

eMAPs: A BENCHMARKING STUDY OF 9 DIGITAL HEALTH MARKETS

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Background

Digital and mobile health (mhealth) products are becoming widely accepted as necessary for the future of efficient healthcare service delivery^{1,2,3}. 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 SMEs⁴.**

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 devices⁵.

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**

Through thematic analysis of the research outputs, comparisons were drawn across a number of fitting into 3 main categories (see Figure 1).



Figure 1: 3 main categories of comparison used to benchmark digital health markets

Results

Analysis of the research outputs shone light on important differences in national regulation and compliance legislation, policy and the maturity of processes in different markets.

Regulations

- Many digital and mhealth products intended to function as aids or alternatives to traditional medical services will fall under the definitions of a medical device⁶
- A challenge recognised in all markets has been **the move to the EU Medical Device Regulation (MDR) which is likely to see many products re-classified and see products in development face more burdensome processes**
- Strong examples of frameworks for evaluation and certification** from governmental bodies in the UK and regions in Spain and from non-government organisations in Denmark and the Netherlands. **These have been focused on usability, security, technical and clinical issues and not health economics**

	UK	France	Germany	Spain	Italy	Denmark	Sweden	Netherlands	Portugal
Regulations Compliance Issues	MDR adoption underway. Arrangements post-Brexit unclear	Significant limitations in capacity for reclassification and conformity assessment	Regulations around remote treatment loosening	Significant limitations in capacity for reclassification and conformity assessment	No specific legislative framework; "Distance diagnosis" prohibited	Significant limitations in capacity for reclassification and conformity assessment	Significant limitations in capacity for reclassification and conformity assessment	Significant limitations in capacity for reclassification and conformity assessment	Significant limitations in capacity for reclassification and conformity assessment
Certification and Evaluation	Examples of national frameworks (e.g. NHS digital apps library & Orcha)	Ongoing development of a framework	No frameworks identified	Multiple regional certification and evaluation processes (Catalonia and Andalusia)	No frameworks identified	Examples of frameworks for specific initiatives (Continua)	No frameworks identified	Multiple frameworks developed outside ministerial support	No frameworks identified
Inter-Operability/EHR Linkage	Compliance legislation for products interfacing clinical systems	Examples of linkage on local and regional level	Nations personal health records currently in development	Few local examples of linkage identified	Technical standards identified around data flows and data security	Reference architecture in place	Involved in cross border digital integration through eHealth Digital Service Infrastructure	Few local/regional portals and platforms linking data	Involved in cross border digital integration through eHealth Digital Service Infrastructure

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)

	UK	France	Germany	Spain	Italy	Denmark	Sweden	Netherlands	Portugal
Assessment processes for digital (HTA)	Specific evaluations for digital in IAB process and MTEP programme	CNEDIMTS is developing guidance for evaluating connected devices	No specific strategy for assessment of digital health products in HTA processes	RedETS strategy identified for assessment of digital products	No specific strategy for assessment of digital health products in HTA processes	No specific strategy for assessment of digital health products in HTA processes	No specific strategy for assessment of digital health products in HTA processes	No specific strategy for assessment of digital and mhealth in HTA processes	No specific strategy for assessment of digital and mhealth in HTA processes
Digital Innovation Reimbursement Pathway	ITT and AAC processes applicable to digital and secure NHS-wide reimbursement	Innovation funding available but not specific for digital ³	"Innovations-fonds" available for evaluation but reimbursement with insurers challenging	No digital innovation funding identified	No digital innovation funding identified	No digital innovation funding identified	mhealth and digital considered alongside other interventions, products and services	No digital innovation funding identified	Innovation funding available but not specific for digital ³

Adoption

- Few digital products have managed to integrate sufficiently into pathways and workflows 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

	UK	France	Germany	Spain	Italy	Denmark	Sweden	Netherlands	Portugal
National or regional adoption of digital solutions	Examples of national initiatives (e.g. myCOPD) although uptake patchy	Good examples in respiratory monitoring, diabetes surveillance	No examples identified	In Andalusia and Catalonia examples of adoption and reimbursement for digital tech	No examples identified	Examples developed through Public-Private Partnerships	Limited examples of digital services adopted over large geographies	Flexible financing and adoption agreed via insurers and providers	No examples identified
Education and Training	Plans for NHS workforce training around digital	IT literacy being included medical training	IT literacy being included medical training	Initiatives in some regions (Catalonia)	No examples identified	Training for healthcare staff and public	Training for healthcare staff and public	eHealth training is voluntary	No examples identified
Digital Maturity	+	+	-	+	-	++	++	++	-
Market Revenue/Capita⁷	€3.92	€4.09	€4.69	€2.97	€3.38	€6.22	€5.05	€4.75	€2.42

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.