Digital Health Technology and Evidence

A report by MedCity, DH.L and BSI

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1. The issue

On 12th July 2017, MedCity, Digital Health.London and BSI hosted a Digital Health Technology and Evidence Stakeholder workshop. It brought together the key experts for the innovation development pathway, as well as SMEs, to outline what evidence is considered a priority and also to share knowledge on what exists already. Participants included:

- Policy Makers, Regulators and Statutory Bodies;
- Research Infrastructure;
- NHS and Academia;
- Customer Facing Organisations;
- Small-Medium Enterprises.

The hypothesis that this workshop tested was whether there was a lack of guidance in how to generate the right evidence for faster and better uptake of digital health technology into the NHS and healthcare systems, or merely that existing guidance is not easily accessible or understood. This particularly impacts SMEs, who may not have easy access to the right research expertise and methodologies. In addition to this, the current pathway for generating evidence is unclear. The Accelerated Access Review digital pathway provides a high level view on the route to speeding up innovation development and access. However, further work will be needed to provide accessible guidance at a granular level and a streamlined pathway for innovators.

2. Evidence themes and their importance along the development path

Participants agreed evidence themes that they considered relevant to the deployment of digital health technologies, and at which point of the innovation journey these would need to be demonstrated. Figure 1 shows a summary of these key themes and topics across the innovation journey, along with their perceived importance. Whilst these results are approximations, they do show some interesting trends, namely:

- Development of strong evidence to support a business case, including stakeholder buy-in, addressing an unmet need, and creating a value proposition was seen as important in the early stages of the innovation journey (particularly concept research and feasibility study stages);
- Usability was an important factor throughout the journey, but was particularly relevant in the early and middle stages of the development path;
- Evidence that related to quality aspects was considered to be important throughout the entire innovation journey;
- Any evidence relating to outcomes was viewed as the most important theme overall, with the level of importance increasing as the development of a solution progressed.

Figure 1 – Summary of digital health technology evidence themes across the innovation journey

Theme	Topics	Concept Research	Feasibility Study	Technology Development	Technology Demo	Ready To Commission
Business Case	Stakeholder mapping, Buy in					
Business Case	Market intelligence, Unmet need & precedence, Size, Competitor landscape, Barriers to adoption					
Business Case	Value proposition, PPI patient need analysis, USP					
Usability	Usability, Utility					
Usability	Real world use, Adherence, Clinical adoption					
Usability	Technical design					
Quality	Regulatory Compliance					
Quality	IG, Interoperability					
Quality	Safety, Risk					
Outcomes	Patient outcomes					
Outcomes	Cost effectiveness, Health economics					
Outcomes	Clinical evidence, Efficacy					

Key: High Importance | Medium Importance | Less Importance | Not Important

3. What information and guidance sources exist for SMEs?

In order to understand what resources are available to guide SMEs in this area, the workshop participants considered guidance known to them in their sphere of influence, which included regulations, NHS guidelines, national and international standards, local and regional best practices, academic research, and professional codes of practice. These have been categorised below as an overview, and a more comprehensive list will be produced at a later date.

Academia: Academic partners and their respective publications were identified as an important source, and some examples were provided. [1] [2]

Research Infrastructure: The National Institute for Health Research was highlighted as an extensive resource, both in terms of expertise and documentation. Examples included Digital Evidence Co-operatives (DEC), National Office for Clinical Research Infrastructure (NOCRI), Clinical Research Network (CRN), Research Design Service (RDS), European reference Networks (ERN), and Innovation Observatory (IO). Citation and impact assessment platforms, such as 'PubMed' and 'ResearchFish' were also mentioned.

Professional & Signposting Bodies – A number of organisations that provide support to digital health innovators were highlighted. Examples included MedCity, Digital Health London, the Knowledge Transfer Network, Medical Royal Colleges, the Digital Health and Care Alliance (DHACA), TechUK, SEHTA and Medilink.

Medical Charities were frequently identified as being very useful information sources for understanding particular healthcare conditions, the market demand, and providing links to patients.

Policy Makers, Regulators, National Bodies: Central Government Departments such as BEIS, Department of Health, Office for Life Sciences and Department for International Trade were considered to be important information sources. HRA (for ethics), MHRA (for medical devices) and ICO (for data and privacy) were identified as important sources for regulatory guidance. National bodies such as NICE (including Health Technology Assessments), Patent Office; BSI and Innovate UK were also highlighted, along with Local Authorities.

NHS Organisations: Information sources included Academic Health Science Networks, NHS Trusts, NHS Choices website, Public Health organisations, NHS Digital (particularly Hospital Episode Statistics and the Quality and Outcomes Framework), the NHS App Store and NHS Developer website.

Web: Several internet sources were identified, including search engines, speciality clinical reference websites, app stores, social media (e.g. for patient groups and rare diseases), evidence repositories and aggregated data sources.

Face to face: Information sources included peer reviews (e.g. NIHR i4i), GP surgeries, seminars, conferences, events, advice from funders and backers, and other sector knowledge specialists.

Customer and User Support: This included patient groups, the Involve national advisory group, and some examples of support organisations. [3] [4]

Overseas: Potentially relevant organisations included EUCOMED, EMA and FDA.

4. How are these information sources navigated, accessed, understood and applied by SMEs?

The participants explored how accessible SMEs find the guidance within the three key themes below:

Market need

- Early signposting to the right people and documents is important;
- Information is of variable quality, and in silos – with no way to determine what is useful.

Clinical and cost effectiveness

- A broad set of information sources are available;
- Providing information across the entire pathway was important;
- Inconsistent quality of information means it isn't possible to determine what is useful.

Information Governance

- A clearly defined set of information sources are available (e.g. ICO, NHS Digital);
- Innovators have information governance expertise and ways of learning from each other;
- NHS takes a risk adverse by default, which can be at odds with innovators.

5. Conclusions and Next Steps

The initial hypothesis of there being a lack of guidance generating the right evidence to test digital technologies is not strictly true. The workshop found that many resources exist, however they are not linked or referenced clearly between the responsible stakeholder groups. In addition, it is not easy for innovators to gauge what type of evidence is considered a priority to stakeholders at particular points in the development pathway. The impact is a slower innovation development.

This report will provide a basis for further work relating to generating evidence for digital health technologies, and as part of a 'quick win' tool for SMEs and others, and in co-ordination with the on-going work of DigitalHealth.London and MedCity. It is also proposed to convene a group to consider further solutions for generating evidence, including raising awareness, navigation and alignment.

Further information about these next steps will be made available shortly, and in the meantime we would welcome any feedback on this report and our proposals. Finally, we would like to thank the participants for their valuable contributions which allowed this workshop to be a success.

6. Bibliography

[1] Imperial College Health Partners Innovation Pathway Tool, http://pathwaytoinnovation.co.uk/

[2] York Health Economics Consortium digital health and apps evidence generation guides, http://www.yhec.co.uk/tools-resources/recent-publications/mtep-publications/

[3] Organisation for the review of Care and Health Applications (ORCHA), www.orcha.org.uk

[4] Our Mobile Health, www.ourmobilehealth.com