Mobile Health for Public Health Practitioners

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Many minds came together to make this work a reality. Our deepest thanks go to the women who opened up to us about their smoking and quitting journeys during pregnancy. Every conversation, every piece of feedback they shared helped us build an app that meets the needs of future moms trying to quit.

Under the guidance of professors Cristian Meghea (Michigan State University), Kristie Foley (Wake Forest University School of Medicine), and Kenneth Resnicow (University of Michigan) the app which many of the examples in this book were built on, came to life through the hard work of researchers, designers, developers, and healthcare providers - each bringing their own perspective and skills to the table. Together, they’ve helped reshape how we think about using mobile apps to help pregnant women quit smoking.

We are particularly grateful to our manuscript reviewers - Laura Micle, Marina Dascăl, Andreea Morar, Teodora Frățilă, Mara Bumbu, and Alexandra Onisor - who, through their critical insights and constructive feedback, have been invaluable in refining our ideas and ensuring the content is accessible for public health practitioners.

Introduction to the book

As future public health practitioners, your work will intersect with the digital realm very frequently, in the shoes of users of technology, but also as shapers (or builders) of tech solutions. Whether you consider yourself a technically savvy person or not, you will find yourself in the position to at least offer feedback on an mHealth solution throughout your career, recommend mHealth apps to beneficiaries, or conduct research intersecting digital health. You might also be in the position to initiate projects with mHealth components, consult tech teams in your niche of expertise, or even be an active member of a digital product development team. Whatever your position will be, a basic understanding of mHealth could help you navigate this space a lot easier. And why not, you might even discover you enjoy working at the intersection of health and digital, and open-up new career perspectives.

On the other hand, with global health challenges becoming more and more complex, teams that embark on designing solutions need to have a diverse set of skills. They need to build on each other's expertise in order to come up with effective and efficient solutions that have a measurable impact. Only by working together can we improve public health in the digital age. But in order for that to happen, public health practitioners should feel comfortable and confident to take a seat at the table, and get involved in designing social change in the digital space too. As mobile technologies are more and more enmeshed in everyone's lives, and they reach even the most remote populations, public health practitioners need to be an active part of how these technologies are being built for people.

This book is meant to serve as an introduction to mHealth, designed specifically for public health students or even early stage practitioners. The digital product development process usually abounds with software development jargon, and quite frankly, can be a bit mystical and intimidating for the non-techie. This book aims to address that. The information presented here builds on the joint experience of the two authors in crossing boundaries from public health to the tech world. As public health researchers who have engaged with technology from different roles, we aim to provide support for new practitioners who want to grow in this space. Our mission is to have more and more public health practitioners fluent in mHealth, who embrace technology and have a common language with our fellow tech specialists.

Throughout this book, we aimed to offer you a more accessible way of understanding what happens behind the scenes and introduce you to the space of mHealth. The first part of the book (first four sections) will equip you with the knowledge needed to understand mHealth. We start with a general overview and introduction to mHealth (section one), follow with a deep dive into the mechanics of mHealth (section two) and then discuss multiple frameworks which will help you understand how mHealth is designed to work (section four). Section

three will offer you a case study which we will use as a reference throughout the next part, to illustrate a real-life example of designing an mHealth application. The second part of this book (section five) is structured to offer you hands-on skills and tools to embark on your first journey of designing a concept for an mHealth app. It will describe the process (and associated steps) to design the concept of a mobile app with the scope of improving population health. It will guide you in integrating behavioral sciences concepts into your mHealth app, especially if you aim to include behavior change strategies in your health intervention. You can use it as a companion for your very first project, to guide you through the phases of articulating an mHealth solution.

By the end of this book, we hope you will have built a foundation to help you engage with mHealth projects, collaborate with tech teams confidently, and even design your first mHealth intervention. We understand that mHealth might feel like a complex field at first. That's why we structured the content in a way that makes it easy to follow and builds gradually on concepts introduced earlier. Our hope is that, through this book, you will discover that working at the intersection of public health and technology is an accessible, feasible, and exciting opportunity to advance public health.

SECTION ONE

Introduction to mHealth

CHAPTER 1

What is mobile health (mHealth)?

As a public health practitioner, you'll often encounter mobile health technologies in your work. This chapter helps you understand what mHealth is, how it can benefit your practice, and what challenges you might face when using it. Mobile Health, or mHealth, **sits at the intersection of mobile technology and health and is part of the broader field of digital health**. As such, an understanding of digital health is essential to grasp the concept of mHealth. This is easier said than done since there are at least 95 unique definitions of digital health (Fatehi et al., 2020). Yet, most definitions describe digital health as using technology across different levels of healthcare service provision, to improve the health and well-being of individuals and populations and streamline the delivery of healthcare services. At the patient level, digital health utilizes technology to prevent, manage, and treat diseases at the patient level, focusing on promoting diagnosis, supporting treatment adherence, and empowering individuals to manage their health. Applications of digital health can include AI-based diagnostic tools, mobile health apps for chronic disease management, or wearable fitness trackers, to name a few. On a health systems level, digital health focuses on patient management tools, the management and processing of clinical and genetic data, and improving the delivery of healthcare services, in general. It is important to mention is the fact that digital health technologies can be used in settings outside of the healthcare system, such as schools, neighborhoods, and communities, but also social media.

Two of the most common terms associated with digital health are eHealth and mHealth. **eHealth** is often used interchangeably with digital health, although they have different meanings, with digital health encompassing eHealth. The latter is defined as "an emerging field at the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies" (Oh et al., 2005). In other words, in eHealth, the focus is on information and communications technologies designed to support and streamline healthcare administration and service delivery. For example, electronic health records and telemedicine platforms are

good illustrations of eHealth components. On the other hand, digital health has a broader scope and encompasses a wider range of technologies beyond information and communications technologies. See Figure 1 for a summarized distinction between the two.

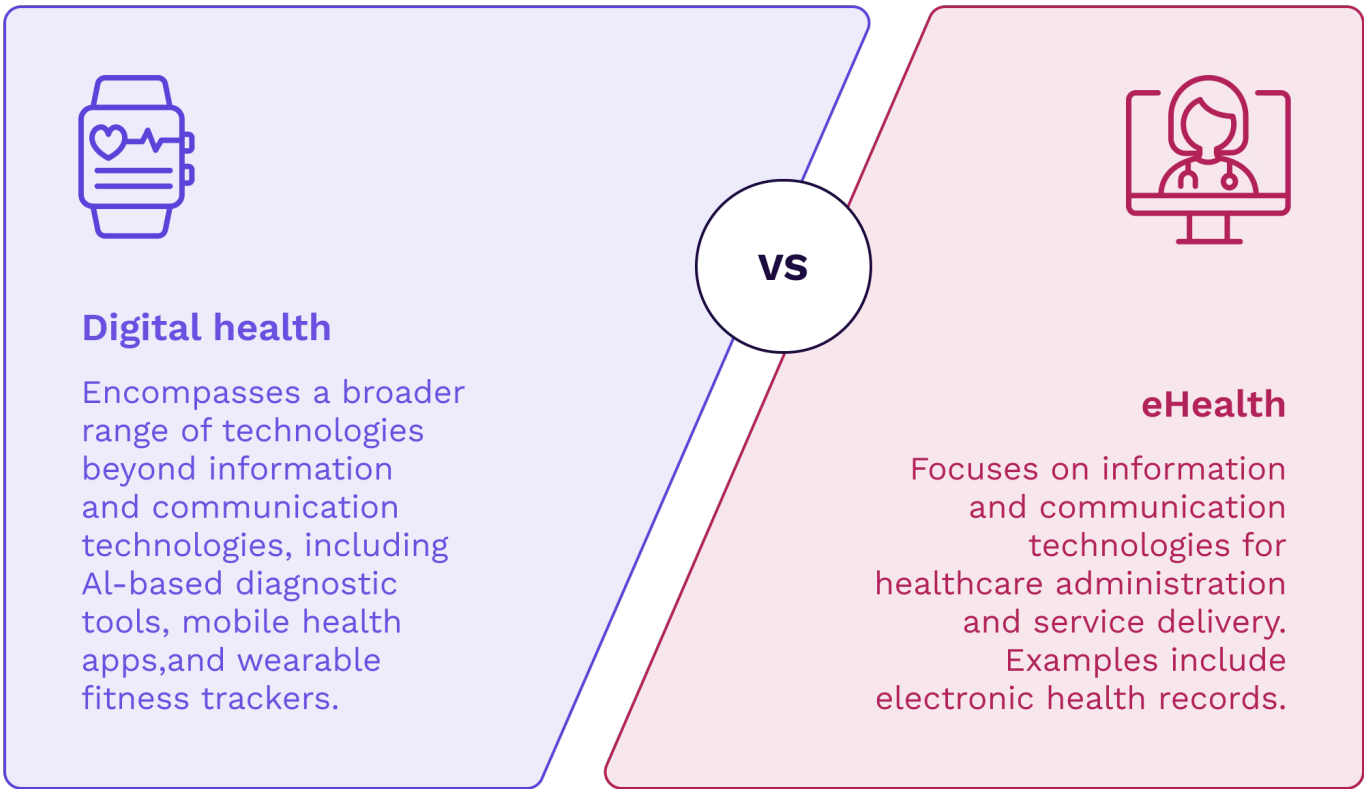


Figure 1. Digital health vs eHealth

The second term, **mHealth**, refers to the practice of public health supported by "software applications that are designed to run on mobile (i.e. handheld) devices such as smartphones, tablets, and wearable devices, like smartwatches" (Adibi, 2015). Yet, most often mHealth is centered around smartphones and how these can be leveraged to prevent diseases (i.e., screening programs), reduce health risk behaviors (i.e., poor nutrition, lack of physical activities), encourage uptake of protective behaviors (i.e., sunscreen use, safe driving), and ultimately improve population's health. As such, **smartphones are used to collect, store and/or transmit, and analyze health-related information** captured through **user input and sensors** (Adibi, 2015) **inserted in wearable devices**. For this definition, **user input** refers to any information inserted in the phone by the user, and this can range from typed-in text to photos, or videos. **Wearables** refer to electronic devices that come in contact with different areas of the body and host **sensors**, which are small components that collect data from the environment. The most common examples of wearables are smartwatches, but these also include fitness trackers (i.e., Google Fitbit or Apple Watch), hearing aids, rings (i.e., the Oura ring, used to capture user's heart rate, temperature, and body movements), smart glasses or lenses (i.e., Google Glasses; Mojo contact lenses that bring augmented reality in the users'

field of vision), smart clothing (i.e., the Smart Belt Pro that uses a combination of sensors and algorithms to predict the risk of a fall and alerts the user), or masks (i.e., Aō-Air's Atōms Air Mask that helps filter particles and prevents outside air penetration by also adapting to the users' breathing, accommodating even users who engage in athletic workouts).

To understand how wearables and sensors work together, let's take the example of a fitness tracker. It can measure users' heart rate, blood oxygen level, and steps. The fitness tracker is a wearable device that includes a heart rate monitor, which is a sensor measuring the heart's electrical signals. In addition to the heart rate monitor, the fitness tracker can have an accelerometer for counting steps and a blood oxygen sensor. The device collects data from these three sensors, processes it, and displays information such as heart rate, number of steps, and blood oxygen levels on its screen. This data is usually also sent to a smartphone app, where users can track their progress and milestones. We summarized this process in Figure 2.

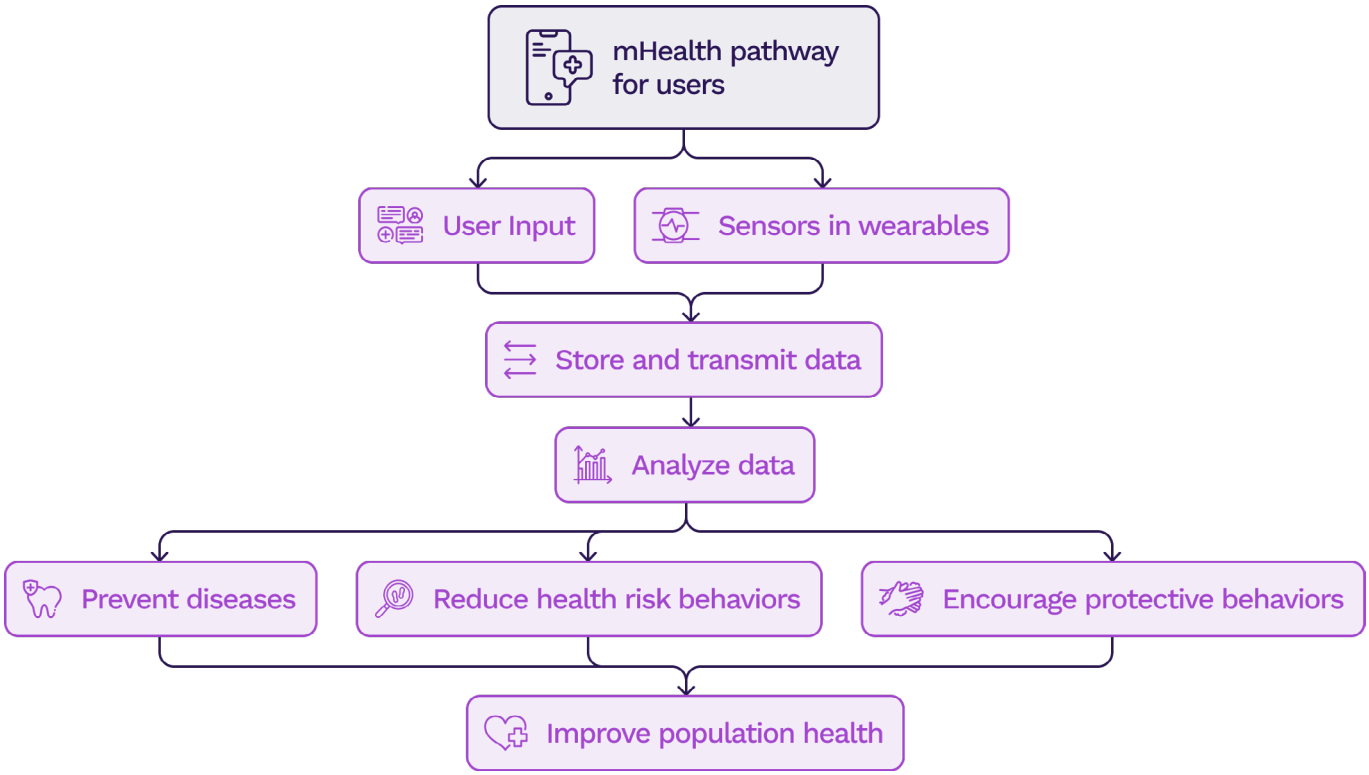


Figure 2. mHealth pathway for users

mHealth advantages and disadvantages

Let us walk you through the key advantages of mHealth that researchers have identified, also summarized in Figure 3. First, mHealth helps **make healthcare more accessible**, especially for vulnerable populations who might otherwise struggle to receive care. Second, it helps **reduce**

healthcare costs (Marcolino et al., 2018; Peiris et al., 2014). For example, Anderson & Cramer (2017) demonstrate the beneficial role of mHealth in the health outcomes of diabetes patients. Other researchers highlight the impact of mHealth in **improving and streamlining the process of care,** including improving antenatal support (Agarwal et al., 2015), appointment attendance rates (Gurol-Urganci et al., 2013; Hall et al., 2014), adherence to treatment (Beratarrechea et al., 2014), and compliance with medication-taking (Krishna et al., 2009). In addition, mHealth serves as a gateway to **promoting healthy behaviors,** and it was found effective in increasing self-reported physical activity outcomes (Free et al., 2013), reducing tobacco use (Whittaker et al., 2016), and reducing risky sexual behaviors (Free et al., 2013). Last but not least, the use of mHealth seems to generate good outcomes for patients who are suffering from long-term, chronic conditions, **improving disease management** for asthma (Krishna et al., 2009), cardiac rehabilitation (Beatty et al., 2013), congestive heart failure (Beratarrechea et al., 2014), chronic lung diseases (Peiris et al., 2014), and diabetes (Bloomfield et al., 2014) patients.

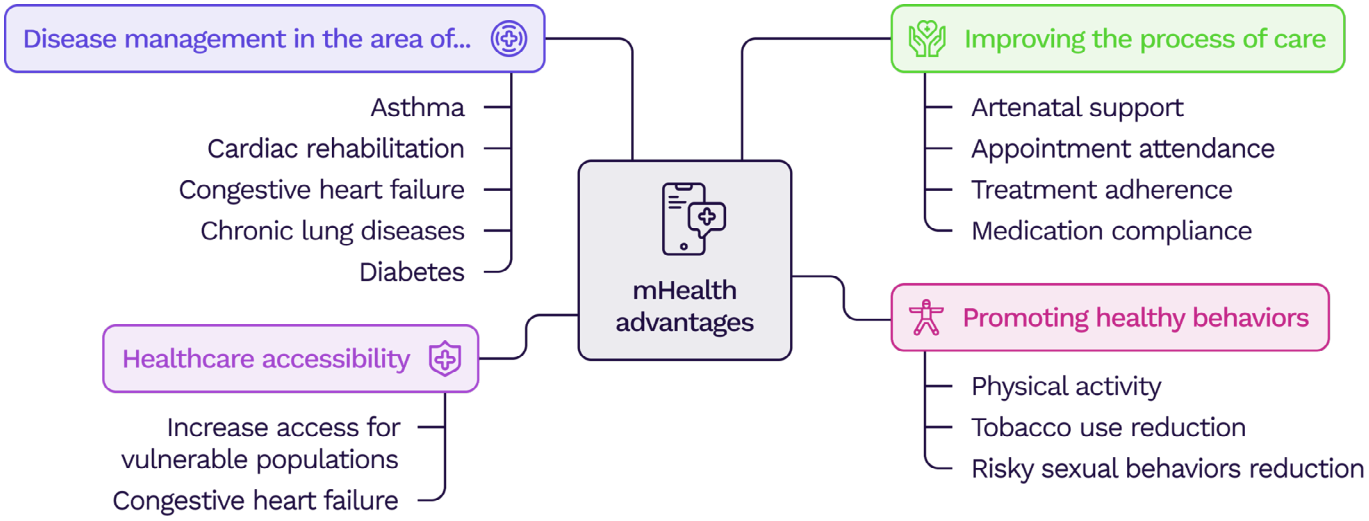


Figure 3. mHealth advantages

Now, let's look at the challenges you might face with mHealth, also depicted in Figure 4. The first **major challenge** you should be aware of is the mixed evidence around **cost-effectiveness** (i.e. is it worth the investment?). Although the cost-saving potential of mHealth is often discussed, there is limited evidence supporting this claim despite the optimism (Iribarren et al., 2017). In addition, mHealth opponents list **privacy and security** concerns, lack of **regulatory and compliance issues**, the **digital divide (disparities in access to technology), lack of integration with the healthcare system**, and **limited user engagement** (i.e., time spend using the app, frequency) **and adherence** as mHealth drawbacks.

We will start with the mixed evidence to establish the cost-effectiveness of mHealth interventions. The research on the **cost-effectiveness** of mHealth interventions has revealed an increasing amount of evidence indicating a generally positive impact on costs and health

outcomes (Lin & Lou, 2021; Rowland et al., 2020). However, the diversity in study methods makes it challenging to compare the interventions (Gentili et al., 2022). This basically means researchers need to do a better job of using consistent methodologies and approaches to systematically evaluate the costs and health benefits of mHealth interventions. Also, most mHealth studies are focusing on high-income countries (Marcolino et al., 2018). For the very limited number of studies implemented in low and middle-income countries, researchers point out that mHealth is particularly cost-effective in these low-resource settings (Beratarrechea et al., 2014), as it increases accessibility to healthcare services for vulnerable populations who otherwise would not be able to see a physician face-to-face.

In terms of **privacy and security**, mHealth disadvantages include the risk of confidentiality breaches due to hacking attempts, unauthorized access, and lack of proper encryption standards (Arora et al., 2014). Tied to this is also the issue of **regulatory compliance** of mHealth apps with health regulations and data safety and privacy directives such as the General Data Protection Regulation (GDPR) in the European Union and the Health Insurance Portability and Accountability Act (HIPAA) in the USA. For example, Fan & colleagues (2020) performed an evaluation study of 796 mHealth apps against GDPR compliance standards and found that "188 (23.7%) of them do not provide complete privacy policies" (Fan et al., 2020). This suggests that almost one-quarter of the analyzed apps are not GDPR compliant.

The **digital divide** refers to technology contributing to widening the already existing gaps in health outcomes between the general population and vulnerable populations (Saeed & Masters, 2021). In other words, instead of technology improving health outcomes, individuals with a poor health status (for example those with a low socio-economic status) continue to report poorer health outcomes despite the latest technological advancements. This might be because they lack access to smartphones, a stable internet connection, or even to the internet. When these are not an issue, literacy, and digital literacy problems might prevent patients from utilizing mobile health apps that would potentially improve their health.

Another significant drawback of mHealth apps is their **lack of integration with the healthcare system** (Madanian et al., 2019)**,** as healthcare administrators and providers cannot access and utilize patient data collected through these apps. The main reasons for this are the challenges associated with interoperability with the existing healthcare system and electronic health records. This issue will be further discussed in Chapter 5.

Estimates suggest that in 2012, 40.000 mHealth apps were available (Boulos et al., 2014) on the market. By 2018, this number had increased to 350.000 (Bates et al., 2018). While no recent estimate is available, it is likely that the number has at least doubled in the past six years, due to rapid technological advances. Yet, most of these apps have **minimal usage and user engagement,** a common concern regarding mHealth interventions (Wei et al., 2020). The minimal usage and user engagement eventually leads to a high attrition rate, where users

drop out from using mHealth apps and interventions. Understandably, a high attrition rate can affect the validity and reliability of studies testing mHealth apps and can reduce the positive impact of mHealth interventions over time. For instance, a mobile phone text message smoking cessation program saw nearly half of its subscribers drop out before completing the two week program (Augustson et al., 2017). The good news is that some strategies and approaches might support user engagement with mHealth apps, including personalization, reinforcement, communication, navigation, credibility, message presentation, and interface aesthetics (Wei et al., 2020).

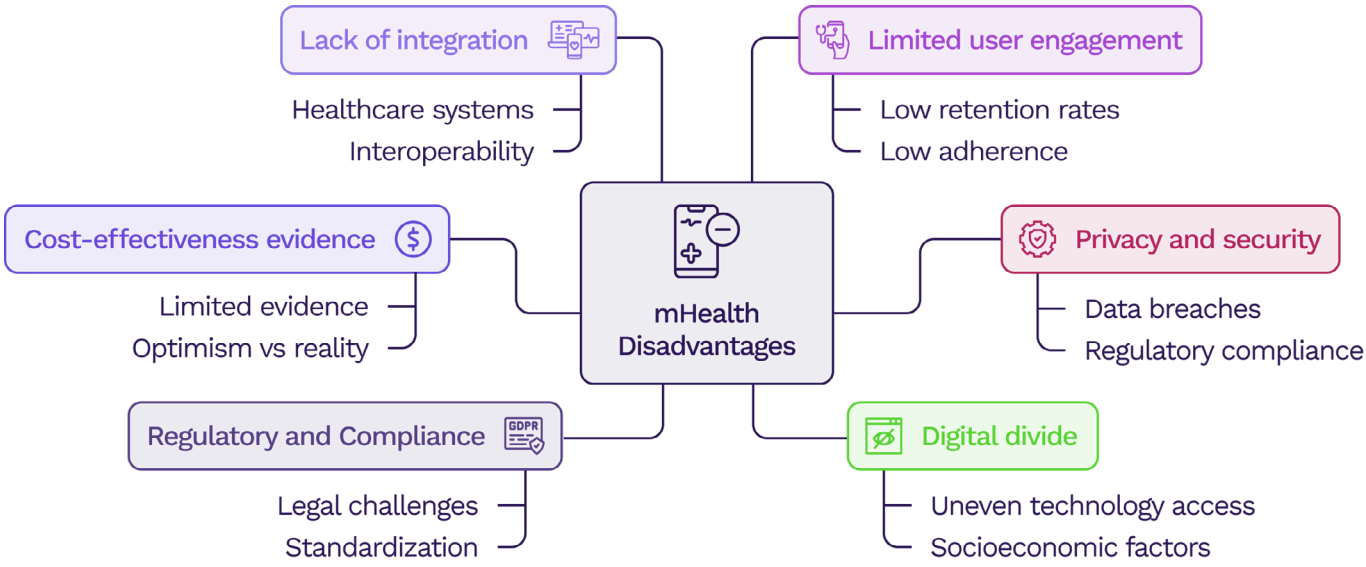


Figure 4. mHealth disadvantages

Examples of mHealth apps

The examples in Table 1 represent just a sample of the diverse mHealth apps available today. We've selected these apps with input from previous students to make this section as relevant as possible for you. While this list isn't comprehensive, we aim to give you an overview of potential mHealth applications. By sharing these examples, we want to show you the many different ways mobile technology can be used to promote and maintain health and well-being. In Chapter 4, we will explore a detailed taxonomy that classifies mHealth apps based on their core functions and we will further dive into how the apps below meet these functions.

Table 1. Examples of mHealth apps	
App	*Short description*
Period tracker	• Health & Fitness app • Developed for women to help track menstrual cycles, ovulation, and the chance of conception
Talk Space	• Mental health support app • Offers support for individuals and couples covering mental health needs
mySugr	• Diabetes app • Blood sugar and carbs tracker
Parentool app	• Educational app for parents • Telemedicine app
Headspace	• Mindfulness and well-being app • Focus on reducing stress and anxiety, improving sleep quality, and enhancing focus and concentration
MilkMan	• App for new dads • Parenting app
Welldoc	• Digital coach app • Supports prediabetes, diabetes, heart failure, hypertension, and weight management
MyChart	• Healthcare management app for individuals and families • Communicate with physicians, and review health information and data.

Let’s wrap up what we’ve shared with you in this chapter. We’ve explored what makes mHealth a part of digital health. We showed you how our smartphones and wearables work together to gather health data - whether you’re tracking your heart rate, counting steps, or monitoring other health metrics. While we’re excited about the great potential mHealth has to tackle complex health problems, we also want you to understand the real challenges involved in working with mHealth solutions. These include questions about cost-effectiveness, making sure people’s private information stays protected, and ensuring that digital health solutions don’t leave anyone behind.

CHAPTER 2

mHealth stakeholders and users

Now that we've introduced you to mHealth, let's see who's actually involved in making these digital solutions work. In this chapter, we'll describe the key mHealth stakeholders - from the patients using the apps to the teams building them. To begin with, a **stakeholder** can be an individual, a group, or an organization that has a stake in the success or failure of a product, service, or business (Freeman, 2010). The most common and simplest categorization of stakeholders divides them into external (i.e. customers, investors) and internal (i.e., employees) stakeholders. The purpose of conducting a mapping exercise with mHealth stakeholders is to identify the key players in the field of mHealth. As such, the list of mHealth stakeholders can include (Malvey & J. Slovensky, 2014): users, such as patients, caregivers, or family members; healthcare system actors, including healthcare providers, hospitals and clinics, health insurance companies, pharmaceutical companies; app developers; information and telecommunication companies, which provide the infrastructure to run mHealth projects; policy-makers; and other stakeholders, such as health researchers and NGOs activating in the area of public health. These are listed in Figure 5.

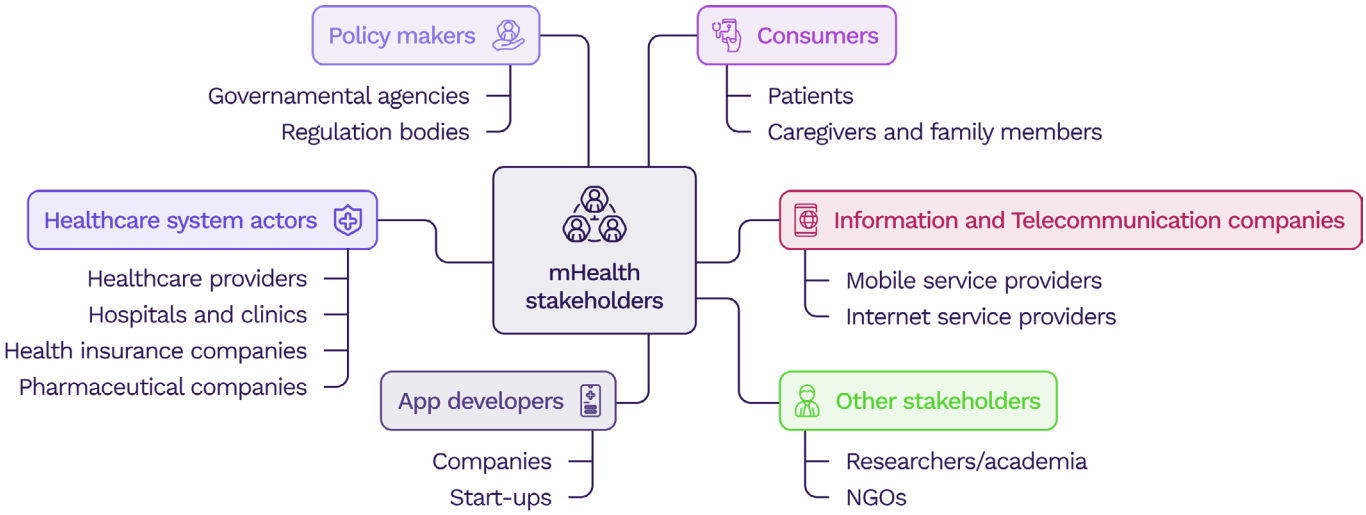


Figure 5. mHealth stakeholders

Consumers

Patients use mHealth apps to prevent diseases, manage long-term conditions, reduce health risk behaviors, or access healthcare services. According to recent research (Koumpouros & Georgoulas, 2020), patients are the main user category targeted by mHealth solutions, followed by healthcare professionals and carers. Nevertheless, consumers are overwhelmed by an excessive number of available apps and need adequate guidance to choose the best ones for their health status or medical condition (IQVIA Institute, 2021). For some users, especially older adults, **caregivers and family members** step up and support their close ones. Yet, research suggests that apps need to cater better to the needs of the aging population with multiple comorbidities and a greater need for easy-to-use apps (N. Liu et al., 2021).

Healthcare system actors adopting mHealth solutions

Doctors and nurses already use mHealth apps to track patient health and stay connected between visits. For providers, mHealth apps have the potential to enhance their communication capabilities (e.g., through virtual medical visits), support the medical act by providing disease diagnosis aids and incorporating medical calculators, support training through providing access to the medical literature and drug references, as well as reduce their workload by providing integration with the hospital's electronic health records (Ventola, 2014). Yet, healthcare workers have yet to widely adopt mHealth due to engagement and funding issues, incomplete infrastructure, lack of training or technical support, mobile cost and ownership, system utility, lack of motivation, and understaffing (Addotey-Delove et al., 2023). Another recent systematic review highlights technical (security and privacy concerns), individual (limited digital literacy), and healthcare systems (financial factors) barriers as systematic obstacles to the adoption of mHealth (Zakerabasali et al., 2021). Closer to home, a survey conducted on primary healthcare practitioners in Germany found that 43% of them are skeptical about using mHealth apps due to data privacy concerns (Wangler & Jansky, 2021). In addition, they mentioned not feeling capable of advising their patients on what apps they should be using from those available in app stores.

Hospitals and clinics often use mHealth solutions to improve patient care and implement cost-effective patient management solutions. Yet, similar to the use of mHealth by practitioners, the adoption of mHealth in hospitals and clinics is influenced by a wide range of factors, including the level of engagement of relevant stakeholders and integration challenges with existing electronic health records or revenue cycle management software (Zanaboni & Wootton, 2012). From the realm of mHealth, hospitals and clinics can decide to use telemedicine (e.g., Ringdoc) and remote monitoring apps (e.g., Teladoc Health), patient engagement and education apps, patient portal apps (e.g., the app of the Regina Maria's private medical network), or administrative and billing apps (e.g., Phreesia).

Health insurance companies are interested in effective mHealth apps that are compliant with HIPAA and the GDPR, as these are seen as ways to reduce healthcare costs. In other words, insurance companies promote using mHealth apps to lower their expenses by improving patient health outcomes through the prevention of diseases and better management of current conditions. Some insurance companies already cover purchasing certain mHealth apps and services (e.g., virtual medical visits and remote monitoring devices), depending on the payment plan of the consumer (Rogers, 2024).

Pharmaceutical companies often use mHealth apps to monitor patients and increase medication adherence in clinical trials (Munos et al., 2016). They also support providers in identifying patients at risk who would benefit from early interventions. A good example is AstraZeneca's Grace 2.0, an app based on the Global Registry of Acute Coronary Events that providers use to identify patients at risk for coronary heart events (van der Sangen et al., 2022) in an attempt to prevent their occurrence by prescribing the required medication.

Information and telecommunication companies

These companies provide the infrastructure (e.g., mobile networks, internet connectivity) that enables mHealth apps to function. They could be key stakeholders especially in settings where infrastructure interventions need to be implemented, in order for mHealth solutions to function (i.e. enhancing mobile coverage in needed settings). On the other hand, mHealth represents a significant market opportunity for **providers of mobile and internet services** as they can extend their customer range and generate new revenues by supporting mHealth projects.

Policy-makers

Regulation bodies and governmental agencies ensure the safety of mHealth technologies. In Europe, the European Medicines Agency (EMA) makes sure that health apps are safe to use, while in the USA, this task belongs to the Food and Drug Administration (FDA). These regulation bodies have a say in how mHealth apps and wearable devices are made and used, what type of data they can collect, and who can use them (for example, most wearables are not supposed to be used by individuals under 18). This is especially true for mHealth apps and wearables that are considered medical devices. Some examples include:

- Blood pressure monitors, such as Biospectal, that connect to a wearable or use phone sensors to measure blood pressure.
- Spirometry apps, similar to SpiroSmart, which uses the phone's microphone to measure lung function.

- Medication dosage calculators, such as NeoMate. This app enables neonatal staff to calculate drugs and fluids for neonatal intensive care unit patients.
- Mental health apps such as Somryst, which is used to treat insomnia in adults above 22 by using cognitive behavioral therapy for insomnia.

In Romania, the governmental agencies relevant to the mHealth landscape include the Ministry of Health, the National Health Insurance House, the National Institute of Public Health, the National Authority for Management of Health Quality, the National Authority for Communications, and the National Supervisory Authority for Personal Data Processing.

Organizations building mHealth solutions

Many **public institutions** have an interest in advancing population health using technology, actively producing, maintaining, and curating mHealth solutions. The National Health System in the UK has a dedicated division (NHS Digital) that designs, develops and maintains tech solutions for clinicians, patients and health system administrators. Similarly, U.S. Digital Services is a unit that works to bring improved governmental services (public health included) to USA citizens through effective technology. And these examples are not singular. Even as far back as 2015, when the last Global eHealth Survey was conducted, almost half of the 46 participating countries in the WHO European Region reported having government-funded mHealth programs (WHO, 2017). Meaning mHealth is a growing and important investment in the public sector.

Universities are also important contributors to mHealth technology, especially from a research and innovation perspective. Academic researchers from all over the world are intensively involved in designing mHealth solutions, whether through dedicated units, or as part of their work on specific public health issues. For example, Johns Hopkins School of Public Health has a dedicated Center for Global Health Innovation, whose mission is to develop and test digital solutions to address major public health challenges. Similarly, Duke Global Health institute in partnership with the University of Cape Town runs a program which also focuses on developing and evaluating mHealth interventions in South Africa. Closer to home, in Europe, the University College London Centre for Digital Public Health in Emergencies conducts interdisciplinary research to enable better response to public health emergencies at the local, national, and international levels. Similarly, the Digital Health & Care Innovation Center at the University of Strathclyde in Scotland helps co-design person-centered digital health solutions.

A recent systematic review (Koumpouros & Georgoulas, 2020) identified 45 research projects implemented by consortiums of universities, small and medium enterprises, and NGOs as part of EU funding schemes. Most of these projects addressed obesity and weight management

(13.33%), but they cover a wide range of health conditions, including depression, malaria, HIV, or aging. Yet, there is a difference between these projects (based on academic research) and those developed by companies and start-ups alone: they are heavily oriented towards theory and lack the involvement of app developers in the research team from the beginning of the project (Siegler et al., 2021). As such, it is critical to merge the expertise of researchers in academia with the experience of the other mHealth stakeholders, particularly the app developers, to support the development of effective mHealth solutions.

The **nonprofit sector** is another relevant actor in the development of mHealth applications. From grassroot organizations, civil society organizations, cause-based foundations, to professional associations and large international ONGs, they often embrace health causes and use technology to attain them. NGOs often work in areas where healthcare resources are scarce, so they use budget-friendly mHealth solutions to improve healthcare delivery, increase awareness of various health issues, or collect data from beneficiaries of their programs. For example, the Australasian Institute of Digital Health is an example of an organization which acts as a consortium for over 160 organizations interested in advancing digital health. Large international non-profit organizations such as UNICEF or Médecins Sans Frontières invest effort in producing digital health solutions to address their causes. For instance, UNICEF health workers are using the OpenSRP (Smart Register Platform) app to electronically register and track maternal and child health indicators. And even grassroot, smaller organizations manage to incorporate mHealth technology in advancing their missions.

And of course, the **for-profit sector** is a major player in the mHealth industry, and an important contributor to research, development and innovation in this field. As health and wellness is becoming more important to societies, and as private insurance and private health services are more common, there is increased economic interest in health products. Additionally, digitalization of health services also follows a natural upward trend as technologies (including mobile tech) are becoming more available and used. This trend was amplified by the COVID-19 pandemic, when fields such as telemedicine grew exponentially. The size of the digital health market was estimated at over 240 billion USD in 2023, and is estimated to grow to 1,635 billion USD by 2033 (Nova One Advisor, 2024). This space is very diverse and includes everything from large tech companies, which produce a fair share of mHealth products, to biomedical, life science, insurance, healthcare and pharmaceutical companies producing many of the digital solutions on the market. Of course, within this space, an impressive number of start-ups emerge each year, aiming to bring innovation in health. For example, digital health startups funded in the US alone raised investments of 15 billion USD in 2022 (Bryant et al., 2023). In other words, whether we are talking about large corporations or smaller companies, mHealth is very much present in the health (and tech) industry.

This chapter mapped out the diverse players in the mHealth landscape - from consumers using apps to manage their health, to healthcare providers implementing digital solutions, to the companies and researchers developing these tools. We saw how health insurance companies view mHealth as a way to reduce costs, while pharmaceutical companies use it to support clinical trials and patient monitoring. Understanding these stakeholders and their needs, motivations, and challenges is important for any public health practitioner working in mHealth. Whether you're recommending apps to patients, providing feedback on digital health solutions, or developing your own mHealth intervention, knowing who's involved and how they interact will help you navigate this complex ecosystem more effectively.

CHAPTER 3

Public health graduates in mHealth: roles and expertise

When it comes to the development of technology for public health, practitioners like yourself are pivotal in the successful implementation of mHealth projects. You are trained in understanding human health behaviors, the context in which they occur as well as in identifying the best approaches from a population health perspective. As a result, you likely have deep knowledge and expertise in public health areas needed for the effective design of mHealth applications. Whether your background is in health policy and management, social and behavioral health, environmental health, biostatistics, epidemiology or health informatics, you have **relevant domain knowledge** that could help shape digital solutions to complex health challenges. And who knows? If you're interested, you could even find a career at the intersection of health and technology, whether in the public sector, academia, the health industry or the nonprofit sector.

Within this chapter, we discuss some contexts and roles you might find yourself in, as a public health practitioner involved in designing mHealth solutions. While we will not cover all possible scenarios, our goal is to help you gain an overview of the ecosystem of mHealth, and understand how teams work together to produce health technology. Of course, these scenarios are context dependent, therefore we highly encourage you to engage with the public health community as well as the health-tech (health technology) or even med-tech (medical technology) industry in the areas in which you operate, to understand local nuances.

As mentioned above, who develops mHealth solutions is highly contextual and it depends on the local landscape. But there are some well established entities who *have* developed mHealth solutions in different parts of the world, as we have discussed in the previous chapter. As health in itself is a subject with multiple stakeholders, mHealth products are developed by a range of actors. As public health practitioners, regardless of the sector you work in, there are increased opportunities to contribute at a certain point in time to the development of mHealth solutions. Understanding the potential of technology in health, how

mHealth solutions are developed, as well as how to collaborate with (or within) a digital product team might be very useful if you want to take this path. The next section will briefly describe the key roles within a software development team, as well as how they interact in the process of bringing solutions to life.

Digital product teams: roles and dynamics

As Marty Cagan describes it in his book *Inspired: How to Create Tech Products Your Customers Love*, a digital product team is "a set of highly skilled people who come together for an extended period of time to solve hard business problems. The nature of the relationship is more about true collaboration" (Cagan, 2018, p. 35). Depending on what your current professional background is, you might have experienced different team dynamics. But probably for people working in public institutions or even universities, the most novel aspect when joining a digital product team is that there is no hierarchy. All roles within such a team have expertise in different fields, bringing their unique contribution to the product development lifecycle. They should feel autonomous and ideally share a passion for solving the difficult health problem your product has set to do.

Depending on the context of the product being developed and the software development process adopted, teams can have different roles, compositions and ways of working. As the purpose of this short chapter is to offer you an introduction to this topic, we will only outline some of the most frequently encountered roles in this field. This is by no means an exhaustive list, but rather some signposts to help you get oriented.

The **product manager** is the person on the team who has a deep knowledge of the business, the market or the industry as well as the beneficiaries or the users, and can make strategic (and informed) decisions about the product. They drive the decisions around what will be developed and in what order by the product team. They are also responsible for managing what we call the "product roadmap" which stores the increments in which different features of the product will be developed and delivered to customers. The product's success relies heavily on the strategic decisions of the product manager, so it is essential that they are skilled in the business side of bringing mHealth solutions to the market.

The **product designer** is another key role in the delivery of successful mHealth solutions, as they are the ones responsible with translating user needs into usable interfaces. They collaborate closely with product managers and the rest of the team throughout the whole software development process, but their role in the initial product discovery and design phases is pivotal. The product designer (or a design team with multiple specialists if the project is more complex) is involved in user research (to understand the users, their problems, and the context in which they occur), designs the concept of the solution, projects the information

architecture (how information is organized and labeled), maps user flows, designs how users navigate information in the app, designs the user interface and interaction behaviors, conducts user testing and supports engineers in implementing the application. In a nutshell, this role is key in ensuring a useful and usable interface between humans and technology for any mHealth application.

The **engineers** in the product team are often referred to as the *developers* (or in short devs) or *programers*, and they can include a whole range of specialties, depending on the needs of the product being developed. They are the specialists writing code and implementing the solution. The size of the team can vary, depending on the workload, and they can be coordinated by a Technical Lead (Tech Lead). A team can have engineers which specialize in writing code for user interfaces (also known as Frontend developers), writing code for the databases that power the mHealth application (Backend Developers), writing code for mobile applications in specific languages, sometimes as specific as dedicated platforms such as iOS or Android (Mobile Developers), or writing code for both frontend and backend (Full Stack Developers). The engineering team also typically has dedicated roles on Testing (or Quality Assurance) which ensure that the engineering team produces solutions which run smoothly and work as intended.

Data or research support roles, such as data analysts, researchers, clinical trials experts or even program evaluation experts are also part of teams which plan to deliver more complex products. Beyond bringing data to inform product development, their role is critical when testing or evaluating digital products. For example, a digital solution which needs to prove its efficacy and impact to be considered as a medical device would require a clinical trials expert as part of the team. Even less regulated health products will need data experts to model health information or at least monitor product performance by making sense of product usage (via product analytics). As a result, data or research support roles can be very important when developing products addressing complex social, health or infrastructure challenges, which have large amounts of data which need to be transformed into information (actionable insights).

Subject Matter Experts (SMEs) are individuals with specialized (in-depth) expertise, experience and knowledge in a specific field or scientific area. Product teams that work to address difficult-to-tackle health or social problems might need such people on their team to help them unpack the health, social or behavioral mechanisms which impact outcomes. Imagine an app supporting breast cancer or HIV screening, would need specialists to consult on how screening is performed, best practices as well as understand user mental models around health screenings. An app which addresses hospital efficiency would benefit from the insights of a healthcare expert. A health psychologist or behavioral scientist with a background in public health often undertakes an SME role, when digital solutions focus on health behaviors. The need for specialized expertise in product teams is critical, and public health experts could take on a SME role in a digital product team, at least once in their professional life. In

that role, they are active members of the product team, participating throughout the product development lifecycle.

Alongside the product team, there are several other roles which are key to the successful delivery of the product. These are connected through their communication sciences focus, and can have one or multiple roles such as **Marketing** and **Communications specialists**. Their traditional role is to inform your users on your product and promote its use. **In the case of products entering the market** (for-profit) you will most likely have **Sales** specialists or in the not-profit sector you would have a role (or a partial one) dedicated to **Partnership** building and management. In small teams, existing team members might take on some of these roles, or you might collaborate with external specialists for this. Beyond these responsibilities, having those roles in the team would be very helpful as they are also important in product discovery and product building. Their insights on users and the market can prove highly valuable to the product team.

Last but not least, **writers** can also be very valuable on a product team, and can take different roles depending on what they are writing about and for whom. We often see content writers who team up with marketing and communications to write *about* the product. These are the people producing marketing content trying to promote the product. Product content specialists are another type of writer which contribute to the digital solution with content which is embedded in the app. For example, a content writer can be responsible for structuring and providing content for a self-help app which needs to have well-written informational materials to achieve its goals. User experience (UX) writers are another group of writers which usually specialize in creating the microcopy (short messages and labels) for the user interface. Some product teams also include technical writers, which can take on a range of roles, from writing specifications, documentation, release notes or content for more technical users.

As we can see, digital product development teams can be diverse, and their expertise and collaboration is essential in developing well-rounded successful solutions which are adopted by users. Beyond the very technical skills which a team needs (such as strong programming abilities), bringing a successful product to life relies heavily on other roles as well. Public health graduates can find themselves working closer with some of these roles, and why not, with further training, they could develop their own competencies in these specialties.

SECTION TWO

Building mHealth solutions: guidelines and implementation

CHAPTER 4

Mapping the landscape of mHealth applications

In this chapter we will map out the diverse landscape of mHealth applications to help you understand the many types of available apps. This mapping exercise utilizes a taxonomy framework. You may wonder what a taxonomy is. Well, a taxonomy is nothing more than an organizational system. Think about the clothes you have in your closet. If you are like most people, all your clothes (for spring, summer, autumn, winter) are stored in one closet (except for the chair that we are all using for the clothes we have just worn and are not dirty enough to wash nor completely clean to store back in the closet). Yet, you might organize them in different ways. For example, keep winter or summer clothes in the back or the front of your shelves and switch their location depending on the season. Or you might have entire shelves only for winter or summer clothes and switch their location based on seasonality (i.e., put winter clothes on eye-level shelves during the winter and summer clothes on upper or lower shelves). Your closet's taxonomy represents how you are sorting your clothes into categories. These categories (i.e., the winter and summer clothes already mentioned) can have sub-categories. Winter clothes can be divided into pants, skirts, blouses, and so on. These categories and subcategories can be different from person to person. How you organize your clothes might differ from how your best friend does it. But that does not mean that your way is better than your friend's. Going back to the taxonomy of mHealth apps, this is nothing more than a system of organizing types of mHealth apps into categories. Yet, it is essential to mention that these taxonomies depend on the individuals or authors who develop them and how they categorize apps. Also, taxonomies can change over time to accommodate new or emerging types of apps.

With these in mind, for this chapter, we selected the mHealth taxonomy proposed by Phillip Olla & Caley Shimskey (Olla & Shimskey, 2015), who conducted a thematic analysis on more than 20,000 records they retrieved from Scopus (a scientific database) and ended up with 50 categories and subcategories that they included in their taxonomy. This is presented in Figure 6 as well. We will look into their categories, which we slightly adapted by adding three

app subcategories (remember that these taxonomies change over time to accommodate new app types) based on our experience. These are presented in Figure 6 and will be briefly described below.

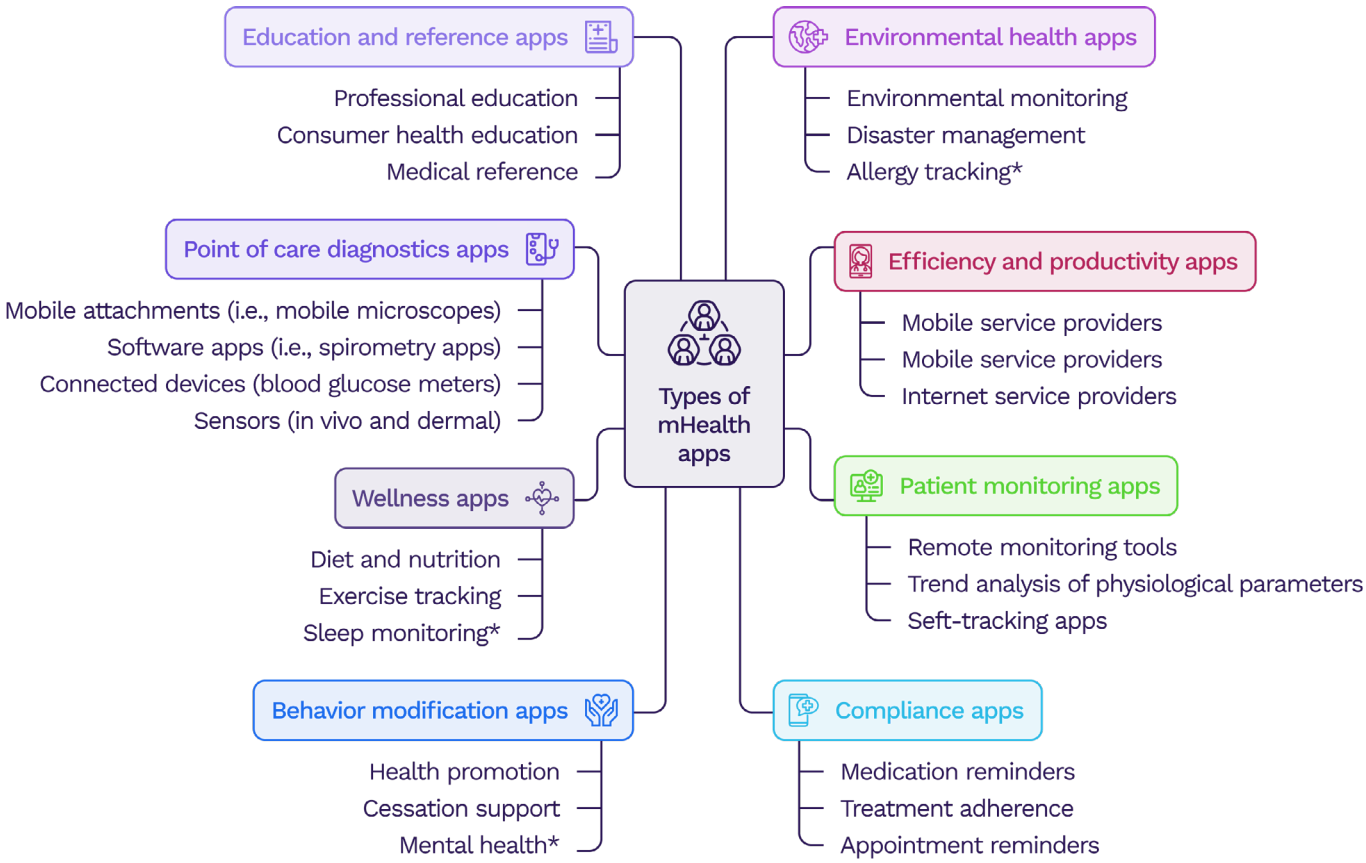


Figure 6. Types of mHealth apps
**Categories added by authors*

Education and reference apps. This category includes apps designed to provide health-related information. These apps deliver health information to two main groups. Healthcare workers use them to quickly look up medical guidelines, drug details, diagnosis guides, and dose calculations. The apps also include training modules and real cases to help professionals keep learning. The public gets simpler versions that break down medical topics in clear language, walk through first aid steps, and share healthy living advice. The goal is to make reliable health information easily accessible, whether for professional use or personal health management. For example, Parentool functions as an educational app by providing parents with reliable health information and guidance.

Point-of-care diagnostics apps transform smartphones into portable medical instruments. For instance, portable lenses can turn phones into microscopes for examining blood samples, and heart monitors can be used to capture ECG readings on the phone's screen. Some apps use the phone's built-in capabilities, like the microphone, to assess lung function.

Others connect to external devices, such as glucose meters, for diabetes management. Yet, the most exciting apps in this category connect to in vivo sensors, particularly ingestible sensors, which are built to collect internal body data, to support personalized medicine. For example, mySugr serves as a point-of-care diagnostic app by helping users track their blood sugar levels.

Wellness apps help users maintain or improve their health by leading a healthy lifestyle. Some might promote healthy eating (through calorie counting or suggested meal plans) or increased physical activity (by proposing workout routines, step counting, etc). More recently, wellness mHealth apps are focusing on improving sleep quality by monitoring sleep cycles and offering tips for better sleep. These apps are often used in conjunction with the phone's built-in sensors or other wearable devices (such as smartwatches). Apps like Headspace exemplify this category by focusing on mindfulness and well-being through meditation and stress reduction.

Behavioral change apps. These apps focus on shifting specific health behaviors and tackling targeted health challenges. While wellness apps broadly promote healthy living, these tools drill down to particular changes like quitting smoking or managing anxiety. Mental health apps in this category might guide users through stress-reduction techniques, mood tracking, or mindfulness exercises. These tools often use strategies like goal-setting, progress tracking, and personalized feedback to encourage positive behavioral changes. Talk Space is a good example, offering mental health support and behavior modification services.

Compliance apps are, as their name suggests, mobile applications that help patients follow their treatment plans and doctors' recommendations. To do this, apps send reminders or notifications when a medication dose is due or when the patient has an upcoming medical appointment. For example, WellDoc supports compliance for various conditions including prediabetes and diabetes.

Patient monitoring apps usually focus on remote monitoring of patients. Remote monitoring means physicians and healthcare staff can access patient data (often collected through sensors/wearables) when the patient is not in the clinic. These apps have two main purposes: 1) send alerts to healthcare providers when the data indicates a potential urgent health event (for example, a spike in the patient's heart rate) and 2) use large amounts of patient data and analyze it to identify potential health issues before they become serious (for instance, a steady but continuous increase in blood glucose level over a couple of months might indicate the onset of type II diabetes). A subcategory of monitoring apps are self-monitoring apps, which individuals use to track their health status indicators (i.e., heart rate, blood pressure, sleep patterns, etc). For instance, mySugr enables diabetes monitoring by tracking blood sugar levels over time.

Efficiency & productivity apps are, as their name suggests, tools designed to save time, reduce costs, and improve healthcare delivery, in general. The four sub-categories include patient medical records apps (enable healthcare staff to access and update patient records from their phone), telemedicine apps (which allow for remote consultations), communications apps (these can support message exchange between healthcare staff members, but also between healthcare staff and patients), and logistics apps (for scheduling appointments, collecting patient data, or managing hospital records). MyChart exemplifies this category by streamlining healthcare management and communication between patients and providers.

Environmental health apps provide information about environmental factors that affect health. These factors include pollution or air quality levels, UV-radiation levels, temperature/ extreme heat, and other weather conditions. Recently, some apps also track allergens like pollen levels and ambrosia locations, helping allergy and asthma sufferers plan their outdoor activities. This tracking lets users avoid high-risk areas and times, giving them more control over their exposure to triggers. Disaster management apps form a crucial subset of this category. They send alerts about incoming natural disasters like earthquakes or floods, show users where to find safe zones, point to emergency services, and mark humanitarian aid locations. A good example is Earthquake - alerts and map, a monitoring app which detects earthquakes and alerts users through push notifications.

CHAPTER 5

Implementation and integration of mHealth in the healthcare system

The implementation of mobile technologies into healthcare systems offers new solutions for health information collection, clinical decision support, and patient engagement. While the adoption of electronic health records (EHR) took decades to reach widespread implementation (and is still in incipient phases in many countries around the world, including Romania), mHealth has experienced a rapid growth due to increased smartphone penetration and advancing mobile technologies. Yet, this rapid evolution translates into challenges for both healthcare systems and mHealth solutions, particularly in terms of interoperability and integration with existing healthcare infrastructure. This chapter examines the key aspects of implementing and integrating mHealth solutions within healthcare systems, introduces electronic health records (and their implementation status in Romania), and describes interoperability and integration challenges of EHR and mHealth.

Introduction to electronic health records (EHRs)

Think of electronic health records as digital versions of patient charts. Electronic health records (EHRs) consist of patient information (demographics, notes, health issues, medical history, medications, and laboratory reports). This information is collected longitudinally, meaning at multiple points in time, during all patient-healthcare provider encounters in care delivery settings (Ambinder, 2005), or generated by the patient (pictures of medical records, scans, etc) based on information they have received from healthcare providers.

Electronic health records have come a long way since their start in the 1960s. The history of EHRs started in the 1960s, but their widespread adoption was initiated in the 1990s and the early 2000s, with varying degrees of implementation and adoption across the world. Some countries started with a gradual implementation of EHRs (with variations between counties/provinces or regions), while others implemented nationwide systems early on. In

Europe, Denmark was one of the early adopters (along with the Netherlands and the UK), with complete records (treatment, diagnosis, medication, and social support) documented back to 1968 across the entire Danish population (Healthcare Denmark, 2025). In this context, there is no surprise that researchers around the world use Danish data to research some of the most crucial and complicated public health problems, from the risk of stillbirth (Bay et al., 2019), recurrent stroke (Hviid Hornnes et al., 2024), traumatic brain injury (Seidenfaden et al., 2024), or childhood epilepsy, among many others. Overall, there is a gradient of EHR adoption depending on the country's income level, with faster implementation in higher-income countries (see World Bank country classification by income level for the distribution) and, as expected, slower or even absent in lower-income countries (i.e., many African countries) (Fritz et al., 2015). Yet, EHR efforts are boosted through mHealth, which contributes to strengthening healthcare systems by enabling data collection, submission, and analysis in over 40 countries (District Health Information, 2018).

Implementation of nation-wide EHRs is highly beneficial, as their support (Upadhyay & Hu, 2022; Uslu & Stausberg, 2021): (1) **improved patient care and safety** through better documentation of patient data, reduced medical errors, improved health outcomes, increased potential for better strategies to prevent and manage acute and chronic illnesses, and having all patient information available at the point of care; (2) **enhanced care coordination and medical decision-making**, since EHRs enable healthcare professionals to access additional medical history information to assist in decision-making and to coordinate care between healthcare providers and facilities; (3) **strengthen operational efficiency and healthcare cost reduction** due to improved delivery of care, reducing redundant paperwork, and supporting financial reimbursements for the medical act and procedures; (4) **support research and population health management** as up to date EHRs are valuable sources for observational and clinical studies and can contribute to developing an efficient healthcare system based on evidence-based medicine; and (5) **enable compliance with legal requirements** regarding data safety, privacy, and confidentiality.

Despite these benefits, implementation of EHRs systems has several significant drawbacks (Kruse et al., 2016, 2016; Menachemi & Collum, 2011), including (1) **implementation and adoption challenges**, such as high upfront and ongoing costs, workflow disruptions during implementation, resistance to change from healthcare providers, and shortage of technical personnel to support implementation; **(2) usability and user experience issues** of EHRs, including time consuming manual data entry and user interface and usability issues leading to frustration; (3) **data quality and management concerns**, for instance, incomplete data entries, challenges with data quality assessment, but also issues related to the provenance of data; (4) **training and education of healthcare providers** on EHRs use and need for continuous education to keep up with system updates and new features; (5) **interoperability and standardization challenges**, as different EHR systems might not be compatible for information transfer; (6) **implementation, and maintenance costs**; and lack of integration

with patient generated data from wearables and mobile health apps. Both the benefits and drawbacks of EHR are depicted in Figure 7.

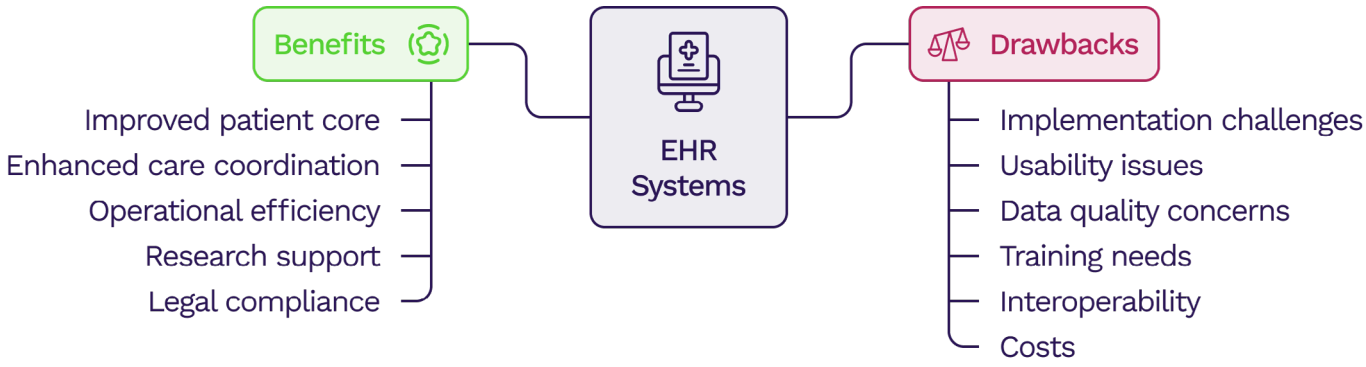


Figure 7. Benefits & drawbacks of EHR systems

Brief overview of EHR status in Romania

Romania's journey with electronic health records began in 2014. Starting with 700,000 unique electronic health records, by late 2021, this number had grown to 16 million (Grad & Mureșanu, 2022). Despite this substantial growth in available records, implementing EHRs in Romania faces significant challenges. Most importantly, their utilization remains limited, with only a small fraction of hospitals actively collecting and contributing to electronic patient data. The bulk of information input comes from primary care physicians.

The use of EHRs in Romania is regulated under the law 45/2009. The law stipulates that these digital records are meant to give a complete overview of a person's health, including important medical details such as history of transplants, implanted devices, allergies, blood type, existing health issues, current medications, and recent hospital visits. They also include lifestyle factors such as sleep patterns and substance use. In addition, the law stipulates that users have the ability to monitor access to their electronic information and control which parts of their data are displayed for healthcare providers.

To enhance the EHR system, the National Insurance House is leveraging European funding for two major initiatives (ECONOMICA.NET, 2020). One project (eDES) focuses on expanding EHR connectivity across health providers. The other project (SIGMA SMART) aims to streamline the reimbursement of medical services from the National Health Insurance Fund. The implementation process, however, has encountered several obstacles (Grad & Mureșanu, 2022), including the absence of a thorough cost-benefit analysis, uncertainties surrounding data ownership and access rights, and skepticism around a potential increase in administrative workload, especially for general practitioners. Furthermore, integrating the new EHR system with the existing digital health infrastructure presented additional difficulties.

In summary, while Romania has shown advancements in establishing a countrywide electronic health record system, this continues to be underutilized, error-prone, and faces integration challenges.

Interoperability and integration of EHR and mHealth

Interoperability and integration refer to how well different systems that collect and store health data (such as electronic health records and mHealth apps) work together and share information to make healthcare more efficient, reduce errors, improve patient care and satisfaction, and save time and money. In this context, the main challenge is for EHR and mHealth apps to work using agreed-upon data standards. Luckily, existing frameworks, such as the Fast Healthcare Interoperability Resources (HL7 FHIR) (*eCQI Resource Center*, 2025), can be used to facilitate interoperability.

A highly cited research paper (Walker et al., 2005) on the benefits of information exchange and interoperability has documented how much money could be saved if healthcare organizations (hospitals, labs, radiology centers, pharmacies, healthcare providers, public health departments, and insurance companies) could easily share patient information electronically by defining four levels of sharing. Level 1 consisted of no electronic sharing, Level 2 was limited to basic electronic sharing (i.e., fax or scanned documents), Level 3 focused on more advanced sharing but not across all data and documents, and Level 4 was defined as fully standardized electronic sharing. The authors' main findings were that even Level 2 sharing could save 21.6 billion USD per year, while Level 4 sharing would yield almost four times more savings (up to 78 billion USD per year).

Despite these savings and existing interoperability frameworks and guidelines, the challenges to implementing a fully interoperable system for electronic health data sharing and exchange remain the high initial costs, the requirement for national data standards according to interoperability frameworks, and data protection and confidentiality concerns (Walker et al., 2005). The latter two highlight the importance of legislative frameworks, data standardization, and ethical considerations in the area of mHealth. The next chapter will delve into these exact issues and explore how mHealth practitioners can ensure data standardization, data privacy, and the protection of patients' rights.

CHAPTER 6

Standards, legislation and ethics in mHealth

The rapidly evolving field of mHealth has brought new solutions to tackle public health problems but has also introduced complex regulatory and ethical considerations. As a public health practitioner, understanding these standards isn't just about regulatory compliance. It's about ensuring that mobile health interventions effectively and ethically approach public health problems while protecting user privacy and data security. This chapter introduces the key standards, regulations, and ethical guidelines that shape development and implementation of mHealth interventions. While you may not need to become a legal or technical expert in the area of mHealth standards and legislation, knowing these fundamentals will help you make informed decisions when developing and implementing mHealth solutions, protect your users' privacy and rights, and ensure your interventions meet the necessary regulatory requirements. We'll explore five key areas: privacy frameworks like General Data Protection Regulation (GDPR), security requirements for health apps, healthcare data exchange standards, medical device regulations, and ethical considerations. For each area, we will focus on what public health practitioners need to know to effectively participate in mHealth projects while providing additional resources for those who want to dive deeper into specific areas.

Privacy frameworks: GDPR and HIPAA

As the title suggests, the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA) are data protection and privacy frameworks (Bakare et al., 2024) that aim to protect personal data and privacy. What do you have to know about them? First, that GDPR is relevant to all personal data of EU residents across all sectors (including health), while HIPAA specifically covers health data in the U.S healthcare sector. This means that if you are building and deploying an mHealth app in the EU you have to comply with the GDPR, while you will have to comply with HIPAA if your target group lives in the US. Second, lack of compliance with any of the two involves significant penalties of up to

20 million Euros or 4% of global annual revenue for the GDPR and up to 1.5 million USD per violation/year for HIPAA infringements.

Since GDPR has a broader scope and more comprehensive requirements, below is a short description of its elements and their relevance to mHealth apps. This description is based on the GDPR official text (EUR-lex, 2016) and the eHealth Network's mHealth guidelines (EU4Digital, 2020). While not all elements may apply to every mHealth app, they provide an overview for implementing privacy-compliant mHealth solutions.

Table 2. GDPR requirements in the context of mHealth apps

GDPR element	*Short description*	*Relevance for mHealth*
Data minimization	Only collect data that are necessary for the specific purpose.	Health apps to only collect essential health data.
Lawful basis	Must have legal grounds to process personal data (consent, contract, legal obligation, etc.).	Health apps need explicit consent to process health data.
Privacy by design	Privacy must be built into systems from the start, not added later.	Essential for mHealth app development process.
Right to be forgotten	Right to be forgotten Users can request the deletion of their personal data.	Users should be able to delete their health app data.
Data portability	Users can request their data in a usable format and transfer it.	Important for transferring health records between apps and EHR.
Breach notification	Must report data breaches within 72 hours.	Important for health data breaches.
Special categories	Extra protection for sensitive data (including health data).	Health data is explicitly considered sensitive.
DPO requirement	Required for large-scale processing of special categories of data.	Larger mHealth platforms might need to hire a Data Protection Officer.
Data transfers	Restrictions on transferring data outside the EU.	Relevant for cloud-based health apps.
Processing records	Must maintain documentation of data processing activities.	Important for health data audit trails.

Transparency	Clear communication about data processing to users.	To be included in health app privacy policies.
Storage limitation	Data shouldn't be kept longer than necessary.	Important for the retention of health records.
Purpose limitation	Data collected for one purpose can't be used for another without consent.	Relevant for health data used in mHealth research.
Data security	Appropriate technical and organizational measures.	Should be implemented in apps for protecting health data.
Child protection	Special provisions for processing children's data.	Relevant for pediatric health apps.
Automated decisions	Right to not be subject to purely automated decisions.	Important for AI-based health diagnostics.

Most mHealth apps fail to meet these requirements currently (Alfawzan et al., 2022), but it would be critical for them to align with these standards. As mHealth apps mostly deal with critically sensitive data, any initiative of building a new digital solution should strive to integrate these requirements, to ensure privacy of personal and sensitive data.

Security requirements for health apps

Beyond data privacy, data security is another important consideration when developing any health applications (including mHealth apps). Research into the mHealth security requirements or measures which should be taken in this regard, point to seven categories of security needs: secure data storage, access controls, data transmission security, audit data trails, permission management, third-party data sharing, and vulnerability management. In this section we will go over each of them, highlighting mechanisms of addressing them. We do not plan to treat them exhaustively, but rather make note of them and introduce the subject. Each of these points should be the subject of discussion within the mHealth app development team, and specific measures should be planned for each of them.

For **secured data storage**, health apps must implement encrypted data storage on devices and servers to protect sensitive medical information. This includes both data at rest (referring to data stored on any device or network) and in transit (data actively moving from one location to another such as on the internet) (Nurgalieva et al., 2020). Regarding **access controls** (referring to restrictions around who can access the data), apps require robust authentication

mechanisms, including secure password policies and optional biometric authentication, such as fingerprint or face ID, where appropriate. Allowing access to certain parts of the data based on roles defined for different types of users, also known as role-based access control, helps ensure users can exclusively access data they are authorized to view (Gelinas et al., 2023). In addition, all **data transmission** between apps and servers must use industry-standard encryption protocols like Secure Sockets Layer (SSL) or Transport Layer Security (TLS) (Nurgalieva et al., 2020). All data transmissions, access, and modifications must be tracked through comprehensive **audit trails** - a documentation of actions, events or changes in the digital system, monitoring compliance with procedures and detecting unauthorized access of data (Gelinas et al., 2023). Similarly, apps should communicate what data they collect and obtain explicit user consent for any data collection. Granular permission controls let **users manage what information they share** (Nurgalieva et al., 2020). If any **user data is shared with third parties**, this must be disclosed to users with clear documentation of security measures those parties employ (Gelinas et al., 2023). Finally, regular **security testing and timely resolution of vulnerabilities** is essential. Apps should undergo penetration testing, a simulated cyberattack meant to identify any possible security vulnerabilities, before release and maintain secure software development practices (Nurgalieva et al., 2020).

Healthcare data exchange standards

Data standards are another critical topic when designing any mHealth app, as they ensure different digital systems are able to "speak the same language" and communicate information in a mutually-understood way. For example, when a blood pressure reading moves from a wireless monitoring device to a phone's health app, and then to a doctor's computer system, the numbers and units must stay accurate and reflect the same information. Healthcare data exchange standards make this possible by **defining common rules for how health data should be collected, formatted, structured, and transmitted**. These standards help handle all data types, from basic measurements like heart rate to complex medical imaging data from brain scans. Beyond technical compatibility, healthcare data standards support data quality and consistency across different systems and facilitate data analysis and research.

Understanding these standards would help anyone build mHealth apps that are able to connect and integrate with broader healthcare systems. While multiple data standards are available, we decided to focus on the three international standards (HL7 FHIR, SMART on FHIR, and IEEE 11073) and one European standard (the European EHR Exchange Format). Let's consider each one of them.

HL7 FHIR (Fast Healthcare Interoperability Resources) (*eCQI Resource Center*, 2025) is the leading modern healthcare data exchange standard that should be followed by all mHealth apps. This standard defines how healthcare information, from patient demographics to

clinical observations, should be structured and exchanged between parties (for example, mHealth apps, EHR, or insurance companies). Below, you can see how three very common health variables are operationalized under FHIR, which will help you better grasp how this standard works.

Table 3. Sample of variable operationalization under the HL7 FHIR standard

Data element	Description	Measurement/ Preferred code systems
Date of birth	The date of birth of the patient [ISO TS 22220]. As age of the patient might be important for correct interpretation of the test result values, complete date of birth should be provided.	Uses ISO 8601 format: YYYY-MM-DD
Gender	This field must contain a recognised valid value for "administrative gender". If different, "physiological gender" should be communicated elsewhere.	Male, female, other, unknown
Health conditions	Health conditions affecting the health of the patient are important to be known for a health professional during a health encounter.	Codes from ICD-10 SNOMED CT GPS ORPHAcode if a rare disease is diagnosed

Note: to review the full list of variables under the HL7 FHIR, access the Guidelines on Patient Summary, Release 3.4, November 2024.

SMART on FHIR (HL7 FHIR, 2023) builds upon the FHIR standard by adding a layer that allows securely integrating third-party apps with healthcare systems. SMART is an acronym which stands for Substitutable Medical Applications, Reusable Technologies and it offers a set of rules and mechanisms to easily connect any mHealth app to any Electronic Health Record that uses the same standard. In other words, it provides a standardized way for mHealth apps to authenticate, access and provide access to health system data securely. As you can imagine, if you are building an mHealth app that needs to read (request) data from an EHR or write (send) data into an EHR, making use of the SMART data standard could prove to be very valuable.

IEEE 11073 is a standard for personal health devices (IEEE 11073 Standards Committee, 2025), such as wireless devices connected to mHealth apps. This standard ensures that health-monitoring devices like blood pressure monitors, weight scales, and glucose meters can reliably communicate their measurements in a standardized way to the apps on the users' phones. As a result, any mHealth app which is designed to receive input from any

health-monitoring device should make use of this standard, to maximise the possibility of it communicating effectively with these devices.

The European Electronic Health Record Exchange Format (*EHRxF Electronic Health Record Exchange Format*, 2025) was introduced by the European Commission in 2019. It builds on HL7 FHIR, and supports the sharing of patient health records across EU borders by establishing rules for six main types of patient data: patient summary, electronic prescriptions, electronic dispensations, laboratory results, medical imaging and reports, and hospital discharge reports. This standard is especially relevant for mHealth apps focusing on medication management, patient portal apps, or chronic disease management apps.

Medical device regulations

We first mentioned mHealth apps as medical devices in Chapter 2, where you can find examples of mobile applications that work as medical devices. But how are these different from regular mHealth apps? First, they are intended for diagnosing, preventing, monitoring, or treating diseases. Second, they may be used to make medical decisions or calculations that directly affect the care received by a patient. Third, they might be used to control the operation/functioning of other medical devices. When categorized as medical devices, mHealth apps have extra compliance measures which need to be respected, as their operation is much more consequential to human life. As a result, they need to comply with the Medical Device Regulation (MDR)/Directives 93/42/EEC (EUR-lex, 1998) in the EU and with the Federal Drug Administration (FDA) in the US. But how do you know if an app is a medical device? This is a very important question. The key factor here is intended use: is the app making some type of medical decision that might affect a person's health? If the answer is "yes," then it is very likely that it might undertake the role of a medical device. And if so, you can proceed to review the Decision steps to assist qualification of Medical Device Software (MDSW) (Directorate-General for Health and Food Safety, 2025), which could help you establish with more certainty if it should be considered a medical device.

Ethical standards when working with human participants in mHealth development

Human participation is essential for mHealth development, especially in formative or initial stages of research, usability testing, and evaluation of mHealth apps. Yet, working with human subjects brings responsibilities for app developers that must not be overlooked. More specifically, participants in mHealth development should offer their informed consent for participation and sign a GDPR form when they share personal information.

As you probably already know, obtaining the informed consent of participants is a fundamental ethical principle that requires mHealth app developer teams to provide participants with written information about the purpose of their involvement in app development, including the procedures they will participate in and the associated risks and benefits. After reading this form, participants must voluntarily agree to participate by physically or electronically signing and dating the form. Similarly, participants who share personal information (i.e., name or medical/ health information) with the mHealth development team should also sign a GDPR form.

While they are not specifically developed for mHealth research, the templates and resources developed by the World Health Organization on informed consent (WHO, 2020) can be adapted and used for studies conducted with human subjects for mHealth development.

To meet the needs of students who read this book, we have also provided an **informed consent template in Annex 1**. Review the template sections and identify what's relevant for your project by keeping in mind that you:

- Can delete sections that don't apply and add any that are specific to your research.
- Should keep language simple and clear, and straightforward. To do this, imagine explaining your research to a friend rather than writing an academic paper.
- Should add concrete details about what participants will actually do. Instead of vague statements like "participate in research activities," spell out exactly what's involved - "use our mobile app for 4 weeks and complete three 30-minute interviews."
- Should format the final document to be easy to read, whether it's being viewed on paper or on a screen. Use headings, bullet points, and white space to break up dense text. The goal is a consent form that helps participants genuinely understand what they're agreeing to join.

This chapter explored key standards, regulations, and ethical guidelines shaping mHealth development. We started with privacy frameworks, looking at how GDPR and HIPAA protect patient data. Through security requirements, we explored what it takes to build safe health apps - from secured storage to access controls and data transmission protocols. Healthcare data exchange standards like HL7 FHIR showed us how health information moves between systems while keeping accuracy and meaning intact. Medical device regulations helped clarify when an mHealth app

crosses into medical device territory and what extra requirements apply. Finally, we examined ethical standards for working with participants in mHealth research and development. All these frameworks come together to ensure mHealth apps serve users effectively while protecting their rights and data.

As a public health practitioner, you don't need to become a legal or technical expert. But understanding these fundamentals helps you make informed decisions when developing mHealth solutions, prompts you to ask the right questions in your project team and ensures your interventions meet necessary regulatory requirements. Whether you're evaluating existing apps or helping design new ones, this knowledge lets you meaningfully contribute to discussions about standards and compliance in mHealth projects - or at least offer you starting points for further exploring the specifics of the ethical and legal landscape you are operating in.

SECTION THREE

mHealth deep dive: a case-study on smoking cessation during pregnancy


Mă energizează
Mă relaxează
Sunt dependentă de fumat
Acasă
Limitele există doar în mintea ta. Îndrăznește să faci tot ceea ce-ți propui!
VEZI TOATE
Jurnal
Săptămâna de sarcină
14
Țigări în fiecare zi
20
Activități cu Ioana
3
Recomandări noi
Data planificată a renunțării
Nestabilită
Nicio dată aleasă
Finalizează personalizarea
Experiența renunțării la fumat este
De ce să renunț la fumat?
01 Fumatul pentru mine
02 Beneficiile renunțării
03 Valorile mele și fumatul
Ce zic datele științifice
Planifică
Decide când vei renunța la fumat și alege acele soluții care să te ajute să-ți pui în aplicare cu succes planul de renunțare.
SARI PESTE
Activități
Activități recomandate
Istoria fumatului
Momentul memorabil
MAI MULTE ACTIVITĂȚI
Lista noastră de activități
Nicio activitate în listă
Informează-te
Află care sunt miturile legate de fumat, ce spun studiile despre beneficiile renunțării la fumat și ce strategii sunt recomandate când iei în calcul renunțarea la fumat.
SARI PESTE
Ce lucruri bune poate aduce în viața ta renunțarea la fumat?
Beneficiile
Sănătatea
Viitorul
Studiile arată că
Evoluție sarcină
14
Săptămâni
Comportamentul de fumat
20 țigări în fiecare zi
MODIFICĂ
AM RENUNȚAT
ALEGE DATA
Cum mă simt
Importanța renunțării 9/10
Încredere în mine 8/10
Pregătire 4/10
Fumatul pentru mine

CHAPTER 7

The Smoke-Free Together project and mobile app (SFT 2.0)

In the previous chapters, we've explored the foundations of mHealth, including its definition, key stakeholders, and the roles public health graduates can play in this rapidly evolving field. We've also examined the various types of mHealth applications, their integration into healthcare systems, and the most important standards, legislation, and ethical considerations that govern their development and use. Now, we'll contextualize this knowledge by examining a real-world mHealth application: the Smoke-Free Together 2.0 mobile app. This app is currently available in Romanian, but it will be used as a case study throughout the remaining chapters of the book, as it will help demonstrate how mHealth principles and concepts are applied in practice. It will also showcase the potential of mHealth to address a critical public health challenge: tobacco use during pregnancy. The app was built in Romanian as it aims to address tobacco use among pregnant Romanian smokers, but with increased scalability potential for other socio-cultural contexts.

This app serves as an ideal case study for several reasons. First, it demonstrates how mobile technologies can be used to leverage complex behavioral change by supporting smoking cessation and maintenance during pregnancy, a period of intense emotional and physical changes. Second, the app is unique as it incorporates a support person directly into the intervention through a connected app; it moves beyond the traditional single-user approach common in many health apps. Third, the app development process illustrates the value of research (including formative research, usability, and evaluation) in the design of mHealth apps. Along this line, the multiple phases of testing and feedback integration show the importance of user feedback in building mHealth apps that resonate with complex target audiences.

Finally, as we'll explore in subsequent chapters, this app incorporates many key elements of successful mHealth interventions: behavioral science, personalization, progress tracking, and behavioral support. By examining how this app was envisioned, designed, and built, readers will gain practical insights into the application of mHealth principles in real-world contexts.

The Smoke-Free Together 2.0 Project

Smoking cessation interventions are among the most cost-effective strategies in public health (Barnett et al., 2015; Streck et al., 2024). They reduce healthcare costs, decrease mortality rates, and improve quality of life for both smokers and those around them. Research has consistently shown that helping people quit smoking provides a strong return on investment through reduced healthcare spending and increased productivity (Connolly et al., 2018).

The SFT 2.0 project is a smoking cessation intervention during pregnancy. Tobacco smoking among Romanian women rose nearly 30% from 2011 to 2018, while quit attempts declined by 37% (Institutul Național de Sănătate Publică, 2018). We also know that 50% of women who smoke continue their habit during pregnancy (Meghea et al., 2012) and nearly 60% of those who quit during pregnancy relapse postpartum (Meghea et al., 2012). Smoking is particularly detrimental for women of reproductive age, as it not only affects maternal mortality and morbidity but also harms pregnancy, birth outcomes, and the health of their children (Avşar et al., 2021; Tarasi et al., 2022). As such, the SFT 2.0 app was aimed at supporting pregnant women in quitting smoking with the help of a support person (their partner, best friend, sibling, or anyone the pregnant woman decides to be involved in her smoking cessation process). Unlike previous smoking cessation apps, SFT 2.0 innovates by allowing pregnant women to choose any support person - not just their partners - to join them in their quit attempt. The project also includes motivational interviewing-based audio and video counseling sessions, making it a comprehensive intervention package.

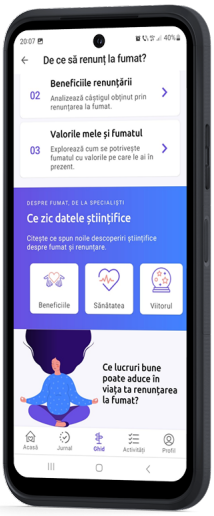
The project was implemented by a multidisciplinary team of researchers from Michigan State University, Wake Forest University School of Medicine, the University of Michigan, and the Department of Public Health at Babeș-Bolyai University in Cluj-Napoca, Romania, as part of the “A Smartphone Intervention for Pregnancy Smoking Cessation with Peer Support” funded by the National Institutes of Health, USA, through grant number R33 HD103039. This project was a hybrid, two-arm effectiveness and implementation randomized controlled trial. In the intervention arm, both women and their support partners benefited from the SFT 2.0 app. At the same time, women also had access to over-the-phone or online, motivational interviewing-based counseling sessions for smoking cessation. In the control group, the women had access to a one-page electronic leaflet describing the effects of smoking during pregnancy and the benefits of quitting.

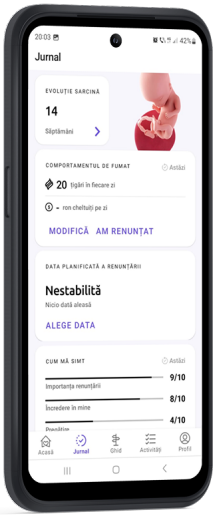
App features and content

The SFT 2.0 app consists of two interconnected mobile applications - one designed specifically for pregnant women who smoke (and want to quit smoking) and one for their

selected support person. The mechanism through which the two applications are connected, is through an invitation code generated by the pregnant woman for their selected support person. Only with that code can the support person access the app content. Both apps are available in Romanian, for Android users, and were designed to work together to support smoking cessation. The app is built on four main functionality groups, each with a specific goal in supporting quit attempts:

- Offers **scientific information** on the risks associated with smoking and on the benefits of quitting from multiple perspectives. The scientific information in the app also includes **multiple practical solutions** for quitting smoking, such as relaxation techniques, breathing exercises, and strategies for preparing for the quit date the users can set within the app. The app also includes a 'Panic' section for the times when women feel that they need help the most, with structured information on panic-scenarios, identified through previous research (such as a high stress moment, intense fear, anger, problems with the pregnancy, feeling overwhelmed by the pregnancy experience or even an intense cigarette craving moment).
- It contains **personalized content** based on their smoking status (all women start the app as current smokers, and in the moment they document a quit attempt, the app changes content for a former smoker/quit status), pregnancy week (providing information on week-by-week changes in their body during pregnancy, along with the baby's development and growth), even how women are feeling about quitting smoking (motivation, readiness and confidence to quit). This information is collected in the app via different modules, and an algorithm decides based on this information what content to push to the user, which would support them most in every given moment. The algorithm also adjusts the personalised content on users' personal barriers to quitting smoking, based on the information they provided when configuring the app.
- To keep users engaged in the quitting process, **the app lets users track their progress** by recording their smoking status, number of cigarettes smoked, how much money they have saved, document a quit date, and send them push notifications to keep them motivated and remind them of their set quit date.
- The **support received from a nominated peer** (partner, family member, friend) is the fourth functionality pillar, which allows the woman to invite a peer supporter through the app. The app teaches this support person how to talk about quitting in a helpful way, and suggests ideas on how to be there for the pregnant woman during the cessation process and beyond. Moreover, the app includes multiple **support activities** designed to help pregnant women in their smoking cessation attempt while improving the quality of the relationship. After completing each activity, both users can rate it on a 5-star scale, allowing app developers to curate activities based on user feedback.





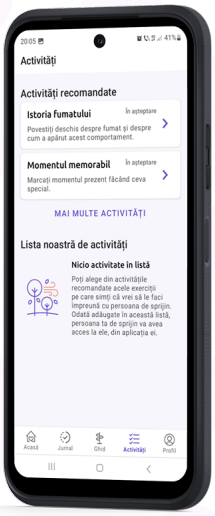
Scientific information

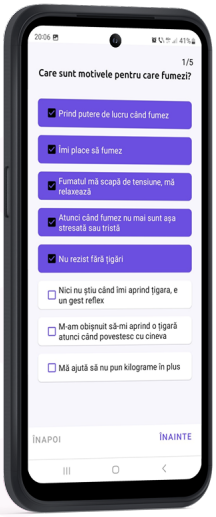
Practical solutions

Ability to track progress

Personalised content

Support from nominated peer





CHAPTER 8

Development process and timeline

The development of the app followed a user-centered approach across several key phases presented in Figure 8. The project began in November-December 2020 with formative research. During this phase, the researchers conducted in-depth semi-structured interviews with pregnant smokers and support persons to better understand their specific needs and challenges related to smoking cessation.

From January to July 2021, the core development of the SFT 2.0 app took place. This phase involved coding, making key decisions about app functionality, and developing the content for both pregnant women and their support persons. Between May and October 2021, the team focused on usability testing. They conducted systematic user testing sessions and made adjustments to the user experience (UX) based on observing users interact with the mobile app, as well as discussions on how they understood the content and perceived the interaction. This overlapping timeline with the development phase allowed for rapid iterations and improvements of the app. In September-October 2021, the project entered a training phase, where six counselors (practicing psychologists) were trained in motivational interviewing techniques - an evidence-based counseling strategy which is very effective in smoking cessation. From October 2021 to April 2022, an open trial phase was conducted. In research, an open trial is a type of study design where all participants receive the same treatment or intervention, and there is no control group. We conducted this study as a first step before the implementation of a more rigorous randomized controlled trial. In this phase, the team tested both the app and the counseling sessions with 20 pairs of pregnant smokers and their chosen support persons. This pilot testing helped identify any final adjustments needed before the full trial. Starting in December 2023, the full trial is planned to continue until August 2025, and it involves a full randomized controlled trial (RCT). This extensive trial aims to evaluate both the effectiveness of the intervention and its implementation with 300 pairs of users, also called dyads (pregnant women and their support persons). This systematic development process demonstrates how mobile health applications require careful planning, user input, and multiple rounds of testing before they can be deployed.

Figure 8. Timeline of developing the SFT 2.0 app

Throughout the remaining chapters of this book, we'll use the SFT 2.0 app to explore key concepts in mHealth development and implementation. In Section IV, we'll examine how the app incorporates behavioral design principles, analyzing how it uses the Social Determination Theory and Motivational Interviewing, tailored content and social support to promote behavior change. The app's use of motivational interviewing techniques and its approach to behavior change will serve as practical examples of theoretical frameworks in action.

By following this app's journey from concept to implementation, readers will gain practical insights into the complexities and considerations involved in developing effective mHealth interventions. Through each chapter, we'll return to specific features and development decisions of SFT 2.0 to illustrate key principles and best practices in mHealth development.

SECTION FOUR

Bridging the gap for mHealth: frameworks and methodologies

Public health, by definition, is a highly interdisciplinary field as it lies at the intersection of multiple domains. At this point in your studies, you are probably familiar with different topics in social and behavioral health, health policy and management, environmental health, biostatistics, and a range of other focus areas which have an impact on population health. Nonetheless, the area of technology is in itself a largely multidisciplinary field. As discussed in the earlier chapters, great tech solutions can only be developed when teams with diverse backgrounds come together, to collaborate toward a joint mission. The skills of managers, engineers, designers, data scientists and many other specialists are all critical when developing technology for humans to use. As a result, you can anticipate that the field of mHealth is even more interdisciplinary, as it is at the intersection of public health and technology.

Because the field draws heavily on multiple disciplines, it is essential to try to understand how to work at their intersection, drawing on the best practices of each. More so, when we bring all these different specialists to the table, we acknowledge they come with different backgrounds and we have to focus on developing a common language. In an attempt to support this type of collaboration, specialists have dedicated a lot of their time to designing frameworks that combine the different discipline practices, in a way that is helpful for mHealth. The field is still emerging, as the field of digital health is constantly developing and more and more teams take on ambitious objectives around mHealth.

In the last section of this book (*Practical mHealth*) we will focus more on learning by doing. But we considered that it would be essential to give you the context of how we arrived at that methodology. So in this section we will discuss a few frameworks which are important to take into account when developing mHealth solutions. We aim to do that by illustrating some of the more important frameworks which lay at the foundation of the approach proposed in this book, while focusing on the work of authors who proposed ways of integrating methods coming from different fields (such as behavioral design, design thinking and program evaluation) to be used for mHealth.

CHAPTER 9

Behavioral science in mHealth development

Behavior change is complex, especially for deeply-rooted behaviors like smoking, physical activity, or dietary habits. In Chapter 1, we introduced a discussion about the large number of available mHealth apps (350,000 apps in 2018, with estimates suggesting this number has since doubled). However, most mHealth apps struggle with minimal usage, poor engagement, high drop-out rates, and failure to change the health behavior they have been developed to tackle. For example, research indicates that up to 74% of users disengage after 10 uses of an application (Torous et al., 2018), which is typically insufficient for positive behavior change. Those who stick around tend to stop using the apps between 3 to 6 months after they first installed them (Taki et al., 2017). With such low engagement and high drop-out rates, most apps do not support behavioral change (Lee et al., 2018). These challenges can be attributed to a lack of integration of behavioral science techniques in app design, despite evidence that behavioral techniques can improve user engagement and support lasting change (Payne et al., 2015).

But what is behavioral science and how should it be applied to mHealth projects? In essence, **behavioral science deals with the study of human behavior and the hypothesized mechanisms underlying behavioral change** (Davis et al., 2015). A more comprehensive definition is that behavioral science is an interdisciplinary field that uses theoretical frameworks to analyze factors (psychological, social, environmental, etc) that influence behaviors, examines how these factors can be altered to contribute to improved behaviors and to better health outcomes, and studies practical applications focusing on changing negative or risky behaviors.

This chapter does not aim to provide a comprehensive list of behavioral change theories and frameworks, but to highlight the importance of integrating behavioral science in mHealth and suggest some potential pathways or key steps to do so. Yet, for those of you who would like to take on the former task, we recommend that you review the 82 theories and

frameworks incorporating social, cultural, and economic factors that influence behavior, explored by Davis and colleagues (2015).

Returning to our endeavor, the key is the systematic integration of behavioral science in mHealth from the initial concept to implementation and evaluation. There are several pathways through which behavioral science can strengthen mHealth development. But first, let's see how we incorporated behavioral science in the Smoke-Free Together 2.0 app.

Behavioral science for the Smoke-Free Together 2.0 app

SFT 2.0 uses the **Social Determination Theory (SDT)** and **Motivational Interviewing (MI)** (Markland et al., 2005) as the main theoretical frameworks for supporting smoking cessation during pregnancy. Both of these frameworks work together in the app. SDT shapes the app design and features, while MI guides content development. This integration helps create an app that goes beyond tracking the number of cigarettes not smoked or the economic savings, but it offers actual behaviour change support to users. Let's dive into some more context on the theories, and understand how they have shaped the design of intervention and the associated digital solution.

Social Determination Theory (SDT) focuses on three core psychological needs that drive behavior change:

- **Autonomy:** Gives users a sense of control over their behavior. The app supports this by letting women select their own quit date and choose from various coping strategies that work best for them.
- **Competence:** Builds confidence in the ability to change. The app tracks achievements like number of smoke-free days and money saved to demonstrate progress.
- **Relatedness:** Fosters connection with others during the change process. The app enables this through its companion app feature, where users can choose and interact with a personal support person (selected by the users themselves, adding to the autonomy component too).

Motivational Interviewing (MI) is a user-centered counseling style designed to help patients resolve their ambivalence about change, such as whether to quit smoking or not. The app implements MI through four key principles:

- **Expressing empathy:** The self-help content in the app acknowledges the challenges of quitting during pregnancy, without judgment.
- **Developing discrepancy:** Weekly fetal development notifications help users see the gap between smoking and their desire for a healthy pregnancy.

- **Rolling with resistance:** A “panic button” feature provides immediate, on-demand support when users struggle with intense challenges, cravings or doubts.
- **Supporting self-efficacy:** The app shares testimonials and success stories from other pregnant women who successfully quit smoking.

These are just highlights of how the theoretical frameworks have influenced the design of the application, and they are very particular to each. Depending on what behaviour change theories you are building your solution on, you might design various ways to integrate them. In the next section, we will discuss in more detail *how* you can approach the integration of behavioural science in the design of mHealth solutions.

Pathways to integrate behavioral science in mHealth

Integration of behavioral science into mHealth app development should start from the **conceptualization phase**, which is basically a concrete idea or vision of how an app will work. Research shows that mHealth apps developed based on scientific theories and frameworks are more effective than those relying solely on developers’ intuition (Mohr et al., 2014). For instance, the PRECEDE-PROCEED model has been used to guide the core development of an obesity-focused app, ensuring the app addresses a comprehensive list of obesity determinants (Selvaraj & Sriram, 2022).

During the formative research or Empathize phase, which we will discuss in more depth in the next chapter, behavioral science can be used to assess behavioral barriers and facilitators. One framework that is especially useful for exploring these in a structured way is the COM-B (which we will come back to in Chapter 13). In this framework, capability (C), opportunity (O), and motivation (M) are used to identify key triggers, motivators, barriers, and social and environmental factors that influence behaviors. These are prioritized using the APEASE criteria in terms of anticipated Accessibility (can target users easily access this intervention? Are there barriers to access?), Practicability (can this intervention be implemented in the real word as intended?), Effectiveness (will this work in addressing the target behavior?), Affordability (what are the cost implications?), Spill-over-effect (are there any unintended consequences), and Equity (does the intervention create or reduce inequalities?).

In the **application’s design phases,** especially when deciding on the features to be implemented to address behavior change**,** integrating behavioral science can ensure that the way we build the solution, will facilitate future user engagement and adherence to the app. For example, goal setting, monitoring, and feedback, with clear and achievable targets and progress tracking, have been found to be effective in supporting adherence (Dugas et al., 2020; S. Liu et al., 2022). Another nice touch is achievement recognition,

with some apps offering badges or some form of celebratory acknowledgement to users whenever they hit a milestone or a goal they have previously set. Personalization, another item on the list of design features, fosters content tailored to the user's needs and wants, and individual goal adjustment. Similarly to goal setting, monitoring, and feedback, this too enhances user engagement and adherence to the app. Researchers have also found that apps that include mechanisms for ongoing support and provide constant feedback are more effective in sustaining behavioral change (H. Wang et al., 2021) and improved health outcomes (MacPherson et al., 2019; Debong et al., 2019). As such, if you ever find yourself in the position to decide on mHealth app features, don't forget about goal setting, monitoring, feedback, and personalization.

Finally, **behavioral science can and should be integrated in the evaluation of mHealth apps**, as it can indicate what outcomes we need to measure, it can guide on how to measure them (i.e., through validated scales and instruments) (Zhao et al., 2016; Vaghefi & Tulu, 2019), and it can help us identify what specific behavioral science techniques have the positive most impact on our desired behaviors and outcomes (Dugas et al., 2020). With these in mind, we can go ahead and develop iterative improvements of the apps, to enhance their effectiveness and user retention.

Introducing the ABACUS tool for rating mHealth apps' behavior change potential

At the end of this chapter we wanted to equip you with a tool that might be useful to you, as a public health specialist, when you are asked to recommend a mobile health app. Of course, there are hundreds of mHealth apps available for almost any health-related condition or behavior. Yet, most of them have not been tested for effectiveness. So how can you know which app to recommend? You can take a look at their potential to generate health behavior change by assessing them with the 21-item App Behavior Change Scale (ABACUS) tool (McKay et al., 2019). ABACUS is a reliable tool consisting of 4 dimensions (knowledge and information, goals and planning, feedback and monitoring, and actions) that you can use to rate and compare multiple apps across various health categories, enabling you to further recommend high-quality apps.

Let's use ABACUS to systematically evaluate the behavior change potential of the Smoke-Free Together 2.0 app, following its 21-item scale in Table 4.

Table 4. ABACUS analysis of the SmokeFree Together 2.0 app			
Category/Item	*ABACUS definition (McKay et al., 2019)*	*Present in SFT 2.0?*	*Evidence from SFT 2.0*
1. Knowledge and information			
1.1 Customize and personalize features	Elements of the app can be personalized through specific tools or functions	Yes	- Personalized by smoking status - Tailored to pregnancy week - Adapts to emotional state - Customized to personal barriers
1.2 Consistent with guidelines/ expertise	Created with expertise and/or provides information consistent with national guidelines	Yes	- Developed through university collaboration - NIH grant-funded - Uses evidence-based approaches (SDT and MI)
1.3 Baseline information	Collects initial user information	Yes	- Smoking status - Pregnancy stage - Quit attempt history - Personal barriers & motivators for quitting
1.4 Instruction on behavior	Clear instructions on performing behavior or preparatory behaviors	Yes	- Practical quitting solutions - Relaxation techniques - Breathing exercises - Quit date preparation strategies
1.5 Information about consequences	Information about behavior consequences	Yes	- Smoking risks during pregnancy - Quitting benefits - Fetal development information
2. Goals and planning			
2.1 Willingness for behavior change	Assesses readiness for change	Yes	- Quit date setting - Milestone tracking
2.3 Review goals/ update	Ability to review and modify goals	Yes	- Switch from smoker to quit state and reverse - Modifiable quit date - Progress tracking

3. Feedback and monitoring			
3.1 Current vs future goals	Shows progress toward goals	No	
3.2 Self-monitor behavior	Regular behavior monitoring	Yes	- Money saved - Cigarettes tracked
3.3 Share behaviors	Social sharing capabilities	No, but...	- Connected supporter app - Progress sharing - Social accountability
3.4 User feedback	Provides feedback on behavior	Yes	- Motivational notifications - Encouragement - Personalized feedback
3.5 Export data	Ability to export information	No, but...	- Shared insights with support person - Accessible to both users
3.6 Rewards/ incentives	Provides rewards or incentives	No, but...	- Money saved tracking - Achievement recognition - Positive reinforcement
3.7 General encouragement		Yes	- Motivational messages - Progress recognition - Supporter encouragement
4. Actions			
4.1 Reminders/ prompts	Activity reminders or cues	Yes	- Motivational notifications - Quit date reminders - Strategy prompts
4.2 Positive habit formation	Encourages positive habits	Yes	- Alternative behaviors - Coping strategies - Healthy habit suggestions
4.3 Practice/ rehearsal	Extra practice opportunities	Yes	- Relaxation exercises - Breathing techniques - Coping practice
4.4 Barrier planning	Plans for overcoming barriers	Yes	- Barrier identification - Coping strategies - ‘Panic’ button

4.5 Environment restructuring	Support for environmental changes	Yes	- Smoke-free environment guidance - Social support integration - Trigger management
4.6 Distraction/ avoidance	Helps avoid triggers	Yes	- 'Panic' button - Alternative activities - Trigger avoidance strategies

The Smoke-Free Together 2.0 app meets all 18/21 ABACUS criteria, demonstrating strong potential for behavior change.

This chapter showed how behavioral science strengthens mHealth apps, moving beyond simple tracking to create tools that actually change health behaviors. We unpacked why most health apps gather dust after a few uses, and how behavioral frameworks can fix this. From the first sketch of an app through testing and launch, behavioral science offers practical ways to boost user engagement and support real change. In the following chapter we will discuss Design Thinking as a core pillar in designing digital solutions (and in our case, mHealth apps), and propose a mechanism of integrating Behavioral Science with Design Thinking.

CHAPTER 10

Design thinking in mHealth

Although you might not regard yourself as a designer, as humans we constantly design things around us. Most things we look at everyday are artificial and human-built, and a result of someone's design. Even as public health experts you might find yourself in the position of designing health programs and interventions, health services or even health systems. But relying solely on a scientific approach to tackle these challenges may not always lead to the most effective, user-centered solutions. Approaching difficult problems with a designer mindset (design thinking or design cognition) might result in innovative solutions that are outside of traditional approaches. With this in mind, this chapter introduces how designers think, how they approach problems, and how they go about developing solutions. It will also introduce you to the concept of Human-Centered Design, an essential approach to designing digital health solutions.

Designers have a different way of perceiving and exploring the world, compared to scientists, engineers or artists. One of the first influential scholars to examine these differences is Nigel Cross, who in his book *Designerly ways of knowing* dives deep into these unique ways of thinking. For example, he references Bryan Lawson's 1979 experiment, who recruited students of architecture (allocated to the designer group) and students of sciences (allocated to the scientist/non-designer group) to compare their problem-solving strategies in solving a practical wooden blocks puzzle. The experiment gave students some of the rules which allowed solving the puzzle, but other rules were not communicated, and left for them to discover. The only tool they did have, was a computer which gave them feedback on a proposed solution, informing the teams if the solution respected the rules or not. The results of the experiment revealed that the science students (the non-designers) tended to analyze the problem structure and the wooden blocks combinations until they discovered all the underlying rules. Only after, they proceed to solve the puzzle, in an analytical, problem-focused way. In contrast, architecture students (the designers) started by exploring all the possible solutions, eliminating the ones which received negative feedback from the computer, and iterated on the remaining solutions, until they found the adequate one. They had a creative, solution-focused approach, based on

learning about the problem through testing possible solutions. Apparently, the designers were used to problems which did not lend themselves to exhaustive solutions.

As seen in the experiment above, a designer's mindset approaches problem-solving differently—favoring synthesis over exhaustive analysis and rapidly generating solution alternatives for testing. Unlike analysis, which involves breaking a problem down into its components and examining each in detail, synthesis focuses on integrating different elements to create a holistic understanding. **Designers draw connections between various aspects of a problem, identify patterns, and generate solutions quickly, rather than exhaustively analysing every aspect before taking action**. This approach lends itself to practical solutions within limited timeframes and to making decisions despite incomplete data, with solutions further refined through testing. As a result, in the day-to-day practice of designers, we often pivot between an analytical mode (focusing on understanding the problem-space) and a creative mode (focusing on modelling the solution-space) and learning by trial and error, rather than exhaustively understanding all the requirements in advance.

Another important difference between designers and other specialists is that designers create for something that does not exist yet. For example, most mHealth apps do not have a direct predecessor at the moment they are built—they need to be built from scratch, requiring designers to test and refine their approach. As a result, the methods we use are a bit different than in other disciplines which work in less ambiguity and uncertainty. But exactly this ability to address poorly defined and difficult (often referred to as *Wicked*) problems, is one of design's superpowers. **As designers we learn about the world and discover what works by building things, testing what we have built and then improving them**. In such a case, building in small increments (based on the best available data) then testing and improving for the next iteration only to then test again (and so on) is the way new products are developed. This might be very different from the way other disciplines (even public health) approach difficult problems, where an initial exhaustive (very detailed) research and a follow-up detailed plan are needed before implementing anything. Building for digital products is no different than other areas of design, so design thinking has also been adapted as a methodology in digital product teams. A simplified version of how designers approach challenges has been formalized in Design Thinking Methodology, which we will use as a guide through the stages of building an mHealth application concept.

Divergent and convergent explorations: introducing the Double Diamond

The Design Thinking approach has gained immense popularity over the years, as a way of supporting the exploration of the world from a designer's perspective. In 2003, the UK Design

Council popularised the Double Diamond, a simplified method to describe and deconstruct the design process. Built on the previous work of theoreticians in the field of problem-solving and design, the Double Diamond (Figure 9) has since been accepted worldwide as a tool of reference (Design Council, 2023).

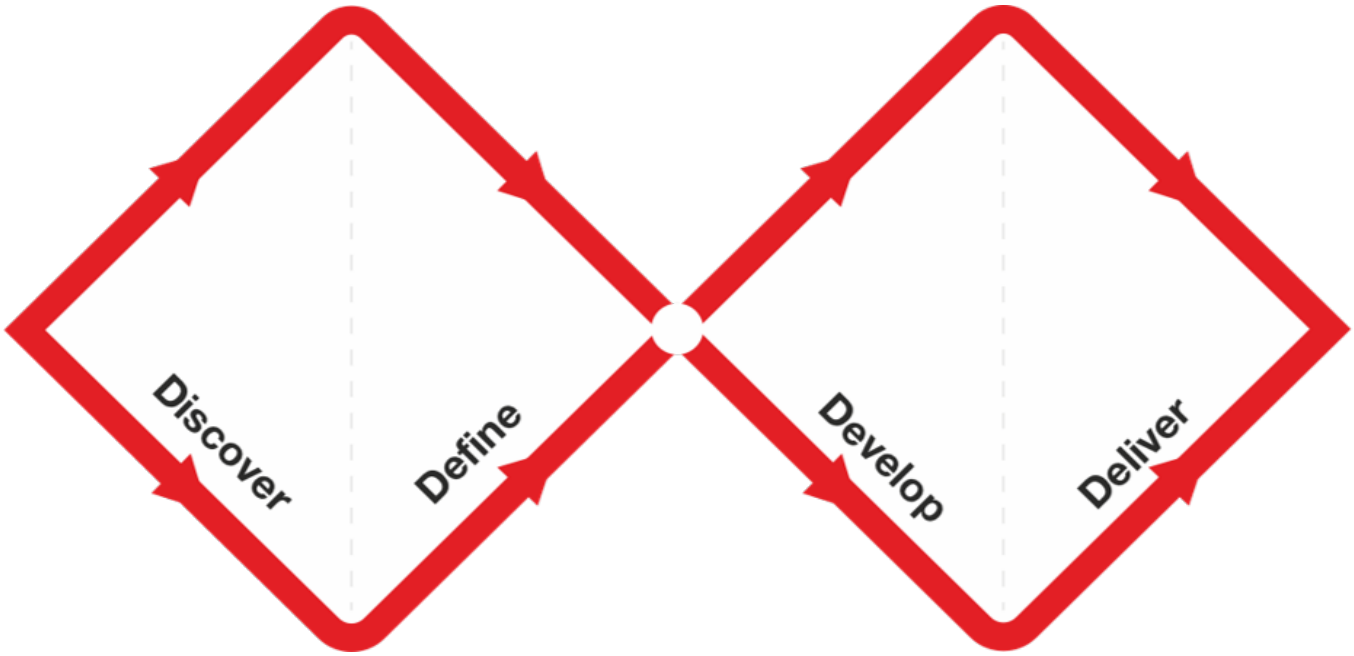


Figure 9. The Double Diamond by the Design Council, licensed under a CC BY 4.0 license.

The *Double Diamond* framework provides a structured approach to problem-solving, guiding us through two key stages: the problem space and the solution space. Each space first consists of a divergent phase, where we expand our thinking to explore multiple possibilities, and a convergent phase, where we narrow our focus to define a clear direction. The framework gets its name from its visual representation, in which the alternation between divergent and convergent phases forms the two diamonds: one representing the problem space and the other the solution space.

The first diamond focuses on the problem space and begins with the Discovery Phase, where our goal is to understand the problem, the people affected by it, and the broader context in which it occurs. This is a **divergent phase**, meaning it involves expanding our perspective, using research to explore the multiple facets of the problem. The Discovery phase is followed by the Definition Phase, a **convergent phase** which narrows the focus as the insights gathered are synthesized to refine the problem into a well-defined design challenge.

Once the problem is defined, we move into the second diamond, which focuses on the **solution space**. The Develop stages encourages us to identify different answers (possible solutions) to address the design challenge articulated in the previous phase. This again is a **divergent** phase, in which we aim for a high volume of various solutions and approaches, to

be then tested in the next phase. Finally, the Deliver phase focuses on testing the solutions in small-scale research initiatives, to discard the ones that don't fit while refining the ones that look most promising. This latter phase is again a **convergent** phase, in which we reduce the number of possible solutions to the one which will be implemented. As we could observe, the first diamond is thus focused more on the problem (also known as the problem-space), while the second diamond focuses on identifying the solution (the solution-space). The Double Diamond uncovers how designers use divergent and convergent approaches, to navigate between the problem space and the solution space.

The way designers think and work brings a unique approach to the development of mHealth solutions. Think back to the wooden blocks experiment - designers tested all possible solutions they could think of, learning as they went along. This same approach is valuable when building mHealth apps. We are facing complex health problems that don't have clear solutions at the start. Yet, by exploring widely, trying our different approaches, and testing with real users, we craft solutions that work and make sense for the users who rely on them.

The Behavioral Design Thinking process

Many times, mHealth technology is used in public health with the goal of changing human behavior for improved health outcomes. In this context, Behavioral Design is highly relevant alongside Design Thinking, in building mHealth solutions that support the behavioral goals. Voorheis and colleagues (2022) have conducted a review of mHealth research that integrated Design Thinking (as a methodology) and Behavioral Design, with the goal of improving health outcomes. The framework which they mapped out defines five phases of what was named the Behavioral Design Thinking process. The five phases are mapped on traditional design thinking stages, such as Empathize, Define, Ideate, Prototype and Test, while the authors integrated and recommended specific behavioral design activities to be integrated in each phase. They are described as follows:

- Step 1. **EMPATHIZE** with users, and their behavior change needs. This stage is traditionally a divergent one and aims to understand the users and their context, their experiences, attitudes, beliefs, preferences, needs, health behaviors, determinants of behaviors as well as relevant behavioral theories/ models/frameworks and behavior change theories (BCTs). Activities undertaken in this stage are primary and secondary research.
- Step 2. **DEFINE** user needs and behavior change requirements. This step focuses on defining the design challenge and system requirements that respond both to user needs as well as behavior change needs.
- Step 3. **IDEATE** user-centered solutions and behavior-change content. The stage is centered around ideation, the creative process of idea generation, and co-design of directions for solutions that would support behavior change, while responding to user needs.

- Step 4. **PROTOTYPE** user-centered solutions which support behavior change. It refers to translating ideated content and functionality (features) into prototypes (wireframes, paper prototypes, use-case scenarios, representations/diagrams) together with BCT flowcharts illustrating how BCTs will be interacted with.
- Step 5. **TEST** against user needs and behavior change potential. This step focuses on piloting and testing the solution, both in terms of acceptability and use, but also behavior change potential. This stage involves a mix of expert evaluations and testing with users.

While the effective integration of Design Thinking and Behavioral Design for the development of mHealth technology and mHealth interventions is still in a process of being operationalized internationally, the work of Voorheis and colleagues offers a good start for bridging the gap between technology, health behavior change and public health.

In the next section of the book (Section V) we will integrate these models (design thinking and behavioral design) in a step-by-step, hands-on approach to mHealth development, which could be used by public health students to navigate their first project in the field. For this purpose, we will use the same five stages described above (Empathize, Define, Ideate, Concept Design & Prototype, and Test), to which we add an additional first step, essential at the beginning of any mHealth intervention - the identification and validation of a health problem to be addressed by the intervention. We have named this initial stage **Discover** and it focuses on understanding in-depth the health problem to be addressed, the scientific and theoretical landscape around the topic, while identifying approaches that have proved successful (and are documented in the literature) to address the health challenge. But before jumping into Section V, we would like to bring another set of methodologies to your knowledge in the next chapter, which focus on evaluating mHealth applications and associated interventions.

This chapter discussed Design Thinking as a methodology for approaching mHealth solutions. As we could see, designers tend to work with design challenges in a creative, solution-focused manner, relying more on data synthesis than exhaustive data analysis. They learn about the world by building solutions and testing them, constantly iterating and improving them. In this sense we also introduced the Double Diamond, a representation of the sequence of divergent and convergent stages in Design Thinking, which are core to the methodology and its iterative approach. Lastly, we introduced the Behavioral Design Thinking framework, and

described each step in the process of designing an mHealth solution with a behavioral component. All the information provided in this chapter is a theoretical foundation for section V of the book, where each Design Thinking stage will be explained in a step-by-step approach, with examples. But before jumping into the practical part of the book, let's discuss one more topic: evaluation frameworks useful for mHealth technology.

CHAPTER 11

Evaluation frameworks for mHealth

Picture this: you've spent months - or maybe more than a year - developing a mHealth app. You used behavioral science and design thinking to guide the content and features, the interface looks great, the features work smoothly, and you and your team are excited to launch. But how do you know if the app helps users improve their health? This is where evaluation comes in. Yet, evaluation should not just be the final step in the app development process; it should be one of the main things you have in mind throughout the development process. But what does mHealth evaluation refer to? We are not talking about the app store's five-star user rating system, which, by the way, is not correlated in any way with the app's effectiveness (Levine et al., 2020). In this chapter on mHealth evaluation we will discuss stress testing, a type of technical evaluation, feasibility studies, usability evaluation, effectiveness studies, and implementation research in relation to mHealth. Looking at the Smoke-Free Together 2.0 case study, evaluation played multiple roles throughout development. Early feasibility testing helped assess whether pregnant women would engage with a smoking cessation app. Usability studies revealed which features needed refinement. The randomized controlled trial currently underway examines both implementation factors and health outcomes.

Stress testing

Before deploying an mHealth app to users, it's crucial to verify that it can handle real-world usage conditions. Stress testing, a type of quality assurance evaluation designed to mimic real-world app usage scenarios, ensures that the app won't fail to do the tasks it was built to do. This type of evaluation looks into app flows (i.e., if screens show up in the correct order based on users' activity), how many users can the app support, how it handles large volumes of health data, or does it work on any phone models/screen sizes or in areas with poor connectivity? This type of testing is usually conducted by more technical, developer teams.

Usability testing

Usability is defined more formally as the "extent to which a system, product or service can be used by specified **users**, to achieve specified **goals**, with **effectiveness**, **efficiency** and **satisfaction**, in a specified **context of use**" (*ISO 9241-11:2018. Ergonomics of Human-System Interaction. Part 11: Usability: Definitions and Concepts*, 2018). This definition highlights the fact that usability is concerned about how target users interact with an interface, to achieve relevant goals to them, in a defined context of use. For mobile solutions in particular, context of use (where and how the solution is being used) is highly relevant when designing an app, so special considerations should be given to this. Finally, the definition also describes three of the most important usability attributes: effectiveness, efficiency and perceived user satisfaction, which we typically measure in usability evaluations (and usability testing).

A more informal definition of usability is offered by Jefferey Rubin in his book *Handbook of Usability Testing*, who notes that "when a product or service is truly usable, the user can do what he or she wants to do, the way he or she is expects to be able to do it, without hindrance, hesitation, or question" (Rubin et al., 2008, p. 3). And Jakob Nielsen more simply states that usability is "a quality attribute that assesses how easy user interfaces are to use." (Nielsen, 2008). Due to the fact that mHealth interventions have a strongly mediated channel of communication (we deliver content to users via an interface of a mobile app), testing the usability of our solutions is critical, to ensure that the information reaches users in a way that can be maximized.

When testing how well your mHealth app can be used by users, you'll likely choose between two main approaches: moderated and unmoderated usability testing. Each serves a different purpose, and you might end up using both during your app's development journey.

Moderated testing puts you (or a researcher) in the room with users as they use your app or a high-fidelity prototype of your app. Think of it as observing users while they explore the features and solve different tasks using the app (we typically call them activities in our user testing sessions). Because you are in the room facilitating the session, you also have the opportunity to probe, explore and clarify in follow-up discussions the experience they have while performing the activities. In our Smoke-Free Together 2.0 project, moderated testing revealed insights about how pregnant women navigated the app, how they found different information, and how they interpreted different messages about quitting smoking. We also asked follow-up questions right when we noticed confused expressions or hesitation, and explored in-depth any challenges in the interaction with the interface. Users are encouraged to think aloud as they go through the activities, giving you immediate insight into their thought process. The method thus offers rich qualitative data which can be used to understand the "why" behind users' actions or behaviors (Meidani et al., 2024).

Unmoderated testing takes a different approach, as users interact with your app and perform different pre-defined activities using the app on their own time, in their natural environment. The usability test is typically set-up in a dedicated testing environment (online), so there is no need for a researcher to facilitate the session. This often leads to more authentic behavior patterns as users can engage with the app as they normally would in their daily lives (Adu et al., 2020), but also less opportunity to explore in more depth aspects which occur in the testing session. As opposed to moderated usability testing, this approach can reach more users and, therefore, generate more usability data and insights (including quantitative metrics such as time on task or task success rates). Some research indicates that it could be more cost-effective, but typically lacks the rich qualitative insights which moderated testing can offer.

A key insight from our experience with the Smoke-Free Together 2.0 app and our recent research (Johnson et al., 2022) is that you don't have to choose only one approach. Consider using moderated testing early on when you need to understand fundamental usability issues, then switch to unmoderated testing to test your solutions with a broader audience.

In the last section of this chapter we would like to invite you to take a look at a standardized tool designed to measure usability of digital systems - the **System Usability Scale (SUS)** (Brooke, 1995). The SUS was developed in 1986, almost 40 years ago, and it contains 10 statements that users are prompted to answer on a 5-point Likert scale from "strongly disagree" to "strongly agree". We can use this tool as a self-administered test, on users which have interacted with a system (in our case an mHealth app), to get insights on perceived user satisfaction and usability. It can be used to evaluate the experience of any type of mHealth app, and it can give you an indication of the usability level of the app on a scale from 0 to 100 (scores above 69 are considered above average, while anything over 80 indicates excellent usability). While the SUS is great for getting a general measure of usability, it won't tell you specifically what needs fixing in your app. That's why we typically use it alongside other evaluation methods, like the usability testing approaches we just discussed.

Feasibility studies

In the public health field, a feasibility study aims "to test whether planned study procedures or intervention components will be workable and practicable" (Bowen et al., 2009). Basically, a feasibility study is warranted in several situations, particularly when (Bowen et al., 2009): your mHealth intervention needs to establish, increase, or sustain community partnerships; you have few previously published studies on your specific intervention; prior studies of your intervention approach weren't guided by behavioral and cultural insights of the target population; previous interventions using similar methods haven't succeeded, but improved versions might work; or you're adapting a successful intervention for a different setting or population.

There are several areas that feasibility studies should examine, including - but not limited to the acceptability of the app and integration into current electronic systems. Let's dive into app **acceptability**. This looks at how your intended users - both the target population and those implementing the program - react to the app. Acceptability studies often measure retention rate (how many of the original users are still using the app at 1, 3, or 6 months after original installation), patterns of app use (including daily active time, user engagement/feature, and time of day for app use), intent to continue use, and whether users would recommend the app to others.

The second key area is **integration** - how well your mHealth app fits into existing healthcare systems and workflows. Integration feasibility studies usually focus on electronic health record (EHR) compatibility, data standards compliance, provider workflow integration, patient journeys, staff training requirements, and cost implications.

Think of feasibility testing as your app's first real-world test: it helps ensure that users will engage with your app, that healthcare systems can integrate it effectively, and that your intervention can deliver its intended health benefits. While feasibility studies require time and resources upfront, they ultimately save both by helping you develop an mHealth solution that works in the real world, not just in theory.

Effectiveness research

These studies assess whether the mHealth intervention has an impact on changing health outcomes and behaviors. Common study designs in effectiveness research include randomized controlled trials (RCTs), quasi-experimental studies, and pre-post evaluation studies.

Randomized controlled trials (RCTs) provide the strongest evidence for whether an mHealth intervention works (Domanski & McKinlay, 2009). Think back to our Smoke-Free Together 2.0 example - we randomly assigned participants to either use our app or receive standard care. If you want to read the full details on the design of our RCT, you can freely access the article which describes our study protocol. This random assignment helps ensure that any differences in quit rates between the groups are due to the app itself, not other factors. While powerful, RCTs come with real challenges. They're expensive, time-consuming, and their highly controlled nature means the results might not fully reflect how your app will work in the real world or with other target groups.

Sometimes, an RCT isn't practical - for instance, if you're evaluating how an existing mHealth app works across an entire healthcare system where random assignment isn't possible. In these cases, **quasi-experimental designs** can help (Cook & Campbell, 1979). In these studies,

you still compare groups who do and don't use the app, but without random assignment. For example, you might compare health outcomes between clinics that implement your diabetes management app and those that haven't yet adopted it.

The simplest approach is measuring outcomes before and after introducing your mHealth intervention - what we call **pre-post studies** (O'Connell et al., 2017). While straightforward to conduct, these studies can't tell us definitively whether changes in health outcomes were caused by your app or by other factors happening at the same time. Still, they can provide valuable initial evidence about your app's potential impact, especially during early development phases.

Implementation research

Implementation science applied to mHealth examines the impact of mHealth solutions in real-world settings. One widely-used implementation evaluation framework is **RE-AIM**. The acronym stands for Reach, Effectiveness, Adoption, Implementation, and Maintenance. Let's explore these elements one at a time.

Reach assesses the extent to which the members of the target population participate in your intervention. For instance, as public health practitioners it is important for us to understand who is participating in health interventions, to ensure that interventions are inclusive and equitable (Kwan et al., 2019). For instance, reach was reported for an intervention for social risk screening by patients and parents in pediatrics clinics by looking into the percentage of participants who completed the screening vs those who were approached (De Marchis et al., 2019), by comparison across the demographic characteristics of participants and non participants.

Effectiveness measures the impact of the intervention on pre-selected primary and secondary health and behavioral outcomes at the individual level. For example, Effectiveness outcomes for an intervention designed to increase physical activity levels might include weight, BMI, waist circumference, and engagement in physical activity (Jauregui et al., 2015).

While Reach and Effectiveness are individual-level dimensions, Adoption, Implementation and Maintenance work together as system-level dimensions that help us understand how interventions are taken up, delivered, and sustained over time. **Adoption** refers to the settings and staff members who take on an intervention. When measuring adoption, researchers look at both numbers - how many settings and staff participate out of those invited - and characteristics - how representative are participating settings and staff compared to those who don't participate. Since health interventions often involve multiple organizational levels, adoption needs to be examined across these different layers, from frontline staff up through departments, organizations, and

broader systems. One example of assessment in the area of Adoption is described in the study by Kwan et al. (2017), who measured to what extent collaborative care in primary care was adopted in primary care settings. Coupled with the number of practices and practitioners who adopted the intervention, the researchers also conducted qualitative interviews to explore their reasons for adopting or not adopting the intervention.

Implementation goes beyond just checking if an intervention is delivered as planned. It examines how programs adapt and evolve during delivery, what resources they require, and how consistently core elements are maintained across different settings. Key aspects include tracking both the fidelity to essential program components and understanding what modifications are made, why they're needed, and what they cost in terms of time and resources. For instance, implementation of tobacco cessation programs in the US NCI-designated Cancer Centers focused on tracking the delivery of tobacco screening across participating sites, along with measuring how consistently providers delivered these services (D'Angelo et al., 2020).

Maintenance operates at two levels - both how well organizations sustain programs and how well individuals maintain changes. At the organizational level, the focus is on whether and how interventions become part of standard practice. At the individual level, maintenance looks at whether people continue positive changes after the program ends. The timeframe for measuring maintenance isn't fixed - it varies based on the type of intervention and what makes sense for that particular context. In our previous example, with the tobacco cessation programs in NCI Cancer Centers (D'Angelo et al., 2020), maintenance evaluation looked at whether tobacco screening and treatment services continued after the end of the project/funding, examining both the plans the centers had for continuing delivery and their organizational commitment.

Effectiveness-implementation hybrid designs

When developing mHealth apps, we often face a challenging question: should we first check if the app achieves its intended outcome (like helping people quit smoking), and then figure out how to make it widely used? Or should we explore implementation strategies alongside testing its effectiveness from the start? Traditional approaches tend to keep these steps separate - first testing if an intervention works (effectiveness research) and only later studying how to implement it successfully (implementation research). But what if we could do both at once? Effectiveness-implementation hybrid designs offer exactly this possibility. These designs combine elements of both effectiveness and implementation research in the same study. For example, while testing if your smoking cessation app helps users quit (effectiveness), you might also study what makes healthcare providers more likely to recommend it to their patients (implementation).

There are three main types of hybrid designs (Curran et al., 2012):

Hybrid Type 1. Testing effectiveness, observing implementation. This design primarily tests whether your mHealth intervention works while gathering information about implementation. This approach makes sense when you have some evidence suggesting your intervention might work (from previous studies), the implementation risks are minimal, and you want to gather early insights about real-world implementation challenges.

Hybrid Type 2. Testing both effectiveness and implementation. This design gives equal attention to testing both your intervention and implementation strategy. You might simultaneously study whether your mental health app reduces symptoms AND test different approaches to integrating it into clinical workflows. You should consider this approach when you have strong preliminary evidence that your proposed intervention works, there is pressure to implement quickly, and you need to understand both if your intervention works and how to implement it effectively.

Hybrid Type 3: Testing implementation, observing effectiveness. Here, the focus shifts primarily to studying implementation while gathering some data about effectiveness. This might happen when a health system is already committed to implementing an mHealth solution, but you want to study the best ways to roll it out while still monitoring its impact. This design fits well when there is good evidence that your proposed intervention works and the implementation process is the main challenge.

This chapter walked through the key steps of testing whether an mHealth app actually helps people get healthier. From early stress testing that catches technical bugs, to watching real users navigate app screens, to tracking health outcomes in clinical trials - each type of evaluation answers different questions about your app. The SFT 2.0 project shows how this works in practice: starting with basic usability checks, moving to real-world testing with pregnant women, and finishing with a full trial measuring both how well the app works and how to roll it out effectively.

Whether you're building a new app or picking one to recommend, knowing these evaluation approaches helps you spot what's been properly tested versus what just looks good in the app store. Remember: stars in the app store don't tell you much. Real evaluation takes work, but it's how we build mHealth solutions that actually improve public health.

SECTION FIVE

Practical mHealth: designing your first mHealth application concept

In this section of the book, we dive into the practical aspects of designing and building an mHealth application, serving as a companion for public health students and scholars as they create their first mHealth app. As described in Chapter 10, we will be anchoring the step-by-step guide into the five stages described by Voorheis and colleagues (Voorheis et al., 2022), to which we have included an additional initial stage. As a result, the process described in this chapter will lead you through the **Discover** stage of validating and defining a public health problem as well as mapping its context, a crucial starting point for developing any intervention. We then move to **Empathize**, the stage in which we discover insights into our users, their context and health behaviors, followed by a convergent stage of **Define**, where we establish the product's direction, based on the discovered insights. After defining the mHealth challenge, an **Ideate** stage moves us in the solution-space, allowing us to discover multiple directions for solutions. This is a divergent phase, in which we encourage the generation of numerous ideas, which we then can refine. From there we progress to **Design the concept & prototype** stage, where we flesh out our ideas into tangible solutions. A final stage, **Test**, focuses on testing and iterating on our solution, as a way to discard the ideas, features or approaches in our solution, which are not fit for the challenge, and to improve solutions which show the most potential to address our mHealth challenge. Although all these stages seem to be integrated in a linear process, please remember that the entire design process is **iterative and cyclical**, and that multiple rounds of employing each type of activity might be needed to develop an effective mHealth app (and associated intervention). Finally, the last chapter of this section will offer insights into what happens next in terms of bringing an mHealth solution beyond the concept stage. It will briefly discuss the product development lifecycle, and what to expect from the process of bringing your mHealth solution to life (and into the hands of users).

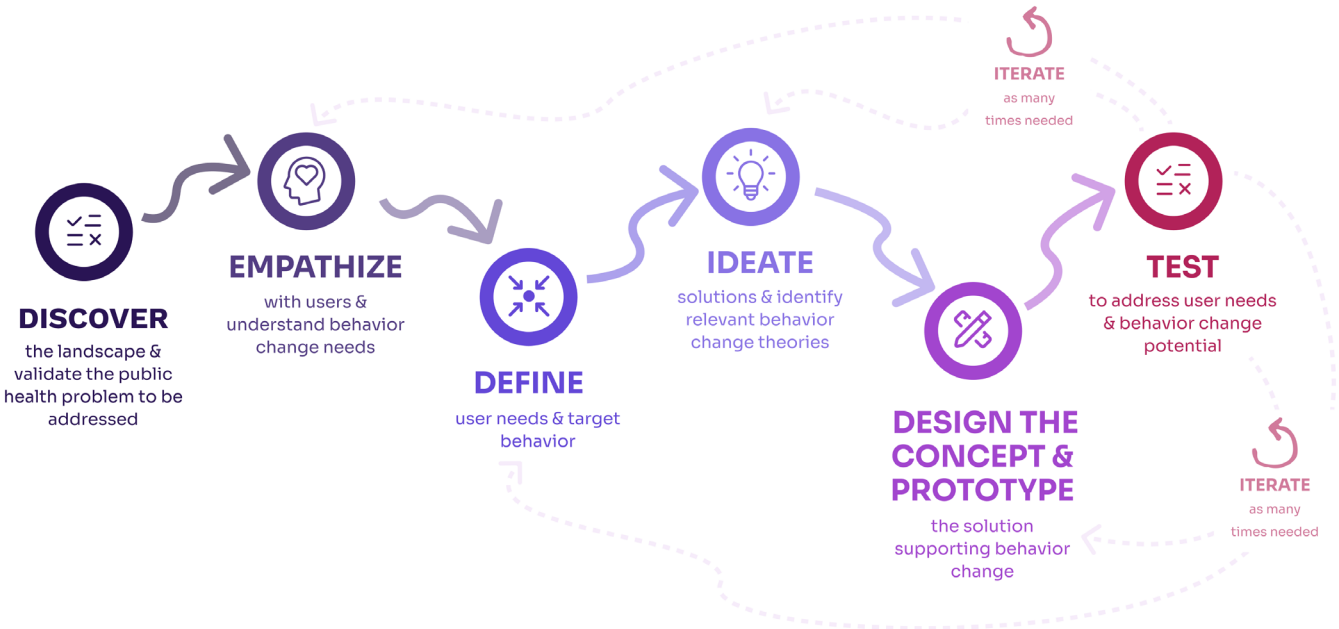


Figure 10. The behavioral design thinking process for mHealth apps, inspired by the work of Voorheis and colleagues (2022) and further expanded

Figure 10 summarizes the five stages proposed for designing mHealth interventions, as they will be followed throughout in the remaining sections of this book. Each chapter in this final section will offer an overview of the mHealth app design stage (or phase), followed by a list of tools which could be used in the respective stage. We broadly use the term “tools” to list relevant methods or instruments which could help you in each of the design thinking stages. We will offer a brief introduction on the tool as well as insights on how to use them, including templates. We will also offer practical examples of design artifacts used in the development of the Smoke Free Together 2.0 mobile app (introduced in section three of the book), to help readers better understand how to use each tool and illustrate possible outcomes for them.

CHAPTER 12

Discover: Identify and validate a public health problem for intervention

This chapter introduces you to the initial discovery phase - a systematic approach to identifying, researching, and validating public health problems suitable for mHealth interventions. The first step in developing any mHealth solution is thoroughly understanding the public health problem you aim to address. Yet, initial discovery in mHealth goes beyond traditional public health needs assessments. While public health students are familiar with epidemiologic research and assessing population needs through surveys, qualitative interviews, and focus groups, validating a public health problem for a mHealth intervention requires additional steps. Recent systematic reviews of mHealth interventions highlight that many applications fail not due to technical limitations, but because they don't effectively address validated health needs (Free et al., 2013) or align with users' actual behaviors (C. Wang & Qi, 2021). As such, understanding the public health problem/behavior, the health landscape, and the digital ecosystem helps validate whether mobile technology offers an appropriate intervention pathway for a specific public health challenge.

We built the Smoke-Free Together 2.0 app after a comprehensive initial discovery phase. Before any app development began, we examined smoking patterns among Romanian women through public health and digital implementation lenses. Our analysis revealed that tobacco smoking among Romanian women rose nearly 30% from 2011 to 2018, while quit attempts declined by 37% (Institutul Național de Sănătate Publică, 2018). More significantly, we found that 50% of women who smoke continue during pregnancy and nearly 60% who quit during pregnancy relapse postpartum (after giving birth) (Meghea et al., 2012). Beyond these epidemiological findings, we examined the digital context: smartphone penetration rates among Romanian women of reproductive age, typical app usage patterns, and existing mobile or digital cessation tools. This analysis revealed a critical gap: while several general smoking cessation apps existed, none specifically addressed the unique challenges, motivations, and barriers associated with smoking cessation during pregnancy or incorporated social support mechanisms.

The role of initial discovery in mHealth development

The initial discovery phase serves at least five main roles: problem validation, context understanding, solution feasibility, resource optimization, and stakeholder alignment. Let's briefly touch upon all of these. First, initial discovery ensures problem validation. In other words, it confirms that the identified health issue or problematic/risky health behavior is significant (it affects a segment of the population and its impact is significant). Second, the context understanding provides insights into the broader ecosystem - both health and digital-related - in which the problem exists. Third, the solution feasibility helps determine if a mobile app could truly be a solution to tackle the proposed public health problem or risk behavior. Fourth, a thorough initial discovery prevents mHealth teams from investing time and resources into apps that try to solve poorly understood problems (and their root causes). And last, but not least, initial discovery creates a shared understanding of the problem among team members and stakeholders.

Conducting desk research

Desk research is the backbone of identifying and validating a public health problem for any mHealth intervention. It involves gathering and analyzing existing information about your target health problem, with the aim of getting familiarized with the problem space. This is an important step when tackling any complex social, environmental or health issue, as it will be crucial in how strategically we can approach a problem space. In addition, it avoids duplication of effort at a global level and promotes learning from other programs, by making sure we are aware of mechanisms that have previously worked (or didn't work) in addressing our particular health challenge. A step-by-step structure for a desk research on this topic could follow four steps (listed in Figure 11), anchored in the type of data you are looking for: scientific literature, public health datasets, the technology landscape and finally the stakeholder landscape.

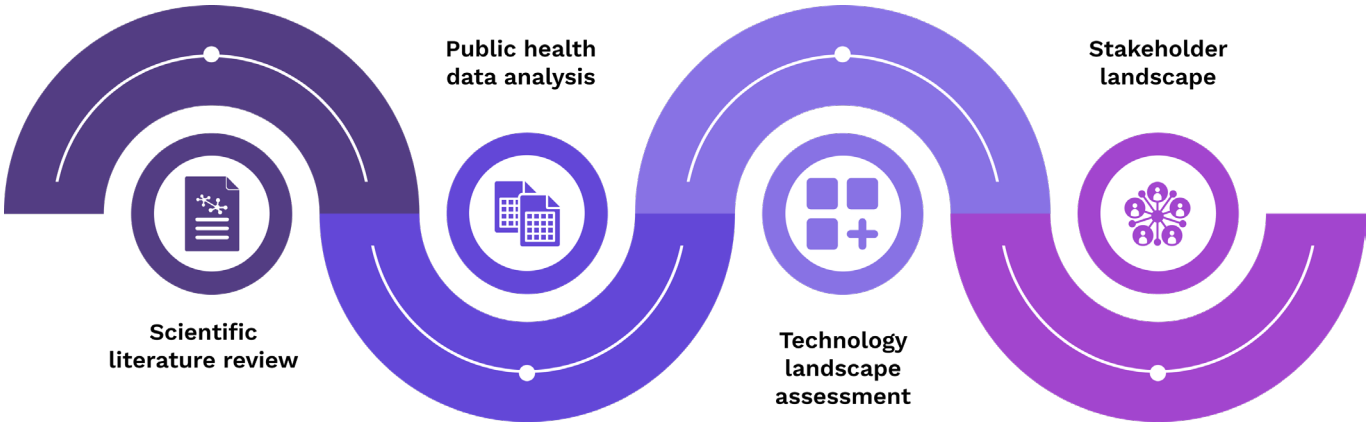


Figure 11. Steps in conducting desk research for identifying and validating a public health problem for mHealth interventions

Step 1. Scientific literature review: Decide on a list of keywords relevant to your public health problem of focus. Search peer-reviewed literature through databases like PubMed, Google Scholar, and Web of Science. Focus your search on: problem prevalence, distribution, and magnitude; current intervention approaches; existing mHealth solutions; documented barriers and facilitators; health outcomes and economic impact.
Step 2. Public health data analysis: Examine national health statistics, WHO global health data, Global Burden of Disease (GBD) data, disease surveillance data (when available), and/or any other relevant health surveys and available demographic data.
Step 3. Technology landscape assessment: Review existing mHealth solutions for similar problems by searching the apps in Google Play and AppleStore. Examine app store analytics for similar solutions (number of downloads, ratings, etc). Investigate mobile technology adoption rates in the target population. Additionally, research digital health policies and regulations that govern mHealth solutions in your country.
Step 4. Stakeholder landscape: Map out healthcare providers, patient organizations, government agencies, technology providers, and potential partners or competitors relevant to your target public health problem.

All this collected information needs to be carefully organized and synthesized to create a comprehensive picture of your public health problem. The data from each step - from scientific evidence to stakeholder insights - should be mapped in a structured way that helps define both the problem and the opportunity for an mHealth solution. To help you organize these findings systematically, we provide a mHealth Problem Template in the next section. This tool will guide you through arranging your desk research insights into a clear, actionable format that will inform your intervention design decisions.

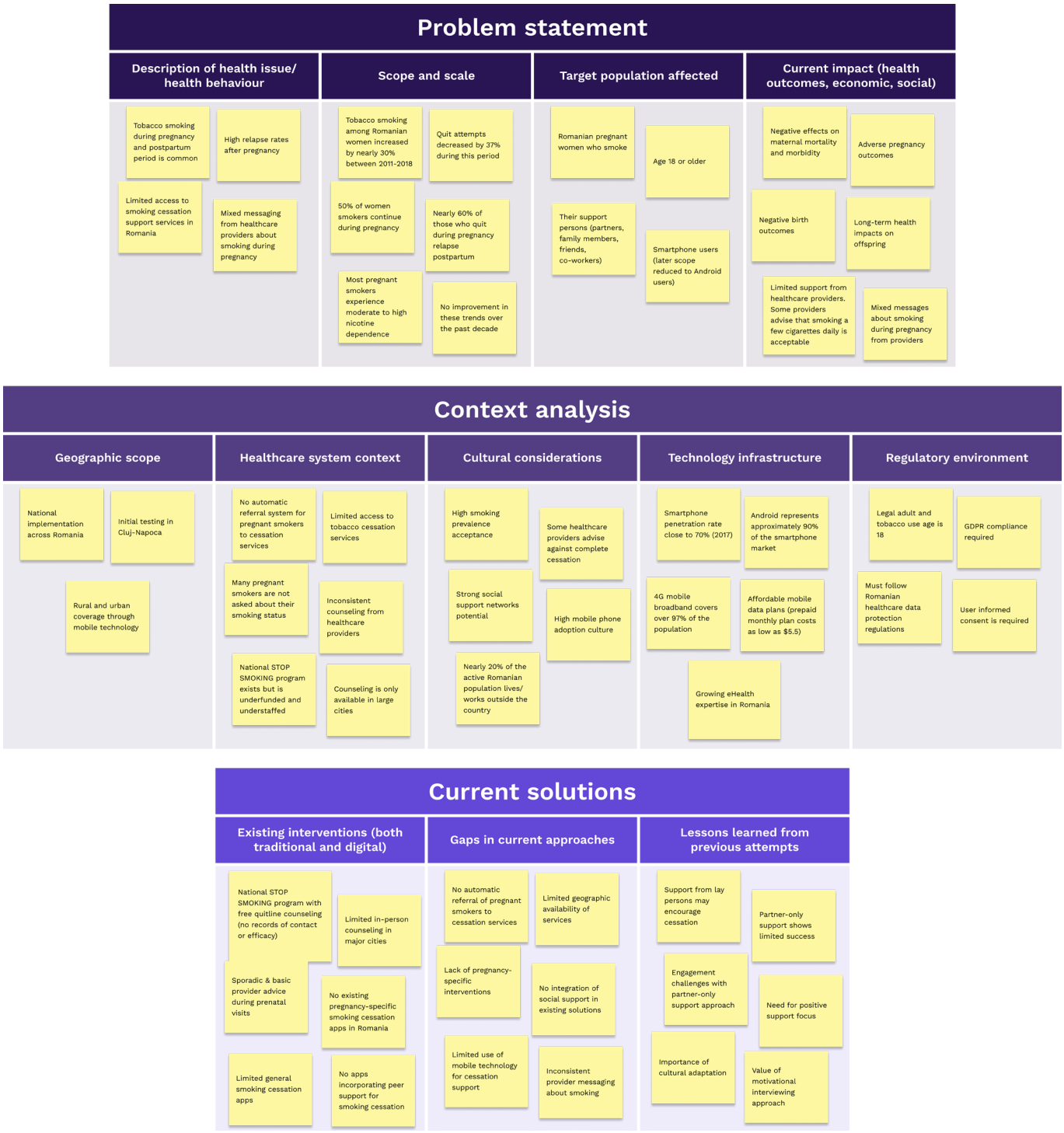
Discovery Tools

mHealth Problem Template

The mHealth Problem Template builds on the results of the four phases of the Desk Research described above and systematically documents your findings to help you build a case for your mHealth intervention. The template is presented alongside a simplified example from the Smoke-Free Together 2.0 app discussed in Section III and consists of six key sections: Problem statement, Context analysis, Current solutions, Technology opportunity, Stakeholder analysis, and Impact potential. Each section contains specific subsections that guide you in mapping out different aspects of your findings from Desk research. To complete the template, all you need to do is go over your findings and place them into each relevant section. For example, your scientific literature review will inform the Problem statement section, helping you define the health issue and its impact. Your public health data analysis will add depth to both the Problem statement and Context analysis sections, while the technology landscape

assessment will feed directly into the Current solutions and technology opportunity sections. Lastly, your stakeholder research will shape your Stakeholder analysis section.

You can structure this information as you wish - either as a detailed table or as a map, as shown in Figure 12. We provided you with an example of how we used this template in developing the SFT 2.0 app.



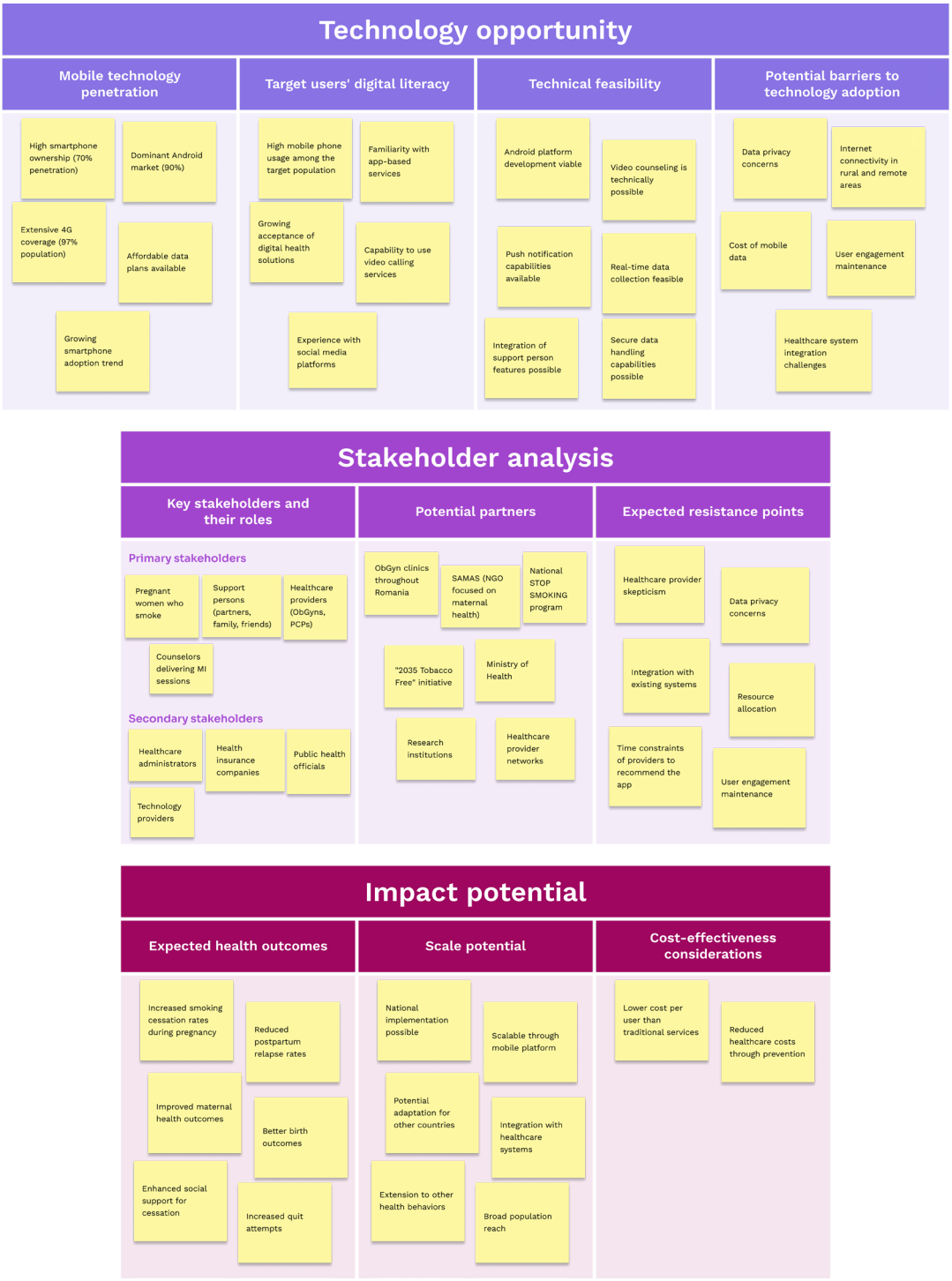


Figure 12. mHealth Problem example - A simplified version derived from the Smoke Free Together app development process for mHealth interventions

CHAPTER 13

Empathize: Observe and understand users, their health contexts and health behaviors

Having a good understanding of the people who are meant to use our mHealth solution is essential in order to ensure that we are solving the right problem, for the right people and in an effective way. Oftentimes in software development, we refer to the humans using tech solutions as *users* (of our digital solution). As a result, **understanding users** is considered an important stage in order to design and implement *user-centered* (or *human-centered*) mHealth apps.

As public health practitioners (either current or to-be) you are familiar with the extensive research we conduct in academic environments to understand health and illness, health behaviors, social determinants of health, health systems, health literacy and many other dimensions which shape the health of our societies. We employ quantitative, qualitative and even more often mixed-methods research designs, in order to fully understand all facets of a health issue. We scan the literature effectively to understand what science can teach us about the mechanisms behind a behavior, the distribution of a health condition or the predictors a health problem has in a specific context. We even do desk research to identify evidence-based mechanisms to intervene. We use **quantitative methods** to understand the distribution, characteristics, determinants and impact of a particular health concern. And we gain deep insights on the lived experiences of different people with that particular health topic using **qualitative methods**. The range of approaches is diverse and well-trained public health practitioners are equipped to understand humans, their context and the health problems they navigate in a comprehensive way. And this is all extremely relevant information for laying a good foundation to designing an mHealth intervention as well.

However, when working on digital solutions, in an ever-changing software development landscape, it can sometimes be tricky to distill all that information. We often need to bring together a lot of knowledge about users into **actionable insights**, to inform design and development. As discussed in chapter 10, we refer to this approach as **research synthesis**, a

process of combining and integrating different information units to generate insights, ideas or directions for solutions (which is different from analysis, a process more familiar to you, which involves decomposing a problem to understand its components, relationships between them, their rules of functioning, etc).

By looking at Design Thinking, we can adopt methods that help us channel our effort into ***gaining empathy*** for our users, both by enabling data collection (and analysis) as well as data synthesis. If we have a quick look in the dictionary, empathy is defined as the action (or capacity) of "understanding, being aware of, being sensitive to, and vicariously experiencing the feelings, thoughts, and experience of another" (Werriam-Webmaster, 2025). The first stage in Design Thinking is intentionally referred to as **Empathize**, because it encourages teams to understand the user in a deeper way, to the extent to which they can walk in their metaphorical shoes. The term (and practice) of empathizing with users might come in as unusual for practitioners like yourself, who have been taught to remain neutral and unengaged emotionally with research participants. But the practice of understanding users to the level of empathizing helps digital product teams focus more on the "human" in human-centered design. In this sense, some still favor using "Understand" instead of "Empathize". But whichever term you use, keep in mind that our goal in this stage is to **understand the diversity and richness of human experiences around a health topic**, and move beyond determinants, distributions and risk factors. While these are extremely useful, they do not provide enough contextual information to be able to design a full digital experience.

Empathize Tools

In order to gain empathy with users, we conduct **in-depth generative research** to understand their experiences, the challenges that they face (which we aim to address) and the context in which they experience them. We typically conduct this research through an array of methods, with interviews, observations and interviews in context (which we refer to as contextual inquiry) being the most common approaches we use to collect relevant data. Surveys and analytics data could also offer some quantitative information, about the distribution and the occurrence of a phenomena, but qualitative data is essential for truly understanding users. Once the data is collected (and transcribed), we engage in a process of **data analysis** and **data synthesis**, which are key steps in designing the mHealth application.

Data analysis is probably more familiar to you, as public health trainees, as it is commonly used in other disciplines you've studied. During this phase, we aim to break down the problem we are studying into smaller units (concepts), understand them and the relations between them. We also examine the rules by which phenomena happen, those by which behaviors form and occur, how health issues are distributed and determined, and we also describe contexts and their impact on health, disease and behavior, etc. During analysis our main goal

is to gain understanding. However, in the space of digital product design (similar to other design disciplines) we **do not spend most of our time in analysis**, as we would do in scientific research or even applied health research. We engage with analysis for a much shorter period of time, just enough to gain sufficient **actionable insights**. As a result, our data analysis is quickly followed by a phase of data synthesis.

Data synthesis refers to the process of **combining components or elements from research in order to produce actionable insights**. Oftentimes, data synthesis is best represented in visual artifacts which help us turn conceptual and unstructured information into palpable instruments. We often call them maps (or information **mapping exercises**) to illustrate that they are pivotal in orienting the design of the product, but are also something tangible. They can be shared with the digital product team and can be easily referred back to during the design process. We often rely on a set of instruments (data collection, data synthesis and insights mapping tools) when doing this, which help us have a common language when analyzing and synthesizing data during digital product design. We will discuss four such tools or instruments in the next section, and offer you templates to help you build them for your own projects.

Semi-structured qualitative interviews

Semi-structured qualitative (in-depth) interviews are one of the most used research methods, in the initial stages of empathizing with users. As mentioned earlier, this stage is **generative** in nature, as our goal is to unpack the users' experience and gain sufficient insights to support us in finding ways to address the issues they face (understand the problem space to have the necessary information to start shaping the solution space). And the flexibility of semi-structured interviews makes them preferrable to other data collection methods in this phase. We use qualitative (in-depth) interviews because they allow us to have an exploratory approach. We typically use **open-ended questions** and we can use follow-up questions to delve deeper into topics that arise during the conversations (that we might have not known or realized to ask about when going into the discussion).

We also prefer **semi-structured interviews** (as opposed to structured or unstructured) as within this type of interviews we use a set of themes (or topics) which we might bring into the discussion, but we also have the flexibility to approach other issues as well or tailor the discussion on the individual participant and the information they might bring. This flexibility together with the minimal structure make them ideal tools to explore an issue for an mHealth challenge. We highly encourage you to refer back to your qualitative research methods training (or get a refresher in such methodologies) in order to maximize this tool for mHealth purposes. We will not go into details regarding building an interview guide or facilitating a semi-structured interview (as it goes beyond the scope of this book), but we will offer some

suggestions or pointers below, and offer some interview guides and consent form templates in the appendix of the book, together with a list of probes you might be able to use during interviewing **(see Annex 1 and 2)**.

Probably the most important suggestion or good practice when building an interview guide for a semi-structured interview is to focus on having open-ended questions, and limit (or even better completely exclude) closed-ended questions. Open-ended questions elicit a story, not a "yes-or-no" or one-word answer. It might take some practice to learn how to formulate open-ended questions, but they generally start with *what* and *how*, or more complex syntaxes such as Could you please describe/ What can you tell me about/ How do you see/ How did you experience/ How did you feel about/ Can you tell me a story about a time when… . When building your first interview guides, we would suggest formulating the questions and reading them during the interview, to ensure you are delivering them in an open-ended way. But in time, you will become more fluent in working with open-ended questions and you will not rely as much on the exact formulation in the guide.

Secondly, interview guides should follow a structure that would enable building rapport during interviewing. Rapport refers to a good interpersonal relation which is built between the researcher and the participant. However, this relation should be characterized by a good balance between building a dynamic of sufficient trust to foster openness and maintaining an ethical distance. As Marilys and colleagues very helpfully clarify this issue, "The purpose of establishing rapport between researcher and participant is to both generate rich data while at the same time ensuring respect is maintained between researcher and participant" (Marilys & Heggen, 2009). To establish good rapport, we usually start an interview by obtaining informed consent, introducing the interview and the research, answering any questions the participant might have and then starting off with some **introductory (or warm-up) questions**, as conversation starters. We can then follow-up with **3-5 key themes** or broader open-ended questions which address the topics we are interested in pursuing during the interview. Each of the key questions is usually accompanied by a set of follow-up questions or probing questions to explore the theme in greater depth. The number of themes we can approach in an interview can vary depending on the complexity of the topics, but we suggest adapting this number to limit the entire interview to 1 hour. At the end, the interview guide should allow both the participant and the interviewer to step back from the discussion - especially when dealing with sensitive or cognitively challenging topics—and shift the discussion to the future or a more neutral or even optimistic perspective. In order to do so, we recommend having some **closing questions** which could focus on solutions or perspectives on improving a particular context. Finally, remember to **leave room for final thoughts**, as the participants might feel prompted to offer some interesting insights at the end. Make sure you do not miss that opportunity.

In terms of facilitating semi-structured interviews, ensure that you go in with genuine curiosity and openness, as Portigal notes: “Check your worldview at the door. You’re not here to educate, just to learn. The person you are speaking with is the expert in their own experience” (Portigal, 2023). Avoid talking too much and focus on asking open-ended questions, while resisting to give examples of answers you might be interested in receiving, as these could prime the participant in a particular direction and limit their ability to come up with original answers. Pay attention to the non-verbal cues that the participant might be giving and be responsive to their needs - offer to take breaks if necessary, especially if working with a difficult or tiring topic. Be respectful of the participants and their lived experience and never forget that they are entrusting you with their life stories and personal experiences, respect their confidentiality and never express judgement, verbally or nonverbally. Be mindful of your own body language and expressions and try to maintain a friendly but neutral demeanor. Finally, ensure you document the discussion (by taking notes or asking permission to record the session) and be reflexive after each interview. Reflexivity in your practice helps you build your skills more efficiently, by creating a context for growth. Ask yourself after each interview you facilitate: How did it go? How did you feel in the process? What did you learn? What could be improved? How have you grown from the previous experience?. Answering these questions will help you grow your skills, gain more confidence and be more reflexive about your practice.

Affinity diagrams

Once we have collected data via interviews and/or other methods, affinity diagramming is one instrument we use often in the process of qualitative data analysis and synthesis. This method helps to break down information and categorize it, in order to extract insights. It closely resembles Thematic Analysis, which is often used in qualitative data analysis, as they both aim to identify themes which emerge from the data, through a process of coding and categorizing smaller units of information (observations). After data is collected, in order to produce an affinity diagram, we use post-its (sticky notes) to map every information unit (or observation we have collected via research). The units are grouped into categories, which are further refined until more conceptual themes emerge. These themes may describe user characteristics, behaviors, attitudes, needs, pain-points, contexts or even direction for interventions, functionalities or ideas. Although the affinity diagramming can be conducted individually, it is most effective as a collaborative exercise, where a team works together to cluster, organize and identify themes in a dataset. It can be conducted in a physical setting, using physical sticky notes on a wall, or virtually or digitally, using a Whiteboard tool such as Miro or Mural.

Figure 13 offers a screenshot of a fragment of an affinity mapping exercise from the process of developing the Smoke Free Together 2.0 app, using the Whiteboard tool Miro. This mapping exercise helped the team synthesize numerous research observations, and identify user

characteristics relevant to how they would interact with the application. These were the foundation we used to create user personas for the app (see sections below for a description of user personas). The blue sticky notes describe cluster names, while the yellow sticky notes capture research insights. Clusters were defined as we mapped research insights on the most relevant dimensions to define our user profiles.

Figure 13. Affinity diagram example - Smoke Free Together app development process

User personas

User personas are **research-informed** descriptions of our target users, which transform abstract information on user segments into embodied representations of possible real people. They are **fictional characters** which **represent user archetypes**, but **depicted as a real person**. They are usually constructed in a visual way and support the process of gaining empathy with users, enabling human-centered design. We usually construct user personas when we have enough research insight on our users, before we engage in any design work (as early as possible). For any given project, teams construct a limited number of personas, enough to represent distinct and realistic types of users, but limited enough for them to be manageable (sometimes one user persona is enough, 1-3 is typical, but we recommend seriously (re)considering if you would need to create more than 3-5 personas).

User personas usually include information on user needs, goals, pain-points as well as relevant background information on their socio-demographics and behaviors. However, the characteristics included in the user persona are highly dependent on each individual design challenge and it is essential to only include information relevant to the project. It is also critical not to reinforce existing social stereotypes in the process, by allocating sociodemographics, visuals or persona characteristics that are widely attributed but are not supported by research. While this is probably one of the most important critiques brought to the use of user personas, we consider that when used thoughtfully, user personas can be a valuable tool for many design challenges.

In an attempt to make user personas memorable, the fictional character is typically given a name, associated with a tagline which describes the type of user. You can even include relevant quotes from interviews to illustrate the persona's characteristics or attitude. In addition, each persona can have a short bio that could synthesize relevant insights from user research, to give context to the behavior or the experience. Try to include relevant information which would bring your persona to life, by making it as realistic as possible without getting lost in irrelevant information. Try to critically appraise each insight you include, to see if it is truly relevant to the design of the application, or if it enriches our understanding of the user. If it is not clear how it is bringing empathy for the user or how it is relevant to the design of the app, then we suggest leaving it out.

For our SFT 2.0 mHealth app, we had created four user personas, two for each type of user (two for distinct pregnant women user types and two for their selected support person). Our goal was to synthesize in these four personas a diversity of user profiles, aggregated around common goals, pain-points, smoking histories, reasons for smoking and quitting as well as feelings around quitting (for pregnant women); for the support persons we had also mapped their relation to the pregnant woman, motivation to support her in the smoking cessation experience as well as activities they were already doing to support these efforts. As such, we had two types of support persons, a life partner/husband and a best friend, illustrating the most typical dynamics documented in our prior research. Below we have reproduced two of the four user personas which were used in the Smoke Free Together 2.0 product design and development process, for your reference (Figures 14 and 15). However, from a visual perspective there are many ways of representing them, from less visual (sticky notes clustered around subheadings) to more visual and polished representations, such as the one below.

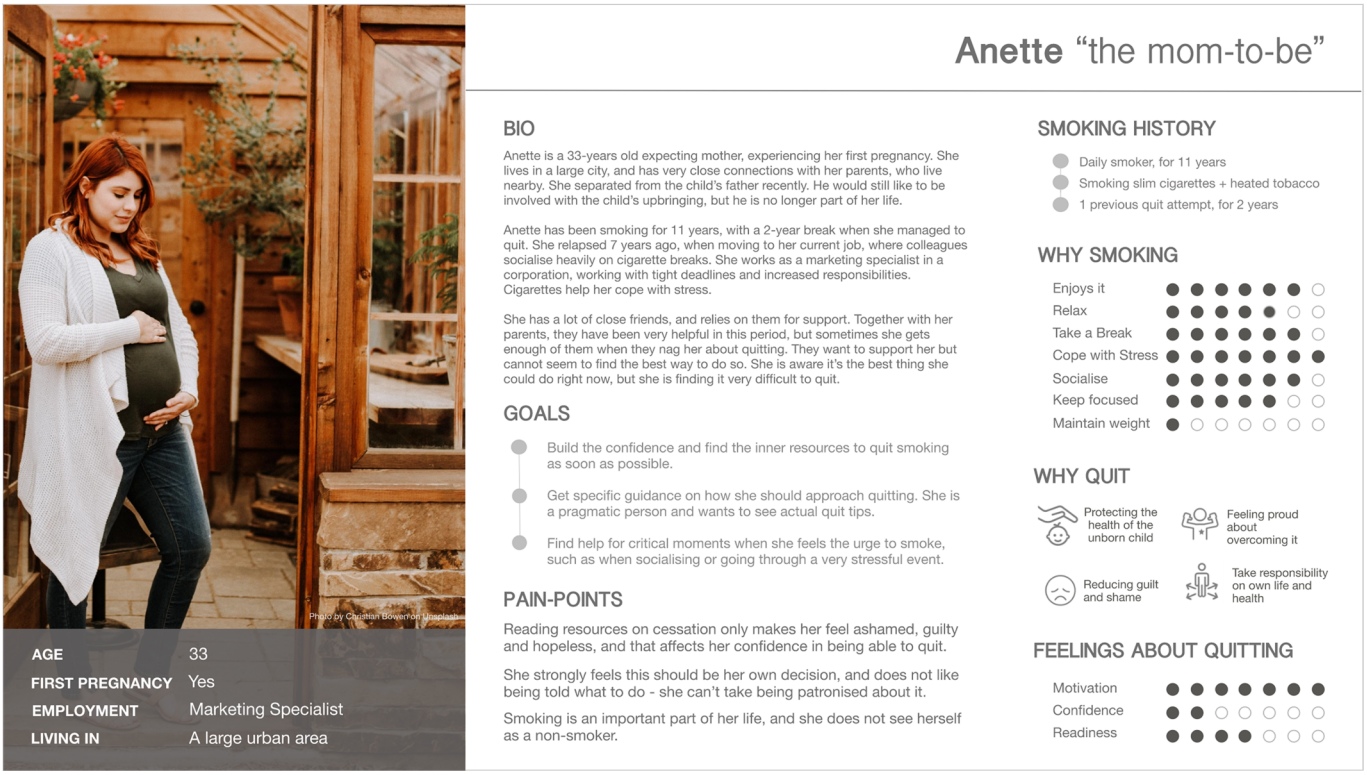


Figure 14. User Persona example 1 (pregnant woman) - Smoke Free Together app

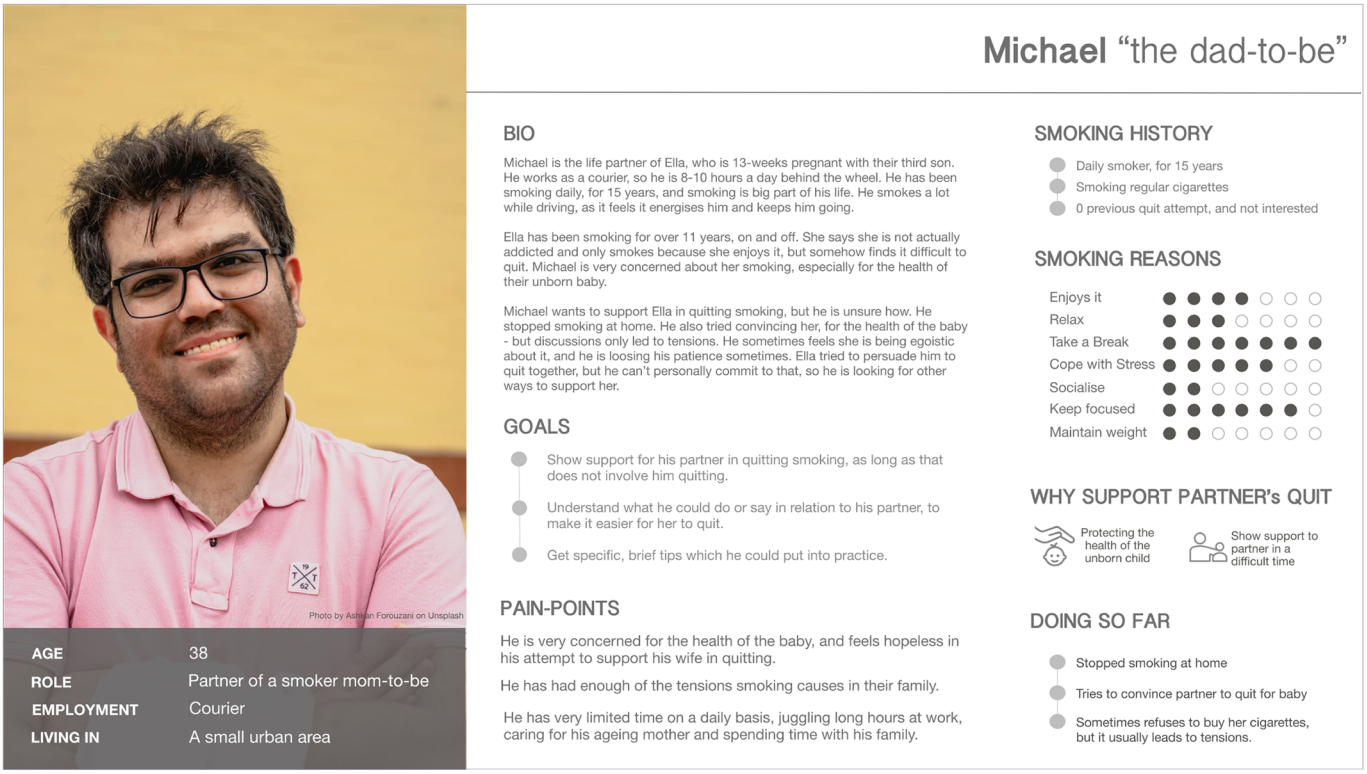


Figure 15. User Persona example 2 (support person) - Smoke Free Together app

Empathy maps

Empathy mapping is an essential tool in design thinking, and is widely employed to synthesize user insights in a visual way. It helps teams to align and to gain a deeper understanding of the users they are designing technology for by presenting essential information from a user's perspective. Empathy maps can be used alongside user personas as design artifacts, and in some cases they can even replace user personas, as they also involve visually mapping the user insights gathered through research, providing a structured understanding of a user.

Human-centered design toolkits have proposed different variations of the empathy map canvas, focusing on mapping what users **Say** (quotes from interviews related to the experience that we are trying to understand/ the design challenge), what users **Think** (insights on what matters to users related to the problem), what they **Do** (reflecting user actions or behaviors) and what they **Feel** (reflecting their emotions related to the actions or the experience). By focusing on these four dimensions, we can ensure a nuanced understanding of the user in relation to their experience and their goals. The initial version of the Empathy Map put forward by Gray and colleagues (Gray, 2017a) used 4 quadrants to map these dimensions (similar to the example we have offered in Figure 16 from the SFT 2.0 project). A revised version of the tool includes more dimensions such as more detailed user information, their goals, as well as more advanced insights such as pains and gains. This more complex version of the Empathy Map Canvas can be accessed and downloaded from the Gamestorming Project website (Gray, 2017b).

Figure 16. Empathy Map example applied to the Smoke Free Together 2.0 Application (pregnant woman user persona)

Experience maps

Experience maps are design artifacts that, as their name suggests, are used to map a human experience or activity in a given domain (Kalbach, 2016, p. 423). They usually follow a user persona through the journey of a personal experience or activity, without a particular focus on a product or a service. The span of the journey (start and end point of this experience) is decided by the project team based on research insights, and should include all the relevant phases or stages that the person goes through. The goal of the map is to gain empathy for users within the context of their lived experience and identify opportunities to support them at each stage of their journey. The process of mapping the journey involves identifying and visually representing a range of actions or events the user is going through, along with their thoughts and feelings. Since each experience might be relevant for different dimensions in the mapping process, your team has flexibility over how the final artifact would look. Because all data used in experience maps comes from research, they are another excellent tool for research synthesis.

In the case of the SFT 2.0 project, the experience we were interested in was the one of smoking during pregnancy. Due to the nature of the project and its goals, the start of the journey was set to the moment of learning about the pregnancy (which can be in different pregnancy weeks for every woman) and the end of the journey was set to 1-month postpartum (after birth). The decision to go beyond the point of giving birth was based on literature suggesting that the immediate period after birth is marked by increased vulnerability for smoking relapse, making it relevant to be included as part of the journey. Figure 17 presents a simplified version of the experience mapping process used in the development of SFT 2.0.

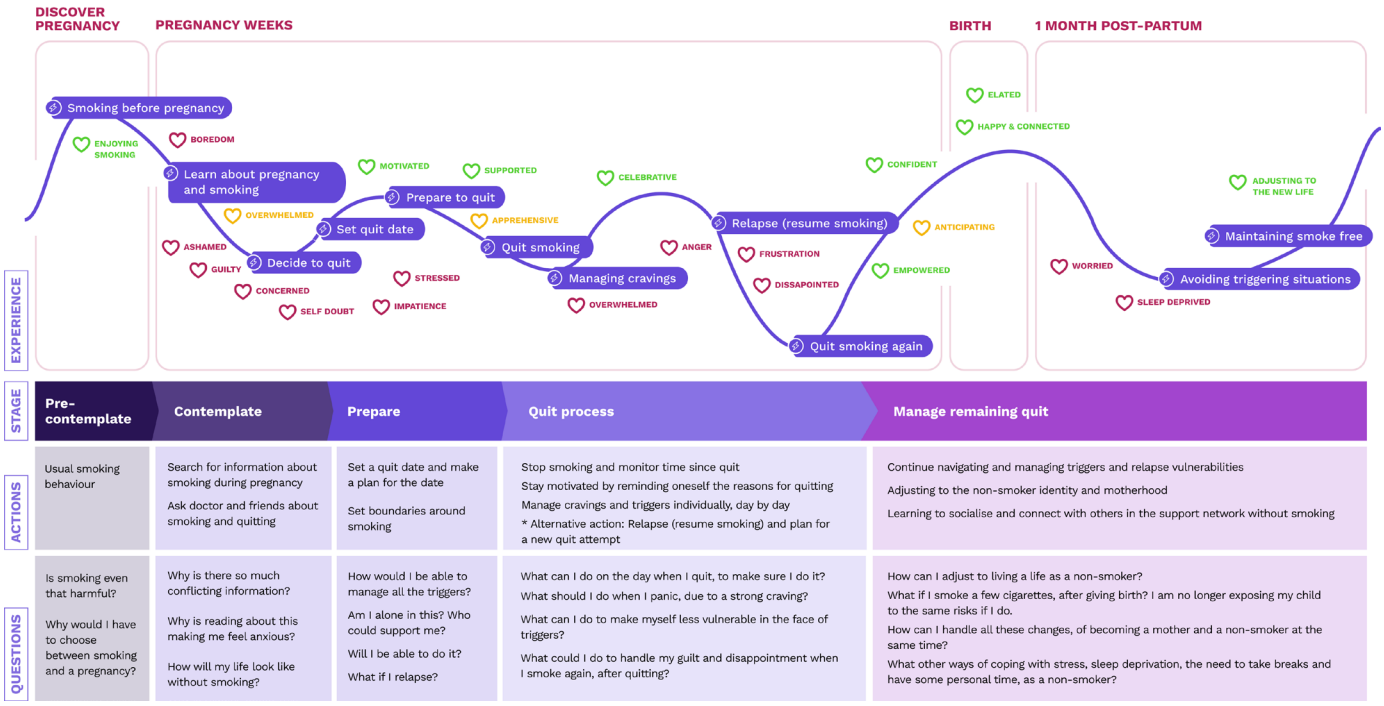


Figure 17. Smoking during Pregnancy Experience Map example applied to the Smoke Free Together 2.0 Application (pregnant woman user personas)

COM-B map for behavioral diagnosis

As discussed in Chapter 9, the COM-B model can be a useful tool for mapping a specific behavior and identifying effective intervention strategies. In chapter 10 we briefly illustrated the importance of understanding the behavior in the Empathize stage of design thinking. As a result, when developing mHealth interventions which have a behavior change component, a COM-B map can be used as a behavioral diagnostic tool to set the direction for possible interventions. It helps us synthesize information about the behavior and document barriers and facilitators within the model's framework. For this purpose we will use the strategy described by The Public Health Wales Behavioral Science Unit (Cline et al., 2023), which we used to build a visual map of a behavior. The authors categorize the determinants of behavior as facilitators (factors that make it easier for users to engage in a behavior) and barriers (factors that hinder or make it more difficult for users to engage in a behavior). The facilitators and barriers are derived from insights collected from research, and not on our assumptions on the users. Each determinant is mapped on COM-B model's domains or targets, defined by the authors (West & Gould, 2022) as:

- **Capability (to perform the behavior)** which includes physical capability (abilities, physical skills/dexterity, strength, stamina needed for the behavior) and psychological capability (knowledge, awareness, techniques, self-regulatory abilities, as well as understanding of the consequences of the behavior)
- **Opportunity (to perform the behavior)** which includes physical opportunity (having access to needed resources, time, location and spaces as well as physical cues to prompt behavior) and social opportunity (favorable social norms, social support, and social cues which prompt the behavior)
- **Motivation (to perform the behavior)** which includes reflective motivation (making conscious decisions, forming and enacting plans, and evaluating) and automatic motivation (habits, instincts, driving emotions, wants and needs)

All of the documented barriers and facilitators are prioritised based on the APEASE criteria, which stands for **A**ccessibility, **P**racticability, **E**ffectiveness, **A**ffordability, **S**pill-over-effect and **E**quity. In the case study we used as an example for this book we did not use COM-B as a model, as we relied on Self Determination Theory and Motivational Interviewing as the main theoretical frameworks. However, we mapped the behavior on the tool presented in Figure 18 for illustrative purposes.

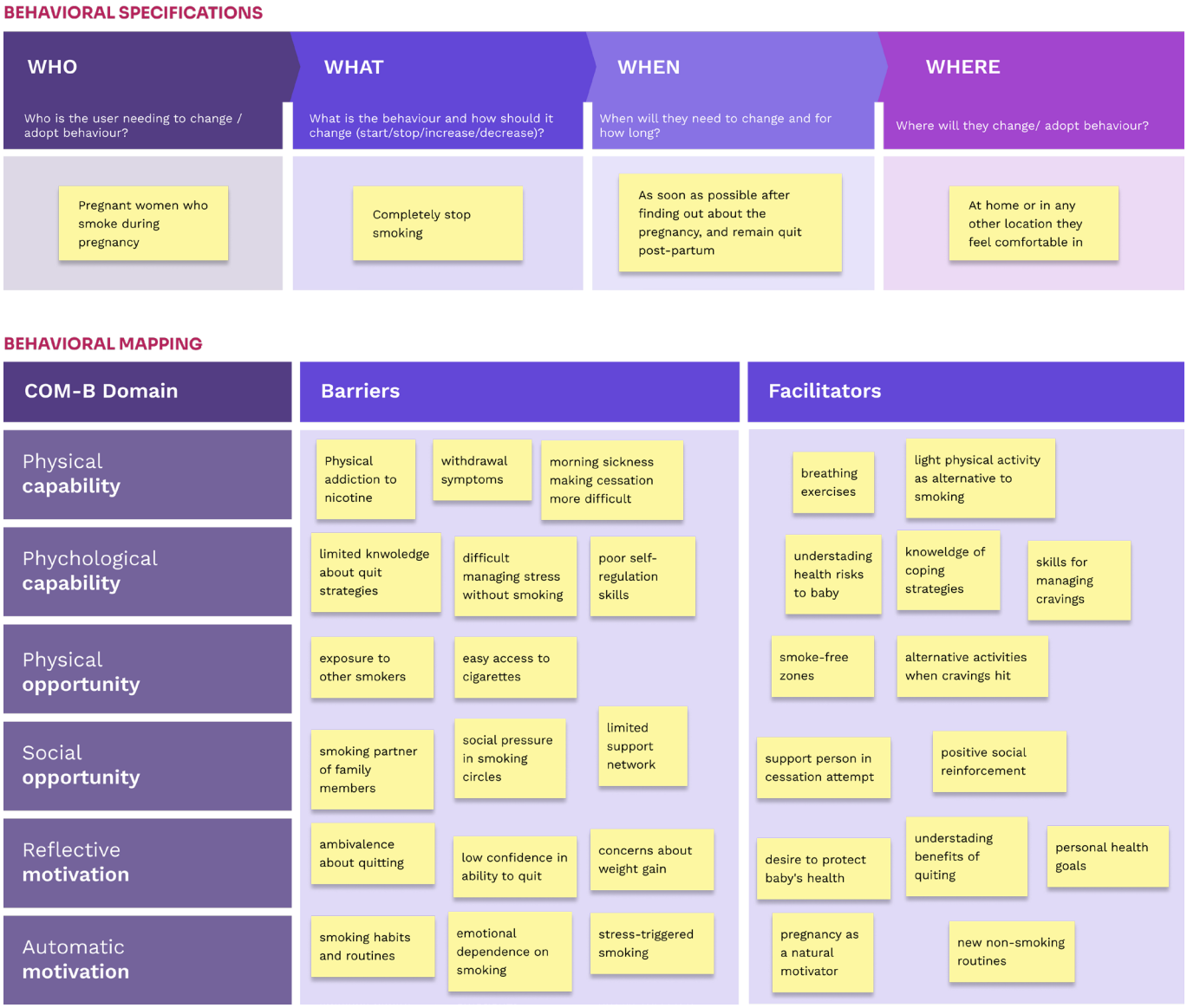


Figure 18. Behavioral mapping diagram based on COM-B model applied to the Smoke Free Together 2.0 Application (pregnant woman user personas)

CHAPTER 14

Define: articulate the design challenge and the scope of the mHealth solution

As described in chapter 10, an important phase in the design thinking process is the Definition stage, an essential step of articulating the scope of the mHealth solution. By nature, this stage is convergent (if you were to refer back to the double diamond discussed in chapter 10), as it focuses on bringing together all the insights uncovered in the Empathize phase. Based on the insights, in this stage we articulate the users' need, and define the scope of the mHealth application. From a behavioral perspective, in this stage we also need to define the behavior change requirements, building on the previous work of behavior mapping.

In order to articulate an mHealth's app scope, it is important to have enough information to be able to identify the so-called challenge space (What type of human experience are we aiming to impact), for whom (Who are the users), in what context (What are the relevant insights describing the challenge) and for what goal (What do do we aim to achieve). Drawing on the insights we have documented in the Empathize stage, we can articulate the design challenge in one paragraph. For example, if we were to build the product scope for the Smoke Free Together app, this could be formulated as follows:

Challenge space & users > Create ways to support smoking cessation, for pregnant women who are interested in quitting but cannot find the resources to spontaneously quit after learning about their pregnancy.

Context > Smoking during pregnancy is a very personal and complex psychosocial and biological process, with a high need to personalize support, and receive peer-support from relevant people in the women's lives.

Goal > Develop a digital, scalable solution that provides tailored assistance to women throughout pregnancy and up to 1-month postpartum while facilitating peer support.

As you can notice, this is a condensed description of the scope of the project which includes critical insights (as context) as well as a direction for the app's future development (a goal). In order to facilitate the articulation of the scope of the mHealth app, several other activities can be undertaken to frame the design challenge and set the direction for the design of the application. We have listed three such activities in the tools section below.

Define Tools

In the definition stage, we can use different approaches to synthesise research insights in order to delineate the challenge space and set a direction for the design of our mHealth solution. We discuss here three distinct approaches: Point-of-View Statements, the Jobs-to-be-done framework and a Mapping exercise for deciding on intervention functions based on behavioral goals. They can be used together or separately, as they offer different perspectives on the scope of the solution you are designing.

Point-of-View (Problem) Statements

Point-of-View Statements (also abbreviated as POVs) are widely used in Design Thinking Methodology, in the Define stage. Their aim is to create an actionable problem statement, grounded in a deep understanding of the users, their needs including any relevant insight. In building Point-of-View Statements, there are three elements to include: The user (who you are designing for), their needs (the most essential ones, extracted from research), and at least one compelling insight (which can be leveraged in the design process). The insights are very important as they offer both context as well as information on strategic directions for the solution. For one particular project you might have multiple POVs, depending on its complexity, and they can be excellent instruments to initiate generation of solutions in the Ideation phase (which is the next stage we'll discuss in chapter 15). We have illustrated in Figure 19 a possible POV statement for the Smoke Free Together app, which focuses on the pregnant women as users and their primary need of receiving support in quitting smoking.

Figure 19. POV applied to the Smoke Free Together 2.0 Application (pregnant woman user personas)

Jobs-to-be-done (JTBD) framework

Although we have included Jobs-to-be-done in the tools section, it is more than just a tool or a single method. It is a framework, a philosophy or a lens through which we look at the process of articulating a design challenge or a need. Within the literature you will find various implementations of the JTBD framework, both for building empathy with users as well as for defining a design problem. However, one essential similarity of all JTBD approaches is a constant **focus on user outcome**, rather than on technology or functionality. JTBD helps map user needs while following people in relation to their own goals (what they wish to achieve) and not in relation to a particular product or service. This approach is particularly useful if used in the Define stage, as it does not constrain the solution-space (mHealth app approach or its functionalities) while still offering structure and a space to synthesize user insights and user goals. As Jim Kalbach describes it in his book, "The Jobs To Be Done Playbook", the JTBD approach:

> *offers a unique lens for viewing the people you serve. Instead of looking at demographic and psychographic factors of consumption, JTBD focuses on what people seek to achieve in a given circumstance. People don't "hire" products and services because of the demographic they belong to (...) instead, they employ solutions* ***to get a job done*** (Kalbach, 2020, p. 2)

In other words, JTBD focuses on defining the job (or jobs) that each particular user type (or user persona) needs the solution to do for them. Or as Kalbach describes above, the job for which a user will possibly "hire" the solution (in this case the mHealth app). In terms of mapping JTBD there are numerous maps available, which focus on defining different aspects of Jobs. In our case, we recommend a map which focuses on defining a **primary job** (main job), any possible **related jobs** (secondary jobs) and **social & emotional jobs**. These are mapped alongside the **process** of the job, the user **needs** for which they "hired" the solution, as well as the **circumstances** in which the job would unfold. In Figure 20 we offer a JTBD mapping (inspired by Kalbach's work) for the Pregnant Woman user archetype in our Smoke Free Together 2.0 application, which includes all the dimensions described above.

Job performer	Pregnant woman who smokes
Main job	Receive tailored support in the process of quitting smoking during pregnancy and remaining smoke-free
Related jobs	• Monitor smoking behaviour as well as feelings about smoking and quitting • Learn about the pregnancy and monitor weekly changes • Include a significant person (partner/friend) to provide support in the quitting process • Receive relevant information when managing a crisis situation • Handle relapse moments and get tailored support for new quit attempts
Social & emotional jobs	• Feeling confident and at ease that she is doing the best for her unborn child • Feeling understood, supported and accepted in her quit attempt • Connecting with significant peers in a supportive way, in the process of quitting smoking
Process	1. Self-assess feelings, beliefs and knowledge on smoking and quitting smoking 2. Increase knowledge on why to quit smoking, how to quit smoking, how to remain quit free 3. Understand implications on mental health of smoking and smoking cessation 4. Include a trusted person in the quit process, and engage in supporting activities 5. Discover the best (personalised) mechanisms to quit smoking and remain quit 6. Receive supplementary support from a trained counsellor 7. Set a quit date and prepare for the quit date 8. Quit smoking and manage cravings and triggers 9. Remain quit free and manage relapse risk
Needs	• Receive empathic and personalised self-help content • Connect to the experience of other women going through a similar situation • Increase motivation and readiness to quit as well as self-efficacy • Receive support from a significant person they choose • Receive specialised support from a trained counsellor • Restructure cognitions around smoking and quitting smoking • Reimagine their life as a non-smoker • Get step-by-step guidance though quit attempts • Monitor quit success (cigarettes avoided, money saved)
Circumstances	• On the go, in between different appointments, at work or on the way to work • At home, with allocated time for this process • With a friend/partner when they meet • During pregnancy and post-partum up to 1 month • At night, when experiencing difficulties to sleep (during pregnancy) or when awake monitoring the newborn baby (post-partum)

Figure 20. Jobs-to-be-done framework map applied to the Smoke Free Together 2.0 Application (pregnant woman user personas)

For the Smoke Free Together 2.0 we also mapped JTBD for the second user archetype (the support person), as their jobs profile as well as reasons for "hiring" the app would have been very different. Throughout the design process we recommend circling back to the JTBD maps, to ensure that all the functionalities you are defining in the solution in the next stages

of the design process align with the jobs described in this stage. This is a helpful tool to stay on track in the complex process of designing an mHealth app.

Mapping intervention functions

As defined by Cline and colleagues, intervention functions are “a broad category of means by which an intervention can change behavior” (Cline et al., 2023, p. 15). The intervention functions the authors refer to are education, persuasion, incentivization, coercion, training, restriction, environmental restructuring, modelling and enablement. These functions are mapped to respond to the barriers and facilitators we have identified in the Empathize stage. The end-goal is to support the facilitators and mitigate the barriers that determine the behavior, through the functions we propose. We do this by approaching the barriers and facilitators that were prioritized as most important, and by assessing what type of intervention function would be needed for each of them.

Depending on the behavior change theories, frameworks or models we use, we can list the defining elements of the respective theory alongside the intervention functions. In this way, we can mark which aspects would be addressed by the intervention, and through what types of mechanisms. We can remain quite high-level in this stage, meaning there is no need to consider specific mechanisms, but we recommend you jot down how that function will be used to achieve the behavior change for each of the model’s dimensions/ domains. As we recommended COM-B as a framework in the previous stage (due to its versatility and comprehensiveness), we will illustrate the exercise of mapping intervention functions on COM-B dimensions in Figure 21.

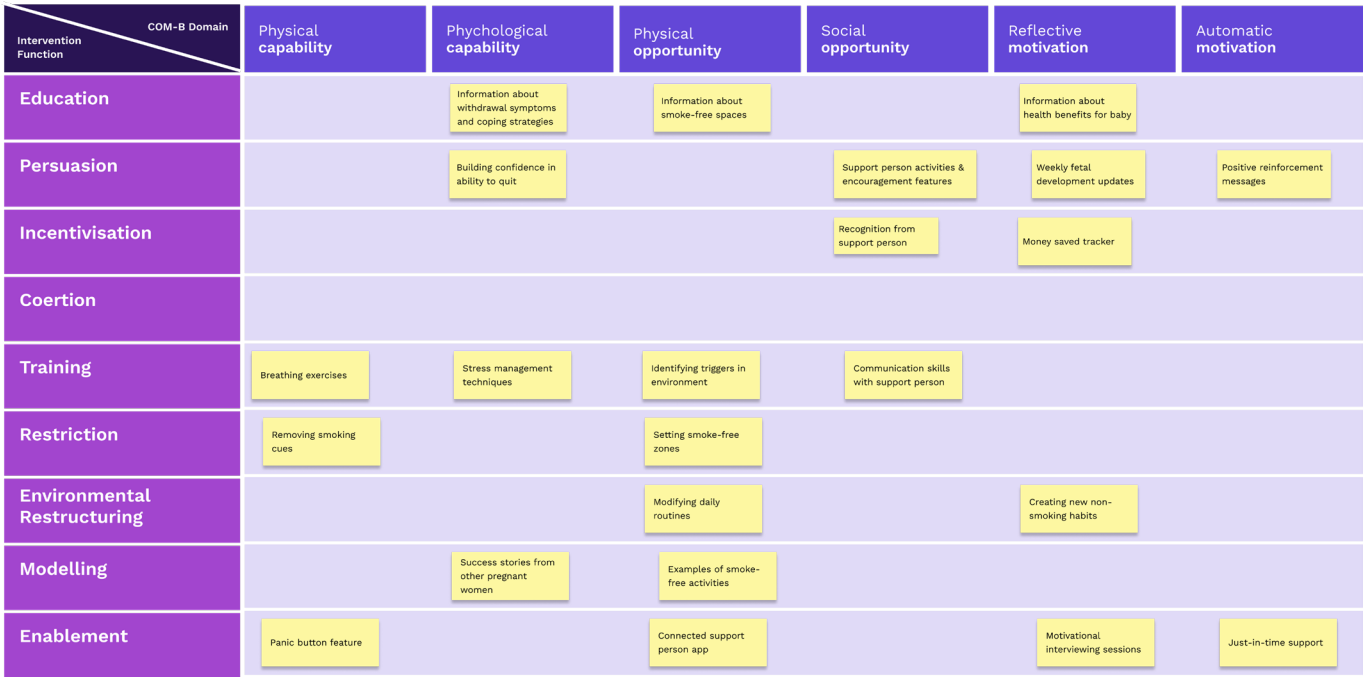


Figure 21. Intervention functions map applied to the Smoke Free Together 2.0 Application

CHAPTER 15

Ideate: Generate ideas to shape the solution

In the solution generation phase, commonly known as ideation, the goal is to come up with a solution to the problem defined in the previous stage. However, this process is not straight-forward, there is no trick or silver-bullet strategy to arrive at a good solution, as was also the case for our mHealth challenge. Similar to the first two stages in which we had to "get lost" in a divergent space of exploring the problem and the users (in Discover and the Empathize phases), before converging on a clear problem definition (in the Define stage), **the Ideation phase is again a divergent space**. If you refer back to the Double Diamond in Chapter 10, the Ideation stage is synonymous to the "Develop" phase in the diagram. So if in the first diamond, representing the problem space, we had to explore divergently to then converge on a problem definition, for this second diamond, representing the solution space, we need to "get lost" once again exploring divergently in search for the best mix of solutions to address our challenge. Worry not, we will once again converge by choosing the preferred solution in the next stage, Concept Design and Prototyping, described in Chapter 16. But until then, let's find out how we can uncover ideas and start our exploration of the solution space.

We can ideate as a team (or a group), which is a very effective way to generate ideas as it allows us to harness the creativity of multiple people. For this purpose, the more diverse the group, the better. But we can also have individual idea generation sessions for which we will offer a method in the tools section. We can use one type of ideation technique in a session, or combine multiple techniques. And we can conduct them in-person (in a physical space, using boards and sticky notes) or we can conduct them online (using a combination of video conferencing tools and online collaboration/ whiteboarding tools). The idea generation space is very flexible and can be adapted to your needs.

You are probably already familiar with brainstorming, as a popular and widely used technique to identify ideas. As IDEO defines it, "Brainstorming is a semi-structured, team-based method of rapid idea generation. (...) It allows teams to generate ideas quickly; it can expand the

portfolio of alternatives; it's generative, so it can help get people unstuck; it injects insights from a broader group; and it can build enthusiasm around a project and new ideas." (Boyle, 2017). However, as you will soon see in the toolbox presented in the next section, there are many variations of, and alternatives to, brainstorming, which could help us get the most out of a session of idea generation. But regardless of the method we use, there are a set of principles that will contribute to the success of your ideation session:

1. **Dispel the myth of "I am not creative":** probably the biggest hurdle of ideation outside the traditional realm of design specialists, is the misbelief that creative people are born that way, and that it takes some type of superpower to be able to contribute to an ideation session. We have seen this with public health students, health workers, scientists, or even participants from vulnerable groups whose voices have not been frequently heard - they all might find it difficult to grapple with the idea of contributing to an ideation session. Our take on this (shared by many working in this space) is that anyone can be creative, given the right environment and context. So try to convey that to your group, and set-up a creativity-inducing space through exercises designed to bring out the creative nature all humans possess.
2. **Promote creative confidence:** everyone should feel comfortable in contributing with the wildest (or silliest) of ideas, while fully limiting self-censorship. We must identify mechanisms to help people shed their seriousness and enter a more playful space, where anything is possible. M. Lewrick in his "Design thinking playbook" states that "before any brainstorming, people must laugh at least once (...) From our experience, it's best when they smile at each other" (Lewrick et al., 2018, p. 91). Laughter and playfulness can be a great way to encourage people to relax, and possibly leave any rigidness aside, for a short while.
3. **Quantity over quality:** the focus of a session should be the production of as many ideas as possible, with no concern for quality, feasibility, adequacy or any other attribute you feel would be important to judge ideas by. Encourage wild ideas, and build on each-other's ideas throughout the session. You can even promote a target number of ideas to come out from the session (but make sure it is a high one), depending on the group.
4. **Defer judgement of ideas:** no ideas should be judged in an ideation space. There will be plenty of time after the session to prioritize, choose and refine ideas, but jumping into that too soon will stifle creativity. People will be less likely to contribute if their ideas are immediately criticized. Also,criticising ideas too early brings us in a mental space of evaluation, which is very different to the mental space of idea generation, blocking creativity.
5. **Engagement and active participation:** having all participants actively involved in the sessions is critical, as team dynamic is extremely important in a group ideation session. Try to encourage one discussion at a time, and avoid having multiple conversations happening simultaneously.

6. **Be visual:** all ideas should be shared in a place that can be seen by anyone throughout the session. User markers, boards, sticky notes, post-its or any tools you have available.
7. **Time-box sessions:** have you ever experienced that creative moment derived from "last-minute panic"? Time pressure often pushes our brain to be more creative and focused. As a result, ideation sessions which are time-boxed will typically produce many more ideas than ones that run without a hard stop.

Ideation Tools

Ideation tools can be extremely diverse and we cannot possibly cover all of them in this short introduction. However, we will introduce How Might We Statements as a tool for framing an ideation challenge, and we will then briefly discuss some group and individual ideation techniques. We will also present the EAST framework, as a way to infuse ideation sessions with behavioral insights. Finally, we will go over co-creation sessions as a method to organise idea generation in a more complex way, through workshops or sets of activities. These basic tools can help you kick-start your first idea-generation sessions for an mHealth app.

Another important topic we only briefly touch upon throughout this chapter is facilitation of group ideation sessions. Although groups can self-organise, especially if they have some prior experience, it is generally more effective to have a facilitator in the sessions, to guide participants and ensure that the session attains its goals, participants are engaged and the group dynamic is productive. If you are interested in further exploring the field of mHealth solution design, we encourage you to build facilitation skills as well. Similar to building skills in research facilitation, solution generation facilitation is a useful competency to master.

How might we (HMW) statements

How Might We Statements (of HMWs) are widely employed in the design thinking to focus idea generation on a theme of interest. Their origins can be traced back to the 1970s, and you might hear others refer to them as HMW questions, with a question mark at the end. In essence, HMWs are a way of formulating design challenges in an open-ended way, starting with How might we… . According to IDEO, one of the organizations that greatly contributed to their use in today's practice, HMWs are a powerful tool to framing and sparking innovative thinking:

> *We use the How Might We format because it suggests that a solution is possible and because they offer you the chance to answer them in a variety of ways. A properly framed How Might We doesn't suggest a particular solution, but gives you the perfect frame for innovative thinking. (IDEO)*

For one particular project we might explore several HMWs in ideation sessions, with the goal of exploring multiple angles of the problem. For example, for a brainstorming session on the Smoke Free Together 2.0 App, we might use one or more HMWs like the ones listed in Figure 22.

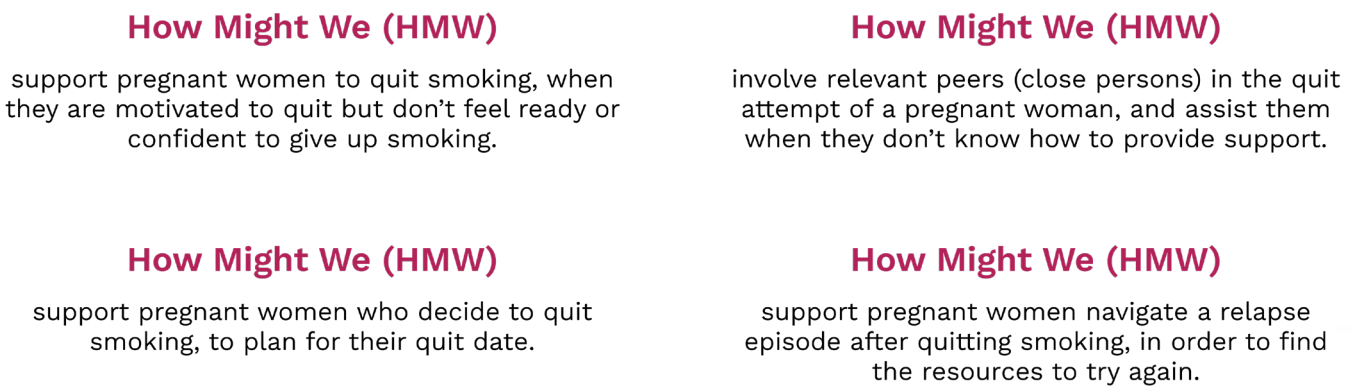


Figure 22. Possible HMWs applied to the Smoke Free Together 2.0 Application context

Each of these HMWs could be the focus of an ideation session, regardless of the ideation technique we use. We build HMWs by adding the phrase *How might we* in front of our design challenge or problem that we are trying to solve. They need to be formulated in a positive way (avoiding negations) and at the same time making sure they do not suggest a specific solution - that would limit the solution space. It takes practice to become fluent in formulating HMWs, but you can make it a team effort to formulate (and reformulate) them, until they reach a format that helps you in the ideation process. Well built HMWs should instantly spark ideas and provide fertile ground for a rich ideation session.

Ideation techniques

As mentioned earlier in the chapter, there are numerous ideation techniques that can be employed to support an ideation session. Think of them as different exercises that you can use to generate ideas (as a team, or individually). We have selected a few that we use more often in our practice, and that we felt would be helpful to the mHealth app design process. However, for an extended list of techniques, you can consult the Gamestorming website, which accompanies the book "Gamestorming: A Playbook for Innovators, Rulebreakers, and Changemakers" (Gray et al., 2010), where you can find numerous activities, together with facilitation resources.

We have discussed **brainstorming**, but we would like to introduce reverse brainstorming, brainwriting and brainswarming as variations or alternatives. In **reverse brainstorming** we typically focus on obtaining the exact opposite of the initial intervention goal. In other words, we turn everything on its head, and try to come up with as many ideas as possible to actually make things worse (i.e. HMW increase smoking during pregnancy). Although counterintuitive,

exploring the problem in reverse might actually give us insights into how to solve it in a more sustainable or systemic way, so it could be a great exercise to stimulate creativity. This works particularly well in situations when the intervention goal is not engaging enough for participants (think of situations where you would conduct ideation sessions with adolescents on healthy eating or reducing soft drink consumption).

Brainwriting is closer to traditional brainstorming in terms of pursued outcome, but has a twist in the methodology. Instead of verbally expressing ideas, and then putting them on a board for all participants to see, we encourage participants to write their ideas individually (e.g. on sticky notes). The original methodology involved completely silent collaboration, where participants write 3 ideas which they then pass to the next member of the group who builds on them or uses them as inspiration for new ideas, a process going in turns. A frequently used variation combines brainwriting & brainstorming by introducing a time-boxed silent collaboration phase where participants silently write ideas individually which they then share with the group, to have discussions emerge around them. This method is very helpful as it allows every participant to contribute, and have their ideas heard/seen, regardless of how loud or quiet they are. In addition, it reduces the risk of ideas being immediately dismissed or judged, as it limits the opportunity to criticise verbally.

Brainswarming was originally designed as a problem-solving technique which used a silent collaboration strategy, similar to brainwriting. In essence, it created a space for teams to silently collaborate in connecting a goal (placed at the top of a board) with a set of resources (placed at the bottom of the board or the working canvas), using ideas written on sticky notes to connect the two (McCaffrey, 2014). In ideation strategies for mHealth applications, brainswarming could be used in its original format, or adapted for group participants to map out a flow, describe a situation by silently adding phases or connect parts of a system on a collaborative board.

Storyboarding or sketching is widely used to visually represent ideas or stages in a flow. Although this strategy might be more intimidating for people who do not consider themselves very talented at drawing or sketching, encouraging them to communicate visually can access areas of their brain which promote creative thinking. In addition, sketching might open up other avenues for idea generation as the ideation board will be even more visual, helping participants build upon each other's ideas.

SCAMPER is a method that promotes out-of-the-box thinking, and creates a thought-provoking context for innovating, within existing solutions or products. The name is an acronym for **S**ubstitute, **C**ombine, **A**dapt, **M**odify, **P**ut to another use, **E**liminate and **R**everse, each representing a different way to rethink an idea. Originating as early as the 1950s and further refined in the 1990s witin the education space (Eberle, 1996), SCAMPER can be a very useful tool in the current mHealth app development landscape. As a method, it creates

the space for participants to ask a set of questions that could help spark innovation for improving solutions, digital products, methodologies or any type of existing approaches to health challenges. It can be used as a tool for individual ideation, or as prompts for group ideation sessions. Figure 23 summarizes the main questions you could use to ask yourself to improve an existing solution or approach.

Substitute

What could be replaced (components, resources, processes, approaches) to obtain a more innovative product?

Combine

What features, functionalities, uses or components could be combined or fusionend, to obtain a more innovative product?

Adapt

What could be adjusted to improve the product or enable it to respond to a connected challenge? How could it adjust to the life dynamics of the users?

Modify

What could be changed (magnified or minimised) so the product is more efficient or desireable?

Put to another use

How could the product be useful in another industry or for another purpose? How could it be used differently than intended and produce benefits?

Eliminate

What could be discarded to make the product lighter and more efficient? What could be simplified or reduced?

Reverse

How could the flow of events or sequence of activities be changed, for an improved outcome?

Figure 23. Summary of SCAMPER dimensions

Cray 8s

Crazy eights is a method typically used for individual idea generation (but it could be adapted to be used in group settings too), and it consists of a rapid sketching exercise. The goal is to push participants beyond the first idea that comes to their mind about solving a particular problem, as the first idea is not always the best one (*Share and Engage with the Design Sprint Community*, 2023). In order to do a Crazy 8s activity, you need a sheet of paper, which you can fold in half once on its shorter edge (horizontally), and then twice more vertically. When you unfold the paper, the lines created would delineate eight quadrants, which could be each used one for a different sketch. Then set a timer for 8 minutes, and within that time, you have to sketch 8 distinct solutions to the challenge at hand.

The EAST Framework in ideation

The EAST framework (Behavioural Insights Team, 2014) was developed in 2014 by the Behavioral Insights Team within the UK Government, with the goal to make the inclusion of behavioral insights into effective interventions easier. EAST is an acronym which stands for **E**asy, **A**ttractive, **S**ocial and **T**imely, which refers to the attributes which a behavior should have in order to be adopted by people. The EAST framework can bring valuable perspectives in our ideation sessions, helping us consider these aspects for more effective mHealth solutions and associated interventions.

How can the EAST framework be integrated into ideation sessions, you might wonder. The easiest and possibly most effective way is to integrate its dimensions in our How Might We (HMW) statements, or use them as prompts in the ideation session. So, when you are organizing an ideation session (regardless of the methods being used), consider integrating some (or all) of the EAST principles in your HMWs or your prompts. Have them written on cards or on your ideations board, and explore them one-by-one with your team, allocating

Table 5. Examples of HWM statements inspired by EAST and applied to the SFT 2.0 app

HMW Statements inspired by EAST	Further prompts on EAST principles
HMW make smoking cessation easy for pregnant women?	How could we break down the quitting process into smaller, manageable steps? How could not smoking become a default? How could the effort of quitting be reduced or barriers eliminated? How could we simplify the message and make it easier to be understood?

HMW make smoking cessation attractive for pregnant women?	How could we attract pregnant women's attention to consider quitting smoking? How could we provide personalized information about quitting smoking in a novel way? How could we frame the information so that the behavior is easier to be uptaken? How could we incentivise women to quit smoking? How could we visualize progress in a compelling way?
HMW make smoking cessation social for pregnant women?	How could we normalize not smoking and present it as a social norm in their group? How could we harness the power of social networks? How could we strategically "seed" the behavior in networks of relationships or friend groups? How could we enhance reciprocity in quit attempts?
HMW make smoking cessation timely for pregnant women?	How could we support women in finding the right moment to quit smoking? What natural changes/ routine disruptions can be leveraged to help women quit smoking? How could we push forward the immediate benefits and savings of quitting smoking, and immediate costs of continuing to smoke? How could we help women plan their quit attempts and for overcoming possible future barriers? How could we tie quitting milestones to pregnancy milestones? How could we help women transition through the postpartum period without relapsing?

Co-creation sessions

Co-creation sessions are ideal tools when you have the context to organise a workshop (either in-person or remote/online) and bring together different people to generate ideas as a group. You can create these sessions within your team, but they can be even more powerful if they engage and include experts from different fields, specialists who deeply understand your users, or even end-users of your solution. Including end-users in your co-creation sessions (people recruited from the population expected to actually use the mHealth solution) is extremely valuable as it increases user-centeredness and can bring insights and ideas that your team alone could have not come up with.

One aspect to keep in mind when organising co-creation sessions is group **size** and **dynamic**. Similar to other participatory qualitative research methods you would conduct with a group, in co-creation sessions we need to be confident we have a number of participants we can work with effectively. If you have more than 5 to 7 participants, consider splitting them in sub-groups so collaboration remains effective. Ensure you offer a space in which everyone's voices

can be heard and everyone can contribute. In addition, the possible dynamic within the group needs to be carefully considered. Some end-users might feel intimidated if assigned to a group with experts, for example. Combining different roles related hierarchically or displaying power asymmetry could make participants uncomfortable.

In terms of structure, co-creation sessions are very flexible and can be designed to the specifics of the participant group and the goals of the session. However, some common aspects are important to note:

1. Decide on a **location** (if in-person) or a set of tools to support organization (if remote/online), as well as an adequate **time-frame** given the context and the participants who would attend. Keep in mind that participants can get tired after 1 hour to 1 and a half hours of activities, so also consider breaks if needed.
2. Decide on a **facilitator** (or more) who would walk the participants through the session, facilitate exercises, ensure the session is on time, and overall ensure the session runs smooth.
3. Make sure to prepare an **introduction**, describing the goals of the session and how it will unfold. If you will have people working individually, in smaller groups and/or the extended group, this would be a good time to mention the logistics of it.
4. Include an **icebreaker** exercise at the beginning to help people get to know each other as well as getting them in a more creative mental space. Icebreakers are usually fun ways to get people collaborating, become familiar with the space (if the session is in-person) or the digital collaboration tool you are using (like Zoom, Teams, Miro or Mural, if online).
5. Prepare some **How might we statements** as well as some insights on the health problem, the users and their challenges, the context, the behaviors of interest - any aspects that you feel would help participants immerse themselves in the story.
6. Define a set of **ideation exercises** to include in the session, to help the group produce as many ideas as possible around the HMW statements. Prepare additional prompts to constrain, remove constraints or change the angle from which they look at the problem, which could be included throughout the session.
7. You could also include a **voting** exercise to help participants prioritise proposed ideas for solutions, as well as an **affinity diagramming** exercise to cluster ideas and functionalities which participants think would work well together
8. Consider a **wrap-up of the session**, which could include a presentation of the ideas the group came up with or a short discussion on a relevant topic which would allow participants to zoom-out from the session.

CHAPTER 16

Design the concept & prototype: Shape an mHealth solution concept

Once we have an idea (or even a few ideas) of how to design our mHealth app, to address the health challenge of interest, it is time to integrate them in a coherent concept. In this stage it is still common for teams to continue with more than one idea (which they turn into concepts), and work with them until it becomes clear which one would be best fitted for the goal. According to IDEO, "A Concept is more polished and complete than an idea. It's more sophisticated, it's something that you'll want to test with the people you're designing for, and it's starting to look like an answer to your How Might We question" (IDEO, 2025). In other words, a concept is **a representation of your solution and its components, which allows you to communicate how you would solve the health challenge through the digital solution you are proposing**. Because it can communicate the high-level solutions, concepts are used to test the solution's alignment with its users (through user testing, which we will discuss in the next chapter), as well as test feasibility (by driving technical proof-of-concepts - a method used by developers to answer the question: *Can we build this?*). As a result, the concept design stage is a pivotal moment in the lifecycle of the design and implementation of any mHealth app, as it is the start of fleshing out the solution as a whole.

The ways we represent mHealth solution concepts can be very diverse, from storyboards, narrative descriptions, concept maps, system maps, prototypes or any (preferably visual) representation of how the different components of our system come together. We often start by diagramming some components on a whiteboard (or on paper), to map out the components of our system, and then draw lines to suggest how they interact in order to attain their goal. We initially aim to produce a bird's eye view of the entire system and how it operates, before we jump into designing each individual section or establish details about how users would interact with each of the elements. In more refined versions of our concept representations (with more detail) we have dedicated tools which can help us recreate even the whole digital product experience, without writing a line of code. And this approach is preferred because it caters to the iterative nature of building tech solutions, in which changes will be brought to

our solution, as we continuously test our concept. And changes are a lot faster and cheaper to do on a prototype than on the actual implementation of an app, because writing code is time consuming and expensive. So designing and communicating our concept in various ways throughout the design process will help us validate our approach before our team starts writing code, to bring it to life.

Concept Design Tools

We have selected three basic tools (more like approaches) to briefly discuss in this section, which could help you communicate your concepts, depending on how advanced you are in your design process. In earlier stages, for the representation of higher level concepts (which have less details), you could use concept maps as a tool. If you are more advanced (have explored in more detail the structure of the mHealth app and have started to flesh out interactions), but you have limited time and limited digital design abilities, you could produce a paper prototype (or other lower fidelity prototypes). And if you are more advanced, and you work with a designer who could produce it, you could also represent your concept in an interactive digital prototype. We will discuss each of them, and guide around using them.

Concept maps

Michael Lewrick, in his book *Design Thinking Playbook* refers to concept maps as "graphic representations of our knowledge and an excellent means for us to bring order to our thoughts" (Lewrick et al., 2018, p. 103). So beyond representing the concept visually to share within and outside the team, concept maps are an excellent tool for us to have "a dialogue" with our solution, ask ourselves questions about how different elements work together, and in this process bring clarity to our solution proposal. The dialogue can also be in the extended team, and built together, ensuring that it covers all the important dimensions of our solution. Concept mapping is thus a great opportunity for advancing understanding of the system we are building, identifying missing parts (or links) and ensuring our concept is coherently built.

Visually speaking, concept maps have at their center the concept we are trying to represent (in the case illustrated below, the mHealth app for pregnant women), together with all the relevant components it contains. Icons can be used to illustrate each of the components, together with a label to clarify their meaning. We also typically illustrate through different types of connectors (full lines, dotted lines, on way arrows, double arrows) how different components connect or what is their relation to each other. In the case we have illustrated in Figure 24, the full arrows suggest components which influence other components. For example, the Self-Help Materials (which have eventually been implemented as a stand-alone component/ section in the app), influence or determine users' perceived importance of quitting smoking as well as their readiness and confidence. They also impact the Planning

of a Quit Attempt and guide the interaction with the Support Person. Dotted arrows on the other hand represent hierarchical relations between concepts. Using Self-Help Materials as an example again, the diagram suggests that it has four distinct domains on which it offers information, more specifically on *Why to Quit*, *How to Quit*, *How to Maintain Smoke Free*, and finally information on *Mental Health and Emotional Wellbeing*. These have eventually been implemented as chapters in the self-help section of the app. Also double-head arrows communicate components that influence each other at some levels (not only in one direction). Nomatter how you decide to build your concept map, keep in mind that consistency in representation, color, elements are critical in ensuring you accurately communicate the concept to the reader.

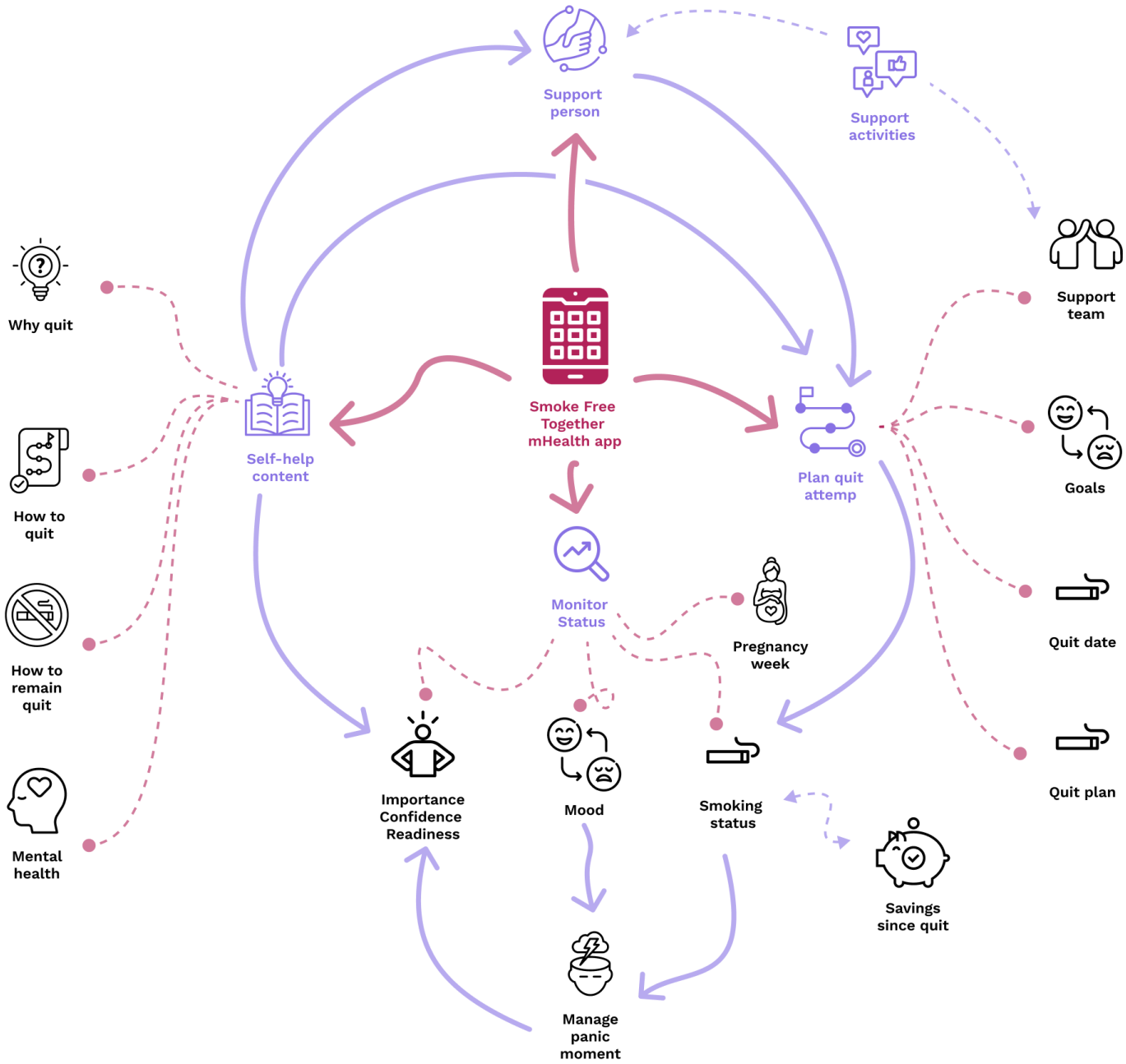


Figure 24. Early concept map of the Smoke Free Together 2.0 App, illustrating the components of the system and how they connect to attain its goal

Paper & other low fidelity prototypes

Once we have a good understanding of the system we are planning to build, we can go into more detail and further clarify how each of the sections would function, and how users would interact with them. In the attempt to communicate the experience of using the solution, prototypes can be a very useful tool. According to the Interaction Design Foundation, "Prototypes are early models of a product that simulate its design and functionality. They are created to test concepts, gather feedback, and iterate on the design before the final product is developed. Prototyping, on the other hand, is the experimental process of making prototypes" (Interaction Design Foundation, 2019). The keyword to mark in the quote is "*simulates",* as the main goal for using prototypes is to try to render a realistic experience of the product we are building, in a rapid and low cost way.

Depending on how advanced we are in the design process, a paper prototype or a low-fidelity sketch of how the interface would look and behave can be sufficient. It could be a good-enough simulation (with the information we have up to that point) of the major or key flows, which users could hold in their hands and test. Having early feedback on our concept and product experience is very helpful, so we can iterate and adjust as early as possible. Because as we have mentioned above, the earlier we make changes, the cheaper and more effective it is. Imagine spending 2 hours building a paper prototype and testing it, compared to months of writing code and bringing a solution to life, only to find out that it does not meet the users' goals or does not address the problem in an effective way.

How to build a paper prototype you might ask? As its name suggests, we can build a prototype/simulation of our solution by cutting, drawing and glueing together bits of paper to illustrate screens. Paper-prototyping multiple sequential screens, and placing them in front of the user as they progress through the flow, could emulate a real-life situation in a satisfactory way, so that users could provide feedback on the high-level experience of using the app. For even faster paper-prototyping you can use downloadable cutout kits, which you can print, to offer you a starting point for common mobile app components (such as this kit from Nielsen Norman Group).

Interactive digital prototypes

Technology today allows us to go beyond paper and sketches and build prototypes which simulate very realistically mHealth applications, without code (or actual development effort) to be used. This enables us to generate in a timely manner interactive (also referred to as "clickable") digital prototypes of mHealth solutions, which look, behave and feel very similar to an actual app. They can be run on mobile devices, and their fidelity and realistic nature can allow us to test and identify even usability concerns, which could be addressed from the design stage.

Building interactive prototypes is a more technical skill, which requires both human-computer interaction and user experience (UX) knowledge, in order to adequately design the interface of the app. In addition, digital prototyping skills and some degree of competence in using a prototyping software would be required. Although we recommend collaborating with a trained designer as early as possible in the process of designing your app, if you haven't included one in your team up to concept design, within this stage you should consider bringing one on board. They could take the lead in designing the overall experience of the solution, together with flows and navigation, support with content strategy and design interface components which users would require to interact with the app. They would also be able to build interactive digital prototypes which your team could use to test with users.

CHAPTER 17

Test: Get feedback, evaluate the concept and iterate to identify the optimal solution

By this point in the process, you probably have at least one mHealth app concept fleshed out (if not multiple, which you would like to further test), and at least a concept map or a sketch to illustrate how your digital solution would work. And now we reach possibly one of the most difficult emotional tasks you might have encountered up to this point: Aligning with the wise recommendation of "**don't get too attached to your solutions**". After putting all the effort into this process, it is a very difficult thing to ask from anyone, especially when they are building their very first mobile app. The enthusiasm of seeing something you are building take shape could be exhilarating and satisfying. But you need to remind yourself that you are working with a **designer mindset**, one focused on testing various solutions and learning about the problem and the users in the process, discarding the solutions which don't work and iterating on the ones which bring promising evidence that they could work. Your work and its value is not measured in the number of hours invested in a solution, but in how rapidly you can learn if you are on the right track, how to change course when needed, how to adapt or adjust, in order to bring a solution to life (which addresses the right problem) in the most effective way possible. In other words, learning quickly that a solution is not a good fit is actually time and energy saved from investing in an unhelpful direction. And every time we let an unfit solution go, we are actually enriched with a deeper understanding of the users, the challenge and closer to a solution which would be more appropriate.

Within this chapter we will discuss in more detail about how we can test our solutions, as an important step in the design thinking process. And although we refer to it as *a* step, it is actually a step we take numerous times throughout the design process, using different tools or methods (aligned with the maturity of the design process and what information we are trying to find out). We can test a concept for an mHealth app, we can test how we structure information and how users navigate it, we can test our content strategy, the usability of our interfaces and even the iconography we use. All these methods allow us to test (preferably often) throughout the design process, and iterate in tighter cycles, in order to advance our

design in a user-centric way.

As different as these user testing methods are, they have one pivotal aspect in common: **we are always testing the solution and never our users**. This perspective is something that you need to internalize and also clearly communicate to participants in your testing sessions. Ask open-ended questions, in a non-directional and non-priming way, and never get defensive or over-explanatory regarding your design. Your role is to ensure that the solution addresses your users, and not the other way around. You want your participants to be as open and honest as possible so you can identify possible vulnerabilities in your solution, which you can then address in a next iteration. And your number one goal is to understand what you can improve.

User Testing Tools

Although there are many user testing methods (as mentioned in the Evaluation Frameworks Chapter and the section above), we will focus on a single one in this section, which is most appropriate for the concept design stage of the process (also known as Concept Testing). This method is typically used at the earlier stages of the design of an mHealth solution, when we have a high-level concept of the solution mapped out. It could also be very valuable when trying to decide between different approaches (or several competing strategies for a solution). There is no point in guessing which one would be a better fit, when we can use research insights to inform our decision, and advance our understanding of the health challenge and the users in this process.

Concept testing

Concept testing can be defined as a process through which we share “an approximation of a product or service that captures the key essence (the value proposition) of a new concept or product in order to determine if it meets the needs of the target audience” (Rohrer, 2022). This *approximation* of the product refers to a high-level description or representation that can be attained by narratively describing the concept, a storyboard, a diagram, a concept map, a set of sketches, a few screens or any other artifact that could get the idea across. It can be a good checkpoint to see if the direction we have set on has any challenges that we did not anticipate, or if it has the potential to address the right problem, in the right way. It can also be a good opportunity to explore and gain more understanding of the user, the problem, the context as well as the solution space.

Typically concept testing is conducted moderated (with a facilitator present, running the session) and obtaining rich, qualitative data. However, it can also be conducted unmoderated, with a test set-up in a dedicated tool (or online software), which has the potential to collect

quantitative data. The latter is specifically useful when we want to test our concept at scale (on a wider and possibly more diverse population), with the limitation of not obtaining qualitative insights. But regardless of the method used, the testing protocol usually includes recruiting a number of participants which are as similar as possible to your target user group. Then in the dedicated session, we would provide a short presentation of the concept we are testing (show any visual artifacts or visual support we have prepared to describe it), followed by a set of questions which can help us infer how our users perceive the solution.

When building questions, try to use open-ended questions (especially when conducting moderated sessions), but steer clear from vague questions and be mindful of questions which elicit behavioral intent (as they are not very reliable). For example, try not to ask vague questions such as: what do you think about this solution/ app, or questions which would elicit answers towards interest to use because people are generally nice and would try to answer with a socially desirable answer. Instead, try to explore their perception from different angles, and possibly in more indirect ways. The table below summarizes some possible questions which could be used in the testing protocol, in parallel with less helpful alternatives which should be avoided.

Table 6. Sample questions for testing protocols

Use	*Instead of...*
✔ What are your first thoughts on the solution/ app I have just presented? **✔ If you had to describe this solution to a friend, how would you describe it?**	✖ What do you think of the solution? Generic questions such as the one listed above usually encourages people to rate or evaluate what was presented, increasing the risk for less helpful, socially-desirable answers such as “it is interesting”. A good alternative is to ask users what are their first thoughts on the solution - it keeps the answers open but allows them to focus on particular aspects of interest. Asking them to describe it using their own words, also gives you insights on how they perceive the solution and how they synthesize its goal/ perceived user benefit.
✔ Based on the description you have just seen/ read/ heard, what can you tell me about this solution? Who is it intended for?	✖ Would you use this solution? Instead of asking directly users if they would use a solution and risk a socially desirable answer, you could ask them who they think it is designed for. This would give them the possibility to say it is designed for someone like them, or if they do not relate to it, they could give you an example of who they think would use it. It then gives you a great opportunity to explore how they see themselves different from the stated users, and what changes would make the solution relevant to them as well.

✔ To what extent would this product support you with addressing <insert relevant user-challenge/paint-point> ✔ What features/ aspects you find most useful for you? What about the least helpful feature you noticed? ✔ How would you improve this solution, to help more people like yourself?	✖ How useful do you think this solution would be? Instead of asking users generically about the perceived usefulness of the solution, you could be more specific and inquire about its possible role in solving one of their specific challenges/ pain-points. You can then explore how it could be designed to help them more, and what is possibly missing. Asking about the perceived usefulness of specific features however could also prove more insightful, because it gives you the opportunity to understand why some are more useful than others, as well as what you could improve to increase usefulness (or alternative what you could discard to make the solution more focused).
✔ What would make you use this solution? ✔ What would constitute a possible barrier for you in using this solution? ✔ In what contexts would you use such a solution?	✖ How often would you use this solution? Instead of asking users about a hypothetical frequency of use, you could ask what would determine them to use such a solution and/or what would be any possible barriers in use (allowing them to bring in the discussion possible concerns). Asking them in what context they would use the solution also brings more valuable insights related to possible context of use, and allows you to further explore how you could adapt it to address other specific contexts.
✔ What information would you need before buying/ paying for this solution?	✖ Would you pay for this solution? As mentioned earlier, us humans are not very good at predicting our behaviors and are also prone to offering socially desirable answers. So instead of asking them if they would pay for it (if the mHealth solution is planned to be monetized), you can focus the discussion on what they would need to know before making a purchasing decision. This will give you insights on their decision-making processes and shed light on what matters more to them, which is more helpful information in this stage of the design process than unreliable predictions.

Once you conduct a concept test with a few possible users, you can synthesize your insights to identify areas of future development, new features or functionalities, adapt existing ones that could be improved, or even discard the ones that seem less helpful. Typically testing (including concept testing) is also an opportunity to gain more empathy for the users, refine the definition of your design challenge, create more How Might We questions for ideation, and more directions to prototype new concepts. As a result, concept testing is a great opportunity to iterate on your design, and strengthen the concept, aligning it closer to user needs. So any successful concept testing session would infuse enthusiasm based on the new discoveries

you have made. It allows you to have enough actionable insights to get “back to the drawing board” and iterate on a new and improved version of your concept. Once we are comfortable with the concept we have designed, we can move to the next stages of designing the actual interface and users’ interaction with the digital system, using higher fidelity prototypes. We then iterate and test on the interface design, up to the point all the details are clarified and the project can move into actual implementation (writing the first lines of code).

CHAPTER 18

mHealth product development: Final notes on bringing a solution to its users

After multiple iterations of your design, typically products go into development, a phase in which engineers pick it up and write the code needed to bring the solution to the market. The development phase is also iterative, typically conducted in an *Agile Software Development* paradigm, an umbrella term for a set of methodologies aligned with the *Agile Manifesto* (Agile Alliance, 2023a). The core values of this paradigm rely on self-organising and cross-functional (or cross-disciplinary) teams, a focus on people and collaboration and less on procedures and exhaustive documentation, and a mindset that can quickly and effectively respond to change while creating working software. Within this mindset, functional software is expected to be delivered at short time intervals (even as short as weeks), instead of waiting for the end of the implementation to release a working product (available for use). Other core principles include daily interactions between business specialists and developers (to promote close collaboration), as well as regular scheduled moments for reflection on how the team is working together, offering an opportunity to improve for the next iterations. There are several popular frameworks which are widely employed in software development teams (such as Scrum, Kanban or Extreme Programming), so depending on the team's dynamic and preferred ways of working, you might have to get familiarized with the individual processes. Discussing all the possible frameworks and methodologies is beyond the scope of this book, so we encourage you to ask questions when joining a new team or collaborating with/ contracting a software development service to get familiarised with their approach to software development.

Digital Product Development Tools

In this chapter we would like to direct your attention to three concepts and instruments that you will very likely encounter in any Agile work system. We consider them central for future public health practitioners to get familiarized with, in order to feel more comfortable when sitting at the decision table with engineering and product management teams. These are the

Minimum Viable Product (also known as the MVP), the Product Roadmap and the essential process of Feature Prioritisation. All three are key tools used in the development of any digital product, so we will discuss them in brief in the next section.

The Minimum Viable Product (the MVP)

The Minimum Viable Product (MVP) is probably the best known concept from the Lean Product Development framework, a concept that is highly illustrative of the iterative nature of product development. It emphasizes the importance of learning about user behavior by developing an initial, often scaled-down version of a product and releasing it to users early on. Based on the information we collect around the use of the MVP, we can then plan for the next stages of development, as we have a better understanding of our customers and their interaction with our product (Agile Alliance, 2023b). It is an excellent way to validate product interest or uptake, so we don't have to only rely on self-reported intent to use or intent to purchase - which are less reliable. As a result, in early discussions around the development of a new software product you might hear teams focusing efforts in delivering first an MVP. Your role as a public health practitioner could be important in the definition stage of the MVP, when teams establish what features would go into the MVP and how they should be structured, ensuring the MVP is not only *minimal* but also *viable*.

The mHealth product roadmap

A product roadmap (as the name suggests) is a tool which allows teams to get on the same page regarding where they currently are, where they are heading, as well as how they could get there. It should be a living document, which is constantly updated and modified to reflect changes in strategy or in the market. A recent systematic review defined the product roadmap as a key instrument that "maps out the vision and direction of the product offering (...) describes the way how a product or a product portfolio is going to meet a set of business objectives and the work that is required to get there" (Münch et al., 2019). Any product needs to have a strategic approach to introducing features or functionalities to their users, as they will be released incrementally. As mentioned earlier, software development is iterative, so the process of establishing priorities for development effort (and its planning) is a big part of product roadmaps, which also offer a great context for aligning teams, effectively allocating resources and setting realistic stakeholder expectations. Given their significance in the software development process, you may be asked to contribute insights to the product roadmap, depending on your role and expertise.

Feature prioritization

For both MVPs as well as Product Roadmaps, teams will often be put in the situation to prioritize the development of features, functionalities or user goals. Depending on the context, we might want to prioritise some or others, in order to ensure we have a coherent approach

and we use resources wisely. Typically, prioritisation lies at the intersection of user feedback, product usage insights as well as strategic vision, enabling teams to make informed decisions around which features would provide the most value and meaningful impact, at any moment in time (Komandla, 2024). The process of prioritizing can be assisted by various tools that help us effectively decide on the development order. We would like to mention one of the most used methods, the MoSCoW method designed to help us understand and manage priorities when building software. MoSCoW is an acronym and stands for **M**ust have, **S**hould have, **C**ould have and **W**on't have this time, defining four categories in which we could place possible new features (Agile Business Consortium, 2025), once we list them.

The **Must-have** category should comprise of any functionality without which the product would not make sense, would not be legal or would be unsafe. In other words, all the features included in this category are core for the functioning of the product and cannot be left out while still maintaining a viable product. **Should-haves** are typically important functionalities that bring value to the product, but are not vital for its use. They usually can be overcome with work-arounds (preferably temporary) and although their absence can be a pain-point for the user, the product would still be viable without them. **Could-haves** are frequently referred to as "nice-to-haves", functionalities which would improve the usefulness or experience of the user, but are less important. Leaving these functionalities out would be less consequential than leaving a should-have out, and they are usually the first in the list to be implemented if there is more time and resources available. The last category of **Won't haves** (this time) include all functionalities which will not be included, at least not in the current version of the solution. We always document this category as well, as it is important for aligning the team and setting expectations - what we are not implementing could bring critical information on the positioning and the boundaries of the solution. Prioritisation efforts could include the extended project team but also stakeholders, which could help us decide what must/should/could as well as won't be implemented. As public health practitioners you might also be involved in this process, especially in situations in which including or excluding some functionalities could impact product viability.

SECTION SIX

Concluding remarks

As we outlined at the start of this book, public health practitioners increasingly find themselves at the intersection of population health and digital technology. Whether recommending apps to beneficiaries, providing feedback on digital solutions, or leading mHealth projects, engagement with mobile technologies has become an integral part of public health practice.

We hope these chapters have made the technical side of mHealth feel more approachable and helped you recognize how valuable your public health expertise is in developing digital health solutions that work. As we discussed when starting this journey together, solving today's complex health challenges requires bringing different perspectives to the table - from public health practitioners to researchers, designers, developers, and beyond. Your understanding of human health behaviors, population needs, and intervention design is essential for creating mHealth applications that truly serve their purpose.

The structure of this book - moving from foundational concepts through frameworks and hands-on skills - mirrors the journey many public health practitioners take when entering the mHealth space. Through the Smoke-Free Together 2.0 case study, we've illustrated how theoretical knowledge translates into practical application, demonstrating that while mHealth development may seem complex, it becomes approachable when broken down into clear steps and processes.

We began this book with the mission of helping you feel confident and capable of engaging with technology teams. We hope you've gained that confidence as you've learned about the mHealth development processes, regulatory requirements, behavioral frameworks, and practical tools. The digital health ecosystem needs public health practitioners who can bridge the gap between population health needs and technological solutions.

As you begin your own journey in mHealth, we encourage you to return to different sections of this book as needed. You might find yourself evaluating health apps one day and joining a development team the next. Or perhaps you'll spot a public health challenge that could be addressed through a mobile solution. Whatever path you take, you've built a foundation to engage thoughtfully in these spaces and bring your public health perspective to the conversation.

ANNEX 1

mHealth research informed consent template

Details & instructions

This template is designed for obtaining informed consent in mHealth research. Sections highlighted in [brackets] should be customized for your specific research context. The language should be clear, accessible, and appropriate for your target population.

Critical points:

- Use clear, simple language appropriate for your target population
- Avoid technical jargon or complex terminology
- Include all required elements of informed consent
- Clearly explain risks and benefits
- Detail data protection and privacy measures
- Specify participant rights and withdrawal procedures
- Include appropriate contact information

Consent documentation details

It is good practice to include the following on the first page of the informed consent.

Field	*Description*
Project name	Include the name or the acronym of the project

Funding	Include the funding source and grant number, if existing
Research team	This usually involves naming the persons who are part of the research team and/or who are implementing the project
Participant code/ research ID	Assign a code (e.g., P001) to avoid using names
Version	Consent form version and date
Ethics approval	This includes reference numbers for ethical approval. All research studies conducted with humans as research subjects need to be approved by an Insitutional Review Board, especially if you are conducting this study as part of a team based in an university. If you work for a company, obtain such approvals is not customary. Yet, to preserve the rights of the subjects, informed consent should be sought before any type of data collection that involves human participants.

Consent form structure

The consent form usually consists of two sections: 1) a participant information sheet that describes the research the participant is about to participate in and 2) a certificate of consent, which usually contains the name of the subject and their signature for agreeing to participate in the study.

Part I: Participation information sheet

Purpose and background

This section covers the main goal of the research being carried out. It usually takes this form: The long-term goal of this research is to [OVERALL GOAL]. You are invited to participate in [CURRENT PHASE] which runs from [DATES] and involves [MAIN ACTIVITIES].

The long-term goal of this research program is to develop, implement and evaluate a mobile app for quitting smoking during pregnancy with the help of a peer supporter. The program has two phases. You are invited to participate in the first phase which is implemented between November 2020 and January 2021 and consists in an online discussion of 30-45 minutes. Because the program is aimed at pregnant women and their nominated peer supporters, we would like you to invite one meaningful person in your life to join you in participating in this project.

Why have you been invited?

You have been invited because you meet these criteria:

- [ELIGIBILITY CRITERION 1]
- [ELIGIBILITY CRITERION 2] [Add sample size information if relevant]
- a pregnant woman
- you smoke, even occasionally. Also, other nine smoker pregnant women and their nominated peer supporters will participate in the program.

Do I have to participate in this research program?

No, participation is completely voluntary. It is up to you to decide if you want to take part in this program or not. You can ask questions at any time, may refuse to answer any questions, can withdraw at any time without penalty, will not lose any benefits if you withdraw.

How does the [NAME OF PRGRAM] program work?

The program is now in the first phase and it aims to explore who are the main persons smoker pregnant women turn to for support when they intend to quit smoking, what support they have received in prior quit attempts and other behavior and life changes, and specifics about how support may be provided in future quit attempts.

What will happen if you participate?

If you decide to participate, you will be asked to:

- [ACTIVITY 1 WITH TIME COMMITMENT]
- [ACTIVITY 2 WITH TIME COMMITMENT]
- [ACTIVITY 3 WITH TIME COMMITMENT]
- Think about one meaningful person in your life who you would like to invite in this program as your peer supporter.
- Sign an informed consent confirming that you understood the aim of the program and you volunteer to participate.
- Sign a General Data Protection Regulation form.
- Provide your name, email, and phone number, for the research team to be able to contact you. We will also ask you to send us the name, phone number, and the email address of your peer supporter.
- Complete a short survey (3-5 minutes)
- Participate in an online discussion of 30-45 minutes

Potential risks

The risks of participating in qualitative interviews on public health topics are usually minimal and of low severity. However, please take time to review potential risks before conducting your research and adjust the text below accordingly.

The potential risks associated with this program are minimal and have a low severity. The probability of physical risks is low. Participants are not required to perform activities that may result in physical injury. The probability of psychological risks is also low. Other possible but unlikely risks include issues related to the safety of research data, risks against which the research team takes all appropriate measures to protect personal data.

Potential benefits

Similar to potential risks, take time to think about the potential benefits the participants will gain if they decide to participate. Usually, these benefits are not direct financial benefits, but go more towards societal and public health gains.

As a result of participating in this program, you will find information that may motivate you to quit smoking or stay quit. The health benefits include immediate relief for the pregnant woman and her peer supporter, to the fetus, during birth, and for the baby, on the long term.

Contact information

We encourage you to ask questions. If you have questions or concerns about this program, such as scientific issues, what your participation involves, or to report an adverse event, please contact [NAME OF PERSON RESPONSIBLE WITH THE PROJECT]. If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the [NAME OF THE ETHICAL REVIEW BOARD THAT APPROVED THE STUDY].

Part II: Certificate of consent

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. By checking the textbozes below I consent voluntarily to participate in this program.

I understand that:

- My participation is voluntary, I can withdraw at any time, and my data will be kept confidential

- Members of the research team who work in this program will have access to all the information (including my name, email, and phone number) I will offer during my participation.
- Members of the research team will use the contact details of nominated peer supporter (name, email, phone number).
- I will participate in an online discussion of 35-45 minutes
- [ANY OTHER KEY POINTS]

By signing below, I agree to participate in this research.

Full name	
Date	
Participant signature	

ANNEX 2

mHealth interview guide template

Details & instructions

This template is designed for conducting semi-structured interviews in mHealth research, with a specific focus on understanding pregnant women's experiences with smoking cessation and mobile app support. Sections highlighted in [brackets] should be customized for your specific research context.

Critical points:

- Formulate only open-ended questions that elicit stories and elaborated responses
- Avoid questions containing multiple topics in a single statement
- Use follow-up questions or probes under each open-ended question
- Don't lead participants toward specific answers
- Don't make assumptions about participants
- Pay attention to non-verbal cues and participant comfort

Interview documentation details

It is good practice to document such information to keep with the interview transcript.

Field	*Description*
Participant code	Assign a code (e.g., P001) to avoid using names

Population segment	Write some anonymized information about the participant, relevant to the segment they belong to. E.g., “Pregnant woman, 2nd trimester, first pregnancy, current smoker”
Date, time & location	Document date, time, and type (online/in-person) of interview
Interview duration	Note duration in minutes

Introduction script

Thank you for agreeing to participate in this discussion. My name is [NAME] and I am a researcher working on developing a mobile application to support pregnant women quit smoking with the help of a support person. We are interested in understanding more about pregnant women’s experience with quitting smoking, particularly regarding the support received during previous quit attempts and how this might be relevant for a future quit attempt during pregnancy.

Your participation is completely voluntary and you can withdraw at any time. All information you share during this discussion will be used strictly for research purposes. We will not use your name or any identifying information in our research.

Do you have any questions before we begin?

- ☐ Yes [answer all questions]
- ☐ No [continue to next question]

Would you agree to audio/video record this discussion? The purpose of recording is solely to help me capture all the information you share and will not be used in this format when reporting results. After this discussion, I will transcribe the interview, remove all personal data (anonymize it) and delete the recording.

- ☐ Provides permission for audio recording
- ☐ Provides permission for video recording (if applicable)
- ☐ No [continue without recording and note to participant]

Initial assessment

Before moving to our open-ended questions, I would like to ask you, on a scale from 1 to 10… How important is it for you to quit smoking?

1	2	3	4	5	6	7	8	9	10

How confident are you that you can quit smoking?

How ready are you to quit smoking?

Section 1: Opening questions

Introduce 1-2 opening questions here to help you get to know the participant in the context of the research topic. These are just to start the discussion and open the topic.

1. I'd like to ask you about [NAME], the support person you nominated when you enrolled. Could you tell me about:
    a. How you met
    b. How long you've known each other
    c. What roles you play in each other's lives
2. Think about a time when you tried to change a behavior (for example, exercising more, reducing unhealthy food, changing drinking habits):
    a. Who did you rely on for support?
    b. What kind of support did you receive?
    c. How was that support provided? (in person, messages, calls, social media?)

Section 2: Main questions

Introduce here 3-5 main questions, constructed on the basis of the participant profile and the research purpose. Keep in mind the complexity of the questions, the time allotted, and the environment in which the interview will take place to ensure that you can cover them during the interview.

3. Regarding quitting during pregnancy, if you tried to quit smoking during this pregnancy, what do you think you would need to succeed?
    a. What kind of support or help would you need and from whom?
    b. Could you give me some specific examples?
    c. What would be helpful, what wouldn't be helpful?
4. Let's imagine having access to a mobile app for quitting support, what do you think such an application should contain?
    a. If there was also a version for a support person you choose, would you invite someone? Who?

b. What information should the app contain for the support person?

c. What functions would be useful to enhance the support provided?

Section 3: Closing questions

Introduce 1-2 closing questions here, summarizing the discussion and bringing the conversation to the present.

5. If you had to describe this application to a close friend in a few words, what would you say?
6. Do you have any suggestions about what we've discussed? Is there anything missing that you feel would help?

Section 4: Final thoughts

Leave space for any final thoughts from participants.

7. My list of questions ends here. Would you like to share anything else to help us better understand how pregnant women can be supported in their quit attempts through a mobile application and support person?

Closing

Thank you very much for your time. Your responses help us better understand how to support pregnant women in quitting smoking through mobile applications and are extremely valuable for our research.

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