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e-Health: Is it good value for money?

Opportunities and challenges surrounding the (development and) use of digital technologies in healthcare: A health economist's perspective

SPEAKER: Dr Cynthia IGLESIAS

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E-health: Is it good value for money? Opportunities and challenges surrounding the (development and) use of digital technologies in healthcare
A health economist's perspective

Cynthia P Iglesias Urrutia MSc Phd

Associate Professor / Senior Health Economist, Department of Health Sciences, University of York, UK

Professor of Health Economics, Department of Business and Management, Aalborg University, Denmark

E-mail: **cynthia.iglesias@york.ac.uk**

Disclaimer

I am employed by the University of York (UK) and sit on the Medical Technologies Advisory Committee (MTAC) of the Medical Technologies Evaluation Programme (MTEP) of the National Institute for Health and Care Excellence (NICE) for England and Wales,

however

The **views** expressed in this presentation **are my own** and do not necessarily reflect the position of my employer of those of NICE

What is Digital Technology (DT)?

- ...includes all types of electronic equipment and applications….
- … that process and use digital information include personal computers, calculators, automobiles, traffic light controllers,….”
- Software - instructions in the form of digital information - is used to control sequences of operations in many devices

Source: http://technologyin.org/digital-technology

DT in Healthcare

- include categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.

(**Source:** https://www.fda.gov/medicaldevices/digitalhealth/)

- refer to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle.

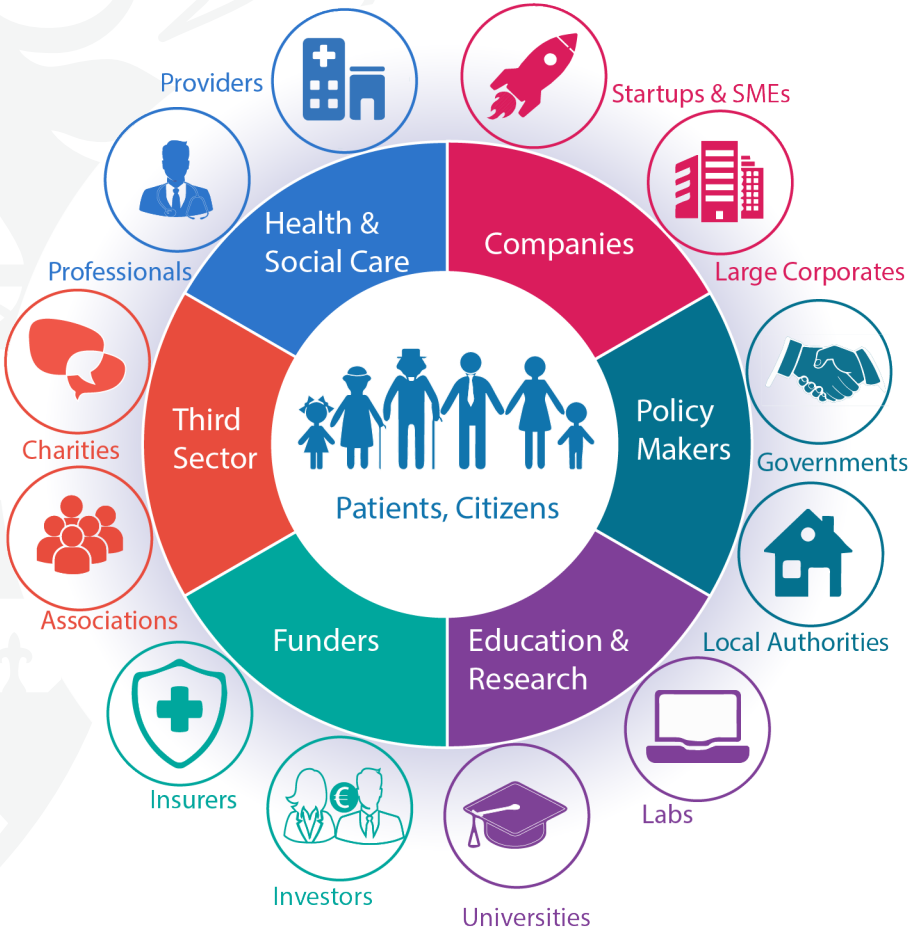
(**Source:** https://ec.europa.eu/health/ehealth/overview_en)

Digital Health Technologies are…

- Often classed as medical devices
- Complex interventions in complex healthcare systems

Stakeholders in Digital Health Technologies

The Digital Health Society



Source: European Connected Health Alliance (https://echalliance.com/page/digitalhealthsociety)

Grand Challenges in DH
Kostkova (2015)

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Multidisciplinary Digital Health

- to address real-world medical challenges, solve clinical or public health problems, and recognize patients' needs
- requires collaboration across multiple disciplines including computer science, engineering, information science, journalism, economics, medicine, public health, epidemiology, etc

Big Data and Public Health

- mobile technology and sensor/wearable devices produce a huge volume of real-time geo-located big data
- offers new opportunities for disease surveillance, early-warning, preparedness, and rapid response
- but it is difficult to regulate and guarantee the quality of the information

Grand Challenges in Digital Health

Kostkova (2015)

- **MedTech, Self-Management, and Personalized Care**
  - mobile technology allows interaction of self-monitoring/tracking and wearable devices
  - increased (some) individuals' engagement with healthy lifestyles and well-being
  - helped patients to independently monitor and self-manage their conditions
  - lack of scientific robust evidence
  - regulation for these new technologies is only now emerging
- **mHealth and Global Health Interventions**
  - mobile phones are everywhere and could be used to deliver interventions, however there are
  - issues regarding: privacy and security, how to reach the intended target, how to regulate their use and evaluate their outcomes
  - need more robust studies producing evidence on tangible quantifiable health outcomes and broader impact on people's health and well-being

Grand Challenges in Digital Health

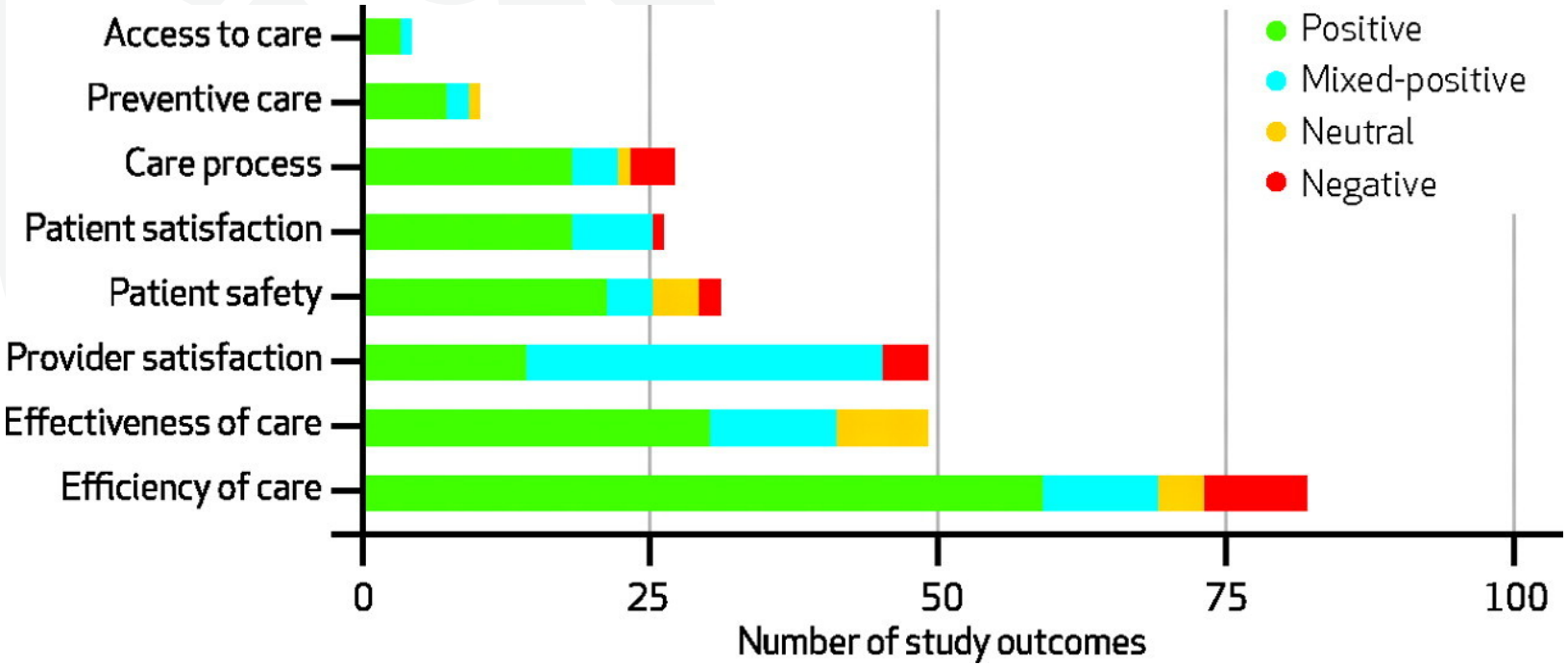
Kostkova (2015)

- **Evidence and Knowledge: Semantics, Social Media, and Persuasion**
  - *Knowledge is the enemy of disease* (Sir Muir Gray, 1999)
  - Many ways we can use digital technologies to share evidence and knowledge to improve health or deliver healthcare
  - More research is needed to demonstrate the impact of these achievements on clinical results.
- **Serious Health Games and Games-Based Learning and Training**
  - huge potential to deliver benefits, especially in certain groups (e.g. children)
  - must assess their effectiveness, using both computing and clinical methodologies, to demonstrate tangible impact on personal health, knowledge, attitude and behaviour change, and ultimately health outcomes and costs
- **Personal and Population Data – To Share or Not to Share?**
  - data ownership, anonymity, cybersecurity issues hinder the next stage in the diffusion of DT for healthcare use

Benefits of Health Information Technology (IT)

Beeuwkes Buntin et al (2011)

- Reviewed recent literature on health IT to determine its effect on a range of outcomes
- Approx 92% of the studies on the effects of health IT reached conclusions that were positive overall.
- Frustration as to the remaining challenges concerning implementation and interoperability



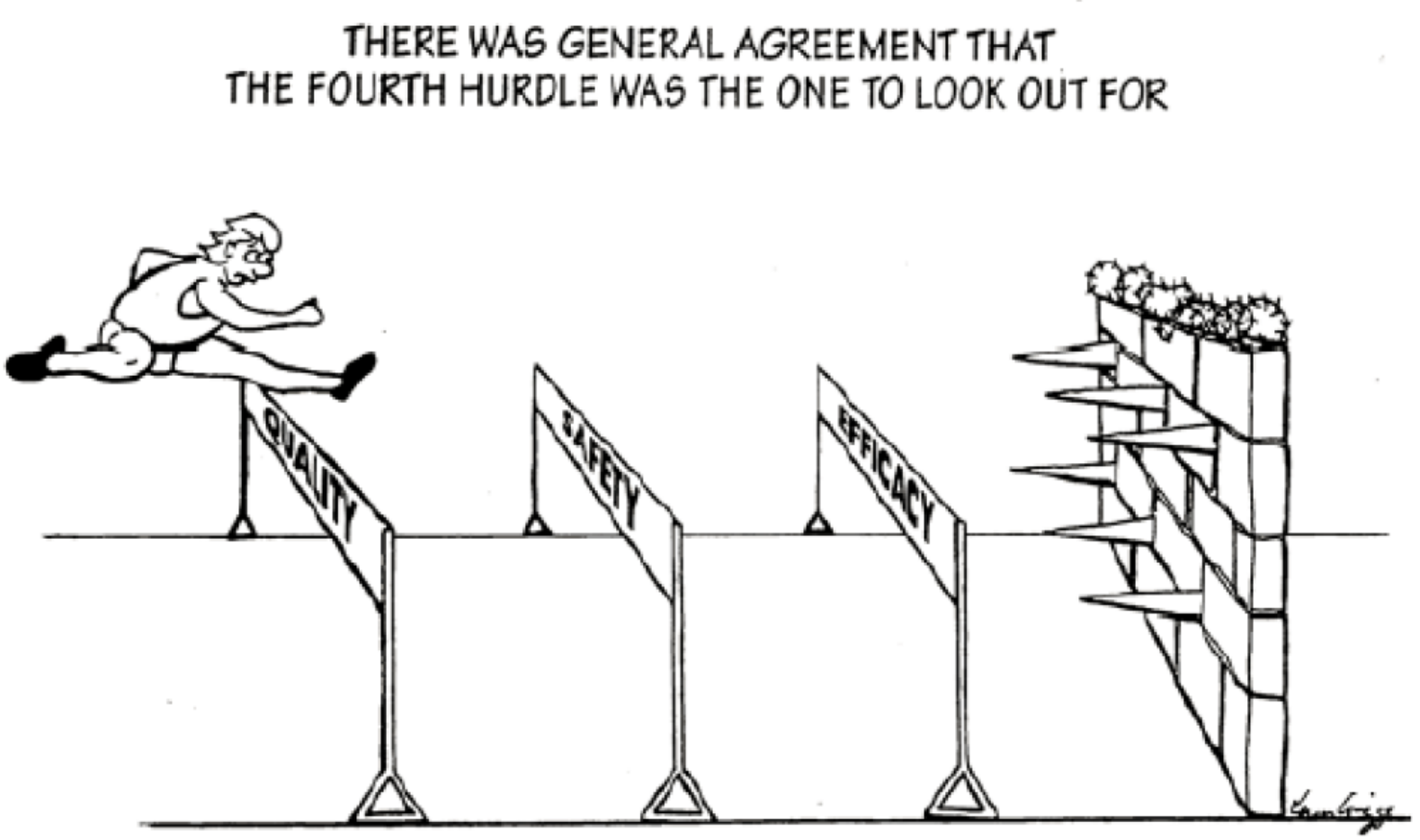
In Healthcare a Main Objective is:

To maximise population health, subject to a number of constraints (e.g. ethical, financial, infrastructural)

By providing those treatments and services that are found to be *value for money*

Investments in digital health technologies as a service or treatment must pass this hurdle

The Fourth Hurdle, …, Most Difficult?



Medical Devices (MDs)
Definition

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the following specific medical purpose:

(i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for, an injury or disability,

(iii) investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state,

(iv) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deem to be medical devices:

(v) devices for the control or support of conception;

(vi) products specifically intended for the cleaning, disinfection or sterilisation of devices;

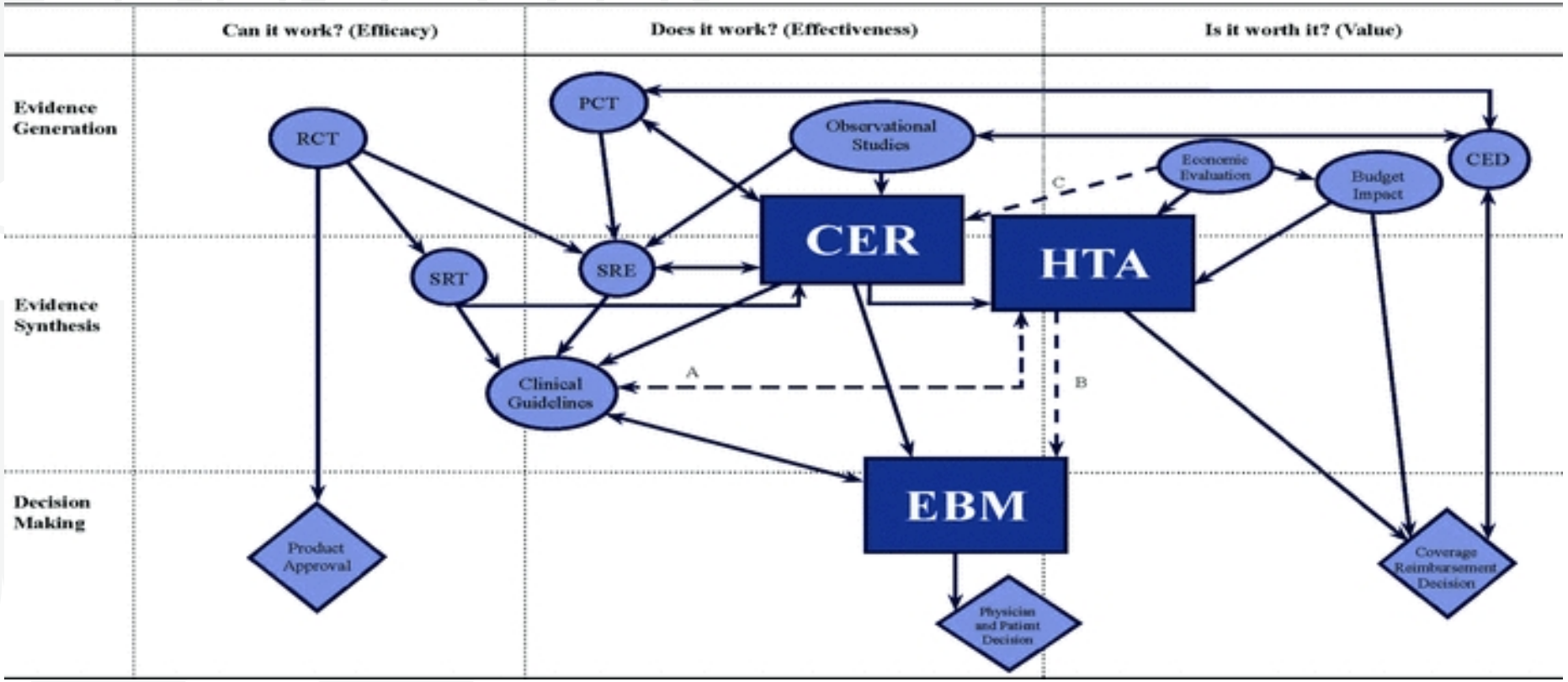
Source: Regulation (EU)2017/745.

Health Technology Assessment
Definition (HTA)

" …A method of evidence synthesis that considers evidence regarding clinical effectiveness, safety, cost-effectiveness and, when broadly applied, includes social, ethical, and legal aspects of the use of health technologies… a major use of HTA is in informing reimbursement and coverage decisions, in which case HTAs should include benefit-harm assessment and economic evaluation."

Source: Luce BR, Drummond MF, Jönsson B, Neumann PJ, Schwartz JS, Siebert U, Sullivan SD. EBM, HTA, and CER: clearing the confusion. Milbank Q. 2010 jun;88(2):256-76

The Evaluation Pathway in Healthcare



Notes:
RCT= randomized controlled trial
PCT= pragmatic clinical trial
HTA= health technology assessment
SRT= systematic review of trials
EBM= evidence-based medicine
SRE= systematic review of evidence
CER= comparative effectiveness research
CED= coverage with evidence development

Solid lines indicate clear relationships, and dotted lines indicate disputed relationships. Diamonds represent decision processes, and circles and ovals represent all other evidence activities, except for the rectangles, which are reserved for EBM, HTA, and CER.

Source: Luce BR, Drummond M, Jönsson B, Neumann PJ, Schwartz JS, Siebert U, Sullivan SD. EBM, HTA, and CER: clearing the confusion. Milbank Q. 2010 Jun;88(2):256-76.

Generating the Right Evidence for Faster and Better Uptake of DHT

MedCity, Digital Health. London and BSI (2017)

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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

Evidence Standards Framework for DHT

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Figure 1 DHTs classified by function and stratified into evidence tiers

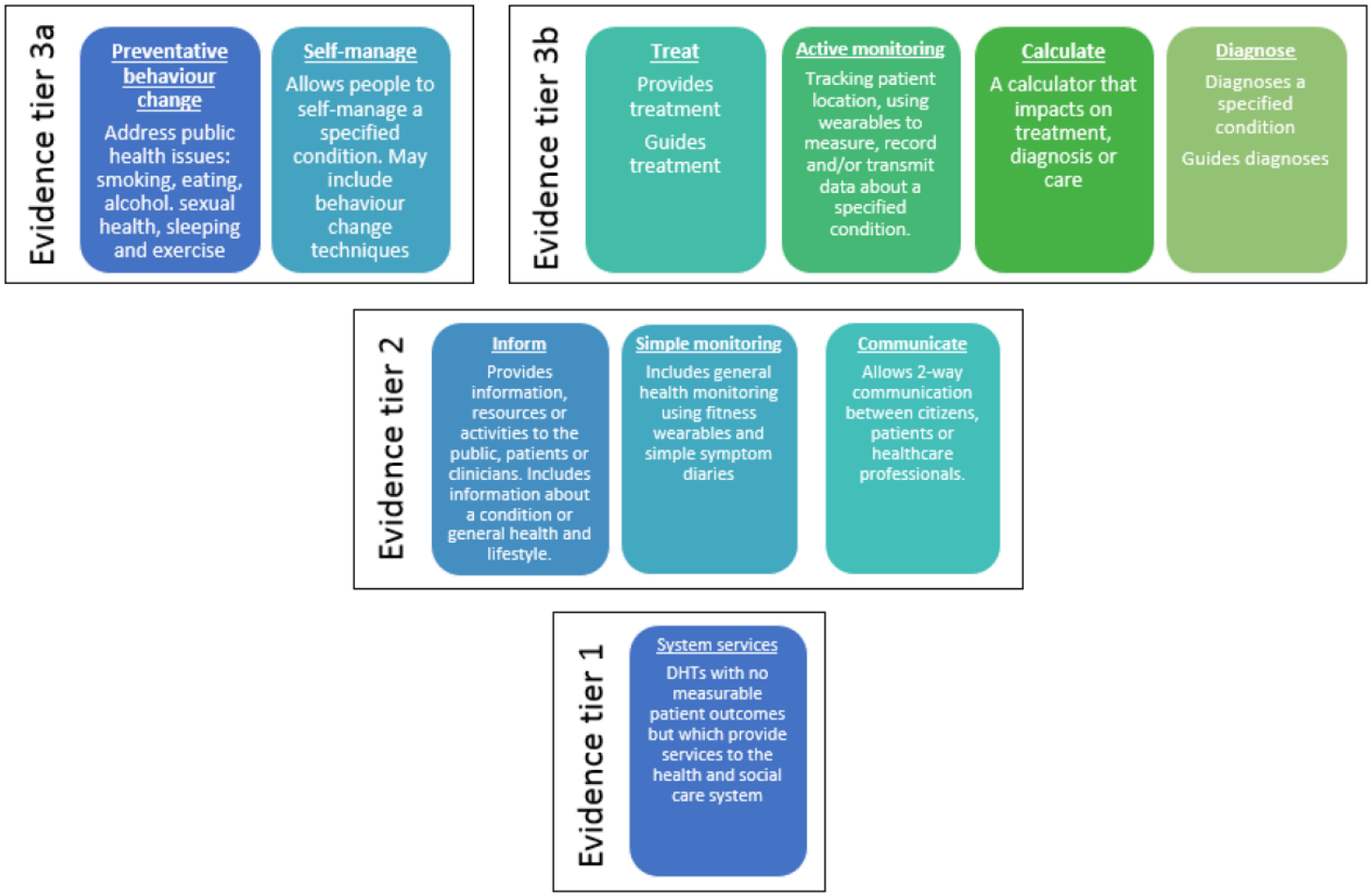

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Table 2 Contextual questions to help identify higher-risk DHTs

Question	Risk adjustment
Are the intended users of the DHT considered to be in a potentially vulnerable group such as children or at-risk adults?	NHS England defines an at-risk adult as an adult 'who may be in need of community care services by reason of mental or other disability, age or illness; and who is or may be unable to take care of him or herself, or unable to protect him or herself against significant harm or exploitation.' If the DHT is intended to be used by people considered to be in a potentially vulnerable group then a higher level of evidence may be needed, or relevant expert opinion on whether the needs of the users are being appropriately addressed.
How serious could the consequences be to the user if the DHT failed to perform as described?	A higher level of potential harm may indicate that the best practice evidence standards should be used.
Is the DHT intended to be used with regular support from a suitably qualified and experienced health or social care professional?	DHTs that are intended to be used with support (that is, with regular support or guidance from a suitably qualified and experienced health or social care professional) could be considered to have lower risk than DHTs that are intended to be used by the patient on their own. *This contextual question may require careful interpretation depending on the individual DHT as the involvement of a clinician may in itself indicate that the DHT presents a specific risk.*
Does the DHT include machine learning algorithms or artificial intelligence?	Refer to the code of conduct for data-driven health and care technology for additional considerations when assessing DHTs that use artificial intelligence or machine learning.
Is the financial or organisational risk of the DHT expected to be very high?	DHTs with very high financial risk should be assessed using the best practice standards to provide surety that the DHT represents good value. High organisational risks may include situations in which implementing the DHT would need complex changes in working practice or care pathways.

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Table 3 Evidence for effectiveness standards for tier 1 DHTs

Evidence category	Minimum evidence standard	Best practice standard
Credibility with UK health and social care professionals.	Be able to show that the DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field. Either: • show that relevant clinical or social care professionals working within the UK health and social care system have been involved in the design, development or testing of the DHT, or • show that relevant clinical or social care professionals working within the UK health and social care system have been involved in signing-off the DHT, indicating their informed approval of the DHT.	Published or publicly available evidence documenting the role of relevant UK health or social care experts in the design, development, testing or sign-off of the DHT.
Relevance to current care pathways in the UK health and social care system.	Evidence to show that the DHT has been successfully piloted in the UK health and social care system, showing that it is relevant to current care pathways and service provision in the UK. Also evidence that the DHT is able to perform its intended function to the scale needed (for example, having servers that can scale to manage the expected number of users).	Evidence to show successful implementation of the DHT in the UK health and social care system.
Acceptability with users.	Be able to show that representatives from intended user groups were involved in the design, development or testing of the DHT. Provide data to show user satisfaction with the DHT.	Published or publically available evidence to show that representatives from intended user groups were involved in the design, development or testing of the DHT and to show that users are satisfied with the DHT.

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Table 4 Evidence for effectiveness standards for tier 2 DHTs

Evidence category	Minimum evidence standard	Best practice standard
Reliable information content.	Be able to show that any health information provided by the DHT is: • valid (aligned to best available sources, such as NICE guidance, relevant professional organisations or recognised UK patient organisations, and appropriate for the target population) • accurate • up to date • reviewed and updated by relevant experts at defined intervals, such as every year • sufficiently comprehensive.	Evidence of endorsement, accreditation or recommendation by NICE, NHS England, a relevant professional body or recognised UK patient organisation. Alternatively, evidence that the information content has been validated though an independent accreditation such as The Information Standard or HONcode certification.
Ongoing data collection to show usage of the DHT.	Commitment to ongoing data collection to show **usage** of the DHT in the target population, and commitment to share, when available, with relevant decision-makers such as commissioners in a clear and useful format.	Evidence that data on **usage** is being collected in line with the minimum standards and can be made available to relevant decision-makers.
Ongoing data collection to show value of the DHT.	Commitment to ongoing data collection to show **user outcomes** (if relevant) or **user satisfaction** (using non-patient identifiable information) to show ongoing value, and commitment to share, when available, with relevant decision-makers such as commissioners in a clear and useful format.	Evidence that data on **outcomes or user satisfaction** is being collected in line with the minimum standard and can be made available to relevant decision-makers.
Quality and safeguarding.	Show that appropriate safeguarding measures are in place around peer-support and other communication functions within the platform. Describe who has access to the platform and their roles within the platform. Describe why these people or groups are suitable and qualified to have access. Describe any measures in place to ensure safety in peer-to-peer communication, for example through user agreements or moderation.	As for the minimum evidence standard.

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Table 5: Evidence for effectiveness standards for tier 3a DHTs

Evidence category	Minimum evidence standard	Best practice standard
Demonstrating effectiveness.	High quality observational or quasi-experimental studies demonstrating relevant outcomes. These studies should present comparative data. Comparisons could include: • relevant outcomes in a control group • use of historical controls • routinely collected data. Relevant outcomes may include: • behavioural or condition-related user outcomes such as reduction in smoking or improvement in condition management • evidence of positive behaviour change • user satisfaction.	High quality intervention study (quasi-experimental or experimental design) which incorporates a comparison group, showing improvements in relevant outcomes, such as: • patient-reported outcomes (preferably using validated tools) including symptom severity or quality of life • other clinical measures of disease severity or disability • healthy behaviours • physiological measures • user satisfaction and engagement • health and social care resource use, such as admissions or appointments. The comparator should be a care option that is reflective of standard care in the current care pathway, such as a commonly used active intervention.
Use of appropriate behaviour change techniques (if relevant).	Be able to show that the techniques used in the DHT are: • consistent with recognised behaviour change theory and recommended practice (aligned to guidance from NICE or relevant professional organisations) • appropriate for the target population.	Published qualitative or quantitative evidence showing that the techniques used in the DHT are: • based on published and recognised effective behaviour change techniques • aligned with recommended practice • appropriate for the target population.

Evidence Standards Framework for DHT

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Table 6 Evidence for effectiveness standards for tier 3b DHTs

Evidence category	Minimum evidence standard	Best practice standard
Demonstrating effectiveness.	High quality intervention study (experimental or quasi-experimental design) showing improvements in relevant outcomes, such as: • diagnostic accuracy • patient-reported outcomes (preferably using validated tools) including symptom severity or quality of life • other clinical measures of disease severity or disability • healthy behaviours • physiological measures • user satisfaction and engagement. Generic outcome measures may also be useful when reported alongside condition-specific outcomes. The comparator should be a care option that is reflective of the current care pathway, such as a commonly used active intervention.	High quality randomised controlled study or studies done in a setting relevant to the UK health and social care system, comparing the DHT with a relevant comparator and demonstrating consistent benefit including in clinical outcomes in the target population, using validated condition-specific outcome measures. Alternatively, a well-conducted meta-analysis of randomised controlled studies if there are enough available studies on the DHT.

Evidence Standards Framework for DHT

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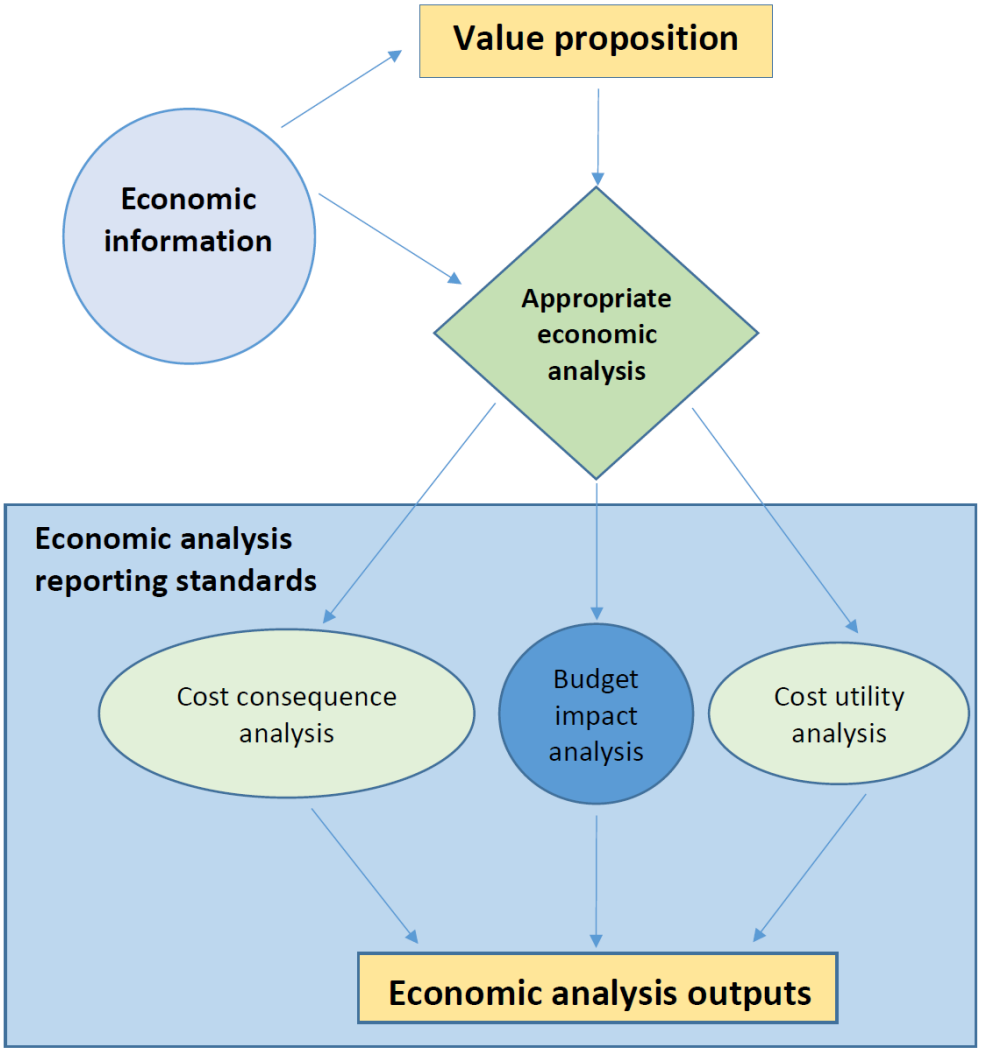
Figure 2. Overview showing the relationship between components of evidence standards for economic impact



Evidence Standards Framework for DHT

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Table 9 Evidence for economic impact standards: appropriate economic analysis

Economic analysis level	Appropriate economic analysis	Outputs
Basic.	Budget impact analysis.	Estimated yearly budget impact for years 1 to 2. Data may be collected to inform future economic analyses.
Low financial commitment.	Cost-consequence analysis.	Estimated costs and benefits. Sensitivity analysis results.
	Budget impact analysis.	Estimated yearly budget impact for years 1 to 5. Sensitivity analysis results.
High financial commitment.	For DHTs with health outcomes funded by the NHS and Personal Social Services, a cost-utility analysis should be done using NICE's guide to the methods of technology appraisal as a reference case.	Estimated incremental cost-effectiveness ratio. Sensitivity analysis results.
	For DHTs funded by the public sector with health and non-health outcomes, or for DHTs that focus on social care, a cost-utility analysis should be done. If this is not possible, a cost-consequence analysis may be acceptable. The analysis should be done using developing NICE guidelines: the manual as a reference case.	Estimated incremental cost-effectiveness ratio (cost-utility analysis) or estimated costs and benefits (cost-consequence analysis). Sensitivity analysis results.
	Budget impact analysis.	Estimated yearly budget impact for years 1 to 5. Sensitivity analysis results.

Evidence Standards Framework for DHT

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Table 10 Evidence for economic impact standards: economic analysis reporting

Component	Standards
Economic perspective	Describe and justify and provide rationale for the perspective used. This should be that of the decision maker or payer (that is, from a UK health and social care system perspective or societal perspective if local authority or public health decision maker).
Time horizon	Describe and justify the time horizon used. This should be long enough to capture all costs and to account for all health outcomes.
Discounting	Describe and justify whether discounting was used. Discounting can be applied to costs and savings that occur after the initial year using standard UK Treasury recommendations.
Sensitivity analyses	Describe and justify the sensitivity analyses used. Present the results of the sensitivity analyses clearly depicting the main parameters and assumptions that have the largest effect.
Equity analysis	If there are good clinical data to show that the effects differ by demographic factors, include subgroup analyses to show the relevant economic impact.
Descriptions of any additional analytical methods	Describe any analytical methods involved in the economic analysis such as methods for synthesising data from different sources, extrapolating, validating or adjusting data and approaches to using skewed, missing, censored, heterogeneous or uncertain data.
Critique of the economic analysis	Present the strengths and weaknesses of the economic analysis and its generalisability to the local context.