

The Imperial Clarify, Design and Evaluate (CDE) approach to mHealth app development

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INTRODUCTION

Mobile health (mHealth) is the practice of using mobile phones and other wireless devices in healthcare. There has been an unprecedented wave of innovation at the intersection of healthcare and technological innovation, and new digital healthcare solutions hold the promise of transforming healthcare delivery. Despite great enthusiasm for digital solutions, there have been ongoing concerns regarding a lack of clinician involvement, end-user engagement and the lack of a robust evidence base, underpinning the development of many apps.¹ Also, a lack of supporting frameworks to help development teams create useful and well-designed apps has hindered their practical usefulness, and subsequent success.

We present the Clarify, Design and Evaluate (CDE) framework, which has been developed and implemented at Imperial College London (figure 1). This framework aims to support the structured translation of an initial idea through to an effective app, the success of which has been rigorously evaluated. Our multidisciplinary team of clinicians, researchers, software developers and technologists at Imperial College London has broad experience in developing mHealth applications that have been developed through the framework. The aim of this article is to outline the development of two apps using the CDE approach so other innovators are aware of the requirement for well-conducted research, design and evaluation methods when implementing their apps in the future. The two apps we describe are (figure 2):

► *Hark*: a clinical task management and collaboration platform that manages, and prioritises, clinical tasks for health organisations, providing an auditable track of all clinical activity.

► *Usher*: a mobile-delivered platform to support patients going through complex patient pathways. Usher has been developed in the first instance for the bariatric surgery pathway at Imperial College Healthcare NHS Trust.

PHASE 1: CLARIFY

Before effort and expense are spent on developing an app, it is important to identify an area of need and the potential role for an mHealth solution. We have identified opportunities through a range of activities including ‘dragon’s den’ events, where we have invited clinicians to submit ideas to an expert panel.² Before any software development takes place, we use two broad approaches to further clarify the opportunity. First, traditional academic research using qualitative as well as quantitative methods can provide useful insights. Second, user-experience research can support idea generation. We have established the HELIX Centre—an embedded design laboratory—at Imperial College London, to provide this expertise.

Hark

The quality of communication between healthcare professionals is vital for quality healthcare delivery and patient safety.^{3 4} The Clarify phase of the Hark app was performed through a literature review and focus groups with healthcare staff.⁵ The literature review was conducted to give us a holistic picture of task management platforms that had already been trialled in the clinical environment and how successful they had been. The focus groups with healthcare staff were conducted early in the CDE approach to ensure early engagement with potential end-users and to gain valuable insights



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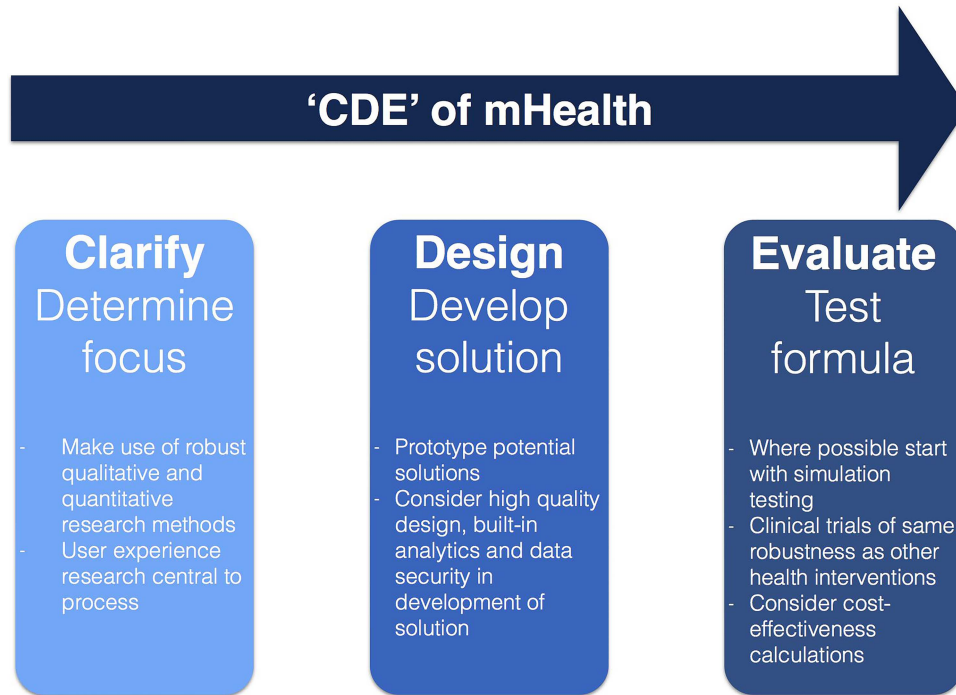


Figure 1 The Clarify, Design and Evaluate (CDE) approach to mHealth app development.

into how task management was conducted in hospitals, and where the areas for improvement lay. This research formed the evidence base on which the Hark app was created.

Usher

Effective education and support in the run up to complex surgery is crucial as patients are required to retain and deliberate over large quantities of information regarding complex operations.⁶ In the case of bariatric surgery, a good understanding of the complex care pathway is pivotal to expectation management, adherence to long-term lifestyle changes and to ensuring successful outcomes.⁷ The Clarify phase

of the Usher app involved a literature review followed by a phase of qualitative research consisting of (1) a structured observational study of current information delivery to patients in order to understand preoperative education processes and (2) a semistructured interview study with all relevant stakeholders (patients and clinicians).

As part of a user-centred approach to design, this qualitative research primarily aimed to identify user requirements for information technology for the preoperative education process in the bariatric surgical pathway. It allowed an enhanced understanding of the process of preoperative bariatric patient education and identification of technological capabilities able to



Figure 2 The Hark and Usher apps.

address these requirements. This work formed the evidence base on which the Usher platform was designed.

PHASE 2: DESIGN

After establishing user and system requirements, the next phase involves designing and developing a solution. This is often best accomplished using a Plan, Do, Study, Act (PDSA) cycle recommended by the NHS Institute for Innovation and Improvement.⁸ PDSA involves rapid-cycle testing that includes data collection and analysis prior to each iteration of an innovation. We start by developing wireframes representing the layout of the app to conceptualise what we are aiming to do and to test functions with end user solutions developed in accordance with relevant information standards, and with an eye on later systems integration to bring the app together with existing systems and processes.

Hark

The design phase of the Hark app was performed using rapid-cycle testing on a prototype version, which underwent six iterations before being deemed ready for formal evaluation. The design team consisted of a surgeon, a junior doctor, a nursing representative, a graphic designer, software developer and software security expert. Each iteration of the app was produced following team meetings, and tested by recruiting potential end-users from local hospitals to trial the app, and provide feedback on its strengths and areas for improvement. This design-test cycle followed the PDSA framework.

Usher

A multidisciplinary team of patients, clinicians, software developers and researchers developed the Usher platform. The app underwent several iterations based on feedback from end-users, again following the test-design cycle of the PDSA framework.

PHASE 3: EVALUATE

Digital health solutions are being developed in a range of domains and research, and evaluation is needed to assess when, where and for whom, the solutions are effective. This phase can begin when an innovation has been cycle-tested to produce a minimal viable product (MVP) ready for formal evaluation. Testing can take place in either a simulated environment or within an actual clinical area, with the key being to test the innovation with potential end-users. As with any healthcare innovation, the study design should be carefully considered. Full ethical approval is sought if indicated. In addition, extensive consultation with information governance and information technology staff is required if testing takes place in an actual clinical environment. Cost-effectiveness calculations should also be considered, particularly if a business case is being made for the app.

Hark

The first part of the evaluation phase of the Hark platform took place in a simulated ward facility at Imperial College London. The second phase is set to take place across a limited number of ward areas in a hospital. We have sought to ensure that the introduction of the app will not alienate staff by changing their working methods too substantially or too quickly.⁹ The app is being implemented following extensive consultation with clinical and information technology staff. Initial stages of the evaluation will focus on the usability and feasibility of the app. Later work will involve comprehensive testing across a whole hospital with a number of sites identified.

Usher

The evaluation phase of the Usher platform for bariatric surgery is taking place in a single bariatric surgery unit. After initial usability and feasibility studies, a 3-month evaluation is taking place where patients are being randomised to control (provided with education through current processes) and intervention (provided with the Usher app in addition to already established education provision processes) groups. Knowledge prior to consent is being evaluated to look for differences between the two groups.

CONCLUSIONS

We present the 'CDE' framework for producing mHealth applications that we are using at Imperial College London to develop effective mHealth platforms. The use of the 'CDE' framework has been described for two different innovative apps, which are both being evaluated prior to full implementation. mHealth researchers can use the CDE framework to produce their innovations using an approach that is grounded in evidence and end-user engagement. The healthcare community can be slow to adopt new innovations and technology,¹⁰ and the CDE framework aims to challenge this behaviour by early engagement of end-users, and inclusion of a solid evidence base. The CDE framework has the potential to improve the standard of mHealth innovations ensuring that the potential of mHealth can be realised.

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