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Combining workflow modelling with scenario planning tools: Process improvement in a Clinical Analysis Laboratory

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I declare that this document is an original work of my own authorship and that it fulfils all the requirements of the Code of Conduct and Good Practices of the *Universidade de Lisboa*.

Preface

The work presented in this thesis was performed in the scope of a nine-month internship at SIEMENS Healthineers (Lisbon, Portugal) during the period March-November 2020, with research being developed with the application to a clinical pathology laboratory. The present work was supervised by Prof. Dr. Mónica Duarte Correia de Oliveira from Instituto Superior Técnico and by Dr. Filipa Matos Baptista from SIEMENS Healthineers.

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Abstract

Private clinical pathology laboratories operate in a highly competitive market, driven by technological developments, and are under pressure to remain efficient and to increase the quality of their services. This dynamic context has been accompanied by other external changes, as the current pandemic, which make more important for managers of clinical pathology labs to make informed decisions based upon evidence and helped by sound decision support methodologies.

This thesis developed a methodology to support the clinical pathology lab managers to analyze strategies to improve the efficiency of the core lab under uncertainty. The methodology is based upon an innovative, socio-technical approach that combines discrete-event simulation with scenario planning. A simulation model is developed to reflect the current context of the core lab, making use of stochastic events to characterize the variability inherent to some of the production processes. The model is calibrated with real production data and information collected from experts, and validated. In parallel and through workshop sessions with the participation of lab professionals, by following a scenario planning approach, relevant external factors are identified and plausible scenarios with possible impact on the production of lab tests in the core lab are constructed. These sessions help create engagement and facilitate the acceptance of possible changes. Parameters to run the simulation model for selected scenarios are then elicited by lab professionals. Finally, the simulation model is run for these scenarios, and managerial changes to the lab are analyzed.

Three scenarios were selected by lab professionals as the most relevant futures for analysis: an approximated *Business As Usual* scenario, in which significant changes are not expectable; another scenario foresees a reform in the health sector in a society with low health literacy; and another scenario anticipates contractual changes to pathology lab, but with the testing paradigm and a society with low health literacy being maintained. The analysis of the results of running these scenarios in the simulation model reveal that the approximated *Business As Usual* scenario and the “Contractual changes in the sector” scenarios would make it necessary to increase the capacity of the production system, while in the “Reform in the sector” scenario, the period of operation of the lab could be reduced and the lab test results reported more quickly, contributing to a faster clinical decision making process. The main objectives of the study have been accomplished: engage lab professionals in a collective strategic thinking, show how external contexts may influence lab tests production in the core lab, and inform decision-making on possible managerial changes to be implemented in light of those scenarios.

Keywords: Process Improvement; Clinical Pathology Laboratory; Decision Support Models; Discrete-Event Simulation; Scenario Planning; Uncertainty.

Resumo

Os laboratórios privados de análises clínicas operam num mercado altamente competitivo, movido pela evolução tecnológica e estão sob pressão para se manterem eficientes e aumentarem a qualidade dos seus serviços. Este contexto dinâmico tem sido acompanhado por outras mudanças externas, como a atual pandemia, que tornam ainda mais importante que os gestores destes laboratórios tomem decisões informadas com base em evidência e ajudadas por sólidas metodologias de apoio à decisão.

Esta tese desenvolveu uma metodologia para apoiar os gestores do laboratório de análises clínicas na análise de estratégias de melhoria do *core lab* sob incerteza. A metodologia baseia-se numa abordagem sociotécnica, inovadora, que combina simulação discreta de eventos com planeamento de cenários. É desenvolvido um modelo de simulação que reflete o contexto atual do *core lab*, fazendo uso de eventos estocásticos para caracterizar a variabilidade inerente a alguns dos processos de produção. O modelo é calibrado com dados reais de produção e informações recolhidas junto de peritos e validado. Paralelamente e, através de sessões de *workshop* com a participação de profissionais do laboratório, seguindo uma abordagem de planeamento de cenários, são identificados fatores externos relevantes e construídos cenários futuros plausíveis, com possível impacto na produção de análises clínicas no *core lab*. Estas sessões ajudam a criar envolvimento e facilitam a aceitação de possíveis mudanças. Os profissionais do laboratório eliciam parâmetros para correr o modelo de simulação para os cenários selecionados. Finalmente, corre-se o modelo de simulação para estes cenários, e analisam-se alterações à gestão do laboratório.

Os profissionais do laboratório selecionaram três cenários como os futuros mais relevantes para análise: um dos cenários é uma aproximação ao *Business As Usual*, no qual não se esperam alterações significativas; outro cenário prevê uma reforma no setor da saúde; e outro cenário antecipa alterações contratuais para o laboratório de análises clínicas. A análise de resultados da execução destes cenários no modelo de simulação revela que o cenário de aproximação ao *Business As Usual* e o cenário que antecipa alterações contratuais tornaria necessário aumentar a capacidade do sistema de produção, enquanto que no cenário que prevê uma reforma no setor, o período de funcionamento do laboratório poderia ser reduzido e os resultados das análises clínicas comunicados mais rapidamente, contribuindo para acelerar o processo de tomada de decisão clínica. Os principais objetivos do estudo foram alcançados: envolver os profissionais do laboratório num pensamento estratégico coletivo, mostrar como contextos externos podem influenciar a produção de análises clínicas no *core lab*, e informar a tomada de decisão sobre possíveis mudanças de gestão a serem implementadas à luz destes cenários.

Palavras-chave: Melhoria de Processos; Laboratório de Análises Clínicas; Modelo de Apoio à Decisão; Simulação Discreta de Eventos; Planeamento de Cenários; Incerteza.

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List of Acronyms

BPI	Business Process Improvement
BPM	Business Process Management
CI	Confidence Interval
CDTT	Complementary Diagnostic Tests and Therapy
DES	Discrete-Event Simulation
EPH	Enterprise Public Hospital
ES	Enterprise Services
FDA	Food and Drug Administration
GDH	General Directorate of Health
HRA	Health Regulatory Agency
HVFX	Hospital *Vila Franca de Xira*
IVD	*In Vitro* Diagnostics
KPI	Key Performance Indicator
Lab	Laboratory
LHU	Local Health Unit
LSS	Lean Six-Sigma
NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
PoC	Point-of-Care
PPP	Public-Private Partnership
RHA	Regional Health Administration
SH	SIEMENS Healthineers
SSS	Scenario Structuring Space
TAT	Turnaround Time
VHI	Voluntary Health Insurance
VSM	Value Stream Map
WHO	World Health Organization

Chapter 1

Introduction

1.1 Motivation and approach

Private healthcare organizations, involved in a highly complex environment, are competitive and driven by technological development. Although between 2014-2019 there has been an increase in the healthcare expenditure with the agreed sector of complementary diagnostic tests and therapy (*Meios Complementares de Diagnóstico e Terapia*) (CDTT) [1], the profit margins of private clinical labs are low [2], being constantly under pressure to increase the quality of services provided and, at the same time, reduce costs, in order to improve efficiency [3]. This is particularly important in today's value-based healthcare era. Improving efficiency in clinical labs is a motivation for providers seeking to improve the quality of service versus cost ratio.

The complexity of the clinical lab sector results from the high number of interacting parts (for instance, including multiple health stakeholders and many evolving technologies) that make it impossible to predict the behaviors of the system [4] and that generate uncertainty in the delivery of healthcare services. This uncertainty inherent to the sector has been accompanied by other source of uncertainty, the current pandemic. The times of disruption and volatility caused by COVID-19 pandemic, and the consequent market evolution in the face of this rapid changing environment make the uncertainty in the external context of the organizations in this sector, the major challenge their management faces, which reveals the need to anticipate and explore plausible future contexts. Although it is known that organizations that seek to match their business to the changing environment can improve their performance [5], managers are often reluctant to change, due to the risk and possible implications resulting from such changes. It is necessary to present evidence that the changes that are intended to be implemented effectively bring added value to the organization. Thus, in such environments, the decision must be sustained [6][7][8].

This is where decision support methodologies come into play, as they significantly improve the quality of the decision-making process, and contribute to efficiency improvements at the organizational level, as this process relies on evidence [6][7].

This thesis focuses on a private provider of clinical pathology and the study is embedded in a SIEMENS Healthineers (SH) Enterprise Services (ES) project and according to their aims, values and mission, the goal is to develop an innovative and potentially generalizable solution that adds value to their end-users.

The objective of this thesis consists in the development of a methodology that supports the lab management to analyze strategies to improve the efficiency of the production process in the core lab under a highly uncertain context. The methodology is developed based upon a socio-technical approach. Technically, it combines discrete-event simulation (DES) with scenario planning. DES is an

effective and widely used technique to manage the dynamics and complexity of healthcare services [9] and it is chosen to develop a model of the core lab and to explore and analyze the actual clinical lab production system and the impact of plausible future scenarios. Scenario planning allows to anticipate future trends and possible external factors of uncertainty [10], culminating with the development of future scenarios with possible impact on the organization's core lab. In this way, this technique complements the simulation in addressing uncertainty. Accordingly, the development of the simulation model and of scenarios is based on data, on observations, and will be supported by workshop sessions and other meetings with key-players from the lab. This social component also allows to overcome the managers' reluctance to change, making them aware of such need.

Individually, simulation allows to explore the actual configuration of the core lab and analyze its performance in the current context. Scenario planning, a technique typically applied in strategic complex problems, enables the development of a structured thinking about how the future of Lab Medicine may unfold, by the exploitation of uncertainties and future trends. By combining this technique with simulation, the results become more tangible, as this integration allows the impact of the anticipated scenarios to be explored through simulation. Therefore, this approach adds value to the current literature, by proposing an innovative methodology that combines two techniques widely used separately that strongly complement each other.

Organizations tend to be focused on operational issues and neglect the impact of uncertainty. The methodology proposed motivates a strategic thinking among lab professionals and seeks to raise awareness of the need and importance of exploring plausible future scenarios in times of environmental disruption and turbulence as a way of accounting for possible impacts and consequences of uncertainty in the organizational decisions.

1.2 Thesis Outline

This thesis is structured in six chapters. The first one presented the thesis' motivation. The second chapter includes the contextualization of the healthcare sector in Portugal as well as of the clinical pathology sector and market both in Portugal and in Europe. The hosting company, SH, is presented, as well as the overall objective of the present study. In the third chapter, a literature review on process improvement techniques under uncertainty, including simulation and scenario planning, is presented. Based on the knowledge acquired in the development of the literature review, the methodological framework to approach the challenges of the study is presented in chapter four and its implementation is described in the fifth chapter, culminating with the presentation and analysis of the impact of the scenarios on the simulation model of the core lab, and the discussion of possible strategies with the lab decision-maker. Finally, in chapter six the main aspects of the study are synthetized and discussed, and the conclusions are summarized.

Chapter 2

Context

2.1 Health Profile in Portugal

According to statistics provided by the Organisation for Economic Co-operation and Development (OECD) and Eurostat, Portuguese population's longevity has been increasing throughout the years and, specifically, over the last decade [11]. However, it has not always been accompanied by life quality, mainly after the 65 years of age, existing significant differences between men and women [11]. Furthermore, the consequent life extension has increased the age-related diseases, associated with comorbidity problems and the increasing impact of the chronic diseases. Consequently, the question of in what type of medical research should be invested in the following years, in order to meet these problems is raised [12][13].

In Portugal, the healthcare system includes both public health providers, which make part of the National Health Service (NHS), and private health providers, with the private agreed sector integrating the NHS [14]. Conforming to estimates provided by Health Regulatory Agency (*Entidade Reguladora da Saúde*) (HRA), more than a half of the healthcare provision activity is nowadays conducted by private corporations, including public-private partnerships (PPPs) [15]. There are different payment modalities depending on the nature of the provider.

In Portugal, healthcare coverage is ensured by three types of entities that coexist, namely, the NHS, Private Voluntary Health Insurance (VHI) and other health insurance schemes, called health subsystems. Regarding the financial coverage, NHS coverage is universal and almost free, being mainly financed by taxation, sometimes requiring out-of-pocket payments at the point of delivery, including co-payments and direct payments [12][16].

When it comes to the private health providers, there is the VHI, covering around 26% of the population in 2017, and being mainly a supplementary system that provides faster access to ambulatory consultations and elective hospital treatment and enlarges the choice options of provider. Only occasionally, VHI acts as a complement to the NHS, providing coverage to certain services excluded from the NHS. In these cases, the payment is entrusted to the insurer and the user, depending on the benefits package offered by the insurance company [16]. The health subsystems usually cover between one-fifth and one-quarter of particular professional sectors of the society, both public and private. In most cases it is financed through contributions paid by the employee and the employer [16].

Both public and private entities provide care at primary care facilities, but the great majority are public providers. Furthermore, private care clinics, both profit and non-profit, and private offices provide this type of healthcare. In terms of secondary and tertiary care, providers are mainly hospitals. Typically, NHS physicians, who act as gatekeepers, refer patients for specialist care. Specialties mainly provided

in the private sector include dental consultation, diagnostic services, rehabilitation and renal dialysis [12].

The NHS is managed by the Ministry of Health, responsible for the planning and regulation of health at a central level. At the regional level, the management is undertaken by five Regional Health Administrations (*Administrações Regionais de Saúde*) (RHAs) [12]. Moreover, HRA, an independent public entity, is responsible for protecting the rights of healthcare users, including the access to healthcare and the freedom of choice. HRA also ensures compliance with the legislation and transparency in what regards the economic relations between purchasers, providers and users, and promotes fair competition among providers [12].

Regarding the provision of care, public providers act mainly in the primary and hospital care, while the private operates predominantly in the pharmaceutical, CDTT, where lab tests (clinical analyses) are the most frequently sought by users [17], and medical appointments fields [18]. Focusing on CDTT, in agreement with the HRA, it has becoming increasingly important in people's life and in the Portuguese Healthcare System, due to the frequency in which these services are sought after by users, whether it is following medical outpatient appointments, or inpatient situations, both in hospital units and long-term care [17].

In terms of expenditure, in Portugal there has been a considerable increase in the total expenditure in the area of CDTT in general, and more specifically in the clinical pathology field, between 2016 and 2019, as can be observed in Table 2.1.

Table 2.1. Annual total expenditure with CDTT between 2016 and 2019, in Portugal (in million euros). (Adapted from [1] and [19]).

Area/ Year	**2016**	**2017**	**2018**	**2019**
Clinical Pathology	169,0 M€	171,2 M€	176,4 M€	186,4 M€
Cardiology	23,3 M€	23,7 M€	25,0 M€	27,2 M€
Gastroenterological Endoscopy	43,9 M€	47,7 M€	52,2 M€	54,7 M€
Physical and Rehabilitation Medicine	86,7 M€	91,6 M€	100,6 M€	110,1 M€
Radiology	104,5 M€	104,5 M€	107,6 M€	114,2 M€
Partial Total of the five most representative areas	427,4 M€	438,7 M€	461,8 M€	492,6 M€
Annual Total	439,6 M€	450,1 M€	473,8 M€	507,0 M€

Table 2.1 presents only the expenditure with the five most representative areas of CDTT, where the clinical pathology is the most representative one, with a 5.7% increase in public expenditure in this area between 2018 and 2019 [1]. In what concerns the costs of the clinical pathology, for each type of service, the average cost varies a lot depending on if the person is covered by health insurance or by the NHS, or if the person pays the costs by his/her own. For the ones covered by health insurance, the costs of clinical analyses depend on the insurance policy and the amount reimbursed by the insurance company varies, and of course also depends on the type of lab tests performed. For those who are covered by the NHS, there is a fixed value for each lab test which is applied in all labs in the country, although not

all of the lab tests are reimbursed by the NHS [20]. On average, the NHS finances 79% of a lab test performed by the agreed providers, and the payment of the remaining amount is borne by the user [21]. Some entities and subsystems, such as ADSE, may also cover a part of the price established by the lab. In these cases, the person covers the value of the analysis and the entity covers the remaining amount [20]. In Portugal there is no entity responsible for the regulation of the clinical analyses prices charged by the labs [20]. Each lab is free to apply the price decided by itself, according to the competitors and the values applied in the market.

2.2 In *vitro* Diagnostics

In vitro diagnostic (IVD) is defined as a test performed on samples, like blood or tissue extracted from the human body, prescribed by a doctor and performed in specialized labs, healthcare facilities, or even, at home, essential to improve outcomes in routine management [22][23]. Depending on the type of IVD, it may be performed in the lab market (clinical labs and healthcare facilities, such as a hospital, a clinic, a primary care center aided by a health professional), and in a point-of-care (which includes pharmacies and self-testing mode, performed at the patients' home), as represented in Figure 2.1.

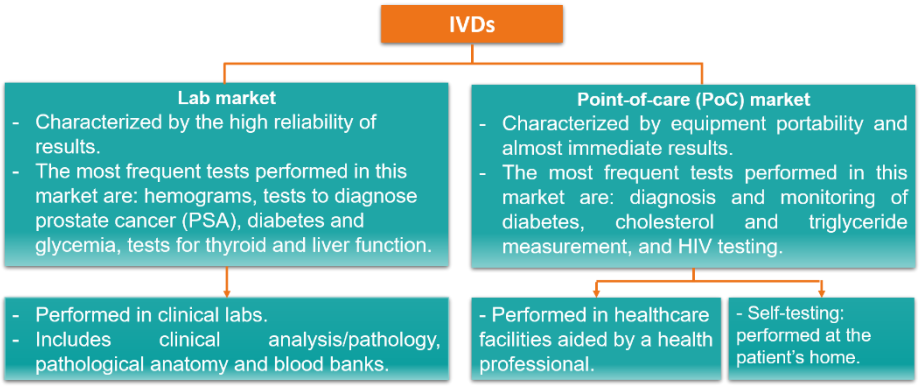
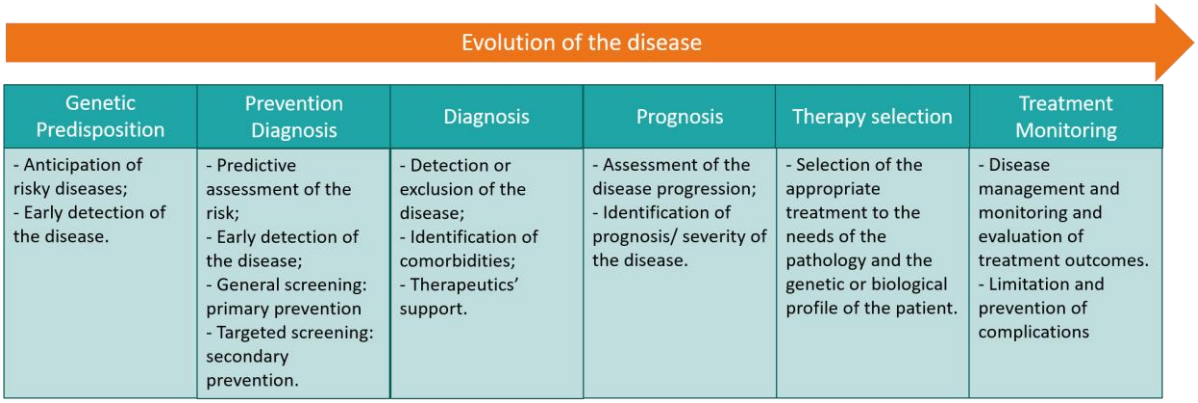


Figure 2.1. Different types of IVDs and their main characteristics.

This study focuses on the lab market, which in 2012 accounted for 73% of the entire market. This market operates in a logic of centralized diagnosis in public and private labs, where a large volume of tests is performed, including complex tests, allowing to achieve gains in efficiency in the collection and sharing of information with the clinician and a lower process cost with the analytical experiments, by taking advantage of the economies of scale. However, it is required a large initial investment in equipment and due to the fast-technological evolution, a continuous reinvestment is needed to maintain the equipment updated. Therefore, given the accuracy of the equipment used, the reliability of the results of the analytical experiments carried out in these labs is very high [21]. In turn, the point-of-care (PoC) market is characterized by the portability of the devices and the short response time of the analysis performed. The IVDs are performed in healthcare institutions, with the support of a healthcare professional or at the users' home, allowing an immediate result, but typically presenting a higher unit cost of acquisition. According to a representative of a private lab, PoC and lab markets are complementary and the presence of PoC market is favorable for the patient [21].

IVD has evolved over the years due to a more comprehensive knowledge of biological systems and disease, together with advances in technology and science. New diagnostic tests, some of whom based on personalized medicine approaches, have been emerging with the potential of revolutionize the clinical practice [3].

When correctly prescribed, IVD allows for early-stage interventions and hence, in a later stage, to reduce the healthcare expenditure [3]. Once the doctor has access to the results of these tests, and by comparing them with reference values, it is possible to diagnose or control a certain disease or pathology, and prescribe the appropriate treatment whenever required. IVDs are not only applied in the diagnostic, but also in the tracking of the progression of the disease and in monitoring of the effectiveness of a prescribed treatment. Thus, IVD is considered the first approach in clinical decision-making in the phases along the evolution of the disease [24][25] and, according to a study conducted by EvaluateMedTech (2015), it is expected to prevail as the first assessment in the diagnostic field until 2022 [26].



Genetic Predisposition	Prevention Diagnosis	Diagnosis	Prognosis	Therapy selection	Treatment Monitoring
- Anticipation of risky diseases; - Early detection of the disease.	- Predictive assessment of the risk; - Early detection of the disease; - General screening: primary prevention - Targeted screening: secondary prevention.	- Detection or exclusion of the disease; - Identification of comorbidities; - Therapeutics' support.	- Assessment of the disease progression; - Identification of prognosis/ severity of the disease.	- Selection of the appropriate treatment to the needs of the pathology and the genetic or biological profile of the patient.	- Disease management and monitoring and evaluation of treatment outcomes. - Limitation and prevention of complications

Figure 2.2. Main applications of the IVD throughout the evolution of the disease (Adapted from [21]).

Figure 2.2 represents the main applications of the IVD along the evolution of the disease [3][21]. IVDs act in several phases of the disease progression, starting with the genetic predisposition assessment, with a crucial role before the emergence of the disease [24]. Then, in a preventive perspective, it prevents future infections and complications of the pathology and the spread of the disease in the population. In subsequent phases, it allows an early diagnosis and the prescription of more effective treatments.

According to a private lab representative, the number of tests with deviations from the reference values has been increasing, indicating that users are seeking health care in more advanced stages of the disease, which may overload the NHS [21]. In fact, the value of IVD can be seen from two different perspectives. One, in terms of health gains, as it allows a fast and reliable diagnosis, the early detection of infections or complications and the implementation of treatments adjusted to the specific needs of the users, thus preventing or delaying complications of chronic diseases [21][24]. By monitoring the applied therapy and its effects, IVD improve treatment efficacy and, consequently, the quality of life and decrease both comorbidity and mortality. The other perspective, in terms of economic gains, since an improvement in the quality of care can improve the allocation of resources and reduce unnecessary expenses, reducing hospital stay and avoiding relapses through the monitoring of appropriate therapies,

ensuring gains in productivity [3][24]. In this way, and as reported by the representative of the IVD Commission of APIFARMA, IVD clearly contributes to the reduction of the overall health expenditure in the medium and long term [25].

Thus, IVD not only allows a better care for the patient, avoiding unnecessary and ineffective treatments, but also a more rational application of the available resources, ensuring at the same time, a timely clinical decision-making and the most appropriate for a given patient [24][25]. Furthermore, the growing set of evidence-based clinical practice guidelines recognizes the crucial role that IVD plays in the health care decision-making process [3]. In fact, today, about 70% of the clinical decisions are made based on the results of IVDs, allowing a reduction of the economic burden of the disease in the society [3]. In that sense, the evolution of diagnostic techniques is very important, as it allows the increase of sensitivity and specificity of tests, which determines the reliability of the results and ultimately leads to more accurate clinical decisions [21].

IVD value chain and samples workflow:

The value chain of the IVD may be divided into six sequential phases, represented in Figure 2.3 [21]. It starts with the prescription of the lab test by the doctor to perform a diagnostic, to analyze the evolution of a certain disease, or to perform routine examinations to assess the individual health status. According to the processing degree of the samples to be analyzed, the production involves three phases: pre-analytical, analytical and post-analytical.

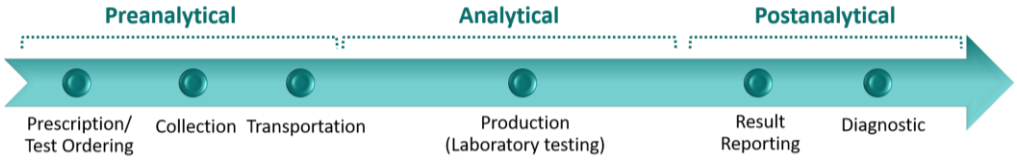


Figure 2.3.Value chain of the IVD in the lab market.

The pre-analytical phase starts with the specimens collection in the collection points, which are afterwards shipped to the lab, where the set of lab tests is performed, when the collection point and the lab are placed in different structures [21][27]. Once in the lab, the sample is divided and prepared to be tested typically using automatic equipment. Pre-analytical phase finishes at this point and the analytical phase begins, which constitutes the core part of the IVD value chain. Samples previously prepared are placed in contact with reagents, and the set of required tests is carried out usually by the analyzers, typically connected through a robotic setup to make the process more automatic and efficient. The samples are then stored for a defined period of time and then incinerated, and the analytical phase is concluded. Post-analytical phase involves reporting the test results to the doctor, through information systems, ensuring a greater efficiency and avoiding loss of data, to support the clinical diagnosis. The process finishes with the interpretation of the tests results by the health professional, supporting him diagnosing or assessing a certain pathology [27].

Errors may occur in the different stages of the IVDs' value change and result in adverse consequences to the quality of testing and patient safety. Errors are more likely to occur in the pre-analytical phase,

accounting for 60-75% of all lab errors [27]. The collection, handling and processing conditions of the biological specimens by the phlebotomist, as well as the transportation and the storage conditions may introduce errors in the process, since these tasks are essentially manual work [28]. Post-analytical phase follows the pre-analytical one in terms of mistakes predisposition and finally the analytical phase. Errors occurring during the post-analytical stage include mainly misinterpretation and consequently misdiagnosis of test results and delay in information reporting [29]. Due to the automaticity of the analytical phase, most of the problems that characterize it are more preventable. In fact, they are more easily avoided through the adoption of a few rules of quality policy, including the implementation of standard practices in the activities and the application of technological advances, which are effective to detect and prevent mistakes. Also, an effective communication between all lab technicians is very important to reduce errors [30].

2.3 Main stakeholders of the IVD

IVD's sector is composed by different stakeholders, which interact amongst themselves along the value chain [3]. The stakeholders, represented in Figure 2.4, include public and private entities having different functions. The government, as legislator, acts on the IVD market through the ministry of health and the parliament, and the main challenge is the identification of measures to reduce costs and meet budgetary goals, without compromising the entities acting in the sector [21].

Demand and supply in this sector are subjected to the regulators and funders [21]. GDH, HRA and '*Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.*', also known as INFARMED, are responsible for the regulation of the health sector in Portugal. GDH coordinates and regulates health promotion activities, disease prevention and quality of care provided. HRA supervises and regulates healthcare provided.

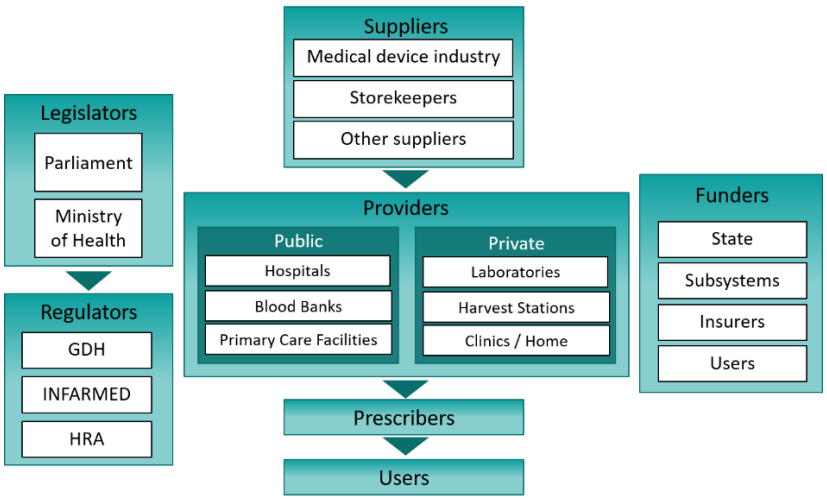


Figure 2.4. Main applications of the IVD throughout the evolution of the disease (Adapted from [21]).

INFARMED is the authority responsible for the supervision and regulation of the medical devices sector. The main challenges faced by these entities are [21]:

i. an adequate management of the healthcare.
ii. equity in the access of the users to the healthcare, being necessary to ensure that new entities can provide services to the NHS users', without an increase in costs.
iii. the monitoring of the implementation and redefinition of policies in case the objectives are not being achieved.

Regarding supply, the main suppliers that make part of this sector are the medical devices industry and the storekeepers responsible for the storage and distribution of the products (covering the distribution at the lab and pharmaceutical levels). One of the main challenges faced by suppliers is the accomplishment of the payment deadlines by the public providers, being the State the main funder of the IVD market. Other concerns include the reducing the profitability of products and services provided, and managing investment in equipment to ensure amortization [21].

Still according to the same source [21], and as previously discussed, the healthcare providers are the ones where samples are collected, and the lab tests are performed. They can be both public and private, being the main players of the public sector the NHS hospitals, the blood banks and the primary care facilities. Starting with the public providers, for the hospitals to act as a provider in this field, it is required to have a clinical pathology service or a department of pathological anatomy. The blood banks are within the scope of the Transplantation and Blood Institute, being responsible for ensuring the blood collected can be used in future blood transfusions. In terms of primary care facilities, they may be equipped with a clinical lab, where it is possible to collect and analyze the samples. When it does not occur, samples are collected and sent to the labs and diagnostic centers with NHS agreement.

Regarding the private sector, labs and collection points are the entities with greatest influence, but there are also some private clinics performing lab tests [21]. As previously mentioned, the present study focuses on a private provider (a private clinical pathology lab).

Finally, prescribers decide when and which lab tests to prescribe, however they are not responsible for the choice of the place where these tests will be performed [21], and now, providing a little perspective of the users' side, the State finances the IVD performed in hospitals through public tenders or in private agreed labs. Health insurance and subsystems, both public and private, have the role of payer in the IVD sector because they finance their users in the access to this type of care. Considering the national economic framework, the need for rational spending in several areas, including the CDTT, where clinical pathology sector is included, is a reality. In fact, according to a report of the Ministry of Health and Portuguese NHS [1], in what concerns the NHS agreed sector, the area of clinical pathology is the most representative in terms of government expenditure (see section 2.1). Consequently, the government challenge is to define policies and implement systems to control expenditure in these areas, ensuring that the quality of the service provided is not impaired [21].

The user covers his/her expenditures in lab tests through the payment of user charges in hospitals and primary care facilities (out-of-pocket payments), co-payment of the lab tests, or the overall value if it is not reimbursed. The reimbursement taxes of the lab tests are defined by the payer, the government, the insurance companies or the health subsystems [21].

Competition between providers makes the market more dynamic and attractive, which is extremely positive for the users' point of view, since the providers are encouraged to offer more competitive services to attract users. Thus, the increasing pressure exerted by potential competitors is expected to be inversely proportional to the barriers to market entry, according to HRA [15].

2.4 Clinical Pathology Market

At the European level, the IVD market revenues have been increasing in recent years [2][31][32], as can be observed in Figure 2.5, however, changes in revenues are not necessarily reflected in changes in the test volume. In fact, many countries experienced a significant increase in tests volume without increasing the revenues [2].

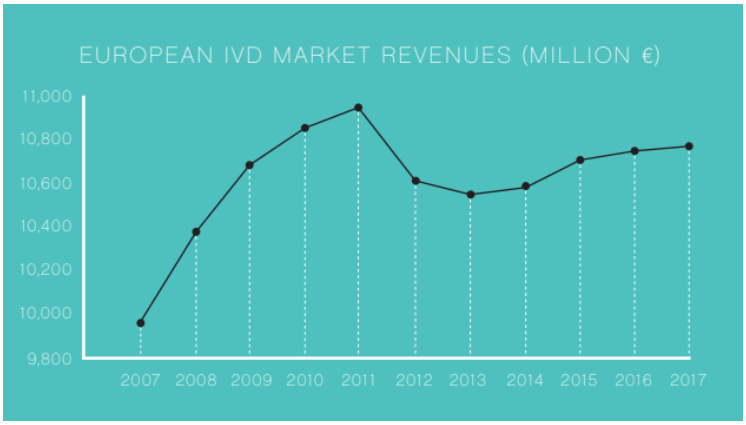


Figure 2.5. IVD market revenues throughout the years, between 2007 and 2017, expressed in million euros (adapted from [32]).

The IVD industry in Europe generated 10.768 million euros in sales in 2017, and 11.094 million euros in 2019, with the five largest contributors being Germany, the United Kingdom, Italy, France and Spain [2][32]. The increase of life expectancy, with the consequent population aging and increase in the prevalence of chronic disease, as well as a greater awareness of the population for the benefits of early diagnosis are factors with a positive impact on the growth of the European IVD market. Furthermore, the demand for IVDs is expected to increase until 2024 [2][31]. Moreover, the pandemic outbreak severely impacted the healthcare services, and overloaded the clinical labs, both public and private. Thus, the revenues for the IVD market are expected to grow in the year of 2020.

At the national level, IVD market has been demonstrating a stable trend from 2015 to 2018, with a small decrease in 2017 [2][32]. The sector has been suffering a high pressure on prices, through political measures of cost containment in healthcare. Furthermore, also the legislative instability in the prices and the reimbursement caused entropy in the system [21].

These measures have been driving the acquisition of small labs by large multinationals, leading to the consolidation of the private lab sector, with a reduction in the number of agreed providers (from 359 in 2010 to 183 in 2019) [1][2]. Furthermore, the intention of the National Government of internalizing part of the IVD in the public settings has been placing private labs under pressure [32]. Regarding the models of funding in healthcare, new approaches have been explored, considering purchasing based-on value

and payments over health outcomes [2][32].

In September 2015, there were 3040 clinical labs and collection points in Portugal, from which only 120 were public (4%) [17][33]. In 2014, NHS hospitals provided more than 82 million of clinical analyses services and the providers having conventions with the NHS (the agreed sector) provided more than 46 million of clinical analyses services, resulting in an annual average of 13 clinical analyses services for each Portuguese inhabitant. It means that, on average, per month, each inhabitant performs more than one clinical analysis publicly funded in a public hospital or in an agreed provider [17].

In Portugal, for an entity to provide healthcare to the users of the NHS, it is required to establish a convention. Based on the Decree-Law 97/98 of April 18, NHS can make use of services provided by the agreed operators (private labs with convention with the NHS) if, and only if, it has not enough installed capacity to meet the users' needs, i.e., when NHS is not able to respond in a timely manner to the users' needs in terms of CDTT [15]. Between the beginning of 1999 and 2013, new conventions have not been established in this field, preventing new operators from providing services to NHS users during this period. This restricted the competitive pressure among the market players and reduced the incentives for them to become more efficient [15]. In October 2013, the rules that regulate these conventions were revised and the conventions were reopened increasing the competition in the sector [34][35].

The enhancement of the competitiveness improves efficiency of the health productive sector and creates benefits for the users, such as, a more extensive range of the services provided, innovation and pressure for price decline [15]. This has allowed the lab sector to evolve over the last decades.

In the healthcare sector, innovation may be the key to ensure the sustainability. In the IVD industry, innovation may be achieved in two different perspectives: technological innovation of the product and incremental or process innovation. The first is based on new biomarkers, faster, more sensitive and promoting a high-clinical value. In fact, the innovation in lab technology, including new tests and state-of-the-art equipment and testing techniques, has contributed to the automation and efficiency of the process. Regarding process innovation, the improvement of the lab workflow allows to save time in terms of the response given to the clinician for him/her to make the decisions [21][36]. This is particularly important in the era we are living, the era of value-based healthcare. Improving lab efficiency is then, becoming increasingly interesting and the focus is being placed on improving the ratio between patient outcomes and costs [37]. The goal is to provide high-quality testing in a timely manner, at low costs. Innovation is then one of the key factors responsible for the differentiation of the main players in the market, which may be introduced in the different phases of the IVD value chain.

Apart from the innovation, there are other factors that differentiate the players in the IVD industry, as well as the reasons that motivate the citizens' choice in terms of the lab where to perform their lab tests. They include the price, the previous experience, the quality of the products, the service level and the delivery times of the results, the specialization in certain lab tests, the variability of exams offered and the collection process [21].

Since the profit margin resulting from an increase in the lab tests volume is short, it is increasingly important to improve efficiency in the lab and identify in which activities is there room for improvement.

2.5 SIEMENS Healthineers

SH is a company focused on the society trends and its implications regarding the healthcare sector, aiming at allowing healthcare providers to increase value by expanding precision medicine, transforming care delivery, and improving patient experience, through the digitalization of healthcare. This company offers a broad and deep portfolio including diagnostic imaging solutions, being a market leader in this field, ultrasound methodologies, characterized by its versatility and functionality of the real-time clinical imaging, advanced therapies, empowering innovative therapy concepts. Lab diagnostics is another field of action, by delivering clinical and workflow excellence, PoC, enabling lab-accurate, actionable and timely results at the point-of-care and the services, helping to achieve the best institutional performance in all these areas.

This study is developed within the SH ES team. SH ES is a very friendly and supportive, young and multidisciplinary team, characterized by their innovative and creative ideas, seeking to improve and optimize workflows to their customers, clinical outcomes and patient experience, having the customer as the core of their decisions and concerns. For the SH ES team, the most important is to create value to the customers and for this reason, the methodologies and developed approaches should promote value-based healthcare. SH has been working for a long time with this private provider of clinical pathology, and this thesis is performed within this collaboration.

2.6 Objective of the study

There is a strong competition between the main private clinical pathology providers that try to distinguish in the market, seeking to be at the forefront of the services provided. The clinical pathology lab on which this study focused on aims at improving the workflow of the lab tests in order to achieve its objectives of efficiency improvement.

This study focusses on the core lab of this clinical pathology lab. The core lab receives and processes around 70-80% of the whole lab workload, and an automation system manages the samples' flow and drives the test tubes to the respective places where they need to go, to perform the required set of lab tests. The major challenges identified in the system were:

i. Samples do not arrive at the lab evenly during the workday.
ii. Need to identify bottlenecks in the system.
iii. Perceiving future challenges for the lab derived from external factors with impact in the production of lab tests along the automation system.
iv. Envision and prepare in advance the response to these new challenges or contexts.

Challenge i. is not directly related with the lab activity, depending heavily on the distribution and allocation of routes and the frequency in which samples are collected from the various collection centers. In challenge ii., the identification and posterior elimination of possible bottlenecks in the automation system may streamline the process along this production system and improve its efficiency. The first two are operational challenges. Numbers iii. and iv. are strategic challenges and are the focus of the current thesis. In this way, the present study proposes a methodology that enables the identification of

plausible future challenges for the lab with impact on the automation system, measuring the impact of these scenarios in the system and envision and prepare in advance responses to those possible future challenges or contexts.

Then, the objectives of the present thesis include: support the lab in identifying external factors relevant to the development of scenarios with possible impact on the lab tests production in the core lab (along the automation system), develop a simulation model of the automation system in the pre-pandemic context, evaluate the performance of the model in this context, and the impact of plausible future scenarios through a set of key performance indicators (KPIs), and provide lab management with evidence of the simulation model for future decision-making in light of these plausible futures.

Considering the aforementioned, this thesis intends to develop a methodology to help this lab to improve the efficiency of its processes in the core lab, under the context of uncertainty.

Chapter 3

Literature Review

This chapter aims at reviewing process improvement techniques, so as to learn from literature and decide upon which techniques are the most suitable for developing the methodology proposed in this thesis. Hence, this chapter provides a broad perspective of process improvement techniques, as well as of process mapping tools to help that end. The impact of uncertainty in strategic decision-making is also covered through the identification of techniques that cope with it. Since the focus of the current work is on clinical lab settings, the literature review covers studies that have considered this environment and seek to analyze and assess current workflows and their improvements. Along this chapter, particular emphasis is given to simulation and to scenario planning and foresight techniques, as they are found to be key for the thesis context – for instance, foresight tools are appropriate for looking into the future when external uncertain events unfold, such as the current COVID-19 pandemic.

For the purpose of reviewing studies in this chapter, Google Scholar, Scopus, Web of Science, PubMed and IEEE were the main databases consulted.

3.1 Business Process Improvement

The set of activities defining how to achieve organizational goals and to produce output that creates value to the customers forms the business process [38]. Nowadays, business process improvement (BPI) is a popular topic for companies, which apply it to keep track of the changing business environment, by adapting themselves to the continuous challenges faced [39]. To support companies in improving their processes, there are several methodologies described in the literature [40]. According to Macdonald, the term BPI has been employed to cover three different concepts about change: process improvement, process redesign and business process re-engineering, all seeking to improve the current system, being the main difference between them the depth of change [40].

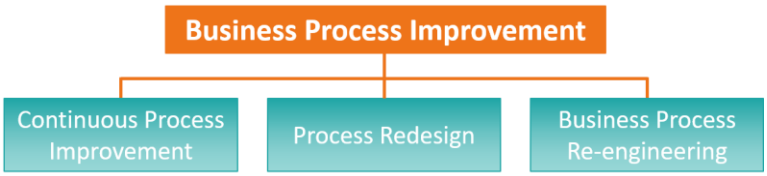


Figure 3.1. Different concepts regarding Business Process Improvement (BPI) [40].

Figure 3.1 summarizes the different concepts of BPI. Continuous process improvement consists in the continuous and incremental improvement of the current system within an organizational structure. Thus, the improvements tend to be individually small and confined within the existing boundaries. It should be applied as a cross principle to business, with the aim of achieving rapid gains [40].

Process redesign goes beyond the improvement of the existing processes, as it tries to identify the current activities that are essential and should remain in the future process, and the ones that are not.

Business process re-engineering involves a greater organizational change, consisting of the rethink and radical redesign of the current business process, with the aim of achieving dramatic improvements in performance. Based on the premise that the organization is no longer competitive with the current organizational system, it breaks away with the conventional process and produces a widespread change, to remain competitive in the global marketplace, which takes longer to be implemented [39][40].

The focus of this study is the continuous process improvement, hereinafter simply referred to as BPI. BPI, by changing processes within an organization, makes it more competitive and successful in the marketplace, as it tends to increase the effectiveness and efficiency of its processes [38][39]. Nevertheless, it is important to consider that the major barrier to redesign system's processes is the change of mindsets, namely at the healthcare level, with the potential risks and disruption associated. Therefore, a reasonable justification is required when large impact changes are proposed for an organization, with communication between all stakeholders being mandatory for the changes to be successfully implemented [41].

3.1.1 Classical Approaches to Process Improvement

Improvement methodologies are essentially indicated for an organization to have the possibility of growing and scaling up [42]. Furthermore, the increasing competition requires companies to revise their processes and implement improvements to highlight at the market. In the healthcare sector, process improvement is crucial to high quality healthcare service provision [43]. In the case of clinical labs, in which lab tests provide the great majority of the information for clinical decision-making, it is critical to provide clinicians with quality information in a timely manner, to support the clinical decision. In fact, the decrease in the turnaround times (TAT) allows doctors to have rapid access to the lab tests results, due to the lab processes improvement namely, the automation of the processes [43].

According to Harmon, the set of atomic activities performed by an organization generates a process [44]. Becker et al. proposes a more complete and consistent definition, stating that a process is a "completely closed, timely and logical sequence of activities which are required to work on a process-oriented business object", as cited in [44].

Different types of managerial decision-making problems may be approached using diverse techniques. Some of them are presented below, in Figure 3.2.

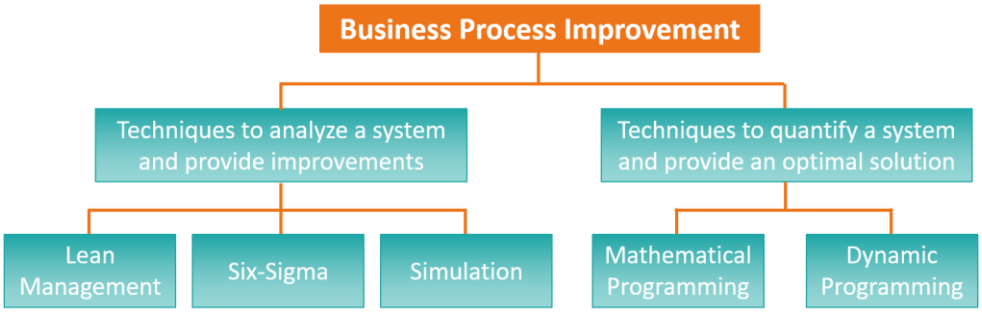


Figure 3.2. Different approaches to process improvement.

All methods illustrated in Figure 3.2 present advantages and limitations [45]. The objective is to find a tradeoff and choose the most suitable technique or a combination of them which allows to mitigate the

limitations of each one and complement their benefits. In the next subsections, a brief description of each one of the techniques described in Figure 3.2 is presented.

3.1.1.1 Lean Management

Lean is considered a philosophy, a supportive management system, to engaging workers to continuously improve, through the identification and elimination of wastes, associated to non-value added activities [46]. These activities do not directly contribute to the final goal of the process, despite consuming resources such as labor, time, and materials. For instance, in the clinical lab settings, the focus of this study, calibrations and maintenance of equipment, reagent preparation, sample's proliferation, decapping, recapping, storing, retrieving, centrifuging and sorting samples are some of the non-added value activities [47]. The implementation of this technique typically starts with the definition of value, followed by process mapping of the current state, identification of wastes and possible improvements, process mapping of the future state and implementation of improvements [48][49].

Simple as it may seem, it can be tricky especially in the healthcare sector. According to Liker, over 90% of the ones who have attempted to apply lean methodology failed [46]. Thus, a successfully implemented lean culture of continuous and integrated improvement requires the engagement and commitment of all company members to the same objective, and the change of the organization's culture itself, which can take around a decade [46][47]. This should focus on the whole process, as trying to improve steps in isolation may not contribute to the overall efficiency improvement [44].

When correctly applied, lean principals may improve quality and safety, reduce mistakes and errors, improve throughput, making it possible to produce more with the same resources, and improve staff's morale. One of the reasons that limits the adoption of lean methodology by healthcare managers is the lack of quantifiable evidence [50].

3.1.1.2 Six-Sigma

Six-sigma emerged as a statistically oriented process improvement method [39][48]. It consists of a data-driven methodology designed for process organization and improvement, and problem solving, with focus on the identification and deletion of variability in a process, measuring the degree to which a process is deviated from its objective [51][52]. This provides an indication of how much products or services deviate from having zero defects, thus helping businesses to reduce the number of defects within the processes. Once detected, these imperfections can be methodically removed from the process [53]. When correctly implemented, it provides cost reduction, quality improvement and reduction of the process time [52]. Hybrid solution combining lean and six-sigma are usually applied to reduce waste, improve process efficiency and increase customer satisfaction by eliminating variation [51][52].

3.1.1.3 Simulation

Simulation has emerged during the fifties as a technique to support analysis, design and improvement of organizational processes and nowadays it remains a relevant technique, providing a decision support

mechanism at different levels: strategic, tactical and operational [54]. The reproduction of the reality over time, through a model of the system, demonstrates to be a loyal and trustworthy representation of real-life situations that are too complex to be modeled using mathematical programming, making the process less computational costly [45][55]. The different variables of the system, as well as their interrelations, are provided to the model and once it has been implemented, it generates a set of outputs.

Besides representing and allowing the evaluation of the performance of the current system, it is also useful to analyze and evaluate different alternatives and scenarios. Before applying simulation, it is required to define the model that is going to be simulated, and the underlying goals. When modeling a given system, the model, which is a representation of its functioning, is simpler than, but similar to the system it mimics [56]. In this process, a trade-off between realism and simplicity is required, as the model should be defined as a close approximation of the system it is reproducing, incorporating its major characteristics, however, it should not replicate all small details making it impossible to understand and perform experiences on it [56]. Furthermore, a simulation model is able to integrate random and structural variation that characterizes the real systems, though stochastic processes [50]. In these cases, the simulation model is able to not only capture dynamic and complex features, but also predict consequences of improvement efforts [52].

Simulation is a decision support technique which provides insights in advance on what should happen under real operating conditions [8]. Several definitions of simulation exist. According to Shannon, “simulation is the process of designing a model of the real system by conducting experiments with this model for the purpose of understanding the behavior of the operation of the system”, as cited in [45].

Moreover, a simulation allows to understand the response of a given system, how it reacts and how it behaves when a particular change or stimulus is induced [57]. Due to its flexibility, it allows to replicate and model different environments, and it has been increasingly applied in the healthcare sector [58].

3.1.1.4 Mathematical and Dynamic Programming

Mathematical programming is a technique mainly designed for resource allocation [45]. This technique provides exact analytical solutions that work fine for simple problems that are easily described by a valid mathematical model. However, real life problems tend to be so complex that to develop a valid mathematical model of them becomes very complex, excluding the possibility of achieving an analytical solution [59]. This technique considers that data is unchangeable over time, being one-time decision process in which the decision variables assume average values. The fact of not considering the uncertainty present in real life situations is another limitation. When uncertainty is related to only few variables, its effect on the decision can be verified through sensitivity analysis. However, when uncertainty impacts several variables, this analysis may become computationally heavy and extremely complex. Furthermore, in situations characterized by a high degree of uncertainty, as is typically the case of real situations, this approach may become less meaningful because there are several factors that are not known with certainty and the results may be strongly impacted, and may present a huge variation that is not realistic [45]. Regarding dynamic programming, its major drawback is that it is more appropriate to tackle situations described by few variables [45]. When increasing the number of state

variables, the computational problem becomes quite complex and difficult to solve [60]. To model real-life complex problems, characterized by uncertainty and dynamic interaction between system variables, the utilization of optimization methods becomes too complex.

3.1.2 Simulation models in clinical lab settings

Simulation provides a number of advantages over mathematical programming to approach complex problems and, in particular, the problem under study [45][54]. Simulation is an intuitive technique which provides transparency in the sense that, at least superficially, it allows to see how the model works and to understand how the outcomes are generated, which results in a greater confidence of the end users, who are not simulation experts, in the simulation model itself and in its results. Therefore, the proposed plans tend to be more easily accepted and implemented [59][61]. This property of simulation allows to overcome the "black box syndrome" which greatly restricts or impairs the use of other types of less intuitive models, namely analytical models, such as mathematical programming. Additionally, when compared to lean and six-sigma techniques, simulation proofs to be much more robust, as, in contrast to these techniques, simulation is able to assess the effects of variation, enables the effects of proposed changes to be validated prior to its implementation in real-life, is able to identify improvement opportunities and to appraise the interactions between system components [50]. Moreover, it envisions how the system reacts in response to the potential changes and improvement efforts, allowing to account for the complexity and variability of the system [52].

Simulation provides a visual understanding of the behavior of a dynamic system along the time, important to communicate its performance [61], and allows the evaluation of the impact of changes applied to the system and the assessment of different managerial strategies for the operation of the system. It enables to anticipate and estimate consequences of changes applied in the system, as well as predicting bottlenecks, identifying and preventing both under and over-utilization of resources and ultimately, improving system performance [45][56]. Due to the flexibility of this technique, the performance of the system may be studied under different scenarios, through what-if analysis, and under different system's configurations [61].

As reported by Yin et al. [62], modeling and simulation techniques are becoming increasingly important research tools for organizational and operational systems in numerous sectors, especially in the healthcare settings, being proposed by researchers as effective approaches to better understand real systems, increase efficiency and support managerial decisions [63]. According to Jun et al., simulation becomes the most suitable approach to tackle problems in the healthcare environment due to the complexity of the systems, and the multiple performance measures it enables to interpret [63]. Simulation is the second most widely used technique in the operation management field [64]. According to this review, process design and improvement, within the scope of “Process Engineering in Manufacturing” were considered the second most popular application of simulation [64].

The powerful features provided by simulation impact on the education and paradigm shift to an objective-oriented one. It is particularly evident when educating decision-makers about managerial changes that are required to implement, reducing their resistance to the implementation of changes [63].

Since the processes associated to the production of lab tests in a clinical pathology lab resembles a traditional production system with the inherent complexity of the healthcare settings [65], simulation seems to be the most suitable technique to approach the problem under study.

3.2 Different types of simulation models

Four leading types of simulation can be identified: Monte Carlo Simulation, Discrete-Event Simulation (DES), Agent-Based Simulation and System Dynamics Simulation [8][64]. Monte Carlo Simulation is a risk analysis technique applied in business before the implementation of a major project or changes in a process [64]. Based on probability distributions, it allows the identification of uncertainty and potential risks [64]. It provides awareness and thorough understanding about the possible threats the system can be subjected to. It is mainly intended to cover static problems or to solve stochastic numerical problems [59][64].

DES models the operation of a system as a sequence of discrete events in time [66]. DES are discrete, stochastic and dynamic models, characteristics that generally describe real-world problems, justifying its popularity [54]. It allows complex real system, characterized by the interactions between individuals and their environments, to be modeled [67]. When describing complex real systems, time-to-event is best represented by stochastic distributions, typically estimated from real-world-data, instead of fixed values [67][68]. By modeling the system as a whole, considering its interdependencies, DES enables the development of a reliable and realistic view of the real system [67]. Each event occurs at a given moment and signals a change of state in the system. Between each discrete event, the system remains unchanged. Thus, the process is described through moments, or events, instead of in a continuous manner, running faster [66][69]. The simulated settings can be seen as queuing networks with individual entities or items passing through a series of discrete events, at discrete intervals, in which, between them and due the restricted availability of resources, entities have to wait in queues. Therefore, DES is considered a suitable tool to address concrete operational and strategic challenges in the healthcare field [67]. It is the most widely used technique in the scope of manufacturing and business, being implemented in more than 40% of the papers reviewed [67]. Moreover, DES is considered an effective tool to address a wide variety of problems within the complex healthcare domain [67]. Agent-Based Simulation is an extension of DES [59][66] that enables the assessment of the impact of an “agent” on the “system”, for example, the impact of a new equipment on the overall assembly line, in the industrial setup. The model includes the agent’s behavior, based on rules, specifying how this agent must act in the system, with the goal of assessing how the system responds to it [62][64]. This technique can tackle organizational development, by modeling the human agents’ behaviors and the communication between agents within an organization [64].

System Dynamics Simulation is a type of continuous simulation [59], which in contrast to Agent Based Simulation and DES, ignore specific and fine details of a given system, such as the individual properties of products, people or events, producing a general representation of a complex system [64]. It was considered the second most widely used simulation technique, being applied in 15% of the papers reviewed [64]. Briefly, the priority of this kind of models is to obtain aggregated-level insights about the

entire system in the face of a given action, being used to support more strategic decisions [59][70].

3.2.1 Discrete-Event Simulation for process improvement in clinical lab settings

Considering the characteristics of the various simulation techniques described in the previous section, DES is the most effective to describe the complexity and variability of healthcare problems and to address operations and improvements in healthcare systems [64][66][70]. Furthermore, it is the most well stablished, documented and widely used technique in both manufacturing and healthcare domains [64]. Moreover, similar studies conducted in clinical lab settings have applied DES, as it will be explored later. Before model implementation in a simulation software, it is important to understand the current process. For this, the next section presents the most widely used process mapping techniques to this end.

3.2.1.1 Classical approaches of process mapping

Before the implementation of the simulation model, it is important to understand the process [39][71]. Process mapping tools allow to structure the processes and to understand how the individual activities are interrelated [53]. It does not provide a solution in itself, but aid in determining unnecessary, repetitive and redundant tasks, in a system, by providing a compact picture of it [42].

According to L. Colligan et al. [72], the correct implementation of quality and safety improvement methodologies in healthcare depends on the utilization of an accurate and complete map of the process. The most effective process mapping technique [72], depends upon the problem at hands, and there is evidence that the way the information is organized affects reasoning and decision-making. There are different tools for process mapping. To support the development of a simulation model, flowchart and value-stream map (VSM) seem to be the most commonly used.

Flowchart is used for capturing and analyzing the process, both the activities that integrate it and its connections, in order to figure out the current process and develop ideas about where and how to improve it. It allows to break up any process into its individual activities, with the sequence of steps or activities forming the work process being represented by different shapes [73]. This is a powerful tool for quality improvement and may be used as a starting point to the design and construction of new processes [74][75].

VSM is a visual representation of the process steps which helps to understand the flow of value in a business process [50]. It allows to find improvement opportunities by making non-value added activities easier to identify, and by discovering where problems lie within the process [76]. Its main goal is to identify and eliminate waste, being considered the primary tool in lean methodology. It not only provides a detailed view of the current process flow, but also the corresponding time each activity takes to be completed, the lead time [76][77].

3.2.1.2 Steps to develop a simulation model

A simulation model provides an iterative view of a real-life problem. Its implementation requires the

collaboration of decision-makers, managers and the simulation analyst, to provide the details of the system. This technique may provide managers with insights about the relations between the available resources and the quality of healthcare provided by the system. Furthermore, simulation detects unexpected problems in a system, promotes the development of manager's decision-making skills and forces him/her to notice the changes experienced by the system [63].

To implement a simulation model, there is an iterative and recursive set of steps that should be addressed, as represented in Figure 3.3, which may not always be followed sequentially [56][59][78].

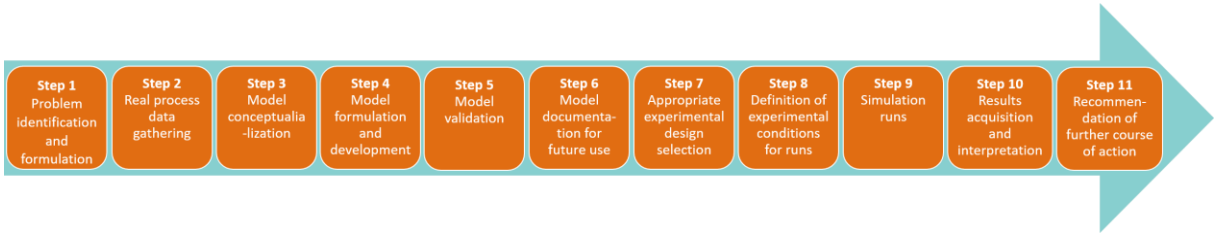


Figure 3.3. Set of steps to develop a simulation model [56][59][78].

Besides the set of steps depicted in Figure 3.3, a simulation study may require various iterations at different sub-stages before the achievement of the simulation objectives, likewise, depending on the problem at hands, additional steps may be useful [56][78]. In step 1, challenges in the system under study must be identified [79]. They can be raised through process mapping tools, presented in the previous section, and defined as precisely as possible, to promote its comprehensive implementation via simulation [50]. The problem formulation, represented in step 1, allows the careful definition of the boundaries of the system under study, and it should be taken into account that different frameworks to the same problem result in different models [80]. Thus, different models provide different views of a given problem, reflecting choices previously made in the decision process. Furthermore, a model which incorporates all aspects of a strategic problem does not exist [80]. These models may not reproduce all the details of a complex real system, however, it is necessary to be careful in the assumptions that are being made. Assuming simple cause/effect relations rather than multiple interactions may lead to meaningless results. The definition of the overall objectives of the study and specific issues to be considered takes place in this step, and the end user of the simulation model should also be identified [56][79].

Step 2 consists in data gathering, including system's specifications, input variables and their randomness characteristic of their stochastic nature, the fit of the appropriate input probability distribution and the associated parameters estimation. When it is possible to collect data on an input variable of interest to parametrize the simulation model, there are different approaches that can be followed to make use of these data to identify the most adequate distribution [59]. The author, presents these approaches in an increasing order of desirability, however, the most adequate approach also depends on the simulation objectives and purposes [59]:

1. Data values are applied directly in the simulation model, known as a trace-driven simulation.
2. The available data values are used to define an empirical distribution function.
3. Statistical inference techniques are used to fit a theoretical probability distribution to the data and then, assess the goodness of fit through hypothesis tests.

According to the author, all the three approaches present drawbacks, however, the third is generally the preferred one, followed by the second. In the first one, the simulation is limited by what happened historically, being able only to reproduce what actually happened according to the available data. Furthermore, historical data that can be collected is typically not enough for all the simulation runs [59]. Regarding the other two approaches, the third should be applied if one founds a theoretical distribution that fits the observed data reasonably well, since when only few data values are available, the empirical distribution function may present some irregularities, while a theoretical distribution smooths out the data, providing information on the overall underlying distribution [59]. Another pitfall of the second approach is that the simulation cannot generate values outside the range of available data values. On the other hand, a fitted theoretical distribution allows to reproduce values outside the range of observed data values [59]. In fact, when fitting theoretical statistical models to the collected data, it is intended to model the behavior of the population from which these data were extracted (which constitute only a particular sample of the population), allowing then the simulation model to generate diverse samples. Law provides guidelines to parametrize theoretical distributions and how to specify empirical distributions [59].

Step 3 consists in the development of the conceptual model, which is a draft that supports the building of the simulation model in the software and should assemble the following information [81]: the process-flow of the system; a detailed description of the system; the assumptions considered; a summary of the model input variables; and the performance measures considered for evaluation. As previously mentioned [63], the participation of managers and decision-makers in this process is important for its success and they should validate the conceptual model proposed, so that it can be used as basis to formulate and develop the simulation model in the software, as identified in step 4.

Step 5 involves model validation, which is pursued by comparing the model's performance when subjected to known input conditions, i.e., model output results are compared with system outputs that are known [56]. The model must be validated by the decision-makers [59][63], to ensure the assumptions are correct, consistent and complete, enhancing the confidence in the model.

In step 6, the constructed model should be documented for further use, including detailed descriptions of the objectives, assumptions, and input variables. Next steps involve simulation experiment, i.e., a test or a set of tests is performed, applying meaningful changes to the input variables of a simulation model. Thus, in step 7, one may select the appropriate experimental design, by selecting a performance measure, few input variables which can influence it, as well as the levels of each input variable [56][79].

In step 8, experimental conditions for runs are established, so that one may obtain accurate and the most information from each run. It is important to determine whether the system is stationary or non-stationary, in case of changes in performance measure over time. The appropriate starting conditions should be selected, as well as the length of the setup or warm-up period. Simulation runs in step 9 should be performed according to steps 7 and 8.

Simulation results are typically difficult to interpret due to the stochastic nature of input variables. A given observation may have result from the system's characteristics or just from a random occurrence. This problem is addressed in steps 10 and 11. The interpretation of the results is performed in step 10, based

on the computation of numerical estimates, such as mean and confidence intervals of desired performance measures, followed by graphical display of the simulation outputs, results documentation and conclusions. In the last step, it is advisable to increase the number of experiments in order to increase the precision and reduce bias of estimator, and assess uncertainty in the model, typically performed by sensitivity analysis [56].

3.2.1.3 Uncertainty in process improvement and in simulation modelling

According to the information presented above, when modeling a system through simulation, the performance is characterized by the intrinsic simulation's uncertainty and the input uncertainty [68]. According to Zouaoui et al. [82], uncertainty in simulation may be disaggregated into stochastic, parameter and model uncertainty. Stochastic uncertainty is related with random inputs of the simulation model leading to variation on the output of a simulation experiment. Stochastic uncertainty can be accounted for in simulation by describing model inputs through known parametric distribution [82]. Nevertheless, it is necessary to define the parameters that characterize these distributions, which are commonly assumed to be fixed. These parameters can be either defined based on real data or based on experts' opinion, in a subjective manner. This can be considered as another source of uncertainty, in literature referred to as parameter uncertainty [82]. The other type of uncertainty, model uncertainty, arises when choosing between different input models. Thus, the overall statistic error may be underestimated by neglecting either source of uncertainty [68].

Another typical way of addressing input uncertainty in simulation modeling is by sensitivity analysis [83][84]. It consists in the assessment of the contributions of the individual inputs of a model on the total uncertainty in the outputs [85]. It allows to analyze how changes in an input value at a time are reflected in the output, which in complex models may not be appropriate due to the large number of variables involved, and it does not consider the impact of variations in more than one variable at a time [83][86]. Therefore, a more efficient way of addressing uncertainty is through strategic foresight [87]. However, it is not commonly combined with simulation. Strategic foresight methodologies emphasize uncertainty and stimulate people's thinking about the future, with the aim of being better prepared to face future plausible occurrences.

3.3 Strategic Foresight

Managers should be aware that due to the inherent uncertainty and volatility, the future a company may face may not resemble the past [88]. Strategic foresight is a set of future-oriented methodologies, combining "thinking", "debating" and "shaping" the future [89], which can be applied to develop perspective and insights which contribute to systematic examinations of the future [90]. The ultimate purpose is not to predict the future, but instead, to explore how the future may unfold in alternative directions, providing adaptive organizational learning skills, in such a way that organizations are able to overcome possible problems that may arise [89][91]. Therefore, this is an *action-oriented* methodology since the purpose is not only analyze and explore how the future may evolve, but also motivate and help people to shape the future [89]. It makes use of participatory methods and social processes, involving a

wide group of stakeholders to capture different perspectives and viewpoints, and relies on the paradigm that problems should be addressed through a holistic approach, considering all variables that may influence it [89]. When applied in firms, corporate foresight allows the development of insights regarding organization's strategic activities and supports decision-making process [90]. According to Vecchiato [92], strategic foresight should be "understood as the processes that assist decision-makers in charting the firms' future course of action".

This methodology involves an initial phase to observe, perceive, identify emergent trends, capture factors likely to foster changes and considers the implications of present actions on future events, and then, a second stage to deal with these changes, by defining organizational responses to overcome plausible future occurrences previously identified in the process [90].

Scenario planning and horizon scanning are two strategic foresight techniques [88]. Both look for driving forces (trends and critical uncertainties) in the external environment, with impact on the central issue and explore possible evolutions of them [88]. Driving forces, or simply drivers, are defined by Wepner et al. [93] as "developments causing change, affecting or shaping the future", afterwards resulting in one or more effects. Then, in both techniques the impact of possible external factors on the central issue is analyzed based on perceptions and judgements [88].

In horizon scanning, current developments and their implications are interpreted by perceptions, while in scenario planning, a collective thinking on the relationships between the identified driving forces to come up with a smaller group of relatively independent clusters preserving time precedence and causal influence or impact is typically developed [10][88]. An important difference between both techniques is that scenario planning considers that the way the identified driving forces interact is not necessarily based on evidence of current developments, admitting the possibility of interconnections that have not yet been revealed and possible causes that have not yet been disclosed [88]. Contrarily, horizon scanning considers only the interactions that currently leave some evidence in the form of weak signals and combinations of causes that have been already perceived [88]. Therefore, in scenario planning, based on the constructed scenarios, one may develop a set of robust strategies that performs well in this set of scenarios, whereas in horizon scanning, planners typically share with the organization management the most relevant findings, which can be further used in other strategic foresight approaches, such as scenario planning [88].

3.3.1 Scenario Planning

Scenarios can be defined as "… plausible and often simplified descriptions of how the future may develop based on a coherent and internally consistent set of assumptions about key driving forces and relationships", as cited in [94]. By considering present evidence, scenario planning explores how the future may unfold and the plausible transformations it may suffer leading to a future that may be substantially different from the present [88]. As an anticipation technique, it equips organizations with the tools to perceive what is going on in their uncertain business environments, understand how the future may evolve and its consequences for the company, thus allowing them to adapt to the possible future changes and act accordingly to the acquired know-how [95][91]. It consists in a well-established

planning methodology [90], with the aim of preparing an organization for changes, stimulating the anticipation of alternative future environments, combining their implications, and defining and testing logics of strategic decisions [88]. Thus, this methodology enables to address and cope with the uncertainty present in real cases decision-making, by perceiving how a given system may react in the face of plausible future occurrences [96]. In fact, scenario planning is adequate and strongly recommended in organizations that are characterized by high complex and uncertain environments, and in high volatility contexts [97]. As suggested by Figure 3.4, while forecast provides a view of the future, as being a linear projection of the past, multiple scenarios provide a broader perspective of possible changes and developments, considering the indeterminate and emergent nature of the future [98][99].

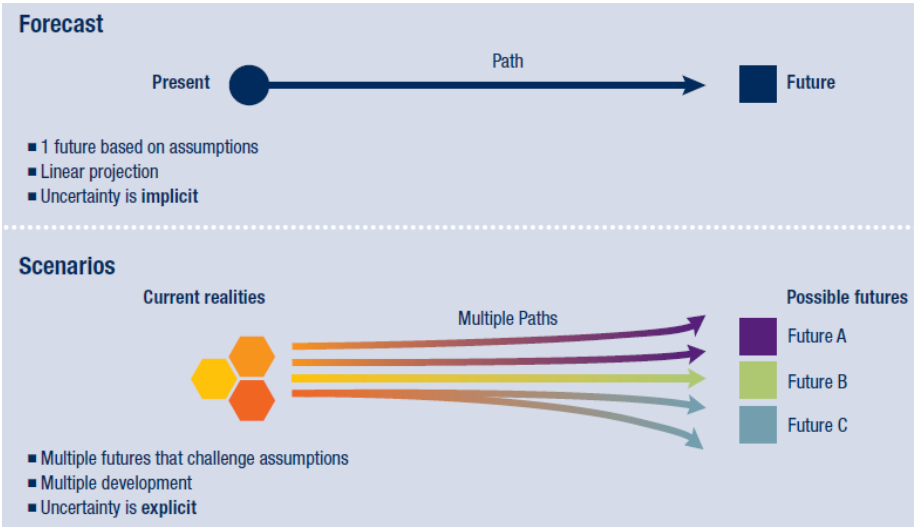


Figure 3.4. Comparison between forecast and scenario planning [100].

According to academics and practitioners, scenario planning process develops cognitive, communicative and cultural skills, as it makes use of participatory methods, allowing a share of perspective and the development of a common vision of the present and the future, stimulating organizational changes [98][101][102]. By promoting strategic thinking between stakeholders, scenario planning leverages a discussion about the system and interactions within it [103], develops a collective thinking towards complex questions [98][104] and forces one to rethink strategies and plans [99][105]. Heijden et al. [91] claims that organizations investing and exploring this technique will ensure its position in the market towards success, as it provides a structured and systematic way to cope with the inherent uncertainty that may impact decisions [106]. As an example, by making use of scenario planning, Shell managed to adapt to expensive oil much faster than their competitors [107][108]. Moreover, in the 1980s, large corporations adopted this methodology, more specifically, in 1981, 75% of the Fortune 100 companies claiming the use of scenario planning in their business. By considering different possible situations, scenario planning enables the conception of a more reliable model of the business process, thus supporting decision-making [106][107].

3.3.1.1 Schools of scenario development

There are three major schools of scenario development: the intuitive logics, the probabilistic modified

trends and *La prospective* [109][110]. The intuitive logics, also described as the Royal Dutch Shell/Global Business Network matrix approach, is recognized by Millet as the “gold standard of corporate scenario generation”, as cited in [110]. The probabilistic modified trends includes two distinct techniques that are applied in very different contexts: the trend impact analysis and the cross-impact analysis [110]. Contrarily to intuitive logics, the other schools of techniques involve quantitative methods, meaning that they make use of computational and statistical tools, while intuitive logics is solely based on qualitative inputs and approaches [111].

From the different schools in the scenario planning literature, intuitive logics is the most popular one, as it accounts for the complexity amongst factors of different nature that influence the business decisions [111]. Furthermore, due to its flexibility, it can be applied in a wide range of contexts. Scenarios are developed around the issue of concern and expands to the external environment. This is a plausibility-based approach and result of the exercise is a set of equally probable and plausible scenarios. The most common instance of this approach is the deductive-style 2x2 matrix approach [109]. The scenarios are mutually exclusive and result from the combination of the two extreme evolutions for each one of the two drivers, so usually this school of techniques results in four divergent scenarios, aiming to explore the limits of possibility. Although this method is widely used, it only allows two drivers and their extreme states to be explored, which may unnecessary polarize the thinking, and consequently reduce the space of possible uncertainties that are exploited, from all possibilities [112]. This drawback was a motivation to develop extensions from the standard intuitive logic approach, such as the morphological analysis that allows the exploitation of a greater number of uncertainties [110].

The trend impact analysis makes use of historical data, usually combining time series analysis, a forecasting technique, with qualitative inputs. On the other hand, cross impact analysis is based on the paradigm that the forecasting exercise should consider not a single event in isolation, but instead, it should account for the occurrence of other impacting factors, and in this way, the interrelationship between key influencing events is captured through this scenario planning approach [111]. Both techniques have emerged as probabilistic forecasting tools, and evolved to scenario techniques after combining qualitative judgements with extrapolation performed on historical data [109].

La prospective schools defend that the future is not something predetermined, and it can be created and modeled [109]. It intends to explore and demystify the contemporary world, generating scenarios and idealizing future images in such a way that scenarios can guide the organization towards a future objective, providing a basis for future action [111]. This technique is more indicated for the public sector planning than to the organizational level planning and makes use of sophisticated computer tools [111].

The literature presents several scenario development approaches, sharing many characteristics. Bishop et al. in their overview on scenario development techniques covered a dozen of them and argued that foresight literature lacks scientific structure, as the scenario development studies do not specify the school on which they were based [110]. Nevertheless, some authors such as Schoemaker, Goodwin and Schwartz are quite popular in the scenario planning literature and commonly cited, as they present the steps of the scenario development in a comprehensive and detailed manner [10][111][106]. In general, scenario planning techniques applied by these authors have in common various steps of the

scenario development process: the definition of the issue of concern, the identification of the system drivers, both predetermined trends and uncertainties, their degree of impact in the issue of concern, the stakeholders that should be engaged in the scenario development process, the formulation of the scenarios based on the system drivers identified and their possible evolutions, and finally, appraise the possible implications of the scenarios and define managerial actions to act accordingly [95][111]. The main general steps typically included in the scenario planning process are presented in Figure 3.5.

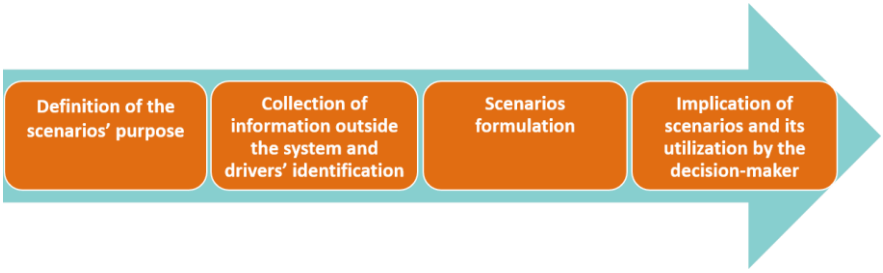


Figure 3.5. General steps involved in scenario planning [102][113].

The discussion between stakeholders around the issue of concern to identify system drivers may be facilitated by tools of external analysis of the system under study. One useful tool for driving forces identification is PESTLE framework [114]. It covers six domains: political, economic, sociodemographic, technological, legal and environmental [115] and allows participants to organize ideas, and promotes a structured framework of thinking on possible external factors driving change and creating uncertainty. Fields covered in this analysis act as a guide to ensure every relevant factor is being considered, and not as discrete and exclusive points [91]. This generates a set of diverging opinions, resulting in a shared understanding within the group of causally determined futures that may motivate managerial actions [10][116].

3.3.2 Horizon Scanning

Horizon scanning seeks to explore, monitor and assess continuously and objectively weak signals of change and their potential future implications [88]. Although there is no consensus in defining this foresight technique, it can be seen as the systematic and comprehensive exploitation of risk, uncertainty and emerging trends to rethink perceptions and identify assumptions concerning the future [117]. This technique enables the identification of subtle environmental changes that may evolve to driving forces and, allowing an informed and effective response in the face of changes. Practitioners claim the value of this technique lies in enhancing planners' cognitive capabilities, as it requires long-term thinking and future developments exploration. Horizon scanning process involves web-based and literature research, although it also might appeal to the participatory activities with stakeholders [88][113]. It is usually complemented by other foresight techniques [88].

3.4 Review of studies conducted within clinical lab settings

Since the current study focuses on process improvement in clinical lab settings under a highly uncertain context, a literature review was carried out on this topic and the research was mainly performed in the

databases indicated at the beginning of the chapter, and also, directly on the web, as the scientific databases found little information on this topic. This literature review revealed a lack of studies addressing strategic process improvement and foresight studies in clinical lab field, however, several studies addressing operational process improvement through DES in this field were found, and they are presented in this section.

In 1993, Godolphin et al. [118] concluded that DES allows the implementation of operational changes in the current system, working well in complex systems, like clinical labs. The authors argued that data collection regarding arrival times, service times and information regarding queues formed during the process, and the fit of the collected data to distribution functions are essential to calibrate the simulation model, thereby enabling the implementation of a useful and effective simulation model.

In 1994, Van Merode et al. [119][120] provided a decision-support methodology to inform managerial actions in a clinical lab. The authors conclude the set of KPIs should be defined based on what managers consider more relevant, and it revealed TAT as important to be considered. The study also concluded that the sustainable growth and improvement of an organization strongly depends on research and development, staff education, and additional investments. Once the KPIs have been identified, the analysis of the current workflow was performed on this basis. A brainstorming involving key stakeholders revealed opportunities for improvement, and alternatives to the current workflow were proposed.

In 2009, Lote et al. [121] studied the operations of a medical lab to improve resources allocation. The main objective was to flatten the workload, avoiding the occurrence of workload peaks, as well as leveling the utilization of resources, by smoothing the workload along the time. The objective of flatten the workload was achieved via the routes optimization, allowing to level the utilization of resources.

In 2014, Hu [122] highlighted the complexity caused by the volume and variety of sample types that daily arrive at clinical labs and argued that the complexity of the systems makes it difficult to translate the key functions of a clinical lab via simulation. This study provided insights on the development of object models of clinical labs in simulation. The author identified the lack of confidence of some conservative experts in this domain in believing the simulation can accurately represent reality, as the main limitation of the study and warns for the required trade-off between detail and model performance.

The study conducted by Alkher et al. [123] in 2019, in a clinical biochemistry department, used VSM tool to map the process and identify all steps not providing a continuous workflow and their causes. DES provided a visual perception of the system evolution and a detailed analysis of the model outputs, which supported management decision-making. This study resulted in a reduction of waiting time for samples and suggested additional changes to improve lab efficiency [123]. The removal of unnecessary movement of samples and employees was identified as a benefit of this combination.

In 2019, Kadi et al. [9] modeled a university hospital lab with the aim of analyzing processes and identifying bottlenecks in the current operations. The current and the proposed systems where modeled and statistically compared. The study included scenario analysis allowed the assessment of improvement opportunities based on the identified bottlenecks, namely, it revealed the possibility of throughput time reduction, explored the utilization of resources and identified the limiting one.

3.5 Combining DES with Scenario Planning

The current study aims to explore process improvement from a more strategic perspective, accounting for the uncertainty present in the current times of disruption and volatility. Then, based on the previous analysis of strategic foresight techniques, one chooses scenario planning to support DES in dealing with uncertainty.

The studies presented in the previous section, conducted within clinical lab settings, approached the improvement process in an exclusively operational way, revealing that the literature lacks studies on strategic process improvement and foresight techniques in this field. A more comprehensive literature review was performed on the combination of DES and foresight to improve processes from a more strategic perspective, accounting for the uncertainty of the current times, without confining it to the clinical lab settings. The main databases consulted were the ones indicated at the beginning of the chapter, and this search also revealed a lack of studies in this field. Studies combining DES with scenario analysis in the healthcare settings are commonly reported in the literature. However, the scenario approach described in these studies does not rely on the principles of foresight literature, in which the scenario development process consists on a well-structured and extremely rich approach, which results in a coherent combination of the possible evolutions of relevant external factors, with meaning to the decision-maker. Instead, scenario analysis commonly considered in the literature consists on performing what-if analysis, based on simply adaptations of the simulation model input parameters, to assess the impact of several parameters' configuration, and choose the one that reveals gains in efficiency, or to analyze the magnitude of change caused by different scenarios, in an exclusively operational perspective [124][125][126]. Thus, the objectives of both approaches are different, and the literature lacks studies that address the issue of process improvement from a more strategic perspective.

Therefore, research on strategic process improvement is required to account for the uncertainty of the current times that may impacts the systems' response, which is the aim of this study. Evaluating improvement opportunities considering not only an operational perspective, but also considering strategic aspects and, therefore, accounting for uncertainty, makes the decision-making more consistent, robust, and informed for plausible future occurrences. Furthermore, the need for socio-technical approaches is evident, since for the development of the scenario planning exercise and a simulation model, social processes are strongly recommended. Regarding scenario planning, knowledge of the organization and its environment is necessary in order to ensure that scenarios cover its concerns and that the various sources of external uncertainty are explored. With regard to simulation, the model should be developed closely with people who are intimately familiar with the system under study, although they are not knowledgeable about simulation, and the interaction on a regular basis with the decision-maker is important since it allows to maintain the interest and involvement in the study, ensures the decision-maker knows the assumptions considered and agrees with them, and his/her knowledge of the real system contributes to the validation of the model.

Chapter 4

Methodological Framework

Based on the literature review developed, one could conclude that the integration of DES and scenario planning may be an appropriate and effective approach to support the decision-making process in a highly complex and uncertain environment, since the uncertainty can be addressed by exploring a set of plausible scenarios. In the disruptive times such as those currently living, scenario planning, by allowing the exploitation of plausible future occurrences, provides organizations with the tools for successful decision-making in the face of high uncertainty [86][127]. On the other hand, DES is a powerful tool to describe real problems in different fields [61] and, in particular, in the clinical lab settings [123], as it provides a visual perspective of the evolution of a dynamic system over time [59] and allows the analysis, through a comprehensive set of KPIs, of the impact of the scenarios developed on the simulation model [63]. In this way, the proposed techniques seem to complement each other and, in an integrated way, respond well to the objectives of the present study.

Therefore, this thesis proposes a socio-technical approach [128] that, in an innovative way, combines DES and scenario planning, as technical and social components are used for modelling in an intertwined format. As it was seen in the previous chapter, the development of both the scenario planning exercise and the simulation model depends heavily on the social component and the contact that is maintained with the end-users. The knowledge and insights provided by lab professionals, covering a broad range of perspectives and viewpoints that derives from their different backgrounds and strong experience in the sector, are extremely important to the scenario planning process and their involvement in the simulation model development allows to come up with a credible and reliable model. In this way, social processes are defined by implemented key technical tasks in the development of the study. At different stages of this methodological approach, some lab professionals actively participate in the project. Accordingly, the methods proposed by this methodological framework are overall combined within a multi-methodology [129] and the different steps are defined and developed based on the complete set of steps to develop a DES model proposed by Law [59][81] and the ones discussed by Banks et al. [78] and in terms of scenario planning, this process is developed mainly based on Goodwin et al. [10] and Schoemaker [106].

To conclude, this framework aims to inform lab management on how plausible future scenarios may impact the lab tests production in the core lab and support the decision-making process in the light of these scenarios, with a focus on improving efficiency in the core lab.

Then, next page presents the proposed methodological framework and the following sections provide an explanation of each phase that make up this framework, as well as a detailed description of the steps that compose the technical and social components.

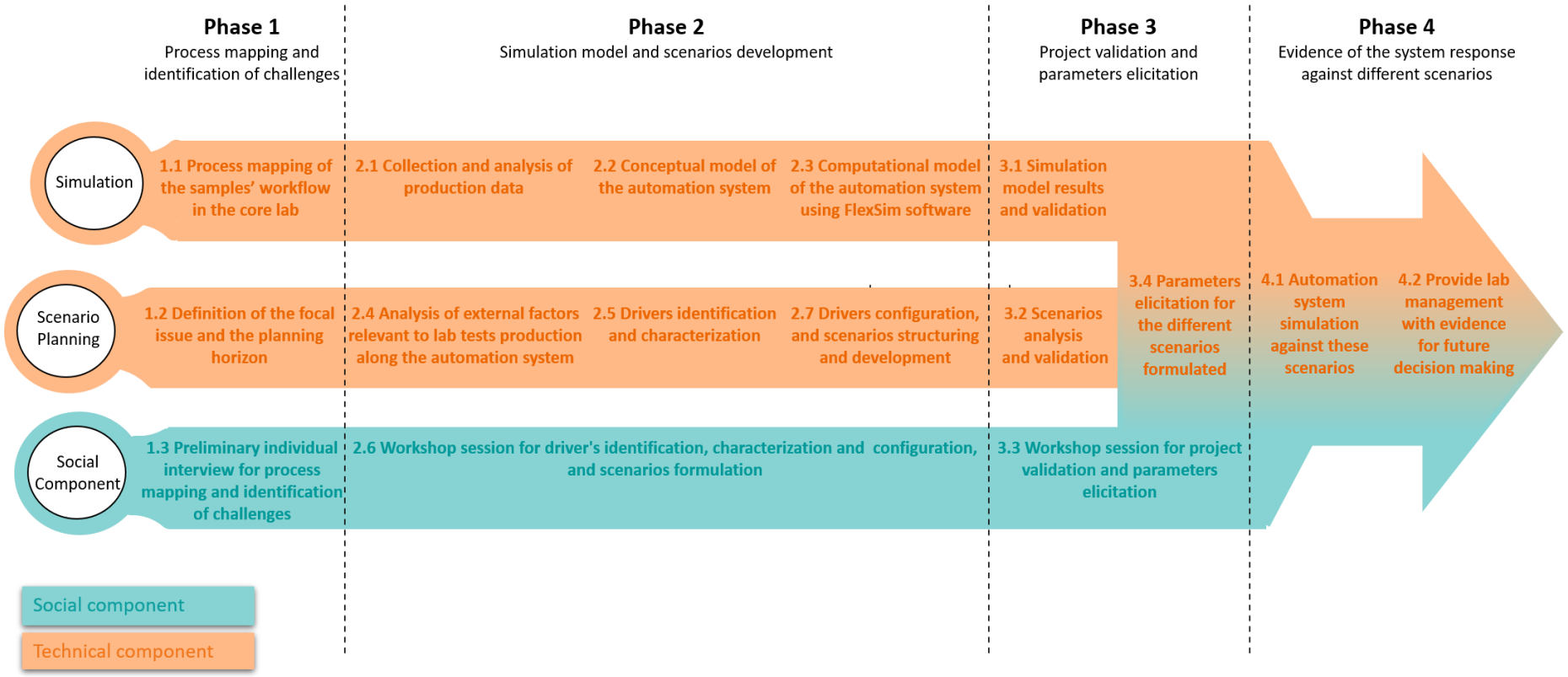


Figure 4.1. Proposed methodological framework within a socio-technical structure. A detailed description of the steps that constitute this methodological framework is provided in the following sub-sections.

To meet the objectives of this thesis that have been identified in section 2.6, the proposed methodological framework illustrated in Figure 4.1 includes a set of steps that combines the technical and the social components. It can be divided in four different phases, all of them with the contribution of both components, and this set of sequential steps culminates in the fusion of both techniques, DES and scenario planning, in phase 4.

Phase 1 intends to map the samples' workflow in the lab in order to support the development of the simulation model, which takes place in phase 2, identify the challenges faced by the core lab of this clinical pathology lab, and define the focal issue that will guide the scenario planning process, as well as the planning horizon.

Then, phase 2 comprises the development of the simulation model, which includes data collection and analysis, the development of the conceptual model and, finally, the computational implementation of the simulation model in the software. Regarding scenario planning, this phase is developed in the context of a workshop session and includes the exploitation and analysis of external factors with possible impact in the focal issue, the characterization and configuration of the system driving forces and the structuring and development of plausible future scenarios.

Afterwards, phase 3 comprehends the validation of the simulation model, the analysis of the scenario narratives and their validation, and the elicitation of a set of parameters to run the simulation model for the scenarios that have been developed, also in the context of a workshop session.

Finally, in phase 4, the simulation model is run for the different scenarios, the impact of the scenarios in the simulation model is assessed through a set of KPIs, and presented to the lab decision-maker, and the managerial changes for the lab are analyzed in light of these results, to ensure their adaptation and preparation to the possible realization of those scenarios.

4.1 Phase 1: Process mapping and identification of challenges

Phase 1 of the proposed methodological framework has the purpose of identifying the major challenges faced by this lab, define the central issue in which the scenario planning process will focus on, and describe the overall process along the system under study to support the process mapping. During this phase visits to the lab take place and an individual interview is conducted with the aim of supporting the technical component of the study.

4.1.1 Simulation

In step 1.1 of Figure 4.1, the processes that occur across the automation system are mapped based on the information collected from the preliminary interview and on-site visits. The observation of the actual system is the first step for the simulation model building and it is mandatory to have a visual understanding of the process flow, to understand how the overall system behaves and how its components interact [78].

Considering the results of the literature review presented in the previous chapter in terms of process

mapping tools, flowchart is selected to map the processes [73]. In fact, by splitting complex processes into its individual activities and allocating resources to each one, one is able to focus on those individual activities at a time, and then, in the way they relate to each other, which facilitate its implementation in the simulation software [75]. This is very useful as an initial step and a guide for the simulation model construction [9][120]. Mapping the flow of the test tube along the system permits collecting the information regarding the main steps involved in the lab tests production, describe the overall pathway of the test tubes in the system and understand which resources are required in each step of the process. This flowchart is then validated by the same lab professional who has been present in the interview, so that it can be used to support the construction of the simulation model.

4.1.2 Scenario Planning

The initial step of the scenario planning technique consists in the identification of the focal issue or central question that guides the process of scenario development and the definition of the planning horizon and takes place in the step 1.2 of the proposed methodological framework, represented in Figure 4.1. The focal issue derives directly from the strategic challenges identified in the preliminary interview that takes place in this phase, and the planning horizon is defined based on what lab professionals consider to be an appropriate time horizon to be explored in the scenario planning exercise bearing in mind the present context of disruption and rapid changing environment that create uncertainty.

4.1.3 Social component

According to what was previously mentioned, as a socio-technical approach, the technical steps are underpinned by the social component. The inputs of lab professionals support the development and implementation of both techniques, and the proposed methodological framework seeks to meet their needs and to respond to the challenges identified in the system under study. Additionally, the insights and know-how of other people intimately familiar with the process under study, namely the SH providers that support the operations in the lab and provide maintenance to the lab equipment is also very important to the simulation model construction, as they have a more operational view of the process.

The preliminary individual interview proposed in step 1.3 of Figure 4.1 should be attended by a lab professional and aims at identifying the main challenges faced by the core lab, in order to define the focal issue and the planning horizon of the scenario planning process [10][111]. Moreover, this interview should provide an explanation of the lab organization, the main types of test tubes processed in this lab, the types of samples whose lab tests are performed in the core lab, through the automation system, and a detailed description of the processes to which samples undergo in this system, to complement the on-site visits and support the mapping of the processes through a flowchart. Therefore, the preliminary interview should allow an initial domain analysis to be performed to understand the system behavior, to become familiar with some domain-specific concepts and to identify the important components that integrate the system under study [65].

4.2 Phase 2: Simulation model and scenarios development

This lab receives a large volume of specimens daily that arrive from multiple routes, coming from several collection centers distributed throughout the country. Although the vast network of clinical labs of this clinical pathology provider covers the entire country, not all of them are of the same size and complexity, and it is in this lab that the most specific tests are performed. Thus, this lab handles a high volume of samples and a wide variety of tests. Additionally, the arrival of samples in the lab follows a pattern that is not uniform throughout the day, which is a major challenge for the operations in the lab. On top of managing the workload peaks along the day, this lab seeks further opportunities for improving its efficiency. One of the targets is to decrease the TAT, as lab testing plays a key role in clinical decisions, impacting about 70% of these decisions. As previously mentioned, the focus of the current study is on the core lab of this clinical pathology lab. The core lab receives and processes around 70-80% of the whole lab workload.

In spite of resembling a traditional production system, the operations in the lab also involve the complexity of the healthcare settings that makes it difficult to translate some essential functions through a simulation model [122]. This complexity arises from the manifold relationships between system elements, such as the test tubes, the tests, and the equipment to process these tests [130].

In phase 2 of the proposed methodological framework, a set of steps of both techniques, simulation, and scenario planning, should be developed in parallel and the latter in the context of a workshop session involving a group of lab professionals.

4.2.1 Simulation

According to the literature review carried out in the previous chapter, once the problem has been identified and the set of processes throughout the system has been mapped, the next step in developing the simulation model is the collection and analysis of production data, described in the step 2.1 of Figure 4.1. A complementary tool is utilized to perform all calculations and analysis on the provided records. Initially, organize the data provided according to the needs is required to extract all relevant information for the simulation model construction [59][78]. The reliability of the analysis performed depends on whether the historical records provided are meaningful and enough to accurately replicate the processes [59]. During data analysis, due to some inconsistencies on the real data provided, assumptions must be performed and documented, explaining what assumptions were considered and why [59], and they should be revised before model implementation.

Then, in step 2.2, based on the developed flowchart of the samples' workflow and on the data analysis from the previous step, system input variables are analyzed and defined. The analysis of the calculations performed in step 2.1 provides insights on possible ways of parametrizing process activities in the simulation software. Afterwards, model parameters and probability distributions that characterize the system variables can be defined [56][59]. When verifying that relevant information for defining an activity is missing, inputs may be elicited from personal working in the lab, bearing in mind that, in doing so, a number of biases is present, and for this reason, additional questions should be asked to confront

elicited values with empirical data [66]. Furthermore, it is also important to collect information from different sources, by asking different people intimatelly familiar with the system under study, and compare the results [66].

In this stage, a conceptual model is developed and used to support the following steps of the proposed methodological framework. The conceptual model should assemble the following information: the process-flow of the system, which in this case was constructed in the form of a flowchart; a detailed description of the system; the assumptions considered; a summary of the model input variables; the performance measures considered for evaluation [59]. Its development takes place in step 2.3 of the proposed methodological framework. The conceptual model should be continuously validated, at the time of its development, by lab professionals and SH providers, who are intimately familiar with the system, and once concluded and validated, it is used as a backbone to support the implementation of the computational model in the simulation software.

Regarding the performance measures, when structuring the model, it is important to define its outputs. The model outputs are defined in terms of KPIs that allow to quantify improvements in the performance of the model, as they are measurable and improvable [37][131]. Thus, KPIs are important sources of information, as they allow to monitor the performance of the system, which is essential to understand the current process, measure at what extent improvements are being achieved, control and monitor the efficiency of the process, quantify the impact of changes applied in the system, and measure the effectiveness of management decisions, ensuring the competitiveness and success of the organization along the time [37][132]. Thus, their choice is of great importance and should be discussed with the decision-maker, since the decisions will be made based on the performance measures used to validate the model [59].

Before the implementation of the model in the simulation software, it is necessary to understand important concepts underlying the principles of DES, as the meaning of *entities*, *attributes*, *events*, *resources,* and *queues*, and to become familiar with the software. *Entities* are the flow items or objects that move within the system, to which a set of attributes is assigned, and that experience events, enter queues and consume resources along the time of the simulation run [59][66]. The *attributes* are labels that store and carry information on a specific entity along the simulation model run, and at any time of the simulation, their values can be modified. All that can happen to an entity or the environment is generally defined as *events*. Entities can be processed by *resources*, i.e., *resources* are the objects that provide services to the entities. The resources may be idle, or processing (“occupied”). When an entity needs a resource that is processing another one, that entity must wait, and a *queue* is formed [66].

At this stage, system modeling in the simulation software begins. Based on the analysis of the production data and on the conceptual model, system variables such as the demand, the number of available resources, the number of human resources allocated to each activity, lab equipment capacities and throughput, the different types of samples and the set of lab tests required to each test tube, among others are configured. The computational model then processes all these input variables and provides a set of outputs.

Regarding the software, available literature reports a diversity of commercial simulation software

packages [133]. For the purpose of this thesis, FlexSim [134] is chosen to model the system under study due to its versatility for replicating different environments, as well as its graphical capabilities. Moreover, this software provides an animation of the simulation model functioning, which enables the visualization of the evolution of this representation of the actual system along the time, which in turn facilitates the communication with the end-users. Furthermore, according to a ranking performed by Decreye Solutions [133], FlexSim was considered the best DES software in 2018 and 2019, being in 2019 the winner in all assessed categories. Therefore, since this software responds well to the needs of simulating a system that resembles both the manufacturing and the healthcare environments, this is considered the most suitable tool to use in this study.

4.2.2 Scenario Planning

Concomitantly to these steps of simulation, a set of steps of scenario planning takes place in this phase. The set of processes that comprehends the scenario planning exercise are developed according to the guidelines proposed by Goodwin et al. [10] and Schoemaker [106]. The workshop agenda includes the analysis of external factors relevant to the central question, using PESTLE technique. According to the literature review in the previous chapter, this approach is considered a comprehensive and systematic way of system driving forces identification, by providing a basis to formulate questions and to guide the discussion among participants towards system drivers' obtention, in step 2.5 [91][115][135].

In this analysis, participants are encouraged to strategically think and debate factors outside the organization, in the different domains covered by the PESTLE framework, that may impact the central question. To facilitate the engagement of the participants in the process, post-its technique is proposed, and a different color is assigned to each domain of the PESTLE framework. Each participant is invited to write possible factors that may impact the central question in different post-its and then, share and discuss them among all participants. For each factor identified, the facilitator asks what the possible evolutions for that factor are and what consequences it may have on the central question. This information provides a basis for the drivers' configuration.

The discussion triggered by the PESTLE framework, carried out in step 2.4, leads to the identification of the drivers, i.e., the key external factors that may impact the central question and the driving forces that shape the system. These factors may be either predetermined factors or uncertain factors. The uncertainty can be defined as a relative measure of the probability of occurrence of the driving force throughout the time horizon [10][95]. The predetermined factors are expected to vary in a predictable way while the uncertain factors are characterized by the lack of clarity as to the direction in which they will evolve in the future, or at least the timing in which they will occur is not known nor predictable [136][137]. To distinguish between them, system drivers are placed into the scenario structuring space (SSS), represented in Figure 4.2.

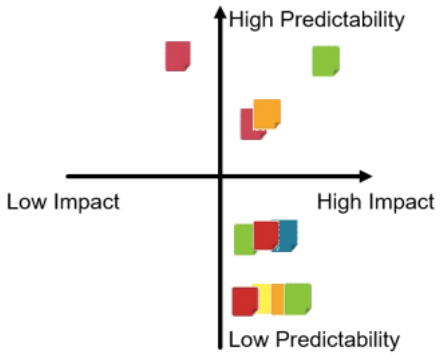


Figure 4.2. Scenario structuring space used to characterize the external factors identified by the different post-its according to their predictability and impact in the central question.

By placing the drivers in the SSS, participants are able to characterize each one of these factors according to its predictability and impact in the central question [10][106].

Critical uncertainties are the most uncertain driving forces, or less predictable events, that have a great impact in the central question, and they are the elements that establish the difference between scenarios. For these drivers, the facilitator should ask [137]:

i. 'Which are the most uncertain driving forces?'
ii. 'What is the uncertainty associated to these drivers, i.e., to what extent these factors may impact the central question?'

These questions do not focus on predetermined trends because these ones are the most predictable factors with great impact in the system, remaining unchangeable in all scenarios. Thus, they are not a distinguishing feature of scenarios [137].

The questions previously presented lead the discussion among the participants and the answers should be agreed by all of them. Then, after reaching a consensus, they should place the post-its in the SSS, in order to characterize the system drivers according to their predictability and impact. Once key-factors have been placed in the SSS, the aim is to try to group them into clusters of interrelated events [10], which are not related with the elements of the other clusters. For this purpose, participants should seek to establish causal and chronological relationships between these different elements of a single cluster [10]. After grouping factors in these sets of related events (clusters), if many clusters still exist, participants are encouraged to identify the 2 or 3 clusters having the greatest impact in the central question. These are the most important factors that should be considered [10]. Finally, participants should identify the possible polar outcomes for each one of these drivers, i.e., the range of possible outcomes or evolutions for each driver by two extremes [10][106].

Having the system drivers and their possible configurations, participants are encouraged to start structuring the scenarios based on the possible configurations for each driver, represented in step 2.6 of Figure 4.1. The resulting scenario structures constitute scenario skeletons, being the starting point to the formulation of scenarios. A catchy name is then assigned to each scenario structure [10][106].

To develop scenarios skeletons, one should try to combine the extremes of the driving forces, assess

these results for plausibility and internal consistency, verify whether inconsistencies can occur and disregard the combinations that are not credible [10][106]. Then, one may start to develop a scenario storyline. To have a visual understanding of the process, all scenario elements can be place along a timeline, which begins in that day and spans along the planning horizon, and causal relationships between these elements are sought, as time precedence is typically a good indicator for potential causality [10].

4.2.3 Social Component

The workshop session taking place in this phase aims at supporting the set of steps of the scenario planning exercise previously describes: identify a set of driving forces that may impact the central question, and to develop a set of plausible scenarios based on these drivers. By bringing together a group of relevant actors from the lab, this workshop promotes the sharing of perspectives and viewpoints among experts in the field of clinical pathology and triggers a discussion regarding future trends and uncertainties that may impact the central question.

To have a representative vision of the values, aims and concerns of the organization, one should guarantee a reasonable number of participants, including elements of the board of directors, managers and the decision-maker, and lab technicians, having different backgrounds, experiences and perspectives, to promote a wide share of knowledge, ideas and viewpoints. The creativity is an important factor that should be stimulated during the session. However, bringing together a group of professionals to participate in the workshop session is a challenging task due to their daily commitments and working requirements. Then, given the conditions imposed by the availability of the lab professionals, one may engage the maximum possible number of participants to ensure a diverse share of ideas and viewpoints and reduce the representativeness biases.

The workshop session is directed by a facilitator, and its environment should be accounted for, since it may influence the effectiveness of the group work. A room configuration in U format is recommended to conduct the session, allowing participants to keep eye-to-eye contact among each other and to have visual access to the screens and whiteboards that present useful information for the development of the session [138][139]. The facilitator is responsible for moderating and conducting the session, thus ensuring the relevant topics are discussed. Furthermore he/she must remain neutral and impartial on the issues being discussed in the session, without providing his/her contribute with ideas, but instead, drive the session. The facilitator should direct the group along the discussion and the defined agenda, solve possible conflicts and stimulate the sharing of ideas and perspectives [139]. This workshop session is expected to last around 3h, with a break between steps 2.3 and 2.4.

4.3 Phase 3: Project validation and parameters elicitation

This phase of the proposed methodological framework has a triple objective which include the validation of the simulation model, the analysis and validation of the scenarios developed, and the elicitation of a set of parameters to run the model for the different scenarios. To carry out all these tasks, a second

workshop session is proposed, as illustrated in step 3.1 of the proposed methodological framework, in Figure 4.1.

4.3.1 Simulation

A simulation model of a complex system, as it is the case of the present one, is just an approximation, a simplification and an abstraction of the actual system [59][130], and Law et al. [59] defend that the absolute validity does not exist. There is a cost-effectiveness trade-off in model validation, as the more time is spent developing the model, the more valid it tends to be. However, increasing model validity above a certain threshold may require a lot of effort collecting and analyzing real data records that might not be reflected in better conclusions to be extracted from the model, and, ultimately, in better decisions being made based on it [59].

As it was previously mentioned, the participation of the end-users in the simulation model conceptualization and implementation is essential to ensure its success, and helps to guarantee model validation and credibility [59][78]. In this way, the verification and validation processes should also be performed in close collaboration with people who are intimately familiar with the actual system under study, by checking the model functioning and providing judgements regarding the simulation model itself and the results extracted from it [78].

The verification and the validation of the simulation model are essential steps to ensure that the model is a correct, complete and thus, a meaningful representation of the real-world system under study, proving its utility the in real-world problem-solving [59][78]. There are several techniques to perform model verification and validation described in the literature [56][59][78]. The objective of the model verification is to guarantee that the conceptual model was correctly translated into the computational model [78]. The verification of the simulation model is performed by debugging the computational model in order to identify and remove possible errors, through the comparison of the simulation outputs with analytical solutions from the actual system [62]. The literature suggests a set of techniques to perform model verification, which include developing the computational model in an iterative way, starting with a simple model, and progressively increasing its complexity, verifying that the model is visually a close approximation of the actual system, through the animation provided by the simulation software, and ensuring the simulation model is checked by a person knowledgeable about the actual system that is being modelled [59][78].

Regarding validation, it is defined by Law et al. [59] as “the process of determining whether a simulation model is an accurate representation of the system, for the particular objectives of the study”. There are some techniques for model validation described in the literature, including statistical procedures (confidence intervals and hypothesis tests), graphical representation of histograms, distribution functions, among others [56][59]. Law argues that an important consideration when applying hypothesis tests is that the null hypothesis that the simulation model and the real-world system are the same is false, since the model is just an abstraction and an approximation of the actual system [59]. Therefore, a more useful way of validating the model, according to the same author [59], is to verify whether the differences between the model and the real-world system are significant enough to trigger the extraction

of wrong conclusions from the model. This analysis should also be performed based on the feedback of lab professionals when checking the model, as the performance of the model with respect to the considered objectives should be assessed on the basis of the confidence that lab professionals place on it [56][59].

There is still another different concept, which is model credibility. One may say the model results are credible if they are accepted as correct by the decision-maker and by the people knowledgeable about the actual system, the lab technicians and the SH providers that support the operations in the lab (subject-matter experts) [59].

Based on the aforementioned, model verification and validation should include different methods: the validation carried out throughout the development of the simulation model, starting with the validation of the conceptual model, then, the verification that the conceptual model was correctly translated into the computational model, and the validation of the computational model itself, which includes “face validity” and the comparison of the simulation outputs with quantitative real data [78]. “Face validity” is performed by showing the animation of the simulation model to people knowledgeable about the actual system and by asking them about the accuracy of the logic behind the model and whether it is able to truly mimic the actual system [78]. Therefore, a part of model validation should be carried out during the workshop session (in step 3.3 of Figure 4.1), where the presence of the lab decision-maker is fundamental to ensure that she/he places confidence on the model developed and considers the model as a valid representation of the real-world system.

4.3.2 Scenario Planning

At this point, as a result of the first workshop session, one should already have both the scenario structures and a proposal of the scenario narratives to be carefully analyzed and validated. Then, the step 3.2 of the proposed methodological framework illustrated in Figure 4.1 intends to analyze and validate the results of the previous workshop session, more specifically, the scenarios developed. This scenario planning activity takes place in the workshop session represented in step 3.3 of Figure 4.1. To refresh participants memory regarding the scenarios developed in the previous session, they are presented to be carefully analyzed and validated, if participants consider that they are able to reflect their concerns and cover a wide range of plausible future occurrences.

4.3.3 Social Component

In this workshop session, the lab members who participated in the first workshop session should be present. This session is expected to last around 2h, where 30 min are assigned to the validation of the simulation model, plus 30 min for scenario analysis and validation, and 1h to elicit a set of parameters based on scenario analysis, to run the simulation model for the scenarios developed.

The agenda for the workshop includes the validation of the simulation model with the end users, which will be performed by running the model and demonstrating the simulation functioning, through the animation provided by the simulation software, and by presenting the results of the performed measures

extracted from the simulation model. To create engagement and capture participants' attention, the workshop session starts with a demonstration of the simulation model animation. The simulation model has been calibrated with the production data provided by the lab technicians, so that it is considered the reference model and, once validated, it can be used as a basis for comparison with the models that recapitulate the essence of the scenarios developed, whose impact will be explored through simulation. After presenting the simulation model running, the results of the performance measures are presented.

In what concerns the scenario planning technique, the objectives comprehend the analysis of both the scenarios developed in the previous workshop session, as well as the scenario narratives proposal, and their validation. Scenario narratives proposal should be carefully analyzed by the participants to ensure they are meaningful and reflect the concerns of the lab professionals regarding plausible future occurrences with impact in the focal issue. These activities are expected to last about 30 minutes.

The last activity to be performed within the context of the workshop session is the parameters elicitation and an hour is set aside for this purpose. This exercise bridges the scenarios developed and the simulation model, as it allows the combination of both techniques, so that one can anticipate and analyze the impact of the scenarios in the simulation model of the automation system, based on a set of KPIs.

4.3.4 Integration of scenario planning and simulation

In this step both components of the study, the technical and the social one, are combined to achieve the final objectives of this thesis.

As the proposed methodological framework relies on an innovative approach, literature lacks information and evidence to support this synergy. However, both techniques in isolation are widely used and well stablished. The combination of both techniques is performed by the elicitation of parameters for the different scenarios and is carried out in the context of the workshop session of the previous step (step 3.3). During the workshop session, based on the scenarios developed and their analysis, and after being validated by the participants, the extent in which the scenarios may be described in terms of parameters should be discussed by the lab professionals attending the workshop session, with the goal of eliciting parameters that are able to inform the simulation model and reflect the different scenarios. Therefore, participants are asked to provide quantitative inputs that describe the essence of the scenarios in terms of the simulation model parameters and they should discuss and reach a consensus on how these parameters may be changed in light of these plausible scenarios. Thus, scenarios are evaluated in concrete system parameters [137].

Predicting how parameters will change in light of the plausible future scenarios is not an easy task, however, it is expected that due to their know-how and experience in the field, lab professionals will be able to provide quantitative estimates of the adjustments needed to the simulation model inputs in order to reflect the scenarios formulated. For this exercise, a set of model input parameters is presented to the participants so that they can identify the ones that should be adjusted to run the simulation model for the different scenarios.

Figure 4.3. proposes a framework to integrate both techniques.

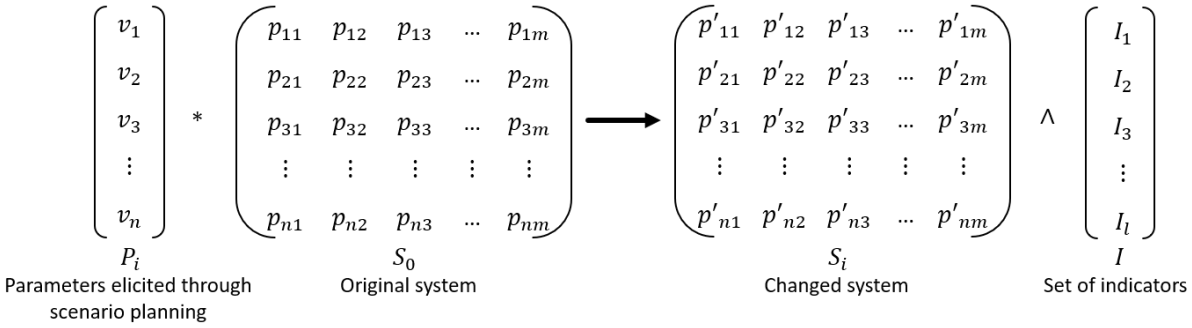


Figure 4.3. Schematic representation of the integration of Scenario Planning and Simulation.

Figure 4.3 suggests that, for each scenario formulated, a set of input parameters of the model (P_i) is elicited, then, these parameters act on the simulation model (S_0), and after running the model, its state changes from (S_0) to (S_i). From this changed state of the system, (S_i), a set of indicators (I) may be derived and analyzed, providing a visual representation and allowing to assess the impact of each scenario in the system. The process is then repeated for all scenarios considered [140].

4.4 Phase 4: Evidence of the system response against different scenarios

After the parameters to run the simulation model for different scenarios have been elicited by the lab professionals, the simulation model can be run for each scenario, in order to capture the impact of the changes caused by each one on the simulation model.

The performance of the simulation model is assessed in the step 4.1 of Figure 4.1, based on the set of KPIs previously defined and by comparing it with the reference model, calibrated with the real production data. Then, in step 4.2, a discussion session with the lab decision-maker takes place to present evidence from the model when it is simulated against the plausible future occurrences addressed by the scenarios developed. The results provided by the simulation model against the plausible scenarios allow to evaluate model variations in these different scenarios and provide insights regarding the evolution of the system in these contexts. The analysis of the results informs lab professionals and supports the decision-maker in defining possible managerial changes to be applied in the core lab in light of those scenarios. It also provides them with a more comprehensive understanding of how the combination of external factors from different domains may impact the system, providing the possibility of making decisions that are informed for plausible future occurrences. Moreover, the managerial changes that are required to be applied to overcome the possible realization of those scenarios may result in an overall improvement of the efficiency of the system.

This session should last around 45 min, depending on the availability of the decision-maker and on the questions she/he may have about the project.

Chapter 5

Implementation and Analysis of Results

This chapter comprises the implementation of the proposed methodological framework.

In light of the current pandemic situation some adaptations to the proposed methodological framework, namely in its key social component, had to be performed. This pandemic outbreak affected all sectors of the economy and the clinical pathology sector is logically no exception. In this context, this lab suffered an increase in demand for its services in what concerns COVID-19 specific tests, and a decrease from about 5000 patients daily to about 500 in the remaining areas of intervention, during the most turbulent period of the first pandemic wave, according to information shared in the preliminary interview with a senior member of the lab.

Due to the current pandemic situation that has overwhelmed clinical pathology labs, the social processes proposed in the methodological framework had to be simplified and adapted to the current context. The participation of a large number of lab professionals in the workshop sessions became unfeasible, however, as the benefits of these sessions for the scenario planning exercise are well established and strongly recommended by the literature, it was decided to hold these sessions even with a reduced number of participants. In this way, one tried to gather the set of participants that could be present in the workshop, in order to capture different perspectives, as well as the effects of this synergy that results from the discussion among the participants. In this way, the participation of representative elements of the lab in the proposed social processes was requested.

The next sections present the implementation of the proposed methodology with slight adaptations.

5.1 Phase 1: Process mapping and identification of challenges

In phase 1, the major challenges that affect the lab were identified, the central question to guide the scenario planning process was defined, as well as the planning horizon, all in the context of a preliminary individual interview with a senior member of the lab. Still in the context of this interview, a brief description of the lab organization and the set of processes the samples undergo in the core lab was provided. The information gathered in this interview complemented the information on the system's behavior collected from the on-site visits that also took place in this step.

5.1.1 Simulation – Process mapping of the samples' workflow in the core lab

As proposed in the methodological framework presented in Figure 4.1, a flowchart of the processes that occur along the automation system was created based on the information collected from the preliminary interview and the on-site visits, and then, validated by the senior member of the lab who participated in the interview. The flowchart developed integrates the conceptual model of the system, and it is

presented section 5.2.2.2, in Figure 5.1.

5.1.2 Scenario Planning – Definition of the focal issue and the planning horizon

Based on the main strategic challenges identified in the preliminary individual interview, that are described in section 2.7, one identified the central question guiding the scenario planning process as:

"How will lab tests production along the automation system evolve in 2 years?"

Considering the rapid changing environment in the current disruptive times leading to a highly uncertain context, the senior member of the lab considered two years an adequate time horizon the be scrutinized through the scenario planning exercise.

5.1.3 Social Component

The preliminary individual interview that took place in step 1.3 of the proposed methodological framework presented in Figure 4.1 was attended by a senior member of the lab, which provided a detailed description of the processes the samples undergo in the core lab since their arrival, until the results of the lab tests are sent, complementing the information on the system's behavior gathered from the on-site visits and supporting the mapping of the processes. Additionally, an explanation of the lab organization, the main types of tubes processed in this lab, the types of samples whose lab tests are performed in the core lab, through the automation system, were also provided. The main challenges faced by the core lab were identified, which supported the definition of the central question to guide the scenario planning process. The main challenges identified, both of operational and strategic nature, have been presented in section 2.7.

5.2 Phase 2: Simulation model and scenarios development

In phase 2, some adaptations to the proposed methodological framework, represented in Figure 4.1, were applied. These adaptations included the objectives of the workshop session, the number of participants and its duration. During this phase, regarding the simulation model development, the analysis of the system variables as well as the entire construction of the conceptual model were supported by the SH providers that support the operations in the lab, who are intimately familiar with the system under study (subject-matter experts). This continuous interaction allowed the conceptual model to be validated at the time of its elaboration by the subject-matter experts. Additionally, after the construction of the conceptual model, it was validated by the lab professionals in order to ensure that the objectives of the study were being addressed and that they were in accordance with the assumptions considered.

5.2.1 Simulation - Collection and analysis of production data

According to the proposed methodological framework presented in Figure 4.1, step 2.1, the initial step for the simulation model development comprised the collection and analysis of the production data. The

real production data provided by the lab technicians concerns the production of lab tests during the week of 13-18 January 2019. Although it is known that some input variables are best described based on distribution functions [59], with data from a single week, this analysis became limited. However, the opinion of subject-matter experts complemented the available data and supported the analysis and parametrization of the model input variables.

Nevertheless, to select the most adequate probability distribution to the different input variables from the data provided, wherever possible, instead of using the values themselves directly in the simulation (trace-driven simulation), one tried to follow one of the two approaches suggested by Law et al. [59]: use the data values to define an empirical distribution function or apply standard techniques of statistical inference in order to fit a theoretical distribution to the data. The arrival rate of samples to the core lab, the number of tests each specimen requires and the frequency of occurrence of each samples profile are important sources of uncertainty and were described through distribution functions.

Poisson process is the most commonly used model to define arrivals of items in a queuing system, however, one of its properties is that the arrival rate is time independent [59]. Many real-life arrival processes violate this property, as in the case of the arrivals of samples in the system under study. In fact, the data provided revealed that the samples' arrivals at the lab follows a daily pattern, which is also confirmed by the lab professionals. It means that the samples' arrival rate and entrance in the automation system vary with the time. In these cases, one may consider non-stationary Poisson processes, where the parameter of the Poisson distribution is a function of the time ($\lambda(t)$) [59]. As the arrival rate changes with time, the interarrival times are not identically distributed, meaning that it is not possible to fit a single probability distribution to the interarrival times [59].

One of the methods described by Law et al. to specify and estimate lambda parameter, and the one followed in this thesis was the piecewise-constant method [59]. Following this approach, the period of time of the simulation run was divided in subintervals and for each one, a different value of lambda was defined and assumed to be constant within this time window. Since lambda parameter of a Poisson distribution coincides with the mean value, for each subinterval, this parameter was defined based on the average arrivals in each of the defined subintervals.

According to the best practices of simulation, when variables show characteristics of seasonality, as it is the case of the arrivals of samples to the lab throughout the week, it is not advisable to use data from the entire week to calibrate the model. Instead, one may build different models to reproduce different behaviors of the system. The focus of this study was to reproduce one of the busiest days at the lab, which coincide with the beginning of the week (Mondays and Tuesdays). Although there is only one week of production data available, lambda parameter for each subinterval was defined based on the average arrival value from Monday and Tuesday.

Regarding the number of lab tests required for each specimen and the frequency of occurrence of each sample profile, no theoretical distribution was found to be appropriate to describe and fit the observed data. In this case, as recommended by Law et al. [59], an empirical distribution was defined. Although the dataset provided covers only one week of production, this is a huge dataset, since during a week, around 21 840 tubes are processed in the core lab, so, one considered that the available data was

enough to define the empirical distribution without the risk of highlighting possible “irregularities” within the data. Moreover, this analysis was validated by subject-matter experts which considered that this data is representative of the number of tests typically required for each specimen that is processed in the core lab and to the sample profiles that are daily processed in the core lab.

5.2.2 Simulation – Conceptual model of the automation system

As proposed in the methodological framework, in this step, a conceptual model of the automation system was developed to support the construction of the simulation model in the software. It includes a detailed description of the system under study, the process-flow in the system, the assumptions that have been considered, a summary of the model input variables and the performance measures defined to evaluate the model [59]. Each one of these topics covered by the conceptual model are presented in detail in the following sub-sections.

5.2.2.1 Detailed description of the system under study

This subsection provides a detailed description of the flowchart presented in Figure 5.1, in the next subsection.

As it was previously mentioned, the core lab, which is the focus of the present thesis, processes all serum samples, which account for 70-80% of the whole lab workload, through an automation system (Aptio Automation) that manages the samples pathway and drives the test tubes to the respective places where they need to go, to perform the required set of lab tests. Apart from the serum samples, a specific test performed on urine samples (Microalbuminuria) is also carried out along this system. The set of tests performed along the automation system is registered in the IT system, so that, when the samples enter this system to be analyzed, they are conveyed to the analyzers where they need to perform the lab tests, according to their requests. The samples enter the Aptio by the RIM (Rack Input Module). All system elements are equipped with barcode readers, and each tube is identified by a barcode. The barcode readers present in all system components read the tube barcode to decide whether it needs to be processed or it should continue its pathway through the system. The pathway in the system is unidirectional and circular, however the tube only visits the places where it needs to go, based on its request.

When the tube leaves the RIM, transported by the carrier, it is forwarded to the decapper. Then, according to the request for this tube, it is directed to the analyzer(s) where the respective test(s) need(s) to be performed. The system allows a maximum of 385 tubes inside, at the same time. There is a total of 9 analyzers connected to the automation system, of which 4 are clinical chemistry analyzers (2 Advia Clinical Chemistry and 2 Liaison analyzers) and 5 of immunoassay (1 Immulite and 4 Centaur analyzers). The IT system of the automation system contains all information regarding the process flow of the lab, that is, for each sample it indicates the analyzers to which it has to move. When passing through an analyzer, if the request for this tube includes tests to perform on it, the tube is side-tracked and enter a secondary rail in front of the analyzer to be pipetted by this analyzer. After the analyzer takes a small sample from the tube, the tube follows its path and the analyzer carries out the test(s)

required for this tube, out of the tube.

When the tests for a sample tube are urgent, the tube can be automatically loaded by the front of the analyzer, instead of having to go through the whole system to reach the analyzer. When the tube has performed all the required tests in the automation system, if its request includes tests in sections outside the automation system, such as RIA, manual techniques, nephelometry, electrophoresis or allergy, the tube is conveyed to the IOM (Input-Output Module) where it leaves the system by a specific line according to the section where it has to go, otherwise, the tube is forwarded to the sealer and then to the storage. The lab technician responsible for this section transports the tube to the respective section. When the required tests in these sections are completed, the tube return to Aptio, entering by the IOM, and it is directed to the sealer and then to the storage. Once in the storage, when the tests result are delivered by the analyzers, lab technicians quickly check the results and when they find some deviation from the reference range for these tests, they inform the system that the respective tube must be placed by the storage again in the system, for it to repeat the required test(s). When this happens, as the tube was already sealed, it must be forwarded to the desealer before being sent to the respective analyzer where it needs to repeat the test. When the tube enters the automation system but its request also includes tests that need to be performed in reference labs, which are external labs that perform special tests, before the tube is sent to the analyzers connected to the system, it is directed to the aliquoter where it takes small samples from the primary tube to secondary tubes. Then, the primary tube follows its path inside the automation system to complete all required tests inside the system, and the secondary tubes are forwarded to the IOM, where they leave the system to be sent to the reference lab, to perform more specific tests. All analyzers require daily maintenance and the reagents and consumables must be replenished. Every day between 7:30 am to 10:30 am, analyzers undergo automatic maintenance, followed by calibration and quality control to check all parameters in the clinical chemistry and immunoassay analyzers. Around 10:30 am the analyzers are ready to start processing tests.

5.2.2.2 Process-Flow of the system

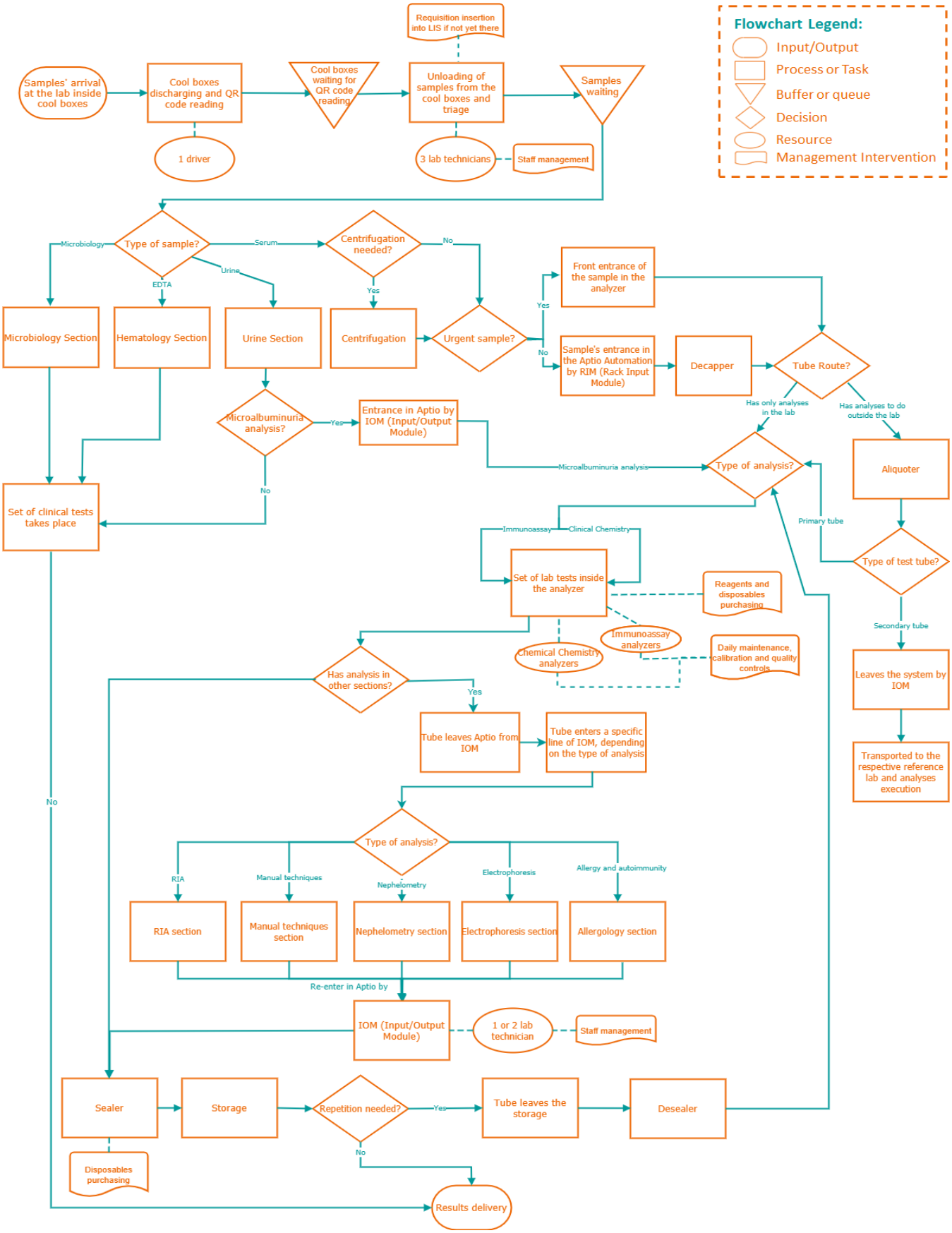


Figure 5.1. Flowchart of the overall process in the lab, from the samples arrival to the end of their process, focusing on the set of processes along the automation system.

5.2.2.3 Assumptions considered

Before the implementation of the simulation model, some simplified assumptions were considered and validated at the time of the conceptual model elaboration, by subject-matter experts. After its construction, it was validated with lab technicians. Lab technicians finish their workday when the analyzers finish the processing of the lab tests of that working day, i.e., the daily service. In the busiest days of activity in the lab, they finish the daily service at around 00:45 am. When technicians leave the lab, the analyzers are turned off. In this way, as the focus is on the busiest days of activity in the lab, one considered the analyzers are in a down state from 00:45 am to 10:30 am. More specifically, from 00:45 am to 7:30 am, analyzers are in a scheduled down state, meaning that they are inactive. Since lab technicians start arriving at the lab at 7:30 am, at this time the automatic maintenance begins, followed by calibration and quality controls, which lasts until around 10:30 am. During this period of time, analyzers are in a setup state.

Regarding the processing of the tests of each tube by the analyzers, in the real system, the tubes only enter one of the analyzers to be pipetted (for it to take a small sample from the tube where the set of required tests are carried out). In the other analyzers, the tube waits in the secondary rail connected to the analyzer to be pipetted by the analyzer. In the simulation model, since there is no animation that resembles the pipetting motion, one considered all tubes enter the analyzer to be pipetted, however, the time it takes inside the analyzer is equivalent to the pipetting time in the real system, which is proportional to the number of tests it needs to perform in the immunoassay analyzers. In this way, this does not impact the performance of the model.

As the set of processes along the automation system are automatic, only one lab technician was considered to model the system. This professional is responsible for transporting the tube from the IOM to the respective section where it must perform the test(s), and then, the opposite transport, from the section outside the automation system, to the automation system, for the tube to be sealed and stored in the storage. The other technicians in the lab are responsible for supervising the system functioning. As these tasks do not add value to the simulation model, and the number of available objects allowed in the student license provided by FlexSim is limited, it was decided not to include them in the model.

5.2.2.4 Summary of the model input variables

Before the implementation of the simulation model in the FlexSim software, important input variables were defined. They included: the different modules of the automation system, the number of analyzers connected to the system, as well as their specifications, such as the throughput, the duration of the tests carried out by them, the samples' pipetting times, and the processing logic of the different analyzers. The throughput of the analyzers allowed to calculate the maximum capacity of each one, which is the maximum number of tests it can perform at the same time. Still regarding the analyzers, the percentage of test repetition per analyzer was also considered. The number of samples that enter the system and the input distribution pattern throughout the day, the different samples profiles, and their frequency of occurrence. The sequence of processes that the different samples profiles undergo in the system, the

throughput of the storage and its sample loading capacity.

Some input variables were easily obtained from the available data, however, others required additional processing and analysis, as the case of the percentage of test repetition per analyzer, the number of samples that enter the system and the samples' input pattern into the system throughout the day, the different samples profiles, its frequency of occurrence and the sequence of processes each one undergoes.

In order to extract all this relevant information, the data had to be carefully processed and analyzed. Graphic representations presented in the following figures, Figure 5.2, 5.3, 5.4 and 5.5 show some of the important findings extracted from the available real production data, relevant to the model building.

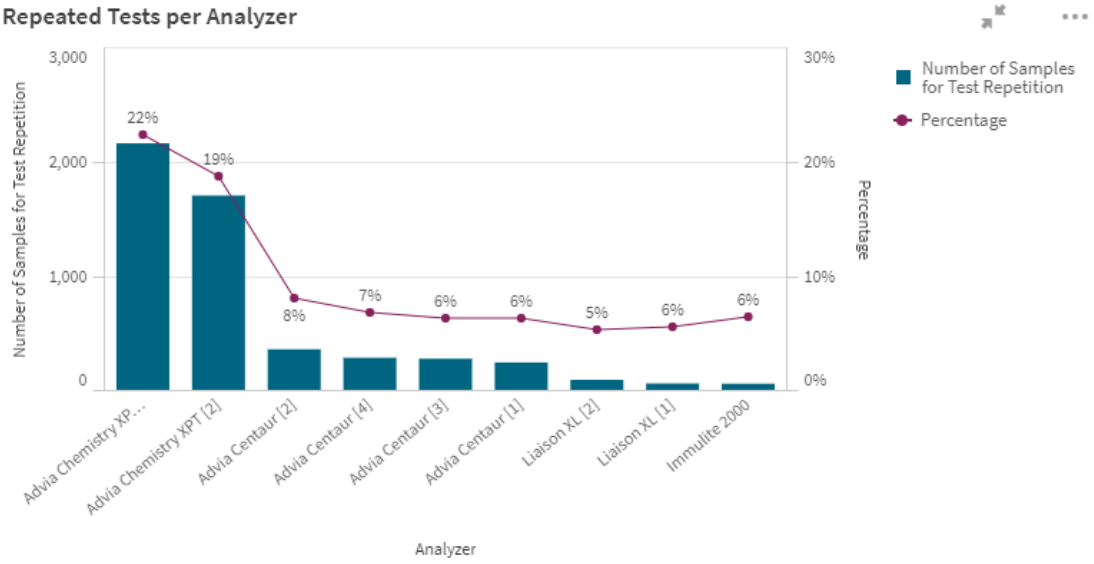


Figure 5.2. Number and percentage of samples whose tests require repetition.

Figure 5.2 illustrates the number and percentage of samples that require repetition in each one of the analyzers.

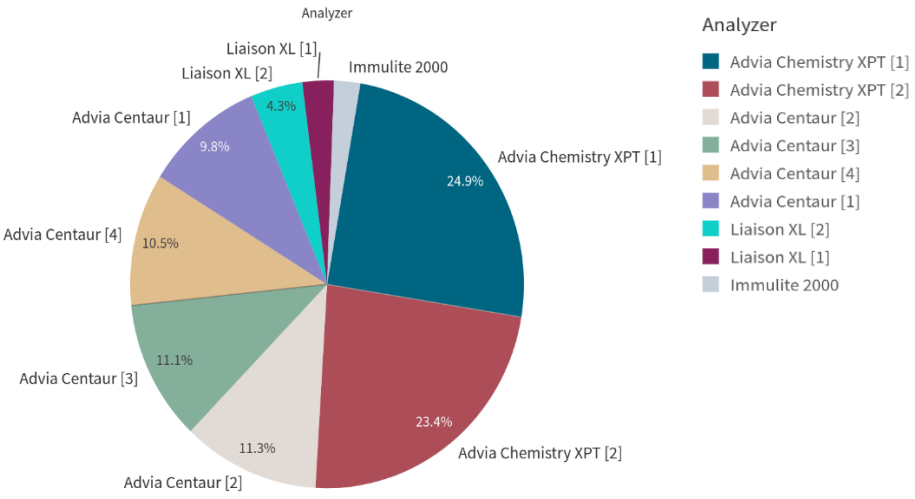


Figure 5.3. Percentage of samples that need to visit each analyzer.

Figure 5.3 describes the percentage of samples that need to visit each analyzer.

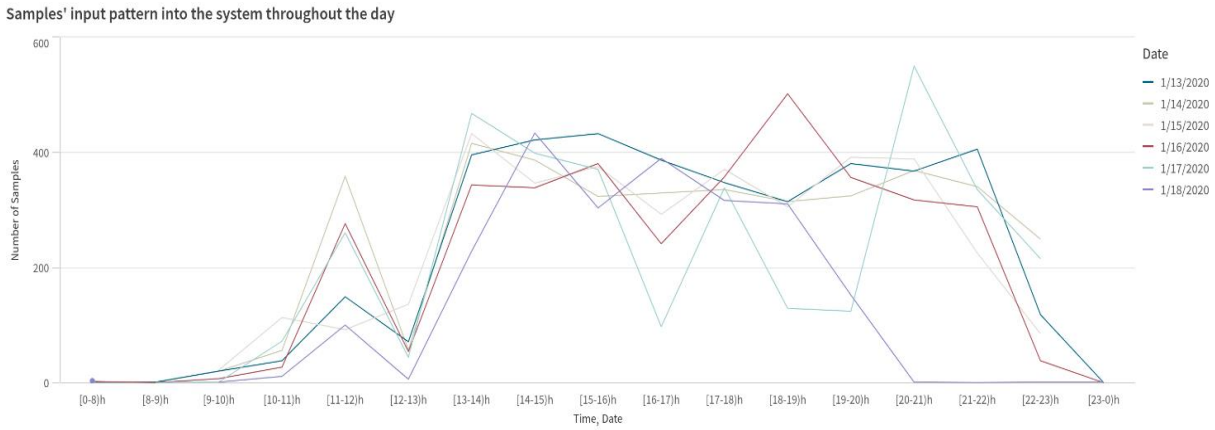


Figure 5.4. Samples input pattern into the system throughout the day in the different days of the week.

Figure 5.4 represents the samples' input pattern into the system throughout the day in the different days of the week. This pattern is reflected in the heatmap of Figure 5.5, which highlights the busiest hours of the day and days of the week.

Count Distinct TubeID	Acceptance Day						
Acceptance Hour	13-jan	14-jan	15-jan	16-jan	17-jan	18-jan	Total Geral
0		2		1		1	4
1				2			2
2						2	2
4	1						1
5						1	1
7	1	1					2
8	2	2		1	1		6
9	22	21	23	9	2	2	79
10	39	61	115	31	73	12	331
11	164	367	94	285	267	102	1279
12	76	58	141	59	49	7	390
13	420	445	444	360	516	255	2438
14	442	426	404	369	411	455	2505
15	441	333	386	383	371	302	2214
16	401	334	297	241	100	387	1759
17	351	339	372	351	341	321	2075
18	308	315	296	507	131	314	1871
19	396	326	406	362	120	153	1763
20	358	367	381	318	546	2	1972
21	417	342	234	297	345	1	1635
22	119	251	86	48	216	2	722
23	1			1		2	4
Total Geral	3935	3964	3660	3596	3472	2310	20907

Figure 5.5. Heat map of the arrivals of samples to the system by day and hour. The values are depicted by colors and more intense colors (reds) describe the busiest hours and days, and the less intense (greens) the less busy hours and days.

Information contained in Figure 5.5 is important to define the arrival rate of samples in each subinterval (period of the day), as it was previously explored in section 5.2.1. At a glance, one can verify which are the busiest period of the day and days of the week.

The in-depth analysis performed on the real data allowed to develop the computational model of the system under study.

5.2.2.5 Performance measures to evaluate the model

The performance measures allow to measure improvements in the performance of the actual system

under study, through the simulation model, and they are defined in terms of KPIs. Since a clinical lab resembles a traditional production system in the way of operating, with the inherent complexity of healthcare settings [65], the most relevant set of KPIs to assess the performance of the system under study was defined based on what is commonly used in both settings [37]. The KPIs identified through the literature research as the most relevant to measure the performance of the system under study, through the simulation model, are presented in Table 5.1 and, like the other topics that integrate the conceptual model, the identification of the most useful performance measures to be considered has also been validated by the decision-maker.

Table 5.1. List of KPIs to assess the performance of the actual system under study, their definition, and the calculation behind.

KPI	**Definition**	**Calculation**
Turnaround Time (TAT)	Time it takes for the system to process the required tests associated to a tube.	Time interval between the moment the tube arrives at the system, until the last required test for this tube is finished.
Cycle Time	Time the tube remains in the system.	Time interval between the moment the tube arrives at the system until the tube enters the storage and its tests do not require repetition.
Analyzers Utilization Rate	Percentage of analyzer utilization throughout the day.	Ratio between the number of tests being performed by the analyzer and its maximum capacity times 100%.

The TAT is the KPI more commonly used in lab medicine, as it is often used by clinicians to benchmark lab performance [37]. The TAT determines the lab capacity to provide timely results to the clinician, which may impact the follow-up of the patient and the quality of care that is provided [37]. There is not a single and tight definition for the TAT, as it is generally defined as the time difference between two steps of the diagnostic process [37]. In this case, it was considered the time difference between the moment in which the samples arrive at the automation system to be analyzed, and the moment in which the last test of this tube finish its processing, which is the moment that set the end of the processing required for a given test tube.

The Cycle Time reflects the time the tube remains inside the automation system. It can provide important information regarding the degree of utilization of some resources in the system, in particular, of the limiting resource(s).

The Analyzers Utilization Rate compares the number of tests that are being performed by the analyzer with its maximum capacity along the time. As the analyzers are very expensive equipment, lab management prefer high utilization rates, as it is reflected in a more efficient utilization of the available resources [37].

5.2.3 Simulation – Computational model of the automation system using FlexSim software

The conceptual model developed in the previous section, which consists in a structured and detailed representation of the system under study, was used as a basis to support the computational model building in the FlexSim software, after its validation. In the following subsections, the steps of the model development in the software are presented.

5.2.3.1 Description of the computational model

Besides all input parameters that have already been explored in section 6.2.2.3, the FlexSim offers the possibility of adding a background, and the model can be built on top of it, so that the objects may be positioned in the correct locations they occupy in the actual layout of the lab and they can be correctly sized. A layout of the lab was provided in the form of a CAD drawing and imported to the software. This is worth to be considered because in simulation not only the values of the performance indicators are important, but the model should be able to truly mimic the system and furthermore, lab professionals should feel comfortable with this representation of their system. Moreover, if the objects are not correctly positioned in the system, this may impact the results of some performance measures.

FlexSim allows users to build their models in different environments, by using 3D objects, process flow activities or both functionalities. To create the model of the automation system, both functionalities were used, resulting in a complex model. In fact, a clinical pathology lab reveals a very complex pattern of relationships among entities, such as tubes (both primary and secondary), tests, analyzers and other lab apparatus, lab technicians, among others.

Moreover, the logic that guides the pathway of each specific tube in the system (tube pathway) was implemented so that each test tube moves only to the required places, as it can be observed in the real system. Since it is a highly customized system, all this logic had to be directly programmed in C++, in the Code Editor available in FlexSim. Although this way of model building offers a great flexibility, its development requires more effort and solid programming skills. Most of the decisions are taken based on attributes (labels assigned to the different components of the system). In fact, labels are key to the overall functionality of the model, as they allow to get and track the information of the system components throughout the simulation run.

The implementation of the computational model tried to replicate, as much as possible, the description of the system included in the conceptual model (section 6.2.2.1). Figure 5.6 presents the computational model of the automation system built in the 3D objects environment.

Description of the labels attached to the test tubes:

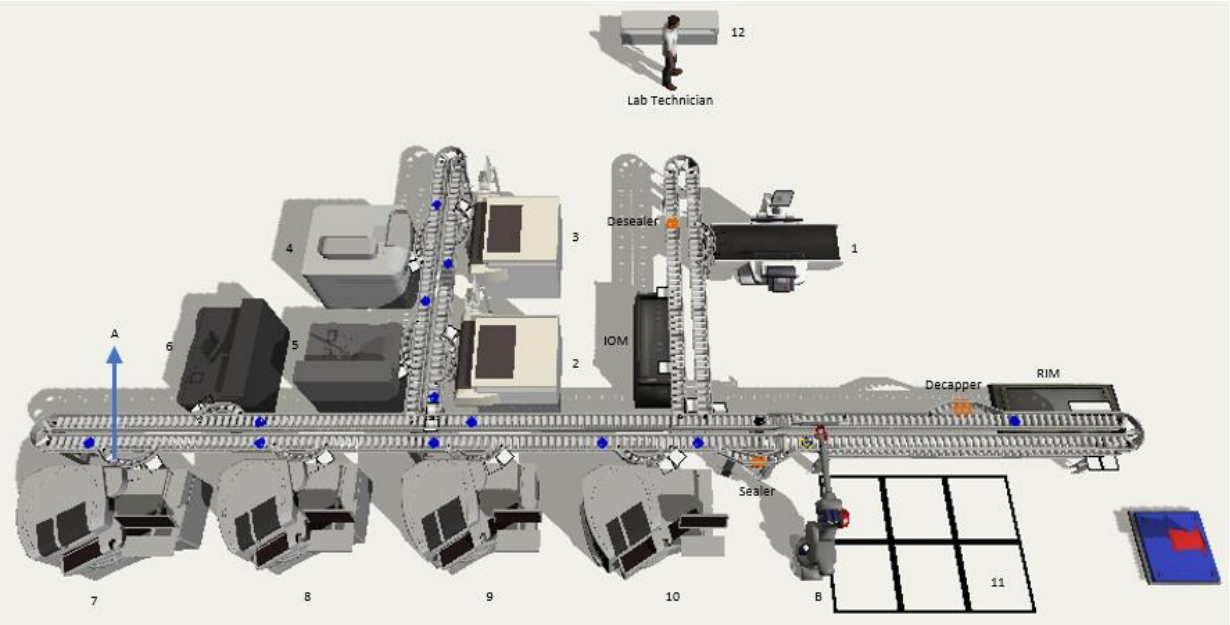


Figure 5.6. Part of the simulation model of the automation system built in the 3D objects environment.

Starting from the beginning, when the test tubes arrive at the system, a set of labels is created and assigned to them. They enable the definition of the tube pathway in the system, as well as the processing logic of the tests assigned to each tube. Each test tube is associated to a sample profile, through a label called "*Tipo*". Its value is assigned based on an empirical distribution, defined based on the available real data. Another label assigned to the tube indicates the step of the process in which it currently is ("*Etapa*"). These two labels allow the creation of table with the sequence of processes required for each sample profile. The rows of that table are the different sample profiles and the columns, the steps of the process. This table defines the tube pathway, with different numbers defining the different system components and the analyzers connected to the system, as can be seen in Figure 5.6. Number 1 is the aliquoter, number 11 is the storage and 12, the respective section outside the automation system where the tube may have tests to perform. The other numbers are assigned to the analyzers connected to the system, and they are listed in Table 5.2.

Table 5.2. Analyzer and the respective number that defines it in the simulation model.

Analyzer	**Associated Number**
Advia Clinical Chemistry XPT 1	2
Advia Clinical Chemistry XPT 2	3
Immulite 2000	4
Liaison XL 1	5
Liaison XL 2	6
Advia Centaur XPT 1	7
Advia Centaur XPT 2	8
Advia Centaur XPT 3	9
Advia Centaur XPT 4	10

When the tube needs to move to other system components which are not identified by a number, such

as the sealer, the desealer, or to enter the analyzer to repeat some tests, additional labels are used to control these decisions. To each tube, a label in a table format ("*EtapaStatus"*) is attached to store, in each row, different information regarding the tube itself. The columns are the different steps. The first row (Sequence) indicates the tube pathway. The second row (Status) indicates whether each step was completed, the third (Nb Tests) refers to the number of tests performed in each analyzer (in each step of the process), and the last one (Repetitions) indicates in which analyzer the tube has tests to repeat. Figure 5.7. demonstrates an example of this label for a given tube.

	Etapa	Etapa	Etapa	Etapa	Etapa	Etapa	Etapa	Etapa	Etapa	Etapa
Sequence	2	3	8	11	11	11	11	11	11	11
Status	1	1	1	1	1	1	1	1	1	1
NbTests	1	1	1	0	0	0	0	0	0	0
Repetitions	0	3	0	0	0	0	0	0	0	0

Figure 5.7. "EtapaStatus" label assigned to each individual tube where different information on this tube is registered in the different table rows.

Row one of the table presented in Figure 5.7 informs that this tube needs to visit Advia Clinical Chemistry XPT 1 (2), Advia Clinical Chemistry XPT 2 (3) and Advia Centaur XPT 2 (8), and finally, in step 4, it is stored in the storage (11). This tube is already in the storage and all the steps of the process are completed, reason why a value of 1 is assigned to all cells of row 2 of the table. The third row informs that this tube performed one test in each analyzer and the fourth row stores the information that the tube needs to repeat a test on the analyzer number 3. The complete list of labels assigned to this tube can be found in Figure 5.8.

Etapa	2
Tipo	15
ReProcess	1
StartTime	37274.50
EndTime	0
CycleTime	0
EtapaStatus	0
ProcessStatus	Complete
TubeCondition	Sealed
ActualTAT	0
TestsOutsideAuto	0
NbTests2	1
OpenTests	1
NbTests3	1
NbTests8	1

Figure 5.8. List of labels assigned to the tube presented as an example in this section.

It is important to mention that images presented in Figure 5.7 and Figure 5.8 were taken at the same time of the simulation run, so that the information contained in both can be analyzed together. The tube presented in this example is of "*Tipo"* 15 (i.e., belongs to the sample profile number 15). The tube is in the 4th step of the process (in the storage), however, as it needs to re-enter the automation system to repeat a test that have been performed on step 2, the "*Etapa"* label points to this step in which a repetition is required, to inform where the tube need to go when it re-enters the system. The value of the "ReProcess" label is one, meaning that the tube has at least one test to repeat, and so, it must re-enter the system. The value stored in this label is updated when the tube enters the storage, according

to the information on the fourth row of "*EtapaStatus"* label. The "StartTime" is the time of the simulation run (in seconds), in which the tube arrives at the system. The "EndTime" is registered when the tube has entered the storage and all the steps of its process have been successfully completed, meaning that it no longer has tests to repeat. Its value is also given in seconds, as this is the default time unit of the software. The "CycleTime" stores the value of one of the KPIs, and it measures the total time the tube is inside the system, i.e., the time it takes for the tube successfully complete its process. It is the difference between the "EndTime" and the "StartTime" and its value is converted to minutes to be easily analyzed. "ProcessStatus" label indicates that the process has been completed, but still not successfully completed. When the tube is moving along the automation system before being stored, the value of this label is "InProcess". Once the tube is sealed, this label is updated to "Complete", meaning that its process is complete, and the tube can be stored. Once the tube re-enters the system to repeat a test, the value of this label is updated to "ToBeReProcessed". Once the analyzer has pipetted the tube to carry out the repetition testing, if the tube do not have more tests to repeat in other analyzers, "ProcessStatus" label is updated to "InProcess", however, if the tube has more tests in other analyzers that require repetition, the value of this label remains "ToBeReProcessed", until the tube has no more tests to repeat. This shows how the values stored in the labels are being dynamically updated during the simulation run. The "TubeCondition" label informs that the tube is sealed since, before entering the storage, all tubes need to move to the sealer. Also, to repeat a test, after re-entering the system, the tube must be forwarded to the desealer, to be desealed, before being directed to the analyzer where the test repetition needs to be performed. The TAT for this tube, which is stored in the "ActualTAT" label, is not yet updated in Figure 5.8., since one test of this tube is still being processed ("OpenTests" label equals 1) and one test needs to be repeated. The "OpenTests" label informs how many tests are being processed. This label is like a counter that is decremented as the tests of this tube that are being processed in the different analyzers finish and their results are made available by the analyzer. When this label reaches zero, the storage robot (B in Figure 5.6.) releases the tube for it to repeat the required tests. When the tube does not have tests to repeat, the "ActualTAT" label value is updated at this moment. In the case of this tube, in which a test needs to be repeated, the value of this label is just updated when the repeat test has been concluded and its results delivered by the analyzer.

As this tube only has tests to be performed inside the automation system, the value stored by the label "TestsOutsideAutomation" is zero. "NbTests2", "NbTests3" and "NbTests8" labels store the numbers of tests performed in the analyzers numbers 2, 3 and 8, respectively. The values stored in these individual numeric labels are used to fill in the third row of the "*EtapaStatus"* label.

How do the tubes move within the system?

All tubes enter the system with a cap. The first component of the system that is visited by all of them is the decapper, which removes the cap of the tube. Then, based on the information contained in the table associated to each tube, it is forwarded to the required places in the system.

The blue objects in the automation system, that can be found in Figure 5.6 represent the decision points. They are responsible for directing the tube to the required places in the system according to a set of

conditions, most of them stored in labels attached to the items (tubes) or to other system objects.

When the tube needs to enter the analyzer to perform the required tests, it is side-tracked and enters a secondary rail in front of the analyzer (identified by A in Figure 5.6). The secondary rails connect the analyzers to the main rail, and they can handle a maximum of 13 tubes, meaning that no more than this number of tubes can accumulate. Figure 5.9 presents the logic that was directly programmed in the FlexSim code editor to define a set of conditions to direct the tube to the required place in the system based on a set of label values and other conditions. This figure represents the logic defined for the decision point just before the analyzer number 7, and similar ones were defined to the other decision points before the remaining analyzers.

DP3 - On Continue

```
/**Custom Code*/
Conveyor.DecisionPoint current = param(1);
Object item = param(2);
Conveyor conveyor = param(3);
Conveyor.Item conveyorItem = conveyor.itemData[item];

Table TipoStatus = item.labels["EtapaStatus"].as(Table);

if (current.centerObjects[3].subnodes.length < 13)
{
    if (TipoStatus[2][item.Etapa] == 1)
    {
        if (item.ProcessStatus == "ToBeReProcessed" && TipoStatus[4][item.Etapa] == 7)
        {
            Conveyor.sendItem(item, current.centerObjects[1]);
        }
        else if (item.ProcessStatus == "InProcess")
        {
            Conveyor.sendItem(item, current.centerObjects[2]);
        }
    }
    else if(TipoStatus[2][item.Etapa] == 0 && Table("Seq")[item.Tipo][item.Etapa] == 7)
    {
        Conveyor.sendItem(item, current.centerObjects[1]);
    }
}
else
{
    Conveyor.sendItem(item, current.centerObjects[2]);
    if (TipoStatus[4][item.Etapa] == 7 || Table("Seq")[item.Tipo][item.Etapa] == 7)
    {
        if(Table("Seq")[item.Tipo][item.Etapa] < 11 && Table("Seq")[item.Tipo][item.Etapa+1] != 12)
        {
            item.Etapa += 1;
        }

    }
}

```

Figure 5.9. Logic defined in the decision point just before one of the analyzers (in this case, analyzer number 7).

Figure 5.10 illustrates the logic that was implemented in the decision point just before the sealer. In this decision point, one starts by checking whether all the steps of the tube processing have been completed. Based on the set of conditions presented in Figure 5.10 a logic is defined to send the tube to the sealer or to keep it moving within the system. Once the tube is sealed, it can be stored, however, during the busiest hours, a huge queue of tubes forms in the secondary rail of the storage, reaching its maximum capacity, and the tube, already sealed, needs to go through the system until the secondary rail of the storage is able to receive it.

DP7 - On Continue

```
/**Custom Code*/
Conveyor.DecisionPoint current = param(1);
Object item = param(2);
Conveyor conveyor = param(3);
Conveyor.Item conveyorItem = conveyor.itemData[item];

Table TipoStatus = item.labels["EtapaStatus"].as(Table);
int UpdatedEtapa = item.Etapa;

for(int INDEX = 1; INDEX <= Table("Seq").numCols; INDEX++)
{
    if (TipoStatus[2][INDEX] == 0)
    {
        UpdatedEtapa = INDEX;
        item.Etapa = UpdatedEtapa;
        Conveyor.sendItem(item, current.centerObjects[3]);
        break;
    }
    else
    { //se todos os analisadores já tiverem sido visitados
        if(item.ReProcess == 1) //se o tubo já esteve no storage
        {
            if(item.ProcessStatus == "ToBeReProcessed") //se o tubo ainda tem testes para repetir
            {
                Conveyor.sendItem(item, current.centerObjects[3]);
            }
            else if(item.ProcessStatus == "InProcess")
            {
                if(item.TubeCondition == "Desealed" && current.centerObjects[4].subnodes.length < 13)
                {
                    Conveyor.sendItem(item, current.centerObjects[2]);
                }
                else
                {
                    Conveyor.sendItem(item, current.centerObjects[3]);
                }
            }
        }
        else
        { //caso o tubo não tenha testes para repetir (e não tenha repetido)
            if(item.TubeCondition == "Desealed" && current.centerObjects[4].subnodes.length < 13)
            {
                Conveyor.sendItem(item, current.centerObjects[2]);
            }
        }
    }
}

```

Figure 5.10. Logic defined in the decision point just before the sealer.

Tube-Test(s) logic in the analyzer:

The tube-test(s) logic in the analyzer was developed in the process flow, instead of in the 3D objects environment, as the concept of test is a more abstract one.

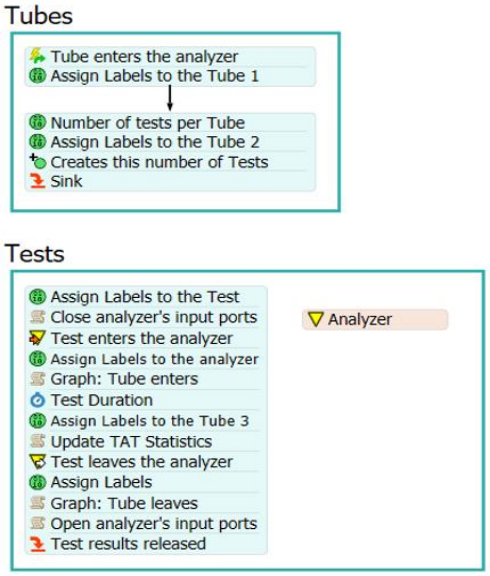


Figure 5.11. Set of process flow activities used to define the Tube-Test(s) logic in each one of the analyzers and to implement some performance measures.

Figure 5.11 presents the set of process flow activities used to define this logic. This controls the test processing logic in all analyzers connected to the automation system. Furthermore, in this set of activities, the "ActualTAT" label value is updated when all the tests of a given tube have finished being processed and the statistics for the TAT performance measures are calculated. Also, the analyzers utilization rate performance measure is implemented within this set of activities.

The capacity of each analyzer limits the number of tests that can be carried out simultaneously by the analyzer. This capacity depends on the number of available positions in the incubation or reaction ring of the analyzer. When its capacity is reached and there is no more available positions inside the analyzer to perform tests, the tube cannot be pipetted by the analyzer and it must wait in the secondary rail for some positions where other tests are being carried out, to become available, when these tests are finished and the results are delivered by the analyzer. When this happens, it is still necessary to ensure that the number of tests that the tube has to perform in this analyzer is less than or equals to the number of available positions in the analyzer. In other words, the analyzer pipettes the tube when it has enough available positions in its incubation or reaction ring to carry out the required tests for this tube. If this is true, the analyzer pipettes the tube and starts the tests execution out of the tube. The duration of the test depends on the analyzer and the type of test, and each type of analyzer also has different capacities.

5.2.4 Scenario Planning – Analysis of external factors relevant to the production of lab tests along the automation system

Scenario planning exercise was developed by adapting the guidelines proposed by Goodwin et al. [10] and Schoemaker [106]. As defined in the methodology, the scenario planning exercise was supported by workshop sessions with key-elements from the lab. These activities were structured and prepared in advance, in order to make the best use of the participants' time. These sessions facilitated the knowledge exchange and the sharing of experiences and viewpoints among participants, created engagement and a relationship of trust between the facilitator and the end-users, and strengthen the collaborative capacity, which were advantageous for everyone and for the final result of the project.

The guide for the first workshop session had to be adapted to what was proposed by the methodology and included the analysis of external factors relevant to the production of lab tests along the automation system. This objective was approached using PESTLE technique, as suggested by the methodological framework. In this analysis, participants were encouraged to think and discuss among themselves external factors that could have an impact on the production of lab tests in the core lab, i.e., in those carried out along the automation system, in each one of the domains covered by this technique, resulting in a set of perspectives and viewpoints representative of the organization.

5.2.5 Scenario Planning – Drivers identification and characterization

The resulting system drivers (driving forces that shape the system) are the external factors that were identified by the participants as having a possible impact on the central issue, after all the categories covered by the PESTLE framework have been explored. Once identified, they were characterized according to their predictability and impact on the central issue. As proposed by the methodological

framework, this classification was performed by positioning the drivers in the SSS. The less predictable factors having a high impact on the central question needs to be grouped in clusters of interrelated events to form the critical uncertainties, and those are the elements that establish the difference between scenarios. For each of these driving forces, the facilitator asked what the possible contrasting evolutions could be for each of these uncertain factors (by two opposite extremes).

5.2.6 Social component – Workshop session for drivers' identification and characterization

The workshop session that took place in this phase was held in person and was attended by three lab professionals, two of them having a more technical background and the other one a more strategic vision of the organization (the decision-maker). Contrarily to what have been previously proposed in the methodological framework, the workshop session lasted one hour and a half, instead of three hours, due to participants time and availability constraints. For this reason, the objectives of the session had to be redefined, excluding the development of the scenarios from the scope of the workshop. Thus, the goals of this session consisted of promoting the discussion among participants on relevant external factors, both predetermined trends and uncertainties, that might shape the future production of lab tests along the automation system, and the classification of the resulting drivers in the SSS.

As previously mentioned, a preparation was required to facilitate the workshop session and for that, web-based and desk research on the clinical pathology sector was performed.

To identify the system drivers, all PESTLE categories were explored, one at a time, and for each one, the facilitator asked what would be the external-factors within each category relevant to the central question and for each identified factor, what would be the possible outcomes for the lab tests production along the automation system. As participants discussed, facilitator wrote down these factors in different post-its of different colors according to the category to which they belonged, using a conceptboard. This is a digital whiteboard or workspace in the cloud that allows more than one user to be updating it at a time. After going through all PESTLE categories and having the system drivers been identified, they were placed by the participants in the SSS previously created in the conceptboard. Figure 5.12 presents the layout of this digital tool before the workshop session.

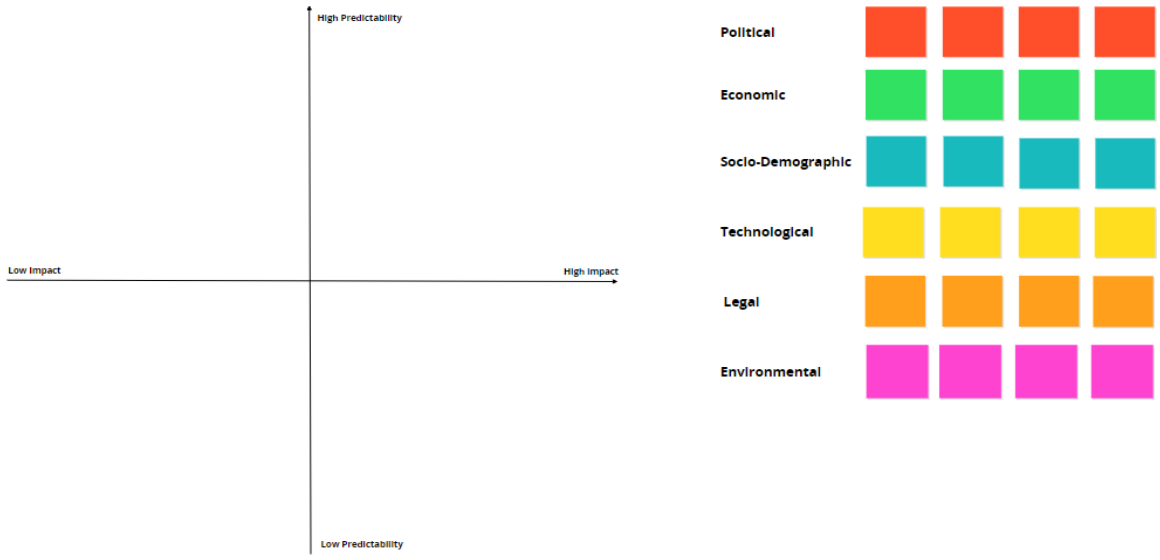


Figure 5.12. Representation of the SSS and the post-its of all categories covered by the PESTLE analysis that were filled in by the participants during the workshop.

By placing the post-its in the conceptboard, participants classified them according to their predictability and impact on the central question. The results of the workshop session are present in Figure 5.13.

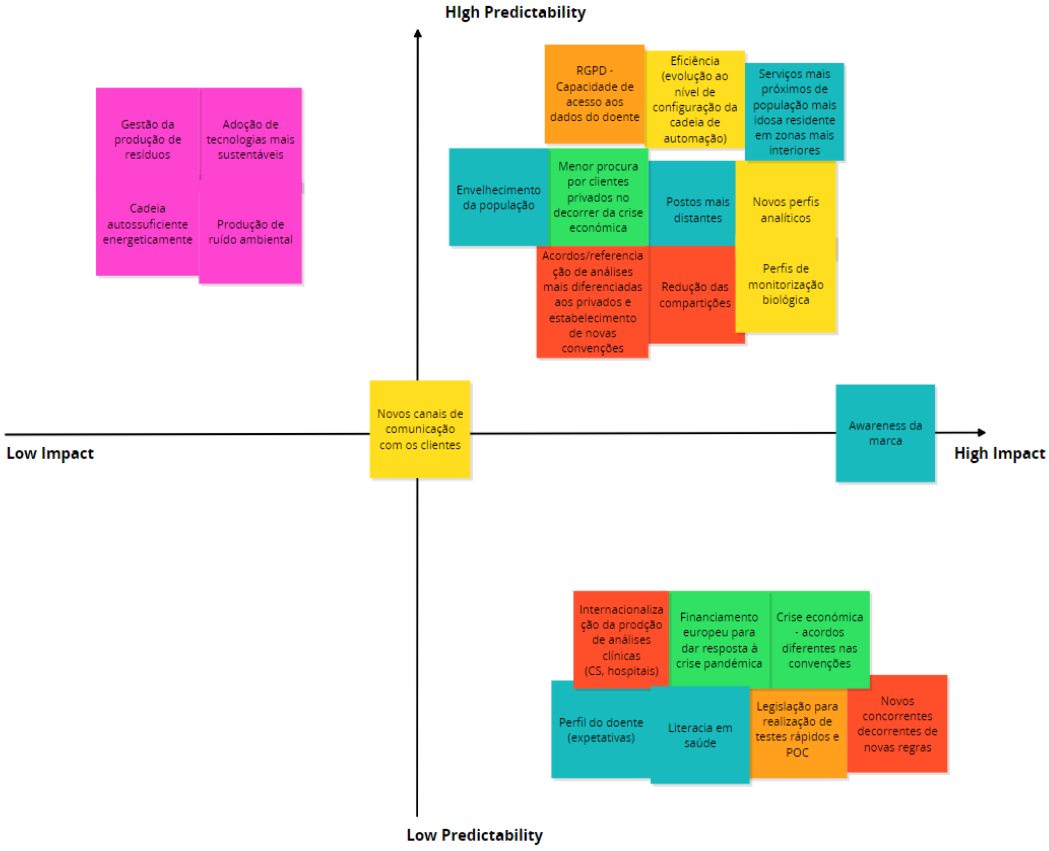


Figure 5.13. Characterization of the system driving forces according to their predictability and impact in the central question performed by the participants in the workshop session.

5.2.7 Scenario Planning – Drivers configuration and scenarios structuring and development

According to the proposed methodological framework, the objective of the workshop session was to perform the tasks of configuring the drivers and structure and develop the scenarios in the presence of the lab professionals. Since it was not possible, the results of the workshop session were analyzed, and the conclusion were taken from it in back-office. Then, the process that was developed in back-office was explained to the lab professionals who attended the workshop and the results were discussed with them. Based on the results gathered from the workshop and on the inputs provided by the participants, the first step was to focus on the post-its present in the 4th (bottom-right) quadrant, and try to group them into clusters of interrelated events, which were not related with the elements of the other clusters.

To facilitate the task, and as it is proposed by the literature [10], one sought to establish chronological and causal relationships between the elements of each cluster. Each cluster represents a critical uncertainty for the lab tests production along the automation system. Following this procedure, three critical uncertainties were clearly identified, as illustrated in Figure 5.14.

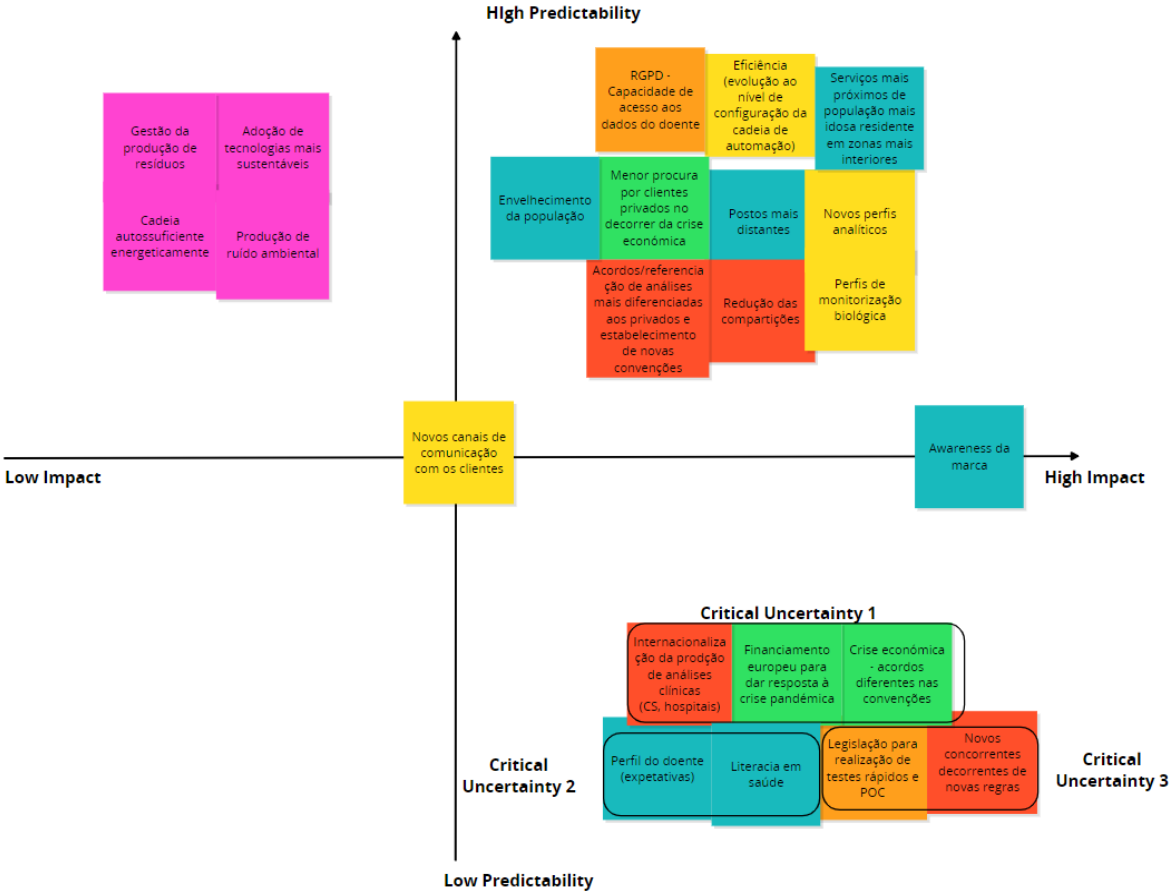


Figure 5.14. Identification of the critical uncertainties for the lab tests production along the automation system.

Since for the driving forces identified as having a high impact and low predictability on the central issue, participants identified the possible contrasting evolutions, the possible future results for the evolution of

each of the identified critical uncertainties came from these inputs provided by the participants and constitute the drivers' configuration.

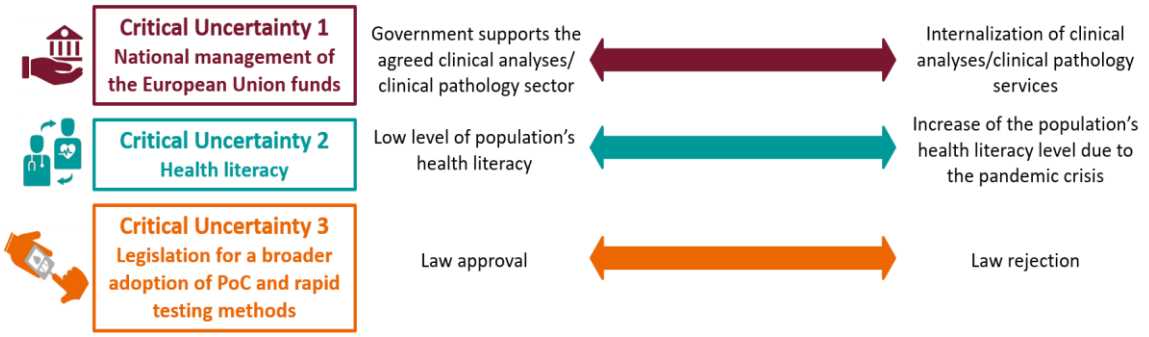


Figure 5.15. Critical uncertainties for the lab tests production and their possible outcomes.

Figure 5.15 presents the three critical uncertainties for the lab tests production along the automation system that have been identified and the possible future outcomes by two extremes that may derive from each one.

The critical uncertainty 1 refers to the national management of the European Union funds in response to the COVID-19 pandemic crisis. National policymakers may choose to compensate the agreed clinical analyses/clinical pathology sector for supporting the NHS in the diagnosis of the SARS-CoV-2 virus, or to increase the NHS installed capacity, in order to internalize part of these services. The critical uncertainty 2 respects the health literacy of the Portuguese population and two diverging evolutions may result. On one hand, the population health literacy may remain in low levels, characteristic of an aging population. On the other hand, as a result of the pandemic crisis, population may have become more aware of health-related issues, and more engaged in the management of their own healthcare, contributing to an increase of the health literacy level. This critical uncertainty may result in different user profiles, with different needs and expectations from the clinical lab and the clinical pathologist. Finally, the critical uncertainty 3 involves a legislation for a more comprehensive adoption of rapid tests and PoC testing methods. On the one hand, the pandemic may have motivated the industry to look for faster forms of testing that could start competing with the standard methods, and, as a result, new operators may enter the market, or, on the other hand, the testing paradigm is maintained based on the well-established and regulated reference methods of the lab medicine.

Having the critical uncertainties and their possible contrasting outcomes been identified, the scenario structures were developed. These resulted from all possible combinations between the extremes of each one of the critical uncertainties, following the morphological analysis approach, as an extension to the 2x2 matrix approach of the intuitive logics school of technics. With three critical uncertainties and two plausible outcomes for each one, eight possible scenario skeletons emerged, since there were no inconsistencies among all possible combinations of the evolution of the different critical uncertainties.

Once scenario structures have been developed based on the possible outcomes of each critical uncertainty, the post-its present in the other quadrants were inspected and included in at least one of the scenarios structures. As literature suggests, post-its present in the 2nd (top left) quadrant could be

included in any scenario structure [10].

Figure 5.16. Scenario structures resulting from the combination of the possible evolutions of the critical uncertainties.

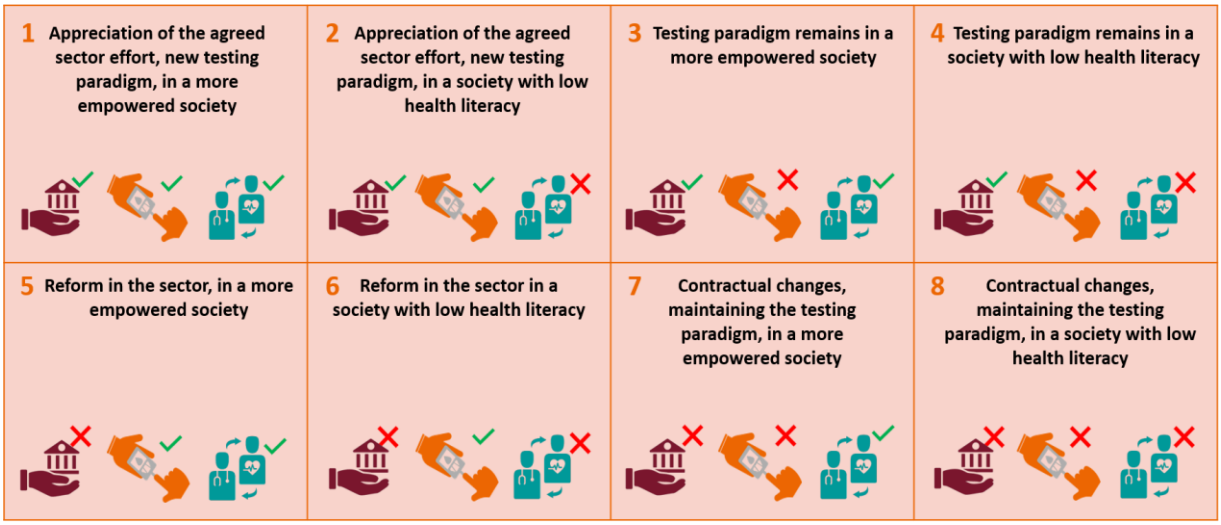


Figure 5.16 presents the scenario structures that resulted from all combinations between the possible contrasting evolutions of the critical uncertainties identified. Based on the scenario structures, scenario narratives, which are the storylines that describe each scenario, were developed. They can be found in Appendix I.

5.3 Phase 3: Project validation and parameters elicitation

5.3.1 Simulation – Simulation model results and validation

As it was suggested in the methodology, the validation process was not only attempted at the end of the computational model implementation, but instead, it was a continuous process, in which an interaction on a continuous basis was maintained with the decision-maker, lab technicians and the SH team who provides support to the operations in the lab (subject-matter experts).This not only allowed the simulation model to be continuously validated, but also, to create engagement between the modeler, the decision-maker and the lab technicians. By actively participate in the model development, and by understanding that his/her inputs were being considered, the decision-maker more easily rely on the developed decision-support methodology.

Thus, several meetings with subject-matter experts took place during the simulation model development, ensuring all inputs were validated by them. Following the process proposed in the methodology to verify and validate the model, the first step of the model validation carried out in this study was the validation of the conceptual model at the time of its elaboration, with subject-matter experts, followed by its validation with the decision-maker and lab technicians. For this validation it was necessary to ensure that the decision-maker agreed with the assumptions made, that the proposed objectives were being met and that the conceptual model was a consistent and detailed representation

of the actual system. After having obtained validation from the decision-maker, the conceptual model was used as a basis for implementing the computational model. The implementation of the model in the simulation software was iteratively performed, and its complexity was progressively increased, at the same time as the model was debugged, looking for possible implementation errors and eliminating them. During this process it was taken into account whether the computational model was translating the conceptual model correctly. Finally, the validation of the computational model included "face validity" and the comparison of the simulation model outputs with quantitative data, extracted from the provided dataset. This validation occurred in two different contexts, a first validation with subject-matter experts, in the context of a validation meeting, and later, the validation with the decision-maker and lab technicians, in the context of a workshop. In the validation meeting, subject-matter experts provided feedback and proposed some adjustments to be further integrated before the presentation to the decision-maker.

The "face validity" consisted in showing the animation of the simulation model and asking whether the model developed was visually a good approximation of the real system and if it was able to replicate it correctly. For the second part of the computational model validation, the quantitative validation, a comparison of the performance measures of the simulation model with those that could be extracted from the provided real records, was performed. From the dataset provided, the statistics for the TAT, which has been one of the KPIs considered to evaluate the performance of the system under study through the simulation model, were calculated. The other performance measures considered in this study for which real data were not available to compare with the simulation model outputs, has been checked for plausibility by the subject-matter experts and lab technicians. When checking the results, it was asked whether the differences verified were not significant and if the model developed was a reliable representation of the actual system.

The continuous work supported by people knowledgeable about the real system under study, carried out from the analysis and conceptualization of the system, to the development of the simulation model itself, as described above, has given credibility to the simulation model developed, which has been recognized as correct and credible representation of the actual system by the subject-matter experts.

As the clinical lab works on a make-to-order basis, meaning that the working day finishes when the daily working volume (the daily volume of samples) is analyzed, and considering that the objective was to study one of the busiest days of activity in the lab (one day's operation), the simulations performed on the model developed have been considered terminating simulations [78]. This consideration is also explained by the daily "restart" nature of the lab operations [121] and terminating simulations are characterized by starting at a defined time or state (in this case, at 7:30 am, when the lab technicians arrive at the lab), and ending when it reaches another defined time or state (in this case, when all samples of the working day have been processed). In this case, the simulation starts with an empty and idle system, meaning that there are no samples at time zero and all resources are idle in the beginning of the working day. Thus, there is no need to define a warm-up period.

To run the model, thirty independent model runs (replication runs, using different random numbers) were considered enough to conclude the model was creating accurate conditions. From these replication

runs, one could obtain different statistical measures of the KPIs, including the average, the standard deviation, the minimum and the maximum registered.

Analysis of the simulation model results:

The simulation model calibrated with the real production data provided was run using thirty replication runs. In these replications, the average number of samples daily processed in the lab was of 3974, with a standard deviation of 76. The minimum registered was 3816 and the maximum 4165.

The results of the simulation were analyzed at different levels of detail: a more global level (macro level analysis) involved the TAT and the Cycle Time, and a more specific level (micro level analysis) that involved the utilization rate of the different types of analyzers during the various periods of the working day, with implications for the daily work in the lab. Moreover, a bottleneck analysis was also presented.

Table 5.3. Results of the key performance indicators, evaluated with different statistical measures, to assess the performance of the actual system under study. Comparison between the TAT performance measure obtained from calculations based on the real data provided and the output of the simulation model.

KPI	**Statistical Measure**	**Original Model**	**Actual System**
TAT (min)	Average	40.4	43.2
	Standard Deviation	34.3	35.1
	Minimum	10.98	11
	Maximum	369	381
Cycle Time (min)	Average	44.2	-
	Standard Deviation	43.0	-
	Minimum	2.90	-
	Maximum	548	-

Based on the information presented in Table 5.3, for each performance measure, one constructed 95% confidence intervals (CIs), informing that with a confidence of 95%, the average value of the performance measure was within the provided range. In the case of the TAT, one can be 95% confident that the true average value was between 27.5 and 53.1 minutes, and for the cycle time, for same confidence level, the true average value was between 28.2 and 60.2 minutes.

From the results of the performance measures obtained from the simulation model, shown in Table 5.3, the inherent variability of the process is evident. Both performance measures (TAT and Cycle Time) presented large standard deviation values, which can be explained by the variability of the process itself, as well as the diversity of sample requests that daily arrive at the lab to be processed, resulting in a coefficient of variation of 0.85 for the TAT and of 0.97 for the cycle time.

From the comparison of the model results with the real data available presented in Table 5.3, the model could be considered valid since the values were close (with an error of about 6% for the average TAT) and the 95% CI contained the average value of the performance measure of the actual system. The results of the other KPI, for which no real data were available for comparison, were checked for plausibility by subject-matter experts and lab technicians.

Moving to a deeper level of detail in terms of KPI analysis, Figure 5.17 illustrates the utilization rate of the different analyzers throughout the working day, by type of analyzer.

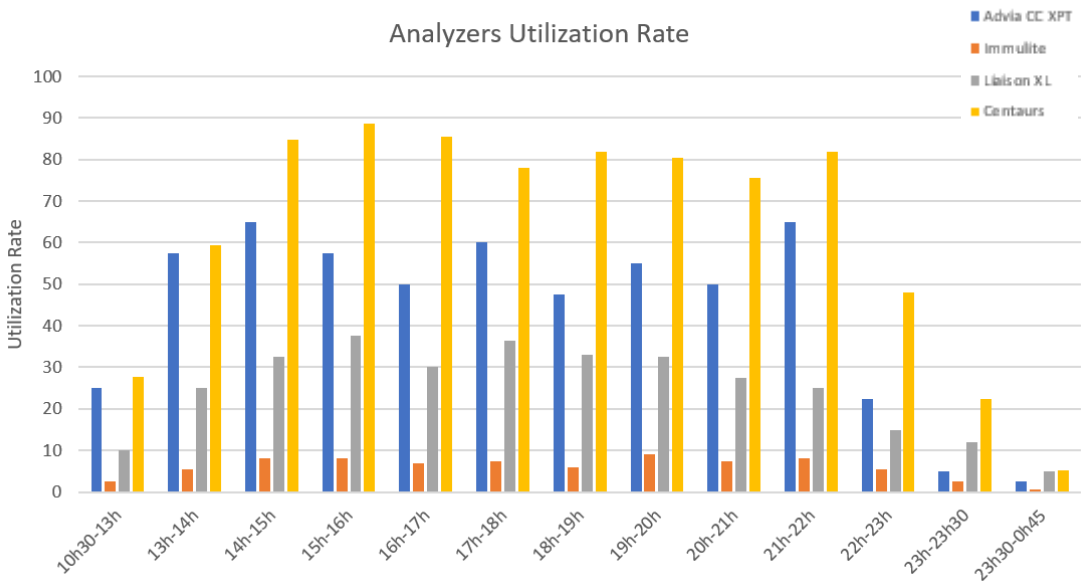


Figure 5.17. Utilization rate of the different type of analyzers along the various periods of the working day.

From Figure 5.17, one could easily verify discrepancies in the occupation of the different types of analyzers, meaning that the utilization of the different analyzers was not balanced. Centaurs, which are immunoassay analyzers, were around 80-90% of utilization at various periods of the day. Immulite, which is the other immunoassay analyzer did not reach the 10% of utilization. These results are in line with reality, since this analyzer only conducts specific immunoassay tests that are not carried out by the Centaur analyzers. Regarding the clinical chemistry ones, Advias CC XPT were clearly busier than the Liaisons, standing between 60-65% and 35-40% of utilization in different periods of the day, respectively. Furthermore, the data revealed that the working volume started decreasing at around 10 pm. This performance measure was also checked for plausibility.

Regarding the bottleneck analysis, one concluded that from about 15 pm, a queue of tubes starts forming to leave the system, and the tubes start accumulating in the secondary rail connected to the storage, reaching the maximum capacity allowed by this rail (90 tubes) during a great part of the working day, which only starts reducing around 10 pm. During this period, there were several tubes that made several attempts to enter this rail, since they had completed the process and were already sealed. However, the storage rail was at its maximum capacity and therefore, could not receive any more tubes. This is due to the fact that the storage robot performs two tasks: the main one, which is to remove the tubes from the automation system and store them in the storage, and the other of placing again the tubes in the automation system when they have tests that need to be repeated. The speed at which it is able to perform both tasks is inferior than the rate at which the tubes are processed and ready to be stored. This analysis allowed to identify the storage robot as the limiting resource, limiting the capacity of samples removal from the system, which in turn, impacts the number of new tubes that can enter the system, as it has a maximum capacity of 385 tubes. This factor strongly determines the time that the tubes remain inside the automation system, which is reflected in higher cycle time values during the busiest periods of the working day.

To conclude, this analysis allowed to achieve a comprehensive understanding of the system under study and infer its behavior in terms of the utilization of the different resources, the queues formed during the process, the TAT and the time the tubes remain in the system. Finally, having the model obtained its final validation using both qualitative and quantitative methods, one considered the simulation model as an accurate representation of the system under study. Therefore, as the objective of this thesis was to develop a decision support methodology that would allow the study of the impact of a set of plausible future scenarios in the lab tests production along the automation system, the model was used to analyze the impact of these scenarios, allowing to investigate how to system would react to changes described by the scenarios.

5.3.2 Scenario Planning – Scenarios analysis and validation

As the scenario planning exercise was not possible to be entirely performed in the workshop session, due to restrictions on the availability of participants, since the involved people were very busy with their daily activities, the results of the analysis conducted in back-office had to be discussed and validated with the lab professionals. The identification of the critical uncertainties for the lab tests production along the automation system, as well as the drivers configuration was not performed in the presence of the lab professionals, so, the procedure that was followed to this end had to be explained and the results discussed with them. Likewise, the proposal of scenario narratives also had to be validated, to ensure that the scenarios formulated met the concerns of the various lab members and covered the different perspectives and viewpoints advocated in the workshop session.

5.3.3 Social component – Workshop session for project validation and parameters elicitation

This workshop session was virtually held with the participation of the same three professionals who attended the first workshop, but its duration had to be reduced to one hour and a half, due to professional commitments. The agenda for the workshop included the demonstration of the simulation model functioning, and the presentation and discussion of the results of the performance measures (these results can be found in section 5.3.1). In what concerns the scenario planning technique, the procedure followed to identify the critical uncertainties based on the results from the first workshop, as well as the drivers' configuration, were presented, explained, and discussed with the participants. The process through which the resulting scenario structures were obtained, was also explained and the workshop finished with the validation of the scenario narratives and the selection by the participants of the scenarios whose impact in the lab tests production along the automation system would be interesting to be explored through the simulation.

To create engagement and capture the attention of the participants, as proposed by the methodological framework, it was decided to start the workshop session showing the animation of the simulation model. After presenting the simulation model functioning, the results of the performance measures were presented and validated, so that the simulation model could be used as a basis for comparison , in terms of KPIs, with the models that recapitulate the essence of the scenarios.

Moving to the scenario planning technique, participants understood the process that have been developed in back-office and agreed on the critical uncertainties identified and their possible contrasting outcomes. Due to the high number of scenarios that have been obtained, participants were asked to select the ones they considered more coherent and whose impact would be interesting to be studied through the simulation model. After having read and analyzed the scenario narratives, participants decided to select scenarios 4, 6 and 8 to explore through the simulation (see Figure 5.17). For these scenarios a catchier name was suggested. Scenario 4 was perceived by the lab members as an approximation to the *Business As Usual*, as the evolution of the three identified critical uncertainties was not far from what is the current state, so this was the name assigned to this scenario. Scenario 6 was simply called "Reform in the sector", and scenario 8, "Contractual changes in the sector". Table 5.4. presents the three scenarios that have been selected by the lab professionals who attended the workshop session.

Table 5.4. Scenarios selected by the lab professionals to be explored through the simulation model.

Selected scenarios	
4 – *Business as usual*	Testing paradigm is maintained in a society with low health literacy.
6 - Reform in the sector	Internalization of several clinical pathology services with a more comprehensive use of rapid testing methods in a society with low health literacy.
8 - Contractual changes in the sector	Internalization of a small part of the clinical pathology services, maintaining the testing paradigm, in a society with low health literacy.

The selected scenarios share the most negative evolution for the critical uncertainty health literacy (level of health literacy remains low). Although participants have selected this set of scenarios, they considered that a higher level of health literacy, characteristic of a more informed, engaged and participatory population, more involved in the management of their own healthcare, could mean users with new needs and expectations, which could motivate the diversification and customization of the services provided to the population. In this sense, the development and introduction of new analytical profiles of biological monitoring and the establishment of new communication channels with the user, through a mobile application that would allow sending the lab tests results to the user and personalized information for monitoring the users' health status would be possible organization's future targets, in light of these scenarios. The set of scenarios that considered this positive evolution for the critical uncertainty health literacy were not chosen by the participants, firstly because they believe the most plausible evolution for health literacy of the Portuguese population during the planning horizon is that it will not increase considerably, and on the other hand, because they do not consider it very likely that new testing parameters will become available in the meanwhile, to allow the exploration of new analytical profiles.

To bridge the scenario planning exercise with the simulation model, so that selected scenarios could be reflected in terms of changes in the input parameters of the simulation model, quantitative estimates of changes to these parameters were elicited to reflect the essence of the scenario. To this end, participants were presented with a set of simulation model input parameters so that they could identify those that should be adjusted to replicate each scenario.

5.3.4 Parameters elicitation for the selected scenarios

This step allowed the combination of both techniques proposed by this methodology, so that the impact of the selected scenarios in the automation system functioning could be assessed through a set of KPIs. Table 5.5. with a set of parameters of the simulation model that could be changed in light of the scenarios, was presented to the lab professionals to support the task of parameters elicitation.

Table 5.5. Set of parameters of the simulation model presented to the lab professionals to support the task of parameters elicitation.

Parameters	**4 – *Business As Usual***	**6 – Reform in the sector**	**8 – Contractual changes in the sector**
Volume of daily requests	15% increase	5% decrease	6% increase
Daily arrival pattern	The same	The same	The same
Type of profile	-	-	-
Frequency of occurrence of this profile	-	-	-

As the elicitation of parameters to translate qualitative scenarios into quantitative estimates to be used as inputs of the simulation model require research, in order to guarantee the consistency of the elicited values and that they were based on reliable data, the participatory contribution of the lab professionals was complemented by on desk research. The research conducted sought to meet the inputs and concerns of these professionals, while developing a structured basis for parameters elicitation. Furthermore, lab members found it reasonable to consider data from the past, regarding the annual growth of the organization in previous periods, in terms of the increase in the number of samples to be processed in the core lab, in order to complement the foresight exercise.

From a cross-cutting perspective across all scenarios, lab professionals have considered that in the planning horizon, lab tests will continue to be seen as the main form of diagnosis, anticipating a growth of this sector [26].

In the "*Business As Usua*l" scenario, lab professionals anticipated that the annual increase in the lab tests requests to be processed along the automation system during the planning horizon (2020-2022) would be at least of the same magnitude that the one registered in the 2017-2019 period. In this way, they anticipated a 15% increase for this variable.

For the scenario entitled "Reform in the sector", lab professionals predicted that the extension of the installed capacity of the NHS might result in the internalization of several clinical pathology services by the public health sector. According to them, this decision might lead to a 50% drop of the lab tests requests coming from the RHA to be processed along the automation system. According to the developed research, the percentage of requests coming from the RHA is currently about 50% of the total volume of requests processed through the automation system. Considering that the annual number of lab test requests processed along the automation system, based on data from 2019, was about 1 057 599, and that one-half of that amount came from the RHA, and will suffer a 50% drop in light of this scenario, assuming the remaining part of the requests will grow at the same rate as in period 2017-2019

(15%), it would be expected a total annual decrease of about 5% in the total number of lab test requests processed along the automation system during the planning horizon.

For the scenario named “Contractual changes in the sector” for which lab professionals anticipated the internalization of a small part of the clinical pathology services, they considered that this scenario would be reflected in a 10% drop in the number of requests from RHA. Following the same line of thought as for the previous scenario, it would result in an annual increase of about 6% in the lab tests requests to be processed through the automation system.

The reasoning behind the parameter’s elicitation was discussed with the lab professionals to ensure they were able to reflect the essence of the scenario and their concerns.

5.4 Phase 4: Evidence of the system response against different scenarios

5.4.1 Automation system simulation against these scenarios

In this phase, the simulation model parameters were adjusted so that the model could replicate the essence of the scenario and the KPIs were able to translate the impact of the scenario in the performance of the automation system.

Once the simulation model has been adapted to represent each one of the selected scenarios, it was run under the same running conditions that were previously established for the analysis of the original model, making it possible to compare the results with this reference model, which have been previously validated. The results provided by these simulations can be found in the next step. The analysis on these results enabled the comparison of the original model with each one of the selected scenarios, in the same set of KPIs as previously considered. This allowed to infer the impact of each scenario on the functioning of the automation system.

5.4.2 Provide lab management with evidence for future decision-making

The analysis carried out in this step considered two levels of detail, likewise the one conducted for the original model, presented in the previous section (the analysis of the original model can be found in section 5.3.1).

Table 5.6. Statistical measures for the number of samples daily processed in the core lab, in the different scenarios.

	Statistical Measure	**Original Model**	**4 – *Business As Usual***	**6 – Reform in the sector**	**8 – Contractual changes in the sector**
Number of samples processed (daily)	Average	3974	5098	3674	4374
	Standard Deviation	76	70	70	76
	Minimum	3816	4911	3500	4194
	Maximum	4165	5244	3810	4552

Table 5.7. Comparison between the results of the KPIs for each one of the selected scenarios and the original model, evaluated with different statistical measures.

KPI	Statistical Measure	Original Model	4 – *Business As Usual*	6 – Reform in the sector	8 – Contractual changes in the sector
TAT (min)	Average	40.4	89.7	36.8	48.9
	Standard Deviation	34.3	67.0	28.6	45.0
	Minimum	10.98	10.98	10.98	10.98
	Maximum	369	672	275	542
Cycle Time (min)	Average	44.2	117.5	32.1	68.1
	Standard Deviation	43.0	89.4	28.2	63.2
	Minimum	2.90	2.90	2.90	2.90
	Maximum	548	712	467	547

Table 5.6. presents different statistical measures for the number of samples daily processed along the automation system for the different scenarios. For each KPI, in each scenario, one constructed 95% confidence intervals (CIs), similarly to what have been done for the analysis of the original model, based on the values present in Table 5.7.

In the case of the TAT performance measure for the *"Business As Usual"* scenario, one can be 95% confident that the true average value was between 64.7 and 114.7 minutes, and for the cycle time performance measure, for the same confidence level, the true average value was between 84.1 and 150.9 minutes.

In the "Reform in the sector" scenario, the ranges obtained for the same confidence level were between 26.1 and 47.5 minutes for the TAT and between 21.6 and 41.7 minutes for the cycle time. In the scenario entitled "Contractual changes in the sector", the ranges obtained for both performance indicators varied between 32.1 and 65.7 minutes for the TAT and 44.5 and 91.7 minutes for the cycle time.

Comparing these values with the ones obtained for the original model, one could verify that the CI for both performance indicators in the *"Business As Usual"* scenario was out of the CI for the same performance measures in the original model. (Remember that the CI for the original model, with the same level of confidence were between 27.5 and 53.1 minutes for the TAT and between 28.2 and 60.2 minutes for the cycle time).

The impact of each scenario in the automation system functioning was assessed individually for each scenario, by comparing, at a time, the KPIs in each one of the scenarios, with those obtained for the original model.

In the *"Business As Usual"* scenario, the maximum number of tubes allowed by the automation system was reached very quickly, right after the first peak of samples' arrival, around 2 pm. Therefore, a queue of tubes started forming to leave the system, in the secondary rail of the storage. The tubes started accumulating in line until reaching the maximum capacity of this rail (90 tubes). The maximum capacity of this rail was reached at around 2 pm and remained at its maximum capacity until around 1:30 / 2 am,

thus, a great part of the day. As the number of tubes in this rail is limited, when reaching its maximum capacity, each tube remained, on average, around 15 minutes inside the rail, to be stored. During this period, several tubes that have completed their process in the system attempted to enter this rail, to leave the system, however as this rail was at its maximum capacity, the tubes started to move around the automation system making several attempts to leave the system, until the storage rail had the capacity to receive them. Due to the fact that the rate at which the storage takes the samples from the system is not proportional to the rate at which new tubes arrive in the system to be processed, a queue of tubes is formed to enter this system, with a large number of tubes accumulating in the RIM (system entrance). They started accumulating from about 3:45 / 4 pm and this queue extended until around 12:30 pm, with some tubes remaining three hours in line to enter the system. The system was overcrowded during this period (most of the working day). In fact, this situation had already been perceived by the analysis of the current model, and, as one could expect, it got substantially worse in this scenario, since the number of samples to be processed considerably increased, which impaired the time the tubes spend inside the automation system, the cycle time. It has almost tripled, on average, when compared to the original model (from 44 min to about 120 min on average), with an average increase of about 168%. The TAT has more than doubled compared to the reference model, an average increase of 125%, reaching about an hour and a half, on average. This has shown that the automation system would not be able to respond in a timely manner to this high number of samples.

In the “Reform in the sector” scenario, in which a large part of the clinical analyses/clinical pathology services were internalized by the NHS, there was no accumulation of tubes to enter the system and the queue of tubes formed to leave the system, in the secondary rail connected to the storage, was substantially smaller, without reaching the maximum capacity of this rail. In this scenario, it was found that the storage robot was able to carry out both tasks, as the number of samples entering the system was lower, and the rate at which new tubes entered the automation system was not much higher than that at which the tubes were removed by the storage robot. This was reflected in lower cycle times, with a reduction of about 12 minutes, on average, compared to the original model, which was equivalent to a reduction of 27%. Likewise, the TAT also decreased, but in a smaller proportion than the previous one. This indicator showed a reduction of about 3 minutes, on average, compared to that of the reference model, i.e., a 10% decrease in terms of variation.

Finally, in the "Contractual changes in the sector" scenario, where contractual changes involving the internalization of part of the clinical analysis/clinical pathology services would be applied while maintaining the testing paradigm, for which a global annual growth of about 6% in the number of requests was anticipated, the system became overcrowded. A queue of tubes was formed to enter the system after the last samples’ arrival peak (8:30 / 9 pm), and a large number of tubes accumulated in line in the secondary rail of the storage, which remained in its maximum capacity during a great part of the working day (from about 3 pm to 11:30 pm). As a result, this affected the cycle times, with an increase of 24 minutes, on average, when compared with the reference model, which was equivalent to an increase of 55%, and the tubes remained, on average, more than an hour inside the system. The TAT increased, on average, about 8 minutes when compared with the original model, i.e., an increase of 23%.

A deeper analysis was performed by considering the analyzers utilization rate along the various periods of the working day, in the different scenarios. Figure 5.18. illustrates the utilization rate of the Centaur analyzers (the busiest analyzers) throughout the working day, for the different scenarios. The equivalent Figures for the remaining analyzers can be found in appendix II.

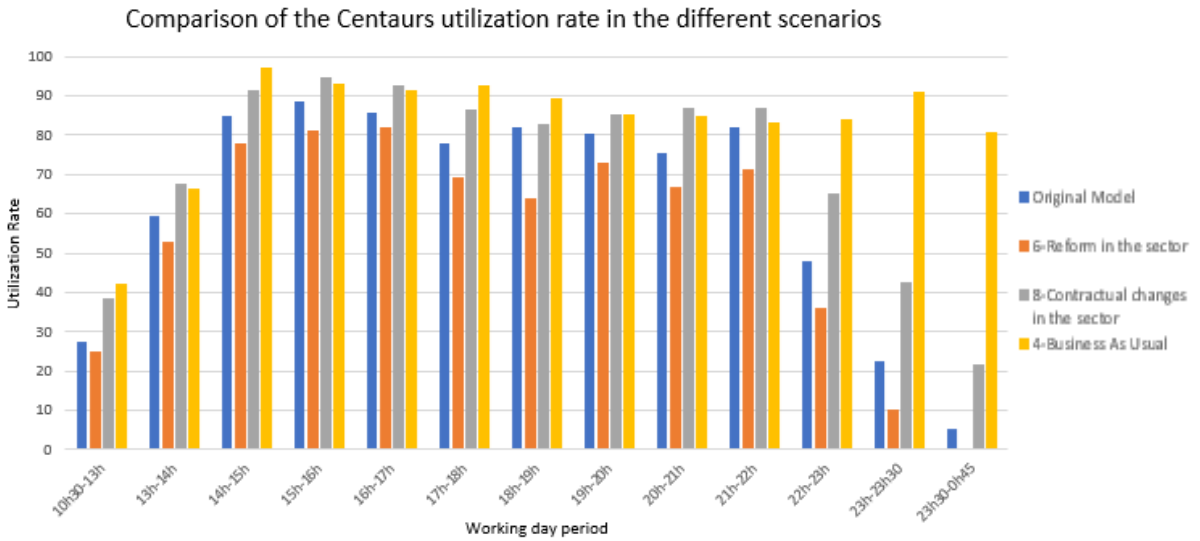


Figure 5.18. Utilization rate of the Centaur analyzers over the various periods of the working day, for the different scenarios.

From Figure 5.18 one could conclude that, in general as it would be expected, the utilization rate of the analyzers tended to be higher in the *"Business As Usual"* scenario. However, this increase was not proportional to the one verified in the other indicators, and in some periods, the utilization rate of the analyzers in the "*Business As Usual*" scenario and in the "Contractual changes in the sector" scenario was very close. This could be explained by the fact that, in the "*Business As Usual*" scenario, the maximum number of tubes allowed by the system was reached very quickly, which in turn led to an accumulation of tubes to enter and exit the system. This reduced the rate at which the tubes in the system were renewed, which means that the analyzers could be longer without receiving new tubes to pipette, in some periods of the day. This had a delaying effect on the process, so the system had to be in operation longer, in order to be able to process all daily requests. That was why, in the remaining scenarios, the analyzers utilization rate tended to decrease from about 10 pm, while in the "*Business As Usual*" scenario, this did not happen. In fact, in the "*Business As Usual*" scenario and in the "Contractual changes in the sector" scenario, but mainly in the "*Business As Usual*", the utilization remained very high until 12:45 pm, the end of the working day in the original model, according to the current daily workload. This means that, at the end of the currently established working period, there were still many tests being performed by the analyzers.

Assuming a growth perspective for this lab, this analysis revealed that it becomes necessary to review and analyze the functioning of the system or to invest on new solutions to ensure the lab is able to process all working volume in a timely manner. If the decision-maker's intention is to maintain the original solution (the automation system), an option would be to establish work shifts, ensuring the lab would be in operation during all day, or at least, a greater period of the day. This would require increasing the

workforce. An alternative would be to explore with the SH providers, the possibility of increasing the automation system capacity, so that it could respond in a timely manner to an increase in demand. This increase in the capacity of the automation system should target what seems to be the most limiting factors of the system: the rate at which the tubes are removed from the system, and the maximum number of tubes allowed within the system. It is worth noting that, although these factors are the ones that most clearly need to be reviewed, one of the types of analyzers (the Centaurs) has shown to have high utilization rates during a great period of the working day, even in the current context. Moreover, from the performance analysis of the of the original model, significant discrepancies have been identified in terms of the utilization rates of the various types of analyzers, and even within each category of analyzers. This revealed that the number of tests performed per analyzer needs to be reviewed, in order to ensure a more balanced distribution of the tests across the different analyzers within the same type. This means that a solution should be explored that integrates improvements to the system at various levels, leading to the improvement of the overall efficiency of the production system, bearing in mind that a non-holistic approach to improving the system performance may not result in its overall improvement.

Ideally, anticipate the arrivals of samples at the lab allowing the beginning of the working day before 10:30 am, and ensure they arrive at the lab more uniformly distributed, would help to improve the situation and to maximize the use, and therefore, monetize the available resources.

Following the same line of reasoning, with a focus on the profitability of resources during the initial period of the day at the lab, one of the possibilities discussed with the decision-maker was to consider increasing the number of sample collections at the users home, through the establishment of agreements with senior institutions. In this regard, samples would be collected during the morning period (between 06:00 am - 11:00 am), with prior appointment, within the region, to ensure that the samples arrived at the lab during the morning period. This decision would allow this clinical pathology lab, on the one hand, to support a social cause, being closer to the user, improving their response to this age group of the population and contributing to the improvement of the user experience, and on the other hand, to make the lab resources profitable during the morning and the less busy period of the working day. However, this decision would have to be explored through a financial analysis, in terms of the costs associated to the drivers to collect those samples, to verify whether it would be cost-effective.

Chapter 6

Discussion and Conclusion

6.1 Discussion

The main aim of this study was to support this clinical pathology lab to analyze managerial strategies to improve the efficiency of its processes in the core lab in a highly uncertain context. Through the simulation model of the automation system that have been developed in this study, the impact of the three scenarios selected by the lab professionals as the most interesting for analysis was assessed. This analysis revealed that in the "*Business As Usual*" scenario, where a 15% annual increase of the lab tests requests to be processed in the core lab has been anticipated during the planning horizon, the system became overcrowded, with the analyzers utilization rate remaining very high until the end of the working day currently defined, meaning that the production system would not be able to process the daily volume of samples within this working period. Moreover, the impact on the other indicators has also been evident, as the cycle time increased in 168%, on average, and the TAT in 125% reaching an hour and a half, which is not be admissible. Regarding the scenario entitled "Contractual changes in the sector", where a 6% annual increase in the number of lab tests requests to be processed in the core lab has been foreseen, the simulation model also showed that the automation system would not be able to process all the daily service within the working period currently defined, as the busiest analyzers presented utilization rates higher than 20% until the end of this period. Even considering this smaller growth, the automation system became overcrowded, which resulted in a 55% increase for the cycle time, with the tubes remaining, on average, more than an hour inside the system, and in a 23% increase for the TAT, when compared to the reference model. For the "Reform in the sector" scenario, where the daily volume of sample requests to be processed along the automation system was anticipated to suffer an annual decrease of 5%, the simulation model revealed that the system would be able to process all the daily samples' volume during the current working period, with the possibility of reducing this period. Consequently, a 27% decrease in the cycle time and a 10% decrease in the TAT, on average, compared to the original model, was obtained, enabling an early delivery of the test results to support the clinical decision-making.

Supported by this analysis, the decision-maker was able to discuss and explore with the providers possible managerial actions to be taken in order to improve the efficiency of the lab testing production process in the core lab. The proposed methodology was successfully applied, and the end-users recognized the benefits of the present work, which allowed to enhance the understanding regarding the nature of the future, and how it is likely to evolve, based on the exploitation of current trends and the possible evolutions of uncertain factors, and anticipate the impact of plausible futures in the performance of the automation system.

Despite the advantages that strategic foresight presents at the organizational level, managers are generally not sensitized and trained to think strategically, tending to focus on more operational aspects of their daily work routine. Engaging lab professionals in the participatory activities for the scenario development process was a challenging but rewarding task. It stimulated strategic and prospective thinking, which they are not used to doing. This exercise developed lab professionals capacity to anticipate trends and to foresee possible external factors of uncertainty, and to explore plausible future scenarios with impact on the organization's core lab, which is of great importance in a complex system, in the current times of external turbulence and disruption, and it was highly valued by this group of professionals that constantly looks for innovation and improvement opportunities. Moreover, this enhanced understanding about the external environment covered by the scenarios, complemented by the evidence of the impact of those plausible scenarios in the lab production system, supported the decision-maker in defining the organizational course of action and possible managerial changes to be implemented in light of these scenarios, ensuring the organization is able to deal with their possible realization.

Business Process improvement in the literature is typically approached in an exclusively operational way. Although it is intended to be applied to keep track of the changing business environment [39], it does not account for the uncertainty. Therefore, a more effective way of adapting to the continuous changes in the business environment is to anticipate plausible futures and try to prepare the organizational response in advance to their occurrence. The present study complements the existing literature with an approach that supports process improvement accounting for the uncertainty present in the current times of disruption and rapid changing environment, allowing to combine a strategic perspective with the operational aspects typically covered by the business process improvement approaches. The devastating COVID-19 pandemic is a clear example of the need to look into the future and explore emerging trends and potential challenges as a way of accounting for the uncertainty inherent in the times of high volatility, mainly in the highly complex environment of the healthcare sector. Looking from a more strategic perspective, system performance can be evaluated by considering more than operational aspects, which makes decision-making more robust, confident and informed for plausible future events.

Although the proposed methodology has been successfully applied, it still presents some limitations, and it is important to consider that it was the first time that the lab professionals had in contact with a scenario planning approach, and were motivated to look into the future and develop a collective strategic thinking. Although scenario planning provides a broad perception of the uncertainty, in such a complex and multivariable context as the healthcare sector, it is impossible to ensure that all possibilities for future occurrences are systematically explored. This is a cross-cutting limitation to the scenario planning methodology, which may have been accentuated by the constraints imposed by the current times, that led to the need to simplify the social processes developed in this study. This limitation can be mitigated by involving a larger group of participants, in order to obtain a representative view of the organizational concerns and objectives, promoting a broad sharing of knowledge, ideas and viewpoints, and stimulating participants' creativity. Then, it is expected that they have become aware and sensitized to the need of exploring plausible future scenarios in the current times, as a way of accounting for the uncertainty in

their managerial decisions. Regarding simulation, the main suggestion to improve the implemented methodology would be to use more data to calibrate the model, in order to define other variables in a stochastic way, through the fit of theoretical distributions to the actual data.

6.2 Conclusion

The present study proposed a methodology, instead of a single solution for the challenges identified in the system under study. As a decision-support methodology, it aimed at providing the organization with a deeper understanding of the problem they face, and facilitate the organizational decision-making process, allowing the decision-maker to make more informed and consistent decisions. By presenting evidence, this decision-support methodology contributed to improve the quality of the decision-making process in terms of changes to be applied in the system and guided the organization to choose the proper course of action to achieve efficiency improvements in the core lab production system [6].

The management support methodology developed in this study was the result of a social-technical approach by combining two techniques widely used individually in the literature: DES and strategic foresight, and thus complementing literature with a process improvement approach that account for the uncertainty of the current times. The utilization of DES has already proved to be beneficial in approaching dynamic environments, by providing a visual understanding of the system under study, allowing the use of stochastic processes, and enabling the analysis of the system through a set of KPIs, and it has been widely used to improve the efficiency of processes in clinical lab settings. In times of disruption and high volatility such as those currently living, strategic foresight is a compelling need at the organizational level, with a positive influence on innovation and allows successful decision-making in the face of high uncertainty [141], which is not easily addressed by the individual use of simulation. Furthermore, the current times are a clear evidence that forecast is not always adequate to guide the future path of an organization [88]. However, the question of how strategic foresight leads to the identification of innovation opportunities in practice, is raised [141]. The present study showed that by combining scenario planning with DES, the opportunities for innovation at the organizational level are revealed. This capability comes from the fact that the simulation model allows the analysis of the impact of a set of plausible future scenarios on the system under study to be carried out, while accounting for uncertainty. This socio-technical approach has allowed lab professionals to gain confidence in the simulation model developed and rely on its results, as it was continuously validated by people knowledgeable about the actual system. Additionally, lab members saw their concerns regarding the production of lab tests in the core lab in a highly uncertain context be accounted for. Consequently, the evidence provided by this methodology was able to reduce the reluctance of managers to implement changes in the system.

The objectives of the present study have been accomplished. It allowed to engage lab professionals in a collective strategic thinking to explore the nature of the future and perceive possible challenges and disruptive factors, revealed how external contexts from different domains may impact the production of lab tests in the core lab and provided evidence of the impact of plausible scenarios defined based on organizational concerns, in the production system, allowing them to make more informed decisions in

light of these plausible occurrences.

This decision support methodology has seen its value recognized by both the end-users (lab professionals) and the provider (SH), allowing to strengthen the relationship between them and create an alignment in order to find the best solutions to improve the efficiency of the processes in the core lab, in light of the evidence demonstrated by this approach. In fact, this study revealed that in a growth perspective for this clinical pathology lab, the production system would need to be revised in order to guarantee it would be able to process the daily service in a timely manner. Moreover, in a future work, it would be interesting for this lab to optimize or improve the distribution of the tests that are carried out by the different analyzers. Such study could be based on the simulation model developed in the current study and, additionally, make use of the optimization tools allowed by FlexSim software, and should be complemented by a financial analysis of different options, now that one has already proved the analyzers are not well balanced in terms of utilization rate, although this is not the major challenge the system presents, as it was demonstrated by the current study.

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Appendix I

Scenario narratives

1 - Appreciation of the agreed sector effort, new testing paradigm, in a more empowered society

Following the COVID-19 crisis, the agreed sector of the clinical analyses/clinical pathology has made its services available to the NHS and has made a major contribution to the diagnosis of the virus causing this disease. In a Europe completely devastated by this pandemic, the Member States of the European Union joined forces in an attempt to recover the economy. National policy makers choose to use part of the resources made available by the EU to invest in the agreed sector of clinical analyses/clinical pathology to increase the diagnostic capacity and continue to support the NHS in this regard. The pandemic has led to the need to develop faster methods of diagnosing this virus. New forms of IVD are emerging by rapid testing and PoC solutions, which are gradually gaining visibility and confidence from the scientific community and policy makers in the healthcare sector. These rapid testing methods begin to be used as effective alternatives to the reference methods for some routine testing. As a consequence of the pandemic, society becomes much more informed, empowered and engaged in the management of their own healthcare, leading to an increase in the health literacy level. Considering the growing concerns of the policy makers with the development of a sustainable ecosystem, a possible legislation that would require the management of the biological and non-biological waste, the adoption of more sustainable technologies and limiting the levels of environmental noise generated by the lab equipment is foreseen.

2 - Appreciation of the agreed sector effort, new testing paradigm, in a society with low health literacy

Following the COVID-19 crisis, the agreed sector of the clinical analyses/clinical pathology has made its services available to the NHS and has made a great contribution to the diagnosis of the virus causing this disease. In a Europe completely devastated by this pandemic, the Member States of the European Union joined forces in an attempt to recover the economy. National policy makers choose to use part of the resources made available by the EU to invest in the agreed sector of clinical analyses/clinical pathology to increase the diagnostic capacity and continue to support the NHS in this regard. The pandemic has led to the need to develop faster methods of diagnosing this virus. New forms of IVD are emerging by rapid testing and PoC solutions, which are gradually gaining visibility and confidence from the scientific community and policy makers in the healthcare sector. These rapid testing methods begin to be used as an effective alternative to the reference methods for some routine testing. In social terms, society maintains low levels of health literacy, characteristic of an aging population. With the growing concerns of the policy makers with the development of a sustainable ecosystem, a possible legislation that would require the management of the biological and non-biological waste, the adoption of more sustainable technologies and limiting the levels of environmental noise generated by the lab equipment is anticipated.

3 – Testing paradigm remains in a more empowered society

Following the COVID-19 crisis, the agreed sector of the clinical analyses/clinical pathology has made its services available to the NHS and has made a great contribution to the diagnosis of the virus causing this disease. In a Europe completely devastated by this pandemic, the Member States of the European Union joined forces in an attempt to recover the economy. National policy makers choose to use part of the resources made available by the EU to invest in the agreed sector of clinical analyses/clinical pathology to increase the diagnostic capacity and continue to support the NHS in this regard. Despite the development of rapid testing and PoC solutions in the context of the pandemic, as an attempt to make a faster diagnosis, they still reveal some limitations in terms of the viability of the results that are provided by these methods, which prevents them from being used on a large scale and replace the reference methods, defined as the Gold Standard of the IVD. In this way, the Lab Medicine paradigm for testing is maintained, and lab tests continue to be performed following the reference methods. Because of the pandemic, society becomes much more informed, empowered and engaged in the management of their own healthcare, leading to an increase in the level of health literacy. Considering the growing concerns of the policy makers with the development of a sustainable ecosystem, a possible legislation that would require the management of the biological and non-biological waste, the adoption of more sustainable technologies and limiting the levels of environmental noise generated by the lab equipment is foreseen.

4 - Testing paradigm remains in a society with low health literacy

Following the COVID-19 crisis, the agreed sector of the clinical analyses/clinical pathology has made its services available to the NHS and has made a great contribution to the diagnosis of the virus causing

this disease. In a Europe completely devastated by this pandemic, the Member States of the European Union joined forces in an attempt to recover the economy. National policy makers choose to use part of the resources made available by the EU to invest in the agreed sector of clinical analyses/clinical pathology to increase the diagnostic capacity and continue to support the NHS in this regard. Despite the development of rapid testing and PoC solutions in the context of the pandemic, as an attempt to make a faster diagnosis, they still reveal some limitations in terms of the viability of the results that are provided by these methods, which prevents them from being used on a large scale and replace the reference methods, defined as the Gold Standard of the IVD. In this way, the Lab Medicine paradigm for testing is maintained, and lab tests continue to be performed following the reference methods. In social terms, the low level of health literacy is still a reality, and a mirror of the country's aging population. Considering the growing concerns of the policy makers with the development of a sustainable ecosystem, a possible legislation that would require the management of the biological and non-biological waste, the adoption of more sustainable technologies and limiting the levels of environmental noise generated by the lab equipment is foreseen.

5 – Reform in the sector, in a more empowered society

In a Europe completely devastated by this pandemic, the Member States of the European Union joined forces in an attempt to recover the economy. National policy makers feel the need to improve the efficiency of the healthcare provided by the NHS and enhance the responsiveness of the public sector. In this way, they choose to use part of the resources made available by the EU to increase the installed capacity of the NHS, ensuring the necessary conditions for the internalization of several clinical analyses/clinical pathology services, which is the area of the CDTT agreed sector that requires greater expenditure. In addition, the pandemic has motivated the health industry to explore alternative and faster forms of testing. In this way, rapid testing methods and PoC solutions with the potential to be used in routine analysis are beginning to emerge. The results of these tests which are gradually gaining visibility and confidence from the scientific community and policy makers in the healthcare sector. New players enter the market, primary care centers start to be able to perform part of the routine testing through these rapid methods, and emergency tests start to be performed in the hospital itself, in order to ensure a faster response. Following the pandemic, society becomes much more informed, empowered, engaged and proactive in the management of their own healthcare, leading to an increase in the level of health literacy. Considering the growing concerns of the policy makers with the development of a more sustainable ecosystem, a possible legislation that would require the management of the biological and non-biological waste, the adoption of more sustainable technologies and limiting the levels of environmental noise generated by the lab equipment is foreseen.

6 – Reform in the sector, in a society with low health literacy

In a Europe completely devastated by this pandemic, the Member States of the European Union joined forces in an attempt to recover the economy. National policy makers feel the need to improve the

efficiency of the healthcare provided by the NHS and enhance the responsiveness of the public sector. In this way, they choose to use part of the resources made available by the EU to increase the installed capacity of the NHS, ensuring the necessary conditions for the internalization of a large portion of the clinical analyses/clinical pathology services, which is the area of the CDTT agreed sector that requires greater expenditure. In addition, the pandemic has motivated the health industry to explore alternative and faster forms of testing. In this way, rapid testing and PoC solutions with the potential to be used in routine analysis are beginning to emerge. The results of these tests which are gradually gaining visibility and confidence from the scientific community and policy makers in the healthcare sector. New players enter the market, primary care centers start to be able to perform part of the routine testing through these rapid methods, and emergency tests start to be performed in the hospital itself, in order to ensure a faster response. In social terms, the low levels of health literacy are still a reality, and a mirror of the country's aging population. Considering the growing concerns of the policy makers with the development of a sustainable ecosystem, a possible legislation that would require the management of the biological and non-biological waste, the adoption of more sustainable technologies and limiting the levels of environmental noise generated by the lab equipment is foreseen.

7 – Contractual changes in the sector, maintaining the testing paradigm, in a more empowered society

In a Europe completely devastated by this pandemic, the Member States of the European Union joined forces in an attempt to recover the economy. National policy makers feel the need to improve the efficiency of the healthcare provided by the NHS and enhance the responsiveness of the public sector. In this way, they choose to use part of the resources made available by the EU to increase the installed capacity of the NHS, ensuring the necessary conditions for the internalization of a part of the clinical analyses/clinical pathology services, which is the area of the CDTT agreed sector that requires greater expenditure. In this way, they are able to reduce the expenditure with the agreed sector and make the best use of the NHS available resources. Although the pandemic has motivated the health industry to explore alternative and faster forms of testing, the reference methods are considered the Gold Standard of IVD and Lab Medicine probably the healthcare sector whose procedures are better regulated. In this way, the reference paradigm for lab testing is maintained. Following the pandemic, society becomes much more informed, empowered, engaged and proactive in the management of their own healthcare, leading to an increase in the level of health literacy. Considering the growing concerns of the policy makers with the development of a more sustainable ecosystem, a possible legislation that would require the management of the biological and non-biological waste, the adoption of more sustainable technologies and limiting the levels of environmental noise generated by the lab equipment is foreseen.

8 - Contractual changes in the sector, maintaining the testing paradigm, in a society with low health literacy

In a Europe completely devastated by this pandemic, the Member States of the European Union joined forces in an attempt to recover the economy. National policy makers feel the need to improve the

efficiency of the healthcare provided by the NHS and enhance the responsiveness of the public sector. In this way, they choose to use part of the resources made available by the EU to increase the installed capacity of the NHS, ensuring the necessary conditions for the internalization of a part of the clinical analyses/clinical pathology services, which is the area of the CDTT agreed sector that requires greater expenditure. In this way, they are able to reduce the expenditure with the agreed sector and make the best use of the NHS available resources. Although the pandemic has motivated the health industry to explore alternative and faster forms of testing, the reference methods are considered the Gold Standard of IVD and Lab Medicine probably the healthcare sector whose procedures are better regulated. In this way, the reference paradigm for lab testing is maintained. In social terms, the low level of health literacy is still a reality, and a mirror of the country's aging population. Considering the growing concerns of the policy makers with the development of a sustainable ecosystem, a possible legislation that would require the management of the biological and non-biological waste, the adoption of more sustainable technologies and limiting the levels of environmental noise generated by the lab equipment is foreseen.

Appendix II

Utilization rate of the remaining analyzers in the different scenarios

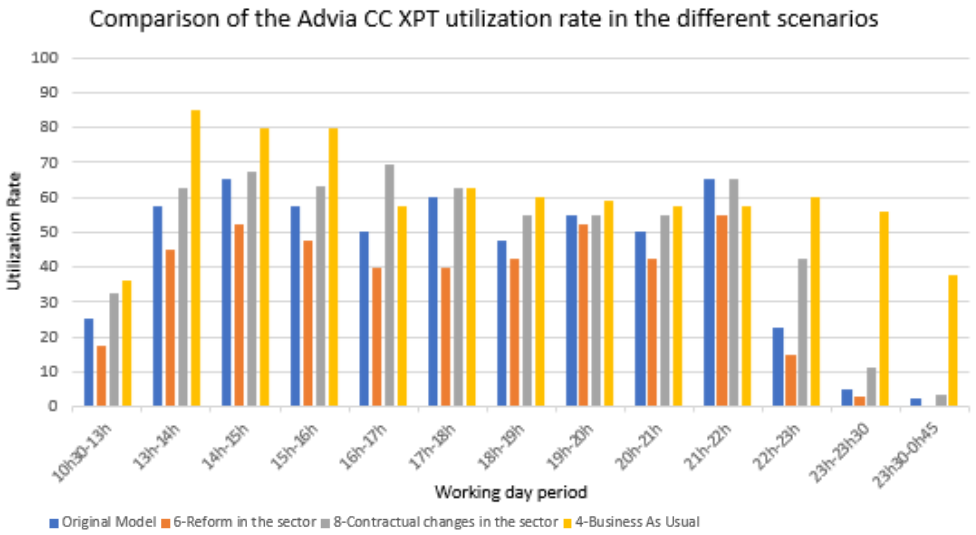

Figure II.1. Utilization rate of the Advia CC XPT analyzers over the various periods of the working day, for the different scenarios.

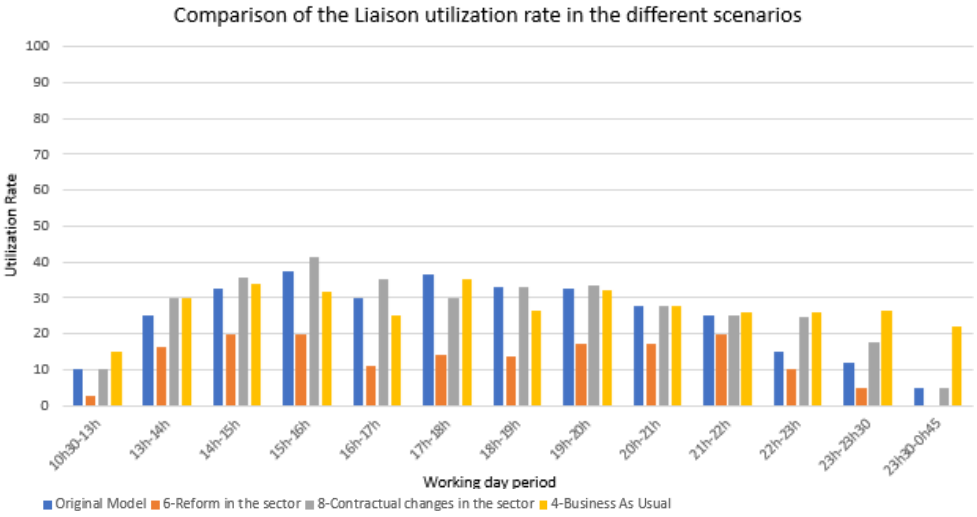

Figure II.2. Utilization rate of the Liaison analyzers over the various periods of the working day, for the different scenarios.

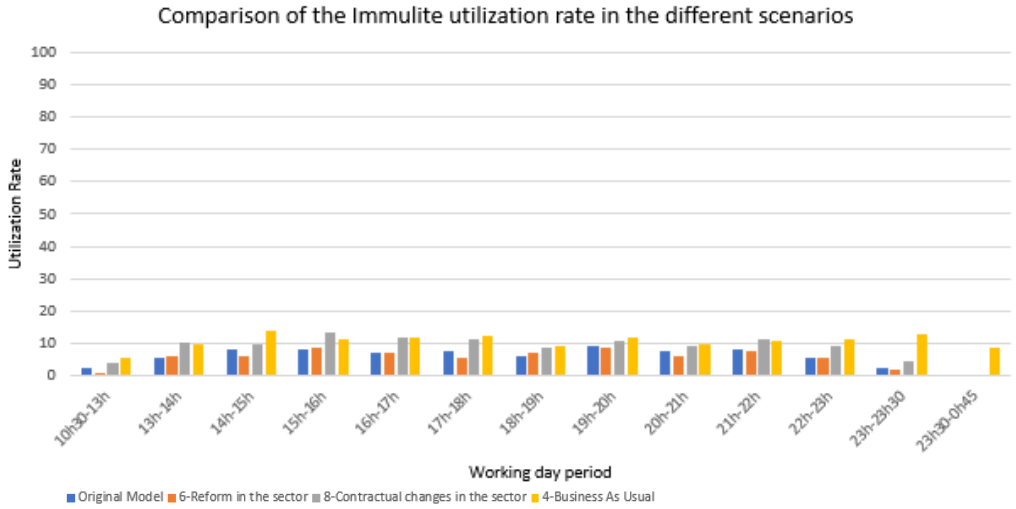

Figure II.3. Utilization rate of the Immulite analyzer over the various periods of the working day, for the different scenarios.