Bridging Gaps in Healthcare Innovation: A Systematic Review of Design Methodologies for Problem Discovery in Technological Health Products

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ABSTRACT

Digital health and medical technology products are often developed with strong technical expertise but shallow early problem framing. This can lead to misaligned solutions, rework, and low adoption in real-world care. This systematic review synthesizes how design methodologies are used to deepen problem understanding during the creation of technological healthcare products.

We followed PRISMA 2020 guidance and structured the protocol using PICOC. We searched PubMed, Scopus, ScienceDirect, and BVSalud for peer-reviewed articles in English published from 2016 onward that described frameworks or methodological processes for developing technological health products. A nine-item quality checklist assessed how clearly studies reported procedures, objectives, structures, challenges, limitations, and multidisciplinary collaboration.

The search identified 513 records; 33 full texts were screened, and 11 studies met the inclusion criteria. Most used a human-centered, user-centered, or participatory design to support the development of medical devices, monitoring systems, digital mental health services, reproductive health platforms, and tools for older adults and children. Design methods were widely applied to improve usability, acceptability, and experience, and to address the needs of specific populations. However, most frameworks focused on solution refinement and usability testing rather than deep, systematic early-stage problem discovery, and regulatory, data, and interoperability constraints were rarely integrated in the initial design phases.

The review indicates that design methodologies play an important role in the included health innovation literature but also reveals a gap: there is no consolidated, early-stage instrument that links problem discovery, evidence synthesis, and explicit go/hold/no-go decisions for technological health products.

KEYWORDS

Health, innovation, human-centered design, digital health, product development, systematic review

1. Introduction

Digital health and medical technology innovation has expanded rapidly in recent years. New devices, digital platforms, remote monitoring systems, and digitally enabled service models promise better diagnosis, coordination, and care delivery. However, many innovations do not progress successfully from promising concepts to sustainable implementation in real-world health settings. Common reasons include poor usability, limited fit with professional workflows, insufficient attention to patient experience, low compatibility with organizational routines, and the late recognition of regulatory, data, and interoperability constraints.

Design methodologies have been widely proposed as a way to reduce these risks. Human-centered design (HCD), user-centered design (UCD), participatory design, co-design, challenge-based learning, and early health technology assessment all offer structured ways to understand users, contexts, unmet needs, and implementation constraints before substantial development effort is invested. In health settings, these approaches are often intended to improve usability, strengthen relevance to target populations, increase stakeholder engagement, and reduce the gap between technical innovation and everyday care practice. Studies in connected health, remote monitoring, children's mental health, reproductive health platforms, and technologies for older adults suggest that such approaches can support better requirement elicitation, more acceptable interfaces, and stronger alignment with user needs.

At the same time, the literature also shows that these methodologies are not easy to apply consistently. Human-centered and participatory approaches can be resource-intensive, rely on multidisciplinary coordination, and produce findings that are difficult to translate into explicit decision criteria. In addition, there is often a gap between the general promise of design methods and their operational use in early health innovation. Some studies emphasize co-design and usability improvement, while others focus on implementation, device selection, or workflow fit. As a result, the field contains many relevant methodological contributions, but fewer syntheses of how these approaches are actually being used during early-stage problem discovery in technological healthcare development.

From a design studies perspective, this gap is important. Classic design literature argues that innovation depends not only on generating solutions, but on carefully framing and reframing problems, engaging stakeholders, and moving iteratively between problem and solution spaces [1–5]. In healthcare, this logic is especially relevant because poorly framed problems may lead to technically functional products that fail in practice due to workflow mismatch, implementation barriers, or weak adoption. Related traditions in human factors and implementation research further suggest that work systems, contextual conditions, and organizational compatibility should be considered early, not only after design decisions have already been made.

Despite this, there is still limited synthesis of how design methodologies are used specifically to deepen problem understanding before or during the earliest stages of technological health product development. Existing papers often focus on a specific intervention, population, or design process, but less often examine the broader methodological picture: which procedures are being used, what benefits they are intended to offer, how standard frameworks are operationalized, what barriers arise in practice, and where gaps remain.

This systematic review addresses that need. The review was structured using PICOC because the topic is not primarily about comparing interventions, but about identifying and synthesizing methodological approaches used in a defined population and context. The population was health innovators and scientific entrepreneurs involved in technological healthcare development; the intervention was the use of frameworks or structured methods to deepen problem understanding; comparison was not applicable; the outcomes concerned methodological procedures, objectives, reported benefits, limitations, and challenges; and the context was healthcare, broadly defined. This structure was intended to support a review that is methodologically transparent while remaining broad enough to capture heterogeneous design-related literature.

By synthesizing how design methodologies are used in early health innovation, this review aims to clarify current practice, identify methodological strengths and weaknesses, and support the development of more explicit early-stage discovery approaches for technological health products.

2. Methods

2.1 Review Design

The review followed the logic of the PRISMA 2020 statement for systematic reviews [6]. The protocol was structured using PICOC (Population, Intervention, Comparison, Outcome, Context) to make inclusion criteria explicit.

The protocol was not registered in a public registry. The review is based on the methodological chapter of a Master's thesis focused on early-stage health innovation.

2.2 PICOC Protocol

Population: Health innovators and scientific entrepreneurs involved in developing technological healthcare products (for example: medical devices, digital platforms, and connected health services).

Intervention: Use of frameworks, methodologies, or structured processes that deepen problem understanding in the development of technological health products (for example: HCD, UCD, participatory design, or design frameworks focused on needs analysis).

Comparison: Not applicable. Studies were not required to compare design versus non-design approaches.

Outcome: Description and assessment of methodological processes, including procedures, stages, and tools used for problem discovery, user needs analysis, requirements definition, and risk identification.

Context: No restriction regarding care setting or country. Studies could take place in hospitals, community health, educational, or home environments.

2.3 Research Questions

The review addressed four research questions:

1. What methodological procedures are used during the creation of healthcare products?
2. What are the objectives of using product design in the healthcare domain?
3. Is the use of standard frameworks common in the creation of technological healthcare products?
4. What challenges are reported in the development of health technology products?

These questions guided both study selection and thematic synthesis.

2.4 Search Strategy

A structured search strategy was developed to combine terms related to design methodologies, health, problem exploration, and development processes.

The core search logic used the following terms: ("framework" OR "methodology") AND ("health" OR "healthcare") AND ("problem" OR "root cause" OR "need" OR "necessity") AND ("product design" OR "product development"). Small adaptations were made to accommodate the syntax of each database, including the use of controlled vocabulary where appropriate.

The intention of this strategy was to identify studies that explicitly described structured methodological approaches for understanding problems and guiding the development of healthcare technologies. At the same time, the search strategy was relatively narrow and emphasized explicit methodological language. It did not systematically include additional terms such as “digital,” “technology,” “technological,” “innovation,” “co-design,” or “participatory design,” nor did it intentionally broaden the search toward earlier pre-product innovation phases that might not yet be described using product development terminology. This decision likely increased precision but may have reduced recall. To ensure transparency, this limitation is revisited in the Discussion and Limitations sections.

2.5 Information Sources

Four databases were searched:

- PubMed
- ScienceDirect
- Scopus
- BVSalud (BVS/Virtual Health Library)

The search covered publications from January 2016 onwards, reflecting the growth of digital health and design methods in recent years. The last search update for the thesis was in 2023. Only articles in English were considered.

2.6 Eligibility Criteria

Inclusion Criteria:

- Peer-reviewed articles that describe methodological procedures for creating technological healthcare products (devices, software, platforms, or service innovations with a technological component).
- Studies that present structures, frameworks, or stepwise processes for deepening problem understanding (for example: needs analysis, contextual research, participatory design, or structured requirements gathering).
- Articles that report applications in healthcare or health-related wellbeing contexts.

Exclusion criteria:

- Duplicate records
- Grey literature (reports, theses, conference abstracts without full papers)
- Short articles or editorials with insufficient methodological detail
- Studies not written in English
- Studies outside the scope (for example, design frameworks not applied to health)
- Studies published before 2016

2.7 Study Selection

All records retrieved from the databases were exported, and duplicates were removed. Titles and abstracts were screened against the inclusion criteria. Potentially relevant articles were read in full. Reasons for exclusion at the full-text stage included lack of explicit methodological description, focus on purely clinical efficacy without design procedures, and absence of a technological product component.

The search returned 513 records. After removing duplicates and screening titles and abstracts, 33 articles remained for full-text assessment. Applying the inclusion and exclusion criteria led to 11 final studies included in the qualitative synthesis. The study selection process is summarized in Figure 1.

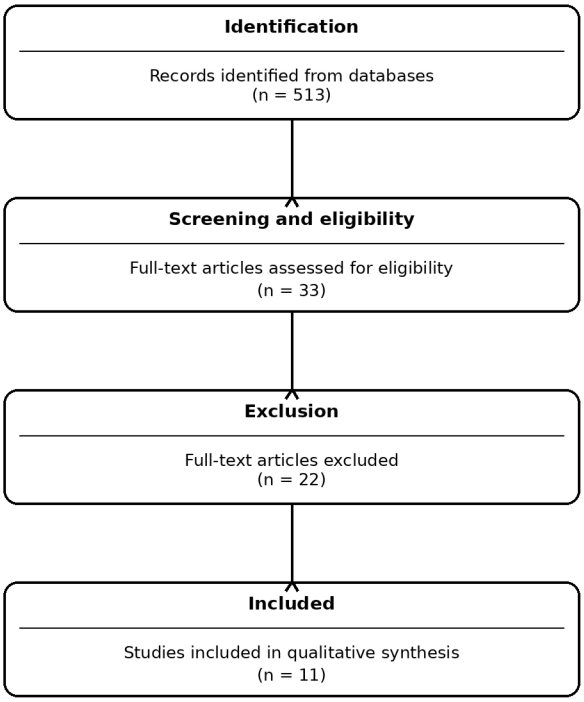


Figure 1: PRISMA flow diagram of study selection.

2.8 Quality Appraisal

A nine-item checklist was used to assess the clarity and completeness of methodological reporting in each included study. Each item was rated as Yes, Partially, or No. The checklist examined whether the study: (1) identified and analyzed methodological procedures used in the creation of healthcare products; (2) presented objectives achieved through product design; (3) provided evidence of the use of generic frameworks; (4) described challenges in developing health technology products; (5) presented a clearly described structure for building a healthcare product; (6) highlighted stages or steps used in creating the product; (7) described limitations encountered during development; (8) clearly related design methodologies to the creation of healthcare products; and (9) adopted a multidisciplinary approach.

The checklist was used descriptively rather than as a basis for excluding studies. Its purpose was to support a structured synthesis of how well the literature reported not only methods and intentions, but also process detail, implementation relevance, limitations, and interdisciplinary characteristics.

2.9 Data Extraction and Synthesis

For each included study, data were extracted on citation details, product or innovation type, target population and context, design methodology or framework used, discovery and development procedures, intended objectives, reported benefits or useful outputs from the design process, structure and stages of development, use of generic or adapted frameworks, reported challenges, stated limitations, and evidence of multidisciplinary collaboration.

To align the synthesis with the quality appraisal logic, the Results section was organized around the same analytical dimensions assessed in the checklist: methodological procedures; objectives and reported benefits; framework use; structure and stages; challenges and limitations; and multidisciplinary collaboration. A thematic synthesis was then developed across studies to identify recurring patterns and cross-cutting gaps.

3. Results

3.1 Overview of Included Studies

The 11 included studies span a diverse set of health innovation contexts, but several clusters are visible. Medical device development and early health technology assessment were represented by Busch et al. [7] and Smith et al. [8], while connected health and usability-oriented digital design for older adults were represented by the two studies by Harte et al. [9, 10]. Community and implementation-focused design was represented by Adam et al. [11], and youth-oriented national digital platform development by Ippoliti et al. [12]. Older adult needs were also addressed through interdisciplinary product design work in Chile [13], while broader conceptual work on design and well-being was represented by Kafaee et al. [14]. Device selection methodology for remote health programs was addressed by Polhemus et al. [15], and child-focused service or technology design by Lyon et al. [16] and Sims [17].

Across the included sample, most studies used qualitative or mixed approaches and relied on interviews, observations, workshops, co-design activities, prototype evaluation, or systematic synthesis. Although the studies varied in product type, target population, and reporting depth, they collectively show that design methodologies in health are being used across device, platform, service, and implementation settings rather than in only one narrow domain. Key characteristics of the 11 included studies are summarized in Table 1.

Table 1: Characteristics of the 11 included studies on design methodologies in technological health product development

Study	Country / context	Health domain / target population	Technology / innovation type	Design methodology	Main stages / procedures	Intended objective	Reported benefits / useful outputs	Reported challenges / limitations	Multidisciplinary involvement
Busch et al. (2021)	Medical device development context; angiographic equipment	Medical devices; complex device development	Medical device innovation / angiographic equipment	Innovation and development process optimization	Analysis of the innovation and development process	Optimize the innovation and development process of medical devices	Highlights the Importance of user involvement and interdisciplinary collaboration in complex device development	Not detailed	Yes
Harte et al. (2017a)	Connected health system context	Health system users	Connected health system	Human-centered design	Three-phase methodology: use case development, usability inspections, and user testing	Improve usability, human factors, and user experience	Improved usability, human factors, and user experience	Not detailed	Yes / implied
Harte et al. (2017b)	Older adult falls risk context	Older adults	Mobile app within an integrated falls risk detection system	Human-centered design	Three-phase methodology emphasizing usability improvement	Improve usability and user experience for older adult users	Improved usability and user experience for older adult users	Not detailed	Yes / implied

Study	Country / context	Health domain / target population	Technology / innovation type	Design methodology	Main stages / procedures	Intended objective	Reported benefits / useful outputs	Reported challenges / limitations	Multidisciplinary involvement
Smith et al. (2019)	Early health technology assessment / medical device innovation	Clinicians in Medical de vice innovation	Early HTA / systematic review	Systematic review	Review of clinicians' role in early HTA	Define the clinician's role in early HTA during Medical device innovation	Identified clinician contributions in needs-driven problem solving, conformity assessment, economic evaluation, and conflicts of interest	Not detailed	Yes / partial
Adam et al. (2020)	Complex health systems / community health volunteer context	Community health volunteers	Human-centered design applied to implementation in health systems	Theory-driven human-centered design	Integration of HCD with theoretical frameworks	Sustain trust in complex health systems and support continued volunteer engagement	Suggests that combining HCD with theoretical frameworks can strengthen implementation capacity and sustained engagement	Implementation challenges in complex health systems are central to the study	Yes / partial
Ippoliti et al. (2021)	Rwanda / national youth reproductive health platform	Rwandan youth	National digital health platform (Cyber-Rwanda)	Human-centered design	Development, launch, and evaluation with active youth involvement	Improve reproductive health for Rwandan youth and ensure usefulness and accessibility	Shows the value of active youth involvement in making the platform useful and accessible	Not detailed	Yes

Study	Country / context	Health domain / target population	Technology / innovation type	Design methodology	Main stages / procedures	Intended objective	Reported benefits / useful outputs	Reported challenges / limitations	Multidisciplinary involvement
Briede-Westermeyer et al. (2021)	Chile / Interdisci-plinary product design context	Chilean elderly	Product design for health needs of older adults	Interdisciplinary product design experience	Baseline interdisciplinary design experience	Address the health needs of the Chilean elderly through product design	Highlights the Relevance of interdisciplinary work for identifying and addressing elderly health needs	Not detailed	Yes
Kafaee et al. (2021)	Conceptual / broader technology development context	User well-being broadly defined	Technology development framework	Design for well-being	Considers well-being across technology development phases	Make well-being a primary design criterion	Supports a more holistic and user-centered view of technology development	Not detailed	Not explicit
Polhemus et al. (2020)	mHealth / remote monitoring context	Patients in mHealth programs	Device select ion framework for remote health programs	Human-centered design-based framework	Development of a framework and case study for device selection	Guide designers to consider patient experience when selecting devices	Provides a practical framework for device selection grounded in patient experience	Not detailed	Yes / partial

Study	Country / context	Health domain / target population	Technology / innovation type	Design methodology	Main stages / procedures	Intended objective	Reported benefits / useful outputs	Reported challenges / limitations	Multidisciplinary involvement
Lyon et al. (2020)	Children's mental health services context	Children	Service innovation / mental health services	Human-centered approach	Design-oriented approach to service improvement	Improve accessibility, effectiveness, and acceptance of children's mental health services	Shows how user-centered design can improve accessibility, effectiveness, and acceptance	Not detailed	Yes / partial
Sims (2018)	Children's healthcare technology design context	Children	Healthcare technology for children	Participatory design	Involvement of children from early design stages	Ensure solutions are appropriate to children's cognitive, emotional, and physical capacities	Ensures children's perspectives are considered from early design stages	Not detailed	Yes

3.2 Methodological Procedures, Structures, and Stages

Across the included studies, the most common pattern was the use of iterative human-centered or user-centered design processes, although the degree of procedural detail varied considerably. Harte et al. [9, 10] provided the clearest examples of explicit multi-phase design structures, describing sequences that moved from use case development and contextual understanding into usability inspection and user testing. Polhemus et al. [15] similarly proposed a structured framework for device selection in remote health programs, while Ippoliti et al. [12] described a development process in which platform design, launch, and evaluation were closely linked to active youth participation. In contrast, other studies, such as Busch et al. [7], Lyon et al. [16], and Kafaee et al. [14], emphasized broader process logic or design orientation rather than a tightly standardized stepwise model.

A recurring pattern across the sample was that later phases of design were described more explicitly than early-stage problem framing. Many papers clearly documented prototype refinement, usability improvement, or implementation-oriented adaptation, but fewer described in detail how they moved from a broad problem space to prioritized development directions. Even so, the sample as a whole shows that design methodologies in health are rarely confined to interface-level refinement alone. Instead, they are used to support requirement clarification, contextual understanding, and the shaping of development decisions across multiple kinds of technological health innovation.

3.3 Objectives and Reported Benefits of Design Method Use

Across the included literature, design methodologies were used for several related purposes. A central objective was to improve usability and user experience, particularly for populations such as older adults and children, as seen in the studies by Harte et al. [9, 10], Lyon et al. [16], and Sims [17]. Another objective was to improve contextual fit by grounding product or service design in the needs, experiences, and constraints of intended users, as in Ippoliti et al. [12], Adam et al. [11], and Polhemus et al. [15]. In medical device and early HTA contexts, Busch et al. [7] and Smith et al. [8] also suggest that design-related approaches can support more relevant collaboration between clinical and technical actors.

The included papers also reported useful outputs from using these methods. In the Harte studies, the design process contributed directly to improved usability and user experience. In Ippoliti et al. [12], active user involvement helped make the platform more useful and accessible to the target youth population. In Adam et al. [11], theory-driven human-centred design was linked to the capacity to address implementation challenges in complex systems, while Polhemus et al. [15] generated a practical framework for device selection based on patient experience. Busch et al. [7] emphasized the value of interdisciplinary collaboration and user involvement in complex device development, and Sims [17] highlighted the importance of ensuring that children's perspectives are incorporated from the earliest design stages. Taken together, these findings indicate that design methodologies often produce concrete intermediate benefits, even when the reporting of those benefits is uneven across studies.

3.4 Use of Generic Frameworks versus Adapted Approaches

Standard methodological families were visible across the included studies, but they were rarely applied as fixed, fully standardized protocols. Human-centered design, user-centered design, participatory design, interdisciplinary design, and design for well-being approaches were all present, yet most papers adapted these traditions to fit a specific health context rather than following one rigid framework. Harte et al. [9, 10], Ippoliti et al. [12], and Polhemus et al. [15] were among the clearest examples of studies that translated broader human-centered design principles into more explicit health innovation procedures.

This suggests partial methodological standardization rather than full uniformity. The field has recognizable design traditions and recurring procedural logics, but these are used pragmatically and selectively. That flexibility can be valuable in healthcare, where users, workflows, and implementation conditions

vary greatly. At the same time, it makes direct comparison across studies more difficult and reduces the availability of clear procedural guidance for early-stage innovators who need more than broad design principles.

3.5 Challenges, Limitations, and Underreported Areas

Several challenges recurred across the included studies. One was the difficulty of developing a sufficiently deep understanding of user needs, especially among populations such as older adults, children, and community-based participants, whose needs may be variable, tacit, or difficult to capture through conventional elicitation methods. Another was the challenge of translating promising concepts into real care settings. Adam et al. [11] explicitly addressed implementation complexity in health systems, while Polhemus et al. [15], Lyon et al. [16], and Ippoliti et al. [12] all suggest that contextual fit and sustained use cannot be assumed from design quality alone.

The review also identified important underreported areas. Explicit study limitations were not always well documented, and the earliest phases of discovery were often described less transparently than later prototyping or evaluation stages. Regulatory fit, interoperability, data governance, and other broader implementation constraints were only inconsistently incorporated into the design processes described in the included sample. This uneven reporting limits the ability to assess how transferable or robust some of the approaches may be in practice.

3.6 Multidisciplinary Collaboration and Cross-Cutting Synthesis

Multidisciplinary collaboration was one of the strongest recurring features across the included studies. Busch et al. [7], Smith et al. [8], Adam et al. [11], Briede-Westermeyer et al. [13], and Polhemus et al. [15] all point, in different ways, to the importance of bringing together clinical, technical, design, implementation, or user perspectives. In some studies, such collaboration was itself part of the design method rather than merely a background condition.

Taken together, the included literature suggests a field that is strongly committed to participatory and user-oriented work but less explicit about early-stage problem prioritization and integrated decision-making. The dominant pattern is not the absence of design methodology, but rather an uneven distribution of methodological detail across the innovation journey. Design methods are clearly being used to improve usability, contextual fit, and stakeholder alignment, yet the transition from early problem exploration to explicit development decisions is still less consistently articulated.

4. Discussion

4.1 Design Methodologies were Prominent in the Included Literature, but Early Problem Discovery was Less Fully Developed

The reviewed studies show that design methodologies were prominent across the included sample of technological health innovation papers. Human-centered, user-centered, and participatory approaches were repeatedly used to improve usability, adapt solutions to specific populations, and support collaboration across stakeholders. In that sense, the literature included in this review consistently treated design methods as relevant to the development of healthcare technologies.

At the same time, the findings suggest an imbalance in how these methodologies are operationalized. Across the included papers, later phases such as prototyping, usability testing, and refinement were usually described more clearly than the earliest phases of problem framing, prioritization, and evidence-based narrowing of scope. This does not mean that early discovery was absent, but rather that it was less systematically documented and less consistently converted into explicit decision logic.

This pattern is broadly consistent with classic design literature, which argues that innovation depends on sustained movement between the problem and solution spaces and on iterative reframing with stakeholders [1–5]. The studies reviewed here suggest that healthcare innovation often adopts the language and later-stage practices of design, but does not always describe early problem exploration with the same level of procedural clarity.

4.2 Fragmentation across the Innovation Journey

One of the clearest interpretive patterns emerging from the Results is fragmentation across the innovation journey. The reviewed studies documented valuable work on contextual inquiry, co-design, usability improvement, implementation support, device selection, and multidisciplinary collaboration, but these elements were not usually integrated into a single end-to-end discovery-to-decision structure. Instead, different studies emphasized different segments of the process.

This interpretation is grounded in the Results in three ways. First, framework use was often generic and adapted rather than standardized, which limited comparability across papers. Second, reporting was stronger for design and refinement stages than for early prioritization and problem framing. Third, contextual constraints such as interoperability, regulation, and data governance were only inconsistently incorporated into the earliest phases of development. Together, these findings suggest that the literature contains many relevant methods, but fewer integrated approaches that connect problem discovery, contextual analysis, evidence synthesis, and explicit innovation decisions.

This fragmentation matters because early-stage health innovation is rarely hindered by design quality alone. It is also shaped by feasibility, workflow compatibility, implementation conditions, and system-level constraints. When these issues are addressed in disconnected ways or only later in development, the risk of rework and misalignment increases.

4.3 Implications for Scientific Entrepreneurs and Health Innovators

For academic teams, hospital innovators, and early-stage entrepreneurs, the implications are clear.

They need structured yet lightweight tools that translate the best of HCD and early technology assessment into actionable steps. These tools should help them move from initial observations or research results to a documented evidence base that supports key decisions. They should also help teams make risks explicit early on, especially in relation to patient safety, ethics, regulatory fit, interoperability, and stakeholder adoption.

Beyond HCD, human-factors and systems-engineering frameworks such as SEIPS 2.0 and SEIPS 3.0 explicitly connect work systems, processes, and outcomes in healthcare and offer practical tools for mapping constraints and risks [18, 19]. Integrating these models with the design methods identified in this review could help teams anticipate workflow, safety, and resource issues before substantial investments are made.

Diffusion-of-innovations research also highlights attributes such as relative advantage, compatibility, and complexity as central drivers of adoption [20]. Positioning these constructs as explicit discovery questions can support more realistic go, hold, or no-go decisions for technological health products.

Finally, well-established usability-testing approaches can be used not only to evaluate solutions but also to trigger reframing of the underlying problem when tests reveal systematic misalignment with users' needs [21].

These broader methodological lenses help explain why the present review identified a gap between user-centered discovery and implementation-aware decision-making. Human-factors frameworks such as SEIPS emphasize that technologies must be understood in relation to work systems, care processes,

and safety outcomes, while diffusion-of-innovation theory highlights compatibility, complexity, and organizational fit as central to adoption. Usability-testing traditions likewise reinforce that testing should not be treated only as interface evaluation, but also as a source of evidence about whether the underlying design assumptions are sound. In this manuscript, these traditions are not treated as part of the included review sample, but as interpretive frameworks that help contextualize the findings.

4.4 Research and Practice Directions

Future work should build on the strengths of the reviewed literature while addressing its remaining fragmentation. One priority is the development of decision-oriented instruments that help innovators document the target problem, relevant stakeholders, evidence gathered, major contextual constraints, and the criteria used to decide whether to proceed, pause, or redirect development. A second priority is to examine whether stronger discovery processes actually improve downstream outcomes such as reduced rework, earlier pivots, lower development cost, or fewer delays related to implementation and regulation. A third direction is to bring implementation science and human-centered implementation frameworks into the earliest phases of design rather than treating implementation as something that happens only after a solution has already been shaped.

A further priority is broader contextual coverage. The reviewed sample already shows that design methodologies are being used across devices, digital platforms, services, and community-health settings, but more studies are needed from underrepresented contexts, including Latin America and other regions where health innovation often develops under different institutional and resource constraints. More explicit reporting of discovery stages, design decisions, and implementation-related trade-offs would also make future literature more useful for both researchers and scientific entrepreneurs.

5. Limitations

This review has several limitations that should be considered when interpreting its findings. First, the final corpus was relatively small, with 11 studies included in the qualitative synthesis. Although this number was sufficient to identify recurring methodological patterns, it limits the breadth of health domains, technologies, and design traditions represented in the review.

Second, the search strategy was deliberately focused on explicit methodological language and combined a relatively narrow set of terms related to frameworks, methodology, health, problems or needs, and product development. This approach likely increased specificity, but it may also have excluded relevant publications that described early design work using different language, including terms such as digital health, technological innovation, co-design, participatory design, service design, or innovation processes occurring before a clearly defined product stage. For the same reason, the inclusion of product-related terminology may have reduced capture of studies addressing earlier innovation phases in which methodological exploration was already underway but not yet described as product development.

Third, the search was restricted to four databases, to publications in English, and to the period from 2016 onward. These choices were justified by the aim of focusing on recent technological health innovation literature, but they may have excluded relevant studies in other languages, databases, or publication types. In a field such as health innovation, this is particularly relevant because some practical design knowledge may appear in conference proceedings, institutional reports, or grey literature rather than in full journal articles.

Fourth, the review used qualitative thematic synthesis rather than meta-analysis. Given the heterogeneity of the included studies, this was the most appropriate strategy, but it also means that the conclusions are interpretive rather than statistically generalizable. Finally, several included papers described their methodologies unevenly across stages, especially in the earliest phases of discovery. As a result, some aspects of problem framing, prioritization, or interdisciplinary interpretation may have been conducted in practice but not fully documented in publication.

Despite these limitations, the review offers a useful synthesis of how design methodologies are being used in the early development of technological health innovations and highlights an important methodological gap: the limited availability of integrated approaches that connect problem discovery, evidence generation, contextual constraints, and explicit early-stage decision-making.

6. Conclusions

The studies included in this systematic review show that design methodologies are widely used in the development of technological health products to improve usability, strengthen contextual fit, and align solutions with the needs of patients, professionals, and other stakeholders. Human-centered, user-centered, and participatory approaches appeared repeatedly across the included literature and were especially relevant in contexts where success depended on acceptability, workflow compatibility, accessibility, and sustained engagement.

At the same time, the review reveals an important imbalance in how these methodologies are described and operationalized. Across the included studies, later phases such as prototyping, usability improvement, and refinement were usually reported more clearly than the earliest phases of problem framing, prioritization, and evidence-based narrowing of scope. The literature therefore provides useful methodological examples and strong general principles, but fewer integrated approaches that connect problem discovery, contextual analysis, implementation-related constraints, and explicit early-stage innovation decisions.

This has practical implications for scientific entrepreneurs, hospital innovators, and early-stage research teams. In these settings, the critical challenge is often not only how to build a good solution, but how to determine whether the underlying problem has been sufficiently understood to justify continued investment. The findings of this review suggest that future methodological work should focus on stronger discovery-to-decision frameworks that preserve the strengths of human-centered design while making early-stage reasoning, trade-offs, and viability assessment more explicit. Advancing that agenda may help reduce rework, improve real-world fit, and strengthen the translation of promising health innovations into viable products and services.

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Conflicts of Interest Statement

The author declares that there is no conflict of interests regarding the publication of this paper.

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