Background

Digital and mobile health (mhealth) products are becoming widely accepted as necessary for the future of efficient healthcare service delivery. Despite this, processes and pathways to market access are not well established and can be complex and costly to navigate for an industry dominated by SMEs.

The Oxford AHSN has built an alliance of partners to develop a digital knowledge hub that can support innovators navigate and benchmark market access processes across Europe (www.eMAPs.co).

The aim of the work presented herein was to benchmark and compare selected healthcare markets in relation to market access processes, pathways and barriers for digital health products. Through comparison, this work aims to shed light on which health economies are likely to offer favourable early markets for innovators and SMEs.

Digital and mhealth products are defined in this work as medical and public solutions supported by mobile devices, which include mobile phones, patient monitoring devices, personal digital assistants, wearables and other wireless devices.

Methods

Recruiting 9 lead investigators across Europe in the UK, Sweden, Netherlands (Phase 1-2017); Denmark, Spain and France (Phase 2-2018) and Germany, Italy and Portugal (Phase 3-2019) a mixed methods approach was used to benchmark each of these states’ digital health market access systems.

Primary research was carried out through semi-structured interviews with innovators and developers of digital health products as well as regulatory and reimbursement experts (n=10). In addition, a structured review (secondary research) of each countries digital health market structure, regulations and reimbursement processes was carried out to contextualise the outputs. Key outputs were developed into a web-based tool for digital innovators which can be found at www.e-maps.co.

Reimbursement

• Value assessments of digital products were perceived in most markets to fit existing Med-Tech appraisal processes with few markets having developed specific digital pathways. 
• Respondents in the UK, Germany, France, Denmark and Netherlands accounted for specific innovation funding pathways which included digital products (e.g. UK’s innovation and Technology Tariff (ITT) offering NHS-wide reimbursement for 6-10 products annually.

Assessment processes for digital products (HTA)

- Specific evaluations for interoperability in IAB programme
- MTEP programme
- ITT and AEC processes applicable to digital and secure NHS-wide reimbursement

Digital Health Adoption

- Few digital products have managed to integrate sufficiently into workflows and pathways to achieve scalable adoption
- Translational research funding (e.g. Health Foundation or Innovate UK’s Digital Health Catalyst) and pilot funding has been the funding mechanism for the majority of large digital adoption projects.
- Netherlands, Denmark and Sweden perceived to be most digitally mature and see largest per capita revenue
- The policy environment for digital health is rapidly evolving with local, regional, national and even EU-wide Digital Health policies identified as part of this work, in many cases these were not well-aligned

Adoption

- Flexibility for innovation funding available but not specific for digital
- No digital innovation funding identified

Conclusions

This work offers a comparison of selected digital health markets. A key finding was that reimbursement processes across these markets were not well set up to deal with the specific needs of digital health solutions. Whilst policies and initiatives in some markets had made progress in clarifying and supporting the path to market, there were still few examples of widespread adoption of digital products in healthcare. Further support for innovators is required if we are to realise the full potential of digital health in Europe.