NATIONAL INFORMATION BOARD

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## Personalised Health and Care 2020

# WORK STREAM 1.2 ROADMAP

## Enable me to make the right health and care choices

### Providing citizens with access to an assessed set of NHS and social care 'apps'

June 2015

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# 1 CONTEXT

## 1.1 Background

The high level objective of work stream 1.2 is to provide citizens with access to a set of NHS and care digital applications which have been assessed by the health and care system to enable them to make the right health and care choices.

The assumption underlying the objective is that an assessment framework for applications will enable health and care professionals to recommend the use of safe and effective digital applications and give greater confidence to patients and citizens to select and use them.

## 1.2 Terminology

Where the words “app” or “apps” are used in this document it should be understood that this is shorthand for digital applications, which may include either a mobile app, a web-based application or in certain cases a digital service.

## 1.3 Approach

The development of an assessment framework for digital applications is worth pursuing if it leads to better outcomes for service users and more efficient use of health and care systems, and personal resources. Our current knowledge about apps and their benefits means that any evaluative process will need to proceed developmentally, with the assumptions on which it is based being tested at intervals as our knowledge improves.

We intend to trial the proposed assessment framework by running a series of carefully selected pilot apps through early prototype versions, challenging and improving the various parts of the emerging framework iteratively. We will also validate the proposal by undertaking user research. We will continue to do this until the model is ready to be adopted and released to the wider app developer community.

It is important to note that assessment of apps is an entirely new endeavour which does not have the benefit of the decades-long research and development foundation of conventional health technology assessment. It may not yield the benefits referred to earlier or it may need to be significantly modified to enable it to do so.

## 1.4 Assumptions

A number of assumptions underpin the approach we are proposing to take. The evidence we have gathered is supportive but more is required to establish if an assessment framework for applications can add value and if so what shape it should take. These assumptions are that:

- Some apps can improve outcomes;
- An assessment system will help improve the confidence of health and care professionals in their use, and promote the development of good apps;

- Careful selection and promotion of apps will improve the use of health and care systems, and personal resources;
- An assessment framework can be developed which will allow the NHS and the care system to exercise a judgement as to whether certain apps can be promoted and recommended for use;
- Developers are interested in improving the quality of their apps and are willing to participate in an assessment process on the basis that is effective, efficient and can help them access the market (and generate revenue).

### 1.5 Document Structure

The remaining sections of this paper cover the following:

- Stakeholder Engagement – outlines the importance and breadth of engagement so far
- Research and evidence base – summarises the evidence and its implications on these proposals
- Building the picture for delivery – outlines a proposed approach and framework for the assessment of apps to stimulate discussion and input. This section also outlines the next steps involved in pursuing this work.
- Benefits – summarises the key benefits that are assumed

## 2 STAKEHOLDER ENGAGEMENT

Stakeholder engagement sits at the very core of work stream 1.2. Indeed, there would be no value in setting up an assessment framework in isolation of what users and the market need. In starting Work Stream 1.2 we were conscious that the idea of assessing apps is not new and that many organisations would have already reflected on the issues we were about to uncover. We fully intended to leverage this knowledge where possible and to build on it where appropriate.

Since this project started, a broad range of experts have directly participated in our weekly project team meetings. By the end of June 2015, representatives from nearly 20 external organisations will have attended our working meetings and engaged in open discussions about the issues associated with the assessment of apps. The organisations we invited ranged from app developers themselves, clinicians, academic organisations, professional societies, trade bodies, patient charities, organisations providing regulation and standards, and commercial organisations providing curation services. In addition to inviting these stakeholders to our group meetings, we have met a number of interested parties in one-to-one meetings as well as part of organised events or conferences, some specifically set up by the National Information Board (NIB). These larger events have given us the opportunity to meet many interested parties but especially to make contact with a large number of app developers. We expect these contacts will be invaluable as we start to test our proposals.

Finally, it is worth noting that we have engaged with colleagues internationally, in the United States and Spain specifically, as the assessment of apps and digital services is an issue which many other health economies are grappling with.

To facilitate future engagement with stakeholders, two advisory groups have been formed. Membership of the groups include NHS and industry experts as well as app developers. The main role of the advisory groups will be to provide key strategic advice and insights to the NIB following publication of the assessment framework proposals in June 2015.

# 3 RESEARCH AND EVIDENCE BASE

## 3.1 What we have done to inform our proposals

To develop our proposals, we have undertaken a number of evidence gathering activities including the following:

### 3.1.1 Structured reviews

- Literature review – considered what existing literature tells us about the current acceptability and adoption of health and wellbeing apps and personal health records. It also reviewed the evidence regarding the impact of these digital technologies on health outcomes.
- State of the apps market review – assessed the current state of the UK health app market to understand the nature of UK's most popular apps but also to understand the level of availability of medical apps for specific health conditions.
- Regulatory framework review – reviewed any existing regulatory frameworks applicable to digital applications, including guidelines, existing models of endorsement and assessment, and regulation. This also covered other sectors and countries.
- Clinical effectiveness review – focused on exploring existing models for assessing the clinical effectiveness of digital applications and the challenges that arise from attempting such an assessment.

### 3.1.2 Stakeholder engagement

Since this project started, a broad range of experts have attended the work stream's weekly delivery team meetings to share their knowledge and experience in this area. Stakeholder engagement has also been conducted via informed expert, industry and NHS representative bodies including international organisations.

To facilitate future engagement with stakeholders, two advisory groups were formed. Membership of the groups includes NHS and industry experts as well as app developers. The main role of the advisory groups will be to provide key strategic advice and insights to the work stream following publication of the assessment framework proposals in June 2015.

### 3.1.3 App developer engagement

The advisory groups include selected app developers but in addition to this we are working directly with developers in the four selected pilot areas. Developers of apps from these four areas have, or will be asked to test the emerging assessment model.

### 3.2 What we have discovered

A number of themes have emerged from the evidence gathering. These are listed below. There is a large volume of apps (over 100,000 currently available in Europe):

- The popularity of apps is not necessarily linked to quality;
- The majority of apps are focused on health and wellbeing and have simple functionality;
- There are concerns over the safety of apps;
- The usability of apps can be a key challenge;
- There is mixed evidence regarding the impact/utility of apps;
- New research methods may be needed to evaluate the effectiveness of apps;
- Entering the NHS is challenging due the lack of a clear regulatory framework. The commercial incentives for doing so are also not clear, and
- There is scepticism associated with the concept of a centralised assessment model for apps.

### 3.3 Evidence still required

More evidence is still required to establish if an assessment framework for applications is needed and if so what shape it should take. Further evidence collection is planned as part of our next steps, as described later in this document.

## 4 BUILDING THE PICTURE FOR DELIVERY

Our initial app assessment framework proposals address the original NIB objectives and take account of the challenges identified in our research. It seeks to build an affordable as well as credible solution. The proposed framework is a staged approach to assessment which blends the use of self-assessment and community participation to identify apps with promising utility, with a more formal evaluative process, in which certain groups of digital applications can be assessed leading to more 'formal' recommendations for use, based on independently evaluated evidence of impact.

### 4.1 Emerging design principles

Our proposals adopt a number of design principles that address the challenges identified during our research. These design principles are:

- The model should be 'open' to support new entrants and innovation. The first stages of the model can be open to all digital applications. However, there is also an opportunity to focus assessment, at least initially, on disease and condition specific apps with the greatest claims of clinical utility;

- The model should be low cost and must deliver value to the health and care system. The bulk of the apps considered will go through a low cost self-assessment stage. Higher levels of investment will only be considered where there is an expectation of positive return on investment from the category of applications subjected to a higher degree of assessment;
- The model should be scalable. By being digitally supported, the model will be scalable for the early stages of assessment where most of the volume might be expected;
- The model should involve health and care community participation. Community participation will be encouraged and integrated into the assessment process;
- The model should involve testing claimed utility/benefits. This type of impact/utility validation is likely to be high cost and not scalable and therefore should only be undertaken where the claimed benefit/impact is significant;
- The model should build on existing standards where possible (for example the new PAS 277 from the British Standards Institute) and connect to existing regulatory frameworks where applicable, for example the MHRA;
- The approach should be flexible and proportionate, adapting the assessment components to the nature of each application – relative risk, benefit, cost of each app; and
- The model should be attractive to the industry. Each stage of the assessment will deliver value to applicants.

## 4.2 Overview of proposed assessment framework

We have developed a high level outline of the proposed assessment framework (see Appendix A). The four stages of the proposed assessment framework are summarised thereafter.

It is important to note that the model assumes that only a small number of apps will go through the entire process and that apps do not need to go through the entire assessment in order to benefit from the process. Visibility, for example exposure on nhs.uk (NHS Choices), will arise from completing Stage 2. However, strong positive recommendations to use and to fund applications will require independent evaluation that will occur in Stages 3 and 4. It is likely this level of assessment will be relevant to only a sub-set of applications.

### 4.2.1 Decision to apply

The assessment process will be open to all apps. In addition, the health and care system may choose to encourage certain groups of applications to participate in the assessment based on strategic or policy priorities, local priorities or public trends. In this illustration, we have assumed that 10,000 apps might eventually be submitted for a Stage 1 self-assessment.

### 4.2.2 Stage 1: Self-assessment against agreed criteria

This stage is designed to screen the large number of apps that might apply and to identify those apps that meet some agreed criteria, based on self-assessment.

Apps which undertake self-assessment will follow a structured set of questions organised against key 'quality' dimensions. These dimensions will include safety, privacy, sharing data onwards, accessibility, usability, technical stability and interoperability. Self-assessment will also use proxy questions to uncover any available evidence of impact.

The intention is for Stage 1 to be supported by a digital service. This will lead developers through the assessment and provide guidance and links to best practice where appropriate.

High transparency and the use of random audits will be used to keep answers honest and prevent some entrants from 'gaming' the self-assessment process.

Some apps may be identified, through the responses given, as higher risk apps. These will be required to undertake additional external assessments - for example, if they are likely to qualify as a medical device, to register with the MHRA and self-certify as a class1 device or employ a Notified Body (for higher class devices) to approve CE certification.

Only those apps that meet the necessary criteria will be progressed into Stage 2 and be available for community evaluation. For illustrative purposes, out of an assumed 10,000 apps entering Stage 1, only 2,000 may be invited to move into Stage 2.

### 4.2.3 Stage 2: Community evaluation

Similar to many online up-voting websites, this stage is designed to use the wisdom of an engaged community of professionals, commissioners or end-users to evaluate and therefore support the better apps emerging from self-assessment. The 'crowd' would be asked to give opinion on functionality, usability and share anecdotal evidence of impact and utility. Much of the feedback may arise from local pilots and the evidence of impact from local implementation projects. Early adopters in the clinical community will be provided with a platform to share their successes and challenges with health apps.

Current models for crowdsourcing can be open to commercial bias or are too unstructured to help clinicians recommend an app so this stage will be designed to take this into account.

Apps that are evaluated by the 'crowd' through Stage 2 will benefit from exposure on nhs.uk. Exposure may also be available through other channels e.g. Public Health England's 'Stoptober' campaign. Exposure in this way will not constitute a formal recommendation for use.

The presentation of the apps may reflect the relative performance of apps across Stages 1 and 2 with only the top scoring apps being visible on nhs.uk.

For illustration purposes, up to 100 apps per year emerge as 'evaluated' by the community through this phase of the process.

### 4.2.4 Stage 3: Preparing a benefit case

Stages 3 and 4 of the framework are about taking selected apps through a more robust assessment process. This level of assessment will be required to ensure that apps that are eventually recommended by the NHS, reimbursed or possibly prescribed, have the evidence to support their claims.

It is likely these stages of the assessment will be reserved for a small number of apps from distinct priority areas, with strong business cases for efficiency or cost effectiveness.

At Stage 3, apps will be enrolled in a range of activities to enable further assessment. This may include data sharing and end user participation, advice on study design.

The type of study and support needed in Stage 3 will depend on the type of applications under consideration. This is where the chosen method of apps categorisation will be of particular importance.

### 4.2.5 Stage 4: Independent impact evaluation

Stage 4 involves an independent impact evaluation. As in Stage 3, different approaches may be required for different categories of apps with clinical interventions likely to require the most robust evaluation process. Some categories of apps may be assessed much faster than others. These approaches still need to be defined (see Next Steps section below).

Apps emerging from Stage 4 will become recommended interventions and as such it is expected they will benefit from a range of adoption support mechanisms that could include branding, commissioning support, or reimbursement.

For illustrative purposes, as few as 10 apps per year may be formally recommended by the NHS. Recommendations may increase over time as more apps evaluated through Stages 1 and 2 undertake robust studies of impact.

## 4.3 Next steps

Key strands of activities expected from June 2015 through to early 2016 include:

- Continued engagement with stakeholders and app developers – engagement with a range of stakeholders to gather feedback on the proposed framework will continue following the publication of the NIB roadmaps in June 2015. This, together with the feedback from the user research (see below), will be used to evolve the model where necessary. The adjustments required may be more or less substantial depending on the nature of the feedback received after June 2015.

- User needs research - We will test that the proposed model serves actual user needs. This will include separate research with commissioners, health and care professionals, patients and citizens. Nurses and GPs will be a key user group to engage as we expect they will be users of the system, as well as core contributors to the crowd-sourced component.

Assuming the key components of the framework are retained, further work to develop the various stages of the framework will be required as follows:

- Further develop Stage 1 self-assessment questions and algorithms;
- Develop of the digital platform for Stage 1;
- Define the principles for Stage 2, the crowd-sourcing of community feedback;
- Further develop Stages 3 and 4 evaluative processes;

- Establish how to deliver the benefits of assessment to app developers working with other NIB work streams; and
- Develop the operating model and business case for this overall framework.

### 4.4 Deliverable timing, including quick wins

The work stream deliverables at the end of June 2015 will be:

- Proposals for an application assessment framework – as articulated in this Roadmap document;
- Digital (early) prototype of the self-assessment stage (Stage 1);
- Structured reviews (as listed in section 1) posted on the NIB pages of GOV.UK; and
- Announcement of a digital mental health development programme.

Key activities will take place in the summer leading to the end of November 2015. These will include:

- User research to test audience needs;
- Piloting of the Stage 1 prototype; and
- Engagement with clinicians: in autumn 2015 we will be directly engaging with a cohort of GPs, and other clinicians to consider the feasibility and interest in the crowd-based component of the model.

These activities will achieve better stakeholder engagement if they can be focused on selected areas of care that will be presented as 'experiments' to the market – experiments to test, learn from and continue to develop the right model.

By early 2016, we expect that a 'beta' version of the Stage 1 digital service can be launched and Stage 2 will have been piloted. Decisions on whether and how to progress Stages 3 and 4 will also have been reached by this time and a plan for operationalising the broader framework will be available as part of a business case for implementation.

## 5 BENEFITS

A number of benefits can be assumed from putting in place an assessment framework for apps. It should reiterated that these benefits are based on the assumptions that an assessment framework can truly identify the better apps, influence decisions and change the adoption levels of apps and lead to the increased use of higher quality apps. If these assumptions hold, then the key end benefits of an assessment framework for digital applications could include:

- Reduced costs to the health and care system: Digital interactions have been shown to be cheaper than other interactions between professionals and the public. There is some good evidence to show that digital interactions cost about 1% of face to face costs;

- Improved outcomes: Although there is some evidence to suggest that digital interactions are more cost effective than face to face equivalents in certain circumstances, this evidence is relatively poor. It is expected that better outcomes will be delivered by channelling scarce funds to deliver face to face services where they are most needed, using digital as an integral part of the suite of treatments and interventions available to the health and care service in therapeutic areas, where a good evidence base exists for the efficacy of digital interventions;
- Improved system: other industries are 10-20 years ahead of the health and care system when it comes to using technology. This model will help to improve the reputation of the English health and care system. The assessment model brand, and the organisations delivering it may come to be synonymous with good quality, trusted digital therapies.

Some intermediary benefits can also be identified and include:

- Developers of good quality, safe and effective apps will be able to market their products much more effectively to the health and care system and, to a lesser extent, the public here and the wider world. An increase in 'good' applications will be available, developed by experienced application developers and their visibility will improve;
- End users will have a more informed choice of apps they choose for themselves or in conjunction with a care professional;
- Clinicians will be able to access apps assessed as meeting some minimum quality criteria and validated by their peers, enabling them to promote or use apps with much less fear of them being ineffective or even causing harm;
- Commissioners will be able to use information produced through the different stages of the assessment process to inform a cost/benefit assessment of adoption of an app for a service or across a catchment area;
- Gaps and areas of needs in the market could be identified and the market influenced to respond to these needs; and
- Over time, stronger evidence around the impact of apps and digital services will emerge, which should lead to higher levels of engagement and support for digital services.

# APPENDIX A: HIGH LEVEL OUTLINE OF THE PROPOSED ASSESSMENT FRAMEWORK