

The value of providing evidence to increase utilization of mHealth in clinical practice



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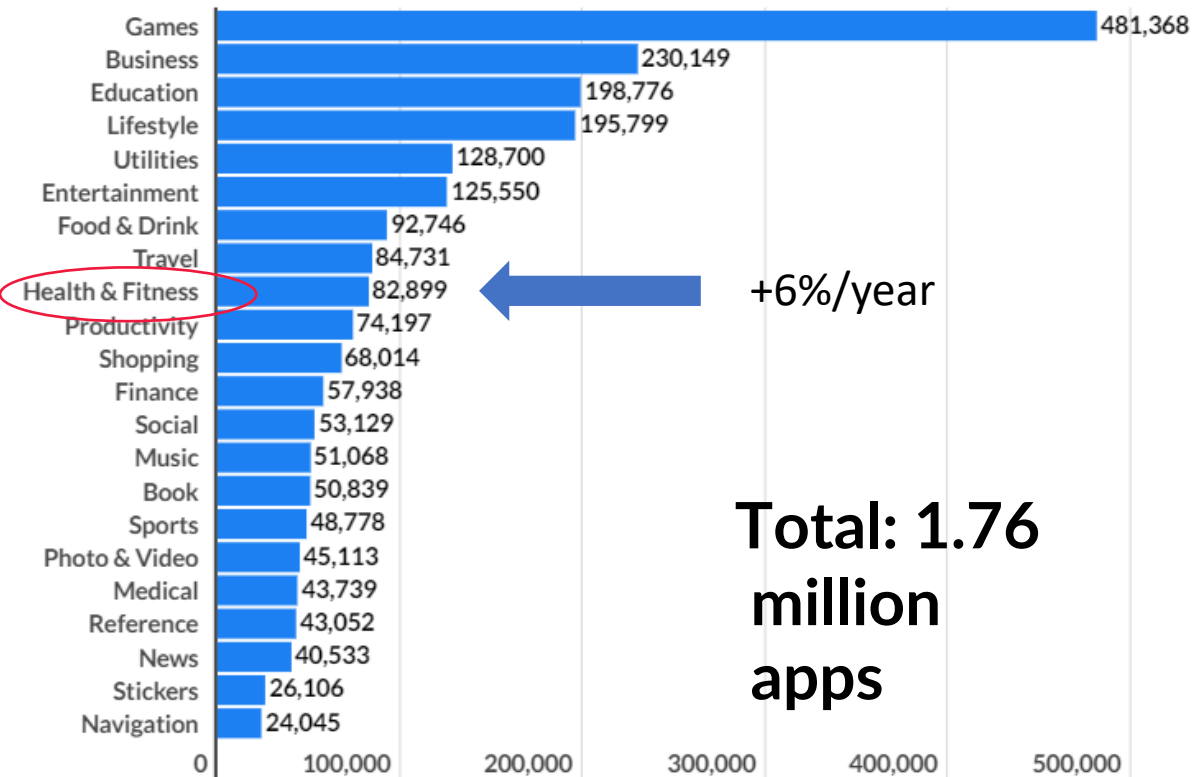
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What there is in the app stores today?

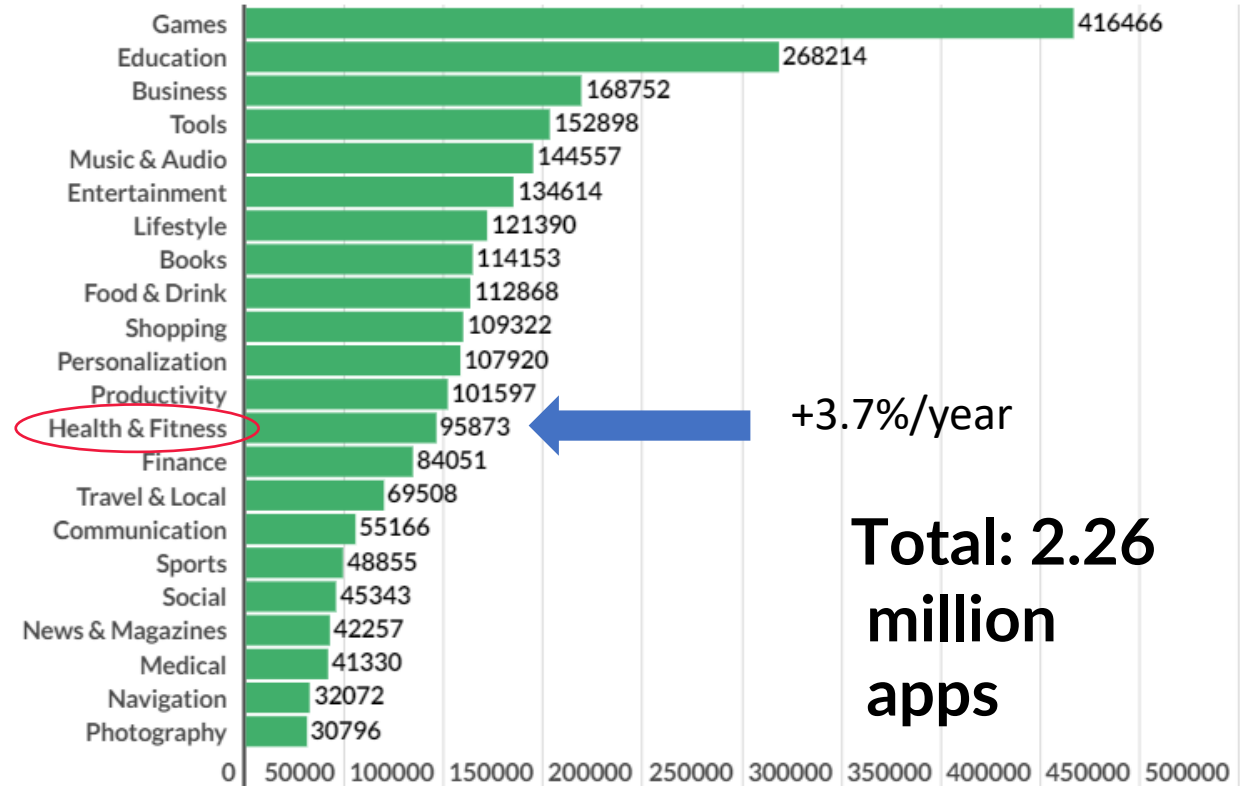
Apple store



Note: Data as of August 2023

Source: PocketGamer

Google store



Note: Data as of August 2023

Source: AppBrain

Abundant supply of health apps → the number of options represents a problem.

[<https://www.businessofapps.com/data/app-stores/> updated on September 2023]

Potential for smartphone-centered healthcare



Decision support systems

Telemedicine

Patient education

Lifestyle wearables

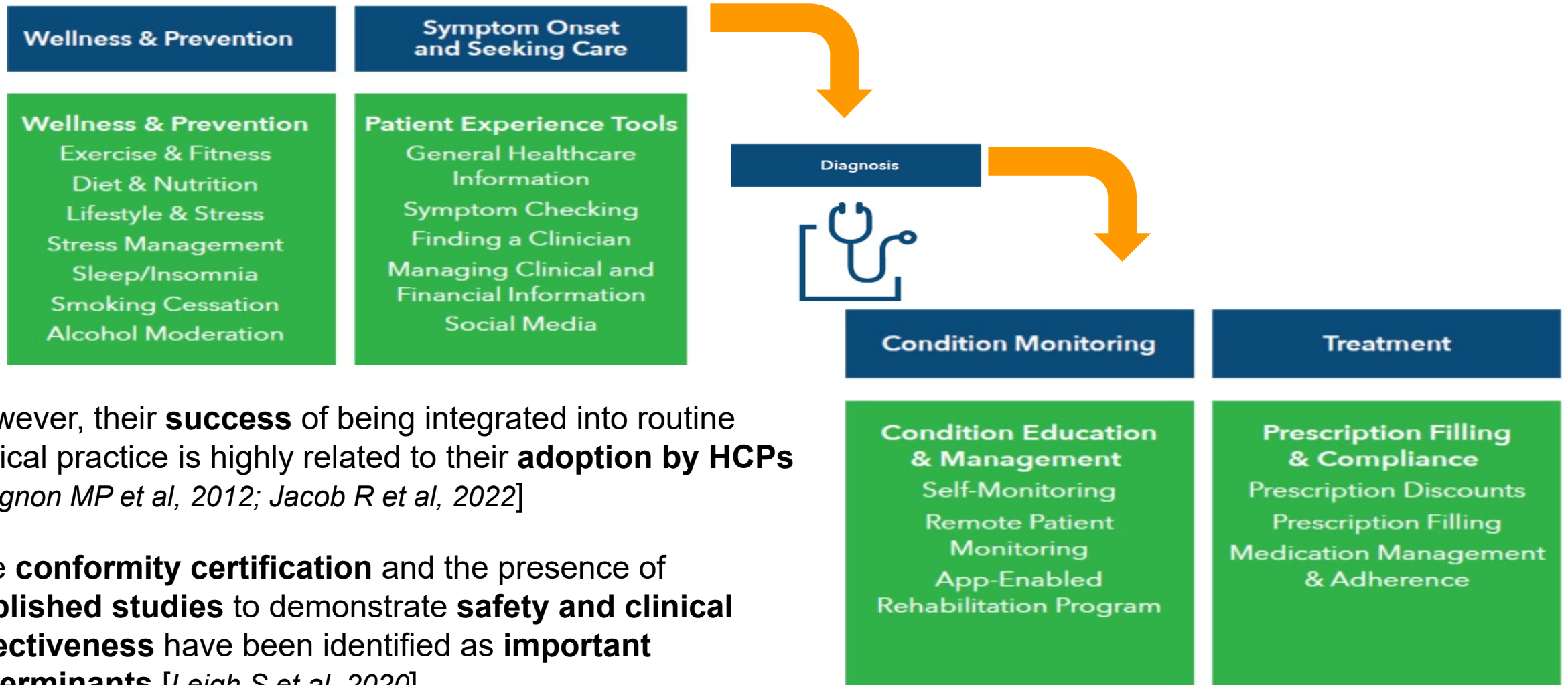
Mobile health

Remote monitoring

Therapy management support



Digital health in the patient journey



However, their **success** of being integrated into routine clinical practice is highly related to their **adoption by HCPs** [Gagnon MP et al, 2012; Jacob R et al, 2022]

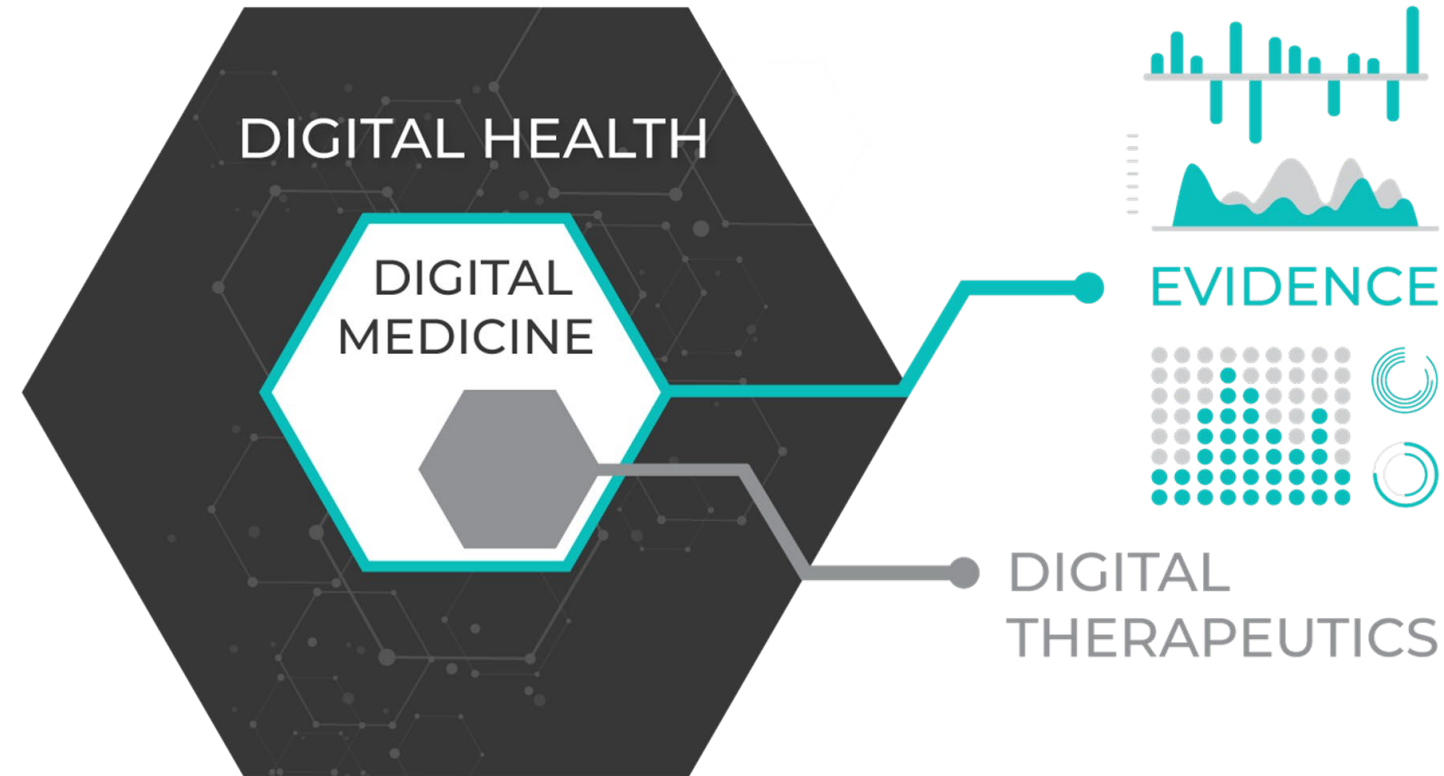
The **conformity certification** and the presence of **published studies** to demonstrate **safety and clinical effectiveness** have been identified as **important determinants** [Leigh S et al, 2020]

Guidance by an HCP represents a significant factor motivating a **patient's adoption** of mHealth [Peng W et al, 2016]

■ Patient Journey ■ Digital Health Use Categories

Source: IQVIA AppScript Use Categories. IQVIA Institute, Sep 2017

For an HCP not all Digital Health solutions are the same...



Validation through appropriate experimental design



Medical device



EU MDR

Medical Devices Regulation

Only a pre-requisite!

Additional barriers for physician's uptake of digital health



App as a medical device



- **Disruption in the traditional workflow of care**

- Use of separate portals: data entry duplication
- Time constraints per visit
- Commitment to review and interpret data (when?)
- Hospital business model

- **Data Interpretation**

- Quality of patient's acquired data?
- Data contextualization
- Automated interpretation: sensitivity vs specificity
- Trust in the SW

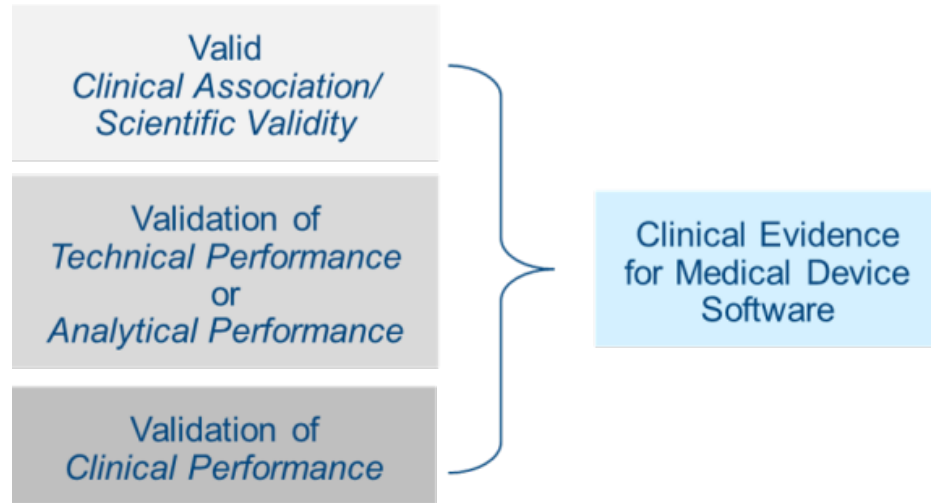
- **Patient-Physician Communication**

- When?
- How?
- Privacy and legal traceability

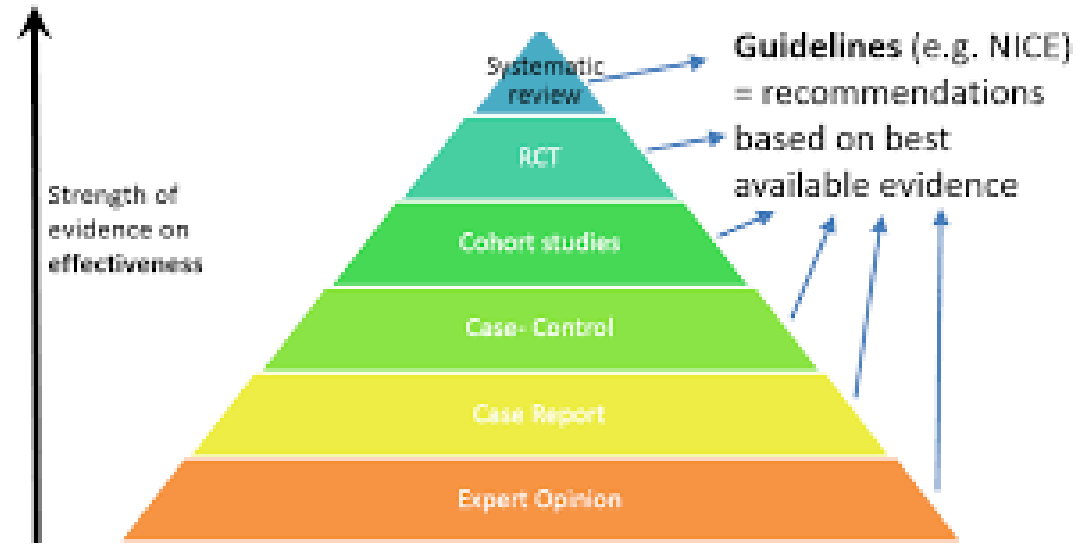
- **Lack of reimbursement for physician time**

How to overcome these barriers?

- Level A: multiple RCTs or meta-analyses
- Level B: single RCT or non randomized
- Level C: Observational



[MDCG 2020-1. Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software]



By providing the proper **level of clinical evidence** about risk/benefit of a certain procedure/treatment to allow its inclusion in the **Clinical Practice Guidelines (CPG)**

Clinical Practice Guidelines (CPG) are the most important documents, redacted by **professional medical Associations**, for incorporating scientific evidence into healthcare **decision-making recommendations** intended to optimize patient care.

The role of professional medical associations

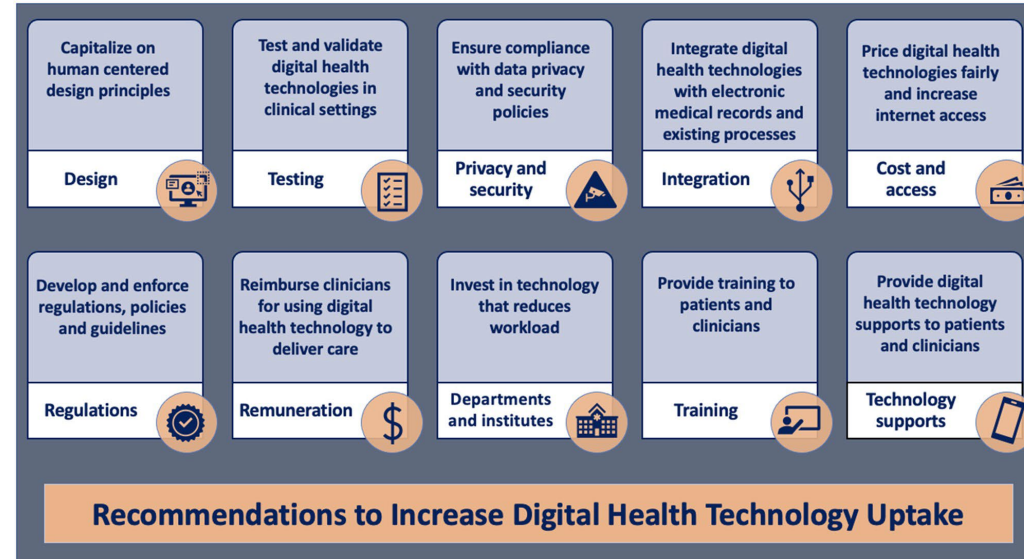
Position paper



ESC e-Cardiology Working Group Position Paper: Overcoming challenges in digital health implementation in cardiovascular medicine

European Journal of Preventive
Cardiology
2019, Vol. 26(11) 1166–1177
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[Whitelaw S, et al. *European Heart Journal - Digital Health*, 2021;2: 62–74]

The need for apriori standardized
assessment of evidence to facilitate
adoption of mHealth in clinical
practice

A scientific statement of the mHealth Task
Force of the ESC Regulatory Affairs
Committee

Caiani EG*, Kemps H*, Hoogendoorn P*, et al (in
preparation)



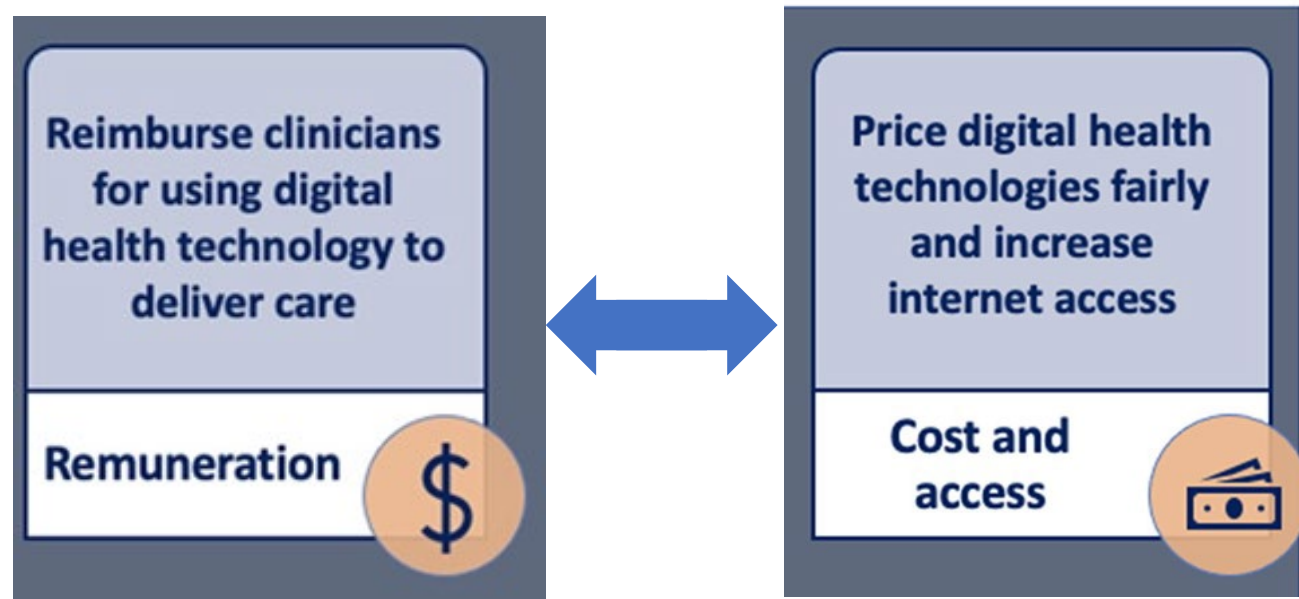
- ✓ Appropriate patient-population, intended use, operating ranges and exclusion criteria? (e.g. age, gender, educational level, health literacy, CV risk profile, exercise capacity)
- ✓ Clinical validation performed using appropriate standards for the intended use? (e.g. 12-lead ECG for the diagnosis of AF)
- ✓ Reported against nominal performance? Is this affected by software updates?
- ✓ Sufficient power and duration longitudinal studies, meaningful clinical differences in the primary end point?
- ✓ Specific domain's recommendations on level of evidence met?
- ✓ Co-development with relevant stakeholders?
- ✓ Maintenance of health information?



Additional factors to consider to increase uptake

Need for **new healthcare organizational models** to deal with patients' use of these tools:

- Consider time for remote data review
- Frequency of data flow
- Dashboard to automatize review process
- Proper patient-physician communication channels



[Whitelaw S, et al. *European Heart Journal - Digital Health*, 2021;2: 62–74]

Additional factors to consider to increase uptake

**Emergency room
and EHR**



**Emergency
services**



**Primary Care
Specialists**

**Mobile
health**



**Integrate digital
health technologies
with electronic
medical records and
existing processes**

Integration



[Whitelaw S, et al. *European Heart Journal - Digital Health*, 2021;2: 62–74]

Conclusions

The availability of **mobile health solutions and apps** on the market is considerable: they can be used for empowering patients to assume a more active role in monitoring and managing their chronic conditions and therapeutic regimens, as well as to provide HCP with data and follow-up in-between visits.

Their success of being integrated into routine clinical practice is highly related to their **adoption by healthcare professionals**.

Medical device certification approval, availability of clinical evidence, assessment by public schemes, reimbursement for physicians, new healthcare organizational models are **factors** to consider to increase their **uptake**.

Thanks for your attention!



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