Universidade do Minho
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Risk Management in HIS Interoperability

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Risk Management in HIS Interoperability

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Thesis performed under supervision of
Professor José Carlos Nascimento

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STATEMENT OF INTEGRITY

I hereby declare having conducted this academic work with integrity. I confirm that I have not used plagiarism or any form of undue use of information or falsification of results along the process leading to its elaboration. I further declare that I have fully acknowledged the Code of Ethical Conduct of the University of Minho.

Gestão de Riscos na Interoperabilidade de Sistemas de Informação Hospitalares

Resumo Os sistemas de informação assumem relevância em vários domínios das nossas vidas, tendo um papel inegável em muitas áreas. É o caso da saúde, em que vários sistemas trabalham em conjunto, ajudando os profissionais a dar o melhor tratamento possível aos pacientes. Infelizmente, e muito frequentemente, estes sistemas não cooperam como deveriam devido à falta de interoperabilidade entre eles. A interoperabilidade, apesar de necessária, coloca sérios desafios às instituições, aos profissionais de saúde, aos criadores e vendedores de sistemas de informação de saúde e, também, aos pacientes. Para lidar com as ameaças que surgem das interfaces de interoperabilidade, é necessário identificar essas ameaças e quais as ferramentas a usar para as tratar.

Este projeto de investigação segue uma abordagem denominada "Design Science Research". Esta abordagem permite a pesquisa de um artefacto técnico para tornar as interfaces de interoperabilidade mais robustas. Os principais fatores de risco relacionados com estas interfaces foram identificados e avaliados, para permitir focar a pesquisa. Foi criado um artefacto para monitorizar o estado das interfaces de interoperabilidade mais relevantes, comunicando esse estado a um servidor central. No fundo, o artefacto funciona como uma tática de resposta ao risco, que implementa conceitos da Observabilidade dos Sistemas Distribuídos.

A instanciação do artefacto ocorreu em 6 instituições médicas. O artefacto de monitorização envia alertas de comportamentos incorretos, como era esperado. As anomalias são detetadas mais rápido, permitindo diminuir o tempo de inatividade das interfaces. Durante o desenvolvimento deste artefacto também foi adquirido conhecimento significativo. Estes resultados são um primeiro passo para responder mais apropriadamente aos riscos inerentes das interfaces de interoperabilidade. Esta pesquisa ajuda a validar os princípios de Observabilidade como uma estratégia de gestão de risco viável neste contexto. Esta estratégia poderá ser expandida para outros riscos que venham a ser identificados.

Palavras-chave: Design Science Research; Gestão de Risco; Interoperabilidade; Sistemas de Informação na Saúde

Risk Management in HIS Interoperability

Abstract Relevance of information systems spans across multiple domains of our daily lives, playing an undeniably role in multiple areas. Such is the case of healthcare, where multiple systems work together, helping professionals provide patients with the best care possible. Unfortunately, more often than not, these systems do not cooperate as well as they should, due to lack of interoperability. Interoperability, although necessary, poses serious challenges for institutions, their staff, health information systems vendors and developers and, ultimately, patients as well. To handle threats arising from interoperability interfaces, it is necessary to identify this threats and what tools could be used to tackle them.

This research project assumes a Design Science Research approach. This paradigm allowed the search for a technical artefact to make Interoperability interfaces more robust. Major risk factors related to these interfaces were identified and scored, allowing a focused research effort. An artefact was created to monitor the state of relevant interoperability interfaces, communicating this state to a central server. In essence, the artefact works as risk response tactic, by implementing concepts of observability in distributed systems.

Artefact instantiation occurs in 6 medical institutions. The monitor artefact sends alerts for erroneous behaviour, as expected. Anomalies are detected much quicker, allowing for less downtime. Significant knowledge was also gathered while developing this artefact. These results are a first step towards responding more appropriately to the inherent risks of interoperability interfaces. This research helped to validate observability principles as a viable risk handling strategy in this context. This strategy ought to be expanded for other identified Risks.

Keywords: Design Science Research; Risk Management; Interoperability; Health Information Systems

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Acronyms

ACSS Administração Central do Sistema de Saúde. 8, 11

DSR Design Science Research. 51, 53–55, 70, 92

EHII European Health Information Initiative. 7

EHR Electronic Health Record. 7, 8

FHIR Fast Healthcare Interoperability Resources. 10

HIS Health Information Systems. 3, 5–11, 18, 19, 21, 73

HL7 Health Level 7. 10, 17

IGIF Instituto de Gestão Informática e Financeira da Saúde. 9

IS Information Systems. 5, 8–11, 32, 51, 70

ISO International Standardization Organization. 21

IT Information Technologies. 9

LIGHt Local Interoperability Gateway for Healthcare. 10

PMI Project Management Institute. 21

SAM Sistema de Apoio ao Médico. 9, 10

SAPE Sistema de Apoio à Prática de Enfermagem. 9, 10

SINUS Sistema de Informação para as Unidades de Saúde. 9

SNOMED-CT Systematized Nomenclature of Medicine Clinical Terms. 17, 18

SNS Serviço Nacional de Saúde. 8, 9

SONHO Sistema Integrado de Informação Hospitalar. 9

SPMS Serviços Partilhados do Ministério da Saúde. 3, 8–11

1 Introduction

This introductory section entices the reader to dive into the topics of this research initiative. We offer a prelude to the importance of this subjects, as well as the research problems and goals.

1.1 Information Systems and our daily lives

Information systems are ubiquitous on today's society, playing a major role on our daily lives, more often than not, without our acknowledgement. Not only we might be unaware that we interact with information systems daily, but also to the fact that most of the times information systems do not exist in a vacuum, interacting with one another seamlessly.

As an anecdotal example, this seamless integration as long been achieved in banking and financial institutions. For instance, when you're paying for your morning coffee with a debit card, multiple stakeholders and their information systems are involved: you card issuer, the payment broker that runs the payment terminal, your bank, the retailer's bank, and so on. The next customer in line might be using a credit card from a completely different issuer or bank or even using their smartphone to pay and the transaction will flow much in the same way.

Certainly more critical than banking, healthcare is also heavily dependent on information systems. Patients, the most central figure in healthcare, do not actively set the outcomes or provide inputs for these information systems to function (Cruz-Correia et al., 2012). Nor could they. Yet, the performance, or lack thereof, of this information systems can have dire consequences for patients who rely on healthcare the most.

1.2 How can Health Information Systems coexist?

Healthcare involves a myriad of functions. It should be of no surprise that several distinct information systems are needed to support these functions. Cooperation between systems is of the uttermost importance in enabling health institutions to deliver quality care for patients. In spite of that, this cooperation is not as straightforward as one would expect of such a crucial field (Cruz-Correia et al., 2012).

Data is often fragmented or generated in information systems with incompatible formats, locked down in silos and almost certainly duplicated across multiple organizational structures Cardoso et al. (2018).

Health information systems lack cohesion, the reason being the way in which they we're developed, often constrained by administrative, legal or economic pressures (Pinto et al., 2019).

Ultimately this means that there is risk and uncertainty surrounding the integration of two or more information systems in healthcare. Said risks pose threats not only to the quality of care, but also to health information system's providers who need to circumvent this pitfalls.

Considering a healthcare institution, an environment where multiple information systems coexist and support different functions, it is to be expected that some information has to be exchanged between them, however difficult this might be. To this cooperation between systems we call interoperability.

1.3 How are health information systems vendors affected

Health Information Systems vendors face the challenges of interoperability on a daily basis. Keeping track of the status of the existing interfaces takes time and diverts human resources. Even if it was feasible to constantly monitor system statuses manually, problems not immediately apparent to human eyes are bound to happen.

It is not a matter of *if* issues regarding interoperability interfaces happen, it is a matter of *when*. And when problems do happen, the response should be timely. Solving these issues in a timely manner ensures that users who depend on our information systems suffer little to no hindrances to the tasks they need to perform.

ST+I, a software company located in Vila Real, Portugal, is currently one of the many healthcare information systems vendors operating in the Portuguese market. It develops and provides hospitals, mainly within the public healthcare system, tools that support medical functions such as prescription, pharmaceutical validation and administration of drugs to patients, chemotherapy treatments, among others. Its software package also supports administrative activities such as purchasing, logistics and infrastructure management. Naturally, its solution does not cover 100% of the information systems' needs a typical hospital has. Being one among many, it too faces the obstacles related to interoperability.

1.4 Objectives

Interoperability is a critical aspect of Health Information Systems (HIS), being cited by Pinto et al. (2019) as a backbone of Serviços Partilhados do Ministério da Saúde (SPMS) data strategy. Simultaneously, interoperability is a major risk factor for Health Information Systems (HIS) vendors. These reasons led to define a set of the objectives for this thesis.

First, to enlighten how safer interoperability can be achieved, through the optics of risk management, by exploring monitoring mechanisms in interoperability interfaces.

Secondly, make use of those mechanisms so that faults with interoperability interfaces are easier and faster to detect, diagnose and solve. Consecutively, a more efficient troubleshooting of said interfaces should improve service levels, client satisfaction and, ultimately, safer and more efficient healthcare for patients.

This dissertation sets the path to scrutinize how the implementation of risk management initiatives affects interoperability interfaces between health information systems. A pragmatic approach will be used in the search for practical solutions, not disdaining scientific rigour and theoretical knowledge (Hevner, 2007). Design Science Research shall be the basis for this research. The proceedings from this project should hopefully help ST+I's interoperability team mitigate the threats they identify in their day-to-day operations.

On a personal note, my personal objectives are to explore concepts and ideas related to healthcare and it's information systems and their state of the art.

1.5 Document Structure

Introduction This document is structured in seven sections. The current section expresses the problematic of healthcare information systems and how they coexist. Main objectives and expected results of this thesis are presented to the reader. The structure of the document is also put forward.

Literature Review The following section is dedicated to the literature review that was necessary to write this thesis. Three main fields of knowledge were explored in order to better understand the problematic at hands. These fields of knowledge are:

- Healthcare Information Systems
- Interoperability
- Risk Management

Methodology and Research Tools After the literature review, the methods and tools necessary in order to achieve the proposed objectives are explored and explained. The research rationale is established and the relevant decisions to the development of this project are explained.

Results Description The fourth section describes the results accomplished, both as prescriptive and descriptive knowledge.

Results Evaluation Closely related to the previous, this section discusses the evaluation process of results accomplished, at different stages.

Discussion Given the results and knowledge acquired during the literature review, all the necessary conditions are gathered in order to provide meaningful insights about the work developed. This insights include lessons learned, how successful were the results and also relevant notes and recommendations for future work. Any shortcomings are also exposed.

Conclusion Final remarks, implications of the research and an overview of this research project are presented.

Bibliography List of bibliographic references.

2 Literature Review

This section expresses the state of the art, regarding the three main knowledge domains identified for the research problem. These domains are Health Information Systems, Interoperability and Risk Management.

2.1 Health information systems

2.1.1 Introductory digest

Information systems are the organizational structures responsible for collecting, processing, storing and transmitting information (Alter, 1999). These structures are not only comprised of technology but also the people who use them and the roles they perform. Information Systems are ubiquitous in our society and, understandably, play a major role in Healthcare (Cruz-Correia et al., 2012; Haux, 2018). For example, throughout the duration of a patient visit, practitioners generate vast amounts of medical data regarding said patient. This data can be diagnosis data, such as x-rays, blood pressure measurements or heartbeat rates. Somehow, this data needs to be stored and eventually processed, thus becoming information. The use of this information in a given context, namely decisions regarding treatment plans or future medical procedures is essential for the quality of care patients ought to receive. The scope of an Health Information System goes beyond patient treatment, as administrative functions such as billing and budgeting also require informed and timely decisions (World Health Organization, 2012; Winter et al., 2011).

Advances in HIS have been observed, pushed by the evolution of IS themselves and by changes in healthcare patterns. Both this driving forces contribute to a paradigm shift, from institution base information, to patient centered information (Haux, 2018).

Until the 2000's, care units worked as standalone providers, each solving their own problems independently (Cruz-Correia et al., 2012). Pacient records would be recorded and updated, by medical staff, on institution centred databases (Teixeira et al., 2021).

After the 2000's, a more patient centred paradigm in healthcare required "wider perspectives and organizational models that foster integrated health networks and discourage isolated health units" (Cruz-Correia et al., 2012, p. 1). At this stage, health services become more personal, resources are rationalized and wellness promotion focuses on prevention (Javaid and Haleem, 2019).

In addition to HIS intended for use by healthcare professionals, we are now before an era in which patients contribute to their medical records. Data gathered by bio-sensors, wearables and remote monitoring of vital signs complements data recorded within healthcare institutions (Teixeira et al., 2021). This data can be used to enhance patient's quality of life, allowing for self management of health parameters and alert next of kin for life-threatening situations (Silva et al., 2019).

The development of HIS is hindered when applications, with noble goals of helping physicians in their job, are built as silos. Information silos have little impact on their environment (Cardoso et al., 2018). HIS need to cooperate in order to achieve their full potential in improving quality of care (Cruz-Correia et al., 2012). Reaching this goal requires interoperability (Temmar et al., 2017; Estrela et al., 2019), a step towards true integration (Estrela et al., 2019). Challenging times await HIS: better understanding and coordinated efforts among stakeholders is necessary to establish national, international and interinstitutional HIS architectures (Cruz-Correia et al., 2012).

2.1.2 The role of HIS in the European Union

A communication from the Commission (2018), on the digital transformation of healthcare, states the importance of HIS for the improvement of the care provided to patients and benefits in disease prevention and healthier societies. The findings from this report will be explored in the following paragraphs.

Healthcare reforms and innovative solutions are needed so that more effective and accessible care is provided to European citizens. The digitalization of health can be a driver for this reforms. Purpose built and cost-effective digitalization of healthcare has the potential of increasing the well-being of millions of patients, supporting continuity of care across EU member states borders. Digitalization of healthcare data can play a role in preventing disease and the transition to more patient-centred healthcare models. Better access to health data facilitates research and scientific work. Data is, as such, a decisive factor in the digital transformation of healthcare.

Although the importance of medical data is undeniable, its heterogeneity in form can be a hindrance. Data is often not managed consistently within the Member States' healthcare systems, much less across borders. Not only is data fragmented but also mostly inaccessible. Patients, medical professionals, researchers, even public authorities see themselves gated from this valuable resource. This obstacles can be attributed to market fragmentation and, more importantly, to lack of interoperability.

Medical data is fragmented, stored in incompatible formats and, more often than not, outright inaccessible. Naturally, privacy constraints are to be accounted, but the value of making medical data more accessible is unmeasurable.

The adoption of standard digital solutions for healthcare remains low, varying across Member States. The European Commission recognizes that further action is necessary to boost the use of digital solutions in public healthcare. Considering the importance of digitalization, the European Commission identified three major areas of action:

- Secure access to health data for citizens and the ability to share that data across borders;
- Improve data quality for the advancement of research, disease prevention and personalized care;
- Provide digital tools for citizen empowerment and person centred care.

A public consultation carried out by the Commission (2018) made the need for further efforts in digital healthcare. The consultation identified issues related to the access to health data, heterogeneity in health records, lacklustre interoperability and concerns related to the safety, security and quality of data. Respondents considered that developing EU-wide data quality standards, standardization of health records and better interoperability through open formats should be the priorities of the EU.

Regarding this issues, the European Commission intents were to mobilize funding from the Connecting Europe Facility and Horizon 2020 programmes for the development of an European EHR exchange format and of the eHealth infrastructure. The European Commission considers that, for health systems to achieve their wider objectives, digitalization is the way forward. Nevertheless, this digitalization should be patient centred, servicing the needs of people and carefully implemented to fit specific local contexts.

A report by the World Health Organization, Regional Office for Europe (2018) underlines harmonization and interoperability of HIS as actionable objectives. An initiative for this domain, the European Health Information Initiative (EHII), is established. The EHII is a multi-partner initiative and coordinates HIS research and knowledge translation to all its member-states. Through this platform, member-states can evaluate their own national HIS and develop strategies for the optimization of current undertakings (World Health Organization, Regional Office for Europe, 2020). Besides this initiative, others with similar objectives exist. For instance, InfAct - Information for Action, a 36 months project launched in 2018, funded

by the European Commission, focused on searching for sustainable infrastructure for HIS in the EU and building political support for such initiatives (InfAct, 2022).

HIS are dissimilar across EU member-states. Progression of IS developed for healthcare also happen at a different pace. Nonetheless, the issues faced are much the same (Bogaert et al., 2021): fragmented data sources; sparse accessibility; usability and reusability of data; constraints in implementing Electronic Health Record (EHR) systems; governance and legal gaps; insufficient funding; weak inter and intra-sectorial collaboration and shortage of skilled professionals. Such barriers can be tackle at national level, but joint European effort would be considerably more valuable (Bogaert et al., 2021). In recent times, the Sars-CoV-2 global pandemic required swift adaptation of HIS. The need to rapidly and accurately transmit COVID-19 related data arises (Negro-Calduch et al., 2021) and inequalities across HIS, within and between countries, are exacerbated. This event confirmed, like never before, the flaws in HIS (Schmidt et al., 2021).

Struggles experienced during the most recent global pandemic support prior observations about the weaknesses of HIS (Schmidt et al., 2021). Broader cooperation and better health information exchange are needed (World Health Organization, Regional Office for Europe, 2018). International strategies should be established to promote tools that allow for highly integrated health platforms across countries (Saigí-Rubió et al., 2021).

2.1.3 Portuguese perspective on HIS

In Portugal, as in other EU member-states, HIS have been evolving. However, the rate at which this development occurs seems lower (Rocha, 2009). Similarly to studies carried out in other countries, the main issues health and IS professionals from 7 Portuguese hospitals report are lack of central guidance and planning and lack of interoperability and integration (Cruz-Correia et al., 2012).

The governmental branch responsible for central leadership and planing national health policies is the Ministry of Health - Ministério da Saúde (XIX Governo Constitucional de Portugal, 2011, Artigo 1.º). The Ministry of Health is, among other responsibilities, accountable for the regulation, planning, funding, guidance, evaluation and auditing the Serviço Nacional de Saúde (SNS), the Portuguese public healthcare service (XIX Governo Constitucional de Portugal, 2011, Artigo 2.º). The Administração Central do Sistema de Saúde (ACSS) is responsible for managing financial and human resources, facilities and equipments for the SNS. Through the Serviços Partilhados do Ministério da Saúde (SPMS), ACSS is responsible to make IS and HIS available for use within the SNS (XIX Governo Constitucional de Portugal, 2011, Artigo 14.º).

SPMS was founded in 2010 (XVIII Governo Constitucional de Portugal, 2010). As the responsible entity for IS and Information Technologies (IT), SPMS has been pushing for the digital transformation of the SNS (de Matos and Nunes, 2018).

Long before the inception of SPMS, technological solutions already existed in public hospitals. Such is the case of the Sistema de Informação para as Unidades de Saúde (SINUS) and Sistema Integrado de Informação Hospitalar (SONHO), created by the now extinct Instituto de Gestão Informática e Financeira da Saúde (IGIF), in the early to mid 1990's (Espanha, 2013). SINUS was responsible for managing patient identification, through the now also obsolete SNS patient card, contacts, vaccination and appointment scheduling. This administrative HIS was implemented in the majority of local health units. SONHO, on the other hand, was geared towards hospitals, but both supported a basic management of patient flows. Growing needs from these institutions mandated the design and implementation of other modules in SONHO, to cover the needs in emergency wards, inpatient and ambulatory care and billing (Administração Central do Sistema de Saúde, 2010).

By turn of the millennia, SINUS and SONHO were staples of SNS hospitals and local health units daily operations. Healthcare professionals, however, saw this systems as unfitted for their needs. This feeling was especially true for physicians (Espanha, 2013). At the same time, the HIS needs kept growing in institutions and this solutions' obsolescence was clearer everyday. By 2002, two new modules entered testing in some hospitals (Espanha, 2013). These are Sistema de Apoio ao Médico (SAM) and Sistema de Apoio à Prática de Enfermagem (SAPE). SAM is intended for use by physicians and covers patient's records and electronic prescription. Similarly, SAPE end users are nurses, allowing the recording of performed nursing practices. Frail political stability from 2002 to 2005 made the roll out of this solutions difficult (Espanha, 2013).

SONHO and SINUS where eventually superseded by its version 2 and SONHO-CSP, respectively. SONHO v2 responds to the technical needs expressed by institutions over the years, having new features and better scalability. Noteworthy are the adoption of a new integration layer, in line with a service oriented architecture. SONHO-CSP uses the same architecture and data models, aligning processes among local health units and hospitals. The replacement of SONHO version 1 is still in progress (SPMS, 2019d, 2020c).

Strategic IT planning from the Ministry of Health for the SNS predicts uniformity of processes in clinical records, normalizing healthcare information. A new HIS developed by SPMS called SClinico appears

around 2014 exactly for this purpose (Pavão et al., 2018). SClinico aims at replacing SAM and SAPE (Pavão et al., 2018). The philosophy behind SClinico is of a single application, focused on patients and common for all healthcare professionals. Currently, this HIS is present in 50 public sector healthcare institutions and is used by roughly 75% of staff, corresponding to an average of 66500 end users (SPMS, 2020b). A version tailored towards local health units also exists, SClinico-CSP (SPMS, 2020a).

Efforts have been made to keep SClinico in line with the needs of public sector healthcare institutions. New features targeted to other classes of health professionals have been created. For instance, profiles for radiology technicians (APMIR, 2016) and psychologists (SPMS, 2019b) have been added. Despite continuous efforts and evolution, usability issues are still being reported by the professionals in the field (Pavão et al., 2018). Concerns about the quality of the information presented to users exist as well (Pinheiro, 2018).

The information quality issue can be attributed to lack of interoperability. Different systems and applications keep being used, often having little or null integration (Pinheiro, 2018). Interoperability deficit is pointed as an obstacle for the evolution of eHealth, to be solved by implementing standards for data collection and exchange, across all branches of public healthcare in Portugal (SPMS, 2015). In this effect, in 2017 an integration bus that manages interfaces viably, is standardized and highly configurable, was created. Local Interoperability Gateway for Healthcare (LIGHt) is a middleware platform for intra-institution interoperability, created by SPMS (SPMS, 2017). Communication is done via HL7 v2.5 messages and, with a central system, via HL7 FHIR. According to SPMS (2017), LIGHt addresses the four interoperability layers: legal, organizational, semantic and technical. SPMS (2019c) iterates a 66% installation rate of the LIGHt platform across public hospitals. Results are positive, with information from other sources becoming available, thanks to interoperability. Local Interoperability Gateway for Healthcare (LIGHt) made it possible that patients' diagnostics, allergies, chronic conditions and vaccination plan are all available in a single user interface (SPMS, 2019c).

Despite clear advantages more recent solutions have, their adoption is slow and is continuously delayed (Silva and Nascimento, 2021). Contributing factors for this state of affairs are lack of insight about the relevance of HIS hospital administration boards have, insufficient funding and lack of properly trained IS professionals in institutions (Silva and Nascimento, 2021). A recent study where multiple key stakeholders - ranging from public healthcare administrators to patients and governmental entities - were interviewed, concluded that the implementation of HIS in Portugal happens at different paces, depending on the specific

area of responsibility, what sectors are involved and legal statutes of the organizations (Teixeira et al., 2021). Healthcare professionals also have their schisms: while admitting that technology brings greater efficiency, making processes such as diagnosis and treatments more agile; professionals fear for the degradation of doctor-patient relationships (Teixeira et al., 2021). Such frictions can have an impact on the modernization of HIS. Fortunately, as professionals' awareness of the importance of HIS in their functions rises, these reservations diminish (Silva and Nascimento, 2021).

Besides institutional factors, indefinition about the operational reach of central organism and what could potentially be offered by the market, creates an unfavourable environment for the evolution of HIS in Portugal (Teixeira et al., 2021). SPMS acts as regulatory body and a services provider, generating vagueness when defining strategies and what the roles government, hospitals and the free market play (Teixeira et al., 2021). A possibility is to transfer regulation responsibilities to the jurisdiction of ACSS. This solution would enforce separation of concerns between the two governmental bodies, making it easier for market players to position their proposals and present solutions for the improvement of HIS (Teixeira et al., 2021).

At the moment, an initiative for contextualizing the roles of the different stakeholders in the public health-care ecosystem in Portugal is taking place (SPMS, 2019a). Objectives of the ENESIS 2020-2022 initiative include creating a set of best practices, improve the delivery of new benefits and optimize resources (SPMS, 2019a). ENESIS encompasses not only the public sector but also private healthcare providers, placing patients at the center of the concerns (SPMS, 2019a). Interoperability is considered a key factor in achieving the mobility of information, making it available to citizens, organizations and professionals (SPMS, 2019a). ENESIS aligns with the recommendations and guidelines pointed by Commission (2018) on the goal towards an European HIS single market.

2.1.4 Observability of distributed systems

In this part, a primer on Observability will be given. Observability is not exclusive to interoperable HIS but useful nonetheless: an integrated HIS can be seen as a distributed system composed of many other connected subsystems.

Observability is the degree to which the state of complex systems can be observed by its outputs. The concept was first coined by Kalman (1960). For IS, particularly distributed Information Systems, the concept of observability refers to tools and procedures for analysing performance data from a distributed

application (IBM, 2021). In theory, the more observable a system is, the faster it is to reach the root cause of any given problem (IBM, 2021).

Observability tools are used to collect and signal telemetry data from individual components of a distributed system. The four pillars of Observability are (IBM, 2021):

- Logs: granular and immutable records of timestamped events;
- Metrics: numeric data, usually displayed displayed over a timespan, such as memory usage, CPU capacity or latency;
- Traces: records the end to end trip of requests made by components of the system, through its architecture;
- Dependency maps: displays how each component relates to one another.

Observable systems are easier to understand, monitor, diagnose and restate to working condition (IBM, 2021).

2.2 Interoperability

2.2.1 Defining interoperability

First and foremost, it is important to define what interoperability is. While there is no single agreed upon definition of interoperability and any given definition can be highly context-specific (Palfrey et al., 2012), generally speaking, interoperability is the ability for two or more systems to exchange data, allowing cooperation between them (ISO 73, 2009).

Regarding the health sector, interoperability is the ability for information systems to collaborate with one another. This systems can be either software or hardware and should perform seamlessly together, despite their differences,S thanks to interoperability. This seamless operation between healthcare information systems should help hospitals, clinics and other facilities to provide patients with the best care possible. Patients, healthcare institutions, their staff and information system suppliers are all potential stakeholders in the health interoperability ecosystem (HIMSS, 2020). Currently, interoperability is more a requirement for HIS rather than an option (Cardoso et al., 2014).

2.2.2 The importance of interoperability in healthcare

The importance of interoperability can be assessed on different vectors. Considering that modern healthcare depends on teamwork and communication, interoperability is needed to provide information when and where it is needed (Cardoso et al., 2014, 2018; Espanha, 2013; Jardim, 2013; Rocha, 2009). Interoperability allows for quicker and better decision making, less repetitive work, thus improving the efficiency of healthcare professionals and, more importantly, improved safety for patients (Benson and Grieve, 2016). We'll be taking into account the importance of interoperability for three major parties interested in the success of healthcare: patients, staff (doctors, nurses and assisting personnel) and finally, institutions.

For patients The most central figure in healthcare should always be the patient. In an environment such a healthcare institution where multiple informations systems coexist, information must flow effortlessly between them. Otherwise, patient data ends up living on information islands, never to be accessed from the outside world. That being said, interoperability is a major factor in achieving a truly integrated electronic healthcare record, thus liberating clinical data across wards and potentially institutions (Aspden et al., 2004). The existence of an integrated electronic health record is the deciding factor in allowing for continuity of care and a multidisciplinary approach to health. The single doctor-patient relationship is giving way to one where a team of professionals in different fields is responsible for a patient's health (Tsiknakis et al., 2002). Potential benefits of higher quality of care, patient service and satisfaction are difficult to quantify. However, HIS can definitely reduce medical errors, contributing for the improvement of healthcare (Erstad, 2003).

For staff Given the mobility of patients between services and institutions, their medical data should be available wherever they are. If this data is not available, healthcare professionals are faced with additional challenges when deciding the most appropriate care the patient needs (Pinheiro, 2018). Lack of information concerning previous hospital visits, adverse drug reactions or allergies poses major risks for patients. Doctors need this data in order to make educated decisions about their patient's health. In fact, healthcare professionals seem optimistic about the advantages of HIS (Grabenbauer et al., 2011; Silva and Nascimento, 2021). For instance, Pinheiro (2018) considers easy data editing, faster information transmission, archiving and backup capabilities points in favor of HIS. Despite undeniable advantages, HIS are also sources of frustration for the professionals who depend on them the most. Some of this drawbacks include clunky and unfriendly user interfaces (Grabenbauer et al., 2011), redundancy in data

entry and difficulties in making information available for other professionals within or beyond the walls of institutions (Pinheiro, 2018). These two issues stated by Pinheiro (2018) can be attributed to lack of interoperability. Interoperability means doctors and other medical staff can work more efficiently and provide better quality care (Lehne et al., 2019).

For institutions Resources and budgets are limited. Considering a free (for the most part) public healthcare system, like the Portuguese Serviço Nacional de Saúde is, a well balanced resource management is essential. Despite the fact that implementing interoperability interfaces between systems are costly, the net gain of doing so can be positive (Wang et al., 2003; Walker et al., 2005). Interoperability frees up essential resources by reducing the amount of duplicate work. A more efficient use of resources means better quality healthcare and more people being treated (Pinheiro, 2018).

2.2.3 Interoperability categories

In the healthcare domain, interoperability can be studied on three different branches (Dogac et al., 2007), to be described in the following paragraphs.

Interoperability of messages In order to exchange clinical information between systems, messaging interfaces must be implemented. This messaging interfaces are responsible for collecting, encoding and transiting data over the network to another application. This applications should conform to a messaging standard. The most common messaging standard is HL7 (Dogac et al., 2007). Interoperability of messages will be the main focus point of this thesis.

Interoperability of electronic health records Electronic health records are, in essence, collections of clinical data about a patient's lifetime in a document structure. Interoperability of electronic health records support continuity of care across different services and healthcare providers (Moreno-Conde et al., 2015). Similarly to messaging interfaces, this document structure also need to comply to a standard (Dogac et al., 2007).

Interoperability of patient identifiers, coding terms and healthcare business processes Patient identifiers, coding terms and healthcare business processes can be summarized in two words: medical ontologies. In order for systems to cooperate, there needs to be a common understanding of what the exchange data means, even if different wording or language is used. However, the obstacle is not the usage of a single nomenclature system, is that multiple ontologies are available (Thiel et al., 2007). Some

examples of systematized medical nomenclatures include SNOMED CT, LOINC and RxNorm (Bodenreider et al., 2018).

2.2.4 Levels of Interoperability

According to HIMSS (2020), interoperability initiatives can be measured at 4 different levels:

- Foundational - level 1: basic requirements for medical data exchange are met; a communication protocol has been established between information systems.
- Structural - level 2: data formats and structure have been defined; information systems are able to interpret the data exchanged.
- Semantic - level 3: the definition of the data fields is standardized and data is coded using publicly available vocabularies; there is shared understanding of data by the people who use it.
- Organizational - level 4: governance and data exchange policies are implemented, legal and organizational considerations are taken into account while delivering an interoperability initiative; there is trust in data shared between systems.

We can summarize the first 3 levels as technical considerations: how data flows from one information system to another, how it's structured and what it means. However, an interoperability endeavour can only achieve it's full potential by collective efforts between decision makers, healthcare information systems suppliers and bodies of knowledge. The full potential of interoperability is data that can be trusted across multiple platforms and stages of a patient's stay at a healthcare institution. The fourth level of interoperability, although the hardest, should be the goal to achieve by hospitals and its information systems vendors. Currently, even the third level, semantic interoperability, remains an elusive goal, as cultural, social and politic challenges are far more difficult to solve than technical issues (Ashrafi and Kuilboer, 2018).

Palfrey et al. (2012) also proposes a four layer approach to interoperability, as follows:

- Technological layer - layer 1: systems connect with one another on a explicit and agreed upon interface; we can think of this layer as the infrastructure that allows communication between systems.
- Data layer - layer 2: systems are able to understand data received from a foreign system; this layer is highly intertwined with the first layer, in fact, if a system cannot understand the data it has received, interoperability between them is for all intents and purposes worthless.

- Human layer - layer 3: more that exchanging information between systems, it is necessary that humans at each end of the communication spectrum understand each other and agree on what the data exchanged means; there needs to be a common language and a set of terminologies used and, more importantly, both parties should invest equal efforts on working together
- Institutional layer - layer 4: the highest and most abstract layer, allows for two different entities, as in two information system vendors, to cooperate; it does not mean that both entities operate on the same rules, rather that there must be some common ground between them so that their interests are assured.

While stemming from different backgrounds, both perspectives score the same concerns equally. There is a one-to-one match between the layers/levels proposed by both sources. One can then conclude that the issue of interoperability is not exclusive to the healthcare domain. Furthermore, interoperability is as much as a technological problem, as it is cultural and societal (Palfrey et al., 2012).

2.2.5 Existing Standards

Complying to standards promotes exchange and substitutability of components in a system. Standardization promotes competition and interoperability across system's borders (Kubben et al., 2019), thus enabling market forces. Interoperability not only prevents vendor lock-in, but also forces market players to adapt and to compete in providing better HIS. Adoption of standards can be the result of driving market trends - industry standards - or regulatory bodies and governance initiatives - *de jure* standards (Kubben et al., 2019).

Data can be seen as an abstraction of real objects or entities in information systems. Knowledge is necessary in order to further process and interpret this data. This knowledge exists only due to a shared and agreed upon representation of reality (Kubben et al., 2019). Simply put, knowledge to understand data requires consensus: it requires standards.

The notion that common understanding of data (i.e. standards) is fundamental to interoperability is well clear in 2.2.4. Both the approach by HIMSS (2020) and Palfrey et al. (2012) share the idea that a common set of definitions that describes data is essential for achieving interoperability.

Another common line of thought between HIMSS (2020), Palfrey et al. (2012) and Kubben et al. (2019) is that interoperability and adoption of standards needs to happen not only at a technical level but also

at social and organizational levels: people and the business processes they perform must be taken into account and involved in a interoperability initiative.

Kubben et al. (2019) also refers the importance of auditing systems and their claimed conformance to standards: developers and systems vendors should be able to demonstrate that their implementations conform to the specifications of any given standard.

Integrating the Healthcare Enterprise (IHE) is an initiative dedicated to developing solutions for a better interoperability in HIS (Rhoads et al., 2010). IHE also promotes the use of standards, like HL7. Bellow a summarized view of HL7 and SNOMED-CT and their scope is exposed. The first one being the most common message exchange standard for HIS (Dogac et al., 2007). The second, SNOMED-CT, is a clinical terminology. In terms of terminology, many others do exist, but SNOMED-CT stands out as a concise clinical data representation (Cardoso et al., 2014).

HL7 The Health Leven Seven International (HL7) is a non-profit organization founded in 1987. The 7 refers to the application layer, the seventh layer of the OSI model. Initial versions of the HL7 standard where essentially syntactic, being a communication protocol that loosely defined message structures. These messages are classified according to the medical process they communicate and associated events. The message structure depends on the message type but shares common characteristics (Cardoso et al., 2018; HL7, 2022b). The most widely used version of HL7 is version 2. Several iterations of version 2 have been launched through the years. Version 2 is widely adopted, used in 95% of healthcare institutions in the US and implemented in 35 countries. For this reason, it continues to be developed alongside version 3 and, more recently, HL7 FHIR (HL7, 2022a). The main goal of HL7 is to provide a comprehensive framework and support standards for interoperability (HL7, 2022b).

HL7 encoded messages consist of data fields, variable in length and separated by a field separator character. Typically, the field separator used is the "pipe" character (ASCII character 124). A set of data fields, logically grouped, is called a segment. Similarly, segments are also separated by a pre-defined character, which is part of the standard. The segment delimiting character is the "carriage return" (ASCII character 13). Each segment begins with a three letter identifier. A message is a group of segments in a defined order. As per message specification, segments can be declared mandatory, optional or repeatable (HL7, 2022b).

Messages are exchanged on the premise that an event happening in the real world creates the need for data to flow from one point to another. A given trigger event can only be associated with one message type. However, the same message type can have multiple triggers associated. HL7 tables 0076 and 0003 define the standard message types and trigger events respectively (HL7, 2022b).

The latest standard proposed by HL7 is called FHIR. FHIR stands for Fast Healthcare Interoperability Resources. This new generation of standards builds upon the features of versions 2 and 3, providing much needed improvements. In particular, the use of web technologies, such as XML and JSON for data exchange and the support for RESTful architectures, makes FHIR an interesting proposition for developing modern HIS for the 21st century.

SNOMED-CT Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT) is a comprehensive clinical terminology set that is scientifically validated and regularly updated. SNOMED-CT aids in consistently represent clinical data across HIS, promoting interoperability. This terminology set aims to be universally accepted, covering a wide range of medical specialities and requirements. SNOMED-CT is promoted by SNOMED International, a non-profit organization (SNOMED International, 2022a).

SNOMED-CT is target towards anyone involved in the use, interpretation and management of clinical data. By providing a pre-defined set of clinical metadata, SNOMED-CT enables high quality standardized medical records. Clinical data are recorded using identifiers associated with a set of medical concepts, covering for differences in use of language. SNOMED-CT is hierarchically defined, meaning different identifiers can be use in conjunction and different levels of detail are available for different stakeholders (SNOMED International, 2022b).

SNOMED-CT design includes Concepts, Hierarchies, Atributes, Identifiers, Descriptions and Relations. Concepts represent a single clinical meaning and has a unique numeric Identifier. Identifiers are meant for electronic means and do not have any human perceptible significance. Each Concept also has a set of Descriptions, including fully specified name and synonyms. Synonyms can either classified the preferred or acceptable description. Relationships represent, as the name implies, relations between Concepts. Relationships are defined by Attributes, which also have their unique Identifiers. Several types of Relationships are available in SNOMED-CT.

The advantages of employing standards in HIS are clear: reducing costs related to the development of interfaces, prevents vendor lock-in, reduces risks and improves usability (Lamprinakos et al., 2014).

For end-users and healthcare institutions, the benefits might not be so obvious at first glance. Still, the implementation of such standards is the staring point for broader ambitions (Kubben et al., 2019):

- To improve the outcome of diagnostics and treatments of patients being observed by a multi-disciplinary team of medical staff;
- To support local and national healthcare systems and their business processes;
- To create commercial interest in creating solutions needed by patients, healthcare staff and institutions.

Interoperability in HIS will be an outstanding issue in years to come. Governments and institutions, both public and private, will continue to face the hardships interoperability entails for the time being (Martins, 2015). Many reduce interoperability to standards. This is certainly not the case. Standards are important blueprints and building blocks but social, legal and governance issues should also be accounted.

2.2.6 Hardships in interoperability

Interoperability is hard (Benson and Grieve, 2016). Implementing interoperability interfaces is no easier. Considering that most interoperability capabilities are implemented on a point-to-point architecture, the number of interfaces (expressed by n) grows exponentially with the number of system to integrate, in what is known as a combinatorial explosion:

$$\text{Number of links} = \frac{n(n-1)}{2} = \binom{n}{2}$$

This means that, for example, linking 6 different systems together would require 15 interfaces and 100 systems would require 4950 interfaces (Benson and Grieve, 2016). Developing and maintain such interfaces becomes repetitive and error-prone if there is no common set of standards and tools from which to build upon.

As stated before, interoperability is not only a technological problem, but also cultural, societal and institutional (Palfrey et al., 2012; HIMSS, 2020). Based on the observations of Benson and Grieve (2016), a collection of challenges and roadblocks was identified.

Information not only needs to be processed by computers, but also be read and understood by humans at different ends of the healthcare system. The problem is that this information is far from homogeneous. Natural language can differ between hospital staff in different specialities. Drugs and prescriptions have a multitude of forms and dosages. Names and addresses of patients can follow different rules. It is a challenge to exchange information between systems without compromising its meaning.

One possible solution for the heterogeneity of data is the implementation of standards, however, defining meanings and data formats will often turn into large, complex and poorly comprehended specifications. The complexity and length of this specifications leads to implementation errors. Besides, there is an appreciable amount of gaps, overlaps and competition between different standards (Atalag et al., 2009). Lack of understanding and agreement on standards can cause serious interoperability issues (Campos et al., 2011). Standards alone are not a cure-all panacea.

HL7, especially version 2.x, does not provide an explicit information model, rather vague definitions of what data segments mean. Making matters worse, in HL7, some of this data segments are considered optional. This vagueness, although it provides great flexibility, makes it so that bilateral agreements are needed between system vendors in order to achieve interoperability (Dogac et al., 2007). Message-based interoperability is more suited for a loose coupling of data, where exchanged messages between systems are mere translations of traditional pen-and-paper workflows into digital (Tsiknakis et al., 2002; Dogac et al., 2007). This transcription of traditional processes into digital form means message-based interoperability is only suited when the number of communications between systems is low and that it does not provide a true solution for the need for a transparent access to an integrated electronic health record (Tsiknakis et al., 2002).

Users and vendors are usually in full agreement until the system is deployed. This stems from the fact that users seldom understand what is and what is not possible in the development life cycle of a product. Expectations are set high, reality often disappoints. Information systems vendors are not innocent either, as managers try to squeeze the existing platforms and functionalities into the user's requirements. Vendors often lack specialized knowledge of the healthcare domain, thus failing to realize what it is exactly that users want. This means that the solutions put in place are often amalgamations of poorly defined software. If this solutions are not well specified internally, it's highly doubtful they will integrate well with other existing solutions.

Interoperability implies coexistence and autonomy in a federated environment, while integration implies coordination, coherence and uniformization. A tightly coupled system is composed of several interdependent components. Such is the case of integrated systems. In the case of interoperability, components are loosely coupled, connected via network, having the ability to interact (Chen et al., 2008). As stated by (Chen et al., 2008, p. 648), "two integrated systems are inevitably interoperable; but two interoperable systems are not necessarily integrated". Interoperability can be a path towards truly integrated HIS. In clinical processes, integration is still lacklustre and done mainly at the presentation level: users have to switch between applications for accessing information. Preferably, users would have the possibility of accessing said information seamlessly, independently of where it is gathered from (Pinto et al., 2016).

2.3 Risk management

2.3.1 What is risk

Risk Management is a key task in project management. Willumsen et al. (2019) conducted a literature review and empirical study on how professionals perceive project risk management and consequent value creation. Willumsen et al. (2019) found that the literature on the subject provide distinct examples on how and what value does project risk management adds. In fact, contradictory perceptions on risk management were found. For instance, the researchers found cases where transparency towards communicating risk would negatively impact the stakeholders' interests. The perception of value creating trough risk management depends on the objectives and circumstances. The findings from this research seem to contribute to the notion that solutions such as the ISO 31000 norm or The standard for risk management in portfolios, programs, and projects by Project Management Institute (PMI) are not a silver bullet for risk management. A final note from Willumsen et al. (2019) states that this frameworks should be tailored to serve the projects needs and objectives.

According to the Project Management Institute (2021), risk is an uncertain event that, if occurs, has either a positive or negative effect on one or more project objectives. Negative risks are called threats, while positive risks are called opportunities. Being that projects are unique ventures, heavily context-dependent and having varied degrees of uncertainty, it is impossible to dissociate them from risk.

In this dissertation, we will consider risk as a threat to the success of an interoperability initiative. Several concepts related to risk management will be explored in this section, matching ideas from the ISO 31000 (2012), Project Management Institute (2019) and ISO 14971 (2007).

ISO 31000 (2012) and Project Management Institute (2019) suggest that risk management should be fostered and embraced in organizations and their business practices. Having risk management as a cornerstone of organizational culture promotes continuous improvement of business processes, a fundamental aspect in the development of sustainable competitive advantages. These competitive advantages in turn contribute for the overall improvement of the organization's performance. Risk management is not a single static activity, but one that should be periodically revisited. The cited frameworks mention several stages for the process of risk management, listed below, while highlighting the importance of approaching this process iteratively.

ISO 31000 (2012) mentions the following key activities in risk management:

- Communication and consultation
- Establishing context
- Risk appreciation
  - Risk identification
  - Risk analysis
  - Risk evaluation
- Handling risks
- Monitoring and revision of risks

Project Management Institute (2019) names the following sequential processes in their Risk Management Life cycle Framework:

- Plan risk management;
- Identify risks;
- Perform qualitative risk analysis;
- Perform quantitative risk analysis;
- Plan risk responses;
- Implement risk responses;
- Monitor risks;

On the other hand, ISO 14971 (2007), a specific norm for risk management in medical devices, proposes requirements for all stages of the life cycle of a medical device, these being:

- Risk analysis;
- Risk evaluation;
- Risk control;
- Evaluation of overall residual acceptability;
- Risk management report;
- Production and post-production information.

Each of the enumerated activities defined by ISO 31000 (2012), Project Management Institute (2019) and ISO 14971 (2007) will be explored below, in increasing specificity.

2.3.2 ISO 31000

Communication and consultation Exchanges between stakeholders, both internal and external to the organization, should occur during all stages of the risk management process. The communication plans regarding risk, it's causes and consequences and what should be done in case said risk occurs, should be developed early in the process. Ensuring good communication is essential for the correct understanding of risk. Communication and consultation should facilitate the exchange of true and relevant information between stakeholders. This activity is essential, since it provides different insights on risk, based on the different perceptions of the multiple stakeholders. In turn, these insights can have significant impacts on the decisions made regarding risk (ISO 31000, 2012).

Establishing context This step serves the purpose of enumerating business objectives, internal and external aspects relevant for risk management.

Establishing the external context in which the organization exists ensures that the external stakeholders and their concerns are taken into account while developing the risk management strategy. The external context of the organization can include social, political, legal, financial or technological aspects, market forces and trends and the relationships with the external stakeholders and their perceived reality and values.

Establishing the internal context ensures that the risk management process is aligned with the organization's culture, values, strategies and objectives. The internal context, in regards to risk management, includes organizational structure, resources available, information flux and decision making processes and any intrinsic aspect capable of undermining a risk management initiative (ISO 31000, 2012).

Risk assessment This activity consists of three sub-activities, namely risk identification, risk analysis and risk evaluation.

Organizations should act to identify risks, potential impacts and specific sets of circumstances that can lead to less than desirable outcomes. A comprehensive list of risks based on the impacts any given set of circumstances have on projects should be created. This list should include risks controllable by the organization but also those which are not (ISO 31000, 2012). According to ISO 31000 (2012), the success of this step is heavily dependent on these factors:

- The use of risk identification techniques and tools aligned with the organization's objectives and capacities;
- The availability of relevant and up-to-date information regarding the project;
- Taking into account any baseline information, when existing;
- Include the people with the appropriate domain knowledge and experiences.

Furthermore, ISO 31000 (2012) establishes that, in order to correctly identify risks, their sources, the events that trigger them and potential consequences should be enumerated.

Risk analysis constitutes an input for risk evaluation. Analysing risk involves taking causes and sources of risk as well as possible positive or negative outcomes a specific risk can have. It is also wise to consider how interdependent risk factors and the sources of said risks are. Considering that uncertainty, different opinions, quality and availability of information can affect the outcome of a risk analysis initiative, this factors should be appropriately expressed. Depending on the severity of the risk at hand, different degrees of detail can be included into this artefact. This artefact can culminate in a qualitative or quantitative analysis or even a combination of both, depending on the context (ISO 31000, 2012).

Risk evaluation is a subsequent activity to risk analysis. With the results of the conducted risk analysis in mind, decision makers can judge how risks should be handled and in what priority. This decisions should take into account how risk-tolerant the project and the organizations involved are, potential benefits in exploring the risks at hand as well as legal and regulatory requirements (ISO 31000, 2012).

Handling risks This risk management activity consists in selecting one or more strategies for risk modification and their implementation. Once implemented, a risk strategy should be assessed for its effectiveness. This activity also should determine if the residual risks after implementing a risk strategy are acceptable and, if not, establish a new strategy (ISO 31000, 2012).

According to ISO 31000 (2012), risk managers have the following strategies at their disposal:

- Avoid the risk, by terminating the risk carrying activity;
- Embrace or elevate the risk, in order to pursue an opportunity;
- Remove the source of risk;
- Work on reducing the likelihood of a risk;
- Work on altering the consequences of a risk;
- Share the risk with a third-party;
- Based on an educated guess, retain the risk.

Selecting any of the strategies listed above is highly dependent on their specific costs and efforts required versus the potential resulting benefits. Furthermore, legal, regulatory or ethical requirements should not be neglected in this decision. Also, the organization can deem more advantageous implementing more than one strategy, either combined or in sequence (ISO 31000, 2012).

Considering that risk often concerns multiple parties, every one of them should be consulted in deciding which risk response strategy to pursue. This stems from the fact that the same risk can affect parties differently. Not only that, but different parties might perceive threats differently, deeming one strategy more adequate than another (ISO 31000, 2012).

The risk treatment plan should set the proprieties for the implementation of the individual risk handling strategies. Also important to consider, is that risk management can also introduce new threats. Failure to identify these secondary threats constitutes a serious hazard. These secondary risks should be taken care much in the same way the primary risks are (ISO 31000, 2012).

The risk treatment plan should document how the threat management strategies were selected and how they will be implemented. Who is responsible for approving the plan and who is responsible for implementing said plan must also be set clear. Technical details such as requirements for implementation, key process indicators and an implementation schedule are also crucial aspects of this plan (ISO 31000, 2012).

Monitoring and revision of risks Monitoring and revision of risks should be part of the risk management plan, to be executed periodically or *ad hoc*. As with the risk handling activity, responsibilities should be clearly set. The monitoring and revision process should include all the aspects of risk management. This process insures the efficiency of the threat controls implemented. Another positive outcome from this initiative is that it helps collecting data for improving the risk assessment process and provides learning opportunities regarding changes, successes and failures. Also important, this exercise provides an opportunity to identify shifts in context, risk criteria and emerging hazards.

2.3.3 Project Management Institute

Plan risk management The risk management plan describes how risk management processes are carried and their relationship with other management processes. This plan should be established as early on as possible. The key idea of this process is that it should be integrated into all project management activities. Nonetheless, as the specific needs of the project's stakeholders change, the risk management plan should be updated. Also worth mentioning is that different stakeholders might perceive risk differently. A stakeholder's risk perception is determined by their ability to sustain the consequences of a risk, should it occur. Naturally, this perception of risk can also differ depending on the overall importance any given business or project objective has. How stakeholders perceive risk is called their risk appetite. Risk appetite is an important influencing factor on how the risk management plan is designed (Project Management Institute, 2019).

In addition to the needs of the parties involved and their risk appetite, project managers ought to balance the costs and benefits of pursuing a risk management plan. That is, allocating excessive resources to any

given risk management strategy is in itself a risk. Conflicting as it may sound, some threats might not be worth the managing effort at all (Project Management Institute, 2019).

In essence, a successful risk management plan should outline what resources are available, how they should be used, how frequently the risk management process should be revised and, most important, be accepted by the intervening parties (Project Management Institute, 2019).

Identify risks The Project Management Institute (2019) establishes that, since risks are emergent in nature, the risk management process, including risk identification, needs to be iterative, so that risks not previously evident are identified. One or more risk identification techniques can be selected with the objective of exposing and documenting any knowable risks while acknowledging that some risks are inherently unknowable. Inputs from the relevant stakeholders should be taken into account, as each might have different perspectives of the risks the project faces. Historical data might also be used as an input for risk identification. A risk owner, an individual responsible for monitoring the risk and implementing appropriate risk responses, can be assigned to that specific risk.

The success factors for risk identification suggested by Project Management Institute (2019) are:

- Early identification;
- Iterative identification;
- Emergent identification;
- Comprehensive identification;
- Explicit identification of opportunities;
- Multiple perspectives;
- Risks linked to objectives;
- Complete risk statement;
- Ownership and level of detail;
- Frequent and effective communication;
- Objectivity to minimize bias.

The Project Management Institute (2019) specifies several risk identification techniques, suggesting, as best practice, to use more than one technique in order to offset any biases or shortcomings one might have compared to another. It is also noted that some of the techniques presented are better suited for identifying threats, while others might be better suited for identifying opportunities. Whatever risk identification strategies are used, it is paramount to highlight cause-effect relationships between the facts and conditions that cause risk and the subsequently the effects that specific risk might have. The techniques listed as useful for risk identification are:

- Assumptions and constraints analysis;
- Brainstorming;
- Ishikawa (or fishbone) diagrams;
- Checklists;
- Delphi technique;
- Document review;
- Expert judgement;
- Facilitation;
- Historical information;
- Interviews;
- Prompt lists;
- Questionnaires;
- Root-cause analysis;
- Swot analysis.

Risk analysis Project Management Institute (2019) also stresses the importance of risk analysis, considering qualitative and quantitative analysis complementary. Qualitative risk analysis considers characteristics such as probability of occurrence, degree of impact, manageability, relationships with another risks as well as frequent causes and effects. Qualitative risk analysis assesses the risks created or updated in the risk identification stage, in order to provide management insights about risk characteristics and what risks potentially have the most influence on the business objectives. Risks perceived as high priority should be given special attention in the risk response planing stage and should be further analysed quantitatively. The success of a qualitative risk analysis is dependent on, but not limited to, the use of agreed upon risk definitions, the collection of trustworthy data about risk and adopting an iterative approach.

Quantitative risk analysis takes into account probabilistic effects and correlations, interdependency and feedback loops of risks, providing an overall risk degree a project faces. The purpose of the quantitative risk analysis is to provide a numeric value to a risk's effects on business objectives. Although quantitative analysis provides more realistic estimates than qualitative approaches, it might not be always feasible, required or even possible to do so. The benefits of quantitative methods should be debated against the additional effort they require. However, only quantitative methods help to determine which particular risks threaten the business objectives beyond what stakeholders deem as acceptable. The success of a quantitative risk analysis is dependent on prior risk identification and qualitative analysis, the use of appropriate models, proficiency with the corresponding analysis tools, the commitment to collect reliable and unbiased risk data and the interdependency between risks (Project Management Institute, 2019).

Plan risk response Project Management Institute (2019) refers that risks, more specifically threats, can be handled in different ways:

- Avoid: act to eliminate the threat;
- Escalate: agree that the threat is outside the scope of the project and that, by responding to it, would exceed the project manager's authority;
- Transfer: shift the ownership of the threat to a third-party that would then manage and bear any impacts the threat might have;
- Mitigate: take actions in order to reduce the likelihood and impacts a threat might have;
- Accept: acknowledge that the threat exists but don't take any proactive action - either develop a contingency plan that should be triggered when the threat occurs (active acceptance) or do nothing at all (passive acceptance).

Implement risk response Following the planning of the risk response, the response actions are included in the appropriated management plan and assigned a action owner. The risk owner is responsible for monitoring the effectiveness of the risk response actions and identifying secondary risks resulting from implementing said actions. Both the risk owner and risk action owner should be briefed of any changes in responsibility, establishing effective communication between themselves and project managers. Transparency of communication ensures accountability for the management of risks and that the interested parties push towards agreed responses swiftly (Project Management Institute, 2019).

The implementation of a risk response strategy is dependent on the accountability of the risk owners, the degree of commitment stakeholders have in implementing said strategy, clear communication, acknowledgement of the costs inherent to the risk response actions and the availability of contingency and management reserves (Project Management Institute, 2019).

Monitor risk As no system exists in a vacuum, project management teams should include risk monitoring in their risk management toolbox. A project context is subject to change as some risks occur or cease to be worthy of attention. Organizational factors might also contribute to the entropy of a project's context. As such, the main objective of the Monitor risk process is to keep identified risk on check and ensure that the response plans remain viable throughout the project's lifecycle (Project Management Institute, 2019).

Periodic status reviews, at reasonable intervals, contribute to pinpoint strengths and weaknesses in the risk management plan. This serves multiple purposes: improving the risk management of the project at hands, maintaining risk awareness and build knowledge to be used in future risk management plans (Project Management Institute, 2019). In addition to regular status reports and risk audits, an integrated risk analysis should be performed when a project or initiative reaches maturity. Again, the findings of this checkpoint help on long term process improvements (Project Management Institute, 2019).

2.3.4 ISO 14971

Risk Analysis Documentation for this step should include a description of the analysed medical device, the people and the organization who carried the analysis and the scope and date of the analysis. In addition to these requirements, manufacturers should include the device's intended use and its safety characteristics, such as potential hazards and respective risk estimation (ISO 14971, 2007).

Risk Evaluation For hazardous situations, the manufacturers must consider the necessity for risk reduction, applying the criteria established in the risk management plan. If risk reduction is necessary, a control step should also exist (ISO 14971, 2007).

Risk Control In order to reduce risk to acceptable levels, risk controls should be identified. One or more of the following risk control options shall be used: inherent safety by design; protective measures; information for safety. The implemented risk control measures should be evaluated for its effectiveness (ISO 14971, 2007).

Evaluation of Overall Residual Risk Acceptability Residual risk should again be evaluated according to the risk management plan. In case the residual risk is not acceptable, a risk/benefit analysis should be conducted to determine if clinical benefits outweigh the risks. If yes, relevant safety information should be disclose the residual risk (ISO 14971, 2007).

Risk Management Report After risk control, it should be decided whether to continue the process and a risk management repost should be produced (ISO 14971, 2007).

Production and post-production information Production and post-production stages should be documented in an appropriate system. Information about the device should be collected and review. This system should also collect and review public information about similar devices on the market (ISO 14971, 2007).

All the presented norms are based on the principle of establishing a risk management plan and maintaining associated documentation. One of the predicted techniques, common to all, is the elaboration of a risk matrix, where probability and severity are scaled. In Figure 1, a comparison of the proposed steps in each norm is given. Each lane groups the risk management activities from the different enumerated frameworks.

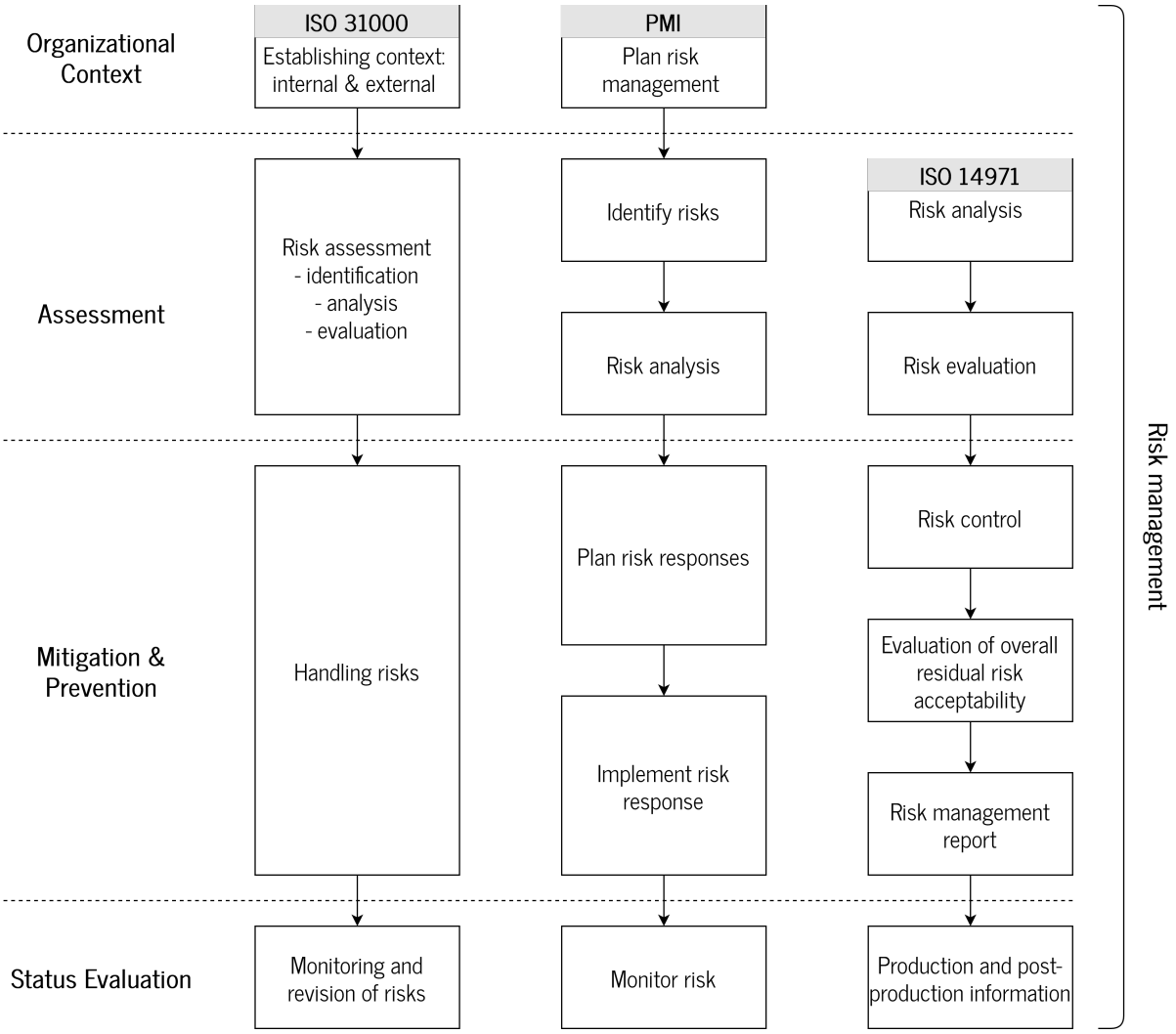

Figure 1: Risk Frameworks Comparison

3 Methods and Research Tools

This section is dedicated to the effort in finding the cornerstone from which to build a solid, rigorous and empirical research process. Much care and consideration was put into this subject. A literature review on research paradigms was conducted to find a convergence point regarding scientific method in IS. The selected methodology and specific tools used are also presented.

3.1 Research Paradigms

From the dawn of times, humans set themselves to understand the inner workings of the world around them. That curiosity paved the way for research, science and the scientific method. The quest for new knowledge is how the academics define research (Carvalho, 2012). All research is kicked off by a question/problem/objective and, by the ways of a research process, it is possible to reach a result/outcome, as presented in Figure 2.

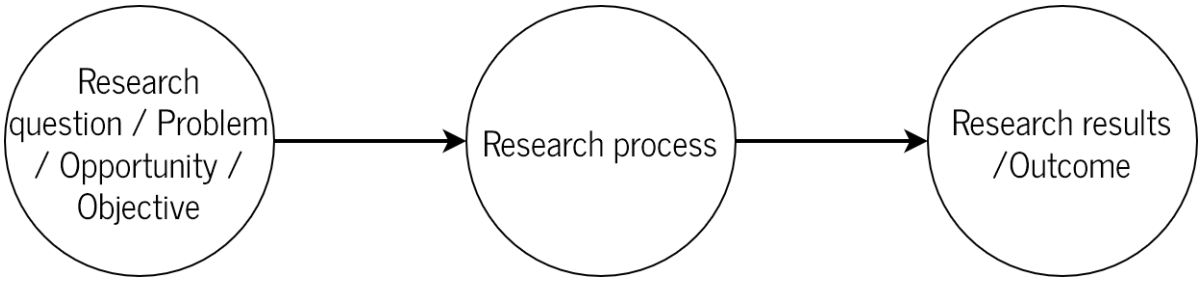

Figure 2: Research Stages, adapted from Carvalho (2021)

3.1.1 Research Question/Problem/Objective

The research question, problem or objective, raised just as the research endeavour starts, will determine the most adequate research process (Thabane et al., 2009). Given the importance of the research question, some care and attention should be given to its inception.

Kastner et al. (2016) point out that, since research is becoming ever so complex, research questions must follow suit. Research questions evolved from simple "what and how it works" inquires to "why, for whom and under what context it works". On the other end, research questions should be specific, with authors such as Vandenbroucke and Pearce (2018) defending their simplification: "pruning a research question means cutting away anything that is unnecessary, so that only the essence remains". The relevance for the study field, in the current state of the art should also be considered (Hunt et al., 2018).

3.1.2 Research Process

The research process includes a research plan, research design and any processes, methods and tools used to conduct research (Nunamaker et al., 1990). The research process is laid out according to the dominant research paradigms at that time or in that particular area. This paradigms set not only the steps and procedures needed but also how to evaluate the observed results.

The first research paradigm aimed at explaining how the world works was Positivism, fostered by Auguste Compte in the XIX century (Rehman and Alharthi, 2016). In the positivist paradigm, the researcher acts isolated from reality and the environment, disconnected from feelings and personal concerns, performing research on immutable natural laws. Reality exists objectively beyond the limits of human cognition and, as such, the phenomena in study exists independently from the researcher. Positivism implies the use of statistics, for quantitative data and content analysis for qualitative data, as paths towards the truth. Data, being measures of reality, must lead to replicable, impartial results.

However, reality is complex and leads to research questions that are hard to respond through a positivist lens. Interpretivism appears rejecting the notion of a single observable reality that is independent from our individual perspectives (Rehman and Alharthi, 2016). Any study subject is interpreted based on the researcher's life experiences. The researcher is indissociable from reality. The methods used to study reality in a interpretative scope are, for example, case study analysis or critical theoretical analysis.

Beyond these two research paradigms, considered the most antagonistic, others have arise. Post-positivism, Pragmatism and Critical Perspective are examples of such. While Post-positivism considers that one cannot possess absolute knowledge of the truth and that human behaviour cannot be studied in a narrow "positive" way (Creswell, 1994), Pragmatism holds that knowledge is derived from actions, not antecedent conditions, and, as such, is concerned with problem solving and "what works" (Rossman and Wilson, 1985). Pragmatics go further, claiming that the problem itself is more important than the methods used (Creswell, 1994). Critical Perspective, with foundations on Realism, while admitting that measurable realities exist, argues that this measure is inherently biased by social and cultural factors.

Despite having fundamental differences, resulting from different times, contexts and schools of thought, the different research paradigms that have appeared throughout history all have contributed to a greater liberalization of the research methods used. In fact, several authors have been dedicated to the conception of the so called, "mixed methods approach" (Creswell, 1999; Creswell and Creswell, 2005; Rossman

and Wilson, 1985), that employ, for the same research question, quantitative and qualitative methods. Researchers use both forms of data in order to acquire a better understanding of the research problem (Creswell, 1994).

The split between Positivism and Interpretivism persists to this day. However, rather than fuelling the controversy, perhaps it might be more useful to understand why researchers favour different research methods. And that researchers should choose the methods better suited for their objectives, as long as they are capable of evaluating their own research in a reflective and critical way (Weber, 2004).

3.1.3 Research Results/Outcome

The research results, whether they are knowledge or new artefacts, are the final product of the research process. The way these results are evaluated depends on the research methods used. In traditional research, where methods such as experiments are used, the criteria are well defined: external, internal and statistical validity, reliability of data and repeatability of results. For novel research approaches, the evaluation criteria is not so clear, as it is still being developed and analysed (Weber, 2004).

In conclusion, the initial research question is of the uttermost importance as it helps to determine what research process to follow. Different research processes will generate distinct outcomes. Nonetheless, whatever the research method used, the main concern is to justify the knowledge claims researchers make while using it (Weber, 2004). In 3.2, a perspective on research in IS is given.

3.2 Research in Information Systems

Information Systems are a relatively novel field of study, built upon multi-disciplinary knowledge. Among other areas such as Computer Science, Software Engineering, Management, Economics, Ethics, Sociology, Psychology, Statistics, all contribute for the development of IS (Wade and Hulland, 2004). Information Systems' context is broad, expanding further than technology. Questions such as how technology is used, it's efficiency and effectiveness and how it impacts organizations are also within the scope of ISs (Ferreira et al., 2012).

In this subsection, we will analyse the research stages presented in 3.1 and how they relate to the research in IS.

3.2.1 Research Question/Problem/Objective

Rising complexity of organizations and society increases the volume of data and information handled. Systems must ensure that this increased flow of data and information is dealt with. Gathering, storage, processing and communication of information must all be safeguarded. Assuring the information flow is necessary for organizations to perform their activities adequately (Varajão, 2003). For this reason, in the field of IS, the research question is often put as problem to solve or as an objective to achieve, related to the information flow.

3.2.2 Research Process

The research process in IS is influenced by the dominant research paradigms in other areas of knowledge. From 1991 to 2001, 81% of the papers published on IS followed a positivist approach (Chen and Hirschheim, 2004). Simon (2008) provides some insights that might explain this phenomena: engineering schools, driven by the race towards academic status, have been shifting curricula from the sciences of the artificial to natural sciences. Simon (2008) points out the pitfalls of this shift, suggesting the validity of a "design science".

Other authors noticed the limitations of existing research approaches when applied to IS. Ives et al. (1980) suggested that a more comprehensive model was needed and proposed a model for IS research, where multiple environments influence the research outcomes. These environments are:

- External Environment:
  - Legal;
  - Social;
  - Political;
  - Economics;
- Organization Environment:
  - Organizational goals;
  - Tasks;
  - Structure and hierarchy;
  - Volatility;
  - Management;
- User Environment:
  - User's profile;
  - User's task;
- IS Development Environment:
  - Methods and techniques;
  - Design personnel
- IS Operations Environment
  - Necessary resources for IS operations;

- Software;
- Hardware;
- Databases;
- Documentation;
- Organization and Management.

The supra-cited environmental factors influence the outcome of the research in IS, the Information Subsystem (ISS). Ives et al. (1980) also used these environments, their characteristics and relationships, to categorize the types of research in IS. Researchers may consider variables within an environment or how variables from distinct environments relate to one another.

With the advent of more comprehensive research frameworks for IS, it became notorious that Systems Development had to be included as a research methodology for IS (Nunamaker et al., 1990). For these authors, "a research process involves understanding the research domains, asking meaningful research questions, and applying valid research methodologies to address these questions" (Nunamaker et al., 1990, p. 91). Results from a good research process contribute to the body of knowledge of the given domain. The proposed methodology is expressed in Figure 3.

The scope of IS is broad, including a wide range of research methodologies. The contributions for the research domain can often be seen as the value of its application, rather than its intrinsic value. That is to suggest that a highly applicable concept goes trough the following research life cycle: concept, development and impact (Nunamaker et al., 1990). Research in IS is important as the developed system serves not only as a proof-of-concept for research but also as an artefact that will be the focus of expanded and continuous research (Nunamaker et al., 1990).

Similarly, March and Smith (1995) reinforced Systems Development as a valid research methodology, drawing concepts from Simon (2008). March and Smith (1995) call "design science" attempts to create "things" that serve human purposes. Later, Hevner et al. (2004) noted that the two most common research paradigms in the Information Systems field are behavioural science and design science. While behavioural science stems from natural science research methods, seeking to develop and justify theories that explain organizational and human phenomena regarding information systems, the design science paradigm has roots in engineering and is primarily an approach for problem solving (Hevner et al., 2004).

These two paradigms are complementary and, as Hevner et al. (2004) puts it, part of the information systems research cycle. While behavioural science seeks to explain how a certain artefact is used, its

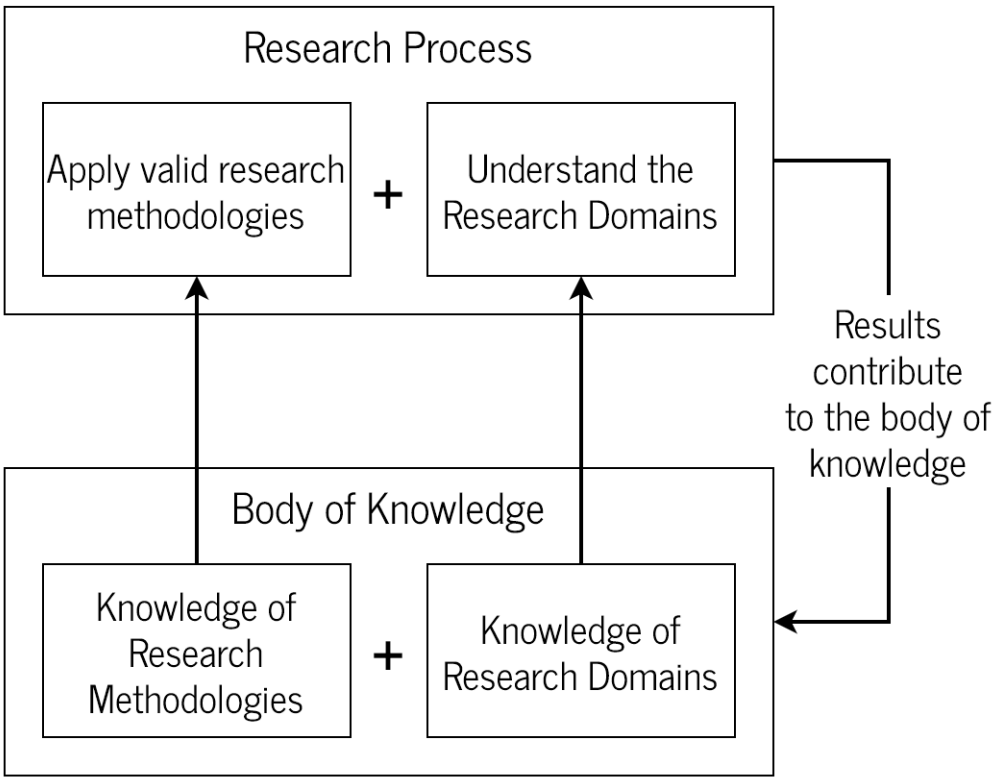

Figure 3: A Research Framework for IS; adapted from Nunamaker et al. (1990)

usefulness and organizational impacts, design science, on the other side of the IS research cycle, generates and evaluates said artefacts, as shown in Figure 4. The contributions from behavioural science and design science are evaluated as they are applied to the business needs and objectives of the organization in which they are being conducted and as they increment the knowledge base.

Artefacts produced, according to March and Smith (1995), are *constructs, models, methods* and *instantiations*. Constructs define the language and terminology in which the problems and respective solutions are defined and communicated. In turn, models use constructs to represent the design problem and the solution space, aiding to understand how problems and solutions relate to one another. Methods determine how to solve problems and can be made of formal algorithms, informal text descriptions of best practices or a combination of both. Finally, instantiations demonstrate that constructs, models or methods can be put into practice and are used to evidence the feasibility of the artefact as solution for the problem researchers propose to resolve.

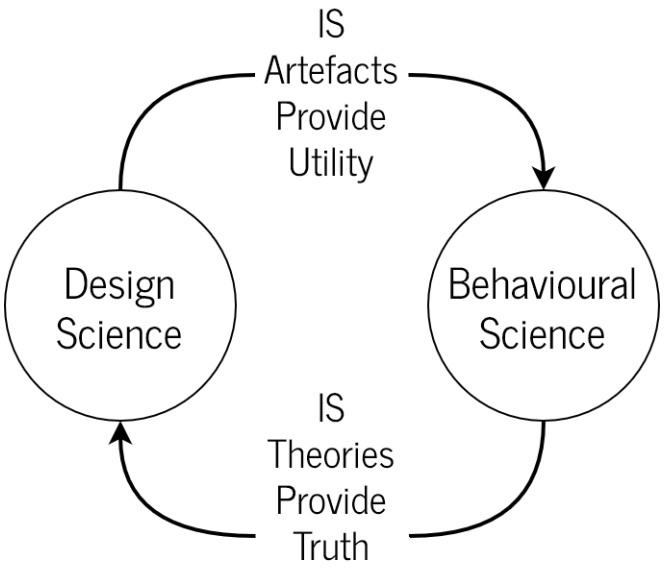

Figure 4: Complementary Research Cycle; adapted from Hevner and Chatterjee (2010b)

More recently, both interpretative and critical paradigms have been gaining attention, by Kroeze (2011) and Richardson and Robinson (2007), respectively. This exchange of ideas has been helping researchers to understand IS in social and organizational contexts, in opposition to the more traditional positivism (Ferreira et al., 2012).

At the same time, pragmatism has also gained traction. Pragmatism has a strong interest in intertwining knowledge and action. This makes pragmatism a prime candidate for the basis of research approaches concerned with influencing the world and not just making observations about it (Goldkuhl, 2012). Since research in IS can, in some cases, be a design activity, where the results are artefacts (March and Smith, 1995), a pragmatic approach is adequate.

Research and design are human activities engaged in expanding the existing knowledge. Research increases scientific knowledge, pushing science forward, while design boosts technological knowledge, contributing for the betterment of the world (Ferreira et al., 2012). This distinct types of knowledge are appropriately called by Carvalho (2012) *knowledge for understanding* and *knowledge for a purpose*.

Research in IS ought to contribute with both scientific and technological knowledge, as there should not be a segregation between professionals and academics (Ferreira et al., 2012). For this reason, there

should be a path that allows the connection between *knowledge for understanding* and *knowledge for a purpose*. One such path is Design Science Research (DSR).

In the following subsection, 3.3, a thorough approach on how and why DSR has been increasing in popularity in IS research.

3.2.3 Research Results/Outcomes

The results differ according to the type of knowledge targeted. In rough terms, one could say that results from research oriented to *knowledge for understanding* are science, while the results from research in *knowledge for a purpose* are technology. As expected, the evaluation methods for each type of produced output is also different. For this reason, we shall explain how this evaluation occurs in respect to science and technology.

For science, the evaluation criteria are well defined, as mentioned by Weber (2004). For IS research, however, there was the need for better understand the objectives of the theories produced. For this purpose, Gregor (2006) divided the theories' objectives in four categories, creating a taxonomy, presented in Table 1. As a sidenote, Gregor admits that theories can cover the creation of artefacts.

If we try to fit the most relevant research paradigms in IS into Gregor's taxonomy, we could conclude that: positivism, historically the *de facto* way to produce knowledge, would be classified as "Explanation" (Goldkuhl, 2012); on the other hand, pragmatism and DSR fit into the "Design and action" category, providing prescriptions on how to do something (Hevner and Chatterjee, 2015).

Regarding the evaluation criteria for technological research results, we're still traversing murky waters. Attempts on establishing clearer measures have been made. In the following paragraphs, a brief analysis on these attempts will be presented.

In the 1980s, the National Aeronautics and Space Administration (NASA) created a seven level index for technological development risk analysis (Sauser et al., 2006). To this index, two more levels where added in 1989 (Sadin et al., 1989) and the name Technology Readiness Level (TRL) was coined.

Appendix A presents the current nine levels that make up the TRL. TRL has been used not only to judge maturity levels of technology but also innovation and commercial viability (Héder, 2017). The use case

ID	Theory Type	Attributes
1	Analysis	Says what is. The theory does not extend beyond analysis and description. No casual relationships among phenomena are specified and no predictions are made.
2	Explanation	Says what is, how, why, when and where. The theory provides explanations but does not aim to predict with any precision. There are no testable propositions.
3	Prediction	Says what is and what will be. The theory provides predictions and has testable propositions but does not have well developed justificatory causal explanations.
4	Explanation and prediction	Says what is, how, why, when and where. Provides predictions and has both testable propositions and causal explanations.
5	Design and action	Says how to do something. The theory gives explicit prescriptions (methods, techniques, principles of form and function) for constructing an artefact.

Table 1: Taxonomy of Theory Types in IS Research; adapted from Gregor (2006)

for TRL has been stretched so far as to be applied as an evaluation method for European Union funding applications (Héder, 2017).

Inspired by TRL and the Open Systems Interconnect (OSI) layers, Sauser et al. (2006) introduced a new five level index called Systems Readiness Level (SRL). An intermediate index called Integration Readiness Level (IRL) was also conceived to bridge the gap between the evaluation of individual technologies and how they behave with one another. Sauser et al. (2006) argue that the whole is greater than the sum of its parts, that is, that the maturity level of a system is measured by the maturity of each piece and how well they fit together. In summary, the convergence between the TRL and the IRL results in a new approach, intended to gauge not only the maturity of singular components, but more importantly, of the system as a whole. The SRL is presented in Appendix B.

As stated before, March and Smith (1995) established four types of research outputs in IS: constructs, models, methods and instantiations. For each type of output, differentiated evaluation criteria should be used. For constructs, *completeness, simplicity, elegance, understandability* and *ease of use*. For models,

fidelity with real world phenomena, completeness, level of detail, robustness and *internal consistency* should be the benchmarks. For evaluating methods, the researcher should consider its *operationality, efficiency, generality* and *ease of use*. At last, for instantiations, *efficiency* and *effectiveness of the artefact and its impacts on the environment and its users* (March and Smith, 1995). Further details on how artefacts should be validated are given in subsection 3.3.2.

3.3 Design Science Research

3.3.1 Perspectives on DSR

As Hevner et al. (2004) says, DSR is proactive in respect to technology, studying innovative ways to solve problems, or already solved problems in order to increase the effectiveness and efficiency of the solution in place. DSR is a research paradigm that aims to solve problems by creating novel artefacts and, therefore, contributing to augment the knowledge available in the pool of scientific evidence. This artefacts should be both useful and central for understanding the problem. Therefore, it is the main principal of DSR that knowledge and understanding of a problem and respective solution are attained by building and applying an artefact (Hevner and Chatterjee, 2010b).

Technology is the embodiment of knowledge: rather than being merely conceptual, it exists as implementations and artefacts. Technology is, in its nature, practical, useful, helping humans, since primordial times, achieving specific objectives. Technologies are often developed in response to a specific need.

From this notion of technology as a practical artefact, it is of no surprise that DSR, historically relevant in applied disciplines such as architecture and engineering, has been widely adopted in the IT field. Since DSR addresses the role of the IT artefact in IS research (Weber, 1987; Orlikowski and Iacono, 2001), more specifically how the IT artefact can be improved in order to better solve business problems in the real world, its acceptance as a research paradigm has been rising since the early 1990's (Hevner and Chatterjee, 2010a).

More recently, the paper by Hevner et al. (2004) has contributed to solidify this paradigm by presenting an IS research methodology for DSR (presented in Figure 5), alongside a set of guidelines, presented in Appendix C. Motivated by the reservations Iivari (2007a) presented, the framework was revised in Hevner (2007), but the basic idea remains the same: DSR is contextualized alongside the environment and the knowledge base. The environment proves the relevance of the built artefact, while the knowledge base

proves its rigour. Efforts on how to present DSR in scientific publications also exits, notably by Gregor and Hevner (2013).

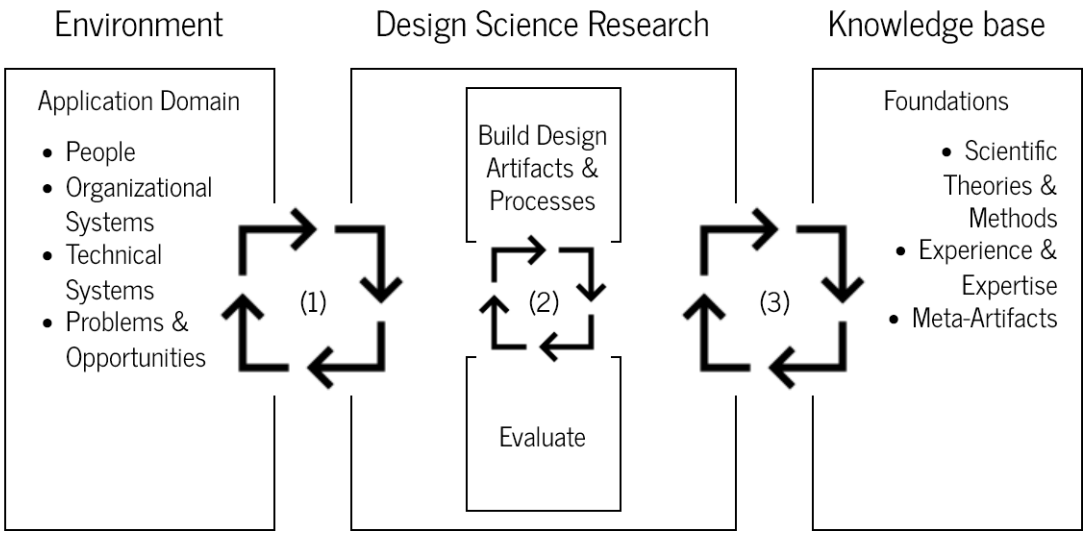

Figure 5: Research Cycles, adapted from Hevner (2007); 1 - Relevance Cycle, 2 - Design Cycle and 3 - Rigour Cycle

Relevance Cycle This Cycle is the starting point for DSR. The Relevance Cycle begins by defining an application context that establishes the opportunities or problems to address and the acceptance criteria from which to evaluate the research results. These are the inputs for DSR. The outputs from DSR must be returned to the Environment in order to be studied and evaluated within the Application Domain. Additional iterations of this cycle are determined by the results of technology transfer methods. If field studies or tests unearths functionality or quality deficits in the designed artefact, its utility might be limited in practice. On the other hand, the results from field testing might determine that the requirements imputed into the DSR were incorrect or insufficient to fulfil the opportunity or solve the problem. The feedback from the technology transfer marks the start for another iteration of the Relevance Cycle, with a restatement of the research requirements (Hevner, 2007).

Rigour Cycle The wide knowledge base of theories, methods, expertise and meta-artefacts (Iivari, 2007b) supports a well structured DSR project. Without prior knowledge, no claims of innovation can be made. Without going through the knowledge base, the researcher cannot guarantee that the designs produced constitute research contributions. Iivari (2007b) claims exactly this, that the line IS and the mere practise of building IT artefacts is drawn by the rigour of research. Nonetheless, both Iivari (2007b) and Hevner (2007) contentiously point out that, while theories are important, to insist that all creative activities

of DSR must be based on descriptive theories is both unrealistic and harmful. Regarding the contributions to the knowledge base DSR makes, they include extensions to the theories or methods used, new meta-artefacts such as design products and processes as well as the acquired experiences from performing the research itself and from field testing the artefact in the Environment.

Design Cycle At the center of any DSR project, one finds the Design Cycle. This cycle rapidly goes through the construction of an artefact, its evaluation and redesigning. Design evaluation, according to Simon (2008), should be performed by:

- Evaluation theories, such as the Utility Theory;
- Computational methods:
  - Linear programming computations for *optimal* solutions;
  - Algorithms and heuristics for *satisfactory* alternatives;
- Formal logics:
  - Imperative logic;
  - Declarative logic.

Alternative artefacts are generated and evaluated until one that satisfies the inputs from the Relevance Cycle is found. Knowledge on how to design and evaluate said artefacts is drawn from the Rigour Cycle. In the Design Cycle, the efforts invested in designing and evaluating an artefact should be balanced and both activities should reflect relevance and rigour. Good practises in DSR mandate that artefacts are exposed to thorough experimental situations before being released into the relevance cycle and field tested (Hevner, 2007).

Peffers et al. (2008) also proposes a DSR methodology, a 6 step iterative process with 4 possible research entry points, providing flexibility to the researcher. These are evidenced in Figure 6 and will be described in the following paragraphs.

Problem Identification & Motivation The first activity is to identify the research problem and the valued added by its solution. To make sure the solution created is effective, it can be useful to break down the problem conceptually into smaller pieces. For this activity to occur, current knowledge of the

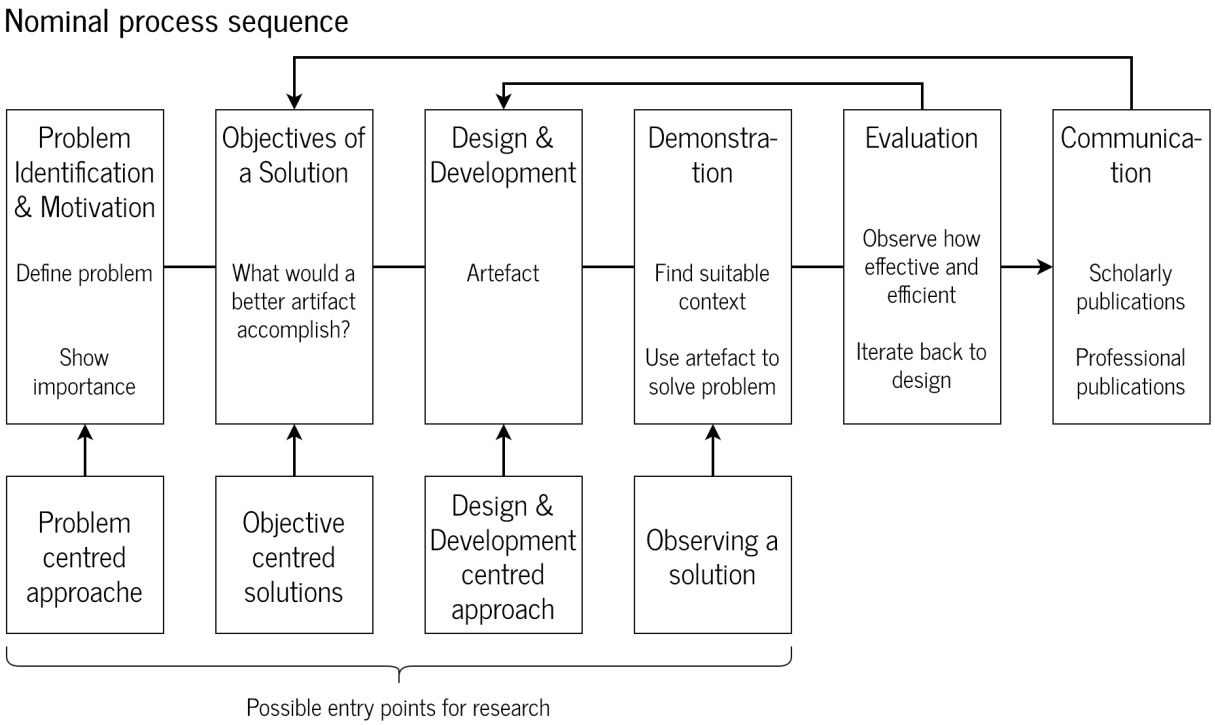

Figure 6: DSR process, adapted from Peffers et al. (2008)

problem should be acquired and the importance of its solution recognized. Justifying the value of the solution motivates the researcher and the target audience to pursue the solution.

Define the Objectives of a Solution After the problem and respective solution were identified, considering what is realistically possible, the objectives for the solution should be defined. Quantitative and qualitative metrics can be used. Defining objectives requires, similarly to the previous step, knowledge of the problem. If any solutions already exist, the researcher should be aware of them and how efficient are they in solving the problem.

Design & Development The artefact's architecture has to be established and its features determined. Then, the artefact is actually built. The leap from objectives to the inception of an artefact requires foundational theory.

Demonstration In this phase, the artefacts ability to solve one or more instances of the problem is demonstrated. Demonstration techniques include experimentation, simulation, case studies or any other suitable activity. For the demonstration to occur, researchers should have knowledge of how to use the artefact to solve the problem.

Evaluation This stage involves measuring how well the developed artefact solves the problem. To do so, it is necessary to compare the solutions objectives and the actual results observed in the Demonstration phase. Artefact evaluation can be done in one of many ways: comparing the artefacts features to the solution objectives; quantitative measures such as budget analysis, satisfaction survey or client feedback. Other performance metrics such as response time and availability could also be useful. In practice, any empirical or logical proof can be relevant evaluation metrics. The results of this activity determine if an iteration back to the Design & Development activity is necessary. If not, research can proceed to the next step.

Communication The sixth and final step is to communicate the problem and the artefact. The artefact's usefulness, novelty and rigour are relevant aspects to be communicated to the relevant audience. The target audience of the research can either be professionals or scholars. For academic publications, this process's structure can be a useful template.

Peffers et al. (2008)	**Hevner (2007)**
Problem Identification and Motivation	Important and Relevant Problems
Objective of a Solution	Implicit in "Relevance"
Design and Development	Iterative search process; artefact
Demonstration	
Evaluation	Evaluate
Communication	Communication

Table 2: Concept comparison between Peffers and Hevner; adapted from Peffers et al. (2008)

In Table 2, a comparison of Peffers' and Hevner's frameworks is expressed. While Peffers et al. (2008) considers that the Demonstration step is not clear in Hevner (2007), one could argue that the artefact demonstration is both part of the Relevance and Design cycles. Hevner (2007) is explicit that the artefact should only be transferred to the Environment if its functionality was thoroughly tested, for example, in experimental situations. Proofing the artefact *in vivo* is its ultimate demonstration. Synthetic tests only go so far to demonstrate the artefact's true capabilities in solving the proposed problem or pursuing the identified opportunities. Uncertainty is always a factor in the Environment. What is certain can be tested but entropies in the system can unveil deficiencies on the artefact's capability to solve problems. Further details on artefact evaluation and validation are enunciated in the following subsection.

3.3.2 Artefact Validity

In any research paradigm, there is a preoccupation with the validity of the results. DSR is no exception and its outcomes, artefacts, should also be validated. The main concern and often the reason DSR is criticized, is that the criteria and methods for artefact validation are not as straightforward or clear as the ones used in, say, positivist research. As there was a concern with the scientific validity of this research and since the subject on how to achieve that goal seems controversial, it was decided to dedicate a few words to this matter.

The controversy begins right at defining what the main outcomes of DSR are. For instance, Carvalho (2012) considers the most significant result of DSR to be knowledge about the artefact, not the artefact itself. This vision is contrary to what March and Smith (1995) portraits, which gives the instantiation of the artefact greater relevance. For Carvalho (2012), the results from DSR should be validated in terms of Success, Generalization, Novelty and Explanation capability.

Success The artefact's success can be measured in terms of Usefulness, Efficacy or Efficiency. Usefulness measures, at broader level, the contributions of the artefact towards achieving a result and is applicable to tools to be used by humans or cooperate with other artefacts. Efficacy also concerns the degree to which the artefact contributes towards the expected results, but should be applied to creations capable of performing their roles independently from human or artefact interaction. Efficiency takes into account the efficacy and resources allocated to the use of the artefact.

An interesting observation Carvalho (2012) makes is that even unsuccessful artefacts are valuable, providing insights on how not to proceed. This notion provides a distinction between the artefact's success and its validity.

Generalization Scientific knowledge should be generally applicable. The applicability of knowledge is expected to be anywhere from universal to a specific socio-cultural conjuncture, but never restricted to one single situation. For this reason, Carvalho (2012) considers that, since "an instantiation is the realization of an artefact in its environment" (March and Smith, 1995, p. 258), the artefact should not be considered the main result of DSR. The knowledge about the artefact, knowledge for a purpose, should be applicable to several instantiations. The architectural patterns of the instantiation should be generalized to fit all instances of that class of situations.

Novelty The product of research should be new knowledge. In DSR, in particular, new knowledge emerges from the creation of new artefacts or from considerable improvements to existing artefacts. Carvalho (2012) makes the distinction between novelty and innovation: innovation presumes gaining benefits or advantages from changes in processes. While novelty and innovation are closely related concepts, for the results of research to be considered an innovation, they ought to be incorporated in economic activities and generate some kind of leverage. This distinction is made to reassure researchers that, from a scientific point of view, demonstrating novelty suffices the requirements of artefact validity.

Explanation capability For Carvalho (2012), researchers should be capable of explaining not only how the artefact works but also why. The *knowledge for understanding* that supports the artefact's success should be enlighten by theoretical support. Researchers ought to be capable to defend the validity of the artefact, even before building it. This background knowledge ensures the artefact's success is not mere fruition. More traditional research approaches might be necessary to understand the reasons of this success or failure.

Sonnenberg and vom Brocke (2012) also considers prescriptive knowledge, akin *to knowledge for a purpose*, terminology used by Carvalho (2012), as the main output of DSR. However, Sonnenberg and vom Brocke (2012) considers that this knowledge exists in the form of the IT artefact in itself. A definition more in-line with March and Smith's (March and Smith, 1995) notion of artefacts: constructs, models, methods and instantiations. Sciences of the artificial are, in some cases, concerned with phenomena not yet existing at the beginning of the research endeavour, posing a challenge in evaluating the results in the same fashion as in natural sciences, where truth is attainable. Sonnenberg and vom Brocke (2012) defend that prescriptive knowledge can have truth-like value if the research process follows three principles: distinguish between interior and exterior modes of DSR inquiry, document cumulative prescriptive knowledge as design theories and continuously assess the progress achieved in a DSR process.

Distinguishing Modes of DSR Inquiry The first principle, marked by Sonnenberg and vom Brocke (2012) draws from the observations by Gregor (2009). DSR should be concerned, in addition to explaining "what is" and "why it is", with building IT artefacts, creating prescriptive knowledge. The question is, how can truth be inferred from this prescriptive knowledge. Gregor (2009) distinguishes the research into two categories: Interior mode and Exterior mode.

The interior mode aims at describing how artefacts can be designed, developed and brought into existence. In this mode, researchers are allowed to use inductive reasoning or prior descriptive and prescriptive knowledge when building the artefact. Researchers are encouraged to document the artefact, its rational, architecture, conditions under which the artefact should work, what steps are necessary to make it work and, if existing, test conditions to be evaluated in the exterior mode. Documenting the artefact assigns truth to the prescriptive knowledge produced. Gregor (2009) suggests that prescriptive design is documented as a design theory.

On the other hand, the exterior mode is intended to analyse, describe and predict the outcomes derived from the use of the artefact in its intended environment. Descriptive knowledge about the artefact stems from this mode. The artefact is a mere black box to be proven against an utilitarian objective.

Documentation of Cumulative Prescriptive Knowledge as Design Theories This second principle is applicable to the interior mode research. While the artefact is conceived, the knowledge used and created should be documented in a certain fashion (Sonnenberg and vom Brocke, 2012). The way to describe this prescriptive knowledge is often referred as the Information Systems Design Theory and, according to Jones and Gregor (2007), should include:

1. The purpose and scope;
2. Constructs;
3. Principles of form and function;
4. Artefact mutability;
5. Testable propositions;
6. Justificatory knowledge;
7. Principles of implementation;
8. Expository instantiation.

Documenting the artefact as a design theory allows the repeatability of the prescriptive knowledge for similar artefacts. The bridge between prescriptive and descriptive knowledge is established by topics 5, 6 and 8. Testable propositions can be evaluated *ex post*, inferring about the utility of the artefact. Justificatory knowledge explains or predicts why the artefact might work within that context, embedding prior knowledge's truth. In the interior mode, expository instantiations are considered artificial evaluations, establishing the feasibility and applicability of the artefact. The descriptive knowledge acquired by instantiating artefacts in the interior mode determines if subsequent build and evaluate cycles are necessary. In the exterior mode, naturalistic evaluation occurs, determining the actual usefulness of the artefact in its actual intended context.

Design theories ingrain truth in DSR, enabling deductions about the validity of the artefact *ex ante* and *ex post*. This validity can be inferred by naturalistic or artificial methods, either we're operating in external or internal mode, respectively. These concepts will be further explored down the line, based on the observations of Pries-Heje et al. (2008) and Venable et al. (2012).

Continuous Assessment of the Progress Achieved in a DSR Process As DSR is, by definition, an evolutionary and cyclic research paradigm, Sonnenberg and vom Brocke (2012) considers reasonable to continuously assess the progress achieved during its duration. For this purpose, evaluation criteria capable of demonstrating progress should be established and how *ex ante* and *ex post* evaluations should fit into the DSR process.

Sonnenberg and vom Brocke (2012) presents the criteria proposed by March and Smith (1995), divided by type of artefact and refers that these criteria should be applied both to *ex ante* and *ex post* evaluations. These criteria are presented in Appendix D.

Some criteria might reflect better than others the progress achieved in DSR depending on the type of artefact, Sonnenberg and vom Brocke (2012) propose evaluation patterns for creating evaluation strategies. These patterns extend the typical design-evaluate sequence into a design-evaluate-construct-evaluate sequence, highlighting the need for continuous assessment of artefacts along the process. The use of such evaluation patterns allows researchers to spread their findings much earlier in their research. This continuous evaluation approach is represented in Figure 7 and the respective evaluation activities , enumerated from 1 to 4, are presented in Appendix E.

Pries-Heje et al. (2008) proposed a framework for selecting evaluation strategies in DSR. This framework consist of four quadrants that express two different dimensions: what type of method to use - naturalistic or artificial - and when the evaluation will occur - *ex ante* or *ex post*.

Natural observations and evaluations explore how a solution performs in its real environment. By performing evaluations involving real people, using real systems in real settings, the complexity added by human particularities in real organizations is taken into account. Natural evaluation methods are always empirical and can be interpretative, positivist or critical, independently of the research paradigm adopted. Natural evaluation methods include "case studies, field studies, surveys, ethnography, phenomenology, hermeneutic methods, and action research" while artificial evaluation can be carried out by conducting "case studies, field studies, surveys, ethnography, phenomenology, hermeneutic methods, and action

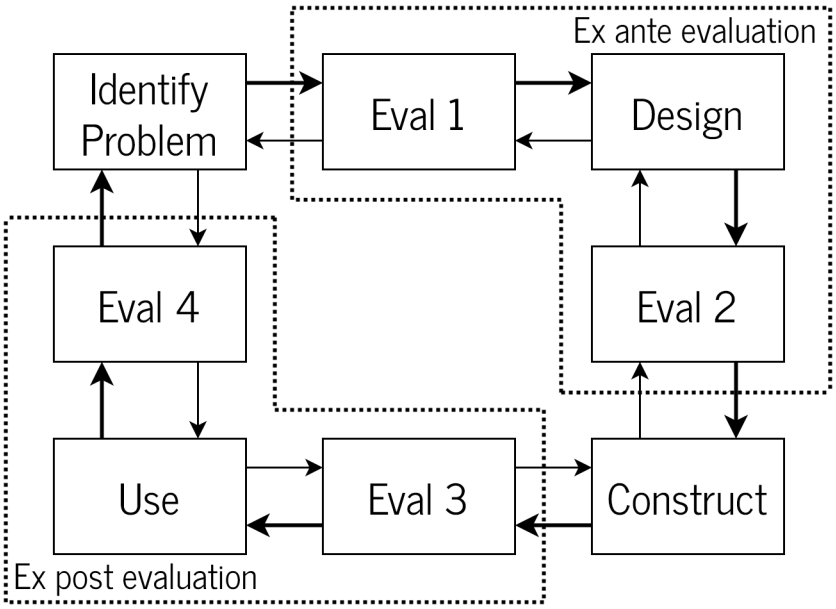

Figure 7: DSR cycle and evaluation activities, adapted from Sonnenberg and vom Brocke (2012)

research" (Venable et al., 2012, p. 429). While natural methods assures stronger internal validity, artificial ones benefit of stronger scientific reliability in terms of repeatability. Venable et al. (2012) recognize that both naturalistic and artificial have their strengths and weaknesses and that, for a more plural view of science, mixing different types of evaluation methods is a robust approach.

Venable et al. (2012) also points out how little consensus there is around evaluation methods for DSR. Their literature review captured the wide range of opinions on what should be evaluated, what goals to pursue and what methods can or should be used. Their 2012 paper extends the evaluation framework by Pries-Heje et al. (2008) by providing clearer guidelines on how to implement it.

Venable et al. (2012) try to bridge what they call the "evaluation gap": the current lack of clear guidance on evaluation within DSR. The objective is to aid researchers make decisions on their research design and evaluation activities of DSR. Venable et al. (2012) note that their proposal does not aim at evaluating DSR projects as whole or after the fact.

The other dimension considered by Pries-Heje et al. (2008) and Venable et al. (2012), *ex ante* and *ex post* research is concerned with whether the artefact has been instantiated or not. *Ex ante* evaluation occurs for artefacts that have not yet been instantiated, namely models and methods. *Ex post* evaluations take place after the instantiation of the artefact.

The criteria and guidance for selecting one or more DSR evaluation strategies are mapped in Appendix F. The specific methods that fit in each category are presented in Table 3.

	Ex ante	**Ex post**
Naturalistic	Action research	Action research
	Focus group	Case study
		Focus group
		Participant Observation
		Ethnography
		Phenomenology
		Qualitative or quantitative survey
Artificial	Mathematical/logical proof	Mathematical/logical proof
	Criteria-based evaluation	Lab Experiment
	Lab Experiment	Role playing simulation
	Simulation	Computer simulation
		Field Experiment

Table 3: Methods mapped to the DSR Strategy Selection Framework; adapted from Venable et al. (2012)

One particularly important aspect of scientific research is its contributions. Determining what DSR contributes depends on the current state of the art on the subject, target audience and where the findings will be published (Gregor and Hevner, 2013). Also, the degree of contribution is variable. DSR can, potentially make different types and levels of contribution (Gregor and Hevner, 2013). This variation reflects how the project itself fits into the timeline of knowledge growth. In order to contextualize the research results, Gregor and Hevner (2013) proposes a 2 by 2 matrix, represented in Figure 8, that expresses contributions in terms of problem maturity and solution maturity. Inventions are total departures from current knowledge where the artefact and the idea behind it are both novel, responding, in some cases, to problems not yet identified. Contributions that are Improvements constitute better solutions for already identified problems, drawing from a wide understanding of the problem. A great deal of DSR projects fit into this category. Exaptations occur when known solutions, for example, from other fields of expertise, are adapted for new problems. This quadrant of DSR contribution is common in IS, where ideas are often refined and iterated upon, for different purposes. The Routine Design category describes situations where extensive knowledge of the problems and tools to solve them exist. Routine Designs

rarely yield research opportunities.

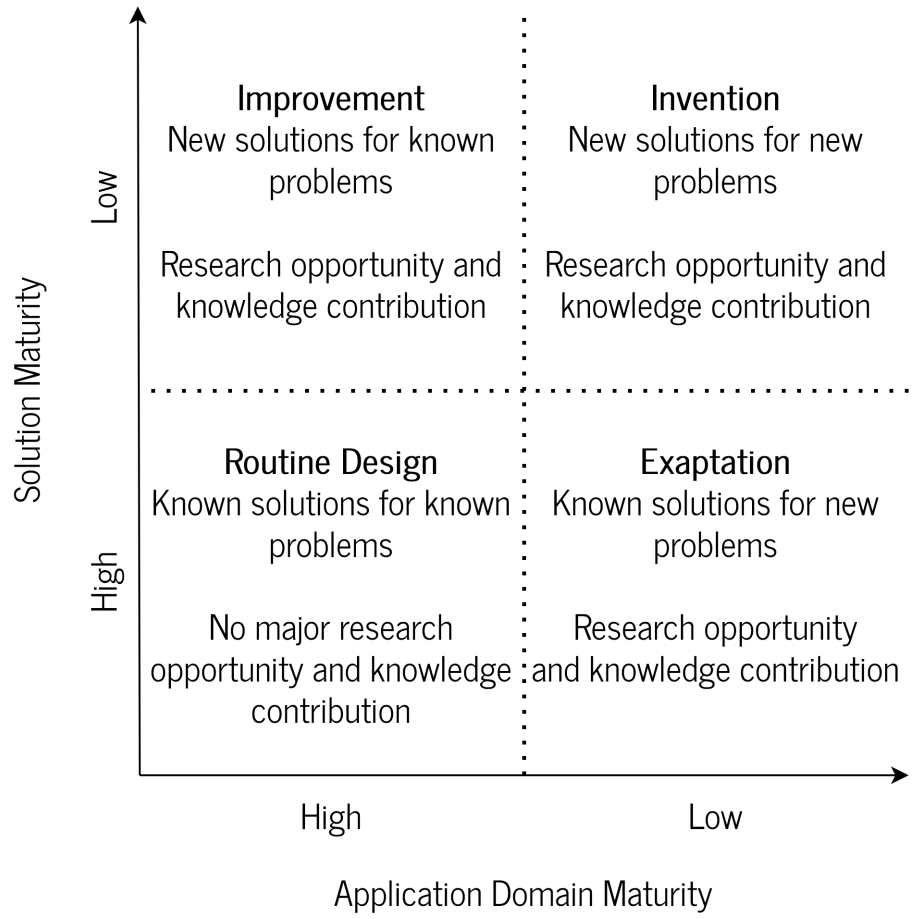

Figure 8: DSR contribution framework, adapted from Gregor and Hevner (2013)

Some consensus is starting to appear on how to evaluate DSR outputs, converging into a process that is accepted among the community of DSR researchers. This process essentially occurs in two stages: *ex ante*, before the artefact materializes and *ex post*, after the artefact has been instantiated in its relevant environment. In layman's terms, *ex ante* determines how good the instructions for assembling the artefact are and *ex post* how good the assembled product is in serving its purposes. While acceptance on the evaluation process is consolidating, the specific tools to be used within the process are a different story. There is not a single agreed upon set of criteria and evaluation methods for the validation of DSR outputs. Also, some of the existing criteria are vague and thus, difficult to apply. This seems to still be a standing obstacle in the way of establishing DSR as a reputable methodology. However, this does not demote DSR as a useful framework for describing the building and evaluation of artefacts and how they contribute for the relevant knowledge base and environment where the instantiation occurs.

3.4 Research Design

Given the objectives of this research process, and how it was developed for the purposes of creating a technological artefact to solve a business need and contributing for a specific knowledge base, we can classify it as being in line with the DSR paradigm. This research project was designed drawing inspiration from the proposals of Peffers et al. (2008), Hevner et al. (2004) and Gregor and Hevner (2013). The processes necessary to put this project in motion and respective flows are presented schematically in Figure 9.

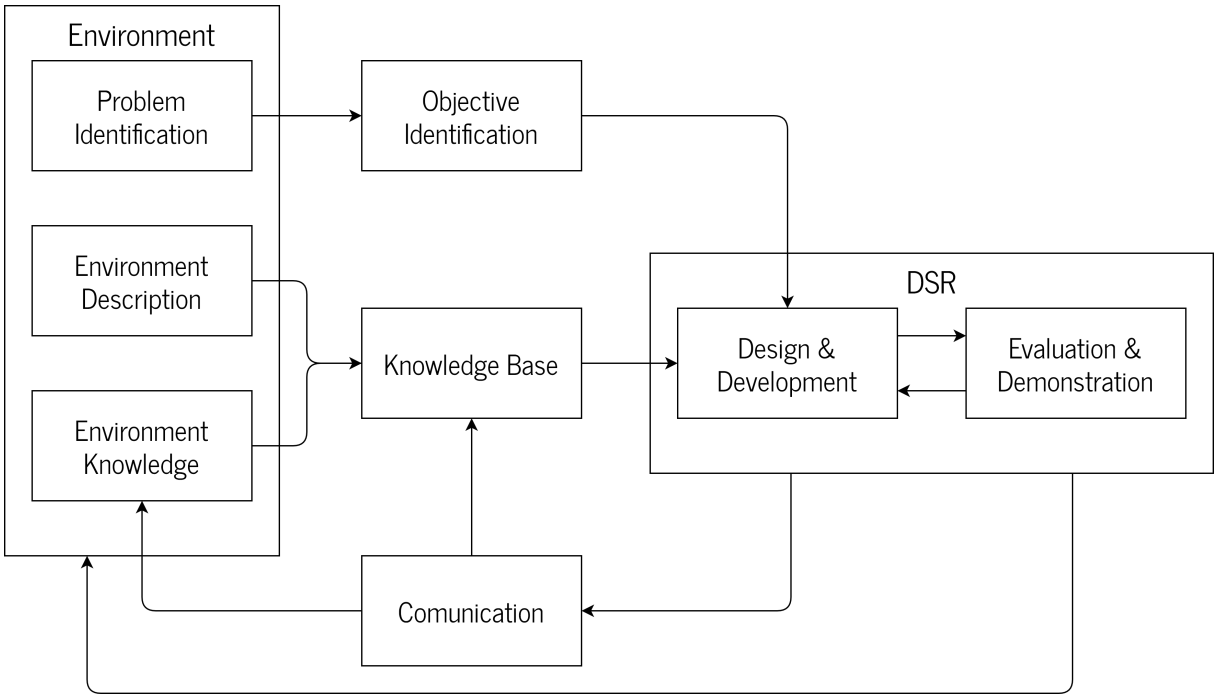

Figure 9: Research design

The first step is to establish the context in which the research will take place, the Environment. From the vast set of issues to be solved and opportunities to pursue, one must be chosen and identified. Objectives regarding this research problem or questions are established and used as inputs for the Design & Development activity of DSR. These objectives are often formally presented as research questions. The problem identification is put into words in Section 1 and the objectives in Subsection 1.4.

The relevant Knowledge Base must be established too, built upon the particularities of the Environment. The existing knowledge present in the Environment, namely, among others, previous experiences, the people's know-how or track records from other projects, are invaluable contributions. It is also natural

and expected that exterior scientific contributions are taken into account. The Knowledge Base is not set in stone, evolving and expanding as the project matures. Both descriptive and prescriptive knowledge make up the useful Knowledge Base (Gregor and Hevner, 2013). Prior knowledge, presented in Section 2 was acquired as described in 4.3. Further details about the environment specific knowledge are exposed in Subsection 4.1.

Having a set of objectives defined and a well established Knowledge Base, the DSR process can finally take place. The Design & Development process, to be described in 4.2.1 will abstract details about specific technologies used, system's architectures, data structures and test scenarios, in order to protect potential trade secrets and business interests. The prescriptive knowledge on how to create a similar artefact is presented. The model was instantiated in a subset of the Environment, composed of 6 client institutions, for demonstration and validation. Complete technological transfer of the solution is expected to occur after the Evaluation & Demonstration of this 6 instances.

Evaluation of the outcomes of the research are presented in Section 5. A primarily naturalistic and interpretative evaluation approach was conducted. This process, mapped to the evaluation activities, proposed by Sonnenberg and vom Brocke (2012), was conducted using the following criteria and methods (Table 4):

Evaluation Moment	**Criteria**	**Method**
Ex ante	Feasibility, Utility and Novelty	Criteria-based evaluation
Ex post	Effectiveness and Utility	Demonstration with prototype

Table 4: DSR outputs evaluation map

The validity of the contributions of this DSR initiative as scientific knowledge is judged by the rigour in following the research process, namely the first two principles put forward by Sonnenberg and vom Brocke (2012).

The last milestone is achieved when the research and respective results are communicated. This dissertation work follows the formal structure proposed in Gregor and Hevner (2013), present in Appendix G.

4 Results Description

In this section, the results of this research project are presented. These results are an artefact and the search process required to achieve it: risk activities depicted in Figure 1 and DSR activities, as described in subsection 3.4. Topic 4.1 describes the application context, 4.2 describes the artefacts and how they were designed and built. Subsection 4.3 focuses on the foundational knowledge of this project and what contributions it provides to the knowledge base.

4.1 Environment

Establishing the context puts the DSR project in motion and is the first step of the Relevance Cycle.

4.1.1 The Organization

The organizational environment where this master's thesis and research project took place is briefly described in subsection 1.3. ST+I, being one among many HIS vendors operating in Portuguese soil, faces the challenges of interoperability on a daily basis. As part of the company's philosophy and commitment to provide its clients high quality and high availability solutions, keeping interoperability interfaces under strict working order is of the uttermost importance.

4.1.2 People, Organizational and Technical Structure

People are the core of any organizational process or initiate. It is indispensable to identity who contributed to this project and what their contribution was. This project required the involvement of the following functional teams at ST+I:

- Management;
- Interoperability;
- Systems and Infrastructure.

Management Having the sponsorship and commitment of Management is a major advantage for any project, helping to establish its importance across the organization. This commitment was only possible since Management had already identified interoperability interfaces as a risk source. Because of Management's acknowledgement of interoperability interfaces as a potential threat to the company's business goals, they understood the intents of this project from day 1.

Interoperability team Being "on the field" a daily basis, the Interoperability team understands and recognises better than anyone else the pitfalls and dangers of interoperability. By providing inputs regarding what the common occurrences were, how they could be identified and the consequences they have, the Interoperability team members played a major role in this project. Their contributions were invaluable.

Systems and Infrastructure team The Systems and Infrastructure team aided in shedding light into the architecture behind ST+I's solution. Without their feedback, the researcher could not know what was and what was not possible from a technical standpoint, given the constraints of the system.

4.1.3 Problems & Opportunities

In section 1.4, we described the objectives of this project. To summarize, one cannot dissociate HIS from interoperability nor interoperability from risk. This poses a threat to the quality of service a HIS hopes to achieve. The aforementioned issue, both a problem and an improvement opportunity, are business requirements to be imputed into the DSR project.

4.2 Artefact design and development

Given the business requirements received from the Environment and the learnings acquired from the Knowledge Base, conditions for designing and building the relevant artefacts where met.

4.2.1 Artefact design and building

Risk assessment Interoperability interfaces are subject to multiple risks. To achieve a good strategic planning of the situation in study, the first step was to conduct a risk assessment. A series of meetings between the interested parties was held with this objective. Since the ISO 31000 and 14971 norms were already being used for other business processes, it was the natural choice to use them as the risk management framework.

Negative outcomes were explored, identified and classified according to Probability (P) and Severity (S), on a scale of 1 through 5. Negative outcomes with higher Risk Score ($RS = P \times S$), both more probable to happen and more serious, were prioritized in subsequent stages. The resulting risk matrix is exposed below, in abridged form, in Table 5.

ID	Risk	Damage	P	S	RS
1	Interoperability interface locks	Clinical data is not exchanged	3	5	15
2	Interoperability interface is down	Clinical data is not exchanged	2	5	10
3	Messages are delivered with delay	Clinical data may arrive later than expected	4	2	8
3	The server's filesystem is full	Interoperability services won't be able to log erratic behaviour	1	5	5
4	Monitoring service overloads on system failure	Server-wide crash	1	5	5

Table 5: Risk Matrix

Having identified the risks with higher Risk Score, risks 1, 2 and 3, the following step was to decide what risk handling strategy was the most adequate. The path forward consists on working on reducing the likelihood of said risks.

In order to achieve this goal, better monitoring of the interoperability interfaces must be put in practice. The tools to do so are the artefacts to be designed and built.

First artefact A first artefact was conceptualized using industry standard log and monitoring tools, namely the Elastic Stack. While very powerful, this tools were deemed too difficult to integrate into the existing architecture and difficult to configure and adapt to the company's needs. This approach did not go further preliminary black box testing, being abandoned soon after.

Second artefact After careful consideration of the system's architecture and exchange of perspectives between the interest parties, we settled on adapting already existing tools for the purpose of monitoring interoperability interfaces.

ST+I's solution gives healthcare professionals the ability to request support directly from the application. This support requests, colloquially know as tickets, are already delivered to the Support team at the company's headquarters. This solves the main technical challenge of transiting data from a healthcare institution to our facilities. Such challenge only exists because, as one would expect, inbound and outbound network connections to a hospital are highly restricted.

Since a VPN connection is already in place between the vast majority of clients and ST+I's infrastructure, for the purpose of sending and responding to support requests, this connection can also be used to transmit the monitoring data collected from the interoperability interfaces residing at the hospital's servers to our offices. This architecture is represented in Figure 12.

As a pilot test, the most critical interoperability interfaces, dealing with sending and receiving drug prescription and administration HL7 messages, were altered to produce a "heartbeat". This interfaces were also given a timeout time, that is, a set amount of minutes after which the interface is considered dormant. Proofing was done by installing this capabilities in 6 hospitals.

The typical interoperability interface runs its routines periodically say, every 5 minutes. This periodic routine determines, for example, if new HL7 messages have to be sent or if HL7 messages have been received and need further processing. Please note that the timeout defined for the interface should always be greater than the periodicity of the routine. As a rule of thumb, it was decided to always define the timeout as twice the periodicity of the routine. If an interface runs every 5 minutes, its timeout should be configured to 10 minutes. The periodicity of a given interface is dependent on the criticality of the data exchanged.

Every time the interface's routine runs, the heartbeat function is called also. The heartbeat function updates a database field with the timestamp at that moment. This ensures that the interface is running and that its subroutines finish within the timeout interval, taking into account risks 1, 2 and 3 expressed in Table 5.

In tandem with the interoperability interfaces, a Monitoring Service was created. The job of this monitoring tool is to read, for each interoperability interface, its timeout and last heartbeat, from the database at the hospital's server and write that data to a database running on a Cloud Server. The Monitor is a risk mitigation strategy for the interoperability interfaces. While the Monitor is in itself a point of failure, no further action is necessary to mitigate this secondary risk. The reasons for this claim will become clearer down the line.

In Figure 10, we present a macro-level architecture of a hypothetical *Hospital A*, running three interoperability interfaces, *S1, S2* and *S3* and the monitoring tool denoted as *M*. Data flows are noted by the dotted arrows. *S1, S2* and *S3* run periodically and each call write their heartbeats to the database every time they run. *M* also runs periodically, reading the currently set timeout and last heartbeat for each interface.

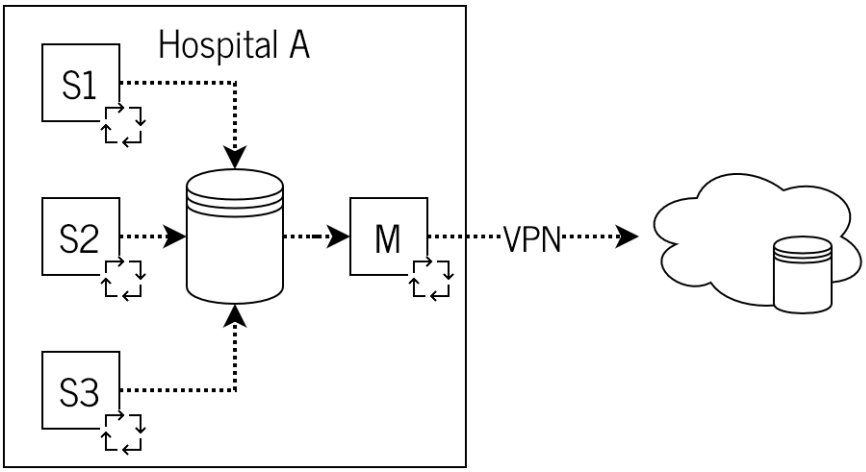

Figure 10: Architecture of Interoperability Interfaces in a Hospital

Other helpful information, such as the healthcare institution where that interface exists is also recorded. The Monitoring Tool *M* then replicates this records into the Cloud Server database. The Cloud Server receives this records from all the hospitals where the monitoring capabilities were introduced.

Data gathered by *M* exists in form of a database table. In a simplified but true to the real implementation, this data structure is exemplified in Figure 11. Each tuple corresponds to its respective interoperability interface. The relevant attributes are *Timeout*, value in minutes after which an interface is considered down, *Heartbeat*, a timestamp of when the heartbeat function was last called by that interface and *Hospital*, which serves as a mere identification of where this interface is running.

```
SELECT
    id,
    timeout,
    heartbeat,
    hospital
FROM
    interfaces
WHERE
    is_active = 1;
```

Listing 1: SQL script to collect monitoring data

SQL code in Listing 1 is a simplification of the true executed code, presented for context. Production code performs other operations. Data about the interfaces is gathered and, for each record, treated by the PL/SQL presented below in Listing 2.

```
DECLARE
    cnt             NUMBER;
    id              VARCHAR2(3);
    timeout         NUMBER;
    heartbeat       TIMESTAMP;
    hospital        VARCHAR2(50);

BEGIN
    _id             := :interfaceID;
    _timeout        := :interfaceTimeout;
    _heartbeat      := :interfaceHeartbeat;
    _hospital       := :atHospital;

    --to determine if that interface already exists in monitoring_data table
    SELECT count(*)
    INTO   cnt
    FROM   monitoring_data
    WHERE  id = _id;

    IF cnt != 0 THEN
        --if exists, update with the current values
        UPDATE monitoring_data
        SET    timeout   = _timeout
         , heartbeat = _hearbeat
        WHERE  id        = _id;
    ELSE
        --if doesn't exist, inserts new record
        INSERT INTO monitoring_data ( id
                                    , timeout
                                    , heartbeat
                                    , hospital)
                             VALUES ( _id
                                    , _timeout
                                    , _heartbeat
                                    , hospital);
    END IF;
END;
```

Listing 2: PL/SQL script to insert monitoring data

ID	Timeout	Heartbeat	Hospital
S1	2	10:00:00 1/1/2022	A
S2	10	9:40:00 1/1/2022	A
S3	20	10:00:00 1/1/2022	A

Figure 11: Data scheme for monitored interfaces

A web based dashboard, developed internally, was already being hosted at the cloud server, for visualization of support requests. This same dashboard, accessible to everyone at ST+I, was adapted to also show alerts regarding the status of interoperability interfaces.

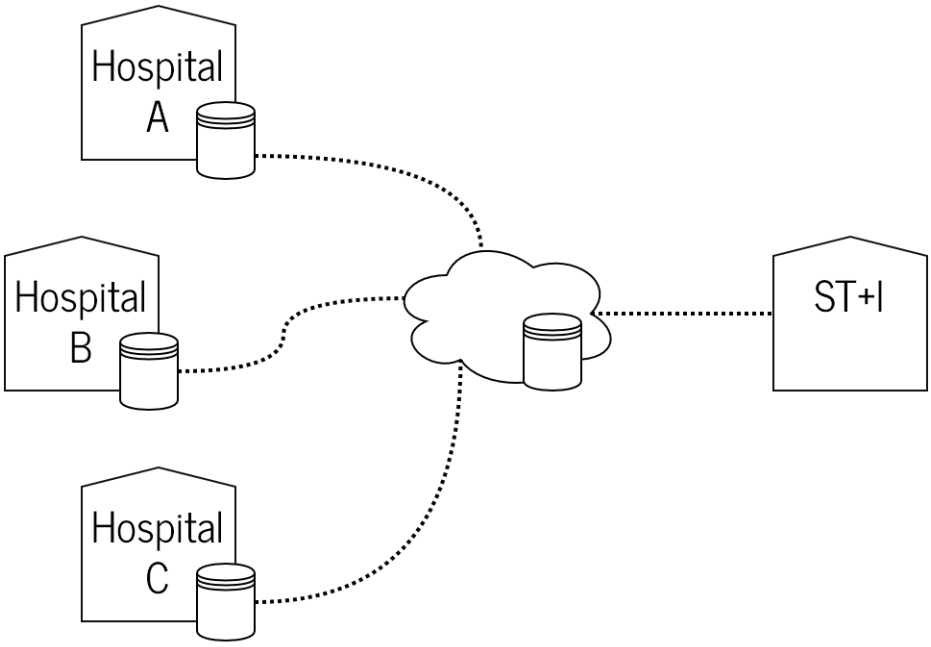

Figure 12: General architecture used by the Monitoring Tools

The dashboard queries the Cloud database every 30 seconds, reading from the previously data inserted or updated by the Monitors at each hospital. To determine whether an alert should be launched, a simple algorithm, implemented in SQL, was written. An abstract implementation is presented below in Listing 3.

```
SELECT
    id,         --interface id
    timeout,    --timeout time of the interface, in minutes
    heartbeat,  --timestamp of the last heartbeat
    hospital,   --the hospital where the interface is running
```

```
FROM
    monitoring_data
WHERE
    sysdate > heartbeat + timeout/24/60
AND timeout > 0;
```

Listing 3: SQL script to determine which interfaces are down

While the SQL instruction above is not the full version the dashboard is running, it is enough to understand the basic idea. First, some clarification: sysdate is a function provided by the Oracle database engine that simply returns the current date and time of the database server's OS. The concept of timeouts and heartbeats have been explained prior. An alert will appear for every interface in which the condition `sysdate > heartbeat + timeout/24/60` is true and timeout has been configured.

For better understanding how this logic works, let's analyse the following timeline (Figure 13). Each hb_n value represents every heartbeat that particular interface records to the database, while tm, a constant amount of minutes, corresponds to the timeout time. As tm is greater than the periodicity in which the interface runs its routines, there should always be an overlap between each time interval $[hb_n, hb_n + tm]$.

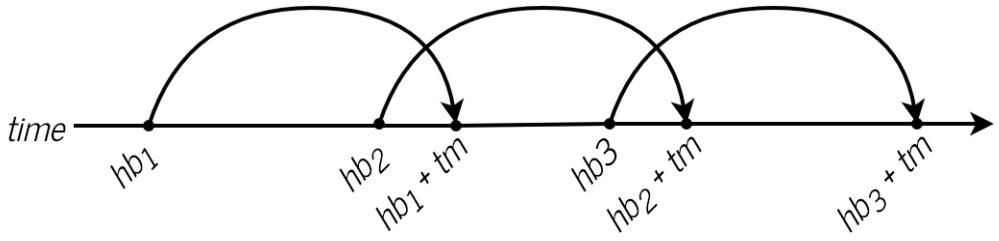

Figure 13: Heartbeats of an interoperability interface in a timeline

In this state, no matter where in time the dashboard runs the SQL command in Listing 3, the condition `sysdate > heartbeat + timeout/24/60` will never return true and no alert will be launched for that interface. This is the desired state.

Now, consider the following scenario, in Figure 14: the interface sent the first heartbeat but, for some reason, any of its subroutines hanged. Execution was never completed and, thus, the interface did not reach the next execution cycle in time. When the dashboard queries the cloud database anywhere in within the $]hb_1 + tm, hb_3[$ interval, the alert condition will return true for that particular interface. This is the undesired state, an alert will appear on the dashboard.

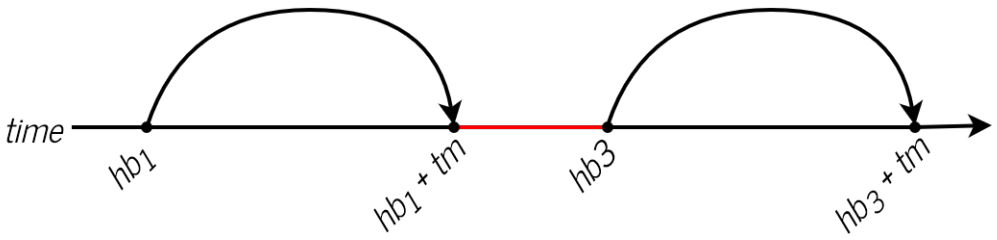

Figure 14: The interface did not send heartbeat hb_2

It was previously mentioned that, while the Monitor is also a point of failure, no additional actions are required to mitigate this secondary risk. If the Monitor fails to synchronize the monitoring data from a hospital to the Cloud Server, eventually all the tuples related to that institution will be out of date. In that case, the condition `sysdate > heartbeat + timeout/24/60` will be true for all these records. Alerts for every one of them will be displayed. While not completely impossible, it is highly unlikely that every single interface fails within minutes of each other. From this assumption, one can assure that, in the event of every alert being triggered, either the Monitor failed or the servers running at the hospital are facing bigger issues. Either one requires immediate attention.

4.3 Knowledge Base

As part of the Rigour Cycle, it is expected that DSR not only collects from the sources of knowledge to support the conception and evaluation of artefacts, but also replenish them. Given the nature of this DSR project and how it was conducted within an business organization operating in a highly specific field, I, the researcher, consider reasonable that there is some overlap between the Environment and the Knowledge Base.

The fields of knowledge deemed relevant for the research are HIS, Interoperability and Risk Management. A literature review was conducted, knitting the current state of the art in this subjects. Grasping the state of the art is the *sine qua non* condition for research to take place.

For each main subject, a keyword search was performed using specialized search engines such as Google Scholar and Research Gate. The keywords searched for each topic are listed in Table 6.

A preliminary selection eliminated any documents not integrally available on-line. From the documents available, the relevant ones for the research objective were picked after reading the abstract. Further sifting was performed by analysing, if applicable, the documents' literature review and results.

Knowledge Field	Keywords
Health Information Systems	”Information Systems”; ”Health Information System”; ”eHealth”; ”Healthcare”; ”SPMS”; ”SNS
Interoperability	”Interoperability”; ”Levels of Interoperability”; ”Interoperability Standards”; ”Semantic Interoperability”; ”Syntatic Interoperability”; ”Medical Ontology”; ”Coding Terms”; ”HL7”; ”FHIR”; ”SNOMED”;
Risk Management	”Risk”; ”Threat”; ”Risk Management”; ”Project Management”

Table 6: Research Keywords

Both the Interoperability and Systems and Infrastructure teams provided invaluable experience and expertise in the fields of HIS, interoperability, distributed systems, databases, networks, among others. Their personal impressions and know-how in HIS contributed vastly for the design and evaluation of the artefacts.

In the opposite direction, the researcher hopes to have contributed to the knowledge base within the scientific community dedicated to research in HIS and Interoperability and to ST+I’s knowledge base on how to tackle the threats related to Interoperability interfaces. The findings from this dissertation should also serve as a guide on how to expand the monitoring capabilities implemented to other sources of risk.

5 Results Evaluation

In this section, the evaluation process this research was subject is stated. The artefact's evaluation process is scrutinized trough the evaluation activities proposed by Sonnenberg and vom Brocke (2012). *Ex ante* and *ex post* evaluations were performed.

5.1 Ex ante

Preliminary validation of existing artefacts and design ideas ensures the truth of subsequent research. Starting from false assumptions would not yield worthwhile research results. The research question and objectives and any known existing artefact should be subjected to an *ex ante* evaluation.

5.1.1 Evaluation 1

A first evaluation activity will have the research question, problems or opportunities and objectives as inputs. Such details, as mentioned before, are expressed in Section 1. Known artefacts potentially fit for the desired purposes should also be evaluated here. In particular, the Elastic Stack was known to be the industry standard for achieving Observability.

Preoccupations regarding interoperability and its safety are well evident in this study's literature review. The same concerns were shared by the relevant stakeholders at ST+I. Meetings involving Management and the Interoperability team evidenced the need for better fault detection methods. The importance of the research question and objectives and the utility of the research results was established.

Feasibility of the Elastic Stack, for our purposes, was practically unknown. The Elastic Stack is well regarded for Observability purposes, being an industry standard. The question was, whether is was the right tool for the job. This technological stack is open source software and offers a free plan. Still, acquisition price is only part of the equation. Training costs and work hours dedicated to this solution also add up. Technical feasibility was also not clear, as the impacts of implementing a new tool into the existing stack were not clear and possible difficulties hard to determine. Determining a schedule for the implementation of this solution was not possible, due to high level of uncertainty surrounding this solution. The solution's utility and operational feasibility could not be determined at this moment either. Regarding novelty, this solution would fall into the high Application Domain Maturity and high Solution Maturity quadrant of DSR Knowledge Contributions Framework (Gregor and Hevner, 2013). Being

a Routine Design, where known solutions would be applied to known problems, no major knowledge contribution would take place.

The objectives for this research project were validated, supported by evidences in literature and a business need. The feasibility and novelty criteria determined that the Elastic Stack was not fit for this research project. This artefact was abandoned in favour of a custom solution.

5.1.2 Evaluation 2

The previous evaluation activity resulted in a set of design goals to achieve. These goals are the inputs for the Evaluation 2 step.

Rejection of the Elastic Stack and the need to achieve the proposed goals demanded a new approach. The second proposal was to make use of the architecture already in place: the VPN connection, between each client and our cloud server, and the dashboard used to display support requests. The general idea was to develop or adapt some kind of mechanism to read the state of the interoperability interfaces at each client and write said state to the database hosted on the cloud server.

Confidence about the feasibility of the new design proposal was optimistic. No new tools would need to be acquired and any new development would occur on a already established architecture. Technical feasibility was more or less guaranteed for that same reason. Operational feasibility and utility were also well ranked. Similar tools, the support request synchronizer service and dashboard, were already in use. From a scheduling perspective, building this artefact seemed feasible within the time constraints of this project and the general business calendar. Developing this new artefact also appeared to be a more interesting proposal in terms of research. While it is true that much of the architecture was already in place, new software components had to be developed. In that capacity, the artefact's novelty is assured. In the DSR Knowledge Contribution Framework (Gregor and Hevner, 2013), the artefact would be categorized as having high Application Domain Maturity and a low Solution Maturity. In going forward with this artefact, we would be before an Improvement. Improvements are new solutions for known problems and constitute a research opportunity. From this research opportunity, there is the aspiration of knowledge contribution.

Sufficient confidence that, when instantiated, this model would respond to the initial goals of safer interoperability interfaces, was established. Next steps include actually instantiating the validated approach.

5.2 Ex post

Ex post evaluations takes place just as the artefact materializes, evolving from a model or concept into an actual IT tool.

5.2.1 Evaluation 3

After put into practice, the instantiated artefact was installed in 6 client institutions. While this step is intended to occur in a artificial setting, this scenario allow us to demonstrate and test the prototype in a subset of the real environment. This was done for four reasons:

- Test for any anomalous behaviour in other systems;
- Identify possible undesired effects resulting from adding a new component to the existing architecture;
- Demonstrate the artefact in its expected environment;
- So that conclusions about the artefact's effectiveness, utility and impact on the environment could be extrapolated.

Alerts launched on the dashboard were recorded from the 21st of March and the 16th of May, 2022. The names of the institutions and interfaces are obfuscated. This records are shown in Table 7.

ID	Hospital	Type	Name	Stopped at	Issue Resolved at	Δ
1	Uxxx	Service	Mxxxr	21/03/22 09:48	21/03/22 15:27	05:39
2	Hxx	Server	Wxx	21/03/22 08:50	22/03/22 10:15	01:25
3	Cxx	Service	Hxxxr	24/03/22 11:59	24/03/22 14:00	02:01
4	Cxx	Service	Exxxr	24/03/22 11:56	24/03/22 14:00	02:04
5	CHxxx	Service	Hxxxr	28/03/22 10:30	28/03/22 11:00	00:30
6	Uxxx	Service	Bxxxe	30/03/22 16:59	30/03/22 17:29	00:30
7	Uxxx	Server	Hxxxr	07/04/22 09:33	07/04/22 10:00	00:27
8	Uxxx	Service	Bxxxe	24/04/22 15:45	26/04/22 09:10	17:25
9	Hxxx	Service	Bxxxe	16/05/22 05:48	16/05/22 14:12	08:24

Table 7: Recorded alerts

While not vast, this result set establishes the artefact's utility and effectiveness as a monitoring mechanism to alert for interoperability interface faults. The issues, as they were more readily identified, were solved in a timespan considered reasonable. All but two of the faults were resolved under 6 hours. Due to human factors, issues 8 and 9 where only noticed much later.

The artefact makes interoperability interfaces' faults more observable, responding to the business objectives. Allocating resources to solve the issue swiftly is now possible. In practice, when problems are detected sooner, less disturbance occurs to the use of interoperable HIS. Implementing the artefact in the 6 selected clients also establishes its technical feasibility. No nuisances were detected after the fact on the existing systems and architecture. The impacts on the environment are, so far, beneficial.

5.2.2 Evaluation 4

Evaluation 4 would occur on a naturalistic setting. In this case, we would consider the full spectrum of clients in Portuguese soil to be that scenario. One could argue that we skipped Evaluation 3 by demonstrating the artefact in a subset of the natural environment. While that did occur, demonstrating the artefact in only 6 clients is not a full proof of usefulness. Complete transfer of the artefact did not yet occur at the time of writing this dissertation. Only then, a complete review of the artefact would be possible.

6 Discussion

This research project, developed in collaboration with ST+I, aimed at searching for ways to manage risks associated with interoperability interfaces. Interoperability is indissociable from risk. While noteworthy initiatives such as the HL7 FHIR are contributing for true standardization and adoption of technical best practices and methods, we are still a long way away from achieving absolute organizational interoperability. In the mean time, we, as professionals in the field of HIS, should direct efforts into making interoperability as safe as possible. In this section, we will be discussing the conducted research: the results we've obtain, what lessons we've learned and potential improvement opportunities.

6.1 Results overview

Overall, we would consider the research results satisfactory. Having few anomaly records is not necessarily negative. This records serve only to demonstrate that the artefact is useful and effective in its function: alerting for faults in interoperability interfaces. In fact, the developed artefact has been helpful in promptly identifying whether the interoperability interfaces are running correctly or not.

6.2 Theoretical and practical significance

How safer interoperability can be achieved, through the optics of risk management, by exploring monitoring mechanisms in interoperability interfaces was our research question. Capturing the state of the art on Health Information Systems, Interoperability and Risk Management was mandatory to answer it. This descriptive knowledge acts as a foundation of the research process. Exploring the three cited domains established the importance of the research question. In particular, the perils and challenges of interoperability became well explicit. Despite standardization efforts and the recognition of the interoperability dilemma throughout the years, HIS professionals still have a long way to go before finally solving this issues.

Interoperability, from a HIS vendor's perspective, first and foremost, requires that the interfaces are running properly. If data does not even reach other relevant HIS and their users, confidence on such technologies is undermined. When dealing with particularly critical data such as prescriptions and administration of drugs, risks for patients can occur if said data does not propagate properly. If no guarantee that the interface is even running can be given, preoccupations with message syntax and semantics,

nomenclatures used and other formalities become utterly irrelevant.

Issues are prone to happen and systems lock down. When interoperability interfaces go down, response should be timely. Practical significance of this research work emerges from the developed artefact. By launching alerts as soon as possible, resources can be assigned to the problem, before bigger issues occur. In this practical sense, the objectives were reached. There is now in place an alert mechanism for when interoperability interfaces misbehave. Preliminary demonstrations in the environment, in general, proves the artefact's utility.

There was an initial distress in finding the most appropriate research referential. An eagerness in conducting this undertaking with scientific worth lead to a parallel study on research paradigms in general and in IS. There was the need to not only describe what was done and how it was done but also how the environment affects and is affected by the research outputs. After much thought, the choice settle on DSR. The chosen research methodology was crucial to establish rigour and transparency to this project (Ferreira et al., 2012).

Nevertheless, one should not blindly follow prescriptions and run the risk of falling into dogmatic behaviour. Hassan and Mingers (2018) postulates that DSR suffers from an epistemology conflict: Hevner et al. (2004), March and Smith (1995) and Simon (2008) try to bridge the gap between prescriptive and descriptive knowledge, while at the same time having the explicit purpose of creating artefacts (Hevner et al., 2004; March and Smith, 1995). Iivari (2007a) also alludes to this dispute: designing products and processes, prescriptive knowledge, is a field of knowledge in itself and cannot be reduced to descriptive knowledge. Once again, Iivari (2020) defends the position that DSR should abstain from the unhealthy obsession with theory, in particular the term "design theory". DSR should be concerned with producing new design knowledge about novel and practical artefacts, which is just as valid as design theories (Iivari, 2020). Authors ought to be more focused on recent design knowledge and new useful artefacts (Iivari, 2020).

This research tried to achieve a reasonable middle ground between these conflicting visions on what DSR ought to achieve. The effort in following the processes suggested for DSR (Hevner et al., 2004; Hevner, 2007; Gregor and Hevner, 2013; Sonnenberg and vom Brocke, 2012; Peffers et al., 2008; Pries-Heje et al., 2008; Venable et al., 2012) grants theoretical validity to this research. Still, the practical goal of creating an artefact for the purpose of monitoring interoperability interfaces was always present.

6.3 Limitations and future work

Choosing the right evaluation methods and criteria was not as straightforward or simple as desired. The artefact was evaluated qualitatively for the degree in which it responds to the objectives. Perhaps it would be interesting to quantify the impacts the artefact had, or evaluate it quantitatively. As a matter of fact, this was initially planed, as described below:

Early on, the thesis that implementing a monitoring artefact would have an impact in the downtime of interoperability interfaces was presented. Statistical validation was to be conducted. Gathering quantitative data of two conditions, before and after implementation, would be required and two hypothesis were formulated:

- $H0$ - downtime of interoperability interfaces is equal before and after implementing the artefact (null hypothesis);
- $H1$ - downtime of interoperability interfaces is lower after implementing the artefact.

Establishing a before and after quantification of the artefact would allow, for example, empirical assessment of risk values after the fact, which this project also lacked. Intuitively, the risk of data not being exchanged, because the interface was malfunctioning, has lowered. When one is aware of incidents sooner and acts upon them accordingly, there's better guarantees that the interfaces have lower downtime. Nevertheless, from a scientific point of view, validating a result on mere intuition can be deceiving.

We consider that there is theoretical and practical significance to be had from this dissertation. Much has been learned about interoperability, risk management activities and the role of HIS. Naturally, these enlightenments can be further expanded. The model adopted for the construction of the artefact can also be applied to other risk factors, some of which were already identified in Table 5. Expanding the implementation of the monitoring capabilities to other institutions, beyond the 6 instantiations performed, is also on the line. This project is not an end into itself, but rather a step towards fool-proofing the existing interoperability interfaces.

7 Conclusion

Existence of multiple and heterogeneous HIS in public hospitals, local health units and even private providers, establishes the necessity for a communication schema between each of this entities. Governance efforts and initiatives, at National and European level do exist, but given the complexity of this field, the implementation of this policies is slow and results are gradual. More than a common language, as in standards, interoperability requires commitment from all four levels.

This study concludes that, while interoperability is complex, it is indispensable in the vast HIS environment in healthcare institutions. Risk management strategies are useful allies in maintaining a certain confidence level on interoperability interfaces. During this research, a risk response tactic was adopted, in the form of a monitoring artefact. This artefact alerts of faults in interoperability interfaces. Theoretical and practical relevance of the artefact is asserted on its ability to promptly warn of potential failures in interfaces, thus reducing potential negative consequences.

The adopted research methods and tools, namely DSR, allied *knowledge for understanding* and *knowledge for a purpose*, guaranteeing rigour and transparency of this process. Initial discovery of the existing research paradigms was fruitful, allowing to choose an adequate framework for artefact creation and interconnecting contributions from and to the environment and from and to the knowledge base.

As final remarks, this project was not intended as an end into itself, but rather a contribution towards scientific and technical progress, opening the gates to expand the strategies and methods proposed to other threat factors that might not allow for the smooth operation of HIS.

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Appendices

A Technology Readiness Level

Adapted from Sauser et al. (2006)

TRL	Definition
9	Actual system proven through successful mission operations.
8	Actual system completed and qualified through test and demonstration.
7	System prototype demonstration in relevant environment.
6	System/subsystem model or prototype demonstration in relevant environment.
5	Component and/or breadboard validation in relevant environment.
4	Component and/or breadboard validation in laboratory environment.
3	Analytical and experimental critical function and/or characteristic proof-of-concept.
2	Technology concept and/or application formulated.
1	Basic principals observed and reported.

B System Readiness Level

Extracted from (Sauser et al., 2006, p. 7)

SRL	Name	Definition
5	Operations & Support	Execute a support program that meets operational support performance requirements and sustains the system in the most cost-effective manor over its total life cycle.
4	Production & Development	Achieve operational capability that satisfies mission needs.
3	System development & Demonstration	Develop a system or increment of capability; reduce integration and manufacturing risk; ensure operational supportability; reduce logistics footprint; implement human systems integration; design for producibility; ensure affordability and protection of critical program information; and demonstrate system integration, interoperability, safety, and utility.
2	Technology development	Reduce technology risks and determine appropriate set of technologies to integrate into a full system.
1	Concept refinement	Refine initial concept. Develop system/technology development strategy.

C Design Science Research Guidelines

Adapted from Hevner et al. (2004)

ID	Guideline	Description
1	Design as an Artefact	Design-science research must produce a viable artefact in the form of a construct, a model, a method, or an instantiation.
2	Problem Relevance	The objective of design-science research is to develop technology-based solutions to important and relevant business problems.
3	Design Evaluation	The utility, quality, and efficacy of a design artefact must be rigorously demonstrated via well-executed evaluation methods.
4	Research Contributions	Effective design-science research must provide clear and verifiable contributions in the areas of the design artefact, design foundations, and/or design methodologies.
5	Research Rigour	Design-science research relies upon the application of rigorous methods in both the construction and evaluation of the design artefact.
6	Design as a Search Process	The search for an effective artefact requires utilizing available means to reach desired ends while satisfying laws in the problem environment.
7	Communication of Research	Design-science research must be presented effectively both to technology-oriented as well as management-oriented audiences.

D Evaluation criteria for different types of artefacts

Adapted from March and Smith (1995)

Criteria	Con-struct	Model	Method	Instan-tiation
Completeness	X	X		
Ease of use	X		X	
Effectiveness				X
Efficiency			X	X
Elegance	X			
Fidelity with real world phenomena		X		
Generality			X	
Impact on the environment and on the artefact's users				X
Internal consistency			X	
Level of detail			X	
Operationality			X	
Robustness		X		
Simplicity	X			
Understandability	X			

E Evaluation activities for the DSR cycle

Adapted from Sonnenberg and vom Brocke (2012)

Input	Output	Criteria	Methods
Problem statement/observation of a problem; Research need; Design objectives; Design theory; Existing solutions to a practical problem;	Justified problem statement; Justified research gap; Justified designed objectives;	Applicability; Suitability; Importance; Novelty; Economic feasibility;	Literature review; Review of practitioner initiatives; Expert interview; Focus groups;
Design specifications; Design objectives; Stakeholders of the design specification; Design tools and methodology;	Validated design specifications; Justified design tools and methodology.	Feasibility; Accessibility; Understandability; Clarity; Simplicity; Elegance; Completeness; Level of detail; Internal consistency; Applicability; Operationality;	Mathematical proof; Logical reasoning; Demonstration; Simulation; Benchmarking; Survey; Expert interview; Focus group;
Instance of an artefact (prototype);	Validated artefact instance in an artificial setting (applicability);	Feasibility; Ease of use; Effectiveness; Efficiency; Fidelity to the real world; Operationality; Robustness; Suitability;	Demonstration with prototype; Experiment with prototype with system benchmarking; Survey; Expert interview; Focus group;
Instance of an artefact;	Validated artefact instance in a natural setting (usefulness);	Applicability; Effectiveness; Fidelity to the real world; Generality; Impact on environment and users; Internal and external consistency;	Case study; Field experiment; Survey; Expert interview; Focus group.

F Guidelines for the DSR Strategy Selection Framework

Adapted and abridged from Venable et al. (2012)

	Ex ante Formative Lower build cost Faster Evaluate design or prototype	**Ex post** Summative Higher build cost Slower Evaluate instantiation
Naturalistic Diverse stakeholders involved Possibility of conflict Higher cost Slow Requires access to the organization Evaluates artefact effectiveness Scientific rigour via experimental proof	Low-medium cost Medium speed Low risk to participants Higher risk of false positives	Highest cost Highest risk to participants Focus group Best effectiveness evaluation Identification of side effects Lowest risk of false positives
Artificial Fewer stakeholders involved Less potential conflicts For purely technical artefacts Lower cost Fast Artefact efficacy evaluation Scientific rigour via control of variables	Lowest cost Fastest Lowest risk to participants Highest risk of false positives	Medium to high cost Medium speed Low-medium risk to participants

G DSR paper structure

Adapted from Gregor and Hevner (2013)

Section	Contents
Introduction	Problem definition; problem significance and motivation; key concepts; research questions and objectives; scope; methods and findings; theoretical and practical significance and the structure of the paper. For DSR in particular, the problem definition and objectives should specify the goals for the artefact to be developed.
Literature Review	Prior work that is relevant for the study: theories; empirical research and findings and reports from practice. Should also include prior knowledge related to the class of problems to be addressed, such as artefacts that have been developed for similar purposes.
Method	The research approach used. The specific DSR approach employed should be explained, referencing existing authorities.
Artefact Description	Concise description of the artefact at the appropriate level of abstraction. This section should constitute the majority of the paper. Its format is likely variable but should include the description of the designed artefact and, if applicable,the design search process.
Evaluation	Evidence of the usefulness of the artefact. The artefact's worth is evaluated to demonstrate its capabilities, using criteria such as validity, utility, quality and efficacy.
Discussion	Interpretation of the results: what do they mean and how they relate to the objectives stated in the Introduction section. Can include a summary of what was learned, how it compares to prior work, its theoretical and practical significance and areas requiring further work. Research contributions are highlighted and the paper's results to research and practice are discussed.
Conclusion	Restatement of the important findings and main ideas of the work and why they are important