

Validation of a Design Architecture to Deliver Health Management and Behavior Change Evidence at Scale

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Abstract. Forty-four percent of Canadians over the age of 20 have a non-communicable disease (NCD). Millions of Canadians are at risk of developing the complications of NCDs; millions have already experienced those complications. Fortunately, the evidence base for NCD prevention and behavior change is large and growing and digital technologies can deliver them at scale and with high fidelity. However, the current model of in-person primary care is not designed nor capable of operationalizing that evidence. New developments in artificial intelligence that can predict who will develop NCD or the complications of NCD are increasingly available, making the challenge of delivering disease prevention even more urgent. This paper presents findings from stakeholder engagement on a design architecture to address three initial barriers to large-scale deployment of health management and behavior change evidence: 1) the challenges of regulating mobile health apps, 2) the challenge of creating a value-based rationale for payers to invest in deploying mobile health apps at scale, and 3) the high cost of customer acquisition for delivering mobile health apps to those at risk.

Keywords. Disease prevention, mobile health apps, design architecture, platform, value-based care, behavior change, barriers

1. Introduction

The evidence base for disease and disease complication prevention is extremely large and growing rapidly. It is estimated that family physicians need to work 24 hours per day to provide all the care required by a typical 2000-patient practice. Primary care practices are designed for an investigate-assess-treat model of care but are poorly structured for the non-communicable disease (such as cardiovascular disease, diabetes, cancer, etc.) care model of educate-motivate-goal set-implement-monitor. The time needed for the latter model is significantly higher and requires a different approach.

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Mobile health applications (hApps) have demonstrated significant potential for improving patient care and health management and usage has increased over the last several years [1]. In the US, Kaiser Permanente developed a digital mental health and wellness ecosystem that includes health apps, patient-facing educational content, and workflow integration with electronic medical records [2]. The digital ecosystem increased patient engagement and improved daily function during treatment. In Germany, doctors can prescribe health apps that are reimbursed by the healthcare system, rather than paid for by the patient [3]. Several studies demonstrate the positive impact of hApps on health-related behaviors including physical activity, diet change, and adherence to medication or therapy [4]. Clinician adoption plays a critical role in the uptake and success of hApps [5,6]. The COVID-19 pandemic has increased end-user interest in hApps, however, hApps face several barriers to wider adoption. Barriers include unclear regulatory guidelines and policies, the high cost of customer acquisition, the lack of consumer willingness to pay [7], and poorly defined value propositions.

2. Methods

An environmental scan on patient accessibility to mobile health apps was conducted. A list of interest holders and their requirements for a hApp platform for patients was developed. Three key issues were identified that needed to be solved before other requirements could come into play. A first iteration of a proposed architecture was designed to solve those 3 key problems, described below. The proposed architecture was presented to a convenience sample of stakeholders (N=10) for validation. By architecture, we mean a minimal configuration of IT and non-IT components that deliver a specific desired functionality.

We asked interest holders their initial thoughts, what was attractive about the proposed architecture, what they were skeptical about, what they would do to improve it, whether it was feasible with their improvements, and suggestions to increase feasibility. The design architecture was iterated based on interest-holder feedback.

3. Proposed architecture to solve key problems in dissemination of health apps

3.1. Key issues that need to be addressed

Any marketplace for hApps cannot get off the ground if the following 3 key problems cannot be resolved:

- Is there a value proposition for at least one stakeholder to invest and overcome the lack of consumer willingness to pay?
- Can the value proposition be delivered at a cost and effort that is feasible?
- Can the marketplace be regulated and governed to deliver value and achieve sustainability?

3.2. *Initial workflow to deliver the benefits*

We developed a workflow that can deliver the benefits envisioned. The workflow is as follows: first, we identify disease areas with high economic burden, where effective treatments exist, AND where hApps are proven to make a difference. We then retrieve the current cost of treating the disease (usually in a hospital, but could also be in an outpatient setting) and then calculate the potential savings if existing evidence-based treatments could be delivered with higher fidelity to a larger number of affected individuals using hApps. We then calculate the value of cost-avoidance per patient and offer financial incentives that are attractive to hApp publishers to make their hApps available to patients with the disease, keeping costs lower than what can be saved; i.e., have a positive return on spending.

Second, we identify all the patients at the highest risk of getting the complication or exacerbation of the disease, which requires acute care, hospitalization or long-term outpatient treatment. This may require advanced predictive machine learning or artificial intelligence algorithms for early identification of an at-risk population. Many such algorithms already exist. Many more are under development. hApps are capable of monitoring the patient's health state if properly designed. Only patients at high risk of health system utilization are offered the hApp to maximize the cost-benefit ratio.

Lists of patients at high risk can be generated using the predictive algorithms in physician practices utilizing data that already exists in their EMRs. Physicians recommend a hApp from the Formulary list provided to them when the list of high-risk patients is generated. By involving physicians in the process, we identify the entire addressable market and decrease the cost of customer acquisition simultaneously. This maximizes the potential benefit of hApp dissemination and minimizes the costs. Physician compensation for their role in recommending and explaining the program to patients could be included in the Physician Schedule of Benefits.

Third, we propose a 'light' regulatory function that reviews the evidence for the use of the hApp, the usability evaluations and user experience reviews and that the hApp supports the latest guidelines for the disease in question. The hApp should be able to do 3 things to receive payment. First, it should be used by the user regularly. Second, it should collect data relevant to the disease or condition. Third, it should provide evidence-based advice to the patient. If the hApp meets all the requirements, it is given a conditional acceptance, which must be proven in actual usage; i.e., prevents the outcome of interest. The hApp is then listed on a formulary of approved products and communicated to physicians to recommend to identified, high-risk patients.

3.3. *Draft design architecture*

Figure 1 illustrates the draft design architecture for delivering the three minimum requirements needed to make large-scale hApp dissemination feasible. The data sources box allows for the training of machine learning and/or artificial intelligence algorithms that can identify at-risk patients at scale. The risk profiling service can help clinicians generate a list of high-risk patients in their EMR. The hApp Formulary service provides the physician with the list of approved hApps. The physician recommends the hApp to the patient using a QR code to minimize errors. The patient downloads it from the App Store after they scan the QR code.

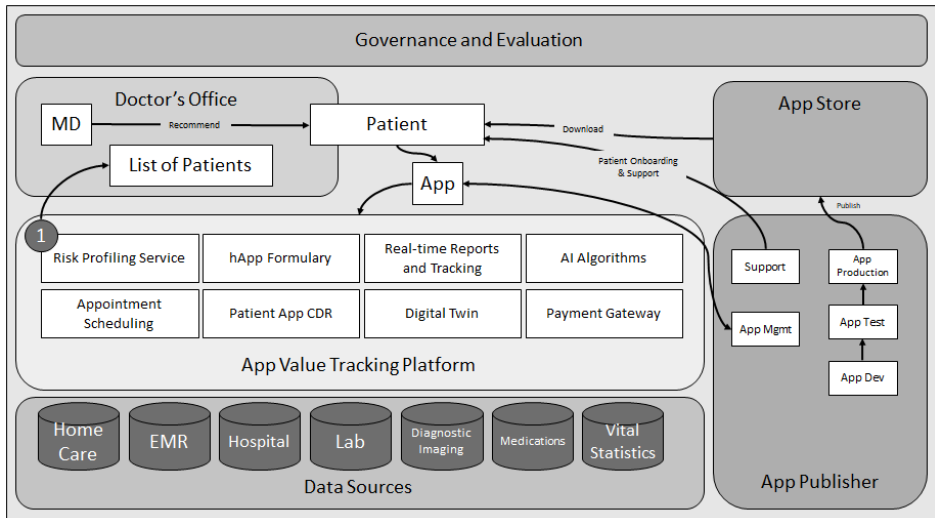


Figure 1. Reference architecture for large-scale hApp dissemination.

In this model, App Publishers are incentivized to ensure patients are properly onboarded and supported since payments depend on patients having a successful experience with the hApp. The Governance and Evaluation function provides regulatory oversight and ensures that value for money is being delivered. hApps that don't deliver value are deprecated from the Formulary if they do not meet pre-set criteria after a reasonable period; e.g., an 18-24 probationary period.

3.4. Example of potential use case

The economic burden of end-stage renal disease (ESRD) in Canada is high, estimated at more than \$4.5 billion per year in Canada [8]. Dialysis treatment for patients with ESRD is one of the most expensive medical treatments, costing over \$1.8 billion per year in Canada. Currently, the most significant contributors of ESRD in patients are diabetes (38.0%) and hypertension (12.2%).

Patients at risk of developing ESRD, their family physicians, and the Canadian healthcare system could benefit from the model proposed in Sections 3.2 and 3.3. At-risk patients can be identified from data in EMRs through the App Value Tracking Platform. Family physicians can prescribe relevant health apps from the formulary list, such as hApps that track and remind patients to take their blood pressure medications. This can help reduce the risk of patients developing ESRD, thus reducing the financial burden of ESRD on the Canadian healthcare system.

4. Stakeholder feedback on the design architecture

First impressions. The concept received positive overall feedback and optimism and garnered interest from the interviewed stakeholders. This positivity was balanced with pragmatic considerations for operationalizing the platform effectively and ethically.

Features –attractive. Interviewees widely appreciated the concept of a hApp marketplace. Several praised the ability of hApps to extend healthcare services beyond traditional facilities, reducing the strain on practitioners and the system at large. Others valued the model for its aim to engage payers, promote preventative care, and use AI and advanced analytics to identify and manage at-risk patients. Similarly, the technical architecture, which facilitates the matching of the right hApps to the right patients, was acknowledged for its potential to reduce waste, improve health outcomes, and curb costs. One interviewee also favored the idea of using the platform as a digital pharmacy, where practitioners could digitally prescribe apps to patients, akin to prescribing medications.

Features –skeptical. Interviewees expressed scepticism over several element of the platform. Some were uneasy about using AI to find at-risk patients, citing the poor quality of medical data, particularly for vulnerable groups. A patient representative was particularly doubtful about whether different groups like the elderly and immigrants would adopt the solution and stressed the need for educating potential users and medical professionals. Some participants questioned the proposed financial plan, technical setup, and the platform's security measures. Concerns extended to market forces such as the competitive hApp landscape and the challenges of integrating existing apps.

Areas for improvement. There were many suggestions to make the hApp platform better, including advice for successful implementation, compatibility with multiple hApps, and ease of use. Interviewees mentioned the importance of keeping user data safe, having a clear business model, and making sure doctors and other stakeholders are on board with the idea. They also stressed making the platform accessible to everyone, including older people, and ensuring that the hApps on the platform were effective and trustworthy. Lastly, interviewees called for better hApp vetting protocols and governance on the platform to maximize clinical benefits.

Assessment of feasibility. There were varying views on the platform's feasibility. Some saw the proposal as promising but suggested a cautious, phased rollout. Others emphasized the need for careful design and experimentation. Others pointed out potential hurdles like getting physician buy-in, challenges with value-based payments, and the readiness of primary care teams for a surge of apps. A few interviewees highlighted the importance of making the platform appealing to both doctors and patients. Some were cautiously optimistic, acknowledging the implementation complexities but appreciating the potential benefits. They suggested refining the approach to match patients with relevant apps better. Overall, most interviewees thought the concept was technically and conceptually feasible, as long as key implementation issues were addressed.

Improving feasibility. Many interviewees advocated for a staged deployment of the platform, initiating particular diseases, and fostering trust with users by offering valuable services. They propose establishing a robust technical framework with an open design that can accommodate various hApps, complemented by a user-friendly interface. Certain experts stressed the importance of validating the hApp's effectiveness through trials and ongoing feedback. They also recommended forming close collaborations with healthcare organizations and governmental bodies for support, coupled with clear guidelines for hApp assessment. Promoting innovation and tackling privacy issues was deemed crucial, alongside redirecting focus to demonstrate how the platform can positively impact employment and the economy. Another common suggestion was the need for government support and new payment models to ensure

the success of the platform. Overall, we collected a list of over a dozen ‘known issues’ that need to be answered to make the project acceptable to a wider audience.

5. Discussion and Conclusion

This study adds to the literature on methods to make hApps available to patients at scale. Interest holders identified many issues that must be overcome to make a hApp platform a reality. Two key areas that need to be addressed include patient education about AI and its value in helping them achieve their health goals and creating a compelling business case for funders to invest in a hApp platform.

Limitations of the study include the small sample size and the limited number of interest holders engaged. Through the interest-holder interviews, we identified over a dozen requirements that need to be addressed to make the platform potentially attractive to additional interest holders. Future research needs to focus on making the platform attractive to physicians, as their role is critical to the success of such a platform. Future interest holder engagement will also address patient concerns and hesitations, the role of researchers, the implementation details for hApp-related payments, and who should provide the governance and evaluation function.

Successful deployment of the hApp platform will require overcoming operational, ethical, and inclusivity challenges. Enabling the direct transfer of evidence-based knowledge to patients, the hApp platform holds the potential to revolutionize patient education and monitoring, particularly for those at risk of non-communicable diseases. This advancement could mark a significant shift towards a more proactive and patient-centered healthcare system.

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