Hosana Cristina
Morales Ornelas

Integrating evidence generation in eHealth development

Bridging design and healthcare practices

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"Empathy is a temporary caring, and becomes instrumental when invoked as a means to improving the design of things or services for sale. Although we may care about the impact of our design work, we do not usually follow and care for the lives of our users, or the patients affected by our systems. We may care about users and patients, but we are not called on to care about any particular person. How we might "care more" is a question that requires rethinking the role of design and human-centered research. The difference may entail moving from performing as contributing designers to coordinating patient-centered service projects. In these scenarios, the health outcomes of future patients are now at stake."

Peter H. Jones
excerpt from Design for Care, Chapter 1, p.17, New York, 2003

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Summary

Motivation

eHealth solutions increasingly shape how healthcare is delivered, monitored, and experienced. By integrating digital technologies into care, these solutions promise improved clinical outcomes, efficiency, and patient-centredness. Realising these benefits, however, depends on generating evidence that demonstrates eHealth solutions are not only clinically safe and effective, but also usable, meaningful, and adoptable in everyday care contexts. In practice, generating such evidence is challenging because eHealth development brings together design and healthcare practices that rely on different ways of defining and producing evidence. Designers typically generate dynamic, context-responsive evidence through iterative engagement with users, while healthcare professionals rely on static, predefined evidence to meet clinical and regulatory requirements. When these approaches are not deliberately aligned, tensions arise concerning what evidence should be generated, how, when, and for what purpose. These tensions can result in fragmented evidence practices and eHealth solutions that are either clinically robust but poorly adopted, or user-centred but insufficiently rigorous. This thesis is motivated by the need to better integrate static and dynamic evidence generation within eHealth development to support

solutions that are both compliant and meaningful for patients and clinicians.

Objective

The objective of this thesis is to establish conceptual, empirical, and methodological foundations for integrating static and dynamic approaches to evidence generation in eHealth development. Specifically, the thesis investigates how evidence is defined and generated by designers and healthcare professionals, and how these practices can be aligned within existing eHealth development standards. The overarching research aim is to develop a shared evidence generation practice that supports user-centred, clinically robust, and standard-compliant eHealth solutions. This aim is addressed through four research questions that examine experience measurement practices, evidence generation in practice, outcome-oriented evidence definition, and the structuring of integrated evidence generation within eHealth standards.

Outline and results

Chapter 1 introduces the research context and frames the central problem of fragmented evidence generation in eHealth development. It conceptualises static and dynamic evidence generation as analytical lenses to explain tensions between design and healthcare practices, identifies four barriers to integration, and formulates the research questions guiding the thesis.

Chapter 2 addresses the first research question by examining how patient and staff experience is measured in eHealth development. Through a systematic literature review focused on remote patient monitoring, the chapter maps existing experience constructs and measurement instruments. The findings reveal substantial diversity

and limited standardisation in experience measurement. To address this, the chapter proposes four experience categories: service-system, usage and adherence, care, and health outcomes, which provide a structured foundation for static evidence generation and create a basis for integrating dynamic perspectives on experience.

Chapter 3 explores how designers and healthcare professionals generate evidence in practice. Using qualitative interviews and thematic analysis, the study identifies five shared evidence practices (i.e., stakeholder-, process-, problem-, solution-, and effect-driven) that span design and healthcare work, despite differing priorities and evaluation traditions. These evidence practices demonstrate how static and dynamic approaches already coexist in practice, but remain weakly integrated due to a lack of explicit coordination and shared structure, thus clarifying integration opportunities.

Chapter 4 examines how designers can apply the outcome-oriented logic commonly used in healthcare to define dynamic evidence generation. Through an in-depth qualitative case study, the chapter analyses how healthcare professionals articulate patient-centred outcomes and translates this logic into design practice. The study identifies three conceptual dimensions (i.e., effect, meaning, and collection) that clarify how patient-centred outcome logic can guide the dynamic definition of evidence. These dimensions are mapped onto adapted design competencies, providing designers with conceptual grounding to define outcome-related evidence in ways that align with healthcare expectations.

Chapter 5 synthesises findings from the previous chapters to address the methodological gap in integrating static and dynamic evidence generation within eHealth standards. Using a theory adaptation approach, the chapter adapts Data-Enabled Design in relation to the ISO 14155 standard for eHealth clinical trials to develop the Clinical Data-Enabled Design (C-DED) framework. C-DED structures eHealth development into four iterative phases and three evidence reflections,

offering guidance on when and how to define, generate, and stabilise evidence while balancing responsiveness to users' contexts with regulatory rigour.

Chapter 6 discusses the contributions of the thesis, reflects on its limitations, and outlines directions for future research. It also translates the framework into a set of recommendations to support designers and healthcare professionals in clarifying what evidence to generate and how, when, and for what purpose during eHealth development.

Conclusions and implications

This thesis concludes that tensions in eHealth evidence generation stem not from incompatible practices, but from insufficient integration between static and dynamic approaches. By articulating shared practices, outcome-oriented logic, and structured reflection points, the thesis demonstrates how these approaches can be aligned in a deliberate and compliant manner. The C-DED framework provides a methodological contribution that supports integrated evidence generation across design and healthcare practices. Its implications extend to designers and healthcare professionals involved in eHealth development, offering a structured way to balance clinical rigour with contextual responsiveness. More broadly, the thesis contributes to ongoing discussions on cross-domain collaboration in healthcare innovation and highlights the importance of evidence practices that balance rigour and standardisation with responsiveness to users' lived care contexts.

Resumen

Motivación

Las soluciones de salud digital (eSalud/eHealth) están transformando cada vez más la forma en que se presta, se monitorea y se experimenta la atención médica. Al integrar las tecnologías digitales en la atención, estas soluciones prometen mejores resultados clínicos, mayor eficiencia y una atención centrada en el paciente. Sin embargo, para lograr estos beneficios, es necesario generar evidencia que demuestre que las soluciones de salud digital no solo son clínicamente seguras y eficaces, sino también utilizables, relevantes y adaptables en los contextos cotidianos de los usuarios que las necesitan. En la práctica, generar dicha evidencia es un reto, ya que el desarrollo de la salud digital combina prácticas de diseño y atención médica que se basan en diferentes maneras de definir y producir evidencia. Los diseñadores suelen generar evidencia dinámica y contextual mediante la interacción iterativa con los usuarios, mientras que los profesionales de la salud se basan en evidencia estática y predefinida para cumplir con los requisitos clínicos y normativos. Cuando estos enfoques no están alineados deliberadamente, surgen tensiones sobre qué evidencia debe generarse, cómo, cuándo y con qué propósito. Estas tensiones pueden dar lugar a prácticas de evidencia fragmentadas y a soluciones de salud digital que, si bien son clínicamente

sólidas, tienen una baja adopción, o están centradas en el usuario, pero carecen de rigor suficiente. Esta tesis surge de la necesidad de integrar la generación de evidencia estática y dinámica en el desarrollo de la salud digital, con el fin de apoyar el diseño de soluciones que cumplan con los estándares de desarrollo y sean significativas para pacientes y profesionales de la salud.

Objetivo

El objetivo de esta tesis es establecer fundamentos conceptuales, empíricos y metodológicos para integrar enfoques estáticos y dinámicos en la generación de evidencia en el desarrollo de la salud digital. Específicamente, la tesis investiga cómo los diseñadores y profesionales de la salud definen y generan la evidencia, y cómo estas prácticas pueden alinearse con los estándares de salud digital existentes. El objetivo general de la investigación es desarrollar una práctica compartida de generación de evidencia que respalde soluciones de salud digital centradas en el usuario, clínicamente sólidas y conformes con los estándares de desarrollo. Este objetivo se aborda mediante cuatro preguntas de investigación que examinan las prácticas de medición de la experiencia, la generación de evidencia en la práctica, la definición de evidencia orientada a resultados de salud y la estructuración de la generación integrada de evidencia dentro de los estándares de salud digital.

Capítulos y resultados

El **Capítulo 1** presenta el contexto de la investigación y plantea el problema central de la generación fragmentada de evidencia en el desarrollo de la salud digital. Este capítulo conceptualiza la generación de evidencia estática y dinámica como lentes analíticos para explicar las tensiones entre el diseño y las prácticas de atención médica que se presentan en el desarrollo de salud digital. El capítulo concluye

identificando cuatro barreras para la integración y formula las preguntas de investigación que guían la tesis.

El **Capítulo 2** aborda la primera pregunta de investigación examinando cómo se mide la experiencia del paciente y del personal de salud en el desarrollo de la salud digital. Mediante una revisión bibliográfica estructurada centrada en el monitoreo remoto de pacientes, el capítulo mapea los constructos de experiencia y los instrumentos de medición existentes. Los hallazgos revelan una diversidad sustancial y una estandarización limitada en la medición de la experiencia. Para abordar esto, el capítulo propone cuatro categorías de experiencia: sistema-servicio, uso y adherencia, atención y resultados de salud, que proporcionan una base estructurada para la generación de evidencia estática y crean una base para integrar perspectivas dinámicas sobre la experiencia.

El **Capítulo 3** explora cómo los diseñadores y los profesionales de la salud generan evidencia en la práctica. Mediante entrevistas cualitativas y análisis temático, el estudio identifica cinco prácticas de evidencia compartidas: orientadas a las partes interesadas (stakeholders), al proceso, al problema, a la solución y al efecto. Éstas son compartidas entre diseñadores y los profesionales de la salud, a pesar de las diferentes prioridades y tradiciones de evaluación. En conclusión, las cinco prácticas basadas en evidencia demuestran cómo los enfoques estáticos y dinámicos ya coexisten en la práctica, pero permanecen poco integrados debido a la falta de coordinación explícita y estructura compartida, lo que expone oportunidades de integración.

El **Capítulo 4** examina cómo los diseñadores pueden aplicar la lógica orientada a resultados de salud, comúnmente utilizada en el sector médico, para definir la generación dinámica de evidencia. Mediante un estudio de caso cualitativo, el capítulo analiza cómo los profesionales de la salud articulan los resultados de salud centrados en el paciente y traduce esta lógica a la práctica del diseño. El estudio identifica tres dimensiones conceptuales (efecto, significado y recopilación) que

aclaran cómo la lógica de resultados de salud centrada en el paciente puede guiar la definición dinámica de la evidencia. Estas dimensiones se relacionan con competencias de diseño adaptadas, proporcionando a los diseñadores una base conceptual para definir la evidencia relacionada con los resultados de salud de forma que se ajuste a las expectativas del sector médico.

El **Capítulo 5** sintetiza los hallazgos de los capítulos anteriores para abordar la brecha metodológica en la integración de la generación de evidencia estática y dinámica dentro de los estándares de desarrollo de salud digital. Mediante un enfoque de adaptación teórica, el capítulo adapta el Diseño Basado en Datos (DED por sus siglas en inglés) en relación con la norma ISO 14155 para ensayos clínicos de salud digital, con el fin de desarrollar el marco de Diseño Basado en Datos Clínicos (C-DED por sus siglas en inglés). El C-DED estructura el desarrollo de la salud digital en cuatro fases iterativas y tres reflexiones sobre la evidencia, ofreciendo orientación sobre cuándo y cómo definir, generar y estabilizar la evidencia, equilibrando la adaptabilidad a los contextos de los usuarios con el rigor regulatorio.

El **Capítulo 6** analiza las contribuciones de la tesis, reflexiona sobre sus limitaciones y describe las líneas de investigación futuras. Asimismo, traduce el marco en un conjunto de recomendaciones para ayudar a diseñadores y profesionales de la salud a clarificar qué evidencia generar y cómo, cuándo y con qué propósito durante el desarrollo de la salud digital.

Conclusiones e implicaciones

Esta tesis concluye que las tensiones en la generación de evidencia en salud digital no se derivan de prácticas incompatibles, sino de una integración insuficiente entre los enfoques estáticos y dinámicos. Al articular prácticas compartidas, lógica orientada a resultados de salud y puntos de reflexión estructurados, la tesis demuestra cómo

estos enfoques pueden alinearse de manera deliberada y conforme a las normas. El marco C-DED aporta una contribución metodológica que respalda la generación integrada de evidencia en las prácticas de diseño y atención médica durante el desarrollo de salud digital. Sus implicaciones se extienden a los diseñadores y profesionales de la salud involucrados en el desarrollo de la salud digital, ofreciendo una forma estructurada de equilibrar el rigor clínico con la capacidad de respuesta contextual. En un sentido más amplio, la tesis contribuye a los debates actuales sobre la colaboración interdisciplinaria en la innovación médica y subraya la importancia de las prácticas basadas en evidencia que equilibran el rigor y la estandarización con la capacidad de respuesta a los contextos de atención vivida por los usuarios.

Samenvatting

Motivatie

eHealth-oplossingen bepalen in toenemende mate hoe gezondheidszorg wordt geleverd, gemonitord en ervaren. Door digitale technologieën in de zorg te integreren, beloven deze oplossingen verbeterde klinische uitkomsten, efficiëntie en patiëntgerichtheid. Het realiseren van deze effecten hangt echter af van het genereren van bewijs dat aantoont dat eHealth-oplossingen niet alleen klinisch veilig en effectief zijn, maar ook bruikbaar, betekenisvol en toepasbaar in alledaagse zorgcontexten. In de praktijk is het genereren van dergelijk bewijs uitdagend. De ontwikkeling van eHealth brengt de ontwerp en medische praktijk namelijk samen, maar deze twee vakgebieden hanteren uiteenlopende methoden voor het definiëren en genereren van bewijs. Ontwerpers genereren doorgaans dynamisch, context-specifiek bewijs via iteratieve betrokkenheid van gebruikers, terwijl zorgprofessionals werken met statisch, vooraf gedefinieerd bewijs om te voldoen aan klinische en wettelijke vereisten. Wanneer deze werkwijzen niet doelbewust op elkaar worden afgestemd, ontstaan spanningen over welk bewijs moet worden gegenereerd, hoe, wanneer en met welk doel. Deze spanningen kunnen leiden tot gefragmenteerde bewijspraktijken en eHealth-oplossingen die óf klinisch robuust maar slecht geaccepteerd zijn, óf gebruikersgericht

maar onvoldoende wetenschappelijk onderbouwd. De aanleiding voor deze thesis is de noodzaak om statische en dynamische bewijsvoering binnen de ontwikkeling van eHealth beter te integreren, om oplossingen te ondersteunen die zowel conform wet- en regelgeving als betekenisvol zijn voor patiënten en zorgverleners.

Doelstelling

Het doel van deze thesis is het leggen van conceptuele, empirische en methodologische fundamenten voor het integreren van statische en dynamische vormen van bewijsvoering binnen de ontwikkeling van eHealth. Meer specifiek onderzoekt de thesis hoe bewijs wordt gedefinieerd en gegenereerd door ontwerpers en zorgprofessionals, en hoe deze praktijken kunnen worden afgestemd binnen bestaande eHealth-standaarden. Het overkoepelende onderzoeksdoel is het ontwikkelen van een gedeelde manier van bewijsvoering om zo eHealth-oplossingen te realiseren die de gebruiker centraal stellen, klinisch onderbouwd zijn en aan de geldende standaarden voldoen. Dit doel wordt behandeld aan de hand van vier onderzoeksvragen gericht op het meten van ervaringen, bewijsvoering in de praktijk, uitkomstgerichte bewijsdefinitie en de structurering van geïntegreerde bewijsvoering binnen eHealth-standaarden.

Opzet en resultaten

Hoofdstuk 1 introduceert de onderzoekscontext en kadert het centrale probleem van gefragmenteerde bewijsvoering binnen de ontwikkeling van eHealth. Het conceptualiseert statische en dynamische bewijsvoering als analytische lenzen om spanningen tussen ontwerp- en zorgpraktijken te verklaren, identificeert vier barrières voor integratie en formuleert de onderzoeksvragen die centraal staan binnen de thesis.

Hoofdstuk 2 behandelt de eerste onderzoeksvraag door te onderzoeken hoe ervaringen van patiënten en zorgprofessionals worden gemeten binnen de ontwikkeling van eHealth. Via een gestructureerde literatuurstudie gericht op monitoring van patiënten op afstand brengt het hoofdstuk bestaande ervaringsconstructen en meetinstrumenten in kaart. De bevindingen tonen aanzienlijke diversiteit en beperkte standaardisatie in ervaringsmetingen. Om dit aan te pakken stelt het hoofdstuk vier ervaringscategorieën voor: service-systeem, gebruik en therapietrouw, zorg en gezondheidsuitkomsten. Deze categorieën bieden een gestructureerde basis voor statische bewijsvoering en vormen een fundament voor de integratie van dynamische perspectieven op ervaring.

Hoofdstuk 3 onderzoekt hoe ontwerpers en zorgprofessionals in de praktijk bewijs genereren. Met behulp van kwalitatieve interviews en thematische analyse identificeert de studie vijf gedeelde bewijspraktijken (namelijk stakeholder-, proces-, probleem-, oplossing- en effectgedreven) die van toepassing zijn op zowel het ontwerp- als zorgdomein, ondanks verschillende prioriteiten en werkwijzen. Deze bewijspraktijken tonen aan hoe statische en dynamische benaderingen in de praktijk al naast elkaar bestaan, maar zwak geïntegreerd blijven door een gebrek aan expliciete coördinatie en gedeelde structuur, waardoor kansen voor integratie naar voren komen.

Hoofdstuk 4 onderzoekt hoe ontwerpers de uitkomstgerichte logica die gebruikelijk is binnen de gezondheidszorg kunnen toepassen om dynamische bewijsvoering te definiëren. Via een diepgaande kwalitatieve casestudy analyseert het hoofdstuk hoe zorgprofessionals patiëntgerichte uitkomsten formuleren en vertaalt deze logica naar ontwerppraktijken. De studie identificeert drie conceptuele dimensies (effect, betekenis en verzameling) die verduidelijken hoe patiëntgerichte uitkomstlogica de dynamische definitie van bewijs kan sturen. Deze dimensies worden gekoppeld aan aangepaste ontwerpcompetenties, waardoor ontwerpers een conceptuele basis

krijgen om uitkomst gerelateerd bewijs te definiëren op en manier die aansluit bij de verwachtingen binnen de gezondheidszorg.

Hoofdstuk 5 synthetiseert de bevindingen uit de voorgaande hoofdstukken om de methodologische kloof in de integratie van statische en dynamische bewijsvoering binnen eHealth-standaarden aan te pakken. Met behulp van een theorie-adaptatiebenadering past het hoofdstuk Data-Enabled Design aan in relatie tot de ISO 14155-standaard voor klinische eHealth-studies, om het Clinical Data-Enabled Design (C-DED)-framework te ontwikkelen. C-DED structureert de ontwikkeling van eHealth in vier iteratieve fasen en drie bewijsreflecties, en biedt richtlijnen voor wanneer en hoe bewijs moet worden gedefinieerd, gegenereerd en gestabiliseerd, terwijl een balans wordt gevonden tussen aansluiting bij gebruikerscontexten en strikte medische en wettelijke eisen.

Hoofdstuk 6 bespreekt de bijdrage van de thesis, reflecteert op de beperkingen ervan en schetst richtingen voor toekomstig onderzoek. Daarnaast wordt het framework vertaald in een reeks aanbevelingen om ontwerpers en zorgprofessionals te ondersteunen bij het verduidelijken welk bewijs moet worden gegenereerd en hoe, wanneer en met welk doel tijdens de ontwikkeling van eHealth.

Conclusies en implicaties

Deze thesis concludeert dat spanningen in de bewijsvoering van eHealth niet voortkomen uit onverenigbare praktijken, maar uit onvoldoende integratie tussen statische en dynamische benaderingen. Door gedeelde praktijken, uitkomstgerichte logica en gestructureerde reflectiemomenten expliciet te maken, toont de thesis aan hoe deze benaderingen op een doelbewuste en conforme manier kunnen worden afgestemd. Het C-DED-framework levert een methodologische bijdrage die geïntegreerde bewijsvoering ondersteunt over ontwerp- en zorgpraktijken heen. De implicaties ervan strekken zich uit tot

ontwerpers en zorgprofessionals die betrokken zijn bij de ontwikkeling van eHealth, en bieden een gestructureerde manier om klinische striktheid in balans te brengen met contextuele responsiviteit. In een breder perspectief draagt deze thesis bij aan lopende discussies over samenwerking tussen domeinen binnen zorginnovatie. Het onderstreept het belang van bewijs verzamelen dat zowel aan strikte normen en standaarden voldoet, als nauw aansluit bij de zorgervaring van gebruikers.

Preface

My PhD journey has been about exploring and building common ground in a sea of differences.

Throughout my life, I have had the privilege of living with a healthcare professional—my mom. I witnessed countless hours of work in the service of others and what 'caring' means as a professional practice. Alongside my creative self, the motivation of 'caring' for others has always stayed with me, leading me to explore the possibility of studying medicine during my high school years. During this exploration, I took courses in anatomy, physiology, as well as advanced chemistry and biology. I even had the opportunity to spend a few days 'in the life of a healthcare professional' inside a hospital, joining medical rounds as well as observing natural childbirths and various surgeries. This experience made me realise that caring for others as a professional practice demanded great responsibility and, thus, entailed strict protocols to ensure patient safety throughout the healthcare service. However, after this experience, I wasn't sure how I could *also* develop my creative self within this environment. Therefore, I decided to first cultivate my

creative skills professionally, and, hopefully later, discover a way to connect them with my motivation to care for others.

While studying my bachelor's in industrial design at Tec de Monterrey, I had the opportunity to create a project where I could apply my creative skills to a care context. Together with a fellow student, we developed 'Endera', a family of six wood toys aimed at facilitating the development of motor skills in children with autism. During this project, I understood that creating products to improve a certain aspect of a person's life required coordination with the professionals working with these persons—in our case, therapists specialised in children with autism. Some years after that project, I volunteered to play with children with cancer at hospitals. During one visit, while playing in a common area, I noticed that a child started crying desperately when the sound of a machine began to play. Later that day, I asked the parents why their child cried, and they told me that their child associated that sound with a painful medical procedure, even when the procedure wasn't happening to him. This event made me reflect on the importance of experience while providing care, but most importantly, it made me realise that I, as a design professional, could make a difference in this situation.

After having these formative experiences during and after my bachelor studies, I decided to search for opportunities where design and healthcare could be bridged professionally. This led me to join TU Delft as a master student in the integrated product design programme, where I could specialise in design for healthcare. As part of my master studies, I had the opportunity to join multiple projects related to healthcare. From the redesign of a wheelchair for children with Duchenne and the co-design of MRI experiences with children, to the redesign of digital care experiences for children with cleft lip and palate and the creation of an asthma management app for adults. These projects showed me the endless possibilities of applying technology in a user-centred manner to healthcare, and the increasing role of digital data to personalise treatment plans and care experiences. With these learnings in mind, for my master thesis, I worked with children with congenital heart defects, their

parents, and their healthcare team to develop a product that increased their physical activity. During this project, I faced various difficulties that made me more aware of differences between design and healthcare. These difficulties included navigating rigorous ethical procedures to ensure safety, applying user-centred design methods into healthcare practice, and bringing all stakeholders into the design process to ensure adoption. Yet, I knew that despite these difficulties we—parents, healthcare professionals and I—strived for the same purpose, improving children's health and doing so through the best possible experience.

When I started this PhD journey, I believed this was a journey about differences between design and healthcare. I knew there were differences, as I experienced them throughout my projects. I further explored them by reading multiple papers explaining the difficulties that designers faced while working in healthcare, and how design was different from medicine—and at its core, to science. How, to explain what the design discipline is, papers explained how design differed from science. Understanding these differences helped me to appreciate what each brings to the development of healthcare products. I also came across various papers in design and healthcare venues arguing that both domains need each other to develop successful products. This need took me back to when I realised that we—the patient, the family, the healthcare team, and I as a design professional— strove for the same purpose: to improve patient's health and quality of life. It was then, when I understood that my PhD was, at its core, about knowledge generation independently of who was generating it. This realisation shifted my research perspective to not only account for their differences and what each brought but also account for this shared need to generate knowledge that helps to design products that improve health and care experiences.

Therefore, in my PhD thesis, you will find an exploration of a sea of differences between design and healthcare, as well as an exploration of their common grounds. But, most importantly, you will find a methodological vision I built to support the development of digital and physical healthcare products from a shared design and healthcare

perspective. A vision where I lay out how design and healthcare professionals can employ their differences and strengths in knowledge generation to create products that are safe and desirable to use as well as clinically and experientially meaningful. A vision that I hope can guide us, (future) healthcare designers, to care more about the health and experience of our users.

Prefacio

Mi trayectoria doctoral se ha centrado en explorar y construir puntos en común en un mar de diferencias.

A lo largo de mi vida, he tenido el privilegio de convivir con una profesional de la salud: mi mamá. Fui testigo de incontables horas de trabajo al servicio de los demás y lo que significa el cuidado como práctica profesional. Junto a mi lado creativo, la motivación de cuidar a los demás siempre me ha acompañado, lo que me llevó a explorar la posibilidad de estudiar medicina durante la secundaria. Durante esta exploración, cursé anatomía, fisiología, química avanzada y biología. Incluso tuve la oportunidad de pasar unos días viviendo la experiencia de un profesional de la salud en un hospital, participando en rondas médicas y observando partos naturales y diversas cirugías. Esta experiencia me hizo comprender que el cuidado de los demás como práctica profesional exige una gran responsabilidad y, por lo tanto, implica protocolos estrictos para garantizar la seguridad del paciente en todo el servicio de salud. Sin embargo, después de esta experiencia, no estaba segura de cómo podría desarrollar *también* mi lado creativo dentro de este entorno. Por lo tanto, decidí primero cultivar mis habilidades creativas

profesionalmente y, con suerte, más adelante encontrar la manera de conectarlas con mi motivación de cuidar a los demás.

Mientras estudiaba la Licenciatura en Diseño Industrial en el Tecnológico de Monterrey, tuve la oportunidad de crear un proyecto donde pude aplicar mis habilidades creativas en un contexto de cuidado. Junto con una compañera, desarrollamos 'Endera', una familia de seis juguetes de madera diseñados para facilitar el desarrollo de las habilidades motoras en niños con autismo. Durante este proyecto, comprendí que crear productos para mejorar un aspecto específico de la vida de una persona requiere coordinación con los profesionales que trabajan con estas personas; en nuestro caso, terapeutas especializados en niños con autismo. Algunos años después de ese proyecto, fui voluntaria para jugar con niños con cáncer en hospitales. Durante una visita, mientras jugábamos en un área común, noté que un niño comenzó a llorar desconsoladamente cuando empezó a sonar una máquina. Más tarde ese día, pregunté a los padres por qué lloraba su hijo, y me dijeron que su hijo asociaba ese sonido con un procedimiento médico doloroso, incluso cuando no se lo iban a realizar a él. Este evento me hizo reflexionar sobre la importancia de la experiencia en el cuidado de la salud, pero, sobre todo, me hizo darme cuenta de que, como profesional del diseño, podía marcar la diferencia en esta situación.

Tras estas experiencias formativas durante y después de mis estudios de licenciatura, decidí buscar oportunidades donde el diseño y la atención médica pudieran converger profesionalmente. Esto me llevó a TU Delft como estudiante de Máster en el Programa de Diseño Integrado de Producto, donde pude especializarme en diseño para el sector médico. Como parte de mis estudios de Máster, tuve la oportunidad de participar en múltiples proyectos relacionados con la atención médica. Desde el rediseño de una silla de ruedas para niños con distrofia muscular de Duchenne y el co-diseño de experiencias de resonancia magnética con niños, hasta el rediseño de experiencias de atención digital para niños con labio y paladar hendido y la creación de una aplicación para el manejo del asma en adultos. Estos proyectos me mostraron las infinitas

posibilidades de aplicar la tecnología de forma centrada en el usuario en la atención médica, y el papel cada vez más importante de los datos digitales para personalizar los planes de tratamiento y las experiencias de atención. Teniendo en cuenta estos aprendizajes, para mi tesis de maestría trabajé con niños con cardiopatías congénitas, sus padres y su equipo médico para desarrollar un producto que fomentara su actividad física. Durante este proyecto, me enfrenté a diversas dificultades que me hicieron más consciente de las diferencias entre el diseño y la atención médica. Estas dificultades incluyeron la necesidad de seguir rigurosos procedimientos éticos para garantizar la seguridad, la aplicación de métodos de diseño centrados en el usuario a la práctica médica y la integración de todas las partes interesadas (stakeholders) en el proceso de diseño para asegurar su adopción. Sin embargo, sabía que a pesar de estas dificultades, todos—padres, profesionales de la salud y yo—nos esforzábamos por el mismo objetivo: mejorar la salud de los niños y lograrlo a través de la mejor experiencia posible.

Cuando comencé mi doctorado, creía que se trataba de explorar las diferencias entre el diseño y la atención médica. Sabía que existían diferencias, pues las había experimentado a lo largo de mis proyectos. Las exploré aún más leyendo numerosos artículos científicos que explicaban las dificultades a las que se enfrentaban los diseñadores en el ámbito médico y cómo el diseño se diferenciaba de la medicina, y en esencia de la ciencia. Estos artículos describían qué es la disciplina del diseño a través de explicar cómo es que el diseño difiere de la ciencia. Comprender estas diferencias me ayudó a apreciar la contribución de cada disciplina en el desarrollo de productos médicos. También encontré varios artículos en revistas científicas de diseño y atención médica que argumentaban que ambos campos se necesitan mutuamente para desarrollar productos exitosos. Esta necesidad me hizo recordar el momento cuando comprendí que todos—el paciente, la familia, el equipo médico y yo, como profesional del diseño—nos esforzábamos por el mismo objetivo: mejorar la salud y la calidad de vida del paciente. Fue entonces cuando comprendí que mi doctorado, en esencia, trataba sobre la generación de conocimiento, independientemente de quién lo

generara. Esta realización transformó mi perspectiva de investigación, permitiéndome no solo considerar sus diferencias y las aportaciones de cada una, sino también la necesidad compartida de generar conocimiento que contribuya al diseño de productos que mejoren la salud y la atención médica.

Por lo tanto, en mi tesis doctoral, encontrarán una exploración de las numerosas diferencias entre el diseño y la atención médica, así como de sus puntos en común. Pero, sobre todo, encontrarán una visión metodológica que desarrollé para apoyar la creación de productos para la salud físicos y digitales desde una perspectiva compartida del diseño y la atención médica. Una visión donde explico cómo los profesionales del diseño y la atención médica pueden aprovechar sus diferencias y fortalezas en la generación de conocimiento para crear productos seguros y atractivos, además de clínicamente relevantes y con un impacto positivo en la experiencia del usuario. Una visión que espero nos guíe, a los (futuros) diseñadores trabajando en el área de salud a preocuparnos más por la salud y la experiencia de nuestros usuarios.

Chapter 1.

Introduction

1.1 Context and motivation

In recent years, eHealth solutions have transformed healthcare delivery, enhancing efficiency, accessibility, and personalisation (WHO, 2016). eHealth integrates information and communication technologies into healthcare, offering solutions such as electronic health records, telemedicine, and remote patient monitoring (Silber, 2003). For example, diabetes management platforms, such as continuous glucose monitoring systems paired with smartphone apps, provide real-time glucose data that can inform tailored treatment adjustments (Battelino et al., 2019). Overall, eHealth solutions support patients and healthcare professionals by facilitating continuous monitoring, treatment adherence, and data-driven decision-making, thereby improving health outcomes (WHO, 2021).

Among current eHealth developments, remote patient monitoring (RPM) has emerged as a prominent approach for supporting care beyond clinical settings through digitally transmitted patient data (de Farias et al., 2020). RPM interventions are increasingly applied across medical specialties and care contexts, partly due to their potential to support continuous care, patient self-management, and data-informed clinical decision-

making (Noah et al., 2018; Vegesna et al., 2017). In RPM, care activities extend into patients' everyday lives through ongoing interactions with monitoring devices, mobile applications, and healthcare professionals. Consequently, RPM interventions depend not only on clinical performance, but also on how patients and healthcare professionals experience, adopt, and sustain these technologies across evolving everyday care contexts. Therefore, RPM solutions require collaborative development across domains to create systems that are user-centred, safe, and clinically effective (Bate & Robert, 2006; Sharp et al., 2016). Within this RPM development context, I focus on design and healthcare practices, as their complementary perspectives on adoption and clinical safety are both essential to developing successful RPM solutions and informing broader eHealth development.

Throughout eHealth development, designers bring together people, technology, and business aspects to encourage eHealth adoption. They work with (potential) users such as patients, their families, and clinicians to understand and align their needs and experiences with the solution's characteristics and, thus, increase its desirability (Melles et al., 2021). Based on this, they work with engineers (e.g., software and hardware developers) to create technological solutions that are feasible to build as well as easy and safe to use (ISO, 2019; Ku & Lupton, 2020). Finally, they work with organisations (e.g., hospitals, health-related companies) to understand the business viability and the strategic implementation of the solution into the healthcare system (Canales Durón et al., 2019; Mager et al., 2017). By iteratively engaging these stakeholders and their social context through principles of human-centredness, co-design, and prototyping, designers generate evidence in a dynamic (and not always predetermined) manner to ensure eHealth solutions remain desirable, feasible, and viable for adoption (Brown, 2008; Ku & Lupton, 2020).`

In the same development context, healthcare professionals (HCPs) focus on creating eHealth solutions that are safe, clinically effective, and responsive to patients' care concerns (Davies & Mueller, 2020). To achieve this, they follow standards (e.g., ISO 14155) and procedures

(e.g., Medical Ethical Reviews) to ensure the development process and the solution are safe for participants (ISO, 2020). In addition, they define rigorous and static research study designs (e.g., randomised controlled trials) and use established outcome measures (e.g., Euro Quality of Life-5D questionnaire) to understand the clinical reliability of the solution before its implementation in care practice (Ammenwerth & Rigby, 2016). Finally, they increasingly engage patients to develop solutions that respond to their care needs in addition to medical advice (Domecq et al., 2014; Jacob et al., 2022). Through these activities, HCPs generate predefined, standardised, and static evidence to establish the solution's clinical safety and effectiveness, following principles of Good Clinical Practice (ICH, 2025) and Evidence-Based eHealth (Wyatt, 2016).

However, as a result of diverging tendencies in evidence generation practices between design and healthcare, tensions may occur concerning what evidence to generate and how, when, and for what purpose during eHealth development (Blandford et al., 2018; Lamé, 2018; Smits et al., 2022). These tensions arise from the interaction between dynamic, context-driven approaches to evidence generation that characterise design practices and the static, predefined evidence generation approaches that often shape healthcare practices. To my knowledge, there is a lack of integration between both evidence approaches within the same development process. As a result, evidence generation risks becoming fragmented, limiting the development of adoptable and clinically safe and effective eHealth solutions.

Therefore, in this thesis, I investigate the tension in evidence generation that arises when design and healthcare practices meet in eHealth development. In particular, I develop a methodological integration of static and dynamic evidence generation practices to ultimately create more effective eHealth solutions. Achieving this integration requires first a better understanding of evidence practices in design and healthcare, since these starting points shape how the tension emerges and what needs to be integrated. Thus, the following section introduces the conceptual and epistemological foundations of each evidence generation practice.

1.2 Background

In this section, I explain why tensions in evidence generation between design and healthcare practices arise by outlining how designers and HCPs understand and generate evidence during eHealth development. First, I clarify how practices and evidence are conceptualised and describe the epistemological orientations that shape design's and healthcare's tendencies in evidence generation. Then, I further explain the static and dynamic evidence generation practices in each field as analytical lenses to make their tendencies explicit and to clarify what needs to be integrated and how the lenses underpin current eHealth development frameworks.

Conceptual use of 'practices'

Understanding how evidence is generated in eHealth development requires attention to the practices through which designers and HCPs carry out their work activities. In this thesis, I use the term 'practice(s)' to refer to socially and materially situated forms of activity shaped by shared understandings and embedded in real-world development contexts. This usage draws on practice theory, particularly the idea that practices are *"embodied, materially mediated arrays of human activity centrally organized around shared practical understanding"* (Schatzki et al., 2005, p. 11). This framing highlights that development work in both design and healthcare consists of patterned ways of doing and knowing through which evidence is produced and interpreted in eHealth development.

Evidence and evidence generation approaches

The concept of evidence encompasses a broad spectrum of interpretations. For instance, legal contexts see evidence as testimonies, objects, or documents strictly evaluated on relevance or admissibility to support claims in courtroom settings (Ho, 2021). Engineering and medicine see evidence as objective and reproducible data to support

claims, often derived from observations, measurements, tests, or scientific inquiries (ISO, 2015; Straus et al., 2000). In design, evidence can be seen as data according to engineering views (ISO, 2019) or as artefacts resulting from generative activities (Sanders & Stappers, 2012). Philosophically, evidence underpins the justification of beliefs, serving as a reliable indicator or a guiding sign towards truth, which highlights its role in substantiating or refuting knowledge claims (Kelly, 2016). This diversity shows that evidence is not universal but shaped by epistemological and methodological orientations, ranging from fixed and generalisable to evolving and context-dependent. Therefore, understanding how evidence is *defined* as 'evidence' for a knowledge claim and how it is *generated* is central to understanding the tension that designers and HCPs face in eHealth development.

Healthcare and design practices draw on different epistemological traditions that shape how evidence is defined and generated. In healthcare, evidence-based practice has foundations in logical-positivism, where credible knowledge depends on minimising bias and demonstrating generalisable effects through rigorous study designs (Djulbegovic et al., 2009; Djulbegovic & Guyatt, 2017). This orientation underpins evidence hierarchies and the emphasis on controlled study designs such as randomised trials (Sackett et al., 1996; Wyatt, 2016). In contrast, design's foundations span epistemological orientations associated with technical rationality and with constructivism traditions. The former aligns with a positivist, problem-solving view in which designing is understood as an information-processing activity aimed at moving from a present to a desired state (Dorst & Dijkhuis, 1995; Simon, 1988). The latter views designing as a reflective, iterative learning process in which meaning is constructed through situated action (Schön, 1992). These orientations do not strictly determine practice but create recognisable tendencies in how designers and HCPs define and generate evidence. To explain why tensions in evidence generation arise, I use these epistemic origins to introduce static and dynamic evidence generation as analytical lenses. These lenses clarify how positivist orientations tend to align with predefined, standardised evidence (i.e.,

static), while constructivist orientations tend to align with evolving, context-responsive evidence (i.e., dynamic).

Based on healthcare and design epistemological origins, I introduce two analytical lenses to evidence generation: the **static** and the **dynamic**. ***Static evidence*** assumes that evidence is a generalisable, fixed entity that can be defined independently of users' contexts. Static evidence is generated through the ***static evidence generation approach***. This approach operates under the assumption that pre-definition of *what* evidence to generate and *how*—before engaging with the real-world user context, produces objective and unbiased data, thus making the generation process linear. The (post)positivist epistemology underpins this static view, treating evidence as an indicator that exists independently of the researcher's knowledge or beliefs, but is defined according to what the researcher knows about the phenomenon (Creswell, 2009; Kelly, 2016). Here, development teams must define what evidence to generate and how in a study protocol and deploy the protocol (and intervention) in the user context. Then, generate the evidence, interpret it, identify insights and modify the intervention based on them. Figure 1.1 presents a schematic of these steps and the linear nature that characterises static evidence generation processes.

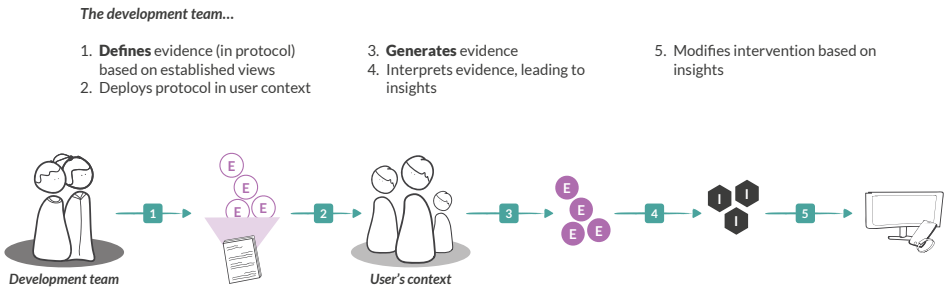

Figure 1.1. Static evidence generation approach.

In contrast, ***dynamic evidence*** assumes that evidence is context-dependent, evolving through continuous interaction with the user's context. Dynamic evidence is generated through the emerging ***dynamic evidence generation approach***. This approach follows the assumption that defining *what* evidence to generate and *how* gets (re)defined and refined as new insights are identified in context, thus making the generation process exploratory and iterative. Constructivism epistemologies underpin this dynamic view, emphasising how individuals (i.e., researchers and users) and their environments interact to construct knowledge (Creswell, 2009; Schön, 1992). Here, development teams first engage informally with users, and based on this they tentatively define evidence to be collected in a study protocol. Then, they deploy the protocol (and intervention) with users, generate evidence, interpret it, and identify insights. These insights are then used to adjust what evidence to generate and how, as well as to modify the intervention. Figure 1.2 presents a schematic of these steps and the iterative-exploratory nature that characterises dynamic evidence generation processes.

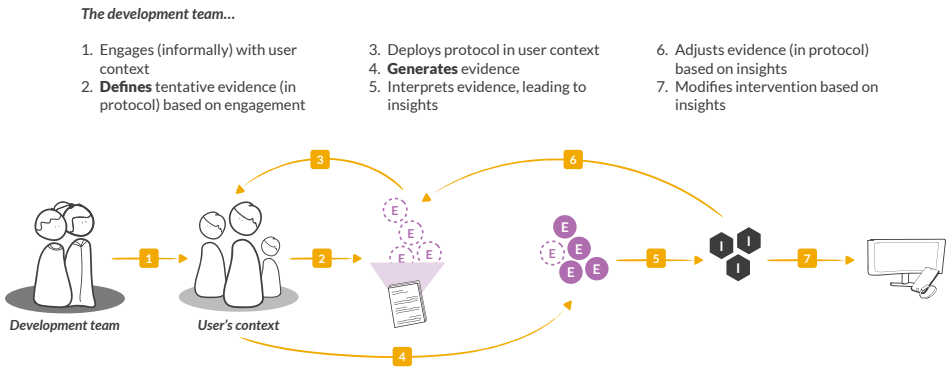

Figure 1.2. Dynamic evidence generation approach.

In practice, static and dynamic evidence generation approaches are not confined to specific professional domains, but domains have a natural preference. Both, design and healthcare, draw on each approach

depending on development demands. For example, design practice can involve static evidence generation through predefined evaluation metrics such as the system usability scale (Brooke, 1996) or standardised testing and validation procedures required for safety certifications (ISO, 2020). Conversely, healthcare practice can employ dynamic approaches through patient-centred outcome measures developed in engagement with patient communities (Kelley, 2015) or adaptive clinical trials that revise evidence-generation procedures in response to accumulated data (Pallmann et al., 2018). However, despite this overlap, static and dynamic approaches are not always deliberately aligned within a single development process as a consequence of the natural preferences of each domain, which can allow one approach to dominate at the expense of the other.

Below, Textbox 1.1 illustrates how a lack of deliberate alignment between static and dynamic approaches can shape evidence generation within an eHealth development process. Based on work I conducted prior to this PhD, the example shows how the predominance of a dynamic approach early in development can later create tensions when predefined evidence requirements arise.

Textbox 1.1. Evidence generation in practice during eHealth development.

To exemplify how evidence generation can unfold during the development of an eHealth solution, I draw on my master thesis project. The project involved the development of an eHealth RPM solution for children with congenital heart defects and their families. It aimed to create Bo—an intelligent eHealth solution (illustrated in Figure 1.3), designed to promote children's safe physical activity and support parents in managing anxiety during exercise.

(Continues on the next page.)

Figure 1.3. Bo—a smart chatbot that connected families with the medical team and a bracelet that monitors the child's heart rate while doing physical activity. Image from Morales Ornelas (2020).

The development process of Bo combined manual and automated text analysis of 300+ parental stories, generative semi-structured interviews with families, and a co-creation session with the medical team (see Morales Ornelas, 2020). These activities informed the design of the prototype and the conversational content integrated into Bo's chatbot. I deployed the prototype with families in their everyday context to explore how it could support the child to increase physical activity and decrease parental anxiety leading to overprotection. During this phase, I followed Data-Enabled Design (van Kollenburg & Bogers, 2019) to refine system functionality and understand how families interacted with Bo in daily use.

Although the process offered valuable contextual insights, defining *what* to evaluate and *how* was not a primary focus. Evaluation considerations emerged pragmatically in response to design and development needs, rather than being structured by a predefined evidence framework. Consequently, while the study produced meaningful insights into family experiences and prototype use, it also revealed limitations in how evidence was defined and

generated during development. This became clear when predefined evidence of effectiveness—such as data about reduced anxiety or increased physical activity—was later required, but the exploratory, dynamic process had not been designed to produce it. This example illustrates how tensions in evidence generation can arise when dynamic approaches are not deliberately aligned with static evidence requirements within a single development process.

Overall, this project exposed a broader concern in eHealth development: how to determine, during the design of a solution, what evidence should be generated, how, when, and for what purpose. The answers to these questions reflect the tension between structured, predefined forms of evidence and more adaptive, evolving approaches to its generation. Together, they highlight the need to integrate static and dynamic evidence generation approaches more deliberately within eHealth development, an issue explored further in this thesis.

Application of evidence generation approaches in eHealth development

Applying static and dynamic approaches *together* is essential for developing eHealth solutions that are both clinically robust and contextually meaningful. Static approaches provide the rigour and comparability required to meet regulatory and clinical standards, ensuring that interventions demonstrate safety, effectiveness, and generalisability across patient or user populations. At the same time, dynamic approaches allow evidence generation to remain responsive to users' needs and the evolving contexts of care, enabling interventions to adapt in ways that enhance relevance and adoption. When combined, these approaches balance the demand for standardisation with the need for flexibility, supporting the creation of eHealth solutions that are both

compliant with eHealth regulations and grounded in users' everyday contexts.

The application of these evidence approaches can be seen in various eHealth development frameworks. Frameworks such as the CeHRes Roadmap (Kip et al., 2025), the Digital Health Design Framework (Wang et al., 2024), and the NASSS Framework (Greenhalgh et al., 2017) emphasise iterative, context-driven eHealth development. However, they do not explicitly consider how the definition of evidence might evolve during development, which gives these frameworks a predominantly static evidence foundation despite their dynamic process orientation. From a different standpoint, Evidence-Based Healthcare Design (Carr et al., 2011; Hamilton, 2018), the NICE Evidence Standards Framework (Unsworth et al., 2021), and the ISO 14155 (2020) emphasise predefined evaluation procedures and standardised evidence requirements aligned with the static evidence generation approach. Finally, the UK Medical Research Council (MRC) framework for complex interventions (Skivington et al., 2021) combines elements of both approaches by emphasising intervention development and evaluation design, yet the interplay between static and dynamic evidence generation remains unclear.

Among these frameworks, Data-Enabled Design (van Kollenburg & Bogers, 2019) is particularly relevant to this thesis because it operationalises a dynamic evidence generation approach through iterative and context-responsive development. Originating from design research, DED uses user-generated data not only to evaluate solutions, but also to continuously inform and refine system functionality during development. Through ongoing engagement with users and contextual data in everyday life, DED supports the evolving definition of what evidence to generate and how during development. In this way, DED exemplifies how dynamic evidence generation can support the development of context-sensitive and user-centred eHealth solutions. However, despite its relevance for eHealth development, DED does not explicitly address how dynamic evidence generation can align with predefined evidence

requirements and regulatory standards in healthcare contexts (Noortman et al., 2022).

Although these frameworks draw on static, dynamic, or both approaches, most emphasise static perspectives, while dynamic approaches remain less explicitly developed for regulated healthcare environments and their integration is unclear. Consequently, these frameworks lead designers and HCPs to generate evidence through approaches that remain weakly integrated, thereby limiting the rigour and contextual relevance of the resulting evidence for eHealth development.

1.3 Problem statement

Previous sections showed that tensions in evidence generation (i.e., what evidence to generate and how, when, and for what purpose) arise when designers and HCPs work together, due to limited integration of static (mostly used and preferred by HCPs) and dynamic (mostly used and preferred by designers) evidence generation approaches within one eHealth development process. Static approaches strengthen the comparability and generalisability of findings, while dynamic approaches sustain their relevance within evolving patient needs and care experiences. When these approaches remain poorly integrated, evidence generation becomes fragmented, resulting in eHealth solutions that are clinically robust or contextually meaningful, but fail to bring both together. Thus, building on this tension, I analyse four barriers that constrain the integration of static and dynamic evidence generation in eHealth development.

Barrier 1 — Unclarity on what evidence to generate about experience

As part of eHealth development, designers and HCPs converge on the need to generate evidence about patient and staff experience, given its relevance to increase adoption and improve health outcomes

(Bodenheimer & Sinsky, 2014; Doyle et al., 2013; Thomas et al., 2021). However, when generating static, quantifiable evidence about experience, the ambiguity in constructs and the diversity of measurement instruments make it unclear what constructs to measure and which tools to use. For instance, even widely used constructs like 'satisfaction' are often undefined, making it difficult to discern positive or negative experiences (Mair & Whitten, 2000), while instrument use is not consistent (Kraai et al., 2011). Ultimately, this unclarity in defining static evidence about experience weakens the foundation on which dynamic situated insights could later build, impeding integration across evidence approaches.

Barrier 2 — Disconnection in evaluation during evidence generation

As part of eHealth development, both designers and HCPs generate evidence to assess and guide intervention development (see Section 1.2). Yet, they tend to do so according to differing priorities—designers focus on improving adoption through iterative refinement, whereas HCPs prioritise clinical safety and effectiveness through confirmatory evaluation (See Section 1.1). For example, design evaluation often takes the form of progressive, small-scale testing cycles, while healthcare confirmatory evaluation typically involves predefined clinical trials to meet ethical and regulatory requirements (Moody, 2015). These contrasting priorities create tensions when developing study design protocols (Cornet et al., 2020), leading to disconnected evaluation purposes. Such disconnection hampers the integration of static and dynamic approaches, as adaptive and confirmatory evaluations rarely exchange insights about what evidence to generate and how.

Barrier 3 — Differences in evidence definition

As part of eHealth development, designers and HCPs define evidence before it is generated (see Section 1.2). However, they differ in how they define dynamic evidence, particularly in terms of scope (i.e., who is involved in the definition), and contextualisation (i.e., how context

is included in the definition) (Wheeler et al., 2019). For instance, in dynamic evidence generation, HCPs may define outcome measures together with patient representatives (Kelley, 2015), reflecting an outcome definition logic that prioritises measurable improvements of a representative population. Conversely, designers may engage directly with potential users to define data collection according to their everyday routines (Jansen et al., 2020; Sanders & Stappers, 2012). These differences make it difficult to establish a common dynamic ground that connects representative and in-situ definitions of evidence. As a result, dynamic evidence definition remains conceptually unclear, lacking a shared basis to define what evidence to generate and how; a tension particularly evident for designers seeking to apply in-situ definitions of evidence into outcome-oriented study protocols (Prendiville, 2019; Wheeler et al., 2019).

Barrier 4 — Regulatory constraints on evidence integration

As part of eHealth development, designers and HCPs are expected to generate evidence in compliance with eHealth development standards to ensure safety and rigour (ISO, 2020; Wyatt, 2016). However, applying static and dynamic approaches together and coherently within these standards is constrained by their underlying requirements. While static approaches are largely compatible with these standards (e.g., Hamilton, 2018; ISO, 2020; Unsworth et al., 2021), dynamic approaches often conflict with formal requirements for predictability and predefinition of evidence and evaluation procedures. For example, Data-Enabled Design (van Kollenburg & Bogers, 2019), a dynamic approach that contextualises data iteratively, failed to receive medical ethical approval because its evolving evidence definitions could not be reconciled with the requirement for predefined outcome-oriented protocols (Noortman et al., 2022). This epistemic–regulatory misalignment makes it difficult to incorporate dynamic approaches into eHealth development in a compliant manner, thereby limiting the integration of static and dynamic approaches within eHealth standards.

Together, the four barriers capture complementary facets of the integration problem between static and dynamic evidence generation. Barrier 1 concerns static evidence about experience; Barrier 2, their interaction during evaluation; Barrier 3, the definition of dynamic evidence; and Barrier 4, their joint application within regulatory standards. Collectively, these barriers explain what prevents integration, consequently limiting the development of eHealth solutions that incorporate established and user-centred perspectives on evidence generation. Below, Figure 1.4 conceptually illustrates these relationships and the focus of each barrier.

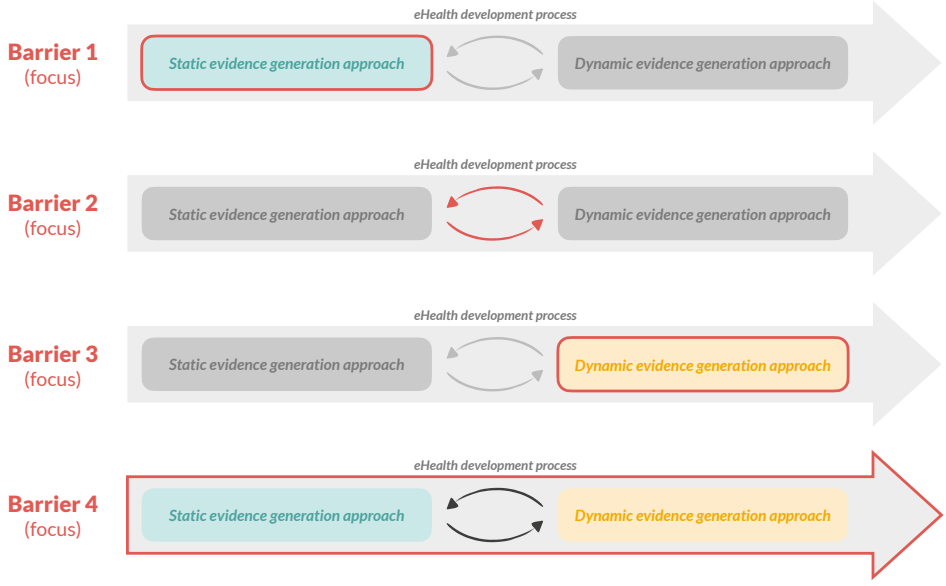

Figure 1.4. Focus of barriers to static and dynamic integration.

1.4 Research aim, knowledge gaps and research questions

Building on the barriers identified in Section 1.3, this thesis examines the lack of integration between static and dynamic approaches to evidence generation in eHealth development. I investigate how such integration can be conceptualised and articulated across design and healthcare practices. This research aims to establish conceptual, empirical, and methodological foundations for a shared evidence generation practice, operationalised through the Clinical Data-Enabled Design (C-DED) framework. This practice is designed to be responsive to users' needs while remaining aligned with eHealth standards. Accordingly, in this section, I outline four knowledge gaps that capture distinct understanding needed for integration and formulate four corresponding research questions (RQs) to guide this thesis. Figure 1.5 below visualises how the four barriers identified in Section 1.3 connect to the corresponding knowledge gaps and RQs developed in this section.

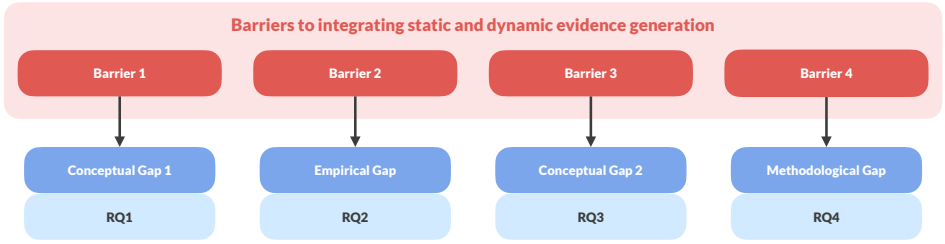

Figure 1.5. Relationships between barriers, knowledge gaps, and RQs of this thesis.

Conceptual Gap 1 — Lack of standardisation in experience measurement

As described in Barrier 1, ambiguity in constructs and diversity of measurement instruments impede the generation of quantitative, static evidence about experience. A recent synthesis effort (see White et al.,

2022) attempted to categorise experience-related engagement measures in eHealth, yet revealed continued inconsistency in how experience is defined and operationalised. This points to a broader **lack of standardisation in experience measurement and consequent limited structured knowledge on experience constructs and instruments.** As a result, there is still uncertainty concerning what experience constructs should be measured and how. This uncertainty limits the comparability of findings and constrains opportunities for shared experience evaluation using static and dynamic evidence approaches.

To address this lack of standardisation and the limited structured knowledge of experience measurement in eHealth development, the first question of this thesis is:

- **RQ1: What experience measures and instruments are currently used in eHealth development?**

Empirical Gap — Limited insight into health and design evidence practices despite procedural differences

As discussed in Barrier 2, designers and HCPs perform disconnected evaluations that challenge the integration of static and dynamic approaches. Various authors highlight how formative, iterative evaluation in design differs from the confirmatory, standardised evaluation dominant in healthcare (Blandford et al., 2018; Pagliari, 2007; Smits et al., 2022). However, there is limited understanding on how this evaluation disconnection unfolds in practice and how it is negotiated between designers and HCPs in eHealth development. Prior work has explored how designers and HCPs collaborate in interdisciplinary settings with a focus on teamwork strategies (Andriessen et al., 2020; Cornet et al., 2020). However, existing studies have not examined the evidence generation practices of designers and HCPs themselves. This suggests a **lack of knowledge on health and design evidence practices despite their differences.** Without this insight, it remains difficult to develop

complementary evidence generation practices between static and dynamic approaches.

Therefore, to address this limited insight into health and design evidence practices, the second question of this thesis is:

- **RQ2: How is evidence generated in practice by designers and healthcare professionals during eHealth development?**

Conceptual Gap 2 — Limited understanding of how designers can apply a health-related outcome logic

As noted in Barrier 3, designers find it difficult to follow the outcome logic established in healthcare evaluation. HCPs define evidence according to an outcome logic—that is, in terms of measurable improvements in patient outcomes used to evaluate effectiveness across a patient population (Porter, 2010b). Earlier research has incorporated the evaluation of outcomes in hospital design processes (Hamilton, 2018). Other studies developed tools to specify outcome measurement (Holden & Carayon, 2021) and methods to map outcomes in a participatory manner (Landa-Avila et al., 2022). However, despite these efforts, it remains unclear how this logic can guide the way designers define and operationalise dynamic evidence generation in eHealth development. This suggests a **lack of understanding concerning how designers can apply an outcome logic, as conceptualised by HCPs, to define dynamic evidence generation in eHealth development.** Without access to HCP's reasoning or logic, designers cannot adapt outcome-focused definitions of evidence in their own dynamic practice.

To address this lack of understanding in how outcome-oriented reasoning can inform designers' dynamic definition of evidence, the third question of this thesis is:

- **RQ3: How can designers apply the outcome logic employed by healthcare professionals to define evidence generation in eHealth development?**

Methodological Gap — Absence of integrated guiding frameworks for static and dynamic evidence generation

Barrier 4 showed that existing eHealth standards constrain the integration and consequent joint application of static and dynamic approaches by designers and HCPs. Current frameworks for eHealth development tend to follow either static approaches (Greenhalgh et al., 2017; Kip et al., 2025; Wang et al., 2024) or dynamic ones (van Kollenburg & Bogers, 2019). Others integrate eHealth standards only with static approaches (Carr et al., 2011; Hamilton, 2018; ISO, 2020; Unsworth et al., 2021), while the one that promotes both lacks incorporation of standards and concrete procedural structuring (Skivington et al., 2021). However, no existing framework provides integrated guidance that combines static and dynamic approaches while remaining aligned with eHealth development standards. This suggests a **lack of methodological frameworks to support the coherent application of static and dynamic approaches together in accordance with eHealth development standards.** Without such guidance, designers and HCPs may default to static methods, overlook user needs in evaluation, or fail to meet regulatory expectations.

To address the absence of methodological frameworks that can guide the joint application of static and dynamic approaches under eHealth development standards, the fourth question of this thesis is:

- **RQ4: How can evidence generation be structured to apply static and dynamic approaches while aligning with eHealth development standards?**

Together, the four RQs address complementary aspects of the integration between static and dynamic evidence generation in eHealth development. **RQ1** establishes a foundation by identifying experience measures and instruments currently employed, clarifying what static forms of evidence designers and HCPs use to evaluate experience. **RQ2** investigates evidence generation practices, examining how epistemic orientations in evidence generation between designers and HCPs create disconnections and how both practices can inform opportunities for integration of static

and dynamic approaches. Building on these insights, **RQ3** investigates how designers can apply the outcome-oriented reasoning used in healthcare to define and operationalise dynamic evidence generation. Finally, **RQ4** explores how evidence generation can be structured to integrate static and dynamic approaches while remaining compatible with eHealth development standards. Collectively, these questions form a research trajectory to advance a shared methodological basis for static and dynamic evidence generation across design and healthcare practice.

1.5 Research methodology

In this thesis, I investigate how static and dynamic approaches to evidence generation can be integrated to support eHealth development that is both user-centred and standard-compliant. To address this aim, I followed a three-phase research methodology (see Figure 1.6 on the next page). Each phase responds to specific barriers and gaps identified earlier and builds upon insights from the preceding one. Together, the phases form a cumulative process through which conceptual and empirical findings were progressively integrated into a coherent methodological contribution: the Clinical Data-Enabled Design (C-DED) framework.

To achieve this integration, I used a mixed-method research design combining structured literature review, qualitative inquiry, and theory adaptation. As this is a paper-based thesis, each chapter presents a distinct study with a methodological approach according to its RQ. Below, I summarise these studies within the three-phase structure, while detailed methodological description appears in each chapter.

Phase 1 — Conceptual foundation

Phase 1 established the conceptual basis for understanding how static evidence about experience is generated in eHealth through **Study 1**. This study responded to Barrier 1, the unclarity surrounding what evidence to

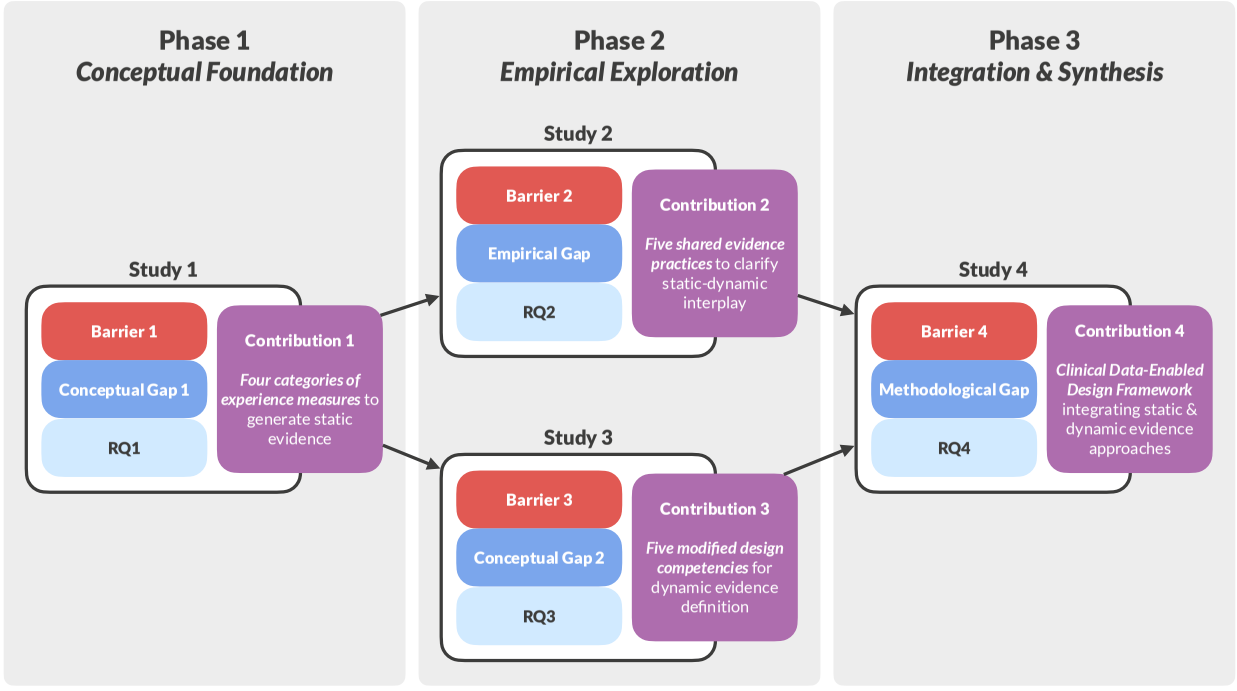

Figure 1.6. Overview of research methodology with barriers, knowledge gaps, research questions and contributions per study.

generate, and Conceptual Gap 1, the lack of standardisation in constructs and measurement instruments.

Study 1 (RQ1) focused on static evidence generation by examining existing patient and staff experience measures. With colleagues, I conducted a systematic literature review following established guidelines (see Page et al., 2021) to identify and categorise experience measures and instruments used in remote patient monitoring (RPM)—a subset of eHealth. RPM was selected as a strategically relevant eHealth context in which care extends into patients' everyday lives through continuous interactions with monitoring technologies as part of the care service. These characteristics make RPM a broad yet bounded domain for examining how static evidence about patient and staff experience is generated across diverse eHealth care contexts. This study allowed us to identify common patterns in quantitative experience assessment and to clarify the static conceptual basis for integrating dynamic perspectives on evidence generation.

Study 1 provided a structured understanding of static experience measures, clarifying both what they capture and what they leave out—the contextual and evolving aspects of human experience. Recognising these omissions highlighted the need to understand how dynamic perspectives inform eHealth evidence generation, prompting Study 2's exploration of how static and dynamic approaches intertwine in current development practice. In parallel, Study 3 extended this foundation conceptually. The breadth of measures identified in Study 1—especially in care and health outcomes—raised the issue of how to select among them in a human-centred, dynamic way. Therefore, Study 3 examined how patient-centred, outcome-oriented reasoning in healthcare could inform such dynamic, human-centred evidence definition.

Phase 2 — Empirical exploration

Phase 2 investigated how evidence generation unfolds in practice from design and healthcare perspectives through two studies. **Study 2**

responded to Barrier 2—disconnection in evaluation during evidence generation, and the Empirical Gap—limited insight into health and design evidence practices despite their differences. **Study 3** examined Barrier 3—differences in evidence definition, and Conceptual Gap 2—limited understanding of how designers can apply a health-related outcome logic to define dynamic evidence generation. This phase explored how designers and HCPs generate and define evidence during eHealth development, clarifying how static and dynamic approaches manifest and interact in practice. Below, I introduce Study 2 and Study 3.

Study 2 (RQ2) investigated how designers and HCPs generate evidence in practice. I employed an exploratory qualitative design using semi-structured interviews and reflexive thematic analysis (Braun & Clarke, 2013, 2021b). This qualitative approach provided a rich lens for exploring the nuanced practices that shape evidence generation, offering in-depth insights into how designers and HCPs conduct this process and manage differences. This study provided an empirical basis for understanding how static and dynamic evidence generation intertwine in practice, offering insight into how designers and HCPs navigate their differing evaluation activities.

Study 3 (RQ3) examined how designers could apply the outcome logic used in healthcare to define dynamic evidence generation in eHealth development. I conducted a qualitative inductive case study (Eisenhardt, 1989) to explore how HCPs articulate patient-centred, outcome-related dynamic evidence during development. This articulation offered insights into how outcome reasoning can inform and extend the core design competencies described by Voûte et al. (2020), particularly regarding the dynamic definition of evidence. Overall, the study helped clarify a shared conceptual ground from which designers and HCPs can jointly define dynamic evidence generation in eHealth.

Insights from Study 2 clarified how static and dynamic evidence generation approaches intertwine in eHealth development, revealing shared practices that enable their interplay but lack methodological

structure. Recognising this absence highlighted the need for integrative guidance to support designers and HCPs in aligning these approaches during development. Study 3 complemented this empirically grounded understanding by clarifying what could be defined dynamically within evidence generation and identifying gaps in existing frameworks addressing enhanced design competencies. Together, these insights established the empirical and additional conceptual basis for developing an integrated methodological framework in Phase 3, aimed at supporting coherent static–dynamic evidence generation in eHealth.

Phase 3 — Integration and synthesis

Phase 3 developed an integrated methodological basis for combining static and dynamic approaches to evidence generation in eHealth through **Study 4**. This study responded to Barrier 4—regulatory constraints on evidence integration, and the Methodological Gap, which concerns the absence of guidance for integrating both approaches within eHealth standards. Phase 3 focused on translating empirical and conceptual insights from the previous studies into a coherent methodological framework, operationalised in Study 4 introduced below.

Study 4 (RQ4) focused on developing integrated guidance for combining static and dynamic evidence generation in eHealth development. I applied a theory adaptation approach (Jaakkola, 2020) to synthesise empirical and conceptual insights from the previous studies with established frameworks. This synthesis drew on Data-Enabled Design (DED) (van Kollenburg & Bogers, 2019) as a dynamic framework and the ISO 14155 standard (2020) as a static framework for eHealth development. DED was selected because its iterative and context-responsive nature supports evolving evidence definition in users' everyday context, yet lacks alignment with predefined evidence structures required in regulated healthcare development (Noortman et al., 2022). In contrast, ISO 14155 formalises confirmatory and standardised evaluation procedures required for regulatory compliance. This synthesis

produced a structured methodological foundation for designers and HCPs to define and generate user-centred and standard-compliant evidence.

1.6 Research contributions

The main contribution of this thesis is the Clinical Data-Enabled Design (C-DED) framework, a methodological contribution that integrates static and dynamic evidence generation to support user-centred and standard-compliant eHealth development. The framework builds on a series of conceptual and empirical contributions developed across Studies 1 to 3, which clarify why evidence is generated, what evidence is generated, and how it is produced and defined. These insights are consolidated and operationalised in Study 4 through the development of the C-DED framework, which clarifies when to generate what evidence, how, and why.

The **first contribution** of this thesis is a **conceptual mapping** of experience measurement in eHealth development. It addresses Conceptual Gap 1 by examining the lack of standardisation in how experience is measured, clarifying which constructs are commonly used and how they are operationalised. This contribution establishes the static conceptual foundation for integrating dynamic perspectives on evidence generation by identifying four measurement categories, presented in Chapter 2. These categories structure experience evaluation and clarify what can be measured and how, forming the basis for both static and later dynamic evidence generation.

The **second contribution** is an **empirical analysis** of evidence generation practices across design and healthcare. It addresses the Empirical Gap by examining how designers and HCPs generate evidence in eHealth development. This contribution empirically demonstrates how static and dynamic approaches intertwine in eHealth development within and across domains, revealing shared evidence practices that support their alignment. The study identifies five shared practices, presented in

Chapter 3, that show how both groups can engage with common factors to define evidence generation purposes, enabling alignment despite domain differences.

The **third contribution** is a **conceptual clarification** of how health-related outcome logic can guide dynamic evidence definition in design practice. It addresses Conceptual Gap 2 in Chapter 4 by examining how HCPs apply patient-centred outcome logic and mapping this onto five core design competencies. This contribution extends the dynamic conceptual basis for evidence generation by translating outcome-oriented reasoning from healthcare into design practice. The study identifies three conceptual dimensions that inform how designers can incorporate health-related outcome logic into their dynamic definition of evidence generation, supporting aligned evidence definition.

The **fourth contribution** of this thesis is a **methodological framework**—Clinical Data-Enabled Design (C-DED)—that integrates static and dynamic approaches to evidence definition and generation in eHealth development. It addresses the Methodological Gap in Chapter 5 by synthesising insights from previous studies with a dynamic methodology and static eHealth standards. C-DED structures eHealth development into four iterative phases and three reflective points, providing integrated guidance on when and how to generate evidence that balances scientific rigour with responsiveness to users' and patients' needs.

1.7 Thesis structure

In this thesis, I investigate how static and dynamic evidence generation approaches can be integrated and aligned with eHealth development standards. The structure of this thesis reflects a progressive exploration of this integration, with each chapter addressing a specific RQ and contributing to the development of the C-DED framework. I organised the thesis into six chapters. **Chapter 1** introduces the research context,

outlines barriers to integration, presents the research aim and questions, and describes the research methodology. **Chapters 2 to 5** each respond to one RQ through either a review-based, empirical, or theoretical development study. In **Chapter 6**, I discuss the findings and reflect on their implications. Table 1.1 below provides an overview of how each chapter relates to its corresponding RQ, study, and main contribution.

Table 1.1. Thesis overview.

Chapter	Research Question	Study	Contribution
CH-1. Introduction.			
CH-2. Mapping experience measurement practices in eHealth development.	**RQ1.** What experience measures and instruments are currently used in eHealth development?	**Study 1**	**Conceptual.** Structured mapping of experience measures and instruments.
CH-3. Exploring design and healthcare evidence generation practices in eHealth development.	**RQ2.** How is evidence generated in practice by designers and healthcare professionals during eHealth development?	**Study 2**	**Empirical.** Five shared evidence practices between designers and HCPs.
CH-4. Exploring evidence definition practices for health outcomes and their translation into design practice.	**RQ3.** How can designers apply the outcome logic employed by healthcare professionals to define evidence generation in eHealth development?	**Study 3**	**Conceptual.** Five modified design competencies incorporating the three HCPs' conceptual dimensions for evidence definition.
CH-5. From practices to integration: Aligning static and dynamic approaches with eHealth development standards.	**RQ4.** How can evidence generation be structured to apply static and dynamic approaches while aligning with eHealth development standards?	**Study 4**	**Methodological.** Clinical Data-Enabled Design (C-DED) Framework.
CH-6. General discussion and conclusion.			

2

Chapter 2 is published as: Pannunzio, V., **Morales Ornelas, H. C.**, Gurung, P., van Kooten, R., Snelders, D., van Os, H., Wouters, M., Tollenaar, R., Atsma, D., & Kleinsmann, M. (2024). Patient and Staff Experience of Remote Patient Monitoring—What to Measure and How: Systematic Review. Journal of Medical Internet Research, 26, e48463. https://doi.org/10.2196/48463

Chapter 2.

Mapping experience measurement practices in eHealth development

Abstract

Background: Patient and staff experience is a vital factor to consider in the evaluation of remote patient monitoring (RPM) interventions. However, no comprehensive overview of available RPM patient and staff experience–measuring methods and tools exists. **Objective:** This review aimed at obtaining a comprehensive set of experience constructs and corresponding measuring instruments used in contemporary RPM research and at proposing an initial set of guidelines for improving methodological standardization in this domain. **Methods:** Full-text papers reporting on instances of patient or staff experience measuring in RPM interventions, written in English, and published after January 1, 2011, were considered for eligibility. By "RPM interventions," we referred to interventions including sensor-based patient monitoring used for clinical decision-making; papers reporting on other kinds of interventions were therefore excluded. Papers describing primary care interventions, involving participants under 18 years of age, or focusing on attitudes or technologies rather than specific interventions were also excluded. We searched 2 electronic databases, Medline (PubMed) and EMBASE, on February 12, 2021.We explored and structured the obtained corpus of data through correspondence analysis, a multivariate statistical technique. **Results:** In total, 158 papers

were included, covering RPM interventions in a variety of domains. From these studies, we reported 546 experience-measuring instances in RPM, covering the use of 160 unique experience-measuring instruments to measure 120 unique experience constructs. We found that the research landscape has seen a sizeable growth in the past decade, that it is affected by a relative lack of focus on the experience of staff, and that the overall corpus of collected experience measures can be organized in 4 main categories (service-system related, care related, usage and adherence related, and health outcome related). In the light of the collected findings, we provided a set of 6 actionable recommendations to RPM patient and staff experience evaluators, in terms of both what to measure and how to measure it. Overall, we suggested that RPM researchers and practitioners include experience measuring as part of integrated, interdisciplinary data strategies for continuous RPM evaluation. **Conclusions:** At present, there is a lack of consensus and standardization in the methods used to measure patient and staff experience in RPM, leading to a critical knowledge gap in our understanding of the impact of RPM interventions. This review offers targeted support for RPM experience evaluators by providing a structured, comprehensive overview of contemporary patient and staff experience measures and a set of practical guidelines for improving research quality and standardization in this domain.

2.1 Introduction

Background and Aim

This is a scenario from the daily life of a patient:

> *A beeping sound, and a message appears on the smartphone screen: "Reminder: check glucose before bedtime." Time to go to sleep, indeed, you think while putting down your book and reaching for the glucometer. As you wipe the drop of blood away, you make sure that both Bluetooth and Wi-Fi are on in your phone. Then, the reading is sent: you notice it seems to be rather far from your baseline. While you think of what you might have done differently, a slight agitation emerges: Is this why you feel so tired? The phone beeps again: "Your last glucose reading seems atypical. Could you please try again? Remember to follow these steps." Groaning, you unwrap another alcohol wipe, rub your finger with it, and test again: this time, the results are normal.*

Some patients will recognize certain aspects of this scenario, particularly the ones using a form of remote patient monitoring (RPM), sometimes referred to as remote patient management. RPM is a subset of digital health interventions that aim to improve patient care through digitally transmitted, health-related patient data (de Farias et al., 2020). Typically, RPM interventions include the use of 1 or more sensors (including monitoring devices, wearables, or implants), which collect patient data in or out of the hospital to be used for remote clinical decision-making. Partly due to a rapid expansion during the COVID-19 pandemic (Fagherazzi et al., 2020; Peek et al., 2020; Pérez Sust et al., 2020; Taiwo & Ezugwu, 2020), the RPM domain has by now expanded to reach a broad range of medical specialties, sensing technologies, and clinical contexts (de Farias et al., 2020; Noah et al., 2018; Vegesna et al., 2017).

RPM is presented as a strategy for enabling health care systems worldwide to face the pressing challenges posed by aging populations

(Coye et al., 2009; Majumder et al., 2017; Schütz et al., 2022), including the dwindling availability of health care workers (Drennan & Ross, 2019) and rising health care costs (Chang et al., 2019). This is because deploying effective RPM solutions across health systems holds the potential to reduce health care resources use, while maintaining or improving care quality. However, evidence regarding RPM effectiveness at scale is mixed (Mecklai et al., 2021). Few large-scale trials demonstrating a meaningful clinical impact of RPM have been conducted so far, and more research is urgently needed to clarify and address determinants of RPM effectiveness (Noah et al., 2018).

Among these determinants, we find the experience of patients and staff using RPM interventions. As noticeable in the introductory scenario, RPM introduces radical experiential changes compared to in-person care; patients might be asked to download and install software; pair, charge, and wear monitoring devices; submit personal data; or attend alerts or calls, all in the midst of everyday life contexts and activities. Similarly, clinical and especially nursing staff might be asked to carry out data analysis and administrative work and maintain remote contact with patients, often without a clear definition of roles and responsibilities and in addition to usual tasks (León et al., 2022).

Because of these changes, patient and staff experience constitutes a crucial aspect to consider when evaluating RPM interventions. Next to qualitative methods of experience evaluation, mixed and quantitative methods are fundamental, especially to capture information from large pools of users. However, the current RPM experience-measuring landscape suffers from a lack of methodological standardization, reflected in both what is measured and how it is measured. Regarding what is measured, it has been observed that a large number of constructs are used in the literature, often without a clear specification of their significance. This can be noticed even regarding popular constructs, such as satisfaction: Mair and Whitten (2000), for instance, observe how the meaning of the satisfaction construct is seldom defined in patient surveys, leaving readers “unable to discern whether the participants

said they were satisfied because telemedicine didn't kill them, or that it was 'OK,' or that it was a wonderful experience." Previous work also registers a broad diversity in the instruments used to measure a specific construct. For instance, in their review of RPM interventions for heart failure, Kraai et al (2011) report that none of the papers they examined used the same survey to measure patient satisfaction, and only 1 was assessed on validity and reliability.

In this proliferation of constructs and instruments, no comprehensive overview exists of their application to measuring patient and staff experience in the RPM domain. The lack of such an overview negatively affects research in this domain in at least 2 ways. At the level of primary research, RPM practitioners and researchers have little guidance on how to include experience measuring in their study designs. At the level of secondary research, the lack of consistently used measures makes it hard to compare results between different studies and RPM solutions. Altogether, the lack of standardization in experience measuring constitutes a research gap that needs to be bridged in order for RPM to fully deliver on its promises.

In this review, this gap is addressed through an effort to provide a structured overview of patient and staff experience constructs and instruments used in RPM evaluation. First, we position the role of RPM-related patient and staff experience within the broader system of care using the Quadruple Aim framework. Next, we describe the systematic review we performed of patient and staff experience–relevant constructs and instruments used in contemporary research aimed at evaluating RPM interventions. After presenting and discussing the results of this review, we propose a set of guidelines for RPM experience evaluators and indicate directions for further research.

The Role of Patient and Staff Experience in RPM

Many characterizations of patient and staff experience exist (LaVela & Gallan, 2014; Wang et al., 2022; Wolf et al., 2021), some of which

distinguish between determinants of experience and experience manifestations (Zakkar, 2019). For our review, we maintained this distinction, as we aimed to focus on the broad spectrum of factors affecting and affected by patient and staff experience. To do so, we adopted the general conceptualization of patient and staff experience as characterized in the Quadruple Aim, a widely used framework for health system optimization centered around 4 overarching goals: improving the individual experience of care, improving the experience of providing care, improving the health of populations, and reducing the per capita cost of care (Sikka et al., 2015). Adopting a Quadruple Aim perspective allows health system researchers and innovators to recognize not only the importance of patient and staff experience in their own rights but also the inextricable relations of these 2 goals to the other dimensions of health system performance (Pannunzio et al., 2019). To clarify the nature of these relations in the RPM domain, we provide a schematic overview in Figure 2.1.

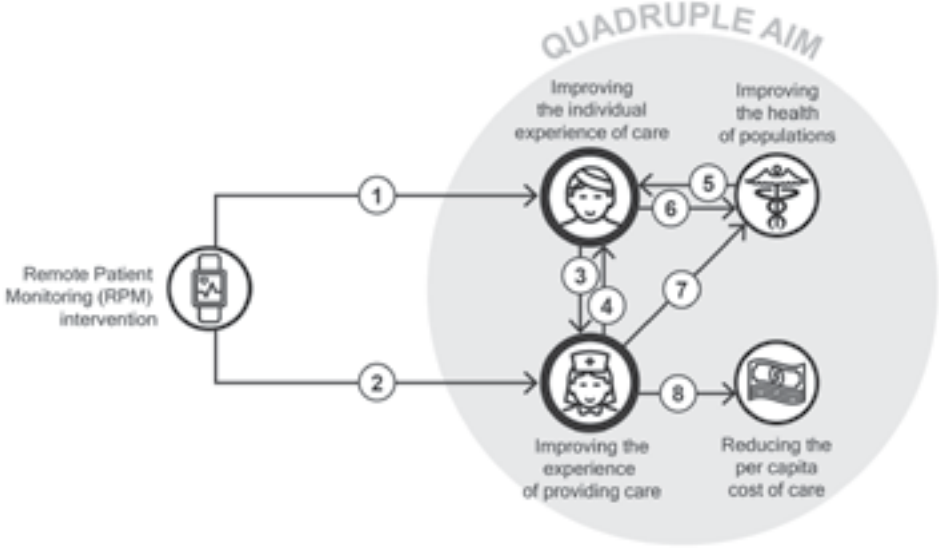

Figure 2.1. Schematic overview of the relations between patient and staff experience in RPM and the other components of the Quadruple Aim framework. Each arrow symbolizes a relation.

Next, we refer to the numbers in Figure 2.1 to touch upon prominent relationships between patient and staff experience in RPM within the Quadruple Aim framework and provide examples of experience constructs relevant to each relationship:

- Numbers 1 and 2: The characteristics of specific RPM interventions directly affect the patient and staff experience. Examples of experience constructs related to this mechanism are expressed in terms of *usability* or *wearability*, which are attributes of systems or products contributing to the care experience of patients and the work experience of staff.
- Numbers 3 and 4: Patient and staff experiences relate to each other through care delivery. Human connections, especially in the form of carer-patient relationships, represent a major factor in both patient and staff experience. An example of experience constructs related to this mechanism is expressed in terms of the *quality of the relationship*.
- Numbers 5 and 6: A major determinant of patient experience is represented by the health outcomes achieved as a result of the received care. An example of a measure of quality related to this mechanism is expressed in terms of the *quality of life*, which is an attribute of patient experience directly affected by a patient's health status. In contrast, patient experience itself is a determinant of the clinical effectiveness of RPM interventions. For example, the patient experience afforded by a given intervention is a determinant of both *adoption* of and *adherence* to that intervention, ultimately affecting its clinical impact. In a recent review, for instance, low patient adherence was identified as the main factor associated with ineffective RPM services (Thomas et al., 2021).
- Number 7: Similarly, staff experience can be a determinant of clinical effectiveness. Experience-related issues, such as *alarm fatigue*, contribute to medical errors and lower the quality of care delivery (Sendelbach & Funk, 2013).
- Number 8: Staff experience can also impact the cost of care. For example, the *time effort* required for the use of a given intervention

can constitute a source of extra costs. More indirectly, low staff *satisfaction* and excessive *workload* can increase health care staff turnover, resulting in additional expenses at the level of the health system.

Overall, the overview in Figure 2.1 can help us grasp the nuances of the role of patient and staff experience on the overall impact of RPM interventions, as well as the importance of measuring experience factors, not only in isolation, but also in relation to other dimensions of care quality. In this review, we therefore covered a broad range of experience-relevant factors, including both experiential determinants (eg, usability) and manifestations (eg, adherence). Overall, this study aimed to obtain a comprehensive set of experience constructs and corresponding measurement instruments used in contemporary RPM research and to propose an initial set of guidelines for improving methodological standardization in this domain.

2.2 Methods

Protocol Registration and PRISMA Guidelines

The study protocol was registered in the PROSPERO (International Prospective Register of Systematic Reviews) database (CRD42021250707). This systematic review adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The PRISMA checklist is provided in Multimedia Appendix 1 (Page et al., 2021).

Criteria for Study Eligibility

Our study population consisted of adult (≥18 years old) patients and staff members involved as participants in reported RPM evaluations. Full-text papers reporting instances of patient and staff experience measuring in

RPM interventions, written in English, and published after January 1, 2011, were considered for eligibility.

For the scope of our review, we considered as RPM any intervention possessing the following characteristics:

- Sensor-based patient monitoring, intended as the use of at least 1 sensor to collect patient information at a distance. Therefore, we excluded interventions that were purely based on the collection of "sensor-less" self-reported measures from patients. This is because we believe the use of sensors constitutes a key element of RPM and one that strongly contributes to experiential aspects in this domain. However, we adopted a broad definition of "sensor," considering as such, for instance, smartphone cameras (eg, postoperative wound-monitoring apps) and analog scales or thermometers (eg, interventions relying on patients submitting manually entered weights or temperatures). By "at a distance," we meant not only cases in which data were transferred from nonclinical environments, such as home monitoring, but also cases such as tele–intensive care units (tele-ICUs), in which data were transferred from one clinical environment to another. Furthermore, we included interventions relying on both continuous and intermittent monitoring.
- Clinical decision-making as an intended use of remotely collected data. Therefore, we excluded interventions in which the collected data were meant to be used exclusively for research purposes and not as a stage of development of an RPM intervention to be adopted in patient care. For instance, we excluded cases in which the remotely collected patient data were only used to test research hypotheses unrelated to the objective of implementing RPM interventions (eg, for drug development purposes). This is because in this review we were interested in RPM as a tool for the provision of remote patient care, rather than as an instrument for research. We also excluded interventions in which patients themselves were the only recipients of the collected data and no health care professional was involved in the data analysis and use.

Furthermore, we excluded:

- Evaluations of attitudes, not interventions: contributions in which only general attitudes toward RPM in abstract were investigated, rather than 1 or more specific RPM interventions.
- Not reporting any evaluation: contributions not focusing on the evaluation of 1 or more specific RPM interventions, for instance, papers providing theoretical perspectives on the field (eg, research frameworks or theoretical models).
- Evaluation of technology, not interventions: contributions only focused on evaluating RPM-related technology, for instance, papers focused on testing sensors, software, or other service components in isolation rather than as a part of any specific RPM intervention.
- Not just RPM: contributions not specifically focused on RPM but including RPM interventions in their scope of research, for instance, papers reporting on surveys obtained from broad cohorts of patients (including RPM recipients) in a noncontrolled way. An example of such contributions would be represented by studies focusing on patient experience with mobile health apps in general, covering both interventions involving RPM and interventions not including any kind of patient monitoring, without a clear way to distinguish between the 2 kinds of interventions in the contribution results. This was chosen in order to maintain the review focus on RPM interventions. Instead, papers including both RPM and other forms of care provisions within the same intervention were included, as well as papers comparing RPM to non-RPM interventions in a controlled way.
- Primary care intervention only: interventions only involving general practitioners (GPs) and other primary care practitioners as health care providers of the RPM intervention. This is because we expected marked differences between the implementation of RPM in primary care and at other levels of care, due to deep dissimilarities in settings, workflows, and routines. Examples of RPM interventions *only* involving primary care providers included kiosk systems (for which a common measuring point was provided to many patients)

or pharmacy-managed medication-monitoring programs. RPM interventions involving primary care providers *and* providers from higher levels of care, however, were included in the review.

- Staff-to-staff intervention: contributions reporting on interventions exclusively directed at staff, for instance, papers reporting on RPM methods aimed at monitoring stress levels of health care workers.
- Target group other than patient or staff: contributions aimed at collecting experience measures in target groups other than patients or staff, for instance, papers investigating the experience in RPM for informal caregivers.

Search Method

To identify relevant publications, the following electronic databases were searched: (1) Medline (PubMed) and (2) EMBASE. Search terms included controlled terms from Medical Subject Headings (MeSH) in PubMed and Emtree in EMBASE, as well as free-text terms. Query term selection and structuring were performed collaboratively by authors VP, HCMO, and PG (who is a clinical librarian at the Leiden University medical library). The full search strategies are reported in Multimedia Appendix 2. Because the aim of the review was to paint a contemporary picture of experience measures used in RPM, only studies published starting from January 1, 2011, were included.

Study Selection

Study selection was performed by VP and HCMO, who used Rayyan, an online research tool for managing review studies (Ouzzani et al., 2016), to independently screen both titles and abstracts in the initial screening and full texts in the final screening. Discrepancies were solved by discussion. A flowchart of study selection is depicted in Figure 2.2.

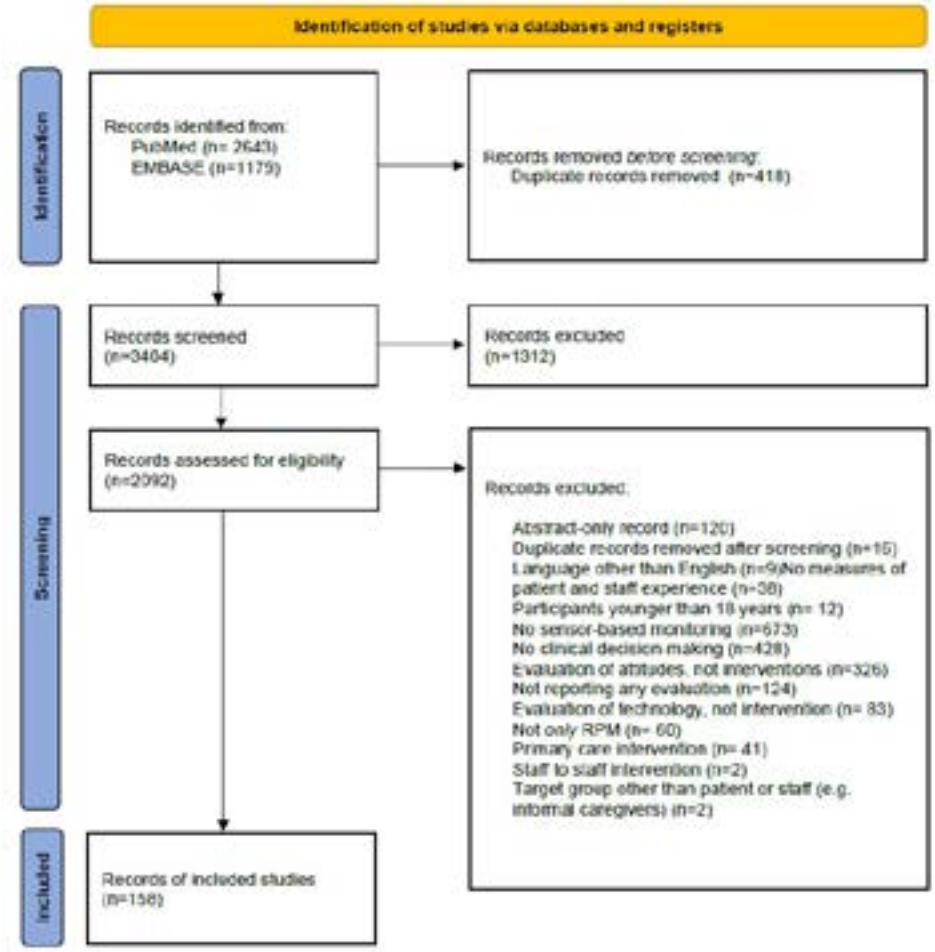

Figure 2.2. Flowchart of study selection. RPM: remote patient monitoring.

Quality Appraisal

The objective of this review was to provide a comprehensive overview of the relevant literature, rather than a synthesis of specific intervention outcomes. Therefore, no papers were excluded based on the quality appraisal, in alignment with similar studies (White et al., 2022).

Data Extraction and Management

Data extraction was performed independently by VP and HCMO. The extraction was performed in a predefined Microsoft Excel sheet designed by VP and HCMO. The sheet was first piloted in 15 included studies and iterated upon to optimize the data extraction process. The full text of all included studies was retrieved and uploaded in the Rayyan environment. Next, the full text of each included study was examined and relevant data were manually inputted in the predefined Excel sheet. Discrepancies were resolved by discussion. The following data types were extracted: (1) general study information (authors, title, year of publication, type of study, country or countries); (2) target disease(s), intervention, or clinical specialty; (3) used patient or staff experience evaluation instrument and measured experience construct; (4) evidence base, if indicated; and (5) number of involved staff or patient participants. By "construct," we referred to the "abstract idea, underlying theme, or subject matter that one wishes to measure using survey questions" (P. J. Lavrakas, 2008). To identify the measured experience construct, we used the definition provided in the source contribution, whenever available.

Data Analysis

First, we analyzed the collected data through building general overviews depicting the kind of target participants (patients or staff) of the collected experience measures and their use over time. To organize the diverse set of results collected through the systematic review, we then performed a correspondence analysis (CA) (Greenacre, 1994), a multivariate statistical technique used for exploring and displaying relationships between categorical data. CA transforms a 2-way table of frequencies between a row and a column variable into a visual representation of relatedness between the variables. This relatedness is expressed in terms of inertia, which represents "a measure of deviation from independence" (Sourial et al., 2010) between the row and column variables. Any deviations from the frequencies expected if the row and column variables were completely independent from each other contribute to the total

inertia of the model. CA breaks down the inertia of the model by identifying mutually independent (orthogonal) dimensions on which the model inertia can be represented. Each successive dimension explains less and less of the total inertia of the model. On each dimension, relatedness is expressed in terms of the relative closeness of rows to each other, as well as the relative closeness of columns to each other. CA has been previously used to find patterns in systematic review data in the health care domain (Franceschi et al., 2021).

In our case, a 2-way table of frequencies was built based on how often any given instrument (eg, System Usability Scale [SUS]) was used to measure any given construct (eg, usability) in the included literature. Therefore, in our case, the total inertia of the model represented the amassed evidence base for relatedness between the collected experience constructs and measures, based on how they were used in the included literature.

To build the table of frequencies, the data extracted from the systematic review underwent a round of cleaning, in which the formulation of similar constructs was made more homogeneous: for instance, “time to review,” “time to response,” and “time for task” were merged under 1 label, “time effort.” An overview of the merged construct formulations is provided in Multimedia Appendix 3. The result of the CA was a model where 2 dimensions contributed to more than 80% of the model’s inertia (explaining 44.8% and 35.7%, respectively) and where none of the remaining 59 dimensions contributed more than 7.3% to the remaining inertia. This gap suggests the first 2 dimensions to express meaningful relationships that are not purely based on random variation. A 2D solution was thus chosen.

2.3 Results

General Observations

A total of 158 studies reporting at least 1 instance of patient or staff experience measuring in RPM were included in the review. The included studies covered a broad range of RPM interventions, most prominently diabetes care (n=30, 19%), implanted devices (n=12, 7.6%), and chronic obstructive pulmonary disease (COPD; n=10, 6.3%). From these studies, we reported 546 experience-measuring instances in RPM, covering 160 unique experience-measuring instruments used to measure 120 unique experience constructs.

Our results included 4 kinds of versatile (intended as nonspecific) experience-measuring instruments: the custom survey, log file analysis, protocol database analysis, and task analysis. All of them can be used for measuring disparate kinds of constructs:

- By "custom survey," we refer to survey instruments created to evaluate patient or staff experience in connection to 1 specific RPM study and only for that study.
- By "log file analysis," we refer to the set of experience assessment methods based on the automatic collection of data through the RPM digital infrastructures themselves (Huerta et al., 2019); examples are clicks, uploads, views, or other forms of interactions between users and the RPM digital system. This set of methods is typically used to estimate experience-relevant constructs, such as adherence and compliance.
- By "protocol database analysis," we refer to the set of experience assessment methods based on the manual collection of data performed by RPM researchers within a specific research protocol; an example of a construct measured with these instruments is the willingness to enroll.
- By "task analysis," we refer to the set of experience assessment

methods based on the real-life observation of users interacting with the RPM system (Diaper & Stanton, 2003).

In addition to these 4 instruments, our results included a large number of specific instruments, such as standard indexes, surveys, and questionnaires. Overall, the most frequently reported instrument was, by far, the custom survey (reported in 155/546, 28.39%, instances), while the most frequently reported experience construct was satisfaction (85/546, 15.57%), closely followed by quality of life (71/546, 13%).

Target Participants and Timeline

We found large differences in the number of RPM-relevant experience constructs and instruments used for patients and for staff (see Figure 2.3). We also found instruments used for both patients and staff. Either these were broadly used instruments (eg, the SUS) that were administered to both patients and staff within the same study, or they were measures of interactions between patients and staff (eg, log file analysis instruments recording the number of remote contacts between patients and nursing assistants).

Figure 2.3. Count of mentioned instances of experience constructs organized by target participant: patient, staff, or both. Different shades of gray indicate different constructs.

RPM research appears to focus much more on patient experience than on staff experience, which was investigated in only 20 (12.7%) of the 158 included papers. Although it is possible that our exclusion criteria contributed to the paucity of staff experience measures, only 2 (0.1%) of 2092 studies were excluded for reporting on interventions directed

exclusively at staff. Of the 41 (2%) studies we excluded for reporting on primary care interventions, we found 6 (15%) studies reporting on staff experience, a rate comparable to the one in the included sample. Furthermore, although our choice to exclude papers reporting on the RPM experience of informal caregivers might have contributed to a reduction in the number of collected constructs and measures, only 2 (0.1%) of 2092 studies were excluded for this reason, and the constructs used in these contributions were not dissimilar from the ones found in the included literature.

Among the included contributions that did investigate staff experience, we noticed that the number of participant staff members involved in the reported studies was only reported in a minority of cases (9/20, 45%).

Furthermore, a time-based overview of the collected results (Figure 2.4) provided us with an impression of the expansion of the field in the time frame of interest for both patient and staff experience measures.

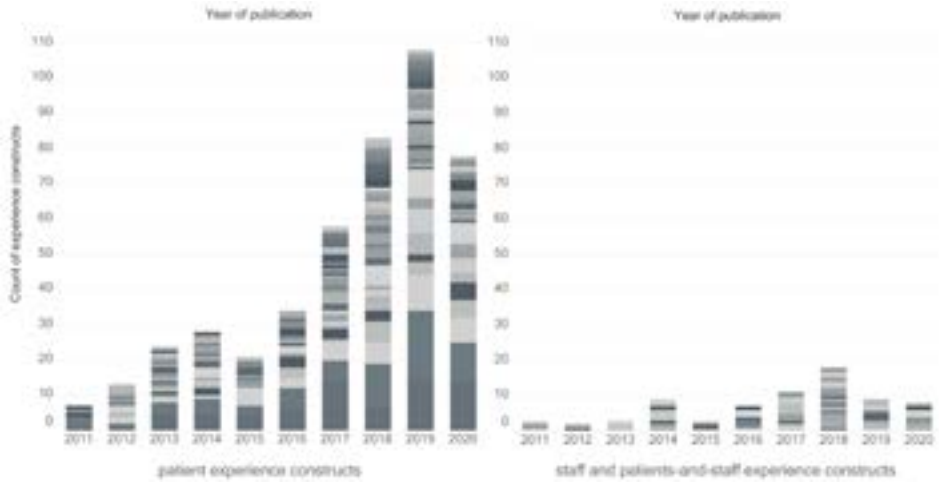

Figure 2.4. Count of mentioned instances of experience constructs for patients (left) or for staff, and patients and staff (right) in the included literature from 2011 to 2020. Different shades of gray indicate different constructs.

Correspondence Analysis

The plotted results of the CA of experience constructs are shown in Figure 2.5. Here, we discuss the outlook and interpretation of each dimension.

The first dimension explained more than 44% of the model's inertia. The contributions of this dimension showed which constructs had the most impact in determining its orientation: satisfaction (36%) and to a lesser extent adherence (26%) and quality of life (17%). On the negative (left) side of this dimension, we found constructs such as satisfaction, perceptions, and acceptability, which are associated with subjective measures of patient and staff experience and relate to how people feel or think in relation to RPM interventions. On the positive (right) side of this dimension, we found constructs such as adherence, compliance, and quality of life, which are associated with objectivized measures of patient and staff experience. By "objectivized measures," we referred to measures that are meant to capture phenomena in a factual manner, ideally independently from personal biases and subjective opinions. Adherence and compliance, particularly, are often measured through passive collection of system data (eg, log file analysis) that reflect objective measures of the way patients or staff interact with RPM propositions. Even in the case of (health-related) quality of life, which can include subjective connotations and components, measures usually aim at capturing an estimation of the factual impact of health status on a person's overall life quality.

In this sense, we attributed a distinction between *how people feel* versus *what happens* experience constructs to this first dimension. We noted that a similar distinction (between subjective vs objective measures of engagement in remote measurement studies) was previously proposed as a meaningful differentiation to structure "a field impeded by incoherent measures" (White et al., 2022).

The second dimension explained 35% of the model's inertia. The contributions of this dimension showed which constructs had the most

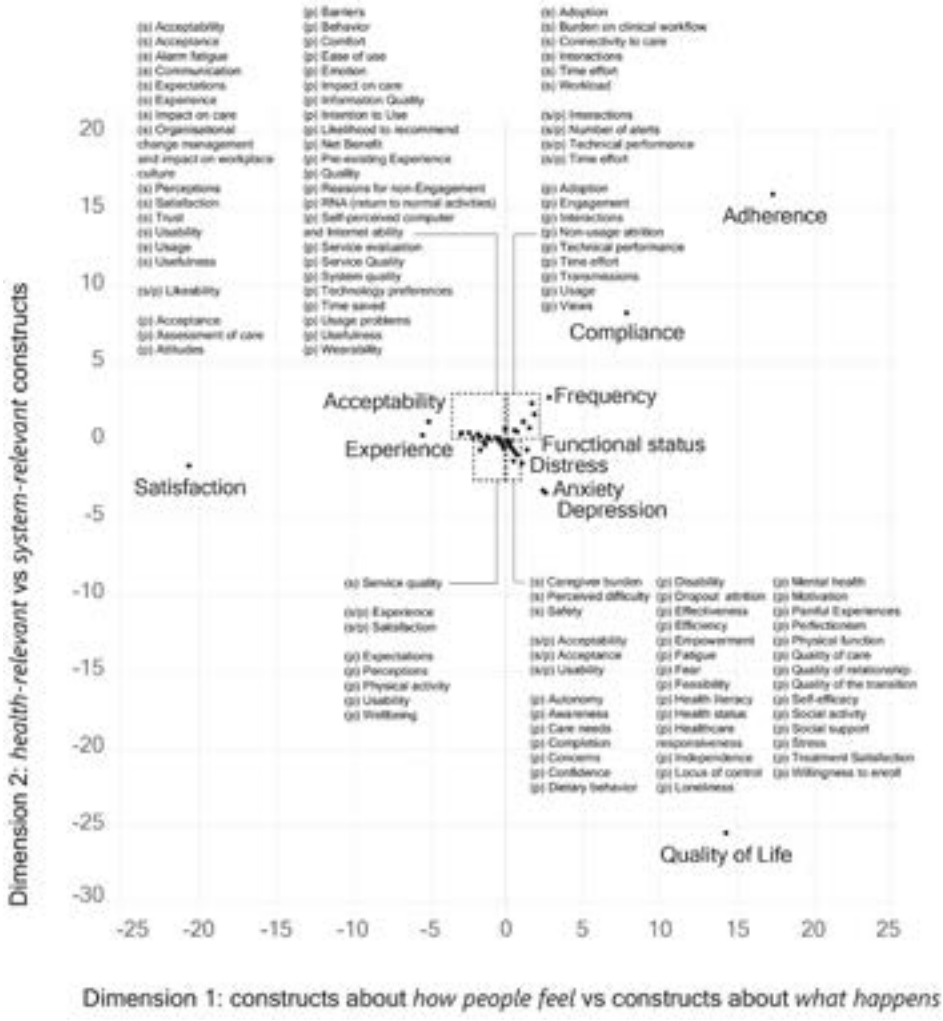

Figure 2.5. Graphical display of the results of the CA, visualized on the coordinates of dimensions 1 and 2. The labels (s), (p), and (s/p) refer to experience constructs used for staff, patients, and both. CA: correspondence analysis.

impact in determining its orientation: quality of life (62%) and adherence (24%). On the negative (bottom) side of this dimension, we found constructs such as quality of life, depression, and anxiety, which are often used as experiential descriptors of health outcomes. On the positive (top) side of this dimension, we found adherence, compliance, and frequency, which are often used as descriptions of the interactions of patients or staff with a specific (RPM) system. Thus, we attributed a distinction between *health-relevant* versus *system-relevant* experience constructs to this second dimension.

Based on the results of CA, we proposed a categorization of patient and staff experience–related constructs into 4 partly overlapping clusters. Coherent with the offered explanation of the 2 dimensions and in consideration of the constructs found in each area, we labeled these as service system–related experience measures, care-related experience measures, usage- and adherence-related experience measures, and health outcome–related experience measures. In Figure 2.6, we display the results of the CA labeled through this categorization. In this second visualization, we presented the results on a logarithmic scale to improve the visibility of constructs close to the center of the axes. Overall, this categorization of patient and staff experience constructs used in the RPM literature paints a landscape of the contemporary research in this field, which shows a mix of influences from clinical disciplines, health psychology, human factors engineering, service design, user research, systems engineering, and computer science.

A visualization of the reported patient experience constructs and some of the related measuring instruments, organized by the categories identified in the CA, is available in Figure 2.7. A complete version of this visual can be found in Multimedia Appendix 4, and an interactive version can be found in (Interactive Sankey, n.d.). In this figure, we can note the limited crossovers between constructs belonging to different categories, with the exception of versatile instruments, such as custom survey and log file analysis.

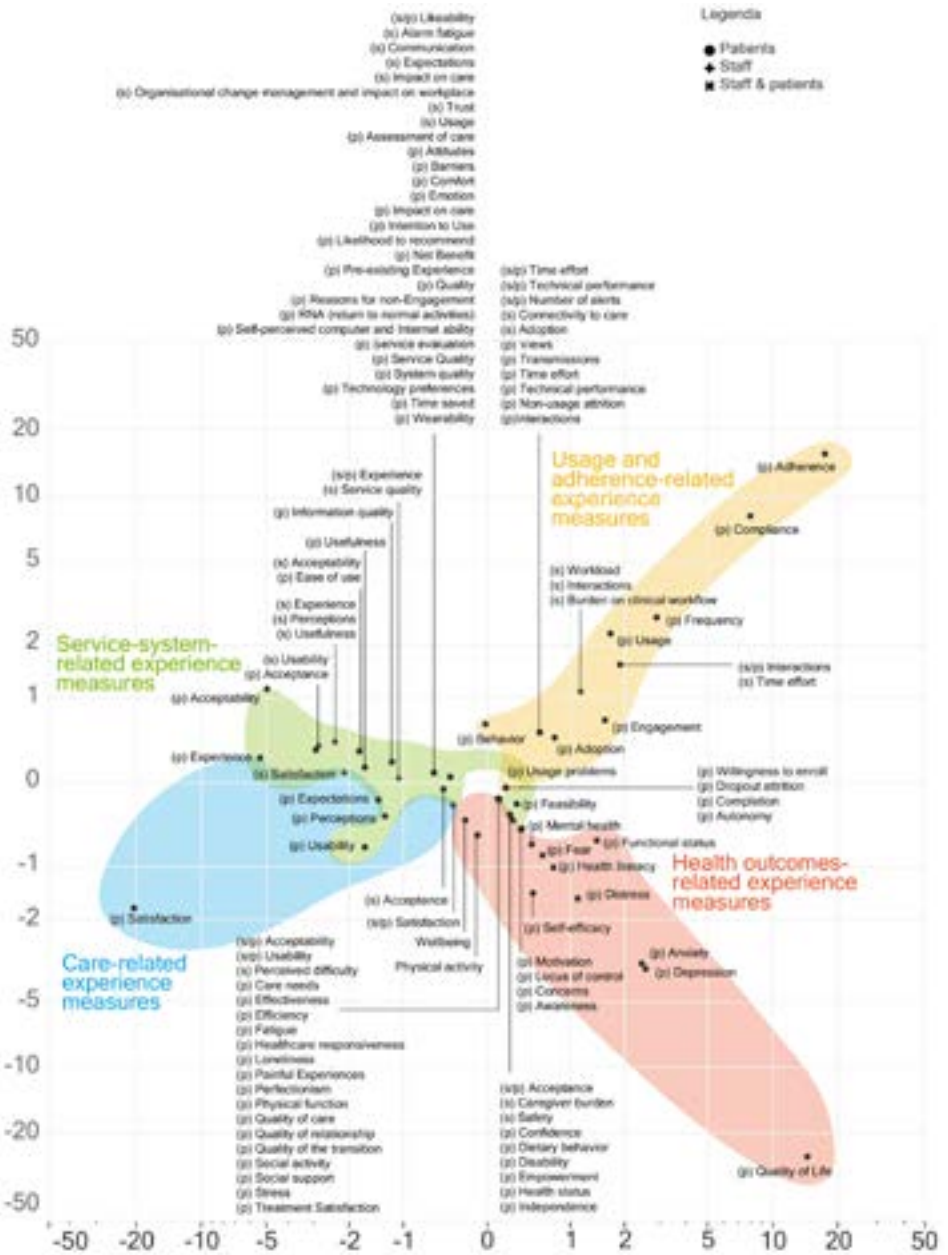

Figure 2.6. Clustered results of the CA (displayed on a logarithmic scale). CA: correspondence analysis.

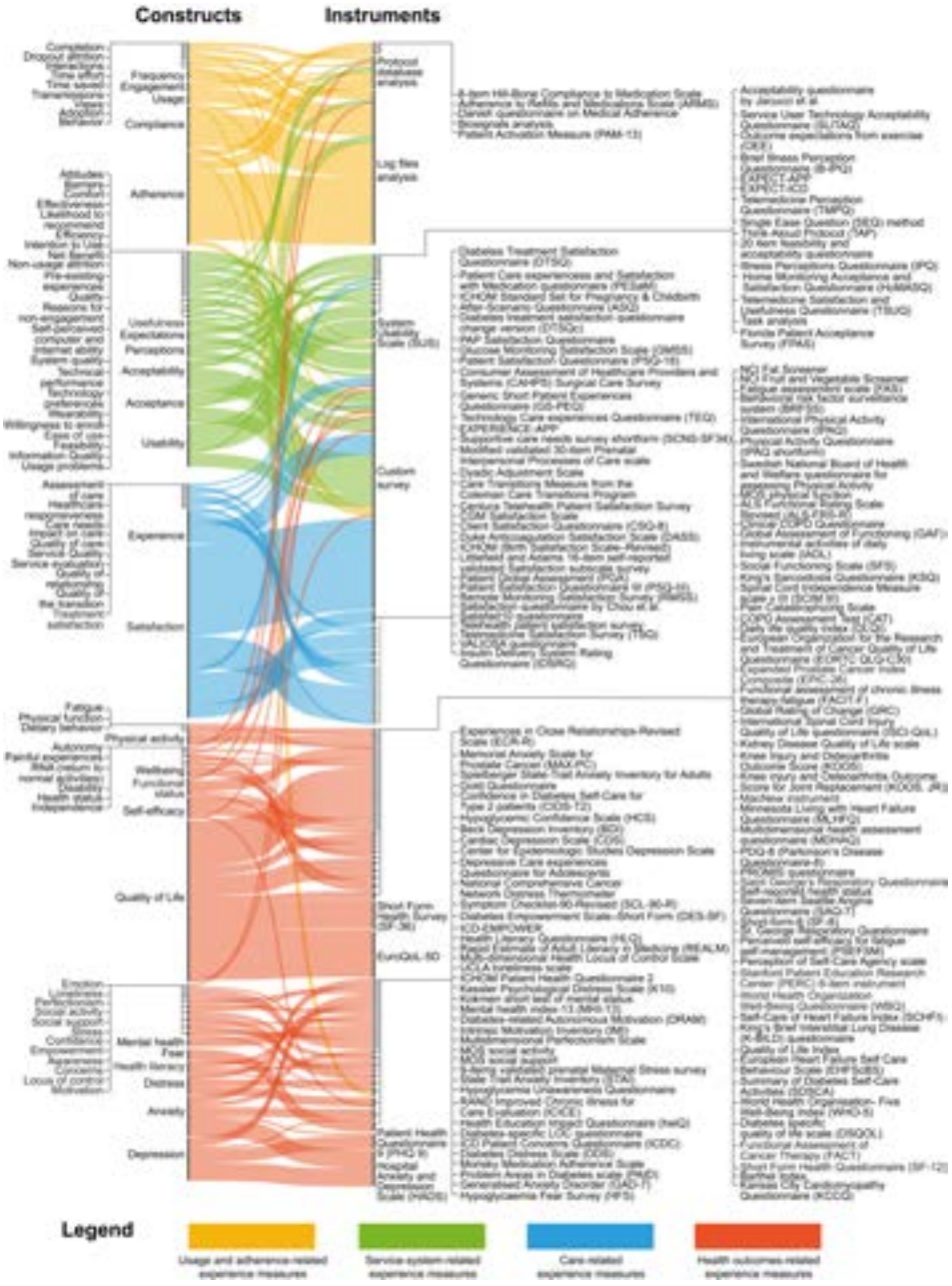
Constructs
Instruments
Completion
Dropout attrition
Interactions
Time effort
Time saved
Trainers/users
Usage
Adoption
Behavior
Frequency
Engagement
Usage
Compliance
Attitudes
Barriers
Comfort
Effectiveness
Likelihood to recommend
Efficiency
Intention to Use
Net Benefit
Non-usage attrition
Pre-existing experiences
Quality
Reasons for non-engagement
Self-perceived computer and internet ability
System quality
Technical performance
Technology preferences
Wearability
Willingness to enroll
Ease of use
Feasibility
Information Quality
Usage problems
Adherence
Usefulness
Expectations
Perceptions
Acceptability
Acceptance
Usability
Assessment of care
Healthcare responsiveness
Care needs
Impact on care
Quality of care
Service Quality
Service evaluation
Quality of relationship
Quality of the transition
Treatment satisfaction
Experience
Satisfaction
Fatigue
Physical function
Dietary behavior
Physical activity
Autonomy
Painful experiences
Well-being
Functional status
Self-efficacy
Disability
Health status
Independence
Quality of Life
Emotion
Loneliness
Perfectionism
Social activity
Social support
Stress
Confidence
Empowerment
Awareness
Concerns
Locus of control
Motivation
Mental health
Fear
Health literacy
Distress
Anxiety
Depression
Protocol database analysis
Log files analysis
System Usability Scale (SUS)
Custom survey
Short Form-Health Survey (SF-36)
EuroQoL-5D
Patient Health Questionnaire 9 (PHQ-9)
Hospital Anxiety and Depression Scale (HADS)
8-item Hill-Bone Compliance to Medication Scale
Adherence to Refills and Medications Scale (ARMS)
Daniel questionnaire on Medical Adherence
Biosignals analysis
Patient Activation Measure (PAM-13)
Diabetes Treatment Satisfaction Questionnaire (DTSQ)
Patient Care experiencess and Satisfaction with Medication questionnaires (PE(Q)aM)
ICHOM Standard Set for Pregnancy & Childbirth
After-Scenario Questionnaire (ASQ)
Diabetes treatment satisfaction questionnaire change version (DTSQc)
PAP Satisfaction Questionnaire
Glucose Monitoring Satisfaction Scale (GMSS)
Patient Satisfaction Questionnaire (PSQ-18)
Consumer Assessment of Healthcare Providers and Systems (CAHPS) Surgical Care Survey
Generic Short Patient Experiences Questionnaire (GS-PEQ)
Technology Care experiences Questionnaire (TEQ)
EXPERIENCE-APP
Supportive care needs survey shorform (SCNS-SF34)
Modified validated 30-item Prenatal Interpersonal Processes of Care scale
Dyadic Adjustment Scale
Care Transitions Measure from the Coleman Care Transitions Program
Centura Telehealth Patient Satisfaction Survey
CSM Satisfaction Scale
Client Satisfaction Questionnaire (CSQ-8)
Duke Anticoagulation Satisfaction Scale (DASS)
ICHOM (Birth Satisfaction Scale–Revised)
Littlefield and Adams 16-item self-reported validated Satisfaction subscale survey
Patient Global Assessment (PGA)
Patient Satisfaction Questionnaire III (PSQ-III)
Remote Monitoring Satisfaction Survey (RMSS)
Satisfaction questionnaire by Chou et al.
Satisfaction questionnaire
Telehealth patient satisfaction survey
Telemedicine Satisfaction Survey (TSQ)
VALIDEA questionnaire
Insulin Delivery System Rating Questionnaire (IDSRQ)
Experiences in Close Relationships-Revised Scale (ECR-R)
Memorial Anxiety Scale for Prostate Cancer (MAX-PC)
Spielberger State-Trait Anxiety Inventory for Adults
Joint Questionnaire
Confidence in Diabetes Self-Care for Type 2 patients (CIDS-T2)
Hypoglycemic Confidence Scale (HCS)
Beck Depression Inventory (BDI)
Cardiac Depression Scale (CDS)
Center for Epidemiologic Studies Depression Scale
Depressive Care experiences
Questionnaire for Adolescents
National Comprehensive Cancer Network Distress Thermometer
Symptom Checklist-90-Revised (SCL-90-R)
Diabetes Empowerment Scale–Short Form (DES-SF)
ICD-EMPOWER
Health Literacy Questionnaire (HLQ)
Rapid Estimate of Adult Literacy in Medicine (REALM)
Multidimensional Health Locus of Control Scale
UCLA loneliness scale
ICHOM Patient Health Questionnaire 2
Kessler Psychological Distress Scale (K10)
Kolmen short test of marital status
Mental health index-13 (MHI-13)
Diabetes-related Autonomous Motivation (DRAM)
Intrinsic Motivation Inventory (IMI)
Multidimensional Perfectionism Scale
MOS social activity
MOS social support
Edinburg validated prenatal Maternal Stress survey
State-Trait Anxiety Inventory (STAI)
Hypoglycaemia Unawareness Questionnaire
IBMG Improved Chronic Illness for Care Evaluation (ICICE)
Health Education Impact Questionnaire (heiQ)
Diabetes-specific LOC questionnaire
ICD Patient Concerns Questionnaire (ICDC)
Diabetes Distress Scale (DDS)
Monaky Medication Adherence Scale
Problem Areas in Diabetes scale (PAID)
Generalised Anxiety Disorder (GAD-7)
Hypoglycaemia Fear Survey (HFS)
Acceptability questionnaire by Jansoni et al.
Service User Technology Acceptability Questionnaire (SUTAQ)
Outcome expectations from exercise (OEE)
Brief Illness Perception Questionnaire (B-IPQ)
EXPECT-APP
EXPECT-ICD
Telemedicine Perception Questionnaire (TMPQ)
Single Ease Question (SEQ) method
Think Aloud Protocol (TAP)
20 item feasibility and acceptability questionnaire
Illness Perceptions Questionnaire (IPQ)
Home Monitoring Acceptance and Satisfaction Questionnaire (HoMASQ)
Telemedicine Satisfaction and Usefulness Questionnaire (TSUQ)
Task analysis
Florida Patient Acceptance Survey (FPAS)
NCI Fat Screener
NCI Fruit and Vegetable Screener
Fatigue assessment scale (FAS)
Behavioral risk factor surveillance system (BRFSS)
International Physical Activity Questionnaire (IPAQ)
Physical Activity Questionnaire (PAQ shortform)
Swedish National Board of Health and Welfare questionnaire for assessing Physical Activity
PROMIS Physical function
ALS Functional Rating Scale Revised (ALS-FRS-R)
Clinical COPD Questionnaire
Global Assessment of Functioning (GAF)
Instrumental activities of daily living scale (IADL)
Social Functioning Scale (SFS)
King's Sarcoidosis Questionnaire (KSQ)
Spinal Cord Independence Measure scale v iii (SCIM III)
Pain Catastrophizing Scale
COPD Assessment Test (CAT)
Daily life quality index (DLQI)
European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
Expanded Prostate Cancer Index Composite (EPIC-26)
Functional assessment of chronic illness therapy-fatigue (FACIT-F)
Global Rating of Change (GRC)
International Spinal Cord Injury Quality of Life questionnaire (ISCI-QoL)
Kidney Disease Quality of Life scale
Knee Injury and Osteoarthritis Outcome Score (KOOS)
Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR)
Machlew instrument
Minnesota Living with Heart Failure Questionnaire (MLHFQ)
Multidimensional health assessment questionnaire (MDHAQ)
PDQ-8 (Parkinson's Disease Questionnaire-8)
PROMIS questionnaire
Saint George's Respiratory Questionnaire
Self-reported health status
Seven-item Satellite Anemia Questionnaire (SAQ-7)
Short-form 6 (SF-6)
St. George Respiratory Questionnaire
Perceived self-efficacy for fatigue self-management (PSEFSM)
Perception of Self-Care Agency scale
Stanford Patient Education Research Center (PERC) 6-item instrument
World Health Organization Well-Being Questionnaire (WBQ)
Self-Care of Heart Failure Index (SCHFI)
King's Brief Interstitial Lung Disease (K-BILD) questionnaire
Quality of Life Index
European Heart Failure Self-Care Behaviour Scale (EHFScBS)
Summary of Diabetes Self-Care Activities (SDSCA)
World Health Organization- Five Well-Being Index (WHO-5)
Diabetes specific quality of life scale (DSQOL)
Functional Assessment of Cancer Therapy (FACT)
Short Form Health Questionnaire (SF-12)
Barthel Index
Kansas City Cardiomyopathy Questionnaire (KCCQ)
Legend
Usage and adherence-related experience measures
Service-system-related experience measures
Care-related experience measures
Health outcomes-related experience measures

Figure 2.7. Reported patient experience constructs (left) and some associated measuring instruments (right). The thickness of each line refers to the number of instances each construct was used in the included studies. A complete version of this visual can be found in Multimedia Appendix 4, and an interactive version can be found in Ref (Interactive Sankey, n.d.).

Recommendations

In the light of the collected findings, here we provide a set of recommendations to RPM patient and staff experience evaluators, in terms of both what to measure and how to measure it (Figure 2.8). Although these recommendations are functional to strengthen the quality of individual research protocols, they are also meant to stimulate increased standardization in the field as a whole.

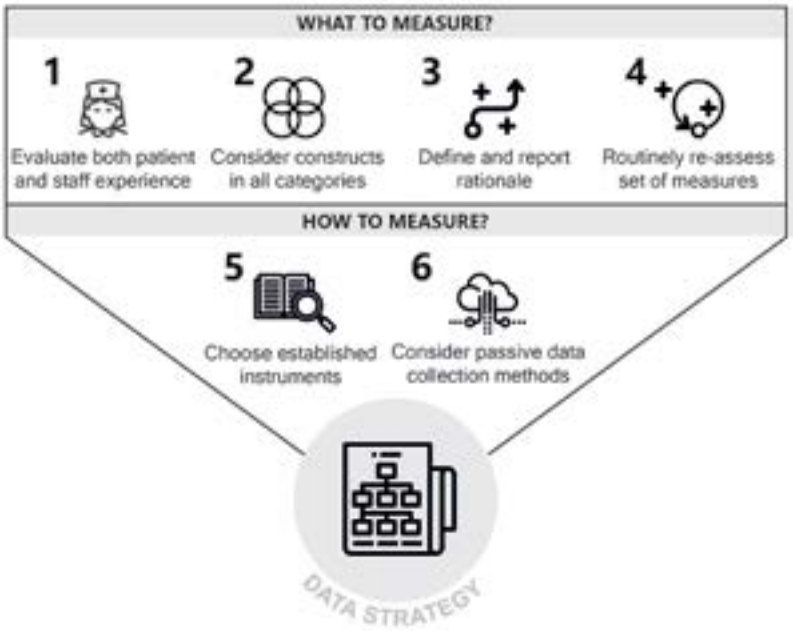

Figure 2.8. Recommendations for patient and staff experience measuring in the RPM domain. RPM: remote patient monitoring.

Regarding what to measure, we provide 4 main recommendations. The first is to conduct structured evaluations of staff experience next to patient experience. Failing to evaluate staff experience leads to risks, such as undetected staff nonadherence, misuse, and overworking. Although new competencies need to be developed in order for staff to unlock the untapped potential of RPM (Hilty et al., 2021), seamless integration with existing clinical workflows should always be pursued and monitored.

The second recommendation is to consider experience constructs in all 4 clusters indicated in Figure 2.6, as these represent complementary facets of an overall experiential ensemble. Failing to do so exposes RPM evaluators to the risk of obtaining partial information (eg, only shedding light on *how people feel* but not on *what happens* in terms of patient and staff experience in RPM).

The third recommendation is to explicitly define and report a clear rationale regarding which aspects of patient and staff experience to prioritize in evaluations, depending on the goals and specificities of the RPM intervention. This rationale should ideally be informed by preliminary qualitative research and by a collaborative mapping of the expected relationships between patient and staff experience and other components of the Quadruple Aim framework for the RPM intervention at hand. Failing to follow this recommendation exposes RPM evaluators to the risk of obtaining results that are logically detached from each other and as such cannot inform organic improvement efforts. Virtuous examples of reporting a clear rationale were provided by Alonso-Solís et al (2018) and den Bakker et al (2019), who offered detailed accounts of the considerations used to guide the selection of included experience measures. Several existing frameworks and methods can be used to map such considerations, including the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) framework (Greenhalgh et al., 2017) and the logical framework (Dey et al., 2006). A relatively lightweight method to achieve such an overview can also be represented by the

use of Figure 2.1 as a checklist to inventory possible Quadruple Aim relationships for a specific RPM intervention.

The fourth recommendation is to routinely reassess the chosen set of experience measures after each iteration of the RPM intervention design. Initial assumptions regarding relationships between experience factors and other dimensions of intervention quality should be verified once the relevant data are available, and new ones should be formulated, if necessary. If the RPM intervention transitions from research stages to implementation as the standard of care, it is recommended to keep on collecting at least some basic experience measures for system quality monitoring and continuous improvement. Failing to update the set of collected measures as the RPM intervention progresses through successive development stages exposes RPM evaluators to the risk of collecting outdated information, hindering iterative improvement processes.

Regarding how to measure RPM patient and staff experience, we provide 2 main recommendations. The first is to work with existing, validated and widely used instruments as much as possible, only creating new instruments after a convincing critique against current ones. Figure 2.7 can be used to find existing instruments measuring a broad range of experience-relevant constructs so as to reduce the need to create new ones.

For instance, researchers interested in evaluating certain experience constructs, ideally informed by preliminary qualitative research, might consult the full version of Figure 2.7 (available in Multimedia Appendix 4 or as an interactive map in Ref. (Interactive Sankey, n.d.)) to find their construct of interest on the left side of the graph, follow the connecting lines to the existing relevant measures on the right, and identify the most frequently used ones. They can also use the visual to consider other possibly relevant constructs.

Alternatively, researchers can use the open access database of this review (Pannunzio & Morales Ornelas, 2023) and especially the "extracted data" Excel file to search for the construct of interest and find details of papers in the RPM domain in which the construct was previously measured.

Failing to follow this recommendation exposes RPM researchers to the risk of obtaining results that cannot be compared to meaningful benchmarks, compared to other RPM interventions, or be included in meta-analyses.

The second recommendation is to consider adopting automatic, "passive" methods of experience data collection, such as the ones we referred to in this review as log file analysis, so as to obtain actionable estimates of user behavior with a reduced need for patients and staff to fill tedious surveys (de Koning et al., 2021) or otherwise provide active input. Failing to consider automatically collected log file data on patient and staff experience constitutes a missed opportunity in terms of both the quality and cost of evaluation data. We recognize such nascent data innovations as promising (Miriovsky et al., 2012) but also in need of methodological definition, particularly in terms of an ethical evaluation of data privacy and access (Fernández-Alemán et al., 2013; Martínez-Pérez et al., 2014) in order to avoid exploitative forms of prosumption (Lupton, 2014).

2.4 Discussion

Principal Findings

This study resulted in a structured overview of patient and staff experience measures used in contemporary RPM research. Through this effort, we found that the research landscape has seen a sizeable growth in the past 10 years, that it is affected by a relative lack of focus on staff experience, and that the overall corpus of collected measures can be

organized in 4 main categories (service system–related, care-related, usage- and adherence-related, and health outcome–related experience measures). Little to no consensus or standardization was found in the adopted methods. Based on these findings, a set of 6 actionable recommendations for RPM experience evaluators was provided, with the aim of improving the quality and standardization of experience-related RPM research. The results of this review align with and expand on recent contributions in the field, with particular regard to the work of White et al (2022).

Directions for Further Research

Fruitful future research opportunities have been recognized in various areas of RPM experience measuring. Among them, we stress the need for comparative studies investigating patient and staff experience factors across different RPM interventions; for studies clarifying the use, potential, and limitations of log file analysis in this domain; and (most importantly) for studies examining the complex relationships between experience factors, health outcomes, and cost-effectiveness in RPM.

Ultimately, we recognize the need for integrated data strategies for RPM, intended as processes and rules that define how to manage, analyze, and act upon RPM data, including continuously collected experience data, as well as clinical, technical, and administrative data. Data strategies can represent a way to operationalize a systems approach to health care innovation, described by Komashie et al (2021) as "a way of addressing health delivery challenges that recognizes the multiplicity of elements interacting to impact an outcome of interest and implements processes or tools in a holistic way." As complex, adaptive, and partly automated systems, RPM interventions require sophisticated data strategies in order to function and improve (Abdolkhani et al., 2019); continuous loops of system feedback need to be established and analyzed in order to monitor the impact of RPM systems and optimize their performance over time, while respecting patients' and staff's privacy. This is especially true in the case of RPM systems including artificial intelligence (AI)

components, which require continuous monitoring and updating of algorithms (de Hond et al., 2022; Feng et al., 2022; Gerke et al., 2020). We characterize the development of integrated, interdisciplinary data strategies as a paramount challenge in contemporary RPM research, which will require closer collaboration between digital health designers and health care professionals (Morales Ornelas et al., 2023, 2024; Pannunzio, 2023). We hope to have provided a small contribution to this overall goal through our effort to structure the current landscape of RPM patient and staff experience evaluation.

Strengths and Limitations

We acknowledge both strengths and limitations of the chosen methodologies. The main strength of this review is its extensive focus, covering a large number of experience measures and RPM interventions. However, a limitation introduced by such a broad scope is the lack of differentiation by targeted condition, clinical specialty, RPM intervention characteristics, geographical area, or other relevant distinctions. Furthermore, limitations were introduced by choices, such as focusing exclusively on contributions in English and on nonprimary care and nonpediatric RPM interventions.

Conclusion

Contemporary patient and staff experience measuring in RPM is affected by a lack of consensus and standardization, affecting the quality of both primary and secondary research in this domain. This issue determines a critical knowledge gap in our understanding of the effectiveness of RPM interventions, which are known to bring about radical changes to the care experience of both patients and staff. Bridging this knowledge gap appears to be critical in a global context of urgent need for increased resource effectiveness across health care systems, including through the increased adoption of safe and effective RPM. In this context, this review offers support for RPM experience evaluators by providing a structured

overview of contemporary patient and staff experience measures and a set of practical guidelines for improving research quality and standardization in this domain.

3

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Chapter 3.

Exploring design and healthcare evidence generation practices in eHealth development

Abstract

Evidence-based practices play an essential role in the development of eHealth systems. Prior research has investigated the challenge of shared understanding between professionals from the fields of health sciences and design and has highlighted the need for effective alignment of development and research practices in eHealth. However, there is a limited understanding of epistemological differences between these fields and how professionals conceptualise evidence. In this paper, we investigate how healthcare and design professionals think about evidence and how they implement evidence practices in their work. We interviewed eight professionals and used reflexive thematic analysis to identify the challenges and strategies associated with their evidence practices. Our results identify five shared evidence practices between healthcare and design professionals: stakeholder-driven, process-driven, problem-driven, effect-driven, and solution-driven. These five evidence practices indicate opportunities for closer alignment of development and research practices among healthcare and design professionals and offer a basis to create a shared understanding of evidence between both fields.

3.1 Introduction

eHealth systems are increasingly being developed to reduce healthcare professionals' administrative tasks or to supervise patients' health conditions in and out of hospital settings using information and communication technologies (WHO, 2016). Within their development, evidence-based practices play a vital role in ensuring healthcare quality. However, the current evidence-based health paradigm fails to meet the needs and values of users during eHealth development (Smits et al., 2022).

Design offers an approach to include users' needs and values in eHealth development, yet health sciences and design face the challenge of a shared understanding of their development practices. Pagliari (2007) and Blandford et al. (2018) have investigated differences in development lifecycles and research methodologies between these fields to foster a shared understanding. Now, the challenge lies in creating a shared understanding of evidence between both fields (Komashie & Clarkson, 2022).

Evidence in system development processes is described as 'objective evidence' and defined as *"data supporting the existence or verity of something"* generated through observations, measurements, or tests (ISO, 2015). Thus, a challenge in shared understanding of evidence suggests a misalignment of evidence practices among fields. By evidence practices, we mean the activities (e.g., tests) that professionals from each field employ to generate and use evidence as part of their development process. However, the literature does not explain the underlying epistemological differences in evidence practices among health sciences and design and how evidence is conceptualised despite these differences in eHealth.

The absence of a clear understanding of evidence practices hampers eHealth systems development, as this brings uncertainty about *what* evidence is needed and *how* to generate it through the process (Lamé, 2018). Hence, it is essential to understand evidence practices in both

fields since it could shed light on unexplored perspectives for evidence generation and ultimately lead to an evidence-based well-being paradigm in eHealth (Smits et al., 2022). This paper aims to dive deep into the epistemology behind health and design evidence practices and their implementation. The research question of this paper is: *how do healthcare and design professionals conduct evidence practices in eHealth development?* Accordingly, we interviewed healthcare and design professionals experienced in eHealth development to understand their practices and used reflexive thematic analysis to identify their implementation.

The paper is structured as follows. First, we explore epistemologies about evidence generation and use in both fields. Next, we explain our study's qualitative methodological approach. Then, we describe the resulting five evidence practices: stakeholder-driven, process-driven, problem-driven, effect-driven, and solution-driven, as well as the challenges and strategies associated with each practice. Finally, we discuss the relationship of the practices with existing theory and its implications for fostering a shared understanding of evidence between health sciences and design in eHealth development.

3.2 Evidence in health and design

Evidence generation in health

One of the earliest areas of health sciences in giving 'evidence' an established role in practice was medicine with the surge of evidence-based medicine to improve decision-making using scientific evidence in clinical practice (Sackett et al., 1996). Since then, evidence-based practice has been prominent in other areas, including eHealth. Evidence-based eHealth requires that, in addition to expert knowledge, the people responsible for developing and implementing eHealth systems

use evidence from rigorous studies on what makes these clinically acceptable, safe, and effective (Wyatt, 2016).

Epistemology in health evidence-based practices has foundations in a logical-positivism view of knowledge (Djulbegovic et al., 2009). Paramount to this epistemology is that what is reasonable or justifiable to believe depends on the trustworthiness of the evidence and the degree to which one believes that a credible process determines this evidence (Djulbegovic & Guyatt, 2017). Accordingly, in eHealth, 'evidence' is regarded as results from scientific research and evaluation, existing scientific literature, and professional experience (Jurkeviciute & Eriksson, 2020). This 'evidence' can refer to multiple aspects of the eHealth system, such as technical, human, societal, clinical, economical, organisational, transferability, ethical, and legal (Enam et al., 2018).

In addition, evidence generation processes follow scientific standards and are ranked according to a hierarchy evaluating the quality of the evidence produced–i.e., evidence with the lowest probability of bias and the capability to predict and establish the effect of interventions (Wyatt, 2016). Thus, this hierarchy rates systematic reviews and randomised controlled trials at the highest level and expert opinions and untested theories at the lowest. Finally, evidence is used in decision-making during eHealth development, scientific publishing, funding proposals, and teaching (Jurkeviciute & Eriksson, 2020).

Evidence generation in design

Conversely, the role of 'evidence' is not explicit in design literature when describing design practice. It is only described in the built environment literature as evidence-based healthcare design following health evidence-based practice. Nonetheless, designers do generate and use evidence as part of their knowledge-generation process in product development. Knowledge generation follows a 'designerly' approach guided by the epistemic interest in reaching appropriateness and is concerned with inventing things of value that do not exist yet (Cross, 1982). Accordingly,

design literature describes two paradigms for design activity: as an analytical problem-solving process and as a reflective practice.

On the one hand, the view of *design as an analytical problem-solving process* based on technical rationality is characterised by being goal-directed and following rational logic to go from a present to a desired situation (Simon, 1988). Here, the design process is seen from a logical-positivism stance as an *information-processing search process* where the problem space is stable (Dorst & Dijkhuis, 1995). Simon (1988) proposes an afferent and efferent world while designing. In the afferent world related to the senses, the designer needs to represent a (problematic) present situation, the desired situation, and the differences between both. In the efferent world related to actions, the designer needs to *search* for and represent actions that modify the present situation and remove the differences between both situations. To know if the actions taken are achieving the removal of differences, the designer needs to *produce* information about the initial state of the afferent world and its changes and *record* this information to enable comparison between situations. In this way, the designer tries to reach a sufficient set of actions– i.e., satisfactory design outcome, that achieves the desired situation–i.e., design goal.

On the other hand, the view of *design as a process of reflection-in-action* based on constructivism states that designers have a *reflective learning process* through 'seeing-moving-seeing' to reveal and construct meaning (Schön, 1992). Schön (1992) proposes reflection-in-action, where designers understand and make normative judgements of quality about the design situation: the designer *observes* what is wrong and needs to be fixed or what is good and needs to be maintained or developed. Then the designer forms an intention, leading to a *move* that generates a change, and *observes* again to detect the intended and unintended consequences of the move, thereby informing future moves. In this way, designers construct the problem, evaluate their actions to structure and solve it (Dorst & Dijkhuis, 1995), and form design intentions that evolve iteratively. Such iterations enable designers to manage complexity by

recognising more in the move's consequences than in their prediction (Schön, 1992).

Based on both paradigms of design activity, 'evidence' is regarded as results from user research and evaluation activities with end-users, relevant literature, and official reports (Muratovski, 2021). In addition, this 'evidence' can refer to user needs and requirements, qualities of the product such as usability or the value perceived by the user (Melles et al., 2021), and the overall product's desirability, business viability, and technical feasibility (Brown, 2008). Finally, evidence is used in decision-making to evaluate design quality based on requirements and objectives (Dong et al., 2016).

Nowadays, healthcare and design professionals work together in eHealth. The complexity arising from the interrelation of the multiple aspects to generate evidence about eHealth systems (e.g., clinical outcomes, usability) calls for a constructivist approach to their development. However, due to its exploratory nature, this approach presents shortcomings for required procedures (e.g., medical ethical approval) in clinical development (Noortman et al., 2022); hence, this approach needs adjustment. Yet, an entirely logical-positivism approach to evidence generation will not satisfy either due to eHealth complexity and the difficulty this represents to formulate and test predictions about the system's intended (and unintended) effects in the real world. In practice, professionals from both fields cope with these epistemological differences, but the literature does not explain *how* they perform this practice in eHealth development. Hence, this paper will investigate their evidence practices through an empirical study.

3.3 Methodology

This study aims to clarify how healthcare and design professionals cope with epistemological evidence differences in eHealth. Our study is grounded in the qualitative tradition, with a relativism ontology

orientation and a constructionism epistemology view (Braun & Clarke, 2013). Our theoretical grounding allows us to explore and produce, rather than discover, the 'truths' of both fields–health and design. Accordingly, we use an experiential approach via interviews since we want to understand the multiple accounts of evidence practice from healthcare and design professionals. Our research question is: *how do healthcare and design professionals conduct evidence practices in eHealth development?*

Sampling and data collection

We recruited healthcare and design professionals from previous eHealth projects via email and selected participants with at least four years of experience in eHealth development. Their expertise in eHealth development and implementation included diverse digital health apps, systems, devices to collect health data remotely, and strategic visions for digital hospitals. We conducted eight semi-structured online interviews with a cohort of four healthcare professionals (HP) and four design professionals (DP) between January and May 2021. DP had an academic background in design (e.g., strategic, product, interaction) and an MSc degree. While HP had a biomedical, medical, or human movement science background and had or were pursuing a PhD (see Table 3.1). All were based in the Netherlands.

Our interview procedure included two steps. First, we asked participants to introduce themselves, and then we briefly presented the evidence differences found in our literature review to explain the research context and to have a starting point for reflection on their practices. Second, we asked open-ended questions about how they managed the generation and use of evidence in recent eHealth projects and follow-up questions about activities or evidence they mentioned. The interviews lasted between 40 to 70 minutes and were audio-recorded for qualitative analysis with the participants' consent.

Table 3.1. Participants' background details.

Participant	Cohort	Job title (years of experience)	Institution affiliation
HP1	Healthcare professional	Assistant professor (5)	Technical university
HP2	Healthcare professional	Professor (21)	University hospital
HP3	Healthcare professional	PhD candidate (5)	University hospital
HP4	Healthcare professional	PhD candidate (4)	University hospital
DP1	Design professional	Strategic designer (7)	Design consultancy
DP2	Design professional	Data-design specialist (6)	Multinational company
DP3	Design professional	UX and Service designer (4)	Design consultancy
DP4	Design professional	Founder and CEO (4)	Start-up company

Note. Years of experience are counted from their final academic degree acquisition to the interview date.

Data analysis

We transcribed all the interviews verbatim, de-identified names, and proceeded to analysis with Reflexive Thematic Analysis–RTA (Braun & Clarke, 2013) in Microsoft Excel. We adopted RTA to identify patterns of shared meaning in the practice accounts described by participants. Within RTA, we used an inductive data approach and interpreted the data with a latent strategy to explore meaning at the underlying level. Below, we describe our analytic process based on the six RTA steps.

The first step involved familiarising ourselves with all the transcriptions by reading them multiple times. In the second step, we coded the transcripts in relation to our research question to identify patterns and themes in the data. For instance, we coded the following sentence 'Running alignment workshops': *"where even from the kick-off for the alignment, we involve all the stakeholders, we run workshops, 1,2,3 workshops, making sure all the stakeholders are involved."* For the third step, we grouped our codes to generate initial sub-themes. For example, the codes 'Running alignment workshops', 'Bringing stakeholders together through co-creation', and 'Conducting ideation sessions with stakeholders' created the sub-theme 'Facilitating stakeholders' participation'. The fourth step consisted of reviewing and gathering sub-themes into themes. For instance, the sub-themes 'Find stakeholder's evidence needs', 'Navigate complex stakeholder spaces', 'Identifying who values what evidence', 'Facilitating stakeholders' participation', 'Fostering project ownership', and 'Creating tailored arguments' were gathered under the theme 'Stakeholder-driven evidence practice' due to their fixation with stakeholder influences. Then, in the fifth step, we continued the process by defining each theme and refining it. For example, we went back to the transcripts to observe how the sub-themes within 'Stakeholder-driven evidence practice' related or not to each other. This step helped us to identify challenges and strategies within themes. Finally, in the sixth step, we wrote the five final practice themes and related sub-themes.

3.4 Results

As a result of our qualitative analysis, we identified five shared themes of evidence practices among healthcare and design professionals: stakeholder-driven, process-driven, problem-driven, effect-driven, and solution-driven (see Table 3.2). A different factor drives each practice (e.g., stakeholder, process) and highlights the perspective from which one can act with regard to 'evidence' throughout the development of eHealth systems. Within each practice, we identified the challenges that

participants face and the strategies they use to overcome these. Below, we present each practice by introducing its description and evidence conceptualisation, the participants involved, and the challenges and strategies identified.

Table 3.2. Overview of shared evidence practice themes.

Evidence practice (participants)	**Description**	**Challenge sub-themes**	**Strategy sub-themes**
Stakeholder-driven (HP2, HP3, HP4, DP1, DP2, DP3, DP4)	Describes how stakeholders' evidence needs (e.g., evidence topic or type, study design) and a persuasive intention influence what evidence is and its generation.	- Find stakeholder's evidence needs - Navigate complex stakeholder spaces	- Identifying who values what evidence - Facilitating stakeholders' participation - Fostering project ownership - Creating tailored arguments
Process-driven (HP3, HP4, DP2, DP3, DP4)	Describes how the type of process (e.g., CE certification) and process phase influence the evidence requirements and its generation.	- Manage the process's evidence requirements - Address incoming people to the process	- Choosing methods based on process phase - Tracing decision-making during process - Mapping who is relevant based on process phase
Problem-driven (HP2, HP3, DP3)	Describes how the reasons giving rise to a problem (e.g., user needs and concerns) influence what evidence is and its rationale.	- Get the right problem-solution picture	- Establishing evidence rationale from people's needs - Finding people's real problems - Defining what success means with people
Effect-driven (HP1, HP2, HP3, HP4, DP1, DP2, DP4)	Describes how the desired effect (e.g., clinical outcome) influences what evidence is and its generation.	- Clarify effectiveness in eHealth - Manage effectiveness uncertainty	- Specifying upfront what evidence is - Managing effect assumptions early on - Scaling-up evidence generation

Table 3.2. (Continued) Overview of shared evidence practice themes.

Evidence practice (participants)	**Description**	**Challenge sub-themes**	**Strategy sub-themes**
Solution-driven (HP2, HP4, DP1, DP3)	Describes how the aspects of the solution being developed (e.g., usability) influence what evidence is and its generation.	- Manage eHealth system's complexity - Handle multiple handover points in product development	- Splitting evidence generation into solution aspects - Building evidence as a documentation process

Stakeholder-driven evidence practice

Stakeholder-driven evidence practice describes how stakeholders' evidence needs (e.g., evidence topic or type, study design) and a persuasive intention influence what evidence is and its generation. Evidence is conceptualised as results from (scientific or user) research, evaluation, and participatory activities with stakeholders that support a statement about what is valuable to them–e.g., a sketch from an ideation session explaining the eHealth system's vision. This practice is shared by three healthcare professionals (HP2, HP3, HP4) and all design professionals (DP1, DP2, DP3, DP4). Participants expressed that during the development of eHealth systems, it is challenging to navigate complex stakeholder spaces where diverse stakeholders' needs must be managed to ensure the products' successful implementation. Stakeholders have different evidence needs to judge for themselves if the solution is successful. They explained that these needs could be regarding specific topics such as costs or value for the user, but also about scientific evidence or other evidence types, as illustrated by DP4: *"The insurance companies, they need very heavy, heavy evidence, scientific evidence. So, what does the key opinion leaders need? the physicians need? Do the hospitals need to learn? So, everybody has a different kind of evidence need."*

In addition, participants described strategies such as facilitating stakeholders' involvement with participatory activities to understand who values and needs what evidence. For example, alignment workshops can help to bring an initial shared understanding. Then, inviting them to join research and evaluation activities can help to increase the project's transparency, and co-creation and ideation sessions can help to understand their concerns, needs, and past failures. This stakeholder knowledge could help to craft a compelling story by (1) capturing the significant evidence for each stakeholder per phase and (2) using storytelling to explain the overall argument of the eHealth system. However, participants mentioned that evidence and arguments sometimes are not enough, and to implement a product successfully, stakeholders need to believe in and own the project throughout the process. They mention that participatory activities such as co-creation could help to create a shared belief and reflect on the overall project rationale could help stakeholders advocate for the project. For instance, DP1 describes that although evidence is subjective at the early stages of development, creating a shared understanding and belief among stakeholders through participatory activities helps to make subjectivity more tangible and actionable: *"Well, I think in that process, evidence tends to be a bit of a fluffy thing right? Because it's mostly quite subjective what people think the future is going to look like. It really depends on, you know, their own needs, but also the concerns and worries that they have for the future. So, in that phase evidence for us meant, you know, gathering all these perspectives and make them as tangible as possible for people. Which means, which is not so much about evidence, but more about creating a shared vision. So, involving a lot of people, throughout the process."*

Process-driven evidence practice

Process-driven evidence practice describes how the type of process (e.g., CE certification) and its phases influence the evidence requirements and its generation. Evidence is conceptualised as documentation that supports a statement about the rationale behind the solution's development in terms of processes, results, and decisions–e.g., a report describing the

development process of the eHealth system. This practice is shared by two healthcare professionals (HP3, HP4) and three design professionals (DP2, DP3, DP4). Participants shared that managing evidence requirements across the development process is challenging due to the various product certifications and corresponding requirements. They explained that the process dictates the different product phases, thereby indicating evidence needed, methods, and stakeholders to be addressed per phase. For example, HP3 explains that the process behind bringing a product to the market will influence its evaluation: *"If you talk about having validity and really putting it on the market, then I do think there's a lot of ask for having that more quantitative assessment."*

Additionally, participants expressed that strategies such as mapping stakeholders' relevance or the recommended methodologies for evidence generation per process phase can provide guidance and that decision-making about evidence generation should be traceable through the process. For example, DP3 explains how the CE certification process demands a chain of evidence starting at the early development stages, where problem and intentions are defined: *"Look into the CE certification process for healthcare products. And if you go through the process to build your product to market, and look at the kind of documentation you have to do, or the evidence you have to show, it starts linking back to your first phase of the design. It's where's this problem coming from? What research was done? What target group was addressed? What were the outcomes of that research? How did it build to the design, and then design research. So, your evidence-based design is really that process of backtracking and ensuring not just stakeholder wise, but also certification wise that at least what's coming out is what it was intended."*

Problem-driven evidence practice

Problem-driven evidence practice describes how the reasons giving rise to a problem (e.g., user needs and concerns) influence what evidence is and its rationale. Evidence is conceptualised as results from (scientific

or user) research and participatory activities that support a statement about the link between the problem and the meaning of success–e.g., a quote from an interview explaining why a specific need is relevant for that user. This practice is shared by two healthcare professionals (HP2, HP3) and one design professional (DP3). Participants mentioned that finding the fundamental problems of people and a solution is challenging, and not clarifying the need for this search upfront can be confusing for others unfamiliar with design practice where the problem space needs exploration. For example, HP3 shares the confusion of working with designers, as they did not understand why designers would not just start working on solutions to the given problem and instead had to search for the problem: *"I noticed that also with colleagues that they said, it's okay, but we have a clear problem, and you want a solution. So, designers go ahead. But then as a designer, you sort of, indeed you redefine that whole problem space."*

In addition, participants shared that evidence finds its meaning when it is connected to the problematic situation aimed to be solved–i.e., people's needs and pain points, and advised establishing an evidence rationale starting from people's needs as a first strategy. Also, they shared that another strategy when creating an eHealth system should be finding people's real problems and unambiguously describing them, as this could help identify future steps within the development and iteratively define the meaning of success with the people experiencing the problem. For example, HP2 shares that analysing the problem from multiple perspectives is essential to define the solution's success later: *"Such process needs to start from a very rigorous analysis of the problem to be solved. And for that, only that aspect alone, it will determine half of the success. Because if you have not really clearly and unequivocally described the problem, you will never know whether you have succeeded. Because what is the, you never know, it's a yes or a no, if it is that vague. It will help you focus on the true, on a true problem. And not something that resembles it or looks like it, no. And also, by doing so, you come to learn the, say the surroundings of the problem, the connotation, the*

context of the problem, both from your perspective, but as well, from the healthcare professional's perspective, or the patient's perspective, much better."

Effect-driven evidence practice

Effect-driven evidence practice describes how the desired effect (e.g., clinical outcome) influences what evidence is and its generation. Evidence is conceptualised as results from (scientific or user) research and evaluation that support (or do not) a statement about the degree to which the effect is being achieved–e.g., data collected using an eHealth system that shows the time a user is physically active. This practice is shared by all healthcare professionals (HP1, HP2, HP3, HP4) and three design professionals (DP1, DP2, DP4). Participants described that evidence of eHealth effectiveness is contested. HP3 explains that one reason is the unclarity of the main eHealth objective guiding evidence generation: *"When do you call that evidence-based eHealth? And, that also has to do with the whole objective of eHealth. Is it indeed that you expect large improvement in quality of life? Or is it sufficient that somebody feels that he is able to self-manage his or her disease more effectively?"* Another challenge explained by participants was the management of effectiveness uncertainty. They shared that a common request before any test with users in healthcare is high certainty that the product is effective, yet it is difficult to meet in the early development phases. One reason, as explained by DP2, is that design is a process based on assumptions and, thus, not 100% certain: *"You cannot, I think, completely hammer down upfront, which ideas are worth to take the leap of faith and you also cannot prove upfront which of these will be a success to the full extent. You can make it a better guess, but it will always be a guess. And that's also due to the part that design is a process based on assumptions."*

Participants expressed that a strategy to deal with effectiveness unclarity is to specify upfront 'why' evidence is needed and then define 'what' evidence could satisfy that need. Then, multidisciplinary teams could

establish desired outcomes, endpoints, and suitable methods to generate this evidence, as establishing evidence upfront makes the process and outcomes more transparent to others. For instance, HP4 describes how they teamed up to look at risk management in app development, evaluated the need for evidence in relation to the effect, and then decided on suitable methods: *"An app, which has quite some risks, or which can really affect someone's health. There, it should contain solid evidence, which really builds on the clinical effectiveness in which supports hypotheses, and which shows that it's actually good and does not harm someone's health. But for apps just helping reaching 10,000 steps, for instance, well, you don't need this kind of heavy clinical evidence, you don't need a very heavy investigation. So, we help them establishing kind of risk classification. And then we think with them, what kind of mainly used methodologies can be used to establish evidence on this part."*

Another strategy shared by participants to deal with effectiveness uncertainty was using scientific literature to manage assumptions about effectiveness at early development stages. They highlighted that literature could be used to uncover assumptions that later could become hypotheses to be tested in conceptual development. For example, HP1 shares that establishing a working principle supported by scientific literature can guide decision-making: *"You can get a lot of your assumptions answered, based on previous literature based on previous models that we know that if you improve a specific part of well, your autonomy, for instance, or a specific part of your external motivation, then that can result into, well, a change in behaviour, for instance. And if you already use like these kind of models for your concept phase, for your design decisions, I think it makes it already a bit stronger."*

The last strategy shared by participants to deal with uncertainty is to scale-up evidence generation by starting with a small-scale test of the assumption(s) related to effectiveness. By small scale, participants meant conducting a test with low-fidelity prototypes and a small group of people–not necessarily from the patient group but in the envisioned context of use. They explained that small iterative tests with different

time frames could indicate which prototype aspects work for the intended purpose. In addition, participants shared that product requirements could establish a quality management system to evaluate the prototype before clinical testing. However, this iterative approach might not be familiar to healthcare professionals, and thus discussing its benefits might help to persuade them, as explained by DP1: *"Is me saying to doctors, so, if I would do it your way, which is probably you know, academically the best way to get the best evidence, the problem is, that is going to cost a lot of money and it's going to take me years […] So, the alternative is, or you wait two years for me to be finished, or we start doing it with the people we can get. And we learn along the way. And we keep making sure that in the end, you know, when you launch the thing, you will have enough evidence to be certain that you should launch it."*

Solution-driven evidence practice

Solution-driven evidence practice describes how the aspects of the solution being developed (e.g., technical functionality, usability) influence what evidence is and its generation. Evidence is conceptualised as results from (scientific or user) research and evaluation that support (or do not) a statement about the solution's requirements being fulfilled– e.g., results from a usability test showing the user's problems when using the eHealth system. This practice is shared by two healthcare professionals (HP2, HP4) and two design professionals (DP1, DP3). Participants described that managing the multiple eHealth aspects that need to be developed complicates evidence generation because they are interrelated. In addition, they shared that one needs to handle the multiple handover points between the development departments to avoid misunderstandings. As an example, HP4 shares that besides finding the aspects to generate evidence for, one should also find the best method and setup: *"What aspects should we look at? And can we do so in one study? Should we do that within clinical studies? Or can we also do this in simulation processes? or just by well, exploring, for instance, whether the eHealth tool uses the law, and it, well, works according to the law, for instance."*

Additionally, participants explained that one strategy to deal with complexity was splitting evidence generation per solution aspects to focus on different studies and facilitate analysis. They mentioned that these aspects could be studied using qualitative and quantitative methods. Also, they expressed that building this evidence starts with jointly generating ideas and then synthesising them into sketches, prototypes or other forms to allow for evaluation, process documentation, and dissemination. As an example, HP4 explains that one should divide evidence generation into multiple studies with focused research questions to facilitate analysis at later stages: *"We evaluated usability by interviews, and we asked general practitioners, what do you think of the system? Do you like it? Is it easy to use the kind of stuff. So, I think that's through usability. And we don't really look at clinical effectiveness yet in that study, because it was more of a feasibility study. But in within that study, we also looked at the technical and legal aspects. […] And you shouldn't make a study too large, but you should really define as small as possible research questions because otherwise it gets extremely difficult to analyse the results."*

3.5 Discussion and conclusion

This study identified five shared evidence practices through interviews with healthcare and design professionals working in eHealth development in response to epistemological evidence differences between health sciences and design. These evidence practices relate to design and engineering literature concepts and eHealth development approaches that could support part of their implementation.

A stakeholder-driven practice brings a systems perspective by addressing all audiences' evidence needs in the development process, as it emphasises the rhetorical dimension of design (Buchanan, 1985). This practice could be supported by the CeHRes Framework (Van Gemert-Pijnen et al., 2011), which proposes a participatory development process for eHealth. However, developers should add explicit discussions about

evidence with stakeholders to the steps stated. A process-driven practice relates to the 'Design Methods Movement' and its attempts to support the designer's intuition and imagination with prescriptive and systematic processes to develop solutions (Buchanan, 2009). Also, this practice relates to the efforts in engineering to create processes that ensure quality and safety through product certifications. In addition to the methods suggested per certification, the E-Health Methodology Guide (Bonten et al., 2020) offers methods per eHealth development phase to support this practice.

A problem-driven practice relates to the theory of co-evolution of problem-solution (Dorst & Cross, 2001), where there is a constant development and refining of a problem and solution ideas. However, it does not have frameworks to facilitate its practice in eHealth. Nonetheless, participants highlighted the essential role of getting the right problem-solution picture to develop effective eHealth systems. Tightly connected to this practice is an effect-driven practice that relates to validation, where one confirms if the requirements for the intended use are fulfilled (ISO, 2015). An effort to support this practice is the NICE Evidence Standards Framework (Unsworth et al., 2021), which advises the evidence of effectiveness that should be generated concerning the eHealth system's intended use. Finally, a solution-driven practice relates to verification, where one confirms if the specified requirements are fulfilled (ISO, 2015). The Digital Health Scorecard (Mathews et al., 2019) proposes a requirements-driven approach that can help to split evidence generation and manage complexity.

The outcomes presented in this paper extend the current understanding of evidence practice in two ways. First, our outcomes show that although epistemological differences in evidence exist between both fields, their evidence practices overlap within five views to act upon evidence generation in eHealth development. This overlap means that both fields recognise the same factors as influence variables for evidence generation (e.g., stakeholders, problem, effect) regardless of the development and research practices from each field, but their implementation across the

process might differ during development. Hence, development teams should use these shared evidence practices as starting points to discuss *what evidence* conceptualisation the team is referring to and *how to generate* this evidence accordingly to foster a shared understanding of evidence between fields during development.

Second, our outcomes show that healthcare and design professionals employ more than one evidence practice, suggesting that the practices complement each other. For instance, at the start of a project, a stakeholder-driven practice could identify stakeholders' evidence needs to be embedded in the process, while later, the focus might shift to validation and therefore follow an effect-driven practice. Hence, this outcome indicates that *evidence has a relational role* that brings together stakeholders, process, problem, effect, and solution. Evidence is constructed for a purpose—i.e., the desired effect of a solution in a problematic situation; it does not just exist, and different stakeholders interpret this evidence across the development process. Thus, development teams should reflect on how the multiple evidence practices influence their process and implement more than one during eHealth development.

Despite interviewing professionals with diverse expertise in eHealth development, our study's sample size and specific context in the Netherlands may hinder the generalizability of our results to other eHealth development contexts. Nevertheless, the five evidence practices offer a basis to create a shared understanding of evidence between health sciences and design. We hope the challenges and strategies per practice help professionals identify problematic situations and provide guidance to solve them. While we acknowledge the emergence of approaches to support individual practices, we urge the research community to explore ways to assist development teams in implementing multiple evidence practices in eHealth development and maintain the discourse about evidence and its relational role alive.

4

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Chapter 4.

Exploring evidence definition practices for health outcomes and their translation into design practice

Abstract

eHealth development faces the challenge of generating evidence about health effectiveness in real-world settings. Designers can potentially support this challenge but must understand health approaches to evidence generation about health outcomes. This case study investigates how health and care professionals conceptualise health outcomes and their evidence generation in eHealth. Our results identify three key conceptual dimensions: effect, meaning, and collection. We discuss how these inform future design competencies to support evidence generation about health outcomes in eHealth design.

4.1 Introduction

eHealth systems play an essential role in improving patients' health and well-being, health service delivery, and overall quality of care (WHO, 2016). These systems apply information and communication technologies and leverage the resulting interoperability to continuously collect and display various data types (e.g., biometric, behavioural) at a large scale—from multiple patients at multiple times (Silber, 2003). Examples include electronic health records that store and share patients' medical information or remote patient monitoring systems that collect and transmit health data (e.g., heart rate, active minutes) in and out of the hospital. However, despite their increased application, scientific evidence regarding their effectiveness in the real world is scarce (Bonten et al., 2020). This scarcity derives from the limited joint evaluation of clinical and sociotechnical factors (e.g., acceptance, safety) in eHealth development that influence its adoption and effectiveness in real-world settings (Enam et al., 2018).

Within eHealth development, designers follow a human-centered design approach to explore contextual factors and create eHealth solutions tailored to the intricate dynamics of the patient's sociotechnical system (Melles et al., 2021). In creating such solutions, designers can potentially support the generation of evidence about eHealth effectiveness by embedding data collection mechanisms. They could leverage their competencies to identify aspects of the problem and solution that meaningfully inform the design of data collection mechanisms about eHealth effectiveness in real-world settings. However, designers are hampered by a lack of understanding and clarity about an evaluation of effectiveness that considers health outcomes and their evidence standards in healthcare (Lamé, 2018; Noël, 2017).

Understanding how health and care professionals (HCPs) generate evidence about health outcomes is essential for eHealth development, as this evidence ensures that eHealth systems do not harm their users (Wyatt, 2016). Thus, there is a need to clarify health outcomes and their related evidence generation for eHealth design. Especially with the

opportunity these systems bring to collect data continuously at a large scale in the real world. Therefore, we conduct an empirical study to understand how HCPs conceptualise health outcomes and their evidence generation in eHealth and identify what designers can do to support this evidence generation. Our research questions are: *how do health and care professionals conceptualise evidence generation about health outcomes in eHealth development?* And *how can designers incorporate this evidence conceptualisation into their competencies?* Accordingly, we explored health outcomes' evidence generation in an eHealth case study via interviews with HCPs and used reflexive thematic analysis to identify their conceptualisation. From our results, we identified how design competencies can be enhanced to support evidence generation in eHealth design.

The paper begins investigating evidence generation about health outcomes. Then, we introduce the case study where we explored the conceptualisation of evidence generation about health outcomes with HCPs. Next, we describe the three conceptual dimensions identified in their conceptualisation of evidence generation: *effect*, *meaning*, and *collection*. Finally, we discuss the implications of these dimensions for design competencies outlined in the literature and highlight design-related frameworks to support their application. We conclude with future research directions to support designers in conceptualising evidence generation about health outcomes with HCPs in eHealth design.

4.2 Evidence generation about health outcomes

Evidence in healthcare refers to any empirical observation about the apparent association between events, where unsystematic observations constitute one source of evidence and experiments another (Guyatt et al., 2000). Central to evidence generation is the extent to which a credible process (e.g., research study design) produces evidence, where systematic and controlled observations provide more trustworthy evidence (Djulbegovic & Guyatt, 2017). Thus, generating evidence

about an association or possible causation between two variables (e.g., intervention and health outcome) concerns systematic experimentation, as this process is one of the strongest to support causation (Hill, 1965). These experiments are called interventional studies—researchers actively interfere in a present situation by introducing an intervention (e.g., drug, device) in some or all participants to establish the effect of the intervention's exposure on the participants (Ranganathan & Aggarwal, 2018). There are various intervention study designs, with randomised controlled trials being one of the most robust studies to generate evidence about the health outcomes of interventions (Aggarwal & Ranganathan, 2019).

As part of the research study design, health outcomes are defined before exposure to the intervention takes place (Ranganathan & Aggarwal, 2018). The WHO defines *health outcomes* as a change in an individual's, group's, or population's health status attributed to one or multiple interventions, regardless of the intervention's intent to change health (Nutbeam, 1998). Here, health status describes or measures an individual's health at a specific time, while health encompasses physical, social, and mental well- being, extending beyond the mere absence of disease. Health outcomes are typically assessed using health indicators—i.e., characteristics of an individual, population, or environment that are subject to measurement and are used to evaluate health in terms of quality, quantity, or time (Nutbeam, 1998). A typical example of health outcomes is survival rate. However, nowadays, defining outcomes that are valuable for patients (e.g., health-related quality of life) is essential to get a holistic view of patients' health and promote value-based healthcare (VBHC) (Porter, 2010a).

In defining health outcomes, HCPs developing the intervention define their measurement. In this regard, VBHC champions a patient-centered measurement of health outcomes that includes what is valuable for patients (Porter, 2010a). Patient-centered measurement stresses that defining what to measure should be clustered by medical condition, consider the health circumstances most relevant to patients and cover all

the stages of care—i.e., consider short and long-term effects on patient health. Once outcomes are defined, one or more measures and indicators are selected to quantify success. Their selection should minimise the ambiguity of the outcome by choosing validated and tailored patient-population metrics. Lastly, contextualising measurement is considered—i.e., when and where to measure in a way that reflects patients' circumstances and allows the health effect to manifest itself.

Accordingly, initiatives to improve patient-centered measurement have been established. For example, international consortia have developed condition-specific standard sets with patients to define patient- centered measures (Kelley, 2015). In addition, patient-reported outcomes (PROs) have been developed to account for the patient's perspective on health outcomes and promote patient-centered measurement (Calvert et al., 2019). PROs are reports about the status of a patient's health condition (e.g., health- related quality of life) coming directly from patients without interpretation by someone else (FDA, 2009). PROs are operationalised with patient-reported outcome measures (PROMs); these are instruments and tools, such as self-completed questionnaires, that measure the patient's health status, for example, symptom burden or health-related behaviours like anxiety and depression (Weldring & Smith, 2013). More recently, eHealth has transformed outcome measurement—from collecting biometric health data (Porter, 2010a) to enabling online interfaces (e.g., diaries) that capture qualitative accounts of patients' health at various times and outside of hospital settings (Johnston et al., 2023).

As discussed above, HCPs apply their health knowledge to define health outcome measurements and then assess the health effects once exposure to the intervention occurs. However, there is still ambiguity and consequent limited practical insight into how health outcome measurement gets conceptualised towards concrete evidence generation in eHealth development. This conceptualisation is particularly relevant for eHealth design as it can elucidate considerations for designers to embed data collection mechanisms during eHealth design and leverage

eHealth's large-scale data collection—i.e., gathering data from multiple users in diverse settings at numerous times. Therefore, in an eHealth empirical study, we will investigate the conceptualisation of evidence generation about health outcomes with HCPs.

4.3 Methodology

This empirical study aims to explore the conceptualisation of evidence generation about health outcomes from an HCP perspective in eHealth development. Our study is grounded in the qualitative tradition. Accordingly, we employ an inductive case study methodology (Eisenhardt, 1989) via interviews to understand HCPs' conceptualisation and ground it in their practical context. Our empirical research question is: *how do health and care professionals conceptualise evidence generation about health outcomes in eHealth development?*

Case: Remote patient monitoring to increase physical activity in children with chronic conditions

Following Eisenhardt's (1989) process, we select our case study based on theoretical relevance. Our theoretical construct of interest is the activity of evidence conceptualisation, focused on evidence generation about health outcomes happening in eHealth development. Based on our literature review, we need a case study that allows us to investigate how HCPs define health outcomes' measurement to generate evidence. In addition, the case should exemplify the development of an eHealth system that aims for patient-centered measurement to observe its contextualisation.

To this end, we selected the case study of an eHealth remote patient monitoring (RPM) system currently being developed to increase physical activity (PA) in children with chronic conditions. This case lets us explore our theoretical construct because there are preliminary desired health outcomes, but their measurement needs clarification for a pilot

evaluation with patients. Additionally, an RPM system for PA allows the exploration of patient-centered contextualisation of evidence generation given the multiple contexts where it will be deployed to promote and assess PA. Below, we describe the case.

PA is crucial for healthy childhood development. However, children with chronic conditions (e.g., heart disease or asthma) may experience reduced PA levels due to parental anxiety (van Deutekom & Lewandowski, 2021). In response, a collaborative research initiative in The Netherlands involving university hospitals and technical and social science universities aims to improve children's PA levels and reduce parental anxiety through an RPM system. The initiative comprises three projects: one focusing on technology, another on clinical implementation, and the third exploring social implications. The conceptual design of the eHealth system began years ago using a human-centered design approach with these families (see Morales Ornelas, 2020). Currently, the initiative is developing a system prototype for pilot evaluation with the children and their parents.

Data collection

HCPs are those who study health promotion or diagnose, treat, and prevent illness (WHO, 2013). We invited the HCPs executing the three projects to an exploratory interview. We decided to recruit HCPs because they are responsible for generating evidence about the health effects on the patient group. The first author conducted six semi-structured interviews between May and September 2023. Participants had an academic background concerned with health promotion in the medical, social, or human movement science area and had or were pursuing a PhD (see Table 4.1). All participants had experience with either physical, social, or mental health outcome measurement. Some (P1, P2, P4, P6) had knowledge about eHealth development and application, including the validation of sensors for clinical use and using sensors in and outside hospital settings for clinical research. Others (P3, P5) were less familiar with eHealth development. Nonetheless, their health-related expertise in

outcome measurement, academic background, and project involvement enable them to share thoughts on how the RPM system could be used in health outcome measurement.

Table 4.1. Participants' background details.

Participant	**Health-related expertise** (holds PhD)	**Years of experience**	**Project**
P1	Paediatric cardiology and epidemiology (PhD)	6	1,2,3
P2	Paediatric cardiology (PhD)	12	1
P3	Human movement science (PhD in-progress)	2	3
P4	Paediatric pulmonologist (PhD)	17	3
P5	Family sociology (PhD)	13	2
P6	Sports medicine (PhD)	11	3

Note. Years of experience are counted from their final academic degree acquisition to the interview date.

The goal of the interviews was to explore with HCPs their conceptualisation of evidence generation in relation to the health outcomes of interest in each project and their measurement. Before the interviews, the first author gathered and read each research proposal to get familiar with the projects. The interview procedure then consisted of three phases. **Phase one** focused on getting to know the participants' expertise to build rapport and understand their health-related perspectives. In **phase two**, the first author asked them to explain their project's overarching aim and health outcomes to have a starting

point for reflection. **Phase three** was divided into two steps to explore the conceptualisation of patient-centered health outcome measurement described in section 4.2 above. The **first step** focused on exploring the perspective of the child and the parents concerning the defined health outcomes of interest. The first author asked participants to reflect on how their health outcomes related to a child and parent perspective and follow-up questions about how they planned to measure and generate evidence about them. In the **second step**, the focus shifted to the contextualisation of the measurement based on the patient group's needs. The first author started by introducing the three meaningful moments found in previous user research (see Morales Ornelas, 2020) with this patient group: (1) follow-up appointment, (2) Before physical activity, and (3) during physical activity, as well as the related needs from a child and parent perspective per moment. Then, she asked participants to reflect on how the health outcomes and corresponding measures for evidence generation related to these moments and needs.

The interview with P1 lasted two hours because P1 participated in all projects and one hour with participants 2-6. Interviews with participants 1-5 were in-person and with P6 online. All interviews were audio-recorded with consent. Our institution's Human Research Ethics Committee approved this study.

Data analysis

The first author transcribed all the audio files verbatim with support from MS Office 365, de-identified the transcripts, and proceeded with Reflexive Thematic Analysis (RTA) (Braun & Clarke, 2021b) in ATLAS.ti. Following RTA quality criteria (Braun & Clarke, 2021a), the first author positions herself as a design researcher interested in bridging the design and health disciplines and acknowledges that her positionality informs her reflexive and interpretative activities. She applied RTA to identify patterns of shared meaning in the conceptualisation accounts described by participants and discussed analytic observations with the third author to elucidate assumptions in the analysis (Braun & Clarke,

2021b). She used deductive and inductive approaches and interpreted the data with a latent strategy to explore the underlying meaning of what participants expressed in the transcripts. We describe the analytic process based on the six RTA steps below.

The **first step** involved familiarising with all the transcriptions by reading them multiple times. In the **second step**, the first author applied deductive coding based on the WHO's definition of health outcomes (see section 4.2) to create an outcome-related dataset from the transcripts. For instance, she coded the following quote 'Outcome': *"So as a healthcare worker, I hope to see that like the cardiac health is improving."* Once all the transcripts were coded, she applied inductive coding to identify patterns and themes in the dataset. For example, the quote above was coded 'Change-increase'. For the **third step**, she grouped the codes to generate initial sub-themes. For example, the codes 'Change- increase' and 'Change-decrease' created the sub-theme 'Change degree'. Initial sub-themes were discussed with the third author to clarify analytic observations and insights (Braun & Clarke, 2021b). The **fourth step** consisted of reviewing and gathering sub-themes into themes. For instance, the sub- themes 'Change degree', 'Target individual', 'Time frame', 'Environment', 'Desirability', 'Duration' and 'Logical relations' were gathered under the theme 'Effect' due to their fixation with health changes' characteristics and influences. In the **fifth step**, she defined and refined each theme. For example, she returned to the transcripts to observe the dataset in its overall context. This step helped her to sharpen each theme by identifying relationships within them. Finally, in the **sixth step**, she wrote the final themes and related sub-themes, supported by the reflexive journal she wrote throughout the analytic process.

4.4 Results

The analysis results indicate that HCPs conceptualise evidence generation in three dimensions: *effect*, *meaning*, and *collection* (see Table 4.2). Each conceptual dimension gathers aspects considered when

defining the generation of evidence about health outcomes. Below, we introduce each dimension by providing its description along with associated aspects and illustrate these with participants' quotes.

Table 4.2. Overview of conceptual dimension themes.

Dimension (participants)	**Description**	**Aspect sub-themes**
Effect (P1, P2, P3, P4, P5, P6)	Describes aspects considered to frame the effect manifestation that the evidence to be generated will support.	Target individual, change degree, time frame, desirability, duration, environment, and logical relations.
Meaning (P1, P2, P3, P4, P5, P6)	Describes levels considered to define observable meaning units as the evidence of effect to be generated.	Outcome definition, measure definition, and data definition.
Collection (P1, P2, P3, P4, P5, P6)	Describes aspects considered to collect data that will serve as evidence.	Contributor, subjectivity, mechanism, temporality, and context.

Theme one – Effect

A conceptualisation of *effect* involves aspects of the health change manifestation that collectively will be supported by the evidence generated. These aspects are: target individual, change degree, time frame, desirability, duration, environment, and logical connections. All are used to frame the effect's manifestation in the patient's life.

In conceptualising the health effect and its manifestation, a primary aspect is the *'target individual'*, which indicates who will experience the effect and thus the effect of who will be investigated (e.g., child, parents, child's sports coach). Another aspect highlighted was the effect's intended *'degree of change'*, usually expressed as an increase (e.g., increased PA level) or a decrease (e.g., decrease of asthma rescue medication). In addition, a *'time frame'* aspect suggests when the effect

is expected to occur in relation to the intervention's exposure, which could be short-term (e.g., two weeks) or long- term (e.g., ten years). For example, in the quote below, P1 describes various degrees of change in psychological health for different individuals expected in a short time frame: *"What I find also very important is that they enjoy sports and that they feel more safe and more secure and more self-efficient, and that parents have less fears and insecurities. So, I guess those are the things that I find most important for the children and the parents in a relatively short term."*

Other aspects in the conceptualisation of effect include the environment, duration, and desirability. *'Environment'* indicates where the effect is expected to manifest. For example, a child's increased PA level is expected to happen in their day-to-day life primarily. Another related aspect is *'duration'*, which describes for how long the effect will be evaluated in relation to how long it should last. In addition, the aspect of *'desirability'* differentiates between what effects are desirable and which are not. Here, monitoring desirable and non-desirable effects is crucial, as the latter can potentially jeopardise individuals' health. For instance, below, P5 describes the importance of investigating the non-desired effect of technology reliance within the family and how the expected duration can have implications for removing the intervention: *"I wouldn't want to create an intervention that stimulates reliance on technology for a child to become active. So, it's reassurance, that's what they're hoping for. And then hopefully when the parent is reassured and confident, yes, my child can play outside and look, he's happy. You know it goes well. That that is enough for the parents like, this goes well for a couple of weeks, I think he's doing fine and then you can also remove the device."*

Finally, the aspect of *'logical relations'* describes the kind of a priori hypothesised rationale that can exist between effects, or effects, interventions, and factors. They can be distinguished into three categories. (1) Causal relations describe the cause-and-effect association, usually between an intervention and a desired change or between effects (e.g., PA is associated with better cardiovascular health). (2) Hierarchical

relations give insight into the primary and secondary effects as envisaged in the study design. Lastly, (3) influential relations describe factors that can impact the health effect positively or negatively. For example, P4 describes environmental factors as negatively affecting physical health: *"if there's a high pollen count in the air, we have much more asthma cases. If air pollution is high, we have more asthma cases. So, in the ideal situation, you would collect this data as well."*

Theme two – Meaning

A conceptualisation of *meaning* involves defining the health outcome subject to be assessed for effectiveness and breaking it down into smaller observable concrete units for examination in the real world. This definition happens at three levels that build upon each other: outcome, measure, and data definition. Collectively, these levels represent the evidence of the effect that will be generated.

At the top level, *'outcome definition'* involves defining the overarching health subject(s) that will be assessed for effect. Once these subjects are defined, in the middle level *'measure definition'*, each subject is broken down into more specific meaning units to facilitate the qualification or quantification of the effect. To illustrate both levels, below, P4 explains different outcome subjects related to respiratory health and how, in this case, asthma control is further broken down into more specific meaning units: *"If you look at outcomes that we are measuring it's lung function, which is of course not a patient reported outcome. It's exacerbations of disease, so asthma attacks, but also exacerbation of infections in patients with cystic fibrosis or admissions, it's readmissions to hospital or ER visits because of their disease, that's a really important outcome. It's asthma control, which is sort of a container idea. Asthma control means symptom control. If you do have nocturnal symptoms, if you use your rescue medication a lot, if you are able to do your daily activities."*

Lastly, at the bottom level, *'data definition'* involves defining the kinds of data that will make the unit observable in the real world. For example,

in the quote below, P1 describes that physical activity is quantified as the aggregation of minutes per day in a specific data range: *"a common way to express physical activity is the mean minutes per day you are in moderate-to-vigorous physical activity, that's like your physical activity."* Here, it is important to note that the definition of data ranges can sometimes be standardised, as in the quote above. Yet, sometimes, data ranges can be adjusted to the patient's characteristics, as explained by P1: *"Also the medical team also sets the boundaries. So, the doctor can say it is safe for you to exercise with heart rates below 160, but above it's dangerous for you."*

Theme three – Collection

A conceptualisation of *collection* describes aspects considered in the generation of the data that will act as evidence for the envisioned effect(s). These aspects are: contributor, subjectivity, mechanism, temporality, and context. Together, they inform data collection characteristics accounted for in eHealth.

In conceptualising collection, a primary aspect is the *'contributor'* participating in data collection (e.g., answering a questionnaire or wearing a device). Here, the contributor's characteristics (e.g., age) influence the type of tests or questionnaires available for assessment. Ideally, the aspects of contributor and target individual will be the same person. Yet, sometimes, questionnaires assess perceptions of the effect from complementary views (e.g., parental view). Additionally, the aspect of *'subjectivity'* indicates the contributor's involvement with the data it generates. Objective collection describes quantifiable values or perceptions of subjective experiences (e.g., minutes in moderate-to-vigorous PA, questionnaire results), whereas subjective collection captures descriptive qualitative accounts of individual experiences (e.g., online diary). For instance, in P2's quote below, the child is the contributor, and the child's participation in the collection could oscillate between a more objective or subjective involvement: *"It's not like we ask the child to grade their participation or if they think they're normal*

enough or not in a quantitative way [...] Of course, qualitatively, we do see how they participate. So how often do they do this? Which sports? Which sports are they doing?"

Other aspects of the conceptualisation of collection include the mechanism, temporality, and context. *'Mechanism'* describes the means (e.g., tools, instruments) used to collect the data. These can range from individual consults, online diaries, or questionnaires to physical tests, medical scans, or (non)wearable devices. Closely related is the *'temporality'* aspect, which refers to the timing and frequency of the collection. Here, timing indicates the moment when the collection happens, and frequency indicates how often the collection happens (e.g., every minute, every day). Lastly, the aspect of *'context'* indicates the conditions where the collection takes place (e.g., play). Ideally, the aspects of context and environment will be the same. Yet, sometimes the collection context will be in a hospital, while the effect's environment will be in the everyday life of patients. To illustrate these aspects, in P5's quote below, we see how the moment of exercise (i.e., timing) can be accessed virtually by a device (i.e., mechanism) in the context of parents' everyday lives: *"if the child is in exercise and the parent is there and the parent has some sort of monitoring this device as well. So, it's not only on the child, but maybe the parent has like a small laptop or iPad or laptop or whatsoever, that as a researcher, we also take time to virtually stand next to the parent and ask them, OK, how are you feeling? How are you interpreting the [monitoring] information?"*

4.5 Discussion and conclusion

This study identified three conceptual dimensions concerning evidence generation about health outcomes in response to conceptual ambiguity on how one goes from health outcomes to concrete evidence generation in eHealth. The conceptual dimensions are *effect*, *meaning*, and *collection*. Each describes aspects HCPs consider to define health outcomes' evidence generation. However, it remains unclear how designers can

incorporate HCPs' evidence conceptualisation into their competencies to support the generation of evidence about effectiveness during eHealth design. Therefore, we elaborate on how the dimensions can enhance the five design competencies outlined by Voûte et al. (2020), as these competencies enable designers to manage the socio-technical complexity in the design process. Additionally, we highlight design-related frameworks accounting for health outcomes from architecture (Hamilton, 2018) and human factors and ergonomics (Carayon et al., 2020) that offer guidance in integrating the dimensions with the competencies into the eHealth design process.

The first competence outlined by Voûte et al. (2020) is *'framing and reframing the design challenge in its emerging future context'*. This competence can benefit from specifying the manifestation of the *effect* during the (re)framing activity to identify what the evidence will support once generated. Designers should clarify with HCPs (1) who the target individual is and (2) what the current health baseline is to measure the degree of change. In addition, designers should specify the environment(s) where the manifestation should be observed within the emerging context and anticipate possible (non)desired health effects with HCPs to include a patient safety perspective. Finally, designers should identify and record the socio-technical factors that (might) influence the challenge to clarify possible logical relations during reframing and understand which factors ultimately influence the effect observed.

The second competence is *'creating and evaluating iteratively to converge towards a desired impact'*. This competence can be enhanced by detailing *effect* and *meaning*. Given the iterative exploration where a creative output (i.e., eHealth system) aims at a desired impact, designers should clarify the logical (causal) thread throughout iterations that explains what was learned. This learning involves a reflection by the designer on the intended cause-and-effect relationship between the eHealth system and its current (health) effect and future exploration directions. This reflection will clarify and systematically build up the rationale embedded in the system that regulatory bodies will demand in

the certification process (Morales Ornelas et al., 2023). Once iterations converge into a reduced solution space, it would be easier to formulate a precise cause-and-effect relation for evaluation in a controlled setting. Additionally, given the interest in a desired impact (i.e., improve health), it is—fundamental—that designers specify the subject of that impact and deconstruct it into observable meaning units. This means defining with HCPs the measures and data that will indicate the current impact of the implemented eHealth system.

The third competence is *'integrating an increasing amount of relevant perspectives into a working whole'*. This competence can benefit from recognising that 'integrating' the desirability, feasibility, and viability perspectives outlined by the authors should also consider the effectiveness perspective of the 'working whole'. Designers should commit to investigating the *effect* of their output for longer (Jones, 2013) by envisioning an evaluation time frame with HCPs that allows observation of (non)desired health effects. In addition, designers should envision with HCPs a proper effect duration, as it has implications for the eHealth system removal, a limitation already highlighted in eHealth design (van Velsen et al., 2022). Finally, designers can embed data *collection* mechanisms in eHealth systems to support evidence generation about its effectiveness in future evaluation phases. In this way, designers will be able to motivate how (in addition to a desirable, feasible, and viable system) the ultimate effect of the eHealth system is also considered during the creation of the system to track its performance.

The fourth competence is *'meaningfully steering the design and stakeholder process'*. This competence highlights the relevance of considering our conceptual dimensions in the design process because they unravel the evidence that HCPs ultimately need. Designers can benefit from conducting participatory processes where HCPs and other relevant stakeholders like patients and their loved ones are involved in conceptualising the *effect*, *meaning*, and *collection* of evidence. This means involving stakeholders in framing the effect manifestation by considering all its aspects (e.g., target individual, change degree,

desirability). It also means facilitating stakeholders' (joint) involvement to identify health subjects, measures, and data that meaningfully inform the qualification or quantification of their health experience. Finally, in terms of collection, it means identifying with stakeholders mechanisms to generate the necessary data and a temporality that accounts for the progression of the effect achieved.

Lastly, the fifth competence is *'working and communicating at varying and multiple levels of abstraction, and across disciplinary perspectives'*. This competence can benefit from bringing together all the conceptual dimensions in designerly ways to elucidate and understand the intricate abstract connections between them. This means visualising, modelling, or prototyping the envisioned manifestation of the *effect*, together with the observable *meaning* units defined in the context where they will be *collected*. Doing so can create boundary knowledge spaces (Carlile, 2002) where HCPs and designers comprehend what effects are aimed for when and where, as well as how these are being observed. These spaces will be useful to identify inconsistencies in measurement (e.g., envisioning an effect manifestation in a specific environment but not defining measures for it) and, thus, improvement opportunities for the design of the eHealth system or the evaluation setting.

Given our suggestions above, we highlight two frameworks that can shed light on (part of) their realisation in the eHealth design process. First, from architecture, evidence-based design (EBD) entails defining goals, using research questions to help gather relevant information, and critically interpreting it to create concepts. Then, it involves defining corresponding hypotheses that can be tested to demonstrate a measurable change in health outcomes (The Center for Health Design, 2023). This process framework can support the second competence and the need for rationale clarification, as it promotes design intent documentation in the form of a design hypothesis before concept evaluation (Hamilton, 2017). This hypothesis acts as a predictive assumption stating the relationship between a design concept and a desired outcome, where outcome clarification allows the selection of measures to evaluate the concept's

effect (Hamilton, 2018). Using this framework in the conceptualisation phase of eHealth systems can clarify the causal logical thread throughout iterations.

The second framework, Systems Engineering Initiative for Patient Safety (SEIPS), comes from human factors and ergonomics. This analytical framework offers insight into how systems affect health-related outcomes (Carayon et al., 2020). As such, SEIPS can support the first competence by facilitating a structured way of clarifying the people, environment, tools, and tasks in the problem-solution framing activity of eHealth design. Regarding the second competence, the 'outcome matrix' (Holden & Carayon, 2021) can be a helpful tool to document outcomes for eHealth evaluation, considering characteristics such as their desirability, priority, and potential measures. Lastly, we see the complementary approach to SEIPS from Landa-Avila and colleagues (2022) as useful for the fourth competence. This approach can facilitate participatory activities where outcome subjects are defined with stakeholders at eHealth design's research and evaluation phases.

Finally, future research is needed to support designers in improving their third and fifth competencies. Future investigations to support the third competence should facilitate processes to ideate strategies and mechanisms for data collection to be embedded in eHealth systems. These should incorporate different data and various durations to assess effectiveness holistically. Lastly, to support the fifth competence, future research should create design tools that enable shared knowledge spaces between designers and HCPs to incorporate the three dimensions into the eHealth design process.

A limitation of this work concerns the focus on one type of eHealth application (i.e., remote patient monitoring systems). The study of this application enabled us to broadly explore the contextualisation of evidence generation, given the deployment nature of this kind of system in multiple contexts. However, more research is needed to corroborate the usefulness and generalisability of our findings to other eHealth

applications. Nevertheless, we encourage the research community to investigate how to support designers in incorporating these conceptual dimensions into their process to advance the impact of designerly ways of knowing on the health and care of individuals.

5

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Chapter 5.

From practices to integration: Aligning static and dynamic evidence approaches with eHealth development standards

Abstract

eHealth systems, such as digital care applications or remote monitoring devices, can improve health outcomes using user-centered design principles to create medical devices that adapt to users' needs and contexts. Data-enabled design (DED) builds on these principles by leveraging user-generated data to iteratively refine systems based on real-world use, enabling adaptive and context-sensitive solutions. However, its exploratory and iterative nature conflicts with the rigid protocols required in clinical trials to evaluate safety and effectiveness. This study revises DED in alignment with clinical trial requirements, identifying four key challenges and proposing a four-phase Clinical Data-Enabled Design (C-DED) framework. This framework reconciles exploratory design with trial methodological demands, supporting the development of safe, effective, and user-centered eHealth medical devices.

5.1 Introduction

eHealth applies information and communication technologies to develop systems, such as digital care applications or remote monitoring devices (Silber, 2003). eHealth systems offer opportunities to create user-centered medical devices and services that improve health by engaging users more effectively. Data-enabled design (DED) is an exploratory approach that leverages user-generated data to develop smart systems (van Kollenburg & Bogers, 2019). Creating systems through DED enables continuous adaptation by digitalising the user's context, behaviour, and experience. This process refines the data a system should monitor, allowing it to automate appropriate functions while iteratively aligning with user needs (Lővei, 2024). DED has shown potential in paediatric remote care, offering actionable health data and community insights (Jung, 2023; van Kollenburg & Bogers, 2019). It has also been used in bariatric post-surgery care to conceptualise user-centered coaching interventions and observe their real-world effects, such as improved patient engagement and health outcomes (Versteegden et al., 2022).

Despite its potential, DED is contested in regulated environments, such as the clinical trials required to establish eHealth systems' safety and effectiveness (ISO, 2020). In eHealth, clinical trials systematically evaluate interventions, such as devices or software, by collecting and analysing standardised data on their effects (ISO, 2020). ISO 14155 (2020) provides international guidelines for devising clinical trials for eHealth medical devices (eMDs), emphasising predefined hypotheses and data collection (ISO, 2020). However, trials, including randomised controlled trials (RCTs), often conflict with the required adaptability to create context-sensitive eMDs (Ammenwerth & Rigby, 2016). RCTs rely on static study designs, generalisable data collection, and predefined outcomes, contrasting with DED's iteration based on context-specific insights (van Kollenburg & Bogers, 2019). Nevertheless, trials and exploration approaches are not inherently incompatible (ISO, 2020). Careful analysis of their methodological assumptions and their application can clarify tensions and inform their integration.

The methodological tension between trials and DED can be understood through two fundamental design theoretical paradigms: Simon's (1988) problem-solving and Schön's (1992) reflective practice (Morales Ornelas et al., 2023). Simon's paradigm emphasises systematic, rational, goal-oriented decision-making, central to clinical trials' static, predefined nature. In contrast, Schön's paradigm focuses on iterative, reflective exploration and generating context-sensitive insights by engaging with the environment– central to DED's process. This framing highlights the conflict between clinical trials' confirmatory approach and DED's exploratory nature. Researchers have proposed integrating community-generated data to enhance DED's generalisability (Jung, 2023) and involving healthcare professionals (HCPs) earlier to align study objectives with clinical practices (Lővei, 2024; Noortman et al., 2022). However, these efforts do not fully resolve the methodological conflict. This unresolved tension limits DED's potential to create safe, effective, and user-centered eMDs that meet clinical methodological requirements and underscores the need for further adaptation of DED to clinical trials.

Therefore, this research revises DED using the ISO 14155 (2020) standard focused on clinical trials of eMDs and identifies adaptations needed to align DED with clinical development and evaluation processes. Our research question is: *What adaptations are necessary to reconcile data-enabled design's exploratory approach with the methodological demands of clinical trials for developing safe and effective eHealth medical devices?* We employ Jaakkola's (2020) theory adaptation approach to examine tensions between DED and clinical trials. Through this approach, we identify four challenges and propose a revised conceptual framework reconciling DED with eMD clinical trials. Our revised Clinical Data-Enabled Design (C-DED) framework can guide designers and HCPs through four phases to devise evaluative DED studies aligned with clinical trial methodological requirements.

5.2 Methodology

This conceptual study revises and adapts DED to meet the methodological demands of clinical trials for developing safe and effective eMDs. Following ISO 14155 (2020), we define eMDs as apparatus, machines and/or software designed for prevention, diagnosis, monitoring, treatment, or disease alleviation. We follow Jaakkola's (2020) theory adaptation approach to achieve our goal. It provides guidance for modifying the scope or perspective of a 'domain' theory by using an alternative established frame of reference or 'method' theory to inform adaptations (Jaakkola, 2020). This approach fits our goal by offering a systematic process to reconcile conceptual inconsistencies between theories.

Jaakkola's (2020) approach consists of three steps. **Step one** (i.e., Section 5.3) describes the domain theory–that is, DED–and articulates its core assumptions. **Step two** (i.e., Section 5.4) problematises these assumptions, in our case, using ISO 14155 (2020) as an established reference to identify challenges when applying DED in clinical trials. **Step three** (i.e., Section 5.5) addresses these challenges by adapting DED with the following method theories: ISO 14155 (2020) standard, SPIRIT guidelines (Calvert et al., 2021; Rivera et al., 2020), and health and design shared evidence practices and data strategies (Morales Ornelas et al., 2023; Pannunzio et al., 2024). These already address key concerns related to clinical trials and user-centered design in eHealth development. We describe our adaptation process and the method theories in Section 5.5, and in Section 5.6, we present the revised clinical data-enabled design (C-DED) conceptual framework.

5.3 Step one: Describing data-enabled design (DED)

As a first step in Jaakkola's (2020) process, we introduce our domain theory: data-enabled design (DED). We describe DED procedurally, outlining its phases, goals, activities, and core assumptions. DED is an

iterative approach that connects two environments: the user's everyday life–i.e., the top loop in Figure 5.1 (see next page), and the design studio–i.e., the bottom loop in Figure 5.1 (see next page) (van Kollenburg & Bogers, 2019). The process begins by situating a prototype in the user's everyday life to collect and transmit data to the design studio, providing real-time insights into the user's context, behaviour, and experience. In design synthesis, these insights lead to design opportunities that prompt designerly explorations with data as creative material to envision (remote) prototype adjustments. The continuous adjustments create data-oriented systems in the everyday loop that learn from and adapt to their users and facilitate continuous data-enabled communication between both environments. Overall, DED follows two design exploration phases: a research-oriented contextual exploration (see Figure 5.1–blue on the next page) and a design-oriented informed exploration (see Figure 5.1–orange on the next page) (Funk et al., 2024; van Kollenburg & Bogers, 2019).

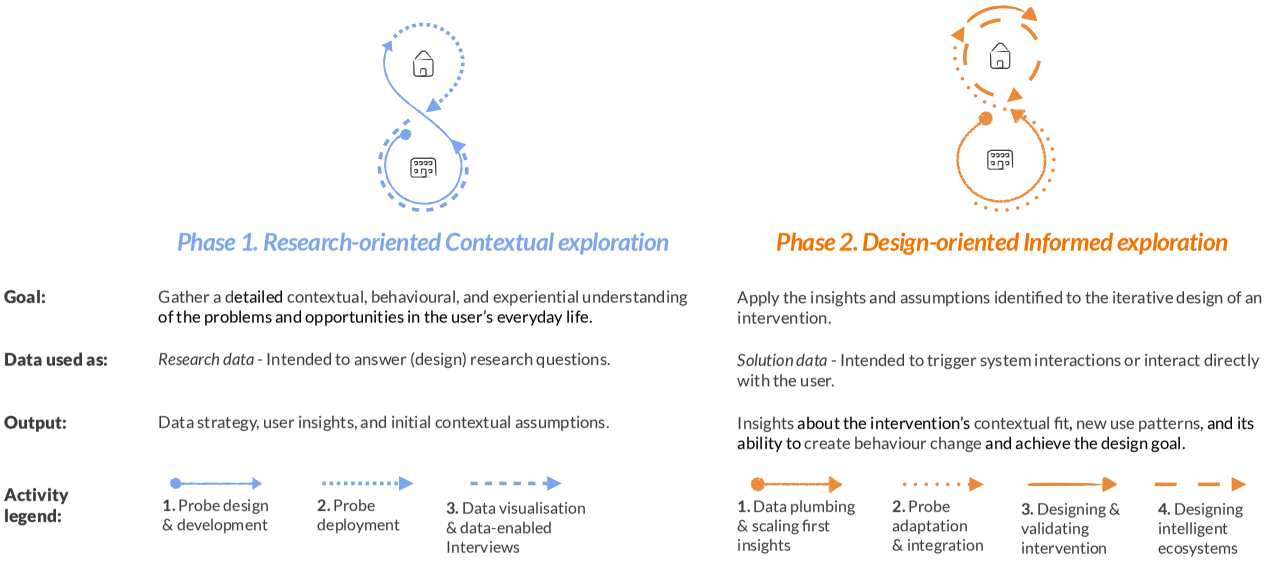

Figure 5.1. DED activities per research—blue and design—orange phases based on Funk et al. (2024).

DED phases and activities

The process begins with a **research-oriented contextual exploration phase** to understand contextual, behavioural, and experiential problems and opportunities in the user's everyday life (Funk et al., 2024). This phase collects research data–i.e., data integrated into the system to answer (design) research questions (van Kollenburg & Bogers, 2019). Funk et al. (2024) enlist three activities (see Figure 5.1–blue arrows). In *probe design and development*, the team examines the context and selects data collection mechanisms that balance insight depth with participant acceptability. These can be personal (e.g., smartwatch), contextual (e.g., motion sensor in object), and open (e.g., event button) data trackers and digital interactive interfaces (e.g., chatbot). During *probe deployment*, the team integrates probes into existing infrastructure, generates test data, and negotiates data collection concerns with participants. In *data visualisation and data-enabled interviews*, they create visualisations and use them in participant interviews to explore the collected data and annotate insightful events. This phase's output includes a data strategy–i.e., what data should (not) be collected, user insights, and contextual assumptions.

Subsequently, a **design-oriented informed exploration phase** applies identified insights to the iterative design of an intervention (Funk et al., 2024). Designers explore if and how research data can become solution data–i.e., data that triggers system interactions or interacts directly with users (van Kollenburg & Bogers, 2019). Funk et al. (2024) enlist four activities (see Figure 5.1–orange arrows). In *data plumbing, scaling first insights*, the team synthesises research data into system functions and solution data by defining and automating data points while reducing data collection and maintaining quality. In *probe adaptation and integration*, the team implements the automation and system functions. In designing and *validating data-driven interventions*, they qualitatively and quantitatively evaluate hypotheses with a new participant group. Research data increases in quantity and depth, while solution data is tailored to intervention functionality. In *designing intelligent ecosystems*, the team gathers insights about the intervention's contextual fit, new

use patterns, and its ability to create behaviour change to improve the current situation. Qualitative insights support contextual sense-making, and quantitative insights bring a comparative perspective against a baseline or context. These insights are the phase's output and can trigger additional design- and research-oriented phases in the same DED study (Funk et al., 2024).

Articulating DED core methodological assumptions

To conclude, using Schön's (1992) and Simon's (1988) paradigms of design activity as lenses, we articulate the following core methodological assumptions underlying both DED phases.

Assumption one: DED builds situated understanding through iteration. Situated understanding refers to how users and their context shape knowledge generation and influence design outcomes. For example, sensors placed in objects based on user routines track specific behaviours that inform particular solution spaces. Iterative learning enables the team to gradually build an understanding of the user (context) in both phases: continuous user data and repeated engagement (e.g., using chatbots) support system refinement through ongoing feedback loops. This assumption echoes Schön's notion of design as a reflective interaction with the environment, where each iteration provides insights that refine the understanding of the problem and the solution.

Assumption two: DED's evaluative and explorative data roles interplay during the process. An *evaluative role of data* indicates that data values inform what happens in the user's everyday life based on a predefined question. This role relates to research data, where data provides an understanding of the users' context, behaviour, or experience. For instance, active minutes in a smartwatch can indicate users' activity levels. Conversely, an *explorative role of data* indicates that the meaning of (research) data is reframed. This role begins when users reinterpret data visualisations in interviews, shaping how designers understand the (research) data collected. For example, morning TV usage may

indicate TV habits (evaluative role) or lack of morning exercise if a user expresses it (explorative role). Both roles interplay as the phases progress by supporting designers in ideating and implementing system functions (solution data) and discovering the results of their implementation (research data). In this assumption, both paradigms are present. Simon's clear goal definition underlies an evaluative role where research questions and data collection are predefined for knowledge generation. Meanwhile, Schön's paradigm substantiates the explorative role during the context-sensitive re-interpretation of data with users.

5.4 Step two: Problematisation of DED when applied in clinical trials

Following Jaakkola's (2020) second step, we critically examine the limitations of DED when applied in trials for eMD development. This problematisation is based on a recent unrealised DED study in which authors were denied medical ethical approval to conduct an eMD clinical trial (Noortman et al., 2022). We use ISO 14155 (2020), focused on trials of eMDs, as an established view to examine and challenge the DED assumptions formulated in Section 5.3. While ISO 14155 is not a legally binding regulation, it is an internationally recognised standard for Good Clinical Practice in eMD trials (ISO, 2020). Its adoption depends on national regulation, but it provides a widely accepted guideline for the design, conduct, and report of trials in compliance with scientific and ethical principles (ISO, 2020).

In eHealth development, clinical trials evaluate the safety and effectiveness of eMD interventions by systematically accumulating evidence on health outcomes before and after market approval (ISO, 2020). To ensure participant safety and ethical compliance, the development team must submit a clinical trial protocol to a Medical Ethical Committee (METC) before the trial (ISO, 2020). This protocol should elaborate on the research methodology and the intervention to allow the assessment of potential risks and benefits for participants

(Rivera et al., 2020). However, in this regulatory context, a METC rejected a DED protocol study. Noortman et al. (2022) proposed an evaluative DED study to develop a smart coaching system to support bariatric patients and their families with lifestyle behaviour change after surgery. Despite collaboration with HCPs in designing the system and protocol, the METC rejected the study, citing concerns over DED's clinical relevance, exploratory nature, and high participant burden (Noortman et al., 2022). While METC decisions vary across institutions and regulatory contexts, this rejection highlights a broader challenge: reconciling DED's exploratory nature with clinical trials' need for predefined protocols and measurable clinical relevance. To better understand this methodological challenge, we examine how ISO 14155 (2020) describes clinical relevance and the nature of clinical trials and identify how this standard challenges DED's core assumptions.

ISO 14155 (2020) describes clinical relevance as a trial's ability to produce reliable data on an eMD's clinical safety, performance, or effectiveness for its intended patient population. A scientifically and ethically sound protocol must anticipate patient benefits and risks and align objectives and hypotheses with data collection and analysis methods (ISO, 2020). Prior scientific studies and non-clinical evaluations should justify the eMD and study design to ensure clinically meaningful insights (ISO, 2020). ISO 14155 (2020) further describes trials' varying nature and characteristics across development phases. Before market approval, a pilot phase may start as exploratory and progress to a confirmatory nature. A pivotal phase is solely confirmatory, while in post-market, the nature can be confirmatory or observational (ISO, 2020). In exploratory trials, eMDs are introduced to generate hypotheses, confirmatory trials test these hypotheses, and observational trials draw inferences without intervening in the context (ISO, 2020). To ensure consistency and scientific rigour, ISO 14155 (2020) requires trial protocols to outline systematic procedures and predefined measures. This requirement means that procedures, prototype modifications, and data collection points must be defined before the trial begins.

Identifying challenges with DED assumptions

Based on the ISO 14155 (2020) descriptions above, we identify four challenges related to the DED's assumptions articulated in Section 5.3. We outline two challenges for assumption one. **Challenge one:** DED's situated understanding does not incorporate the scientific grounding required in trials, which relies on generalisable insights from prior studies to justify the eMD's design and clinical trial protocol. **Challenge two:** DED cannot rely solely on its exploratory nature and situated iterative approach but must also integrate a confirmatory trial nature in its development process to comply with regulations for market approval. For assumption two, we outline two additional challenges. **Challenge three:** DED's multiple inquiry focus on users' context, behaviour, and experience does not include the clinical trial's need for rigorous data on clinical safety, performance, and effectiveness. **Challenge four:** DED's evaluative and explorative data roles cannot interplay during trials, as clinical trials require predefined evaluation measures and static data meanings throughout the study.

5.5 Step three: Adaptation of DED with method theories

As part of Jaakkola's (2020) third methodology step, we adapt DED to address the four challenges in Section 5.4, revising key characteristics to reconcile DED with trial methodological demands. We first addressed challenges two and three as they form the foundation for integrating DED into trials, followed by challenges one and four. Below, we outline our adaptation process and the method theories used.

Addressing challenges two and three

Our adaptation process began by integrating a confirmatory nature and a clinical inquiry focus into the original DED phases to address challenges two and three. We used ISO 14155 (2020) pilot and pivotal trial phases,

given their transition guidance from exploratory to confirmatory eMD trials and their distribution of clinical objects of inquiry across phases. A pilot phase evaluates an eMD's limitations and advantages with a target population sub-group. Outputs guide eMD modifications and inform future study parameters for the pivotal phase. Examples include 'proof of concept trials' for initial safety and performance assessment and 'traditional feasibility trials' for preliminary clinical performance, safety, and effectiveness evaluation. The pivotal phase confirms an eMD's clinical performance, effectiveness, and safety with the target population for market approval. Pivotal trials are strictly confirmatory and typically use statistically justified population groups. Due to its non-interventional purpose, we left the initial DED phase, 'research-oriented contextual exploration', as the first phase. We added a health- related inquiry to it as a research goal to inform subsequent clinical inquiries required by ISO while keeping its original study population and outputs. Then, we extended the goal, study population, and output of the DED second phase, 'design-oriented informed exploration'. We incorporated the research goals, population, and outputs of the 'proof of concept trial', 'traditional feasibility trial', and 'pivotal trial' from ISO 14155 (2020), given their common interventional purpose. This adaptation resulted in four DED clinical trial phases transitioning from exploratory to confirmatory nature: (1) research exploration, (2) design conceptual exploration, (3) design feasibility exploration, and (4) design pivotal confirmation. Each phase has updated research goals, study populations, and outputs.

Addressing challenge one

Once we established the nature and clinical inquiry in each new phase, we incorporated the scientific grounding needed per phase to address challenge one. We employed two variants of the SPIRIT trial protocol guidelines to inform this grounding. SPIRIT-AI (Rivera et al., 2020) provides guidance for smart eMDs, aligning with DED's object of design, while SPIRIT-PRO (Calvert et al., 2021) focuses on patient-centered evaluation, reinforcing DED's user-centeredness. To

complement ISO 14155, we used both variants as they offer additional guidance specific to DED's concerns, particularly for smart eMDs and patient-centered evaluation in trial protocol development. SPIRIT-AI requires trial protocols to justify clinical trials with prior studies and detail the eMD's intended use, target users, and artificial intelligence model (Rivera et al., 2020). SPIRIT-PRO mandates trial protocols to outline patient-centred research questions and evaluation measures, as well as relevant patient-centred intervention findings (Calvert et al., 2021). We used the SPIRIT-AI and SPIRIT-PRO to add and inform the phases' literature grounding needed for the eMD and study design based on each phase's research goal.

Addressing challenge four

To conclude, we enabled the interplay of evaluative and explorative data roles by dividing it between phases to address challenge four. We used shared evidence practices (Morales Ornelas et al., 2023) and shared data strategies (Pannunzio et al., 2024) to guide this division because both inform evaluative knowledge transitions in eHealth from an integrated health and design perspective. Shared evidence practices represent factors (e.g., problem, solution, effect) influencing how design and health communities generate and use evidence in eHealth development. We tailored these practices to DED using shared data strategies to inform evaluation measures across phases. Shared data strategies define joint purposes, rules, and processes for data collection in eHealth development. They include four categories of evaluation measures: service-system, usage and adherence, care, and health outcomes, with corresponding measurement instruments. Based on phase goals and outputs, we used problem-, solution- and effect-driven evidence practices to guide knowledge transitions between phases. We then applied the shared data strategy categories to (pre)define evaluative data collection per transition and consolidate shared research data on patient context, behaviour, experience, clinical effects, and safety. We indicated the required knowledge transition as an 'evidence reflection' activity between phases.

5.6 Results: The revised clinical data-enabled design framework

The Clinical Data-Enabled Design (C-DED) framework addresses the identified four challenges of applying DED in clinical trials (see Section 5.4) by introducing a process with four conceptual phases: research exploration, design conceptual exploration, design feasibility exploration, and design pivotal confirmation. The framework (in Figure 5.2, see next page) splits and extends DED phases, integrating trial requirements for market approval, including the shift from exploration to confirmation (i.e., challenge two) and a clinical inquiry focus on safety, performance, and effectiveness (i.e., challenge three). ISO 14155 (2020) informed the framework's structure, research goals, study populations, and outputs, while SPIRIT guidelines (Calvert et al., 2021; Rivera et al., 2020) added literature grounding (i.e., challenge one) to justify the eMD rationale and study design, ensuring compliance with trial protocols. Finally, shared evidence practices (Morales Ornelas et al., 2023) and data strategies (Pannunzio et al., 2024) guided evidence reflection activities, enabling phase insights (i.e., explorative role) to transition into confirmatory evidence (i.e., evaluative role), addressing challenge four. Below, we introduce each C- DED phase and the evidence reflections required for effectively reconciling DED's explorative approach with clinical trials' methodological demands.

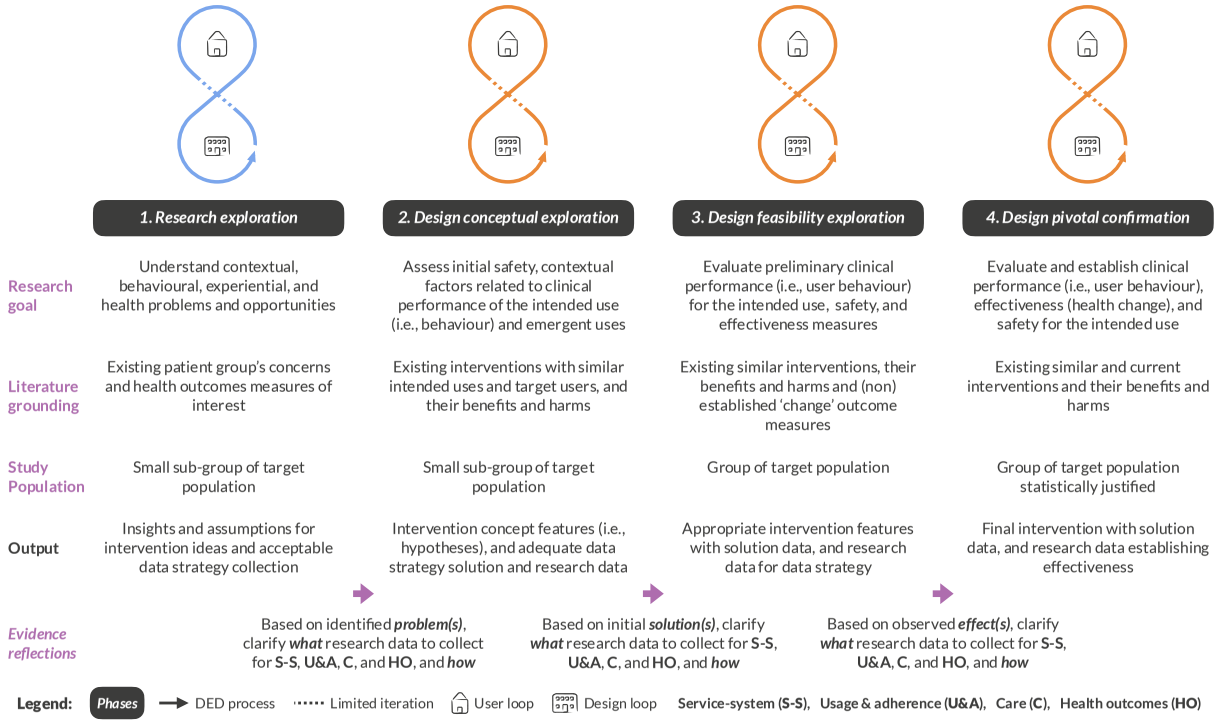

Figure 5.2. Clinical data-enabled design (C-DED) framework with phases and evidence reflections.

Phase one: Research exploration

The **first C-DED** phase is a **research exploration** (see Figure 5.2–number one). The research goal focuses on understanding the health problems and opportunities in addition to the contextual, behavioural, and experiential ones. This phase should be grounded in existing literature about the patient's group concerns and related health outcomes of interest. This phase relies on a problem-solving theoretical paradigm as design knowledge generation concerns the representation and further definition of known problem-solution spaces given its research goal and required motivation. Studies in this phase should be conducted with a small sub-group of the target patient population, and exploratory data collection with personal, contextual, and open data trackers and interactive interfaces. Ultimately, this phase will provide insights and assumptions for the intervention based on identified problems and opportunities and acceptable data collection mechanisms for the data strategy.

After this phase, a **first evidence reflection** should guide the transition to a design conceptual exploration phase. The objective is to clarify the research data points that frame the current understanding of the problem from a shared perspective. This reflection should be based on the intervention's rationale–i.e., the identified insights and assumptions about contextual, behavioural, experiential, and health problems and opportunities and the acceptable data collection mechanisms. The team should reflect on *what* data points could offer insight into problems with the service or system interaction and its usage and adherence, as well as problems concerning care and health. They should also reflect on *how* to collect this data in an acceptable manner, where possible, with established measurement instruments. The resulting research data overview can define data collection to assess the contextual factors related to clinical performance in phase two.

Phase two: Design conceptual exploration

The **second C-DED** phase is a **design conceptual exploration** (see Figure 5.2–number two). The research goal focuses on assessing the initial safety, contextual factors related to the clinical performance of the intended use (i.e., user behaviour), and the emergent uses of the intervention. The study's motivation and the eMD's conceptualisation should be grounded in (un)published literature about existing interventions with similar intended uses and target users and their benefits and harms. While literature grounding complements previous insights to create the concept, the theoretical underpinning of this phase is a reflective paradigm. This is because the knowledge goal concerns identifying emergent changes in the user's environment given the implementation of concept ideas. Studies in this phase should be conducted with a small sub-group of the target patient population. In addition, exploratory data collection with personal, contextual, and open data trackers and interactive interfaces will still be possible in this phase to identify emergent changes. This phase will result in a preliminary set of conceptual intervention features (i.e., hypotheses) and findings about adequate solution and research data for the data strategy.

After this phase, a **second evidence reflection** should guide the transition to a design feasibility exploration phase. The objective is to clarify the research data points that frame the current understanding of the solution concerning the problem it aims to solve from a shared perspective. This reflection should be based on the solution–i.e., the identified conceptual features with their adequate solution and research data. First, the team should reflect on the problems that the features tackle. Then, they should identify *what* data points from the previous overview relate to these problems from a service- system interaction, usage and adherence, and care and health outcomes perspective. Later, they should reflect on *how* to collect this data adequately, where possible, with established measure instruments. The updated (research) data overview with identified problem data based on the features and their solution data will define data collection informing how to make 'change' observable in phase three.

Phase three: Design feasibility exploration

The **third C-DED phase** is a **design feasibility exploration** (see Figure 5.2–number three). The research goal focuses on evaluating the preliminary clinical performance (i.e., user behaviour) and safety of the intervention, as well as the effectiveness measures–i.e., the data collection to make health 'change' observable. This phase should be grounded in (un)published literature about existing (similar) interventions and their benefits and harms, as well as the appropriateness of the chosen (non)established patient outcome measures for 'change' evaluation. The phase's foundation lies in a reflective paradigm because of the narrower exploration goal concerning the effect(s) of the updated intervention and the exploration of the data points' appropriateness–i.e., a problem setting to observe a change in the user's environment. Studies in this phase should be conducted with a target patient population group. Given the preliminary clinical performance evaluation goal, only personal and contextual data trackers and defined data collection in interactive interfaces will be possible at this phase. Ultimately, this phase will provide insights into the preliminary effectiveness of the intervention features and the corresponding appropriate solution and research data for the data strategy.

After this phase, a **third evidence reflection** should guide the transition to a design pivotal confirmation phase. The objective is to clarify the research data points that frame the current understanding of the solution's effect from a shared perspective. This reflection should be based on the intervention's found effect(s). That is the appropriate intervention features with their solution data and the appropriate (behaviour and health) 'change' research data. First, the team should reflect on what (non)desired changes were produced by the solution. Then, they should identify *what* data points from the previous overview relate to these changes from a service-system interaction, usage and adherence, and care and health outcomes perspective. To conclude, they should reflect on *how* to collect this data appropriately, where possible, with established measure instruments. The updated (research) data overview with the

identified 'change' data points will guide the definition of hypotheses for confirmation purposes and their related data collection in phase four.

Phase four: Design pivotal confirmation

The **fourth and final C-DED phase** is a **design pivotal confirmation** (see Figure 5.2–number four). The research goal focuses on evaluating and establishing the clinical performance (i.e., user behaviour), effectiveness (i.e., health change), and safety of the final eMD intervention. This goal should be grounded in (un)published literature about existing (similar) interventions and their benefits and harms. The theoretical underpinning of this phase is a problem-solving paradigm. This, given the goal-directed confirmation activity, where predefined hypotheses and a stable problem definition–framed with the data points from the previous phase–guide evaluation. Studies in this phase should be conducted with a statistically justified group of the target patient population. In addition, studies might involve comparative evaluation with a controlled study set-up (e.g., RCT) where there is an evaluation between interventions or the intervention and the standard of care. Given the evaluative confirmatory purpose of this phase, only personal and contextual data trackers and defined data collection in interactive interfaces will be possible in these studies. The results of this phase will provide evidence (i.e., research data) of the safety and effectiveness of the intervention and the necessary solution data for its functionality.

Implementation considerations

The C-DED framework guides the design of study protocols for each phase, ensuring compliance with clinical trial methodological requirements for eMD development and evaluation. All original DED activities are maintained across C-DED phases. However, the activities *probe design and development* and *probe adaptation and integration* have limited iteration, as prototype changes and iteration criteria must be predefined based on literature. This change is depicted in Figure 5.2, with a dotted line between the top and bottom loops. To implement the

C-DED framework, interdisciplinary teams with designers and HCPs should ideally follow its structured phases, beginning with exploratory research and transitioning into confirmatory studies to reach market approval. For evidence reflections, we encourage a creative workshop setup where the team first clarifies the phase outcomes and then thinks creatively about the data points based on each reflection description. Close collaboration between designers and HCPs is crucial for developing clinical trial protocols informed by evidence reflections at each phase.

5.7 Discussion and conclusion

This study proposes the Clinical Data-Enabled Design (C-DED) framework, a conceptual adaptation of DED that reconciles its exploratory, user-centered approach with the methodological requirements of clinical trials. The C-DED framework provides a structured four-phase process, integrating established guidance. It includes ISO 14155's (2020) evaluation phases and SPIRIT guidelines (Calvert et al., 2021; Rivera et al., 2020) for scientific grounding, and shared evidence practices and data strategies (Morales Ornelas et al., 2023; Pannunzio et al., 2024), to facilitate systematic evidence reflections between phases. These adaptations enable an iterative clinical development of safe and effective eMDs.

For designers, the C-DED framework maintains advantages of the original DED approach, such as iterative design and exploration, while embedding these practices within a methodological clinical context. For instance, integrating safety-related data collection into prototype iterations enables the development of features that enhance safety in addition to effectiveness. This fosters a responsible shift in DED, ensuring the design output meets user needs and clinical standards. In addition, C-DED (as the original DED) is applicable across a wide range of eMDs, including software-based (e.g., mobile health apps) and hardware-integrated solutions (e.g., clinical wearables). For HCPs,

the framework provides guidance to align DED's underlying user-centeredness with clinical trial evaluation. By introducing systematic evidence reflections, our framework creates knowledge transitions between phases that refine research data for user(s)- and patient-centered evaluation of eMDs.

A central contribution of the C-DED framework is ***problem data***, a concept describing how research data gets dynamically (re)defined to align with evolving problem settings across C-DED phases. We define ***problem data*** as a type of research data that reflects the observable setting of a design problem for evaluative purposes. Problem data refers to the (research) data points selected to observe the impact of an intervention on an identified problem. Problem data arises in evidence reflections. These describe a meta-design process that reflects on the problem's current understanding from diverse angles as the phases progress–i.e., intervention rationale (phase one), solution features (phase two), and observed effects (phase three). This meta-design process operationalises the conceptual dimensions of *meaning* and *collection* identified by Morales Ornelas et al. (2024), which emphasise the need to (re)define evidence generation within its context iteratively. Evidence reflections reframe *what* data points are used to observe problems (i.e., the meaning of data points) and *how* they should be collected across phases. By systematically (re)defining research data into problem data, the framework ensures that evaluations are context-sensitive, enabling patient-centered evidence generation.

Previous efforts to adapt DED for clinical contexts stress aligning design with clinical priorities but miss formal guidance on methodological clinical demands and its integration within design activities. Noortman et al. (2022) suggested involving HCPs earlier in DED processes to align study objectives with clinical priorities. Jung (2023) proposed using broader online community data to enhance the generalisability of design output. However, these suggestions do not offer formal guidance to incorporate a clinical inquiry focus. To address this, the C-DED framework proposes a structured process incorporating clinical research

goals, scientific grounding, and evidence reflections across phases. In addition, existing eHealth frameworks offer rich insights into user-centered development or evidence generation but lack a procedural and comprehensive integration with trial demands. The CeHRes framework (Van Gemert-Pijnen et al., 2011) aligns with C-DED's iterative, user-centered approach but does not elaborate on how to manage trials' methodological requirements. The NICE Evidence Standards Framework (Unsworth et al., 2021) highlights evidence requirements, while the NASSS framework (Greenhalgh et al., 2017) examines user adoption barriers. Yet, both describe what should be investigated rather than how to investigate this. C-DED addresses this by combining DED's user-centered exploration with clinical evaluation to develop compliant, user-centered eMDs.

Despite its contributions, our C-DED framework introduces certain limitations and areas for further investigation. As the framework progresses from exploratory to confirmatory phases, DED's original open-ended exploration becomes limited. Designers must predefine iteration criteria, prototype changes, and data collection, reducing reactive prototype modifications. These constraints, while necessary for clinical trial protocols, may hinder the adaptability that defines DED's creative strength. As a conceptual study, the framework's practical application remains untested. While the C-DED framework offers a strong theoretical foundation, future empirical research is needed to assess its feasibility and effectiveness. Pilot implementations could evaluate the framework's results using measures such as usability or clinical outcomes. And interviews with project stakeholders could collect feedback on how well the framework balances creativity with clinical trial rigour and aligns design outputs with clinical requirements. Nonetheless, the C-DED framework highlights the importance of integrating design methodologies with clinical evaluation practices to develop safe, effective, and user-centered eMDs. By reconciling DED's exploratory strengths with clinical trial demands, it offers actionable guidance for fostering collaboration between design and healthcare communities in future evaluation studies.

Chapter 6.

General discussion and conclusion

6.1 Overview

In this chapter, I discuss how the findings address the research questions as well as the overarching research aim and interpret their significance for evidence generation in design and healthcare practices. I describe the implications of integrating static and dynamic evidence approaches for developing user-centred and clinically robust eHealth solutions across both domains. This thesis examined the tensions that arise between designers and healthcare professionals (HCPs) concerning what evidence to generate and how, when, and for what purpose during eHealth development as well as how to integrate them.

Therefore, my research sought to establish conceptual, empirical, and methodological foundations for a shared evidence practice that integrates both evidence approaches to establish coherent and strong evidence generation. In this thesis, I addressed four research questions (RQs), each corresponding to a barrier and subsequent knowledge gap in integrating static and dynamic evidence generation (see Chapter 1):

- **RQ1** investigated how experience measures and instruments are used in eHealth development to identify and categorise existing static evidence about patient and staff experience.
- **RQ2** explored how designers and HCPs generate evidence in practice, identifying shared evidence practices that can shape integration between static and dynamic approaches.
- **RQ3** examined how designers can apply the patient-centred outcome logic used in healthcare to define dynamic evidence generation.
- **RQ4** investigated how static and dynamic evidence generation can be coherently structured within eHealth standards to outline an integrated framework.

Collectively, the four studies formed a cumulative progression from conceptual clarification to empirical exploration and methodological synthesis (see Figure 6.1 on the next page). Contributions from the first three studies were consolidated in Study 4, which developed the Clinical Data-Enabled Design (C-DED) framework—a structured proposal for integrating static and dynamic evidence generation within eHealth standards.

The remainder of this chapter is organised as follows. Section 6.2 summarises how the findings from the four studies answer the four RQs. Section 6.3 discusses the thesis's conceptual, empirical, and methodological contributions. Section 6.4 examines the implications of these contributions for designers and HCPs and translates them into recommendations to support an integrated approach to evidence generation. Section 6.5 reflects on the limitations of this research, while Section 6.6 proposes directions for future work. Finally, Section 6.7 offers concluding reflections on how this thesis conceptually advances approaches to evidence generation in eHealth development.

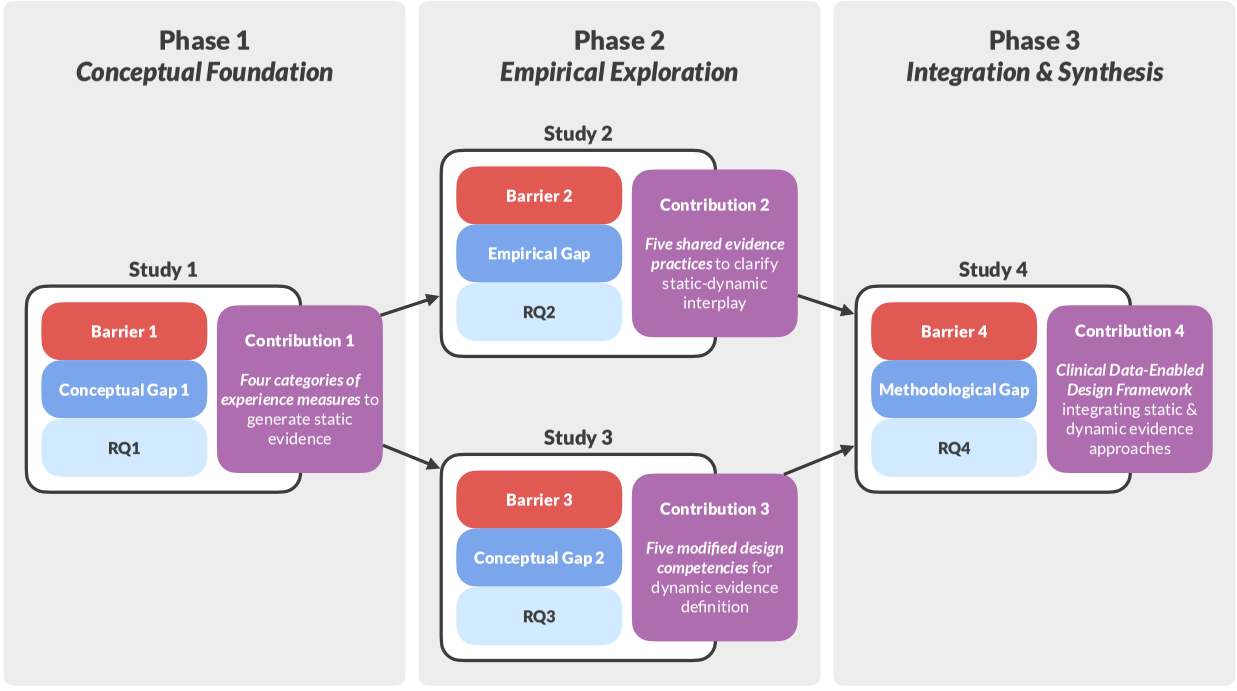

Figure 6.1. Overview of logical connections between the four studies conducted in this thesis.

6.2 Answers to the research questions

This section summarises how each study engaged with a specific barrier and corresponding knowledge gap, contributing progressively to the theoretical integration of static and dynamic approaches to evidence generation. Each study built on the preceding one: the first established a static foundation, the second examined their interplay in practice, the third elaborated the dynamic definition of evidence, and the fourth integrated these insights into a methodological framework. Together, they trace a cumulative progression toward the overall research aim, as illustrated in Figure 6.1. Textboxes 6.1–6.4 provide concise summaries of the key insights from each study.

Study 1 - RQ1: What experience measures and instruments are currently used in eHealth development?

This investigation began with Study 1, which examined the static dimension of evidence generation by identifying experience measures used in eHealth and exploring how they structure static evidence about experience. Understanding this static foundation on experience was essential before examining how dynamic approaches—those grounded in contextual and situated practice—could later complement or extend it. This study clarified what static experience measures capture and what they overlook, particularly the contextual and evolving aspects of experience that dynamic approaches seek to address. These insights motivated Study 2 to examine the interplay of static and dynamic approaches in practice, and Study 3 to explore how patient-centred outcome reasoning can guide dynamic evidence definition.

In RQ1, I investigated which measures and instruments are currently used to evaluate experience in eHealth development. This question responded to Barrier 1 (see Section 1.3), concerning the unclarity around what static evidence to generate about experience. In particular, ambiguity in constructs and diversity in instruments make it difficult to choose what measures and tools to use, limiting coordination in quantitative experience evaluation. This Barrier stems from Conceptual

Gap 1 (see Section 1.4), which highlights the lack of standardisation in experience measurement and the absence of structured knowledge on constructs and instruments used in practice. To address this gap, Chapter 2 presents a systematic literature review I conducted with colleagues, reviewing 3,404 studies on remote patient monitoring—a subset of eHealth solutions. In this review, we explored which experience measures and instruments are currently used and analysed existing measurement patterns across studies.

Through a systematic analysis of the 158 included studies, we identified 546 instances of experience measurement, involving 120 unique experience measures and 160 distinct measurement instruments. The measures, together with their instruments, were analytically clustered into four categories: *service-system*-related, *care*-related, *usage and adherence*-related, and *health outcomes*-related experience measures, highlighting four areas to generate static evidence about experience in eHealth. However, through our findings, we observed a fragmented experience measurement landscape, with limited consistency in either the measures selected or the instruments applied. For example, patient satisfaction was measured using diverse tools—from validated instruments like the 'After-Scenario Questionnaire (ASQ)' to numerous custom surveys—highlighting both the absence of standardisation and the resulting fragmentation. To address this, we concluded the review with six recommendations: four to decide *what* to measure—(1) evaluate both patient and staff experience, (2) consider factors across the four categories, (3) define and report the rationale for measure selection, (4) routinely reassess the set of measures; and two to decide *how* to measure—(5) select established instruments where possible and (6) consider passive data collection methods, all to improve consistency and comparability across static experience measurement. These findings contributed to the structure of the C-DED framework developed in Study 4 (see Textbox 6.5).

Textbox 6.1. Key insights and take-aways for RQ1.

Experience in eHealth development is measured using a wide range of measures and instruments, which cluster into four categories: service-system, care, usage and adherence, and health outcomes. These categories offer a shared conceptual structure to reduce ambiguity and improve coordination in quantitative experience evaluation. They, along with related recommendations, were embedded in the C-DED framework's evidence reflections to guide systematic experience measurement across phases. By clarifying the static conceptual foundation for experience evidence, this study established the groundwork for integrating dynamic, context-responsive perspectives across evidence reflections.

Study 2 - RQ2: How is evidence generated in practice by designers and healthcare professionals during eHealth development?

Building on the static foundation identified in Study 1, Study 2 shifted attention to how evidence generation unfolds in practice—where static and dynamic approaches interplay and conflict. This step was crucial to move from identifying what evidence is generated to examining how these approaches intertwine and how designers and HCPs navigate differing evaluation purposes. By investigating their evidence practices, this study revealed shared empirical patterns showing how static and dynamic approaches interplay in eHealth development but remain methodologically unstructured. These findings provided the empirical basis for later conceptual integration in Study 4.

In RQ2, I explored how evidence is generated in eHealth development by both designers and HCPs. It responds to Barrier 2 (see Section 1.3) concerning the disconnection in evaluation during evidence generation. This disconnection arises as designers prioritise iterative refinement to enhance adoption, while HCPs prioritise confirmatory testing for clinical safety and effectiveness. Underlying this barrier, the Empirical Gap (see

Section 1.4) highlights that there is limited understanding concerning how evidence generation unfolds in practice despite procedural differences. To address this gap, Chapter 3 presents a qualitative exploratory interview study I conducted with designers and HCPs involved in eHealth development. Through reflexive thematic analysis I explored the research and evaluation activities they performed and the influences that motivate them, offering insight into how evidence is generated and used in practice.

As part of my findings, I identified that, despite procedural differences, designers and HCPs engage in five shared evidence practices. I characterised these practices as *stakeholder*-driven, *process*-driven, *problem*-driven, *effect*-driven, and *solution*-driven. Each practice foregrounds a different influence factor—such as stakeholder needs, development phase, problem framing, intended outcomes, or product qualities—that shapes evidence generation activities and evidence use across eHealth development. Additionally, I identified that these shared practices do not operate in isolation. Participants used the evidence practices *relationally*, linking more than one influence factor to decide what evidence to generate and how to generate it. For example, participants described the need to address stakeholders' 'evidence needs', while, at the same time, also generate the required evidence for a market approval phase. These findings later informed the relational structure and reflection activities of the C-DED framework developed in Study 4 (see Textbox 6.5).

Textbox 6.2. Key insights and take-aways for RQ2.

During eHealth development, designers and HCPs generate evidence through more than one of the following five shared practices: stakeholder-, process-, problem-, effect-, and solution-driven. These practices can serve as a shared empirical foundation to coordinate evidence generation activities and reduce disconnection

Textbox 6.2. (Continued) Key insights and take-aways for RQ2.

throughout development. The C-DED framework draws on these practices within its structure and evidence reflections to inform phase-sensitive decisions about what evidence to generate and how. By connecting structured (static) and contextual (dynamic) perspectives, these practices help support coherent and adaptive evidence generation across the C-DED phases.

Study 3 - RQ3: How can designers apply the outcome logic employed by healthcare professionals to define evidence generation in eHealth development?

Building on Study 2's examination of the static–dynamic interplay, Study 3 delved deeper into the dynamic side—how designers might define dynamic evidence that follows healthcare's patient-centred outcome logic. This exploration built on the understanding that while static approaches provide rigour, they lack contextual responsiveness, highlighting the need for a shared conceptual ground for defining dynamic evidence generation. By translating HCPs' dynamic reasoning into design-oriented competencies for dynamic evidence generation, this study clarified a joint conceptual dynamic foundation for developing the integrated framework in Study 4.

In RQ3, I explored how designers can apply the patient-centred outcome logic employed by HCPs to define evidence generation in eHealth development. This question responds to Barrier 3 (see Section 1.3), which concerns the differences in evidence definition between designers and HCPs. In particular, differences regarding who is involved and how context is considered hinder designers' ability to align with healthcare's outcome-focused evaluation logic. Underlying this barrier, Conceptual Gap 2 (see Section 1.4) highlights limited understanding on how designers can apply a health-related outcome logic to define

dynamic evidence in their practice. Chapter 4 responds to this gap through a case study I conducted with HCPs to understand their dynamic outcome logic and embed it into core design competencies. I examined how HCPs define patient-centred evidence in eHealth development and systematically translated this conceptual understanding into enhanced design competencies, some consistent with existing frameworks and others newly articulated.

Through reflexive thematic analysis, I identified three conceptual dimensions that capture the aspects HCPs consider when defining dynamic evidence generation based on their patient-centred outcome logic. The *effect* dimension refers to how impact is framed, considering who should be affected and where, the desirability and degree of change, the timing and duration, and the logical relations. The *meaning* dimension concerns how abstract outcomes are translated into observable data, through layers of defining outcomes, selecting measure indicators, and identifying appropriate data. The *collection* dimension addresses the practical aspects of evidence generation, such as data generator, generation mechanisms, timing and context of collection, and degree of subjectivity in the data collected. Based on these dimensions, I adapted the five core design competencies outlined by Voûte et al. (2020), to guide designers in applying HCPs' dynamic definition logic into their practice. The adaptations per competence include: (1) *clarifying* during reframing the expected effect and who, where and for how long it should be experienced, (2) *refining* cause–effect links and impact indicators through iteration, (3) *integrating* effectiveness by planning effect duration and its data collection, (4) *co-defining* effect, meaning, and data collection with stakeholders, and (5) *visualising* effect, meaning, and collection to support coordination. These adaptations offer designers recommendations to include the dynamic outcome logic in evidence definition. Overall, these findings later guided the integration of dynamic competencies within the C-DED framework developed in Study 4 (see Textbox 6.5).

Textbox 6.3. Key insights and take-aways for RQ3.

Designers can apply the patient-centred outcome logic used by HCPs by working with three core dimensions—effect, meaning, and collection—translated into five adapted design competencies. These competencies help clarify how to involve stakeholders and how to respond to context when defining what dynamic evidence to generate following an outcome evaluation logic. By strengthening the dynamic side of evidence generation, they enable designers to connect contextual reasoning with the procedural consistency of static frameworks. The competencies were embedded in the C-DED framework to guide activities across phases and reflections, supporting coherent and context-responsive dynamic evidence definition.

Study 4 - RQ4: How can evidence generation be structured to apply static and dynamic approaches while aligning with eHealth development standards?

Building on the previous conceptual and empirical insights, Study 4 finalised the research process by structuring an integrated approach to static and dynamic evidence generation under eHealth development standards. It consolidated previous findings into a cohesive methodological foundation, for designers and HCPs to define and generate user-centred and standard-compliant evidence.

In RQ4, I investigated how to structure evidence generation to combine static and dynamic approaches while aligning with eHealth development standards. It responds to Barrier 4 (see Section 1.3), concerning regulatory constraints on evidence integration. The limited compatibility of dynamic approaches with eHealth standards hinders designers' and HCPs' ability to apply both approaches and compromises the balance between established and user-centred views in eHealth development. This barrier stems from the Methodological Gap (see Section 1.4), which

highlights the absence of frameworks to support the application of both evidence approaches according to eHealth standards. To address this gap, Chapter 5 presents a theory adaptation study aligning the dynamic approach of Data-Enabled Design (DED) (van Kollenburg & Bogers, 2019) with the static methodological structure of the ISO 14155 standard (2020). I used established trial guidelines (e.g., SPIRIT-AI and SPIRIT-PRO) and the findings from my previous three studies to revise and adapt DED to meet ISO 14155's methodological requirements.

In this study, I developed the *Clinical Data-Enabled Design (C-DED) framework* (see Figure 6.2 on the next page) to support the integration of static and dynamic evidence generation in eHealth development. I structured the framework into four development phases—(1) research exploration, (2) design conceptual exploration, (3) design feasibility exploration, and (4) design pivotal confirmation—each aligning with methodological expectations of ISO 14155. The first and final phases apply a static evidence generation approach, while the second and third adopt a dynamic one. I also introduced three evidence reflections that occur between phases. These serve as structured transition 'checkpoints' where teams redefine their evidence generation in response to findings from the previous phase. This structuring offers a phased, reflective process that enables the integration of iterative evidence re-definition with the static and confirmatory evidence generation required in eHealth standards.

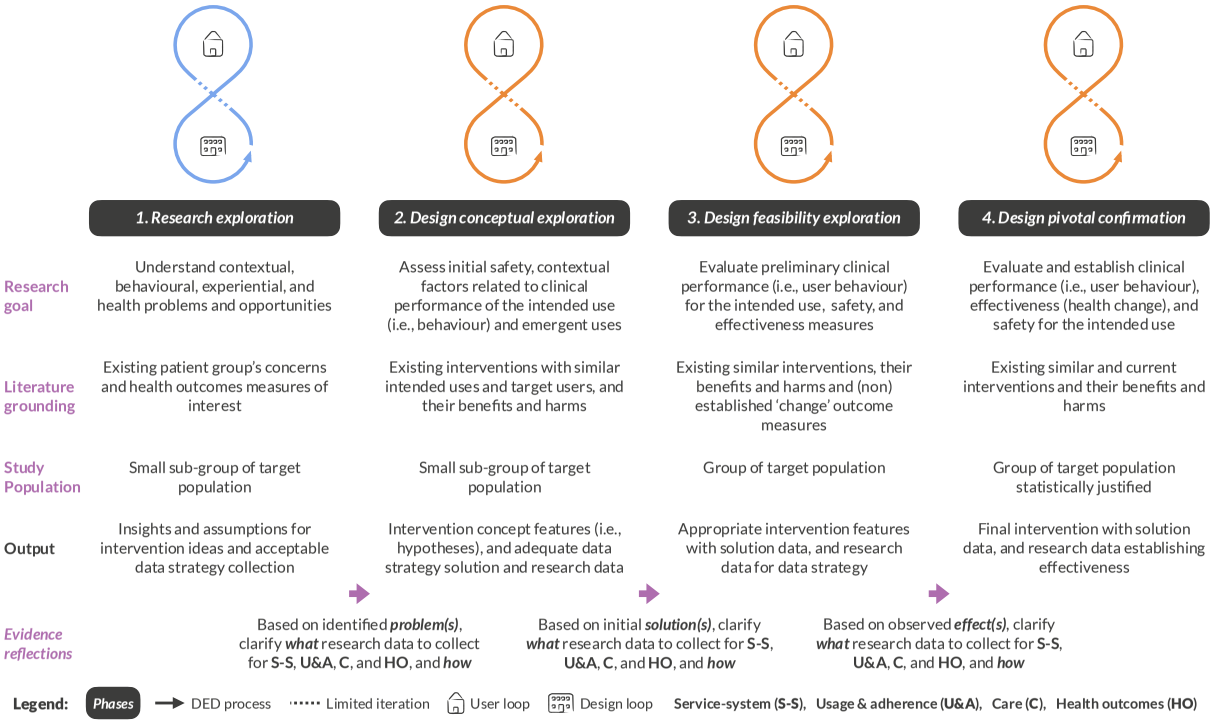

Figure 6.2. Clinical data-enabled design (C-DED) methodological framework.

Textbox 6.4. Key insights and take-aways for RQ4.

Evidence generation can be structured to apply static and dynamic approaches in a standard-aligned way through the Clinical Data-Enabled Design (C-DED) framework. It addresses the limited compatibility of dynamic methods with eHealth standards by structuring static and dynamic approaches across four phases and three evidence reflections. In doing so, it consolidates findings from all previous studies into a theoretical foundation for structuring evidence generation that is both standard-aligned and context-responsive in eHealth development.

As mentioned earlier, Study 4 also integrated findings from Studies 1–3, alongside established trial guidelines, to adapt DED for alignment with ISO 14155. Textbox 6.5 summarises how these earlier findings informed the structure and content of the C-DED framework.

Textbox 6.5. Summary of incorporation of RQ1–RQ3 findings into the C-DED framework.

RQ1. All four categories of experience measures—service-system, care, usage and adherence, and health outcomes—and recommendations two to six—(2) consider factors across the four categories, (3) define and report the rationale for measure selection, (4) routinely reassess the set of measures, (5) select established instruments where possible, and (6) consider passive data collection methods—informed the internal structure and conceptual grounding of the C-DED framework. I left recommendation one (i.e., 1—evaluate both patient and staff experience) as a broader suggestion, because not all eHealth solutions involve healthcare staff. Then, I incorporated the four categories and remaining

Textbox 6.5. (Continued) Summary of incorporation of RQ1–RQ3 findings into the C-DED framework.

recommendations into the framework's evidence reflections. The four categories provide a structured foundation for planning quantitative evaluation before each C-DED study. I translated recommendations 2, 3, and 4 into reflection activities aimed at defining and justifying appropriate experience measures. Finally, I embedded recommendations 5 and 6 as guiding principles to support the selection of instruments and data collection methods during these reflections. Together, these contributions established a static conceptual foundation, enabling the subsequent dynamic definition of evidence within the reflections and the creation of context-responsive insights on a consistent and comparable basis. Overall, these contributions helped shape the content and function of evidence reflections, offering designers and HCPs guidance for defining and evolving experience evidence in a systematic and coordinated way.

RQ2. All five shared evidence practices—stakeholder-, process-, problem-, effect-, and solution-driven—informed both the general and internal structure of the C-DED framework. I applied the process-driven practice by aligning each C-DED phase with the evidence expectations of the corresponding ISO 14155 phase, thereby embedding the static perspective within the framework's procedural structure. The stakeholder-driven practice underpins the structure of evidence reflections, which are conceived as joint activities between designers, HCPs, and other project-relevant stakeholders. I used the problem-, solution-, and effect-driven practices to shape the focus of each evidence reflection from a dynamic perspective, supporting situated reasoning about what evidence is needed, when, and why. Overall, each reflection relationally integrates three influence factors: process phase,

Textbox 6.5. (Continued) Summary of incorporation of RQ1–RQ3 findings into the C-DED framework.

stakeholder needs, and identified problems in the first reflection; process phase, stakeholder needs, and solution qualities in the second; and process phase, stakeholder needs, and intended effects in the third one. Through this structure, the practices facilitate the interplay of static and dynamic approaches by linking procedural rigour with contextual responsiveness. Together, they establish a shared foundation for defining what evidence to generate and how, supporting coherent evidence generation between designers and HCPs throughout development.

RQ3. I applied all five adapted design competencies—(1) clarifying during reframing the expected effect and who, where and for how long it should be experienced, (2) refining cause–effect links and impact indicators through iteration, (3) integrating effectiveness by planning effect duration and its data collection, (4) co-defining effect, meaning, and data collection with stakeholders, and (5) visualising effect, meaning, and collection to support coordination—to inform specific dynamic activities across the C-DED framework phases. The first competence supported evidence definition by clarifying the target group, the location of expected effects per phase, and the benefits and harms to monitor for (non)desired outcomes in Phases 2, 3, and 4. The second competence motivated the progressive refinement of the intervention's cause–effect link across these phases, as well as the evolving specification of outcome measures within the evidence reflections. I applied the third competence to enable integration of effectiveness tracking by assessing data points in Phase 3 and using them in Phase 4 to evaluate the intervention's impact. The fourth competence reinforced the co-definition of outcomes, measures, and data between stakeholders during each evidence reflection. Finally, the

Textbox 6.5. (Continued) Summary of incorporation of RQ1–RQ3 findings into the C-DED framework.

fifth competence motivated the creation of 'data point overviews'—visual summaries to carry forward modifications to outcomes, measures and data across reflections. Together, these adapted competencies strengthen the dynamic side of evidence generation by translating healthcare's patient-centred outcome logic into actionable design practices. In doing so, they connect contextual reasoning with structured evaluation, linking dynamic evidence definition to the procedural consistency established through the ISO 14155 static foundation. Overall, the adapted competencies clarified how to define and maintain dynamic evidence generation across phases and reflections, offering designers and HCPs a phase–reflection–phase structure for integrated evidence generation.

6.3 Discussion

This thesis explores how static and dynamic approaches to evidence generation can be integrated conceptually in eHealth development. Static approaches define evidence as predefined and generalisable, whereas dynamic approaches view it as evolving and context-dependent (see Section 1.2). These approaches are often applied separately, limiting opportunities to connect scientific rigour with contextual responsiveness in evidence generation. In this thesis, I propose four interrelated contributions: a structured mapping of experience measures, shared evidence practices, adapted design competencies, and the Clinical Data–Enabled Design framework that brings them together. Overall, these contributions provide empirical, conceptual, and methodological foundations for integrating static and dynamic evidence generation across design and healthcare. The rest of the section first discusses each contribution in relation to the corresponding knowledge gaps identified in

Section 1.4. Then, it concludes with a broader reflection that reconnects these insights to the analytical static and dynamic evidence generation lenses introduced in Section 1.2.

Contributions addressing the knowledge gaps

Structured mapping of experience measures

Recent attempts to categorise experience engagement measures in eHealth reveal continued inconsistency in how experience is defined and operationalised (White et al., 2022), highlighting limited guidance for its quantitative, static evaluation (see Section 1.4). In this thesis, I present a structured mapping of experience measures, organised into four categories: service-system, usage and adherence, care, and health outcomes (see Chapter 2). This builds on prior efforts from White et al. (2022) by extending beyond engagement to structure a broader set of experience constructs and instruments across domains. While the authors focused on engagement, the four categories capture a wider range of experience evaluation measures. These include measures related to the system, its usage, the care it provides, and the health experiential outcomes it impacts. These categories offer a shared reference point that clarifies what experience constructs to measure and what instruments to use. Overall, these categories can support more consistent static evaluation and open opportunities for experience assessment using static and dynamic approaches by creating a conceptual space for discussion about experience measures.

Shared evidence practices across design and healthcare

Previous studies examined collaboration strategies between designers and HCPs in eHealth (e.g., Andriessen et al., 2020; Cornet et al., 2020). However, they do not examine how designers and HCPs generate evidence in practice (see Section 1.4). In this thesis, I identify five shared evidence practices—stakeholder-, process-, problem-, effect-, and solution-driven—used by designers and HCPs to engage in evidence

generation (see Chapter 3). Unlike prior work focused on collaboration during development, my study identifies shared factors shaping what evidence is generated, how it is generated, and how it is used in eHealth development. For example, Andriessen et al. (2020) identified strategies to manage disciplinary misalignments, while Cornet et al. (2020) examined design challenges and strategies in eHealth with a focus on coordination. My work complements these by shedding light on shared points for evidence reflection and negotiation among design and healthcare. Ultimately, the identified practices offer insight into how designers and HCPs navigate the interplay of static and dynamic evidence generation approaches during eHealth development.

Adapted design competencies for patient-centred, outcome-based evidence definition

Despite efforts to integrate HCPs' patient-centred outcome logic into design practice (e.g., Hamilton, 2018; Holden & Carayon, 2021; Landa-Avila et al., 2022), it remains unclear how designers can adopt this dynamic logic to complement how they define dynamic evidence generation in eHealth (see Section 1.4). In this thesis, I introduce five adapted design competencies building on the initial competency set by Voûte et al. (2020). These competencies are redefined through three conceptual dimensions—effect, meaning, and collection—derived from HCPs' dynamic outcome logic investigated in Chapter 4. Previous work introduced processes (Hamilton, 2018), tools (Holden & Carayon, 2021), and participatory methods (Landa-Avila et al., 2022) to support the application of patient-centred outcome logic in design processes. In contrast, my conceptual contribution proposes a different kind of intervention: adapted competencies. These redefine designers' core abilities to apply a dynamic outcome logic within, and through, their own design practice. Overall, they clarify how designers can relate their dynamic evidence definition to healthcare expectations by engaging with aspects of effect, meaning, and data collection in evidence generation.

Clinical data-enabled design (C-DED) framework

Existing eHealth development frameworks support either static (e.g., Greenhalgh et al., 2017; Kip et al., 2025; Wang et al., 2024), dynamic (e.g., van Kollenburg & Bogers, 2019), or static approaches integrated with standards (e.g., Hamilton, 2018; ISO, 2020; Unsworth et al., 2021). While the one that promotes both evidence generation approaches lacks incorporation of standards and concrete procedural structuring (e.g., Skivington et al., 2021). In this thesis, I propose the Clinical Data-Enabled Design (C-DED) framework, described in Chapter 5, which integrates static and dynamic evidence generation within eHealth standards. My work differs from current eHealth frameworks by structuring the integration of Data-Enabled Design (van Kollenburg & Bogers, 2019), a dynamic approach, with the procedural structure of static approaches and eHealth standards gained from ISO 14155 (2020). The C-DED framework provides a structure for navigating eHealth standards, supporting reflection on how evidence generation approaches can be negotiated to meet regulatory expectations while attending to user needs.

In practice, applying C-DED would require new forms of collaboration between designers and HCPs during protocol development and evidence reflection activities. Rather than working sequentially or according to separate evaluation priorities, teams would need to negotiate what evidence to generate and how it should evolve across development phases. Evidence reflections could provide shared moments for discussing identified problems, conceptual features, intervention effects, and appropriate data collection approaches. However, the framework does not eliminate disciplinary differences. Designers may contribute expertise in contextual inquiry, iterative exploration, prototyping, and experiential aspects of intervention use. HCPs may contribute expertise related to clinical appropriateness, patient safety, and outcome evaluation. In this sense, designers and HCPs may continue prioritising different forms of evidence according to their disciplinary responsibilities. Evidence reflections could support negotiation about

how these priorities can be aligned throughout development. C-DED therefore structures *negotiation* between disciplinary perspectives instead of fully merging them into a unified evidence generation approach.

Theoretical reflection on evidence generation

In this thesis, I frame evidence generation as an *ongoing negotiated process* rather than a universal methodological act. Across eHealth development, evidence is shaped through epistemological orientations that emphasise different forms of validity and relevance. Static approaches prioritise objectivity and comparability through predefinition and standardisation, whereas dynamic approaches value situated understanding and continuous adaptation (see Section 1.2). My findings indicate that evidence generation unfolds not through choosing between these orientations, but through *ongoing negotiation across them*. Such negotiation concerns what is recognised as evidence for a claim, whose perspective informs its definition, and how these definitions evolve throughout the course of eHealth development.

Evidence generation can therefore be understood as the negotiation of *relationships* between *data and claims*, between the *actors* involved in defining them, and within the *contexts* in which such definitions take place. This interpretation aligns with social constructivism perspectives that view knowledge as a justified belief shaped through interaction rather than an absolute truth (Creswell, 2009). From this standpoint, evidence generation can be seen as a social process in which meanings and justifications are continuously co-constructed. Applied to eHealth development, negotiation does not represent a dynamic approach itself but the epistemic work that mediates static and dynamic approaches. Through this lens, data does not constitute evidence on its own. Evidence is a provisional alignment of reasoning that connects what is observed and collected (e.g., data) with the claims made across different approaches to evidence generation. This is consistent with work in health informatics that defines evidence as context-dependent support for specific claims (e.g., Dammann, 2019). Negotiation thus becomes the

mechanism through which evidence gains coherence and meaning across the static–dynamic continuum.

In addition, my findings suggest that this negotiation unfolds across two interdependent levels: the individual and the system. At the individual level (with a patient or user), concerns associated with dynamic approaches often appear, as lived experiences and contextual insights shape how evidence is understood. At the system level, concerns associated with static approaches tend to arise, as professionals, institutions, and stakeholders (such as designers, HCPs, engineers, regulators, funders, and patient communities) work with established indicators and outcome measures. Within evidence generation, these levels often operate in parallel, with limited interaction between what is learned through context and what is required by standards. This disconnection highlights the need for ways to articulate how insights from lived experience and standards-based requirements and expectations inform one another in evidence generation.

In this regard, the contributions of my thesis make visible how negotiation between individual and system levels can be understood across different aspects of evidence generation. The conceptual dimensions of evidence generation (see Chapter 4) clarify which sub-aspects require negotiation when linking *data to claims* about patient-centred health-related change in evidence definition. The five shared evidence practices (see Chapter 3) and four experience measure categories (see Chapter 2) show how *actors* bring distinct strategic and experiential rationales to negotiating evidence generation. Finally, the C-DED framework (see Chapter 5) makes visible how negotiation is shaped by development *contexts* and their requirements. Rather than resolving the tension between static and dynamic approaches, it offers conceptual structure to reflect on how these approaches can coherently coexist in eHealth development.

Overall, in this thesis I consolidate a theoretical understanding of evidence generation as an ongoing negotiated epistemic practice. I do

not conceptualise evidence as either a fixed, standardised (static) entity or a purely constructed, situated (dynamic) one. Instead, I understand it as a provisional result of negotiating relationships between data and claims, between those involved in defining them, and within the development contexts shaping these definitions. This understanding connects individual and system considerations by showing how insights from lived experience and standards-based requirements can be brought into dialogue, supported by the C-DED framework across development. In doing so, the thesis offers a foundation for a shared evidence practice that can be taken up by both designers and HCPs.

6.4 Implications and recommendations

The theoretical reflections presented in Section 6.3 suggest that evidence generation in eHealth development involves ongoing negotiation concerning how evidence is defined, structured, and revised throughout development. These negotiations may require designers and HCPs to reconsider their existing evidence generation practices in eHealth development, particularly when balancing exploratory and confirmatory activities. The implications discussed in this section therefore address the epistemological and methodological aspects of evidence generation in eHealth development. They reflect how my findings can clarify how evidence is defined, reasoned about, and structured across a development process, and how negotiation shapes these processes. These implications remain conceptual in nature, as the C-DED framework developed in this thesis has not yet been tested in practice. The following parts of this section outline what these implications offer to designers and HCPs and present five recommendations that synthesise the thesis's contributions into practical considerations for eHealth development.

Implications for designers

Designers encounter barriers when defining static and dynamic forms of evidence in ways that align with protocol-driven expectations while

reflecting user-centred concerns during eHealth development. Static experience constructs remain fragmented and inconsistently measured (Kraai et al., 2011; Mair & Whitten, 2000; White et al., 2022), while dynamic evidence definitions differ between designers and HCPs due to distinct outcome logics (Prendiville, 2019; Wheeler et al., 2019). These conditions limit clarity about how static and dynamic definitions of evidence can relate to one another. This thesis offers two clarifications that relate to these barriers. Chapter 2 introduces four experience-related measure categories—service-system, usage and adherence, care, and health outcomes. These offer a shared basis for reasoning about static evidence by supporting discussion and selection of experience constructs when defining evidence within protocols. Chapter 4 presents adapted design competencies, grounded in the evidence generation dimensions of effect, meaning, and collection. These outline considerations for defining dynamic evidence in ways that relate to healthcare's outcome logic. Taken as a whole, these findings provide a conceptual basis for designers to reflect on how static and dynamic forms of evidence can be defined and reasoned across the development process.

An additional barrier for designers is working across exploratory and confirmatory activities during eHealth development. Both kinds of evaluation efforts often conflict as differing priorities shape evidence generation (Blandford et al., 2018; Moody, 2015), and dynamic approaches remain difficult to apply within static regulatory expectations (Noortman et al., 2022). Such constraints make it difficult to maintain coherent evidence generation across a development process. In this thesis, I offer two clarifications that relate to these barriers. Chapter 3 identifies five shared evidence practices—stakeholder-, process-, problem-, effect-, and solution-driven. They clarify how designers reason about evidence generation by showing how concerns around stakeholders, processes, problems, effects, or solutions can influence evidence decisions across exploratory and confirmatory activities. Chapter 5 extends this by presenting the C-DED framework. It clarifies how to structure exploratory and confirmatory activities through four phases and three evidence reflections that guide iteration of dynamic

evidence or specification of static evidence. Collectively, these findings offer a conceptual foundation for considering how exploratory and confirmatory evidence generation activities may be jointly structured, motivated by different influence factors, and adjusted as development progresses.

Implications for healthcare professionals

A central barrier for HCPs concerns the integration of experiential and contextual factors into clinical evaluation during eHealth development. Static experience constructs remain ambiguous and inconsistently measured (Kraai et al., 2011; Mair & Whitten, 2000; White et al., 2022), while differences in evaluative priorities often separate iterative and contextual work from confirmatory clinical evaluation (Blandford et al., 2018; Cornet et al., 2020). These conditions limit the extent to which evidence captures aspects of experience and context that patients or users may consider important for adoption and ongoing use. This thesis presents two clarifications that relate to these barriers. Chapter 2 organises experience constructs and instruments into four categories—service-system, usage and adherence, care, and health outcomes. These offer HCPs a structured way to reason about different aspects of experience and how these might be included within evaluation. Chapter 3 extends this by identifying five shared evidence practices—stakeholder-, process-, problem-, effect-, and solution-driven. These clarify how contextual factors, such as stakeholder needs, process constraints, or problem framings, can shape reasoning about evidence generation across clinical evaluation stages. Together, these findings offer HCPs a conceptual basis for reflecting on how experiential and contextual considerations could be integrated into clinical evaluation.

HCPs also face constraints when attempting to revise what evidence should be generated in response to emerging insights, as regulatory standards privilege predictive static approaches over more iterative, dynamic ones. These regulatory conditions limit the compatibility of exploratory evaluation activities with formal expectations for clinical

rigour and safety (ISO, 2020; Noortman et al., 2022). As a result, decisions about what evidence to generate risk becoming fixed early, even when emerging insights indicate a need for reformulation. In this thesis, I propose a conceptual structure that relates to this limitation. Chapter 5 introduces the C-DED framework, which clarifies how static and dynamic evidence generation approaches can be structured within the procedural expectations of ISO 14155 (2020). It incorporates three evidence reflections as checkpoints for revisiting decisions about what evidence to generate. These reflections enable iterative adjustment while maintaining compatibility with regulatory expectations. Overall, the C-DED framework provides HCPs with a conceptual foundation for integrating evidence iteration into standard evaluation processes.

In conclusion, these implications suggest that integrating static and dynamic evidence generation approaches in eHealth development may require designers and HCPs to engage more explicitly with evidence practices they already partially share, but do not necessarily apply simultaneously or in the same manner. Designers may continue contributing expertise related to contextual, experiential, and user-centred forms of evidence generation, while HCPs may continue contributing expertise related to clinical appropriateness, safety, and confirmatory evaluation. However, the findings of this thesis suggest that both groups already engage with aspects of these approaches, although they apply them differently within eHealth development. In this regard, designers may need to adopt a more strategic role in evidence definition and protocol development discussions within eHealth standards, while HCPs may need to accommodate more iterative and context-sensitive forms of evidence generation throughout development. Rather than eliminating disciplinary differences, the C-DED framework offers a structured way to support negotiation between these perspectives across development phases.

Recommendations for shared evidence generation between design and healthcare practices in eHealth development

Based on the implications described above, I synthesise five recommendations that provide a basis for designers and HCPs to reflect on how evidence is generated during eHealth development. These recommendations are particularly relevant during early planning stages, such as when preparing transitions between exploratory and confirmatory activities or when developing research or evaluation protocols. Rather than prescribing a specific process, they highlight points in the development process where teams may benefit from making their reasoning, definitions, and overall structuring of evidence generation more explicit. In doing so, they can help designers and HCPs clarify what evidence to generate and how, when, and for what purpose.

1. Negotiate evidence definition and generation across eHealth development

Designers and HCPs can benefit from negotiating what evidence to generate and how during eHealth development. The C-DED framework provides structured points for this negotiation through its three evidence reflections, where designers and HCPs can co-define outcomes and data points before generating evidence in the next phase. For example, when developing a diabetes monitoring system, both could discuss which outcomes (e.g., glucose-level stability) and data points (e.g., daily logins) are most relevant for evaluating system's adherence and health outcomes. In practice, such negotiated decisions can elucidate the rationale for evaluation choices and contribute to a more coherent development process.

2. Plan iteration and stabilisation of both solution and evidence

Designers and HCPs can use the four C-DED phases and three evidence reflections to consider when to iterate or stabilise the solution and the evidence informing its development. In C-DED, each phase centres on designing and evaluating the solution, while evidence reflections

offer moments for (re)defining and assessing outcomes and data points. Findings from each phase feed into subsequent reflections, allowing evidence to evolve alongside the solution while gradually stabilising for later validation. For instance, when developing a diabetes monitoring system, designers together with HCPs may adjust app features after early use (i.e., solution iteration in Phase 2) while refining adherence measures (i.e., evidence iteration in the second reflection), before stabilising both for clinical testing in Phase 4. In practice, this iteration of solution and evidence can help designers and HCPs examine emerging adoptability considerations while avoiding overly early commitment to predefined evidence generation, supporting contextually responsive development.

3. Balance and contextualise exploration and confirmation

Designers and HCPs can use the five shared evidence practices to reflect on the purpose of exploration or confirmation activities concerning the solution's problem, qualities, or effects as well as process-related contextual factors (e.g., stakeholder needs or process constraints). C-DED embeds these practices in its evidence reflections, supporting both in considering exploration and confirmation choices while helping ensure relevant stakeholder perspectives are brought into each reflection. For example, during an evidence reflection on a diabetes monitoring system, designers and HCPs may decide to use glucose-level indicators for confirmation (i.e., effect-driven) while identifying workload measures that need exploration, such as alerts handled per shift (i.e., stakeholder-driven). In practice, this can support both in deciding what to stabilise for confirmation and what to keep open for exploration, while helping them incorporate context-specific considerations without compromising methodological rigour.

4. Develop protocols integrating design and healthcare evidence definition

Designers can draw on the five adapted design competencies when developing evaluation protocols to help them define evidence in ways

that meet healthcare requirements while remaining attentive to contextual and experiential considerations. C-DED integrates these competencies across its phases and reflections, offering activities to clarify expected effects, refine cause–effect links, and co-define outcomes and data points as evidence definition evolves. For instance, when developing a protocol for a diabetes monitoring system, they may clarify together with HCPs how long patients must adhere before effects on glucose-level stability are expected and co-define these adherence measures. In practice, using these competencies in protocol development can support designers and HCPs in conducting evaluations that are both clinically valid and contextually meaningful.

5. Structure experience evaluation

Designers and HCPs can use the four experience categories—service-system, usage and adherence, care, and health outcomes—to support the selection of experience measures and instruments for evaluation. C-DED incorporates these categories into its evidence reflections, offering a four-part structure for defining what aspects of experience will be examined in the next phase and how evidence about them will be collected. For example, when evaluating a diabetes monitoring system, designers and HCPs may include usability (service-system), daily log-ins (usage and adherence), staff workload (care), and quality of life (health outcomes) as measures. In practice, drawing on the experience categories can help them select measures that reflect diverse aspects of patient and staff experience while remaining compatible with healthcare methodological requirements.

Exemplifying the application of the five recommendations in practice

Returning to the eHealth development example in Textbox 1.1, the following reflection illustrates how the five recommendations could have supported evidence generation in a project where static and dynamic approaches were not deliberately aligned. This project involved

developing a prototype of an eHealth solution (i.e., 'Bo') to support children with congenital heart defects and their families during everyday physical activity (see Textbox 1.1). During Bo's development, evidence generation was largely driven by exploratory, context-responsive activities, leading to evidence considerations that emerged reactively without being structured by a predefined framework. This made it difficult to determine what and how to evaluate, when, and for what purpose, particularly when predefined static evidence requirements later arose.

The first recommendation—negotiating evidence definition and generation, could have established clearer moments for discussing whose perspectives shaped evidence priorities. It could also have supported explicit conversations about evidence generation for safety, experience, or clinical relevance. Planning iteration of solution and evidence (i.e., Recommendation 2) could have helped to align prototype development and evidence definition with emerging insights from families. Following Recommendation 2 could have also helped to anticipate later stabilisation for clinical evaluation, rather than allowing evaluation considerations to arise ad hoc. In addition, the third recommendation—balancing exploration and confirmation—could have supported clearer reasoning about what to explore or confirm and how those choices related to stakeholder needs, process requirements or project concerns (e.g., problem framing, intended outcomes, or solution qualities). This could have clarified the purpose of evidence generation at different development phases.

Drawing on the adapted design competencies (i.e., Recommendation 4) could have helped articulate and explore expected effects and refine causal assumptions in preparation for later clinical evaluation. Finally, the four experience categories in Recommendation 5 could have offered a shared basis for selecting measures that captured broader experience aspects, such as adherence, care, or health outcomes. At the same time, these measures could have remained compatible with predefined evaluation requirements. Overall, these recommendations illustrate

how a more deliberate alignment between static and dynamic evidence generation approaches might have supported the project in anticipating and aligning exploratory and predefined evidence requirements.

6.5 Limitations

As with any research, this thesis is shaped by limitations that define the scope and applicability of its findings. Chapters 2, 4, and 5 focused on remote patient monitoring (RPM), a specific but illustrative subset of eHealth solutions that enabled detailed examination of experience evaluation and health-related outcome evaluation logic. While RPM offered a rich context for studying evidence generation, its hybrid nature (i.e., combining hardware and software) may not represent the full range of other eHealth solutions (e.g., stand-alone apps or AI algorithms). Consequently, the C-DED framework should be understood as a methodological and conceptual contribution for guiding the integration of static and dynamic evidence generation, rather than as a fixed procedure applicable to all eHealth development processes. Since the framework was primarily developed through RPM contexts, where care extends into patients' everyday lives through continuous monitoring and iterative system refinement, its application to other eHealth solutions may require adaptation, particularly in contexts where evidence generation follows shorter, less iterative, or more technically predefined development processes. Therefore, further empirical application across different eHealth development contexts is needed to examine how C-DED can support evidence generation beyond RPM development.

Furthermore, Chapters 3 and 4 were situated in the Dutch healthcare and innovation system, a context that supports interaction between designers and HCPs. While this context enabled deep insight into designers' and HCPs' eHealth development practices, the findings may not reflect conditions in systems with different regulatory, organisational, or cultural structures. These chapters also drew on a small but diverse sample of participants, suitable for generating situated insights into how designers

and HCPs negotiate evidence generation in interdisciplinary eHealth contexts. This qualitative focus enabled detailed exploration of evidence practices across different professional roles and development settings. Consequently, the findings should be understood as identifying epistemic tendencies, shared practices, and conceptual dimensions grounded in the specific contexts studied, rather than as exhaustive representations of all eHealth development practices. As a result, additional or alternative evidence generation practices may emerge in other professional, organisational, or eHealth contexts. Finally, this thesis focused on designers and HCPs—two key actors in eHealth development and evidence generation. Other stakeholders, such as patients, policymakers, industry partners, engineers, behavioural scientists, or other development professionals, may offer additional perspectives that enrich understanding of how evidence is defined and generated in eHealth development.

6.6 Future work

In this section, I outline future research directions based on the findings and limitations of this thesis. These directions focus on evaluating the C-DED framework in real-world eHealth development, designing tools to support its practical use, and deepening theoretical understanding of how static and dynamic approaches are negotiated.

Evaluation of the C-DED framework

Future work could focus on evaluating the application of the C-DED framework in real-world eHealth development. As outlined in Chapter 5, C-DED contributes a structured process for integrating dynamic and static evidence generation through four development phases and three reflective evidence checkpoints. However, its feasibility and practical value remain untested. A pilot implementation study could assess whether the framework's phases support alignment of design activities with clinical requirements and enable teams to revise evidence in response to emerging insights. Such an implementation study could combine

outcome-based indicators (e.g., usability, specific health outcomes) with qualitative feedback from development teams. This feedback could evaluate whether the framework supports negotiation between static and dynamic evidence generation approaches while aligning contextual responsiveness with clinical and regulatory expectations. Below, Textbox 6.6 presents an illustrative pilot implementation study scenario to evaluate the application of C-DED in practice.

Textbox 6.6. Illustrative pilot implementation study of the C-DED framework.

For example, a future pilot implementation study could evaluate the application of the C-DED framework during the development of a remote patient monitoring (RPM) intervention for adults with Type 2 diabetes. The intervention could combine wearable glucose monitoring and mobile self-management support for disease management in everyday life. This context would provide a relevant setting for evaluating C-DED because diabetes management involves predefined clinical requirements, such as glucose regulation, as well as evolving contextual factors related to patients' lived experiences, routines, motivations, and self-management practices. The long-term and contextual nature of diabetes care would therefore require ongoing negotiation between static and dynamic evidence generation approaches across development phases.

During the *research exploration phase*, development teams could investigate patients' self-management practices, daily routines, and contextual barriers through exploratory data collection in everyday contexts. Grounded in existing literature on Type 2 diabetes management and relevant health outcomes, evidence generation could focus on identifying contextual, behavioural, experiential, and health-related problems and opportunities, as well as acceptable data collection mechanisms. The first evidence

Textbox 6.6. (Continued) Illustrative pilot implementation study of the C-DED framework.

reflection could support clarification of what research data to generate in subsequent phases by reflecting on identified problems and opportunities from a shared perspective.

During the *design conceptual exploration phase*, teams could explore preliminary intervention features with a small sub-group of Type 2 diabetes patients. Grounded in existing literature on similar interventions and their benefits and harms, evidence generation could focus on initial safety, contextual factors related to clinical performance, and emergent uses of the intervention. The second evidence reflection could support clarification of what research and solution data to generate by reflecting on how identified conceptual features relate to the problems they aim to address and how these changes could be made observable through appropriate data collection.

During the *design feasibility exploration phase*, the intervention could be deployed with Type 2 diabetes patients to evaluate preliminary clinical performance, safety, and the appropriateness of selected data collection approaches for observing behavioural and health-related change. Grounded in existing literature on similar interventions and patient outcome measures, evidence generation could focus on identifying preliminary intervention effects and the appropriateness of corresponding solution and research data. The third evidence reflection could support clarification of what research data should be stabilised for confirmatory evaluation by reflecting on identified desired and undesired changes.

Finally, during the *design pivotal confirmation phase*, teams could evaluate the clinical performance, effectiveness, and safety of the final intervention with a statistically justified target patient

Textbox 6.6. (Continued) Illustrative pilot implementation study of the C-DED framework.

population of Type 2 diabetes patients. Evidence generation could focus on confirming predefined hypotheses and stabilised research data concerning behavioural and health-related change. Studies in this phase could involve comparative evaluation through controlled study set-ups, such as comparisons between the intervention and standard care.

Such a pilot implementation study could evaluate whether C-DED supports coordination between designers and HCPs when defining and refining evidence generation across development phases. Evaluation could examine how teams negotiate static and dynamic evidence generation approaches, revise research and solution data in response to emerging insights, and align contextual evidence generation with clinical and regulatory expectations. The study could also assess whether the framework supports clarity regarding what evidence to generate, how to generate it, and for what purpose across development phases. Qualitative feedback from development teams could be combined with indicators related to usability, adherence, clinical appropriateness, and intervention performance.

Finally, because this thesis focused on RPM in the Dutch context, future studies should explore whether the framework supports evidence generation in other healthcare systems and types of eHealth solutions.

Development of supporting tools for evidence reflections

To support the practical application of evidence reflections introduced in Chapter 5, future work could develop tools such as workshop templates or decision-making canvases based on the implications provided in Chapter 5. These tools would help development teams surface, discuss,

and document evolving evidence needs. They would clarify the rationale behind changing evidence choices at key transition moments in development. In doing so, they would operationalise evidence reflection and support negotiation between static and dynamic evidence generation. This would improve traceability of evidence changes and strengthen coherence between design reasoning and clinical requirements. Ultimately, such tools could extend the real-world applicability of C-DED, particularly within complex, multi-stakeholder projects.

Exploring boundaries of evidence negotiation through legal perspectives

A central challenge for future work lies in clarifying the boundaries of flexibility in negotiating static and dynamic evidence approaches. As discussed in Chapter 5, evidence is reshaped during multiple evidence reflections. Here, teams align data with claims in response to identified problems, envisioned solutions, and expected effects, all highlighting distinct project contextual angles. Yet, the limits of such negotiation remain unclear. How much can evidence adapt before it undermines generalisability or regulatory trust? To explore this, future work could draw on institutional theories of evidence, particularly from the legal domain, where evidence is not fixed but actively negotiated between actors with differing expertise, standards, or goals (Ho, 2021). This could clarify how development teams judge relevance, validity, and acceptable adaptation limits across development and project-level concerns. Understanding these boundaries is critical for practical implementation, as it could help teams remain flexible while ensuring legitimacy in a regulated context.

6.7 Concluding remarks

In this thesis, I investigated how static and dynamic approaches to evidence generation can be integrated during eHealth development. I examined the lack of guidance on how these approaches can be

negotiated across design and healthcare practices, a gap that often results in either user-centred or standards-aligned evidence generation. To address this, I developed the Clinical Data-Enabled Design (C-DED) framework, which offers structured phases and reflections to support integration of lived experience, contextual reasoning, and system-level requirements into evidence generation. As the main outcome of this thesis, C-DED provides conceptual, empirical, and methodological foundations for a shared evidence generation practice that designers and HCPs can adopt. Using this foundation in practice could help designers and HCPs navigate ongoing tensions over what evidence to generate and how, when and for what purpose, as static and dynamic approaches intersect. By supporting evidence generation that is user-centred and clinically robust, C-DED may contribute to eHealth solutions that are clinically safe, adopted, and grounded in patients' lived experiences and *their* desired forms of care.

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Appendices

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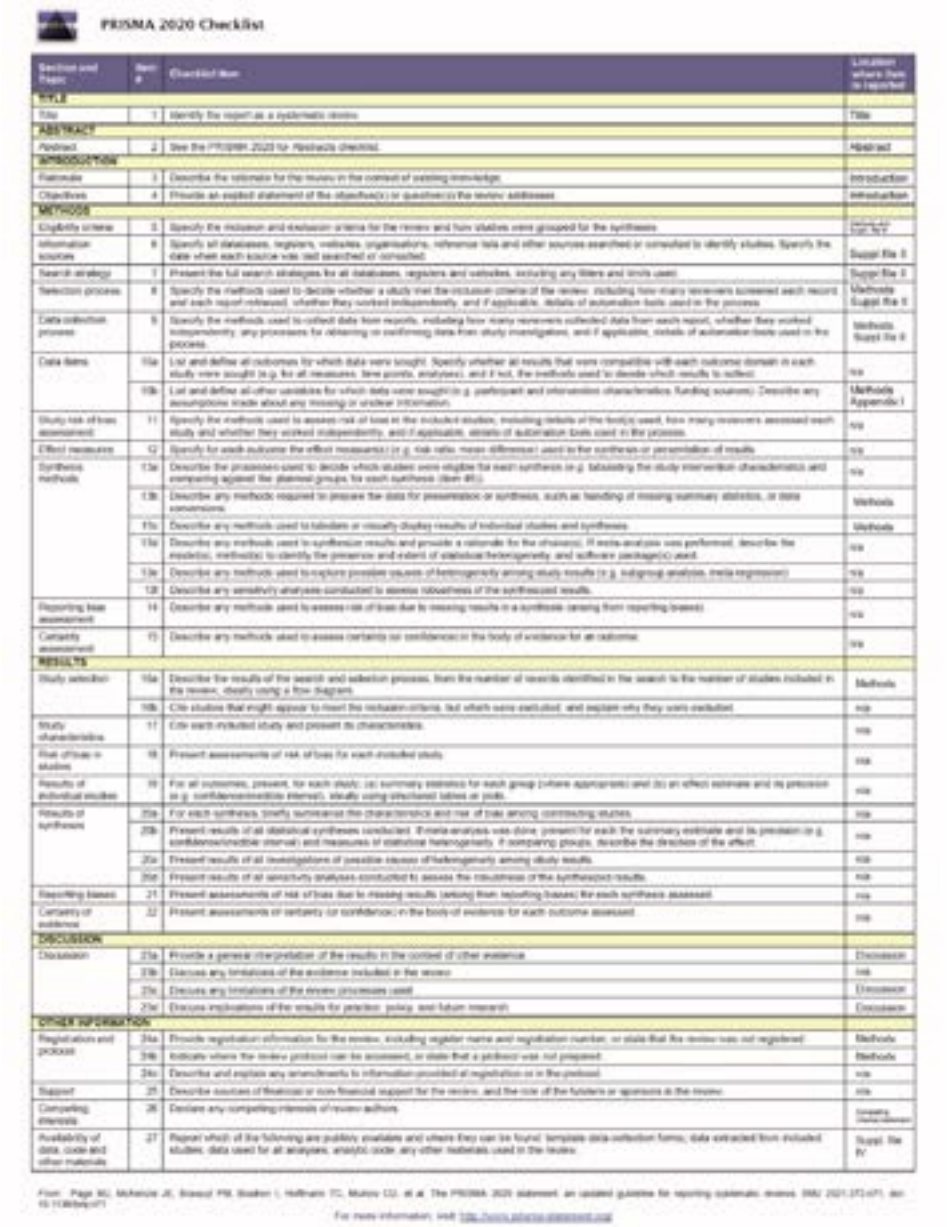
Multimedia Appendix 1 - PRISMA checklist



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Abstract
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Introduction
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Introduction
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the reviews and how studies were grouped for the syntheses.	Methods; Suppl. file 1
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Suppl. file 1
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Suppl. file 1
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Methods; Suppl. file 1
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Methods; Suppl. file 1
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	n/a
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Methods; Appendix I
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	n/a
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	n/a
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	n/a
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Methods
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Methods
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	n/a
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	n/a
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	n/a
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	n/a
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	n/a
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Methods
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	n/a
Study characteristics	17	Cite each included study and present its characteristics.	n/a
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	n/a
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	n/a
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	n/a
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the directions of the effect.	n/a
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	n/a
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	n/a
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	n/a
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	n/a
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Discussion
	23b	Discuss any limitations of the evidence included in the review.	n/a
	23c	Discuss any limitations of the review processes used.	Discussion
	23d	Discuss implications of the results for practice, policy, and future research.	Discussion
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Methods
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Methods
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	n/a
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	n/a
Competing interests	26	Declare any competing interests of review authors.	Competing interests statement
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Suppl. file IV

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

Multimedia Appendix 2 - Full search strategies.

For both databases, the sets of keywords for each concepts were first searched separately.

Concept 1: Remote Patient Monitoring
Concept 2: Measures and indicators
Concept 3: Staff experience
Concept 4: Patient experience

Following, the separate searches were merged through Boolean operators following the scheme:

[Concept 1] AND [Concept 2] AND (Concept 3 OR Concept 4)

to find all papers containing mentions of patient experience measures used in RPM research, staff experience measures used in RPM research, or both.

The search entries for both databases are reported hereafter. The query was performed on both databases on the 12th of February 2021, including papers published from the 1st of January 2011.

1.2 Medline (PubMed) search entry

CONCEPT 1. Remote Patient Monitoring
“telemedicine”[majr] OR “telemedicine*”[tiab] OR “telehealth”[tiab] OR “Wearable Electronic Devices” [majr] OR “Wearable Electronic Device*” [tiab] OR “Wearable Electronic*”[tiab] OR “Wearable Technolog*”[tiab] OR “Wearable Device*”[tiab] OR “Wearable computer*”[tiab] OR “Wireless Technology”[majr] OR “Wireless Technolog*”[tiab] OR “Wireless sens*” [tiab] OR “Wireless monitor*” [tiab] OR “Monitoring, Physiologic”[majr] OR “physiologic monitor*”[tiab] OR “vital signs monitoring*”[tiab] OR “Patient Monitor*”[tiab] OR “self-monitor*”[tiab] OR “self monitor*”[tiab] OR “continuous wireless monitor*”[tiab] OR “continuous monitor*” [tiab]

OR “remote monitor*”[tiab] OR “Remote Sensing Technology”[majr] OR “Remote Sensing*”[tiab]

CONCEPT 2. Measures and indicators
“Quality Indicators, Health Care”[majr] OR “Outcome and Process Assessment, Health Care”[majr] OR “Patient Reported Outcome Measures”[Majr] OR “Patient Reported Outcome Measure*”[tiab] OR proms [tiab] OR “Patient reported Outcome*”[tiab] OR “Patient-reported Outcome*”[tiab] OR “Patients reported Outcome*” [tiab] OR “Patients-reported Outcome*” [tiab] OR “patient-reported experience measure*” [tiab] OR “patient reported experience measure*” [tiab] OR “Surveys and Questionnaires” [Majr] OR “survey*” [tiab] OR “measurement instrument*”[tiab] OR “assessment tool*” [tiab] OR “measurement tool*” [tiab] OR “assessment instrument*” [tiab] OR “variable*” [tiab]

CONCEPT 3. Staff experience
ergonomics [majr] OR Ergonomic* [tiab] OR “Cognitive Ergonomic*”[tiab] OR “Engineering Psychology” [tiab] OR “Attitude of Health Personnel”[majr] OR “Attitude to Computers”[majr] OR “attitude of health personnel” [tiab] OR “staff attitude*” [tiab] OR “staff acceptance*” [tiab] OR “Alert Fatigue, Health Personnel”[majr] OR “alarm fatigue*”[tiab] OR “alert fatigue*”[tiab] OR “Burnout, Professional”[majr] OR “burnout*”[tiab] OR “Occupational Diseases”[majr] OR “occupational disease*”[tiab] OR “occupational risk*”[tiab] OR “occupational hazard*”[tiab] OR “occupational dysfunction*”[tiab] OR “Job Satisfaction”[majr] OR “job satisfaction*”[tiab] OR “professional satisfaction*”[tiab] OR ((“Attitude” [majr] OR attitude* [tiab] OR acceptance* [tiab] OR “Perception”[majr] OR perception* [tiab] OR “staff experience*” [tiab] OR “physician experience*”[tiab] OR “physicians experience*”[tiab] OR “doctor experience*” [tiab] OR “doctors experience*” OR “nursing experience*” [tiab] OR “nurse experience*”[tiab] OR “nurses experience*” [tiab] OR “caregiver experience*” [tiab] OR “caregivers experience*” [tiab] OR “Personal Satisfaction” [majr] OR satisfaction [tiab] OR “Stress, Psychological”[majr] OR “Psychological Stress*”[tiab] OR

"Occupational Stress"[Majr] OR "Occupational Stress*"[tiab]) AND ("Health Personnel"[majr] OR "personnel"[tiab] OR "Medical Staff, Hospital"[majr] OR staff*[tiab] OR "Nursing Staff, Hospital"[majr] OR nurs*[tiab] OR "Caregivers"[majr] OR caregiver*[tiab]))

CONCEPT 4. Patients experience
"Attitude to Health"[Majr] OR "Patient Satisfaction"[Majr] OR "Patient Satisfaction*" [tiab] OR "patient experience*" [tiab] OR patients experience* [tiab] OR "patient-centered care"[Majr] OR "patient-centered care" [tiab] OR "patient-centred care" [tiab] OR "Patient Acceptance of Health Care"[Majr] OR "Health Behavior"[Majr] OR ((ergonomics [majr] OR Ergonomic* [tiab] OR "Cognitive Ergonomic*"[tiab] OR "Engineering Psychology" [tiab] OR "Stress, Psychological"[majr] OR "Psychological Stress*"[tiab] OR "Attitude to Computers" [Majr] OR attitude* [tiab] OR acceptance* [tiab] or acceptabilit* [tiab] OR "Perception"[majr] OR "perception*"[tiab] OR "Emotions"[majr] OR "emotion*"[tiab] OR "Personal Satisfaction" [majr] OR satisfaction* [tiab] OR "usability" [tiab]) AND (patient* [tiab]))

1.2 EMBASE search entry

CONCEPT 1. Telemonitoring
*telehealth/ or *wearable computer/ or *wireless communication/ or *physiologic monitoring/ or *remote sensing/ or *telemedicine/ or (Wearable Electronic Device* or Wearable Electronic* or Wearable Technolog* or Wearable Device* or Wearable computer* or Wireless Technolog* or Wireless sens* or Wireless monitor* or physiologic monitor* or vital signs monitoring* or Patient Monitor* or self-monitor* or self monitor* or continuous wireless monitor* or continuous monitor* or remote monitor* or Remote Sensing* or telemedicine* or telehealth). ti,ab,kw.

CONCEPT 2. Measures and indicators
*health care quality/ or *patient-reported outcome/ or *outcome

assessment/ or *health care survey/ or (Patient Reported Outcome Measure* or Proms or Patient reported Outcome* or Patient-reported Outcome* or Patients reported Outcome* or Patients-reported Outcome* or patient-reported experience measure* or patient reported experience measure* or measurement instrument* or assessment tool* or measurement tool* or assessment instrument* or variable*).ti,ab,kw.

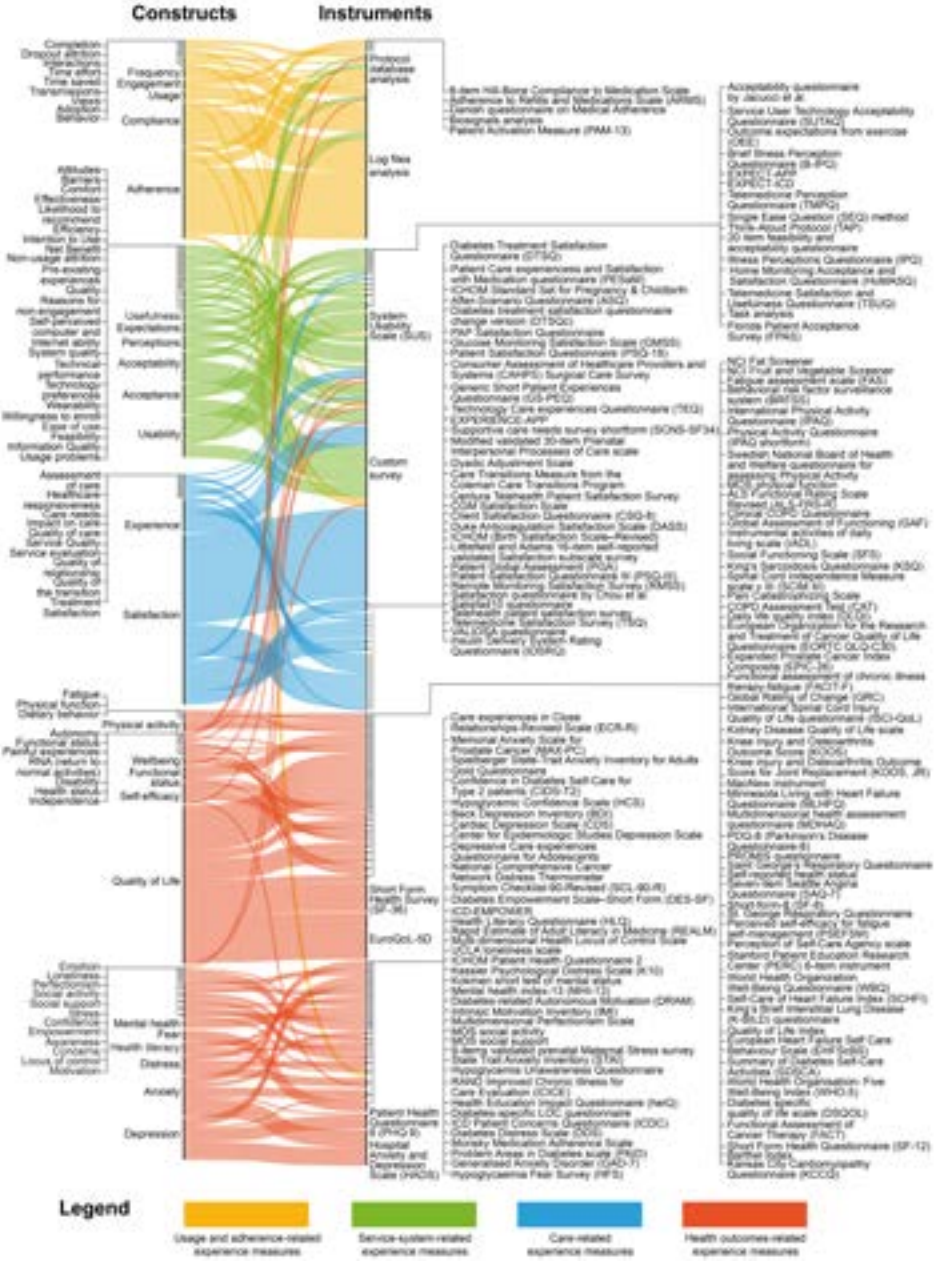
CONCEPT 3. Staff experience
*attitude to computers/ or *"alert fatigue (health care)"/ or *professional burnout/ or *occupational disease/ or *job satisfaction/ or *mental stress or *job stress/ or
(Ergonomic* or Cognitive Ergonomic* or Engineering Psychology or attitude* of health personnel or staff attitude* or staff acceptance* or alarm fatigue* or alert fatigue* or burnout* or occupational disease* or occupational risk* or occupational hazard* or occupational dysfunction* or job satisfaction* or professional satisfaction* or attitude* or acceptance* or perception* or experience* or mental stress* or job stress*).ti,ab,kw or (*attitude/ or attitude*.ti,ab,kw. or *perception/ or perception*.ti,ab,kw. or *satisfaction/or satisfaction*.ti,ab,kw.) AND (*personnel/ or personnel.ti,ab,kw. or *staff/ or staff.ti,ab,kw. or *caregiver/ or caregiver*.ti,ab,kw.)

CONCEPT 4. Patient experience
*attitude to health/ or *health behavior/ or *patient satisfaction/ or (patient* satisfaction or patient experience* or patients experience* patient-centred care or patient cent?ed care).ti,ab,kw or ((*ergonomics/ or ergonomic*.ti,ab,kw or usability.ti,ab,kw or *attitude/ or *attitude to computers/ or attitude*.ti,ab,kw or *perception/ or perception*.ti,ab,kw or *mental stress/ or stress.ti,ab,kw or *emotion/ or emotion*.ti,ab,kw or *satisfaction/or satisfaction*.ti,ab,kw or acceptability.ti,ab,kw or acceptance*.ti,ab,kw) AND (patient*.ti,ab,kw))

Multimedia Appendix 3 - Overview of the merged construct formulations.

Construct formulation as extracted	Construct formulation after cleaning
User satisfaction	Satisfaction
Helpfullness	Usefulness
User-friendliness	Usability
Utility	Usefulness
User experience	Experience
Desired information	Information quality
Service evaluation	Service quality
Time to review	Time effort
Time to response	Time effort
Time for task	Time effort
Technical problems	Technical performance
Participation	Engagement
Proactive management	Engagement
Patient activation	Engagement
Usage and potential problems	Usage problems
Self-care agency	Self-efficacy
Self-care behavior	Self-efficacy
Health education	Health literacy
Knowledge	Health literacy
Functioning	Functional status
Functional recovery	Functional status
Mental status	Mental health
Use and adoption	Adoption
Uptake	Adoption

Multimedia Appendix 4 - Reported patient experience constructs and associated measuring instruments (complete visual).


Constructs
Instruments
Completion
Dropout attrition
Interactions
Time effort
Time saved
Transmissions
Views
Adoption
Behavior
Frequency
Engagement
Usage
Compliance
Attitudes
Barriers
Comfort
Effectiveness
Likelihood to
recommend
Efficiency
Intention to Use
Net Benefit
Non-usage attrition
Pre-existing
experiences&
Quality
Reasons for
non-engagement
Self-perceived
computer and
internet ability
System quality
Technical
performance
Technology
preferences
Wearability
Willingness to enroll
Ease of use
Feasibility
Information Quality
Usage problems
Adherence
Usefulness
Expectations
Perceptions
Acceptability
Acceptance
Usability
Assessment
of care
Healthcare
responsiveness
Care needs
Impact on care
Quality of care
Service Quality
Service evaluation
Quality of
relationship
Quality of
the transition
Treatment
Satisfaction
Experience
Satisfaction
Fatigue
Physical function
Dietary behavior
Physical activity
Autonomy
Functional status
Painful experiences
RAQ (return to
normal activities)
Stability
Health status
Independence
Wellbeing
Functional
status
Self-efficacy
Quality of Life
Emotion
Loneliness
Perfectionism
Social activity
Social support
Stress
Confidence
Empowerment
Aggressiveness
Concerns
Locus of control
Motivation
Mental health
Fear
Health literacy
Distress
Anxiety
Depression
Protocol
/database
analysis
Log files
analysis
System
Usability
Scale (SUS)
Custom
survey
Short Form
Health Survey
(SF-36)
EuroQol-5D
Patient Health
Questionnaire
-9 (PHQ-9)
Hospital
Anxiety and
Depression
Scale (HADS)
8-item Hill-Bone Compliance to Medication Scale
Adherence to Refills and Medications Scale (ARMS)
Danish questionnaire on Medical Adherence
Ecological analysis
Patient Activation Measure (PAM-13)
Diabetes Treatment Satisfaction
Questionnaire (DTSQ)
Patient Care experiences and Satisfaction
with Medication questionnaire (PESaM)
ICHOM Standard Set for Pregnancy & Childbirth
After-Scenario Questionnaire (ASQ)
Diabetes treatment satisfaction questionnaire
change version (DTSQc)
Glucose Monitoring Satisfaction Scale (GMSS)
Patient Satisfaction Questionnaire (PSQ-18)
Consumer Assessment of Healthcare Providers and
Systems (CAHPS) Surgical Care Survey
Generic Short Patient Experiences
Questionnaire (GS-PEQ)
Technology Care experiences Questionnaire (TEQ)
EXPERIENCE-APP
Supportive care needs survey shortform (SCNS-SF34)
Modified validated 30-item Prenatal
Interpersonal Processes of Care scale
Dyadic Adjustment Scale
Care Transitions Measure from the
Coleman Care Transitions Program
Centura Telehealth Patient Satisfaction Survey
CGM Satisfaction Scale
Client Satisfaction Questionnaire (CSQ-8)
Duke Anticoagulation Satisfaction Scale (DASS)
ICHOM (Birth Satisfaction Scale–Revised)
Litterfield and Adams 16-item self-reported
validated Satisfaction subscale survey
Patient Dialog Assessment (PDA)
Patient Satisfaction Questionnaire iv (PSQ-iv)
Remote Monitoring Satisfaction Survey (RMSS)
Satisfaction questionnaire by Chiou et al.
(modified)
Telehealth (patient satisfaction survey)
Telemonitor Satisfaction Survey (TSQ)
VALIDEA questionnaire
Insulin Delivery System Rating
Questionnaire (IDSRQ)
Care experiences in Close
Relationships-Revised Scale (ECR-R)
Memorial Anxiety Scale for
Prostate Cancer (MAX-PC)
Spielberger State-Trait Anxiety Inventory for Adults
Joint Questionnaire
Confidence in Diabetes Self-Care for
Type 1 patients (CDS-T2)
Hypoglycaemic Confidence Scale (HCS)
Beck Depression Inventory (BDI)
Cardiac Depression Scale (CDS)
Center for Epidemiologic Studies Depression Scale
Depressive Care experiences
Questionnaire for Adolescents
National Comprehensive Cancer
Network Distress Thermometer
Symptom Checklist-90-Revised (SCL-90-R)
Diabetes Empowerment Scale–Short Form (DES-SF)
ICD-EMPOWER
Health Literacy Questionnaire (HLQ)
Rapid Estimate of Adult Literacy in Medicine (REALM)
Multidimensional Health Locus of Control Scale
UCLA loneliness scale
ICHOM Patient Health Questionnaire 2
Kessler Psychological Distress Scale (K10)
Kolerian short test of mental status
Mental Health index-13 (MHI-13)
Perceived Calculated Autonomous Motivation (DRAM)
Intrinsic Motivation Inventory (IMI)
Multidimensional Perfectionism Scale
MOS social activity
MOS social support
Q-items validated prenatal Maternal Stress survey
State Trait Anxiety Inventory (STAI)
Hypoglycaemia Unawareness Questionnaire
RAND Improved Chronic Illness for
Care Evaluation (CICE)
Health Education Impact Questionnaire (heiQ)
Diabetes-specific LOC questionnaire
ICD Patient Concerns Questionnaire (ICDC)
Diabetes Distress Scale (DDS)
Morisky Medication Adherence Scale
Problem Areas in Diabetes scale (PAID)
Generalized Anxiety Disorder (GAD-7)
Hypoglycaemia Fear Survey (HFS)
Acceptability questionnaire
by Jacucci et al.
Service User Technology Acceptability
Questionnaire (SUTAQ)
Outcome expectations from exercise
(OEE)
Brief Illness Perception
Questionnaire (B-IPQ)
EXPECT-APP
EXPECT-ICD
Telemedicine Perception
Questionnaire (TMPQ)
Single Ease Question (SEQ) method
Think-Aloud Protocol (TAP)
30 item feasibility and
acceptability questionnaire
Illness Perceptions Questionnaire (IPQ)
Home Monitoring Acceptance and
Satisfaction Questionnaire (HoMASQ)
Telemedicine Satisfaction and
Usefulness Questionnaire (TSUQ)
Task analysis
Florida Patient Acceptance
Survey (FPAS)
NCI Fat Screener
NCI Fruit and Vegetable Screener
Fatigue assessment scale (FAS)
Behavioral risk factor surveillance
system (BRFSS)
International Physical Activity
Questionnaire (IPAQ)
Physical Activity Questionnaire
(PAQ shortform)
Swedish National Board of Health
and Welfare questionnaire for
assessing Physical Activity
(NBH) physical function
ACS Functional Rating Scale
Revised (ALS-FRS-R)
Clinical COPD Questionnaire
Global Assessment of Functioning (GAF)
Instrumental activities of daily
living scale (IADL)
Social Functioning Scale (SFS)
King's Sarcoidosis Questionnaire (KSQ)
Spinal Cord Independence Measure
scale y (SCIM III)
Pain Catastrophizing Scale
COPD Assessment Test (CAT)
Daily life quality index (DLQI)
European Organization for the Research
and Treatment of Cancer Quality of Life
Questionnaire (EORTC QLQ-C30)
Expanded Prostate Cancer Index
Composite (EPIC-26)
Functional assessment of chronic illness
therapy-fatigue (FACIT-F)
Global Rating of Change (GRC)
International Spinal Cord Injury
Quality of Life questionnaire (ISCI-QoL)
Kidney Disease Quality of Life scale
Knee Injury and Osteoarthritis
Outcome Score (KOOS)
Knee Injury and Osteoarthritis Outcome
Score for Joint Replacement (KOOS, JR)
MacNew instrument
Minnesota Living with Heart Failure
Questine (MLHFQ)
Multidimensional health assessment
questionnaire (MDHAQ)
PDQ-8 (Parkinson's Disease
Questionnaire-8)
PROMIS questionnaire
Saint George's Respiratory Questionnaire
Self-reported health status
Seven-item Seattle Angina
Questionnaire (SAQ-7)
Short form-8 (SF-8)
St. George Respiratory Questionnaire
Perceived self-efficacy for fatigue
self-management (SEFF-fatm)
Perception of Self-Care Agency scale
Stanford Patient Education Research
Center (PERC) 6-item instrument
World Health Organization
Well-Being Questionnaire (WBQ)
Self-Care of Heart Failure Index (SCHFI)
King's Brief Interstitial Lung Disease
(K-BILD) questionnaire
Quality of Life Index
European Heart Failure Self-Care
Behaviour Scale (EHFScBS)
Summary of Diabetes Self-Care
Activities (SDSCA)
World Health Organization Five
Well-Being Index (WHO-5)
Diabetes specific
quality of life scale (DSQOL)
Functional Assessment of
Cancer Therapy (FACT)
Short Form Health Questionnaire (SF-12)
EuroQol (EQ-5D)
Kansas City Cardiomyopathy
Questionnaire (KCCQ)
Legend
Usage and adherence-related experience measures
Service-system-related experience measures
Care-related experience measures
Health outcomes-related experience measures

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About the author

Hosana Morales is a Mexican design researcher born in 1993 in Chihuahua, Mexico. From 2011 to 2016, she studied Industrial Design at Tecnológico de Monterrey, where she graduated with honours and developed a strong foundation in user-centered design and product development. Between 2018 and 2020, she completed a Master of Science in Integrated Product Design with a specialisation in Medical Design at Delft University of Technology. During this period, she collaborated with healthcare institutions including Erasmus Medical Center, Amsterdam University Medical Center, and Philips Design on projects focused on digital health services, patient experience, and AI-enabled healthcare innovation.

From 2020 to 2026, Hosana conducted her doctoral research at Delft University of Technology within the Faculty of Industrial Design Engineering. Her research explored evidence-based approaches for the

design and evaluation of eHealth products in clinical contexts, bridging design practice and healthcare innovation. Alongside her research, she contributed as a lecturer and mentor in strategic design and healthcare innovation courses at both Delft University of Technology and Tecnológico de Monterrey. Since 2026, she has also worked as an AI Strategic Design Consultant in Guadalajara, Mexico, supporting the development of AI-enabled healthcare products and conversational health technologies.

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- **Morales Ornelas, H. C.**, Kleinsmann, M., Kortuem, G., & van Deutekom, A. W. (2025). Reconciling data-enabled design and clinical trials: conceptual phases for eHealth development. Proceedings of the Design Society, 5, 2681–2690. https://doi.org/10.1017/pds.2025.10282
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