

EmERGE

Deliverable D2.4

Policy and practice guidelines: Report on guidelines to support co-design for improved usability, acceptability and patient outcomes in mHealth developments.

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D2.4 Executive Summary

1.	The policy and practice guidelines proposed here are designed to support digital health innovation stakeholders understand the inter-relationships between co-design and empowerment, with specific focus on how these apply to mHealth. These stakeholders include - policy makers, clinicians, healthcare decision-makers, activist groups, patients and digital health companies.
2.	The guidelines are based on evidence collected as part of the EmERGE H2020 project which carried out a 5 year co-design process for improved usability, acceptability and patient outcomes in mHealth technology.
3.	The EmERGE project sought to improve empowerment through research, innovation, evidence generation and the commercialisation of mHealth technology for HIV care. Empowerment was conceptualised in three inter-related but distinct ways: empowerment as patient activation; empowerment through innovation co-design; and empowerment through systems and policy change.
4.	These three aspects of empowerment are inter-related, but complexly inter-related, meaning that they shape and reinforce each other in dynamic ways which become 'hard-to-measure' as direct cause and effect relationships. For this reason, the concept of 'empowering environments' is used in these guidelines to explain the difference between patient rights as legal framework and patient lived experience of social, political and health care environments.
5.	The concept of empowering environments is introduced as a means of explaining how co-design can a.) form part of creating empowering environments and b.) how its capability building effects are amplified when co-design is recognised as part of existing processes of empowerment within a specific environment.
6.	Based on evidence collected throughout a 5 year co-design process undertaken by the EmERGE project we can conclude that, as a minimum requirement, co-design can ensure that technologies are usable, acceptable and accessible. To achieve this, technology co-design processes must be inclusive and involve mechanisms for ensuring voice, participation and accountability.
7.	Co-design ensures that knowledge of the complexities and issues encountered within health service and technology design are opened out to people beyond technologists and healthcare professionals. This enables engagement in expert debate and therefore greater scrutiny of technology design choices, enhancing the capacity of civil society and policy stakeholders to influence and participate in innovation.
8.	Co-designing mHealth highlights the significance of digital care pathways that do not simply provide access to patient data, but which support people to navigate complex health environments by offering timely access to accurate and personalised information. Care pathway design requires clinic-patient collaboration to ensure that pathways are effective within local systems.
9.	Co-design of mHealth technologies - particularly those that seek to improve access to the medical record and other health information conventionally held within clinics and hospitals - opens out important questions regarding data security and data protection. To engage with these questions effectively requires improved understanding of the technologies through which clinical data passes.
10.	Co-design of digital health innovation opens out questions for digital health business of how commercial organisations seeking to supply services in this space can contribute to the creation of empowering environments and strive set to new standards in collaborative business and stakeholder governance.
11.	In our view, the question of whether there is evidence to say mHealth technologies or technology co-design can improve patient outcomes (understood as clinical or psychometric outcomes) requires further deliberation. However, the question of whether the co-design of mHealth technologies can contribute to the creation of empowering environments is answered resoundingly and in the affirmative by the evidence produced by the EmERGE project.

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1.0 Introduction

1.1 Background

This deliverable is one of two reports that summarise the outcomes and findings from WP2 Sociotechnical Evaluation and Co-design. In this deliverable, policy and practice guidelines are proposed to support digital health innovation stakeholders understand the inter-relationships between co-design, empowerment and healthcare utilisation.

The EmERGE project sought to provide evidence of how empowerment and healthcare utilisation are affected by the introduction of mHealth. The overall objectives of WP2 Sociotechnical Evaluation and Co-design were to:

- develop and implement a 5-year co-design process working in partnership with community partners The European Aids Treatment Group (EATG)
- conduct a sociotechnical evaluation of the innovation process based on data collected from workshops and interviews with clinicians, people living with HIV (PLHIV) at the 5 clinical sites at three separate time points over the 5 years
- engage in a broader set of interviews and participant observation conducted with a broader set of project stakeholders, referred to 'sociotechnical evaluation wider lens research'

The main focus of WP2 Sociotechnical Evaluation and Co-design was on 'key users of the system' meaning, principally, clinicians and patients. Findings from this part are reported on in D2.3 Final Evaluation Report. To complement this focus, a 'wider lens' programme of research was pursued which included project participants and stakeholders beyond clinicians and patients. The evidence on which these guidelines are based is taken from data collected from across all 3 elements of WP2 activity with particular focus on WP2 wider lens research.

1.2 Co-design, rights and empowerment

Fundamentally co-design signals a commitment to power sharing within design processes. Its precise meaning varies depending on the context in which it is used and the subject discipline with which it is associated. Co-design in the context of digital health innovation concerns i.) co-design of health services and ii.) co-design of digital innovation. Health services and digital innovation are themselves products of environments that influence local co-design processes and outputs. Therefore, how principles of power sharing play out in local contexts can vary considerably.

Co-design in health-related fields can be understood as a variant of patient public involvement (PPI) which in many European countries has been, or is currently in the process of being made, a legal duty of organisations who provide health services. Levels of political and practical commitment to PPI policy vary considerably, resulting in a spectrum of involvement practice, from:

- sharing information on new developments
- initiating consultations with people affected by health service change
- involving patients and the public in change processes
- power sharing, co-decision making, co-leadership and co-production
- patient and public leadership of policy and practice developments

The relationship between PPI and patient rights is not always clearly understood by health service providers and policy makers. Involving people and empowering them to lead multi-stakeholder processes increases the degree to which understanding of lived experience of rights infringement, lack

of recognition or denial becomes part of frontline and system level innovation. Bringing system designers together with people who have lived experience, in addition to those who advocate for those people, produces a tiered, multi-stakeholder approach through which practical engagement with how to embed rights recognition and realisation within service and system level design is achieved.

Advocacy and activism support recognition of rights and their presence or absence within a local or national environment can be indicative of social and political apathy or oppression. Advocacy and activist organisations play a vital role in supporting people to recognise their rights at local, regional and global levels. In the health context they support and improve utilisation of health services and recognition of rights.

In section 1.4 we introduce the concept of empowering environments as a framework for explaining these inter-relationships and supporting understanding of how co-design can:

- a) form part of a rights-based approach to innovation that supports the development of empowering environments
- b) produce capability building effects that are amplified when co-design is recognised as part of existing processes through which people become empowered within a specific locality

The question of how digital innovation and specifically innovation that involves the use of mobile phones in pursuit of health goals is can form part of a rights-based approach is important and is addressed below.

1.3 Co-design, digital innovation and mHealth

In this deliverable we focus on innovation co-design and within that digital innovation co-design – and very specifically - mHealth based digital co-design. Therefore, the practice and policy guidelines offered range from confirming well-established and generally applicable knowledge of how to engage in participatory practice, to the particular characteristics of mHealth pathway design.

In its narrowest sense, mHealth can be defined as the use of mobile phone applications (apps) by patients or people seeking health information and/or data. However, it is clear that empirical, analytical and practice concerns need to extend beyond this focus to fully understand mHealth developments.

In most cases, mHealth is made possible through a combination of interconnected technologies via which data flows and new ways of engaging in care are opened up. Retaining focus on this broader definition is necessary in order to understand the part that mHealth co-design can play in catalysing and extending empowerment. It is also important to understanding the implications mHealth holds for information rights, data protection, security and use of data within health systems and by third party organisations.

1.4 Co-design: supporting and catalysing empowering environments

In this deliverable we develop the concept of ‘empowering environments’ as a framework to support understanding of empowerment as simultaneously:

- a legal and policy framework
- a lived experience of the degree to which social, political and legal rights are recognised
- a capacity to collectivise, organise and take action in the face of lack of rights or their recognition

- design and delivery of services
- the formation of stakeholder groups who have a shared commitment to creating empowering environments at system level

Using this framework supports our analysis of how and in what ways co-design contributes to policy and practice. It enables us to produce analytical findings that are generalisable to other policy areas and examples of co-design. It also offers a means of capturing the diverse ways in which empowerment was understood and approached within the project. These approaches were:

- explicit and stated at the outset
- implicitly part of the project design and embedded in the co-design process
- emergent, meaning that empowerment and its definition as an object of research was itself defined by what took place through project activity

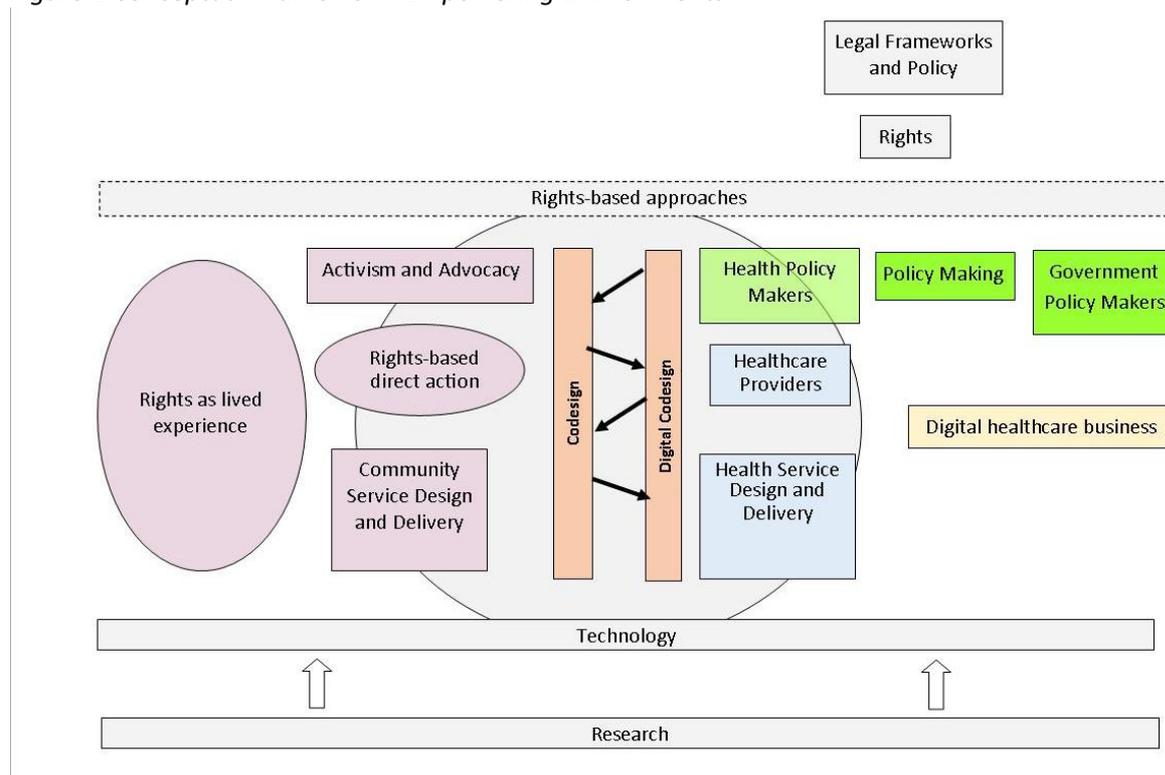
On this basis, we can say there 3 different ways in which the EmERGE project conceptualised empowerment:

- empowerment as patient activation
- empowerment through innovation co-design
- empowerment through systems and policy change

As described previously, the concept of empowering environments is situated within a broader framework of research, policy and practice on rights-based health activism and health policy making. It is developed through use of the capability building approach to research design described in section

3. In this conceptualisation the designation of an environment *as empowering* is aspirational. Whether the environment *is* empowering, or not, will be experienced differently, by different people, at different times. However, the framework supports scrutiny and accountability of common ways in which empowerment and disempowerment can occur. Figure 1 provides an overview of empowering environments framework.

Figure 1 Conceptual Framework: Empowering Environments



Co-design processes and outcomes sit within broader environments that *are more or less* empowering. Therefore, inevitably, the process and outcomes of co-design will be subject to local variation. Understanding the inter-relationships between empowering environments and successful (or less successful) co-design is therefore crucial to understanding how the two can work together synergistically.

Positive effects of co-design, patient activation, inclusive design and other forms of power sharing or co-decision making can be amplified or suppressed depending on i.) the quality of those processes and ii.) the environment they take place within. When stakeholders from different settings are linked together as part of a larger network, best practice in co-design can be shared and experiences of barriers and disempowerment can be addressed collectively by people both within the context and outside it. From the experience of the EmERGE project and based on the working practices of community partners the European Aids Treatment Group a tiered or 'networked stakeholder' approach where experience and knowledge sharing across different environments is supported, benefits the creation and extension of empowering environments.

1.5 Co-design policy and practice guidelines

A summary of the policy and practice guidelines that form the focus of this deliverable are provided in Appendix 1. The full guidelines and supporting evidence are provided in Section 4 of this report and are organised into 5 categories and are described in Table 1 below.

Table 1. Summary of policy and practice guideline sub-sections

1. Commitment to co-design: programme and project design
2. Co-design as knowledge building, sharing and mobilisation
3. Co-design of digital care pathways; specific implications for mHealth
4. Co-design and mHealth advocacy
5. Co-design and commercialisation: recommendations for digital health business

People who will benefit from these guidelines include:

- HIV clinics currently using EmERGE technologies
 - o the hospitals and clinics who may use EmERGE technologies in the future
- Hospital and health system decision-makers at the local level
 - o Digital and public health policy makers at local, regional and international levels
- Non-government organisation (NGO) advocates and activists currently working with EmERGE app users or potential users at local level
 - o Non-government organisation (NGO) advocates and activists working at local regional, national and European levels
- EmERGE mHealth Ltd. who will commercialise EmERGE technologies
 - o The broader digital health business community

In the next section we provide a brief overview of the policy context relevant to these guidelines and the research design through which the evidence on which they are based was produced.

This is an excerpt only. Sections 2 to 4 of this report have been removed.

5. Co-design Challenges

Co-design can enable the boundaries of empowerment to be explored and where possible extended. This requires constant reflection on how, when and where the limits of inclusion are set. The EmERGE project structure and multi-stakeholder tiered approach to co-design operated alongside the WP2 practice of combining active listening with accountable programmes of action enabled and supported this.

Digital health innovation can compound people's lived experiences of social, political and economic exclusion. It can also compound existing differences between local, regional and country-level capacity adopt or engage in digital innovation. The EmERGE co-design process took steps to counter digital inequality but more can be done to address this.

Extending co-design to include clinicians highlights the challenges that local clinical innovators face and the role that expert users play in supporting usability, acceptability and accessibility. Although the focus of the EmERGE co-design process was on those groups who are most in need of rights-based intervention further focus on the specific local and project level situations faced by clinicians in their local settings could have been pursued.

Extending co-design to include hospital IT personnel enables knowledge of local IT contexts to emerge and the differences that variations in digital experience, skillsets, infrastructure and resourcing make. This level of data was harder to elicit due to the technical and unmediated character of these discussions.

There was a consensus among EmERGE Community partners that separating the community partner network from whole consortium meetings had created a barrier to building local relationships and to local partners gaining knowledge of European level research and activity.

I would have loved to see more involvement. I thought from the beginning to have separate meetings for physicians and for community is not the way to go forward. If you want to do something together then do it from the beginning, and especially where this concerns design. So, I would have loved to see a bigger collaboration from the beginning.

There was also feedback on the format of community partner meetings which in some cases were felt to be 'too broadcast mode' with not enough time and opportunity for community partner led activity and interactions.

Community partners were invited to the final consortium meetings and EATG were responsible for organising and leading the end of project stakeholder meeting to which all EmERGE community partners were invited.

6. Conclusion

Co-design significantly supports the production of technologies that are usable and acceptable to end users. However, when viewed in terms of empowerment, the effects of co-design can go far beyond this. The extent of these effects is not adequately captured by conventional patient outcome measures because they are complex and inter-relational. Nonetheless, this does not mean that evidence of those effects cannot be produced.

Within EU policy making, interest groups such as Non-Government Organisations (NGOs), charities and patient groups are recognised as playing a significant role within the lobbying ecology of the EC which can otherwise become dominated by industry and large corporations. Within this ecology, interest groups have access to inclusion mechanisms and financial support in order to have a presence and influence policy.

The role of digital health business within this is a topic for further discussion. Digital health business can be constituted and led in ways that support a stakeholder approach to corporate governance and cultivate strong ties to the political objectives of the EU. To date, corporate contribution to citizen empowerment has been largely directed toward financial supports and partnership work with interest groups. Evidence from the EmERGE project suggests that a further form of corporate engagement with policy objectives can be achieved through collaborative business or 'doing business together'. In this model a networked model of stakeholder governance feeds directly into the corporate structure of the business enabling the value brought by each stakeholder group to be mobilised as effectively as possible. By this means the value brought by business, policy, citizens, clinicians and research is combined supporting timely and effective realisation of innovation alongside social and political rights.

The corporate entity that will commercialise the technology assets produced through the EmERGE project, EmERGE mHealth Ltd., has committed to including the guidelines provided here going forward. This commitment extends beyond a simple pledge or statement of values to the inclusion of these practices in its corporate governance model and business operations. These include the creation of a user group network for bringing together community and clinical voices and product feedback and along with capacity to address innovation barriers and opportunities from across Europe.

Appendix 1

D2.4 Summary of EmERGE Co-design Policy and Practice Recommendations

1. Commitment to co-design: programme and project design	
1.1	<p>Foundations of Co-design</p> <p>Co-design processes are particularly effective where significant power imbalance exists between designers and intended beneficiaries of design. Co-design processes can either be used: to influence a specific element of a design process, in which case inclusive and participatory practices are applied to a specific stage of a process; or they can be mobilised as a means of effecting broader, systemic change. To achieve the latter, and therefore amplify the capacity for co-design to effect change across a system, conditions for power sharing, co-decision making, co-learning, accountability and dissemination need to be established at the outset of a project, programme or technology deployment. Equal status, equal contribution, equitable resourcing and the inclusion of capacity building for empowerment as a strategic goal all contribute to the effects achieved.</p>
1.2	<p>Rights-based advocacy and networked stakeholder governance</p> <p>Patient involvement and representation can take many forms. Networks of rights-based health organisations acting within a specific field can support equal access to treatment and services within and across countries. Supporting local rights-based organisations to federate and build capacity strengthens campaigning and activist activity and this then feeds into service innovation and policy making to create systemic change. Partnership with rights-based networks creates a foundation for networked stakeholder governance, co-creation of value, improved geographic reach and inclusion of groups who experience lack of access to treatment or services, discrimination and stigma.</p>
1.3	<p>Community and academic collaboration</p> <p>Academic collaboration with rights-based advocacy networks and activist organisations can support and reinforce representation, co-decision making and power sharing and should be included within the design of projects and programmes design where possible. Rights-based organisations and networks working in the field of health have a systemic view of how, when and where rights to services and treatment are and are not being recognised in and across local contexts. This network provides an effective framework for catalysing research and knowledge sharing which academic collaborators can support.</p>
1.4	<p>Time and Resource</p> <p>In order to achieve systemic impact from co-design activity it should be programmed to begin at project launch and continue through to the end of project activity. As a funding priority it should be made of equal significance as other elements of research. Funding should include time for: building academic and community partnership, paying for co-design planning and facilitation by local community partners; and paying for participant time.</p>
1.5	<p>Co-design of co-design</p> <p>How co-design processes begin is indicative of co-design commitment and willingness to share power and so should be given due consideration. The design process should not begin before technology users and those representing them have met to plan and discuss the co-design process. In technology co-design, different starting points and methods for representing early design choices are possible (see 4.2 below). Co-creating diagrams, workshop plans, interview schedules, strategies for feeding back findings to participants and communication of results are all important co-design mechanisms.</p>

1.6	<p>Language use and Identity</p> <p>Co-design processes should reinforce and mobilise language use and identities that empower. Language that collectivises rather than individualises ‘the patient’ and which appropriately recognises level and status of expertise including capacity for international, multi-level political engagement, is important to apply accurately. Digital health innovation is systemic, meaning that it touches on and reconfigures relationships that reach beyond the healthcare system itself, therefore ‘people first’ language is preferable. However, in some cases it is important to be specific, for example when referring to patient data or the clinician-patient relationship. Being appraised of language use and identity, or learning from participants as conversations progress, is a foundation of good co-design.</p>
<p>2. Co-design as knowledge building, sharing and mobilisation</p>	
2.1	<p>Co-design as knowledge building, sharing and mobilisation</p> <p>Co-design can anticipate and build relationships that will be necessary to ‘real world’ development and use of a technology. It can help to overcome institutional barriers, including access to expert knowledge that may form future barriers to adoption and effective use. This process is supported by regular meetings, network structures and inclusive meeting spaces that create specific opportunities for integrating knowledge through co-learning and deliberation</p>
2.2	<p>Building knowledge: becoming expert together</p> <p>Scoping, planning and initiating co-design with participants at the very beginning of project or programme activity instils a culture of: need differentiation and recognition; active listening; and responsive, accountable action. As complex technology development typically requires development of a ‘joint field’ of expertise, involving people from the beginning enables project stakeholders to ‘become expert together’. Co-design needs to account for the specific nature of ‘what’ is being designed and the legacy or stage of development the co-design process creates or builds upon.</p>
2.3	<p>Building person-centred, holistic knowledge of the health environment</p> <p>For knowledge to move beyond conventional hierarchies or boundaries of expertise it must be actively translated and taken to stakeholders. Proactively creating structures and mechanisms for achieving this can extend the capacity of co-design processes to build, share and mobilise knowledge, and consequently support empowerment.</p>
2.4	<p>Co-design mechanisms for digital innovation</p> <p>Co-design mechanisms for ensuring knowledge sharing and accountability create a material basis for knowledge brokering, meaning that the priorities of a group whose voice is hard to collectivise and hear are conspicuously included in decision-making processes. This is particularly the case in digital innovation projects where the detail and history of decision-making requires explanation from both clinical and technology stakeholders.</p>
<p>3. Co-designing of digital care pathways: specific implications for mHealth pathways</p>	
3.1	<p>Community-Clinic Pathways</p> <p>Co-design can produce place-based, knowledge of lived experience that when combined with formal approaches to pathway design, enables an integrated understanding that grounds digital innovation in knowledge of rights-based issues that affect equal access and treatment.</p>

3.2	<p>Digital and mHealth Care Pathways</p> <p>mHealth care pathways introduce technical architecture and data integration (the achievement of a flow of data between systems) into i.) the clinical care pathway and ii.) the care pathway as lived experience. Feasibility and usability of mHealth technologies are dependent on local capacity to produce this architecture and achieve data integration ensuring appropriate data security. These are conditions upon which mHealth care pathways depend in order to produce a routinised flow of medical, and other relevant data, to the mobile phone application. Only if these conditions are achieved will the technology be usable. Within this complex work, user priorities compete with technical and integration challenges requiring particular focus on brokering and accountability.</p>
3.3	<p>Data security, data protection and trust in mHealth care pathways</p> <p>Co-design of digital innovation requires the combination of different types of stakeholder knowledge and lived experience if the technologies produced are to be acceptable, usable and produce beneficial outcomes for users. Technology developers are stakeholders in this process. Ensuring robust mechanisms exist for knowledge sharing between stakeholder is key to ensuring that usability and acceptance are achieved. It also has implications for recognising the need for how people’s advocacy needs are affected, shaped and influenced by mHealth.</p>
<p>4. Co-design and mHealth advocacy: project, country and European levels</p>	
4.1	<p>Recognising the full scope of knowledge and expertise</p> <p>Co-design of digital innovation with groups who experience institutional, social and political disempowerment requires a multi-stakeholder, tiered approach that privileges lived experience, and which draws specific focus to lived experience of rights denial and infringement.</p>
4.2	<p>Opportunities for empowerment</p> <p>Co-design processes can provide local contexts with resources to reflect upon and create new opportunities for empowerment at the local level. Co-design builds collective and individual capacity to advocate, that when understood as part of a broader context for empowerment through connections with national and international advocacy work, empowers people and enables them to see themselves as empowered advocates for positive social change.</p>
4.3	<p>Co-design as a process of empowerment</p> <p>Co-design processes benefit from the presence of existing networks of trust where people are attuned to the broader context and implications of building local capability and creating opportunities for empowerment.</p>
4.4	<p>Reference points for innovation and rights-based approaches beyond the local context</p> <p>Attuning to the context-specific needs of people in terms of the arrangements needed to engender trust is a key determinant of whether a co-design process will be successful or not. The effect of prioritising and reinforcing the value of community ideas through co-design holds implications beyond the co-design of technology itself. The effects of seeing those ideas take form through digital innovation design produces opportunities for empowerment.</p>
4.5	<p>Reference points for innovation and rights-based approaches beyond the local context</p> <p>mHealth innovation has potential to strengthen rights, including: patient access to data; equal access to treatment; equal access to health services; and country-level rights to equal access to digital innovation opportunity. However, strengthening these rights requires expert knowledge of mHealth, advocacy and reference points beyond the local context.</p>

4.6	<p>Co-design as a first step to forming user group networks for digital health innovation</p> <p>Co-design can extend conventional or institutional boundaries of expertise providing a basis for future advocacy and co-decision making. Developing a stakeholder model that places value co-creation for societal benefit supports and can be supported when a capacity building approach to co-design is taken. Co-design processes that seek to achieve greater geographic or demographic reach play an important role in achieving integration between different forms of experience and expertise which in turn support systemic change. Co-design can also help to identify and overcome regional or local barriers to adoption and use.</p>
<p>5. Digital health innovation, co-design and commercialisation</p>	
5.1	<p>Breaking new ground: co-designing commercialisation</p> <p>Co-design can contribute to every stage of an innovation project or programme including commercialisation. Commercialisation concerns questions that are central to the real-world deployment of innovation. Deployment and future service provision will be determined by type of company, commercialisation strategy, exploitation plan, business model and openness to future involvement of co-design partners. Co-design can extend to business co-design where appropriate levels of knowledge brokering and shared decision making is sustained.</p>
5.2	<p>Significance of stakeholder model of corporate governance for digital health business highlighted through co-design</p> <p>Stakeholder models of corporate governance support commercialisation processes through embedding collective action in the success of a commercial entity and; through supporting people to recognise they have a stake in commercial success and therefore an active part to play in ensuring the commercial entity remains accountable to them. Correspondingly, a stakeholder model ensures that the commercial entity reciprocates by providing mechanisms for ensuring accountability to its stakeholders, which in turn, ensure that the business goals and operations of the company remain aligned to the creation of mutually valued, financial and non-financial outcomes.</p>
5.3	<p>Co-design as foundation for longer term commercial value co-creation</p> <p>Co-design processes support relationship building across stakeholder groups such that opportunities to enhance the value of resulting commercial products and services are recognised as mutually significant, shared opportunities. These relationships can form the basis of a longer-term commitment to collaboration. This is easier to achieve in the case of products and services that are not-for-profit and intended for societal benefit. Nonetheless, the practical benefit of recognising ‘customers as stakeholders’ and the provision of mechanisms to support their involvement is established best practice in many industries.</p>