POLYTECHNIC SCHOOL OF THE UNIVERSITY OF SÃO PAULO

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Design Thinking Impact on the Value Creation and Value Capture of New Solutions: a Multicase Analysis

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RESUMO

O conceito de Design Thinking tem atraído interesse crescente de profissionais e acadêmicos desde a primeira década dos anos 2000. Muitas publicações descrevem como o Design Thinking pode ser aplicado, oferecendo *frameworks*, modelos, processos e diretrizes para facilitar sua aplicação bem-sucedida. Estudos empíricos descrevem a criação de soluções seguindo a abordagem de Design Thinking, que se mostra eficaz em impulsionar a inovação em contextos amplos e diversos. No entanto, a pluralidade de pontos de vista sobre Design Thinking pode trazer entendimentos difusos e dificultar a comparação de achados empíricos. Nesse contexto, este trabalho inicia com revisão teórica sobre Design Thinking e elabora um mapa conceitual dos níveis de aplicação da abordagem que permite situar os estudos empíricos na literatura e facilita comparações. Em seguida, considerando que Design Thinking pode ser aplicado em nível organizacional, individual ou de projeto, são apresentados estudos publicados que demonstram como a abordagem ocorre em cada contexto. Com foco em Design Thinking para projetos de inovação, a parte empírica deste trabalho avalia como a abordagem impactou os resultados de projetos de desenvolvimento de novos produtos. Para tanto, foram analisados três casos de criação de produtos para o setor saúde. O modelo de avaliação dos projetos considera que a abordagem de Design Thinking é composta por princípios que podem ser aplicados ao longo de todas as etapas do processo de inovação para a criar soluções de sucesso. A avaliação de sucesso leva em consideração a conceituação de valor e considera que as soluções devem promover tanto a criação de valor para o usuário final quanto a captura de valor no mercado. Por fim, o trabalho traz proposições teóricas sobre como Design Thinking pode influenciar a criação e captura de valor em projetos de inovação e aponta oportunidades para avançar na abordagem a fim de aumentar as chances de sucesso dos projetos. As contribuições têm relevância prática e teórica, direcionando projetos de desenvolvimento de novas soluções e dando suporte a pesquisas futuras sobre Design Thinking.

Palavras-chave: Design Thinking; Inovação; Saúde; Criação de valor; Captura de valor.

ABSTRACT

Design Thinking has been attracting increasing interest from practitioners and scholars since the 2000s. Many publications describe how Design Thinking can be applied, offering frameworks, process-like models, and guidelines to enable its successful application. Empirical studies have described the creation of solutions following the Design Thinking approach, which has proved to be effective in driving innovation in broad and diverse contexts. However, the plurality of points of view about Design Thinking can bring diffuse understandings and hinder comparison of empirical findings of the construct. In this context, this work starts with a review-based study that provides an overview of academic researches on Design Thinking and draws up a conceptual map for the approach's application levels to situate empirical studies within the literature and facilitate comparisons. Then, considering that Design Thinking can be applied at organizational, individual, or project-level, published studies are presented to demonstrate how the approach takes place in each context. Focusing on Design Thinking for innovation projects, the empirical part of this work evaluates how the approach has impacted the outcomes of new product development projects. To this end, three cases of healthcare products creation were analyzed. The project evaluation model considers that the Design Thinking approach is composed of principles that can be applied along all stages of the innovation process to create successful solutions. The success evaluation takes into account the conceptualization of value and considers that solutions are intended to provide both value creation for the end-user and value capture from the marketplace. Finally, the work draws up theoretical propositions about how Design Thinking can impact the value creation and value capture at innovation projects and points out opportunities to advance the approach to increase the odds of solution success. The contributions have practical and theoretical relevance, directing new solution development projects and supporting further research about Design Thinking theory.

Keywords: Design Thinking; Innovation; Healthcare; Value Creation; Value Capture.

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1. INTRODUCTION

1.1. Importance of Research on Design Thinking

Design Thinking is a construct that has been attracting increased interest from practitioners and scholars since the first mid-decade of the 2000s (Micheli, Wilner, Bhatti, Mura, & Beverland, 2019). Popular management books about Design Thinking practice and benefits have grown considerably in volume and relevance reaching thousands of citations (e.g., Brown, 2009; Liedtka & Ogilvie, 2011; Lockwood, 2009; Martin, 2009)[1]. Major business practitioner publications, including Harvard Business Review and The Economist, have devoted special issues or entire sections to Design Thinking and prominent academic journals such as *Journal of Product Innovation Management* and *Academy of Management Journal* have recognized Design Thinking as a central issue in business and management (Liedtka, 2015; Micheli *et al*., 2019).

Many publications describe how Design Thinking can be carried out, offering frameworks, process-like models, and guidelines to enable the successful application of the approach in driving innovation issues. Seidel & Fixson (2013) pointed out the works of Brown (2008, 2009), Lockwood (2009b), and Martin (2009) as the most commonly cited references in promoting Design Thinking adoption. Brown (2008) presents the three spaces of innovation model for Design Thinking that encompass different sorts of related activities that form the continuum of innovation. Lockwood (2009b) draws up the Three Gears of Design, an iterative and a non-linear framework intended to knit together user needs, powerful ideas, and enterprise success. Martin (2009) put Design Thinking as a form of thought that balances analytical reasoning and intuitive originality to enable companies to explore new opportunities and convert them into profitable business exploitations.

Among the academic strands of Design Thinking research, this work follows the strand of Brown (2008), named by Johansson-Sköldberg, Woodilla, & Çetinkaya (2013) as the *IDEO Way of Working with Design and Innovation*. In this context, the Design Thinking methods and tools are described as being effective to guide the creation of

[1] Search made in google scholar database on March 8, 2020 pointed out that books ‘Change by Design’ (Brown, 2009) had 4705 citation, ‘The Design of Business’ (Martin, 2009) had 1931 citations, ‘Design Thinking’ (Lockwood, 2009) had 684 citation and ‘Designing for Growth’ (Liedtka & Ogilvie, 2011) had 527 citations.

new solutions by deeply understanding the customer needs and getting their feedbacks in iterative cycles of prototyping and testing (Institute of Design at Stanford, 2010; Liedtka, 2015; Seidel & Fixson, 2013). In addition, to highlight the constituent elements of Design Thinking, Micheli *et al*. (2019), from a systematic review assessing more than one hundred papers, identify ten principal attributes involved in Design Thinking practice. Moreover, the approach has proved to be effective in developing solutions in broad and diverse contexts, ranging from the conception of a robot for elderly assistive care (McGinn *et al*., 2020) to supporting public policy elaboration (Howlett, 2020) and training for teachers (Boloudakis, Retalis, & Psaromiligkos, 2018).

Nonetheless, the plurality of points of view about the theme of Design Thinking can bring diffuse understandings and hinder a cohesive perspective on the construct. Despite the numerous calls of adoption of Design Thinking, a "generally accepted definition of Design Thinking has yet to emerge, and even the term itself is a subject of controversy among its practitioners and advocates" (Liedtka, 2015, p. 926). A broadly defined construct used to loosely encompass a set of diverse phenomena, called by Hirsch and Levin (1999) as an "umbrella construct", can be initially useful to provide a way to join and organize an extensive range of events that otherwise could be considered unrelated findings (Micheli *et al*., 2019). However, an umbrella construct risks losing specificity and applicability at the limit, meaning all things to all people. It would be the collapse of the construct, decreasing its relevance considerably. Thus, studies that contribute to clarify the constitution and specificity of Design Thinking are useful to make progress in understanding the phenomena and ease the comparability of empirical findings (Micheli *et al*., 2019).

1.2. Objective and Research Questions

In this context, this work aims to evaluate how Design Thinking can influence the success of new solutions creation, seeking to clarify which aspects along the development process are indeed impacted by using the Design Thinking approach. Thus, to evaluate the success of Design Thinking, the first step is to set out what factors indicate it was successfully applied. According to Brown's (2008, 2009) perspective, the Design Thinking approach has two main objectives: (i) match people's needs with what is technologically feasible and (ii) create customer value and market opportunity by means of a viable business strategy. Therefore, it can be considered that Design

Thinking was successfully applied in an innovation project whether its outcome is a promising solution.

In addition, to enhance the theoretical background, this work turns to organizational theory to get more references about how organizations operate to achieve such objectives. Taking the perspective of Bowman & Ambrosini (2000), the first objective can be related to the way companies create *use value*, which represents the customer expectations about the usefulness the solution can offer. The perception of use value is completely subjective and varies according to customers' beliefs, needs, experiences, and wishes. On the other hand, the second objective can be linked to how companies capture value in the marketplace. The value capture occurs when the companies successfully perform their business strategy carrying out exchange transactions with their customers, setting the price that represents the *exchange value* of the sold solution.

Thus, the evaluation of Design Thinking success in this work explores how the approach can impact the innovation projects to obtain new solutions that can promote both value creation and value capture. To this end, the following research questions were drawn up to guide the inquiries of this work:

> Q1) How does the Design Thinking approach contribute to value creation?
>
> Q2) How does the Design Thinking approach contribute to value capture?
>
> Q3) What are the opportunities to improve the Design Thinking application in innovation projects to increase the potential of value creation and value capture?

Finally, this work ends up providing discussions and propositions around those research questions intending to contribute to theory-building about the Design Thinking practice. Thus, providing greater clarity and specificity about how the approach can drive the success of new solution projects and direct opportunities identification for future research.

1.3. Research Approach

In order to evaluate the success of the Design Thinking application, this work follows the framework of Design Research Methodological (DRM) of Blessing & Chakrabarti (2009). Overall, the DRM framework has two main objectives: (i) "formulating and validating models and theories about the phenomenon of design" and (ii) "developing and validating knowledge, methods and tools that aim to improve design, that is, to improve the chances of producing a successful product" (Blessing & Chakrabarti, 2009, p. 13). Thus, considering the Design Thinking approach as the "support"[2] used to improve the design practice and the development of new solutions, this study follows the steps of DRM to evaluate the impact of Design Thinking in terms of driving the use value creation and the value capture with the newly created solutions.

The DRM framework consists of four macro stages of the research project: Research Clarification, Descriptive Study I, Prescriptive Study, and Descriptive Study II. However, not all research projects may contain all those stages or undertake all stages in equal depth. It depends principally on the state of the art of literature in the field the research takes place. In some cases, the literature provides sufficient references to conduct a particular stage on a review-based approach, while in other cases, a research project may focus on a specific stage for an in-depth empirical study (Blessing & Chakrabarti, 2009). Thus, the DRM framework offers seven types of project structures most commonly applied to research projects, as represented in Figure 1. Among these options, the fourth type of project was chosen to guide this work, bearing in mind the reasons presented thereafter.

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[2] The term *support* is used within DRM framework to generally designate any possible means, aids and measures that can be used to improve design. This includes strategies, methodologies, procedures, methods, techniques, software tools, guidelines, information sources, *etc*., addressing one or more aspects of design. Support thus covers a spectrum as diverse as: checklists for identifying requirements, drawing aids, guidelines for embodiment design, project management tools, plans for new organizational structures, etc. (Blessing & Chakrabarti, 2009)

Figure 1 – Choice of design research project type – based on DRM framework

Research Clarification	Descriptive Study I	Prescriptive Study	Descriptive Study II
1. Review-based →	Comprehensive		
2. Review-based →	Comprehensive →	Initial	
3. Review-based →	Review-based →	Comprehensive →	Initial
4. Review-based →	Review-based →	Review-based → Initial/ Comprehensive	Comprehensive
5. Review-based →	Comprehensive →	Comprehensive →	Initial
6. Review-based →	Review-based →	Comprehensive →	Comprehensive
7. Review-based →	Comprehensive →	Comprehensive →	Comprehensive

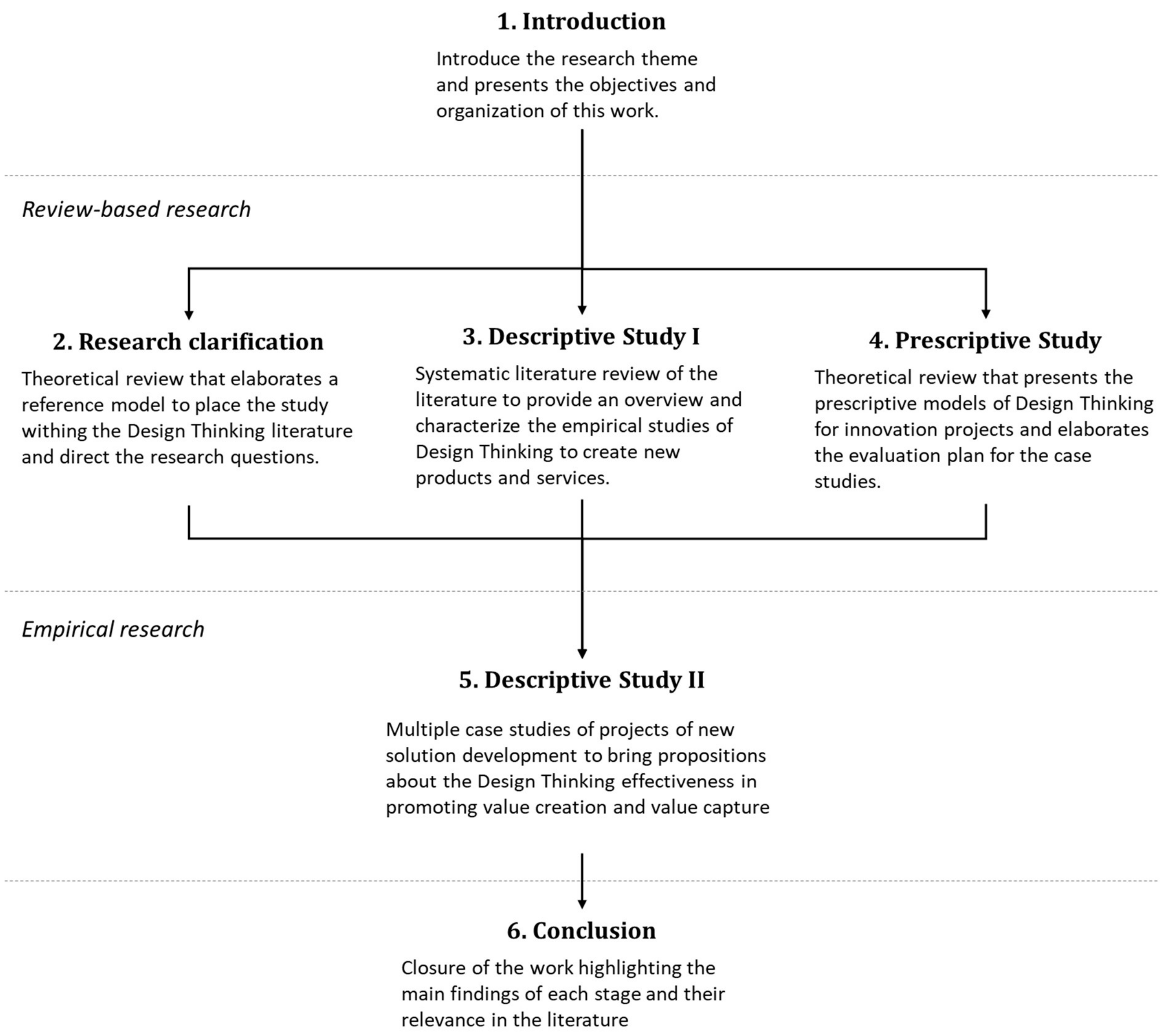
Source: Adapted from Blessing & Chakrabarti (2009)

The Research Clarification is a review-based stage mandatory for all research projects. The first step of any research is to build the theoretical framework that serves as the base to sharpen the assumptions and objectives of the research project. The Descriptive Study - I involves the investigation of the phenomenon through empirical research. In this work, it can be carried out based on the literature review as many publications describe the creation of solutions employing the Design Thinking approach (e.g., Geissdoerfer, Bocken, & Jan, 2016; Lin, Yu, Chu, & Chien, 2017; Song *et al*., 2020). The Prescriptive Study is about developing support for improving the design. As previously mentioned, this study takes the Design Thinking approach as the support to be evaluated. This stage can also be carried out based on literature review as there are many published models prescribing how to apply Design Thinking (e.g., Brown, 2008; Liedtka & Ogilvie, 2011; Lockwood, 2009a). The Descriptive Study-II focuses on the evaluation of support. This stage comprises multiple case studies of new product development projects to evaluate the success of the Design Thinking application in such cases.

1.4. Organization of this Work

This work is organized into six chapters, and it has a specific objective for each stage of the DRM framework, as represented in Figure 2.

Figure 2 – Organization of this work and specific research objectives



Source: Elaborated by the author

In the Research Clarification stage, the first specific objective is to create an initial reference model to position this study within the literature, identifying the academic streams of Design Thinking and the expected results in new solution projects. The second objective, in Descriptive Study I, is to get an overview of emergent literature about Design Thinking related to the creation of new solutions. For this purpose, a systematic review of the literature was carried out, highlighting the empirical studies that have taken the Design Thinking approach at a project level to conceive new products or services. In the Prescriptive Study, the third objective is to identify the existing prescriptive models of Design Thinking to drive innovation projects. For this purpose, a theoretical review gathers the main models of Design Thinking, elaborating a comparative framework to summarize the main topics of the models, serving as the basis for the evaluation plan of case studies in the following stage. At the stage of Descriptive Study II, the fourth objective is to evaluate the impact of Design Thinking in innovation projects outcomes. Thus, multiple cases studies are performed to investigate how the Design Thinking approach may influence the potential of value creation and value capture of the new solutions.

Finally, this work draws up propositions and discussions about Design Thinking practice seeking to bring more clarity and specificity about how this approach can boost the success of new solution development. Besides dialoguing with the theoretical conceptualization of Design Thinking, these contributions have a practical implication in supporting further empirical projects of solution development to achieve better outcomes.

2. RESEARCH CLARIFICATION

The objective of this stage is to build the theoretical background and reference model to clarify the assumptions and place this work within the literature and also to guide the elaboration of research questions. Thus, the research clarification is organized in five sections that encompass the analysis of the origin and basis of the Design Thinking (Section 2.1), the identification of principles that constitute the construct (Section 2.2), the discussion of the application levels (Section 2.3) and the exploration of the expected results of this approach (section 2.4). As a result, a synthesis of the literature is presented as a theoretical framework (Section 2.5).

2.1. Design Thinking Basis and Origins

The term Design Thinking (DT) has been attracting an increasing interest of scholars in general management and innovation studies from the mid-first decade of the 2000s and became a central concept in both fields (Micheli *et al*., 2019). Although the concept of Design Thinking seems to be relatively new for the business world, the origin of the term remains in the studies about designers and related disciplines, such as architecture, planning, or design history. Research about design practice and theory has been developed at least since the late 60s (Johansson-Sköldberg *et al*., 2013).

In their review about academic discourses of Design Thinking, Johansson-Sköldberg *et al.* (2013) classify the studies in two research strands. The first one, called by the authors of “Designerly Thinking”, concerns the academic construction of the professional designer’s practice and theoretical discussions exploring their non-verbal competencies and reasoning. On the other hand, the authors reserve the term “Design Thinking” for the second strand, which explores design practice and competence beyond the design context, especially in management. Thus, Design Thinking might be interpreted as a limited perspective of ‘Designerly Thinking’ to promote the application of design principles, methods, and tools by non-designers to address management and business issues.

2.1.1. Designerly Thinking Discourses

Johansson-Sköldberg *et al.* (2013) pointed out that the Designerly Thinking stream of academic studies brings contributions to both designers and related disciplines, such as architecture, planning, or design history. The authors identified five main theoretical perspectives within designerly studies, which are listed below with its respective foundation work:

1) Design and Designerly Thinking as the creation of artifacts – Simon (1969)
   Simon was the winner of the Nobel Prize in Economics in 1978 to criticize traditional decision-making models based on the 'rational individual' and proposed the "bounded rationality" as an alternative approach. His work, *The Sciences of the Artificial*, published in 1969, suggests that design encompasses all the capabilities and knowledge to create artifacts. Thus, design is responsible for human creations, i.e., what is artificial, while other sciences study what already exists. Regarding the singularities of artificial sciences, even though without using the term "Design Thinking", Simon (1969) is a primary reference in Designerly Thinking studies as he confers legitimacy of an experimental approach of design research (Johansson-Sköldberg *et al.*, 2013).

2) Design and Designerly Thinking as a reflexive practice - Schön (1983)
   Schön (1983), based on a philosophical pragmatism, explored the relationship between the designers' creation and their reflection on creation. So that reflective practice would allow designers to improve their competencies and creations constantly. The practice-based point of view of Schon (1983) fosters reflection about the role and importance of technical knowledge in the development of professional excellence in design, rather than considering design as an essentially artistic process (Johansson-Sköldberg *et al.*, 2013).

3) Design and Designerly Thinking as a problem-solving activity - Buchanan (1992) based on Rittel & Webber (1973)
   Buchanan's (1992) article about wicked problems is considered a foundation reference not only in Design Thinking studies but also in the whole design field (Johansson-Sköldberg *et al.*, 2013). The conception of wicked problems as a matter of design activity was formulated by Rittel and Webber (1992). The two

authors proposed an alternative to the linear, step-by-step model of the design process based on two phases: (i) problem definition, an analytical set of activities to determine the main requirements to drive a good solution creation and (ii) problem solution, a synthetic approach to combine and balance solution requirements to yield a final plan to be carried into production (Buchanan, 1992). Wicked problems emerge from ill-defined contexts, and Rittel and Webber (1973) listed ten main attributes of such kind of problem. Buchanan (1992) suggests that design problems are essentially wicked, and they have a fundamental characteristic called *indeterminacy,* which implies that there are no definitive conditions and boundaries to design problems. To address the indeterminacy, Buchanan (1992) introduces the concept of *Placements*, a set of tools used by designers to shape a situation, considering the views of all participants and the main issues to work on hypothesis development.

4) Design and Designerly Thinking as a way of reasoning/making sense of things - Lawson (2006) and Cross (2006, 2011)

   The works of Lawson and Cross are based on practical cases. Both authors apply abductive processes to make sense of and construct generalizations from observations and find patterns to describe designers thinking and working. Ultimately, they propose a 'model' of the design process (Johansson-Sköldberg *et al.,* 2013). Lawson and Cross's works could be placed in the same group as Schon's studies since these authors propose a practice-based discourse of Designerly Thinking. However, Johansson-Sköldberg *et al.* (2013) chose to designate a separate research stream for Lawsons and Cross, as those authors build their contributions grounded on practical experiences and real cases, rather than taking a purely philosophical perspective as Schön did.

5) Design and Designerly Thinking as the creation of meaning - Krippendorff (2006)

   In contrast with Simon's (1969) point of view, who characterizes design as the science whose finality is creating artifacts, Krippendorff (2006) advocates that the core of the design process is the creation of meaning, while the artifacts are just means to communicate such meaning.

As the objective of this work is to explore and study how is the adoption of Design Thinking in the business and innovation field, there is no intention to deepen the theoretical discussion in the Designerly field. However, it is important to highlight and recognize the origin of the term 'Design Thinking' from academic studies about the theory and practice of the designer work and clearly remark the difference from Designerly to Design Thinking academic discourses. Furthermore, it is important to avoid misunderstanding, as there are publications in Designerly fields using 'Design Thinking' and related terms, whose meaning and conceptualization are different from 'Design Thinking' in management and innovation contexts. Following the taxonomy of Johansson-Sköldberg *et al.* (2013), this work considers the 'Design Thinking' definitions in the context of management and innovation while the term 'Designerly Thinking' is reserved for studies related to design disciplines.

Even though Designerly and Design Thinking are two distinct research fields, it is also valid to remark that some principles of Design Thinking, such as abductive reasoning' (further detailed in Section 2.2), are grounded in Designerly Thinking studies.

2.1.2. Design Thinking within the Management Discourse

Studies about Design Thinking in the management and innovation fields gained relevance from the middle of the 2000s (see Micheli *et al.,* 2019). Even though the Design Thinking concept is much younger than the 'Designerly Thinking,' it has been grown rapidly (Johansson-Sköldberg *et al.*, 2013). Despite several publications about Design Thinking in the past two decades, a general and accepted definition of the concept is yet to emerge (Liedtka, 2015; Micheli *et al*., 2019). Johansson-Sköldberg *et al*. (2013) suggest that one possible interpretation about Design Thinking may also be a way for managers to understand 'design' straightforwardly and apply it in their routine.

Brown (2008, 2009) and Martin (2009) are the principal authors who drove the spread of Design Thinking in the management field. Both authors wrote their works based on their professional experience promoting innovation in large companies. Their discussions and contributions are strongly supported in case reports, exploring how the design principles, methods, and tools were applied in successful innovative initiatives. Johansson-Sköldberg *et a*l. (2013, p. 127) stated that "with some experience from design practice, it is hard to think about innovation without including design". Thus, the dissemination of Design Thinking for innovation purposes allows the non-designers to capture some aspects of design practice and how designers make sense of their task to face business challenges or gain inspiration.

Two main discourses of Design Thinking can be highlighted, which are listed below with their respective foundation works.

1) <u>Design Thinking as design company IDEO's way of working with design and innovation - Brown (2008, 2009)</u>

   IDEO, considered one of the most important design companies globally, started its operation marketing itself as an innovation company (Johansson-Sköldberg *et al*., 2013). IDEO provides innovation consulting principally for product development. The stories about their successful cases and how they organize their teams and tasks are told by Kelley & Littman (2001, 2005). Brown (2008, 2009), then CEO of IDEO, labeled as 'Design Thinking' the approach performed by the company to conduct innovation projects, describing methods, work culture, infrastructure, and problem-solving skills they use that were inspired by design principles. The IDEO's approach for Design Thinking has fundamentals based on Designerly Thinking discourses, although it is not clearly expressed in Brown's (2008, 2009) references (Johansson-Sköldberg *et al*., 2013).

   Brown (2008, p. 2) defines Design Thinking as a "discipline that uses the designer's sensibility and methods to match people's needs with what is technologically feasible and what a viable business strategy can convert into customer value and market opportunity". The author also provides a theoretical framework of IDEO Design Thinking as a circular process organized in three phases: Inspiration, Ideation, and Implementation (further detailed in Section 4.1.1).

2) <u>Design Thinking as a way to approach indeterminate organizational problems, and a necessary skill for practicing managers - Martin (2009)</u>

   Roger Martin was the Dean of the Rotman School of Business at the University of Toronto and a strategy consultant interested in the cognitive processes of successful executives (Johansson-Sköldberg *et al.*, 2013). Based on March's (1991) trade-off of exploitation vs. exploration, Martin (2009) pointed out Design

Thinking as a solution to managers taking advantage of both innovation and efficiency, building a sustainable long-term competitive edge.

March (1991) discussed that exploitation and exploration were two leading and often conflicting ways companies benefit from business opportunities. Exploitation remains on making a profit from ongoing operations, where efficiency and incremental improvements play a key role in increasing business outcomes. On the other hand, exploration encompasses the company's capabilities to seek and take advantage of new business possibilities, which include searching, risk-taking, experimentation, flexibility, and innovation. As the ongoing businesses are more predictable and less risky than new opportunities, companies tend to move their efforts and resources to gain exploitation efficiency rather than make uncertain investments for exploration. Nevertheless, relying only on exploitation makes the company less adaptative to environmental changes, which can be self-destructive in the long term. Thus, companies looking for long-term competitiveness have to balance their investments between exploration and exploitation initiatives.

Martin (2009) argues that exploitation activities are commonly based on existing knowledge, and decisions are driven by past data analysis. This greatly favors the use of analytical reasoning by managers, who often are trained and rewarded to look to the past for proof before making big decisions. But to explore new business opportunities, companies may face new mysteries and extend the knowledge of the company beyond current boundaries. For that, analytical reasoning is not suitable, no matter how skillful it is applied.

Martin (2009) presents that the answer to not get stuck in the knowledge funnel lies in embracing a particular form of thinking, which he calls Design Thinking. According to the author, the heart of Design Thinking is the abductive reasoning, which allows the company to “both hone and refine within the existing knowledge stage and generate the leap from stage to stage, continuously, in a process called design of business” (Martin, 2009, p.20).

Martin (2009) also suggests that the Design Thinking businesses can continuously redesign themselves to create advances in both efficiency and innovation, consolidating a powerful long-term competitive edge.

Comparing Brown and Martin's discourses, both authors presented Design Thinking as a manner for non-designers, especially managers, to apply principles, methods, and tools from designer practice to improve business performance. They focus their discourses on the benefits that companies may experience if business teams incorporate the core of Design Thinking in their way of work.

The authors differ from each other in the way they propose how Design Thinking should be implemented. Brown (2008) presents the adoption of Design Thinking from a project-level perspective. He uses the case of Shimano’s new bike coast to demonstrate how the main elements of Design Thinking were applied throughout the new product development. On the other hand, Martin (2009) describes the adoption of Design Thinking at an organizational level. The case of Procter & Gamble illustrates how the CEO managed a traditional publicly-traded company to become a Design Thinking organization, driven to push knowledge as far and fast as possible to externally explore new boundaries of market opportunities and to internally shape the culture and redesign some aspects of the organization.

Although Martin and Brown's visions of Design Thinking adoption are significantly divergent, both authors recognize the importance of individual capabilities to apply Design Thinking properly and achieve its benefits. Martin (2009) discussed the figure of Designer Thinker and stated the central role of leaders to conduce structural, process, and cultural adjustments to transform an organization into a Design Thinking business. Design Thinkers, leaders or non-leaders, must develop their stance, tools, and experiences to nurture their originality to discover and explore new boundaries of knowledge in the business environment. Brown (2008) mentions the Design Thinker’s Personality Profile, which are desirable subjective qualities a professional may have to boost Design Thinking outcomes. This profile basically requires empathy, integrative thinking, optimism, experimentation, and collaboration.

Martin (2009) and Brown (2008, 2009) were effective in describing the purpose of Design Thinking, and they make tangible the benefits it can bring to companies. Their cases are compelling stories that invite managers to discover the designer world and challenge themselves to experiment with a new way to cope with business issues. The application of Design Thinking cases goes from P&G strategy to consolidate a brand builder until the Kaiser Permanent improvement of the communication process between nurse and patient. However, these authors do not present a consolidated theoretical framework about Design Thinking. They do not clearly state what constitutes and what does not constitute Design Thinking principles and practice.

In this scenario, Design Thinking might be viewed as an ‘umbrella construct’ – a “broad concept or idea used loosely to encompass and account for a set of diverse phenomena” (Hirsch & Levin, 1999, p. 200). Micheli *et al*. (2019) argue that umbrella constructs are initially useful to provide a way to connect phenomena that otherwise would be seen as unrelated findings. But if there’s no clarity and coherence around the construct meaning and validity, it may result in a concept meaning all things to all people, which would be the collapse of the construct. The following two sections explore aspects of Design Thinking practice, detailing its principles and application levels.

2.2. Principles of Design Thinking

Micheli *et al*. (2019) argue that tensions about what constitutes Design Thinking are partly due to the varied origins of the term. As discussed in Section 2.1, Designerly and Design Thinking became different fields of research. Although some studies use similar terms in both fields, their contents and conceptual background are considerably distinct. To clarify the conceptualization of Design Thinking constituent elements, Micheli *et al*. (2019) worked on a systematic review of the literature and identified its ten principal attributes (see Table 1). Another study whose purpose is also to investigate Design Thinking constituent elements was performed by Carlgren, Rauth & Elmquist (2016). These authors studied six cases of large companies which have implemented Design Thinking. The implementation purpose was varied. One company used Design Thinking to improve all large projects of innovation but keeping a cascade-like approach. Another company experienced Design Thinking in an organizational level approach, disseminating Design Thinking as a set of principles to employees to encourage them to incorporate a human-centered approach in their activities. A third company used Design Thinking to guide innovation projects aside from its core business. Despite the diversity of application, Carlgren *et al*. (2016) identified five principal themes to characterize Design Thinking and built a structured framework unfolding the themes into techniques and practices. Table 1 lists the ten Design Thinking attributes of Micheli *et al.* (2019) and the five themes of Carlgren *et al.* (2016). It is possible to correlate the themes with the attributes almost in a one-on-one relationship. All themes but ‘Diversity’ have an equivalent attribute. However, the code used to identify ‘Diversity’ from interviews had two keywords ‘collaboration’ and ‘systemic perspective.’ From that perspective, it is possible to link the code key-words, respectively, with ‘Interdisciplinary collaboration’ and ‘Gestalt view’ attributes.

Table 1 – Design Thinking attributes and themes

Principal attributes of Design Thinking (Micheli *et al*., 2019)	**Themes of Design Thinking** (Carlgren *et al*., 2016)
Creativity and innovation	-
User centeredness and involvement	User focus
Problem-solving	Problem framing
Iteration and experimentation	Experimentation
Interdisciplinary collaboration	Diversity (as collaboration)
Ability to visualize	Visualization
Gestalt view	Diversity (as systemic perspective)
Abductive reasoning	-
Tolerance of ambiguity and failure	-
Blending rationality and intuition	-

Source: Elaborated by the author

Considering that both authors presented a list of Design Thinking principles and the attributes of Micheli *et al*. (2019) encompass the themes of Carlgren *et al*. (2016), Micheli’s perspective was chosen to describe Design Thinking principles that are presented thereafter. Micheli *et al.* (2019) selected 104 articles in their review, and the occurrence frequency of attributes in the articles database is shown in parentheses.

i. Creativity and innovation (100%)

   Considering creativity as “the production of novel and useful ideas by an individual or small group of individuals working together” (Micheli *et al*., 2019, p.10) and innovation as “the successful implementation of creative ideas within an organization” (Micheli *et al*., 2019, p.10), all articles in the database are related to these two concepts. Some authors put them in the core of Design Thinking output, and others mention them as individual elements or enablers to Design Thinking application (Micheli *et al*., 2019).

ii. <u>User centeredness and involvement (80%)</u>

Being user-centered (or human-centered) is frequently noted as a core feature of Design Thinking (Brown, 2008; Lockwood, 2009a; Martin, 2009), and only a few authors seem to disagree (Micheli *et al*., 2019). Empathy is put as the key element to promote the user-centered perspective of Design Thinking. Carlgren *et al*. (2016, p. 51) affirm that empathy is “the core value of human-centeredness”, and Brown & Katz (2011) argue that incorporate the ‘people first’ perspective is mandatory to Design Thinking practice.

iii. <u>Problem solving (70%)</u>

Design Thinking might be considered a problem-solving approach, particularly effective in dealing with “wicked” ones. Buchanan (1992), from Designerly Thinking, argues that design problems are wicked in their essence and differ from some science disciplines that apply deductive analytical methods to study principles and rules that shape phenomena. Design Thinking incorporates designers' reasoning and problem solving strategies to offer an alternative perspective to the typical linear approach of “problem definition” and “problem solution”, frequently used in management and business (Micheli *et al*., 2019).

iv. <u>Iteration and experimentation (62%)</u>

The iterative loops of tests and experimentation frequently appear in Design Thinking practice, especially when applied as an innovation process (Liedtka, 2015). Experiments are often supported by prototypes, which are any means by which users can interact and give feedbacks (Liedtka & Ogilvie, 2011). Being a human-centered approach, the criteria of evaluation of experiment results may emerge from users. Tests allow to learn about an idea's strengths and weaknesses and identify new directions the solution may take (Brown, 2008). In addition, experimentations are also helpful to learn about users. Each interaction with them can be viewed as an opportunity to gain and reinforce empathy (Institute of Design at Stanford, 2010).

v. <u>Interdisciplinary collaboration (56%)</u>

Multidisciplinary teams with good synergy can combine knowledge from different backgrounds to create unexpected and more robust solutions. The underlying logic to build cross-functional teams is to enhance the group's capability to deal with complexity, ensuring that the technical, business, and human dimensions of a problem are represented. Brown (2008) also put the interdisciplinary collaboration as a desired quality of designer thinkers profile, who can work alongside multidisciplinary teams, and good design thinkers often have experienced more than one discipline (Micheli *et al.*, 2019).

vi. Ability to visualize (39%)

Some authors highlighted the importance of making concepts and ideas visual, even in the early stages of innovation, to facilitate communication within the team or with users. It is worth remarking that visualization often, but not necessarily, entails physical artifacts such as the creation of sketches or objects. Brown (2008) reinforces that prototypes do not have to be physical but must be tangible, so it is easier to understand. Thus the experimentation relies less on the user’s cognition and imagination. Liedtka & Ogilvie (2011) suggests that ability to make things visual goes beyond prototyping and testing and permeates the whole process of Design Thinking (Micheli *et al.*, 2019).

vii. Gestalt view (34%)

A remarkable characteristic of the Design Thinking approach is adopting integrative thinking to drive a deep understanding of problem context and identify relevant insights. The integrative view is not just related to the product or service conception. Still, it is multiple perspective views of the whole context and environment that involve the design project. Thus, the term gestalt may be used to refer to broad conceptualization and representation of a problem, considering people’s needs and emotions, the environment, social factors, market issues, and emerging trends (Micheli *et al*., 2019).

viii. Abductive reasoning (29%)

Abductive reasoning is a third type of logic apart from deductive and inductive reasoning. The abduction is more likely to figure out what might be, rather than the analysis of what already exists (Martin, 2009).

Dorst (2011) didactically differentiates abductive reasoning from induction and deduction using equations of three elements. First, equation (1) represents the analysis of an existing phenomenon, where something (what) having a working principle (how) will lead to a result.

$$\underset{\text{(Thing)}}{\textbf{What}} + \underset{\text{(Working principle)}}{\textbf{How}} \xrightarrow{\textit{Leads to}} \underset{\text{(Observed)}}{\textbf{Result}} \quad \ldots \text{ eq. (1)}$$

Deduction reasoning is applied to infer an unknown result from a known thing and work principle. Stating the “what” and “how”, the deductive logic allows arriving in the result. In contrast, induction is played to infer the working principle when the thing and the result are given. However, abductive reasoning appears when there is no result observed but an intended value to achieve, as represented in Equation 2 (Dorst, 2011).

$$\underset{\text{(Thing)}}{\textbf{What}} + \underset{\text{(Working principle)}}{\textbf{How}} \xrightarrow{\textit{Leads to}} \underset{\text{(aspired)}}{\textbf{Value}} \quad \ldots \text{ eq. (2)}$$

In this scenario, the abductive reasoning can be used in two manners: the first one is when both the value and the working principle are known, and the missing part is only the “what” (an object, a service, a system) that should be created. The second type of abduction occurs when only the value is known, and there is no specific "working principle" to start working with. Thus it is necessary to create the “what” and the “how” simultaneously (Dorst, 2011). In this context, a Design Thinking approach can either rely on existing frames or reframe and challenge existing practices and assumptions (Dorst, 2011).

ix. Tolerance of ambiguity and failure (29%)

Facing ambiguity and uncertainty are inherent to wicked problem-solving. The literature states that Design Thinkers may embrace ambiguity and engage in the logic of test and learning to reduce the unknown aspects about the problem and the solution. As the nature of experimentation is to make assumptions that might be true or not, inevitably, at some point, the result of the tests will not be the desired ones. In this perspective, it is better to fail quickly to succeed soon (Micheli *et al*., 2019).

x. Blending rationality and intuition (24%)

Although Designing Thinking is an alternative to the analytical logic that dominates management theory and decision making, Design Thinking should not be considered totally segregated from analytical reasoning. Instead, it blends analysis with intuition and abduction. Martin (2009) extends the notion of blending different types of reasoning to the consolidation of an organizational competitive edge by combining exploitation and exploration capabilities (Micheli *et al*., 2019).

In addition, Micheli *et al.* (2019) have identified 37 tools of Design Thinking mentioned in the articles reviewed. From which, the seven most frequently cited were: *ethnographic methods; personas,* a symbolic representation of “typical” users; *journey map,* as a representation of the sequence of activities and steps involved in customer experience; *brainstorming,* a collaborative process to foster ideas generation; *mind map,* a visual and sensemaking technique that summarizes information; v*isualization,* as a principle to make the communicate less subjective, whether within the team or with users; p*rototyping and experiments,* as a basic mechanism to validate hypothesis through users perspective (Micheli *et al*., 2019).

Although the principles and tools are not necessarily new in management literature, when those individual elements are combined and viewed together as an end-to-end approach for problem solving and solution creation, Design Thinking emerges as a distinctive practice. It provides outcomes and consequences that individual elements by themselves could not achieve (Liedtka, 2015; Micheli *et al*., 2019).

2.3. Application Levels of Design Thinking

Despite the increasing general understanding of the Design Thinking core principles and tools, its application and practice, as discussed by Carlgren *et al.* (2016), are diverse. Liedtka (2015) draws attention to the challenge of evaluating Design Thinking practice and application with rigorous testing methods. The complex and multivariable environment where Design Thinking takes action puts many barriers to establish causality relations between factors and variables to properly assess the outcomes produced using Design Thinking. Micheli *et al*. (2019) also highlight that many examples of Design Thinking applications found in their review are placed in well-known companies and are based on the authors' experience, often without citing any formal research methods. Examples of those cases are P&G (Martin, 2009), IBM (Lockwood, 2009a), or Samsung (Yoo & Kim, 2015).

The comparison between cases of Design Thinking application is not immediate because, besides the singularities and contingencies of each case study, Design Thinking tools and principles might be applied in different levels. By the cases reported by Carlgren *et al*. (2016), Design Thinking application may be classified in: (i) organization-level, where Design Thinking is understood as a set of principles to be incorporated into the work and culture of the company, in which the set of principles and the way they are applied may vary from company to company; (ii) at project-level, where Design Thinking is applied in a logical sequence of phases or activities to drive innovation, to either increment existing products and services or to launch new solutions; and (iii) the third level of application is mentioned by Micheli *et al*. (2019), who remarks that scholars also explore Design Thinking in an individual-level approach, highlighting personal traits and mindset required to apply Design Thinking properly. Hereafter, there are more details and examples to illustrate those three levels of application of Design Thinking.

1) <u>Organizational-level</u>

   At P&G, a global consumer goods company with more than 100.000 employees, the initiative to turning the company into a design organization came from its CEO, who created in 2001 the vice presidency for design strategy and innovation. The mandate of the new VP was to build P&G's design capability and act as the corporation's champion of Design Thinking. The VP's work began by raising the sensibility of senior leadership to design issues. In 2005, consultants helped build a program to spread Design Thinking. In 2007, P&G personnel were capable of leading Design Thinking exercises independently (Martin, 2009).

   Between 2011 and 2013, Carlgren *et al*. (2016) interviewed P&G's design and R&D leaders, who reported the Design Thinking in the company was seen as an emphasis on some principles, such as: "empathy", "from defining to framing", "from validation to learning through prototyping", "from ideas to stories" and "from knowing to collective curiosity". P&G personnel used three initiatives to apply those principles: first, as elements of training to support teams to improve innovation capabilities; second, as workshops to promote idea generation, team alignment, and learning, supported by a network of facilitators; third, in some teams where prototyping and testing were incorporated in their routine and activities. Design Thinking activities and techniques were project-dependent, and teams have developed their own way to use Design Thinking (Carlgren *et al.*, 2016).

At Intuit, a software firm based in Silicon Valley with 8.000 employees, the use of Design Thinking also began as a top-down initiative, led by the head of designer and innovation and supported by the company's founder. Their first step was to create forums with company leaders to discuss how to delight the customer. But, even being well attended and engaging people, the forums did not produce the excepted results. People were not putting into practice what they talked. So, to promote Design Thinking adoption, they have focused on only three main principles: "deep customer empathy", "go broad to go narrow" and "rapid customer experimentation". The teams were free to apply the principles in their activities as they wanted. To disseminate Design principles among the company, the Innovation Catalysts was created, a group with strong design capabilities whose mandate was not to do Design Thinking but to facilitate and encourage the use of Design Thinking by others. Borrowing the model of P&G, Innovation Catalysts did sessions on how to do Design Thinking. In three years, the team of Innovation Catalyst grew from ten to two hundred members. The members came from every business unit from Intuit and were responsible for supporting design initiatives not only in their own team but also in others (Liedtka, King, & Bennett, 2013).

2) <u>Project-level</u>

The iconic cases of Design Thinking application as a process are the IDEO innovation projects. Brown (2008, 2009), then CEO of IDEO, mentions their experience as consultants working in projects in large companies, such as Shimano, Kaiser Permanent, and Bank of America.

At Shimano, a Japanese manufacturer of bicycle components with more than 10.000 employees, IDEO supported developing a new line of products: the coasting bikes. As the company was facing a flattening growth in its main segments of actuation, high-end road-racing, and mountain bikes, it intended to keep growing by exploring a new customer segment: the casual bikes. For this purpose, IDEO was hired to support the innovation project, acting since from the very early stages of new product development. Within a human-centered approach of investigation, IDEO consultants helped to identify that 90% of adults in the USA didn't ride bikes in their routine, although most of them had pleasant memories of riding a bike when they were children. The reasons to stop riding bicycles were mainly the feeling of the danger of cycling on roads not designed for bicycles and the complexity and cost of cycling equipment. Thus, following the Design Thinking process led to creating a new line of bicycles to entice lapsed bikers into an activity simple and fun. The solution was the Coasting bikes, designed for bike paths near the shore, having features focused on comfort and simplicity rather than performance and sport (Brown, 2009).

At Kaiser Permanente, a US-American group of healthcare providers with more than 200.000 employees, to improve the overall quality of healthcare experience, IDEO proposed to internal staff learn how to apply Design Thinking principles rather than hire design specialists. IDEO consultants conducted series of workshops to empower Kaiser teams with design and innovation capabilities. One of those teams identified problems of communication in nursing shift changes. The solution developed was a process to improve shit transfer. Instead of waiting until the end of the shift to transfer the information of all patients, the nurses could register information in front of the patient throughout the entire shift. As measured by Kaiser staff, the process innovation enhanced nurses' efficiency and improved the quality of information recorded (Brown, 2009). Carlgren *et al*. (2016) also mention Kaiser's cases and interviewing of Design leaders (from VP level until mid-level managers) and nurse managers. The scholars noticed that Design Thinking within Kaiser's group is deployed as a process with iterative phases: gaining empathy through ethnographic and participatory research, synthesizing insights, brainstorming and prototyping, pilot testing in the field, and scaling up. Prototyping was cited as the cornerstone of the process. Design Thinking is played at Kaiser Permanente in small innovation teams looking for relevant healthcare problems to develop scalable innovation (Carlgren *et al*., 2016).

At Bank of America, one of the largest banking institutions in the USA, IDEO's challenge was helping to create product ideas to retain current customers and bring new ones. Among the product concepts generated, one seemed to be particularly challenging: a service to help people saving money. In their research, the innovation team stated that most people wanted to save money, but only a few performed actions for doing so. Thus, the innovation strategy was not to encourage changes in customers' behavior but to benefit from their current habits. As many families saved changes tossing coins into a jar, the solution “Keep the Change” allowed customers to round their debit card payments to the closest dollar. The additional cents were automatically transferred to the customer's saving account. In the first year, 2,5 million customers joined the Keep the Change program, which resulted in 700 thousand new current accounts and one million new saving accounts (Brown, 2009).

Those three project cases illustrate that Design Thinking is suitable for different markets and types of companies where the output can be service, products, or process innovation.

3) <u>Individual-level</u>

Micheli *et al*. (2019) mention that some scholars have explored individual-level characteristics of Design Thinking. However, it is valid to note that the examples given remain at the theoretical level of discussion, describing the role and ideal capabilities of the individuals throughout the Design Thinking application.

Luchs (2016) argues that Design Thinking is not just about a process but also mindset, where mindset can be understood as an integrated set of beliefs and attitudes. The lack of predefinition in the way Design Thinking activities are described and organized may seem, at first glance, at odds with the logic and efficiency of traditional processes. Thus, Design Thinking application would require a shift of mindset from traditional standards.

Martin (2009) goes much deeper into the discussion about the conflict that may emerge between the traditional decision-making methods *versus* the Design Thinking ones. The author argues that traditional management decisions are based on past data analysis and reliable models, where the basis is analytical logic. In contrast, Design Thinking has at its core abductive reasoning, another form of reasoning different from intuition or analytical logic. Although Martin (2009) does not bring an explicit definition for “abductive reasoning”, he emphasizes that an essential premise of this type of thinking is that

> it is not possible to prove any new thought, concept, or idea in advance: all new ideas can be validated only through the unfolding of future events. To advance knowledge, we must turn away from our standard definitions of proof and from the false certainty of the past (Martin, 2009, p. 20).

In such a way, the Design Thinker is the one able to embrace the abductive knowledge and use it to explore new opportunities using experimentations and heuristics to validate hypothesis advance the knowledge.

Brown & Katz (2011) also mention the figure of Designer Thinker, who can tackle more complex problems and put people in the center of the problem-solving approach. For these authors, the Design Thinkers are motivated to face the greatest challenges, searching out the problems that allow them to work on the edge because, in such conditions, they are more likely to achieve something that has not been done before.

Moreover, in a prescriptive approach, Brown (2008) describes the Design Thinker’s Personality Profile, encompassing a set of subjective qualities a professional may have to take benefits from Design Thinking better. Such qualities are: (i) empathy, being able to imagine the world by multiple perspectives, using a “people first” approach; (ii) integrative thinking, not relying only on analytical process and having the ability to see the big picture and sometimes contradictory aspects of a confounding problem; (iii) optimism, assuming that no matter how challenging the situation might be, there will be at least one potential solution better than the current situation; (iv) experimentalism, posing questions and test hypotheses in entirely new directions; and (v) collaboration: being enthusiastic with interdisciplinary issues and working alongside with other disciplines and having experience in more than one (Brown, 2008).

Brown (2008) describes the qualities of Design Thinkers to motivate people with no formal training in design to experience Design Thinking. Those qualities are not formally taught in schools, so professionals with no specific background could become a Design Thinker if they want.

2.4. Expected Results of Design Thinking

This study focuses on Design Thinking application at a project level, wherein the principles, tools, and methods of Design Thinking are used to guide the creation and launch of new products and services in the marketplace. In this context, Brown (2008, 2009) is a central reference in describing the benefits of the Design Thinking approach to promote successful product and service innovation cases guided by IDEO consulting. Thus, according to this author, Design Thinking uses the designer's sensibility and methods to achieve two main goals: (i) match people's needs with what is technologically feasible and (ii) create customer value and market opportunity by means of a viable business strategy. Furthermore, to complement Brown's point of view, this work turns to the literature of organizational theory and gets references about how companies operate to achieve the mentioned objectives. Thus, following the perspective of Bowman & Ambrosini (2000), it is possible to relate how companies create and capture value with the Design Thinking objectives. The first objective of matching people's needs with what is technologically feasible can be directly related to how companies create use value. The second objective of creating market opportunities can be linked to how companies capture value from the marketplace.

However, when discussing the concept of value, it is important to state that there are multiple perspectives within the literature about value creation that ranges from the individual to the society level as the source of value creation, and it can be studied through different theoretical lenses such as sociology, ecology, organizational theory, psychology, among other fields of knowledge (Lepak, Smith, & Taylor, 2007). In addition, the concept of value itself might have multiples dimensions such as the value of use, the value of exchange, the value of production, intrinsic and extrinsic value (Harrison & Wicks, 2013). Thus, to get a coherent base of comparison in the literature, it is essential to identify which perspective is taken into account to deal with the concept of value. Thus, this work follows the strand of Bowman & Ambrosini (2000), who consider the dimensions of *use value* and *exchange value* to explain how companies work to both create and capture value. The perspective of those authors is suitable for this work because, for an innovation project to successfully launch new products or services on the market, it must create and capture value with the new solution.

Based on classical economic theory, Bowman & Ambrosini (2000) present the concepts of *use value* and *exchange value*. The use value is related to the specific qualities of the product perceived by customers considering their needs, expectations, and past experiences. The judgment about use value is essentially subjective and varies from person to person. Two different people may perceive different use values for the same product, as they have different needs and expectations. On the other hand, the two authors presented the exchange value as the monetary amount agreed between seller and buyer when they exchange the goods at the market, that is, the price.

The perceived use value can also be translated into monetary terms as the willingness to pay from a particular customer regarding a specific product. Thus, a product or service would only be purchased whether the use value perceived by a customer is greater than the exchange value represented by the price of the good. The difference between the perceived use value and the exchange value can be called "*consumer surplus"* (Bowman & Ambrosini, 2000). Such *surplus* is relevant to repeatedly engage the consumer into commercial relationships over the long term (Lepak *et al*., 2007). In other words, Harrison & Wicks (2013, p. 101) also present the use value as the "subjective evaluation of how much an item is worth to a particular individual; may not be visible to others and may vary from zero to nearly infinite value".

To answer the question of "how value is created?" Bowman & Ambrosini (2000) argues that value creation depends on the work of organization members to combine and transform the resources acquired by the company to create something that might be *valuable* to someone. That is, the members of the organization work to create something that the consumer would perceive its use value, whose judgment of how valuable this could be is strictly related to the consumer's needs and desires. Such approach of Bowman & Ambrosini (2000) about how companies create value is practically the same perspective of Brown (2008) regarding the objective of Design Thinkin of "matching people needs with what is technically feasible". Therefore, it can be considered that one of the main objectives of the Design Thinking application in innovation projects is to create products and services that promote the perception of use value in its consumers.

Complementary, to answer the question of "how organizations capture value?" Bowmand & Ambrosini (2000) argue that after creating value through a product or service, the capture of value occurs when the new use value is sold. That is, the buyer and the seller must get on an agreement about the price of the good to be sold to perform the exchange. Harrison & Wicks (2013) highlight that exchange value is negotiated and inter-subjective, depending on two people establishing a deal and an exchange transaction. With this regard, Bowman & Ambrosini (2000, p. 5) reinforce that “the amount of exchange value the organization can capture is known only at the time of sale, that is the organization will not know what the newly created use value is worth until it is exchanged”. Thus, the organization must first create the use value using its resources to conceive a product or service, and the value capture can only be held posteriorly when sales occur. In this context, resuming the second objective of Design Thinking of creating value for the customer and market opportunity through a viable business strategy can be associated with the moment the new product or service developed with Design Thinking is sold in the market. In addition, if there is a well-executed business strategy, it can successfully promote profitable value capture with exchanges in the market.

Moreover, considering that the value creation and value capture are held at different times in dissociated ways, it is not possible to assure how much exchange value can be captured during the value creation process. Therefore, there is no guarantee that a new use value created (associated with a new product or service) will lead to the capture of the exchange value. In the end, if the new use value could not be traded, there will be no value captured. In the literature of Design Thinking, Liedtka & Ogilvie (2011) warn that only creating value is not enough while applying Design Thinking in innovation projects. For the business's survival, the organization members must be able to capture part of the use value they have created and turn it into profit.

Finally, the framework of this work considers the Design Thinking approach at a project level aiming to develop new solutions to be launched in the market. Therefore, as there is a commercial intent associated with the outcome of the innovation process, it is expected that a new solution created with the Design Thinking approach will promote both value creation and value capture.

2.5. Reference Model

This section summarizes the main topics of discussion at the Research Clarification stage and provides a reference model framework on which this research project is based. According to Blessing & Chakrabarti (2009), one of the main objectives of Research Clarification is to provide the theoretical basis to frame the current knowledge about the research theme that will guide the drawing up of research questions. Therefore, as a deliverable of this stage, the two authors recommend building an Initial reference model to outline the scope of the research project. Specifically, in the studies focused on Descriptive Study II, it is desirable that the reference model provides the basis for evaluating the effects of the "support", which in this work is the Design Thinking approach for innovation projects.

For this matter, the work of Johansson-Sköldberg *et al*. (2013) has a central relevance for having organized clearly and cohesively the main strands of academic discourses about Design Thinking. This study is placed within the Design Thinking discourse in the management and innovation fields of research. Thus, despite having some concepts and terms that might be found in Designerly studies, the research project does not dialog with Designerly scholars, nor does it allude to the practice of the professional designer and his related disciplines. Thus, to reinforce the distinction from Designerly studies, this work follows the perspective of Johansson-Sköldberg *et al*. (2013, p. 123) about Design Thinking that represents the use of "design practice and competence beyond the design context (including art and architecture), for and with people without a scholarly background in design, particularly in management". In other words, it can be considered a simplified and straightforward way for managers to use design principles to address business issues.

Although the position of Johansson-Sköldberg *et al*. (2013) is very useful to delimitate the field of interest of Design Thinking, it is too broad to be taken as a final definition. To get a narrower understanding of Design Thinking, this work sought to clarify the constituent elements of Design Thinking and the contexts and purpose they could be applied. Thus, based on Micheli *et al*. (2019) review, the ten attributes they have identified were considered the constituent elements of Design Thinking. They are creativity and innovation, user-centeredness and involvement, problem-solving, iteration and experimentation, interdisciplinary collaboration, ability to visualize, gestalt view, abductive reasoning, tolerance of ambiguity and failure, blending rationality and intuition.

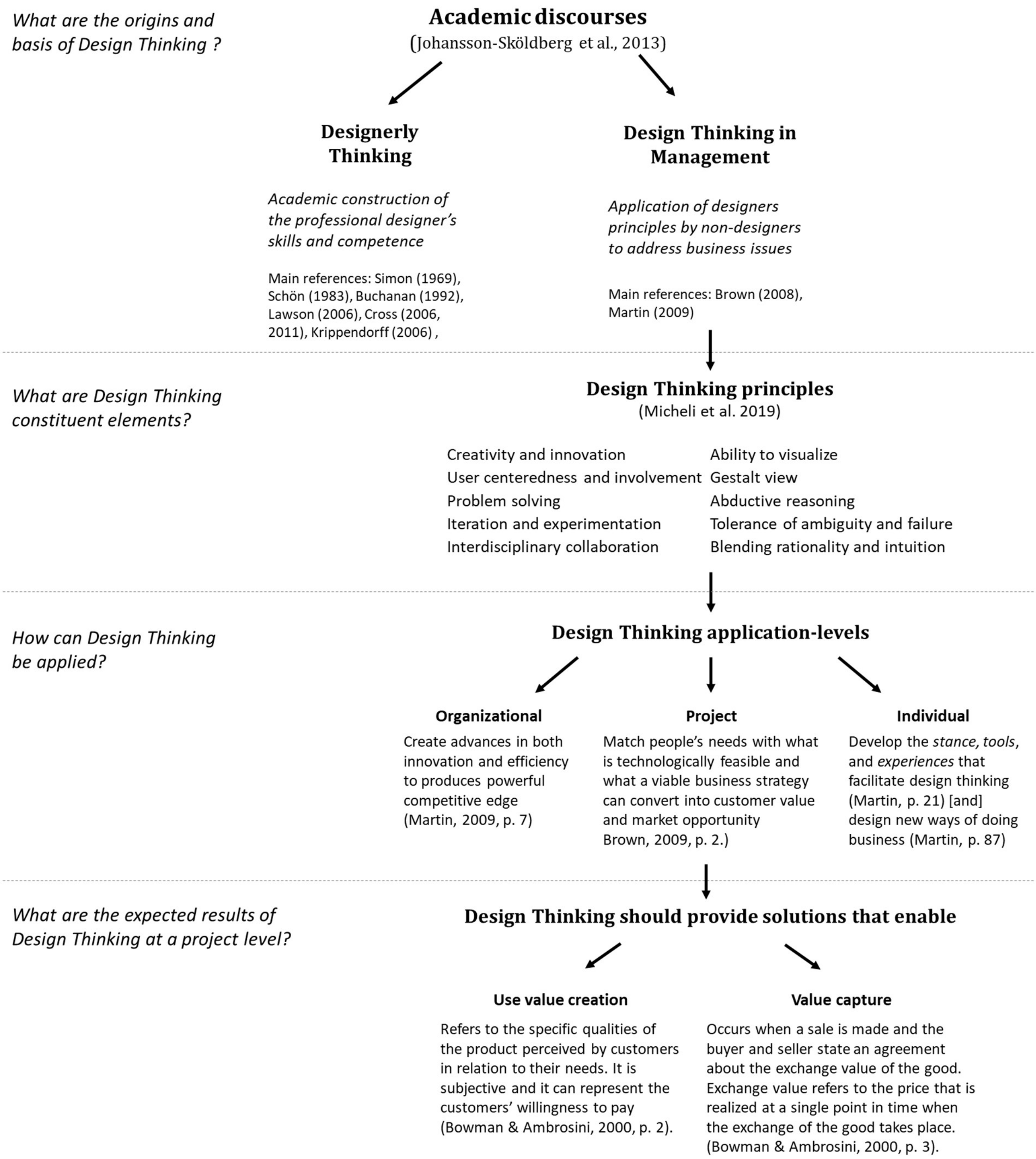
However, those principles are intentionally too generic so that they can be applied in several contexts. By the cases described by Brown (2008, 2009) and Martin (2009), the two main authors responsible for disseminating Design Thinking application among managers, it was possible to identify at least three application levels of Design Thinking principles: (i) organization-level, where Design Thinking principles are incorporated into work and culture of the company; (ii) at project-level, where Design Thinking is applied in to drive innovation, to either increment existing products and services or to launch new solutions; and (iii) individual-level, exploring personal traits and mindset required to lead and carry out Design Thinking application.

Among these options, this work focuses exclusively on Design Thinking applications at a project level to develop new solutions. Therefore, it directly connects with the literature strand derived from Brown’s (2008, 2009) works, grounded on the *IDEO’s* way of working with design to promote product and service innovation. In this context, Brown (2008, p. 2) brings a simple definition of Design Thinking, that is ”a discipline that uses the designer’s sensibility and methods to match people’s needs with what is technologically feasible and what a viable business strategy can convert into customer value and market opportunity”.

To understand how the companies can achieve such objectives, this study turns to the work of Bowman & Ambrosini (2000) and explores the concepts of value creation and value capture. When using Design Thinking to drive innovation projects to develop products and services, the new solutions would only be successful in the market if it promotes both value creation and value capture. That is, both the client and the organization can benefit from the new solution.

Finally, to summarize the main topics of the Research Clarification discussion, the reference model is represented in Figure 3, which contains the main references and classifications to place this work within the literature and clarifying the research project's focus.

Figure 3 – Initial reference model of Research Clarification



Source: Elaborated by the author

Finally, based on the references presented, the following steps of this work address issues related to the study of Design Thinking and innovation projects. The Descriptive Study - I brings an overview of the emergent literature involving empirical studies of Design Thinking. Then, the Prescriptive Study describes the models to support the Design Thinking application and draws up the evaluation plan, which is the basis to perform the case studies in the Descriptive Study II.

3. DESCRIPTIVE STUDY - I

The Descriptive Study was performed to outline the big picture about the emergent studies on Design Thinking in management and innovation fields and then get a deep dive into the empirical research at a project level approach, which is the focus of this work. Blessing & Chakrabarti (2009) mention that investigation at the Descriptive Study can be performed by reviewing literature or undertaking empirical research. As there is a vast literature exploring the use of Design Thinking to create new solution solutions, it was chosen to perform this stage with a review-based approach.

In this context, a Systematic Review of Literature (SRL) was carried out to find and select emergent publications related to the theme of this work. Considering that the objective of Design Thinking is to promote use value creation and value in innovation projects, there is a premise of commercial intent to launch the solutions in the market. Thus, the value capture presupposes the new solution must be related to a product or service to be traded in the market.

Therefore, the Descriptive Study is organized into three sections, starting by searching and selecting publications involving Design Thinking studies related to the development of new products and services (Section 3.1). Then, the analysis of articles first outlines an overview of the studies considering the three levels of application of Design Thinking presented in the initial reference model: Organizational, Project-level, and Individual (Section 3.2). Finally, the SRL ends with an in-depth analysis of the project-level studies to explore how the findings of this work could dialog with emergent literature and push the knowledge of Design Thinking for innovation projects (Section 3.3).

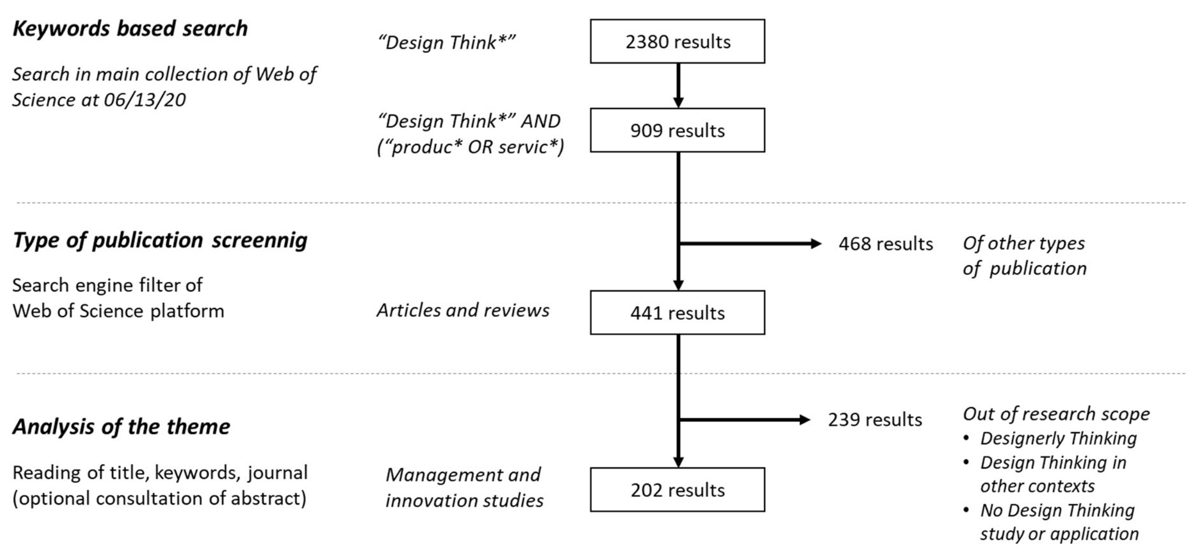
3.1. Publications Selection for Systematic Literature Review

The search for articles was performed in the main collection of the Web of Science database at the date of 06/13/2020, with the following search string: “design think*” AND (produc* OR servic*) at the “topic” field that includes search on the title, abstract and key-words. As a result, 907 publications were obtained. Then, only articles or reviews were selected, as those types of publications are assessed by peer reviewers

(Takey & Carvalho, 2016). Thus, a total of 441 publications were selected, of which 420 were articles and 21 were reviews.

Then, the theme of the selected publications was analyzed, aiming to identify the articles and reviews in the context of management and innovation tackling business-related issues. Such analysis was held based on the assessment of title, keywords, and journal. If necessary, the abstract examination could complement the analysis of the theme. Figure 4 summarizes the steps of publication selection for the systematic review purpose.

Figure 4 – Selection of articles at the systematic review of literature



Source: Elaborated by the author

Then, the content analysis of the selected publication occurred in two steps, described in the following sections. The first one classified the publications according to the application level of Design Thinking, providing an overview of Design Thinking publications in the management and innovation field. The second step focused on project-level studies to identify the main research topics addressed by the empirical research.

3.2. Design Thinking Studies in Management and Innovation

In the group studies that explored the Design Thinking approach for innovation and management purposes, the Design Thinking approach can be employed in several manners to drive the search and creation of new solutions and address business-related issues. Following the reference model presented at the Research Clarification stage, the studies were organized according to the Design Thinking application levels.

1) <u>Individual-level - 47 publications</u>

The studies in this group explored how the subjective aspects of individuals, especially topics related to cognition, reasoning, and creativity, contribute to Design Thinking application. The studies can be focused on a specific topic of innovative activities, such as Dong, Lovallo, & Mounarath (2015), who explore the effect of abductive reasoning on concept selection decisions with an experiment with committee members called upon to decide whether or not to invest in new product concepts. Or the studies can assess the subjective characteristics more generally, like Thompson & Schonthal (2020) that analyzed the social-psychological phenomena involved in Design Thinking practice and illustrated practical implications at real projects at IDEO.

In this group, there are also studies aiming to explore how the principles of Design Thinking can be used to better training and qualifying students and professionals in several contexts. For example, as the training of entrepreneurship (Larso & Saphiranti, 2016), engineering (Mabogunje, Sonalkar, & Leifer, 2016), marketing (Chen, Benedicktus, Kim, & Shih, 2018), and business (Foster & Yaoyuneyong, 2016).

2) <u>Project-level - 82 publications</u>

This group of studies is related to the creation of new solutions. Some studies describe the solution development as a whole, such as Song *et al*. (2020) that present the development, implementation, and evaluation of a digital solution to streamline the creation and maintenance of wound care product formularies. Another example is the study of Bautista-Arredondo *et al*. (2018) that describes the designing of a management toolkit and evaluates its impact on the costs reduction of HIV prevention services for female sex workers in Nigeria. Nevertheless, the studies are more commonly focused on a single part of the innovation process. Hankammer, Brenk, Fabry, Nordemann, & Piller (2019) and Rojas, Nash, & Rous (2017) put their efforts to uncover the needs of people, respectively, in the context of the consumer electronics industry and child care providers. Haldane *et al*. (2019) focus on the design of personas to increase medication adherence in the cardiovascular disease context. Kockmann (2018) summarizes the concept generation of 12 digital solutions to be used in industrial processes.

It is worth mentioning that, as being in a context of innovation and management, the studies included in this group are related to solutions that would have some potential for commercialization or to be inserted in the market, even though there was no mention of commercialization or business strategy in the articles. As exemplified before, it involves healthcare service initiatives, consumer goods, industrial processes, etc. Studies concerning the creation of new solutions applying Design Thinking that were dissociated of a commercial focus, such as support to public policies formulation (Howlett, 2020), pedagogy techniques (Androutsos & Brinia, 2019), ethical reasoning (Lewis, Ludwig, Nagel, & Ames, 2019) or museum visitors experience (Larson, 2017), were considered out of the scope of this research project as "design thinking in other contexts". This decision was made because value creation and value capture objectives may not be suitable for these projects.

3) <u>Organizational-level – 70 publications</u>

This group of studies explores how Design Thinking principles can positively impact the structure, performance, culture, and way of working in organizations. For example, Beverland, Wilner, & Micheli (2015), based on multiple cases studies of innovation at firms, discuss how Design Thinking can trigger brand ambidexterity; D'Ippolito (2014) conducted a review and brought propositions about how design can impact firms' competitiveness; Luotola, Hellström, Gustafsson, & Perminova-Harikoski (2017) used Design Thinking and actor-network theory to deal with uncertainty management; Elsbach & Stigliani (2018) reviewed empirical studies that related the practice of Design Thinking to the development of culture in organizations.

In addition, there are also studies that report practices used to disseminate Design Thinking principles and practice within the organizations. Such studies often explore how workshops, organized individually or within design sprints, promote innovation issues in companies. For example, Endrejat, Simon, & Hansen (2018) investigate how

Design Thinking can shape leadership culture, analyzing a ten-week Design Thinking concept with three on-site workshops at a German industry company. Heck, Rittiner, Meboldt, & Steinert (2018) defend that ideation workshop-based on Design Thinking principles may increase the innovation capability of companies. Klamerus *et al*. (2019) describe how a single-day workshop successfully engaged stakeholders to promote healthcare innovation.

4) <u>Multilevel – 3 publications</u>

The last group gathers only three studies that explore more than one application level of Design Thinking. The first study of Jaaron & Backhouse (2018), based on case studies in UK's service sector companies, has identified twelve guidance topics for service design innovation that can be held in three levels within the company: employee level (i.e., Micro), functional level (i.e., Meso), and corporate level (i.e., Macro).

The second study of Dell'Era, Magistretti, Cautela, Verganti, & Zurlo (2020), from 47 case studies of consulting organizations in Italy, identified four main interpretations of the Design Thinking approach characterized by different practices: Creative Problem Solving; Creative Confidence; Sprint Execution; Innovation of Meaning. The first two interpretations are directly related to the individual application level of Design Thinking, as they are ways to work on the subjective characteristic to promote innovation. The Problem Solving explores the use of analytical and intuitive thinking to solve problems, and Creative Confidence concerns engaging people into an innovation mindset to boost the creative process. The third interpretation, "Sprint Execution", is an approach to deliver and test viable products and learn from customers. As it works at the level of solution creation, it is deeply connected to the project level way to apply Design Thinking principles. Finally, the last interpretation, the "Innovation of Meaning", envision innovative perspectives to support new strategic directions, whether employed by managers and directors to point out business opportunities to explore, is intrinsically related to the organizational level of Design Thinking application.

The third study that explores more than one level of application is the review of Micheli *et al*. (2019) that identifies ten main attributes of Design Thinking that companies can apply in several ways, as discussed in more detail in Section 2.2.

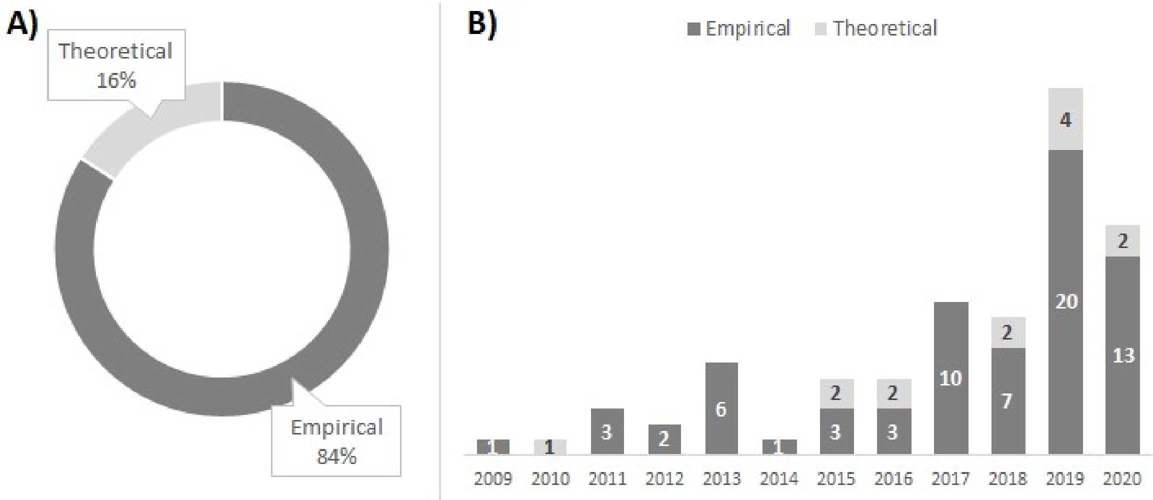
3.3. Empirical Project-Level Studies

The last stage of this Descriptive Study focuses on characterizing empirical studies of Design Thinking at the project level, describing their evolution over time, their application field, and exploring how scholars have addressed value creation and value capture issues in such studies.

The first step was to identify among the 82 publications classified into the project-level group, those comprising empirical studies. For that, studies that mention a real project regardless of the method used were considered empirical studies. For example, many articles involve case studies about product and service development, in which the researchers have worked on or followed the development team's performance. In such studies, the authors describe how the steps of the innovation process took place, starting from the needs finding and ideation until the conception of the final solution. In addition, some papers focus on evaluating the performance of new solutions, either with a qualitative approach based on the perception of users or with a quantitative approach applying methods to estimate the benefit brought by the solution. Finally, other studies have used surveys and interviews to work on a specific topic or assess the development process more broadly. On the other hand, the articles classified as theoretical research were essentially essays or reviews with no practical study mentioned. Following such criteria, 69 empirical studies were identified, representing 84% of project-level publications.

Figure 5 presents the proportion of theoretical and empirical studies found and the evolution of both types of publication over time. The increasing volume of publications is remarkable, with the predominancy of empirical studies. It is a favorable scenario to promote discussions about the Design Thinking's success drivers, which may contribute to further project-based studies in achieving more promising outcomes.

Figure 5 – A) Proportion of theoretical and empirical studies and B) Number of publications over time

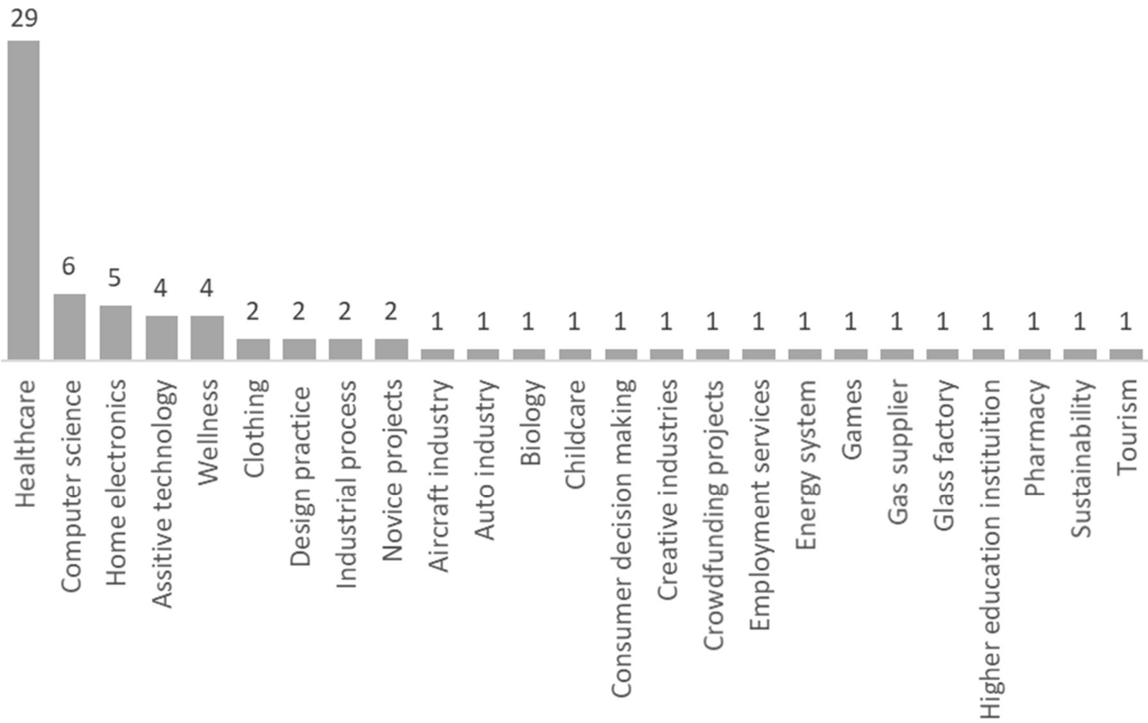


Source: Elaborated by the author

After selecting the paper with empirical research, the field of application of each project was identified. It is worth mentioning that this analysis was based on the sector in which the projects of new solutions were carried out, which was not necessarily the same field of article publication. For example, the project studied by Pericu (2017) that developed a solution for the wellness and safety for elderlies was included in the group "wellness" solutions, even though the article was published in Design Issues, a journal that traditionally explores themes related to the practice of designers. Thus, the chart in Figure 6 indicates the field of application of the projects involved in the empirical studies.

Despite being a long-tailed chart, the health sector draws attention by concentrating about 40% of the projects. This proportion might be even more relevant if projects in correlated areas such as "wellness " and "assistive technology" were considered in the same healthcare group. Therefore, this group of projects that seeks health solutions in a broad perspective would represent more of the half of the projects studied. The large volume of healthcare projects highlights the potential of the Design Thinking approach to enhance innovation in the sector, especially in occasions where the solution depends on patient engagement.

Figure 6 – Number of studies according to application field of Design Thinking projects



Source: Elaborated by the author

To conclude the Descriptive Study, the empirical studies were assessed to identify patterns and characterize the most relevant approaches used to address value creation and value capture in the innovation projects. Three main approaches were identified and described hereafter. It is worth noting that a study can be mentioned in more than one topic considering the scope and contributions of the publication.

1) Studies of new value creation

The first way that the empirical studies explore value creation is by directly analyzing and describing the projects of new solutions development. There is often a design perspective in such studies to figure out how to create a solution to provide a desired value. This group encompasses a pretty large body of publications going from the initial conceptualization of solutions to the end-to-end development approaches to conceiving new products and services.

The initial conceptualization concerns creating preliminary prototypes and support tools that can demonstrate how the potential solution could be, regardless of the experience of people involved in the design process. As examples of initial conceptualization, Vela (2017) presents a series of solutions and ideas related to financial topics developed by novice designers, and Kockmann (2018) summarizes 12 concepts of solutions to improve the use of digital tools in industrial processes developed in workshops with industrial experts in Germany.

Regarding the end-to-end development of new solutions, the cases of robot Steevie (McGinn *et al.*, 2020) and the Veggeon app (S. A. Mummah, King, Gardner, & Sutton, 2016) stand out. The robot Steevie case started with activities to empathize with the elderly and to state the problem definition. Then, based on benchmarking and ideation sessions, four rounds of prototyping were carried out to achieve the final version of the robot capable of interacting with elderlies and contributing to the caregivers' social assistive work. The study ends with the robot evaluation in focus groups and provides clues to further research about design projects and innovation to assist elderlies. Similarly, in the Veggeon case – a mobile app to increase vegetable consumption –, the study's narrative is organized around the stages of the development process sequentially presented. It starts with the development team getting empathy with potential users. Then, based on behavioral theory, the team draws up requirements to guide the ideation of new concepts and features. Next, the team performed two rounds of prototype and getting feedback from users to refine the solution and obtain its final version. Finally, the publication ends by describing a pilot study to evaluate the efficacy and usability of the new app.

2) <u>Studies of created value assessment</u>

This group comprises studies concerned with assessing the new value created with the new solutions, evaluating its performance and benefits. This evaluation can focus on functional assessment of the solution’s features, the user perception about the solution, or the impact the solution promotes when used in real situations.

As an example of functional assessment, there is the case of HighChest (Bonaccorsi *et al.*, 2017), a smart freezer to promote energy-efficient behavior and the responsible use of food. This study details the main features of the freezer, such as the hardware, the graphical user interface, inventory creation service, and localization system. At the end of the paper, the authors present experimental tests about the localization system, which is 100% accurate in identifying weights greater or equal to 0.5 kg.

The study of Crespin *et al*. (2018) illustrates the assessment usability and user perception of new solutions. The publication describes the adaptation of an existing training surgery toolbox to develop methods to assess the endoscopic skills of doctors. Then, two initiatives were conducted to evaluate the new solution. First, a cognitive task study with 18 participants assessed the difference in performance between experts and trainees. Next, a pilot test with 38 people was carried out that demonstrated a higher satisfaction of those who experienced the new solution.

Finally, to exemplify the measurement of the impact caused by the new solution, there are the study of Bautista-Arredondo *et al*. (2018) that evaluates the cost reduction of implementation of management toolkit for HIV prevention in Nigeria and a second study of the Veggeon app (S. Mummah *et al*., 2017) that tests the effect of a digital intervention to increase vegetable consumption among adults attempting weight loss maintenance. A strong point of both studies is that they performed randomized trials, a method based on intervention and control groups comparison to evaluate their differences quantitively. However, the first study in Nigeria could not statically state that the new management tool has induced a cost reduction in the 16 community-based organizations that have used it. In contrast, the second study of Veggeon proved that daily vegetable consumption was significantly greater with the 51 adults that used the app.

It is worth stating that the solution evaluations of the empirical studies, considering all the methods used, are essentially related to value creation assessment. In functional assessment, the tests are designed to evaluate if the product works as it was conceived to, which is the first step to deliver an intended value to the user. Then, tests with users usually aim to clarify whether they can use the new solution or how satisfied they are with it. Both factors of usability and satisfaction are means of assessing the user's perception of the solution, which is fundamentally the use value assessment. Finally, tests or experiments to objectively evaluate the impact of the solution, despite the quantitative appeal, are still related to the creation of value. In the mentioned studies, these methods were applied to evaluate if the solution could deliver the value it was designed for. The performed trials could statistically confirm if the solution can reduce Nigerian healthcare public service costs or increase the vegetable consumption of Veggeon app users. Although it is an excellent starting point, it cannot be stated that those solutions will promote value capture in the market. Taking the assumption of

Bowman & Ambrosini (2000) that the amount of exchange value to be captured can only be assessed when the solution is finally offered and traded in the market, it can be understood that the trials are relevant to reinforce the potential of the solution to deliver the use value. However, they do not allow to infer how much people will be willing to pay for the solution or how much value could be captured.

3) Studies to conceive models, methods, and tools to support value creation

A group of studies analyses the activities performed in the projects of new solutions to create or evaluate models, methods, and tools to improve the development process. An example of a support to guide the development process in an end-to-end approach is the model of Ana, Umstead, Phillips, & Conner (2013) for balancing stakeholder voices in medical devices development. This study proposes a spirally represented innovation process to guide the development of medical devices, considering and balancing three stakeholder voices: the voice of customer, the voice of business, and the voice of technology. Although being designed and applied for a medical device development case, the concepts and guidelines of these models are generic enough to be translated and employed in other contexts and other solution developments that involve several stakeholders. Another study that brings guidelines to the development process as a whole is the work of Bosch & Bosch-Sijtsema (2011). Based on a single case study of QuickBooks, a digital product of Intuit company, the authors explore how to combine the approaches of agile development, Design Thinking, and self-organizing teams to improve the responsiveness and accuracy of building customer value.

In contrast, to illustrate a support tool with a narrower application, Baldassarre *et al.* (2020) developed a tool to improve prototyping by planning and executing small-scale pilots. Those authors followed a Design Science Research methodology to design, evaluate and improve the tool working with nine startups and one multinational company.

In summary, the major objective of those support materials is to guide the development process to achieve a better solution, able to deliver greater use value to its consumers. However, each support acts in a specific manner on the development process. The supports can bring principles and guidelines to influence the project as a whole or be used on particular actives to improve their outcomes.

To conclude the Descriptive Study, it can be noticed that Design Thinking is a relevant construct for products and services innovation, and its application is gaining increasing relevance in empirical studies. In project-level studies, many authors have used the Design Thinking approach to promote better and more compelling solutions. Most empirical studies devote efforts to value creation-related issues, whether describing the creation of new value itself by developing products and services; evaluating the created value with qualitative and quantitative approaches; or bringing support tools to enhance the potential of value creation in the innovation process.

However, there is a lack of Design Thinking studies focused on value capture. Although the themes and methods related to value capture may be less frequent in the Design Thinking literature, for any innovation to be successfully launched in the market, it must both deliver use value to the end-user and enable the value capture by the companies. As mentioned by Liedtka & Ogilvie (2011, p. 20), "even value creation is not enough. Businesses, to survive, must care about more than just creating value for customers. It is an important, but insufficient, first step. To survive in long-term, businesses need to be able to execute and to capture part of that value they create in the form of profits". In this context, the following stages of this work are organized to evaluate how the Design Thinking application promoted value creation and value capture in innovation projects. The Prescriptive Study provides an evaluation plan used in the Descriptive Study II to guide the evaluation of Design Thinking success in product development cases.

4. PRESCRIPTIVE STUDY

According to the DRM framework (Blessing & Chakrabarti, 2009), in research projects of type IV (see Figure 1), in which support assessment is performed during Descriptive Study II, it is necessary to develop – in the Prescriptive Study – an evaluation model of the support application. As there are many references promoting Design Thinking adoption with prescriptive models and guidelines, the Prescriptive Study is conducted in a review-based approach to get the basis to evaluate Design Thinking in projects of new solutions development.

With such purpose, the Prescriptive Study is organized in three steps: (i) reviewing the existing prescriptive models of Design Thinking, summarizing its mains topics and characteristics (Section 4.1.); (ii) composing a comparative framework of those models to find out similarities, highlights and opportunities of improvement (Section 4.2); and (iii) outline an evaluation plan of Design Thinking application at a project level to guide the empirical research at Descriptive Study (Section 4.3).

4.1. Prescriptive Models of Design Thinking

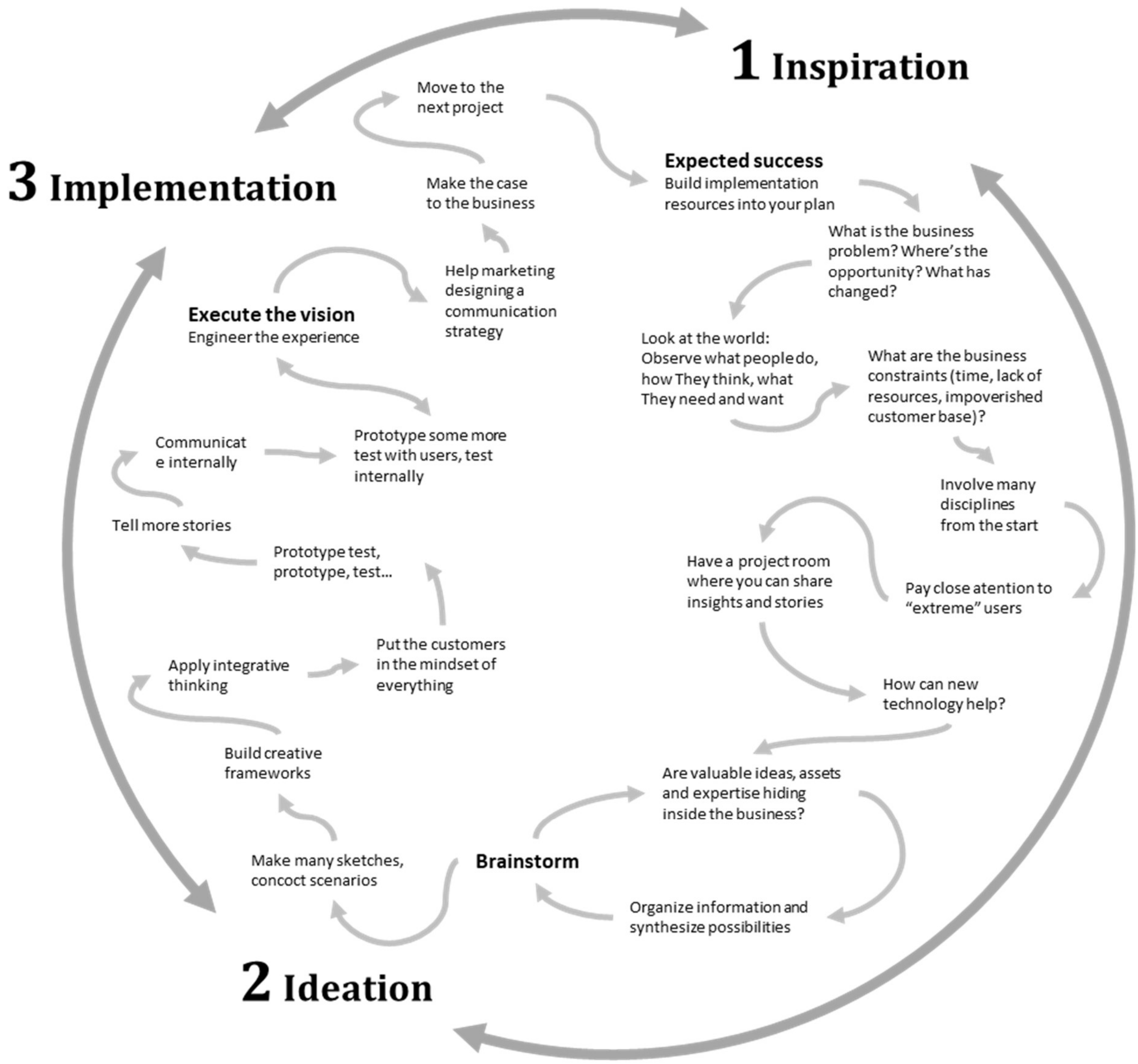
This section lists and presents the prescriptive models of Design Thinking to guide innovation projects, elaborated from different authors and schools.

4.1.1. IDEO Three Spaces of Innovation

Brown (2008, 2009) describes the Design Thinking process in three main phases that he calls “spaces of innovation”. Each space demarcates sorts of related activities whose execution does not necessarily have a strict and predefined organization. According to the author, this can make the Design Thinking process look chaotic as it differs from the linear or milestone-based processes traditionally found in business activities.

Brown (2008, 2009) presents the three spaces called Inspiration, Ideation, and Implementation. The first space, Inspiration, begins with the team going deep into the problem context through a human-centered discovery approach, using methods of investigation, such as interviews and observation. In this space, it is important to create a holistic view of the situation to get insights to solve the problem. The second space, Ideation, is when the team starts to look for solutions. It is recommended to use brainstorming, integrative thinking, frameworks to generate ideas and then develop iterative cycles of prototyping, testing, and refinement. Time, effort, and resources spent on prototypes must be only the minimum necessary to get valuable feedback and evolve the idea. The objective of prototyping is not to get finished solutions but to learn about the concept's weaknesses and strengths and identify new directions that further prototypes may take. Finally, the last space, Implementation, is where the solution takes the path from the project room to the market. At this moment, other professionals may join the development team, but designers are responsible for ensuring the best experience for the customer, reviewing relevant points of interaction with customers from branding until sales and support strategy (Brown, 2008, 2009). Figure 7 contains the circular framework used by Brown (2008) to represent the Design Thinking Process.

Figure 7 – IDEO Design Thinking Process

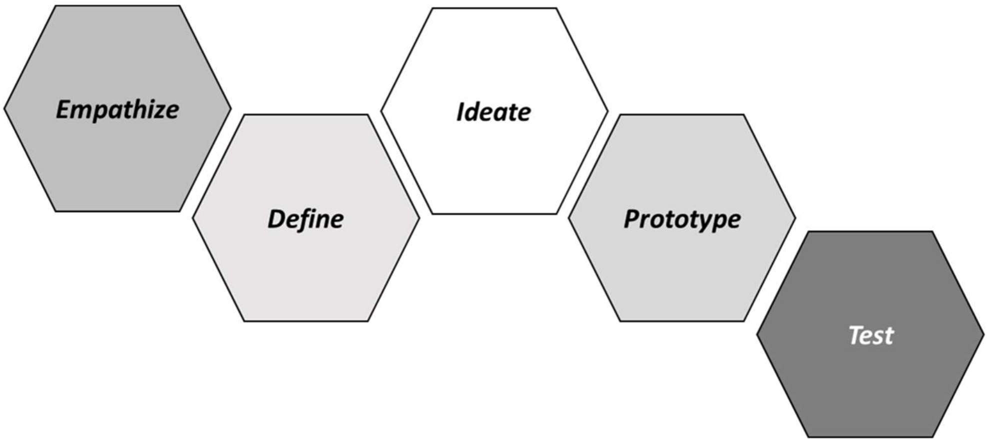


Source: Brown (2008)

4.1.2. Stanford d.school

The d.school's Design Thinking process is organized in five "modes": Empathize, Define, Ideate, Prototype, and Test, as represented in Figure 8. Each mode represents a major step to guide the application of Design Thinking (Institute of Design at Stanford, 2010).

Figure 8 – d.school Design Thinking Process



Source: Institute of Design at Stanford (2010)

Empathy, the first process mode, is the "centerpiece of a human-centered design process". As the problem to be solved is rarely the team's own, it is mandatory to empathize with people the team is designing for and find out what matters for them. The main techniques to promote empathy are observation and engagement. Observation is helpful to get insights into people's behaviors and the way they interact with their environment, giving clues about people's needs, feelings, and emotions – what are elements that people do not necessarily show in their speeches. Some of the most powerful realizations come from noticing some disconnection between what people say and do. Engagement, sometimes called interviewing, is the technique used to learn about people's past experiences through their storytelling. Engagement it is a preferred term rather than interviewing because sometimes the interaction feels much like a conversation, eliciting the person to tell stories and making question to uncover deeper meaning and causalities (Institute of Design at Stanford, 2010).

The goal of Define, the second mode, is to craft a clear, meaningful, and actionable problem statement – which is called point-of-view. Although it seems quite counterintuitive, focusing on a problem statement more narrowly defined tends to yield greater quantity and higher quality about solution generation. So it is up to the design thinker to properly synthesize and create a point-of-view to guide the problem-solving approach. That requires gathering all the experiences, information and insights got from the empathize mode. Insights do not automatically appear in mind. They rather emerge from a process of synthesizing information and discovering patterns. A good point-of-view frames the problem highlighting the user and their needs to inspire the team to work on further activities (Institute of Design at Stanford, 2010).

After the first two modes focused on the user’s problem, the Ideate mode starts the activities related to the solution creation. It is the moment to combine the understating of the problem space with imagination and knowledge to yield concepts of solution. The ideation can be viewed as ‘go wide’ process, where it is fundamental to work in a group to promote synergy between people, leveraging the potential of creation building on others’ ideas. It is worth noting that creating many ideas is important to separate moments of generating ideas from the moment of evaluating them. Throughout the ideation mode, the creativity and the imagination may take action, letting critics and assessments coming later (Institute of Design at Stanford, 2010).

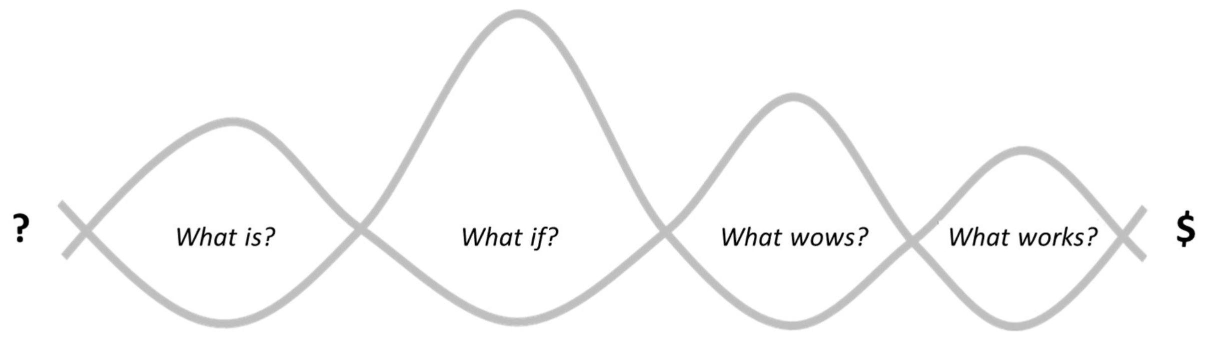
The Prototype mode comprises the iterative creation of artifacts to answer questions to move toward the final solution. As the goal of prototypes is to get users' feedback about the solution, anything a person can interact with can be considered a prototype. Prototypes in the early stages should be simple and inexpensive. A wall of post-it notes, a gadget, a role-playing activity, or even a storyboard may be useful manners to get users’ feedback. Time and efforts to build a prototype should be as lower as possible to allow the team to fail quickly and cheaply. The main objective of prototypes is to communicate to the user and test possibilities in order to drive the development of a compelling solution.

The Test mode is a natural sequence from the Prototype mode. As prototyping aims to test hypotheses and answer questions around the solution, the Test encompasses the activities required to get feedback from users through the built prototypes. Ideally, the tests are done in real contexts of the user’s life, where people can use physical prototypes or live an emulated experience. If a test in-situ is not possible, it is interesting to create scenarios and circumstances that allow capturing user feedback as much closer as possible to the real situation. As the Test mode is played iteratively, each contact with the user is a new opportunity to create empathy and learn. Tests allow to refine the solution and also to revisit the point-of-view statement. If the result of a test is not as expected, perhaps the understanding of the problem should be updated. In all cases, whether to test prototypes, to refine point-of-view, or to gain empathy, tests always allow the team to advance in the solution development (Institute of Design at Stanford, 2010).

4.1.3. Darden Business School

Liedtka (2015) mentions the Design Thinking process from Darden Business School is organized into four phases “what is?”, “what if?”, “what wow?” and “what works?” as represented in Figure 9. The widening and narrowing outlines around each question represent the “divergent” and “convergent” thinking, which means in the early part of each stage the team seeks to expand its field of vision as broadly as possible to avoid bias of previous knowledge and beliefs, and next they converge progressively narrowing down the most promising options.

Figure 9 – Darden Business School Design Thinking Process



Source: Liedtka & Ogilvie (2011)

The first stage “What is?” concerns the accurate assessment of current reality. Before designing anything, it is strongly recommended to pay attention in an ongoing scenario to identify the problem or opportunity intended to be tackled. Three tools my help in this stage: (i) the journey mapping to represent the result of an investigation of customer actions and behavior; (ii) value chain analysis to assess the potential for value capture and profitability for a future solution and (iii) mind mapping to organize and synthesize the information collected during investigation and insights about the intended innovation (Liedtka & Ogilvie, 2011).

In the second stage “What if?”, new possibilities are pursued. This is a creativity-focused stage where the team starts to develop hypotheses about what a desirable future might look like. It is the ideation process. The classical used to apply divergent thinking in ideation is brainstorming. When it is played in a structured approach, it puts together innovators to create new perspectives of the solution. In the convergent part of this stage, organizing the outputs of brainstorming into clusters may help find the most promising ideas to architect them into solution concepts (Liedtka & Ogilvie, 2011).

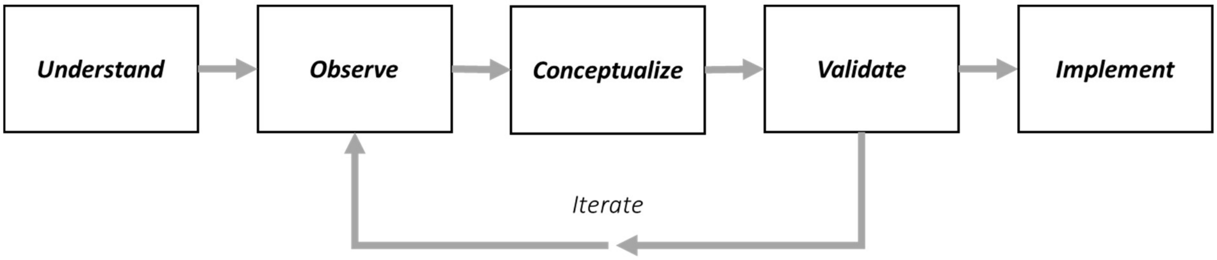
The third stage "What wows?" seeks the provide an objective evaluation of concepts drawn in "What if?" stage. The underlying logic behind this stage is the test of hypothesis. Thus, following divergent thinking, the first step is to make assumptions and take hypotheses to support the creation of new business from the generated concepts. The hypothesis can be derived from questions such as "Under what conditions would that become a good business?" or "What would need to be true for my concept to be a good one?". Next, following the reasoning of convergent thinking, the goal is to select the hypotheses that are more likely to be true. The main tool used is the rapid prototyping, whose intent is to create some visual and sometimes experimental manifestations of concepts to facilitate the conversation to get feedback about what needs improvements. Prototyping should be robust and fast. Designers talk about "low-fidelity" prototypes, which are just good enough to share with those whose opinions matter. The intention is rather to learn than test an almost finished product (Liedtka & Ogilvie, 2011).

After selecting the most promising low fidelity prototypes, it is time to get into the market in the last stage "What works?". The objective is to test the potential customer's willingness to pay for the new solution. Therefore, it is necessary to build a higher-fidelity prototype and offer it to potential customers. To reduce risks involved in designing the new offer, it is possible to engage customers in active conversations, in which they give clues to make the solution more attractive – it is called consumer co-creation. Once the improvements are made, the solution is ready to go to market. As important as the efficacy of the prototype is the way it is communicated to potential customers. And to improve both of them, working in fast feedback cycles is helpful to minimize the costs of experimentation. Key trade-offs and assumptions must be tested early under the motto of "fail early to succeed sooner".

4.1.4. Other Models

Lockwood (2009), the former president of Design Management Institute, is also a relevant reference in the constitution and dissemination of Design Thinking in the management field. He is placed by Johansson-Sköldberg *et al*. (2013) into the same research stream of Brown (2008, 2009), named *IDEO's way of working with design and innovation.* Although Lockwood (2009) defines Design Thinking as a human-centered innovation process, the author does not provide a formal theoretical framework organizing the steps or phases of the whole Design Thinking process. But he mentions *experimental intelligence* as a central element to unleash the power of Design Thinking. The *experimental intelligence* can be executed in the loops of experimentations, illustrated in Figure 10, that starts by understanding the problem, then concepts are created and tested iteratively and once they are considered valid, they can be implemented.

Figure 10 – Experimental loop of Design Thinking



Source: Lockwood (2009a)

Liedtka (2015) also cites two other references of the Design Thinking process. The first one from Continuum – a global innovation design company –, is organized in five stages: (i) discover deep insights, (ii) create, (iii) make it real: prototype, (iv) test, and (v) deploy. The second one from Rotman Business School, the institution in which Martin (2009) was dean from 1998 until 2013, organizes the process in four stages: (i) empathy, (ii) ideation, (iii) prototyping, and (iv) experimentation.

In addition, with similar stages, Micheli *et al*. (2019), without citing any formal reference, mention that the global technology company IBM also developed a formal Design Thinking process organized in following stages: (i) understand, (ii) explore, (iii) prototype and (iv) evaluate.

Liedtka (2015) and Seidel & Fixson (2013) also present their interpretation of the existing models of Design Thinking. In both studies, the Design Thinking model is reported with three stages that involve gathering data about user needs, generating ideas, and performing tests with prototypes.

4.2. Comparative Framework of Design Thinking Models

All the prescriptive models are based on the human-centered perspective that is the core of Design Thinking and a common thread that connects all the activities along the solution development. The organization of the models may vary in number and name of stages, but all of them have a common background that promotes empathizing with users and building the solution with test and learning cycles with prototypes. In this context, three main topics that guide the application of Design Thinking were identified assessing the similar characteristics of the models:

1) Starting by deeply understanding the user
   The initial phase of the process does not consider the solution. The focus is on the understanding of the context and user needs. This phase requires getting closer to the people the team will design for, understanding their needs rationally, and establishing a deeper connection with them. For that reason, empathy appears as the central aspect of the first stage and is considered the basis of the human-centered approach.

2) Having a dedicated moment to generate ideas
   After consolidating information and insights from the first stage, the innovation team starts to work on the solution. The creative process is called by designers of 'ideation', which aims to work collaboratively to create as many ideas as possible. It is worth remarking that the moment to create ideas and solutions should be completely separated from the moment to evaluate them. In this context, it is essential to build on other people's work and keep in mind the solution is for the user and not for the innovation team. To this end, structured brainstorming sessions and personas are often mentioned as very useful tools.

3) Evaluating ideas based on user feedback through prototypes
   The evaluation criteria of the solution must come from the user. Therefore, the team must validate their ideas and hypotheses, interacting and getting feedback from users. To facilitate communication and avoid an overload of subjective aspects, the team must use prototypes to present the solution to the user. Anything tangible and visual the user can interact with can be considered as a prototype. Prototyping should consume only the minimum time and effort

needed to get feedback from users, using inexpensive and simple artifacts are often called “low-fidelity prototypes”. The interaction with users and prototype testing occurs iteratively. The objective is to learn continuously about the solution and discover how to improve it, rather than evaluating the user’s reaction or developing an almost finished product.

The final stage of the process differs among the models. Some models end just after the prototyping and testing activities, such as the d.school’s framework, while others, such as IDEO and Darden School models, have a final stage encompassing the planning and first actions to insert the new solution into the marketplace. As the prototypes are built to get insights and feedback from users, they are far away from being a final and refined solution. Therefore, the concepts, often represented by a simple and partial effective prototype, may be developed, honed, and transformed into a functional, reliable, and desirable product. The activities and tools in this late stage of Design Thinking are often blurrier and more ill-described than in the earlier phases. For example, in the last stage of the IDEO model, Brown (2008) argues the “Implementation” stage involves charting a path to market, but the authors do not discuss what contains such a chart. In the case of Shimano, Brown (2008) mentions that senior professionals from the company joined the innovation team to carry out the Implementation phase and build the final solution to be launched in the market. However, it was not clear how was the division of roles and responsibilities between the innovation team and the other professionals. It suggests that some competencies should complement the Design Thinking innovation team to successfully bring the solution to the market. The final Darden Business School process presents a more detailed prescription to the final stage, where the preliminary commercial tests should be played. According to that process, the cycles of testing prototypes must result in a validated concept of solution which adds value to the end-user. But if the potential customers will be willing to pay for the new solution is an entirely new matter that should be addressed apart in the last stage “What works”. To do so, the Darden School recommends building a “high-fidelity” prototype and test commercial hypotheses following a “learning launch” framework.

A comparative framework, represented in Table 2, was designed to summarize and compare the discussed Design Thinking models. A four-stage model was chosen to represent the Design Thinking approach to comprise the three common topics of

Design Thinking models respectively in the three first stages, and the fourth stage involves the late activities related to the launch of the new solution in the marketplace. The name of each stage was given regarding the expected outcomes of each phase rather than the activities and techniques involved, such as empathize or ideation.

Table 2 – Comparative framework of models of Design Thinking for innovation projects

Reference model	Stages of Design Thinking for innovation projects			
	Needs finding	Concept generation	Concept validation	Concept development
IDEO (Brown, 2008)	Inspiration	Ideation	Ideation	Implementation
d.school (Institute of Design at Stanford, 2010)	Empathize and Define	Ideation	Prototype and Test	
Darden School (Liedtka & Ogilvie, 2011)	What is	What if	What wows	What works
Rotman School (Liedtka, 2015)	Empathy	Ideation	Prototyping and experimentation	
IBM (Micheli *et al.*, 2019)	Understand	Explore	Prototype and Evaluate	
Continuum (Liedtka, 2015)	Discover deep insights	Create	Make it real: prototype and test	Deploy
Lockwood (2009)	Understand and Observe	Conceptualize	Validate	Implement
Seidel & Fixson (2013)	Needs finding	brainstorming,	Prototyping,	
Liedtka (2015)	Data gathering about user needs	Idea generation	Testing	

Source: Elaborated by the author

Generally, the prescriptive models are useful to support and lead the Design Thinking application in innovation projects. As the Design Thinking approach might feel chaotic to those who experience it for the first time (Brown, 2008), the models are a way to shed light on the fuzzy innovation process bringing guidelines, tools, methods, and hints to facilitate Design Thinking application. Specifically, the presented comparative framework is helpful to summarize and highlight the similarities and divergences of prescriptive models in the Design Thinking literature. In addition, it will serve as the backbone to elaborate the evaluation plan to guide the investigations at the Descriptive Study - II.

4.3. Evaluation Plan of Design Thinking for Innovation Projects

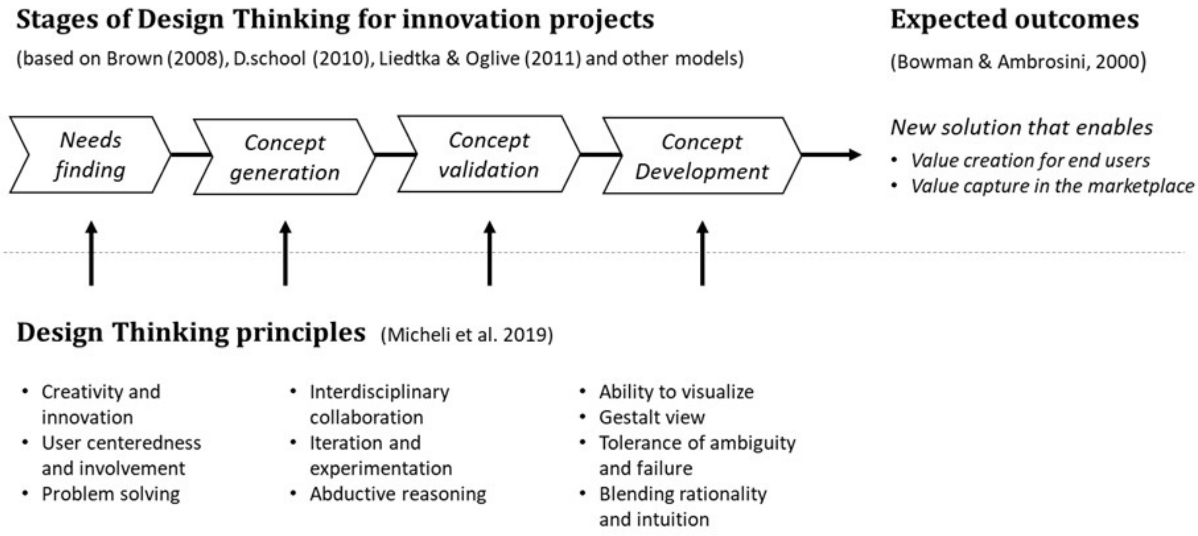
The evaluation plan is a main deliverable of the Prescriptive Study to support the empirical research of Descriptive Study - II (Blessing & Chakrabarti, 2009). In this work, the Descriptive Study - II aims to evaluate the success of Design Thinking based on project case studies of new product development. To this end, an evaluation plan was composed correlating the three main elements: (i) the four stages of the Design Thinking model, which represent the moments of the team's activities throughout the project; (ii) Design Thinking principles, which represents the essence of Design Thinking to guide the team's activities and (iii) the results that are expected at the end of the development, that is a solution able to promote the value creation and value capture.

For each project case study, the first step is to describe the development team's activities over time according to the four stages of the Design Thinking model. Many scholars describe that there is no straightforward formula or predeterminate rule to apply Design Thinking (Brown, 2008; Carlgren *et al.*, 2016; Liedtka, 2015). In this sense, the linear representation of the stages of Design Thinking does not mean that the activities are planned and carried out sequentially, but instead, it refers to a generic timeline that outlines the chronological evolution of the projects.

In such context, the principles of Design Thinking presented by Micheli *et al*. (2019) summarizes the main topics of Design Thinking that can be used to perform their innovation activities better. It is worth mentioning that all the principles can be used at any stage of solution development. Moreover, the principles do not necessarily need to be applied in a punctual or individualized manner, they can be combined and explored over time to improve the team's performance on the project.

Finally, at the end of the development, it is expected to obtain a new solution capable of creating value for its end-user and making the value capture feasible by the organization responsible for its insertion in the market. Thereby, the success evaluation of Design Thinking in the Descriptive Study II will explore the causalities and cause-effect relation between the Design Thinking application, which encompasses ten principles application over the four stages of development, with the project outcomes in terms of value creation and value capture. Figure 11 provides a visual representation of evaluation plan elements.

Figure 11 – Elements of the evaluation plan of case studies



Source: Elaborated by the author

Finally, after conducting the evaluation plan in the case studies, the empirical part of the research project brings discussions and propositions around the following research questions.

Q1) How does the Design Thinking approach contribute to value creation?

Q2) How does the Design Thinking approach contribute to value capture?

Q3) What are the opportunities to improve the Design Thinking application in innovation projects to increase the potential of value creation and value capture?

Therefore, it is expected that the discussions can contribute to the theory-building about Design Thinking practice in projects of new solutions, providing a better understanding of Design Thinking impacts and identifying the opportunities that can be addressed in further research.

5. DESCRIPTIVE STUDY - II

The Descriptive Study - II explores how empirical findings can drive the impact and effects evaluation of the *support* (Blessing & Chakrabarti, 2009). As previously mentioned, the Design Thinking approach is considered the *support* to be assessed in this work. Thus, to clarify and investigate how the Design Thinking approach has impacted the success of the new solution development, the Descriptive Study - II relies on multiple case studies of product development projects that followed the approach.

The Descriptive Study - II starts discussing the method choice of multiple case analysis to address the research questions (Section 5.1) and briefly presents the selected project cases to compose the analysis (Section 5.2). Then, for each project case, a case description is shown containing the main events and decisions throughout the projects and the within-case analysis, which assesses how the principles of Design Thinking were employed and then evaluates the success of the project outcome considering the value creation and the value capture (Section 5.3). Next, the cross-case analysis (Section 5.4) summarizes and compares the main topics and highlights of cases to uncovering patterns and push generalizations to guide the discussions and propositions around the research questions (Section 5;5).

5.1. Method Choice and Justification

The method of multiple case study method was chosen to answer the research questions intending to contribute to theory-building about Design Thinking applied in innovation projects. As indicated by Eisenhardt & Graebner (2007), the qualitative analysis of the case studies enables the advance of theory building by creating new constructs, theoretical propositions, or medium-sized theories from the empirical evidence found.

In the Design Thinking literature, many articles and books promote the adoption of the approach, highlighting the benefits Design Thinking can bring to innovation projects (Brown & Katz, 2011; Lockwood, 2009b; Luchs, 2016). Other studies describe how Design Thinking is employed to build solutions in different contexts, such as the development of robots to assist the elderly (McGinn et al., 2020), improvements in health care service (Sunder, Mahalingam, & Krishna, 2020), and the development of a video game based on brain-computer interface (Zapata, Jaramillo, Rodriguez, & Restrepo, 2019). However, as Micheli *et al.* (2019) discuss, the broad spectrum Design Thinking application and the multiple perspectives around the subject can induce the loss of specificity of the construct that can have various meanings to different people. Aiming to bring greater clarity and specificity about Design Thinking, Micheli *et al*. (2019) provide significant advances indicating the constituent principles of the approach. Following this line of research, this work aims to provide greater clarity about the impacts and effects of Design Thinking at the level of innovation projects.

With the purpose to investigate the cause-effect relationships that have not been explored by other empirical studies in the literature and seeking to answer questions of "how" the application of Design Thinking has influenced the outcome of the projects, the case study method is seen as an appropriate choice (Eisenhardt & Graebner, 2007). The inductive character of case studies enables generating insights from qualitative data and delineating patterns of behavior that would not be possible to obtain with quantitative data (Eisenhardt, 1989). Therefore, with the study of three project cases of new product development, it is intended to outline propositions and suggestions that can contribute to the theory about Design Thinking.

5.2. Sample Selection

The sample of cases comprises three product development projects that originated in partnerships between the University of São Paulo and large institutions operating in the Brazilian healthcare sector. The choice of cases is considered a theoretical sampling, as all projects passed through the four stages of Design Thinking and had commercial intent to launch the solutions in the market. Despite the common origin of the projects, each one had a particular evolution, which allows comparing how Design Thinking was applied in different contexts, exploring how the approach has influenced the outcome of each project.

Table 3 provides an overview of the projects, summarizing their main topics and achievements in each stage of the Design Thinking process. The name of each case resembles the focus of the solutions that were developed.

Table 3 – Case studies summary

Case	Needs finding	Concept generation	Concept Validation	Concept Development
1. Sharps Counter	The nursing team from the partner hospital indicated the need to increase safety and reduce accidents and errors during the sharps count after surgeries.	A multidisciplinary team of students from the USP Integrated Product Development course proposed a device for counting sharps with optical sensors.	After two rounds of projects financed by the partner hospital, USP students with greater design experience developed a Sharps Counter version with better precision and good product architecture. However, for gaps in sterilization, the device could not be tested in surgeries.	After two more rounds of prototyping financed by the hospital, a team was built with the commercial intent to launch the solution in the market. They have developed a pilot version of the product tested in more than 20 surgeries at the hospital.
2. Hemolysis Detector	The clinical analysis team from the partner laboratory indicated the need to improve the process of detecting hemolyzed blood samples.	A multidisciplinary team of students from the USP Integrated Product Development course proposed a device to evaluate the compliance of blood samples tube with computer vision and artificial intelligence classifiers.	In a project financed by the partner laboratory, USP students developed a functional version of the device, trained with 200 real samples. The result was published in the International Journal of Medical Devices.	A team of three graduating engineers founded a startup, supported by the advising professor, and received a grant from FAPESP to proceed with the project. Tests of the device were carried out for six months in the laboratory operation.
3. Remote Cardio	The team of cardiovascular rehabilitation from the partner hospital indicated the need to expand rehabilitation services for out-of-hospital patients.	A multidisciplinary team of students from the USP Integrated Product Development course proposed a remote Electrocardiogram (ECG) monitoring system connected to the patient's mobile phone.	In a project financed by the hospital, the monitoring system is refined to obtain a version with stable transmission via cell phone. However, for reasons of vital signal quality transmitted, it could not be used to monitor patients.	A team is formed to evolve and commercialize the solution and receives mentoring and grant from *Instituto TIM* to refine the wearable device to be able to be used in real patients.

Source: Elaborated by the author

All the project cases had a similar beginning. In the needs-finding stage, the partner institutions were responsible for identifying needs in their operation routines, with each institution having its own selection methods and evaluation criteria. In the Sharps Counter case, the partner hospital had a structured innovation sector that organized a process to find needs and opportunities from the whole hospital personnel. The innovation staff received suggestions of problems from different areas and selected the most relevant ones. Then, on some occasions, as in the Sharps Counter case, they established partnerships with external players to develop new solutions. In the cases of Hemolysis Detector and Remote Cardio, a similar pattern was followed. The innovation management areas of the diagnosis laboratory group and the other hospital gathered internal needs and searched for external partners for solution development. In these cases, a close relationship was established directly with the technical sectors of the healthcare institutions, which were, respectively, the clinical analysis of the diagnosis laboratory group and the cardiovascular rehabilitation center of the hospital. The managers of these sectors detailed the problems experienced by their teams for development in partnership with the university.

Another common aspect in all cases was that the concept generation stage was carried out within the scope of the “Integrated Product Development” course at the University of São Paulo (USP). This course is supported by Inovalab@Poli, an innovation laboratory at USP with teamwork and prototyping facilities. Over one semester, multidisciplinary teams composed of undergraduate students from different courses at the University of São Paulo work on real problems brought by companies in an academic challenge format (Inovalab@Poli, 2020). At the end of the course, the developed concepts are presented to the representatives of the institutions. If they appraise the concept as a promising opportunity, they could finance a further project to evolve the solution.

Among dozens of projects carried out in the course, the selected cases were those whose development has continued aiming to launch the products in the market. The concept validation was held in projects funded by the partner institutions, and the stage of concept development was carried out by a dedicated team interested in commercializing the solutions.

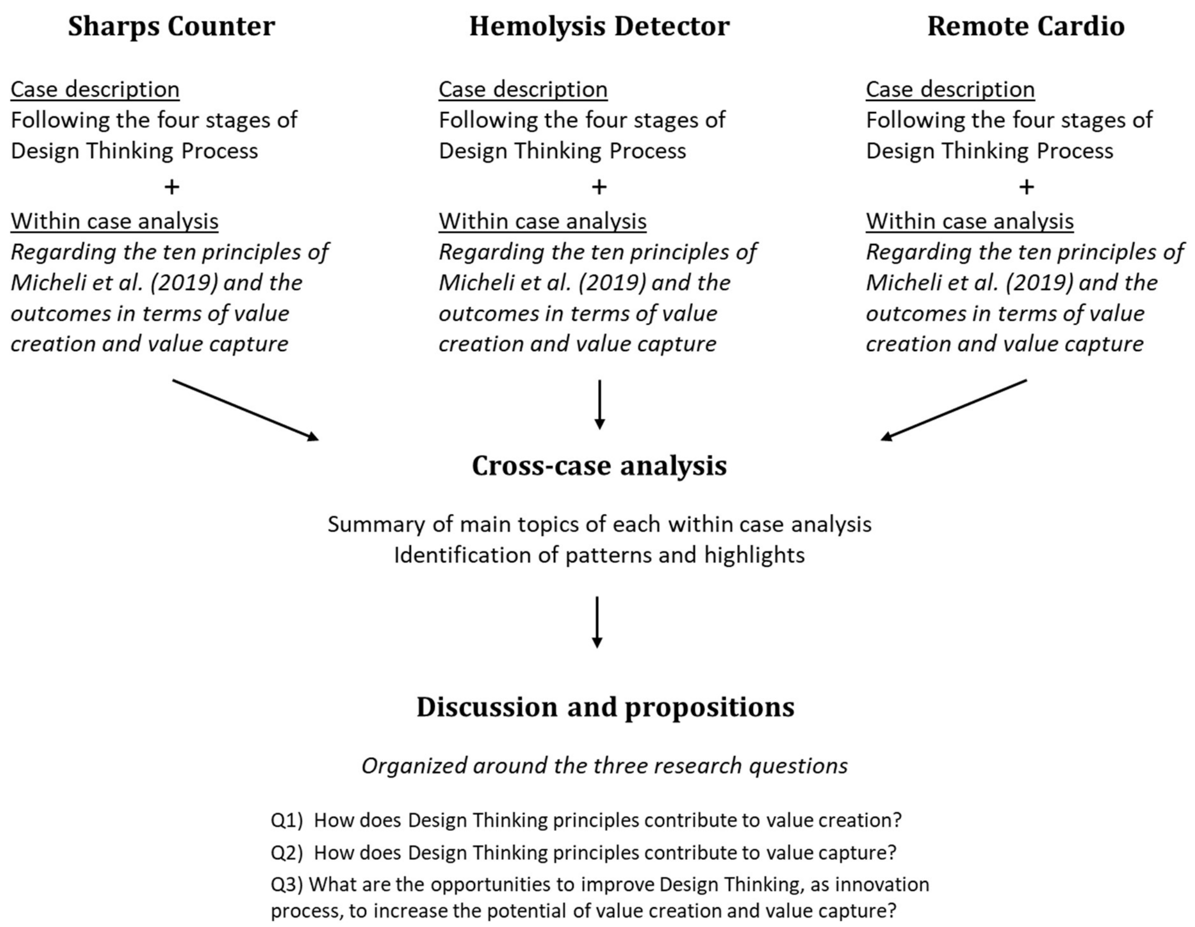
It is worth mentioning that the team members of each project changed along the stages of Design Thinking. The concepts generation stage of each project was held in distinct offerings of the Integrated Product Development course with different students at this stage. In the concept validation stage, the team was formed partly by students who worked on the course group and partly by members with previous project experience and greater technical knowledge to evolve the solution.

Finally, the concept development stage of the three projects was conducted by the same team of three members. Two of them had already participated in previous development activities on the projects and were in the final year of their engineering undergraduate studies. One of these two is specialized in electronic circuits, and the other had experience in product design and software programming. The third member, at the time, had recently graduated in industrial engineering. This third member is also the author of this research project. He worked only in the concept development stage and joined the team to support the founding of a startup aiming to commercialize the developed solutions.

5.3. Case Studies

The case studies are organized in four stages: (i) case description, (ii) within-case analysis, (iii) cross-case analysis of the cases, and (iv) discussions and propositions. The two first steps were conducted three times, once for each project, and the two last stages consisted of an overall assessment considering the findings of all cases. Figure 12 shows a schematic representation of the case studies organization.

Figure 12 – Schema of case studies organization



Source: Elaborated by the author

The case descriptions present how the main events have occurred and the project milestones were achieved. The description follows the four stages of the Design Thinking approach, seeking to build a narrative to serve as the basis for the analysis of each case. To this end, the narratives point out relevant decision-making and explore some details of the initiatives that promoted advances throughout the innovation process. The information of case descriptions was obtained through interviews with project members and people from partner institutions and document analysis, including commercial proposals, presentations used by the project team members, reports, and technical schemas of the solutions.

Thereafter, following the guidelines of Eisenhardt (1989), the data analysis was carried out in two steps: the within-case analysis and the cross-case analysis. According to the author, the first type of analysis provides deep immersion in each case's context and pushes the discovery of relations and unique phenomena of each case. Such a tactic has a major role in promoting the generation of insights. It helps the researchers at the beginning of the analysis process to deal with a considerable volume of information. As the objective of this work is to investigate the relationships between the application of Design Thinking and the outcomes of projects, the within-case analysis is conducted around each principle of Design Thinking and how the value creation and value capture took place.

According to Eisenhardt (1989), the second step of cross-case analysis aims to figure out patterns between cases and outline generalizations that can contribute to theory building. This type of analysis helps to avoid hasty conclusions in which investigators consider only part of the information available in the cases. In this context, to facilitate the comparison of the cases, the main topics of the analysis were gathered in a summary table to facilitate the comparative assessment of the cases to find out the similarities, differences, and highlights.

Finally, the discussions were organized around the research questions seeking to answer them considering both empirical data analysis and contributions from other authors in the literature. Hence, this work achieves its main goal of investigating the cause-effect relationships of the Design Thinking approach with the outcomes of innovation projects, bringing propositions and discussions.

5.3.1. Case 1 – Sharps Counter

The Sharps Counter results from a partnership between the University of São Paulo and Hospital 1, which is a major private, not-for-profit hospital in São Paulo. The project's goal was to create a solution to improve effectiveness and security in the sharps counting process at the end of surgeries. The project started at the beginning of 2016, and after several rounds of development, the last activities took place in the first quarter of 2019.

The count of sponges, instruments, and sharps is important to provide safety in surgical procedure execution to prevent those items from inadvertently being left inside the patient. Retained foreign items not only can result in severe or even fatal injuries and, because additional treatment is often needed and litigation is often provoked, they can drive up the cost of treatment and severely affect the reputation of clinicians and treating institutions (Egorova *et al.*, 2008).

In this context, the process of manually count all instruments, sponges, and sharps at the start and conclusion of a surgical operation is standard practice for numerous nursing organizations (WHO, 2009). Nonetheless, the manual methods are not fool-proof, and errors may occur during the count. The errors and counting mismatch can be driven by risk factors, such as the duration of the operating procedure – the probability of mistakes increases 2,5 times every additional 2 hours of surgery (Egorova *et al*., 2008) –, the emergency of the operation, and if there are unexpected changes (Gawande, Studdert, Orav, Brennan, & Zinner, 2003).

To improve the safety and accuracy of the count, the World Health Organization (WHO) recommends the use of automated counting techniques such as bar-coded sponges and radiofrequency tags for instruments (WHO, 2009). As there is room for new products and methods for automated sharps count, the project's goal was to develop a solution for sharps counting to improve the accuracy of the count and the safety for both patients and healthcare professionals.

5.3.1.1. Case Description

The project activities and events are described hereafter following the Design Thinking process stages.

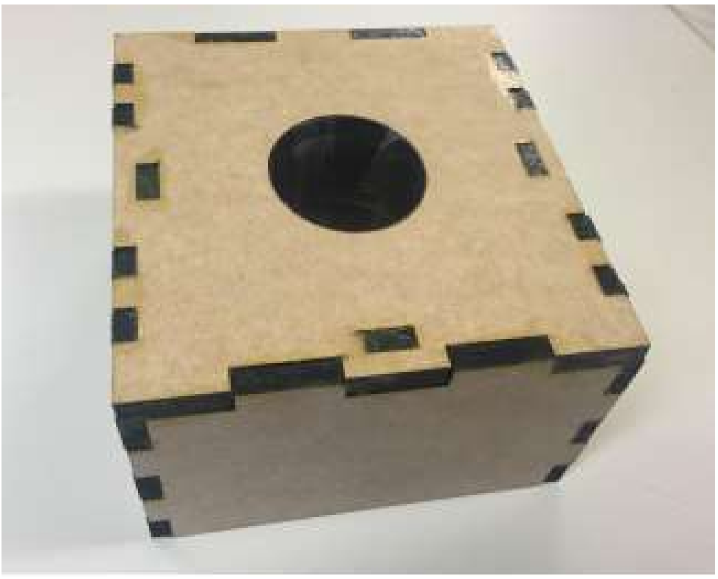
Needs Finding

The first activities of the project were performed by the Hospital 1 team involving nursing professionals and innovation personnel. The hospital has a dedicated function of Innovation responsible for coordinating and facilitating the innovation initiatives supported by the hospital. One of the function divisions was the Innovation Lab, a space for learning, experimentation, and new product design to support hospital teams in developing intellectual property and innovative solutions. To achieve these goals, the lab establishes partnerships with project leaders and clinical teams within the hospital and partnerships with external stakeholders such as universities, startups, and health tech companies. The Innovation Lab led a program that encouraged the operation and clinical teams to reports their needs and problems. Then, the innovation lab evaluated and screened the issues reported to select the most promising opportunities for new solutions considering the seriousness of the problem and potential market size. Within this program, the perioperative nurses reported the need to improve safety and effectiveness of sharp count – which was chosen by the innovation team to be carried on.

Concept Generation

A partnership between Hospital 1 and Inovalab@Poli was held to seek concepts of potential solutions within the scope of the Integrated Development Product course. In this context, six students started their activities interviewing the perioperative nurses to emerge into the problem context and empathize with the potential users. Then, after researching the problem context, performing brainstorming sessions, and passing through two cycles of prototyping, the group came up with a concept of a device for sharps count with a slotted enclosure where the nurses should drop used materials one by one. At the slot sides, there was an optical sensor to detect the passage of dropped material. The prototype presented at the end of the course was simple enough to demonstrate the counting mechanism and showed how the potential solution should work (see Figure 13). It was built with inexpensive materials and handmade techniques that facilitated the rapid prototyping process. Although it was not a functional prototype, it allowed getting feedback from stakeholders around the proposed solution.

Figure 13 – First version of Sharps Counter



Source: Innovation course report (Gusmão et al., 2016)

The prototype was presented to the hospital team (innovation personnel and nurses), who were willing to proceed with the product development. However, despite the positive expectations, the prototype was rudimentary, and it was required considerable effort and resources to validate the solution. To that end, the hospital team accepted the proposal to support the following stage of development to deepen the understanding of user needs, review the technology and materials, and go further on an advanced prototype.

Concept Validation

To develop a more robust and functional version of the solution, the concept validation stage started with a four-month length project with a dedicated multidisciplinary development team composed of four undergraduate students of different courses supervised by a master researcher of industrial engineering. Part of the students came from the course group, and two new members with previous experience in engineering projects were invited to join the team.

With a more well-defined scope, the team visited the hospital facilities to interview the nurse team to get more details about their needs and expectations about the solution and observe how the team dealt with their operational equipment. The main insights were to use proper materials in the next prototype, show the count on display, and build a device that could be placed on the operating table working autonomously without cables and external sources.

Guided by the insights, the next prototype was built with metal sheets to enclose the counting system, which comprises several optical receptors close to the slot sides to get a more accurate signal. Finally, the sensors were connected to an embedded system that transformed the received signal in the count and showed the result on an eight-segment led display. The second version of the solution is shown in Figure 14.

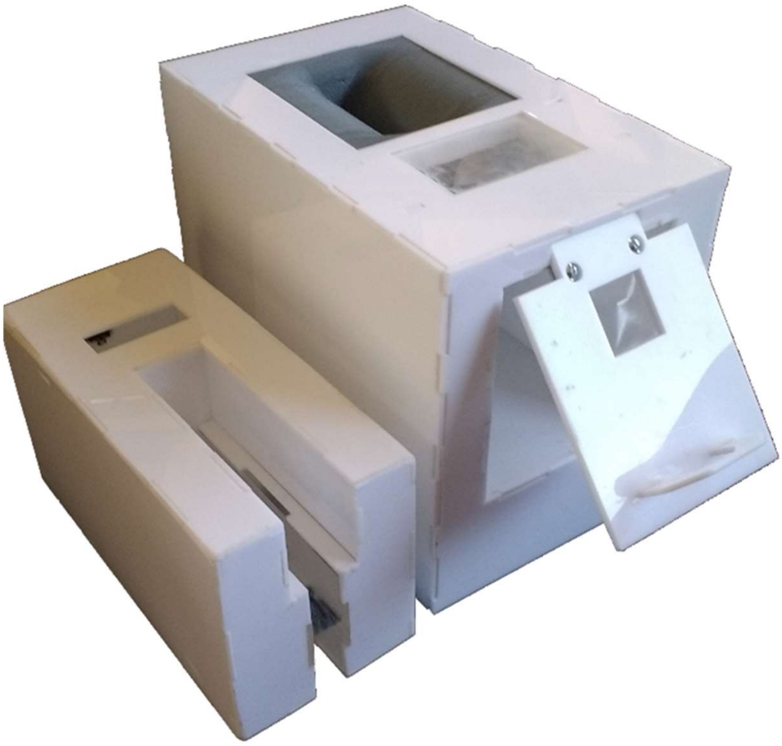
Figure 14 – Second version of Sharps Counter

Source: Collection of projects documentation (Inovalab@Poli, 2017)

The prototype was submitted to nurses appraising. Among their feedback, two topics stood out: (i) the occurrence of count errors, occasionally by the double count of needles, especially those attached to suture lines, and the non-count of small needles. And (ii) the electronic system was not compatible with the sterilization methods. To be placed on the operating table, the device's enclosure had to be completely sterile. However, the electronic system physically attached to the inside of the device could not be sterilized because the high temperatures and pressures would melt the electronics components.

Thus, a new product architecture was required to validate the concept, and the next round of prototyping resulted in the device shown in Figure 15. The third version of the counter had an internal and removable module that comprised all the electronics so that just the external structure should be submitted to the sterilization methods. In addition, the electronic circuit was reformulated with capacitors and inductors to stabilize and filter the signal from optical sensors and built with more accurate manufacturing methods for printed circuits.

Figure 15 – Third version of Sharps Counter



Source: Project proposal for Sharps Counter development (FCAV, 2017)

The nurse team checked the prototype and stated the device counted the sharps materials in all tests, but the very tiny needles commonly used in cardiac surgeries. In addition, the external structure of acrylic was compatible with the Sterrad® sterilization system that uses low temperature (50ºC) and hydrogen peroxide gas. However, after sterilization, some prototype pieces had a slight deformation, and some areas at the bottom of the cavity were not fully sterilized.

Despite the problems faced in the sterilization process, the advances of concept were remarkable. It could perform its critical function - i.e., correctly counting the dropped sharps - and had an architecture that could be submitted to sterilization. The nurse and innovation personnel were optimistic about the prototype, and they asked for a new version of the solution aiming its application in real situations. The next version should have a smaller size, better nozzle slot geometry (to avoid retaining small needles), and suitable materials with cleaning and sterilization methods.

In this stage of development, the presented solution can be considered a valid concept as it had appropriately performed the counting function, the product architecture contained all the elements of the final solution, and the potential users were interested in the product. However, some adjustments were needed so that the solution could be used in the field.

Concept Development

The concept development stage began with a two-month project focused on building the fourth version of the solution to overcome the mentioned challenges, allowing its use in real situations. In this stage, just two of the undergraduate members were engaged in the project, and they carried out the construction of the new device supervised by a master researcher and a professor. After two months, the result was a device with a polypropylene enclosure shown in Figure 16. The new material was chosen for the new device being sterilized in an autoclave – the most used sterilization method in the hospital surgery center. The new version also had a smaller size, more battery, and more optical sensors than the previous one. Finally, the new device was delivered to the hospital innovation personnel, who were receptive and signaled that there was room for ordering more device units.

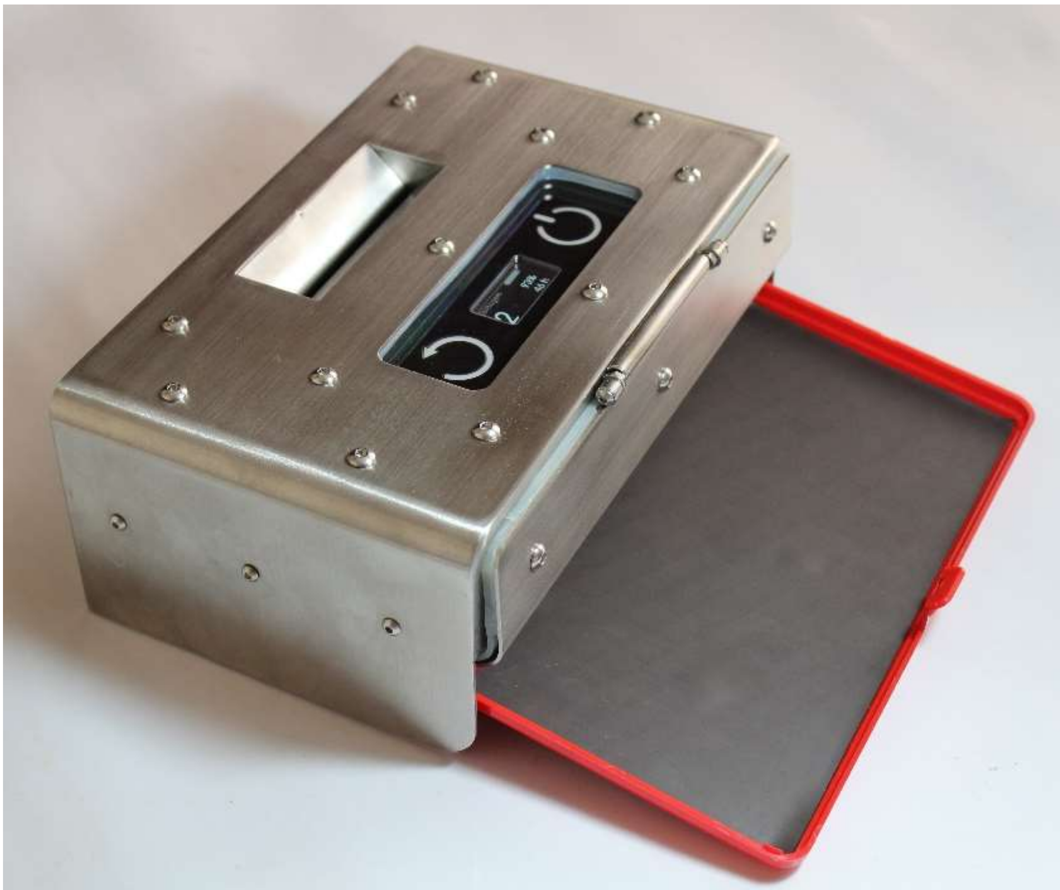
Figure 16 – Fourth version of harps Counter

Source: Collection of projects documentation (Inovalab@Poli, 2018)

Intending to build a startup of medical devices supported by the professor, a new member graduating in industrial engineering joined the team. Then, they sent a proposal to sell 30 units of the device to the hospital. However, the innovation team criticized the proposal, mainly due to the high cost to build more units of a device that looked more like a prototype than a final product. In addition, the device received more negative feedback from the nurse team after the sterilization in an autoclave that has deformed thinner parts of the enclosure. Then, the team took a step back in the startup foundation and decided to review the prototype with the remaining resources of previous projects.

After receiving all feedback, the product was redesigned with two main goals: allow properly sterilizing in an autoclave and being robust and looking like a final product. Therefore, the team visited the hospital for a guided tour throughout the surgery center, following all the nurse team's steps to clean, sterilize, store, and use surgical materials. In addition, they interviewed a specialist nurse in sterilization to learn about materials they could use. She pointed out that three better materials to deal with were stainless steel, polycarbonate, and silicone. The visit was also valuable to get inspiration about the design of other professional instruments and equipment used in surgeries. After several rounds of brainstorming, the fifth version of the device was conceived, represented in Figure 17. A 3D model of the product was presented to the hospital team with overall positive feedback. To handle the sterilization problem, in which the device should withstand a 140ºC and 3 bar in the autoclave, the team firstly made thermal strain and stress simulations in CAD and machined a specimen with new device geometry to test the mechanical fasteners in a sterilization cycle at the hospital autoclave. After those tests, the team reviewed the project and sent the models to a third-party supplier to cut and assembly the new enclosure. In addition, the electronic system was honed to have greater reliability, fit in the new enclosure shape, and provide more information for users in an OLED display.

Figure 17 – Fifth version of Sharps Counter



Source: Elaborated by the author from project documentation (Indigo Labs, 2018)

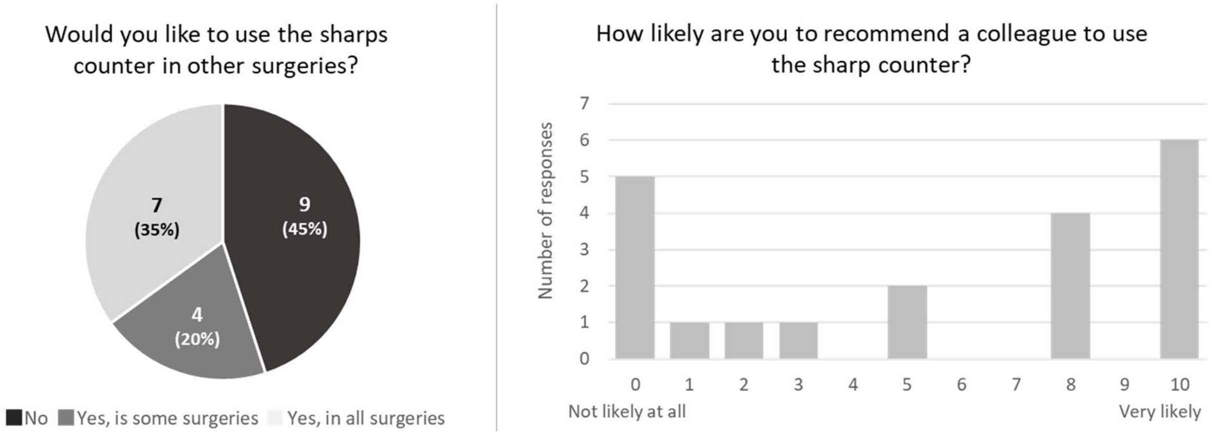
The new version of the device was brought to the hospital and submitted to autoclave sterilization with biological indicators. After the test, the device's shape was preserved, and all indicators showed that the sterilization was successfully performed. Then, the device was presented to the nurse leaders of the surgical center, who approved the new version and arranged surgery for its first use. The chosen surgery was a gastrointestinal procedure that used a dozen of sharps materials – all of them were counted correctly by the device. It was a successful milestone.

After the positive results, rounds of several tests in surgeries were jointly planned with the senior nurses of the hospital. The objectives of such tests were both to assess the opinion of different professionals about the solution and to evaluate the device performance in repeated uses. The development team prepared a questionary to be responded to by the surgery team after each operation. The questionary was reviewed by senior nurses and adjusted after a pilot surgery. The choice of surgeries the device should be used was in charge of the senior nurses. They requested the person responsible for counting to use the device and to answer the questionary, regardless of whether the surgery team has expressed interest in the new solution.

After many cycles in sterilization, the device presented slight deformations that hinder the insertion of its internal module. In this context, a recurring maintenance scheme was established to ease the cadence of testing. At the end of every week, the development team collected the device, fixed whatever was needed, and returned it next week to the hospital.

The device was tested over four months with such an organization, and twenty different surgery teams answered the questionaries. In more than half of the surgeries, there was at least one error of counting. By the commentaries of professionals, some errors occurred by unproperly use the device and by failures of the counting system. In some cases, the device miscounted tiny needles and needles with blood on the suture line that got gripped on the slot side. To evaluate the users' opinions, it was asked whether they would like to use the device in another surgery and how likely they would recommend the solution for a colleague. The charts in Figure 18 show the result of the answers.

Figure 18 – Responses to questionnaires about the intention to use and recommendation of Sharps Counter



Source: Elaborated by the author from project documentation (Indigo Labs, 2019)

Those results were presented to the nurse leaders and senior nurses, who acknowledged that about four device units would be suitable to meet the hospital's needs. However, such demand would be justifiable only if all problems of miscounting were solved. Therefore, considering the potential demand of the hospital was much lower than the initial forecast of at least 30 units and the high efforts to achieve an extremely accurate count, the development team decided not to continue working on the solution and focus their efforts on other initiatives.

5.3.1.2. Within Case Analysis

Following the guidelines of Eisenhardt (1989) for case studies, a key step for analyzing data is the within-case analysis. It allows to get a deeper immersion into case reality and find out unique relation in each case before drawing up patterns in cross relations and generalizations about all the cases. The case analysis starts by assessing how the principles of Design Thinking were used and then evaluates the success of the project outcome considering the value creation and the value capture.

<u>Principles of Design Thinking Application</u>

The first step of within-case analysis explores how the application of each Design Thinking principle occurred throughout the development process.

i. <u>Creativity and innovation</u>

   Creativity as a manner of pursuing new solutions and novelty has been present throughout the whole project. The Sharps Counter was a totally new concept to the development team and the hospital personnel. As no previous solution was known, creativity was required in many activities to figure out how to overcome challenges and obstacles.

ii. <u>User centeredness and involvement</u>

   The project activities were organized according to stakeholders' and users' feedbacks about the proposed solution. In every interaction with them, new needs and opportunities for improvement were discovered. In such a way, the user's perspective allowed the team to gradually and abductively identify the most relevant challenges and obstacles that must be overcome to enable device use in real surgeries.

   The feedback from users and stakeholders had different nature. In some cases, it might be direct and objective, e.g., "the device has to be sterilized", and in other cases, it has subjective aspects, e.g., "it does not look like a final product". However, it was in charge of the team to consolidate the feedback and unfold them into actionable issues on any occasion. Then, the team should decide and prioritize which of those issues should be addressed to meet the main demands. In this process, it is crucial to balance the user's needs and desires with the team's interests and objectives – ideally, both should be met.

iii. Problem solving

Problems have appeared in all the stages and of the project. The problems were more poorly defined in the early stages with a broader scope, for example, "what mechanisms can we use to count material?". As the project progressed and uncertainties decreased, the problems were more specific. The intended solution had more defined goals, such as, "how can we make the device look like a final product?" or "how can we avoid deformation during the sterilization?". As the specificity of problems increases, the complexity and robustness of the required solution increase as well. To answer the first question of seeking mechanisms of counting, simple and even non-functional prototypes can show how a solution should work. However, to answer the second group of questions related to the performance and design of a final product, the complexity of the solution was much higher considering all the features it has to deliver the expected performance.

To deal with more specific and complex questions, new members joined the team due to their experience in previous projects to use their technical background to face the unaddressed challenges of the solution. Acknowledging that the problem-solving capacity depends on the team's previous knowledge, when recruiting members, it is important to consider that all the main capabilities required to face the project challenges should be present among the team members. However, in the first stages, especially during the needs finding, it is improbable to anticipate all the challenges that would be faced in the project. Therefore, having ways to adapt the team composition according to the type of solution was helpful to get an entire team with all the main desired capabilities.

iv. Iteration and experimentation

As previously mentioned, the project activities were organized in iterative rounds of prototyping, which gradually showed the path to the final version of the solution. However, the rapid prototyping cycles described by Brown (2008) and the d.school of Institute of Design at Stanford (2010) as a way to quickly learn about the user needs in a specific moment should make room for developing more robust and functional solutions. Furthermore, as the rounds of prototyping evolved, stakeholders and users had greater expectations of getting a totally functional and ready-to-use solution. To exemplify, after the fourth presented version of Sharps Counter, it was expressly said by nurses and innovation personal that the device should be as a final product.

Another relevant factor in design tests and experiments is the need for resources - as the solution complexity increases, the tests demand even more resources. For example, the first version of Sharps Counter, made with easy-to prototyping and inexpensive materials, was useful to join efforts to validate the concept. In contrast, the fourth version of the solution may be considered a complete failure considering the challenge of sterilization. Despite being built with better materials and techniques than previous prototypes, it had significant deformation, and internal parts were not properly sterilized. With this iteration, the team learned how to build a sterilizable device, but more resources were needed to carry on the development. For the next round, it was too risky to test the sterilization with the final and assembled device. Thus, the team decided to build more specific and isolated tests with the specimens and simulations. Although the experiment demanded resources in terms of material, time of the project, and time of nurses to run the test into the autoclave, it was helpful to avoid the risk of having another failure testing the whole and final device (which is much more expensive than specimens).

v. Interdisciplinary collaboration

From multidisciplinary teams of students to strong interaction between the development team and nurses, the interdisciplinary collaboration was fundamental to carry out the project and progress on the solution development. The collaboration with the nurse team deserves a special mention. They provided key resources to the project, such as feedback from user’s perspectives, knowledge about materials and sterilization, access to hospital facilities to observe their context and support, and resources in sterilization tests. In addition, they also have a central role in final tests in several operations mobilizing the surgery teams and performing the procedures of storing, cleaning, and sterilizing the device to be appropriately provided to scrub and circulating nurses. In this context, good communication and relationship between nurses and the development team were key factors in successfully running the tests. The nurses' participation was not only about providing feedback. They have actively collaborated on the solution evaluation and development.

vi. Ability to visualize

Since the beginning, the visualization through prototypes had a significant role in project progression. Despite the prototypes, the team used visual tools to coordinate the development activities in brainstorming, project management, and technical documentation.

The visualization also served as support for external communication, in which the visual artifacts may vary according to the public and occasion. For example, the physical prototypes were excellent to get feedback about the usability or effectiveness of the solution. But in order occasions, such as meetings and presentations, charts, pictures, and virtual models were most suitable.

vii. Gestalt view

Although it was not carried out explicitly with the name of "Gestalt View", the team incorporated the different perspectives to consolidate a holistic view of the context. A good example was the efforts of the development team to identify the requirements not verbalized by users, especially when it was stated the device should look like a "final product", but the users did not say which features or characteristics the solution should have. To unfold this feedback, the team visited the hospital to observe how the nurses dealt with the surgical materials following the equipment preparation and handling process steps.

viii. Abductive reasoning

From a macro perspective, it can be stated that the development process followed abductive reasoning. The solution had been shaped and constructed from unfolding events to discover how the device should be and how it should work to lead to the expected outcome of the effective and safe count. Thus, it followed the logic of abductive reasoning described by Dorst (2011), when both the thing ("what") and the working principle ("how") must be conceived to deliver value.

But within a micro perspective, the team chose the method and reasoning specific for the context and challenge they faced for each activity. For example, it could have more abductive principles like brainstorming sessions, but it could also be strictly analytic when performing simulations.

ix. Tolerance of ambiguity and failure

The lessons learned from the mistakes and failures allowed the team to continuously improve the solution to get at the final version of the Sharps Counter that could be used in the field. The tolerance to failure is not just a matter of behavior and mindset of people involved in development activities but also a question for resources management and expectations alignment with stakeholders outside the team.

x. Blending rationality and intuition

As previously mentioned, different types of problems were faced. Some of them required greater intuition and others more rationality. A useful way to apply these two forms of reasoning may be by unfolding the solution's creation into smaller and more specific problems and choosing the appropriate resolution method for each case.

Outcomes – Value Creation and Value Capture

Considering the problem context and the solution scope, the use value is created when the hospital's surgical center incorporates the new method of sharps counting, and the surgery teams can use it to enjoy greater security and reliability than manual counting. In this context, the value creation encompasses delivering a safe and completely sterilizable device with a very accurate method of counting and all the services related to support, training, and maintenance that enable the proper use of the Sharps Counter by hospital teams.

The Design Thinking principles were favorable to guide the team to evolve the Sharps Counter throughout the innovation process to create use value. The iteration and experimentation principle played a significant role in the solution creation as five rounds of prototyping were carried out to get at the final version of Sharps Counter. In each round, the feedback from nurses gradually showed the main weakness of the solution so that the team could overcome them. For example, in the first prototype, it was remarked that materials should be compatible with surgical center guidelines and that the device should work autonomously. In the next round, it was stated the product architecture should allow the removal of electronic parts to enable sterilization, and the method of counting should be improved to avoid miscounts. In the third and fourth versions, the nurses told the devices could not be sterilized adequately considering the deformations and the residual presence of biological markers in sterilization tests. This approach illustrates how the interdisciplinary collaboration and user-centeredness combined with iterations showed the clues to improve the solution and get a final version capable of being used and deliver value in real surgeries. However, it is worthy to remark that users' guidance did not mean meeting all their feedback and desires immediately. Indeed, the development team had to interpret the received feedback and established priorities to use their resources to create value through the designed solution.

The iterative process also resulted in many intermediate prototypes of Sharps Counter. Due to the context of solution application, those prototypes did not create use value as they did not meet the minimum requirements to be used in real surgeries. The main constraint that prevented the prototypes from being tested and used in surgeries was the sterilization requirements of the hospital to assure that all materials and equipment used in surgery will offer no risk to patient safety and will not harm the work of the surgery team. In this regard, the principles of Design Thinking did not create use value gradually in each prototype. Instead, the principles contributed to value creation as they guided the solution development process and facilitated identifying what features should be improved and where the development team should work on.

Finally, considering the use value creation, the principle of interdisciplinary collaboration was a cornerstone to make the Sharps Counter feasible. The partnership with nurses provided much more than user feedback. The nurses actively collaborated with the development activities and provided key resources and access to hospital facilities. The collaborative process also contributed to the nurse team to notice advances over the rounds of prototyping, perceiving the potential value of the solution that was being developed. Such value perception can be stated as the nurses kept involved with the project and invested their time to drive the solution development even though the intermediate outcomes and prototypes could not deliver the value they were expecting.

On the other hand, the value capture within the Sharps Counter design process took place in the form of projects funding, pushed by the hospital's interest to invest in innovation. Nonetheless, even applying all the Design Thinking principles, having the support of the hospital team, and providing a functional solution, there was no capture of value related to the sale of the Sharps Counter product.

As Bowman & Ambrosini (2000) discussed, a company to be able to capture value should offer a product or service that the customer perception about the use value he can get is greater than the price it will be paid. In the context of Sharps Counter, the solution must have a very accurate method of count to deliver its main value that is to avoid errors on the count. For example, a cardiac operation may use more than 100 sharps, so the accuracy of 99% would not be enough to avoid errors of counting in such surgery. Thus, to reach a minimum accuracy to provide a reasonable use value perception would require considerable technological advances. However, even putting great development efforts in was quite uncertain it was possible to reach such accuracy. In addition, regarding the potential of value capture, after using the Sharps Counter in several surgeries, the nurses realized that it would not be necessary to have one device for each surgical room. Few units would be able to meet the demand of the surgical center as the solution would be preferably used in surgeries with a high quantity of sharps and by the teams that were most engaged with the solution. Thus, the initial expectations to deliver dozens of Sharps Counter was considerably reduced.

Thus, after such feedback from nurses, the development team realized that the potential to capture value was much lower than the amount of investment required to get the desired accuracy. This unfavorable balance between value capture and development efforts was crucial in deciding not to continue working on the solution. Therefore, although the value capture was not an immediate outcome of applying Design Thinking principles, it was a major factor in project viability and product evolution. Thereby, including methods to assess the relationship between value capture and development efforts throughout the Design Thinking process could have been a promising way to increase the odds of success of the solutions in this case.

5.3.2. Case 2 – Hemolysis Detector

The Hemolysis Detector project started in 2016 in a partnership between USP and one of Brazil's five largest laboratory groups. Its goal was to enhance the blood sample screening methods in the pre-analytical phase of laboratory operation with computer vision and artificial intelligence. After two development cycles, the project reached a certain level of maturity that requires an organization with a dedicated team to advances the development and launch the product in the market. To this end, the project team set up a startup advised by a professor to carry on the product evolution. They worked on the project until the first months of 2020.

In the context of laboratory medicine, the laboratory tests are estimated to guide about 70% of diagnoses in medicine (Plebani, 2004) and to impact over 60% of decisions of hospital admission and discharge decisions and the patient therapeutical guidance (Forsman, 1996). Thus, reducing errors is a central concern in laboratory operations due to patient safety and economic factors. The occurrence of errors may have serious consequences threatening the patient's health, cause false positives and false negatives, and delay and block the report's emission. For such reasons, diagnostic errors are a major cause of legal claims in the United States (Guimarães, Wolfart, Brisolara, & Dani, 2011).

Most of the errors in laboratory tests occur during the pre-analytical phase (Carraro & Plebani, 2007; Stahl, Lund, & Brandslund, 1998; Wiwanitkit, 2001). This phase comprises receiving the patient, obtaining information, collecting and identifying the biological sample, transporting and storing the collected materials, and finally receiving and evaluating the rejection criteria of the samples (Guimarães *et al*., 2011).

In this context, many studies explore the causes and prevention of pre-analytical errors (Bonini, Plebani, Ceriotti, & Rubboli, 2002; Carraro & Plebani, 2007; Livesey, Ellis, & Evans, 2008; Plebani, 2006). A factor that makes the exam unfeasible is the occurrence of hemolysis, which is the rupture of red blood cells and the release of hemoglobin and intracellular substances in the serum or plasma (Howanitz, Lehman, Jones, Meier, & Horowitz, 2015). Hemolysis is an issue present in laboratory routine, and its prevalence can be as high as 3.3% of all of the collected samples, accounting for up to 40% of all unsuitable specimens identified (Lippi *et al*., 2008). In the study within an Italian hospital, the hemolyzed was the main cause for rejecting blood samples from inpatients (Bonini *et al*., 2002).

The hemolysis index, i.e., the level of hemolysis in a sample, can be measured on a numeric scale of hemoglobin concentration in the serum. The gold standard equipment for that measurement is large machines used in the analytical phase, such as Roche Cobas c501 (ROCHE, 2017) and Siemens Dimension Vista 1500 (SIEMENS, 2018). Such equipment is usually placed in analytical centers, a central unit that receives samples from several collection points and analyzes biological material.

To anticipate the detection of unsuitable samples for analysis, technicians in collection units may perform a visual inspection of samples to identify, among many rejection criteria, the presence of hemolyzed specimens. However, visual inspection methods are subjective and often inaccurate and misleading (Janatpour, Paglieroni, Crocker, DuBois, & Holland, 2004). Therefore, it is strongly recommended to use, whether available, automated, and objective methods instead of visual inspection to detect hemolyzed samples (Hawkins, 2002; Janatpour et al., 2004). Due to the lack of robust and objective methods for hemolysis detection in the pre-analytical phase, the personnel of the Diagnosis Laboratory Group brought the need for a reliable and accessible solution for being used in collection and screening units to provide decentralized detection of hemolyzed samples.

5.3.2.1. Case Description

The project activities and events are described hereafter following the Design Thinking process stages.

<u>Needs Finding</u>

The project's starting point took place when the partnership between the University of São Paulo and Diagnosis Laboratory Group was established to work on innovative projects. Thus, facing the opportunity to get new solutions to enhance the laboratory operation and contribute to developing intellectual property, the management of the clinical analysis team supported by the R&D personnel sought the most prominent problems to address. For this purpose, the managers and coordinators listed the main problems experienced throughout the operation of clinical analysis tests, which involves examining the biological material of patients, such as blood, urine, saliva, etc.

Furthermore, blood tests are the most common clinical analysis tests, corresponding to more than half of all tests performed in a typical laboratory. Thus, reducing the rate of blood sample rejection is a significant achievement to gain quality in laboratory operations and improve the patient experience that receives all the reports on time and is not requested to make a new collection. For those reasons, the clinical analysis team pointed out the need to improve methods to detect hemolyzed samples, one of the leading causes of sample rejection.

The hemolysis level can only be accurately measured in the analytical center, a big unit responsible for receiving samples for several collection units and performing the analytical phase using high-end technology. However, the hemolysis causes occur almost totally in collection units, for example, due to inadequate handling in blood collection or the non-homogeneity of the biological material. Thus, the need of the laboratory team was to obtain an affordable and accurate method to identify hemolyzed samples systematically in the collection units before sending the specimens to the analytical center.

Concept Generation

After defining the problem, the search for new concepts of potential solutions was carried out within the Integrated Product Development course, taught by professors of Inovalab@Poli. In this context, a multidisciplinary team composed of undergraduate students from different USP schools was in charge of the challenge.

The student's team started working by getting immersed in the problem and the laboratory context. They visited the central unit of the laboratory group, interviewed the personnel from clinical analysis, and observed the operation. With those inputs, the group of students made a persona for representing the clinical analysis operator and designed a user journey organized in three main stages: reception, preparation, and visual inspection of samples. The most critical stage was the visual inspection, which required higher effort and concentration from the operator, who often felt insecure due to the possibility of incorrectly screening the sample. This process led the search for new solutions to improve hemolysis detection accuracy and relieve the operator's pain points.

Next, the ideation process explored two main topics: the method to evaluate the blood samples and the mechanical structure of the solution. By brainstorming sessions, the team considered using the evaluation method to measure viscosity, fluorescence, magnetism, diffraction, and refraction of the tube, using optical lenses, color sensors, and mobile apps. For the mechanical structure, the team got inspired in the shape and usability of existing products such as pagers, thermometers, and bar code readers and considered other structural elements such as conveyors, belts, magnifying glasses, and led.

In the first prototype round, the feedbacks from the laboratory operation team brought restrictions to the solution that could not open the tube to preserve the biological material, and it also could not change the flux of samples within the laboratory units. Therefore, the project team planned another prototype round with those feedbacks that resulted in a solution with an analysis and conveyor modules. The first module evaluated the R, G, B levels of blood samples using a color sensor connected to external computer software. Then, the R, G, B data was processed by a regression method to classify the sample into three categories: hemolyzed, not hemolyzed, and uncertain. Finally, the conveyor system moved the sample to three baskets according to the classification. Figure 19 illustrates the prototype.

Figure 19 – First version of Hemolysis Detector

Source: Innovation course report (Longo, Torrano, Carmo, Cayres, & Lovatti, 2016)

The prototype was presented to the laboratory collaborators that stated a positive potential and were willing to support a new phase of the project to improve the solution technically. However, they noted that the most critical part of the solution was the analysis module, which deserved greater development efforts. They also pointed out that the solution should have a reduced size and work autonomously without any external computer due to space restrictions in the screening bench of laboratory units.

Concept Validation

Based on feedback from the last stage, a four-month project proposal was presented and approved by the laboratory personnel. The main objectives of the proposal were to review the technologies of the analysis module to improve the accuracy and reliability of the hemolysis level evaluation and develop dedicated electronics to enable the autonomous operation of the solution.

In this stage, two members of the original course group remained on the team, and two new members with previous experience in engineering projects joined them. At the development round, a new version of the solution was created that was capable to numerically estimate the hemolysis index of blood samples on a scale of mg/dL of hemoglobin concentration. The new device and its performance evaluation were published in the Journal of Medical Devices of the American Society of Mechanical Engineers in the work of Lopes *et al.* (2019).

The solution had four main features: (i) mechanical structure (see Figure 20) made of acrylics that hold the sensors and all the embedded electronics and also had a hole where the sample tubes are placed to be analyzed; (ii) an LCD screen, that provided a more-user friendly interface displaying the main instructions to use the solution properly and returned the result of hemolysis index estimative; (iii) Computer vision and image processing system, that captured three images of the sample in red, green and white lightning and extracted the R, G, B data only from the correct part of the tube; (iv) classifier intelligence, based on input data processing functions and neural network algorithm (Lopes *et al*. 2019).

Figure 20 – Second version of Hemolysis Detector

Source: Lopes *et al*. (2019)

After four months of device construction, a dataset with the hemolysis index of 204 real blood samples was created to train and test the neural network classifier. The batch of samples was randomly collected in the laboratory and then undertaken for Cobas 8000 c702 analysis. Within the set of 204 samples, there were 188 tubes with two white labels overlaid and 16 tubes with different kinds of labels. The first group was considered the “standard samples” as they were the most usual type of tube identification found in the laboratory. For standard samples, considering the critical zone of analysis between 50 mg/dl and 100 mg/dl, the device had a reasonable error (about ± 10 mg/dl), which allowed identifying the hemolyzed samples correctly. On the other hand, the samples out of the critical zone, with a very low or very high hemolysis level, can be easily recognized by human visual inspection (Lopes *et al*., 2019).

The Hemolysis Detector device and its performance evaluation were presented to the laboratory personnel, who were optimistic with the results and willing to use the solution in their routine operation. However, the laboratory team pointed out that, besides the technical performance evaluation, to consider purchasing more units of the solution, it would be necessary to get evidence showing the equipment use in the field would be reliable and positively impact the operation.

After the assessment of the second version of the solution, the Hemolysis Detector device can be considered as a validated concept. It has well performed its critical function, measuring the hemolysis index within a reasonable error range, had a product architecture suitable for its use in the field, and there were people interested in involving the solution in the laboratory operation.

Concept Development

Regarding the achievements and remarks from the last stage, the laboratory personnel and the development team agreed to put more effort to evolve the solution establishing three workstreams: (i) perform tests to evaluate the impact of the device in laboratory operation, (ii) conduct the intellectual property assessment, and (iii) elaborate and submit a project to apply for grant in a FAPESP (São Paulo State Research Support Foundation) program called PIPE Phase 1. For this stage, the two most senior members involved in the previous stage continued in the team, and a third member, who recently graduated in production engineering, joined the group.

1) Tests in laboratory operation

The tests took place for nine weeks between July 2018 and January 2019 in two laboratory units in the city of São Paulo, one placed inside a hospital and the other, a common collection unit opened to the general public. In both units, the technicians used the device to screening the samples before sending them to the analysis center. If the specimen had an acceptable level of hemolysis, it could be dispatched to the analytical center under special conditions. If the sample had an unacceptable level of hemolysis, it should be rejected. On such occasions, the patient is often called to go back to the laboratory for a new blood collection. For each case of hemolysis suspicion, the technician noted on a worksheet the hemolysis index measured by the ruler of visual inspection and the device and registered the decision to dispatch or reject the sample. At the end of the tests, there were 39 hemolyzed cases registered in the common unit and 93 cases at the hospital unit. Table 4 shows the decisions made by technicians with the hemolyzed samples.

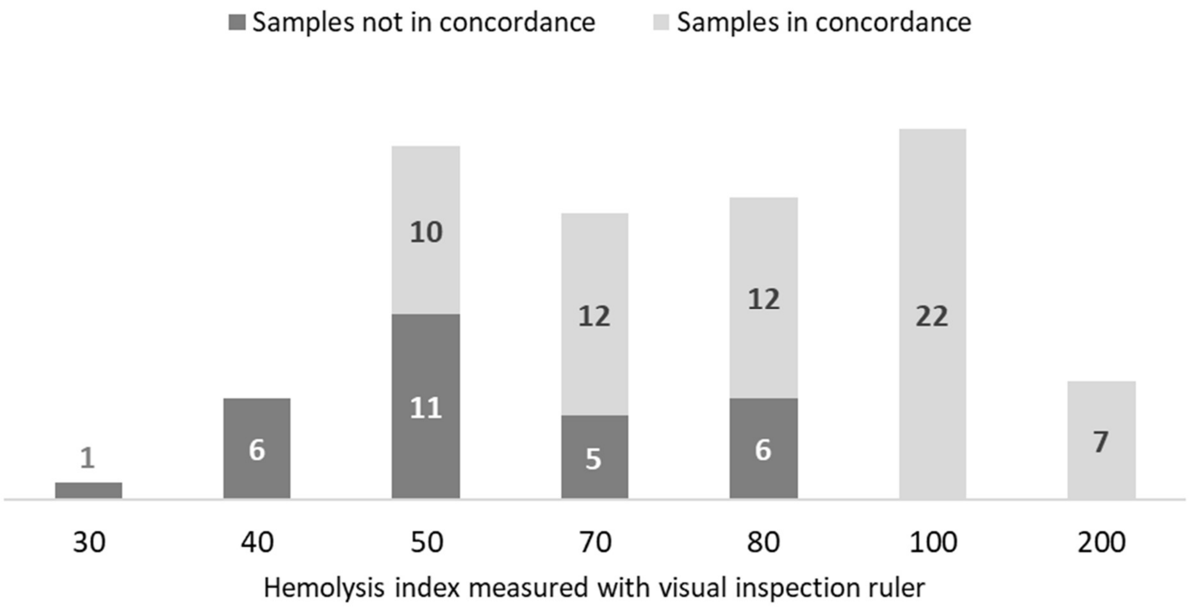
Table 4 – Decision of laboratory technician of blood samples analyzed with Hemolysis Detector

Decision	Common unit	Hospital unit
New collection	15	70
Dispatched under special condition	5	2
Dispatched replacing tube (aliquot)	15	-
No register of decision	4	21
Total	**39**	**93**

Source: Elaborated by the author from project documentation (Indigo Labs, 2019)

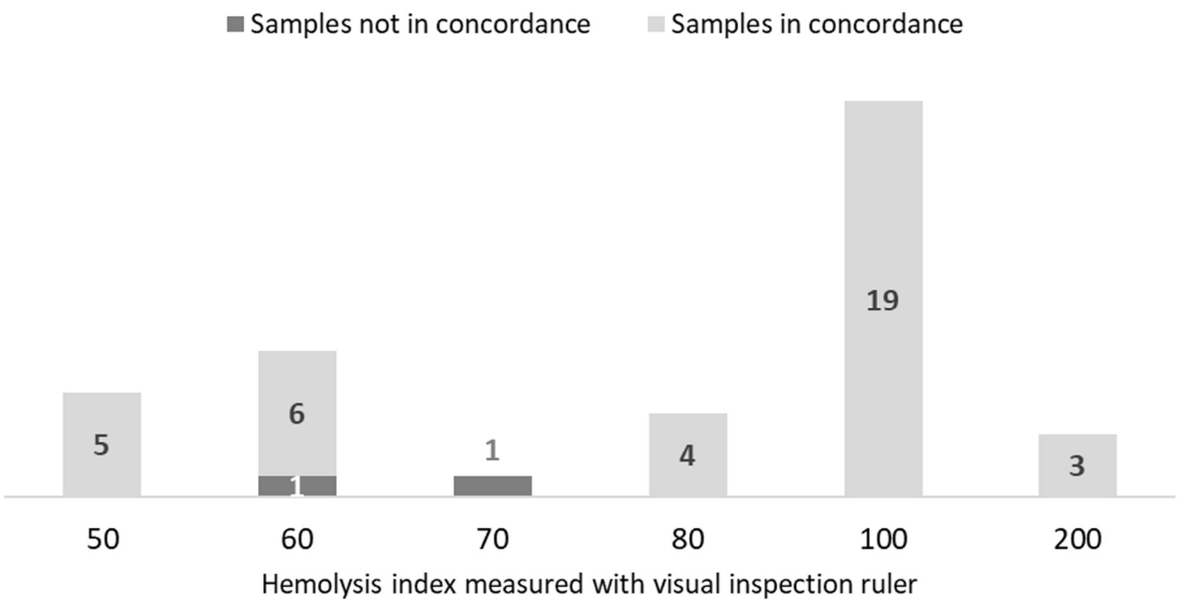
Regarding the comparison of hemolysis index estimated between using the rule of visual inspection and the device, they were considered convergent when both measures were below the threshold to reject the sample or when both measures were above the threshold. Thus, the convergent results induced the same decision of rejecting or dispatching the sample, even though the numeric value of the hemolysis index differed between the two methods. Therefore, it was considered a divergence if the results induced a different decision. One of the estimative of the hemolysis indexes was below the threshold, and the other one was above. The charts in Figure 21 and Figure 22 show the concordance of hemolysis index measured using the ruler of visual inspection and the device, performed respectively at the hospital and common laboratory units.

Figure 21 – Comparison of hemolysis index measurements by ruler and the Hemolysis Detector device at hospital laboratory unit



Source: Elaborated by the author from project documentation (Indigo Labs, 2019)

Figure 22 – Comparison of hemolysis index measurements by ruler and the Hemolysis Detector device at common laboratory unit



Source: Elaborated by the author from project documentation (Indigo Labs, 2019)

After the tests, it can be concluded that detecting hemolyzed samples in using the device and performing the procedure of aliquoting blood samples may reduce the occurrences of calling the patient for new blood collection. At the common laboratory unit, in 30 cases, the original blood sample should be rejected. However, in half of them, the new collection was avoided by replacing the original tube. This result positively impacted the operation, contributing to reduce the sample rejection rate and providing a frictionless experience to the patients that avoided being called for a new collection.

Considering the comparison between the ruler of visual inspection and the Hemolysis Detector performance, they converged in most cases, especially on evaluating high-level hemolyzed samples. However, it can also be stated that convergence level varies according to laboratory unit, which suggests that there may be differences in the analysis according to the technician and the specific.

Those results and conclusions were presented to the laboratory leaders of clinical analysis and R&D management. Unfortunately, despite the reduction of the rejection rate, those results were not yet sufficiently convincing to justify investments to order new units of the device. However, the laboratory personnel kept willing to support the intellectual property analysis and the project submission to FAPESP.

2) Intellectual property analysis

The laboratory's R&D sector hired a specialized law firm to guide the process of analyzing and submitting the claim for intellectual property. Thus, the lawyers supported by the laboratory and development teams conducted the search for prior patents related to the theme of the solution. They concluded that there was freedom to explore the technology in Brazilian territory and that there was room to submit a patent application to protect both the method of analysis and the device. Then, the patent draft was also carried out collaboratively between lawyers, the development team, the university IP Office and the laboratory. With the final version of the draft, the law firm submitted a patent request at Brazil’s National Institute of Industrial Property (INPI). Until the moment of writing this dissertation, the request was awaiting the Institute analysis.

3) FAPESP project

The purpose of submitting the research project to the PIPE FAPESP program was to raise funds to evolve the solution to have greater commercial potential. With such resources, the development team would set up a company in charge of the evolution and commercialization of the product. However, it is worth remarking that FAPESP finances only expenses related to research and development. Other activities necessary to keep the business running are in charge of the company.

To identify how the new version of the solution could most significantly impact the laboratory activities, the development team visited the analytical center and interviewed laboratories employees to learn more about the operation and create a broader view of how the blood screening related to other laboratory processes. After the visit, two main issues were taken to evolve the solution. The first was to obtain greater precision and reliability in the hemolytic index measurements, reducing the influence of external factors in the sample analysis, such as external lighting, presence of different types of labels over the tube, variations in the proportion of the blood phases. The second was to enhance the scope of analysis to include evaluating other interferents that may make blood tests unfeasible and can be assessed by color analysis. Such interferents are icterus, associated with the presence of bilirubin in the blood, and lipemia, related to the presence of triglycerides (DIAGNOSTICS, 2007). Thus, it was intended to have a solution that would impact a larger number of blood samples during laboratory operation with a more accurate and broader scope analysis with those two working fronts. Based on such assumptions, the objective set for the research project was to explore how the technologies based on optical phenomena and image analysis could be used to improve the blood samples assessment in the pre-analytical phase of laboratory tests. The research project proposal was written by the development team supported by the university professor as an associate researcher, who composed the team of project researchers.

The proposal was submitted to FAPESP in April 2018, and four months later, the evaluation of the proposal made by FAPESP assessors was received. Then, the development team was invited to attend an in-person interview with FAPESP assessors, who requested some adjustments to the proposal to provide further details about the technical activities and experiment design to evaluate the solution. In addition, the assessors also asked for including a clinical analysis specialist in the research team and the signing of an intellectual property agreement with Diagnosis Laboratory Group. With these directions, the development team updated the scope of the research project and contacted the Diagnosis Laboratory Group to inform them about FAPESP's requests. Then, the Diagnosis Laboratory Group indicated two clinical analysis managers, who accepted the invitation to compose the team of researchers. The intellectual property agreement with the Diagnosis Laboratory Group was signed. After meeting all the requests of the advisors, the proposal was approved by the research support agency.

Then, the team members founded the Indigo Labs company to receive the resources from the foundation, and the project activities started in January 2019. Two months later, the team applied for and was selected to participate in the tenth class of the entrepreneurship training program offered by FAPESP - called PIPE Entrepreneur. The program's goal was to support entrepreneurs in validating and refining their business model based on in-field feedback of potential customers. To this end, the program follows the guidelines of the I-Corps Program, created by the National Science Foundation (NSF) of the United States in partnership with Professor Steve Blank, to boost the economic and social benefits of projects financed by FAPESP (FAPESP, 2020).

During the nine months of PIPE Entrepreneur, the participant teams were instructed to conduct 100 interviews with people who worked in markets related to the solution context. Each team had an exclusive mentor and attended classes about business model validation with the program instructors to support this process. Although the team initially intended to operate in the market of a clinical analysis offering solutions to laboratories, the mentors and instructors suggested exploring new potential market segments, getting in touch with people working in the veterinary clinics, medical clinics, and blood centers.

To find a relevant number of potential interviewees, the mentors and instructors have indicated the first people to contact, and then the team learned to reach people outside of its network asking contacts from interviewees and performing cold calls. In addition, the FAPESP offered financial assistance up to R $ 10,000 to cover transportation and daily expenses to support interviews out of São Paulo. Thus, the team could expand the number of people they could reach, and through the nine weeks of the program, the team interviewed 81 people from 29 institutions in 7 cities.

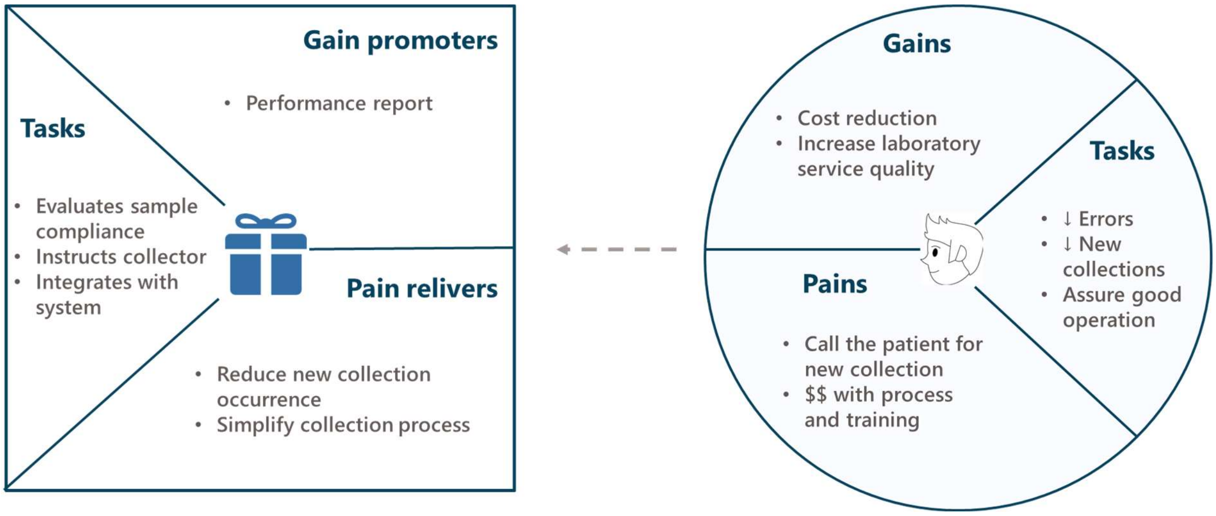
As stated in the document presented by the team at the end of PIPE Entrepreneur training, at the beginning of the program, the main question related to the business model validation were: (i) whether the problem of hemolysis detection was relevant for other laboratories, (ii) whether other market segments could be served by the developed technology and (iii) if there were other problems in clinical analysis market the team could attend to increase the solution added value. Therefore, the lessons learned from interviews were organized in two phases: the first with a broader understanding of the market segments and the second with a specific focus on the segment of interest. This process allowed the team to refine the solution value proposition by mapping the interests of market stakeholders.

In the first phase, the team understood that the clinical analysis market was composed of three main types of institutions: end-to-end laboratories (which collect and analyze the samples), collection centers (which only perform the collection), and support laboratories (which only perform the analysis). In addition, the team also found that hospitals, blood banks, genetic analysis laboratories, and veterinary clinics also handled blood samples and could benefit from the solution. However, the people who most appreciate the solution's value proposition were those who worked with the collection of blood samples from human beings on a large scale. So, the team decided to focus on end-to-end laboratories and collection centers of medium and big size, which are the major players responsible for collecting blood samples.

In the second phase, the team discovered that the operations managers of such institutions were the most relevant stakeholder to influence the adoption of solutions like the proposed device. The laboratory technicians that are the potential users had a deep understanding of the details of laboratory operation and described the problems and the challenges they faced in the blood collection routine. However, they had very little autonomy to influence the laboratory process and acquire new equipment. The team also interviewed few directors of the laboratories, which were responsible for approving the budget for purchasing new equipment for the laboratory; hence, they would directly influence the solution adoption. However, the upper-level managers do not deal with the detail necessary to assess the benefit of the solution, and they directed the Indigo team to talk to the operations managers. In this context, the middle manager knew the operation details and could assess the value proposition of the proposed solution and influence the directors in purchasing and investment decisions. Therefore, the operation managers were considered as the central persona for the business model validation.

Thus, to represent the persona, the team explored the main subjective aspects of the operation manager by portraying his main objectives, concerns, and activities related to the solution context. He/she is primarily responsible for ensuring the quality of the operation, seeking to reduce errors and provide reliable and quick test results. Therefore, its main objectives were to assure the quality of laboratory services at the lowest possible cost. Specifically, regarding the rejection of blood samples by hemolysis, this was a problem for the manager because when a sample is rejected, it is necessary to call the patient for a new collection, and it may cause friction in the customer experience and harm the perception of quality associated with the laboratory image. Finally, to reduce sample rejections, the main initiative of the managers was investing in training to improve the quality of the collection. In this context, the value proposition canvas of Figure 23 was used to represent the operations manager's point of view about the solution, highlighting the main features of the device to increase his perception of gains and relieve his pains.

Figure 23 – Value proposition canvas



Source: Elaborated by the author from project documentation (Indigo Labs, 2019)

At the end of the PIPE Entrepreneur training, the team decided to continue working on the solution and adjusting the scope to increase its perceived value. Thus, it was intended to enlarge the range of analysis evaluating other factors besides hemolysis and improve the traceability of samples, capturing information during the collection and integrating with the laboratory systems. With such adjustments, the Indigo team moves forward in negotiations with two laboratories sending commercial proposals for pilots.

In the first laboratory, the manager approved the proposal's scope but demanded the exclusive use of the solution. As the team did not accept this clause, no deal was held. In the second negotiation, the manager agreed with the terms of the proposal and received approval from the technical director to continue the contract. The proposal was sent for commercial and legal analysis, but due to long delays in communicating with the laboratory personnel, the pilot was not hired. The delays lasted more than five months. According to the development team, the delay and lack of interest in communication would indicate that the solution had low priority for the laboratory operation. Finally, the team concluded the activities of the research project of FAPESP, and facing the low commercial prospects, decided not to proceed with the development and commercialization of the solution.

The final report of the research project was sent to FAPESP in January 2020. The FAPESP ad hoc technical assessors indicated in the report evaluation that the research project was well executed and understood the team's arguments not to continue the research. Then, the team's decision was communicated to the Diagnosis Laboratory Group managers, justifying the team did not have sufficient working capital to keep the expenses of a nascent company and conduct further development activities. Nonetheless, the developed technology can still be a compelling solution to increase the portfolio of established companies.

5.3.2.2. Within Case Analysis

The within-case analysis explores how the principles of Design Thinking were applied in the innovation project and relates how the approach impacted the project outcomes in terms of capturing and creating value.

<u>Principles of Design Thinking Application</u>

The case analysis investigates how each Design Thinking principle was used throughout the development process based on the narrative of the case description.

i. <u>Creativity and innovation</u>

   Creativity was remarkably important was in the prototyping process. In the first prototype round, at the concept generation stage, the team uses their creativity to explore different working principles, draw inspiration from existing solutions, and combine elements to build a prototype to demonstrate how the new solution should work. In the second prototype round, to meet requirements from laboratory professionals, the team used its creativity to design and elaborate a portable, autonomous, and user-friendly device. However, not all requirements were achieved based on sheer creativity. For example, to meet the performance requirements, the team had a more analytical approach to choose the most suitable type of algorithm and identify the factors that reduced the precision and reliability of the sample analysis.

Beyond the context of prototyping, another situation that required the team's creativity was to carry out the number of interviews demanded by the instructors of the PIPE Entrepreneur program. As the whole team network provided access only to a small portion of interviewees, the team had to be creative to contact unknown people, attract their interest and convince them to spend their time in an interview.

ii. User centeredness and involvement

In the first stages, from needs finding to concept validation, there was constant interaction between the development team and clinical analysis professionals from the Diagnosis Laboratory Group. Their contributions provided a deep understanding of the problem context with a robust technical and operational perspective that guided the decisions throughout the development process. In addition, combining such perspective with the technological capabilities of the development team, the second version of the solution had a pretty good performance, so it could be used and tested within laboratory operation.

Nevertheless, throughout interviews of the PIPE Entrepreneur training, it became evident for the team that other stakeholders, in addition to laboratory operation staff, were relevant to influence product adoption. Thus, the needs and desires of those stakeholders impacted both solution and business model design. In this context, besides the users-centeredness, the interaction with potential buyers was also relevant to guide the solution design.

The device users were the laboratory technicians, but they had very little influence on the choice of equipment and resources used in operation. After several interviews, the operation manager was identified as the most relevant stakeholder for product acquisition. Thus, the solution should meet not only the expectations of technicians but also of managers. In this context, having access to more managers from other laboratories and reviewing the value proposition, the development team got the opportunity to send two commercial proposals to potential buyers. However, it is worth remarking that, despite all the support and interaction with Diagnosis Laboratory Group, the team did not send this kind of proposal.

Finally, one more insight that emerges from the interviews was that user-centeredness, when possible, should consider users from different institutions and contexts. Otherwise, it is risky to get a biased point of view restricted to a specific perspective, and then the designed solution may not meet the needs of other users out of the considered context. Taking multiple user perspectives is especially important if the commercial strategy aims to sell the solution not only for a specific public or organization. For example, in the Hemolysis Detector design, until the validation stage, the team focused exclusively on the context of the partner Diagnosis Laboratory Group. This focus was valuable to get closer to the laboratory staff and to develop a solution to meet the presented demands. However, in the concept development stage, a startup was funded to carry on the product evolution and commercialization. Unfortunately, selling the solution to one single laboratory would not be enough to keep the startup operation. Then, the team needed to explore ways to find customers from more laboratories. Interviewing laboratories representatives during the PIPE Entrepreneur program, the team stated that hemolysis detection was a matter in almost all laboratories, but considering the strategy and context of different laboratories, their managers had other interests and priorities. Thus, the solution and value proposition had to be redesigned to attract the interest of more potential buyers. After the concept validation stage, the redesign of the solution did not mean that the validation was mistaken or improperly performed. Indeed, it reinforces that the validation is context-dependent. As the validation took place within a narrow context, focused on one laboratory, the design process resulted in a valid solution only to that context.

iii. <u>Problem solving</u>

The problems faced throughout the solution development had different characteristics and natures. Thus, the problem-solving approach was chosen according to the kind of problem and the question to be answered. The three following situations exemplify the problem-solving approach fitting to the problem context. First, in concept generation and concept validation stages, the team tried to answer the question “how to improve the hemolysis detection process?”. The solution was built iteratively using prototyping and gathering users’ feedbacks. The solution conception by unfolding events emphasizes the abduct aspect from the design process. Next, to answer the questions of “how accurate was the analysis method?” and “how did the solution impact the operation?” two studies were planned and carried out with the support of laboratory personnel. In the first study, real blood samples had their hemolysis index evaluated for both Hemolysis Detector and Cobas, and then those measures were confronted. In the second study, the impact of the proposed solution in reducing the sample rejection rate was assessed by a pilot test in two laboratories units. Both studies followed the analytical logic to answer the mentioned questions. The studies were previously designed, and their execution should follow the plan to provide conclusive data analysis. Otherwise, if the study execution changed according to unfolding events and intermediate results, the final data would not be comparable and conclusive.

The third example concerns the search to validate the business model assumptions motivated by PIPE Entrepreneur instructors. In this context, the team members tried to answer three questions: “is the hemolysis detection a relevant problem for laboratories in general?”; “is there another market segment that might be interested in the solution?”; and “is there any other problem in laboratories more relevant than hemolysis detection addressable by team’s technology and capabilities?” Although the business model was not objectively validated, as there were no sales and value capture, the interviewing process helped identify the lack of willingness to pay from operation managers to improve the hemolysis detection process in their laboratories. The interviews also helped the team to get a broader understanding of potential market segments and discard the segments with very little or no interest in the solution. The interviews process also had an abductive approach as the feedbacks obtained in an interview changed the team’s perspective, which refined the value proposition to arouse greater interest in the next interviewees. Following this approach, the team got the opportunity to send two commercial proposals to laboratory managers. With this regard, assessing commercial interest early, gathering feedback through direct interaction with potential buyers can lead to solutions with higher commercial potential.

iv. Iteration and experimentation

The solution design was based on prototyping cycles guided by users' feedbacks. The iteration and experimentation in the solution design occurred relatively effectively and quickly. The second prototype round resulted in a device able to be used for more than four months within the laboratory operation. However, the studies to evaluate the accuracy and benefits from the Hemolysis Detector did not have the iterative aspect typical of the design process. Instead, they were conducted following a straightforward and analytical approach.

The iteration and experimentation principle also appeared during the interviews process, as the value proposition evolved as the team got feedback from people working in the clinical analysis market.

Both processes of prototyping and interviewing allowed the team to improve the solution design and value proposition iteratively. The first was more focused on users and technical aspects, while the second focused on potential buyers and assessed their interest in the solution. As the solution has to meet expectations from users and buyers, balancing the feedback from both stakeholders may be a way to leverage the outcomes of Design Thinking.

v. Interdisciplinary collaboration

Multidisciplinary collaboration was essential throughout the whole project. The knowledge about the context and problem initially came from the laboratory personnel, and the design approach and technical expertise to create solutions came from the development team. The merge of knowledge held since in the early stages of needs finding and concept generation to shape the problem-solution fit was carried out until the last activities in the concept development stage with the support of FAPESP.

Furthermore, the collaboration with laboratory professionals deserves a special mention as they actively engaged in the project activities providing several key resources and advances. Among their contributions it can be highlighted: they facilitated the access to laboratory facilities, allowing the development to observe and interview the laboratory workers; they continuously provided feedback to improve the solution design; they supported the research project submission to FAPESP, both in terms of clinical analysis knowledge and institutional support; they led the process of intellectual property analysis and patent application; they supported the experiments to assess the device performance, allocating resources and providing samples of real patients to enable studies accomplishment.

The involvement between development and laboratory teams was also valuable to plan and detail the scope of the research project sent to FAPESP. The blend of those visions and knowledge led to elaborating a research plan to advance the state of the art of clinical analysis operation, exploring how image processing and photometric techniques could enhance sample screening methods.

In addition, through the interviews of PIPE Entrepreneur, it became evident that if the team wondered about getting market value by selling the new solution, it would be mandatory to have people with commercial capabilities in the group. Therefore, the interdisciplinary collaboration should also embrace the business and commercial disciplines to boost the value proposition and solution's main features to hone a more attractive offering to potential buyers, improving the commercial potential of the solution.

vi. Ability to visualize

The visual supports were used in different situations to improve communication and facilitate interaction with stakeholders and the team. Some visual supports used by the development team, identified in project documentation, were: prototypes to facilitate the demonstration of concepts and to get more reliable feedback from users; draws and sketches in brainstorming sessions; presentations and reports to university professors and laboratory managers about the results and main topics of development activities; figures and graphs in the research project submitted to FAPESP to describe what was done and highlight the main achievements; presentation to introduce the team to interviewees during PIPE Entrepreneur; the final presentation to show the results of interviews at the end of PIPE Entrepreneur program. The visual tools were elaborated according to the context and the audience faced by the team.

So, making good visual tools may have facilitated the team to achieve its goals when interacting with stakeholders. Along the project, the team became more capable of clearly expressing its intentions and spotting what draws the stakeholders' attention.

vii. Gestalt view

The search for a broad and holistic view involving multiple perspectives occurred through all the stages of the innovation process. The view became more extensive and complex as the team acquired and accumulated knowledge from different sources of information. In the report at the end of the concept generation stage, the team had a specific understanding of blood sample screening from the perspective form the analytic center of the laboratory. Next, in the device performance evaluation study, the team went deeper into details of the hemolysis index measurement, assessing the accuracy of the Hemolysis Detector compared to gold-standard equipment. Then, in the study to evaluate the benefits of the device to operations, the team explored the laboratory operation more broadly, indicating how the solution could reduce the rate of new blood collection, which was a major quality indicator of the laboratory. Then, both in the paper published in the Journal of Medical devices and in the project submitted to FAPESP, the presented arguments brought information from secondary sources, preferably published in academic journals, which reinforced the relevance of the problem among other institutions. Finally, in the presentation at the end of PIPE Entrepreneur, the team enhanced their understanding with market information acquired through primary sources, that is, interviewing people related to the clinical analysis environment.

viii. Abductive reasoning

As mentioned in the problem-solving topic, the reasoning and methods choice varied according to the problem nature and context. However, two occasions favored the use of abductive reasoning: (i) the solution conception and design, oriented through user interaction and prototypes; (ii) value proposition evolution, throughout the interviews in the PIPE Entrepreneur program, involving various people from the clinical analysis market. Analogously the way the prototypes evolved from interacting with users to provide the desired value, the value proposition also got refined from the contact with potential buyers, who indicated what most aroused their interest.

ix. Tolerance of ambiguity and failure

The tolerance of ambiguity and failure was important among the team members and in the representatives of the institutions that supported the project. The laboratory personnel understood that the solution needed to evolve gradually, and they kept their support even though the intermediate results of the Design Thinking approach were not extraordinary. In addition, tolerance to failure was also demonstrated by FAPESP, which financed part of the project's activities. At the end of the PIPE Entrepreneur training, the instructors advised the teams not to proceed with their project if they found evidence that there was no market interested in the solution. Finally, the foundation advisors praised the project execution, despite the team's decision not to continue developing the solution.

x. Blending rationality and intuition

As discussed in the problem-solving and abductive reasoning topics, the blend of rationality and intuition occurs in distinct moments of the project. Thus, when facing certain types of problems, it was preferable to use analytical methods and reasoning. Meanwhile, on other occasions, it was preferable to opt for a more abductive approach.

Outcomes – Value Creation and Value Capture

Considering the solution scope, the use value was created when the laboratory team started using the Hemolysis Detector in blood sample screening and took benefits in terms of quality, reliability, reducing the rate of sample rejection and new collections. In this context, the use value is only perceived if the laboratory gains operational efficiency, which depends on the new solution's performance and accuracy and on adapting the sample screening process to consider the proposed device measurements in decision-making. Thus, even though failures and mistakes are part of the Design Thinking approach, the use value creation only occurs when the new solution has a minimum performance and works correctly. In this regard, the individual application of each Design Thinking principle did not create value by itself. Instead, the value creation happened when the principles were combined and coordinately performed, leading to a solution with minimum performance and properly used by the laboratory technicians.

The Design Thinking principles were very useful to discover how to create value. During the visits and interactions with laboratory personnel, the development team figured out the pain points related to hemolysis detection and sample rejection. Then with the first prototype, they identified the features and characteristics of the solution the laboratory team most enjoyed. Such interactions directed the development of the second version of the solution, which achieved robustness and reliability enough to be used in laboratory activities. In addition, the technological knowledge underlying the solution was the matter of an international journal publication. In this approach, the user-centeredness combined with iteration and experimentation showed where the development team had to put their efforts to evolve the solution to create use value and improve the hemolysis detection practice.

Interdisciplinary collaboration was also an outstanding principle in the path to value creation. The development team was composed of members with complementary backgrounds. In such a way, people from design, software development, mechatronic engineering, and electrical engineering worked on the project. Those competencies gathered knowledge to create a technologically robust solution, as Lopes *et al*. (2019) described. However, there was a lack of clinical analysis and laboratory operation knowledge in the team, and to close this gap, collaborative work with laboratory professionals was essential. Such collaboration enabled to perform the development activities better. For example, using hundreds of real samples to test and train the algorithm of hemolysis index evaluation was only feasible because development and laboratory teams were working together.

On the other hand, the need to explore how to convert the value created into market value did not arise from the users but from the development team's need. When the team funded a startup to carry out the concept development stage, they needed the revenue of products and services they offered to maintain their activities. The resources from FAPESP supported the beginning of startup activities related to research and development expenses, but, as soon as possible, the team would have to capture value from the market either to apply for a new funding stage or to operate the startup independently.

The activities to explore value capture were held more intensely after the participation at the PIPE entrepreneur program when the program instructors provoked the development team to validate the business model assumptions by interviewing people from potential market segments. The direct contact with those people contributed to a more reliable perspective of the team's capability to capture value with the solution. In the project proposal submitted to FAPESP, the arguments were primarily based on secondary sources of information published in academic journals. For example, by the study of Howanitz *et al*. (2015), it was identified that about 95% of laboratories had problems with blood sample rejections due to high levels of hemolysis, with almost half of those laboratories used only methods based on visual inspection in blood sample screening. By these data, it is possible to infer that the solution would have a high potential of adoption in laboratories since the hemolysis detection unproperly performed harms most laboratories' operation. However, interviewing people from the clinical analysis market, which are primary sources of information, the team found that although the rejection of hemolyzed blood samples occurred in all laboratories from interviewees, this matter was not necessarily a priority of managers to make investments. Thus, the secondary sources of information can be considered to estimate the maximum value the team ideally might capture. In contrast, the primary sources provided a more reliable perspective of the team's capability to capture value from the market.

Another relevant aspect of the value capture initiatives was that the value proposition could be improved by interacting with people from the clinical analysis market in a similar and complementary way to the user-centeredness approach. For example, in the Hemolysis Detector project, the solution was initially conceived and designed within the context of the specific Diagnosis Laboratory Group units. However, after conducting more than 80 interviews, the team stated that managers from other laboratories had no interest in paying for the solution as it was conceived. Thus, based on interviewees' feedback, the team revised the value proposition and some features of the solution, and they could advance in negations and sent commercial proposals to two laboratories. The adjustments in the solution were discussed and agreed upon in reunions without having a physical or functional version of the new solution version. The team would effectively implement the updates on the product only if the proposal were accepted. Therefore, it can be remarked that issues related to value capture (that are important to shape solution and value proposition) can be explored without having a final product or a ready-to-use solution. Thus, one way to possibly improve the Design Thinking approach to avoid the risk of developing a solution with little potential of capturing value is to incorporate initiatives related to value capture through the development stages, from the needs finding to concept development.

Finally, the interview process suggested the value capture depends on the team's capabilities, resources, and networking. As the number of required interviews was considerably high, the team was forced to seek contact beyond their network. To this end, the team had to attract the attention of unknown people based on the problem and the solution. If the team was unable to access people interested in the value proposition, it could be a risk to business model viability. Because if the team fails to reach potential buyers, they would probably struggle in the future when trying to sell their product and execute their business model.

5.3.3. Case 3 – Remote Cardio

The Remote Cardio project resulted from a partnership between the University of São Paulo and a major private, not-for-profit hospital located in São Paulo, with a strong focus on cardiovascular diseases (Hospital 2). The project aimed to expand the cardiac rehabilitation service to patients out of the Hospital 2 facilities through remote and real-time cardiac monitoring.

Cardiac rehabilitation is the set of activities to ensure a healthier physical condition for patients, in which they perform physical training being monitored and supervised by health care professionals. This program is indicated to recover patients who have undergone invasive cardiovascular procedures and prevent and reduce symptoms in patients at risk of developing coronary heart disease. Cardiac rehabilitation benefits the patients in many ways, such as increasing tolerance to physical exercise, improving lipid profile, providing better psychosocial well-being, reducing stress, and increasing survival. In addition, cardiovascular rehabilitation reduces the rate of hospital readmission and costs per hospitalization (Souza et al., 2000).

However, the cardiovascular rehabilitation services depend on the physical infrastructure of the hospital with the workout equipment, the monitoring systems, and healthcare professionals to supervise the patient. Thus, the patient must displace himself until the hospital to carry out the rehabilitation therapy. In this context, the hospital team wanted to expand the offering of rehabilitation services to patients out of the hospital with the support of real-time and remote ECG monitoring to enable the health care team to supervise patients in outdoor activities. The remote rehabilitation would be a continuation of in-person service for patients who have already shown progress in their health condition but still need supervision and assistance to be completely recovered.

With such background, the project activities started in early 2017 when the hospital team defined the problem to be tackled. After some rounds of development, initiating with a team within the USP Integrated Product Development course and progressing to a dedicated team intending to commercializing the solution, the project activities finished in the first quarter of 2019.

5.3.3.1. Case Description

The project activities and events are described hereafter following the Design Thinking process stages.

Needs Finding

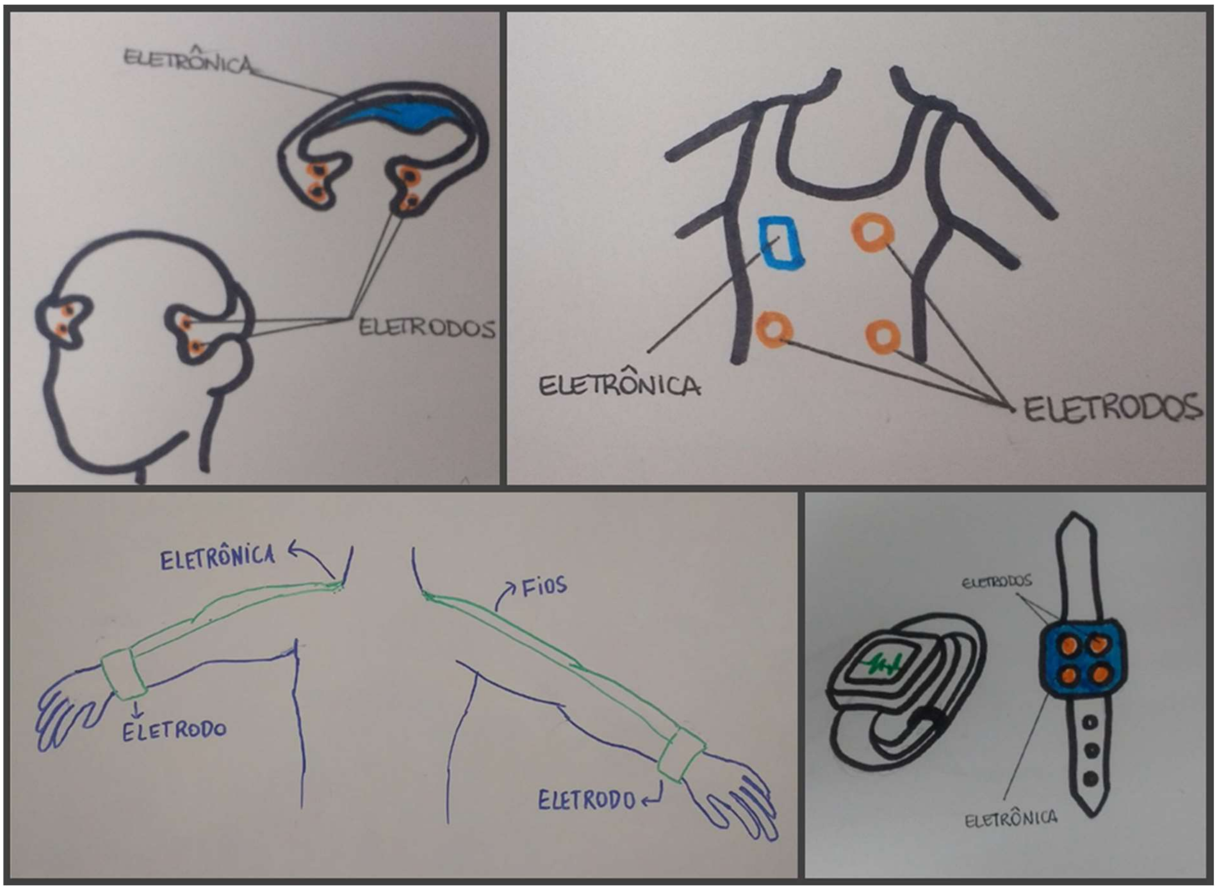
The needs finding process was entirely carried out by Hospital 2 personnel in the first months of 2017. At this time, the hospital had an emerging innovation sector in charge of coordinating the initiatives in the hospital to support the creation of new solutions. Thus, the innovation manager, a part-time physician, supported establishing the partnership between the University of São Paulo and Hospital 2 to collaboratively create solutions through the Integrated Product Development course offered by Inovalab@Poli. The partnership counted with significant involvement of cardiac rehabilitation personnel, composed of nurses, physiotherapists, technicians, and physicians. Facing the opportunity to get new solutions through the partnership with the University, the hospital team mobilized to identify the problems and opportunities in its routine to propose a challenge within the scope of the innovation course. Thus, based on the reported needs and ideas by healthcare professionals, Hospital 2 considered the issue to enhance cardiac rehabilitation through remote monitoring the most promising opportunity to innovate and brought this topic to be addressed along with the University.

Concept Generation

Within the university innovation course, the challenge to improve cardiac rehabilitation was tackled by a multidisciplinary team of students with design, engineering, and computer programming background. First, to get immersed into the problem context, the team gathered information about the electrocardiogram (ECG) technology, the conditions of cardiovascular diseases, and the solutions existent in the market for measuring ECG. Next, to complement learnings from public information, the team members visited the cardiac rehabilitation facilities at Hospital 2 and interviewed healthcare professionals and patients. The contact with the healthcare professionals allowed the team to identify the main requirements about patient safety, electrodes asepsis, and ECG monitoring. The students could also learn about the limitations of ECG technology used at the hospital. In addition, by interacting with the patients, the team could get some feedback about the usability of ECG monitoring devices. The patients especially complained about the discomfort of using many wires and big devices during the exercise. Finally, the visit and the interviews provided insights to outline the persona they would design for.

After getting emersed in the problem, the team started working on the solution and decided to build a wearable system to get the ECG signal connected to the patient's mobile phone to transmit the vital sign via the internet. The main requirement of the solution was: be portable, be comfortable, not restrict movements during exercise, have electrodes well attached to the patient, have good signal filters, have good asepsis, have a user-friendly mobile interface, send information to healthcare professionals, and measure the cardiac frequency. Guided by those requirements and based on learnings from research, benchmarking, and in-field interviews, the team sketched many wearable solutions and then clustered similar models. After refining the models, the team arrived at four possible product architectures represented in Figure 24.

Figure 24 – Wearable systems for ECG monitoring



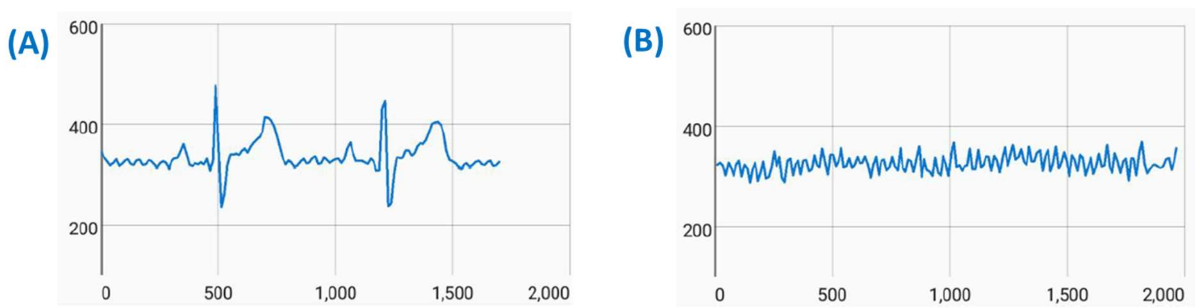
Source: Innovation course report (Domingues et al., 2017a)

From the ideation outcomes, the team organized the prototyping activities on two fronts. The first one was centered on developing the critical function underlying all concepts, which involved structuring and building the flow of the ECG signal, from capturing the patient's cardiac activity to transmitting the data for medical analysis. To this end, the solution was a communication system that connected the wearable device to the patient’s mobile phone via Bluetooth and transmitted the digitalized ECG via the internet from a mobile app to a desktop interface to the healthcare professionals.

The second front of prototyping involved designing and building the wearable device itself. Based on the requirements of being easy to use, comfortable and stable during the exercises, the team chose to capture ECG signals through electrodes placed over the head. Such positioning favored the patient's usability, as there were no wires, and it did not restrict movement during exercises. In addition, it also favored the ECG signal acquisition as the electrodes could be stably fixed over the head, and there is little interference from head muscles activity during physical exercise.

The prototyping evaluation also took place in two moments, the first to assess the quality of the ECG signal and the second to get feedback from patients regarding usability issues. In the signal assessment, it was found that the ECG tracing was too far from the expected. The ECG tracing obtained with the electrodes on the head, shown in Figure 25, had low amplitude and whose morphology did not allow the evaluation of the cardiac activity. On the other hand, the usability was very positively assessed by patients. The team visited the hospital one more time and asked the patients to use a wearable mockup while performing some physical exercises. The patients reported that the shape of the new device did not bounce on their heads, was light, comfortable, practical to use, and could use it at home or on the street if it would have a neutral color.

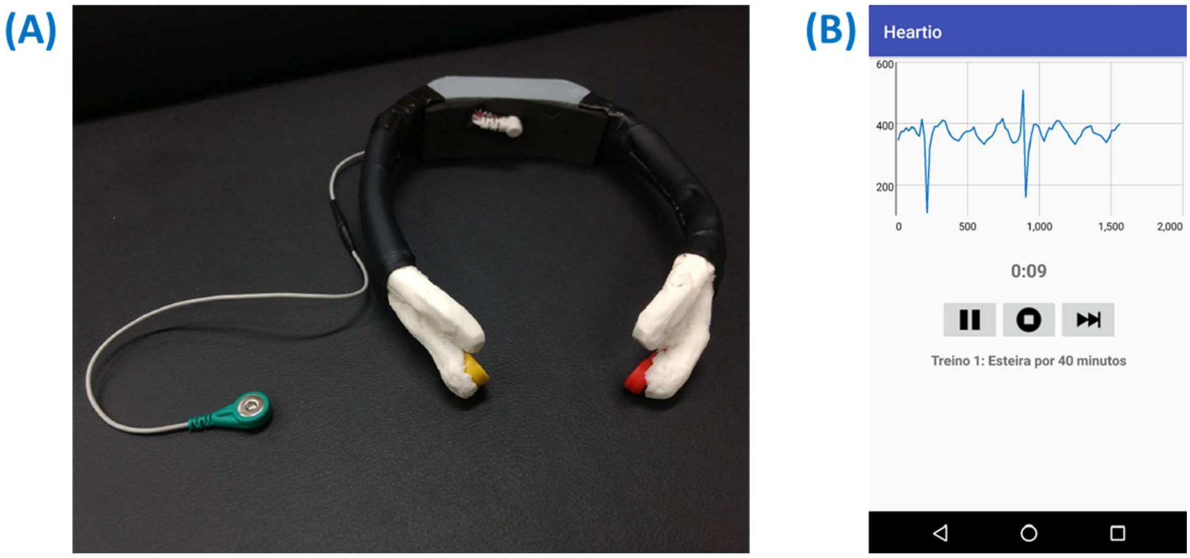
Figure 25 – (A) Usual ECG waveform (B); ECG waveform with two electrodes on the head



Source: Innovation course report (Domingues et al., 2017b)

Bearing in mind the feedbacks, the team decided to keep the product architecture, placing the wearable device over the patient's head. Still, in the course scope, the team worked on a new wearable version with three electrodes (two on the head and one on the heart) to obtain a signal with greater amplitude and quality. In addition, the team also developed a mobile application integrated with the wearable that displayed in real-time the ECG signal on the mobile screen. The prototype built at the end of the course is shown in Figure 26.

Figure 26 – (A) Wearable with three electrodes; (B) Mobile app receiving ECG signal via Bluetooth



Source: Innovation course report (Domingues et al., 2017b)

The solution was presented to the hospital innovation personnel and the cardiovascular rehabilitation leaders. The prototype was very well appraised by them, who appreciated the solution was already integrated with a mobile environment and had an end-to-end flow of ECG capture and transmission. However, they noted the need to improve the ECG signal quality as it is the basis to support clinical decisions during patient monitoring.

Concept Validation

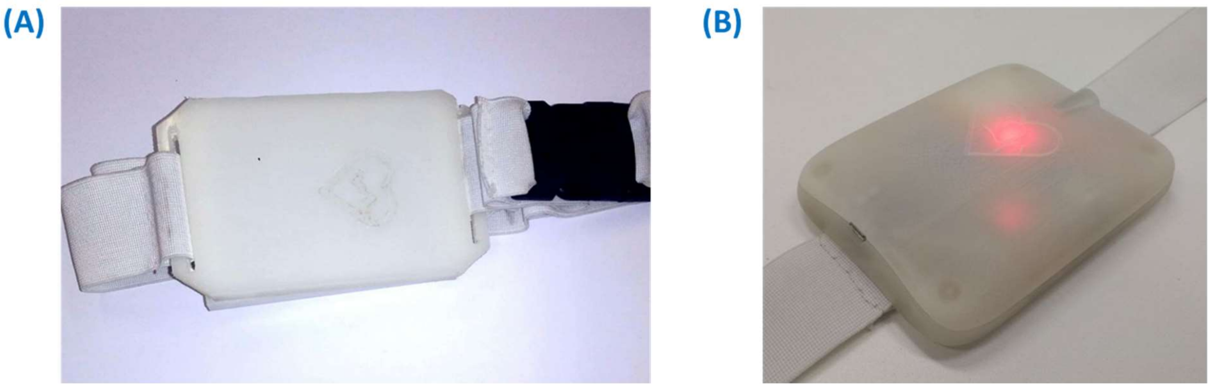
As the leaders of hospital innovation and cardiovascular rehabilitation appreciated the designed solution concept, they were willing to continue supporting the project and accepted a project proposal to improve the solution. The proposal consisted of a four-month project from November 2017 to February 2018 to be carried out in partnership between Hospital 2 and the University. The project team was composed of four undergraduate students who had worked in the original course group. In the middle of the project, the author of this dissertation, at the time graduating in production engineering, was invited to reinforce the team.

The project had five main objectives defined jointly with University and Hospital 2 representatives. The objectives were: (i) review the wearable system to enable the capture of good quality signal in the D2 lead; (ii) review the cell phone communication system and monitoring transmission via the Internet to enable real-time ECG transmission to the web platform; (iii) implement basic algorithms to detect heart rate; (iv) perform tests and present the new solution version to the Hospital team and (v) to outline business model proposals.

Regarding the first goal, the ECG signal is traditionally used in three leads D1, D2 and D3, obtained placing the electrodes on the patient's chest and abdomen - one close to the left shoulder, another close to the right shoulder, and the third on the lower part of the abdomen near the left leg. The need to capture the signal at the D2 lead was an express demand from healthcare professionals who needed to have the ECG signal in a known waveform for the clinical practice. In this context, even though patients preferred to wear the wearable over their heads, this positioning offered an unrecognizable signal to physicians. Thus, the team followed the hospital professionals to make the wearable similar to traditional equipment, such as the Holter monitor.

Throughout the four-month project, two more rounds of prototyping were carried out. Thus, the second version of the monitor gathered all the elements of the final solution. Finally, the third version used more refined components and high-end 3D printing methods to look more like professional equipment. Figure 27 contains the images of those two versions of the wearable.

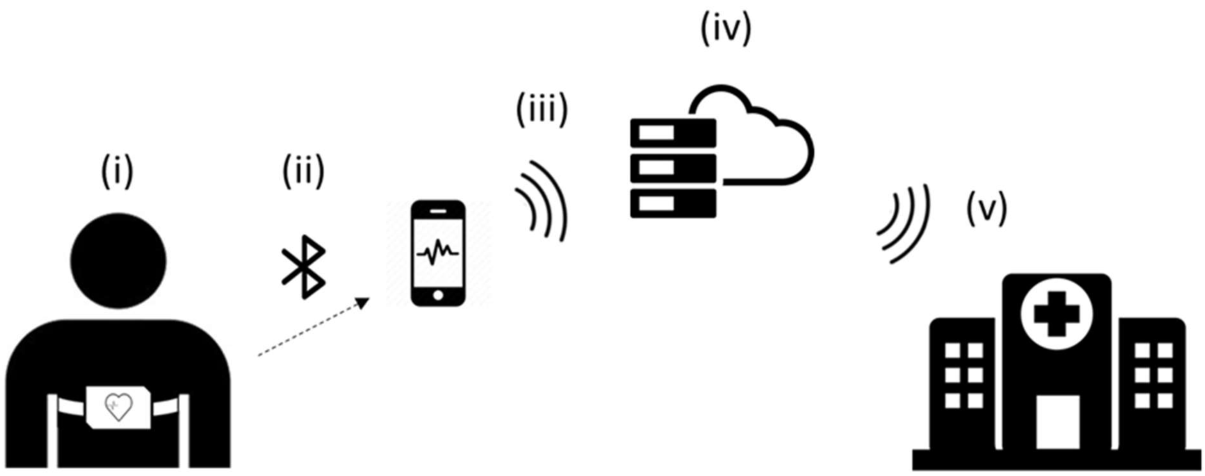
Figure 27 – (A) Second version of ECG capturing wearable; (B) Third version of ECG capturing wearable



Source Collection of projects documentation (Inovalab@Poli, 2017)

To achieve the second objective, related to improving the ECG transmitted to health professionals via the web interface, the team reviewed the entire flow of capture, treatment, and transmission of the ECG signal. Figure 28 represents the implemented flow, that comprised: (i) wearable for capturing the vital sign of the patient; (ii) Bluetooth connection between wearable and patient's mobile phone; (iii) data sent to a web server via the internet; (iv) information storing in a database; (v) real-time ECG trace transmission via the web to health care professionals. Besides reviewing the communication architecture and infrastructure, the team rebuilt the data transmission code using more efficient language for real-time communication. In addition, they applied digital filters to stabilize the signal and implemented data package validation between the wearable and the cell phone and between the cell phone and the server to ensure no loss of information throughout the flow.

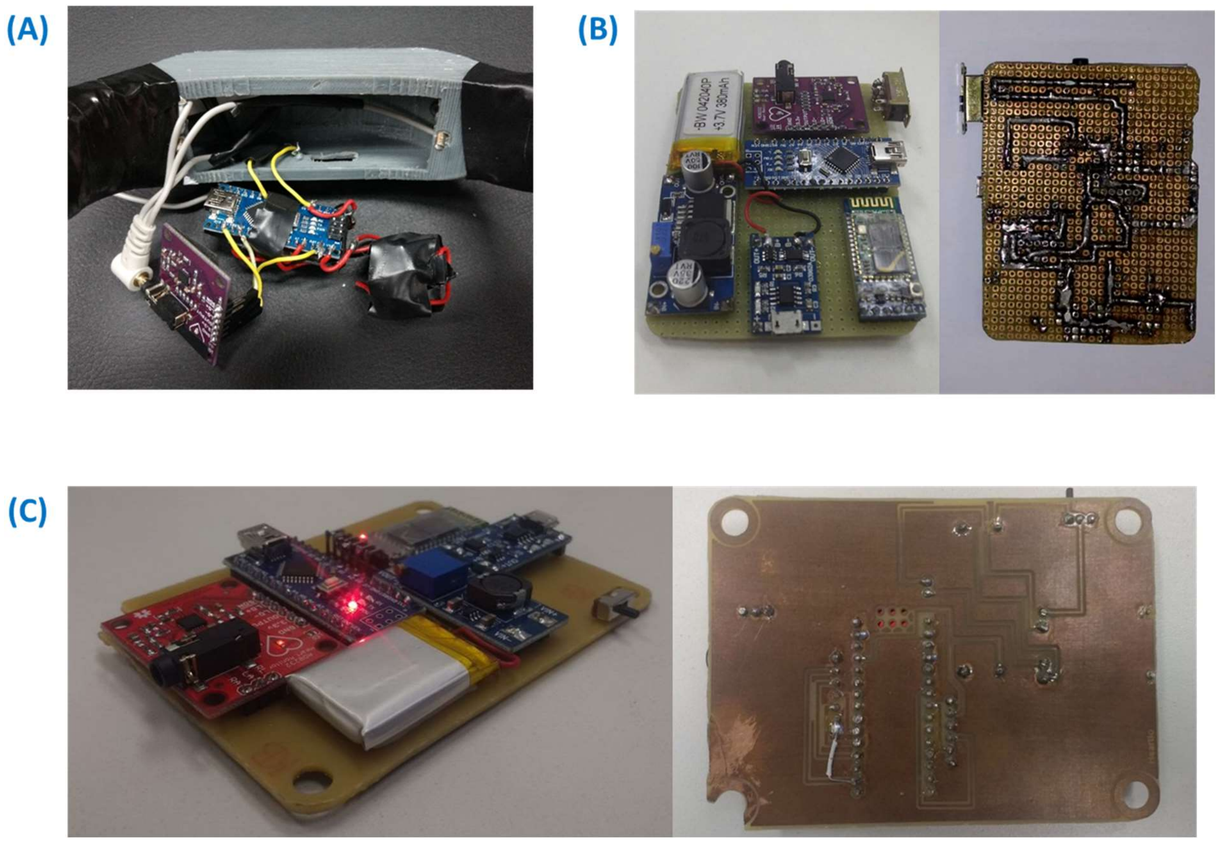
Figure 28 – ECG monitoring flow



Source: Collection of projects documentation (Inovalab@Poli, 2018)

In addition to digital improvements, the team also reviewed the electronic project to get a higher ECG sign acquisition quality. To this end, more robust components and manufacturing methods were used, such as a longer-life and rechargeable battery and printed circuits to connect the components. Figure 29 illustrates the Evolution of electronic parts in the three versions of the wearable.

Figure 29 – (A) Electronics of the Remote Cardio first version, presented at the course; (B) Electronics of the Remote Cardio second version; (C) Electronics of the Remote Cardio third version



Source: Collection of projects documentation (Domingues et al., 2017b; Inovalab@Poli, 2018)

With the improvements of the technological infrastructure, the team could evolve the solution interfaces. From the patient's point of view, if there was a loss of connection between the cell phone and the server, the mobile app tried to restore the connection automatically. If it failed, the user received a notification informing him he was no longer being monitored. In addition, the patient was also notified with messages sent by the health care professionals supervising the patient during the exercises. From the healthcare professionals' point of view, the algorithm to detect the heart rate was implemented to meet the project's third objective. Figure 30 represents the interface for health care professionals displayed in a web browser, containing the patient identification, his heart rate, the ECG trace, and the space to send messages to the patient. Finally, at the end of the monitoring, the professionals could export a PDF report of the last section.

Figure 30 – Web interface for healthcare professionals to supervise patients

Source: Collection of projects documentation (Inovalab@Poli, 2018)

The tests with patients mentioned in the fourth objective of the project were carried out after having built the second version of the monitor. The team went to the hospital and invited the patients to experience the new wearable while performing their exercise routine. Such an approach allowed to identify some improvement points, mainly related to the loss of connection and interference in the ECG signal during physical activity. The team tried to address such pain points in the third version of the solution.

Finally, to address the fifth and final objective, the team drew up three business model propositions for the new solution:

i) Provide remote monitoring services of cardiovascular rehabilitation, in which hospital professionals supervise patients with the new solution.

ii) Offer Holter and looper exams, using an intelligence associated with the device to facilitate the generation of reports.

iii) Offer monitoring technology and support from the hospital's specialized professionals to allow the physiotherapy clinics to offer cardiovascular rehabilitation services. It is an option similar to (i) but places the existing clinics as an intermediary to increase the solution's scalability.

All those topics regarding the project's objectives were presented in a meeting with the hospital innovation team and the cardiovascular rehabilitation leaders. The hospital professionals recognized and praised the progress of the solution and seemed to be motivated to support further activities. However, they also brought feedback about the current version of the monitor, pointing out it was needed to improve the ECG trace with greater details and quality to enable the use of the solution in clinical practice. The filters used to remove noise and stabilize the signal during the exercises also removed a relevant part of the cardiac activity signal. In view of the need for technological improvements, despite having demonstrated an intention to support the project, the hospital members signaled they could not finance further development rounds as it was not compatible with the innovation sector budget. Thus, the hospital professionals agreed to support submitting a research project to raise the resources to enable technological development.

At this point, the Remote Cardio third version can be considered as a validated concept. This validation is based on the approval of the healthcare specialists, who recognize the potential of the solution and validated the functioning of the elements of the product architecture that, with proper refinements, were able to offer the remote monitoring service.

Concept Development

At the end of the previous stage, three of the four members stopped working in the team, and a new member, the author of this work at the time graduating in industrial engineering, was invited to join the group. Then, the next initiative to continue the development was elaborating and submitting a project proposal to the FAPESP PIPE program that supports research in small companies. The development team wrote the project proposal, supported by the University professor and by the hospital professionals. The vision brought from the healthcare specialists directed the project's focus and contributed to the foundation of the proposal. They sent reference articles, reviewed the document, and wrote a letter declaring the hospital's support for the solution development. However, four months after the submission, the funding agency advisors denied the proposal arguing it comprised a low innovation level in the project and that the leading researcher would not have the necessary skills to direct the project.

The team looked for an alternative route to keep advancing to overcome the technological challenges in view of the funding agency's negative response. Thus, another member at his last undergraduate year in Electrical Engineering, who specialized in electronic systems, joined the team to evolve the ECG acquisition project within his graduation thesis. To get support at this stage, the team applied for the Academic Working Capital (AWC) program, financed by Instituto TIM. The program provided financial support and mentoring for teams that intended to rise to new businesses with their graduation work. With the new configuration, the team was approved to participate in the AWC program held from May 2018 to December 2018.

Throughout the program, the team had weekly meetings with the mentors and participated in three in-person workshops. The first four months of the program were focused on getting a deep dive into the problem context, and the teams were pushed to interview as many people as possible related to the problem they would like to solve. From the interview deck, a document in which the team recorded the summary and main insights of the interviews, the team interviewed 43 people in the four months, including healthcare professionals, patients, and other specialists in the healthcare market.

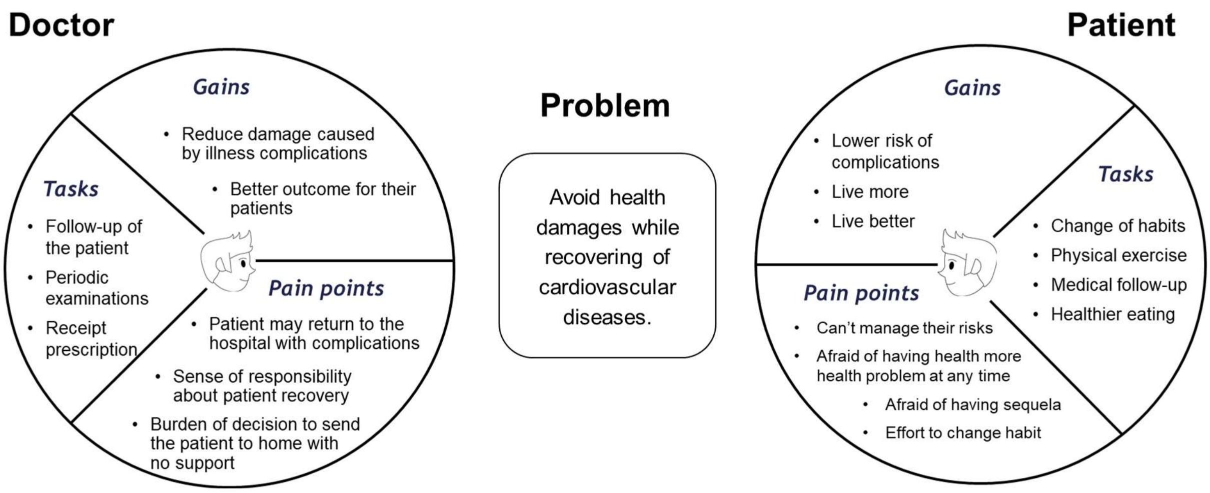
From the interviews with doctors and health professionals, the team had insights related to possible challenges in adopting a new solution by health professionals. For example, the following quote was noted: “any solution in the hospital has to be aligned with the health team routine; otherwise, if they struggle using the solution, they might abandon it”. In addition, the team got insights about the business model by interviewing a cardiology clinic owner, who stated that “the clinic is not interested in buying a cheaper ECG device. Nowadays such equipment costs R$ 5,000 and can be used for 20 years. Entering this fight is not worth it for you". The doctors from the clinic also mentioned they were not interested in monitoring patients by themselves: “Imagine having the alarm of 100 patients beeping on my cell phone. No way." Finally, the doctors also suggested the types of patients that would be more likely to be indicated for remote monitoring, such as patients with multiple complaints, at a moderate to high risk or difficult to diagnose”. In all cases, the doctor said, "the monitoring solution has to stand alone. You must have your assistance service. If it depends on cynical doctors, it is not viable”.

The team could also get more insights by interviewing patients enrolled in cardiac rehabilitation programs. The team observed the public who attended the rehabilitation at Hospital 2, in general, had a high monthly income, and for the elderly patients go to the hospital was a positive moment in their routines. Some insights recorded by the team about the patient’s point of view were “The patients do not like to exercise, but they like to go to rehabilitation sessions to be accompanied”. In addition, the team also registered that “the period the patients have the greatest insecurity and search for solutions is after the trauma", whether it could be a heart attack, surgery, or another relevant cardiac event. In this context, the medical indication was decisive for patient engagement. "The patient only follows the doctor's instructions; the doctor is the main channel to get to the patient". Finally, given that most interviewed patients enjoyed going to the rehabilitation session and felt safe at the hospital, the team wrote down, “it is worth exploring other public or other situations to market the solution”.

In addition to health professionals and patients, the team also interviewed specialists working in the health market, such as one magazine editor and professionals working in different hospitals' innovation sectors. From those interviews, the team recorded insights related to business development: "it is worth negotiating with health insurance companies only after we have the clinical part well addressed and it would be possible to estimate the rate of prevention of cardiac accidents". In addition, an outstanding interview was with a seed money investor of healthcare companies that reported: “one of the main barriers that hinder insertion of new solutions into health market is the lack of credibility of the medical community and the need to change medical protocols”. To overcome those barriers, the investors stated it is necessary to “create an endorsement in the medical community through academic research, participation in events and congresses” and that “the confidence of doctors is built among their peers”. In this context, it is important to have doctors on the team or senior doctors in the medical council to promote the new solution.

After conducting the interviews in the first part of the program, the instructors questioned the team members if they would keep the initial business model or they would pivot based on the evidence found. In the presentation to AWC instructors, the Remote Cardio team decided to keep the concept of remote cardiac monitoring, arguing there were many situations in which monitoring could bring enormous benefits to patients. However, the members mentioned they would like to pivot the initial approach focused only on cardiovascular rehabilitation, as it was a relatively small market. According to their estimates, the city of São Paulo has a pool of demand and offers for this therapy. Nonetheless, only 2,500 patients were being treated for rehabilitation per year in the city. Thus, the team was willing to explore how to offer solutions to patients who have undergone a relevant cardiovascular event, such as heart attack, coronary surgery, or arrhythmia. To represent the opportunity to create a solution to support the recovery of cardiac patients, the team prepared the diagram in Figure 31 to indicate the point of view of the patient and the doctor regarding the addressed problem.

Figure 31 – Doctor and patient's point of view on the Remote Cardio problem

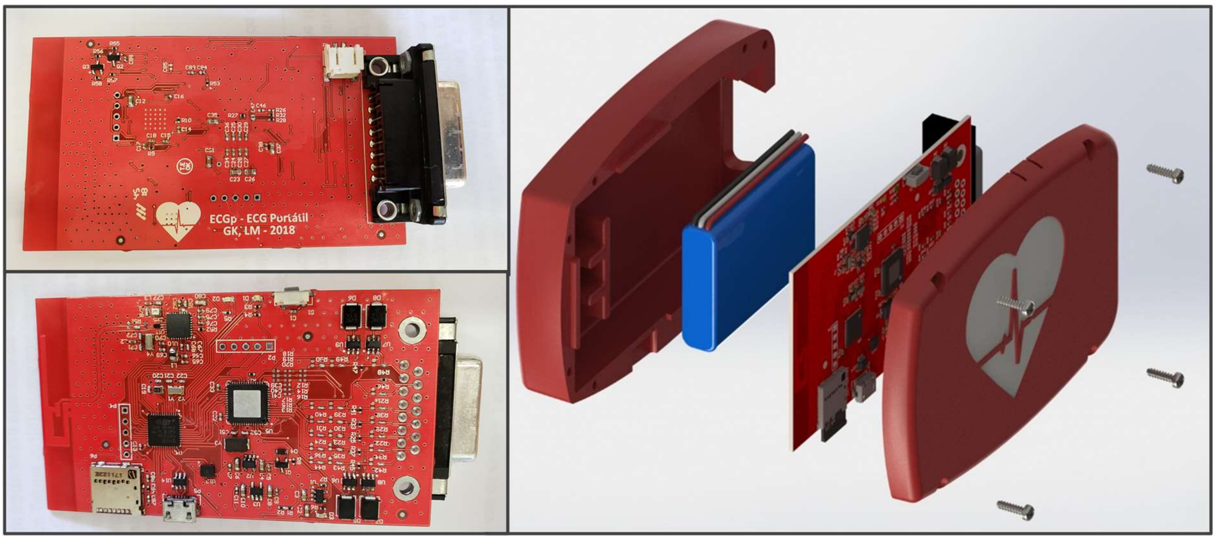


Source: Elaborated by the author from project documentation (Indigo Labs, 2018)

With the new directions, the team relied on the hospital partnership to evolve the solution to explore new possibilities beyond the universe of cardiovascular rehabilitation. In addition, as noted in the interviews, the monitoring solution must have a higher maturity level and gain credibility to be accepted in the medical community. In this context, Hospital 2 support would be relevant to enable the access of first patients and get the endorsement to promote the credibility of the new monitor within the market.

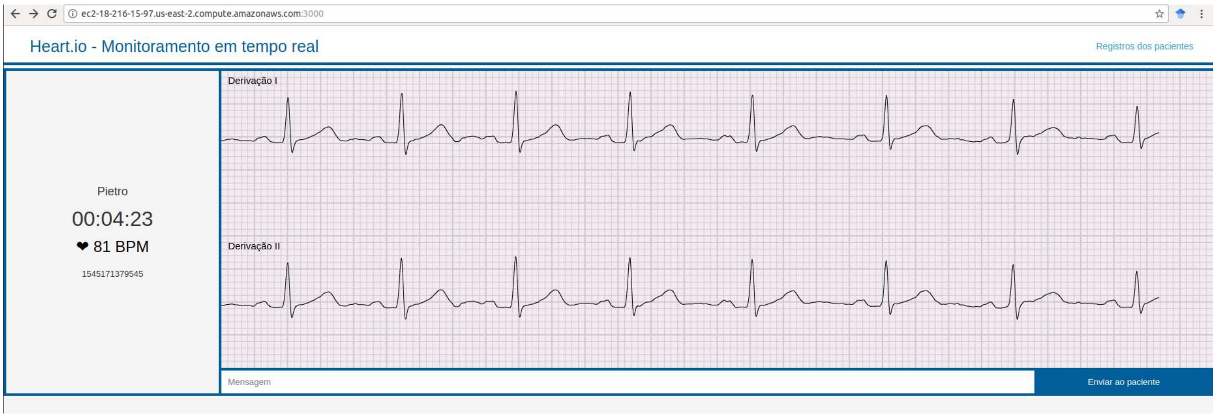
Thus, the team decided to continue technically evolving the solution to obtain a version able to remotely transmit the ECG signal in real-time, with the quality required to assess the patient's condition and support clinical decisions. To this end, the team uses around R$ 10,000 offered by the AWC program to purchase new components and contract manufacturing services to build two units of a new version of the cardiac monitor. The new wearable is represented in Figure 32, and its major improvement comparing to the previous versions was in the electronic project to acquire a higher quality signal of ECG. The whole architecture of the communication system for data transmission remained the same. However, the final interface accessed via a browser was improved so the healthcare professionals could supervise patients, monitoring up to two ECG leads and heart rate in real-time. Figure 33 demonstrates an example of patient monitoring displaying the DI and DII leads and the patient's heart rate in beats per minute.

Figure 32 – Fourth version of the wearable device for ECG monitoring



Source: Elaborated by the author from project documentation (Indigo Labs, 2018)

Figure 33 – ECG waveform obtained with the fourth version of ECG monitoring solution.



Source: Elaborated by the author from project documentation (Indigo Labs, 2018)

After finishing the development of the fourth version, the development team met with the leaders of the innovation and cardiovascular rehabilitation at the Hospital 2 to present the progress achieved and to discuss the possible development of a remote patient monitoring service offered in partnership with the hospital. One of the topics brought by the team was the suggestion to explore new applications for the monitoring system to bigger markets segments, which could facilitate the rise of investments and financing. To illustrate the new market possibilities, the team presented estimates of the size of the cardiovascular rehabilitation market in São Paulo, based on the volume of patients seen at the main clinics in the city. Even extrapolating this base to the whole country, assuming that the demand for the service would be proportional to the population size, the potential market volume would remain much smaller than other cases of cardiological care. This comparison can be made based on the data in Table 5.

Table 5 – Market size estimates for different conditions of cardiac patients

Patient condition	Baseline	Number of patients	Expenses per year
Cardiovascular rehabilitation[1]	City of São Paulo	3 k	R$ 6 M
Cardiovascular rehabilitation[2]	Brazil	50 k	R$ 100 M
Myocardial Infarction[3]	Brazil	335 k	R$ 16 Bi
Heart failure[3]	Brazil	2,8 M	R$ 14 Bi
Atrial fibrillation[3]	Brazil	1,2 M	R$ 3,7 Bi

Sources:
[1] Estimated based on the volume of patients attended in main clinics in São Paulo
[2] Extrapolation of demand from São Paulo to Brazil in proportion to the size of the population
[3] Data from Stevens *et al*. (2017)

The hospital professionals were satisfied with technological advances and recognized that the quality of the trace was compatible with the equipment used in clinical practice. Facing the challenges of raising financial resources and market sizing data, the person responsible for innovation agreed with the team and suggested presenting the new solution to the head of the hospital's research institute to assess new possibilities for monitoring patients. However, the decision to explore new markets led the rehabilitation team to move away from the next initiatives.

In January 2019, the team met the person in charge of the hospital's research institute. The researcher praised the solution and recognized that there would be opportunities for its application in studies carried out by the hospital. Discussing the possible applications for the ECG monitor, the researcher suggested that the most suitable case would be monitoring patients with heart failure, as it is a disease with high prevalence in Brazil, affecting up to 2% of the adult population and requires follow-up by health professionals. However, to enable monitoring these types of patients, it was necessary to include the monitoring of new vital signs, such as blood pressure, respiration rate, and oxygen saturation. As the next step, he suggested holding a further meeting with a specialist physician, who was a reference in heart failure assistance in Brazil.

This meeting was held two months later, and in the meantime, the team worked to improve the monitoring solution to be compatible with the heart failure assistance. With adjustments to the existing solution, it was possible to monitor the respiration rate and exhibit the waveform of the oxygen saturation, which represented part of the demand of the researcher. However, to monitor all the required vital signs, including the absolute value of oxygen saturation and blood pressure measurement, it would be possible to integrate the developed wearable with OEM solutions on the market. After presenting the solution to the heart failure specialist, he complimented the team with development achievements, but he did not see how he could employ the new monitor in the studies carried out in the hospital. After the meeting, there was no direction of the next steps, and the development team could not align new initiatives with the hospital innovation team.

A few weeks later, acknowledging that the involvement of doctors and health professionals was essential to evolve the solution, and in view of the distance with the hospital team and the need to obtain financial resources to make the activities feasible, the team chose to put their efforts in other initiatives they believed they would have greater chances of return. Afterward, the hospital team did not contact the university or the development team about the project, and there were no further activities related to the project.

5.3.3.2. Within case analysis

The within-case analysis follows the guidelines of Eisenhardt (1989) and explores how the use of Design Thinking principles occurred throughout the development process and then assesses the outcome of the process in terms of value capture and value creation.

<u>Principles of Design Thinking Application</u>

The case analysis investigates how each Design Thinking principle was used throughout the development process based on the narrative of the case description.

i. Creativity and innovation

Taking as a reference the point of view of Micheli et (2019), which characterizes creativity as “the production of novel and useful ideas by an individual or small group of individuals working together”, it can be considered that creativity was present throughout the entire project, as the development team constantly sought and implemented new ideas to evolve the solution. However, it is worth noting that creativity stood out in the concept generation stage when the team explored different configurations for the solution and product architectures to provide higher benefits to the users. Once the concept has been defined, the evolution of the solution was mainly focused on performance improvements and technical feasibility. In such a context, it was necessary to complement creativity with specialized engineering knowledge to make the solution meet the expected requirements. Therefore, it was required to include new team members with previous experience and expertise in technological projects.

On the other hand, according to Micheli *et al*. (2019), the concept of innovation refers to “the successful implementation of creative ideas within an organization”. Bearing in mind the team's main objective was to offer monitoring services to cardiac patients, it can be considered that the team has failed to achieve this goal and was not successful in pushing the innovation to the market. However, taking into account the specific objectives set by the team throughout the development trajectory, it can be stated that the team could successfully implement creative ideas to achieve those objectives. For example, at the concept generation stage, the team created the concept of a monitoring system that was very well received by patients and hospital professionals. Then they managed to technically evolve the solution in three rounds of prototypes to transmit ECG data in real-time with good quality. And else, they conducted several interviews throughout the AWC program, which contributed to a greater understanding of the market they intended to operate.

ii. User centeredness and involvement

The Remote Cardio case has the peculiarity of having multiple stakeholders involved, such as patients, healthcare professionals of cardiovascular rehabilitation, prescribing physicians, and the hospital's innovation department.

Throughout the development process, the team prioritized the feedbacks of patients and health professionals, who would be the users of the solution.

Initially, in the concept generation stage, the team took the patient’s point as a priority to design and select the concepts of wearable monitors to be comfortable and easy to use. This approach can be stated by the requirements used to guide the ideation process and the choice of product architecture to place the electrodes. The decision to position the electrodes on the patient's head was mainly due to factors that promote a better experience during the exercise, such as being wireless, comfortable, and stable during the training. Then, the positive feedback of patients in the usability test was a major factor for deciding to keep the chosen solution architecture.

However, after the health professionals having assessed the solution, they pointed out the positioning over the head did not provide information to support clinical decisions, as the ECG tracing was unrecognizable. Facing this feedback, the team decided to prioritize the point of view of health professionals over that of patients. Because not meeting the professionals' requirements would be a greater risk for the solution viability than not providing the best usability for the patient. In the interviews of the AWC program, this factor became even more evident, as patients mentioned that they followed the doctor's instructions and that they often did the exercises even without liking the equipment. This scenario evidences that although the patient is the user and payer of the rehabilitation service, he is not the main responsible for making decisions about the solution. This means that patients' feedback, despite being quite relevant to build the solution, tends to be put in the background because they do not directly impact the adoption of the equipment. Thus, an atypical situation arises in the design process, in which meeting the user's needs as a priority will not necessarily lead to the solution adoption and increase its perceived value.

iii. <u>Problem solving</u>

The initial challenge of finding a way to monitor patients to enable the remote rehabilitation service is a problem of a highly wicked nature. First, there was no reference from other institutions offering such service, so that the solution was gradually created as the team got more information about the problem. In addition, the formulation of the problem has been adjusted over time, which suggests the indeterminacy of the problem.

In this context, it is worth exploring how the re-formulation of the initial problem and the team's background can direct the development approach. For example, to solve the initial problem of " how can we provide a remote rehabilitation service?", the team decided to develop the end-to-end solution, from the wearable conception to the communication and data transmission system. Then, the team broke down the problem on two fronts: one focused on the wearable conception and the other to build the remote communication system. Both the fronts addressed only technical issues and guided most of the project activities. The discussions involving the elaboration and offer of the service for monitoring patients out of the hospital took place late in the project. The choice of development approach may have occurred due to the team's composition, which was formed exclusively by engineers, bringing a strong bias towards technological issues.

In contrast, an alternative to formulate the initial problem would be "what is the simplest way to offer the benefit of cardiovascular rehabilitation outside the hospital?". It would be interesting to include health professionals and people with a service design background in the team to address that issue. In such a hypothetical approach, perhaps the unfolding of the activities and results of the project could have been different. For example, since the concept generation phase, the team could monitor real patients with non-scalable methods, depending on existing technology and human interventions. Then, the team could gradually integrate more technological solutions, developed by the team or purchased from the market, to improve the experience of the service offered.

iv. Iteration and experimentation

The iterations and experiments have guided the solution development, showing the main topics that needed improvement. With the prototypes, the team obtained feedback from users and healthcare professionals about the most appreciated features and the solution weaknesses. Based on the directions acquired, the team organized to review and improve the solution to achieve the desired performance.

It is worth mentioning that, analogously to the principle of problem-solving, the technological and engineering bias of the team had influenced how iterations occurred. As the team started from the premise of building an end-to-end technological solution, the prototyping and iteration cycles uncovered the technical performance bottlenecks to be addressed in the next iteration. In this context, the direction brought by the problem formulation was a factor that directly influenced the result of the iterations and experiments. When starting from the question of "how might we monitor patients' cardiac activity remotely in real-time?" the unfolding of iterations directed the creation of the technology that would make monitoring possible.

It is interesting to note that despite the complexity of the technological project, the team could develop a solution capable of monitoring vital ECG signals with a similar quality used in the clinical practice, demonstrating the great technical capacity of the development team. This scenario reinforces that the team did not reach the major objective of offering a solution in the market, not because of technical limitations or experimentation failures. But probably because the team has chosen a direction that took a lot of time and resources to deliver value to real patients.

v. <u>Interdisciplinary collaboration</u>

The interaction among disciplines was fundamental to make the solution development advance. Collaboration with hospital professionals was one of the key factors in enabling the development activities. The professionals contributed by providing feedback about the product and guiding visits to hospital facilities, mobilizing patients to be interviewed, and supporting initiatives to raise financial resources and explore new applications for the solution.

However, there was a considerable dependency on the hospital team to deliver the value of monitoring patients, as they were the only people working on the project with the expertise of supervising patients. At the end of the project, even with all the technological advances, the team composition was unable to provide patient care.

Although the hospital team was receptive and easy to contact, they did not have the availability to allow rapid experimentation with patients. A possible way for the team to have greater autonomy would be to have all the necessary skills in the team to create value for the patient. It involves gathering people who understand technological and healthcare issues. The lack of autonomy to create value might have influenced the team's decision to stop working on the project and seek new opportunities. Thus, the project activities have ended.

vi. <u>Ability to visualize</u>

Since the concept generation phase, the team has used tools to make the representation ideas tangible and visual. It helped the team with internal communication. For example, when the group conducted the ideation sessions, the drafts and visual models ease the organization and clusterization of the ideas into four main concepts of the wearable device. In addition, the ability to visually present the solution, whether through prototypes, videos or images, was useful to learn from people outside the team. After choosing the concept, the team used the prototypes and visual materials to present the solution to hospital health professionals and several interviewees during the AWC program. This approach facilitated the acquisition of insights to guide the team's performance.

vii. <u>Gestalt view</u>

The team members adopted integrative thinking, as they explored several fronts and interacted with several people to understand how to position the solution in the context. However, it is worth noting that, despite actively working to build this integrative vision and exploring new points of view in the context of monitoring cardiac patients, the team still maintained a strong technological bias. Thus, even having worked to build a holistic vision exploring subjective issues linked to people's interests and perceptions concerning the created solution, the lens brought by the team members transformed this holistic vision into an action plan focused on improving technological development.

viii. <u>Abductive reasoning</u>

The project's macro-objective to build a solution and determine its working principle for monitoring cardiac patients is directly linked to the core of the abductive approach described by Dorst (2011). With this perspective, the construction and refinement of the solution occurred iteratively, based on the development of four versions of the solution. In each iteration, new challenges and barriers were found and prioritized by the team to be further addressed. This iterative approach is one of the factors that differentiates the linear approach to problem definition and the search for a solution from strictly deductive analytical methods.

ix. Tolerance of ambiguity and failure

Considering as failures the negative points of the solution that made it impossible to be used in the field, the learning with those failures allowed the team to move forward and obtain a solution with a technologically potential of being used in patient monitoring. Such failures were identified interacting with health professionals and were mainly related to the quality of the ECG trace. Identifying the points for improvement, the team worked to address them, making the project evolve.

In contrast, at the end of the project, despite the advances, the team failed with its primary objective of launching a solution on the market to support cardiac patients' recovery. However, it is important to note that learning from failures takes time and resources. At the end of the fourth version of the solution, the team members did not have a prospect of getting the resources to keep working on the monitoring solution. So then, they chose to move their efforts towards other opportunities. In this context, to convert the learning from failures and ambiguities into solution improvements, it is necessary to have a team open to experiment and take risks and resources to make test and learning activities feasible. Thus, in addition to the subjective factor of team members to tolerate ambiguity and learn from the failures, it is also essential to obtain resources that allow experimentation activities to be carried out considering the odds and costs of failures.

x. Blending rationality and intuition

As discussed in the principle of "Abductive reasoning", the team followed an abductive approach to seek to achieve the main goal of conceiving a solution that would enable the monitoring services outside the hospital environment.

However, to achieve the specific objectives determined along the development trajectory, there were occasions in which the team used methods with higher creativity and intuition. While at other times, it took an approach with a greater deductive analytical aspect. In general, to figure out how to meet the subjective expectations of patients and stakeholders, the team had to use more intuition and sensibility to interpret the messages and got the feeling of people's impressions. On the other hand, in situations that required better technical performance of the solution, such as overcoming the challenge of the ECG trace quality, it was necessary to apply a more rational and technical approach and refine the electronic design of the solution.

Outcomes – Value Creation and Value Capture

The first expected result of the Design Thinking approach is the creation of use value through the solution. In this case, the use value would be created when the patient participates in the remote rehabilitation service and enjoys the benefit of safe and outdoor physical exercise. Thus, it can be concluded that there was no creation of use value in the Remote Cardio case since no patient was monitored and assisted with the solution. Among the factors that have hindered the team in delivering value to the patient, two of them stand out: the decision of developing the whole technologic infrastructure before assisting patients and the fact the team did not have health professionals to deliver value without depending on hospital professionals.

As mentioned in the topics of problem-solving and iteration, and experimentation, the team opted to follow an approach to develop the end-to-end technology solution to enable remote monitoring. This choice probably held because the team was composed exclusively of engineers. Even though they were from different specialties, they still had a technological bias brought by their formation. The strategy of developing the entire technology base, on the one hand, creates a competitive differential that makes it difficult for new players to launch a similar solution. But on the other hand, it took too much effort and time to validate the value proposition, building a solution minimally capable of creating value for the patients.

Besides, the second factor that hindered the creation of use value was the team did not have all the necessary skills to offer the remote assistance service to patients. Despite the strong technological capacity, the team did not have healthcare competencies to provide the necessary support to the patient during remote monitoring. As a result, a large dependency on hospital professionals was created, which resulted in a lack of team autonomy to create value for the end-user. Consequently, the team had difficulties in testing and validating the design of the service of monitoring patients. Finally, in the project's last activities, the team's lack of autonomy in delivering use value also hampered the process of exploring other types of patients to assist. To this end, the team tried to mobilize the areas of the hospital to offer services to patients with heart failure, but there was no success on such an initiative.

An alternative to overcome the barriers of creating value for patients would be to involve health professionals in the team since the beginning of the project's activities. As mentioned in the problem-solving topic, it would be desirable for the team's autonomy if it got members capable of supervising and supporting patients. With such configuration, it would be possible to explore more direct ways of offering the rehabilitation service outside the hospital, even if with non-scalable solutions and with a low technological level. Once real patients were assisted by the team, the solution could be gradually evolved while value creation would be incrementally improved and refined.

It is worth noting that even though the team's trajectory has not enabled the value creation for the users, the application of Design Thinking principles occurred throughout the project. The principles of interaction and experimentation jointly with user-centeredness allowed pointed directions to drive the solution to increase the perception of value from patients and healthcare professionals.

Although the chosen development strategy took a long time to build the solution to create use value, the Design Thinking principles were very useful in guiding the development route, stimulating users to demonstrate what was desired to be improved in the solution. Furthermore, the iterations indicated the improvements based on what was presented to users. As technological features were presented to health professionals and patients, the feedback remained on technological issues. Therefore, it can be considered that the Design Thinking approach did not lead to the leanest development strategy. Instead, it provided valuable clues to guide the team within the chosen strategy.

The second expected result of the Design Thinking process is the value capture. Bowman & Ambrosini (2000) discuss that value creation occurs when the company sells its products and services on the market and captures value from its customers. Following this perspective, as the resources in the case were raised through project funding and not due to the offer of solutions for patient monitoring, it can be considered that no value was capture in the case.

A major factor that made it difficult for the team to capture value was not being able to create value in use with the solution versions developed. Bowman & Ambrosini (2000) discuss that the value capture only occurs if the customer's perception of the use value is higher than the exchange value represented by the price. Thus, as no patient was monitored, it became harder to promote the perception of value without existing a tangible case to demonstrate how the value is created. Therefore, without providing a clear perspective of value creation, it becomes challenging to consolidate the potential of value capture of the solution.

In addition, even if there was value creation, it might be necessary to explore relationships with other stakeholders to launch the solution to the market. As indicated by the interviews conducted in the AWC program, the patient was not responsible for choosing which therapies and medications he will use in the treatment. The choice to participate in cardiovascular rehabilitation was not made spontaneously by the patient. First, the patient needed to be influenced by the doctor who prescribes the treatment. Then, with the prescription in hand, the patient could decide whether or not to adhere to the prescribed treatment.

This scenario is atypical in design practice, in which the patient, who is the user and payer for the rehabilitation service, is not responsible for adopting the solution. In this context, the primary decision-maker for the solution adoption is the prescribing doctor. Therefore, it would be necessary to influence the physicians to recommend remote rehabilitation to eligible patients. To this end, as commented by one of the investors interviewed, a new solution needs to gain credibility among the medical community to be prescribed and used. Therefore, besides all the evidence indicating the solution would be safe and effective, it would be necessary to promote the doctors' awareness and confidence to prescribe the new solution to their patients.

In addition, the assessment of prescribing physician's needs and expectations did not emerge naturally in the Design Thinking process, but when the team was encouraged to conduct interviews by the instructors of the AWC program. This might have occurred because the Design Thinking approach is heavily centered on the user and the prescribing physicians are not solution users. Thus, to make value capture feasible, it would be necessary to complement the Design Thinking approach with tools and activities to understand the decision-making chain and build valid revenue streams, involving more stakeholders than users.

5.4. Cross Case Analysis

Following Eisenhardt's (1989) guidelines for data analysis in case studies, the cross-case analysis was performed to identify patterns and get the basis to draw up propositions in theory building. Eisenhardt (1989) suggests a tactic to perform cross-case analysis choosing dimensions to assess and compare the cases to find similarities and divergences among them. Thus, the chosen dimensions to compare the cases were the ten principles of Micheli *et al.* (2019) as the means to apply Design Thinking and the value creation and value capture as the expected result of Design Thinking application. With such a perspective, it is intended to get an empirical base to answer the research questions of this work.

Therefore, the first step of the cross-case analysis was to summarize the most relevant topics of each case about the mentioned dimensions to ease the comparison. Thus, Table 6 gathers the main issues of the Design Thinking principles application in each case, and Table 7 shows the main results obtained in each case in terms of value creation and value capture.

Table 6 – Summary of Design Thinking principles application in each case

Principle	Sharps Counter	Hemolysis Detector	Remote Cardio
i. Creativity and innovation	Creativity was required throughout the whole project to find out how to handle problems and seek ideas to compose the solution.	Creativity stood out in two contexts: (i) prototyping activities, exploring the solution working principle, and addressing usability issues; (ii) carrying out the number of interviews required in the PIPE Entrepreneur program, exploring how to enlarge their network and how to get the interest of interviewees.	Creativity was present throughout the project, as the team constantly sought new ideas to evolve the solution. At concept generation, the design of solutions demanded greater creativity. In later stages, to deal with performance and technical feasibility issues, it was needed to complement creativity with specialized engineering knowledge.
ii. User centeredness and involvement	Users' feedbacks helped to gradually discover the main technical challenges to overcome to reach a solution able to be used in real surgeries. The user feedbacks were multiples and diverse, so it was up to the team to interpret them and to establish priorities to act. To take priorities was essential to balance the resources to fulfill user interests and also the development team's interests.	User interaction provided a solid technical and operational perspective about the laboratorian activities to guide the solution development process. In addition to users, the involvement of potential buyers and decision-makers, especially the operational managers, were fundamental to shape the value proposition and solution design.	Multiples stakeholders interacted with the solution: patients, healthcare professionals for supervising patients, prescribing doctors, and hospital innovation staff. The team focused mainly on the voice of patients and healthcare professionals, that were the users. However, as the patients could not decide on their own which treatment to undergo, meeting exclusively their feedback would not necessarily lead to solution adoption.

Table 6 continues on the following pages

Table 6 continuation

Principle	Sharps Counter	Hemolysis Detector	Remote Cardio
iii. Problem-solving	In the early stages until concept generation, problems were more poorly defined with a broader scope than the later stages. As the specificity of problems increased, the complexity and robustness of the required solution also increased. Problem-solving capacity depended on the previous capabilities of team members. The team composition varied as the new problems required new capabilities.	The problem-solving approach was chosen according to the kind of problem. To conceive how the solution should be and its working principle, the team took an abductive approach. Then, prototypes were used to get user's feedback to improve the solution continuously. Once the working principle was defined, the team tried to answer the questions related to the performance of the new product. Then, the team took a more analytical approach to plan and execute studies with real blood samples.	The initial problem formulation to determine how to make the remote rehabilitation service possible had an intense wicked-problem aspect. Then, the course of solution development was guided by the reformulation of the initial problem. This process was greatly influenced by the engineering background of the team, which led the project's focus towards technology development. The team successfully solved problems related to technology development but failed to solve the main problem of enabling remote rehabilitation services.
iv. Iteration and experimentation	The iteration and experiments led to the final version of the solution, able to be used in real surgeries. To such achievement, rapid prototyping was gradually replaced by more complex and robust prototyping. As the solution complexity increased, more resources were required for experimentations.	The iteration and experimentation stood out in two main activities: (i) designing solutions from iterative prototypes gathering users' feedbacks and (ii) reviewing the value proposition and solution main features from interviewing people from the clinical analysis market. There were experiments to evaluate solution performance, but they got a straightforward and analytical approach.	The iteration and experimentation led the solution evolution, uncovering the main topics to be improved based on users' feedbacks. The technological and engineering bias also influenced the approach to iterations. As the team assumed building an end-to-end technological solution, the prototype cycles indicated the technical performance bottlenecks.

Table 6 continuation

Principle	Sharps Counter	Hemolysis Detector	Remote Cardio
v. Interdisciplinary collaboration	This coloration was fundamental to carry out the project and progress on the solution development. The interdisciplinary collaboration stood out in two main contexts: (i) within the development team with multiple backgrounds to create complex and robust solutions; (ii) between the development team and the nurse team, to obtain key resources to the project and conduct several tests at the surgery center to validate the solution.	Multidisciplinary collaboration was essential throughout the whole innovation process. The collaboration with the laboratory personnel was decisive to make the project feasible. It got far beyond only getting user feedbacks - they provided access to laboratory facilities, guided visits, gave detailed explanations about the operation, supported the PIPE project submission, and led IP analysis and patent application.	Collaboration with hospital professionals was a key factor in making development activities viable. They provided feedback on the solution, gave access to hospital facilities and patients, financed the early activities, and supported fundraising. The team members did not have all the competencies to offer the solution of remote rehabilitation. Thus, they depended on the hospital team to provide patient care and had limitations in doing experiments with patients.
vi. Ability to visualize	Prototypes were the best way to show the solution and get feedback from users. Other visualization tools, such as charts, pictures, and 3D models, helped support internal and external communication.	Visual tools were elaborated according to the context and the audience faced by the team. The capability to make good visual tools are not restricted to product design but is also valuable to improve team communication, especially with stakeholders out of the team.	The ability to visually present the solution with sketches, prototypes or presentations, was helpful to facilitate communication within the team and guide interactions with people outside the team.

Table 6 continuation

Principle	Sharps Counter	Hemolysis Detector	Remote Cardio
vii. Gestalt view	The team incorporated perspectives from several people from hospital surgical center operations to consolidate a broad view of the context of solution use.	The search for a broad and holistic view occurred through all the stages of the innovation process. The view became broader and more complex as the team acquired and accumulated knowledge from different information sources. Starting from the people of the partner laboratory, then from paper publication, and then from several stakeholders of the clinical analysis market.	The team members got integrative thinking, as they explored several perspectives to figure out how to place the solution in the context of patient assistance and monitoring. However, the lens brought by the team members transformed the inputs from this holistic view into an action plan for technological development.
viii. Abductive reasoning	From a macro perspective, the development followed abductive reasoning to design the solution in five rounds of prototyping.	Two occasions favored the use of abductive reasoning: the solution and value proposition design.	From a macro perspective, the creation of a solution ("what") and its working principle ("how) for monitoring cardiac patients reflects the core of the abductive approach.
ix. Tolerance of ambiguity and failure	The lessons learned from failures allowed the team to improve the solution until the last version. To recover from failure, more resources and time were required. So it is crucial to managing the budget allocation and aligning expectations with stakeholders to overcome failures.	Tolerance of ambiguity and failure was relevant not only among team members but also to the representatives of institutions that supported the project.	The learning of intermediate solutions failures guided the solution evolution until the latest version. In addition to the subjective factor of the team to tolerate ambiguity and failures, resources are needed to perform experimentation activities, bearing in mind the costs and risks of failures.

Table 6 conclusion

Principle	Sharps Counter	Hemolysis Detector	Remote Cardio
x. Blending rationality and intuition	As different types of problems were faced, some of them required greater intuition and others more rationality.	When facing certain types of problems, it was preferable to use analytical methods and reasoning. Meanwhile, on other occasions, it was preferable to opt for a more abductive approach.	The abductive approach was performed to find out how to make remote rehabilitation feasible. However, to achieve specific objectives, the team either took a more intuitive or rational approach.

Source: Elaborated by the author

Table 7 – Summary of Design Thinking expected outcomes in each case

Outcome	Sharps Counter	Hemolysis Detector	Remote Cardio
Use value creation	Value creation occurs when the hospital's surgical center uses the new method of sharps count, and the surgery teams can use it to have greater security and reliability than manual counting. The Design Thinking principles were useful in guiding the team to evolve the solution. The feedbacks of nurses about prototypes pointed out the weakness of the solution to be overcome. Interdisciplinary collaboration was a key success factor in creating use value. The nurses gave user's feedback and clues of development, and they also invested their time providing knowledge, resources and mobilizing the surgical center to test the solution. Use value was not created in intermediate and nonfunctional prototypes as they did not meet the minimum requirements of safety to be used in surgeries.	Value creation occurs when the laboratory adapts its blood sample screening to use the Hemolysis Detector measurements for decision-making and takes profits in terms of reliability and accuracy. User-centeredness combined with iteration and experimentation showed where the development team had to put their efforts to evolve the solution to create use value to improve hemolysis detection practice. The interdisciplinary collaboration improved the synergy between the laboratory and development teams that joined efforts to better perform development activities. The value creation occurred when the Design Thinking principles were usefully combined, leading to the creation of a solution with minimum performance to enhance the laboratory operations.	Value creation did not occur as no patient was using and being assisted by the created solution. Two factors may have hindered the creation of use value: (i) the choice of the strategy of first developing end-to-end monitoring technology, to later assist real patients (ii) the team had no autonomy to deliver value to the patient, as there was no health professional in the development team to assist patients during the monitoring. Even though there was no use value creation itself, the Design Thinking principles were applied and contributed to the development process. The principles of interaction and experimentation jointly to user-centeredness allowed the team to identify what should be improved to promote the use value for patients and healthcare professionals. Those principles did not lead to the leanest development strategy, but they effectively guided the team within the chosen strategy.

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Principle	Sharps Counter	Hemolysis Detector	Remote Cardio
Value capture	Value capture took place in the form of projects funding, but there was no value captured related to Sharps Counter sales. After testing the Sharps Counter in several surgeries, it became more evident that the prospect of capturing value would be much lower than the amount of investment required to get the desired accuracy of the counting method. The unfavorable balance between value capture and development efforts was a crucial factor in deciding not to continue working on the solution. Thus, although value capture was not an immediate outcome of Design Thinking principles, it was a major factor for making the solution viable.	The need to capture value came from the development team when they funded a startup to proceed on the concept development stage. Published studies (secondary sources) provided an estimation of the maximum value capture potential. Almost all laboratories could be potential clients as sample rejection by hemolysis is a problem in 95% of laboratories. Interviews with stakeholders from the clinical analysis market (primary sources) provided a more realistic perception of value capture potential, as hemolyzed blood samples detection was not necessarily a priority of managers of all laboratories to make investments. Seeking value capture, the team got potential buyers' feedback to evolve the solution and value proposition. Value capture depended both on solution aspects and on the team's capabilities and resources to reach and negotiate with potential buyers.	There was no capture of value in the case. The funds raised were due to project financing, and there was no revenue related to remote patient assistance services offering. A major factor that hindered the value capture was that the team could not create use value with the solution. Even though the use value was delivered to the patients, they were not the primary decision-makers in adopting the solution. Thus, to present the new solution to the market to capture value, the prescribing physicians must become aware and confident in the new solution to indicate it to their patients. The need to deal with the expectations and decisions of prescribing physicians did not naturally emerge in the Design Thinking process. Instead, it occurred when the team was encouraged by the instructors of the AWC program to interview the most people as possible involved in the solution context.

Source: Elaborated by the author

Concerning the application of Design Thinking principles, some of them stood out by themselves throughout the innovation process. Creativity and innovation were themes present in all project cases since the teams worked to develop a new product and sought solutions to overcome the problems they have faced. Creativity was essential when teams dealt with a completely new problem, and there were no previous references or people to consult who could contribute to finding the solution. For example, it took creativity to improve the Sharps Counter design to make it look like a final product, or in the Hemolysis Detector case when the team had to find ways to conduct one hundred interviews during three months of the PIPE Entrepreneur program. The situations that demand creativity might occur in several moments of the innovation process because the team probably has to cope with uncertainties and problems demanding new solutions over the entire project. Thus, creativity can be seen as a fundamental element that underlies the realization of the Design Thinking approach as a whole in the studied cases. Therefore, it is not surprising that creativity was present in all studies analyzed by Micheli *et al*. (2019).

Another principle that deserves special mention was interdisciplinary collaboration. The configuration of the studied projects, which gathered the market experience and the operational practice of the partner institution with the expertise of technological development of the project teams, played a major role in enabling the progress of the innovation process. Such collaboration joined efforts and complementary knowledge that allowed the teams to deal with challenges they could not overcome if they were working independently. The partner intuitions teams embraced the design discourse and principles and worked actively and collaboratively on the projects.

Complementarily, certain groups of principles can provide better results whether employed together. For example, it is the case of principles of iteration and experimentation, user-centeredness, and interdisciplinary collaboration. Iteration and experimentation stood out in the projects since all solutions, especially the Sharps Counter, underwent several rounds of prototyping to get to the final version. However, if the iteration and experimentation principle would be carried out in an isolated way, probably the progress of prototyping rounds would not have been the same. What made the solution evolve in each prototyping round was the interplay with the users to capture their perceptions and critics to generate inputs to guide the subsequent development. In these cycles, interdisciplinary collaboration, both within the development team and partner institutions, boosted the potential to overcome challenges and build a more complete and effective solution.

Another set of principles that presented strong cohesion and seemed to be valuable of being employed together was problem-solving, abductive reasoning, and blending rationality with intuition. This cluster of principles broadly represented the way the teams dealt with the problems encountered. From a macro perspective, all cases followed an abductive approach as they set out to determine “what” the solution would be and “how” it should work to create the value expected by users. This approach is the core of Designerly Thinking and distinguishes it from other forms of reasoning, as discussed by Dorst (2011). In this sense, the Sharps Counter case sought a way to improve the safety and accuracy of the count of surgical materials, the Hemolysis Detector case improved the methods of detecting hemolyzed blood samples, and the Remote Cardio aimed to find out a way to enable the remote monitoring of patients undergoing cardiovascular rehabilitation. Nonetheless, as those problems were quite broad, it was necessary to break them down into more specific issues to guide the team's performance.

The problem breakdown was present from the earlier stages. For example, in the Remote Cardio case, the ideation was divided into two fronts: one focused on the wearable designed to capture the vital signs and the second one dedicated to developing the communication system to transmit the ECG signal to be monitored by health professionals near in real-time. The problem breakdown also occurred in later stages of development, as in the case of the Sharps Counter, when the team conducted stress tests with specimens with particular geometries and materials to discover the configuration of a sterilization-resistant device enclosure. Thus, organizing the team to solve smaller and more precise problems contributed to direct efforts and resources toward a more explicit objective, reducing the risk of not achieving it.

In addition, the type of reasoning and approach used in dealing with specific problems varied according to the nature of the problem. As discussed by Dorst (2011), to deal with issues related to determining the composition of the solution ("what") and its working principle ("how"), the teams got great advances following an abductive approach. For example, figure out what the wearable would be to capture the vital signs in Remote Cardio or determine how the analysis mechanism would work in the

Hemolysis Detector solution. In contrast, since the constitution and working principle of the solution was defined and the intention was to evaluate or improve its performance, the deductive analytical approaches proved to be more efficient. For example, there are the experiments to assess the impact of the Hemolysis Detector solution in laboratory operation and the review of the Remote Cardio electronic system to improve the quality in the ECG signal acquisition.

Finally, considering the results of the projects, the principles of Design Thinking proved to be more relevant to address value-creation-related issues rather than promote value capturing in the market. The Design Thinking approach and discourse, in general, is oriented to put the user at the center and outline routes to respond to their needs. However, in the studied cases, the users were not responsible for deciding to acquire solutions, and they had little autonomy and influence in choosing the solutions they used. On such occasions, to discover how to capture value, it was necessary to complement the user-centered perspective with the understanding of the interests and needs of potential buyers and decision-makers. Thus, the value proposition and the design of the solution must meet the expectations and needs of both users and potential buyers. The next session seeks to answer how the principles of Design Thinking influenced value creation and value capture based on the empirical findings of case studies and discussions of published studies in the literature.

5.5. Discussions and Propositions

The discussion in this section is organized regarding this work's research questions to bring propositions to contribute with theory building about Design Thinking application at innovation projects.

Q1) How the Design Thinking principles contributed to value creation?

Proposition 1.1) The value creation did not occur with the individual application of Design Thinking principles, but indeed when the principles were successfully combined to leading the creation of solutions that worked.

Pieces of evidence from the three cases indicate that the value is created for the users only when they can minimally enjoy the benefits they expect to obtain with the new solution. Therefore, the solution offered needs to have minimum performance and features to deliver the intended benefits to the user. This aspect becomes more evident in Sharps Counter and Remote Cardio cases, which had relatively strict technological minimum requirements, as they were related to patient safety. For example, the Sharps Counter could not be used in surgery until the device was wholly sterilizable, and the Remote Cardio solution could not be used to monitor real patients without a minimally reliable cardiac monitoring. Nevertheless, in those projects, the Design Thinking principles were applied through all the stages of the innovation process, even before obtaining a solution that could be used, creating value for the user. Hence, the use value was not created gradually over time when each principle of Design Thinking was applied. Instead, the use value was created when users had solutions that could bring them benefits.

To reinforce the importance of working with Design Thinking in a broad and complete way, Liedtka (2015) argues the differential of Design Thinking does not remain on its individual methods and tools, but the distinction of the approach is on how its elements are combined into an end-to-end system for problem-solving. The author also states that the Design Thinking methods individually are not new to the management literature. For example, the needs-finding process can be linked to the marketing literature with consumer research methods that uncover and understand the customer needs, and the construction of solutions based on test and learning methods dialogs with the effectuation strategy of Sarasvathy (2001) and the lean startup of Ries (2011). But, considering Design Thinking as the joint application of its tools and principles, it stands out as a distinct practice, providing a series of attitudes capable of directing the innovation process.

Proposition 1.2) Design Thinking was more useful to discover how to create value than to create value itself

The Design Thinking principles were very useful to guide the discovery of how to create use value. They have contributed to understanding the benefits most appreciated by the users and what features should be improved to increase the use value perception. In this context, the set of principles of iteration and experimentation, user-centeredness, and interdisciplinary collaboration played a major role. As discussed in the cross-case analysis, the interactions with users to appraise prototypes enabled the development team to get clues to improve the solution and get a higher perception of value from the people the team was designing for. In addition, the interdisciplinary collaboration helped to gather knowledge and competencies to work on more complete solutions to match user needs.

The process of interacting with users to discover how to provide a greater value perception is presented in almost all Design Thinking processes assessed in the Prescriptive Study. For example, the d.school model (Institute of Design at Stanford, 2010) focuses on creating empathy with the user to drive the cycle of prototyping and testing to understand what solution pleasures the user. Likewise, Brown (2008) and Liedtka & Ogilvie (2011) describe the low-fidelity prototypes as a helpful way to figure out how to create value for the user, as they are inexpensive and provide quick interactions with users to get their impressions.

However, it is worth stating that testing prototypes with users does not create use value itself. Instead, it helps to identify how to create the use value in further developments. For example, in the cases studies, at a particular moment of the innovation process, the teams had to evolve the low-fidelity prototypes into more robust solutions that would really work and would be able to deliver value to the user.

In general, the Design Thinking preceptive models do not indicate when and how the low-fidelity prototyping should be replaced with more complex solutions. In this sense, Brown's (2008) model of three spaces of innovation can be criticized as it lacks clarity of how and when the solution goes from the ideation to the implementation stage. In addition, the author mentions that in the implementation space, in Shimano's case, the collaboration of senior professionals of the company was required to complement the work of design thinkers. But Brown (2008) did not clearly describe how this collaboration took place and how was the interface between design thinkers' and senior teams' works. With the case studies in this work, it can be stated that the building of functional and robust solutions that will create use value requires previous technological knowledge of developers, and the Design Thinking principles could help them to identify what features and functionalities they should put their efforts on. The only prescriptive model of Design Thinking that mentions the need to make high fidelity prototypes before testing the market was the model of Liedtka & Ogilvie (2011). In the last stage of the process, named "what works", the authors recommend involving customers throughout the high-fidelity development with co-creation techniques. Then the authors suggested deploying a "learning launch" process to insert the solution in the marketplace, creating affordable experiments to let customers experience the new solution and test the key assumptions of the business model.

In this context, this work proposes that the main principles of Design Thinking are useful to guide the development team to discover where they have to focus their efforts to create value for the users. But the creation of value itself and the construction of high-fidelity prototypes and final products depend on previous knowledge and competencies of the development team.

Proposition 1.3) Design Thinking does not contribute to choosing the best strategy to create value, but it is effective in guiding the team within the strategy they chose

Considering the standout role of Design Thinking in directing development by identifying the points that enhance the user's perception of value, it is worth noting that the application of the approach will not necessarily lead to the most direct or efficient path in creating value for the user. This phenomenon becomes more evident in the Remote Cardio case, in which the team took the premise of building for themselves the entire technological infrastructure to enable the remote rehabilitation service before assisting the patients and delivering value to them. The application of Design Thinking made the team identify what was needed to evolve in the solution based on the created prototypes. As the prototypes initially contemplated only the technological part, the team discovered the technical bottlenecks that hindered the prototype from being used with real patients. Then, working on those bottlenecks, the team was able to find a new solution closer to being used in the field.

In this process, it does not mean that Design Thinking directed the team towards the most effective strategy to create value for the user. But within the chosen development strategy, the Design Thinking approach indicated how to evolve the prototypes and get a solution closer to meet patients' and healthcare professionals' needs within the chosen development strategy.

As discussed in the analysis of the Remote Cardio case, another possible development strategy would be to include in the team people with healthcare background and expertise in supervising cardiac patients. So, since the beginning of the project, the team could figure out a simple way to assist real patients out of the hospital facilities. In this hypothetical situation, the development strategy would start with non-scalable and straightforward solutions based on health professionals' in-person intervention and existing technologies. Then, as the context became better known, the solution would be improved with technologies capable of providing greater autonomy and monitoring quality. The application of Design Thinking in this alternative strategy would have provided a completely different outcome from what happened in the case. This phenomenon can also be observed in other cases in which the Design Thinking approach indicated in each iteration what could be improved to increase the user's perception of value. This can be observed more clearly in the Sharps Counter case, which had the highest number of prototyping rounds until the final solution. In this case, Desing Thinking has shown how to evolve the presented concept of solution chosen by the team. However, the approach did not point out alternative strategies for delivering value to the nurse team, for example, acquiring a market solution or exploring new ways of offering services to the operating room, in addition to the Sharps Counter device. Finally, an analogy can be made that the principles worked as a compass to guide the teams to create value within their chosen development trajectory.

Proposition 1.4) Abduction drives the use value creation in a macro perspective, but throughout the innovation process, there are specific problems that can be addressed either by analytical or abductive reasoning

As discussed in the cross-case analysis, taking the cases from a macro perspective, the abductive approach directs value creation. Since the ultimate goal of the projects was to create a solution and its working principle to generate the intended value. This goal is the basis of the abductive reasoning described by Dorst (2011), which differs from the deductive and inductive methods that started from a known object. The macro problems that drive the creation of value have strong wicked characteristics, according to the perspective of Buchanan (1992). Even though it is possible to enunciate the problems at the end of the needs-finding stage, their formulation adjusts as the knowledge about the context and the solution moves forward. There is no conception of a right or wrong solution within this process, but the end is to hone the solution until it delivers the desired value.

Obtaining a final solution that delivers value to its end-user can be a considerably broad problem. In the studied cases, to advance the innovation process, it was necessary to break down the initial problem into smaller ones to direct the work of the involved people. When dealing with specific issues, on some occasions, it is better to use an abductive approach, while on others, it is more advantageous to use deductive and analytical approaches. One suggestion to decide which approach to use is to assess the question related to the problem. Following Dorst's (2011) propositions, if the questions allude to "what" would be the solution and "how" it should work, abduction tends to be a more effective method. Whereas, once the solution and its working principle are minimally defined, and it is necessary to evaluate or improve its performance, analytical reasoning tends to bring better results.

Finally, as discussed in the cross-case analysis, the dynamic of using different approaches to solve problems put closer the principles of problem-solving, abductive-reasoning, and blending rationality with intuition as a broad problem-solving approach throughout the innovation process. In this way, each specific problem has its own resolution approach, but they have a major common objective of creating value with the new solution.

Q2) How the Design Thinking principles contributed to value capture?

Proposition 2.1) Although the principles of Design Thinking were useful in driving value creation, they were not sufficient to provide value capture with the solution.

Bowman e Ambrosini (2001) discussed that the use value creation is a previously required condition to make value capture possible in the marketplace. In such a way, the transaction to capture value only occurs if the perceived use value by the customer is greater than the exchange value agreed between the parties. Thus, it can be considered that use value creation is a necessary condition to enable value capture.

Nonetheless, in all case studies, the solutions were developed with the Design Thinking approach to create compelling solutions to meet the user's needs and expectations, but it was not sufficient to enable value capture with the solutions. The resources used to support the project activities were captured by means of project funding. In the first stages of the innovation process, the resources were provided by the healthcare partner institutions. In the late stage of concept development, in two cases, the team raised resources from third-party institutions, such as FAPESP and Instituto TIM, in programs to support R&D projects. However, in none of the cases, the team was capable of capturing value directly by selling products or providing services related to solution use.

The value capture in the marketplace means the people have to make deals and trade products and services. In this process, it may emerge conflicts of interest intrinsic to negotiation in which the buyer wants to save money and enjoy the solution with maximum performance, while the seller wants to increase earnings and avoid expenses that will not lead to the revenue increase. Thus, it can be considered that the value capture streams will not naturally emerge from the user's point of view. As the Design Thinking principles are generally focused on discovering and addressing user needs, the Design Thinking approach will not necessarily lead to a way to capture value. Therefore, if those responsible for development are interested in capture value with the solution, it is in charge of them to perform initiatives to figure out how to capture value with the solution that is being developed.

Proposition 2.2) *Although value capture was not an immediate outcome of Design Thinking principles, it was a major factor to make the solution viable*

Despite the value capture is not an immediate result of the Design Thinking approach, it proved to be one of the main factors in the decision not to continue working on the projects. In the Sharps Counter case, the decision of not proceeding with the project came after tests in real surgeries indicated that the Sharps Counter demand was much lower than initially presumed and that the investments to obtain a minimally attractive performance for the nursing team were considerably high. Thus, the unfavorable balance between the expectation of capturing value and the efforts to create value in use was preponderant in the decision. In the Hemolysis Detector case, the decision not to continue with the project was made after conducting several interviews with potential buyers. Even making adjustments to the solution and value proposition, it was not possible to conclude the negotiations to capture value. Finally, in the Remote Cardio case, the decision of stopping working on the project was made after holding meetings with hospital specialists and failing to find a clear path to offer remote monitoring to patients and capture value with the new service.

Thus, even if the capture of value is not an immediate result of the Design Thinking approach, it is essential to enable the innovation process. Therefore, those interested in offering the solution on the market would be able to establish revenue streams obtain the necessary resources to keep, at least, the team working and supporting the solution.

Q3) What are the opportunities to improve the Design Thinking approach for innovation projects to increase the potential of value creation and value capture?

Proposition 3.1) Refining the value proposition and revenue streams throughout the Design Thinking process may increase the potential of value capture

Identifying and establishing value capture streams are important factors to enable the development and commercialization of the solution. Thus, including activities throughout the Design Thinking approach to gradually refine the value capture assumptions can increase the success potential of the solutions. However, as seen in the Hemolysis Detector case, the late evaluation of the purchase interest may provoke changes in the developed concept, demanding more resources to adjust the solution. In a more pessimistic scenario, not evaluating the purchase interest during development can lead to creating a solution that does not arouse the interest of potential buyers and has no potential to capture value.

Another relevant aspect of the Hemolysis Detector case was the value proposition evolved gradually and iteratively as long as the team got feedback from potential buyers. With the interviews in the PIPE Entrepreneur program, the team fine-tuned the value proposition to be more adherent to the expectations of the laboratories managers. After making adjustments to the scope of the solution, the team used presentations and 3D models to demonstrate how the solution would work and managed to move forward in the negotiation with potential buyers. This evidence suggests that it is possible to evaluate the purchase interest without having a final and fully functional solution. Therefore, to avoid the risk of building solutions with a low potential of value capture, a possible way to improve the Design Thinking approach is to review and validate the value capture assumptions iteratively. These iterations could be conducted in a similar way the solution design is tested and honed with cycles throughout the development.

There are few references, such as Biodesign (Yock *et al*., 2015) and Liedkta and Ogilvie (2011), which work on aspects to increase the potential of value capture along the innovation process. However, when they do so, it is punctual at a specific part of the process, and there is no constant refinement and evolution of the value proposition based on the feedback acquired from the market.

The Biodesign (Yock *et al*., 2015) explores marketing issues in the initial phase of the process using stakeholder mapping and market analysis tools. These analyzes contribute to the criteria for choosing which market the team will enter. Then, in the concept screening phase, the Biodesign (Yock *et al*., 2015) also suggests that the type of business model and aspects of reimbursements should be considered criteria for selecting concepts. However, once the problem and the kind of solution are defined, the process takes a straightforward approach, and the solution concept and the value proposition are not necessarily reviewed with market information. The Liedkta and Ogilvie (2011) model, on the other hand, address themes related to marketing issues in two moments: firstly, in the initial stage, “what is”, in which the authors recommend performing the value chain analysis to guide the search for opportunities, and later at final stage “what works” to insert the solution in the market, when the team can use co-creation and learning launch techniques.

What is proposed in this work is to complement the use of marketing analysis tools at specific moments in the process with a continuous approach to refine the value proposition and revenue streams assumptions. In the same way the solution design is iteratively shaped based on the user’s feedback, the value proposition and revenue streams can be iteratively refined based on the feedback from potential buyers and decision-makers. Thus, it is intended to gradually build a solution aligned with market interests, avoiding a straightforward development approach or the late contact with potential buyers only in the last stage of the process.

Proposition 3.2) Interacting with primary sources of information, such as potential buyers and decision-makers, may provide a more realistic perspective of value capture

As seen in the Hemolysis Detector case, the potential of value capture was initially assessed through secondary sources, indicating that almost all laboratories were affected by blood sample rejection due to hemolysis, so they could be interested in the new solution. This approach provided an ideal scenario about the maximum potential market that the solution could reach. However, to actually capture value from such a market, the team must get in touch with potential buyers and make deals offering the solution. Thus, some factors related to the team's capability to reach potential customers and the lack of interest of buyers may reduce the initial and ideally estimated value capture potential. Thus, getting in contact with primary sources, such as potential customers and decision-makers, may provide a more realistic perspective of the team's capability to capture value in a serviceable market. In such a scenario, the prospect of value capture depends on the team and the market context.

Some prescriptive models of Design Thinking, like the one of Liedtka and Ogilvie (2011) and Biodesign (Yock *et al*., 2015), address marketing issues related to value capture. Liedtka and Ogilvie (2011), in the first stage "what if", propose to perform the value chain analysis to guide the choice of what opportunity and problem the team will tackle. The first stage of Biodesign (Yock *et al*., 2015) suggests performing the stakeholder mapping to estimate the potential market size to guide the choice of which market the team will enter. However, what's is being proposed by this work is to complement the analysis based on secondary sources mentioned by those models with the information directly collected by the interaction with potential buyers and decision-makers. Such interaction can take place at any stage of the innovation process.

In this context, possible activities are presented to exemplify and make more tangible the way to use the direct interaction with potential buyers throughout innovation projects. However, it is worth mentioning that the detailed investigation and validation of the effectiveness of such initiatives are the scope of future research.

As a suggestion of activities for the needs-finding stage, the interviews with potential customers could be conducted to assess how they deal with the problem and if they have already sought for any market solutions to solve it. Inquiring on past experiences of potential customers and users can help to understand how they make purchasing decisions and identify some reasons that have pushed them to hire solutions from the market. This type of information can generate insights to drive concept generation activities to conceive solutions that are minimally aligned with potential customers' buying interests.

In addition, in the concept validation stage, it may be helpful to use the opinion of potential buyers on the idealized concepts as a criterion to select and validate the concepts. Although, as at this stage, there is no functional solution developed, the team can build visual supports, such as presentations, flyers, videos, or 3D models that represent how the idealized solution would work. Then they can assess whether the potential customers are interested in what is being presented. With that, it would be possible to anticipate obtaining feedbacks and, if necessary, refine elements of the solution or value proposition without having committed resources in the concept development stage.

Proposition 3.3) Decision-making within the Design Thinking approach should consider the relationship between efforts to create use value versus the potential to capture value

As seen in the case of Sharps Counter, the relation between the need for development efforts to create value and the prospect of value capture with the solution was a major factor in the decision making to stop working on the solution. If the innovation team wants to have some return on the investments it has made, it is important to have a positive expectation in the balance between the development efforts and potential return. Therefore, as soon as the team can identify whether the prospect of return is much lower than the required efforts, they will avoid spending time and resources on building economically unviable solutions.

One way to increase the chances of having a positive prospect of value capture is to address a relevant problem that affects lots of people. However, a moderately relevant problem solved by a simple solution can still be profitable. In this sense, assessing whether it is worth continuing working on the development activities depends not only on the problem but also on the solution.

Thus, this works proposes to include the assessment of efforts required to create value versus the expectations to value capture as criteria in decision-making through the innovation process to seek solutions with favorable balance and profitable perspective. For example, in the concept generation stage, such criteria could be used to select concepts to be developed. However, in that moment of development, there are plenty of uncertainties. Therefore, as the team progresses in the innovation process and has greater clarity about technical complexity and the perception of value from potential buyers, it is worth reviewing whether the initial assumptions remain still valid.

Proposition 3.4) The interest of those responsible for development should be balanced with the interests of other stakeholders in decision-making

In the case studies, collaboration with healthcare professionals of partner institutions played a major role in guiding the innovation process, providing feedback and knowledge to enable solution improvement. But as there are restrictions related to resources, team capacity, and technology limitation is not always possible to meet all the user's feedbacks and expectations. In this sense, the team must list the priorities to act, seeking to create the most valuable solution. Furthermore, as both value creation and value capture involve multiple stakeholders, the team must deal with the different stakeholders' perspectives in decision-making.

The balance of multiple stakeholders' voices in medical device development is deeply studied by Ana, Umstead, Phillips, & Conner (2013). Those authors present a model to guide the innovation process balancing the voice of three main stakeholders: the voice of the customer, the voice of the business, and the voice of the technology. The authors argue that each stakeholder has diverse and unique needs relating to the solution, and the needs of one may highly affect the needs of another. Thus, it is not a trivial matter to balance their interest in decision-making throughout the solution development.

Although it is not new to the literature to include multiple perspectives in the product development process, the prescriptive models of Design Thinking tend to excessively focus on the user perspective. At the end of the process, if the created solution is worthless for its user, the organization will be unlikely to capture value with the solution, and the expectations of others stakeholders will probably not be met. Thus, it is comprehensible that the user's voice deserves greater relevance in the Design Thinking approach. However, the other stakeholders' voices cannot be neglected.

What is being proposed in this work is to clearly state the interest of people responsible for carrying the development and consider such interests in setting priorities and making decisions through the Design Thinking approach. This proposition is very close to the perspective of Ana *et al.* (2013) regarding the voice of business. However, those authors build their model for big companies, and the voice of business represents the corporate or marketing strategies, which are predominantly influenced by upper-level managers and executives. In the case studies, the innovation was not conducted by a single organization. Instead, there were the healthcare partner institutions, the university, and the development team. Even though they do not work and coordinate their activity as big companies do, with marketing and strategic plans, it is important to state their interests and minimally meet their expectation to keep people engaged in making the Design Thinking approach feasible and viable.

Proposition 3.5) *Complementing Design Thinking approach with specific technical and commercial competencies is required to implement and commercialize the solution*

The Design Thinking approach should be reinforced by senior competencies in the development process to create a more complete and robust solution to deliver value for its user. This need becomes more evident as the technical complexity of the solution increases. In Sharps Counter and Remote Cardio cases, to overcome the technical barriers to enable the use of the solution, the team had to involve members with more experience in technological projects to work on the solution. Those two cases had strict requirements regarding the patient safety condition, so the stakeholders expressly stated that it would not be possible to use the solution if such requirements were not met. In the Sharps Counter case, the device had to be completely sterilizable to be placed over surgery tables, and in the Remote Cardio case, the wearable should provide an accurate and reliable ECG signal to support the clinical decision about patient's care. In those cases, it is more evident that to deliver the intended value to its final user, the development team should have deep technical knowledge and capabilities to improve the solution to meet the requirements.

As Design Thinking principles are intentionally generic to create solutions in different contexts, they do not include the specific knowledge that each solution requires to be developed. In addition, as previously discussed in this section, the Design Thinking principles seemed to be much more useful to discover how to create value than to create value itself. Therefore, to actually enable value creation, it is important to complement the knowledge acquired through the Design Thinking approach with technical and specialized expertise to implement and deploy the solution.

Similarly, it is also needed to complement the Design Thinking approach with previous commercial competencies to capture value with the developed solution. As discussed in this section, value creation is not an immediate outcome of the Design Thinking application, so it is important to complement the approach with the knowledge to operate in the target market. In the Remote Cardio case, even though the team could not actually capture value with the solution, the knowledge acquired from market experts during the interviews of the AWC program allowed the team to anticipate challenges they could face along the trajectory to launch the solution in the market. For example, the team realized that prescribing physicians had a central role in adopting new solutions since they are the most influent decision-makers in the patient’s treatment. As explained by an interviewed investor, to influence these professionals is important to gain credibility among doctors. However, as the interviewee pointed out, credibility in the medical community is built among peers, so it would be necessary to have endorsement by some health professional and prove that the new solution would be safe, effective, and beneficial to the patient.

As each target market might have particular conditions, complementing the Design Thinking approach with specific knowledge about the market and target customers may increase the success potential of new solutions. Herzlinger (2006) discusses about the particular conditions of the healthcare market that may hinder innovation. Among the six forces that can drive or kill innovation presented by the author, there is the influence of the multiple players of the healthcare sector. Each player has its own agenda, and they often have conflicting interests. Considering a hypothetical case of new technology to perform exams, a hospital can view the technology as an opportunity to improve the quality of care and increase their portfolio of services, but health insurance companies might negatively perceive the same technology if it leads to a significant increase in the cost of care. Thus, as Herzlinger (2006) states, “unless innovators recognize and try to work with the complex interests of the different players, they will see their efforts stymied”.

Therefore, due to each market's special and particular conditions, for being able to capture value with the new solution, it is essential to have team members with the knowledge and capabilities to dialog with stakeholders and drive the commercialization of the solution. Such a commercial approach should complement the knowledge acquired through the Design Thinking application to promote the value capture with the solution.

6. CONCLUSION

This work brought together review-based and empirical studies to assess how the Design Thinking approach has influenced the outcome of innovation projects, focusing on creating and capturing value. In addition, following the framework of the Design Research Methodology, this work also brought contributions along the research stages that collaborate with Design Thinking conceptualization.

In the Research Clarification stage, the elaborated reference model - whose cornerstones are the works of Johansson-Sköldberg *et al*. (2013), Micheli *et al*. (2019), Brown (2008), Martin (2009) e Bowman & Ambrosini (2000) - indicates the main academic discourses of Design Thinking research and guides the positioning of this work in the literature. It is worth noting that this model can also be valuable to situate and establish a basis of comparison of further empirical studies.

In the second stage, Descriptive Study – I, a systematic review of the literature was carried out to find studies that related Design Thinking with creating new products and services. The first result obtained was an overview of the emerging literature, presenting studies for each application level of the reference model to exemplify how Design Thinking can be applied in innovation and management. In addition, the detailed analysis of publications focused on innovation projects indicated that, in general, studies tend to address more issues related to value creation than to value capture.

The Prescriptive Study stage started by summarizing the models from different authors to guide the Design Thinking approach in innovation projects. Although these models are organized in sequential macro stages that gather similar activities, the innovation team has complete freedom to adapt them to the context of the project. By performing comparative analysis, a four-step model of Design Thinking for innovation projects was elaborated, serving as the backbone in the evaluation plan of case studies.

In Descriptive Study - II, multiple cases of innovation projects for the health sector were analyzed. The projects were described according to the four steps of the Design Thinking model. Then, comparing the main topics and highlights of each case analysis, it was possible to draw correlations and infer how the Design Thinking approach has influenced the projects' outcomes. The multicase study indicates that the Design

Thinking application in a project-level context is more closely related to value creation than value capture.

Moreover, the presented propositions bring insights for theory building of Design Thinking and implications for practice. Within the path to value creation, Design Thinking serves as a compass directing the innovation team towards where they should put their efforts to increase user's perception of value. However, it is necessary to complement the Design Thinking approach with specific project knowledge to create a high-ended and robust solution to deliver the expected value to users. At the same time, although the capture of value is not an immediate outcome of the Design Thinking approach, the potential of capturing value has proved to be decisive for making the projects viable. Therefore, it is important to incorporate initiatives towards the value proposition refinement and validate the assumptions for capturing value throughout the innovation process to build solutions with good market prospects.

However, it is worth mentioning that a limitation of the case studies was that the analysis relied on three projects placed in the same sector of healthcare. Thus, to enlarge the validity of the aforementioned propositions, further research could assess how the Design Thinking approach has impacted the outcomes of projects developed in other sectors and contexts. Such studies may have a hypothesis-testing perspective to validate the propositions presented to answer how Design Thinking principles contribute to value creation and capture. For example, new studies can evaluate whether the hypothesis that the Design Thinking principles do not immediately lead to value capture remains valid in projects carried out in other sectors (such as retail, telecommunication, or agriculture) or projects focused on different types of solutions, such as purely service-based solutions or products sold directly to final consumers.

Finally, this work can also contribute to guiding further research with an investigative and propositive nature. For example, new studies can investigate how companies combine the Design Thinking approach with the senior technical and commercial knowledge to boost the new solution creation, or the studies can identify which tactics, tools, and methods can complement the Design Thinking principles to mitigate uncertainties related to the capture of value and increase the market potential of the solution.

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