

CLASSIFICAÇÃO E ANÁLISE COMPARATIVA DE METODOLOGIAS DE DESIGN: Propondo Categorias de Métodos

CATEGORIZATION AND COMPARATIVE ANALYSIS OF DESIGN METHODOLOGIES: Proposing Method Categories

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Resumo

Este estudo explora e categoriza métodos de metodologias de design clássicas e contemporâneas para aprimorar o desenvolvimento de dispositivos assistivos e médicos. Ao realizar uma revisão abrangente da literatura e uma análise comparativa, identificamos fases-chave de análise, síntese e implementação, mapeando diversos métodos dentro dessas fases. Examinamos metodologias clássicas influentes e abordagens modernas, destacando a continuidade e a evolução das práticas de design. Os resultados enfatizam a importância de integrar princípios fundamentais com técnicas contemporâneas para criar soluções eficazes e centradas no usuário. Esta pesquisa contribui para uma compreensão mais profunda das metodologias de design, defendendo uma abordagem sistemática que aproveite insights históricos e avance as práticas atuais para enfrentar desafios complexos de design.

Palavras-Chave: métodos de design; categoria de métodos; metodologia de design.

Abstract

This study explores and categorizes methods from classical and contemporary design methodologies to enhance the development of assistive and medical devices. By conducting a comprehensive literature review and comparative analysis, we identified key phases of analysis, synthesis, and implementation, mapping various methods within these phases. We examined influential classical methodologies and modern approaches, highlighting the continuity and evolution of design practices. The findings emphasize the importance of integrating foundational principles with contemporary techniques to create effective, user-centered solutions. This research contributes to a deeper understanding of design methodologies, advocating for a systematic approach that leverages historical insights and advances current practices to address complex design challenges.

Keywords: design methods; category of methods; design methodology.



1 Introduction

Design methodology is the science of tools and methods that can be applied to a project (ROOZENBURG & EEKELS, 1995). The integration of logical and systematic thinking into the Design process was crucial for the discipline to be taken seriously, making it teachable, learnable, and communicable. This methodological foundation, often attributed to Cartesian thinking, emerged prominently in the 1960s. The first generation of methodologists advocated for a Design methodology that involves a thorough understanding of the task at hand before any Design decisions are made, recognizing that different tasks necessitate different approaches (BURDEK, 2005). In this first moment, the use of methods is considered the base of the discipline's existence (REDIG, 2006). They used to divide the Design process into two distinct phases: Problem definition and Problem solution.

Problem Definition is an analytic sequence in which the designer determines all of the elements of the problem and specifies all of the requirements that a successful design solution must have. Problem Solution Is a synthetic sequence in which the various requirements are combined and balanced against each other, yielding a final plan to be carried into production (BUCHANAN, 1992, page 15).

Traditionally, Design methodology has been viewed through a linear lens, where problem definition (analysis) precedes problem solution (synthesis). However, design theorists began to critique this linear perspective, prescribing that designers must first generate a solution conjecture, to then analyze and evaluate it (ROOZENBURG, 2002).

Design methodologies can be categorized as: descriptive, when it describe what was done, or prescriptive, when it defines steps that must be followed; linear, where processes follow a sequential flow with defined beginnings and ends, or cyclical, featuring feedback loops that can be repeated multiple times within the stages. These feedback loops can be flexible or discriminated between phases (VASCONCELOS 2010).

The analysis-synthesis evolution both from expanding phases as from linear to cyclical development can be observed in Don Koberg and Jim Bagnall's (1972) Seven-Step Process. Initially, their analysis-synthesis process model involved breaking situations into parts and then reassembling them. However, the authors quickly expanded this approach by further breaking down the process into seven distinct steps. In their refined model, Koberg and Bagnall incorporated cyclical and flexible feedback loops into their seven-stage framework, noting that one stage need not to follow another. They proposed that the Design process is continuous, highlighting the non-linear dynamic nature of Design development. This approach allows alternative views of the design process, where different stages can progress simultaneously rather than in a strict sequence (DUBBERLY, 2005) (Figure 1).

Banathy (1996) presents an interesting interpretation regarding the analysis-synthesis model. For the author, Design manifests in a dynamic interaction of divergence and convergence (Figure 2). In this framework, we first diverge by creating a number of alternatives, and then converge as we evaluate and select them. This is a dynamic cyclical process that keeps happening until there is confidence in the production viability.

Divergent thinking is characterized by ideation and a fluency with unusually associated ideas: it moves away from the known and predictable. Any one of the ideas generated may be acceptable. This kind of thinking seems natural to designers, and is highly productive where value is placed on difference for its own sake. Conversely, convergent thinking progresses toward the production of a single, right answer to a problem, and is a style of thinking characterized by a logical, analytical approach to problem-solving. It moves



towards the known and the specified. This kind of thinking seems more natural to scientists and technologists. Designers exhibit playfulness and a readiness to generate ideas, and these can sometimes be humorous or ridiculous. Designers' creativity also seems to be linked strongly to intuition (DURLING, CROSS and JOHNSON, 1996, page 1).

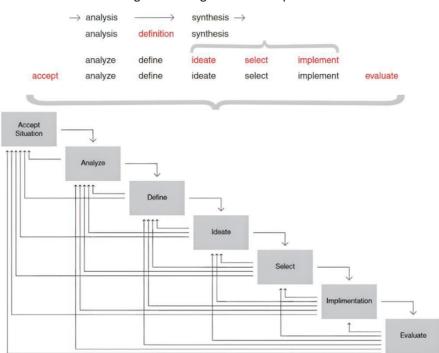
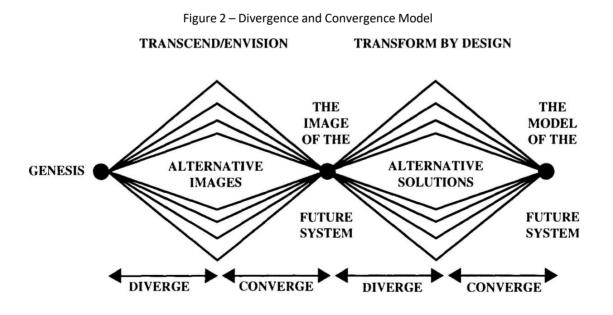


Figure 1 - Evolution of Don Kolberg and Jim Bagnall Seven-Step Process as a Cascade with Feedback

Source: Dubberly (2015)



Source: Bannathy (1996)

Significant gaps exist in assistive devices design, particularly in using structured methods (PICHLER & MERINO, 2017). In Brazil, unsystematic development has caused technological stagnation, relying on incomplete models or adaptations that often fail to meet user demands. Key



issues include the lack of design resources, neglect of aesthetics, exclusion of key stakeholders, and empirical evaluation methods (SANTOS & SILVEIRA, 2021). Medical devices also demands rigorous Design methods, ensuring they meet stringent regulatory requirements of safety and efficacy (OGRODNIK, 2020).

The development of assistive and medical devices necessitates a robust and systemic approach to design methodology, yet the existing literature reveals a significant gap in comprehensive methodologies tailored to these fields. The creation of effective assistive devices and medical devices relies on a structured development process that incorporates a variety of design methods. Understanding the different kinds of methods used in various design methodologies is essential to address the unique challenges and requirements of these devices. Thus, the objective of this paper is to identify and categorize these methods, providing method categories that should be presented into a cohesive design methodology, thus, can be assertive used tailored for assistive and medical device development.

2 Methodology

This study employs a qualitative research design, utilizing a comprehensive literature review and comparative analysis. The research focuses on identifying methodologies and classifying the methods recommended around the delimited phases in each design process.

The foundation of this research is built on an extensive review of design methodologies documented over several decades. To compile a comprehensive list of methodologies, we referenced the works of Ximenes & Neves (2008) and Vasconcelos (2009), who compiled a catalog of design methodologies covering the main approaches from the 1960s to the 2000s. Their studies provided insights into the contextual influences of each timeline and proposed a classification model for these methodologies. Dubberly (2005) contributed with a compendium of models, presenting several design methodologies with reflections and further classifications, enriching our understanding of the evolution and diversity of design methodologies.

To establish a comprehensive framework for analysis, we first identified the main phases from these several seminal design methodologies. By examining these methodologies, we identified the key phases that are common across different approaches. These phases - analysis (identified as green), synthesis (identified as blue), and implementation (identified as red) - serve as the foundation for our comparative analysis. Each methodology offers unique methods and tools within these phases, providing a rich tapestry of techniques that inform contemporary design practice, that were further broken down into categories. For clarity, we refer to these methodologies as the "Classic Design Methodologies," encompassing a broad spectrum of influential approaches documented over the past several decades.

Weber's (2010) doctoral thesis analyzed this classical design methodologies and specifically examined the methods utilized by influential authors such as Jones, Lobach, Bonsiepe, Bomfim, Baxter, Morales, Bürdek, and Cross. This analysis led to the recommendation of 40 methods for teaching design, which were categorized and presented.

In this sense, the primary method data sources for this study are the design methodologies derived from the aforementioned classic compilations, alongside contemporary methodologies such as the Double Diamon (DESIGN COUNCIL, 2004), Human-Centered Design (IDEO, 2015), Design Thinking (INSTITUTE OF DESIGN AT STANFORD, 2018), Guia de Orientação para o Desenvolvimento de Projetos (GODP) (MERINO, 2016), AT-D8sign (SANTOS & SILVEIRA, 2020), and Medical Device Design (OGRODNIK, 2020).



Finally, the study undertakes a thorough analysis of the similarities and differences among the categorized methods within the three macro-phases across the selected design methodologies. By comparing these methods, the research aims to highlight the overlap and divergence in the approaches taken by various methodologies, providing a comprehensive understanding of their practical applications. This step ensures that the method categories are robust and well-defined, offering valuable insights into how these methodologies can be effectively integrated and adapted for the development of different projects. The outcome of this similarities analysis contributes to the understanding of a cohesive design methodology.

3 Results

3.1 Classic Design Methodologies

Board 1 illustrates the diverse yet interconnected approaches to the design process. By mapping these phases, we can see the evolution of design thinking and the commonalities that have emerged over time. This comparative analysis not only highlights the shared foundations of these methodologies but also underscores their unique contributions to the field of design. Understanding these phases allows for a deeper appreciation of the structured yet flexible nature of the design process, providing valuable insights for contemporary design practice. Despite variations in terminology and specific focus, there are notable similarities and thematic consistencies that emerge upon closer examination.

Most methodologies start with an analysis phase, which involves understanding the problem, defining elements and functions, and collecting data. This phase is crucial for setting the groundwork for the design process. The synthesis phase typically involves ideation, combining elements, generating alternatives, and developing concepts. This phase focuses on creative problem-solving and generating potential solutions. Evaluation is a recurring phase where concepts are tested, analyzed, and refined. This phase ensures that the proposed solutions meet the necessary criteria and requirements. Decision-making or selection is often a distinct phase, where the best solutions are chosen based on evaluation criteria. This phase is critical for moving forward with the most viable options. Implementation involves developing and executing the chosen solution. This phase may include detailed design, manufacturing, and market launch, depending on the methodology.

Methodologies like Asimow's and Roozenburg and Eekels' emphasize iterative refinement through optimization and simulation, ensuring that the solution is continuously improved. Pugh and Eppinger and Ulrich's methodologies highlight the importance of market analysis and identifying customer needs, ensuring that the design process is aligned with user requirements. Munari's methodology stands out for its focus on creativity, materials, and technology, incorporating experimentation and verification phases to foster innovation.



Board 1 – Main Design Phases in Classic Design Methodologies

Morris Asimow	John Chris Jones	Don Kolber g and Jim Bagnal I	Bernhard Burdek	Bruno Munari	Gui Bonsiepe	Stuart Pugh	Steven D. Eppinger and Karl T. Ulrich	Roozen burg and Eekels	Cross
Analysis	Define Elemen t	Accept	Problemati zation	Problem Definition	Problemati zation	Market	Identify Custome r Needs	Analysi s	Exploratio n
Synthesis	Define Functio n	Analyz e	Situation Analysis	Problem Compone nts	Analysis	Specific ation	Establish Target Specifica tions	Sintesy s	Generatio n
Evaluatio n	Analyze Costs	Define	Problem Definition	Data Collection	Problem Definition	Concept Design	Generat e Product Concept s	Simulat ion	Evaluatio n
Decision	Consid er Alterna tives	ldeate	Alternative Generatio n	Data Analysis	Alternative s Generatio n	Detail Design	Select Product Concept s	Evaluat ion	Communi cation
Optimizati on	Combin e Elemen ts	Select	Evaluation and Selection	Creativity	Project Developm ent	Manufa cture	Test Product Concept s	Decisio n	
Revision	Prelimi nary Sorting	Imple ment	Developm ent Planning	Materials and Technolog Y		Sell	Set Final Specifica tions		
Implemen tation	Technic al Analysi s	Evalua te		Experimen tation			Plan Develop ment		
	Selecti on			Model					
	Final Analysi s			Verificatio n					
	Present			Constructi on Design					

Source: Developed by the Author based in Ximenes & Neves (2008); Vasconcelos (2009) and Dubberly (2005)



3.2 Weber Recommended Methods Based in Classic Design Methodologies Methods

Weber's (2010) recommended methods are categorized and presented in Board 2, organized according to the three macro-phases of design: analysis, synthesis, and implementation. This table provides a clear and structured overview of the methods, illustrating their application within each phase of the design process.

In the Analytic macro phase, User-Centered Analysis focuses on understanding user needs and behaviors through methods like user research, interviews, and social relation analysis. Product and Market Analysis evaluates the market context and product characteristics, involving market needs assessment and various product analyses. Stakeholder Involvement ensures engagement from all relevant parties. Requirements and Specifications define and prioritize project needs, compiling comprehensive requirement lists and establishing a project briefing.

In the synthesis phase, Visualization and Representation methods help conceptualize and communicate ideas using techniques such as Personas and Scenarios, Concept Panels, and Mental Maps. Creative Ideation methods stimulate creation of alternatives through Brainstorming, 635 Method, MESCRAI, and others. Concept Development and Assessment involves refining design concepts with methods like Mockups and Models. Decision-Making Tools offer structured approaches to select the best solutions, ensuring alignment with project goals and user needs.

Weber's implementation phase includes Detailed Design and Configuration methods for refining design details, ensuring feasibility and manufacturability. Prototyping and Testing methods create prototypes to test and validate designs, resolving issues before full-scale production. Documentation and Finalization methods provide guidelines for manufacturing and assembly, ensuring accurate reproduction and maintenance of the design over time.

Analytic	Synthetic	Implementation	
User-Centered Analysis	Visualization and Representation	Detailed Design and Configuration	
Product and Market Analysis	Creative Ideation	Prototyping and Testing	
Stakeholder Involvement	Concept Development	Documentation and Finalization	
Requirements and Specifications	Decision Making		

Board 2 – Classification Of Methods in Classical Design Methodology

Source: Developed by the Author Based in Weber

3.3 Double Diamond Design Methodology and Recommended Methods

Design Council's (2004) applies the divergent-convergent model in their Double Diamond Design methodology. As we can see in Figure 3, this model is also cyclical as they state that no idea is ever finished. Its four macro-phases are Discover; Define; Develop and Deliver and it works with four core principles: People first; Communicate; Collaborate and co-create; Iterate. Iteration regards to the cyclical process of constantly getting feedback on how products and services are working and continue to improve them.

Double Diamond also presents a methods bank, which consists of design methods to help the utilizer to explore, shape and build his ideas to address their challenges. As we can see in board 3, although the macro-phases are presented in sequence, when analyzed under the analysis-



synthesis-action perspective, the categories created don't respect this organization method. This can be because of the iterative nature of the methodology.

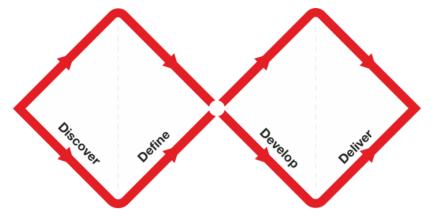


Figure 3 – Design Council Double Diamond Methodology

Source: Design Council (2024)

The Double Diamond methodology begins with a strong emphasis on analysis during the Discover and Define phases. In the Discover phase, the methods are essential for gathering comprehensive information about the project, stakeholders, and users. Moving into the Define phase, the methods further refine this gathered data. The techniques are used to prioritize information and establish criteria that guide the design process, ensuring that all insights are systematically analyzed to inform the next stages.

Board 3 – Classification	Of Methods in Clas	sical Design Methodology
Duard 5 Classification	Of Methous III Clas	sical Design Methodology

Discover	Define	Develop	Deliver
Project Initiation and Planning	Information Prioritization and Analysis	Context Visualization and Representation	Implementation and Rollout
Stakeholder Engagement and Collaboration	Mapping and Understanding User Experience	Prototyping and Testing	Evaluation and Feedback
Understanding User Needs and Context	Assessment Criteria		Knowledge Management
Alternatives Visualization and Representation		-	

Source: Developed by the Author Based in Design Council

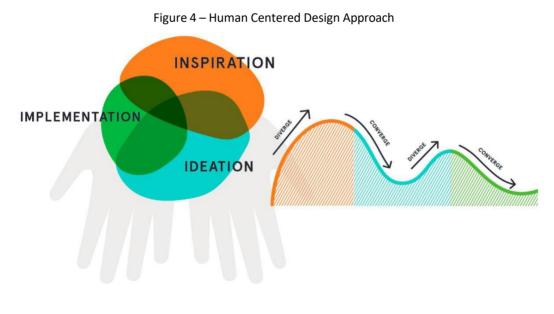
In the Discover phase, Alternatives Visualization and Representation methods, such as fast visualization, help in conceptualizing initial ideas. This synthesis continues more robustly in the Develop phase, with Context Visualization and Representation techniques like character profiles, scenarios, and service blueprints. These methods help in visualizing the context and developing a comprehensive understanding of how the product will interact with its users. This phase bridges the gap between raw data and actionable ideas, but methods for generating alternatives are scarce and not on focus.



The final part of the Double Diamond methodology emphasizes action, covering the Develop and Deliver phases. In the Develop phase, Prototyping and Testing methods are employed to bring the concepts to life and test their feasibility. This hands-on approach helps in identifying potential issues and making necessary adjustments. The Deliver phase categories focus on methods like final testing and feedback loops, ensuring that the product is thoroughly tested, launched effectively, and continuously improved based on user feedback. Knowledge management ensures that the methods used are documented and shared, supporting ongoing improvement and innovation in the design process.

3.4 Human Centered Design Methodology and Recommended Methods

Human-Centered Design (2015), like the Double Diamond, recognizes that anyone, not just professional designers, can engage in the design process, unlocking their potential as dynamic problem solvers with a bit of creative confidence. Empathy is at the heart of Human-Centered Design, as it involves understanding the lives and perspectives of the people you are designing for, making them central to the design process. This methodology is cyclical and iterative, starting with the people you're designing for and evolving through continuous feedback and refinement to create tailored solutions. The process includes three phases: Inspiration, where designers immerse themselves in the users' lives to build deep empathy; Ideation, where insights are translated into a multitude of ideas and prototypes; Implementation, where the refined solution is brought to life and introduced to the market (Figure 4). Additionally, the Field Guide offers 57 methods to guide designers from the initial challenge framing to market launch, which are categorized in board 4. The methodology also employs the divergence and convergence interpretation, exploring a broad range of solutions before narrowing down to those with the greatest potential impact, iterating until a market-ready solution is achieved (Figure 4).





In the Human-Centered Design methodology, the Inspire phase methods focuses on identifying the main design problem and organizing the project and the team. It also encompasses Secondary Research, which involves understanding what has already been addressed in relation to the design problem in both literature and real world applications. Lastly, User-Centric Methods, such as Interviews and Engage with Users, often marginalized ones, focus on building empathy and 15° Congresso Brasileiro de Pesquisa e Desenvolvimento em Design, Manaus (AM)



gain deep insights into their needs and experiences.

In the Ideation phase, methods are grouped into five categories. This methods helps structure and prioritize gathered information, and also does not limit the phase into synthesis methods. The Creation Process methods, with methods like Brainstorm and Create a Concept, generates alternatives and motivates creation. Evaluation of Concepts resumes an important phase among the first design authors, assessing the viability of the developed concepts. Lastly, the methods focus on how prototypes will perform in real-world scenarios, integrating feedback and Iteration to ensure continuous improvement and alignment with user needs and decreasing risk in the implementational phase.

Implementation methods are divided into four categories defining the project's progression and ensuring necessary resources. The focus is to create, test and evaluate the prototype, define its success and keep Iterating and refining it.

Discover	Define	Develop	Deliver
Project Initiation and Planning	Information Prioritization and Analysis	Context Visualization and Representation	Implementation and Rollout
Stakeholder Engagement and Collaboration	Mapping and Understanding User Experience	Prototyping and Testing	Evaluation and Feedback
Understanding User Needs and Context	Assessment Criteria		Knowledge Management
Alternatives Visualization and Representation			

Board 4 – Human Centered Design Methods Categorized	
bourd + Human centered besign Methods categorized	

Source: Developed by the Author Based in IDEO

3.5 **Design Thinking Methodology and Recommended Methods**

Institute of Design at Stanford presents a set of tools and methods called Design Thinking Bootleg (2018, Figure 5). They present their phases as: empathize; define; ideate; prototype; test. However, the definitions of these components are somewhat superficial, offering a broad outline without delving into the deeper nuances and practical applications of each phase. Additionally, the linearity of the process is not clearly defined, leaving ambiguity about how these phases interact and overlap. The rest of the Design Thinking Bootleg provides a wealth of tools and methods to be applied at each phase, filling in some details and offering practical guidance.

In the D.School Design Thinking Bootleg methodology, numerous methods are repeated across different phases, underscoring the iterative and cyclical nature of the design process. They are categorized in board 5. Methods such as Storytelling, shooting and editing video, and the "I Like, I wish, What If" are integrated throughout all stages. This approach emphasizes continuous documentation, reflection, and user feedback, ensuring that the design process remains user-centered and adaptive to new insights. Storytelling is pivotal in conveying user insights and design narratives, while video recording ensures comprehensive documentation of the process and user interactions. Feedback mechanisms like "I Like, I wish, What If" provide real-time reflections and help in refining the design at every step.





Source: D.School (2018)

The Empathize phase focuses on understanding and immersing in the user's world. This phase includes Project Initiation and Planning methods, as well as Stakeholder Engagement methods. Understanding User Needs is achieved through Interviews and visual panels to help and visualize the user's context. Prototyping for Empathy and User-Driven Prototyping ensure early-stage user centered prototypes.

Empathize	Define	Ideate	Prototype	Test
Project Initiation and Planning	Information Prioritization and Analysis	Alternative Proposal	User Centered Prototyping	User Centered Prototyping
Team Engagement and Collaboration	Visualize User Context	Selection of Proposals	Creative Ideation	Continuous Feedback and Documentation
Understanding User Needs	Requirements and Specification	Continuous Feedback and Documentation	Selection of Proposals	
Visualize User Context	Alternative Proposal		Continuous Feedback and Documentation	
User Centered Prototyping	Team Engagement and Collaboration			
Continuous Feedback and Documentation	Continuous Feedback and Documentation			

Source: Developed by the Author Based in D.School

In the Define phase, methods are oriented towards synthesizing and analyzing information to frame the problem and propose alternatives. Information Prioritization methods help in organizing insights and establish requirements and specifications. The phase also focuses on generating alternative solutions and clear team communication.



During the Ideate phase, the focus shifts to generating and refining ideas. Alternative Proposal methods such as Brainstorming stimulate creative thinking. Selection of Proposals is achieved through methods like Impose Constraints, ensuring the most viable ideas are chosen.

In the Prototype and Test phases, the emphasis is on creating tangible solutions and validating them with users. Prototyping and testing methods ensure that prototypes are usercentered and iteratively refined based on feedback. Creative Ideation methods like Scenes/Props/Roles help in visualizing context and refine the selected ideas. Continuous feedback and documentation, including storytelling and video recording, ensure that the prototypes are evaluated comprehensively and iteratively improved based on user insights.

3.6 GODP Methodology and Recommended Methods

It is based on Human Centered Design and Design Thinking that Merino (2016) developed the Orientation Guide to Developing Projects (GODP, Figure 6). Its configuration is cyclical and involves 8 phases (-1, 0, 1, 2, 3, 4, 5 and 6), also classified among inspiration, ideation and implementation macro-phases. Furthermore, it presents recommendations of tools in specific key phases, like the Universal Design Checklist. The project is initiated by defining the three reference blocks: Product; User; Context. The phases numeration beginning at -1 is a differentiation element in the methodology, as opportunities and prospection generally are prior to project development and tend to be disregarded among Design Methodologies. This might be because of the author's proximity to the Design Management field. Board 6 presents the recommended methods categorized.





Source: Merino (2016)

The Inspiration phase in the GODP methodology focuses on identifying and creating opportunities for a project. This includes evaluating the financial viability of project demands and opportunities and assessing the technical capacity of the team and available resources. Market and product analyses are conducted through preliminary market surveys and detailed market studies, ensuring a thorough understanding of the landscape. Additionally, legal and technical feasibility is



examined to ensure compliance with patents, legislation, and organizational procedures. User and context research, such as preliminary field research, field surveys, and anthropometric studies, provide a deep understanding of the user needs and context. Finally, existing knowledge is reviewed, and analytical techniques are decided upon to guide the project forward.

Inspiration	Ideation	Implementation	
Identify Project Opportunities	Data Classification and Analysis	Testing and Legal Compliance	
Evaluate Resources and Capabilities	Requirements Definition	Production Preparation	
Market and Product Analysis	Creative Ideation	Post-Production and Monitoring	
Legal and Technical Feasibility	Alternative Selection and Refinement		
User and Context Research	Proposal Presentation		
Existing Knowledge and Method Selection			

Board 6 – GODP Methods Category

Source: Developed by the Author Based in Merino

In the Ideation phase, data gathered during the inspiration phase is organized and analyzed. This includes cataloging data, selecting relevant information, and applying techniques such as functional and structural analysis to define the problem clearly. Requirements for the project are defined, setting the stage for creative ideation. Concepts are developed using semantic panels, and ideas are generated through brainstorming sessions. Alternatives are created and prototyped, with criteria defined for proposal selection. Refinement of these proposals ensures they meet the set requirements, and the final proposal is presented in a comprehensive manner.

The Implementation phase is where ideas are turned into tangible solutions. Alternatives are tested to ensure they meet the necessary criteria and function as intended. Legal authorizations are requested, and legal records are forwarded to ensure compliance. Production is prepared by specifying items and setting up production with third parties. Tests are conducted in real situations to validate the solutions. Post-production activities include following up on production, collecting results, and checking the impacts of the product. Continuous monitoring of performance is conducted to ensure the product meets expectations, and new opportunities are identified for future iterations and improvements.

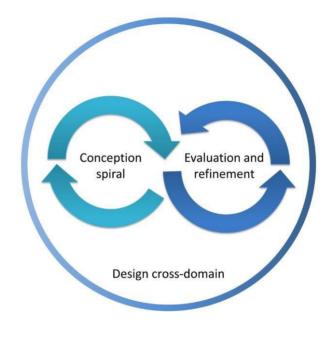
3.7 AT-D8sign Methodology and Recommended Methods

While many existing proposals merely outline the steps of an assistive device development process, with minimal use of design tools and techniques, the AT-d8sign methodology offers a more comprehensive approach. This methodology focuses on developing Assistive Technology with the aid of Additive Manufacturing and is divided into three main phases: Design Cross-Domain, Conception Spiral, and Evaluation and Refinement (Figure 7). The Design Cross-Domain phase aims to create a fundamental structure of knowledge, skills, and experiences for development,



integrating all relevant domains. The Conception Spiral is the most creative phase, where concepts and solutions for the assistive device are developed and refined using design tools and techniques, with mock-ups, prototypes, and products manufactured via additive manufacturing. The Evaluation and Refinement phase assesses user and stakeholder satisfaction with the assistive device, along with its functionality and effectiveness. The process is iterative and dynamic, with a continuous flow of information between stakeholders and phases, which are not strictly sequential but develop in a parallel and cyclic manner, especially in phases 2 and 3. New individuals and domains may be added as new needs are identified during the process. The recommended methods are categorized in board 7 (Santos & Silveira, 2020).





Source: Santos & Silveira (2020)

In the Design Cross-Domain phase of the AT-D8sign design methodology, the focus is on stakeholder engagement, research, user surveys, and project planning. This phase begins with identifying and integrating various design domains, ensuring that all relevant stakeholders are engaged in the process. Comprehensive bibliographic and technological research is recommended to understand the current state of the art and techniques, including patents and commercial products. User surveys are performed to gather insights and understand user needs. The project is then meticulously planned and scheduled, setting clear goals and deadlines to guide the design process.

The Conception Spiral phase revolves around a clear definition of design requirements, followed by the generation of multiple concepts. These concepts are translated into virtual models, providing a visual and functional representation of the ideas. Finally, materials and manufacturing methods are carefully selected to ensure that the designs can be feasibly produced and meet all necessary standards.

The Evaluation and Refinement phase involves presenting concepts, engaging with users, conducting tests, and following up on delivery. Concepts are presented to stakeholders for feedback. An adaptation period allows for follow-up with users and necessary training to ensure



smooth implementation. Both qualitative and quantitative tests are conducted to assess the functionality and effectiveness of the designs. This phase concludes with the delivery of the final product and ongoing follow-up to ensure it meets user needs and performs as expected.

Design Cross-Domain	Conception Spiral	Evaluation and Refinement
Stakeholder Engagement	Requirements Definition	Concepts Presentation
Bibliographic and Technological Research	Concepts Generation and Modelling	User Engagement
User Survey	Materials and Manufacturing Selection	Testing and Assessment
Project Planning and Schedule		Delivery and Follow Up

Source: Developed by the Author Based in Santos & Silveira

3.8 Medical Device Design Methodology

Ogrodnik (2020) outlines a comprehensive Medical Device Design Process that emphasizes fundamental design principles, such as the convergent-divergent model. This process underscores the importance of thoroughly understanding project requirements and developing a detailed product design specification. The author highlights the necessity of involving all stakeholders to identify these requirements and to generate a wide range of ideas, ultimately selecting the most promising one through a robust design process. Transforming this potential solution into a final product involves another cycle of divergence and convergence, incorporating iterative feedback. The methods categorization is presented in board 8.

Design Specification	Concepts Generation	Detailed Design	Evaluation and Post Market
Defining the Design Problem	Creativity and Ideation	Design Implementation	Evaluation and Testing
Stakeholder Analysis	Concept Selection and Analysis	Evaluation and Calculation	Outcome and Compliance
Requirements Definition	Optimization and Refinement	Component and Material Selection	
Literature Review			-

Source: Developed by the Author Based in Ogrodnik

The Design Specification phase in medical device design is centered around clearly defining the design problem and conducting a thorough stakeholder analysis. This analysis includes understanding the needs and requirements from customers, regulatory bodies, technical



specifications, performance benchmarks, biomechanics considerations, sales targets, manufacturing constraints, packaging and transportation logistics, and environmental impact. This phase also involves defining detailed requirements based on conducting an extensive bibliographic research to gather and analyze relevant content.

In the Concepts Generation phase, creativity and ideation are crucial. A creative space is established to foster idea generation using methods such as radial and analogue thinking, brainstorming, and morphological analysis. The generated concepts are then evaluated and selected using criteria and weighted criteria assessments, risk analysis, and optimization methods. Further refinement is done through Failure Modes and Effects Analysis (FMEA) principles to ensure the concepts are optimized. Suppliers are also contacted to check the feasibility of these concepts.

The Detailed Design phase focuses on implementing the design, which includes the design realization process, assembling the design team, and delivering the final project. It involves detailed calculations, Finite Element Analysis (FEA), and the selection of materials and components using CAD modeling. The Evaluation and Post Market phase involves rigorous evaluation and testing, including clinical studies and further FEA. It includes data analysis, outcomes presentation, healthcare value analysis, labeling, IP protection, and regulatory market approval (including FDA). This ensures that the device meets all necessary standards and performs effectively in real-world scenarios, highlighting the stringent regulations and critical nature of medical devices.

3.9 Similarities Between the Studied Design Methodologies

The diverse design methodologies analyzed share several foundational principles but also exhibit unique approaches tailored to their specific contexts. Board 9, 10 and 11 shows the analysis, synthesis and action methods that overlap in each methodology as new categories, while the text seeks to further analyze their similarities and differences.

	Weber	Double Diamond	HCD	Design Thinking	GODP	AT- D8sign	Medical Device Design
Defining the Problem			х				х
Project Planning, Team Engagement, and Stakeholder Identification	x	х	x	х	x	х	х
Market Analysis	х				х		
User Analysis	х	х	х	х	х	х	
Organizing and Analyzing Data		х	х	х	х		
Conducting a Literature Review			х		х	х	х
Defining Clear Requirements	х	х	х	х	х	х	х

Board 9 - Analysis Methods Similarities and Differences Across the Studied Methodologies

Source: Developed by the Author Based in Weber (2010), Design Council (2024), IDEO (2015), D. School (2018), Merino (2016), Santos & Silveira (2020) and Ogrodnik (2020).



The first major category exhibited in the analysis methods is related to the problem definition. The primary difference lies in the nature of the outcomes: HCD often aims for broader social and user-oriented inspiration, while Medical Device Design is more specific, typically grounded in clinical and regulatory needs.

Every methodology emphasizes the importance of planning, team engagement, and stakeholder collaboration, albeit with varying focal points. Despite the different terminologies, the underlying principle is the same: thorough initial planning and continuous stakeholder engagement are critical for successful design outcomes. This universal approach underscores the necessity of establishing a clear, actionable plan and ensuring that all relevant voices are heard and considered.

Market Analysis appears prominently in Weber and GODP methodologies but is notably less emphasized or absent in others. The limited presence of explicit market analysis in some methodologies suggests that these methods might inherently incorporate market considerations into broader phases such as stakeholder engagement or problem definition. However, explicit market analysis remains crucial for ensuring the product's market fit and competitive edge, particularly in commercial and highly regulated industries.

User Analysis is a central theme across most methodologies, highlighting the importance of understanding user needs and behaviors. While Medical Device Design incorporates user needs within stakeholder analysis, the explicit focus in other methodologies reflects a broader trend towards human-centered approaches.

Organizing and Analyzing Data is crucial for making informed design decisions. Data organization methods highlight the importance of transforming raw data into actionable insights. This step is vital for guiding the design process and ensuring that decisions are based on a thorough understanding of the gathered information.

Conducting a Literature Review is essential for understanding existing knowledge and identifying gaps. Literature reviews serve to ground the design process in existing knowledge, helping to avoid redundancy and identify opportunities for innovation. This step is particularly critical in fields like medical device design, where regulatory compliance and safety are paramount.

Defining Clear Requirements is universally acknowledged as a critical phase in Design. The consistent emphasis on requirements definition across methodologies highlights its importance in establishing clear, actionable goals and constraints. This step ensures that the design process remains focused and aligned with user and other relevant stakeholder needs, regulatory standards, and market demands.

The analysis methods across these design methodologies exhibit significant overlaps, particularly in project planning, stakeholder engagement, user analysis and requirements definition. These commonalities underscore the foundational principles of effective design processes, highlighting the importance of comprehensive preparation, collaboration, and definition for achieving successful outcomes. However, each methodology also brings unique elements tailored to its specific context, such as the rigorous regulatory focus in medical device design or the broad inspiration-driven approach in HCD, Design Thinking and Double Diamond. Understanding these nuances allows designers to select and adapt methods that best fit their project's specific needs and constraints.

The synthesis methods can be broadly grouped into four main categories: Visualization and Representation, Creative Ideation, Concept Creation and Evaluation, and Optimization and Iteration. Each category highlights the methodologies' shared goals of understanding, creativity,



rigorous evaluation, and continuous improvement, while also showcasing their unique approaches.

	Weber	Double Diamond	HCD	Design Thinking	GODP	AT- D8sign	Medical Device Design
User and Context Visualization/Representation	х	х		х			
Creative Ideation	х			х	х		х
Alternative Generation and Assessment	x		x	х	х	х	х
Optimization and Iteration			х				х

Board 10 – Synthesis Methods Similarities and Differences Across the Studied Methodologies

Source: Developed by the Author Based in Weber (2010), Design Council (2024), IDEO (2015), D. School (2018), Merino (2016), Santos & Silveira (2020) and Ogrodnik (2020).

User and Context Visualization/Representation methods are crucial for synthesizing information about users and their environments. These methods aim to create a clear, visual understanding of user experiences, needs, and contexts. Across methodologies, tools such as user journeys, personas, and experience maps are commonly used to transform complex data into accessible and actionable insights. This visualization process is vital for aligning the design team's understanding and maintaining a user-centered focus throughout the project. While all methodologies emphasize the importance of visual tools, they vary in their specific applications and depth. Some methodologies provide detailed, technical visual representations, while others focus on structured exploration of different design paths and user interactions. The underlying principle remains the same: effective visualization fosters a deeper understanding of users and their contexts, guiding the design process toward more informed and empathetic solutions.

Creative Ideation is a step where designers generate innovative concepts to address user preferences. This phase involves creativity techniques to explore the aesthetic, symbolic, and practical dimensions of the product. The goal is to define what the product should communicate, ensuring it resonates emotionally and functionally with users. Methodologies differ in how they channel creativity. Some prioritize emotional and symbolic aspects, using tools like mood boards and panels to inspire innovative thinking. Others ensure that creative ideas are grounded in practical applications, aligning closely with market demands and regulatory constraints. Despite these differences, the emphasis on creativity as a driving force for innovation is a common thread, highlighting the importance of fostering an environment where new ideas can flourish.

The Alternative Generation and Assessment are central to synthesizing viable design solutions. This phase involves developing multiple alternatives, assessing them against the creative ideation criteria and measurable requirements and selecting the most promising ones. Structured evaluation processes, including decision matrix and house quality are crucial for ensuring that the chosen concepts meet user needs and project goals.

Different methodologies employ various approaches to concept creation and evaluation. Some methodologies are highly iterative, continually refining concepts based on user feedback and testing. Others are more structured, with formal processes for generating, presenting, and selecting



alternatives. The consistent emphasis on developing and rigorously evaluating multiple concepts underscores the importance of thorough exploration and informed decision-making in the design process.

Optimization and iteration are essential for refining design solutions based on continuous feedback. This process ensures that the design evolves to better meet user needs and regulatory standards. Feedback loops, whether from user testing or formal evaluations, drive iterative improvements, enhancing the design's functionality, usability, and overall effectiveness. The approach to iteration and feedback varies among methodologies. Some focus heavily on user-centric feedback, emphasizing continuous refinement based on direct user input. Others incorporate formal testing and stakeholder feedback, especially in contexts where compliance and safety are paramount. The shared goal is to ensure that the final design is not only innovative but also thoroughly vetted and optimized for real-world use.

The synthesis methods across these design methodologies reveal a shared commitment to user-centered design, creative ideation, rigorous evaluation, and continuous improvement. While the specific applications and emphases may vary, the foundational principles remain consistent. Effective visualization and representation, fostering creativity, thorough concept development and evaluation, and continuous optimization through feedback are critical components of successful design processes. Understanding these similarities and differences allows designers to adapt and integrate methods that best fit their project's specific needs and constraints, ensuring a balanced and effective approach to design.

Implementation methods in various design methodologies emphasize practical execution and ensure the designed product or service meets its intended purpose effectively. Five main categories encapsulate these methods: planning and resource allocation, component, material and manufacture selection, prototyping and testing, implementation and follow-up, and documentation and information sharing.

	Weber	Double Diamond	HCD	Design Thinking	GODP	AT- D8sign	Medical Device Design
Planning and Resource Allocation			х				
Component, Material and Manufacture Selection					х	х	х
Prototyping and Testing	х	х	х	х	х	х	х
Implementation and Follow Up		х	х		х	х	х
Documentation and Information Sharing	х	х					

Board 11 – Implementation Methods Similarities and Differences Across the Studied Methodologies

Source: Developed by the Author Based in Weber (2010), Design Council (2024), IDEO (2015), D. School (2018), Merino (2016), Santos & Silveira (2020) and Ogrodnik (2020).

Effective planning and resource allocation are foundational to successful implementation. This involves detailed scheduling, budgeting, and resource management to ensure the project progresses smoothly and meets its goals. HCD emphasizes thorough initial planning, ensuring that



the design process is well-structured and that all necessary resources are identified and allocated effectively. This method sets the stage for a systematic approach to design implementation, ensuring that the project remains on track and within budget.

Selecting the right components, materials, and manufacturing processes is crucial for ensuring the product's quality, durability, and cost-effectiveness. GODP, AT-D8sign, and Medical Device Design methodologies place significant emphasis on this aspect. They involve rigorous selection processes, often based on criteria like performance, cost, availability, and compliance with regulatory standards. This ensures that the final product is not only functional and reliable but also manufacturable and scalable.

Prototyping and testing are universal methods across all design methodologies, highlighting the importance of iterative development and validation. Prototyping involves creating tangible models or simulations of the product, allowing designers to explore and refine ideas in a practical context. Testing these prototypes with real users or through simulations helps identify flaws and areas for improvement, ensuring that the final design is user-friendly and meets all requirements. All methodologies emphasize this iterative process, underscoring the need for continuous feedback and refinement. This step is critical for mitigating risks, enhancing usability, and ensuring the design's feasibility and effectiveness.

Implementation and follow-up methods ensure that the designed solution is effectively deployed and continues to perform well over time. Implementation involves putting the design into production, whether through manufacturing, development, or deployment. Follow-up ensures that the solution remains effective, often involving monitoring, maintenance, and iterative improvements based on real-world performance and user feedback. This continuous engagement ensures that the product or service remains relevant and effective, adapting to changing needs and conditions.

Documentation and Information Sharing are essential for transparency, collaboration, and compliance. These methods involve creating detailed records of the design process, decisions, and outcomes, which are crucial for communication, training, regulatory compliance, and future reference. Weber and Double Diamond methodologies emphasize the importance of thorough documentation. This ensures that all stakeholders are informed and aligned, and that there is a clear record of the design process for accountability and improvement.

The implementation methods across these design methodologies underscore the importance of structured planning, practical feasibility, iterative refinement, continuous engagement, and thorough documentation. Each methodology offers unique approaches tailored to their specific contexts, but the foundational principles remain consistent. Effective planning and resource allocation, careful selection of components and materials, iterative prototyping and testing, diligent implementation and follow-up, and comprehensive documentation are all critical for successful design implementation. Understanding these similarities and differences allows designers to adapt and integrate methods that best fit their project's specific needs, ensuring a balanced and effective approach to turning design concepts into reality.

4 Discussion and Conclusion

The new design methodologies often draw from these original sources, showing a clear lineage and evolution in design thinking. This connection underscores the relevance of classical design methodologies, as the methods they established can still be categorized in the same way as



modern approaches. Recognizing this lineage is crucial for contemporary designers to ensure they do not lose sight of the foundational principles of design thinking. By integrating both classical and contemporary methodologies, designers can enhance their practice, ensuring that their projects are grounded in time-tested techniques while also incorporating innovative strategies. This synthesis of old and new allows for more robust and effective design solutions.

It is essential to understand and appreciate the origins and significance of design methods. The foundational principles laid out by early design theorists provide a critical context for modern practices. By comprehending where these methods come from and their intended purposes, designers can more effectively adapt them to contemporary challenges. This understanding helps maintain the integrity of design thinking, ensuring that new methodologies are built on a solid foundation and are capable of addressing complex, evolving needs in innovative ways.

A complete design project must utilize a broad spectrum of methods across all categories analysis, synthesis, and implementation. Each category encompasses various techniques that address different aspects of the design process. By employing a diverse range of methods, designers can ensure a more comprehensive and thorough approach to their projects. This holistic application of methods allows for a deeper understanding of user needs, more creative and viable solutions, and a smoother transition from concept to reality. Ensuring that each category is adequately addressed helps to create well-rounded, effective, and user-centered design outcomes.

This paper set out to explore and categorize the diverse methods utilized in both classical and contemporary design methodologies, aiming to establish a comprehensive understanding of their applications in complex project like assistive and medical devices. Through an extensive literature review and comparative analysis, we identified and classified methods within the phases of analysis, synthesis, and implementation. By examining the lineage from classical design methodologies to modern approaches, we highlighted the enduring relevance of foundational principles and the necessity of integrating them with contemporary practices. Our analysis reveals that a robust and systemic approach, utilizing a broad spectrum of categorized methods, is essential for creating effective, user-centered design solutions. This study underscores the importance of building on historical knowledge while continuously advancing design practices to address the evolving challenges in the field.

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