetitive, boring and unhelpful steps through the "intelligent" application of technologies and reshape existing processes by optimising them in terms of quality and efficiency[15].

- Managing the process over time: life cycle (see Figure 2.4 according to [100]).

The process model plays an important role in the life cycle of the process itself. Indeed, it is not a static structure but evolves over time through different stages, which have different tasks and actors, linked to the roles played [100, 107, 108, 3, 73, 325].

Table 2.1 describes the details of the tasks in the various stages of the process life cycle. The life cycle starts with the process modelling phase. The model is specified using the BPMN language and then validated through animation and simulation phases in which the model results are compared with the actual data of the identifiers to ensure a good "fit" of the model to the business reality. Once validated, the model can be optimised through restructuring actions that can be verified by simulation and "what-if" analysis of different scenarios. The "internal" cycle ends when the model produced shows satisfactory results on the simulator. In the implementation phase the model is "translated" into the input specifications of the workflow engine to then be automated during the execution of the process. The engine is a software system that, once it has received the executable version of the model, manages the process during execution, takes

[15]For example, to find out whether the number of staff made available to date for a given task is surplus, i.e. with fewer people the output is the same or even more efficient, or whether an extra person would ease the surplus and thus improve the working environment as well as efficiency.

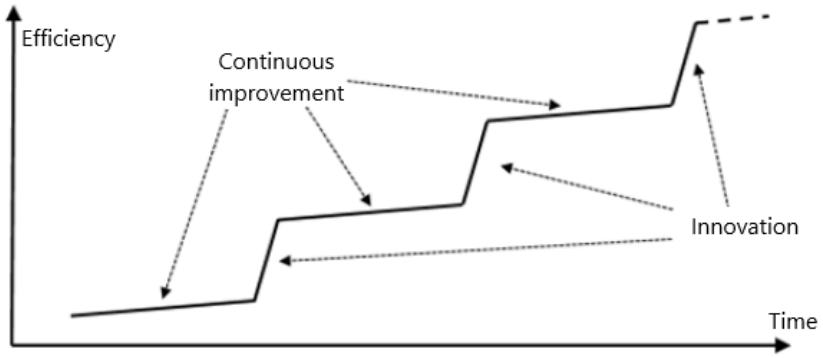

Figure 2.3: The efficiency and innovation improvement curve over time.

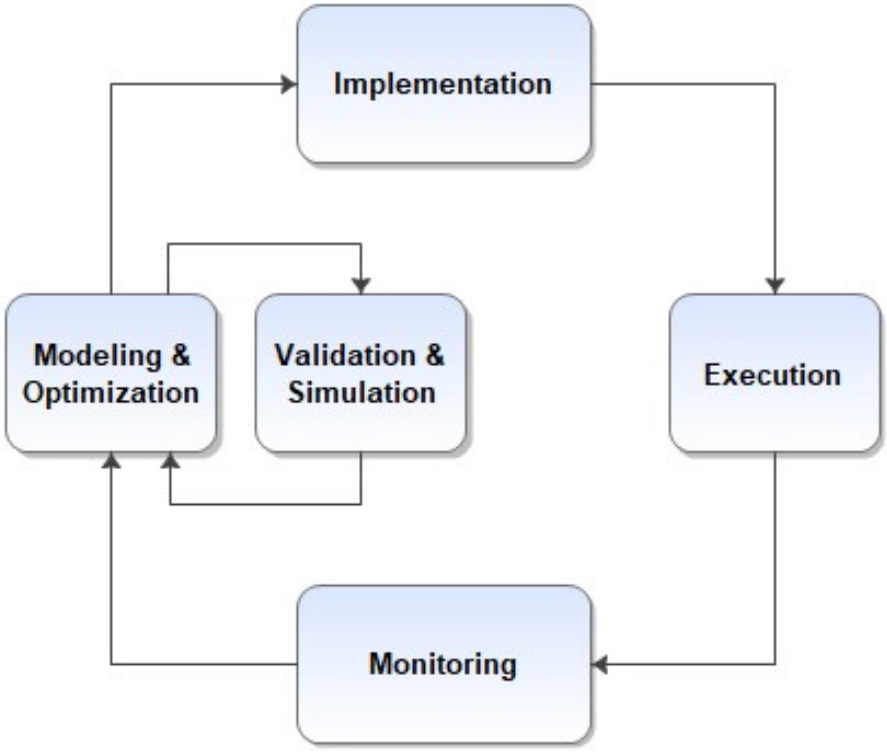

Figure 2.4: Process life cycle.

Table 2.1: Details of tasks in the various stages of the process life cycle.

Stages	Tasks	Actors
Modelling & Optimisation	Building the model Define indicators Optimise the model through simulations and "what-if" analysis	Analyst
Validation & Simulation	Validating the model through simulation Check the model on current indicators	Analyst
Implementation	Translating the model on the workflow engine	Developer
Execution	Executing the workflow	Manager
Monitoring	Check the indicators Identifying the possibilities for improvement Deciding on renewal	Analyst & Manager

care of the interaction between the various participating actors and coordinates their activities. Since the engine keeps track of all operations that are carried out, monitoring uses this data to understand whether the performance of the process is within the expected levels or whether a new process optimisation cycle is required [100, 107, 108].

2.3 How to build and analyse a process model: the BPM methodology.

Building and analysing a process model is, in real cases, a complex project. The project needs techniques (methodologies), descriptive tools (languages) and supporting tools (tools).

The methodology is a specification of the "good criteria for" designing the system: it is a sequence of elementary steps consisting of suggestions and rules used for the construction of models and for their verification according to defined criteria (e.g. correctness, completeness, adequacy to the requirements).

Languages are descriptive tools used for model specification.

The tools are automated tools to assist the designer in building the models and to verify and validate them[16]. The BPM methodology is organised in phases and steps and refers to the life cycle of BPM projects [100, 107, 108, 3]. It is important to always bear in mind that there will always be resistance to change, to a greater or lesser extent, from within the company.

This section introduces the methodological framework based on the BP-M* methodology and the BP-M* process model [101].

Figure 4.1 shows the four phases of the methodology used in this thesis[17].

The phases consist of:

[16] What we used in the actual case is iGrafx Process2015 [158]

[17] The phases are briefly described. The chapters on use cases take up these phases and show their application.

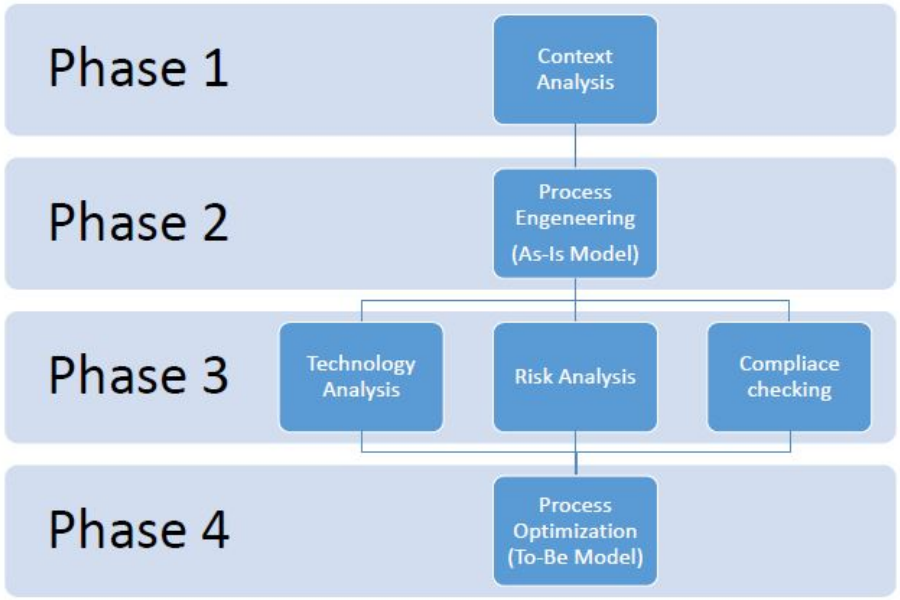

Figure 2.5: Phases of the BPM methodology.

PHASE 1: CONTEXT ANALYSIS. The context analysis phase aims to establish the general strategic scenario of the company and to determine the organisational components that will be investigated.

In this phase, the context in which the intervention is to be developed is first analysed. The context involves first analysing the company strategy in order to determine the objectives to be achieved, and then selecting the company functions and activities that affect these objectives. For example, if the objective is to increase production, it is obvious that activities related to relations with suppliers and the processing of raw materials should be evaluated in order to optimise the company's performance.

This phase is important both for the management of the company (the "client" of the restructuring project) which is helped to fine-tune the requirements at the origin of the intervention, and for the team which has to carry out the intervention taking into account the limits and constraints of the intervention itself.

PHASE 2: PROCESS ENGINEERING. This phase aims to identify, through the analysis of the current situation (As-Is) of the company and the modeling of the processes to be re-engineered, the main deviations from the needs dictated by the company's strategy.
The initial aim of this phase is the determination of the activities taking place

in the business functions involved in the process and of the causal factors relationships between them. The process is then reconstructed from external input/output events and/or objects, leading to the definition of the process diagram (or process map, or flow chart). The process model has to be validated with the stakeholders involved in the process, using animation and simulation of its specification, resulting in the so called As-Is model. This model provides managers and engineers with an accurate specification of the enterprise as it is, from which they can make:

- a good assessment of its status, and
- an accurate estimate of available capabilities.

There is sometimes a tendency to neglect this phase in order to go straight to the specification of the new restructured processes (this is the so-called radical approach to restructuring) with the risk of reproducing old mistakes and not reflecting the real organisational needs of the company. For these reasons, an approach aimed at reconstructing the framework of the current processes in order to identify critical points is preferable. Comparison with the objectives of the intervention should make it possible to assess the improvements to be made by restructuring.

In this phase it is necessary to be methodologically rigorous, and to effectively involve the company structures linked to the intervention as they have the real knowledge of the processes.

The phase consists of two steps:

- Structural and functional analysis. This step constitutes the so-called analysis of the current situation of the company in question and seeks to describe the company "as the company sees itself" (i.e. as if it were made up of structural components that perform functions). In this way, the structural and functional architecture of the company is determined.
  - Structural analysis: the objective of the task is to acquire information regarding the general organisation of the company, its division into units and jobs and the resources available.
  - Functional analysis: the objective of the task is to specify the way in which the company operates by describing its functions and specifying the activities that the functions manage. The analysis is generally conducted with a series of interviews with the executor of the functions. The interviews should try to highlight for each node of the functional network: 1) the input, 2) the output, 3) the objects of control and 4) the resources the function allocates to its activities.
- Process reconstruction and engineering. The objectives of this step are: firstly, to reconstruct the diagram of the process under analysis to specify the way in which the company operates. Secondly, to engineer the process by specifying the context in which it operates; in particular: the resources

that the process uses across the various organisational units of the company (relations towards the inside of the company) and the events through which it interacts with the outside by exchanging objects (data, modules, products, etc.) must be specified. Finally, verify the specification obtained through the static and dynamic validation steps; the dynamic validation must allow the process indicators defined in the previous phases to be estimated on the model.

The step involves the following tasks:

- Process reconstruction.
- Validation of processes and estimation of indicators.

PHASE 3: TECHNOLOGY ANALYSIS, RISK ANALYSIS, COMPLIANCE CHECKING. According to the previously established objective, in this phase there is the search for optimisation. The search may involve one or more of these stages:

- Technology research and analysis. The aim is to investigate which are the most appropriate technologies or devices to introduce in the process in order to improves it.
- Risk Analysis. The purpose is to check the current process to understand the possible causes of risk in order to decide which corrective actions shoud be introduced. The procedure for managing risks consists of:
  - Risk identification: in order to carry out risk identification, managers may consider reports of reporting errors (usually stored in an incident reporting database), such as events that caused problems and complaints. Results of inspections and audits may provide useful information.
  - Risk analysis: the objective of this step is to determine the causes of risks and the factors favouring errors, as well as their effects.
  - Risk assessment: decision-makers need to determine which types of risks should be prioritised.
  - Risk treatment: a risk can be treated by introducing preventive measures and/or accepting the risk with or without supervision.
- Compliance Checking. Monitoring regulatory compliance is one part of the risks that can occur in a company.

  Therefore, the compliance check could be considered as a sub-step of the risk analysis. The objective is to verify that both the current process and, more important, the optimised and final process comply with the law. The addiction of some devices, rather than the modification of some activities or resources within the process could lead to a non-compliance of the process. For example, the introduction of a technological device might

lead to the introduction of a new rule, to the extent that a compliance checks of an As-Is process might not be sufficient. Even if an initial process is compliant, at the end of the optimisation it may not be compliant either.

Although this verification has always been done manually in the past, it is easy to imagine how many laws and regulations may be involved in a company, creating a huge workload for analysts. For this reason, tools that perform this verification in a semi-automatic way are becoming more and more common. In general, these tools are based on a logical language. In conclusion, compliance checking is increasingly linked to logical based languages and their evolution.

PHASE 4: PROCESS OPTIMISATION. The purpose of this phase is to trace back from the problems highlighted in the previous phase to possible solutions to restructure the As-Is model generating the new To-Be version.

The aim of this phase is to formulate proposals for the restructuring of processes, through the application of typical re-engineering tools, selecting the most efficient and effective alternative, compatible with the constraints imposed by company management (e.g. the cost of the intervention).

Design solutions must then be discussed and approved by the company's management, while trying to link the chosen solution with the organisational size and resources available in the company. It may be necessary to coherently redefine the responsibilities, roles and tasks of resources to ensure the control, effectiveness and efficiency necessary for the restructured process.

2.4 The BPMN standard language

The main purpose of the development of the Business Process Model and Notation (BPMN) standard is to provide a notation that is easily understood by all users of the business; both analysts, who have the task of drawing process diagrams, and developers, who have to put in place the technology that will implement these processes, and managers of the various processes, who will have the task of managing and controlling their operation.

Business processes are represented through the creation of process diagrams, called Business Process Diagram (BPD): a graphic notation capable of representing in a clear and comprehensible way the flow of activities that are carried out during operation of the process under study.

The graphic elements of the notation have to be organised into some specific categories. In this way, it is possible to read and understand a process diagram through the use of a limited number of symbol types.

At the same time, various shapes and information can be added within the basic categories of elements to represent the complexity associated with the process without affecting the clarity of the diagram.

Compared to traditional flow charts, BPMN introduces some innovations, such as the possibility of having mobile (i.e. non-contiguous) and mobile depart-

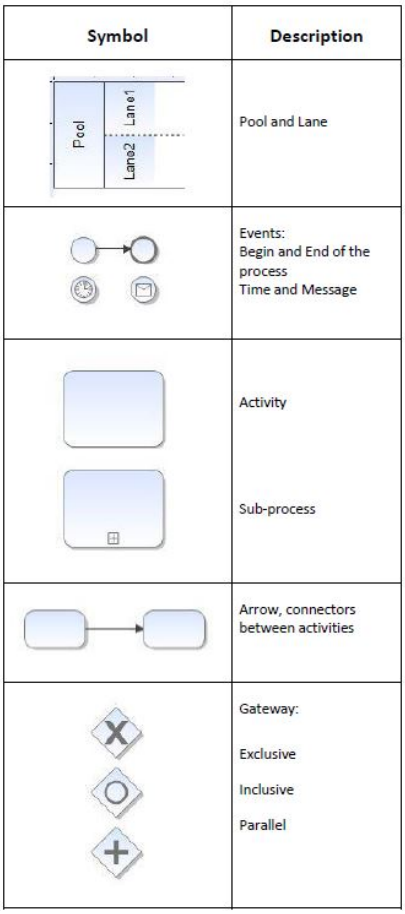

Figure 2.6: Main symbols of BPMN.

ment to represent not only sequences of activities, but also "sets of activities", not necessarily consecutive.

The departments, which are also divided into lanes or swimlanes, are populated with the shapes shown in Figure 2.6 and structured according to certain rules: circles represent events, rectangles indicate operations (activities) and rhombuses represent control over flows. In addition, it is possible to insert accessory elements or certain graphic shapes that are intended to facilitate understanding of the process.

Another novelty is the graphic distinction between the connectors: a solid line represents the physical flow between activities along the process, and a dotted line indicates the flow of information linked to the process.

Another difference from traditional flow chart is the exception handling, which in BPMN is more advanced and sophisticated. The BPMN also allows

the implementation of ad hoc processes in which the sequence of operations is not essential or not known [100, 108, 3].

The four basic categories of BMPN elements are:

- Flow objects.
- Connecting objects.
- Departments (or Swimlanes).
- Artifacts.

Flow objects. A BPMN diagram can have three basic types of shapes within it:

- Event.
- Activity.
- Decision (or Gateway).

Event: is represented by a circle and indicates an event that occurs during a business process. Events influence the flow of a process and usually represent the trigger or a result of the process itself (outcome). Events are circles with empty centers to allow, through different icons within them, different causes or results to be identified. There may also be intermediate events, especially timer-type events to represent delays that may occur during the process.

Activity: is represented by a rounded rectangle and represents one of the generic elementary action into which a process can be decomposed. Activities can be atomic or non-atomic (compound) depending on whether they cannot or can be further broken down into simpler steps: in the first case they are called Tasks, in the second case Sub-Processes. A sub-process is marked by a small "+" sign at the bottom of the form.

Decision (or Gateway): is indicated by the rhomboid shape that in traditional mapping is used to represent decisions. In BPMN it has a different use, because it is used to control the divergence and convergence of the flow sequence. Here too, different icons within the rhombus specify the type of action that the controls have on the flow (decision: "X", parallelism: "+") [100].

Connecting objects. The shapes are linked together in a diagram to create the basic structure of a process diagram. Three types of connectors can be distinguished according to their function. The connectors are:

- Sequence.
- Message.
- Association.

Sequence: a continuous arrow represents the physical flow of the process (how activities are coordinated with each other).

Message: a dashed arrow represents a flow of information that two separate processes (different entities or business roles) exchange with each other.

Association: a dotted arrow is used to associate data, text, and other ancillary elements with shapes. Associations can be used to specify the inputs and outputs of activities [100].

Departments (or Swimlanes). Many mapping methodologies use the concept of Department as a mechanism to organise activities into separate categories, referring to the functions that manage the activities by providing them with the necessary resources. Departments in BPMN can be expressed in two ways:

- Pool.
- Lane.

Pool: represents an entity that participates in a process, and acts as a graphical container of shapes, usually in a business-to-business (B2B) context.

Lane: this is a subdivision within a pool and extends along the entire length of the pool, both horizontally and vertically.

Lanes are used to organise activities and divide them up, for example, according to their function and the department in which they take place. Pools are used when the process diagram involves two business entities (or participants, if you prefer) that are physically separated in the diagram. However, in BPMN diagrams the physical process flow cannot cross the boundaries of a pool. The physical process flow passes smoothly through the boundaries that delimit the lanes [100]. Conversely, the information flow (that of the Message type) can go beyond these boundaries, as it indicates the information exchange that exists between two participants.

Artifacts. The BPMN is designed to allow modellers and modelling tools flexibility in extending the basic notation and providing the possibility of adding elements to contextualise the diagram to the specific situation. A number of additional elements can be inserted into the diagram to make it more appropriate to the context in which the process takes place. The current version of the specification establishes three types of additional elements:

- Data object.
- Group.
- Annotation.

Data Object: is a means of clarifying what an activity requires or produces, and is linked to an activity via the connection line called the Association.

Group: is represented by a rectangle drawn with a dashed line. The assembly may be used for documentation or analysis purposes, but, like other auxiliary elements, it does not affect the physical flow of the process.

Annotation: serves to provides additional information, in the form of text, to those who have to read BPMN diagrams.

Analysts may create additional elements to introduce more details about the process implementation (e.g. inputs and outputs of the activities). Nevertheless, the basic structure of a process, determined by activities, controls and connectors, does not change as a result of the use of additional elements [100].

2.5 Simulation: a way to validate the model

An appropriate simulation model is a simplified representation of reality and can be used to simulate that reality using a computer. Simulation has become one of the standard analysis techniques used in the context of operations research and management. It is particularly attractive because it is versatile, imposes few constraints and produces results that are relatively easy to interpret. Analytical techniques have other advantages but typically impose additional constraints and are not as easy to use [74].

However, it is also important to emphasise that today's simulation tools can be used to quickly build simulation models, but faulty simulation models or incorrectly interpreted results can lead to wrong decisions. Therefore, the validation of simulation models and the correct derivation and interpretation of simulation results are of major importance.

It is no surprise that in the BPM context, simulation is one of the most established analysis techniques, supported by a wide range of tools [4], and based on control flow modeled using the BPMN representation for activities, events and gateways [107, 295, 316].

The correctness, effectiveness, and efficiency of an organisation's business processes are vital for survival in today's competitive world. A poorly designed business process can lead to long response times, low service levels, unbalanced use of resources, angry customers, backlogs, damage claims and loss of reputation. This is the most important reason to analyse processes before they are put into production (to find design flaws), but also while they are in operation (for diagnosis and decision support).

Process modelling and simulation offer substantial cost savings in validation of industrial processes. As new equipment and research often require significant investment, the process validation for the approval of new solutions must be fast and foolproof. The benefits of modelling and simulation are clearly visible in phases ranging from initial research and development (R&D) to optimisation of an operational plant.

First of all, let us distinguish between modelling and simulation:

- Modelling is the construction of an accurate, often mathematical, representation of a system or process.

- The simulation makes calculations of how changes in the system model should affect an industrial process.

There is a close link between the two: in order to make successful simulations, you need a well-built model that defines the behaviour of the processes accurately as possible.

Once the model has been created, it must be validated.

There are several way to validate a model, including having it validated by stakeholders, such as workers at different levels, or simulating the model and comparing the simulation results with the real business data.

The simulation is based on KPI indicators and the validation is based on the comparison of these KPIs with actual business data. Subsequently, after restructuring, the level of optimisation of the scenario models is verified by the improvement of these KPIs in the new models compared to the value of the same KPIs in the starting model.

Modelling and simulation offer several benefits. The four key benefits are:

- **Speed.** Modelling and simulation allow you to calculate changes in complex systems in just a few hours. You can then analyse a large set of scenarios efficiently to support your decision-making.
- **Resource saving.** Simulation results can guide an industrial process to significantly reduce energy or raw material consumption, thereby increasing production efficiency.
- **Flexibility.** Many competing solutions can be tested simultaneously before arriving at a decision and making an investment.
- **Predictability.** The entire life cycle of a plant or piece of equipment can be analysed in advance with simulations, which helps to make data-driven decisions.

In addition, some important reasons for using a simulation model are [1, 7]:

- Gain an insight into an existing situation or proposal for the future. Understand what is important and what is not.
- A real experiment might be too expensive. Simulation is a convenient way to analyse different alternatives, such as hiring extra staff or adding new servers.
- A real experiment may be too dangerous and may not be repeatable. Some experiments cannot be conduct in reality for legal, ethical, or safety reasons.
- The simulation is flexible, so any situation, even a complex one, can be studied.
- A wide range of questions such as waiting times, utilisation rates and error rates can be answered using the same model.

- Simulation is easy to understand. Unlike many analytical models, little specialist knowledge is required to understand the analysis technique used[18].

In conclusion, simulation can be transformed into a powerful tool for operational decision-making using real-time process data. Business process need to be optimised due to competition and changing regulations. Modelling and simulation are risk-free ways to experiment with new solutions that could make the production process more efficient or environmentally friendly. Simulation provides a flexible approach to analysing business processes. Through simulation experiments, various "what-if" questions can be answered and redesign alternatives compared to KPIs.

2.5.1 BPM-based simulation and risks to be avoided

For the purpose of using simulation as an analysis tool, it is useful to use the BPM life cycle steps (see Figure 2.4).

- The simulation process begins with a definition of the problem, describing the objectives and setting the scope of the simulation study. The scope tells what will and what will not be a part of the simulation model. The problem definition should also state the (preferably quantifiable) questions to be answered.

- The next stage is modelling with the creation of the conceptual model. The conceptual model defines the classes of objects and the relationship between these objects. The relevant characteristics (properties) of these objects must be determined and perhaps the problem definition adapted.

- After the conceptual modelling phase, the implementation phase begins. The conceptual model is mapped onto an executable model that can be simulated directly on the computer. The way of creating this model depends strongly on the simulation tool used. Simulation languages require a general design and implementation phase. Simulation packages that are adapted to the problem domain only require correct parameterisation. The objects of the conceptual model are mapped to the building blocks of the package and their quantitative characteristics (e.g. speed) are translated into parameter values of these building blocks.

- An executable model is not necessarily correct, so it must be verified. Model verification is necessary to examine whether the model contains

[18]There are many mathematical models that can be used to analyse abstractions of business processes. Such models are often called analytical models. These models can be analysed without simulation. Some examples are queuing models [173], queuing networks [48], Markov chains and stochastic Petri nets [141, 207]. If a simple analytical model can do the job, simulation should not be used. Compared to a simulation model, an analytical model is typically less detailed and requires fewer parameter settings [3].

qualitative or quantitative errors, such as programming errors or incorrect parameter settings. For verification purposes, small test runs can be simulated step by step, or a stress test can be applied to the model.

- Validation is the next step. During validation, the simulation model is compared with reality and the results of a simulation run can be compared with observations from historical data.

- Starting from the validated model, experiments can be carried out. These experiments must be conducted in such a way as to obtain reliable results as efficiently as possible. At this stage, decisions will be made regarding the number of simulations and the length of each one.

- Simulation results should be interpreted to allow feedback to the problem definition. Confidence intervals should be calculated for the various KPIs based on low-level measurements collected during the simulation. Furthermore, the results should be interpreted to answer the questions of the problem definition and the corresponding reliability should be indicated. All these issues are summarised in a final report with answers to the problem definition questions and proposed solutions.

Normally, several alternative situations are compared with each other and different simulation models are created and tested and the results compared.

Often, *several possible improvements of an existing situation have to be compared through simulation. This is called "what-if" analysis.* Simulation is suitable for "what-if" analysis because it is easy to vary the parameters and compare alternatives according to the selected KPIs.

Simulation is a powerful and flexible tool that can be used to support decision-making. If simulation is applied incorrectly (faulty model or poor analysis of results), then this can lead to incorrect decisions that are very costly. Therefore, there are some typical risks of simulation that should be avoided:

- **One-sided problem definition.** If the problem definition is written solely by the user or systems analyst. The user may have extensive knowledge of the problem area, but does not have the expertise to define his/her problem. The systems analyst knows perfectly well the elements that should be present in a problem definition, but does not have the background of the specific problem.

- **Wrong level of detail or scope.** Too much detail causes the model to become unnecessarily complex and introduces extra parameters that need to be evaluated; too many abstractions can lead to a model of simulation that leaves the essential questions of the problem definition unanswered. The right level of detail is chosen if these three statements are satisfy together:

  - Information is present that allows experiments with the model.
  - The important questions of the problem are addressed by the model.

– The complexity of the model is still manageable for all stakeholders.

Related to the level of detail is the scope of the model. One department may be linked with other, such as the use of the same resources and other departments interacting with the process. Enlarging the scope or increasing the level of detail may lead to more accurate models. However, greater detail or a wider scope may lead to increased modelling and data collection efforts.

- **Hidden assumptions.** During modelling and when building an executable simulation model, many assumptions have to be made, but hidden assumptions can also lead to invalid conclusions and wrong decisions. Therefore, all assumptions must be documented and discussed regularly with the user.

- **Validation by the wrong people.** Due to time pressure or user indifference, the simulation model is only validated by its creators and may lead to some errors. Therefore, the user should be involved in the validation of the simulation model before any experiment is conducted.

- **Forcing the model to adapt.** In the validation phase, the results of the simulation model often do not correspond to the real observed or recorded data. Forcing the model to "fit" by changing some parameter values is very dangerous. Parameters should only be adjusted after understanding why the model deviates from reality.

- **Underexposure of model sensitivity.** Certain model parameters (e.g. intensity of the arrival process) are often fixed at a specific value. For example, a small increase in workload can have dramatic effects on average throughput or waiting time. Therefore, the sensitivity of the model to small adjustments of its parameters should be seriously considered.

- **No sub-runs.** A single long simulation cannot guarantee correct results, nor can it derive a confidence interval from the measured mean variance because, for example, the mean variance of the measured waiting time is not related to the reliability of the estimated mean waiting time. The only way to derive independent measures is to have independent sub-runs.

- **Careless presentation of results.** Interpreting the results of a simulation study may require complex statistical analysis and may be very difficult to translate into a language that a user can understand.

- **Animation dangers.** Modern simulation tools allow impressive visualisations of simulation results that graphically show the process as it unfolds. These facilities improve communication with the user. However, by displaying the tangible aspects of the simulation model, the user can develop a faith unfounded in the model. The choice of parameters or decision rules profoundly influences the results of the simulation, yet are just visible in

an animation. The same applies to the presentation of simulation results. A statistical analysis is always necessary.

- **Unnecessary use of simulation.** Simulation is a flexible analysis tool that can be applied in almost any business context. However, if a simple mathematical model or spreadsheet is sufficient, simulation is "overkill".
- **Abstract relevant contextual factors.** Processes take place in a particular context [254] that is often overlooked in simulation studies. Not capturing this context may result in simulation models with limited predictive value. The context could be related to:
  - *Instance:* the way firms handle a customer's order. The type of customer placing the order may influence the path the instance follows in the process. The size of the order may influence the type of shipment the customer chooses or the transportation time.
  - *Process:* the process may handle thousands of customer orders per year or the process model typically describes the life cycle of an order in isolation.
  - *Social:* refer to all of these factors as the social context, which characterises how people work together within a particular organisation. People and organisations are typically not assigned to a single process and may be involved in many different processes and friction between individuals may delay process instances, and the speed at which people work may vary due to circumstances that are not entirely attributable to the process.
  - *External:* e.g. weather, economic climate, and changing regulations may affect how organisations handle cases.
- **Ignoring concept drift.** Processes can change due to periodic or seasonal changes. Predictable drifts (e.g. seasonal influences) with a significant influence on the process must be incorporated into the simulation models. For unpredictable drifts (e.g. changing economic conditions), different "what-if" scenarios should be explored. Such changes affect processes and organisations must detect and analyse them.
- **Ignoring that people are involved in more than one process.** There are few people who perform activities only for a single process. Often people are involved in many different processes, e.g. a doctor or specialist may perform activities in a wide range of processes. Simulation often focuses on a single process, often ignoring competing processes. In this case, it is possible to make the assumption and set 2 resources available 50% of the time (because the other 50% is involved in another process) but with the wrong result that one resource is sufficient.
- **Assuming that people work at a constant speed.** People do not work at a constant speed and the speed is based on their workload, personal attitude and work pressure.

- **Ignoring the fact that people work in batches.** People prefer to let work items related to the same task accumulate, and then process them all into one lot. In most simulation tools a resource is either available or not, it is assumed that a resource is looking forward to work and reacts immediately to any work items that arrive (such as people replying to emails). Clearly, this does not correspond to the way people work in reality.

Fortunately, modern IT infrastructures and the huge amounts of event data collected in many organisations also enable new forms of simulation. IT systems are becoming increasingly interconnected with the business processes they aim to support, resulting in an "explosion" of available data that can be used for analysis purposes. Today's information systems already record huge amounts of events and it is clear that data-driven analytics such as process mining [71] will become more important. Increasingly, simulation techniques will have to incorporate data from real events [3].

2.5.2 Types of simulations

There are various models for different purposes, ranging from the study of molecular changes to more general models covering effects on the whole.

At least three main categories of computational simulations have been conceived in the last four decades.

- System Dynamics
- Discrete-Event
- Agent Based

First, *System Dynamics (SD)* models are *top-down approaches to modelling and simulation*, where *a set of mathematical (i.e. differential) equations defines the behavior of the input-output system. These types of models focus on how populations of agents behave as a whole by studying how different populations change over time* [119]. SD was initially proposed in urban management studies [120], but was quickly applied to different types of systems. In a typical SD model, *the current output of the system depends on both its past history and current state.*

The second type of approach is *Discrete-Event Simulation (DES)* [44], which *focuses on an ordered chronological sequence of events occurring at precisely defined moments of time. The simulation is event-driven, and the state of the system is discrete in time and space* [322].

Finally, *Agent-Based Simulation (ABS) typically focuses on programming the behaviors of individual agents to observe phenomena that emerge from their interactions.* This type of approach has not been adopted as widely in management and organisational studies as in other domains. A recent review has

suggested a demarcation for this field, proposing the term Agent-Based Organisational Simulation (ABOS). In fact, the authors argue that ABOS refers to the application of agent-based simulation in business and management [125].

To improve a holistic view, a *hybrid simulation* [66] has recently been proposed, combining two or more of the following methods: SD, DES and ABS.

Although we have explored the potential of the use of agent-based simulation in healthcare in article [287], this thesis will focuses on discrete-event simulation. This choice is based on the fact that the processes that will be analysed in the thesis concern activities carried out by physicians and nurses according to protocols defined and tested in time by the hospital. These processes are therefore generally well structured and, in addition, in recent years the hospital has collected a relevant set of data. For all these reasons, according to the theory of discrete event systems [3], the most suitable theoretical tool for the analysis of this type of processes is DES.

2.5.3 Discrete event simulation

Discrete event simulation (DES) *is used to reduce uncertainty and create consensus by visualizing dynamic views of the process.*

It is based on a current state or As-Is, which is mapped to capture a snapshot of how things are done and where improvement solutions lie, and on a future state or To-Be map, constructed to show how things should be done considering potential requirements.

DES has been regarded as one of the most flexible analytical tools in the areas of design and operation of business systems. It is aggressively used to manage uncertainty and create dynamic views of lead time and machine utilization. This allows the quantification of results and provides the possibility to compare expected performance against actual performance. It can then be used to assist organisations in the decision-making and implementation.

Initially, data on routing time are received from the company (in this case the healthcare department). The outputs of computer calculations and models are only as good as the inputs, and inaccurate data guarantees less meaningful outputs. Therefore, the department sèends a lot of time observing the entire process to confirm the consistency of the time data with those reported one.

In the follow case study, a detailed simulation model is built using iGrafx software [158] to assess potential gains. It offers various process analysis solutions that help to document, analyse and improve their operations. In particular, it is used to create process models that serve as an environment for running process simulations.

In general, building a model and simulation process using iGrafx involves several basic activities:

- Create a diagram of the process model using departments, shapes, and connector lines.
- Describe the behavior of each activity.

- Building the simulation environment.
- Execute a simulation and analyse the results.

Once the initial analysis is completed, only a few realistic scenarios are selected by looking at the actual processing times of activities and then characterising their variation with statistical distributions. In the end, a scenario is chosen as a potential map of the optimised future state [320].

2.6 Process Mining: a way to reconstruct the process

In modern companies, information systems and information technology have become increasingly important due to the large amount of data recorded on a daily bases [96].

For the correct management of the company, Information Systems (IS) must be integrated within the company organisation, which implies a perfect knowledge of the company's operational processes. In this sense, Information Systems can be included in the broader category of Business Process Management systems.

One of the emerging areas of Business Process Management is Business Activity Monitoring [165], which extends the functions of information systems to the diagnosis of processes from the collection of data stored in the form of event logs, which are used to obtain models of the processes implemented and detect their strengths and weaknesses.

Information Systems record data about the execution of activities in particular event logs [306]. These event logs collect instances called traces, for which time-ordered events are listed. Therefore, it can be seen as a chronology of what happens within a particular organisation. Each event carries single or multiple pieces of information, therefore, the recorded data can be used to obtain a clear description of ongoing business processes.

To study such event logs, a field has grown in the recent years, linking process and data sciences: Process Mining (PM) [5, 305]. Thanks to these techniques, it is possible to infer, monitor and improve processes in a wide variety of application domains [306]. If workflow design techniques allow to model a process on the based of information derived from literature, from interviews with personnel involved in the process itself or from direct observation, process mining techniques allow to derive process models from data concerning their concrete and punctual execution.

Process mining is a family of techniques focused on gaining valuable insights from the data that processes generate as they run. It functions as a bridge between process science (which includes areas such as business process management and operations research) and data science (which includes areas such as data mining and predictive analytics), resulting in methods for analysing processes through data [305]. Therefore, one of the first objectives of PM is

the creation of a graphical model that comprehensively describes what actually happens during the execution of a process: the technique that allows the identification of this model is called Process Discovery [2].

In detail, the main challenge is to try to exploit data in a way that is significant, to model real processes and provide suggestions for a better allocation of the resources dedicated to their execution, identify bottlenecks, predict problems, record rule violations, recommend corrective actions. By applying process mining techniques, some fundamental aspects need to taken into account:

- Events constitute the central point of any process mining activity. Events are not necessarily stored in logs, but can also be stored in relational tables, messages, e-mail archives and other information sources, and extracted from these in the form of an event log [151]. Events must have certain characteristics:
  - Each event is uniquely defined at a specific stage of the process.
  - Each event refers to a case, i.e. an instance of the process.
  - For each event, an originator is specified, i.e. the personnel or resources used to carry out the activity.
  - For each event, a timestamp is given, i.e. a time reference indicating when the activity is took place.
  - Attributes may be present for each event, providing additional information on the characteristics of the activities carried out.
- The quality of a PM result is closely linked to the quality of the input data: consequently, logs are of primary importance within the information systems supporting the processes to be analysed and must be examined prior to analysis. There are some criteria, listed below, to assess the quality of the available data [306]:
  - **Reliability.** Refers to the ability to state with certainty that recorded events have occurred and that events attributes are correct.
  - **Completeness.** Once a precise context has been established, no event should be missing.
  - **Semantics.** The definition of each event must be clear.
  - **Security.** Event data must be recorded in accordance with privacy and security criteria.
- Process mining techniques have to be applied with the clear aim of answering certain questions: without a concretely defined goal it is very difficult to extract meaningful data and events. Models extracted from event logs can provide different views of reality and can focus on different aspects and show them at different levels of granularity and precision, depending on the level of choices to be decided by the various stakeholders. The interpretation of the models as maps also allows to emphasise certain

steps or aspects of the process or even eliminate process activities that are considered insignificant. These considerations show that it is essential to choose the right representation and size it according to the end users.

- In order to correctly interpret the results of PM, these ambiguities must be eliminate through knowledge of the application domain. In fact, the process model extracted from the event log may cover various aspects: organisational, temporal, data, resources, etc. For this reason, the identification of the relationship between the events in the log and the elements of the model is the starting point for different types of analysis: the events must be precisely linked to the process instances (event correlation). In some cases, establishing this relationship may not be trivial without a domain expert, since, for example, an event may refer to two different activities or this link may not be clear.

2.6.1 Process Mining for healthcare

In the healthcare sector, processes are rapidly evolving and characterised by a large number of variables and information systems are increasingly supporting process management and control activities. Process mining techniques are therefore an important tool to improve the knowledge of the processes themselves and their monitoring [224]. In fact, t*he premise of PM is to discover, monitor, and improve real processes*[19] *by extracting information about their actual execution.*

In recent years, various Process mining techniques have been proposed for different fields of application[20]. As far as healthcare processes are concerned, among the various techniques in this category, Business Process Discovery stands out for its importance and application[21]. The choice of these methods is mainly

[19]The term real arises from the need to distinguish a merely hypothesised or assumed behaviour, based on various pieces of information, from the real behavior of the system.

[20]A huge and recent review was made in [104]

[21]Some important revisions have been made recently:

- From Rojas et al. on 74 papers focusing on health processes (excluding studies related to clinical pathways) and published before 8 February 2016, in [253].
- By Erdogan and Tarhan on 172 studies, between 2005 and 2017, with 93 on health processes and 59 on clinical pathways, in [111].
- By Garcia et al. who on a general review on PM devote a section to healthcare where it can be seen that most of the contributions were related to clinical pathways, using conformance checking or process discovery. The topics of interest are numerous, but mostly focused on resource utilisation, identification of bottlenecks and indication of potential process improvements [265].

On the other hand:

- Yang et al. in a review of the literature on process mining studies applied to clinical pathways, out of 37 selected studies show that the identification of variants is a key point for adapting the clinical pathway (leading to its adjustment or redesign). In connection with adaptation, the improvement of self-learning of the clinical pathway is also necessary. Furthermore, the diversity of events and the complexity of chronic disease in clinical pathways is a challenge. These complexities make traditional process mining algorithms not practically suitable for clinical pathways. Finally, the whole medical process has to be considered when studying clinical pathways in hospitals.

driven by the noise and less structured processes encountered in healthcare data. This may illustrate the need for customised methods for healthcare process mining, motivated by the complexity and the challenges of healthcare data. High variability in health event logs is identified as a major challenge. Furthermore, a lot of context-specific information is needed to successfully conduct process discovery on healthcare data. Therefore, mobilising medical experts to retrieve specific knowledge is necessary, but can also be challenging in some organisations [104].

When developing and using process mining in healthcare, the distinctive features of healthcare processes, such as their variability and patient-centered focus, require focused attention. In this context, healthcare organisations, such as hospitals, are aware of the need to manage and improve both their clinical processes (e.g. care pathways that describe the treatment of a particular medical condition over time) and their organisational/administrative processes (e.g. billing processes) [194, 210].

Process execution data are a valuable source of information to support the management and improvement of healthcare processes [224].

Increasingly, healthcare organisations make intensive use of Health Information Systems (HIS), such as the information system of a hospital. During the execution of a process, several entries are recorded in HIS (e.g. when a patient has been registered or undergone a clinical examination by a physician). The entries in the databases of these HISs can be exploited to generate an event log that describes the sequence of activities that were performed, when they were performed, by whom, and for whom (e.g. for which specific patient) [305]. As the event log reflects how a process was performed in reality, it can support clinicians, managers of healthcare organisations and other decision-makers with a wide range of process-related questions. Some examples of these questions are: how does the process flow of patients with a particular medical complication differ from other patients? To what extent is the care pathway for a particular medical condition followed in practice? Where are the bottlenecks in the emergency department processes? How do several clinical experts interact in a care process?

To answer process-related questions such as those exemplified above, process mining techniques can be of great value. PM is a set of techniques used in many domains, including healthcare, to retrieve valuable insights from an event log [210, 305, 155]. A multitude of PM techniques have been developed in industry and academia [305, 253], which allow healthcare stakeholders to identify the actual order of activities in a process [42], to determine the conformity between an existing model (e.g. regulatory) and reality [80], and to provide insights into the involvement of resources in a process [305, 75].

Compared to alternative approaches, such as process mapping exercises with

The integration of pre-care and pre-hospitalisation (before) and rehabilitation (after) is necessary to fully consider the patient pathways. The study of the disease trajectory is another topic of interest when working on health processes. In these studies, the aim is to identify the relationships between disease and their progressions over time [139].

staff members [46], PM takes data about the actual behaviour of a process as a starting point. In this way, PM can support healthcare institutions in achieving each of the four goals for healthcare improvement [57, 52, 224]:

- Improving the health population (e.g. by supporting the analysis and improvement of care pathways).
- Improving the patient experience (e.g. by highlighting how a process can be streamlined from the patient's perspective).
- Reducing costs (e.g. by making bottlenecks explicit)
- Improving the work-life balance of healthcare workers (e.g. by improving the analysis of the involvement and requirements of resources in a healthcare process).

The main problem, at least as far as the Italian public health system is concerned, is that many steps are still on paper. The new administrations are evolving towards an ever wider digitization, but the practice used so far was different. Therefore, the information systems do not yet contain all the data of all the activities actually carried out in the process. If this is added to the fact that care processes can be complex and susceptible to variations due to the patient's care needs, it can be concludes that the data contained in information systems are not yet truly exhaustive and self-sufficient for an optimal use of process mining techniques.

Chapter 3

Organisational analysis of case studies

3.1 Introduction

In order to achieve the objective of the thesis and merge the organisation with risk management and regulatory compliance, this chapter follows the structure already announced (see Section 1.5). After having shown in the previous chapter some methodologies, instruments, and tools to analyse a company from an organisational point of view, in the following it is shown how to apply the theory to some real use cases. In this regard, some hospital services and departments are used.

This chapter analyses different aspects of the real hospital process and uses the real database. The results have always been validated in several steps, both by stakeholders and by simulations.

Following the four phases of the methodology explained in Figure 4.1: different contexts are analysed (OAD, R@dhome, Blood Bank), As-Is models are created and, after re-engineering, different scenarios are shown in To-Be models with alternative situations according to the optimisations requested. This chapter focused on the optimisation of the management of the organisation and we will mainly use two cases of the HaH service. The Blood Bank use case is mainly used in the following chapter to show the risk and compliance part (Phase 3 of Figure 4.1).

The notions presented in this chapter are the fusion of the many partial results we have found thanks to the experiments carried out in recent years. All the models, analyses, simulations, and results explained in this chapter have already been published in the following articles: [26, 27, 28, 29, 32].

3.2 Phase 1: the context analysis of the Hospital at Home

Widespread improvement in socio-economic conditions, primary and secondary prevention initiatives, and the advancement in diagnostic and therapeutic possibilities have led to an increase in life expectancy in industrialised countries. This, combined with a reduction in the birth rate, has led to a progressive increase in the proportion of elderly people, often suffering from multiple chronic diseases, with a consequent growing burden on the structural and economic sustainability of health services. According to demographic estimates of global and European ageing, this picture will worsen in the coming decades. The design, validation and implementation of more flexible and less costly treatment models, capable of optimising the management of exacerbations of chronic pathologies and minimising their impact on functional autonomy, increasing disability-free life expectancy, will became indispensable and urgent [244, 298, 160, 10].

The average age of the population in Western societies has increased in recent years and the incidence of the elderly is still rising. In public health services this is associated with a higher prevalence of chronic, often disabling, as well as a progressive extension of life expectancy in conditions of chronicity and disability (so-called frail patients) [202]. The degree of frailty is very high and so is the risk that even trivial factors may trigger cascading. Health policies must avoid that frail people fall into a long-term hospitalisation, which would imply strong functional losses and serious psycho-physical disturbances linked to the removal from their usual living context. Among these patients, hospitalisation often involves delirium, nosocomial infections, pressure sores and falls. [300, 206, 138].

Already in 2005, the Italian Ministry of Health in an urgent report stressed the need "to identify an organisational model for the management of the chronic rehabilitation phase using not only dedicated facilities but also alternative structures such as home hospitalisation and integrated home care" [138].

The hospitalisation at home [62] is increasingly a matter of interest, leading to fewer number of First Aid visitors compared to patients hospitalised in the hospital, with a reduction of costs [300].

These models of care are a "bridge" between the hospital and the territory, two pillars of public health that have the task of implementing the care process together [219]. These innovative models also represent a challenge because, in addition to meeting specific requirements in terms of appropriateness, effectiveness, efficiency and safety, they have to fit into a political and economic context in order to represent relevant changes.

In Turin, HaH is based on the OAD department. The OAD is an active service since 1985, thanks to the pressure of the San Giovanni Battista hospital (Department of Geriatrics and Metabolic Diseases Bons) [12, 206].

It has provided to be a viable alternative to the hospital for a whole range of recurrent acute and chronic diseases, such as uncomplicated ischemic stroke, congestive heart failure, obstructive congestive heart failure, onco-hematological

pathology with high fabsisno transfusion, dementia and behavioral disorder.

Since March 16, 2010, the Piedmont Regional Council has issued resolution no. 85-13580[1], which defines the *Hospital at Home as a form of paediatric health care, which provides for the organisation of the type of pressure that the home receives the pathology in the acute phase, but not necessary for attraction to high technological complexity, intensive/invasive monitoring, as an alternative to paediatric recovery.* As mentioned (see Section 1.4), *it is characterised by the entire take over of the patient's clinical type by the hospital from a pedestrian facility structure, and operates personal health expressions formatted and documented in the patient's experience being in the acute phase, but in the immediate tract.* The definition is in line with the degree of stability of the scientific literature, which identifies *homeless-ness as the modality of attraction towards the pedagogical structure, in consideration of specific evaluations, followed by personnel, direct or indirect necessary with particular complexity, to enrich a care process of the outpatient department* [278].

In addition, Regional Resolution established a specific remuneration for clinic-assistive activities: Euro 165 per day for pathologies of the respiratory system, cardiovascular system, blood vessels and hematopoietic organs, both oncological and Euro 145 for the other diseases [206].

It is important to underline that the OAD service is possible thanks to the support and constant evolution of advanced technological innovation in care [187, 301, 293]. In particular, it was initially possible thanks to the existence of the R@dhome service. R@adhome consists of a home radiography service. The service is really requested by geriatric patients in the OAD. Without a home x-ray service, to hospitalise a geriatric patient at home with the need for frequent trips to the hospital would have made no sense from a logistic point of view and for the hospital's budget.

The evolution of technology and of the cultural context has also made it possible transport radiographic techniques out of the hospital. Public home and territorial radiology in Italy was born in Turin in the context of the current City of Health in 2007. Radiology acquired an increasing role in patient management to work with almost all geriatric pathology without transferring patients to the hospital [138]. Other Italian regions (e.g. Veneto, Tuscany and Liguria) are now adopting this type of service, which is already a reality in other European countries, for example in Sweden, Norway and Denmark [317] with encouraging results [172, 14].

R@dhome started as an experimental home radiology project in the Piedmont Region, as a sub-department of the Radiology Hospital of the City of Health and Science of Turin, since 2007 [62]. This project represents the first experience in Italy and one of the first in the world to be implemented in a public setting and the radiological territorial activities are fully integrated with ICT through the implementation of a remote system for sending images, in compliance with current regulations, using broadband [218].

[1]Delibera della Giunta della Regione Piemonte del 16 marzo 2010, n. 85-13580, "Attività di continuità assistenziale: organizzazione e remunerazione delle attività di assistenza specialistica di ospedalizzazione domiciliare". http://www.cittadellasalute.to.it.

The Piedmont Region's Socio-Health and Territorial Assistance Plans from 2007 to 2016 affirms the need for technological and social research in the field of ageing and ICT [218].

The R@dhome research group pointed out that performing x-rays at the patient's home has a "protective" effect against the behavioural disorders and/or pain and, therefore, indirectly contributes to an improvement in the quality of life of patients; the clinical-diagnostic quality of the radiograms performed at home is certainly comparable to that of the hospital examinations and the risk of exposure is contained for both operators and population; costs are lower; patient satisfaction is very high and; the patient-professional relationship is greatly enhanced, with great benefit and satisfaction for both parties [138].

Finally, among the various services provided by the OAD are blood tests and transfusions. Test tubes are processed by the Blood Bank and procedures are subject to strict regulatory discipline.

3.2.1 OAD service

The organisational modelling effort includes a resources analysis. The service is available every day from 8 a.m. to 8 p.m. In the case of night emergencies, patients are referred to the Regional Emergency Service, with which they have a specific memorandum of understanding [206, 12, 300]. This is an integrated care service, so the team is multidisciplinary and includes:

- 4 geriatric physician
- 2 geriatric graduates students
- 14 nurses (including one nursing coordinator and one case manager)
- 1 counselor
- 1 social worker
- 4 part-time physiotherapists.

Patients are visited daily, either by a physician and a nurse together or by at least one nurse. For the individual patient, therapeutic objectives are planned during collective team meetings according to clinical progress, helping to provide the best possible care for the patient and optimise available resources.

There are 25 patients on average, and each patient considers what he or she has recovered in the traditional branch: the paediatric department for legal and financial responsibility, pharmacy, medical and non-medical materials, technology [12, 206].

Characteristic of the service is the actual hospitalisation (medical and nursing) of the patient. The fundamental moment is the joint organisation of the intervention plan for each individual patient by having a constant update. For each patient there is a Geriatric Clinic Orientation Dossier (medical dossier from here on) for problems occurring at home. Further on, a nursing dossier (or nursing folder) is available for quick orientation in case of emergency interventions.

Other routine activities with home visits, programs based on the patient's different clinical and assistive care needs, ensuring the possibility to be part of the treatment team (physician + nurse), responding quickly (20'-30' min) to emergency calls and effective complex diagnostic setups:

- **Non-pharmacological treatments**
  - Multidimensional geriatric assessment
  - Planned and urgent medical and nursing visits
  - Physiotherapy
  - Evaluation of aids and posture systems
  - Evaluation of neuro-motor disorders
  - Specialist advice
  - Counseling

  In addition, there is an information service for families with an online course[2].

- **Pharmacological procedures and treatments**
  - Blood samples (venous and arterial)
  - Intravenous therapy (including antibiotics and cytostatics) and management of oral therapy (including TAO)
  - Transfusion of blood products
  - Placement of bladder catheters and SNG
  - Echo-guided placement of central and peripheral venous catheters such as Midline and PICC
  - Paracentesis and thoracentesis
  - Surgical treatment of decubitus lesions
  - Positioning of Holter-type instruments (blood pressure, cardiac)
  - Spirometry
  - Electrocardiograms
  - Internal ultrasounds
  - Echo-color Doppler
  - Echocardiography
  - X-ray at home
  - Telemonitoring

Pathology most commonly treated in OAD:

[2]The information service is: Conoscenza dei cittadini sui soci sanitary services errogati da Torino e Provincia.

- Acute heart failure requiring infusion
- Cerebrovasculopathy
- Respiratory diseases (timely supply of oxygen at home is guaranteed)
- Infections requiring multiple daily intravenous antibiotic administration
- Advanced neurological diseases (ALS, multiple sclerosis, ...)
- Serious metabolic disorders
- Oncological diseases
- Haematological diseases with high transfusion requirements.

The service is activated by:

- Family doctor (15% of cases).
- Medical departments of the hospital branch (25% of cases).
- ED of the hospital (60% of cases).

Physicians propose this type of hospitalisation mainly on three occasions:

- When the patient requests this service because he or she already uses it and the condition of the pathology conforms to this type of admission.
- When the physician is fairly convinced that the patient would benefit greatly from this type of admission.
- When there are only a few ward beds and some patients could take advantage of this type of hospitalisation and freeing up beds, especially in the emergency department.

The evaluation of patients is based on the interaction between the ED team or ordinary departments team on one side and the case manager of OAD on the other side. Using this multidimensional geriatric file, the case manager assesses all patients and their caregivers to analyse the possibility of hospitalising the patient at home and to provide information on the characteristics and organisation of the service.

Already from ED an assessment is made with a Multidimensional Evaluation (MDE). From this initial assessment, a diagnosis, treatment and care pathway is established that optimises the existing human and material resources, that is aimed at an outcome considered to be the best possible, that reduces the number of days of hospitalisation, finding, if necessary, an appropriate solution of continuity of care. It is already from the moment the patient is taken in charge that possible problems for future discharges are analysed, such as to prepare disability claims if necessary, the prevision of aids that may be useful at home, including applying with an emergency procedure for liquid oxygen.

The case manager carefully evaluates the family member's actual availability through a structured interview. It is important to immediately establish a relationship of trust, without which it would not be possible to manage a patient at home in an acute situation.

In this interview, the characteristics of the service, the organisation, the need for a family member or a trusted person to collaborate with the team are explained to the patient (if he/she is able to decide) and to the family member. If there is a good willingness to accept care at home and a caregiver can be identified, the Hospitalisation Card is given [12, 206].

The criteria for admission to the OAD are:

- Informed consent of the patient and/or family members.
- Domicile in a defined geographical area.
- Residence in the Piedmont Region.
- Clinical features requiring hospitalisation but not invasive or intensive monitoring.
- Adequate family and collaborative support, without which it is not possible to manage the patient in the acute phase.

If the evaluation is positive, the patient, after signing the consent for admission under the OAD regime, is transferred to his or her home by an ambulance from the transport service agreed with the hospital.

Medical and nursing care is ensured from 8 a.m to 8 p.m. throughout the hospitalisation period. Visits may be daily or multi-daily, with the frequency determined by the patient's clinical conditions.

If the patient requires instrumental examinations or consultations that cannot be performed at home, the AOD staff book an ambulance to transfer the patient to the hospital and back home. All aids, various medical materials and drugs are brought to the patient's home during daily visits and are provided by the hospital [12, 206].

At the end of the treatment period:

- 81.5% of patients are discharged to the family doctor (with or without activation of local integrated care services).
- 10.5% die during hospitalisation.
- 8% have to be transferred to the hospital to continue their treatment.

Despite the increase in clinical complexity and the burden of care for the patients in charge, the proportion of patients unable to continue in their homes has remained constant over the last eight years[3].

The geriatric clinical foundation of HaH for some acute diseases and exacerbations of chronic diseases comes from:

[3]Taken as a sample, there were 492 patients followed in OAD in the year 2018. They have a high average age (84 years), but with a very wide range: 19 to 105 years, with an average weight of hospitalisation of patients in the acute ward.

- The minor risk of complications (e.g. nosocomial infections, delirium, malnutrition, sleep disorders).
- The importance of the treatment environment, especially for the elderly frail patient.
- The economic advantage for the National Health Service.

Therefore, both from the personal point of view of the patient and the family, and from the management point of view, the need to transfer the patient to the emergency room, and the possible continuation of his or her treatment in a traditional inpatient setting may be a negative outcome.

3.2.2 R@dhome

R@dhome is a service that provides x-ray at home. It refers to the hospital x-ray department, but has its own resources and costs.

The human resources are three radiologists plus a radiologist in charge. The hospital provides them with a car and they provide the radiological examinations at home to the entire metropolitan city of Turin.

The metropolitan city of Turin is made up of 316 municipalities with a total of 2,300,000 inhabitants.

In the territory of the metropolitan city there are:

- 88 accredited public and private Social Assistance Residences (RSA). These are out-of-hospital residential facilities aimed at providing accommodation, health and rehabilitation services, protection and rehabilitative treatment to elderly people in conditions of lack of physical and psychic non-self-sufficiency, without family support.
- 1600 Family Doctor or General Practitioner (GP) operating and throughout the Piedmont Region. There are about 25,000 patients in Integrated Domiciliary Assistance and in the metropolitan city are about 9,000.

R@dhome is a service available to frail people in the metropolitan city of Turin, both for patient under hospital care but located outside the hospital walls, and for patient not under hospital care.

- Patient external to the hospital come from:
  - RSA
  - GP
- Patient in hospital charge but outside of the hospital walls come from:
  - OAD
  - IRV: hospital ward located elsewhere, for post-acute patients.

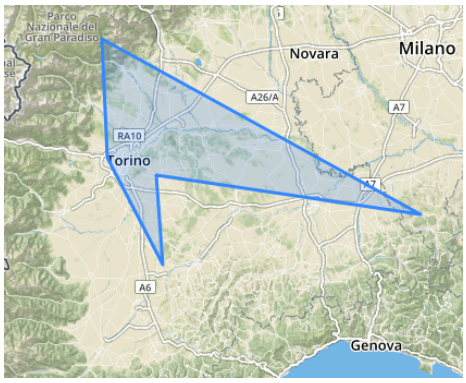

Figure 3.1: Geographical area covered by R@dhome in 2017.

The actual geographical area covered by the R@dhome radiology technicians during the year 2017 is shows in Figure 3.1).

The service is aimed at patients who need x-ray examinations because they have:

- Advanced degenerative/progressive neurological diseases.
- Advanced and complicated stages of chronic diseases.
- Lung diseases.
- Cardiac, oncological or osteoarticular diseases.
- Results of orthopaedic surgery for trauma or severe osteoarticular diseases.
- Major disabilities with transport difficulties.
- Conditions of non-self-sufficiency, frailty and with existing diseases or outcomes requiring home care.

The categories included are very narrow. Home diagnostics only make sense when, from a clinical point of view, examinations are performed for which the same quality is obtained as if the patient were examined in a residential radiology facility. This consideration has a strong impact on the economic aspect: R@dhome is only cost effective when the service is provided to the right patient and in the right setting [106, 138, 218].

3.2.3 Blood Bank

Among the different types of treatments provided at home by the OAD are transfusions. This is a special treatment, which normally has to take place in a hospital, under the constant supervision of a physician and under certain specific procedures established by law. This is because it is a procedure with a

high risk of error and possible serious damage that can easily lead to the death of the patient.

For the blood test and subsequent blood supply they turned to the Blood Bank (BB) of the City of Health Hospital.

The BB supplies blood units, not only to all the departments of the City of Health, but is at the top of a distribution chain covering the whole Piedmont Region. In addition, the BB has its own outpatient clinic (the SAUB) for periodic polytransfusions, such as haemophiliacs and thalassemics.

The BB works 24 hours a day, 7/7 days for an estimated 200 analysed samples per day for a total of about 90,000 units per year, for a much larger amount of processed requests. It analyses blood samples with the aim of allocating the most suitable blood for transfusion purposes.

3.3 Phase 2: As-Is and processes engineering

The As-Is model is a representation of the situation as it is in the present time. The closer this first representation is to reality, the more realistic and therefore useful the analysis of the derived data or the suggested improvement or in general the results obtained can be.

The first step to shaping the situation is to observe it.

The best thing is to spend some time in the company, follow the workers, talk to them, see actions, time and resources. In short: find out what the real procedure is.

Many companies have a business procedure written on paper, but normally it is what the manager has established in the past and with time and experience the workers have made some changes to avoid some problems. Furthermore, this step is also useful to find out what the real problems are in production or at the lower levels of the chain, which often create bottlenecks in next steps, but of which managers are often not aware.

Engineering a process and creating the As-Is model imply not only modelling the process but also validating it. Validation is a fundamental step. After validation, it is possible to take certain actions. Validation in all these use cases is done by stakeholders and simulations.

The process diagram is integrated with a description of how each activity deal with a transaction, how long it takes and what resources are needed to perform it. In addition, it is necessary to specify how transactions are introduced in the model and how long the simulation should last. The integrated As-is model can be simulated by means of a design and simulation environment, based on the iGrafx Process tool [158].

All simulations transactions are based on the hospital's real databases[4].

[4]All databases used are antecedent to the COVID-19 period. During the pandemic, all procedures and the number of patients changed due to the emergency. Using the data from the pandemic years would lead to distorted conclusions.

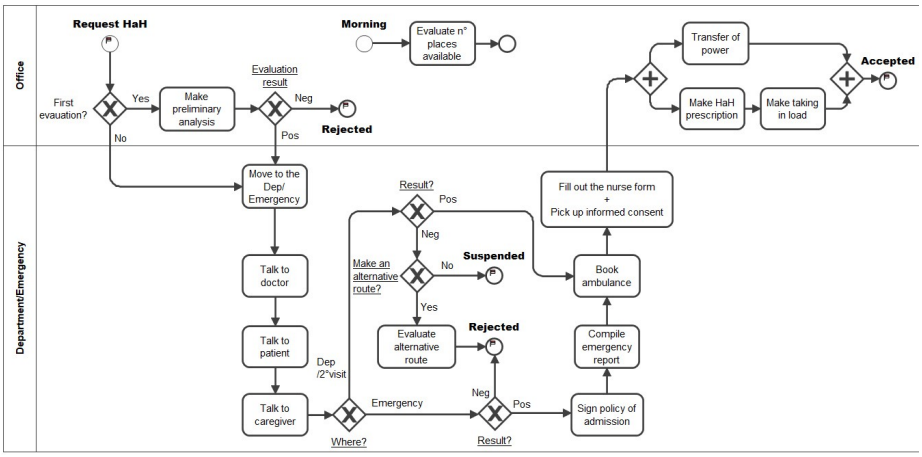

Figure 3.2: OAD Acceptance process.

3.3.1 Modelling a process

In this section, a model of a fairly simple process is presented: the OAD Acceptance. This process has only one human resource: the case manager (CM). She has to evaluate all the requests and to assess, according to some guidelines, if the patient has the required characteristics to be taken in charge by this type of hospitalisation.

Although it seams like a simple process, it is full of qualitative variables, as well as quantitative once, which make the process really complex.

In any case, as Figure 3.2 shows, the model does not contain many activities. It is important to always have in mind what the objective of the analysis is. The objective must be clear during the context analysis. According to the objective, it is important to understand the level of detail the process should contain.

Looking at the Figure 3.2, the first task of the CM every morning is to evaluate the numbers of available places (**Evaluation n° places available**, which corresponds to the maximum numbers of patients that she could accept on the day. The task takes about 45 minutes because the CM has to evaluate:

- The number of patients during the day is likely to be released.
- The number of staff available. For example, if we are close to Christmas or the summer holiday there are fewer staff, so the patients have to be proportionate.
- How long each patient, whom they already have in charge, being. Some patients have a pathology that must involve more time than others, for example, blood transfusions are longer than bandages, which are longer than giving medicine. The first type of patient occupies two slots, the

second type of patients occupies one and a half slot, and the third type occupy only one slot.

This first evaluation involves both types of variables (qualitative and quantitative), is based on the CM's best experience from years of experience, and is very important because it determines the future workload of all staff involved in the service.

At the same time, requests can arrive by telephone from the ED as well as from any other department of the hospital. Requests are made by the doctors' departments who have made a rapid initial assessment.

The arrival of a request (generator **Request HaH**) implies a first telephone evaluation (gateway *First evaluation?*) by the doctor and the CM (**Make preliminary analysis**). If there are indeed characteristics that do not conform to this type of hospitalisation (gateway *Evaluation's result?*) the request is immediately rejected (end of the process **Rejected**). Otherwise, the CM moves to the ward to evaluate the patient (**Move to the Dep/Emergency**).

Initially, the CM talks to the requested doctor to assess the clinical condition (**Talk to doctor**). All patients are in acute disease, but must not be in a state of bleeding or at risk of reanimation. Then the CM talks to the patient if he/she is conscious and capable of understanding (**Talk to patient**), as well as to the family and caregiver (**Talk to caregiver**).

During this meeting the CM explains:

- The characteristics of the service.
- The organisation of the service.
- The need for a person from the family, or someone else, cooperate with the hospital team.

Already at this stage:

- Evaluation of clinical, functional and cognitive aspects.
- A pathway of diagnosis, treatment and assistance are established to optimise existing human and material resources, which is finalized to a held the best possible outcome, reducing days of hospitalisation.
- If necessary, a suitable relief solution is evaluated.
- Since the eventual taking in charge of the patient that possible list of problems is analysed for future discharge.
- Predispose applications for the provision of aids and facilities that may be useful to the domicile (i.e. it is possible to require in urgency procedure the liquid oxygen that will be delivered in a few hours to the patient's house).

The access requirements are also evaluated.

Quantitative variables: the patient's residence in the Piedmont Region, the patient's domicile in the geographical area covered by the service (half city of Turin) and, clinical characteristics to be required for hospitalisation without invasive or intensive monitoring.

As qualitative variables:

- Signature on the informed consent of the patient and/or the family, implying consent and willingness to access this service.
- Adequate family support.

Through this structured interview of mutual knowledge, the CM carefully appraises the real availability to accept the cares to house, whether a caregiver can be identified and, the availability of taking in charge the patient in OAD.

After talking to all the interesting parties, the trial is different depending on whether the patient came from ED or a hospital department (gateway *Where?*).

Any bed of the emergency department cannot be occupied 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/she is transferred to the traditional department.

If the parties (CM-patient/caregiver/family) agree to this service, a real contract of collaboration is created for the taken in charge. Moreover, it is important that this type of collaboration remains as established at the beginning for the whole time of the service. Otherwise, if the caregiver is absent or the family is exhausted, the patient is immediately transferred to hospital and admitted within the hospital walls.

Once this agreement has been reached, the CM signs the admission policy (**Sign policy of admission**), the emergency department's physician fill in the emergency report (**Compile emergency report**) and then the CM books the ambulance for transport to the patient's home (**Book ambulance**). Finally, the CM (**Fill out the nurse form + Pick up informed consent)**:

- Fill out the nurse form asking dates to the patient/caregivers.
- Collects some information about the patient.
- Give to the patient and to his/her family some information about the service, including an "Informative Sheet" with information about the service and the organisation of upcoming tasks.
- Makes to sign and pick up informed consent to the patient, or to the caregiver if the patient is unable.

If the request came from a classical department of the hospital, the evaluation result (gateway *Result?*) might be:

- Positive: the patient is taken in charge, then the CM books the ambulance, gives and takes various information, fills the nurse's form and makes sign the informed consent of 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 OAD request is definitively rejected (**Rejected**).
- Negative but really Suspended: often the family needs time to organise themselves or to required medical products or it is necessary to talk also to the "real" caregiver who stays with the patient or to other family members, so it is a temporary refusal (**Suspended**), but the CM books another appointment.

In order to establish this contract of trust and collaboration between the patients and the hospital, it is essential that the CM talks to the whole family to narrow contact with the patient (who has to take care and share tasks and responsibilities) and finally with the caregiver, who may or may not be a relative. It is necessary that all these people are informed, aware and give consent to the service, otherwise, there could be serious consequences in terms of cooperation that could affect the patient's care.

According to this, it is not uncommon for the CM to have several tours (on average 1, 2, 3 or at the most 4 in the particular case of each patient) to the same patient (gateway *First evaluation* arrow 2^o visit). For these secondary interviews, the CM makes the appointment on a case-by-case basis directly with the patients. The activities remain the same, but need less time than the first ones. This second evaluation might exists only in the department (gateway *Where*, 2° visit), for the reasons already explained. In all these visits it is possible to either take in charge of the patient, reject the request or suspend it for another visit and the process can be repeated until the patient is taken in charge, or the service is refused, or the patient dies or is discharged.

In all cases in which the patient goes home on a different day from the first request, the CM goes to the patient independently before he/she leaves, in order to make sure that all information is clear. It implies redoing the three activities already explained, but in less time.

At the end of this trial with the patient, the CM is back to the office department and does the administrative tasks for the newly patients taken in charge. On the hospital's computer system, the CM has to make the prescription of the hospitalisation at home (**Make HaH prescription**) and the formal taking in charge in the OAD department (**Make taking in charge**). Meanwhile, as soon as the doctors and the nurses arrive, the CM informs them about the new patients (**Transfer of power**). At this moment the request is also formally accepted and the patient is definitively in the workload of the OAD department (**Accepted**).

3.3.2 Simulation and some possible data analysis (qualitative and quantitative variables)

After the model is created, it receives its first validation from the OAD staff. The second validation is done by the simulation results. The simulation results are always checked by the OAD staff and managers.

But, going deeper into the simulation analysis is of fundamental importance to underline the premises. To do some general data analysis, some prototype databases are easily available on the internet. These data are "perfect". It is possible to choose how big the database is, the type of data, the format, the database is always complete in all its fields. The real database is normally not like that, more so if the data are not collected in an automated way.

The analysis and the simulations are based on the real OAD database of the years 2017 and 2018[5].

Table 3.1: Distribution of arrival requests.

	R + CM visit	**R rej. by phone**	**Total**
2017	468	96	558
2018	516	103	619
Total	*994*	*199*	*1,193*

Table 3.1 reports the number of OAD requests during 2017 and 2018. The daily arrival of patients' requests, as in every hospital, does not follow a uniform distribution. The table divides the number of requests that have wanted at least one CM visit (**R + CM visit**) and the number on average of the requests immediately refused by phone, without a CM visit (**R rejected by phone**). The number of requests immediately rejected is an average number because they do not report these calls in the database. This value was agreed with the CM[6].

The workload of the CM depends not only on the real number or the request made by the different physicians, but also, as shown in the process (Figure 3.2), on the other case-by-case appointment that the CM autonomously takes with the patients.

Based on this assumption and by analysing the databases, it is possible to estimate that the CM workload is increased by 57% by the visits after the first one, more repeated in Table 3.1.

Table 3.2: Increasing of the CM's workload by the seconds visits, in 2017-2018.

Tot.R+CM visits	**Tot.CM visits**	**Diff.(%)**
994	1,742	43%

[5]These analysis and results have been published in [29].

[6]The transactions that start the process simulation comes from the generator. The generator can be set or can be loaded from a file. In this case, to estimate the real workload of the CM, it is interesting to set the generator in a way that generates a random call in a fixed interval.

Table 3.2 considers the sum (**Total**) of the column **R + CM visit** of Table 3.1 comparing the results of the CM database of the OAD.

The increasing of the workload of the CM (almost 50%) shows how much balancing all these variables, above the qualitative ones, increases the workload. This is made with the aim of creating a clear collaboration, stable over time, which will lead to advantages in the workload of the team going home and in the patient's care[7].

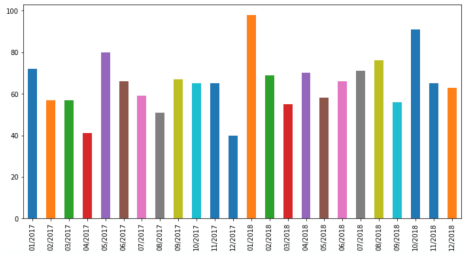

Figure 3.3: Patients taken in charge by the OAD in 2017 and 2018 in different months.

In addition, Figure 3.3 describes how the CM's workload changed on a monthly basis in the two years examined. For example, in January or autumn, there were some peaks, mostly related to flu periods. In contrast, around (Italian) festivity days (i.e. April 2017) there were fewer requests, perhaps because people are less willing to travel from the city.

Another interesting analysis concerns the comparison of the CM's workload derived from the ED and the other departments of the hospital. This analysis is shown in Figure 3.4.

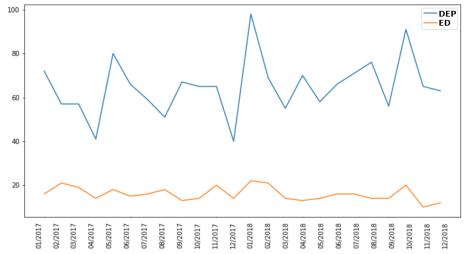

Figure 3.4: OAD CM's worlkoad in 2017 and 2018 from Hospital Departments (DEP) and Emergency Department (ED).

It is notable the difference as the requests by the ED imply only one visit, a

[7]According to Article 4 of Code of Ethics for Nurses: in acting professionally, the Nurse establishes a relationship of care, also using listening and dialogue. It guarantees that the assisted person is never left in abandonment involving, with the consent of the interested party, his or her reference figures, as well as other professional and institutional figures. Relationship time is treatment time.

quicker decision and two more documents for each patient. The request provided by the different departments, in addition to the fact that the departments are more than one, there is some more time and the visits are frequently more than one.

It is also possible to calculate the average daily arrival of patients, which is about 3.5 with a standard deviation of about 2. Interestingly, the distribution varies across days with a peak in the first part of the week. Table 3.3 describes the average value of the patients the modal value and the standard deviation for each day considering the period between 2017 and 2018.

Table 3.3: Daily distribution of the CM's workload: average (Avg), modal value (Mode) and standard deviation (StDev).

	Mon	**Tue**	**Wed**	**Thu**	**Fri**
Avg	4.05	4.05	4.09	3.35	2.56
Mode	4.00	4.00	3.00	3.00	2.00
StDev	2.04	2.04	2.03	1.72	1.62

The output of the CM evaluation directly affects the workload of the OAD department: physicians and nurses who have to go to the homes of different patients day after day.

The OAD staff deals with about 25 patients per day, and on average 500 patients per year.

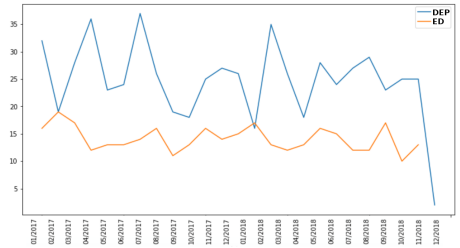

Figure 3.5: Patients taken in charge in the OAD in 2017 and 2018, by Hospital Departments (DEP) and Emergency Department (ED).

Figure 3.5 shows the requests accepted, i.e. the patients taken in charge in 2017 and 2018, by the Hospital Departments (DEP) and the Emergency Department (ED). Curiously, the requests accepted by the Emergency Department follow a similar trend of the requests provided. This is because, if possible, it is preferred to free up a bed in the ED rather than simply moving the patient to another bed in a traditional department.

In addition, in order to ensure an adequate workload for the team and an adequate level of care, the number of patients in charge each day must be balanced with patients leaving the service, according to the first evaluation activity explained in Figure 3.2 (**Evaluate n° place available**).

Table 3.4: Details of accepted and rejected requests in 2017 and 2018.

	2017	**2018**
Patients taken in charge	468	489
Patient rejected from DEP	10	22
Patient rejected from ED	2	5
Request rejected by phone	96	103

Table 3.4 describes the number of patients taken in charge over two years. The fact that very few patients are refuses is also due to adequate information and collaboration between ED-DEP doctors and OAD staff.

3.3.3 Processes and sub-processes

If we think about an enterprise, it is easy to see that there is unlikely to be one process that handles everything. It is more likely that there is one large high-level process, made up of many more or less small sub-processes. These sub-processes impact each other in a way or another, on shared resources, or time, or costs, or more than one variable together.

This section presents R@dhome and shows all the parts that make up the service.

Figure 3.6 represents the main high-level process.

The activity boxes with a + at the bottom are those containing a sub-process.

Even more, this process has two generators. It means that there are two processes that start in the morning and run in parallel during the day. It is easy to imagine that in a company, there might be several departments (production, management, call centre, etc.), which start together in the morning, interact with each other, maybe influence each other, but each one with its proper sequence of activities to do. This is the meaning of the different generators.

The service opens at 9:00 a.m. (*Start*). At the beginning, the staff checks if any requests have arrived (**Check requests**). At any time of the day, prescriptions can arrive. They are stored on voice mail, on the mail address and into the Hospital Information System (HIS).

The arrival methodology depends on the source of the requestor (gateway *Request type?*). Internal requests are generated by the internist on HIS and are related to patients already in hospital charge, therefore they only need the technical evaluation done by the radiologist (**Technical evaluation**). He/she assess the planned visit and some technical aspects. External requests are made by the general practitioner external to the hospital on an online format (because they do not have direct access to the HIS) and are related to patients not already in charge of the hospital. For this reason, they need a medical radiologist evaluation (waiting for time *Medical radiologist evaluation*) before the technical once (**Technical evaluation**). If the request is approved (gateway *Approved request?*) the staff uploads it into the HIS and the taken in load (**Upload in HIS + take in charge**), otherwise, they propose an alternative route to

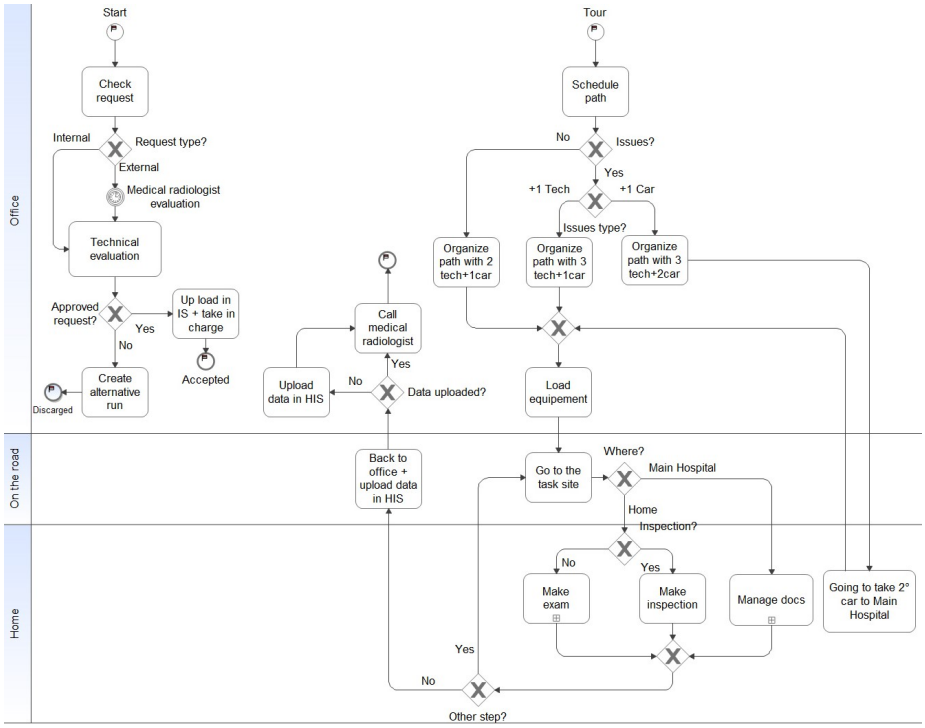

Figure 3.6: Process of home examinations.

the patient and eventually make calls to re-book the patient for the right visit (**Create alternative run**).

All requests accepted on one day will be fulfilled in the next day workflow, unless otherwise indicated. From the arrival of the request, the staff takes on average 24-72 hours to visit the patient.

At about 9:30 a.m. (*Tour*) the staff organises the examinations path of the day (**Schedule path**). If there are no particular problems (gateway *Issues?*) the tour is organised and done by two technician radiologists (**Organize path with 2 tech + 1 car**). Otherwise, there could be two types of problems (gateway *Issues type?*):

- An additional radiologists is required (**Organize path with 3 tech + 1 car**), e.g. in the case of an overweight patient, or if the patient lives in a house without a lift, or where there are known architectural barriers.
- An additional car is needed (**Organize path with 3 tech + 2 cars**), e.g. if there is a heavy workload in a some different settings. In this case, they have to book one more hospital's car and one additional technician goes to deliver the documents, while the other two do the normal visiting paths.

The department only has one car, so in the latter case they have to book a hospital car and they have to go to pick it up in the hospital car park with their car and drive back (**Going to take 2° car to Main Hospital**).

When the team is ready they can load the equipment into the car (**Load equipment**) and leave the base (**Go to the task site**). They can have two different destinations (gateway *Where?*): the main hospital to pick up or drop off patient documentation (**Manage docs**) (see process detail in Figure 3.7)) or the patient site. In this case, staff can make an examination (**Make exam**) or a site inspection (**Make inspection**), for example, to prepare a specific room in an RSA (see detail in Figure 3.8)).

At the end of the exam, if there are other patients to visit (gateway *Other step?* they go to the next patient's house (**Go to the task site**) and repeat the process; otherwise, they return to the office. On the way one technician drive the car, meanwhile the other one tries to upload the x-ray images into the HIS (**Back to office + upload data in HIS**).

When they arrive at the office, if the data are not all uploaded to the HIS (gateway *Data uploaded?*), they finish doing it (**Upload data in HIS**). At the end of this, they call the medical radiologist (**Call medical radiologist**), who is in the main hospital, to let him know that he can start the report.

The delivery or collection of clinical documents or medical reports in the main hospital (as shown in Figure3.6) (**Manage docs**), contains within it another sub-process, shown in the Figure3.7.

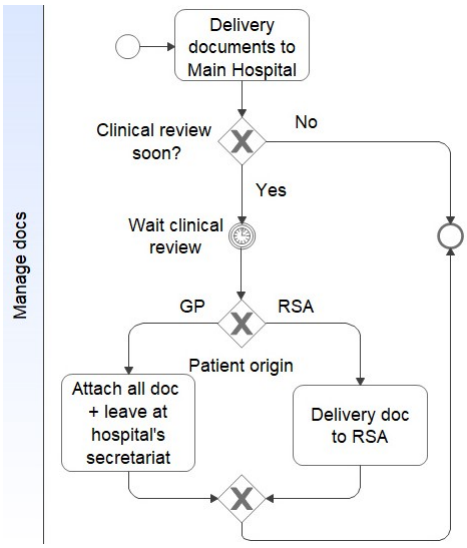

Figure 3.7: Process of delivering or collecting clinical documents or medical reports in the main hospital.

In some particular cases, in order to make the medical report, it is necessary to have some historical patient documentation. In this case, when the techni-

cians goes to do the x-ray they also collect these documents and deliver them to the main hospital (**Delivery documents to Main Hospital**). If it is not possible to do the clinical review (gateway *Clinical review soon?*), maybe because the medical radiologist is not there or is too busy, they leave the documents and go back to their office department or to visit some patient, otherwise, they wait for the clinical review (time delay *Wait clinical review*). When ready, if (gateway *Patient origin*) the patient came from the GP, they collect all the documents together and leave them at the hospital's secretariat (**Attach all doc + leave at hospital's secretariat**) because the collection of the documents is the patient's responsibility. If the patient came from an RSA they have to take the examination report and deliver it to the patient's home, the RSA (**Delivery doc to RSA**).

As mentioned, there are two requests typologies: internal and external (see Figure 3.8)).

The internals are for patients already in charge of the hospital: from IRV and OAD.

- IRV is a hospital department, so when the technicians arrive, they have to go to the right floor, talk to the nurses, take some documents if necessary, find the patient's bed (**Find a patient's bed**) and make the x-ray exam (**Make exam**). Then, if there are other patients (gateway *Other patients?*), go to make the other exams, otherwise, leave.

- OAD patients are physically in their own house, so when the technicians arrive the first thing is to analyse whether the exam is possible (e.g. there is electricity available to connect the x-ray machines). If the exam is available (gateway *Available?*) they assemble the x-ray machine and other equipment (**Assemble equipment**), talk to the patient and the caregiver (if any) to give and take some information regarding the exam or previous important medical information (**Talk to patient**), do the x-ray exam (**Make exam**) and, at the end, disassemble the equipment (**Disassemble equipment**) and leave, giving the last information to the patient (**Taking leave**).

The externals are for patients not in charge of the hospital: from RSA and GP.

- RSA patients are often on their bed (gateway *Patient location*) and the process is similar to IRV. Rarely, patients are able to move, alone or with help, in this case, a room can be prepared ad hoc, after a previous inspection in previous days. In these cases, they can collect all the patients in this room, assemble the equipment only once, do all the exams, one by one, and disassemble the equipment once at the end. The technician will return to deliver the reports (Figure 3.6).

- For GP patients the examination process is almost the same as the OAD. The peculiarity is that they get signed informed consent (**Get sign informed consent**) (patients who are already in charge in the hospital or in

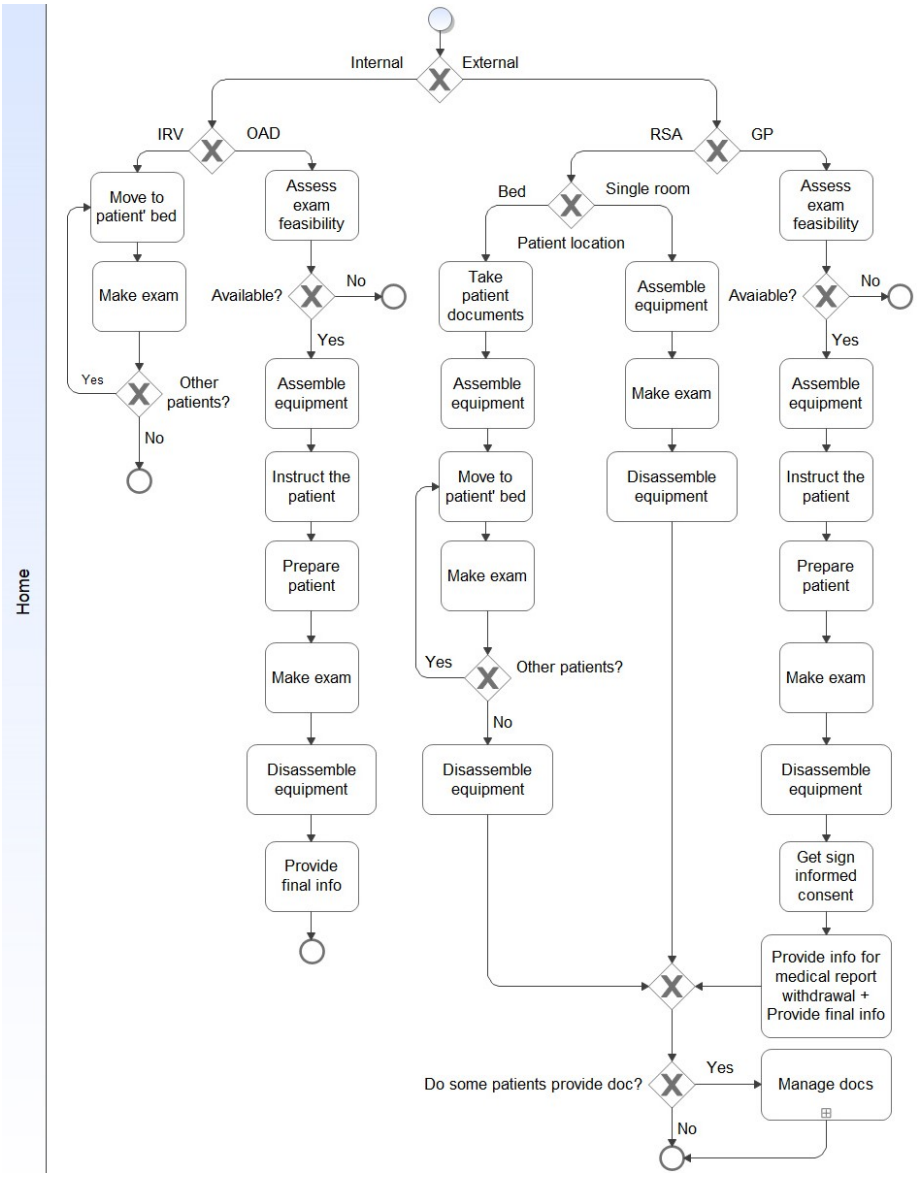

Figure 3.8: Typology of the arrival requests for x-ray examinations.

another facility have signed this document at the time of admission) and before taking leave, they provide all the information for the medical report withdrawal (*Provide info for medical report withdrawal + taking leave*),), which is the responsibility of the patient to collect from the hospital.

For both RSA and GP patients it may be the case that technicians hand

over to the radiologist in the hospital some previous historical documents useful for the radiological medical report (**Delivery doc to Main Hospital/Home**) (according to Figure 3.7).

3.3.4 Simulation and some possible data analysis: details of sub-processes

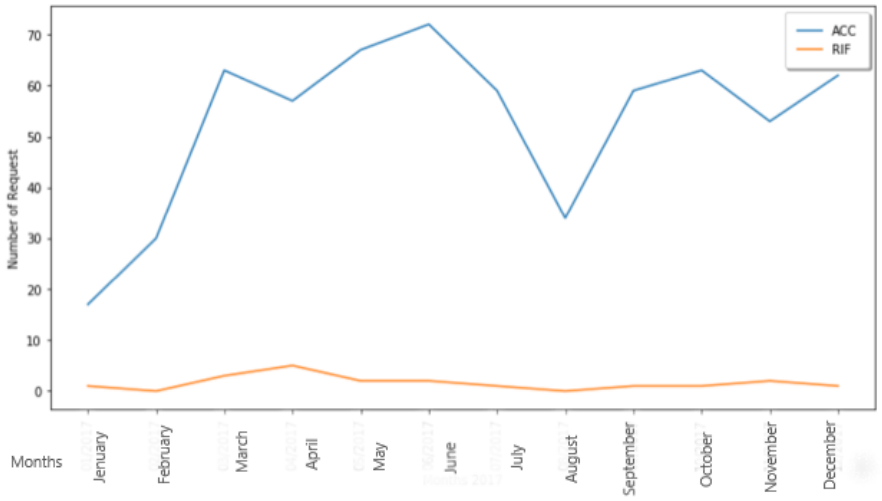

Figure 3.9: R@dhome workload in the year 2018.

The R@dhome workload comprises approximately 670 requests handled during the year 2018. Figure 3.9 shows the accepted (ACC) and rejected (RIF) requests arrived at the department and divided by month.

The sum of the two constitutes the first generator of the simulation (Start) (see Figure3.6), while the line *ACC* corresponds to the output *Accepted* and the line *RIF* corresponds to the output *Discharged* of the process. The only accepted requests correspond to the patients actually visited (transactions that enter the sub-process shown in Figure 3.8). These transactions are then divided into two main groups: *Internal* requests (already in charge by the hospital) and *External* requests (not in charge by the hospital), divided into two further sub-groups each: OAD - IRV as Internal; RSA - GP as External.

The results of the real workload analysis carried out throughout the year are:

- Internal: 81% of all requests accepted.
  - OAD: 24% of all accepted requests and 30% of internal requests.
  - IRV: 57% of all requests accepted and 70% of internal requests.
- External: 19% of all requests accepted.

– GP: 17% of all requests accepted and 90% of external requests.
– RSA: 2% of all requests accepted and 10% of external requests.

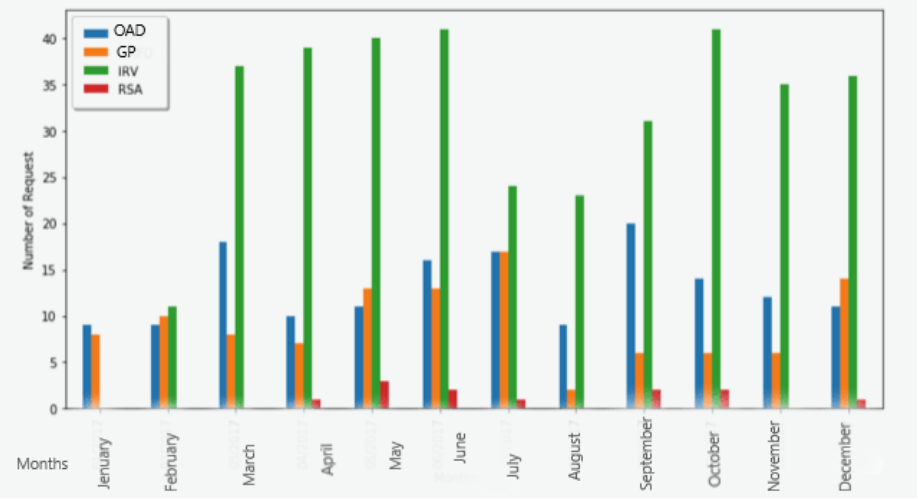

Figure 3.10: Categorisation of the arrival requests of an x-ray examination.

In detail, Figure 3.10 shows the number of patients visited by the R@dhome technicians, in OAD, GP, IRV and RSA, divided by mouths, throughout the year.

As shown in Figure 3.8 each of the four routes has different tasks and, some tasks that are the same may involve a different time interval depending on the working environment.

The following figures show the number and the type of exams performed during the year for respectively: OAD (Figure 3.11), GP (Figure 3.12), IRV (Figure 3.13) and RSA (Figure 3.14).

The most commonly requested x-ray examination is of the thorax (*TORACE*).

Moreover, the radiographic examination implies a different time interval depending on the body part to be examined. On average, , examinations are grouped into 4 macro sets according to an estimated time interval, as described in Table 3.5.

Observations can be made, for example, although the thoracic x-ray exam is the most required, it is also the one that takes the least time to be performed on average.

The analysis focuses on working time as a Key Performance Indicator. Table 3.6 summarises the main results for the relevant monitoring metrics introduced to measure process operation. Working time is defined as the period of time an operator spends on paid work. The average waiting time for acceptance and discharge processes is 36 and 25 minutes respectively. Furthermore, the most relevant activities in these simulation results are the handling of requests for

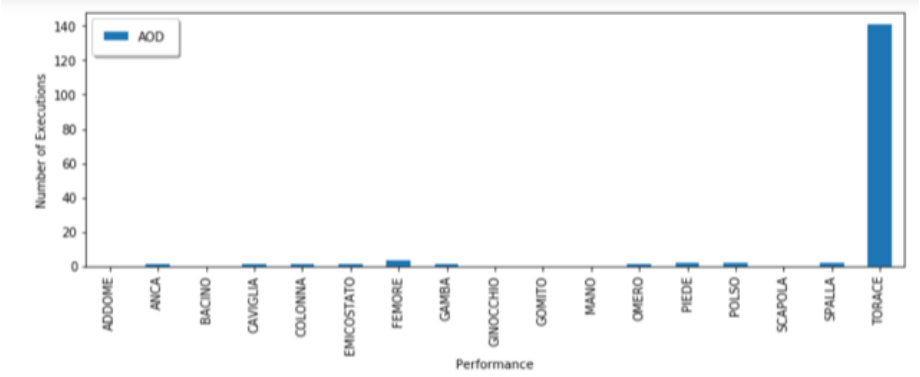

Figure 3.11: Typology of arrival requests of an x-ray exam from OAD.

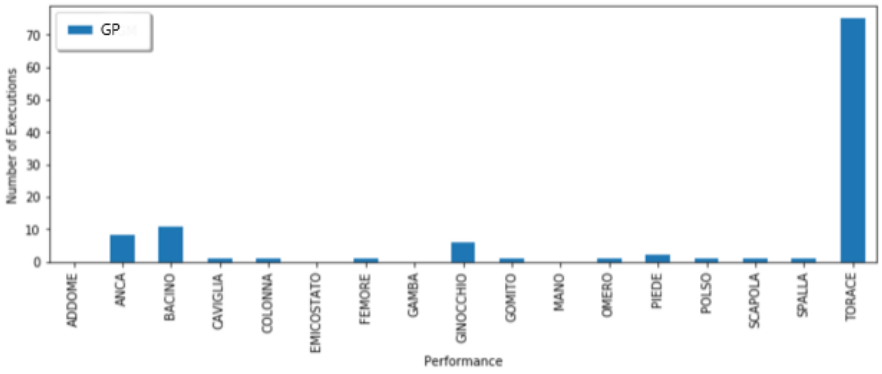

Figure 3.12: Typology of arrival requests of an x-ray exam from GP.

both OADs and RSAs. This output was carefully examined and evaluated by the operators and management staff, providing a good test for the validation of the simulation model.

Model validations and simulations should more or less give a clear picture of the situation of the enterprise. These analyses should provide an idea of the business context: what is the corporate spirit, the objectives, the principles of the company, but also the existing problems, the budget and the human and instrumental resources available. This initial data is already good information for management. Especially in large companies, this analysis can be useful to bring to the managerial attention problems that exist at the initial levels of the production chain and that could then create a cascade effect in the subsequent stages, perhaps creating problems or damage or generating greater risks.

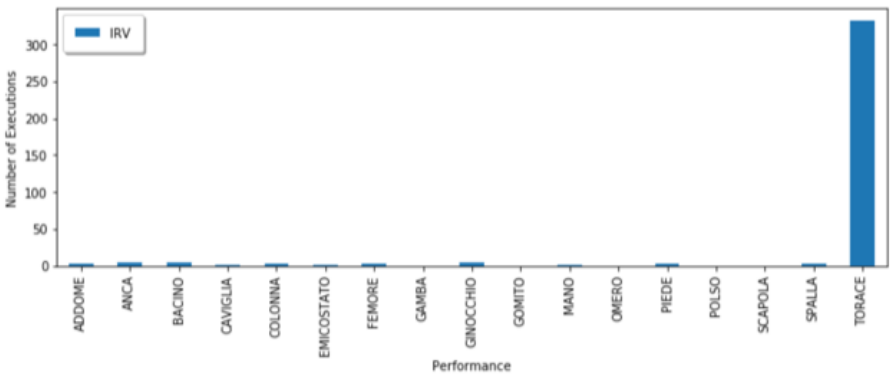

Figure 3.13: Typology of arrival requests of an x-ray exam from IRV.

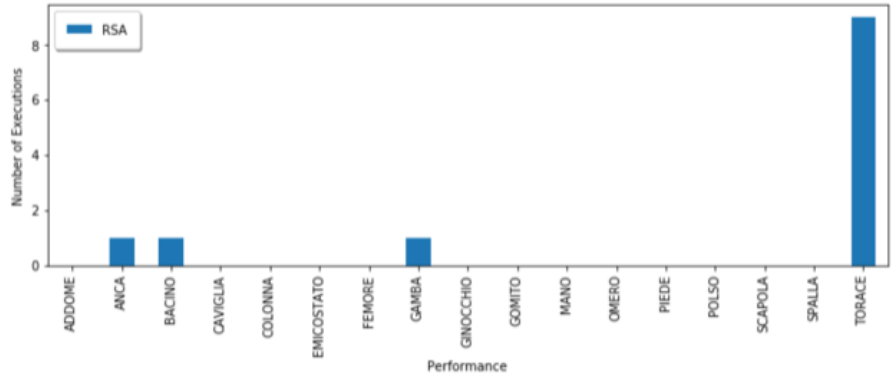

Figure 3.14: Typology of arrival requests of an x-ray exam from RSA.

3.4 Phases 3 and 4 : To-Be and process re-engineering

The previous phases are very important, even more so, if the goal of the work is not just an analysis of the data itself, but to provide some suggestions for optimising a real enterprise. It is easy to imagine that not all the improvements could fit all enterprises, a a perfect solution for one case is not sure to be available or desirable for all. An immediate example concerns the budget, certainly not all companies have the same budget and resources The context of the company should not be underestimated either. The pure economic aspect is not the only factor for better optimisation. It is very important to understand the company's objectives, values and principles. The healthcare use case is a perfect example. Although the economic aspect is fundamental, the quality of the service, therefore, of the care, should not be underestimated. Optimising processes like an assembly line, trying to get as many patients through as quickly

Table 3.5: Average times used for each macro set examination.

Body Parts	**Average time for exam**
Thorax	5 - 10 min
Arts and Ends	10 - 15 min
Trunk, Rachis, Spine segment	15 - 20 min
Hip and Pelvis	15 - 25 min
Whole spine	35 - 45 min

Table 3.6: Results of working time as a KPI.

Monitor	**Average working time**	Count
Accepted	36.24	77
Discharged	25.21	3
DOCrequests	69.26	20
IRVrequests	132.27	16
OADrequests	187.17	15
RSArequests	167.83	3
GPrequests	122.01	1

as possible, would not be optimal for the hospital. Leaving aside the fact that, for example, a manufacturing company is different from a service company. The latter always has to take into account the fact that working with the public will always have a human factor that might impact in some way. For example, a delay could create a queue. Furthermore, in this use case, the hospital's objective is not to get as many patients through as possible, but to treat as many patients as possible. Therefore, dedicating more time to the actual patients is not necessarily a waste of time. On the contrary, it could mean that once the patient is discharged, he or she is no longer back. Conversely, a dissatisfied or sick patient may return to the hospital or make emergency calls. This would mean using double resources for a single patient.

In conclusion, the analyses of the two previous phases are of fundamental importance to propose the To-Be re-engineering scenarios that are not just generally optimised, but are the most balanced and suitable possible for the analysed company.

In this section are showing some improvements of the process of OAD visits. It is explained how to move from an As-Is model to a To-Be model. The context analysis and the As-Is model are exposed to understand the needs; then, according to them, some possible optimisations are proposed.

3.4.1 From As-Is...

The OAD service is made by the patient's acceptance process (shown in Section 3.3.1 and the tour visits process. According to Figure 3.2, after the taking

in charge, there is the transfer of power. The CM provides OAD staff with the information about the new patients and they definitively enter in the daily workload of the OAD.

All patients receive home visits every morning. Some patients, with special conditions (poly-transfused or antibiotic therapy), may also receive an afternoon visit.

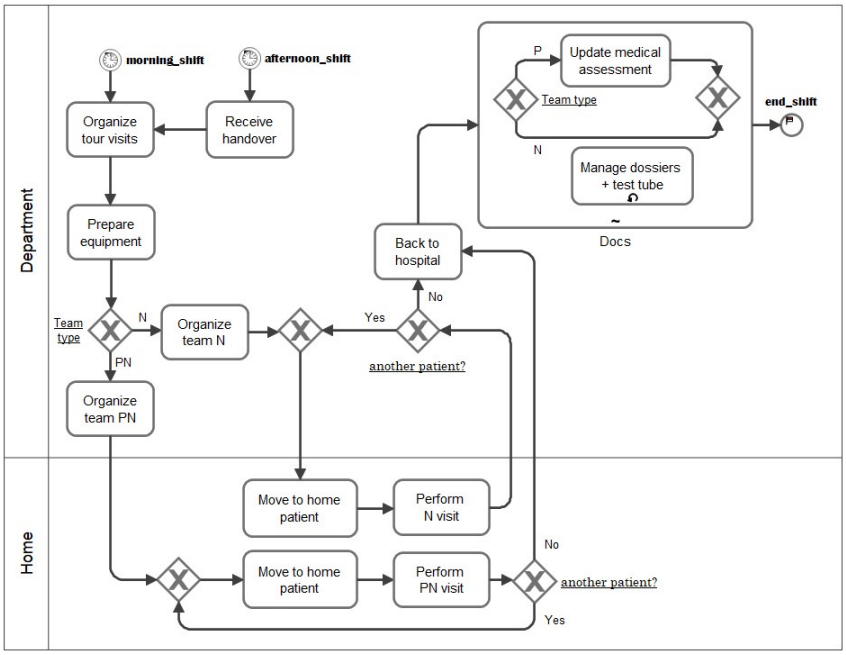

Figure 3.15: Business process model of the OAD tour visits.

At full workload, there are 7 nurses and 4 physicians in the morning, and 2 nurses and 1 physician in the afternoon. The staff is then divided into teams to carry out visits tours. The teams are composed as follows:

- Morning, 6 team:
  - 4 team: 1 physician (or 1 grad student) + 1 nurse
  - 2 team: 1 nurse
- Afternoon, 2 team:
  - 1 team: 1 physician + 1 nurse
  - 1 team: 1 nurse

Each team visits about 4 patients.

As shown in Figure 3.15), in the morning, all physicians and nurses together organise the tour visits (**Organize tour visits**). This activity consists

in analysing all the patients' situations according to four impact factors: medical and nursing complexity care, condition of the caregiver and geographical location of the house's patient. This allows to divide the whole amount of patients into balanced groups in the sense of time to spend in visits and time to go from one to the other. Each group of patients is assigned to a staff 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 patient assigned (**Prepare equipment**). On average at 9:00-9:30 a.m. each team takes an hospital car and leaves for its ride.

Once they arrived at the patient's home (**Move to home patient**), they carry out the visit.

According to the goal of the work, the model of the process could have more of less details.

In this first phase all the activities carried out at the patient's home are grouped together in one activity called **Patient visit**. It should be noted that for the same type of staff team the activities performed are multiple and different but similar in terms of type, time and responsibility.

Once the first visit is finished, the team heads to the second patient's house. The cycle resumes until the assigned patients are finished (gateway *Another patient?*); only then the team will be back to the hospital (**Back to hospital**).

The teams return to the ward more or less at the same time: around 12:30-13:30 p.m. In the hospital department both physicians and nurses have to complete some "administrative" tasks (**Update medical assessment** and **Manage dossiers + test tube**). The duties are different and specific to each of the two professional categories, including responsibility.

Here is the first big problem to be solve:

- For nurses: each one has to update 3 folders. The folders are on paper. They have to take paper notes in the patient's house and then report them on the official dossiers. Besides the risks of reporting errors and of privacy, there is a problem with the waiting queue. If the folders are on paper and the nurses are six at once, only one at a time can write.

- For physicians: there is the same problem of the waiting queue. They have to report the information in the HIS but there is only one computer.

In the meanwhile, at 12:30 p.m., the afternoon shift staff arrive at the department. All the present staffs do the handover: the morning staff tell the different patient's situation, one by one; and the afternoon staff receive the information (**Receive handover**) useful for organising the future work. Subsequently, they **Organize tour visits**, they decide the team composition, the nurse **Prepare equipment**, and the tour visit begins. All the activities are the same already explained in the morning, sometimes with some difference in terms of time.

The handover is mostly by voice.

Simulation and data analysis: monitors and creation of a complex generator

In this process there are two generators of events. The first one creates the morning transactions, while the second one generates the afternoon transactions. Both the generators are based on an input Excel file.

Figure 3.16 shows the first few lines of the Excel file.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	Team	N_patient	Shift	TT1	TV1	TT2	TV2	TT3	TV3	TT4	TV4	TT5	TV5	TR
2	PN	3	0	20	45	7	46	4	70	-	-	-	-	13
3	PN	4	0	21	33	24	31	14	28	13	27	-	-	15

Figure 3.16: Workload specifications. An example of the spreadsheet file used to generate the simulation.

Each line of the file represents all the team's visits:

- Team: indicates the team type N, PN.
- N_patient: the number of visits of the team on that shift.
- shift: indicates the shift of the team and is a useful flag for deciding the simulation flow in front of a gateway and for setting some customisation on the task's duration.
- TT: duration of the transfer to a patient's house.
- TV: duration of a given visit in a patient's house.
- TR: duration in minutes of the travel back to the hospital department.

Teams can visit between 3 and 5 patients. Therefore, the first team has only three patients to visit, so only the first three travel times and visit times are complete. Equally, the second team has four patients, so the last two columns are free. This is the reason for some empty cells. The number of patients is proportionate to the time available. If there are fewer patients assigned it is because they are geographically further away or because they require more time for treatment.

The software is similar to Colored Petri Network, so each transaction can be distinguished from the others easily by looking at transaction values like the transaction ID.

In the process, two matrices are used to store, transfer and visit times from Excel files (scenario attributes). A row of the matrix corresponds to a transaction; each row contains the whole team tour. Once created, all transactions are collected in a batch (from n to 1 transactions). Subsequently, the single transaction will disjoint at the level of team creation.

The simulator tool, iGrafx, allows to model the process in BPMN standard language, but it is also possible to add other instruments, such as monitors.

Table 3.7: Activity statistics (Minutes) As-Is.

	Activity Statistics (Minutes)		
	AvgCycle	***AvgWork***	***AvgWait***
Docs	52.58	30.00	22.58
Update medical assessment	60.96	30.00	30.96
Manage dossiers and test tubes	52.58	30.00	22.58

Table 3.8: Resource statistics (hours) As-Is.

	TavgUtil
Pm_Nurse	85.76
Pm_Physician	86.22
Am_Nurse	65.94
Am_Physician	59.05

During the process simulation, some monitors are introduced to detect the team activities. Simulation results are shown in Table 3.7, Table 3.8 and Table 3.9.

In Table 3.7, each activity (sub-process Docs, Update medical assessment and Manage dossier and test tubes) includes the average cycle time employed by the task (**AvgCycle**), the average working time (**AvgWork**) and the average waiting time (**AvgWait**).

It is significant to note that cycle time is divided almost in halfway between the actual working time and the waiting time in these particular activities.

Table 3.8 shows the average utilisation time (**TavgUtil**) for the whole week (cycle time of simulation) for each type of resource: physician and nurse, both morning and afternoon shifts.

Table 3.9 shows the statistics in the cycle time. For both the morning shift (**PmShift**) and the afternoon shift (**AmShift**) is described the average time of the cycle (**AvgCycle**), the standard deviation (**StdevCycle**), the average of real working time (**AvgWork**), the maximum recorded waiting time

Table 3.9: Monitor statistics (minutes) As-Is.

	Monitor Statistics (Minutes)				
	AvgCycle	***StdevCycle***	***AvgWork***	***MaxWait***	***AvgWait***
AmShift	367.36	30.81	337.05	86.02	30.31
PmShift	385.92	7.38	385.90	0.02	0.02

(**MaxWait**) and the average waiting time (**AvgWait**). Similar relevant observations about the waiting time are to be made on the data of Table 3.7.

Based on the results obtained, it can be seen that the main bottleneck is created by the updating of documentation when doctors and nurses return from their visits. In fact, this corresponds to one of the problems expressed by the staff. There is a large amount of waiting time that could be used in a better and more optimised way.

3.4.2 Phase 3: Analysis and choice of technologies

The problems arising from the last considerations of the previous section are logistical. The right technologies could be the solution to the problem. First of all, is important to choose the appropriate technology. When choosing it is crucial to consider not only the problem, but also the social and economic context of the company (for example, there are almost always limited funds available).

In order to propose an improvement, two different technologies are analysed: a digital platform for support the logistic and a telemedicine device.

The Digital Platform. A first solution is a prototype digital platform designed for physicians and nurses. The application takes into consideration the main pain-point and users' needs, specifically regarding the management and the logistical planning of the OAD.

The prototype digital platform, named GoCare, consists of software that enables medical staff to monitor the status of patients, schedule the home visit calendar, manage logistics and medical teams. The dashboard also allows the OAD staff (during the visit and back in the hospital) to update and share information helpful to manage the day-by-day visit reschedule. Moreover, the collected data allows health professionals to evaluate the OAD workload and its capacity to accept new patients.

The telemedicine, telemonitoring, and the analysis of behavioral habits suite, developed by Ticuro Reply (TM). The application enables the process of guaranteeing the management and continuity of care, by using integrated medical devices with real-time data monitoring capabilities. The suite also includes a secure channel that allows performing Televisit and Teleconsultation sessions, ensuring secure connections between patients and professional users or amongst professionals. The collected data and the possibility of remote and continuous assistance, allow health professionals to establish an interactive relationship with patients and their caregivers, providing them with personalised treatment paths, from anywhere.

- **The GoCare Platform.** GoCare is a prototype platform developed by Experientia. It is a management tool that helps doctors and nurses optimise the organisation and logistics task management. The platform provides medical staff with a visual and interactive dashboard (shown in Figure 3.17) to organise and manage the patient's assignment, grouping them into different visiting teams and time slots according to the impact

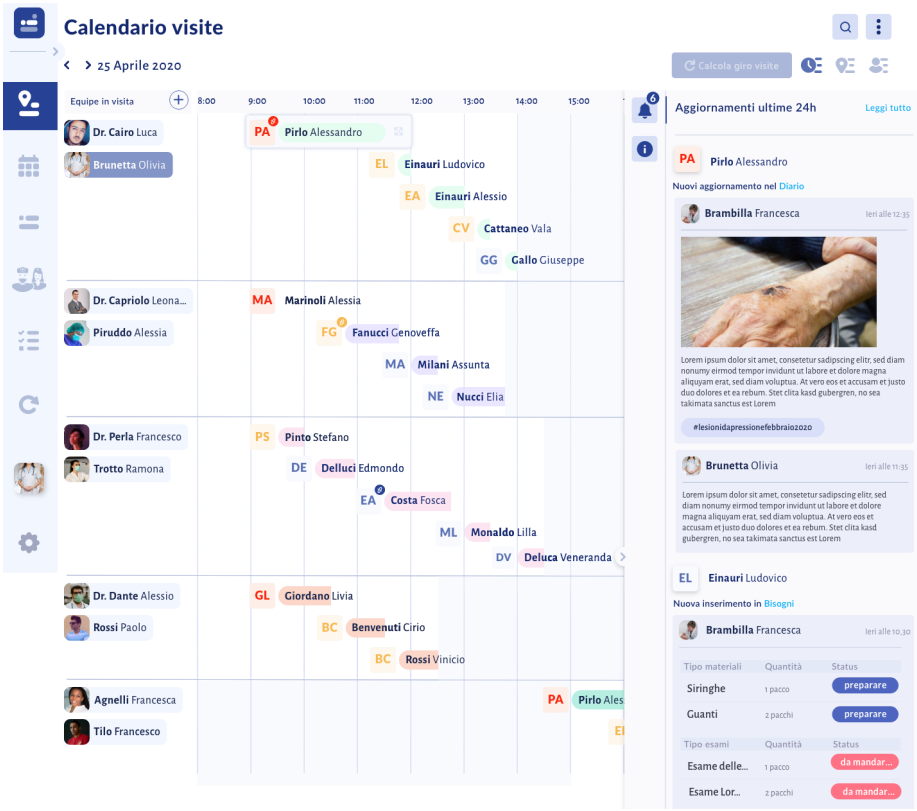

Figure 3.17: Screenshot of an example page of the GoCare platform. This image shows the team composition and assignment of patients to teams, distributed over the potential expected working time of the different patients based on the inserted complexity indices.

of specific indexes. The most relevant features taken into account by the platform are the medical and nursing complexity care, the condition of the caregiver and the geographical location of the various patients. Such indexes are already evaluated manually by the medical staff to schedule and prepare the visits. As shown in Figure 3.18, it is possible to see on a map how patients are distributed within the territory, and the dashboard allows manual changes. Also, the platform provides doctors and nurses the possibility of accessing the personal patient page, shown in Figure 3.19. Herein it is possible to update all information regarding the patient trend (including complexity and priority indices), exams to be considered, supplies and drugs required to be prepared for the next visit, and a section to fulfill with notes, useful to analyse and evaluate patient's status. The possibility to quickly update this information, as soon as the visit

Figure 3.18: Screenshot of an example page of the GoCare platform. This image shows the geolocation of the various patients, the assignment of patients to teams, and the proposed road hogs.

is complete, allows for time savings and reduction of risk of having stray information. In conclusion, unlike the current procedure, which consists of transcribing handwritten notes on paper and then returning them to the hospital, this platform allows having all information in one single shared place accessible to all the relevant medical staff.

- **The Ticuro Replay Platform.** During the hospitalisation period each group of patient-main caregiver will provided with the necessary tools of telemedicine via the Ticuro Reply platform [8]. The kit provided includes a sphygmomanometer, a pulse oximeter, a balance, a thermometer, a glucometer, a electrocardiograph, a spirometer (see attached technical datasheet). At the time of the delivery of the instruments, a specially trained nurse will give a short training to the primary caregiver and, if possible, to the patient, explaining how to use the various equipment. During pre-established time slots, the caregivers should carry out the detection of arterial pressure, peripheral arterial hemoglobin saturation, and tympanic body temperature twice a day, or once a day concerning body weight. The glucometer will be used exclusively by healthcare professionals in the case of patients requiring capillary blood sugar monitoring and the electrocardiograph will be used according to the clinical progress of the patient, always by the health care professional. All the data recorded by the instruments will be automatically sent, in real-time, to the data col-

[8]Ticuro Reply platform by Santer, Reply S.p.A., Turin, To, Italy

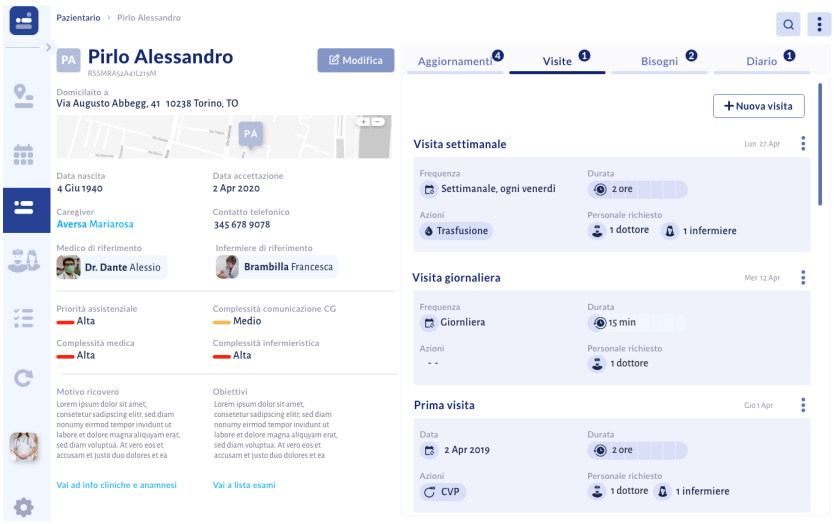

Figure 3.19: Screenshot of an example page of the GoCare platform. This image shows the patient's page where it is possible to consult and update the patient's actual data, their level of complexity, and information about the visit they need.

lection platform Ticuro Reply and will be visible by medical and nursing staff on the same platform (as shown in Figure 3.20). This allows not only timely interventions, but also preventive interventions in case values start to be outside the parameters, but not yet critical to make the caregiver or the patient understand the need to make an emergency call.

3.4.3 ... To To-Be: Phase 4

The scenario analysis and the reorganisation of the process introduce a simulation of business processes to investigate changes in the As-Is model by generating the new To-Be version. It allows investigating the performance of the business process with the introduction of technological applications and e-Health technologies.

To explain the improvements that the chosen technologies can bring, some activities of process in Figure 3.15 have been expanded, as shown in Figure 3.21. The extended activities are those that will be impacted by the re-engineering and they were (in the previous process) **Docs** and **Perform visit**.

In particular, the process activity **Perform N visit** include:

- Screening situation
- Evaluate +treat patient
- Update Nurse Record (paper dossier)
- Write data for update folders (paper notes)

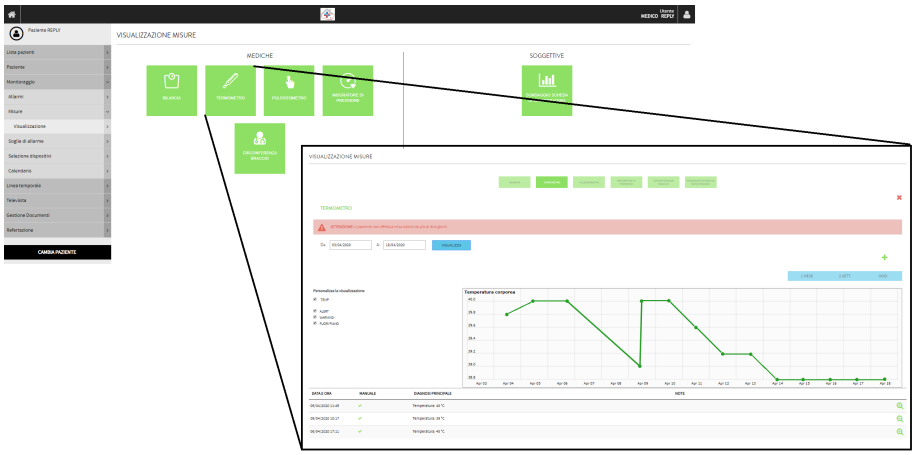

Figure 3.20: Screenshot of an example personal patient's page in the Ticuro Reply platform visible to hospital staff. For each patient active telemedicine devices are visible and for each device it is possible to view the data collected directly concerning the patient.

- Plan next visit
- Educate on treatment

The process activity **Perform PN visit** include the activities of the task "Perform N visit" plus:

- Visit patient
- Update Medical Record (paper dossier)

The process activity **Update medical assessment** include:

- Plan diagnostic assessment (PC)
- Plan medical advice (PC)
- Update handover (PC)

And finally, the process activity **Manage dossers + test tube** include:

- Update documents
  - Update folder (paper dossier)
  - Update patient organize (paper dossier)
  - Update patient visits (paper dossier)
  - Update delivered materials (dossier paper)

  - Update nursing records (paper dossier)

- Send blood samples to Laboratory
- Prepare equipment for next visit

Looking at Figure 3.21, the coloured activities are those that are directly affected by the improvements (GoCare: yellow; Ticuro: blue).

The Ticuro platform could supports the organisation before leaving the hospital and during the visit. During the morning organisation, the medical staff has to check the measurements of the vital parameters measured with the telemedicine devices. These results may influence the choice of pharmaceuticals to bring to patients' home. Currently, these vital parameters are detected by the nurse for each visit as a first step. If they are measured by caregivers several times a day, this action is not necessary during the tour visit.

On the other side, at the moment, nurses have paper folders in which they take notes during the visit. Once in the office, they transcribe these notes in three different paper dossiers. This process leads to problems:

- Waste of time in reporting the same things twice.
- Increasing the chance of making mistakes.
- Increasing the waiting time in the process.
- Privacy.

Using the GoCare platform, nurses can write directly on a personal tablet at the patient's house, saving both the transcript activity in the office and the wait to do it.

The Table 3.10 and Table 3.11 show in detail the differences between the As-Is and the To-Be processes in terms of changing actions, human resources,

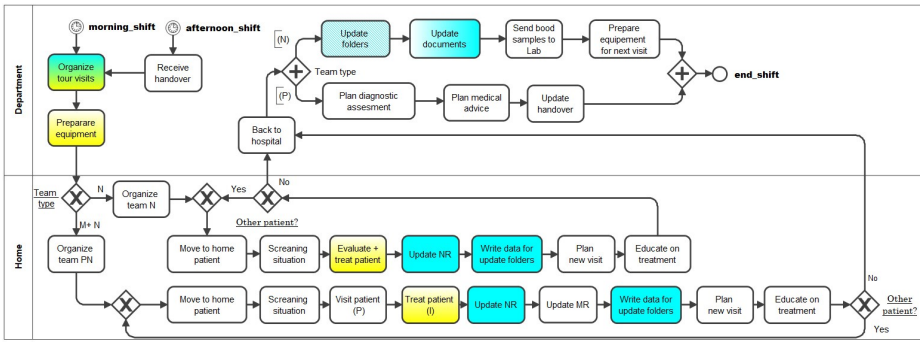

Figure 3.21: Detailed process of the OAD home tour visits.

Table 3.10: Implementation of the telemedicine using the Ticuro Reply platform: comparison between the As-Is and the To-Be model of the tour visits process.

	As-Is	**To-Be**
Activity	***Organize Tour Visits***	***Organize Tour Visits***
Action	-	Check vital signs for all patients
HR	All staff	All staff
ER	-	Tablet
Time	-	15-20 min
Activity	***Evaluate+ Treat patient***	***Evaluate+ Treat patient***
Action	Evaluate+treat +Check vital signs	Evaluate+treat -Check vital signs
HR	Nurse	Nurse
ER	Medical equipment	Medical equipment
Time	Treat+(3-15 min)	Treat+ 0 min
Activity	***Treat patient***	***Treat patient***
Action	Treat + Check vital signs	Treat - Check vital signs
HR	Nurse	Nurse
ER	Medical equipment	Medical equipment
Time	Treat+(3-15 min)	Treat+ 0 min

equipment needed, resources involved, and expected average time for each activity. The analysis only considers the coloured activities of Figure 3.21, as they are the only ones that change.

In particular, Table 3.10 specifies the difference made with the implementation of the Ticuro Reply platform while Table 3.11 specifies the difference made with the implementation of the GoCare platform.

After re-engineering the process according to these modifications, some simulations are carried out using the same generators of the previous As-Is simulations.

The results in Table 3.12 and Table 3.13 demonstrate that the digitisation on one side and the telemedicine on the other are indeed capable of optimising the process.

Looking in particular at the waiting time columns on the two To-Be tables, it is easy to understand the significant contribution provided by these types of improvements. In fact, they significantly reduce the workload of resources and the waiting queues once the staff returns to the department.

This saved time could be used to add an extra patient for each team or to extend the geographical area of the service, which currently covers about half of the city of Turin.

Table 3.11: Implementation of the GoCare platform: comparison between the As-Is and the To-Be model of the tour visits process.

	As-Is	**To-Be**
Activity	***Organize Tour Visits***	***Organize Tour Visits***
Action	Organize plan visits	Organize plan visits
HR	All staff	All staff
ER	Paper dossier of: patient organize, patient visits, addresses, nursing records	Tablet
Time	90-120 min	30-50 min
Activity	***Update NR***	***Update NR***
Action	Update on paper	Update on platform
HR	Nurse	Nurse
ER	Nurse record/ folder	Tablet
Time	10min	10min
Activity	***Write data for update folder***	***Write data for update folder***
Action	Write data on notes paper	Write data on platform
HR	Nurse	Nurse
ER	Paper notes	Tablet
Time	10-20 min	10-20 min
Activity	***Update documents***	***No activity***
Action	Update paper dossier patient organize, patient visits, delivered materials, nursing records,	-
HR	All nurses	-
ER	Paper dossier 1patient organize for all, 1patient visits for all, 1delivered materials for all, 1nursing records for each,	-
Time	(30 min X 6 nurses)	0 min

Table 3.12: Activity statistics (minutes) To-Be.

	Activity Statistics (Minutes)		
	AvgCycle	***AvgWork***	***AvgWait***
Docs	21.76	17.11	4.65
Update medical assessment	39.48	30.00	9.48
Manage test tubes	21.76	4.86	16.90

Table 3.13: Monitor statistics (minutes) To-Be.

	Monitor Statistics (Minutes)				
	AvgCycle	***StdevCycle***	***AvgWork***	***MaxWait***	***AvgWait***
AmShift	330.36	21.30	324.10	29.02	6.26
PmShift	373.19	16.97	373.17	0.02	0.02

3.5 Process Mining

In addition to the use of BPM and simulations, process mining techniques can also be useful for investigating the organisation of healthcare processes.

In this section is shown an experiment that adopts process discovery technique from Process Mining [114] to automatically extract relevant information from event log data concerning the patient's workflow [306].

This example focuses on two research problems:

- If it is possible to derive digital information even in the absence of an information system that accurately collects data.
- On this basis, if it is possible to automatically derive the healthcare process.

The PALIA Process Discovery algorithm [115][9] is adopted to perform process discovery from the data log.

What is reported here has been extrapolated from an article that we previously published [27].

3.5.1 Log and process discovery

This experiment is based on OAD admission process already contextualised in Chapter 2, Figure 3.2.

[9]PALIA Algorithm has been successfully used in several medical problems like surgery [115], Emergency Rooms [157], or Diabetes [87], among other health solutions.

Table 3.14: Data log made by hospital database.

ID	SDO	PROV	CALL	HaH1	OUT	END
045	2017500110	SPEC	02/02/17	06/02/17	ORD	14/02/17
048	002017500552	PS	21/06/17	27/06/17	TRASF	09/07/17
045	2018500025	MDB	04/01/18	04/01/18	DEC	25/02/18

It is very important to underline that the availability of real service data is at the core of the healthcare business process mining perspective [201, 253]. Nevertheless, the adoption of a complete HIS in most hospitals has not been yet achieved, and the healthcare managers are more often dealing with conventional aggregated information. A large part of HIS is actually not well equipped for process analysis, whereas data can be difficult to extract, including several well-known problems concerning data quality [208]. Moreover, as mentioned above, some of these data are not reported at all or not reported in the HIS but elsewhere.

Process Mining can support healthcare professionals in truly understanding the process, not only by discovering the process but also by performing assessments to enable the application of Value based healthcare [157].

Process discovery begins with the analysis of data recorded in the HIS representing the data log (Table 3.14). The extracted patient information includes: patient number (ID), corresponding case (SDO), provenience (PROV), first call to the CM for the evaluation (CALL), admission date (HaH1), type (OUT) and discharge date (END).

The result of the process discovery is the model presented in Figure 3.22. The acceptance process was automatically extracted from the raw data.

The process starts with a call to the CM (CALL0), the patient is taken in charge (HaH1) and follows three types of output: the ordinary management of HaH activities (ORD) until dismission (END), the transfer of the patient, for example, surgery or the recovery to a hospital ward (TRASF), or death of the patient (DEC), during the admission process or during the OAD hospitalisation.

The three types of output (TRANSF-ORD-DEC) are part of the output of the acceptance process of Figure 3.2 (Rejected-Accepted).

As mentioned, not everything is recorded in the HIS. It is recorded if the patient has at least the first interview with the CM and then if he/she is transferred to another facility/ hospital in the traditional way, if he/she is taken in charge by the OAD, or if during the process dies. The various individual intermediate meetings are not officially recorded. So the model that can be extracted automatically via the data log is the one shown. This is one of the limits of using real databases.

However, with process discovery it is also possible to reveal less intuitive information. A second model is presented in Figure 3.23, which also describe

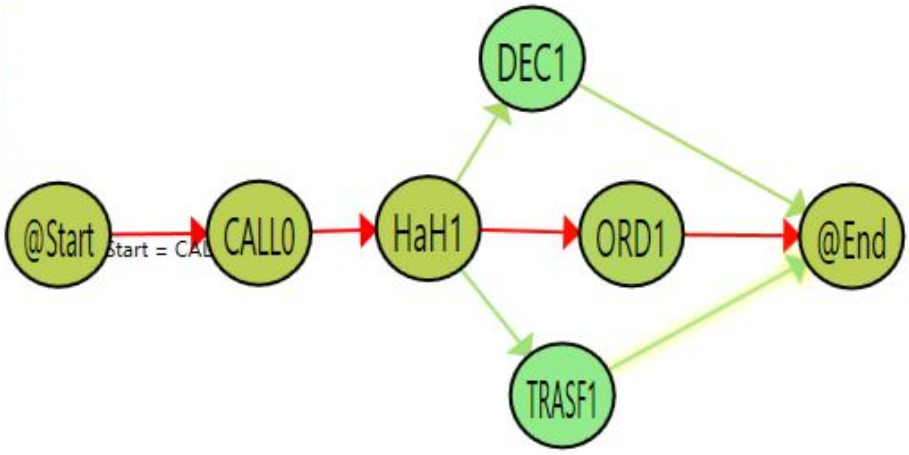

Figure 3.22: Output of acceptance process of OAD service.

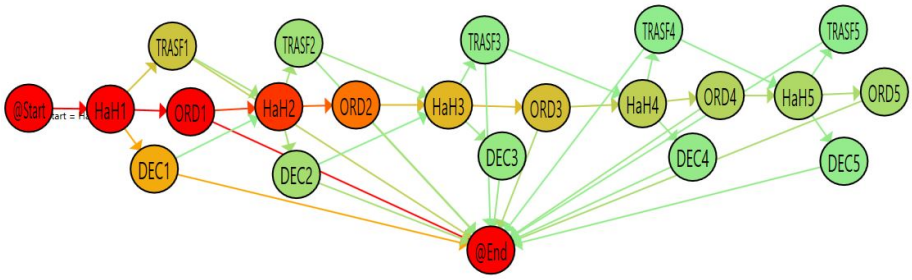

Figure 3.23: Process discovery from OAD admission database with occurrence details.

the amount of occurrences. Here, the colour reflects the frequency of each occurrence: as the number of occurrences increases, arrows and circles tend towards the red colour. As clearly indicated by the figure, the most frequent output is patient hospitalisation (only once) and then the ordinary discharge.

Surveying the database, it is immediately possible to observe that the service works well, in general, as most patients are discharged in the ordinary way. In fact, further investigation identifies that most patients, once discharged, do not return to the hospital. Moreover, it can be observed that the number of re-hospitalisation is not very significant. On one hand, must always bear in mind that this is a geriatric department and minimal re-hospitalisation is physiological. On the other hand, a high rate of traditional re-hospitalisation or transfer could have meant an imprecise selection of patients by the CM.

In conclusion, with process mining techniques it is theoretically possible to

perform an analysis of healthcare process, automatically deriving process information from not well-structured data (for example, data that is not recorded in standard XES (Extensible Event Stream) event log format). However, so far it is a good technique when used on well-structured or previously created ad hoc databases. The main problem using real data is that actually many HISs are still not process-aware.

In the future, the understanding of the advantages of using process mining techniques might push towards a wider adoption of HIS in the near future, as it is actually happening in the industry.

Chapter 4

Risk, risk management and regulatory compliance

4.1 Introduction

Risk is part of every business activity and therefore part of every business process [4, 148]. The occurrence of a risk may lead to loss of quality, increased costs, time delays, complaints, and legal problems [53].

From this chapter on, it will begin the second part of the thesis: the part on risk management and regulatory compliance.

As mentioned (see section 1.5), the goal is to balance the logistic organisation with risk and compliance. Having deal with the first topic in the previous chapters, from this chapter we will begin to address the second issue.

In this third Chapter it will show the definition of risk and what business risk management is. It will explain the difference between some types of risk, in particular procedural and legal risks. It will analyse methodologies, instruments and tools to manage them, in particular in the field of healthcare.

In order to support the manual work and thus allow a semi-automation of the legal compliance of processes checking, the state of the art and some IT tools using a logic-based language are shown.

4.2 Business risk

In classical decision theory, *risk is conceived as the variation in the distribution of possible outcomes, their probabilities and their subjective values* [204]. With this definition, *the risk can be expressed mathematically as the probability of occurrence of loss or gain multiplied by the relative magnitude* [163]. *The Project Management Institute defines risk as "an uncertain event*[1] *or condition, that if*

[1] In ISO 31000:2018 "Risk management — Guidelines" a definition of event is given. *Event* is defined as occurrence or change of a particular set of circumstances:

it occurs, has a positive or negative effect on a project's objective.

[171]. The key element of this definition is that the effect of the uncertainty, if it occurs, may be positive or negative on the objectives of the planned endeavour. Many things are uncertain, risks are by definition only those uncertainties that will have an impact on the project if they occur. Uncertainty refers to a situation that may, or may not, occur. Whereas every process has an intrinsic level of variability, the existence of variation in a process is not a risk, it is a guaranteed fact. Typically, there may be uncertainty about the degree of variability in a process and/or uncertainty about the actual variability in the process remaining within acceptable limits. Quality processes do not attempt to eliminate variability, but to minimise unexplained variability and to achieve outcomes that are consistently acceptable [314].

Since risks are commonly associated with negative outcomes [204], the distinction between risks and problems is often unclear. A risk is not a problem, but rather a "potential problem" that could arise from taking a particular decision [83].

Perhaps, the most widely acknowledged definition of internal controls is from the Committee of Sponsoring Organizations of the Treadway Commission (COSO)[2]. It is defined as *a process, effected by an entity's board of directors, management and other personnel, designed to provide reasonable assurance regarding the achievement of objectives regarding* [272]:

- *Corporate strategy*
- *Effectiveness and efficiency of operations*
- *Reliability of financial reporting*
- *Compliance with applicable laws and regulations.*

When a person makes an investment, he or she bears the possibility of suffering damage or negative consequences upon the occurrence of an event not always foreseeable and as a result of the business in which he or she has invested. This is the *business risk: "the probability of unintended consequences of an event or decision"* [83] *that could jeopardise the achievement of a goal.* Therefore, it is closely connected to the initial expectation and has an intrinsic concept of uncertainty [232].

The risk of the enterprise, although unitary, is the result of a plurality of factors and comes from various sources. Some of them are [69]:

- Competitive risk: linked to the competitive structure and the degree of technological development of the market in which the company operates.

- Note 1 to entry: An event can have one or more occurrences, and can have several causes and several consequences.
- Note 2 to entry: An event can also be something that is expected which does not happen, or something that is not expected which does happen.
- Note 3 to entry: An event can be a risk source.

[2]https://www.coso.org/Pages/default.aspx

- Regulatory risk: linked to the possibility of changes in legislation affecting the management of the company.
- Political risk: linked to political decisions involving certain sectors or the economy as a whole (e.g. the nationalisation of certain enterprises has the constraints and the return of capital).
- Natural risk: refers to the occurrence of unforeseen natural phenomena (such as fires, earthquakes and hurricanes).
- Risk of raw materials: linked to the possibility that the price of a given input undergoes fluctuations that affect the economic and financial conditions of the enterprise.
- Interest rate risk: linked to fluctuations in interest rates, which may lead to, for example, changes in borrowing costs.
- Foreign exchange risk: affects companies that hold assets and liabilities in foreign currencies, exposing them to losses and gains related to changes in exchange rates.

4.3 Business risk management

Risk management is the technique of managing enterprise risks. Its purpose is to reduce or neutralise potential risks, with the aim of safeguarding, through the use of various types of instruments and under the best cost conditions. The assets of the company against losses that may affect it in the course of its business and, at the same time, offer opportunities for betting on positive performance [312]. The ISO (International Organization for Standardization)[3] defines the risk management as the *set of coordinated activities to direct and control an organisation with respect to the risks to which it is exposed.* In other words, risk management can be seen as the systematic process of identifying, analysing, evaluating and mitigating risk.

There are several profiles in risk management: economic, we talk about risks; legal, because sometimes problems have criminal or civil profiles, and it is a question of quantifying damages for compensation: and finally, technical, because it is important to take into consideration the production processes and the technologies used.

In the light of risk management, the definition of risk becomes more operational. As foreseen by the Basel Committee, the operational risk is the risk of suffering losses resulting from the inadequacy or malfunction of procedures, human resources and internal systems, or from external events. This type includes, among other things, losses resulting from fraud, human errors, business interruptions, unavailability of systems, contractual breaches, natural disasters.

[3]Specifically, in 2009, the ISO (International Organization for Standardization) made public the ISO 31000 standard on "Risk Management - Principles and Guidelines" (updated later in 2018) and the ISO 31010 standard on "Risk Management - Techniques for Risk Assessment".

Operational risk includes legal risk, while strategic and reputational risks are not included[4].

Risk Management is fundamental to the business and, therefore, the provision of all those mechanisms that allow facing possible risks, arising from defects in the process or external.

Risk assessment is the methodology used to determine hazards or sources of risk. It consists of identification, evaluation, and actions put in place to reduce risk. In the field of risk management, risk analysis focuses on the possibility of preventing errors and unfavourable situations that can become a major cost for the company.

These steps are made in order to carefully consider all relevant information before making decisions about the selection and implementation of risk control measures to ensure that the selected measures are relevant, effective and sustainable. As shown in Table 4.1

Risk Assessment	**Risk Management**	**Risk Control**
Preliminary analysis	Analysis of the activities generating the identified risks	Monitoring of the risk level and comparison with the target risk
Risk identification	Evaluation of the organisational and structural safeguards already adopted by the Company	Control and management of residual risk
Risk measurement	Definition and choice of the most efficient strategies	Assessment of the need for further corrective actions
Assignment of the "Target Risk"	Adoption of further interventions for risk mitigation (e.g. risk transfer/hedging process)	Evaluation of the cost/benefit trade-off

Table 4.1: Steps and comparisons between Risk Assessment, Risk Management and Risk Control.

The risk can be managed by:

- Transfer: insurance policy.
- Avoidance: giving up the goal.
- Mitigation: by activating controls.
- Acceptation: doing absolutely nothing.

Risks are accepted when they have a low impact even if the probability is high [118, 91]. The cases in which a behaviour is obligatory or justified by strategic considerations that escape economic quantification are exempt from this logic.

[4]See www.gazzettaufficiale.it

However, risk can also be a risk-opportunity: taking advantage of the risk because it could lead me to an opportunity.

It is essential to be aware of the risks, to implement one of these four strategies and to manage the risks it is necessary to know them, this means:

- Identifying the risks, which can come from:
  - External factors
  - Internal factors
- Evaluate/measure their potential effect on the objectives (possibly in terms of financial return for the funding entities) [232, 69, 73].

Therefore, the risk management objectives are:

- Helping to maximise business profit while minimising costs.
- Serenity and tranquility in management.
- Continuity of productive life given sufficient risk protection.
- External (towards customers and suppliers) and internal (towards employees) image and security.
- Reducing and eliminating the likelihood of business failure.
- Consistency with the company's general objectives.

The adoption of a Risk Management model produces both an immediate impact on the correct management of corporate risks, and a medium-term impact in the development of a correct corporate risk management culture, producing behaviors consistent with the objectives of risk containment and minimisation of risk management costs.

This model should be seen not as a "burden" on the activities and responsibilities of management, but as an effective operational tool to facilitate the performance of corporate functions, improving the perception of corporate security both internally and internally outside the company.

4.4 Procedural risk: improvement methods and risk analysis

When we are faced with processes-related problems in the reality of companies, we encounter a number of difficulties:

- Real processes are generally complex and involve various business functions. These may have different visions of the company, different objectives, reactions to the need for change, ambitions regarding process control: each process analysis and restructuring action, therefore, requires a lot of prudence.

- When starting a corporate restructuring project, you are not faced with a "blank slate": every company generally has a large number of applications and systems inherited from even distant times, whose documentation has been lost and which use different platforms. Especially, if there have been mergers between companies, integrating all this is not easy and it is unthinkable to "erase" everything and "do things all over again".
- Processes restructuring implies the existence in the company of a workgroup capable of interacting with the company management, with expertise in various fields (such as analysis, design and process optimisation), with the ability to manage data integration projects and complex application management projects (like workflow engines, and so on). Furthermore, any initiative of this type has little chance of success if there is no strong sponsorship from the top management within the company.

Risks can be summarised in three main factors:

- Complexity of processes
- Technological skills
- Corporate culture

Often, during the analysis of an activity (or even a process) very specific problems are highlighted, for example, a large number of errors or rejects to be reworked in a production activity (or sub-process). In this case, for the restructuring of the process, it is useful to initially seek possible local solutions for the activity or the sub-process itself.

The analysis of a problem can be conducted with Cause → Effect Diagrams, also called "herringbone", in which the "head" is the problem, the "thorns" are the causes [47, 264, 107, 4].

4.4.1 Root Cause Analysis

Root Cause Analysis (RCA) is a structured investigation that aims to identify the true cause of a problem, and the necessary actions to eliminate it [33].

RCA is a methodology applied to the study of the causal factors of an adverse event[5], or more generally of an accident, which is based on the organisational conception of the error. In fact, the analysis is not limited to identifying the error or shortcomings closest to the event, but aims to analyse the entire process that generated the event itself. The main objective of this methodology is to get to understand in depth what happened, why it happened and what can/should

[5] Adverse event is defined as An incident that resulted in harm to a patient. Intended as any unexpected, unintentional and undesirable event that has caused or had the potential to cause damage to a patient, visitor or operator, that is, any event involving the malfunction, damage or loss of equipment or property, or any event that could give rise to litigation. Adverse events can be predictable and unpredictable. An adverse event attributable to error is "a foreseeable adverse event". See The Agency for Healthcare Research and Quality (AHRQ) Common Formats for Event Reporting – Users' Guide, May 2017.

be done to prevent it from happening again. That is to find the so-called root cause, i.e. "*the most basic cause that can be reasonably identified and is in the power of management to control*" [236].

Analysing the definition:

- "Basic cause" means the reasons at the origin of the concatenation of circumstances for which an event occurred and on which it is possible to intervene to prevent its recurrence (reminding an operator to be careful does not avoid the possibility that an event happen).
- "Reasonable identification" means that the investigation must reconstruct the picture of the situation in which the event occurred while respecting suitable times and costs.
- "Management control" emphasises that the investigation must highlight the possible intervention actions by the company management (it makes no sense to propose solutions that do not exist or on which the manager has no competence).

The root cause is therefore a deep cause that is generally not found in the immediate circumstances of the event. The identification process is also complex and resource-intensive, and therefore there are limits of reasonableness in investigations. In particular, the root causes are generally located at the level of latent failure, i.e. at the level of organisation and work environment. Therefore, it is necessary not to focus on errors and violations (active failure), but always to look for the critical issues at the level of latent failures [107, 47, 264].

To carry out the analysis, proceed according to the following steps:

- Identify the problem.
- Identify as many causes as possible through group meetings ("brainstorming") and proceed through a progressive breakdown of the problem. To do this for each cause, the main question is: "why did things happen the way they did?". By applying this question repeatedly, the cause is in turn considered as a problem to refer to increasingly more detailed causes, thus not only the immediate causes of the problem but also remote ones.
- After having exhausted the causes, it is necessary to "weigh them". The person conducting the analysis must assign relative percentages to the causes based on the experience of its members. Alternatively, if there is a historical series on the occurrence of the problem under analysis, it is possible to calculate the relative probabilities of the individual causes directly.
- Once the cause $\rightarrow$ effect diagram has been constructed, it is important to select the most relevant causes. In this way, it is possible to intervene in a targeted manner and apply the most suitable strategies to solve the problem [107, 47, 264].

For the selection of the causes is used:

Pareto's law: most of the effects are due to a small number of causes

The analysis of multiple situations in which the law has been applied has allowed to note that:

> Law of 80/20: generally 80% of the results depend on 20% of the cases[6].

To conduct the Pareto diagram:

- The causes are ordered in order of importance by decreasing frequencies (percentages).
- A histogram graph is created by adding the frequencies for each branch.
- By introducing a cut-off on the cumulative graph corresponding to 80% of the distribution, the sub-set of causes that causes 80% of the problems is obtained.

Pareto's law explains that this sub-set typically comprises about 20% of all causes [100, 107, 47, 264].

Starting from the causes identified with the Pareto Diagram, an FMEA (Failure Model and Effects Analysis) can be carried out, which is particularly important when it is essential to assess the product reliability (towards the customer) of an activity or process [100].

4.4.2 FMEA method

Failure Model and Effect Analysis (FMEA) is a qualitative analysis intended to define what could happen (the failure/error mode) if a defect, an omission or an error occurs[7].

FMEA is a systemic technique for identifying and preventing problems with products or processes before they occur. For this reason, it cannot be classified as a problem-solving technique. However, it has been shown to be effective when

[6] These laws are widely applied in the most diverse fields, for example:

- Economics: 20% of customers produce 80% of a company's turnover. 20% of sellers make 80% of sales. 80% of complaints come from 20% of customers. By eliminating 20% of defects, 80% of defects are eliminated.
- IT: 80% of the execution time is used by only 20% of the instructions of a program. 80% of visitors to a site only see 20% of the pages.
- Logistics: 20% of the goods in the warehouse provide 80% of the handling. 80% of the products stored in a warehouse belong to 20% of suppliers.

[7] The Failure Mode and Critical Effect Analysis (FMECA) adds a quantitative path aimed at making consistent operational decisions. In use now when FMEA is referred to it mean FMECA.

applied retrospectively to highlight critical points and prioritise them in order to intervene with continuous improvement tools to support changes.

The analysis correlates the causes of defects that may arise in a given situation with the effects of those defects (failures) in relation to what the customer expects and the controls (in use or planned) to detect those defects in advance and reduce the likelihood of any potential failure reaching the customer.

These techniques formalise the mental processes normally adopted by designers, who ask themselves implicit questions such as:

- What are the weak points of my project?
- At what point in the production process is a failure most likely to occur?
- Which of the possible product failures could be eliminated - or its probability of occurrence reduced - by modifying the design?
- What damage could be caused to the user or the manufacturer if a fault occurs in the production process or in the product?
- What is the most urgent change?
- Which is the most convenient?

A distinction is made between project FMEA and process FMEA.

The project FMEA aims to reduce the risk of defects/errors in a good or service caused by a failure or incorrect consideration of the possibility of failures/errors at the design phase, always referring to the end customer. By taking into consideration all possible failures/error modes in advance, FMEA allows to objectively evaluate the project and its alternatives, to foresee tests and controls and to provide a reference against which to compare the subsequent, "real" product behaviour.

In the process FMEA, the goal is to lower the risk of defects/errors in a good or service as a result of of poorly executed or non-executed operations or activities during the production/supply process. The analysis takes into consideration in advance all possible errors in the execution of the process and thus allows the inclusion of tests and controls, the development of procedures, the preparation of countermeasures such as instructions for use or complaint management. In the case of process FMEA, the customer is both the final and the intermediate customer. Support is provided by the competence of the employees and by all the information that can be obtained from the complaints of the end customers, from the reports of the intermediate customers, from what is known about corrective actions for defects in similar products or services [100].

Methodology

The analysis starts with the description of the process: the description of the correct performance of all the individual activities necessary to achieve the service/good. This is followed by a list of all the possible factors that contributed

to or caused the occurrence of the accident or near-miss[8], trying to trace back to the most distant causes, the roots of the event, followed by a list of their effects and error/failure modes[9].

Process ⇒ Cause → Effect → Failure

Therefore, the starting point is the Pareto Diagram. From here, the correlation of the causes of defects and failures is evaluated by means of a risk index (calculated for each sequence Cause → Effect → Failure), which can be seen as an indicator of the potential criticality of the process. In this way, it is possible to determine the priority of the intervention with the relating corrective actions [100].

Calculation of the risk index

The analysis is carried out by assessing three indicators:

- SEVERITY (S): indicates the severity that each single fault, if it occurs, assumes for the Customer. It is rated on a scale of 1 (not serious) to 10 (extremely serious).
- OCCURRENCE (O): indicates the probability that the sequence (Cause → Effect → Failure) occur, taking into account controls currently in place. O is rated on a scale of 1 (the fault has a very low probability of occurring) to 10 (it almost certainly occurs).
- DETECTION (D): indicates the ability that the current controls have to detect and stop the sequence (Cause → Effect → Fault) before the potential fault occurs. D is rated on a scale of 1 (it is almost certain that the current controls will detect the fault) to 10 (it is almost certain that the current controls will not detect the fault).

Introduce a risk index or RPN (Risk Priority Number) of the process given by:

$$RPN = S * O * D(Itcanrangefrom1to1000) \tag{4.1}$$

[8]Near miss is defined as patient safety event that did not reach the patient, in ISO/TS 20405:2018 Health informatics — Framework of event data and reporting definitions for the safety of health software. Intended as any occurrence that could have bus has not (fortunately or for management skills) originated an event.

[9]Especially in the health sector, it is clear that the more competent (or able to obtain information) who is called upon to develop the analysis is, the more possible failure modes will be identified. In addition, the effects of the failure, as far as the applications of the method in healthcare organisations are concerned, are described from the patient's point of view and on the bases of experience and knowledge available in the literature. These effects can be minimal or catastrophic, such as death or severe functional damage. Finally, the last element to be considered is the possible cause of the error/method of failure whose analysis is based on a strong subjective component concerning the competence of the experts and the access to information.

A measure of the risk associated with the actual occurrence of a fault is obtained which can be used to determine, for example, priorities for action [100, 92, 73].

The scores, taken individually, have little significance. On the other hand, the product of the three judgments represents the most critical elements of the project or process to a fair degree of approximation. The fact that it is used by a multidisciplinary working group which must reach a consensus on scoring moderates the negative aspects of the subjectivity of the evaluations, and the result constitutes good material for decision-making.

The RPNs obtained are sorted in descending order: the threshold up to which action is taken depends on considerations to be made on the spot (e.g. according to the Pareto criterion 80-20).

Once the critical points have been identified, action is taken using problem-solving tools, collecting specific data and information and planning the most appropriate preventive measures [100].

In conclusion, the operative steps for create an FMEA are:

- Define the object of the analysis.
- Clearly defines the project or process to be studied.
- Describe the correct way of implementation (service) or operation (good).
- Perform qualitative analysis describing the error/failure modes, their effects and possible causes.
- Build the three necessary rating scales: severity of the effect, probability of the cause, detectability of the fault/error.
- Carry out the quantitative assessments with reference to the three elements above.
- Calculate the risk priority index (RPN).
- Sort by descending index.
- Making decisions to lower the level of risk (control, reduction, elimination).

4.4.3 Risks and BPM project

While the phases of the methodology represent an ideal process of continuous management strategy, its execution is subject to numerous risks that need to be managed. Some of these risks occur in a specific phase, while others are specific to the transition between two phases

Table 4.2 lists the common risks encountered in and between these phases.

Most of the risks identified reside in:

- A discrepancy in the methods used in different phases.
- A lack of clarity in the individual phases or in their results.

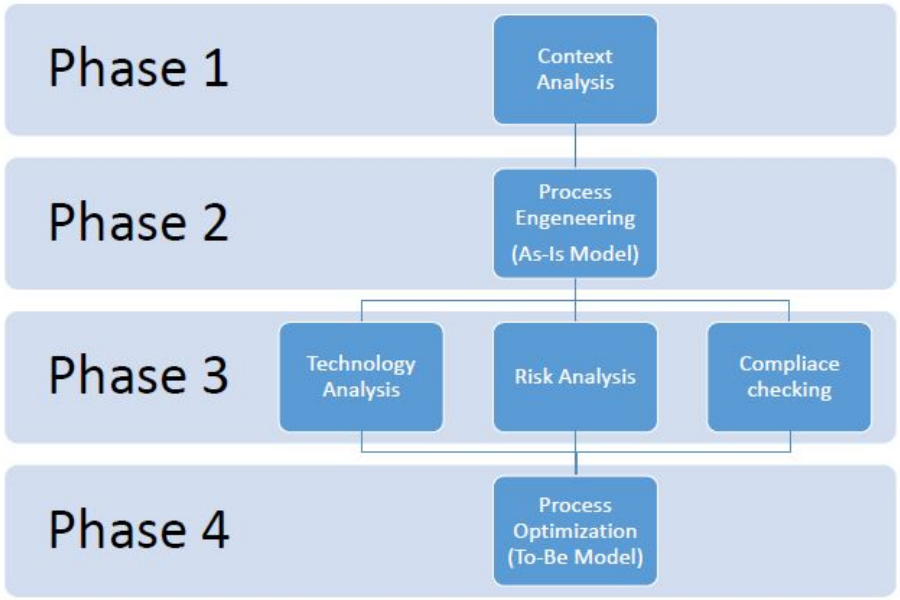

Figure 4.1: Phases of BPM methodology.

- A mismatch between the design process, automation and evaluation objectives (i.e. objective mismatch).

The classification of risks in BPM projects is useful from a managerial perspective, as it allows BPM project managers to address specific risks that relate to the current phase of the BPM project. Furthermore, there is an overlap between risks occurring in different phases.

In order to identify these risks, a functional classification of BPM project risks is necessary, as they often have common underlying problems, such as lack of training, management skills or technology choices. By managing the root causes of these risks, a BPM project manager may be able to control the risks affecting the different phases more effectively [73].

Table 4.3 contains a classification of the risk categories that apply subsequently to the risks listed in Table 4.2.

Once a classification has been established for the different types of risk, the BPM-specific risks can be mapped.

A BPM project manager should address these orthogonal risks before the start of the project, while the more phase-specific risks may lend themselves to a deferred mitigation approach [4, 73].

BPM phase	BPM specific Risk
Context	Conduct analysis without a view on enterprise/processes/task strategy Failure to define process goals
Context → Engineering	Failure to properly map analysis outcomes to design models Loss of information during the mapping process Failure to relate systematic/organisational risks to the analysis Lack of communication between process designers and process stakeholders Designers ignore the organisational perspective of process design Lack of process management knowledge at the management level
Engineering	Implementation modeling languages are not capable to represent desired process semantics Design using incompatible modeling technologies Analysis language is not capable to represent observed process semantics Overemphasis of technical variables Resulting models do not fit the current organisational structure
Engineering → Optimization	Risk handling mechanisms are missing in the design Service vendors merge or go out of business New regulatory requirements make current process practices illegal Failure to relocate resources (plans for transformation) Failure to rearrange/reassign roles and responsibilities to process stakeholders (instantiate process management) The selected technologies are not suitable Incompleteness of the laws or risks considered
Optimization	Lack of communication and a common language among stakeholders Resistance from stakeholders to perform process-oriented activities Stakeholders take too long time to adapt to process-oriented work style Stakeholders fell uncomfortable under process-oriented leadership The composition of stakeholders changes the run-time System is unstable in the run-time environment Results differ from original design objectives Process stakeholders assume they know the new processes and their roles without review of the redesign

Table 4.2: Specific risks in the BPM project life cycle.

Risk Factor	Definition
Method	Lack of understanding or misuse of methods.
Communication	Lack of communication among BPM stakeholders and participants. This includes conversations, meetings, training, reporting and communication in all other forms.
Information	Absence of information efficiency, effectiveness, security, flexibility for transfers from As-Is to To-Be.
Change Management	Inability to manage/perform changes.
Technology	Failure of technology implementation due to the technology's nature or through improper human interference.
Risk/ Regulatory Compliance	Failure of risk management due to improper/incomplete risk assessment or lack of checking. Failure of regulatory compliance checks due to improper/incomplete norms taken into account.
Leadership/ Management	Failure to display strong leadership and/or proper project management.
Resource/ Skill	Lack of desired resource/skill sets or the misuse of resources/skills.
Strategy	Failure to define vision, goals, functions of all BPM stakeholders, participants and components involved.

Table 4.3: Classification of risks.

4.5 Procedural risks in healthcare

The clinical risk is the probability that a patient will experience an adverse event, i.e. suffer any "harm or discomfort attributable, even if unintentionally, to the medical treatment provided during the period of hospitalisation, which causes an extension of the period of stay, a worsening of the health conditions, or death" [175].

Clinical risk is the medical error. When dealing with the issue of clinical risk, it is necessary to define the error and the possible damage that may result for the patient.

Many definitions of "error" and "adverse event" can be found in the literature [260, 263]. They all share some substantial characteristics:

- The error is an insufficiency of the system that conditions the failure of planned actions.
- An error is an "unsafe action" or "omission" with potential negative consequences for the outcome of the treatment process.
- An error is a behaviour that can be judged inadequate by "peers" of recognised experience and expertise, at the time the event occurs, regardless of whether there have been (or not) negative consequences for the patient.
- The adverse event is, therefore, by its nature, undesirable, unintentional and harmful to the patient.
- The adverse event resulting from error is defined as "preventable".
- The error may cause an adverse event, which is an undesirable event that involves damage to the patient not due to the patient's clinical condition but **related to the care process**.

In order to identify the prevention measures to be implemented, not only the analysis of adverse events but also of the so-called "near miss"[10] is of great importance.

For this purpose, at the national level, it has been established that all public and private structures providing health services should activate an adequate monitoring, prevention and management function of the health risk. To this end, audit paths, or other methodologies, must be activated, aimed at studying the internal processes and the most frequent criticalities, with anonymous reporting of near-miss and analysis of possible activities aimed at making the healthcare pathways safe[11].

[10] Italian Ministry of Health www.salute.gov.it

[11] Firstly, in Legge 28 dicembre 2015, n. 208, in GU del 30 dicembre 2015. Secondly, in Legge Gelli-Bianco 8 marzo 2017, n. 241, in GU il 17 marzo 2017, n. 64. About provisions on the safety of care and the person assisted and on the professional responsibility of persons exercising the health professions. Finally, detailed guidelines have been provided for the management and communication of adverse events in health care (www.salute.gov.it). In particular, for the sentinel event "Transfusion reaction due to AB0 incompatibility" a specific reporting procedure is provided by the Ministry of Health's sentinel event monitoring protocol (www.salute.gov.it).

The events to be reported are sentinel events[12], adverse events and near-misses. Any operator involved or anyone who becomes aware of an adverse/near-miss event can report it.

Reporting these events is the basis for conducting optimal risk management. Increasing reporting does not mean that health care is worse. But that reporting is more accurate and this will be a sign of maturity of the risk prevention system.

For clinical risk management, the focus is on the processes and activities of healthcare facilities that are inherently risky. The objective is the evaluation and governance of the risks associated with these activities, improving the overall management of the health companies themselves [77][13].

4.5.1 Safety of transfusion process

The total safety of the blood transfusion system is the final result of all measures and tools that are adopted to ensure safety and efficacy at each stage of the process: any non-compliance or error, at any level, may lead to adverse events on the donor or the patient. Total transfusion safety is determined by the sum of blood safety and transfusion safety (Figure 4.2).

Errors in transfusion process account for about 70% of all adverse transfusion events[14], making them the main contributors to the still incomplete safety of transfusion and the resulting life-threatening transfusion accidents that follow. In contrast, blood safety, which is commonly perceived almost exclusively as an infectious risk, has now reached levels close to 100%[15].

With regard to transfusion safety, the incidence of errors leading to the transfusion of incorrect blood component units to the patient is 71%, much higher than the sum of the incidence of all other transfusion incidents. This type of accident is almost exclusively due to human error[16]. It can determine the onset of the most serious transfusion-related injury: the potentially fatal acute haemolytic reaction due to AB0 incompatibility (10% of deaths).

The damage actually found in the patient and causing serious, irreversible or

[12]Sentinel event is defined as an adverse event of particular severity, which may result in death or serious harm to the patient and which results in a loss of public confidence in the health service. Due to their gravity, it is enough that it occurs only once for the organisation to make it appropriate:

- An immediate investigation to determine which deletable or reducible factors caused or contributed to it.
- Implementation of appropriate corrective measures.

[13]Italian Ministry of Health www.salute.gov.it and Joint Commission on Accreditation of Healthcare Organizations (JCAHO)www.jointcommission.org.

[14]An average of one error per 2,000-30,000 transfused units.

[15]These dates refer in particular to Italy. However, the epidemiology of transfusion risk shows very similar incidences in all countries of the advanced world: the phase most at risk is that of the identification at the patient's bedside (more than 75% of the total). See REGIONE EMILIA ROMAGNA, Tecnologie per la sicurezza nell'uso del sangue. Sussidi per la gestione del rischio 5, Dossier 122 – 2006.

[16]The first author to highlight the problem of human error in the field of transfusion was Sazama in 1990.

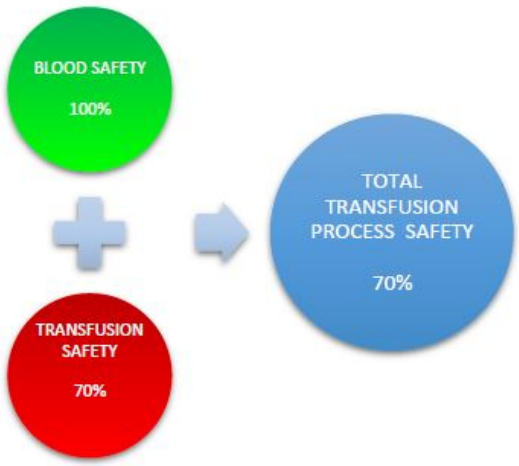

Figure 4.2: Safety of the process transfusion.

fatal injury is not the only one, but only those that are particularly serious and not intercepted in time. To understand the actual number of errors, to these, which are fortunately rare, we need to add all the transfusion incidents in which AB0-compatible units have been transfused and the near-misses.

The fact that most of errors are made by human mistakes has led to the enactment of a series of increasingly specific regulations to manage processes[17].

[17] As a result of Directive 2002/98/EEC17, from 2002 onwards, haemovigilance systems have been implemented in various states, European and non-European, from which it is possible to draw real data reports on a larger scale (Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.).

As regards blood transfusion legislation, the main important once at European and Italian level are:

- Legge 14 luglio 1967, n. 592, Raccolta, conservazione e distribuzione del sangue umano, in GU del 31 luglio 1967, n. 191. About collection, storage and distribution of human blood.
- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. Implemented by Decreto legislativo 20 dicembre 2007, n. 261.
- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Implemented by Decreto legislativo 6 novembre 2007, n. 191.
- Legge 21 ottobre 2005, n. 219, Nuova disciplina delle attività trasfusionali e della produzione nazionale degli emoderivati, in GU del 27 ottobre 2005, n. 251. About new

Until minimum activities and controls, so-called guidelines, are provided by law.

In Italy, the most important is the "Recommendation for the prevention of AB0 incompatibility transfusion reaction"[18].

In conclusion, *procedural errors are those errors made during the process.* However, they are often handled at the regulatory level. Much more the process is high-risk, much more error management is managed at the level of law. Therefore, procedural risk management is closely linked to regulatory compliance.

4.6 Risk management and regulatory compliance

As mentioned from the beginning of this chapter, risk is part of every business activity, therefore of every business process [4, 148], and risk management is the discipline that allows the management of these different types of risks through the applications of certain principles [260, 214, 143].

With regard to legal risks, it has to be considered that the process has to comply with law, while rules and regulations are constantly evolving and new reorganisations have to be implemented with the introduction of new procedures [149], such as for privacy control and AI technologies.

---

rules on blood transfusion activities and national production of blood products.

- Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events. Implemented by Decreto legislativo 9 novembre 2007, n. 207.
- Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments. Implemented by Decreto legislativo 9 novembre 2007, n. 208.
- Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells and Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. Implemented by Decreto legislativo 30 maggio 2012, n. 85, Modifiche ed integrazioni al decreto legislativo 25 gennaio 2010, n. 16, in GU del 26 giugno 2012, n. 147..
- Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations Text with EEA relevance.
- Decreto 2 novembre 2015, Disposizioni relative ai requisiti di qualità e sicurezza del sangue e degli emocomponenti, in GU DEL 28 dicembre 2015, n. 300. About provisions concerning the quality and safety requirements for blood and blood components.

[18] Raccomandazione per la prevenzione della reazione trasfusionale da incompatibilità AB0, Ministero della Salute. Dipartimento della qualità. Direzione generale della programmazione sanitaria, dei livelli di assistenza e dei principi etici di sistema. Ufficio III, marzo 2008

The need to comply with regulations or law forces organisations to redesign their internal processes, in the context of change management [149].

One of the main research topics of BPM concerns regulatory or compliance management, i.e. the analysis of compliance to norms [4, 108, 225]. The increasing pressure of regulatory authorities on organisations led to the development and application of Compliance Management Frameworks (CMFs). In this context, compliance management can be addressed at the operational level by focusing on business processes, understood as the set of activities that achieve a specific organisational goal.

The analysis of business processes usually introduces performance targets to be considered in addition to the constraints imposed by external pressures (e.g. regulatory issues).

The investigation of undesirable events and violations of norms has adopted traditional techniques, for example root cause analysis (commonly used in manufacturing processes to improve performance). The problem is that RCA has to be done by hand and there are many regulations, so this analysis could be really huge.

More recently, CMFs have explored the relationship between the formal representation of a process model and its relevant regulations.

There are many different regulatory compliance management strategies that can be adopted that consist of approaches to automate the verification of the compliance of a business process with the current regulation [136].

The aim is to ensure that such approaches correctly model business processes as well as rules. Moreover, in the last decades, many compliance management approaches have been proposed in the context of digitisation to automate business processes [257].

Compliance in healthcare considers the conformity of care processes with laws, regulations and standards relating to patient safety, privacy of patient information and administrative practices.

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

Several studies can be found on compliance with laws, rules or regulations in the case of processes related to patient health [70, 242, 25, 18, 21].

The intensive use of ICT solutions to collect, share and digitise data of a health care process, makes it necessary to prepare tools able to identify any possible risk scenario related to the use of IT systems and the lack of awareness about the agents, as well as to facilitate the adoption of appropriate countermeasures. Previous research on IT has explored the challenges of digitisation for organisations [18, 19, 21, 20, 22]. These innovations may require the application of new regulations, such as the GDPR, without forgetting that the healthcare sector is full of strict and constantly evolving healthcare regulations.

4.6.1 Business process compliance

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

Norms are many in continuous evolution and one of the central issues in BPM is change management [6, 8, 103].

A business process analysis is an autonomous, temporal and logical order in which a set of activities is expected to be performed to achieve a business objective. Typically, a process model describes what needs to be done and when (control flow), who will do what (resources), and what is being worked on (data). In this context, a possible execution, called a process trace or simply a trace, is a sequence of tasks and events that respect the order given by the connectors.

Following this reasoning, it is also possible to check whether the activities of the process comply with the regulations in general, but also whether the sequences and resources are compliant. For example, the legislation may require the doctor to give approval to perform the treatment. It is necessary not only that the activities "approval" and "performing the treatment" are present, but also that they take place in that order and not vice versa. The treatment would not be compliant without the doctor's prior approval. It is also essential to verify that the activities are carried out by the resource indicated in the legislation. In the case of the example, it is not enough that there is an approval, but there must be the approval of the doctor; i.e. not from a different resource such as a nurse.

4.6.2 Using logic for semi-automated compliance

Specifically, *business process compliance is a relationship between the formal representation of a process model and the formal representation of the relevant regulations* [133]. Any approach to automate the verification of the compliance of a business process with the regulations governing it must ensure that it is able to correctly model business processes as well as norms. Over the past decades, many approaches to automate business process compliance have been proposed [199, 50] and legal informatics was experiencing growth in activity, including at industrial level [60, 15].

A challenging research topic is, therefore, the possibility to model standards in a conceptually valid, detailed and exhaustive way that can be used in practice for companies and, at the same time, has the ability to be used generically for any type of standard while also taking into account the regulatory environment as a whole [129].

The formalisms adopted are based on logic. Temporal Logic and Event Cal-

culus have been used in various contexts. However, it has been shown that when norms are formalised in Linear Temporal Logic the assessment of whether a process is compliant produces results that are not compatible with the intuitive and more natural legal interpretation [147, 130]. Furthermore, it has been argued that while such logics can properly model norms, such formalisations would be completely useless from the point of view of process compliance, as they would require an external oracle to identify the compliant executions of the process, and construct the formalisation from the traces corresponding to the traces deemed legal by the oracle. This means that, there is no need for the formalisation to determine whether the process is compliant or not, as this is done by the oracle [130, 131]. Some studies have focused on the application of Natural Language Processing (NLP) methods to design legal document management systems to assist legal professionals in navigating legislation and retrieving information of interest [59, 58]. An example is Eunomos [61, 60]. These types of systems classify, index and discover interconnections 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)[19]. This is often done by transforming the source legal documents into XML standards and tagging the relevant information to then allow for subsequent archiving and querying the XML files.

However, the overall usefulness of these systems is limited because of their focus on terminological issues and information retrieval, neglecting the specific semantic aspects that enable legal reasoning. Just as standard deontic logic focused primarily on the notion of obligation, later developments of deontic logic also adopt an abstract view of law, with a very loose connection to the texts of norms. For jurists, the meaning of laws can only be truly understood in the rich expressiveness of natural language because "like language generally, legal discourse can never escape its own textuality" [239].

Therefore, there is a gap between a powerful reasoning mechanism on the formalisation of law and the textuality of law, which can be addressed by solutions from the literature on Natural Language Semantics.

A new standardisation initiative called LegalRuleML[20] [41, 39] tries to address these problems. LegalRuleML is an XML format that extends the RuleML standard[21] to define a rule exchange language for the legal domain. While legal XML standards are used to tag the original textual content of legal documents, LegalRuleML represents and stores the logical content of the provisions separately. In particular, LegalRuleML allows semantic/logical representations to be specified and associated with both the structural elements of the documents and the tasks in a business process. LegalRuleML allows encoding RuleML representations of formulas in Defeasible Deontic Logic (DDL) [127]. This is an extension of the standard Defeasible Logic with deontic operators and the operators for the compensatory obligations [135]. Defeasible Logic is an efficient

[19] See https://www.w3.org/OWL
[20] See https://www.oasis-open.org/committees/legalruleml/
[21] See http://wiki.ruleml.org/

and simple rule-based, non-monotonic, computing-oriented formalism designed to handle exceptions in a natural way.

According to its formalisation, Defeasible Logic is a constructive logic with its theory of proof and inference condition as its core [34]. The logic exploits both positive proofs, a conclusion that has been constructively proved using the given rules and inference conditions (also called proof conditions); and negative proofs, which show a constructive and systematic failure to reach particular conclusions, or in other words, constructive refutations. The logic uses a simple language, which has been successful in many areas of application, due to the scalability and constructiveness of the logic. These elements are extremely important for normative reasoning, where an answer to a verdict is often not enough, and full traceability is required.

4.6.3 Legal reasoning and Defeasible Deontic Logic

Norms describe general cases and what behaviour should be adopted, or the consequences, if the actual 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. In short, the purpose of norms is to regulate the behaviour of their subjects and to define what is legal and what is illegal.

From a compliance perspective, the important normative effects are deontic effects (also called normative positions). The fundamental and most important deontic effects are: obligation, prohibition and permission.

- **Obligation:** when there is a situation, act, or course of action to which a bearer is legally bound, and if it is not achieved or performed results in a violation.
- **Prohibition:** when there is a situation, act, or course of action that a bearer should avoid, and if it is achieved results in a violation.
- **Permission:** when a thing is permitted if the prohibition of it or the contrary obligation does not hold.

This gives rise to a number of 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 resulting in the cessation or impossibility of continuing the business process.
- Violations may generally be compensated, and processes with compensated violations are still compliant [136, 132] (for example, contracts typically contain compensatory clauses specifying penalties and other sanctions caused by violations of other contractual clauses [128]).

- Not all violations are compensable, and uncompensated violations mean 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 ¬A (the opposite of A), and then if A is obligatory, then ¬A is forbidden [268].

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

- **Punctual obligations:** an obligation is in force at a particular time point.
- **Persistent obligations:** a rule indicates when an obligation comes in force. An obligation remains in force until it is terminated or removed.
  - For persistent obligations, we may ask whether to fulfil an obligation we must obey it for all instants in the interval in which it is in force, **maintenance obligations**, or
  - If doing or achieving the content of the obligation at least once is enough to satisfy it, **achievement obligations**.
  - For achievement obligations, another aspect to be considered is whether the obligation could be fulfilled even before the obligation is actually in force. If this is allowed, then there is a **preemptive obligation**, otherwise the obligation is **non-preemptive**.
- **Termination of obligations:** rules may specify the interval during which an obligation is in force.

As mentioned above, what differentiates obligations and other constraints is that obligations can be violated.

- If we still have to comply with a violated obligation (the obligation persists after having been violated) we speak of a continuing obligation: **perdurant obligation**.
- Otherwise, we speak of a **non-perdurant obligation** [129].

Rules are usually modelled as if-then rules that represent the conditions under which the norms are applicable and the normative effects they produce when applied. From a compliance perspective, the important normative effects are deontic effects: permission, obligation, and prohibitions. Thus, an if-then rule in the form "$a \rightarrow b$" that represents a norm says "if a holds, then b is permitted/obligatory/prohibited". However, it is standardly assumed that prohibitions are indeed obligations; something is prohibited if and only if there is obligation to the contrary [268]. In this thesis, for the sake of simplicity, we assume the term "obligation" also includes prohibitions.

Obligations are constraints that limit the space of action of processes. If the antecedent of an if-then rule that represent an obligation applies in the context and the bearer of an obligation does not comply with the consequent, then it violates the obligation. However, a violation does not imply an inconsistency within a process resulting in the cessation or impossibility of continuing the business process.

Violations may be compensated, and processes with compensated violations are still compliant [132] [136]. For example, contracts typically contain set-off compensatory clauses that specify penalties and other sanctions triggered by violations of other contract terms [128]. Not all violations are compensable; if a process contains uncompensated violations, then it is not compliant.

On the other hand, 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. Permissions may be codify explicitly in legislation (positive permissions) or they may be derived, for example, by noting that there is nothing in the code that prohibits them (negative permissions) [250].

Compliance usually means identifying whether or not a process violates a set of obligations, and the first step is to determine if and when an obligation is in force. In other words, is important to understand the lifespan of an obligation and its implications on the activities carried out in a process.

However, a serious limitation remains. Having made all the above considerations, it is understandable that the formalisation of rules in DDL must be exercised manually by an expert who knows both the laws and the legal interpretation, and this type of formalisation. This is the major limitation for the use of this methodology. It often happens that companies do not have a resource with such specific skills. Consequently, it is difficult to disseminate these methodologies on a large scale, including small and medium-sized enterprises.

Chapter 5

The analysis of the case study: risk analysis and regulatory compliance with BPMN Model

5.1 Introduction

According to the outline thesis of Section 1.5, in this chapter is shown how to apply the methodologies, instruments, and tools analysed in Chapter 4.

For this purpose, the Blood Bank department and the OAD service are used. The results were always validated in several steps, both by the stakeholders and by the simulations. At the end of the chapter, it will become clear how it is possible to reorganise an enterprise logistically and, in the meantime, to check the regulatory compliance after the modification.

All the things presented here are part of Phase 3 to reach Phase 4 of the methodology in Figure 4.1.

Also in this chapter, the notions exposed are the fusion of the multiple partial results we have found thanks to the experiments carried out in these recent years. All models, analyses, simulations, and results explained in this chapter have already been published in the following papers:

- To manage procedural risks and manual regulatory compliance checking: [18, 19, 20, 21, 22, 23, 24, 25].
- For the semi-automation of regulatory compliance [31].

5.2 Blood bank procedural risks

For reasons of exposition, the following section will introduce the Blood Bank As-Is model. Subsequently, risk analysis and simulations will be carried out. Finally, the conclusions will show the results of the To-Be model.

5.2.1 Analysis of the As-Is blood bank process

The Blood Bank (BB) is a department of the hospital that ensure that donated blood, or blood products, are safe before being used in blood transfusions and other medical procedures. BB includes blood typing for transfusion and testing for infectious diseases.

The BB analysis is carried out with the support of a working group comprising doctors, biologists and technicians..

The BB department consists of three functional units: Acceptance, Laboratory and Distribution.

The process starts with the arrival in the Acceptance of a blood request by using a special form. Requests coming from other hospital departments (e.g. ED) are verified: staff must confirm whether the information on the tube label and on the transfusion request form are identical. In case of discrepancies or doubts, a new sample should be obtained. The request and the test tube with the patient's blood is then sent to the Laboratory. When a patient's blood sample arrives at the Laboratory, a number of standard test is performed, including, but not limited to, the following:

- Typing: AB0 group (blood type).
- Rh typing (positive or negative antigen).
- Screening for any unexpected red blood cell antibodies that may cause problems in the recipient.

In Distribution, if a blood unit (or component) is required, it is taken from the blood deposit and sent to the requesting department by the appropriate personnel.

The Acceptance sub-process is the one with the highest number of procedural risks and the one that is particularly targeted by the controls contained in the guideline[1]. It is therefore the one that will be analysed in more detail.

The Acceptance sub-process is illustrated in Figure 5.1. For the simulation, some monitors (blocks M1, M2, M3, M4 and M5) were added to count all transactions corrisponding to errors.

Requests are received (**Receive Request**), the staff adds requests in the local management system and applies a barcode identification (**Manage Re-**

[1]Recommendation for the prevention of the transfusion reaction from incompatibility AB0 (Raccomandazione per la prevenzione della reazione trasfusionale da incompatibilità AB0, Ministero della Salute. Dipartimento della qualità. Direzione generale della programmazione sanitaria, dei livelli di assistenza e dei principi etici di sistema. Ufficio III, marzo 2008).

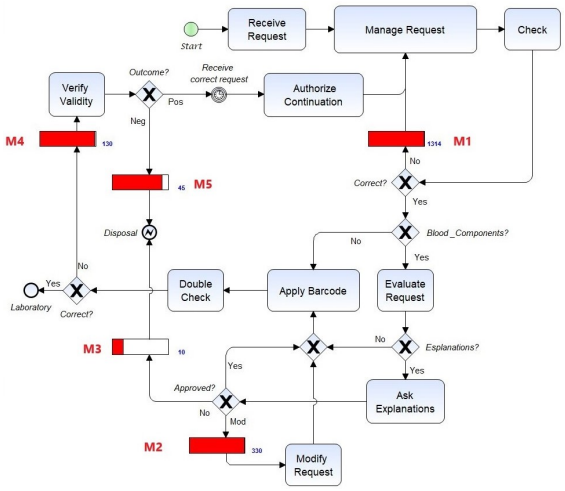

Figure 5.1: Sub-process of Acceptance requests with counters of errors.

quest). Then the correctness of the request and test tube data are checked (**Check**).

If errors are detected (monitor M1) the corrected data are re-entered.

The gateway *Blood components?* checks whether only blood tests or also blood components are required.

In the latter case, the BB doctor verifies the correctness of the request (**Evaluate Request**) and, if he/she has any doubts, calls the doctor in the ordering department for an explanation (**Ask Explanations**).

At this point (*Approved?* gateway), one of three things may happen:

- The BB's doctor is convinced of the correctness of the request.
- The request is changed by agreement between the two doctors (**Modify Request**).
- The request is considered unsuitable and deleted (the sub-process is closed with a *Disposal* error report).

If no blood components are requested or the request is deemed suitable or modified, an identification barcode is applied to the test tube (**Apply barcode**). A final check is carried out by two people at the same time (**Double Check**), at least one of whom must be a graduate (doctor or biologist), who finally puts an approval signature on the request. If no errors are detected (*Correct?* gateway), the request and the test tube are sent to the Laboratory. If not, (monitor M4) a check is made with the requesting department (**Verify Validity**). Once an agreement has been reached, the requesting department sends back a modified request with the corrected data, which are re-entered into the system (after a certain delay, timer *Receive correct request*). Otherwise, the request is considered unsuitable and deleted (monitor M5).

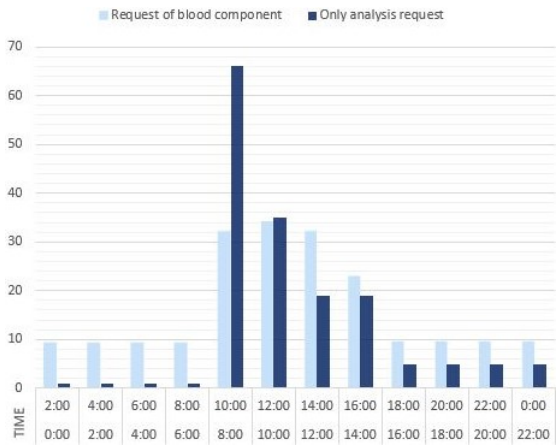

Figure 5.2: The BB daily workload.

5.2.2 Procedural risks analysis and simulations

The hospital's policy is that each department should self-report its own errors. Whether it is the department itself that notices them, or whether the error is communicated by other departments.

The self-report of errors is not punitive, but corrective. If it is possible to understand what the problems are and so-called corrective actions can be implemented to reduce the error. For this reason, and to encourage staff and departments to self-report, it is hospital policy that these reports are anonymous.

The input data analysed concern the function of the BB department in 2017. The generator corresponds to the initial event *Start*. It introduces about 350 requests per day distributed according to the schedule in Figure 5.2 for a total amount of about 86,000 requests received during the initial 8 months of 2017. This scenario has been simulated and, as shown in Table 5.2, the total number of errors detected in the sub-process simulation is 1,829 (sum of the M1 - M5 monitors). This number has to be compared with the number of errors reported by the BB staff during the same period. These errors are stored (together with the causes that generated them) in a self-report database (managed by the local system) and shown in Table 5.1[2].

In this table the causes of errors have been divided according to the units of the BB in which they can occur, corresponding to Acceptance, Laboratory and

[2]Although in Section 4.4 we talked about the RCA technique as a starting technique to detect the true causes of errors, here we skipped this step because we were not starting from a blank sheet. The goal was to optimise error management, but a risk management system was obviously already in place. Indeed, the hospital already had a list of causes of errors (i.e. Table 5.1), on which the database of errors reported overtime was based. Therefore, to verify the correct detection of the errors we had to start from the list of the causes of errors already used by the hospital, going directly to the FMEA technique and skipping the RCA.

Table 5.1: Table of reported errors, detected errors and complaints.

Dep	TErr	Causes	Err	Com
Acceptance	**Internal Acceptance**		511	10
		Incomplete data	134	
		Switching Errors	20	
		Insert Error	349	10
		Other	8	
	Internal Check in Acceptance		127	
		Cross check (request-test tube) missing	14	
		Signature check missing	31	
		Doctor check missing	82	
	Inappropriate Request		63	
		Data: inappropriate/reconsidered	16	
		Quantity: inappropriate/reconsidered	26	
		Urgency: inappropriate/reconsidered	21	
Laboratory	**Internal Test**		18	
		Not performed	11	
		Insert missing	6	
		Other	1	
	Internal Assignment		93	4
		Barcode check missing	9	
		Unsuitable reservation	79	
		Wrong labeling		3
		Wrong assignment		1
		Computer transmission problem	5	
Distribution	**Internal Distribution**		78	8
		Wrong document delivery	1	1
		Wrong number of unit delivery	27	1
		Late delivery	43	
		Wrong blood component delivery		1
		Error on the medical report	3	
		No correspondence bag/data	2	5
		Various	2	
	External Output			4
		Wrong Department Delivery		2
		Switching Errors		2

Table 5.2: Table of reported errors, detected errors and complaints.

	Rep	**Det**	**DetButNotRep**	**Com**
Acceptance	701	1,829	62.0%	10
Laboratory	111	700	84.0%	4
Distribution	78	400	80.5%	12
BB Process	890	2,929	70.0%	26

Distribution. The columns **TErr**, **Causes**, **Errors** and **C** respectively represent the Type of Errors, Causes, Errors and Complaints in these three units. The number of self-reported errors for the Acceptance is 701. This means that about 62% of the errors were not reported.

For Laboratory and Distribution units, similar results are obtained. As shown in Table 5.2, the columns **Rep**, **Det**, **DetButNotRep** and **Com** respectively represent the errors Reported, Detected, Detected but not Reported and the Complaints for each unit and for the whole BB process.

The table provides the starting point for two important conclusions:

- BB staff have a poor attitude towards reporting errors as they are discovered in the process. This is partly due to the workload being particularly heavy at certain times of the day. The consequence is that management has limited information about the actual causes of errors. As a result, improvement initiatives clearly suffer from this deficiency.

- The complaints column shows that the number of undetected errors in the BB process is very low. This indicates that the current process is

Causes	Occurrence (O)	Detection (D)	Severity (S)	RPN
Incoming from the outside				
Improper sample	1	1	5	5
Inaccurate request	1	3	5	**15**
Delivery delay request	2	6	6	**72**
Other	1	1	1	1
Internal Acceptance				
Incomplete data	2	2	5	**20**
Switching Errors	1	1	7	7
Insert Errors	2	5	5	**50**
Other	1	1	1	1
Internal Check in Acceptance				
Cross check (request-tube) missing	1	1	7	7
Signature check missing	1	1	3	3
Doctor check missing	1	2	5	**10**
Inappropriate Request				
Data: inappropriate/reconsidered	1	1	7	7
Quantity: inap./recons.	1	1	7	7
Urgency: inap./recons.	1	1	7	7

Table 5.3: FMEA matrix for the Acceptance process.

very efficient. However, as the consequences of certain errors can be very serious, the need to improve the process is always present.

Table 5.1 is the starting point for analysing the risks related to the various causes.

The risk analysis uses the FMEA technique. The method is based on assigning three types of score for each cause (and its effect):

- (S) Severity: shows the severity of the effects eventually occur. It can range from 1 (very moderate problems) to 10 (death).
- (O) Occurrence: estimates the frequency with which an effect will occur. It can range from 1 (unlikely to occur) to 10 (almost certain to occur).
- (D) Detection: refers to the possibility of the operators and the control measures to detect error before the effects occur. It can range from 1 (the system will always detect error) to 10 (detection is not possible).

To calculate the Risk Priority Number (RPN) the 3 scores were multiplied:

$$RPN = S * O * D(Itcanrangefrom1to1000) \tag{5.1}$$

The S, O and D scores were estimated by the working group and validated by analysing the detailed data for a limited number of days. This yields the FMEA matrix shown in Table 5.3.

The most relevant RPN indices were highlighted and discussed in depth in the working group.

- (F1) Inaccurate request and (F2) Delivery delay request: these concern errors committed in the requesting departments and therefore will not be

considered further (they will be treated at the high-level of hospital risk management).

- (F3) Incomplete data and (F4) Insert error: refer to errors made by the BB staff in uploading patient data and requests to the HIS.
- (F5) Doctor check missing: concerns the lack of a final check by the doctor.

The causes of error (F3) and (F4) will be taken into consideration in the next optimisation phase.

5.2.3 To-Be model: procedural risks optimisation

This section refers to Phase 4 of the methodology in the Figure 4.1.

The last considerations of the FMEA analysis are the starting point to propose some possible restructuring actions to improve the process.

Errors (F3) and (F4) are related to human errors. The digitalisation of these tasks could address the issues raised during the risk analysis. A new web-based version of BB HIS is currently under development.

The new BB system will be integrated with the central management system of the hospital and developed with the following requirements:

- The requesting department prepares the label with the patient's data and the barcode, places it on the test tube and loads, with the same barcode, the request (which will be dematerialised) on the central system.
- At the Acceptance, the test tube arrives and through the barcode, with the new local system, the request is retrieved (the control will be much faster).

A new To-Be model was proposed and discussed by the working group. Figure 5.3 shows the new process, which is much simplified.

The integration of local and general management systems means that patient data is only recorded and requested once. This avoids rewriting errors and limits the need for checks. Digitisation allows to eliminate the causes of errors (F3) and (F4) detected by FMEA analysis.

The simulation of the two models As-Is (Figure 5.1) and To-Be (Figure 5.3) allows a comparison between the two scenarios in relation to the errors detected. Table 5.4 shows the results for the entire process. In this table, the columns **As-Is**, **To-Be** and **Elim** respectively represent the errors detected by the current As-Is Acceptance sub-process, by the To-Be web-based sub-process and the percentage of errors that would be eliminated by the restructuring.

These results in Table 5.4 indicate that the introduction of digitalisation significantly reduces (54%) the number of errors that would be detected in the BB.

This leads to a much more efficient process in terms of request processing time and costs for the organisation. In fact, by introducing some KPIs and

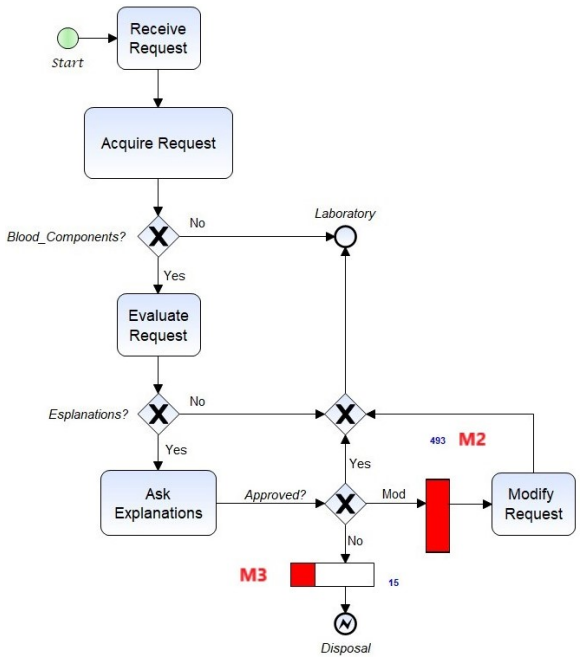

Figure 5.3: To-Be model of the Acceptance process: optimisation of procedural risks.

	As-Is	To-Be	Elim
Acceptance	1,829	509	72%
Laboratory	700	494	29%
Distribution	400	335	16%
Process	2,929	1,337	54%

Table 5.4: Comparison between the As-Is model and the To-Be model.

	As-Is	To-Be	Earn
Total request in input	86,160	86,160	-
Disposal request	58	25	33
Average cycle time	35.22	2.61	32.61
Average work time	5.46	2.20	3.26
Average waiting time	29.75	0.41	29.34

Table 5.5: Comparison between the As-Is and the To-Be model of the Acceptance process.

monitors, it is also possible to compare the two models from a purely logistical point of view.

The KPIs considered are: the number of incoming and rejected requests, the average cycle time, the average working time and the average waiting time for requests going through the Acceptance process (between the initial event **Start** and the final event **Laboratory**). The measurements are carried out with the help of monitors. A monitor collects the statistical data for all requests travelling between these two points. The simulation of As-Is and To-Be models with the same workload allows the comparison between the two processes and the results are shown in Table 5.5 (times are expressed in minutes).

Table 5.5 shows how digitalisation and integration of the two information systems could lead not only to a reduction in procedural risk errors but also to logistical improvements in working time.

In fact, there would be a drastic reduction in waiting times when processing requests. This is particularly important during peak request hours, between 8 and 12 p.m. (see Figure 5.2). In particular for urgent and very urgent requests that require a quick delivery of blood: between 15 and 20 minutes for very urgent requests, within 1 hour for urgent requests.

In addition, in the interests of transparency and safety of care (including the prevention and the management of risks associated with the provision of health services), one of the techniques used to date and encouraged by most States is the reporting of adverse events and sentinel events[3]. Digitisation could facilitate such reporting.

[3] `https://www.jointcommission.org/sentinel_event_policy_and_procedures/`

5.3 Blood Bank manual regulatory compliance checking

This section refers to Phase 3 and Phase 4 of the methodology in the Figure 4.1.

The Italian "Recommendation for the prevention of reaction AB0 incompatibility transfusion"[4] contains some controls and minimum requirements to be followed: when collecting blood sample for blood grouping, when requesting blood components, to avoid errors due to sample exchange and recording or the delivery of the wrong units in the transfusion facilities, in the wards, in the operating room and in intensive care unit.

In particular, to prevent the wrong person from taking the sample or the wrong sample identification:

- A specific company procedure for correct patient identification must be prepared and implemented.
- The sampling operator must clearly and completely record the blood samples on the tubes: department of origin, surname and first name of the patient, date of birth of the patient, date of sampling.
- The operator taking the sample must sign the test tube, preferably at the patient's bedside.

Furthermore, to avoid errors, the request form, which accompanies the patient's blood sample and on which the requesting doctor must sign, must contain at least the following information in a clear and legible manner:

- Department, surname, first name and date of birth of the patient.
- The blood components required and any treatments.
- Diagnosis and justification of the request.
- Date of request.

In addition to errors that can come from outside, the main errors that can be made in Acceptance are: human errors, typing or transcription errors, double names, anonymity. The underlying problem lies in the fact that the process is based only on the paper application (filled in by hand) which may contain errors and therefore needs to be checked several times to ensure that the patient and tube data are loaded correctly into the local management system.

The efficiency of the BB process is the result of continuous improvement initiatives. For this reason, several data correctness checks were introduced by BB in order to detect as many errors as possible.

[4]Raccomandazione per la prevenzione della reazione trasfusionale da incompatibilità AB0, Ministero della Salute. Dipartimento della qualità. Direzione generale della programmazione sanitaria, dei livelli di assistenza e dei principi etici di sistema. Ufficio III, marzo 2008

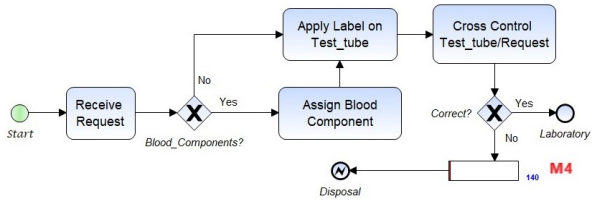

Figure 5.4: Scenario of the Acceptance sub-process with only mandatory controls and errors detected.

An interpretative analysis of the legislation was made and the current Acceptance sub-process was analysed. The objective is to assess whether the sub-process meets the minimum legal requirements.

Both analyses were conducted manually.

It turns out that the current sub-process not only complies with the minimum controls, but BB has added additional controls to further reduce errors.

The simulation was used to create a scenario, but in this case not an improved one. The simulation was used to reproduce what the sub-process would have looked like if it had only had the mandatory controls (Figure 5.4).

Therefore, at the arrival of the request (**Receive Request**) if a blood component is required, it is assigned by the BB doctor (**Assign Blood Component**). In both cases, an identification label is applied to the test tube (**Apply Label on Test_tube**) and then the data on the request and the test tube are checked (**Cross Control Test_tube/Request**). If no errors are detected (*Correct?* gateway) the request and the test tube are sent to the Laboratory, otherwise (Monitor M4) the request is disposed.

The law requires a check on certain data. Therefore one control is sufficient to be compliant. Cross-checks and double-checks are corrective actions introduced over time by BB to reduce adverse events or near-miss.

With only one control, some errors could be missed and, if errors were made in recording patient data in the BB, there would be no way to detect them.

If we compare the two sub-processes (As-Is in Figure 5.1, and To-Be scenario in Figure 5.4), especially their monitors, it is possible to see that in the BB sub-process many more errors are detected. It is important to emphasise that, in this case, a high number of errors is a good thing. What is monitored is the detection of errors, not whether they are made or not. So it can be assumed that the same errors are made, the two models show how many are caught.

In detail, Table 5.6 illustrates the results obtained for the entire BB process if only the mandatory obligations are implemented. The columns **Actual**, **Compliant** and **Lost** represent the errors detected in the actual BB and in the compliant processes respectively, and the percentage of errors lost. Looking at the Acceptance results, 92% of the errors would not be detected (lost errors) if only the mandatory checks are implemented.

In conclusion, if in the previous paragraph checking the procedural risks also the regulatory compliance has been checked; in this case, on the contrary, by

	Actual	Compliant	Lost
Acceptance	1,829	140	92%
Laboratory	700	53	92%
Distribution	400	43	89%
BB Process	2,929	236	92%

Table 5.6: Comparison between As-Is and To-Be compliant sub-processes.

checking regulatory compliance it was also possible to test the procedural risk management system.

5.4 Semi-automatic control of regulatory compliance

The analysis of regulatory compliance in the previous paragraph was done manually, but manual analysis is not always so easy and fast.

In any field of business, there are several laws to be complied with from different sources (international agreements, European laws, constitutions, national laws, regulations, guidelines, etc.) and relating to various aspects of business (labour laws, safety laws, privacy laws, specifics of the product/service in question, related to the field of business, etc.). Moreover, the legislative field is not something fixed. Laws are constantly being updated, created, repealed. A company has to keep up with regulatory reforms, if it does not want to incur in penalties. Therefore, checking whether all business processes and sub-processes comply with all applicable legislation is a huge job. Not only in terms of compliance, but also in terms of the company's ability to remain in the market. Failure to comply with regulated standards can compromise the image of the product and affect the company's image by making it no longer competitive. Finally, there is also the question of administrative, civil and criminal liability (especially in the health sector).

A logic-based tool in this work nay be useful. In this way, the verification of compliance could be semi-automated. The law is formalised in Defeasible Deontic Logic (DDL) and with the tool Regorous, the BPMN process could be checked.

One of the latest pieces of legislation that has created many changes in different areas at European level is the General Data Protection Regulation (GDPR)[5].

In detail, the OAD Acceptance sub-process of Figure 3.2 is used. It is shown how to model the norms in DDL and, in particular, how to encode GDPR norms related to healthcare. Finally, it is explained how to link the codified standards

[5]Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

with the process in Rogorous, how to perform the compliance check and how to read the results.

This part is an in-deepening of Phase 3 of the methodology of Figure 4.1.

5.4.1 Coding of GDPR norms in DDL and OAD process compliance checking

Norms are usually modelled as if-then rules that represent the conditions under which rules are applicable and the normative effects they produce when applied. From a compliance perspective, the important regulatory effects are the deontic effects.

Regulatory compliance usually means identifying whether or not a process violates a set of obligations. Therefore, the first step is to determine if and when an obligation is in force. In other words, an important aspect of the study of obligations is to understand the duration of an obligation and its implications on the activities carried out in a process.

A first general classification is that between punctual obligations and persistent obligations, the former at a particular time, the latter holding over an interval of time.

The latter are further sub-classified into maintenance obligations and achievement obligations, the former being in force for all instants in the interval, the latter only until they are reached/fulfilled. Finally, achievement obligations are further sub-classified into preemptive and non-preemptive obligations and between perdurant and non-perdurant obligations. Preemptive obligations are those that could be fulfilled even before the obligation is actually in force. On the contrary, perdurant obligations are those that are still in force even if/after they have been violated.

Finally, positive permissions are involved in the compliance verification process because positive permissions imply that there are no obligations or prohibitions to the contrary or other deontic effects.

Regorous is a propositional DDL system. It formalises the different subclasses of persistent obligations as follows, where "p" is a propositional symbol:

- **[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, "p" is a predicate, called a "term" in Regorous terminology.

Regorous lists all terms used in a formalisation set, together with their description, in a special XML `<Vocabulary>` tag.

Below, Article 6, paragraph 1, point 1 of the GDPR[6] is modelled, which specifies a condition of lawfulness of processing (and indeed the main one): the **processing of personal data is lawful if "the data subject has given consent to the processing of his or her personal data for one or more specific purposes"**.

In order to model this norm, we need the concept of personal data processing and the concept of consent. These correspond to two propositional symbols, i.e. in Regorous, the following two terms that we add to the vocabulary:

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

According to Article 6, it is possible to assume that the processing of personal data is prohibited unless one of the legal bases exists. Thus, unless a more specific and stronger if-then rule, based on a given consent, allows it, e.g. unless the patient has given consent to the processing of personal data (GDPR, Art. 6.1(a)).

The maintenance obligation (**Personal data processing is prohibited**) is formalized as follows:

```
<Rule xmlns:xsi="..." xsi:type="DflRuleType" ruleLabel="Art.6.0">
   <ControlObjective>Personal data processing
                              is prohibited.</ControlObjective>
   <FormalRepresentation>=>[OM]-Proc</FormalRepresentation>
</Rule>
```

Permission based on given consent (**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**) is formalised as follows:

[6] `https://eur-lex.europa.eu/eli/reg/2016/679/oj`

```
<Rule xmlns:xsi="..." 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>
```

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

In this case, the antecedent of the if-then rule is not empty: the rule will only be triggered when the term `GiveConsent` is asserted. In the BPMN Acceptance sub-process, this will be done in the task "Fill out the nurse form + Pick up informed consent".

Naturally, the two formulas cannot hold together, since the first implies that the processing is prohibited, while the latter entails that it is permitted. To resolve these conflicts, both LegalRuleML and DDL implement overriding relationships between rules.

In this example, the permission `[P]Proc` must override the obligation `[OM]-Proc` in order for the business process to comply with the GDPR.

In Regorous, DDL overriding relations are implemented as "superiority relations", encoded via the homonym tag, where the "superiorRuleLabel" overrides the "inferiorRuleLabel".

Therefore, in the example under consideration we have:

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

By asserting these superiority relations, Regorous is able to deduce that if both terms `Proc` and `GiveConsent` holds, the process is compliant.

The assertion of `GiveConsent` does not only entail that processing of personal data is permitted. According to GDPR, Article 7(1): **Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.**. Therefore, the assertion of `GiveConsent` also entails another maintenance obligation for the hospital, formalised in Regorous as follows:

```
<Rule xmlns:xsi="..." ruleLabel="Art.7.1" xsi:type="DflRuleType">
   <ControlObjective>If processing is based on consent,
       the controller shall be able to demonstrate the
       consent.</ControlObjective>
   <FormalRepresentation>
       GiveConsent=>[OM]DemonstrateConsent
   </FormalRepresentation>
</Rule>
```

The obligation is again a maintenance obligation, rather than an achievement one, because the GDPR requires the controller (the hospital, in our case) to retain and provide evidence of the consent given *at any time*, upon request of the data protection authority or any other appointed auditor. In the OAD Acceptance sub-process, the patient's personal data record, which includes the evidence of his/her given consent, is prepared and stored in the hospital's digital repository in the "Make taking in load" task, along with all other administrative details referring to the OAD service that will be implemented. At the same time, the term `DemonstrateConsent` will be asserted in Regorous. The term will remain true as long as the record is kept in the hospital's archive, so that Regorous will always be able to assess compliance with `[OM]DemonstrateConsent` which, being a maintainance obligation, must be satisfied at every instant of the execution.

It is important to note, that this reasoning only focuses on Article 6.1(a) of the GDPR. However, the given consent is only one of the legal bases that allow the processing of personal data, the one that is used by the OAD Acceptance sub-process. The whole formalisation includes other legal bases, specified in other GDPR norms, and used in other healthcare processes within the hospital.

For instance, Article 6.1(b) of the GDPR permits processing if it is "necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract" while Article 6.1(d) of the GDPR permits processing if it is "necessary in order to protect the vital interests of the data subject or of another natural person.".

Article 6.1(b) and Article 6.1(d) then provide two further sufficient conditions to allow the processing of personal data, so that they are respectively formalised in the if-then rules "`Contract=>[P]Proc`" and "`VI=>[P]Proc`". Two corresponding superiority relations are also added to the Regorous knowledge base in order to allow the override of `[OM]-Proc` in these two cases as well.

The fact that these two sufficient conditions are not used in the BPMN under review highlights the fact that the Regorous file is not associated 1:1 with the OAD Acceptance sub-process. Thus, the formalisation of the legislation is kept independent of the modelling of the healthcare processes and shared among several ones.

In the event that new legislation comes into force or, alternatively, existing legislation is updated, it will initially only be necessary to modify the `<Rule>`(s). Regorous will then be able to identify which business processes are affected by the changes: those that no longer comply with the new legal framework.

The XML file for Regorous with all the formalised rules related to the OAD process are available on GitHub[7].

[7] `https://github.com/liviorobaldo/TrECECpaperAttachments`

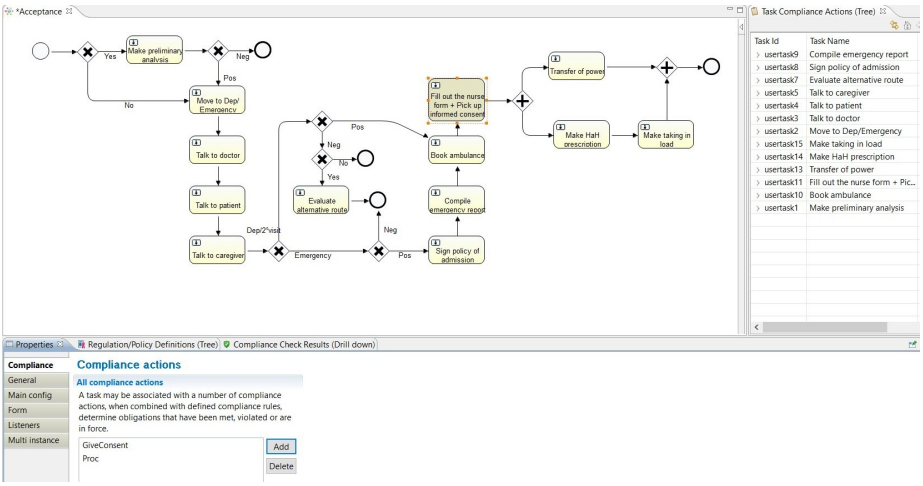

Figure 5.5: OAD Acceptance sub-process and GDPR norms loaded into Regorous.

5.4.2 Executing Regorous on the OAD Acceptance sub-process

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

Regorous is implemented as a Eclipse[8] plug-in. After creation or uploading of the BPMN process it is possible to import a file with a set of rules in Regorous XML format.

In each process activity, it is possible to specify which vocabulary terms are true or false through special Eclipse windows provided by the plug-in. In this way, it is possible to describe the resources used and the detailed tasks that are executed for each activity. The truth value of these terms could also be stated programmatically during the real-time execution of the business process.

The OAD Acceptance sub-process was downloaded from iGrafx in a file .bpmn and uploaded to Regorous. Figure 5.5 shows the OAD Acceptance sub-process on the left and the detail of the XML file with the formalised GDPR rules on the right.

At the bottom, the plug-in includes special tabs that allow the values of the terms to be specified for each task. For example, by specifying "`GiveConsent`" and "`Proc`" in the task **"Fill out the nurse form + Pick up informed consent"**, Regorous infers that the process complies with the ruleset, since the superiority relation seen above will make the processing of personal data permitted. On the contrary, by specifying the single action "`Proc`", Regorous

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

deduces that the process does not comply with the ruleset because the rule with ruleLabel="Art.6.0" states that the processing of personal data is forbidden and, contrary to the previous case, this prohibition is not overridden by a stronger permission.

After specifying the rules or checks performed in that task in the various activities, the Regorous control can be executed.

Thanks to the superiority rules and the BPMN, Regorous follows the process flow for control. In this way, it is able not only to check whether each rule is respected, but also whether the sequence of them is compliant with the sequence imposed by law. Moreover, starting from the generator (the rod on the left) and executing the various flows for each branch (gateway) of the process and up to all the various possible ends of the process, all possible individual paths are checked. Furthermore, each path is not executed only once, but several times. This is where the superiority rules come into play and therefore it is also possible to verify even if some activities are generically controlled sooner or later within the process, whether they are for all possible branches and if they are (for each branch) in the sequence established by law.

Indeed, it is important to emphasise that:

- **A rule may generically state that an action must be executed.** In this case, by executing it more than once, it is possible to check whether the action is carried out sooner or later in an activity of the process, but also if this activity is not only present, but is present for all possible branches of the process. For example, it is possible that one requirement may be ignored if another occurs.

  In the case of GDPR, the rule is that personal data cannot be processed, this is the main rule. But then the rule allows exceptions, for example, if consent is given. Of course, it is not possible to know from the beginning, by law, if and when (in which activity) consent will be given. Therefore, the primary rule will apply until the requirement contained in the superior rule of consent arrives. If there were no rules of superiority, the primary requirement that personal data may not be processed would continue to apply. Moreover, if the consent were revoked, this would be a superior rule to the "`GiveConsent`" rule, which would then override the consent previously given. In this case, however, it should be noted that it is as if consent had not been obtained from the beginning, so if other branches of the process are running in parallel in the meantime, they may no longer be compliant. If the Regorous control stops at the first execution, without possibly having some subsequent steps in memory, it could provide an incorrect output. It would be enough if the consent was given before a gateway with two parallel activities/pathways and then revoked in only one of the two branches (e.g. the patient would probably communicate the revocation to the doctor or nurse, but not at the laboratory).

- **A rule may provide that one activity must be done after or before another.** In the case of GDPR, the consent must be signed after

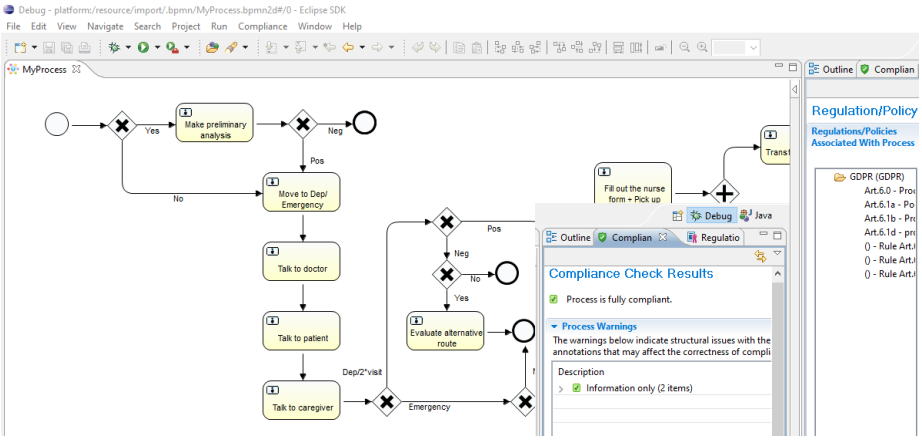

Figure 5.6: OAD Acceptance sub-process semi-automated compliance checking according to GDPR norms using Regorous.

receiving the information and before having the treatment. Therefore, it is not only important that the activities of talking, signing, being taken in charge exist, but it is important that, in any branch of the process, if there is the activity of signing, it is preceded by having the information and whether a patient is registered it is preceded by having the consent signed.

At the end of the execution, the plug-in allows an output with the "Compliance Check Results", as shown in Figure 5.6. It can indicate three different results:

- **The process is compliant (in green).** As in Figure 5.6. It means that the whole process, i.e. all the paths that form the process are fully compliant. In this case, there will be no further information.
- **The process is not compliant (in red).** It means that there is one or more missing mandatory controls or activities. In this case, it is also explained what they are. It is indicated by the names used in the Vocabulary and the missing control indicated in the formalised law.
- **The process may not be compliant (in orange).** This is a warning. It means that the control detects non-conformities or anomalies. For example, there may be mandatory activities, but in some branches they may not be in the right sequence, therefore it is indicated where to carry out the check.

In conclusion, using this methodology, there are three final aspect to consider: Firstly, once a law has been formalised, the file remains saved, so in the

event of partial changes by the legislator, it will only be sufficient to modify the new part.

Secondly, it is possible to upload more than one file, one for each regulation. Each company is likely to be subject to more than one law (e.g. national, European, guidelines; or in different areas, such as sector, labour contract, security, and privacy). Since it is possible to enter and then check compliance with more than one law at the same time, it is also possible for Regorous (in orange) to report steps that may be compliant for one law but not quite correct for another.

Finally, both the iGrafx simulator and the regulatory compliance tool Regorous can download and upload the project in a .bpmn file. Using these or similar tools, working on .bpmn files, it will be possible to continuously cross-check until an optimised process is achieved from both an organisational and a legal compliance point of view. Moreover, in the event of regulatory changes, the perfect balance between organisation, risks and new regulations can be easily restored.

Chapter 6

New perspective: towards automatic control

6.1 Introduction

The regulatory compliance tools available today and the logic-based language are great supports, but in the meanwhile, they have a big limit: they need a human expert.

With the large number of regulations, constantly evolving, to which it is necessary to comply, today it would be almost impossible to carry out legal risk management only and completely manually. The ICT and IA tools available today are certainly a great support and help to carry out the compliance checking in a semi-automatic way. But it's still semi-automatic and not fully automatic support for two big reasons:

- The need of a human expert.
- The interpretation of law.

To set the actual tools is needed, a person that is an expert both in the specific business, both in logic-based language and in the legal field. This merge of expertise is not common and easy to find. It is rare that a person specializes in both IT and logic-based language and in the legal field. Thus, it is rare that this resource is included in the company's staff.

On the other hand, the languages of logic are still evolving, especially to find the most suitable for the legal field. In addition to the strictly technological problem, in fact, in the legal field, there is the problem that laws are not an ordered list of points to be verified[1]. In this case, it would be sufficient to formalise the process and the pointed list and to have the tool checked. The biggest

[1]More precisely, there are detailed regulations, such as the transfusions guidelines (of Section 5.3), but general laws covering more fields such as the GDPR (analysed in Section 5.4) are more common.

problem in the legal field is that laws must be interpreted and contextualised in the regulatory system that contains them. The question of interpretation, therefore, opens a new chapter of research. The interpretation for its definition, is an activity purely of the human intellect, therefore a machine today can serve as a support but not replace considerations that can also include ethics, common sense, good faith, the socio-cultural context, the aim which the legislator had in writing that norm, etc. more abstract concepts that would be difficult to formalize with an absolutely precise and well-defined mathematical formula.

Most of the research in this area is aimed at constructing platforms or finding languages that are increasingly adapted to solve the problem of the formalisation of laws. This last chapter focuses on a new (and still ongoing) perspective that begins from a legal point of view. What it means to interpret a law, what is the purpose of the interpretation, what are the principles and finally what are the reasoning of a jurist when he must interpret a law. The goal is to understand if it is possible to codify such reasoning, instead of finding an existing language that fits them.

As said, this last chapter does not contain a finished job with a definite result. Contains more than other initial considerations and first experiments of a work that will be part of a work in progress and future research projects.

It may be considered as part of Phase 3 of the methodology of Figure 4.1.

Also this Chapter is a merge of some considerations and results already published in [30, 17, 290, 289].

6.2 The problem of legal Interpretation: facts, cases and doubts

Norms are not "legal flowers without stem or root" [256]. A normative provision almost always has to be read in the context of other norms. Generally, the law has a holistic character which emerges from a network of legal documents[2]. This means that at times the meaning of legal norms emerges not from single parts of a normative provision, but from a wider legislative corpus (it is arguable that the context is even wider including parliamentary debates, legal common practice, and doctrinal interpretation). As such, legal interpretation takes much effort, and can be helped by automated efforts to find such links.

Legal interpretation is the process for transforming the written dispositions in norms through a cognitive activity [321, 203]. At the exact moment that a norm is reading it is also interpreted. The easy interpretation is the assignment of the meaning of every single word (so-called textual interpretation), then other types of interpretations exist with an also different types of difficulty levels. Therefore, every norm has to be interpreted. Moreover, norms are general and abstract rules that serve to regulate life in society and, through the interpretation, written words in the laws acquire normative power.

[2]See [274] and [137] among others.

One of the main problems is that cases, so the written disposition made to solve a generic situation, and facts, the specific real-life scenarios, most of the time do not match.On the other side, there are a lot of kinds of laws, derived from different organs with different powers, made at different times, referring to different subjects, etc.

The world of law, while aiming for certainty, is peopled by interpretative doubts. They are the element of the interpretation on which legal reasoning is based [240].

The fact is the source of the consultation. The words are written in the law begin to live when they are subjected to interpretation. The interpreter is the one who, having to answer a practical case, puts them in relationship with the problems of life that ask for juridical answers [321].

Any interpretative doubt arises from the point of view of the fact. It means that the starting point is the fact and not the case or the norm in general[3]: either if the fact creates new cases, or if the fact creates cases deserving to be considered from a new point of view. In the second scenario, we are therefore wondering about the actual meaning to be assigned to the norm, that may change if society evolves.

The interpreter who acted without considering the historical-concrete reality of his object would adopt “the method of ignorance about the sense of his acting" [282]. He would carry out operations that are not interpreted in a real sense [35]. He makes mere “translations" of the words of the legislator in other words [321], but without real interpretation, although words change, they do not acquire the normative power, they do not become a norm. In the field of law, there are no “mere facts" which can be analysed in quantitative and descriptive terms and this is confirmed by the experience. The right has to do with “human facts", facts that derive from everyday life comprehensible according to categories of sense and value. They provide the interpreter with “cases to be settled legally" and these cases are full of regulatory expectations [321]. In conclusion, the law may regulate types of generic cases, but in people’s actions, there is a flood of intersecting variables that create the fact. Moreover, all these facts must be contextualised also in the historical period and in the society in which it happens. What is considered illegal in a society or historical period is not said, indeed history demonstrates, that it can endure evolutions until it is overturned. Women’s rights are an example of this. It is therefore very difficult, if not improbable, that the facts, what really happens in everyday life, coincide perfectly and without doubt, nor overlap with the cases provided in the rules. In conclusion, the interpretation is the starting point to apply the rules, but to interpret is fundamentally taking into account a lot of variability at the time, the context, the hierarchy of the sources, the society, the intention and the goal of the rule, etc [240].

[3]The current starting point of the support compliance checking tools.

6.2.1 The nature of legal reasoning

The problem of vagueness pertains to all human reasoning, not just legal interpretation. It was said that: "vagueness gives rise to borderline cases. Think, for example, of a colour spectrum. There are clear cases of red and clear cases of orange, and in between there are borderline cases: shades which we don't feel inclined to classify either as red or as orange. [...] It is natural to suppose that, if an area on the spectrum is red, then if you move a tiny distance in either direction, the area you get to must be red too; but if you move a large distance the area may not be red. In other words, a small difference does not matter to the correctness of applying "red" but a large difference does" [261].

The doctrine shows how context can influence the meaning of even a simple question such as whether a leaf is green: ''Suppose a Japanese maple leaf, turned brown, was painted green for a decoration. In sorting leaves by colour, one might truly call this one green. In describing leaves to help identify their species, it might, for all the paint, be false to call it that" [303].

In the legal context the most famous example of such phenomena is the vehicle in the park scenario: ''A legal rule forbids you to take a vehicle into a public park. Plainly this forbids an automobile, but what about bicycles, roller skates, toy automobiles? What about airplanes? ... We may call the problems which arise outside the hard core of penumbral instances "problems of the penumbra" ... If a penumbra of uncertainty must surround all legal rules, then their application to specific cases in the penumbral area cannot be a matter of logical deduction, and so deductive reasoning, which for generations has been cherished as the very perfection of human reasoning, cannot serve as a model for what judges, or indeed what anyone, should do" [145].

These problems are well-known and have been alluded to in the AI & Law community: ''The law is normally represented in natural, albeit technical, language: the language of statutes and cases. These sources of law are not the law itself, but one possible representation of the law. It is clear that these documents are not themselves the law from the fact, that we must first interpret statutes and cases to get at the law which they represent, and from the fact that reasonable persons can disagree as to just what the law is, although there is rarely disagreement as to what, words make up the statute or case in question. It is the meaning of the statute or case which is the law, not the text of the document itself" [126].

The degree of interpretation required is dependent on the nature of the legal document itself. Some technical legal instruments, such as medical clinical guidelines, are very precise, such that it is possible to identify the hierarchy of norms and model them with defeasible logic [241]. But a different approach is required for EU legislation. For example, EU directives are deliberately imprecise and abstract to allow the Member States to fulfil the objectives in their own way. It follows that deontic norms in EU directives cannot be properly understood without consideration of the context and the motivation behind those norms, as well as consideration of how other provisions, or even other laws, may affect the scope or effectiveness of the norm in question.

One important issue is that the determination of whether a normative provision applies to a particular case is rendered difficult when the norm is less precise. A second issue is that the handling of conflicting legal principles is different to the handling normative rules. Rather than one principle winning to the exclusion of the other, more often conflicting principles are ''balanced" to ensure that aspects of both principles are respected in a way that is proportional and fair[4].

6.2.2 The nature of European law in the global context

The phenomenon of globalisation has put into question the inter-state structure of the international community. The global dimension of some phenomena (for example, climate change, underdevelopment, immigration, terrorism, nuclear proliferation, financial transfers, information technology, human rights, etc.) has shown the inadequacy of an international community founded upon the independence and sovereignty of states. They require international rules and institutions due to their transnational character. Traditionally, international law governs relations between independent states. The norms that bind states to originate from their free will in treaties or customs. The development of international law tends to reduce state autonomy. In certain matters, such as human rights, environmental protection, financial crime and terrorism, international law binds national law. There has been a movement from international commercial relations from direct inter-state mechanisms (above all the General Agreement on Tariffs and Trade) towards a system of international economic relations in the sphere of specific international organisations bestowed with normative, penal and judicial powers. For example, the evolution of GATT into the World Trade Organisation, as well as other international institutions such as the World Bank created to resolve controversies in the world of investment. Unlike states, international organisations are not given general competence, but are governed by the principle of specialisation and limited powers to pursue common interests attributed by the states. Not all organisations have a legal personality. To this end, they must both be given sufficient autonomy, also organisational, distinct from that member state and have a well-defined mission with corresponding competence and status within the international community. There are actors that do not truly have an international legal personality, but are involved and participate in such activities, including NGOs and multinational companies. The first represents public interests of the universal civil society, while the second represents productive interests of the current economic-financial system [79].

International law leaves great liberty to states in their choice of implementation, being interested only in that the objectives are achieved. This principle is not dissimilar to the treaties of the European Union. Notwithstanding many similarities to international law, European Union law has certain characteristics

[4]More deeply, there is a demarcation between principles and rules. This is a point of contention among experts with some arguing that it is a continuous spectrum [97].

that render it unique. In particular: to "exercise the Union's competences, the institutions shall adopt regulations, directives, decisions, recommendations and opinions. A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States. A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. A decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them. Recommendations and opinions shall have no binding force"[5].

The limits of EU competences are governed by the principles of conferral[6]: "the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein. Competences not conferred upon the Union in the Treaties remain with the Member States"[7].

The use of Union competences is governed by the principles of:

- **Subsidiarity**: "in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States [...] but can rather [...] be better achieved at Union level"[8]. Moreover, "when the Treaties confer on the Union a competence shared with the Member States in a specific area, the Union and the Member States may legislate and adopt legally binding acts in that area. The Member States shall exercise their competence to the extent that the Union has not exercised its competence. The Member States shall again exercise their competence to the extent that the Union has decided to cease exercising its competence"[9].

- **Proportionality**: "the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties"[10].

The primary characteristic that distinguishes the European Union from other international organisations is that member states have relinquished some sovereign powers to the European Union.

It follows other interesting phenomena:

- The European Union has the competence to conclude agreements with third states or international organisations, where such competences have been expressly given, or if they are acting within their limits.

- According to the "principle of sincere cooperation, the Union and the Member States shall [...] take any appropriate measure, general or par-

[5] Article 288 Treaty on the Functioning of the European Union (TFEU)
[6] Article 5.1 Treaty on European Union (TEU).
[7] Underline bot in the Article 4.1 and in the Article 5.2 of TEU.
[8] Articles 5.1 and 5.3 of TEU. See also Article 4.1 of TEU and Article 352 of TFEU
[9] Article 2.2 TFEU. We want to underline that the concept of subsidiarity also exist in some Member States government, but with a meaning more similar to division of competences e.g. see Article 118 of the Italian Constitution.
[10] Articles 5.1 and 5.4 of TEU.

ticular, to ensure fulfilment of the obligations arising out of the Treaties or resulting from the acts of the institutions of the Union [...] and refrain from any measure which could jeopardise the attainment of the Union's objectives"[11].

- The increasing trend towards harmonisation of EU law has put the European Court of Justice as the supreme arbiter of European law, and national judges are required to interpret their own laws in accordance with European law, even when there is apparent conflict between those laws[12]. The European Court can "review the legality of acts of bodies, offices or agencies. It shall for this purpose have jurisdiction in actions brought by a Member State, the European Parliament, the Council or the Commission on grounds of lack of competence, infringement of an essential procedural requirement, infringement of the Treaties or of any rule of law relating to their application, or misuse of powers"[13].

- Peculiar characteristic of the EU is that "[a]ny natural or legal person may [...] institute proceedings against an act addressed to that person or which is of direct and individual concern to them", and more important "and against a regulatory act which is of direct concern to them and does not entail implementing measures"[14]. "If the action is well founded, the Court of Justice of the European Union shall declare the act concerned to be void"[15]. It means that the Court has the power to "delete" some national law, and with it, delete also the future, present, and even past effects that law, as if that law never existed.

6.3 A first experiment

The first practical analysis starts with a manual analysis of a lengthy European Union (EU) directive that revealed not only very different kinds of norms, but also different kinds of relationships between norms.

The main assumption is that understanding of particular normative provisions can be greatly enhanced by reading them in conjunction with those norms that influence them in some way. Therefore, the aim is to focus on the links between normative provisions in the same piece of legislation.

The first step was to analyse a directive and say which rules are legally linked to each other. In doing this work, it has been found that there are so many reasons why a legal expert can say that two norms are related.

Therefore, a Gold Standard is create to report the types of existing links. Each type of link is a motivation. For each reason there is a fairly common

[11] Article 4.3 of TEU.
[12] See Articles 258 to 260 of TFEU.
[13] Article 263, pararaphs 1 and 2 of TFEU.
[14] Article 263, paragraph 4 of TFEU.
[15] Article 264 of TFEU.

reasoning that leads to say that two rules are linked to each other for one motivation or another.

The reasoning of analysis and classification that the jurist makes in his mind can be said to be completely natural and intuitive. However, it follows passages and looks for common lines to tell if this norm is part of a subset.

For every type of motivation, it has been tried to understand which is the reasoning followed, which is the process that is naturally carried out by the mind of the jurist, what are the elements that are sought in order to decide if two norms are connected and for what reason.

The aim is to verify if it is possible to formalise for every motivation (so for each type of link) the reason done. If they are formalisable with a good precision it is probably possible to program a technology that can reproduce them. So obtain a technological support that not only recognizes the recurrence of numbers or of equal phrases in more norms (important but not sufficient), but that can extract and connect even more important concepts such as context, tacit abrogations, regulatory antinomies.

The goal is not to automate the interpretation, but to provide automatic legal support to help in selection, from the entire regulatory system, all the rules to be taken into account for verifying the regulatory compliance.

The focus of this experiment is on European directives, which as mentioned above, are prescriptive but sufficiently general to allow member states to articulate their own detailed norms and procedures as they prefer in order to achieve the goal of the directive. Being by nature goal-oriented, directives are particularly given to principle-based (balance) rather than defeasible reasoning. Almost half of the text of directives consists of recitals, which are intended to be explanatory and do not have the same status as normative provisions. There are different doctrinal positions on the relationship between recitals and normative provisions [174]:

1. Recitals have no effect.
2. Recitals are dominant over normative provisions.
3. Recitals have an equal position in relation to normative provisions.
4. Recitals encompass a subordinate position towards normative provisions.

The ECJ has assumed both positions 3 and 4 in its judicature in cases 24/62[16] and C-162/97[17]. The proportion of recitals in directives has increased over the years.

Also the doctrine upholds that "recitals are used by the Member States to insert normative provisions which they have failed to get into the text, and by the Commission to dump normative provisions which they do not want to prolong debate and disagreement on" [170].

[16]Position 3: Case 24/62, F.R.G. v. Comm'n of the Eur. Econ. Cmty., 1963 E.C.R., paragraph 18.

[17]Position 4: Case C-162/97, Nilsson et al, paragraph 54, 1998, E.C.R. I-07477.

From all these reasoning it is possible to conclude that recitals cannot be ignored. While recitals lack the prescriptive status of normative provisions proper, their main purpose being to provide the wider context. Thus, they have an important influence on the interpretation of normative provisions.

In conclusion, the first analysis concern on normative provisions and recitals in EU directives.

The two goals are to find:

1. What kind of norms are present in normative provisions and recitals?
2. What kind of links are there between norms, be they normative provisions or recitals?

6.3.1 Classification of norm types

There are different kinds of norms with different functions (they serve different purposes), and these different types are found in both normative provisions and recitals. The following categorisation is purely semantic and is intended to be generalisable to all directives.

In particular, it was found that the structural aspects (e.g. type of modal verb used) are not a definitive indication.

Five different types of norms are detect: objective, constitutive, deontic, scope and meta-norms (procedural and contextual).

All the examples provided come from a lengthy directive analysed in detail: Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[18].

Objective

Definition:

> Outlines the purpose behind the directive as a whole, or some parts of it, and the wider social and legal context. Sometimes the objective is lofty and is a general principle for the existence of the directive. Other times the objective may be a more specific sub-goal.

Example 1:

> ARTICLE 1: This Directive lays down standards of quality and safety for human tissues and cells intended for human applications, in order to ensure a high level of protection of human health.

Constitutive

Definition:

[18] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

Official definitions of directive-specific technical concepts. Legislative constitutive norms are usually general descriptions, but also not uncommon are definitions by example, which allow extension by analogy, as well as definitions that explicitly include or exclude certain items from counting as the legal concept in question.

Example 2:

ARTICLE 3: For the purposes of this Directive: (a) "cells" means individual human cells or a collection of human cells when not bound by any form of connective tissue; (b) [...]

Deontic

Definition:

Specifies types of behaviour to be expected or permitted. Deontic norms have been further classified as permission, obligation, prohibition etc (see [153] for an elaborate study), but this level of detail is not required for our purposes[19].

Example 3:

ARTICLE 7.7: Member States shall, upon the request of another Member State or the Commission, provide information on the results of inspections and control measures carried out in relation to the requirements of this Directive.

Scope

Definition:

Outlines the extent of applicability or non-applicability of norms (or entire legislation) in the context of other norms (or other legislation) with which they may otherwise conflict. Scope also concerns norms that specify the areas of competence in different jurisdictions, in this case the EU and member states.

Example 4:

RECITAL 11: This Directive does not cover research using human tissues and cells, such as when used for purposes other than application to the human body, e.g. in vitro research or in animal models. Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this Directive.

[19] In this first classification the term deontic norm is uses to describe what we originally called detailed technical norms and to distinguish them from objectives. In some legal traditions, e.g. Italian, detailed norms also may include norms that are not strictly deontic.

Meta-norms

Meta-norms are norms about norms. Laws do not only pertain to certain behaviours but also (1) the way in which the norms are produced, (2) the way in which they are applied and (3) the way in which upon violation a sanction is imposed. The distinction between norms and meta-norms is that the first concerns behaviour, the second concerns other norms or the production or application of other norms [113]. We distinguish between two kinds of meta-norms:

Meta-norms: Procedural

Definition:

> Procedural refers to step-by-step processes for implementing law e.g. get signatures, agreement from the Committee, further signatures.

Example 5:

> ARTICLE 10.3: Member States and the Commission shall establish a network linking the national tissue establishment registers.

While the above example is a procedure particular to the subject-matter of the directive, there are also other procedural norms that occur in practically all directives, and are part of the law-making process.

Example 6:

> ARTICLE 26.1: Member States shall send the Commission, before 7 April 2009 and every three years thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the measures taken in relation to inspection and control.

Meta-norms: Contextual

Definition:

> Contextualisation is about time, space, addressee and hierarchy of norms.

Example 7:

> ARTICLE 32: This Directive shall enter into force on the day of its publication in the Official Journal of the European Union.

6.3.2 Classification of link types

Norms are related to one another in many different ways. Below are provide definitions with examples from the above-mentioned Directive 2004/23/EC[20], and are mainly focused on links between normative provisions and recitals. Where not all parts of the recital or sub-article are connected, the underlined sections highlight the related parts of the text.

Conceptually Similar

Definition:

> There is content within the provisions that are about the same subject-matter and may use similar or different wording to say more or less the same thing.

Example 8 (using same wording):

> *ARTICLE 2.1*: This Directive shall apply to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications. Where such manufactured products are covered by other directives, this Directive shall apply only to donation, procurement and testing.
>
> *RECITAL 13*: The donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications should comply with high standards of quality and safety in order to ensure a high level of health protection in the Community. This Directive should establish standards for each one of the steps in the human tissues and cells application process.

Example 9 (using different wording):

> *ARTICLE 5.1*: Member States shall ensure that tissue and cell procurement and testing are carried out by persons with appropriate training and experience and that they take place in conditions accredited, designated, authorised or licensed for that purpose by the competent authority or authorities.
>
> *RECITAL 27*: Personnel directly involved in the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells should be appropriately qualified and

[20] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

provided with timely and relevant training. The provisions laid down in this Directive as regards training should be applicable without prejudice to existing Community legislation on the recognition of professional qualifications.

Constitutive

Definition:

The constitutive link is where one provision provides a definition of domain-specific terms contained in another provision. Often, directives contain a glossary of terms in one specific Article.

Example 10:

ARTICLE 3: For the purposes of this Directive:
(a) 'cells' means individual human cells or a collection of human cells when not bound by any form of connective tissue;
(b) 'tissue' means all constituent parts of the human body formed by cells;
(c) 'donor' means every human source, whether living or deceased, of human cells or tissues;
(d) 'donation' means donating human tissues or cells intended for human applications; [...]
(f) 'procurement' means a process by which tissue or cells are made available; [...]
(p) 'allogeneic use' means cells or tissues removed from one person and applied to another; [...]

RECITAL 16 Tissues and cells used for allogeneic therapeutic purposes can be procured from both living and deceased donors. In order to ensure that the health status of a living donor is not affected by the donation, a prior medical examination should be required. The dignity of the deceased donor should be respected, notably through the reconstruction of the donor's body, so that it is as similar as possible to its original anatomical shape.

In this case Article 3 contains definitions of many domain-specific terms in Recital 16, so there is a Constitutive link between these provisions.

Motivation

Definition:

A link between a deontic norm and the motivation behind it. The provisions have the same goal but different levels of granularity. Sometimes the motivation is lofty and is a general principle for the

existence of the directive, alternatively the motivation may be a core value of human rights or a fundamental principle of European Treaties. Other times the motivation may be a more specific sub-goal.

Example 11:

ARTICLE 16.3: Tissue establishments shall take all necessary measures to ensure that the quality system includes at least the following documentation:

- standard operating procedures,
- guidelines,
- training and reference manuals,
- reporting forms,
- donor records,
- information on the final destination of tissues or cells.

RECITAL 1: The transplantation of human tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases. The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases.

RECITAL 15: It is necessary to increase confidence among the Member States in the quality and safety of donated tissues and cells, in the health protection of living donors and respect for deceased donors and in the safety of the application process.

Impact

Definition:

A provision may affect the scope or effectiveness of another provision, or add additional requirements. This may be because the norm requires some kind of synchronisation with another procedure in another norm, or because two norms have conflicting goals. The content may be granularity independent.

Example 12 (conflicting goals):

ARTICLE 8.1: Member States shall ensure that all tissues and cells procured, processed, stored or distributed on their territory can be traced from the donor to the recipient and vice versa. This traceability shall also apply to all relevant data relating to products and materials coming into contact with these tissues and cells.

RECITAL 23: All necessary measures need to be taken in order to provide prospective donors of tissues and cells with assurances regarding the confidentiality of any health related information provided to the authorised personnel, the results of tests on their donations, as well as any future traceability of their donation.

Traceability is a sub-goal of health protection, and that confidential information is a sub-goal of respecting the dignity of the individual, and that both these higher goals are sub-goals of maintaining the well-being of persons. However, there is a potential risk of conflict between these sub-goals e.g. traceability can be achieved without anonymity. As such, it is useful to link such norms to any norms that impose restrictions or additional requirements.

Example 13 (enforcement):

ARTICLE 6.3: The tissue establishment shall not undertake any substantial changes to its activities without the prior written approval of the competent authority or authorities.

RECITAL 26: Member States should organise inspections and control measures, to be carried out by officials representing the competent authority, to ensure that tissue establishments comply with the provisions of this Directive. Member States should ensure that the officials involved in inspections and control measures are appropriately qualified and receive adequate training.

RECITAL 30: In order to increase the effective implementation of the provisions adopted in accordance with this Directive, it is appropriate to provide for penalties to be applied by Member States.

The impact of Recitals 26 and 30 on Article 6.3 is to render the norm enforceable via monitoring and penalties.

Indirect Internal

Definition:

An indirect internal link is a structural (not semantic) link that exists purely because of an internal reference to a (sub)article. An indirect structural link between Recital X and (Sub)article Y depends on the existence of a primary semantic link between Recital X and another (sub)article that is cited by (Sub)article Y.

Example 14:

ARTICLE 11.3: The responsible person referred to in Article 17 shall ensure that the competent authority or authorities is or are notified of any serious adverse events and reactions referred to in paragraph 1 and is or are provided with a report analysing the cause and the ensuing outcome.

ARTICLE 11.1: Member States shall ensure that there is a system in place to report, investigate, register and transmit information about serious adverse events and reactions which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells, as well as any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells.

RECITAL 25: An accreditation system for tissue establishments and a system for notification of adverse events and reactions linked to the procurement, testing, processing, preservation, storage and distribution of human tissues and cells should be established in the Member States.

In this example, Article 11.3 is indirectly structurally linked to Recital 25 because Article 11.3 refers to Article 11.1, which is Conceptually Similar to Recital 25.

Via Other Law

Definition:

When an article mentions another legal source. Applies only if reading this source is required in order to understand the provision or recital. This is a structural link, and not a semantic link.

Example 15:

ARTICLE 13.1 The procurement of human tissues or cells shall be authorised only after all mandatory consent or authorisation requirements in force in the Member State concerned have been met.

RECITAL 22: This Directive respects the fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union (1) and takes into account as appropriate the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine. Neither the Charter nor the Convention makes express provision for harmonisation or prevents Member States from introducing more stringent requirements in their legislation.

In the above example, the fundamental rights and dignity of the human being mentioned in Recital 22 is the motivation behind the requirement for consent for the procurement of human tissues and cells in Article 13.1.

Procedural

Definition:

> Involving routine bureaucratic procedures of some precision. The procedures referred to here are only descriptions of what the Commission, other EU body, or Member State, have undertaken to do to render the directive effective. They are not norms in the deontic sense. Procedural links do not pertain to norms about what lower bodies within Member States are required to do, which are still deontic norms, in the sense that they impose an obligation.

Example 16:

> *ARTICLE 29.1*: The Commission shall be assisted by a Committee.
>
> *RECITAL 34*: The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

The procedural link exists to distinguish between deontic norms and descriptions of procedures that render the law effective. However, the linked sub-articles and recitals can have different levels of granularity.

Contextual

Definition:

> Contextualising the applicability of all norms involved in the directive in terms of time, jurisdiction, addressee and position in the hierarchy of norms.
>
> The following are the contextual meta-norms that should be linked to other articles and recitals of Directive 2004/23/EC.

Example 17:

> *ARTICLE 32 (time)*: This Directive shall enter into force on the day of its publication in the Official Journal of the European Union.
>
> *ARTICLE 33 (addressees)*: This Directive is addressed to the Member States.
>
> *RECITAL 31 (jurisdiction)*: Since the objective of this Directive, namely to set high standards of quality and safety for human tissues and cells throughout the Community, cannot be sufficiently achieved by the Member States and can therefore, by reason of scale and effects, be better achieved at Community level, the Community may

adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

Norm Group

Definition:

A link between norms that are connected due to being part of the same general requirement. The links between the norms may be conjunction, disjunction or sequence. Such norms may be paragraphs of the same article, or may occur in different provisions.

Example 18:

ARTICLE 20.1: Tissue establishments shall include in their standard operating procedures all processes that affect quality and safety and shall ensure that they are carried out under controlled conditions. Tissue establishments shall ensure that the equipment used, the working environment and process design, validation and control conditions are in compliance with the requirements referred to in Article 28(h).

ARTICLE 20.3: Tissue establishments shall include in their standard operating procedures special provisions for the handling of tissues and cells to be discarded, in order to prevent the contamination of other tissues or cells, the processing environment or personnel.

ARTICLE 21.1: Tissue establishments shall ensure that all procedures associated with the storage of tissues and cells are documented in the standard operating procedures and that the storage conditions comply with the requirements referred to in Article 28(h).

This classification of norm types and link types was data-driven and based on line-by-line coding with an open mind, as espoused by grounded theory [90, 84], followed by comparison and alignment with theories in the literature.

The analysis was carried out by researchers with a background in law, computer science and legal informatics.

6.3.3 Insights for automated identification

The automated identification of norm types is a task which lends itself to well-known supervised classification techniques, such as SVM, Bayes, decision trees, and most recently neural networks [179].

The automated classification of links types, on the other hand, requires closer scrutiny. The input is two different texts and the output is the relation between

them. Much literature on relevance, particularly in information retrieval, assume that relevance correlates with similarity. However, the classification shown underline that norms are related in different ways. Surely, different techniques are required to identify those links.

In the previous classification, the granularity is treated in different ways for different classes. Relevant sections in Conceptually Similar links are on the same level of granularity. On the other hand, a Motivation link features different levels of granularity, although the difference in granularity may be big or small. For Impact, Procedural and Contextual, the level of granularity is inconsequential.

An important thing to underline is that while the categories were agreed by all to be evident in the data, the attribution of individual norm to a particular category was more problematic.

For these reasons, three further parallel works followed:

- An initial review of the state of the art about different techniques and researches about the automated classifications of links types and related works.
- A teorical analysis with the aim to formalise some technique of interpretation to try to find the better technique to use for each category.
- Some practical experiments that involve annotation of a corpus of directives by a larger group of annotators in order to properly elicit the distribution of categories, evaluate inter-annotation agreement and, where necessary, refine the categories.

6.4 Background on automated classification of links

Legal citation networks is by now a mature research area involving a range of different approaches and specific sub-problems.

Several NLP techniques have been applied to the analysis of legal texts [88], increasing the interest of AI in Law [37, 152]. Numerous practical applications typically exploit a NLP pipeline to address machine learning experiments [251, 124], e.g., by performing the classification of judgment norms [283, 310, 311]. Text mining techniques have proven to be useful in extracting structured information from legal sources [85], to explore text classification, information extraction, and information retrieval [82]. While these kind of studies generally performs well, is recognised how standard NLP approaches may still work better than recent neural-based methods. "It is observed that the more traditional methods (such as the TF-IDF and LDA) that rely on a bag-of-words representation performs better than the more advanced context-aware methods (like BERT and Law2Vec) for computing document-level similarity" [200].

There are some notable work for developing the automatic classification of legal text informed by legal philosophy, even if tested on national law legislation[21].

[21] In particular, Tiscornia and Turchi [302], analysing Italian legislation, provisions are clas-

Although there are similarities in the categorisation, there are also differences due to the nature of the legislation being modelled[22]. EU law is particular for having less definite, more goal-based and principle-based norms both in the recitals and provisions. Another important difference is in the motivation for classifying the norms. The past classifications serve to model the content of norms, the one presented here may help in determining the relatedness between norms. Other important work on automated classification of norms have also been explored in order to correctly forecasts 69.7% of Case Outcomes and 70.9% of Justice Level Vote Outcomes of the supreme court of the united states over the sixty year period, but without exploiting any network features [169]; in predicting the violation of 9 articles of the European Convention on Human Rights with an average accuracy of 0.75 [216]; and, to classify of legal norms in German statutes with regard to their semantic type [310, 311].

In the field of legal citation networks, the major tasks are related to identify and extract the citations themselves, challenging when references to different entities are in a range of formats [185] or where the citations are anaphoric or imprecise [9]. Citations can differ in the level of specificity, it may relate to the legislation as a whole or to a specific sub-article (specified with an Arabic number) [65].

Approaches include gazeteers and concept markers [9], regular expressions [258, 65], Conditional Random Fields and BiLSTM neural networks [191] (with the latter two achieving similar performance in an evaluation [185]). In some works, a combined named entity recognition approach which engages rules and supervised learning is used to identify citations, with approximate string matching step employed to resolve typo issues and imperfect entities [262]. In an important paper, provisions are tagged with the stems of noun phrases, legislative definitions or glossaries from reference books. The similarity analysis core takes as an input the parsed regulations and associated features, and produces a list of the most similar pairs of provisions [188]. The most similar research to this paper explored the feasibility of semi-automated mapping between recitals and (sub-)articles in EU legislation [156], and after between (sub-)articles in EU Directives and National Implementing Measures considering the degree of similarity and different types of algorithms usable [227, 228].

However, the focus of those papers was deontic norms and the links explored were only *Conceptually Similar* or, in any case, based on techniques that reveals only the similarity.

---

sified as definitions, attributing competence, constitutive, interpretative, instituting, prescriptive, procedural, sanctioning, material link (derogation or extension, amending link (abrogation, substitution), temporal link (prorogation, suspension). While Maat[94], analysing Dutch legislation, finds core rules, procedures for citizens, procedures for civil servants, rule management and definitions in the body of law, with introduction, conclusion and appendices completing the model of legislative text.

[22]Noteworthy are the following: Tiscornia and Turchi [302] define constitutive norms more broadly, including also power-conferring norms. De Maat's [94] categorisation includes procedural norms also for the addressees of norms, whereas the category presented here as procedural norms describe the procedures undertaken by institutions of the EU to implement and maintain EU legislation.

Some studies concern the task of ranking legal sources, based on a network analysis of citations among (French) legal codes, where the weights are the number of citations between the two codes [64].

Case law are often ranked in terms of authority (often-cited) and 'well-founded in law' hubs (citing many important decisions) or a combination of these measures. The problem is that is not sure that a rarely cited judgment is not important. It could became very significant if it is cited in an important judgment [98]. Some domain-specific methodologies take into account aspects such as the competence level of the court, whether a news item was published on the courts' website, publication in jurisprudence magazines, and age of the judgments [230, 229, 213].

There is also a wealth of literature on the discovery and classification of citations in legislation [324, 38, 184, 259, 309, 9, 182][23]. A first research has the aim to support legal practitioners with the task of gathering citations to case law to support their argumentation. Starting with a seed case, they undertake a recursive process of forward chaining to find cases citing by the current case, and backward chaining to find cases cited by the current case. It is used the text area around the citation, the Text of Interest (TOI), to identify the "Reason for Citing". A simple term-based vector comparison is used to measure the similarity between TOIs. In this way, it is possible to obtain a network of explicitly linked cases focussed on a particular legal issue [324]. Another work investigates explicit cross-references to external legal texts in order to identify a taxonomy of edges in a citation graph [212].

Also in these case, most of the techniques are based on similarity matches. Interestingly, some authors, in addition to full-explicit references, take in consideration also semi-explicit references, implicit citations [235] and tacit references[24] building a network of individual text units or paragraphs to draw a more complete picture of implicit citations.

All these researches are really important to find some useful techniques regarding to *Indirect Structural* and *Via Other Law* links.

It is possible to observe that the studies conducted so far lead to identify mostly explicit links, whether semantic (Conceptually Similar) or structural in nature (Indirect Structural - Via Other Law). A next step was taken with some studies involving also theoretical analysis on contextualisation.

Contextualisation is important because '[P]rovisions, rules, applications of rules, references to text, and references to physical entities. All of these entities exist and change in time; their histories interact in complicated ways...[A] rule has parameters which can vary over time, such as its status (e.g., strict, defeasible, defeater), its validity (e.g., repealed, annulled, suspended), and its jurisdiction (e.g., only in EU, only in US). In addition, a rule has temporal aspects such as internal constituency of the action, the time of assertion of the

[23] Sadeghian [259] classifies according to 9 labels: legal basis, authority, definition, example, exception, criterion, limitation, procedure and amendment.

[24] In particular, tacit references are defined as follows: "[t]he connection between the norms emerges due to systemic interpretation and cannot not be determined by exclusively analysing the norm text." [309]. Even if they are just defined and not used in the model.

rule, the efficacy, enforcement, and so on' [40]. As such LegalRuleML annotates each rule with its defeasibility status, temporality, jurisdiction and authorial tracking. In the tool Akoma Ntoso [45] the temporal dimension is modelled in Legal Knowledge Interchange Format (LKIF) [234] by ascribing to each norm blocks of information covering time of entry into force, time of efficacy and time of application. The tool has a multi-layered approach to modelling laws with the text layer continuing the original legal text, the structure layer providing a hierarchical representation of the parts present in the text layer, and the metadata layer associating the first two layers with ontological information to allow advanced reasoning using logic frameworks, and allowing for multiple interpretations of norms by different actors. It also incorporates the Functional Requirements for Bibliographic Record (FRBR) model [270] to identify different versions of the same norm.

There is a wealth of theoretical research on conflicts between norms [16] and defeasibility [241]. The main features of formal approaches to defeasibility are arguments that are satisfied with certain criteria, counter-arguments that serve to attack or undercut other arguments, and the non-monotonic nature of legal reasoning, where conclusions can be revised with the addition of new information. Such analyses can be used to build a formal legal reasoning expert system [277, 180]. Some attention has been paid to contrary-to-duty obligations, i.e. a conditional obligation arising in response to a violation of another obligation, particularly for compliance management [134]. According to legal reasoning, there is an obligation only if the infringement is accompanied by a sanction. For logical implication: a norm of one class, such as prohibition, will of necessity be linked to a norm of another class, such as sanction [302].

These studies are important to analyse the *Impact* links.

The use of automated systems in legal settings has gained credibility with the rise of AI in general. However, there are certain kinds of laws that are simply too abstract or dependent on other laws to be modelled in this way with certainty.

It has been highlighted that 'given the importance of digital information for legal professionals - lawyers easily spend up to fifteen hours per week on search, most of it in electronic resources although the abandonment of paper does not always seem to be a voluntary choice - the gap between LIR systems and user needs is still big'. This is because 'retrieval engineering is focused too exclusively on algorithmic relevance, but it has been proven sufficiently that without domain specific adaptations every search engine will disappoint legal users' [307].

6.5 Teorical analysis on methodologies of interpretation

The Vienna Convention is an International Treaty that establishes some laws on the treaties themselves. Inside, it also has an entire section concerning in-

terpretative methodologies.

Various approaches have been proposed in the past, providing semantic analysis methods to produce meaning representations but just by analysing the lexical and grammatical (syntactical) characteristics of language at the sentence level [221, 313, 323, 271, 269].

Starting from all the five interpretation methodologies, some abstract preliminary decoupled semantics for each interpretation methodology is provide. These methodologies can be in the future be modularly developed and then coordinated within a framework to produce interpretations for legal documents taking into consideration additional parameters, such as for instance the application context.

6.5.1 The Vienna Convention on the Law of Treaties

The system of law imply that there are different types of law sources. Therefore, not all laws are at the same level, so some laws are superior to others. The more the law is in a superior source, and have greater force or range of action, the more generic it is. It follows that also the cases contained in them are generic.

An important and international convention was drafted by the International Law Commission (ILC) of the United Nations and opened to signature on the 23rd of May 1969. It is "The Vienna Convention on the Law of Treaties (VCLT)[25]. It is an international agreement regulating treaties between states. Known as the "Treaty on treaties", it establishes comprehensive rules, procedures, and guidelines for how treaties are defined, drafted, amended, interpreted, and generally operate. It is considered a codification of customary international law and national practices concerning treaties [43, 215, 281, 51].

The VCLT is regarded as one of the most important instruments in treaty law, and remains an authoritative guide in disputes over treaty interpretation.

In was written, in particular:

- Considering the fundamental role of treaties in the history of international relations.
- Recognizing the ever-increasing importance of treaties as a source of international law and as a means of developing peaceful cooperation among nations, whatever their constitutional and social systems.
- Affirming that disputes concerning treaties, like other international disputes, should be settled by peaceful means and in conformity with the principles of justice and international law.
- Believing that the codification and progressive development of the law of treaties achieved in the Convention will promote the purposes of the maintenance of international peace and security, the development of friendly relations and the achievement of cooperation among nations.

[25] Vienna Convention on the Law of Treaties. Vienna, 23 May 1969.

A whole section was devoted to the interpretation. The Section 3 is entitled "Interpretation of Treaties" and the relevant provisions for treaty interpretation are Article 31, 32 and 33. These articles show some macro principles to be taken into account for a legal interpretation.

In particular, it is established that a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the *terms* of the treaty in their *context* and in the light of its *object* and purpose. it means that literal interpretation, that is the mere meaning of words, is important but it is not enough on its own. The literal meaning must always be coordinated and read in accordance with the objective of the rule in question and everything must be brought into context. Furthermore, not only the text itself must be considered, but are also to be included in the interpretation preamble, annexes, any agreement relating to the treaty and any instrument which was made by one or more parties. Particular importance is given to contextualisation. It is not only the text itself but also its position in the system, that is, what is related to it as any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions, any subsequent practice in the application of the treaty and any relevant rules of international law[26].

The interpretation must be guided always taking into consideration the object. Especially, in case of doubt, when the literally meaning leads to a result which is manifestly absurd or unreasonable (in this case the objective may emerge from the preparatory work)[27], or when a treaty has been authenticated

[26] Article 31. General Rule of Interpretation.

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
   (a) any agreement relating to the treaty which was made between all the parties in connexion with the conclusion of the treaty;
   (b) any instrument which was made by one or more parties in connexion with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.
3. There shall be taken into account, together with the context:
   (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
   (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
   (c) any relevant rules of international law applicable in the relations between the parties.
4. A special meaning shall be given to a term if it is established that the parties so intended.

[27] Article 32. Supplementary means of interpretation.

1. Recourse may be had to supplementary means of interpretation, including the prepara-

in two or more languages[28].

6.5.2 Methods and semantics

In addition to the principles, there are some interpretation methods. The main and most significant are:

Textual Interpretation while this method focuses on establishing the meaning of the text used in the documents, the interpretation of the meaning of the words composing the legal documents is outside of the scope of the present paper, therefore we assume that at this particular level of interpretation, the outcome is a set of possible interpretations derived from the combination of the ways in which the words composing the text are interpreted.

Teleological Interpretation this methodology concerns itself to determine the interpretation of a legal text according to the underlying objective of the document itself.

Systematic or Contextual Interpretation this methodology states how the interpretation of a legal text depends on the context in which it is applied.

Subjective or Historical Interpretation the intention of the drafters should be consider by interpreting it.

Comparative Method of Interpretation provides an interpretation considering existing law from different countries.

For each method it is provide some abstract semantics serving as guidelines for their development and implementation. The goal is to lay down the first steps

tory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:

(a) leaves the meaning ambiguous or obscure; or

(b) leads to a result which is manifestly absurd or unreasonable.

[28] Article 33. Interpretation of treaties authenticated in two or more languages.

1. When a treaty has been authenticated in two or more languages, the text is equally authoritative in each language, unless the treaty provides or the parties agree that, in case of divergence, a particular text shall prevail.
2. A version of the treaty in a language other than one of those in which the text was authenticated shall be considered an authentic text only if the treaty so provides or the parties so agree.
3. The terms of the treaty are presumed to have the same meaning in each authentic text.
4. Except where a particular text prevails in accordance with paragraph 1, when a comparison of the authentic texts discloses a difference of meaning which the application of articles 31 and 32 does not remove, the meaning which best reconciles the texts, having regard to the object and purpose of the treaty, shall be adopted.

for formalising such methodologies and organising them into a framework aimed at interpreting such documents automatically, even if the proposed semantics is fairly abstract and preliminary.

From an engineering perspective, decoupling the different interpretation modalities brings the advantage to allow their independent development. Being able to independently develop an interpretation modality module allows to purely focus on the characteristics and requirements of such module, while ignoring the ones belonging to the others. This could bring the additional benefit of simplifying the development of these modules due to the more focused scope.

However, for such a modular framework to properly work, it is required to provide the interfaces between the different modules. Intuitively, such an interface that allows to communicate information between the modules should be played by the interpreted rules, as the interpretation result of a model can then be fed to another to refine such result.

Textual Interpretation

A textual interpretation focuses on assigning meaning to the norms contained in a legal document. Abstractly, a legal document can be seen as a collection of terms, which describe the contained norms as described in Definition 1.

Definition 1 (Legal Document) *A legal document D consists of a set of norms $\mathcal{N}$, where each norm is multi-set of terms $\mathcal{T}$.*

Definition 2 (Textual) *Let ϕ be the* textual interpretation *function, $\phi(D) = \mathcal{P}(O)$ is the application of the function over a legal document D, where the resulting power-set $\mathcal{P}(O)$ contains in each of its inner sets O an interpretation of D and is* consistent*.*

Notice that Definition 2 describes the abstract semantics of a textual interpretation methodology requiring only for the produced interpretations to be consistent. Such consistency constraint can be implemented in different ways. We discuss now a possible implementation of such constraints.

One of the simplest implementation of the consistency constraint for the textual interpretation function can be defined by considering the consistent interpretation of the terms. Such constraint requires that a term, appearing across the legal document multiple times, either in the same norm or in multiple norms, to be associated the same meaning in the output $\mathcal{O}$. In other words, a consistent interpretation abiding to the proposed constraint implementation would consist of any possible permutation of meaning assignment to terms that do not assign different meaning to the same term in the same interpretation. Following from this, the output power-set of the textual interpretation function ϕ would contain every possible permutation of meaning assignment to terms which follow the consistency constraint.

Notice that given such simplistic abstract semantics, the output power-set of the interpretation function should possibly contain many different interpretations. While we are aware of the computational complexity issues related to

compute the output power-set, this problem is currently outside the scope of the present paper, and can be possibly tackled or reduced by using more refined implementation of the consistency constraint.

Example 1 (Textual Interpretation) *Considering the norm "Vehicles are not allowed in the park", lets assume for simplicity that the norm is composed by the terms: "vehicles" and "are not allowed in the park". Again for the sake of simplicity, lets assume that the term "are not allowed in the park" has a single interpretation. By assigning a meaning to the term "vehicles" we can obtain the following non exhaustive list of interpretations:*

i_1**:** cars *are not allowed in the park.*

i_2**:** bicycles *are not allowed in the park.*

i_3**:** motorcycles *are not allowed in the park.*

An instance of a more complex consistency constraint, can include constraints on the scope of the meaning assigned to the terms, in other words the meanings chosen for the terms of a document must all be consistent with respect to the same scope. Such additional constraint can be used to refine the output power-set of the interpretation function, and possibly reduce the complexity of computing such set.

Teleological Interpretation

This interpretation methodology focuses on the underlying objective of the legal document, meaning that the resulting interpretations should be aligned with such objective.

Definition 3 (Teleological) *Let ϕ be the* teleological interpretation *function, $\phi(O_{in}, \Omega) = O_{out}$, where O_{in} and O_{out} are sets of interpreted obligations, Ω represents the* the underlying objective of the document*, $O_{in} \subseteq O_{out}$, and every obligation in O_{out} is* consistent *with Ω.*

The semantics illustrated in Definition 3 is described as considering the subset, among the whole spectrum of possible interpretations of the norms in a legal document, which pursued goal aligns with the one underlying the legal document.

Notice that possible implementations of such semantics would most likely require a technique to extrapolate the underlying pursued goal from a formalised interpretation of a norm in order to allow its comparison with the goal pursued by the document. A possible way of extracting such goals has been discussed by Dastani and van der Torre [93]. We do not underplay the critical aspect of such technicality in possible implementations, however we focus on a more high level view and abstract description of the semantics of the interpretation to discuss the interaction between the various modalities.

Example 2 (Teleological Interpretation) *Considering the output* $\{i_1, i_2, i_3\}$ *shown in Example 1 as the input set of interpretation. Assuming that the goal of the legal document considered aims at reducing pollution in parks, then the resulting interpretation set would be* $\{i_1, i_3\}$*, as the goal of* i_2 *intuitively does not encompass reducing pollution.*

Differently, if the goal of the legal document would be the safety of pedestrians in the park, then the output interpretation set would consist of the input set $\{i_1, i_2, i_3\}$*, as the presence of any of the mentioned vehicles can be potentially dangerous for pedestrians.*

Systematic Interpretation

The goal of this interpretation methodology is to consider the context in which the norms are being applied.

Definition 4 (Systematic) *Let* ϕ *be the* systematic interpretation *function,* $\phi(O_{in}, \mathcal{C}) = O_{out}$*, where* O_{in} *and* O_{out} *are sets of interpreted obligations,* $\mathcal{C}$ *represents the* context in which the obligations are applied*,* $O_{in} \subseteq O_{out}$*, and every obligation in* O_{out} *is a* valid *interpretation in a context* $\mathcal{C}$*.*

A possible implementation of the proposed semantics can consider for instance the meaning assignments to the terms composing the norms. We can reasonably assume that a meaning assignment to a term can be associated to a set of contexts in which such assignment is valid. Thus, an implementation could for instance prune every interpretation in the input set containing non valid meaning assignments according to the given context.

Example 3 (Systematic) *Considering two rules on the some topic, provided from two different sources, as a national law and an European law. The European law has much power of the national law. So the national law have to be interpret at the light of the European one so, the interpretation of national law could make more restrictive or expansive changes to certain rules or to certain ambiguous words (as "vehicle") in order to comply with European laws. Furthermore, if an interpretation of national law can be made, by expanding or narrowing the meaning, to bring it into conformity with European law, national law does not need to be rewritten. If, on the other hand, there is no way of making the two rules coincide, the interpreter will tacitly repeal the national law in contrast with the European law, so the result of the interpretation of the national norm is to "delete" the national norm and take the rule from the European.*

Subjective Interpretation

This methodology considers the intention of the drafters in the historical environment of the legal document being interpreted.

Definition 5 (Subjective) *Let* ϕ *be the* subjective interpretation *function,* $\phi(O_{in}, \Omega) = O_{out}$*, where* O_{in} *and* O_{out} *are sets of interpreted obligations,* Ω

represents the intention of the drafters *, $O_{in} \subseteq O_{out}$, and every obligation in O_{out} is* consistent *with* Ω.

Notice that the semantics proposed is similar to the one proposed for teleological interpretation in Definition 3. This is because the underlying intention of the drafters can be considered as the general goal of the document being interpreted. We purposely decided not to collapse the two methodologies into a single function, as both methodologies can potentially be applied together when interpreting a document, both methods pruning non consistent interpretations with. respect to both the goals of the drafters and the document.

Example 4 (Subjective) *Considering again the norm "Vehicles are not allowed in the park", to understand what is a vehicle we can also point the attention of the age of the law document and at the objective of the writer. A vehicle can be a carriage, if the rule was written in the past, or a car, or maybe a bike. The point is that probably the aim of the drafter is leave the park for pedestrians, so the meaning of what is a vehicle can change in the time, simply during the interpretation keeping in mind what is the objective, without the law having to be rewritten.*

Comparative Interpretation

This methodology focuses on interpreting a legal document by taking into consideration how similar ones have been interpreted and applied in other subjects or countries, mostly in case of doubt or lack of rule.

Definition 6 (Comparative) *Let ϕ be the* comparative interpretation *function, $\phi(O_{in}, O_{past}) = O_{out}$, where O_{in}, O_{past} and O_{out} are sets of interpreted obligations, O_{past} a set of past interpretations coming from comparable regulative systems, and $O_{out} = O_{in} \cap O_{past}$,*

Notice that the semantics described for this method involves considering the intersection between a set of possible interpretations of the legal text, and a set containing previous interpretations. However, it must be taken into consideration that these previous interpretations may be from similar legal documents, meaning that the textual source of such interpretations is another one. Because of this reason, when computing the intersection illustrated in the semantics, in a proper implementation it may be necessary to adopt a more flexible approach to the intersection, allowing similar enough interpretations to belong to the intersection.

Example 5 (Comparative) *Considering the transnational sale of movable property or the transnational employment contracts, the rules of both countries must be followed and uniform treatment have to be guaranteed. This type of interpretation is also connected to the evolution of some civil law institutions through the working of different legal systems, such as the evolution in recent decades of cross-cutting family law in European countries or the progressive equality of rights between men and women.*

6.5.3 Discussion, issues and future works

It is possible to notice that there could be a relationship between the interpretation methodologies of the Vienna Convention and the type of links of Section 6.3.2. Table 6.1 shows these relations.

Table 6.1: Relations between interpretation methodologies and link types.

Interpretation Methodology	**Link Type**
Textual	Conceptually Similar Constitutive
Teleological	Motivation Impact Norm Group
Systematic or Contextual	Indirect Internal Via Other Law Procedural Contextual
Subjective or Hystorical	Motivation Impact Norm Group
Comparative	Via Other Law

The abstract semantics just discussed aim at decoupling the functionalities characteristic of the different modalities discussed in the Vienna Convention. The goal of decoupling such functionalities, such as happens in software engineering during modular software development, is to allow the focus of a module to be completely devoted to their main purpose.

The *textual interpretation* is the first and necessary step to interpret written legal documents but, although the most intuitive is not the only one to consider. A different framework architecture could be required to properly define the relations between the interpretation methods. For instance, it could be theoretically possible, when a written document is not source of the regulation, that *textual interpretation* becomes a more marginal methodology.

According to the discussed abstract semantics, the textual interpretation purely focuses on assigning meanings to the written terms in a legal text by abiding to consistency constraints of various degrees depending on the chosen implementation. Because of the simplified requirements of the proposed semantics, such methodology would produce a set of interpretation candidates consisting of the possible permutations of meaning-terms assignments satisfying the consistency constraints. Therefore an initial application of a textual interpretation methodology would produce a, possibly large, set of possible interpretations simply considering the possible meaning assignable to the terms used in a legal document.

Such interpretation methodology used in isolation would most likely produce a large amount of possible interpretations to be of any practical use. Proba-

bly there are two possible ways of addressing the returned interpretation set size problem exist. The first option involves adopting more complex and refined consistency principles to act as constraints to obtain only the more fitting possible interpretations. However notice that functional decoupling should be preserved, hence including within such constraints functionalities belonging to other modalities should be avoided. The second option is to coordinating the usage of the various interpretation methodologies. This option follows also the jurist reasoning in legal interpretation.

Depending on the requirements when interpreting a legal documents, such as for instance considering the goal of the document, hence using a *teleological interpretation* methodology, such methodologies can be used to refine the set of interpretations produced by the textual methodology. Notice that by applying multiple methodologies in sequence would allow to further refine the set of interpretations.

These evolution of the research will be part of the future works.

6.6 Practical experiment for automated classification

This part of the research starts from the fact that, as mentioned above, while the categories of the type of norm were easy to agree on, the attribution of the individual norm to a particular category and the identification of the types of link between norms were more problematic.

The objective of interpretation is to determine the normative messages that derive from a given legal text, and the relationship (i.e. the links) between the norms are at the heart of this activity.

This section proposes a general framework for the development of an automatic system to identify and classify both explicit and *implicit* interrelationships between the parts of a legal text.

The methodology combines a pipeline that includes NLP, ML, and a graphical representation of the legal text. In particular, a specific contribution of the proposed approach is the adoption of a Co-occurrence Network (CN) analysis to improve the identification of implicit interrelationships between parts of a legal text. Text CN is a particular type of network between elements (of the given text) known as unigrams (e.g. words), of which graphical measures of the role and importance of vertices and edges can be calculated.

There have been several previous research that have addressed the detection, resolution and labeling of citations in the legal domain, but those related to the systematic approach that exploits CNs to improve a legal classification effort are rare.

Identifying the types of interrelationships between the parts of a norm, neither is a trivial task nor do annotated datasets exist. Therefore, the experiment aims to address a system for the discovery of *implicitly* related norms, first by human annotators, and then by automated means.

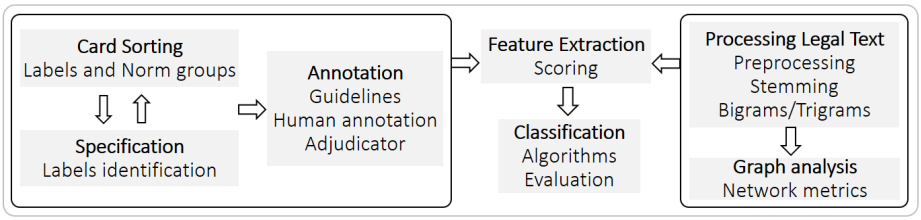

Figure 6.1: The general methodological framework for dealing with experiments on interrelationships between types of norms.

In detail, the methodological framework comprises three analytical steps shown in Figure 6.1.

A first part focuses on the identification of norm types for links between parts of a legal text. Manual annotation of a corpus is used to construct a training set (Section 6.6.1) and the exercise of card sorting methodology (Section 6.6.2).

The aim is to test whether this method better helps to identify implicit links between recitals and (sub)articles.

A second part (Section 6.6.3) deals with the graph-driven feature extraction process to integrate a typical NLP feature representation of legal text, to check if it is useful in link detection.

In a third part (Section 6.6.4) several binary classification tasks explore the role of lexical features and network metrics in identifying interrelationships in a legal document, in order to improve the performance of classification algorithms.

The legislation analysed is the EU Regulation No 141/2000 on orphan medicinal products[29].

Directives and Regulations are prescriptive, but sufficiently general to allow addresses to articulate their own detailed norms and procedures as they prefer in order to achieve the objective(s) of the legislation. Not only is this type of legal text, typically goal-oriented, but it is also particularly given to principle-based reasoning (balance) rather than defeasible reasoning.

This Regulation was chosen because it concerns health care, although there are also interesting economic issues. Moreover, its comprehensibility and length: long enough to provide a variety of different implicit links but short enough to be annotated.

6.6.1 Annotation process and Gold Standard

The text of the regulation under consideration comprises 11 recitals and 11 articles. Considering the division of the articles into paragraphs are 38 (sub)articles. Each part of the law (both recitals and articles) must be interrelated. Therefore, the complete combination of interrelationships between recitals and (sub)articles

[29]Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products

explored in this work is 418. Each of them can be labeled out of a total of eight, according to the above-mentioned typology (in Section 6.3).

The labels used are those of the categories described in Section 6.3.2. Manual annotation is required using an excel file in all categories except for the *Norm Group* for which the card sorting methodology is used.

The annotators involved in this effort were two with a legal background, working independently. Two other annotators with a background in legal informatics were asked to resolve disagreement cases.

Agreement between annotations is measured using the Cohen's kappa metric [36] and the result of the adjudication process is considered as a Gold Standard corpus obtained from the collaborative inter-annotation process.

Finally, each annotator was asked to indicate the time spent in annotation for each session. The running time averaged 62 minutes. One annotator was faster than the other, but divided the effort into multiple work sessions: 6 sessions with an average time of 24 minutes, instead of 3 sessions with an average time of 99 minutes.

In detail, the annotators had to decide which type of relationship exists (if any) and the type of relationship between each recital and with each article, or sub-articles where present.

To give an example, between the first recital (henceforth R1) and Article 1(1) (henceforth A1.1). If there is a relation of any kind, a value of 1 is provided, while a value of 0 means that there is no relationship. The results may be expressed as a sequence of comma separated values, e.g. a list of triplets for each type:

$$(R1, A1.1, 0; R1, A1.2, 1; R1, A1.3, 0; etc.) \tag{6.1}$$

For an analysis of the results, at first, it is important to observe the inter-annotator agreement on the existence or non-existence of a link between the recitatives and (sub)articles studied (see Table 6.2). There are: 86 cases in which both annotators agree on the existence of a link; 54 cases in which the annotators agree on the existence of a relationship; 32 cases in which both annotators agree on the absence of a relationship; and 28 cases of disagreement - 22 cases in which only the first annotator considers that a relationship exists, and 6 cases in which only the second annotator considers that a relationship exists. This gives a percentage agreement of 75.4%, and a Cohen's kappa agreement of 0.5.

However, this encouraging result is balanced by significant differences in the labelling of individual types of relationships. In fact, there are very different values in the distribution among classes (Table 6.3).

Looking at the raw values in Table 6.3, the agreement seems to be quite low, mainly due to the attitude of the annotators: Annotator 2 chose to label 617 relationships, compared to only 260 by Annotator 1. Consequently, a similar proportion is observed for each individual class. There are significant numeric differences in some classes, especially for some of the most frequent: Motivation, Via Other Law and Procedural.

The cases of the initial agreement are quite encouraging: at least, the two annotators agree on the existence of 141 relationships, and the absence of a

Table 6.2: Results of annotation on the existence or non-existence of an inter-relationship.

	Recital 1	Recital 4	Recital 8	All 3 recitals
Number of R-A pairs	38	38	38	114
Annotator 1: link exists	21	36	19	76
Annotator 2: link exists	24	25	11	60
Agreed cases of link	20	23	11	54
Agreed cases of lack of link	13	0	19	32
Agreement on existing link	33	23	30	86
Disagreement on existing link	5	15	8	28
Annotator 1 only: link exists	1	13	8	22
Annotator 2 only: link exists	4	2	0	6

Table 6.3: Annotation results from two initial annotators (Annotator1 and Annotator2), with initial agreement and disagreement cases; the final annotated corpus after disagreement resolution (by an arbiter)

	CS	**Co**	**Mo**	**Im**	**Pr**	**Cx**	**II**	**VOL**	**Total**
Annotator 1	15	16	81	38	53	11	11	35	260
Annotator 2	12	23	254	6	122	13	56	131	617
%Annotator 1	5.8	6.2	31.2	14.6	20.4	4.2	4.2	13.5	100
%Annotator 2	1.9	3.7	41.2	1.0	19.8	2.1	9.1	21.2	100
Agreement YES	3	10	56	0	30	10	6	26	141
Agreement NO	394	389	139	374	273	404	357	278	2,608
Disagreement YES	21	19	223	44	115	4	55	114	595
YES - Annotator 1 only	12	6	25	38	23	1	5	9	119
YES - Annotator 2 only	9	13	198	6	92	3	50	105	476
Percentage of agreement	95.0	95.5	46.6	89.5	72.5	99.0	86.8	72.7	82.2
Cohen's kappa	0.2	0.49	0.06	n/a	0.20	0.82	0.14	0.20	0.24
Gold standard corpus	9	18	238	3	57	11	55	73	464

relationship in 2,608 cases. The remaining cases of disagreement (595) were resolved by two other adjudicators. The final annotated corpus after resolution of the disagreement contains 464 links covering all eight classes.

There are: 139 cases in which the annotators agree on the existence of a relationship; 99 cases in which both annotators agree on the absence of a relationship. On the 180 cases of disagreement, in 22 cases only the first annotator considered that there is a relation; and in 6 cases only the second annotator considers that a relationship exists. This gives a 57% agreement rate, and a Cohen's kappa agreement of 0.2 on the existence of a relationship.

However, when a particular type of link is identified, the percentage of agreement is generally higher, ranging from 46.6% to 99.0%. This is due to the high agreement on pairs of norms that do not have a link to a particular class. Cohen's kappa values, on the other hand, never rise above moderate.

The data show that the agreement is highest for classes with clear objective criteria and identification involving formulaic language - Contextual and Constitutional. While the Via Other Law class also involves identification of citations through formulaic language, the lower percentage of agreement is explained by the fact that one annotator applied this class only when it was really necessary to refer to the cited law in order to understand one of the norms under consideration, while the other applied the class systematically whenever one of the norms contained a reference to another law. Relatively modest results appear for the classes Conceptually Similar and Motivation, which are clearly defined classes but of more 'subjective' nature.

It is important to stress that the poor results for Impact and Procedural are largely due to the differences between the Directive on which the classification scheme is modelled and the Regulation that is annotated. While both legislation belong to the health domain, norms of Directive 2004/23/EC mention a range of actors including Member States, their competent authorities, donors, tissue establishments and their personnel, while Regulation No 141/2000 mainly focuses on activities required by the European Agency for the Evaluation of Medicinal Products and Committee for Orphan Medicinal Products. In both legislation, the rules involving EU institutions such as the European Commission, Parliament, Council and specialised Committees are clearly subject to Procedural, and not Deontic norms (i.e. these rules are descriptions of what the aforementioned institutions will do, rather than prescriptions of what they should do), and therefore subject to Procedural links with related norms.

On the other side, post-annotation discussion with the annotators revealed that while the European Agency for the Evaluation of Medicinal Products and Committee for Orphan Medicinal Products are both considered part of the EU rather than autonomous bodies, the norms involving them could be considered Deontic, Procedural or both, depending on the content of the rule itself rather than simply on its addressee. This means that the Procedural class as applied to the Regulation is subject to a greater degree of subjectivity than expected.

The worst results are for the Impact class where the annotators disagreed on a single pair. The difference between Directive 2004/23/EC and Regulation No 141/2000 also led to different interpretations of the meaning of the class. While

the Directive contained potentially conflicting sub-objectives (transparency versus confidentiality), thus requiring balancing or defeasibility, such potential conflicts were not so obvious in the Regulation annotated for this article. The other type of Impact - linking Deontic norms to norms specifying enforceability measures - are not present in the same way in the Regulation. One annotator extended the Impact category to include the impact of planned future guidelines, in consultation with member states and other parties, on the interpretation and efficacy of the stated objectives of the regulation. However, this interpretation is not shared by the other annotator.

In conclusion, it is clear where greater effort is required in fine-tuning or even redefining certain classes, and that there is a need for a greater range of legislation to be annotated by more annotators.

Finally, post-annotation discussion with annotators revealed that:

- Both found the use of the term Procedural for both a norm type and a link type confusing and suggested renaming one of these classes.
- The definition of link types provided in the guidelines is highly coherent for both (a post-annotation questionnaire provides a score of 4.5 for this measure). However, one annotator stated that while the definitions are quite comprehensive, indecision could arise because the content of the norm could be interpreted in more than one way.
- A previous accurate training session might be useful before annotation in the future (one rating of 3 out of 5 and the other 5 out of 5). The definitions are often clear in theory, but questions arose when reading the norms, so a training seminar with an intermediary featuring practical exercise with sample norms could be useful to ensure that the class definitions have been interpreted by everyone in the same way.

6.6.2 Classification of the "Norm Group" using the card sorting technique

In order to detect the interrelations between norms for the category *Norm Group*[30] the card sorting methodology is applied.

Card sorting is a popular method aimed at identifying patterns among data, commonly used by information architects [284]. Participants, working alone, group physical or digital cards, each showing a piece of information, based on their own mental model of the information domain. More specifically, while in closed card sorting participants are provided with a set of initial groups, in open card sorting they can define the groups they consider most appropriate and then have to describe each group with a label.

[30]Norm Group category has been defined as: "A link between norms that are connected due to being part of the same general requirement. The links between the norms may be a conjunction, disjunction or sequence. Such norms may be paragraphs of the same article, or may occur in different provisions".

Table 6.4: Closed card sorting results from two annotators (Annotator1 and Annotator2), with cases of agreement and disagreement

	Ob	**Cns**	**De**	**Sc**	**Pr**	**Cnt**	**Total**
Annotator 1	5	11	31	2	0	1	50
Annotator 2	11	3	16	0	34	1	65
Both	16	14	47	2	34	2	115
%Annotator 1	10	22	62	4	0	2	100
%Annotator 2	16.92	4.62	24.62	0	52.31	1.54	100
%Both	13.91	12.17	40.87	1.74	29.57	1.74	100
Agreement YES	5	2	12	0	0	1	20
Agreement NO	38	37	14	47	15	48	199
Disagreement YES	6	10	23	2	34	0	75
YES - Annotator 1 only	0	9	19	2	0	0	30
YES - Annotator 2 only	6	1	4	0	34	0	45
Percentage of agreement	87.76	79.59	53.06	95.92	30.61	100	74.49
Cohen's kappa	0.56	0.21	0.14	n/a	n/a	1	0.19

In the case of legal text, cards can be used to display individual paragraphs, the output of the process consists of labelled groups of norms. The aim is to evaluate the experience of the annotators and the usefulness of card sorting compared to the manual annotation method adopted. For the final evaluation, a survey with both open-ended questions on a 5-point Likert scale is used.

The card sorting exercise is carried out by the same people who previously acted as annotators.

The annotators are asked to sort the norms into as many groups as they preferred and to identify a suitable label for each of them.

It is envisaged that the identification of such groups of norms may not only be useful in itself, but may also help to improve the identification and classification of links between norms.

Each annotator was provided with a set of physical cards, where each card was used to display a single paragraph, and multiple copies of the same card were available in order to allow card assignments for multiple groups. Forty-nine different cards, corresponding to 11 recitals and 38 articles, were included in each set.

Results of closed card sorting. Table 6.4 summarises the main results of the closed card sorting exercise. One hundred and fifteen card-category (recital/article-norm type) matches were identified, with 16 cards out of 49 (33%) assigned to more than one category by the same annotator. The annotators agreed on 20 matches: of these, 8 referred to cards that has been placed in only one category by both participants and 2 to a card which had been placed in the same two categories, meaning that perfect agreement could be observed for 9 out of 49 cards (18%). Overall, Chen's kappa (0.19) indicates slight agreement.

The percentage of cards assigned to each category was highly variable and differed for the two annotators. The highest levels of agreement were observed for two categories, *meta-norms: contextual*, which had exactly the same composition for both participants (Cohen's kappa: 1), and *objective*, where annotators agreed on about half the cards assigned to the group (Cohen's kappa: 0.56). On

Table 6.5: Overall open card sorting results from two annotators (Annotator1 and Annotator2)

	Annotator 1	**Annotator 2**	**%Annotator 1**	**%Annotator 2**
#1	2	n/a	3.51	n/a
#2	13	4	22.81	3.45
#3	7	n/a	12.28	n/a
#4	5	5	8.77	4.31
#5	18	n/a	31.58	n/a
#6	12	n/a	21.05	n/a
#7	n/a	17	n/a	14.66
#8	n/a	3	n/a	2.59
#9	n/a	6	n/a	5.17
#10	n/a	3	n/a	2.59
#11	n/a	6	n/a	5.17
#12	n/a	2	n/a	1.72
#13	n/a	13	n/a	11.21
#14	n/a	9	n/a	7.76
#15	n/a	20	n/a	17.24
#16	n/a	2	n/a	1.72
#17	n/a	11	n/a	9.48
#18	n/a	4	n/a	3.45
#19	n/a	9	n/a	7.76
#20	n/a	2	n/a	1.72
Total	57	116	100	100

Table 6.6: Results of open card sorting for groups shared by two annotators (Annotator1 and Annotator2), with cases of agreement and disagreement

	#2: committee	**#4: market exclusivity/monopoly**	**Total**
Annotator 1	13	5	18
Annotator 2	4	5	9
Both	17	10	27
%Annotator 1	22.81	8.77	31.58
%Annotator 2	3.45	4.31	7.76
%Both	9.83	5.78	15,61
Agreement YES	4	3	7
Agreement NO	36	42	n/a
Disagreement YES	9	4	n/a
YES - Annotator 1 only	9	2	11
YES - Annotator 2 only	0	2	2
Percentage of agreement	81.63	91.84	n/a
Cohen's kappa	0.40	0.55	n/a

the contrary, no overlap could be found for *scope* and *meta-norms: procedural* categories (Cohen's kappa: n.a.).

Results of open card sorting. Table 6.5 summarises the main results of the open card sorting task. The annotator identified 6 and 16 groups, with an average of 10 and 7 cards per group, respectively. The grouping structure and the proposed labels reflected quite different mental models: in fact, only in two cases the annotators use the same or very similar labels (namely, *committee*, Cohen's kappa: 0.40, and *market exclusivity/monopoly*, Cohen's kappa: 0.55, see Table 6.6). Overall, the annotators only agreed on 7 correspondences between card-norm (recital/article-norm) groups.

Forty-one cards out of 49 (84%) were assigned to more than one categories, by the same annotator, suggesting more overlap between spontaneously iden-

tified norm groups than norm types. One of the annotators stated that she purposely identified various groups and subgroups, due to her hierarchical mental model of norm groups.

Final observations. With regards to the objective of assessing how easily identifiable norm types are, the closed card sorting activity highlighted that:

- Some concepts, in particular the *scope* and *meta-norms: procedural* norm types, are understood differently by the annotators. If confirmed by several annotators, these results could lead to an update of guidelines and norm types' list.
- Open card sorting proved to be suitable for annotation tasks where a hierarchical structure between identified concepts can be expected, and possible labels cannot be defined a priori. However, if there is a need to define a gold standard, it should be noted that handling disagreement between participants may be more complex, as not only item-group, but also group-group relations have to be taken into account.
- As far as user experience is concerned, the survey shows that card sorting was rated as slightly less useful and easy to use than spreadsheet sorting. In particular, one of the annotators pointed out that card sorting can be more chaotic. However, the ease of working with physical cards was appreciated, and it was suggested that annotators be provided with a printed copy of the overall legal text so that they have an overview of the content they have to work with according to the annotation method (3.5 vs. 4.5 out of 5 for both measures).
- It is known that this activity is normally carried out with 15-20 participants [304]. The decision to conduct a preliminary card sorting tank with only two annotators was made in order to obtain some feedback about the difficulty of the task and the feasibility of card sorting as an alternative annotation method when labels are to be applied to sets of items.
- During the first step, it was found that adjustments to the traditional card sorting are necessary. Firstly, a single part of the legal text can in principle be part of a different normative group. Thus, several cards were prepared for each recital/paragraph considered. Secondly, at the end, the number of different cards obtained is higher than the number of cards commonly used in card sorting, and the content in each card is longer as well. Therefore, the plan is to assess the cognitive load of the annotators, through both quantitative measures such as NASA-TLX [146] and in-depth, qualitative interviews, in order to adapt the card sorting methodology to new areas of application beyond Information Architecture.
- Some advantages in using card sorting emerge:

– It can be used as a preliminary step to assess whether there is a common understanding of labels to be used in subsequent annotation activities (corrective actions should be applied when necessary).
– When applied to the definition of norm groups, it can be used as a preliminary "training" step to help annotators familiarise themselves with the legal text and improve their ability to identify and classify links between norms.
– Provided the overall user experience is improved, it can be used as an alternative annotation method.

6.6.3 Graph analysis based on NLP approach

Following a fairly traditional NLP pipeline, the purpose of this part is to start with pre-processing the legal steps to obtain stems of the terms. In linguistics, stemming means reducing words into their corresponding root form. For example, it will be possible to compare singular and plural forms of the same term occurring in different parts of the legal text. Typical pre-processing steps include conversion to lower case and removal of punctuation marks and stopwords. The next step is tokenisation, in order to separate terms into tokens, followed by stemming. Further analysis is possible by identifying parts of speech (POS) such as verbs, nouns, adverbs, adjectives and so on. The text processing phase can be performed using common programming languages (e.g. Python or R) with well-established NLP libraries.

The analysis concerning the existence of interrelationships between two parts of a legal text can benefit from two graphic representations. In this case, we either represent the relationships between the parts of the law connected by a common stem (i.e. the root form of a term), as well as the co-occurring stems in the same part of the text. By focusing on stems, rather than words, we gain more benefit from a larger number of co-occurring stems. Network metrics are calculated to describe the role of the vertex in the graph with respect to relations with other vertices.

Therefore, Figure 6.2 describes two "toy examples" of small indirect subgraphs for the two different analyses considered (G1, G2).

A graph with text parts as vertices (G1). A first graph (Figure 6.2, [a]) considers each part of the law (i.e. recitals and (sub)articles) as vertices, which are (possibly) connected by an edge if there is at least one stem on both parts. The edge weight corresponds to the number of co-occurring stems. If a stem is found in different parts (e.g. recital 2 and article 6) of a legal text, then an edge will connect the two parts.

Four well connected vertices are found, namely recitals *R5*, *R10*, *R11*, and *Article 8.2*. The weight of the corresponding edges is the number of co-occurring stems. In order to clarify the steps in the construction of the graph, the focus is on the edge from *Article 8.2* to *Recital 10*. The following paragraphs highlight in bold the co-occurring stems (in Italian) of both *Article 8.2* and *Recital 10*.

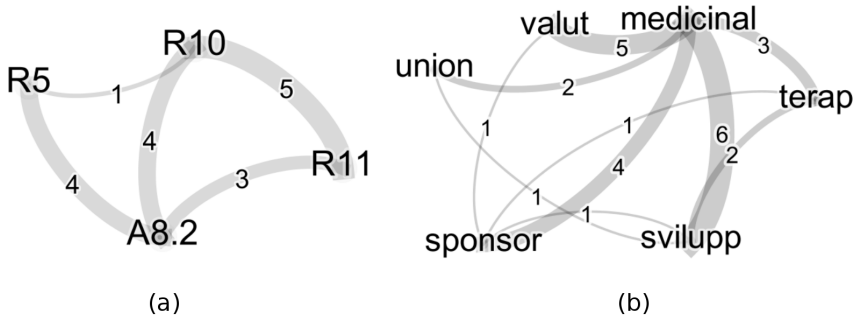

Figure 6.2: Two sub-graphs for stems co-occurrence networks. On the left an example of G1 (identified with the letter 'a') and on the right an example of G2 (identified with the letter 'b').

Stems of recital 10 are[31]:

> programm specif biomed quart programm quadr ricerc svilupp tecnolog 1994-1998 sovvenzion ricerc terap malatt rar metodolog istitu programm celer svilupp medicinal orfan inventar medicinal orfan **dispon** europ tal fond intes promuov collabor internazional mater ricerc bas ricerc clinic malatt rar comun continu attribu ricerc malatt rar import prioritar previst **quint** programm quadr ricerc svilupp tecnolog 1998-2002 present regol defin quadr giurid consent tempest effett applic **risult** tal ricerc

Stems of article 8.2 are[32]:

> tal period può tuttav esser ridott anni scadenz **quint** anno **risult** medicinal question conform criter articol **risult** fra altro bas dat **dispon** rend tal giustific manten esclus merc tal fin stat membr inform agenz criter bas concess esclus merc potrebb esser rispett segu ciò agenz avvi procedur defin articol sponsor forn agenz inform necessar riguard

Note that the two parts of the law considered have three co-occurring stems: *risult*, *quint*, and *dispon*; and *risult* appears twice. Computing the weight of the

[31] For a better understanding, the English version is: "the specific programme Biomed 2, of the fourth framework programme for research and technological development (1994 to 1998), supported research on the treatment of rare diseases, including methodologies for rapid schemes for the development of orphan medicinal products and inventories of available orphan medicinal products in Europe; those grants were intended to promote the establishment of cross national cooperation in order to implement basic and clinical research on rare diseases; research on rare diseases continues to be a priority for the Community, as it has been included in the fifth framework programme for research and technological development (1998 to 2002); this Regulation establishes a legal framework which will allow the swift and effective implementation of the outcome of this research".

[32] For a better understanding, the English version is: "This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, inter alia, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5. The sponsor shall provide the Agency with the information necessary for that purpose".

edge as the sum of all the co-occurrences, the final weight between *A8.2* and *R10* is *4*.

A graph with stems as vertices (G2). A second graph (Figure 6.2, [b]) explores the role of stems in the document by focusing on the relationship between stems (as vertices), where the edge weight is the number of parts where the two stems co-occur. For instance, an edge between Stem X and Stem Y weighted by 3 indicates that Stem X and Stem Y co-occur in the same part of the document three times.

The G2 focuses on the link between "medicinal" and "sponsor". The starting point is the text of the law (in Italian) transformed into the corresponding stems.

In order to get a clear view, the stems of article 5.2 are reported, to finally look for the co-occurring stems (above in bold):

> **sponsor** domand dev esser corred inform document seguent nom ragion social indirizz permanent **sponsor** princip attiv **medicinal** indic terapeut propost giustif relat osserv criter articol paragraf nonc descrizion stat svilupp compres indic previst

The same operation is performed for all the parts of the law (i.e. all recitals and all articles), adding up the number of co-occurrences of both *medicinal* and *sponsor*.

Results of the graph analysis. The representation of the graph allows us to investigate the structural links in the document conveyed by lexical links. To describe the two different graphs exploited, several network metrics are used. Besides the number of vertices (#V) and edges (#E), the following metrics are also consider: average degree (AvDegr), diameter (Dia), average path length (AvPaLe), density (Den), transitivity (Tra), average clustering coefficient (AvClCo).

Table 6.7 summarises the main characteristics of G1 and G2.

Table 6.7: Network metrics of graphs G1 and G2.

Name	**#V**	**#E**	**AvDegr**	**Dia**	**AvPaLe**	**Den**	**Tra**	**AvClCo**
G1	49	320	13.1	3	1.729	0.272	0.394	0.645
G2	548	1,279	4.7	7	3.248	0.009	0.069	0.132

The specific set of network features extracted by the two graphs are:

- *Graph of Recitals and Articles.* To give an idea of the resulting graphs, a representation of G1 is shown in Figure 6.3. It describes the parts of the text (recitals and (sub)articles) as vertices, connected to each other where they share at least one common stem. The size of vertices is proportional to their degree, while the size of each class of vertices depends on their betwenness centrality. Edges are proportional to their weight, i.e. the number of co-occurring stems between the two corresponding vertices. These values can represent the strength of the relationship between the

two parts of the law. Community identification is performed to further investigate the existence of more cohesive groups by applying the Louvain modularity algorithm [55]. This algorithm identifies four groups, with different colours in the graph of 18, 14, 12 and 5 vertices.

The network metrics provide some insights into the graph topologies. G1 is a relatively compact graph, with a quite fair density (about 0.3). In fact, it is quite easy to reach most of the other vertices with a limited number of connections: the average length of the shortest path is 1.7, and the diameter of the whole network is 3. Consistently, the average degree appears to be of some importance: each part of the text is connected on average to 13 other vertices. The values of transitivity and clustering coefficient indicate interesting connectivity, i.e. a certain local neighbourhood, where a region is connected to its neighbours.

- *Graph of Stems.* G2 is quite a sparse graph, as expected with regard to the links between stems. The density is low, and the average degree indicates how each of the 548 stems (corresponding to the vertices of our graph) is connected on average to less than 5 other stems. However, the graph is not so wide, having a diameter of 7, and the average path length is slightly higher than 3. While G1 exhibits the small-world network property (having both a high clustering coefficient and a low average path length), G2 metrics indicate how there are few connections in the neighbourhood of stems. Considering G2, each vertex (i.e. stem) metric can be used to create a feature related to the corresponding parts of the legal text (e.g. articles or recitals). Indeed, the average value of the vertices metrics (e.g. degree, betweenness centrality, closeness centrality) computed for each stem can be exploited in the classification phase.

  We note that this pair occurs four times in the following parts of the standard: R9, A5.2, A5.12, A6.1. Consequently, the edge between the *medicinal* and *sponsor* vertices has a weight of 4.

6.6.4 Classification and results

The classification problem typically involves statistical text categorisation to learn automatic rules based on human-labelled training documents. It is considered distributed words representation, as a standard technique to represent each part of the legal text using vectors [86]. A convenient text representation for each part (i.e. recitals and (sub)articles) in a legal document d encodes the presence of words (unigrams) or sequence of words (n-grams) as $x_{(i)}$. The document as a whole is represented as a feature vector of length:p, $x = (x_{(1)}, \ldots, x_{(p)})$.

The BoN approach is a standard method typically used with the Term Frequency-Inverse Document Frequency (TF-IDF) weighting scheme [166], where TF(i,d) (term frequency) is the number of times a term i occurs in document d. In order to reduce dimensionality, features with the highest document frequency are detect as a feature selection method.

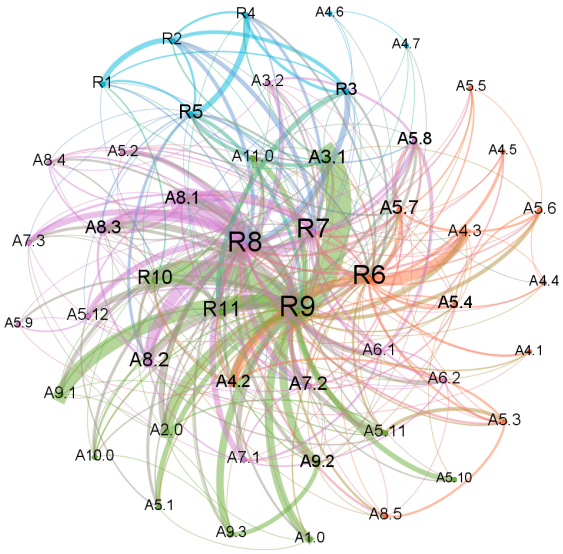

Figure 6.3: A representation of the G1 graph concerning the relationship between recitals and (sub)articles. The vertices are recitals (R) and (sub)articles (A), where edges represent a connection if two vertices have at least one common stem (the sum of the weights of all co-occurring stems in the two parts of the document).

The classification concerns both a binary problem, i.e. the existence or non-existence of a relationship between two parts (a pair) of a legal document, and the identification of the specific class type (with eight classes). The last "multiclass" problem is a difficult task for machine learning approaches, therefore binary classification tasks are performed for each category. Furthermore, the binary classification problem adopts the training sample in an experimental supervised learning context. The goal is the identification of a classification rule, i.e. a function mapping from the p-dimensional feature space to the one-dimensional class label. Finally, the binary classification problem adopts the training sample in an experimental supervised learning environment. The goal is the identification of a classification rule, i.e. a function mapping from the p-dimensional feature space to the one-dimensional class label.

A first step involves vectorizing. Each part of the legal text is vectorized by automatically extracting a set of features to be used in machine learning experiments. Documents are pre-processed including conversion to lower case characters, removal of punctuation marks and stop-words, and tokenization (to separate terms into items). Bag-of-Ngrams (BoN) model is adopted to consider stems, which is more informative than Bag-of-Words, as it captures more context around each item. For example, it will be possible to compare the singular and the plural forms of the same term occurring in different parts of the legal text. In order to provide more importance to rare stems that were more prominent in the text under consideration than other texts, TF-IDF is performed. In this way, stem ngrams in that document scaled down by the count of documents that have that stem ngram are counted. Both bigrams and trigrams of stems, created from pairs and triplets of stems appearing in sequence. Finally, BoNs that contain information are counted on the most important stems. In the experiments, the top 200 ones for bigrams and trigrams are adopted (from now on, we will refer to the features sets as Bigr200 and Trig200)[33].

Several network metrics are used. Table 6.8 summarises them all, with a brief definition and the corresponding acronym. Finally, they are grouped into the following three sets (NM1, NM2, NM3) shown in Table 6.9.

Two sets of metrics are based on G1. A first set (NM1) comprises network metrics at the vertex level, i.e. Degr, DegC, BetC, CloC, EigC, LoaC, ClCo, Cons. A second set (NM2)) specifically concerns metrics related to edges in the same graph, i.e. a boolean feature *isLink* to control an edge between two vertices (1 in case of a link, otherwise 0), *Weig* (the weight of the edge), in addition to EdBC, CFlo, Effi, Conn, Cliq, kCli, Jacc. A third set of metrics (NM3) is based on G2.

For each part of the legal text, the average values of the corresponding stem-related graph-based features is computed. The averaged centrality metrics is considered for all the stems included in the same part of the law, i.e. Degree (avDegC), Betweenness (avBetC), Closeness (avCloC), Eigenvector (avEigC), and Load centrality (avLoaC). At the end, the average values of two relevant

[33]In a preliminary exploration, a larger number of stems were also considered (e.g. top 1,000 for bigrams), but the results did not improve, so the focus shifted to Bigr200 and Trig200.

Table 6.8: Description of network metrics and their respective acronyms in brackets.

Name	Description
Degree	The number of edges that are incident to a vertex (Degr).
Clustering Coefficient	The fraction of possible triangles through that vertex (Clus) [266].
Centrality	Centrality metrics [121] address the position of the vertex in a graph by considering different perspectives, e.g. the neighbours of the vertex: Degree centrality (DegC); the importance of the position in the graph: Betweenness centrality (BetC); the distances from other vertices: Closeness centrality (CloC); the influence of the vertex in the network: Eigenvector centrality (EigC); Current-Flow betweenness centrality (CFlo) [67]. By focusing on edges, we consider also edge betweenness centrality (EdBe).
Constraint	A measure of the extent to which a vertex is invested in those vertices that are themselves invested in the neighbors of the vertex (Cons) [72].
Clique	A clique is a subset of vertices of an undirected graph such that every two distinct vertices are adjacent. We distinguish vertices and edges of the maximal clique (Cliq), as well as k-clique communities (kCli) [233].
Jaccard Coefficient	Compute the Jaccard similarity index (Jacc) between all pairs of vertices [197].
Efficiency	The efficiency of a pair of vertices is the multiplicative inverse of the shortest path distance between the vertices (Effi) [186].
Connectivity	Returns local edge connectivity as the minimum number of edges that must be removed to disconnect them (Conn) [112].

Table 6.9: Sets of network metrics (NM1, NM2, NM3) from two types of graphs G1 and G2.

Name	Graph	Network Metrics
NM1	G1	Degr, DegC, BetC, CloC, EigC, LoaC, ClCo, Cons
NM2	G1	isLink, Weig, EdBC, CFlo, Effi, Conn, Cliq, kCli, Jacc
NM3	G2	avDegC, avBetC, avCloC, avEigC, avLoaC, avClCo, avCons

vertices properties are also included, such as Clustering Coefficient (avClCo), and Constraint (avCons).

Experimental settings and classification results

The combination of the above methodological steps allows a series of supervised binary classification experiments to be carried out.

The first objective is to consider the existence of at least one relationship between two parts of the legal text.

The second goal is to focus on predicting the existence of an individual label.

Each part of the legal text is thus represented as a concatenation of features obtained from both a BoN model and a graph-based analysis.

Several classification algorithms are explored, namely Logistic Regression (LR), Decision Tree (DT), Support Vector Machines (SVM), k-Nearest Neighbors (kNN) [167], as well as, Naive Bayes (NB) and a Dummy (DU) classifier

that makes predictions using simple rules.

For the validation, standard k-fold cross-validation is considered to test the effectiveness of our models. This is a well-known re-sampling procedure used to evaluate a model, keeping aside a portion of the data that is not used to train the model.

As a standard way of predicting the error rate of a classifier, ten-fold cross-validation is performed. . Specifically, the process repeats ten times both the splitting training data into 10 equally-sized partitions and the application of the classification algorithm on nine parts, while testing on the remaining folds. The final measure is the average performance of the ten parts.

The classifiers can be evaluated by computing Accuracy as well as F-measure, which provides information by combining the ratio between precision and recall measures. Accuracy is the ratio of correctly predicted observations to total observations. Precision is the ratio of correctly predicted positive observations of the total predicted positive observations. The recall is the ratio of correctly predicted positive observations to all observations in the actual class (i.e. the existence of a relationship). Since the class distribution is uneven, it is mainly considered F-measure, i.e. the weighted average of precision and recall measures.

The computation performed in this work used the Python programming language and related libraries, e.g. NLTK [54], Scikit-learn [238], and NetworkX [142]. A graph analysis is also perform using the open-source software Gephi [49].

The existence of a relationship between two parts of the legal document is explored as supervised machine learning experiments performed by models trained on the basis of the annotation results.

Three sets of experiments are carried out:

- **Predicting interrelationships.** It focuses on the existence of at least one type of interrelationship (no matter of what kind) between two parts of the legal text.

  The results indicate that the full feature set is able to predict with a certain degree of accuracy (F-measure is about 0.84 with both LR and SVM) the existence of a relation between two parts of legal text. The two feature sets (Bigr200 and Trig200) obtained very similar results (trigrams slightly better than bigrams in 4 classifiers out of 5). Table 6.10 describes the output of different classification algorithms in terms of F-measure and Accuracy. The results are quite satisfactory when considering both the complexity of the task and the output from the Dummy classifier.

- **Predicting link norm types.** It considers the ability to predict distinct individual labels.

  This is a very difficult task for several reasons. Firstly, link norm types convey a more precise meaning, which is not easy to capture with lexical features or relations. Secondly, some link norm types are quite rare, so they will require significant annotation effort to derive a meaningful golden standard corpus to obtain results of interest. Table 6.11 describes the

binary classification results concerning a subset of the most promising algorithms (LR, DT, SVM) by adopting bigrams (Bigr200), as the output with trigrams is very similar. It is also considered F-measure of the four more frequent norm link types in the annotated corpus: Mo, II, VOL, and Pr. The results show a certain possibility for classifiers to explore the difficult topic of identifying relationships of a specific type.

- **The role of network features.** It investigates whether the adoption of network metrics alone can be useful, without the addition of a BoN representation.

  The results described in Table 6.12 show how network metrics alone obtain an F-measure of about 0.81 from two classifiers. These measures are lower but not too far from the values obtained by only adopting ngrams-based classification (about 0.83). Furthermore, the results indicate how helpful it is to add the network metrics to a BoN model to improve the classification results (about 0.84, as detailed in the previous point). Although the improvement is quite slight, it seems significant that it occurs in almost all the classifiers considered in this study.

  In order to shed some light on network features, the classification results are explored by focusing on different sub-groups of network metrics.

  In particular, is considered the inclusion or the exclusion of some network metrics presented in Table 6.9 to assess the specific impact on the classification task.

  In this sort of feature ablation experiment, the considered sub-groups are NM1, NM2, and NM3, as previously introduced in Table 6.9. Every configuration may include a sub-group (henceforth T, which stands for "true") or its absence (F). For instance, TTT means that all the three groups are considered, TTF means that only NM1 and NM2 are considered, TFT includes only NM1 and NM3, and so on.

  Finally, Figure 6.4 shows the output for Bigr200, as the results for Trig200 are similar. Noticeable two regularities: first, best F-measure performances regard LR and SVM, while best Accuracy performance involves DT; second, the configurations providing the best results are FFT, TFT, and TFF.

  This analysis suggests that an important focus should be on the edge-based metrics (NM2), which is always present in the best performing groups.

Table 6.10: Classification results for the existence of interrelationship between two norm parts in each features set (Bigr200 and Trig200).

Set	Performance	LR	DT	SVM	kNN	NB	DU
Bigr200	F-measure	**0.838**	0.792	**0.838**	0.752	0.488	0.656
	Precision	0.814	0.806	0.775	0.825	**0.921**	0.666
	Recall	0.869	0.781	**0.914**	0.695	0.334	0.709
	Accuracy	**0.768**	0.720	0.758	0.687	0.522	0.579
Trig200	F-measure	0.840	0.775	**0.843**	0.783	0.505	0.699
	Precision	0.806	0.783	0.777	0.819	**0.949**	0.680
	Recall	0.879	0.770	**0.924**	0.731	0.349	0.652
	Accuracy	**0.768**	0.696	0.765	0.701	0.538	0.57

Table 6.11: Classification results: F-measure values (average and standard deviation) on the existence of an interrelationship for each link norm type by adopting Bigr200.

Norm types	LR	DT	SVM
MO	0.753 (0.057)	0.715 (0.079)	**0.775 (0.04)**
II	**0.789 (0.159)**	0.760 (0.175)	0.550 (0.146)
VOL	0.753 (0.094)	**0.755 (0.139)**	0.686 (0.118)
PR	**0.564 (0.124)**	0.535 (0.143)	0.522 (0.168)

Table 6.12: Classification results to predict the existence of interrelationship between two norm parts only with Bag-of-bigrams model (left column) and only with network features (right column).

	Only Bag-of-bigrams				Only network features			
Performance	LR	DT	SVM	kNN	LR	DT	SVM	kNN
F-measure	0.828	0.828	**0.832**	0.726	**0.808**	0.777	**0.808**	0.757
Precision	0.809	0.821	0.776	**0.840**	0.698	**0.798**	0.691	0.71
Recall	0.852	0.839	**0.900**	0.650	0.962	0.760	**0.979**	0.819
Accuracy	0.756	**0.763**	0.751	0.670	0.689	**0.701**	0.684	0.644

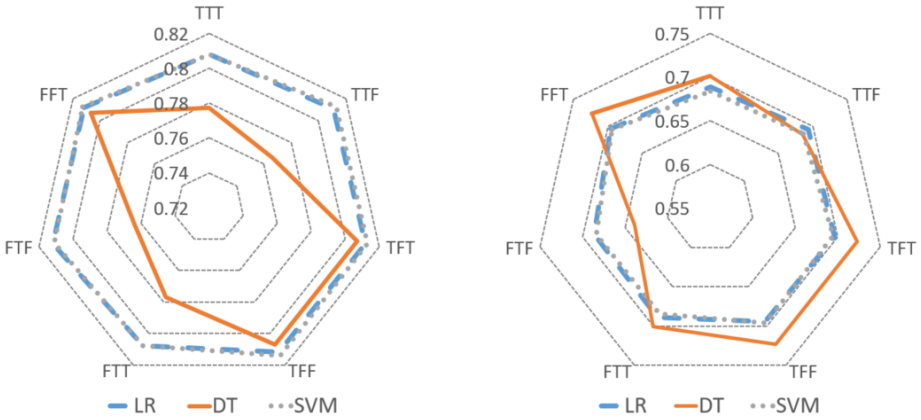

Figure 6.4: F-measure (radar-plot on the left) and Accuracy (right) for Logistic Regression, Decision Tree and Support Vector Machine classification of network metrics configurations.

Chapter 7

Conclusions

This thesis introduces ICT tools to create a methodology for balancing, in the context of a business, the organisational point of view (in term of resources, time and costs), with risk management and regulatory compliance.

It is a multidisciplinary work with the aim of analysing several different aspects and integrating them together in a horizontal way, rather than an in-deep analysis of a single vertical aspect. In particular, the health sector is considered.

The organisational point of view is handled by modelling and simulations of processes in order to optimised them.

Process optimisation often involves modifying, adding or removing some activities or resources. Sometimes this implies that these changes assume (or eliminate) some procedural risks or some legal regulations.

Risk analysis and regulatory compliance are often done by entities other than those dealing with organisational optimisation, with the result that often either the process is not really optimised or some risks are not managed or some regulations are not fully complied with.

This thesis shows how these factors can be balanced for a satisfactory result using the BPM methodology.

It analyses three hospital departments concerning an innovative hospital service: the Hospital at Home.

Considering an innovative service has allowed us to make some optimisations both at the organisational level and in the management of risks and regulatory compliance.

In conclusion, the list of the research objectives (of Sections 1.2) will be taken up below, and the following conclusions for each point will be explained.

Research objectives of this thesis:

- How BPM methodology could be applied to healthcare sector.
- How to support process optimisation when new technologies are introduced.

- How to support the reconstruction of processes from data.
- How to support the procedural risks management.
- How to semi-automatize the regulatory compliance checking.

BPM methodology applied to healthcare. Following the phases of the BPM Methodology of Figure 4.1 the analysis of some hospital processes are made in order to show which details have to be considered in the context analysis taking into account the different goals to be achieved, the problems to be solved, and the needs of the service.

It highlights how to use BPMN standard language to model some process and which are the possible degree of detail that can be considered depending on the purpose of the analysis. Subsequently, how it is possible to validate the model and to obtain the first type of results using BPMN-based simulation tool, which type of information can be obtained from analysing these results and how to use them as a starting point for optimising processes.

Supporting process optimisation when introducing new technologies. In order to improve certain hospital processes with the introduction of different technologies, process modelling and simulations are carried out. The simulations are also based on real data, therefore, the results of the optimisations will reflect the actual workload of the process and not a general prediction.

It is explained how to optimise some hospital processes and To-Be models are presented. Depending on the analysed process and on the technology that was introduced into the process, it is shown how to analyse changes in terms of activities details, resources (human and material), time (of each activity and for the whole process), queues and bottlenecks.

Automatic process reconstruction. Using process mining, and in particular process discovery techniques, a healthcare process is reconstruct starting from real data logs.

The advantages and the limitations in the use of these techniques are highlighted and it is shown how process mining can help in process optimisation, even more if the results of process mining and process modelling and simulations are combined.

In particular, it has been demonstrated how with these techniques it is possible to extract some implicit knowledge contained in the data and perhaps reveal more unexpected results, difficult to extract for a person who only has the vision of single process. In fact, by using process mining techniques it is possible the simultaneous automatic analysis of a large amount of data that cannot be processed simultaneously by the human mind alone and the results proved knowledge that is normally precluded if only manual analysis is performed. Indeed, it provides a high insight into the process or the business because a business is composed of many processes that could be more or less connected to each other and some times a problem in our process derives from something

outside the process itself, or a "wrong" output of the process considered might create problems in the next process that could directly or indirectly affect our process, creating a vicious circle.

For example, data may show that some patients following a certain short path are more likely to be hospitalised again and thus contribute to a bottleneck which could be solved a priori by a longer time at first admission but that would have a second entry.

In the future, with the integration of machine learning or NLP techniques, maybe it will be possible to extract some more details, like patients arriving at the hospital with a particular merge of diagnosis or using some drugs are more likely to be hospitalised again, or to be hospitalised again after a range of time, or to improve more quickly.

Although both process simulation and process mining are based on real data, the data to be considered may be different. In our case study, the useful data for simulations are, above all, the number of incoming patients, the time of arrival, how long a patient remains hospitalised, or stops in a particular activity, and what is its output characteristic (for example, discharged, deceased, transferred). These are data that have been recorded by hospitals for years and are also very generic. The data used for process discovery should be much more complete and possibly not just for a specific department. For example, sometimes it would be useful to know if the patient has already been hospitalised, for how long, in which department, the detailed diagnosis of arrival and exit, the drugs taken, etc.

It follows that the results of the process extrapolations are optimal if databases are available, if they are complete and, if the process is fully or highly automated. Unfortunately, this is not always the case.

This gives rise to two problems: the first is that these include personal data and are therefore subject to special regulations on their processing; the second is that actually a lot of hospital information systems are not yet process-aware, some documents are not yet dematerialised but on paper because staff often have to give more priority to the patient than to the recording of each single step. Therefore, the available data to be analysed are not always sufficient to extract truthful and useful results because some passages of minor clinical importance, but perhaps of greater organisational importance, could be lost.

In the future, understanding the benefit of using process mining techniques could push towards a wider adoption of HIS in the near future, as is actually happening in the industry.

Supporting procedural risk management using simulations. Various risk analysis and procedural risk management techniques are shown. Traditional risk analysis stops at establishing which are the main risks, their weight and in which activity they are found. Using a process-based methodology, once the risk analysis has been carried out, and the major sources of risk have been identified, simulations can be used to assess whether, how and where, by making changes to activities or by introducing technologies, the risk changes, for

the better or fot the worse. It is shown how process simulations supports the analysis of procedural risks. With simulations, it is also possible to have not only qualitative, but also quantitative results about the process risk assessment and, therefore, to have a sweater and more complete overview of the business.

In the field of healthcare, it is not uncommon for high-risk procedures to be regulated by legislation. Therefore, in parallel with the analysis of the procedural risks it must be carried out an analysis of the **regulatory compliance** of the same process.

Semi-automated verification of regulatory compliance. Some norms regulate certain procedures in detail. They are very clear, are often lists of do's and don'ts and are therefore not open to various possible interpretations. Other regulations cover much broader areas, are more general, and have more possible interpretations. In addition, all regulations are part of a wider and more complex legal system which should not be underestimated.

It has been shown, since norms have an holistic character, how it is possible to proceed manually to check if the process is regulatory compliant according to a particular guideline, but also how this work would be too extensive if one wanted to consider whether a process is compliant for the whole regulatory system of that area.

Starting from a BPMN process and formalised norms in logic languages, a tool capable of performing a regulatory compliance check is applied. By using tools that work on files with some extension, it is possible to work on the same process both with the simulator and with regulatory compliance checking tools to continuously cross-checks until an optimised process is obtained both from an organisational and a legal compliance point of view. Moreover, in the event of regulatory changes, the perfect balance between organisation, risks, and new regulations can be easily restored.

However, some limitations must be stressed. Firstly, there are multiple types of logic-based languages and the field of research is still evolving. Secondly, and more importantly, the formalisation of laws must be done by hand by an expert in both the logic-based language and the legal field. This merge of expertise is not common and easy to find. Thus, it is rare that this resource is included in the staff of the company.

The last part proposes a new "in progress" perspective that will be part of future projects. The aim is to find a new methodology for the automatic or semi-automatic compliance checking starting from a legal point of view. Starting from the principles of legal interpretation, some practical and theoretical work has been carried out, which may lead to the reproduction of the individual cognitive passages carried out by legal experts when they perform a work of interpretation of a law. The goal is to understand whether it is possible to codify such reasoning, instead of finding an existing language that fits it.

Chapter 8

Future works

Currently, we are already working on new projects that continue to have their focus on process optimisation based on the BPM methodology explained in this thesis.

A first project, "Circular Health for Industry"[1], concerns multidisciplinary analysis in the health sector focusing on the collection, management and analysis of process data. The project focuses in particular on a predictive task in a circular health approach, without maintaining separate data silos on human, animal and plant health, to develop artificial intelligence algorithms working on them, to improve the infrastructure for collecting and analysing such data and to retrain workers for the adoption AI technologies[2]. In particular, the objective of the project focuses on the exploitation of AI techniques to improve the organisation of industries for human health, animal welfare, and agri-food safety, preserving and progressing towards sustainable development goals such as economic, social and environmental ones. For human health, in a sub-project focused on City of Health and Science, the objectives are to increase the quality of care offered, while reducing the costs associated with treatment to optimise the care pathways associated with individual patients. As in this thesis, this streamline will investigate clinical and healthcare processes. In particular, these objectives will be achieved through process analysis integrated with process mining and NLP techniques and the training of a neural network with deep learning techniques in order to produce an algorithm, useful for the planning and management of the processes of the interventional radiology department.

A second project concerns process optimisation and is called "Next Generation UPP"[3]. It concerns the optimisation of the processes in courts in Northern Italy and the improvement of digitization.

Both of them are big projects that involve several partners. These projects will allow not only to continue experimentation on process optimisation based

[1] https://ch4i.di.unito.it/

[2] https://ch4i.di.unito.it/

[3] Next Generation UPP: nuovi schemi collaborativi tra Università e uffici giudiziari per il miglioramento dell'efficienza e delle prestazioni della giustizia nell'Italia nord-ovest.

on real data, but also to further explore the BPM methodology and integrate it with new techniques that can support process optimisation, such as machine learning, NLP techniques, process mining and deep learning.

Other collaborations with UK are also underway to improve the task of regulatory compliance. On one hand, we are working on some experiments using Input/Output logic, instead of DDL, in order to find a simpler way to formalised the rules, which better fit the considerations of legal interpretation.

On the other hand, other experiments are underway with regard to the "work in progress" explained in Chapter 6, in order to find a support for regulatory compliance monitoring that is stated from a legal perspective and based on principles of legal interpretation.

Bibliography

[1] Wil Van der Aalst and Christian Stahl. *Modeling business processes: a petri net-oriented approach*. MIT press, 2011.

[2] Wil Van der Aalst, Ton Weijters, and Laura Maruster. "Workflow mining: Discovering process models from event logs". In: *IEEE transactions on knowledge and data engineering* 16.9 (2004), pp. 1128–1142.

[3] Wil M. P. van der Aalst. "Business Process Simulation Survival Guide". In: *Handbook on Business Process Management 1, Introduction, Methods, and Information Systems, 2nd Ed.* Ed. by Jan vom Brocke and Michael Rosemann. International Handbooks on Information Systems. Springer, 2015, pp. 337–370. DOI: 10.1007/978-3-642-45100-3_15.

[4] Wil MP Van der Aalst. "Business process management: a comprehensive survey". In: *ISRN Software Engineering* 2013 (2013).

[5] Wil MP Van der Aalst and Anton JMM Weijters. *Process mining: a research agenda*. 2004.

[6] Wil MP Van der Aalst et al. "Business process simulation". In: *Handbook on BPM 1*. Springer, 2010, pp. 313–338.

[7] WMP van der Aalst and M Voorhoeve. "Simulation handbook". In: *BPM Center Report BPM-00-04, BPMcenter. org* (2000).

[8] Waleed Abo-Hamad and Amr Arisha. "Simulation-based framework to improve patient experience in an emergency department". In: *European Journal of Operational Research* 224.1 (2013), pp. 154–166.

[9] Morayo Adedjouma, Mehrdad Sabetzadeh, and Lionel C Briand. "Automated detection and resolution of legal cross references: Approach and a study of luxembourg's legislation". In: *2014 IEEE 22nd International Requirements Engineering Conference (RE)*. IEEE. 2014, pp. 63–72.

[10] N Aimonino et al. "Depressive symptoms and quality of life in elderly patients with exacerbation of chronic obstructive pulmonary disease or cardiac heart failure: preliminary data of a randomized controlled trial". In: *Archives of gerontology and geriatrics* 44 (2007), pp. 7–12.

[11] N Aimonino Ricauda et al. "Sperimentazione di un Servizio di telemonitoraggio geriatrico," in: *e-Health Care* 11 (2011), pp. 18–23.

[12] Nicoletta Aimonino Ricauda et al. “Lo sviluppo del servizio di ospedalizzazione a domicilio”. In: *Fondazione promozione sociale, relazione convegni*. (on line), 2010. URL: http://www.fondazionepromozionesociale.it/CONVEGNI/2010_10_22_anziani/relazioni/Aimonino_OaD.pdf.

[13] Nicoletta Aimonino Ricauda et al. “Substitutive “hospital at home” versus inpatient care for elderly patients with exacerbations of chronic obstructive pulmonary disease: a prospective randomized, controlled trial”. In: *Journal of the American Geriatrics Society* 56.3 (2008), pp. 493–500.

[14] Nicoletta Aimonino Ricauda et al. “The rad-home project: a pilot study of home delivery of radiology services”. In: *Archives of internal medicine* 171.18 (2011), pp. 1678–1680.

[15] Gianmaria Ajani et al. “The European legal taxonomy syllabus: a multilingual, multi-level ontology framework to untangle the web of European legal terminology”. In: *Applied Ontology* 11.4 (2016), pp. 325–375.

[16] Carlos E Alchourrón and David Makinson. “Hierarchies of regulations and their logic”. In: *New studies in deontic logic*. Springer, 1981, pp. 125–148.

[17] Ilaria Angela Amantea and Silvano Colombo Tosatto. “Formalising Legal Interpretation: Decoupling Methodologies and Abstract Semantics”. In: *JuL.IA-1st International Workshop on Artificial Intelligence in JUrisdictional Logistics*. (somwhere on line), 2020. URL: https://www.julia-jurix2020.com/.

[18] Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. “A Simulation-driven Approach in Risk-aware Business Process Management: A Case Study in Healthcare.” In: *SIMULTECH*. 2018, pp. 98–105.

[19] Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. “A simulation-driven approach in risk-aware business process management: A case study in healthcare”. In: *Proceedings of 8th International Conference on Simulation and Modeling Methodologies, Technologies and Applications*. Vol. 1. SciTePress. 2018, pp. 98–105.

[20] Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. “A Simulation-Driven Approach to Decision Support in Process Reorganization: A Case Study”. In: *Exploring Digital Ecosystems: Organizational and Human Challenges* 33 (2019), p. 223.

[21] Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. “A Simulation-driven Approach to Decision Support in Process Reorganization: a case study in healthcare”. In: *Proceedings of the 15th Conference of the Italian Chapter of AIS*. Vol. 1. ITAIS. 2018, pp. 98–105.

[22] Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. “A Simulation-Driven Approach to Decision Support in Process Reorganization: A Case Study in Healthcare”. In: *Exploring Digital Ecosystems*. Springer, 2020, pp. 223–235.

[23] Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. "Risk-aware business process management: a case study in healthcare". In: *The Future of Risk Management, Volume I.* Springer, 2019, pp. 157–174.

[24] Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. "Using Simulation in Business Process Analysis and Risk Management: The Blood Bank Case Study". In: *International Conference on Simulation and Modeling Methodologies, Technologies and Applications*. Springer. 2018, pp. 20–38.

[25] Ilaria Angela Amantea, Antonio Di Leva, and Emilio Sulis. "A Simulation-driven Approach in Risk-aware Business Process Management: A Case Study in Healthcare". In: *Proceedings of 8th International Conference on Simulation and Modeling Methodologies, Technologies and Applications - Volume 1: SIMULTECH,* INSTICC. SciTePress, 2018, pp. 98–105. ISBN: 978-989-758-323-0. DOI: 10.5220/0006842100980105.

[26] Ilaria Angela Amantea et al. "A Modeling Framework for an Innovative e-Health Service: The Hospital at Home". In: *International Conference on Simulation and Modeling Methodologies, Technologies and Applications*. Springer. 2020, pp. 111–132.

[27] Ilaria Angela Amantea et al. "A Process Mining Application for the Analysis of Hospital-at-Home Admissions." In: *Studies in health technology and informatics* 270 (2020), pp. 522–526.

[28] Ilaria Angela Amantea et al. "Adopting Technological Devices in Hospital at Home: A Modelling and Simulation Perspective." In: *SIMULTECH*. 2020, pp. 110–119.

[29] Ilaria Angela Amantea et al. "Modeling and Simulation of the Hospital-at-Home Service Admission Process." In: *SIMULTECH*. 2019, pp. 293–300.

[30] Ilaria Angela Amantea et al. "Modelling Norm Types and their Interrelationships in EU Directives." In: *ASAIL@ ICAIL*. 2019.

[31] Ilaria Angela Amantea et al. "Semi-automated checking for regulatory compliance in e-Health". In: *2021 IEEE 25th International Enterprise Distributed Object Computing Workshop (EDOCW)*. IEEE. 2021, pp. 318–325.

[32] Ilaria Angela Amantea et al. "X-ray at your home: the Business Process analysis of R@dhome service". In: *ITAIS AND MCIS 2019: the 13th Mediterranean Conference on Information Systems and the 16th Conference of the Italian Chapter of AIS*. (somwhere on line), 2019. URL: http://www.itais.org/ITAIS-MCIS2019_pub/ITAISandMCIS2019-pages/pdf/97.pdf.

[33] Bjørn Andersen and Tom Fagerhaug. *Root cause analysis: simplified tools and techniques*. Quality Press, 2006.

[34] Grigoris Antoniou et al. "Representation results for defeasible logic". In: *ACM Transactions on Computational Logic (TOCL)* 2.2 (2001), pp. 255–287.

[35] André-Jean Arnaud. *Le médium et le savant: signification politique de l'interprétation juridique*. 1972.

[36] Ron Artstein and Massimo Poesio. "Inter-coder agreement for computational linguistics". In: *Computational Linguistics* 34.4 (2008), pp. 555–596.

[37] Kevin D Ashley. *Artificial intelligence and legal analytics: new tools for law practice in the digital age*. Cambridge University Press, 2017.

[38] Kevin D Ashley, Matthias Grabmair, and Rebecca Hwa. "Network Analysis of Manually–Encoded State Laws and Prospects for Automation". In: *Workshop Format*, p. 1.

[39] Tara Athan et al. "LegalRuleML: Design principles and foundations". In: *Reasoning Web International Summer School*. Springer. 2015, pp. 151–188.

[40] Tara Athan et al. "LegalRuleML: Design Principles and Foundations". In: *Reasoning Web. Web Logic Rules - 11th International Summer School 2015, Berlin, Germany, July 31 - August 4, 2015, Tutorial Lectures*. 2015, pp. 151–188. DOI: 10.1007/978-3-319-21768-0_6. URL: https://doi.org/10.1007/978-3-319-21768-0_6.

[41] Tara Athan et al. "LegalRuleML: From metamodel to use cases". In: *International Workshop on Rules and Rule Markup Languages for the Semantic Web*. Springer. 2013, pp. 13–18.

[42] Adriano Augusto et al. "Automated discovery of process models from event logs: Review and benchmark". In: *IEEE transactions on knowledge and data engineering* 31.4 (2018), pp. 686–705.

[43] Anthony Aust. *Modern treaty law and practice*. Cambridge University Press, 2013.

[44] Jerry Banks. *Handbook of simulation: principles, methodology, advances, applications, and practice*. John Wiley & Sons, 1998.

[45] Gioele Barabucci et al. "Multi-layer markup and ontological structures in Akoma Ntoso". In: *International Workshop on AI Approaches to the Complexity of Legal Systems*. Springer. 2009, pp. 133–149.

[46] P Barach and JK Johnson. "Understanding the complexity of redesigning care around the clinical microsystem". In: *BMJ Quality & Safety* 15.suppl 1 (2006), pp. i10–i16.

[47] S Bartolucci, I Molinaro, and AM Pulimeno. "LA SICUREZZA DEI PAZIENTI E DEGLI OPERATORI". In: *POLO PER L'ISTRUZIONE* (), p. 28.

[48] Forest Baskett et al. “Open, closed, and mixed networks of queues with different classes of customers”. In: *Journal of the ACM (JACM)* 22.2 (1975), pp. 248–260.

[49] Mathieu Bastian, Sebastien Heymann, and Mathieu Jacomy. “Gephi: An Open Source Software for Exploring and Manipulating Networks”. In: *Third international AAAI conference on weblogs and social media*. The AAAI Press, Mar. 2009, pp. 361–362.

[50] Jörg Becker et al. “Generalizability and applicability of model-based business process compliance-checking approaches—a state-of-the-art analysis and research roadmap”. In: *Business Research* 5.2 (2012), pp. 221–247.

[51] Rudolf Bernhardt. *Thoughts on the interpretation of human-rights treaties*. 1988.

[52] Donald M Berwick, Thomas W Nolan, and John Whittington. “The triple aim: care, health, and cost”. In: *Health affairs* 27.3 (2008), pp. 759–769.

[53] Stefanie Betz, Susan Hickl, and Andreas Oberweis. “Risk-aware business process modeling and simulation using XML nets”. In: *Commerce and enterprise computing (cec), 2011 IEEE 13th conference on*. IEEE. 2011, pp. 349–356.

[54] Steven Bird, Ewan Klein, and Edward Loper. *Natural Language Processing with Python*. O’Reilly Media, 2009.

[55] Vincent D Blondel et al. “Fast unfolding of communities in large networks”. In: *Journal of statistical mechanics: theory and experiment* 2008.10 (2008), P10008.

[56] Lynda Blue et al. “Randomised controlled trial of specialist nurse intervention in heart failure”. In: *Bmj* 323.7315 (2001), pp. 715–718.

[57] Thomas Bodenheimer and Christine Sinsky. “From triple to quadruple aim: care of the patient requires care of the provider”. In: *The Annals of Family Medicine* 12.6 (2014), pp. 573–576.

[58] Guido Boella, Luigi Di Caro, and Livio Robaldo. “Semantic relation extraction from legislative text using generalized syntactic dependencies and support vector machines”. In: *International Workshop on Rules and Rule Markup Languages for the Semantic Web*. Springer. 2013, pp. 218–225.

[59] Guido Boella et al. “A system for classifying multi-label text into EuroVoc”. In: *Proceedings of the Fourteenth International Conference on Artificial Intelligence and Law*. 2013, pp. 239–240.

[60] Guido Boella et al. “Eunomos, a legal document and knowledge management system for the web to provide relevant, reliable and up-to-date information on the law”. In: *Artificial Intelligence and Law* 24.3 (2016), pp. 245–283.

[61] Guido Boella et al. “Nlp challenges for eunomos, a tool to build and manage legal knowledge”. In: *Language resources and evaluation (LREC)* (2012), pp. 3672–3678.

[62] Guido Boella et al. “Tecnologia e salute: il progetto CANP della Regione Piemonte”. In: *Ital-IA conference, Rome* (2019).

[63] Andrei Borshchev and Alexei Filippov. “From system dynamics and discrete event to practical agent based modeling: reasons, techniques, tools”. In: *Proceedings of the 22nd international conference of the system dynamics society*. Vol. 22. Citeseer. 2004.

[64] Romain Boulet, Pierre Mazzega, and Danièle Bourcier. “Network approach to the French system of legal codes part II: the role of the weights in a network”. In: *Artificial Intelligence and Law* 26.1 (2018), pp. 23–47.

[65] Daniele Bourcier and Pierre Mazzega. “Codification, law article and graphs”. In: *Frontiers in Artificial Intelligence and Applications* 165 (2007), p. 29.

[66] Sally C. Brailsford et al. “Hybrid simulation modelling in operational research: A state-of-the-art review”. In: *European Journal of Operational Research* 278.3 (2019), pp. 721–737. ISSN: 0377-2217. DOI: https://doi.org/10.1016/j.ejor.2018.10.025. URL: https://www.sciencedirect.com/science/article/pii/S0377221718308786.

[67] Ulrik Brandes and Daniel Fleischer. “Centrality measures based on current flow”. In: *Annual symposium on theoretical aspects of computer science*. Springer. 2005, pp. 533–544.

[68] Juergen Branke et al. “Automated design of production scheduling heuristics: A review”. In: *IEEE Transactions on Evolutionary Computation* 20.1 (2015), pp. 110–124.

[69] GW Brown. *ChewD. H.,″ Corporate Risk. Strategies and Management.* 2005.

[70] James Joseph Buddle et al. *System and method for compliance management*. US Patent 6,912,502. 2005.

[71] Joos CAM Buijs, Boudewijn F van Dongen, and Wil MP van der Aalst. “Towards cross-organizational process mining in collections of process models and their executions”. In: *International Conference on Business Process Management*. Springer. 2011, pp. 2–13.

[72] Ronald S Burt. “Structural holes and good ideas”. In: *American journal of sociology* 110.2 (2004), pp. 349–399.

[73] Christoph Bussler and Armin Haller. *Business Process Management Workshops: BPM 2005 International Workshops, BPI, BPD, ENEI, BPRM, WSCOBPM, BPS, Nancy, France, September 5, 2005. Revised Selected Papers*. Vol. 3812. Springer, 2006.

[74] John A Buzacott. “Commonalities in reengineered business processes: models and issues”. In: *Management Science* 42.5 (1996), pp. 768–782.

[75] Cristina Cabanillas et al. “The RALph miner for automated discovery and verification of resource-aware process models”. In: *Software and Systems Modeling* 19.6 (2020), pp. 1415–1441.

[76] Jorge Calvillo, Isabel Román, and LM Roa. “How technology is empowering patients”. In: *A literature review* (2013).

[77] S Canitano et al. “Risk management, strumenti e cultura organizzativa per il governo della patient safety: dalla teoria alla pratica”. In: *Mecosan* 76 (2010), p. 89.

[78] Gideon A Caplan et al. “Hospital in the home: a randomised controlled trial”. In: *Medical Journal of Australia* 170.4 (1999), pp. 156–160.

[79] Sergio Maria Carbone et al. *Istituzioni di diritto internazionale*. G Giappichelli Editore, 2016.

[80] Josep Carmona, Matthias Weidlich, and Boudewijn van Dongen. “Actionable Conformance Checking: From Intuitions to Code”. In: *European Big Data Management and Analytics Summer School*. Springer. 2019, pp. 1–24.

[81] Josep Carmona et al. *Conformance Checking - Relating Processes and Models*. Springer, 2018. ISBN: 978-3-319-99413-0. DOI: 10.1007/978-3-319-99414-7. URL: https://doi.org/10.1007/978-3-319-99414-7.

[82] Ilias Chalkidis and Dimitrios Kampas. “Deep learning in law: early adaptation and legal word embeddings trained on large corpora”. In: *Artificial Intelligence and Law* 27.2 (2019), pp. 171–198.

[83] R. Charette. *Applications Strategies for Risk Management*. McGraw-Hill, New York, 1990.

[84] Kathy Charmaz. “‘Discovering’chronic illness: using grounded theory”. In: *Social science & medicine* 30.11 (1990), pp. 1161–1172.

[85] T. T. Cheng et al. “Information extraction from legal documents”. In: *2009 Eighth International Symposium on Natural Language Processing*. 2009, pp. 157–162.

[86] Alexander Clark, Chris Fox, and Shalom Lappin. *The handbook of computational linguistics and natural language processing*. John Wiley & Sons, 2013.

[87] Tania Conca et al. “Multidisciplinary Collaboration in the Treatment of Patients With Type 2 Diabetes in Primary Care: Analysis Using Process Mining”. In: *Journal of medical Internet research* 20.4 (2018).

[88] Jack G Conrad and L Karl Branting. “Introduction to the special issue on legal text analytics”. In: *Artificial Intelligence and Law* 26.2 (2018), pp. 99–102.

[89] Crystale Purvis Cooper et al. “Physicians who use social media and other internet-based communication technologies”. In: *Journal of the American Medical Informatics Association* 19.6 (2012), pp. 960–964.

[90] Juliet M Corbin and Anselm Strauss. "Grounded theory research: Procedures, canons, and evaluative criteria". In: *Qualitative sociology* 13.1 (1990), pp. 3–21.

[91] A Coviello and G Di Trapani. "Il risk management nelle imprese italiane tra previsione e ritenzione dei rischi". In: *Rivista elettronica di diritto, economia, management* 3 (2015).

[92] Viola Damen and Francesca Novaco. "Il contesto L'esperienza della Root Cause Analysis rappresenta una fase compresa nel processo di gestione del rischio clinico implementato a livello aziendale1 (figu-ra A16. 1) ed in particolare è lo strumento scelto per la fase di analisi del rischio." In: *Vania Basini* (2004), p. 281.

[93] Mehdi Dastani and Leon van der Torre. "What Is a Normative Goal?" In: *Regulated Agent-Based Social Systems* (Mar. 2004), pp. 210–227. DOI: 10.1007/978-3-540-25867-4_13.

[94] Emile De Maat and Radboud Winkels. "Categorisation of norms". In: *Frontiers in Artificial Intelligence and Appplications* 165 (2007), p. 79.

[95] Fabiola De Marchi et al. "E-health solutions for amyotrophic lateral sclerosis patients: A chatbot for dietary monitoring". In: *Journal of the Neurological Sciences* (2021).

[96] Marco De Marco. *I sistemi informativi aziendali. Temi di attualità*. Vol. 21. FrancoAngeli, 2000.

[97] P Caretti-U De Siervo. "Istituzioni di diritto pubblico". In: *Giappichelli, Torino, ultima ed.(dal Cap. X alla fine)* (2002).

[98] Mattias Derlén and Johan Lindholm. "Goodbye van G end en L oos, Hello B osman? Using Network Analysis to Measure the Importance of Individual CJEU Judgments". In: *European Law Journal* 20.5 (2014), pp. 667–687.

[99] Antonio Di Carlo et al. "Influence of different screening procedures on the stroke prevalence estimates: the Italian Longitudinal Study on Aging". In: *Cerebrovascular Diseases* 9.4 (1999), pp. 231–237.

[100] Antonio Di Leva. *La gestione dell'azienda basata sui processi ei sistemi informativi aziendali*. Celid, 2014.

[101] Antonio Di Leva and Salvatore Femiano. "The BP-M* methodology for process analysis in the health sector". In: *Intelligent Information Management* 3.02 (2011), p. 56.

[102] Antonio Di Leva and Emilio Sulis. "Process analysis for a hospital Emergency Department". In: *International Journal of Economics and Management Systems* 2.1 (2017), pp. 34–41.

[103] Antonio Di Leva et al. "Business Process Analysis and Change Management: The Role of Material Resource Planning and Discrete-Event Simulation". In: *Exploring Digital Ecosystems*. Springer, 2020, pp. 211–221.

[104] M Ludovic Lamarsalle Dirigeant. "Hugo De Oliveira". PhD thesis. Institut Pasteur, 2020.

[105] Razvi Doomun and Nevin Vunka Jungum. "Business process modelling, simulation and reengineering: Call centres". In: *Business Process Management Journal* 14.6 (Nov. 2008), pp. 838–848. ISSN: 1463-7154. DOI: 10.1108/14637150810916017.

[106] MF Drummond et al. "Analisi dei costi". In: *Metodi per la valutazione economica dei programmi sanitari. Terza edizione italiana* (2010), pp. 69–130.

[107] Marlon Dumas et al. *Fundamentals of Business Process Management.* Springer, 2013, pp. I–XXVII, 1–399. ISBN: 978-3-642-33142-8.

[108] Marlon Dumas et al. *Fundamentals of Business Process Management, Second Edition.* Springer, 2018. ISBN: 978-3-662-56508-7. DOI: 10.1007/978-3-662-56509-4.

[109] Marlon Dumas et al. "Introduction to business process management". In: *Fundamentals of Business Process Management.* Springer, 2018, pp. 1–33.

[110] D Jack Elzinga et al. "Business process management: survey and methodology". In: *IEEE transactions on engineering management* 42.2 (1995), pp. 119–128.

[111] Tugba Gurgen Erdogan and Ayca Tarhan. "Systematic mapping of process mining studies in healthcare". In: *IEEE Access* 6 (2018), pp. 24543–24567.

[112] Abdol-Hossein Esfahanian. "Connectivity algorithms". In: *Topics in structural graph theory.* Cambridge University Press, 2013, pp. 268–281.

[113] Carla Faralli. *Argomenti di Teoria del Diritto.* G Giappichelli Editore, 2016.

[114] Carlos Fernández-Llatas and Juan Miguel García-Gómez. *Data mining in clinical medicine.* Springer, 2015.

[115] Carlos Fernandez-Llatas et al. "Process Mining Methodology for Health Process Tracking Using Real-Time Indoor Location Systems". en. In: *Sensors* 15.12 (Nov. 2015), pp. 29821–29840.

[116] George Fishman. *Discrete-event simulation: modeling, programming, and analysis.* Springer Science & Business Media, 2013.

[117] Luciano Floridi. "Soft ethics, the governance of the digital and the General Data Protection Regulation". In: *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences* 376.2133 (2018), p. 20180081.

[118] Giancarlo Forestieri. "Risk Management. Strumenti e politiche per la gestione dei rischi puri dell'impresa". In: *Milano: Egea* (1996).

[119] Jay W Forrester. "System dynamics, systems thinking, and soft OR". In: *System dynamics review* 10.2-3 (1994), pp. 245–256.

[120] Jay W Forrester. "Urban dynamics". In: *IMR; Industrial Management Review (Pre-1986)* 11.3 (1970), p. 67.

[121] Linton C. Freeman. "A Set of Measures of Centrality Based on Betweenness". In: *Sociometry* 40.1 (Mar. 1977), pp. 35–41. ISSN: 00380431.

[122] G. Gans Noah Koole and Avishai Mandelbaum. "Telephone call centers: Tutorial, review, and research prospects". In: *Manufacturing and Service Operations Management* 5 (2003), pp. 79–141.

[123] Nigel Gilbert and Klaus Troitzsch. *Simulation for the social scientist*. McGraw-Hill Education (UK), 2005.

[124] Ingo Glaser, Elena Scepankova, and Florian Matthes. "Classifying Semantic Types of Legal Sentences: Portability of Machine Learning Models." In: *JURIX*. 2018, pp. 61–70.

[125] Nelson Alfonso Gómez-Cruz, Isabella Loaiza Saa, and Francisco Fernando Ortega Hurtado. "Agent-based simulation in management and organizational studies: a survey". In: *European Journal of Management and Business Economics* (2017).

[126] Thomas F Gordon. "The Role of Exceptions in Models of the Law". In: *Formalisierung im Recht und Ansätze juristischer Expertensysteme* (1986), pp. 52–59.

[127] Guido Governatori. "Practical normative reasoning with defeasible deontic logic". In: *Reasoning Web International Summer School*. Springer. 2018, pp. 1–25.

[128] Guido Governatori. "Representing business contracts in RuleML". In: *International Journal of Cooperative Information Systems* 14.02n03 (2005), pp. 181–216.

[129] Guido Governatori. "The Regorous approach to process compliance". In: *2015 IEEE 19th International Enterprise Distributed Object Computing Workshop*. IEEE. 2015, pp. 33–40.

[130] Guido Governatori. "Thou shalt is not you will". In: *Proceedings of the 15th international conference on artificial intelligence and law*. 2015, pp. 63–68.

[131] Guido Governatori and Mustafa Hashmi. "No time for compliance". In: *2015 IEEE 19th International Enterprise Distributed Object Computing Conference*. IEEE. 2015, pp. 9–18.

[132] Guido Governatori and Zoran Milosevic. "Dealing with contract violations: formalism and domain specific language". In: *Ninth IEEE International EDOC Enterprise Computing Conference (EDOC'05)*. IEEE. 2005, pp. 46–57.

[133] Guido Governatori, Zoran Milosevic, and Shazia Sadiq. "Compliance checking between business processes and business contracts". In: *2006 10th IEEE International Enterprise Distributed Object Computing Conference (EDOC'06)*. IEEE. 2006, pp. 221–232.

[134] Guido Governatori and Antonino Rotolo. "A conceptually rich model of business process compliance". In: *Proceedings of the Seventh Asia-Pacific Conference on Conceptual Modelling-Volume 110*. Australian Computer Society, Inc. 2010, pp. 3–12.

[135] Guido Governatori and Antonino Rotolo. "Logic of Violations: A Gentzen System for Reasoningwith Contrary-To-Duty Obligations". In: *The Australasian Journal of Logic* 4 (2006).

[136] Guido Governatori and Shazia Sadiq. "The journey to business process compliance". In: *Handbook of research on business process modeling*. IGI Global, 2009, pp. 426–454.

[137] Davide Grossi, John-Jules Meyer, and Frank Dignum. "The Many Faces of Counts-as: A Formal Analysis of Constitutive-rules". In: *Journal of Applied Logic* 6.2 (2008), pp. 192–217. URL: `http://www.davidegrossi.name/Site/publications_files/grossi07many.pdf`.

[138] M. Grosso et al. "Il ruolo della radiologia nella gestione della cronicità tra ospedale e territorio". In: *eHealth. Innovazione e tecnologia in ospedale* 59 (2017), pp. 12–18.

[139] Zhao Guihong and Fang Yu. "Research on evaluation system of social media's advertising effect from the air traveller's perspective". In: *2014 11th International Conference on Service Systems and Service Management (ICSSSM)*. IEEE. 2014, pp. 1–6.

[140] Thomas R Gulledge Jr and Rainer A Sommer. "Business process management: public sector implications". In: *Business Process Management Journal* 8.4 (2002), pp. 364–376.

[141] Peter J Haas. *Stochastic petri nets: Modelling, stability, simulation*. Springer Science & Business Media, 2006.

[142] Aric Hagberg, Pieter Swart, and Daniel S Chult. *Exploring network structure, dynamics, and function using NetworkX*. Tech. rep. Los Alamos National Lab.(LANL), Los Alamos, NM (United States), 2008.

[143] Yacov Y Haimes. *Risk modeling, assessment, and management*. John Wiley & Sons, 2015.

[144] Michael Hammer. "What is business process management?" In: *Handbook on business process management 1*. Springer, 2015, pp. 3–16.

[145] Herbert Lionel Adolphus Hart. "Positivism and the Separation of Law and Morals". In: *Harv. L. Rev.* 71 (1957), p. 593.

[146] Sandra G Hart and Lowell E Staveland. "Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research". In: *Advances in psychology*. Vol. 52. Elsevier, 1988, pp. 139–183.

[147] Mustafa Hashmi, Guido Governatori, and Moe Thandar Wynn. "Modeling obligations with event-calculus". In: *International Symposium on Rules and Rule Markup Languages for the Semantic Web*. Springer. 2014, pp. 296–310.

[148] Mustafa Hashmi, Guido Governatori, and Moe Thandar Wynn. "Normative requirements for regulatory compliance: An abstract formal framework". In: *Information Systems Frontiers* 18.3 (2016), pp. 429–455.

[149] John Hayes. *The theory and practice of change management*. Palgrave Macmillan, 2014.

[150] C Hernandez et al. "Home hospitalisation of exacerbated chronic obstructive pulmonary disease patients". In: *European Respiratory Journal* 21.1 (2003), pp. 58–67.

[151] David M Hilbert and David F Redmiles. "Extracting usability information from user interface events". In: *ACM Computing Surveys (CSUR)* 32.4 (2000), pp. 384–421.

[152] Mireille Hildebrandt. "The meaning and the mining of legal texts". In: *Understanding Digital Humanities*. Springer, 2012, pp. 145–160.

[153] Risto Hilpinen and Paul McNamara. "Deontic logic: A historical survey and introduction". In: *Handbook of deontic logic and normative systems* 1 (2013), pp. 3–136.

[154] Adrian Holfter et al. "Checking Compliance in Data-Driven Case Management". In: *Business Process Management Workshops - BPM 2019 International Workshops, Vienna, Austria, September 1-6, 2019, Revised Selected Papers*. Ed. by Chiara Di Francescomarino, Remco M. Dijkman, and Uwe Zdun. Vol. 362. Lecture Notes in Business Information Processing. Springer, 2019, pp. 400–411. DOI: 10.1007/978-3-030-37453-2_33.

[155] Zhengxing Huang et al. "On local anomaly detection and analysis for clinical pathways". In: *Artificial intelligence in medicine* 65.3 (2015), pp. 167–177.

[156] Llio Humphreys et al. "Mapping Recitals to Normative Provisions in EU Legislation to Assist Legal Interpretation." In: *JURIX*. 2015, pp. 41–49.

[157] Gema Ibanez-Sanchez et al. "Toward Value-Based Healthcare through Interactive Process Mining in Emergency Rooms: The Stroke Case". In: *International Journal of Environmental Research and Public Health* 16.10 (2019). ISSN: 1660-4601.

[158] iGrafx. *iGrafxProcess 2015*. http://www.igrafx.com, 2015. (Visited on 09/14/2016).

[159] Sharon K Inouye et al. "A predictive model for delirium in hospitalized elderly medical patients based on admission characteristics". In: *Annals of internal medicine* 119.6 (1993), pp. 474–481.

[160] Gianluca Isaia, Vittoria Tibaldi, and Nicoletta Aimonino Ricauda. "Non-pharmacological prevention of delirium". In: *Age and ageing* 38.6 (2009), pp. 766–766.

[161] Gianluca Isaia et al. "Delirium in elderly home-treated patients: a prospective study with 6-month follow-up". In: *Age* 31.2 (2009), pp. 109–117.

[162] Gianluca Isaia et al. "Home management of hematological patients requiring hospital admission". In: *Archives of gerontology and geriatrics* 51.3 (2010), pp. 309–311.

[163] Ali Jaafari. "Management of risks, uncertainties and opportunities on projects: time for a fundamental shift". In: *International journal of project management* 19.2 (2001), pp. 89–101.

[164] Mirou Jaana and Guy Paré. "Home telemonitoring of patients with diabetes: a systematic assessment of observed effects". In: *Journal of evaluation in clinical practice* 13.2 (2007), pp. 242–253.

[165] Wei Jiang, Tom Au, and Kwok-Leung Tsui. "A statistical process control approach to business activity monitoring". In: *Iie Transactions* 39.3 (2007), pp. 235–249.

[166] Karen Sparck Jones. "A statistical interpretation of term specificity and its application in retrieval". In: *Journal of documentation* (1972).

[167] Ameet V. Joshi. *Machine Learning and Artificial Intelligence*. Springer, 2020.

[168] Lalit Kalra et al. "Alternative strategies for stroke care: a prospective randomised controlled trial". In: *The Lancet* 356.9233 (2000), pp. 894–899.

[169] Daniel Martin Katz, Michael J Bommarito II, and Josh Blackman. "Predicting the behavior of the supreme court of the united states: A general approach". In: *arXiv preprint arXiv:1407.6333* (2014).

[170] Sylvia Mercado Kierkegaard. "Here comes the 'cybernators'!" In: *Computer Law & Security Review* 22.5 (2006), pp. 381–391.

[171] Steven M Kinsella. "Activity-based costing: does it warrant inclusion in a guide to the project management body of knowledge (PMBOK® Guide)?" In: *Project Management Journal* 33.2 (2002), pp. 49–56.

[172] Elin Kjelle and Kristin Bakke Lysdahl. "Mobile radiography services in nursing homes: a systematic review of residents' and societal outcomes". In: *BMC health services research* 17.1 (2017), p. 231.

[173] Leonard Kleinrock. *Queueing systems: theory*. John Wiley, 1975.

[174] T. Klimas and J. Vaiciukaite. "The Law of Recitals in European Community Legislation". In: *ILSA Journal of International & Comparative Law* 15.6 (July 2008). Available at: https://nsuworks.nova.edu/ilsajournal/vol15/iss1/6, pp. 61–93.

[175] LT Kohn, JM Corrigan, and MS Donaldson. "To err is human: Building a safer health system National Academy Press". In: *Washington, DC* (1999).

[176] Ger Koole and Avishai Mandelbaum. "Queueing models of call centers: An introduction". In: *Annals of Operations Research* 113.1-4 (2002), pp. 41–59.

[177] E.D. Kosiba, D.G. Newhard, and N.C. Papadopoulos. *System and method for generating forecasts and analysis of contact center behavior for planning purposes*. US Patent 7,103,562. Sept. 2006. URL: `https://www.google.com/patents/US7103562`.

[178] Andrej Kovacic and Bojan Pecek. "Use of simulation in a public administration process". In: *Simulation* 83.12 (2007), pp. 851–861.

[179] Kamran Kowsari et al. "Text Classification Algorithms: A Survey". In: *Information* 10.4 (2019), p. 150.

[180] Ho-Pun Lam and Guido Governatori. "The making of SPINdle". In: *International Workshop on Rules and Rule Markup Languages for the Semantic Web*. Springer. 2009, pp. 315–322.

[181] Kokin Lam and RSM Lau. "A simulation approach to restructuring call centers". In: *Business Process Management Journal* 10.4 (2004), pp. 481–494.

[182] Guiraude Lame. "Using NLP techniques to identify legal ontology components: Concepts and relations". In: *Artificial Intelligence and Law* 12.4 (2004), pp. 379–396.

[183] Steven H Landers. "Why health care is going home". In: *New England Journal of Medicine* 363.18 (2010), pp. 1690–1691.

[184] Jörg Landthaler, Ingo Glaser, and Florian Matthes. "Towards Explainable Semantic Text Matching". In: *Legal Knowledge and Information Systems: JURIX 2018: The Thirty-first Annual Conference*. Vol. 313. IOS Press. 2018, p. 200.

[185] Damian Langone, Alfredo Fulloni, and Dina Wonsever. "A citations network for legal decisions". Jurisin conference. 2020. URL: `http://research.nii.ac.jp/~ksatoh/jurisin2020/`.

[186] Vito Latora and Massimo Marchiori. "Efficient behavior of small-world networks". In: *Physical review letters* 87.19 (2001), p. 198701.

[187] Fabrizia Lattanzio et al. "Advanced technology care innovation for older people in Italy: necessity and opportunity to promote health and well-being". In: *Journal of the American Medical Directors Association* 15.7 (2014), pp. 457–466.

[188] Gloria T Lau, Kincho H Law, and Gio Wiederhold. "Similarity analysis on government regulations". In: *Proceedings of the ninth ACM SIGKDD international conference on Knowledge discovery and data mining*. ACM. 2003, pp. 711–716.

[189] David Lazer et al. "Life in the network: the coming age of computational social science". In: *Science (New York, NY)* 323.5915 (2009), p. 721.

[190] Bruce Leff et al. "Hospital at home: feasibility and outcomes of a program to provide hospital-level care at home for acutely ill older patients". In: *Annals of internal medicine* 143.11 (2005), pp. 798–808.

[191] Elena Leitner, Georg Rehm, and Julian Moreno-Schneider. "Fine-grained named entity recognition in legal documents". In: *International Conference on Semantic Systems*. Springer. 2019, pp. 272–287.

[192] Jacques Lemelin et al. "Patient, informal caregiver and care provider acceptance of a hospital in the home program in Ontario, Canada". In: *BMC health services research* 7.1 (2007), p. 130.

[193] Robert Lempert. "Agent-based modeling as organizational and public policy simulators". In: *Proceedings of the National Academy of Sciences* 99.suppl.3 (2002), pp. 7195–7196.

[194] Richard Lenz, Mor Peleg, and Manfred Reichert. "Healthcare process support: achievements, challenges, current research". In: *International Journal of Knowledge-Based Organizations (IJKBO)* 2.4 (2012).

[195] Di Leva, Emilio Sulis, and Manuela Vinai. "Business process analysis and simulation: The contact center of a public health and social information office". In: (2017).

[196] Bruce G. Lewis et al. "Agent-based simulation of a multi-queue emergency services call centre to evaluate resource allocation". In: *MODSIM 2007, International Congress on Modelling and Simulation, Modelling and Simulation Society of Australia and New Zealand*. 2007, pp. 11–17.

[197] David Liben-Nowell and Jon Kleinberg. "The Link Prediction Problem for Social Networks". In: *Proceedings of the Twelfth International Conference on Information and Knowledge Management*. CIKM '03. New York, NY, USA: Association for Computing Machinery, 2003, 556–559. ISBN: 1581137230.

[198] Patrick Lohmann and Michael zur Muehlen. "Regulatory Instability, Business Process Management Technology, and BPM Skill Configurations". In: *Business Process Management - 17th International Conference, BPM 2019, Vienna, Austria, September 1-6, 2019, Proceedings*. Ed. by Thomas T. Hildebrandt et al. Vol. 11675. Lecture Notes in Computer Science. Springer, 2019, pp. 419–435. DOI: 10.1007/978-3-030-26619-6_27.

[199] Linh Thao Ly et al. "Compliance monitoring in business processes: Functionalities, application, and tool-support". In: *Information systems* 54 (2015), pp. 209–234.

[200] Arpan Mandal et al. "Unsupervised approaches for measuring textual similarity between legal court case reports". In: *Artificial Intelligence and Law* (2021), pp. 1–35.

[201] Ronny Mans, Wil M. P. van der Aalst, and Rob J. B. Vanwersch. *Process Mining in Healthcare - Evaluating and Exploiting Operational Healthcare Processes*. Springer Briefs in Business Process Management. Springer, 2015. DOI: 10.1007/978-3-319-16071-9.

[202] Vittorio Mapelli. *Il sistema sanitario italiano*. il Mulino, 2012.

[203] Valeria Giusi Francesca Marceno. *La neutralizzazione del potere giudiziario. Regole sulla interpretazione e sulla produzione del diritto nella cultura giuridica italiana tra Ottocento e Novecento*. Jovene, 2009.

[204] James G March and Zur Shapira. "Managerial perspectives on risk and risk taking". In: *Management science* 33.11 (1987), pp. 1404–1418.

[205] Biljana Maric et al. "A systematic review of telemonitoring technologies in heart failure". In: *European journal of heart failure* 11.5 (2009), pp. 506–517.

[206] R Marinello et al. "Ospedalizzazione a domicilio: cronaca di un'esperienza". In: *I luoghi della cura* 1 (2015), pp. 27–31.

[207] M Ajmone Marsan et al. "Modelling with generalized stochastic Petri nets". In: *ACM SIGMETRICS performance evaluation review* 26.2 (1998), p. 2.

[208] Niels Martin, Benoît Depaire, and An Caris. "The use of process mining in business process simulation model construction". In: *Business & Information Systems Engineering* 58.1 (2016), pp. 73–87.

[209] Niels Martin et al. "Recommendations for enhancing the usability and understandability of process mining in healthcare". In: *Artif. Intell. Medicine* 109 (2020), p. 101962. DOI: 10.1016/j.artmed.2020.101962.

[210] Niels Martin et al. "Recommendations for enhancing the usability and understandability of process mining in healthcare". In: *Artificial Intelligence in Medicine* 109 (2020), p. 101962.

[211] Suzanne Martin et al. "Smart home technologies for health and social care support". In: *Cochrane database of systematic reviews* 4 (2008).

[212] Jeremy C. Maxwell et al. "A Legal Cross-References Taxonomy for Reasoning about Compliance Requirements". In: *Requir. Eng.* 17.2 (June 2012), 99–115. ISSN: 0947-3602.

[213] Pierre Mazzega, Danièle Bourcier, and Romain Boulet. "The network of French legal codes". In: *Proceedings of the 12th international conference on artificial intelligence and law*. 2009, pp. 236–237.

[214] Alexander J McNeil, Rüdiger Frey, and Paul Embrechts. *Quantitative risk management: Concepts, techniques and tools*. Princeton university press, 2015.

[215] Peter McRae. "The search for meaning: continuing problems with the interpretation of treaties". In: *Victoria U. Wellington L. Rev.* 33 (2002), p. 209.

[216] Masha Medvedeva, Michel Vols, and Martijn Wieling. "Using machine learning to predict decisions of the European Court of Human Rights". In: *Artificial Intelligence and Law* 28.2 (2020), pp. 237–266.

[217] Hokey Min and Vincent Yu. "Reengineering call centre operations using simulation". In: *International Journal of Services Technology and Management* 9.1 (2008), pp. 71–78.

[218] D Minniti et al. "Radhome: la radiologia domiciliare come driver di sviluppo della sanità digitale in ambito territoriale". In: *Sanità Pubblica e Privata* 2 (2010), pp. 96–104.

[219] Davide Minniti et al. "Transitional Care: implementazione di un modello organizzativo multidimensionale di cure intermedie". In: (2014).

[220] Business Process Model. "Notation (BPMN) version 2.0". In: *OMG Specification, Object Management Group* (2011).

[221] Richard Montague. "The Proper Treatment of Quantification in Ordinary English". In: *Approaches to Natural Language*. Ed. by K. J. J. Hintikka, J. Moravcsic, and P. Suppes. Dordrecht: Reidel, 1973, pp. 221–242.

[222] Michael Montalto. *Hospital in the Home: principles and practice*. ArtWords Pty Limited, 2002.

[223] Michael zur Muehlen and Robert Shapiro. "Business Process Analytics". In: *Handbook on Business Process Management 2, Strategic Alignment, Governance, People and Culture, 2nd Ed.* Ed. by Jan vom Brocke and Michael Rosemann. International Handbooks on Information Systems. Springer, 2015, pp. 243–263. DOI: 10.1007/978-3-642-45103-4_10.

[224] Jorge Munoz-Gama et al. "Process mining for healthcare: Characteristics and challenges". In: *Journal of Biomedical Informatics* 127 (2022), p. 103994.

[225] Robert Muthuri et al. "Integrating value modeling and legal risk management: an IT case study". In: *Information Systems and e-Business Management* (2021), pp. 1–29.

[226] JW Myles et al. "Hospital at home. Scheme in Peterborough is expanding." In: *BMJ: British Medical Journal* 313.7051 (1996), p. 232.

[227] Rohan Nanda et al. "A unifying similarity measure for automated identification of national implementations of european union directives". In: *Proceedings of the 16th edition of the International Conference on Artificial Intelligence and Law, ICAIL 2017, London, United Kingdom, June 12-16, 2017*. 2017, pp. 149–158. DOI: 10.1145/3086512.3086527. URL: https://doi.org/10.1145/3086512.3086527.

[228] Rohan Nanda et al. "Multilingual Legal Information Retrieval System for Mapping Recitals and Normative Provisions". In: *JURI SAYS* (2020), p. 123.

[229] Marc van Opijnen. "A model for automated rating of case law". In: *Proceedings of the Fourteenth International Conference on Artificial Intelligence and Law*. 2013, pp. 140–149.

[230] Marc van Opijnen. "Citation Analysis and Beyond: in Search of Indicators Measuring Case Law Importance." In: *JURIX*. Vol. 250. 2012, pp. 95–104.

[231] David O'Sullivan and George LW Perry. *Spatial simulation: exploring pattern and process*. John Wiley & Sons, 2013.

[232] Vera Palea. *La valutazione del rischio d'impresa. Logica e metodologia dell'analisi finanziaria*. G. Giappichelli Editore, 2007.

[233] Gergely Palla et al. "Uncovering the overlapping community structure of complex networks in nature and society". In: *nature* 435.7043 (2005), pp. 814–818.

[234] Monica Palmirani, Guido Governatori, and Giuseppe Contissa. "Modelling temporal legal rules". In: *Proceedings of the 13th International Conference on Artificial Intelligence and Law*. ACM. 2011, pp. 131–135.

[235] Yannis Panagis, Urska Sadl, and Fabien Tarissan. "Giving every case its (legal) due the contribution of citation networks and text similarity techniques to legal studies of european union law". In: *30th International Conference on Legal Knowledge and Information Systems (JURIX'17)*. Vol. 302. IOS Press. 2017, pp. 59–68.

[236] Mark Paradies and David Busch. "Root cause analysis at Savannah River plant (nuclear power station)". In: *Conference Record for 1988 IEEE Fourth Conference on Human Factors and Power Plants,* IEEE. 1988, pp. 479–483.

[237] Guy Paré, Mirou Jaana, and Claude Sicotte. "Systematic review of home telemonitoring for chronic diseases: the evidence base". In: *Journal of the American Medical Informatics Association* 14.3 (2007), pp. 269–277.

[238] Fabian Pedregosa et al. "Scikit-learn: Machine learning in Python". In: *the Journal of machine Learning research* 12 (2011), pp. 2825–2830.

[239] Gary Peller. "The metaphysics of American law". In: *Calif. L. Rev.* 73 (1985), p. 1151.

[240] Henry Prakken and Giovanni Sartor. "Law and logic: A review from an argumentation perspective". In: *Artificial Intelligence* 227 (2015), pp. 214–245.

[241] Henry Prakken and Giovanni Sartor. "The three faces of defeasibility in the law". In: *Ratio Juris* 17.1 (2004), pp. 118–139.

[242] Nicolas Racz, Edgar Weippl, and Andreas Seufert. "A process model for integrated IT governance, risk, and compliance management". In: *Proceedings of the Ninth Baltic Conference on Databases and Information Systems (DB&IS 2010)*. Citeseer. 2010, pp. 155–170.

[243] Hajo A. Reijers. *Design and control of workflow processes: business process management for the service industry*. Springer-Verlag, 2003.

[244] N Aimonino Ricauda et al. "Telemonitoring of elderly patients affected by COPD or acute heart failure". In: *GIORNALE DI GERONTOLOGIA* 59.3 (2011), pp. 163–166.

[245] NA Ricauda et al. "Acute ischemic stroke in elderly patients treated in hospital at home: a cost minimization analysis". In: (2005).

[246] Nicoletta Aimonino Ricauda et al. "Home hospitalization service for acute uncomplicated first ischemic stroke in elderly patients: a randomized trial". In: *Journal of the American Geriatrics Society* 52.2 (2004), pp. 278–283.

[247] Michael W Rich. "Heart failure in the 21st century: a cardiogeriatric syndrome". In: *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences* 56.2 (2001), pp. M88–M96.

[248] Michael W Rich et al. "A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure". In: *New England Journal of Medicine* 333.18 (1995), pp. 1190–1195.

[249] Dee A Richards et al. "Home management of mild to moderately severe community-acquired pneumonia: a randomised controlled trial". In: *Medical Journal of Australia* 183.5 (2005), pp. 235–238.

[250] Livio Robaldo and Xin Sun. "Reified input/output logic: Combining input/output logic and reification to represent norms coming from existing legislation". In: *Journal of Logic and Computation* 27.8 (2017), pp. 2471–2503.

[251] Livio Robaldo et al. "Introduction for artificial intelligence and law: special issue "natural language processing for legal texts"". In: *Artif. Intell. Law* 27.2 (2019), pp. 113–115.

[252] Matilde Rodríguez-Cerrillo et al. "A prospective study of the management of non-massive pulmonary embolism in the home". In: *European journal of internal medicine* 20.6 (2009), pp. 598–600.

[253] Eric Rojas et al. "Process mining in healthcare: A literature review". In: *Journal of biomedical informatics* 61 (2016), pp. 224–236.

[254] Michael Rosemann, Jan Recker, and Christian Flender. "Contextualisation of business processes". In: *International Journal of Business Process Integration and Management* 3.1 (2008), pp. 47–60.

[255] Juliette Rouchier and Sophie Thoyer. "Votes and lobbying in the European decision-making process: application to the European regulation on GMO release". In: *Journal of Artificial Societies and Social Simulation* 9.3 (2006).

[256] Rodolfo Sacco. "Legal formants: a dynamic approach to comparative law (Installment I of II)". In: *The American Journal of Comparative Law* 39.1 (1991), pp. 1–34.

[257] Stefan Sackmann, Stephan Kuehnel, and Tobias Seyffarth. "Using business process compliance approaches for compliance management with regard to digitization: evidence from a systematic literature review". In: *International Conference on Business Process Management*. Springer. 2018, pp. 409–425.

[258] Ali Sadeghian et al. "Automatic semantic edge labeling over legal citation graphs". In: *Artificial Intelligence and Law* 26.2 (2018), pp. 127–144.

[259] Ali Sadeghian et al. "Semantic edge labeling over legal citation graphs". In: *Proceedings of the workshop on legal text, document, and corpus analytics (LTDCA-2016)*. 2016, pp. 70–75.

[260] Kit Sadgrove. *The complete guide to business risk management*. Routledge, 2016.

[261] Mark Sainsbury. *Logical forms: An introduction to philosophical logic*. John Wiley & Sons, 2000.

[262] Neda Sakhaee and Mark C Wilson. "Information extraction framework to build legislation network". In: *Artificial Intelligence and Law* 29.1 (2021), pp. 35–58.

[263] Ministero della Salute. "Risk Management in Sanità: il problema degli errori". In: *Commissione Tecnica su Rischio Clinico. Decreto Ministeriale* 5 (2003).

[264] DIREZIONE GENERALE DELLA PREVENZIONE SANITARIA. "Ministero della Salute". In: *Ministero della Salute* (2011), p. 38.

[265] Cleiton dos Santos Garcia et al. "Process mining techniques and applications–a systematic mapping study". In: *Expert Systems with Applications* 133 (2019), pp. 260–295.

[266] Jari Saramäki et al. "Generalizations of the clustering coefficient to weighted complex networks". In: *Physical Review E* 75.2 (2007), p. 027105.

[267] Giovanni Sartor. "Compliance with normative systems". In: *International Workshop on AI Approaches to the Complexity of Legal Systems*. Springer. 2011, pp. 1–32.

[268] Giovanni Sartor. "Legal reasoning". In: *A Treatise of Legal Philosophy and General Jurisprudence* (2005).

[269] Giovanni Sartor et al. "Argumentation Schemes for Statutory Interpretation: A Logical Analysis." In: *JURIX*. 2014, pp. 11–20.

[270] KG Saur. *IFLA Study Group on the functional requirements for bibliographic records. Functional requirements for bibliographic records: final report*. 1998.

[271] Antonin Scalia and Bryan A Garner. "Reading law". In: *The Interpretation of Legal Texts. St. Paul: Thomson West* (2012).

[272] A Schandl and PL Foster. "COSO INTERNAL CONTROL–Integrated framework: An implementation guide for the healthcare provider industry". In: *Committee of sponsoring organizations of the treadway commission* (2019).

[273] August Wilhelm Scheer and Markus Nüttgens. "ARIS architecture and reference models for business process management". In: *Business Process Management*. Springer, 2000, pp. 376–389.

[274] J.R. Searle. *The Construction of Social Reality*. London: Penguin, 1995.

[275] K. Seetharaman, J. Fama, and E. Hamilton. *Methods for long-range contact center staff planning utilizing discrete event simulation*. US Patent 8,015,042. Sept. 2011. URL: https://www.google.com/patents/US8015042.

[276] Asli Sencer and Birgul Basarir Ozel. "A simulation-based decision support system for workforce management in call centers". In: *SIMULATION* 89.4 (2013), pp. 481–497. DOI: 10.1177/0037549712470169. eprint: http://dx.doi.org/10.1177/0037549712470169. URL: http://dx.doi.org/10.1177/0037549712470169.

[277] Marek J. Sergot et al. "The British Nationality Act as a logic program". In: *Communications of the ACM* 29.5 (1986), pp. 370–386.

[278] Sasha Shepperd and Steve Iliffe. "Hospital at home versus in-patient hospital care". In: *Cochrane database of systematic reviews* 3 (2005).

[279] Sasha Shepperd et al. *Admission avoidance hospital at home*. 2008.

[280] Sasha Shepperd et al. "Avoiding hospital admission through provision of hospital care at home: a systematic review and meta-analysis of individual patient data". In: *Cmaj* 180.2 (2009), pp. 175–182.

[281] Marco M Slotboom. "Do Different Treaty Purposes Matter for Treaty Interpretation? The Elimination of Discriminatory Internal Taxes in EC and WTO Law". In: *Journal of International Economic Law* 4.3 (2001), pp. 557–579.

[282] Rudolf Smend. *Costituzione e diritto costituzionale*. Giuffrè, 1988.

[283] Jerrold Soh, How Khang Lim, and Ian Ernst Chai. "Legal Area Classification: A Comparative Study of Text Classifiers on Singapore Supreme Court Judgments". In: *Proceedings of the Natural Legal Language Processing Workshop 2019*. Minneapolis, Minnesota: Association for Computational Linguistics, June 2019, pp. 67–77.

[284] Donna Spencer. *Card Sorting: Designing Usable Categories*. 1st ed. Rosenfeld Media, Apr. 2009. ISBN: 1933820020.

[285] Jochanan Stessman et al. "Decreased hospital utilization by older adults attributable to a home hospitalization program". In: *Journal of the American Geriatrics Society* 44.5 (1996), pp. 591–598.

[286] H Steven and MD Landers. "Why health care is going home". In: *New Engl J Med* 363.18 (2010), pp. 1690–1.

[287] Emilio Sulis, Ilaria Angela Amantea, and Giulio Fornero. "Risk-aware business process modeling: a comparison of discrete event and agent-based approaches". In: *2019 Winter Simulation Conference (WSC)*. IEEE. 2019, pp. 3152–3159.

[288] Emilio Sulis et al. "An Ambient Assisted Living Architecture for Hospital at Home coupled with a Process-oriented Perspective". In: *Journal of Ambient Intelligence and Humanized Computing* 1 (2022).

[289] Emilio Sulis et al. "Exploiting co-occurrence networks for classification of implicit inter-relationships in legal texts". In: *Information Systems* (2021), p. 101821.

[290] Emilio Sulis et al. "Exploring Network Analysis in a Corpus-Based Approach to Legal Texts: A Case Study." In: *COUrT@ CAiSE*. 2020, pp. 27–38.

[291] Emilio Sulis et al. "Monitoring patients with fragilities in the context of de-hospitalization services: An Ambient Assisted Living Healthcare Framework for e-Health applications". In: *2019 IEEE 23rd International Symposium on Consumer Technologies (ISCT)*. IEEE. 2019, pp. 216–219.

[292] Suriadi Suriadi et al. "Current research in risk-aware business process management: overview, comparison, and gap analysis". In: *Communications of the AIS* 34.1 (2014), pp. 933–984.

[293] C Tamone, N AimoninoRicauda, M Rocco, et al. "Progetto di telemedicina Nuvola It Home Doctor: l'innovazione tecnologica in ambito sanitario". In: *Professione& Clinical Governance* 4 (2012), pp. 13–27.

[294] C Tamone et al. "Progetto di telemedicina Nuvola It Home Doctor: l'innovazione tecnologica in ambito sanitario," in: *Professione&Clinical Governance* 4 (2012), pp. 13–17.

[295] Arthur HM Ter Hofstede et al. *Modern Business Process Automation: YAWL and its support environment*. Springer Science & Business Media, 2009.

[296] V Tibaldi et al. "A randomized controlled trial of a home hospital intervention for frail elderly demented patients: behavioral disturbances and caregiver's stress." In: *Archives of gerontology and geriatrics. Supplement* 9 (2004), pp. 431–436.

[297] V Tibaldi et al. "Clinical outcomes in elderly demented patients and caregiver's stress: a 2-year follow-up study". In: *Archives of gerontology and geriatrics* 44 (2007), pp. 401–406.

[298] Vittoria Tibaldi, Gianluca Isaia, and Nicoletta Aimonino Ricauda. "Acute decompensation of heart failure in the elderly frail patient: an innovative model of care". In: *Recenti progressi in medicina* 101.4 (2010), pp. 139–144.

[299] Vittoria Tibaldi et al. “Hospital at home for elderly patients with acute decompensation of chronic heart failure: a prospective randomized controlled trial”. In: *Archives of internal medicine* 169.17 (2009), pp. 1569–1575.

[300] Vittoria Tibaldi et al. “L’innovazione tecnologica e l’ospedalizzazione a domicilio”. In: *Recenti Progressi in Medicina* 104.5 (2013), pp. 181–188.

[301] Vittoria Tibaldi et al. “Technological advances and hospital-at-home care”. In: *Recenti progressi in medicina* 104.5 (2013), pp. 181–188.

[302] Daniela Tiscornia and Fabrizio Turchi. “Formalization of legislative documents based on a functional model”. In: *International Conference on Artificial Intelligence and Law: Proceedings of the 6 th international conference on Artificial intelligence and law*. Vol. 30. Citeseer. 1997, pp. 63–71.

[303] Charles Travis. “On constraints of generality”. In: *Proceedings of the Aristotelian Society*. Vol. 94. JSTOR. 1994, pp. 165–188.

[304] Thomas Tullis and Larry Wood. “How Many Users Are Enough for a Card-Sorting Study?” In: *Learning*. June 2004, pp. 1–10.

[305] Wil Van Der Aalst. “Data science in action”. In: *Process mining*. Springer, 2016, pp. 3–23.

[306] Wil Van Der Aalst. *Process mining: discovery, conformance and enhancement of business processes*. Vol. 2. Springer, 2011.

[307] Marc Van Opijnen and Cristiana Santos. “On the concept of relevance in legal information retrieval”. In: *Artificial Intelligence and Law* 25.1 (2017), pp. 65–87.

[308] Bonnie J Wakefield et al. “Outcomes of a home telehealth intervention for patients with heart failure”. In: *Journal of telemedicine and telecare* 15.1 (2009), pp. 46–50.

[309] Bernhard Waltl, Jörg Landthaler, and Florian Matthes. “Differentiation and Empirical Analysis of Reference Types in Legal Documents.” In: *JURIX*. 2016, pp. 211–214.

[310] Bernhard Waltl et al. “Classifying Legal Norms with Active Machine Learning.” In: *JURIX*. 2017, pp. 11–20.

[311] Bernhard Waltl et al. “Semantic types of legal norms in German laws: classification and analysis using local linear explanations”. In: *Artificial Intelligence and Law* 27.1 (2019), pp. 43–71.

[312] Stephen Ward and Chris Chapman. “Transforming project risk management into project uncertainty management”. In: *International journal of project management* 21.2 (2003), pp. 97–105.

[313] David H. D. Warren and Fernando C. N. Pereira. “An Efficient Easily Adaptable System for Interpreting Natural Language Queries”. In: *Comput. Linguist.* 8.3-4 (July 1982), pp. 110–122. ISSN: 0891-2017. URL: `http://dl.acm.org/citation.cfm?id=972942.972944`.

[314] P Weaver. *The meaning of risk in an uncertain world, PMI Global Congress 2008-EMEA*. 2008.

[315] Mathias Weske. *Business Process Management - Concepts, Languages, Architectures, Third Edition*. Springer, 2019. ISBN: 978-3-662-59431-5. DOI: 10.1007/978-3-662-59432-2.

[316] Mathias Weske. *Business process management architectures*. Springer, 2007.

[317] Mathias Weske. "Business process management architectures". In: *Business Process Management*. Springer, 2012, pp. 333–371.

[318] Mathias Weske, Wil MP Van Der Aalst, and HMW Verbeek. "Advances in business process management". In: *Data & Knowledge Engineering* 50.1 (2004), pp. 1–8.

[319] Andrew Wilson et al. "Randomised controlled trial of effectiveness of Leicester hospital at home scheme compared with hospital care". In: *Bmj* 319.7224 (1999), pp. 1542–1546.

[320] Wei Xia and Jiwen Sun. "Simulation guided value stream mapping and lean improvement: A case study of a tubular machining facility". In: *Journal of Industrial Engineering and Management (JIEM)* 6.2 (2013), pp. 456–476.

[321] Gustavo Zagrebelsky and Marcenò Valeria. *La Giustizia costituzionale. I. Storia, principi, interpretazioni*. Vol. 1. Il mulino, 2018.

[322] Bernard P Zeigler, Alexandre Muzy, and Ernesto Kofman. *Theory of modeling and simulation: discrete event & iterative system computational foundations*. Academic press, 2018.

[323] Luke S. Zettlemoyer and Michael Collins. "Learning to Map Sentences to Logical Form: Structured Classification with Probabilistic Categorial Grammars". In: *Proceedings of the Twenty-First Conference on Uncertainty in Artificial Intelligence*. UAI'05. Edinburgh, Scotland: AUAI Press, 2005, pp. 658–666. ISBN: 0-9749039-1-4. URL: http://dl.acm.org/citation.cfm?id=3020336.3020416.

[324] Paul Zhang and Lavanya Koppaka. "Semantics-Based Legal Citation Network". In: *Proceedings of the 11th International Conference on Artificial Intelligence and Law*. ICAIL '07. New York, NY, USA: Association for Computing Machinery, 2007, 123–130. ISBN: 9781595936806.

[325] Michael Zur Muehlen and Danny Ting-Yi Ho. "Risk management in the BPM lifecycle". In: *International Conference on Business Process Management*. Springer. 2005, pp. 454–466.