

An Ethical Approach to Co-Designing Scalable Digital Health Interventions for Vulnerable Populations

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Abstract: Digital health interventions (DHIs) have expanded rapidly across prevention, care, and self-management, yet their development often excludes populations most affected by health inequities, including older adults, women (including people assigned female at birth), individuals with cognitive decline, and people with low socioeconomic status (SES). This paper proposes an Ethical Co-Design Framework that integrates principles from Ethics by Design, Value-Sensitive Design, and the Assessment List for Trustworthy AI. The framework outlines a continuous cycle of ethical framing, participatory engagement, evaluation and accountability, and iterative reflexivity, offering a practical method for embedding ethical reflection throughout the innovation lifecycle, to enhance DHI scalability. To illustrate its application, the paper presents two early-stage case studies: GRACE, a voice-based conversational agent for people with early dementia, and PreDiaTx, a GenAI-powered precision digital therapeutic for type-2 diabetes prevention among women, older adults and low-SES groups. Across both cases, ethics emerges not as a constraint but as an enabler of inclusive, context-sensitive and trustworthy design. The paper argues that ethical co-design provides a replicable pathway for aligning DHI development with the needs and values of vulnerable populations and calls for organisational and policy structures that embed ethical co-design as a standard component of scalable digital health innovation.


1 INTRODUCTION

Digital health interventions (DHIs) have rapidly expanded into domains of prevention, care, and self-management, promising scalable and personalised health support. Yet, the benefits of digital innovation and its scalability are not distributed equally (Yao et al., 2022). Many technologies are developed without meaningful involvement of the people they aim to serve, particularly those most affected by health inequities, such as older adults, women¹ (including people assigned female at birth), individuals with cognitive decline, and people with low socioeconomic status (SES) (Loo et al., 2025; Papoutsi et al., 2021). As a result, DHIs can inadvertently reinforce structural disadvantages rather than reduce them, especially when they are scaled up. Most DHI frameworks, such

as the Design and Evaluation Framework for Digital Health Interventions (DEDHI) (Kowatsch et al., 2019) or the Multiphase Optimisation Strategy (MOST) (Collins, 2018), encourage participatory or user-centred design, however, lack naming co-design as a principle. Such disparities raise the question of how ethical and inclusive design can be systematically embedded within innovation processes, ensuring that DHIs advance not only clinical or commercial outcomes but also fairness, autonomy, and trust.

Within digital women's health, these challenges are particularly pronounced. These include gender data gaps (Weinberger et al., 2025), historically male-centred clinical evidence (Dresser, 1992; Merone et al., 2021), unpaid care responsibilities (Donelan et al., 2001) and gendered patterns of digital access (Dixon et al., 2014). These examples demonstrate how

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¹ This paper uses the term “women” as an inclusive category referring to all individuals who identify as women.

women are both primary targets of many preventive DHIs and simultaneously at higher risk of exclusion or misrepresentation. As digital women's health tools increasingly move from pilots to scaled deployment, ethical co-design becomes critical for ensuring that personalisation, risk stratification and behavioural guidance do not reproduce gender bias, inequitable burden, or moralised notions of responsibility.

The importance of ethically informed design becomes especially evident in the context of vulnerable populations, i.e., groups that face barriers to participation, reduced decision-making power, or increased risk of harm from technology use (Moll et al., 2020). In dementia care, for example, conversational agents may enhance companionship but also raise concerns about authenticity, deception and informed consent (Bradwell et al., 2020; Sharkey, 2014). Similarly, artificial intelligence (AI)-based DHIs for prevention of other non-communicable diseases, such as type-2 diabetes, may use AI for personalisation, but may also risk amplifying gender or socioeconomic bias (George et al., 2018; Yao et al., 2022). Designing DHIs for such contexts requires ongoing reflection, not only on technical parameters, but on social meaning and moral responsibility.

This paper argues that co-design, when approached ethically, offers a way to make DHIs more inclusive, trustworthy and socially responsible. While user-centred design has become standard in digital health innovation, it often remains limited to usability testing, interface optimisation and individual preference elicitation (Norman & Draper, 1986). Such approaches risk treating users as sources of feedback rather than as moral stakeholders embedded in social, institutional and power-laden contexts (Antonini, 2021). In contrast, co-design refers to participatory methods that involve end users and stakeholders directly in design and evaluation (Messiha et al., 2023). An ethical approach to co-design extends this participation beyond usability and preference testing, by incorporating human values throughout the innovation process.

This paper draws on two applied research projects that exemplify this challenge: (1) GRACE: a voice assistant for people with early dementia, and (2) PreDiaTx: a Swiss precision digital therapeutic for the prevention of type-2 diabetes in women, older adults and individuals with low-SES. Although these projects target different health domains, they share a common ambition: to make DHIs ethically trustworthy through participatory, iterative and reflexive design. For this reason, the overall aim of this paper is to explore how we can ethically co-design DHIs for vulnerable populations.

2 ETHICAL FOUNDATIONS

Ethical reflection has long been a part of technology design (Collins, 2018; Kowatsch et al., 2019), but its practical integration into digital health innovation remains uneven and undefined. As DHIs become more embedded in clinical and preventive care, the question is no longer whether ethics matters, but how it can be meaningfully operationalised in design. Several frameworks have emerged to address this challenge, each offering complementary perspectives on embedding human values into technology.

2.1 Ethics by Design (EbD)

Ethics by Design (EbD) offers compelling guidance for addressing these challenges from the earliest stages of innovation (Brey & Dainow, 2023; Dignum et al., 2018). It argues that ethics should not be an afterthought or a compliance exercise, but rather a proactive anticipation of moral and social impacts across the technology lifecycle (Brey & Dainow, 2023). EbD seeks to ensure that technologies promote human well-being, autonomy and justice by embedding moral reasoning into technical decisions such as data use, interaction design and feedback mechanisms.

In the context of DHIs, proactive ethics becomes imperative. Conventional ethical oversight (such as institutional review boards or regulatory compliance) often occurs after key design decisions are made, focusing on data protection or safety rather than participatory justice or empowerment. Frameworks such as EbD, thus call for embedding ethical reflection within design workflows through interdisciplinary collaboration among developers, researchers, policymakers and target users (Brey & Dainow, 2023). However, the framework often stops short of specifying how to operationalise this integration in participatory settings or across diverse populations.

2.2 Value-Sensitive Design (VSD)

EbD conceptually converges with Value-Sensitive Design (VSD), a methodology from human-computer interaction that operationalises the integration of moral and social values into technology development (Friedman et al., 2013). VSD proposes a tripartite iterative process: conceptual, empirical, and technical investigations, through which designers identify and explore stakeholders' values in use contexts, and translate them into design specifications.

VSD emphasises participation and inclusion, recognising that different users hold different (sometimes conflicting) values, providing tools to find balance in stakeholder values (Friedman et al., 2013). Yet, while VSD excels at uncovering values, it can underplay broader ethical principles such as justice or respect for human dignity, which are especially salient when designing for vulnerable groups (Manders-Huits, 2010). Here, EbD insists that some minimal ethical commitments should constrain design regardless of stakeholder preference (Dignum et al., 2018). Therefore, VSD ensures inclusivity and contextual sensitivity, while EbD secures ethical consistency and accountability, a synthesis which is particularly powerful for co-design.

2.3 Assessment List for Trustworthy AI (ALTAI)

The European Commission’s Assessment List for Trustworthy AI (ALTAI) provides an evaluative bridge between abstract ethical principles and concrete design criteria, particularly for AI systems (High-Level Expert Group on Artificial Intelligence, 2020). It identifies seven ethical dimensions: (1) human agency and oversight; (2) technical robustness and safety; (3) privacy and data governance; (4) transparency; (5) diversity, non-discrimination and fairness; (6) societal and environmental well-being; and (7) accountability, which help transform ethical reflection into assessable checkpoints.

For AI-based DHIs, ALTAI provides measurable criteria to assess whether a system respects human rights, avoids bias, and remains explainable to users and clinicians. It is especially relevant for AI-based technologies like GRACE and PreDiaTx, which rely on data-driven personalisation. However, its focus lies primarily on evaluation rather than participatory design, making it more diagnostic than generative.

2.4 Integrating Co-Design and Ethics

While EbD, VSD and ALTAI each contribute valuable elements, none alone fully capture the complexities of designing for vulnerable populations in healthcare contexts. Vulnerabilities add layers of moral responsibilities, including relational ethics (i.e., how technologies mediate care relationships), contextual consent and equitable access, that require ongoing, participatory negotiation (Manders-Huits, 2010).

To bridge this gap, we propose a conceptual framework for ethical co-design, integrating:

- EbD’s normative grounding (why ethics must be part of design), informing ‘Ethical framing’;
- VSD’s participatory methodology (how values can be elicited and embedded), informing ‘Participatory engagement’; and
- ALTAI’s evaluative structure for AI systems (how trustworthiness can be assessed), informing ‘Evaluation & accountability’.

This synthesis positions ethical co-design as an iterative and inclusive process, in which ethics is not a single phase, but a continuous thread connecting problem definition, design, evaluation and scale-up.

2.5 Conceptual Model for Ethical Co-Design

Our ethical co-design framework consists of four interlinked components to form a continuous learning cycle (Figure 1):

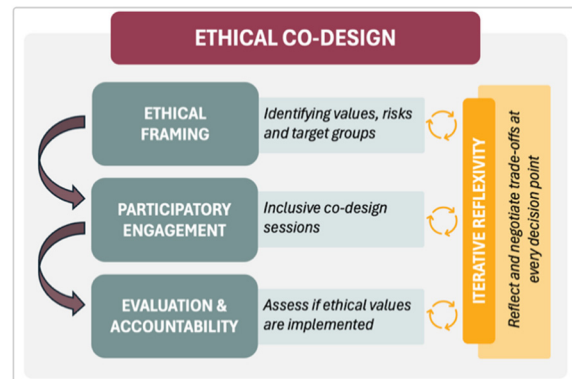


Figure 1: A conceptual framework depicting ethical co-design and its four components.

Each component informs the next in a cyclical (not sequential) process, following:

1. **Ethical Framing:** Identifying ethical values, risks and target groups early in the project. Clarifying whose needs the DHI serves, what forms of vulnerability are involved, and what ethical principles (e.g., autonomy, fairness) are most relevant.
2. **Participatory Engagement:** Conducting inclusive co-design sessions with stakeholders, where they can share their values, concerns and lived experiences.
3. **Evaluation & accountability:** Assessing how ethical values are enacted in the resulting DHI, using structured tools such as ALTAI to ensure transparency, fairness and trustworthiness.
4. **Iterative Reflexivity:** Integrating ethical reflection into every design or decision point. Research teams should revisit ethical

assumptions, negotiate any trade-offs, and document rationales as the DHI evolves.

Vulnerability in digital health is multifaceted, it can arise from gender, age, cognitive abilities, digital literacy or socioeconomic background. Within our framework, vulnerability is not treated merely as a risk factor but as a resource, allowing us to reframe vulnerability as a site of moral imagination rather than deficiency.

Within existing lifecycle frameworks, such as DEDHI and MOST, using the ethical co-design framework can strengthen their design decisions to remain grounded in fairness, autonomy and care.

3 CASE STUDIES

The case studies presented here are intentionally prospective. Rather than reporting completed co-design processes, they illustrate how the ethical co-design framework can be applied to guide decision-making in early-stage and pre-implementation phases. The examples therefore function as design roadmaps, clarifying how ethical co-design could be operationalised as these projects evolve. As both studies are in their early stages, embedding ethics now ensures the technology grows in ways that respects dignity, supports relationships, and maintains trust.

3.1 Case Study 1: GRACE

Individuals with cognitive impairments face distinctive barriers in their understanding, memory, and physical mobility, which raises concerns about autonomy, authenticity and deception. Therefore, it becomes imperative to address these tensions through co-design, to enable ethical reflection in technology development.

GRACE was developed to explore how embodied voice-based conversational agents could support people with early dementia and their caregivers in improving their quality of life (Centre for Digital Health Interventions, 2023). It provides meaningful conversations and lifestyle interventions and has been tested with healthy adults for technology reiteration (Vinay et al., 2024, 2025). Figure 2 provides a roadmap for GRACE along the ethical co-design framework. To date, participatory input has focused on interdisciplinary expert workshops and pilot testing with healthy adults to refine interaction logic and ethical safeguards. Direct co-design involving people with early dementia and caregivers is planned for subsequent phases.



Figure 2: Ethical co-design roadmap for GRACE.

3.2 Case Study 2: PreDiaTx

Prevention-focused DHIs introduce another set of ethical challenges compared to dementia care. Women, older adults and people with low-SES often experience intersecting vulnerabilities in relation to chronic disease prevention, including limited access to care, higher exposure to structural risk factors, financial constraints, and lower digital literacy. These factors shape how people understand risk, engage with health information and experience lifestyle or behavioural interventions.

PreDiaTx is a GenAI-based precision digital therapeutic targeting these underserved groups, at risk of type-2 diabetes (Jovanova et al., 2025). It is a text-based conversational agent, delivered through a smartphone and digital coach. PreDiaTx combines personalisation with behavioural support, serving as another strong example of how ethical co-design can shape an AI-driven DHI before development begins. In Figure 3, we propose a roadmap for the ethical co-design of PreDiaTx among women, older adults and people with low-SES.

As PreDiaTx is currently in the conceptual phase, the roadmap outlines planned participatory methods, including co-design workshops with women, older adults and community stakeholders to inform feature selection, risk communication and acceptable modes of AI-driven support.

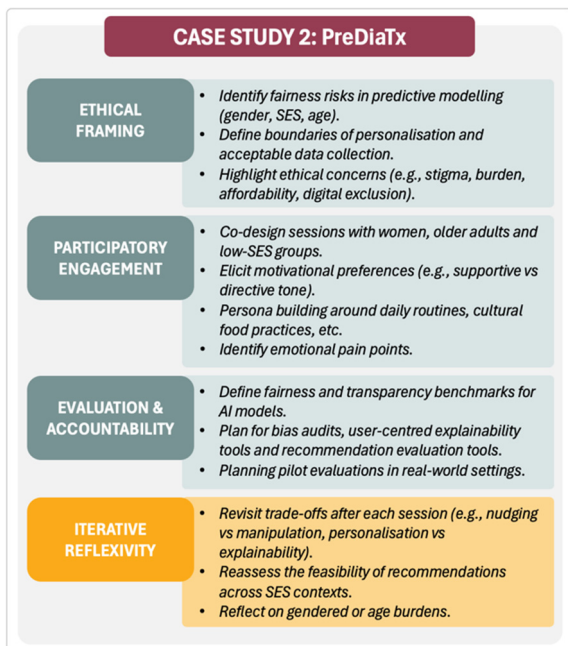


Figure 3: Ethical co-design roadmap for PreDiaTx.

4 RESEARCH APPLICATIONS

As digital health research matures, it is increasingly clear that ethical reflection cannot be confined to the early design stage but must be embedded throughout the entire lifecycle of innovation. The proposed ethical co-design framework offers a foundation for this work, yet its full potential becomes evident when paired with existing lifecycle models such as DEDHI and MOST. A combined innovation lifecycle was also suggested by Schlieter and colleagues, Scaling-up health-IT—an expansion of both the DEDHI and MOST frameworks, exploring sustainable digital health implementation and diffusion (Schlieter et al., 2024). This model adds a scalability phase to the existing lifecycle phases of DEDHI and MOST, to address the sustainability of building DHIs, and therefore becomes a relevant anchor for the ethical co-design framework.

In the scale phase, the ethical co-design can enable structured, value-sensitive adaptation to real-world settings. For example, in an inter/national roll-out of PreDiaTx, the evaluation and accountability component could be extended to include local co-design sprints with community clinics, where women and older adults help tailor the intervention to cultural dietary norms, financial constraints or varying levels of digital literacy. Through these participatory micro-cycles, issues such as affordability of recommended

foods, comfort with AI-driven messaging or differences in caregiving responsibilities can be surfaced before deployment. Ethical reflexivity would therefore guide not only initial design but also adaptation, ensuring that scale, in itself, does not produce inequitable outcomes across regions or demographic groups.

Another alternative, and more straight-forward approach to applying the ethical co-design framework, is in the conceptual phases—such as the Preparation Phase of MOST (Collins, 2018). In these phases, ethical co-design can shape the definition and selection of early intervention components before optimisation begins. For instance, in GRACE, early ethical framing sessions with people with dementia, other cognitive impairments and caregivers could identify what types of conversational behaviours are acceptable (e.g., supportive prompts that do not mimic human emotions) or the kinds of intervention support they would find most helpful. Similarly, participatory workshops could co-create candidate features, such as modes for cognitive fatigue, transparent reminders of the system’s artificial nature or boundaries around unsolicited advice. These ethically grounded components can then feed directly into MOST’s Preparation Phase, ensuring that the elements tested during optimisation reflect user values, cognitive needs and clearly articulated ethical constraints rather than assumptions made by designers alone.

In summary, ethical co-design cannot resolve all tensions inherent in the development of DHIs, nor can it fully eliminate the structural inequities that shape vulnerability. However, it offers a pragmatic, relational and value-oriented approach for navigating these complexities. As the digital health field moves towards more adaptive, scalable and AI-driven interventions, the challenge will be to institutionalise ethical reflection not as a peripheral activity but as a core design competency. By embedding ethics throughout conceptualisation, optimisation and scale-up, researchers and implementers can move toward DHIs that are not only effective, but also dignifying, context-sensitive and socially just.

5 CONCLUSION AND OUTLOOK

This paper has presented an ethical approach to co-designing DHIs for vulnerable populations, with particular relevance for the scaling of digital women’s health interventions, through the proposed ethical co-design framework, and two early-stage case studies.

The ethical co-design framework offers a practical pathway for embedding ethical reflection into the development of DHIs across diverse contexts. By integrating normative principles, participatory methods and accountability mechanism, the framework supports teams in navigating value tensions, engaging vulnerable users meaningfully and ensuring that emerging technologies remain transparent, fair and trustworthy. Future work should explore applying the ethical co-design framework across different DHI use cases and target groups, as well as other digital health lifecycle frameworks, to further refine the interlinked components.

This paper further introduced two DHI case studies: GRACE, a voice-based conversational agent for people with early dementia; and PreDiaTx, a GenAI-powered precision digital therapeutic for type-2 diabetes prevention among women, older adults and people with low-SES. Across both cases, ethics emerged not as a constraint but as an enabler of innovation. By embedding ethical reflection into participatory design, both studies show how co-design sessions can be transformed into spaces for negotiating values such as autonomy, fairness, care and trust. This approach moves ethics beyond compliance, fostering DHIs that are more inclusive, context-sensitive and trustworthy.

While promising, this approach is not without limitations. First, both case studies present early-stage projects, meaning the framework is presented as a prospective roadmap rather than an empirically validated process. Second, vulnerability in digital health is highly context-specific, therefore additional work is required to adapt the framework to other groups such as migrants, children or individuals with severe mental health conditions and other disabilities. Third, embedding ethics across an entire innovation lifecycle demands resources, interdisciplinary expertise and organisational commitment. Practical constraints such as tight timelines, technical limitations or regulatory requirements may at times conflict with ethical ambitions.

Finally, ethical co-design also raises persistent challenges related to power asymmetries and epistemic injustice (Ndaka & Majiwa, 2024). Vulnerable populations may face barriers to participation due to cognitive load, time constraints, digital literacy or mistrust toward institutions, while professional or technical actors retain greater influence over decision-making (Muller & Brown, 2024). Even when participatory processes are implemented, experiential knowledge may be discounted in favour of technical or clinical expertise. Addressing these risks requires deliberate mitigation

strategies such as supported participation, iterative consent, facilitation by trusted intermediaries and explicit documentation of how user input shapes design outcomes.

Moreover, tensions inevitably arise between the depth of participatory engagement and the pressure of scalability, standardisation and regulatory compliance, particularly in commercial or large-scale public health deployments (Young et al., 2024).

Despite these challenges, ethical co-design offers a replicable framework for advancing equitable digital health. It invites innovation teams and researchers to integrate structured ethical reflection throughout design, evaluation and scaling phases, ensuring that user voices guide both moral and technical decisions. In the context of digital women's health, the framework is especially salient for addressing gender data gaps, intersecting vulnerabilities, and the ethical risks introduced by large-scale personalisation and automation.

Looking ahead, the key task lies in institutionalising ethical co-design (i.e., building organisational cultures, funding models and policy environments) that recognise ethics as a central component of innovation rather than a peripheral review step. Doing so can help scale DHIs that not only improve outcomes but also uphold dignity, justice and care in the digital age.

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