

Digital Health Interventions: A Review of Economic Evaluation Guidelines From Health Technology Assessment Agencies



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Objectives

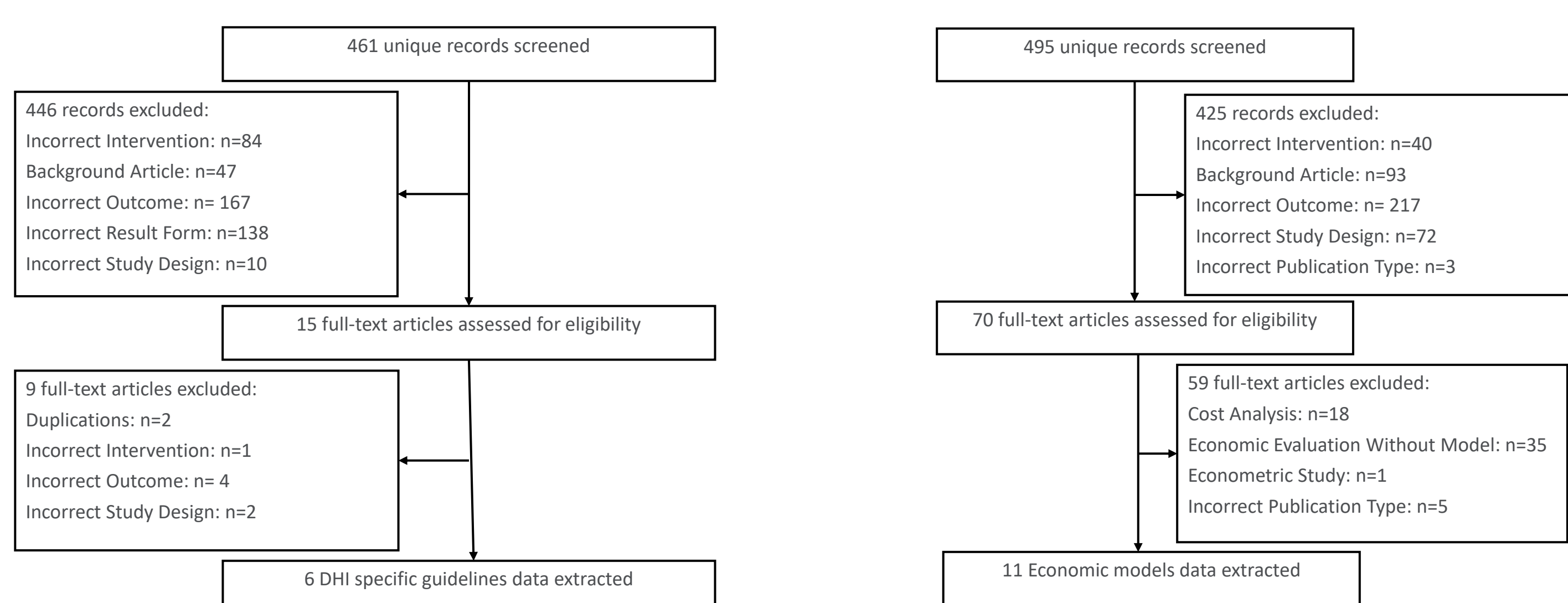
- > The Covid-19 pandemic made a huge barrier to providing face-to-face health care services and accelerated the uptake of digital health interventions (DHIs) and brought health care services online.
- > The conventional health technology assessment (HTA) guidelines require the appraisal of time- and resource-consuming evidence, such as clinical trials in various stages, which may not fit the features of rapid changes in DHIs.¹
- > A systematic review by Kolasa et al.² identified 11 DHIs' assessment guidelines published during Sep 1998 - Dec 2019. These guidelines focused specifically on telemedicine and mobile health applications and none of them provided a methodological approach to the calculation of economic value. The study calls for the need for a new DHI's value assessment framework instead of a QALY approach.²
- > This study aims to understand the latest development in DHI assessment guidelines, focusing on HTA methods guidelines for economic evaluations of DHIs and the latest status of economic evaluations of DHIs in practice.

Methods

- > To ensure all evidence was identified two targeted literature reviews (TLRs) were completed in addition to a grey literature search.
- > The first TLR searched HTA methods guidelines from national HTA agency websites across EU5 countries, Netherlands, Sweden, Australia, Canada, USA, Japan, and Korea, using the keywords "artificial intelligence", "digital", "health app", "tele", "mhealth", and "wearables".
 - > If available, data on the scope and functional classification of DHIs as well as evidence requirements were extracted.
 - > Each identified guideline was analyzed with a 12-item checklist based on a EUnetHTA core model³ with additional criteria (interoperability, data security, and stability/usability).
- > The first search also updated the search and review by Kolasa et al.² by covering the period after 1st December 2019 to 1st July 2022.
- > The second TLR searched PubMed, Scopus, and Web of Science databases using terms "digital health" + "economic" + "evaluation" for the same period as above.
- > English publications using economic models to evaluate DHIs were included.
- > All types of DHIs used for disease diagnosis, prevention, treatment and management were included. DHIs used for health promotion were excluded.

Results

> PRISMA flow-charts of literature selections are shown below.



> The first TLR identified 6 DHI assessment guidelines:

- > 3 DHI specific HTA guidelines among 12 countries;
- > 1 economic evaluation guidelines for LMICs and 2 assessment frameworks all developed by academia.

Authors	Location	Scope	Use of the technology	Characteristics of the technology	Clinical effectiveness	Safety	Economic evaluation	Organisation al aspects	Legal aspects	Ethical aspects	Social aspects	Data security	Interoperability	Stability/ Usability
NICE, 2021; 2022 ⁴	United Kingdom	DHTs including those with AI using fixed (not adaptive) algorithms	✓	✓	✓	✓	✓	✓	X	X	✓	✓	✓	✓
HAS, 2021 ⁵	France	mhealth	✓	✓	✓	✓	X	✓	X	X	✓	✓	✓	✓
BfArM, 2020 ⁶	Germany	DIGA (digital health app)	✓	✓	✓	✓	X	✓	✓	X	✓	✓	✓	X
Babigumira et al., 2021 ⁷	United States	DHIs	✓	✓	X	X	✓	X	X	X	X	X	X	X
Tarricone et al., 2022 ⁸	European Union	mobile medical apps or mHealth	✓	✓	✓	✓	~	✓	X	✓	X	✓	X	✓
Li et al., 2022 ⁹	United States	Telehealth	✓	X	✓	✓	~	~	X	X	✓	X	~	X

> The 12 countries can be divided into 4 groups, according to whether DHI specific guidelines are available.

France, Germany and the UK have DHI specific guidelines	Canada, Spain, and USA do not have DHI specific guidelines but have HTA reports on DHIs
Italy, the Netherlands, and Sweden only have documents discussing the potential opportunities for using DHIs in specific therapeutic areas	Australia, Japan, and Korea do not have DHIs documents on their official websites

- > While Germany and the UK have general guidelines for DHIs, France focuses on a specific category (i.e. mobile health).
- > Only the UK requires economic evaluation of DHIs using CUA, CEA, and BIA based on basic, low or high level of financial commitment.
- > The second TLR identified 11 economic evaluation models on DHIs. A majority of studies used CUA (2 used both CUA and CEA) and Markov models to evaluate the value for money of DHIs.

	DHI Form	Purpose of Use	Analytics Method	Decision Model
AI	4	Diagnosis	7 CUA	*8 Markov Model
Telemedicine	4	Treatment	2 CEA	Decision Tree
Telehealth	2	Disease Management	1 CBA	A Hybrid Decision Tree / Microsimulation Model
mhealth	1	Monitor	1 CMA	No Decision Model

Conclusions

- > There is a fast-increasing DHI specific assessment guidelines since Dec 2019. While Kolasa et al.² found 11 published guidelines over the 21 years from September 1998 to December 2019, our review found 6 including 2 updated version of DHI specific HTA guidelines in France, and the UK and one additional guideline from Germany.
- > There is an increasing attention on economic evaluation of DHIs. While Kolasa et al.² found no DHI specific guidelines for the assessment of economic value of DHIs, our review found that the UK NICE updated DHI guidelines includes evidence requirements for economic evaluation and the guidelines developed for LIMCs also includes economic evaluation methods.
- > Although multiple dimensions such as clinical, organization, behavioral and technical have been widely discussed, CUA and QALY are still the most commonly used approach in economic models for DHIs. This is consistent with the existing systematic reviews on published economic models on DHI.^{10,11}
- > While the volume of economic evaluations of DHIs is growing, challenges remain on the estimation of costs and outcomes of DHIs due to the potential high fixed costs, probable low variable costs and multidimensional characters of DHIs' benefits.
- > DHI specific methods guidelines for economic evaluations are urgently needed. The rapid development, distinct features and complexity of DHI assessment require clinicians, patients, DHI companies, regulators and payers as well as academia cooperatively establish an appropriate approach for appraising the value of DHIs so that DHIs can benefit all those involved.

AI, artificial intelligence; BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte; BIA, budget impact analysis; CEA, cost effectiveness analysis; CUA, cost utility analysis; DHI, digital health intervention; HAS, Haute Autorité de santé; HTA, health technology assessment; LMICs, low- and middle-income countries; mHealth, mobile health; MMA, mobile medical apps; NICE, National Institute for Health and Care Excellence; QALY, quality adjusted life year; TLR, targeted literature review

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