Supplementary Table 1: Peer-reviewed literature search strategy

| **Database**[[1]](#footnote-1)  **(Ovid)** | **Search terms**[[2]](#footnote-2) |
| --- | --- |
| MEDLINE, Embase, CINAHL, Econolit, Cochrane | (1)[[3]](#footnote-3) exp Telemedicine/ or (telehealth or telemedicine) or exp Medical Records Systems, Computerized/ or (ehealth or (electronic adj2 health)) or (digital adj2 health) or (digital adj1 health adj1 intervention) or exp Mobile Applications/ or ((mobile adj1 health) or mhealth) or ((mobile adj1 health adj1 app) or (mobile adj1 health adj1 application)) or (((mobile adj1 medical adj1 app) or (mobile adj1 medical adj1 application))) or exp Text Messaging/ or (sms or text messag$) or (chat room$ or chatroom$ or chatbot$ or avatar) or (wearable$) or ((artificial adj1 intelligence) or (machine adj1 learning)) |
| (2)[[4]](#footnote-4) (health adj evaluation\*) or (project adj evaluation\*) or (program\* adj evaluation) or (evidence adj1 standards) or (health adj service adj evaluation) or (health adj promotion adj evaluation\*) or (systematic adj1 review) or (technology adj2 evaluation) or (implementation adj evaluation\*) or (impact adj evaluation\*) or (outcome\* adj evaluation\*) or (decision adj2 making adj2 framework) or (decision adj2 making adj2 standard\*) or (decision adj2 making adj2 guideline\*) or (technology adj2 appraisal\*) or (technology adj validation) or (evaluation adj1 framework\*) or ((implementation or translation\*) adj2 (study or research)) or (subsid\* or rebat\* or reimburs\*) or Comparative Effectiveness Research/ or exp patient harm/ or exp patient safety/or exp Insurance, Health, Reimbursement/ or exp Legislation, Medical/ or exp Financing, Government/ |
| (3)4 Economics/ or exp "Costs and Cost Analysis"/ or (cost benefit analysis) or (economic\* adj evaluation\*) or (cost adj effect\*) or (cost adj benefit) or (cost adj utility) or (cost adj effic\*) or (economic\* adj analysis) or quality-adjusted life years/ or (quality adjusted life years) or (QALY\*) |
| (4) randomized controlled trial.pt. or controlled clinical trial.pt. or randomized.ab. or placebo.ab. or Clinical Trials as Topic/ or randomly.ab. or (crossover or cross-over).tw or trial.ti. |
| (5) 4 exp epidemiologic studies/ or (Case control) or (cohort adj (study or studies)) or (Cohort analy$) or (Follow up adj (study or studies)) or (observational adj (study or studies)) or (Longitudinal) or (Retrospective) or (Cross sectional) |
| (6) ((Health adj2 technology adj2 assessment) or HTA or (technology adj2 assessment)).tw. |
|  | (7) Animals/ not (animals/ and Humans/) |

Supplementary Table 2: Grey literature search strategy

| The following databases were searched with the terms: “electronic health" or eHealth or “mobile health” or mHealth or telehealth or telemedicine or “digital health” or “digital medicine” over the period January 2015 to August 2020. | |
| --- | --- |
| **Database and website** | **Country/region** |
| **Health Technology Assessment (HTA) Agenciesa** | |
| Canadian Agency for Drugs and Technologies in Health (CADTH) <https://www.cadth.ca/search?keywords> | Canada |
| Health Quality Council of Alberta (HQCA). Completed Reviews <http://hqca.ca/studies-and-reviews/completed-reviews/> |
| Health Quality Ontario (HQO). <http://www.hqontario.ca/Evidence-to-Improve-Care/Health-Technology-Assessment> |
| [The Hospital for Sick Children (SickKids)](http://www.sickkids.ca/AboutSickKids/who-we-are/index.html). (TASK) <http://lab.research.sickkids.ca/task/reports-theses/> |
| Institut national d’excellence en santé et en services sociaux (INESSS) <http://www.inesss.qc.ca/en/publications/publications.html> |
| Institute of Health Economics (IHE). Publications <http://www.ihe.ca/index.php?/publications> |
| Manitoba Centre for Health Policy (MCHP). Deliverables <http://mchp-appserv.cpe.umanitoba.ca/deliverablesList.html> |
| McGill University Health Centre (MUHC). Technology Assessment Unit Reports <https://muhc.ca/tau/page/tau-reports> |
| NLCAHR: Newfoundland and Labrador Centre for Applied Health Research. Contextualized Health Research Synthesis Program (CHRSP) Completed CHRSP projects <http://www.nlcahr.mun.ca/CHRSP/CompletedCHRSP.php> |
| Programs for Assessment of Technology in Health (Canada). Reports (PATH): <https://www.path-hta.ca/research> |
| University of British Columbia. Centre for Health Services and Policy Research <http://chspr.ubc.ca/publications/> |
| INAHTA Secretariat. International Network of Agencies for Health Technology Assessment <http://www.inahta.org/publications/> | International |
| World Health Organization Regional Office for Europe. Health Evidence Network (WHO HEN) <http://www.euro.who.int/en/what-we-do/data-and-evidence/health-evidence-network-hen/publications/by-keyword> |
| Australian Government. Department of Health and Ageing. Australia and New Zealand Horizon Scanning Network (ANZHSN)  <http://www.horizonscanning.gov.au/internet/horizon/publishing.nsf/Content/technologies-assessed-lp-2> | Australia |
| Australian Government Department of Health and Ageing. Medical Services Advisory Committee (MSAC). MSAC Applications  <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/completed-assessments> |
| Joanna Briggs Institute (JBI). The Joanna Briggs Institute EBP Database <http://connect.jbiconnectplus.org/Search.aspx> |
| Monash Health. Centre for Clinical Effectiveness (CCE) <http://monashhealth.org/health-professionals/cce/cce-publications/> |
| Queensland Government (Australia). Health Technology Reference Group. Health Technologies Evaluated-Reports and Briefs (COAG Health Council) <https://www.coaghealthcouncil.gov.au/Health-Technology-Reference-Group/Reports-and-Briefs> |
| Institute of Technology Assessment (ITA). Projects <http://www.oeaw.ac.at/ita/en/projects> | Austria |
| Ludwig Boltzmann Institute of Health Technology Assessment <http://eprints.hta.lbg.ac.at/> |
| Belgian Health Care Knowledge Centre (KCE) <https://kce.fgov.be/en/all-reports> | Belgium |
| French National Authority for Health/Haute Autorité de santé (HAS).  <http://www.has-sante.fr/portail/jcms/c_946986/en/english-toutes-nos-publications-ligne-principale?portal=r_1457306> | France |
| German Institute of Medical Documentation and Information (DMDI) <https://www.dimdi.de/dynamic/en/further-services/health-technology-assessment/hta-reports/> | Germany |
| Health Information and Quality Authority. <https://www.hiqa.ie/reports-and-publications/health-technology-assessments> | Ireland |
| Health Service Executive. Irish Health Repository (Lenus) <http://www.lenus.ie/hse/> |
| De Gezondheidsraad (GR). Health Council of the Netherlands <http://www.gezondheidsraad.nl/en/publications> | The Netherlands |
| Zorginstituut Nederland. National Health Care Institute Netherlands <https://english.zorginstituutnederland.nl/publications> |
| Folkehelseinstituttet. Norwegian Institute of Public Health. Publications <https://www.fhi.no/en/publ/> | Norway |
| Institute of Health Carlos III <http://publicaciones.isciii.es/> | Spain |
| Agency for Health Quality and Assessment of Catalonia <http://aquas.gencat.cat/ca/publicacions/> |
| Swedish Council on Health Technology Assessment (SBU): <https://www.sbu.se/en/publications/> | Sweden |
| Healthcare Improvement, Scotland. Published Resources. <http://www.healthcareimprovementscotland.org> | United Kingdom |
| National Institute for Health and Care Excellence (NICE) <http://www.nice.org.uk/> |
| National Institute for Health Research. (NIHR). Innovation Observatory <http://www.io.nihr.ac.uk/> |
| NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC). <https://www.journalslibrary.nihr.ac.uk/programmes/> |
| Agency for Healthcare Research and Quality (AHRQ). Technology Assessments: <http://www.ahrq.gov/research/findings/ta/>  Evidence-Based Practice: <http://www.ahrq.gov/research/findings/evidence-based-reports/search.html> Effective Health Care Reports: <https://effectivehealthcare.ahrq.gov/products-tools/> | United States |
| Centers for Medicare & Medicaid Services (CMS). Technology Assessments: <http://www.cms.gov/medicare-coverage-database/indexes/technology-assessments-index.aspx?TAId=85&bc=AAAQAAAAAAAA&> |
| ECRI Institute: <http://www.ecri.org/> |
| Institute for Clinical and Economic Review (ICER): <https://icer-review.org/materials/> |
| Washington State Health Care Authority (HCA). Health Technology Review: <https://www.hca.wa.gov/about-hca/health-technology-assessment/health-technology-reviews> |
| **Health Economicsa** | |
| Hospital for Sick Children [Toronto]. Paediatric Economic Database Evaluation (PEDE): <http://pede.ccb.sickkids.ca/pede/search.jsp> | Canada |
| McMaster University. Centre for Health Economics and Policy Analysis (CHEPA) <http://www.chepa.org/research-products> |
| Toronto Health Economics and Technology Assessment Collaborative (THETA) <http://theta.utoronto.ca/content.php?pid=411861&sid=3372336> |
| Federal Reserve Bank of St. Louis. Economic Research Division. Ideas database (IDEAS): <http://ideas.repec.org/> | International |
| NHS Economic Evaluation Database (EED), economic evaluations of health care interventions. Searchable as part of the University of York NHS CRD databases. |
| University of Aberdeen. Health Economics Research Unit (HERU) <http://www.abdn.ac.uk/heru/outputs/publications/> |
| **ProQuest Dissertations and Theses Global (PQDT)** |  |
| ProQuest Dissertations and Theses Global (PQDT) | International |

a Source: Canadian Agency for Drugs and Technologies in Health (CADTH)’s, “Grey Matters: a practical tool for searching health-related grey literature,” updated April 2019(13)

Supplementary Table 3: HTA Core Model 3.0(19) description of domains and list of domain topics

| **HTA Domain Number and Name (Three letter acronym)** | **Description of the HTA domain** | **HTA domain topics (example topic issues; to clarify topic if required)** |
| --- | --- | --- |
| 1. Health problem and current use of technology (CUR) | CUR provides background information on target groups, target conditions, and their epidemiology; the individual and societal burden of the health problem; the availability, patterns of use, alternatives, and the technology's regulatory status; and the requirements for the technology's use. | (1) Target population, (2) Target condition, (3) Current management of the condition, (4) Utilisation (current and future use), (5) Regulatory status (market authorization, reimbursement status) |
| 2. Description and technical characteristics of technology (TEC) | TEC describes the technology (or sequence of technologies) in sufficient detail to differentiate it from comparators. Details should cover: When it was developed, first used, and for what purpose(s); claimed benefits over its comparator and current phase of development; who will use it and in what manner, for what conditions and for what level of health care; material requirements for the premises, equipment and staff; and any specific training and information requirements for staff/patients/family/general public. Although this domain covers the technology's regulatory status as a topic, the questions are identical to CUR, so for our assessment purposes, we remove "Regulatory Status" from TEC to prevent duplication. | (1) Training and information needed to use the technology, (2) Features of the technology, (3) Investments and tools required to use the technology, (5) Other (Who manufactures the technology?)  Excluded due to duplication with CUR: (4) Regulatory status |
| 3. Safety (SAF) | Safety is an umbrella term for any unwanted or harmful effects caused by using a health technology. Safety issues to be covered are those important to patients, or otherwise likely to be important in guiding healthcare providers and policymakers' decisions. This domain aims to identify any unwanted or harmful effects, estimate each probability and severity, and then identify controls to mitigate or reduce these risks. | (1) Patient safety, (2) Occupational safety, (3) Environmental safety, and (4) Safety risk management |
| 4. Clinical effectiveness (EFF) | EFF focuses on health benefits and the benefit harm balance, using the harms identified in SAF. To provide evidence of a causal relationship between the technology and health outcomes, the generally accepted standard is an appropriately designed and conducted randomized controlled trial (RCT). This RCT should directly compare the new technology with a well-justified comparator in patients who are typical in day-to-day health care settings. The assessment of health benefits should primarily consider patient-relevant outcomes such as mortality, morbidity, and quality of life. | (1) Mortality, (2) Morbidity, (3) Function (Impact on body functions, workability, return to previous living conditions, activities of daily living), (4) Health-related quality of life, (5) Quality of life (Does the knowledge of the test result affect the patient's non-health-related quality of life?), (6) Patient satisfaction, (7) Test-treatment chain (If relevant, is there an effective treatment for the condition the test is detecting?), (8) Test accuracy (If relevant), (9) Patient safety (Consequences of false positive, false negative and incidental findings), (10) Change in management, (11) Benefit harm balance |
| 5. Costs and economic evaluation (ECO) | ECO aims to inform value-for-money judgements about health technologies with information about costs, health-related outcomes, and economic efficiency. The topics and issues are limited to important items for all healthcare settings and are required for other jurisdictions in assessing the transferability of ECO information into their own setting. | (1) Resource utilisations (Resource identification, measurement, valuation, and budget impact of technology and comparator), (2) Measurement and estimation of outcomes (Outcome identification, measurement, and valuation of technology and comparator), (3) Examination of costs and outcome (incremental cost and outcome of technology over comparator), (4) Characterising uncertainty, (5) Characterising heterogeneity (Subgroup analysis), (6) Validity of the models (Methodological assumptions, the validity of estimates of costs, outcomes, and economic evaluations) |
| 6. Ethical analysis (ETH) | ETH considers prevalent social and moral norms and values relevant to the new technology. It involves an understanding of the consequences of implementing or not implementing a healthcare technology in two respects: The prevailing societal values and the norms and values that the technology itself constructs when it is put into use. ETH also covers moral and ethical issues related to the consequences of performing the health technology assessment (HTA), e.g., choice of specific endpoints and ethical problems related to economic evaluation. ETH includes six topics and 19 issues that stem from the general values of the population, aims of the healthcare system, and values arising from using a technology. | (1) Benefit harm balance, (2) Autonomy, (3) Respect for persons, (4) Justice and Equity, (5) Legislation, (6) Ethical consequences of the HTA |
| 7. Organisational aspects (ORG) | ORG considers how different kinds of resources (e.g., material artifacts, human skills, and knowledge, money, attitudes, work culture) need to be mobilized and organized when implementing technology and the consequences they may produce in the organization and the health care system as a whole. Organizational issues include, e.g., work processes and patient/participant flow, quality and sustainability assurance, centralization, communication and co-operation, managerial structure, and acceptance of technology. Organizational aspects should be considered on three levels: (1) intra-organizational; (2) inter-organizational; and (3) health care system level; to ensure the different aims and expectations of various stakeholders, e.g., payers, providers, and suppliers, are taken into account. | (1) Health process delivery, (2) Structure of health care system, (3) Process-related costs, (4) Management, (5) Culture |
| 8. Patients and Social aspects (SOC) | Patient aspects relate to issues relevant to patients, individuals, and caregivers. Patient refers to a person who receives (or has received) and uses (or used) health technologies and health services in the healthcare sector. The term individual is sometimes used synonymously with ‘patient.’ Still, it can also refer to a healthy individual who receives health technologies, e.g., a person taking part in a screening program. The term caregivers (sometimes referred to as carers) refers to family, friends, and other persons from the patient’s/individual’s social network who provide care to the patient and are in other ways involved during the disease. It excludes those paid to give care, such as healthcare professionals.  Social aspects are related to social groups, specific groupings of patients, or individuals of specific interest in an HTA, such as older people, people living in remote communities, people with learning disabilities, ethnic minorities, immigrants, etc. | (1) Patients' perspectives, (2) Social group aspects, (3) Communication aspects |
| 9. Legal aspects (LEG) | The objective of LEG is to detect rules and regulations which need to be considered when evaluating the implications and consequences of implementing a health technology. Rules and regulations have been established to protect the patient’s rights and societal interests. The rules and regulations may be a part of patient rights legislation, data protection legislation, or health care personnel’s provisions, rights, and duties in general. | (1) Autonomy of patients, (2) Privacy of the patients, (3) Equality in health care, (4) Ethical aspects, (5) Authorisation and safety, (6) Ownership and liability, (7) Regulation of market |

Supplementary Table 4: Characteristics of included framework papers

| **Framework** | **Year** | **Country/ Regiona** | **Journal citation/ website** | **Author affiliation** | **Intended audience** | **Purpose (name of framework)** |
| --- | --- | --- | --- | --- | --- | --- |
| Eysenbach 2011 (35) | 2011 | International | Journal citation | Hospital/ university | Not stated, but assume writers of eHealth trial reports and evaluators of eHealth trials | Information to include when reporting ehealth/mhealth trials (CONSORT‐EHEALTH checklist) |
| Andalusian Health Quality Agency (AHQA) 2012 (36) | 2012 | Spain | Website/ | HTA agency | Citizens, Health Professionals, Health Services Suppliers, and Developers | (Recommendations on design, use, and assessment of mobile health apps) |
| Kidholm et al. 2012(20) | 2012 | Europe | Journal citation | Hospital/ university | Not stated, but assume telemedicine users and stakeholders in decision making | To present the Model for ASsessment of Telemedicine applications (MAST) |
| Haute Autorité de Santé (HAS) 2013 (22) | 2013 | France | Website/ Guideline | HTA agency | For manufacturers, research organizations, and project developers | To identify a set of methods and conditions that will allow high-quality clinical assessment, mainly when conventional randomized controlled trials cannot be performed |
| Khoja 2013 (37) | 2013 | International | Journal citation | University | Managers, healthcare providers, and clients | eHealth evaluation tool (Khoja–Durrani–Scott Framework for e-Health Evaluation) |
| Lewis and Wyatt 2014 (38) | 2014 | International | Journal citation | University | App commissioners, developers, and users | A framework to assess the likely risks posed by a specific app in a specific context |
| Bergmo 2015 (29) | 2015 | International | Journal citation | University | Researchers interested in conducting future economic evaluations in eHealth | How to apply economic evaluation to eHealth |
| Mohr et al. 2015 (39) | 2015 | International | Journal citation | University | Not stated, but assume researchers in behavioral intervention technologies | Propose adaptations of traditional randomized controlled trial methodology that can support the evaluation of behavioral intervention technologies |
| Mookherji et al. 2015 (24) | 2015 | International | Journal citation | University/ NGO | Decision-makers such as ministries of health, technical agencies, donors, and implementing partners | Results of a survey on monitoring, evaluation, and impact assessment of mHealth projects using a (6-point scale of evaluation rigor) |
| Steventon et al. 2015 (40) | 2015 | International | Journal citation | University | Not stated, but assume comparative effectiveness researchers and policymakers | Methods to test the generalizability of an RCT of digital health intervention effectiveness |
| EU Draft Consard Ltd 2016 (41) | 2016 | Europe | Website/ Report | Consultant | Specifies an initial list of target groups: Citizens, mHealth developers, App aggregators, health professionals, and decision-makers in the healthcare system | To propose a set of common quality criteria and assessment methodologies to help stakeholders assess the validity and reliability of mHealth apps (EU guidelines on assessment of the reliability of mobile health applications - 2nd draft) |
| Gorski 2016 (42) | 2016 | International | Journal citation | University | mhealth project developers | Identification of nine distinct value propositions for mHealth projects Identification of best practices for financial sustainability in mHealth projects |
| McMillan et al. 2016 (43) | 2016 | UK | Journal citation | University | App developers, standards organizations, researchers | Rating tool for health-behavior change apps, based on the 2014 NICE behavior change guidance |
| McNamee et al. 2016 (27) | 2016 | UK | Journal citation | University | Developers of refined economic tools and methods | To stimulate debate so that existing economic techniques may be refined or new methods developed |
| Murray et al. 2016 (44) | 2016 | International | Journal citation | University | Those charged with appraising evidence for using specific digital health interventions within a publicly funded, resource-limited health system | To outline an evaluation strategy in terms of the research questions needed for digital health interventions |
| Rojahn et al. 2016 (34) | 2016 | Europe | Journal citation | Corporate (health care company) | Developers/ manufacturers | Identify public policies concerning remote monitoring in four European countries |
| IRB Advisor 2017 (45) | 2017 | International | Journal citation | Consultant | Not stated, but publication is for health professionals | To raise ethical issues in mHealth |
| Lennon et al. 2017 (33) | 2017 | International | Journal citation | University | Stakeholders in creating the right market and environment | To examine barriers and facilitators to implementation of digital health at scale |
| Maar et al. 2017 (46) | 2017 | International | Journal citation | University | mhealth project developers and managers | a framework for the process evaluations for mHealth interventions in multiple cultural settings |
| Michie et al. 2017 (47) | 2017 | UK | Journal citation | University/ Government agency | eHealth researchers and developers, government decision-makers | Considerations for development of guidelines to create, evaluate and implement effective digital healthcare interventions |
| Philpott et al. 2017 (25) | 2017 | International | Journal citation | University | Not stated, but assume researchers in digital health technologies | Design and validation of response-adaptive randomized (RAR) trial design to testing mHealth apps |
| Drury et al. 2018 (32) | 2018 | Asia | Website/ Report | Consultant | Those who need to brief decision-makers (e.g., senior government officials, health manager, donors) about the issues to be considered when making small or large investments in digital health | A digital health impact framework (DHIF) |
| European Commission (EC) 2018 (48) | 2018 | Europe | Website/ Report | Government agency | Not stated | Presents the main results of a European Commission consultation focussed on barriers and enablers of health data sharing with a wide range of stakeholders. European focussed, but with a majority of German respondents (individuals 52 percent and organizations 17 percent). |
| Hogaboam 2018 (49) | 2018 | International | Thesis | University | Assessors in neurosurgery and orthopedics | Assessment framework for wearable medical devices in neurosurgery |
| Jurkeviciute 2018 (50) | 2018 | International | Thesis | University | eHealth evaluators | Report on the use of standards in eHealth evaluation planning practice |
| Nielsen and Rimpiläinen/ The Digital Health & Care Institute 2018 (51) | 2018 | Ireland, Northern Ireland, and Scotland | Website/ Report | Government agency | For the decision-makers in the mPower project - evaluating mHealth Apps for use | Overview and examination of current international initiatives and practices to develop, assess and evaluate the use of mobile health and wellbeing apps and services |
| Sax et al. 2018 (30) | 2018 | International | Journal citation | University | Not stated | A framework to evaluate mHealth apps to ensure user autonomy is protected; free from influences on economic behavior |
| UK Academy of Medical Sciences 2018 (52) | 2018 | United Kingdom | Website/ Report | Charity | Those who may use or be responsible for developing, evaluating, regulating, or commissioning data-driven technologies in different contexts and settings | A framework of actionable principles to guide their development, evaluation, and use. |
| Wyatt 2018 (26) | 2018 | International | Journal citation | University | mHealth app users, developers, health professionals, and app distributors | Provides checklists and evaluation methods that can be applied to apps and suggestions for how clinical specialty organizations can develop a low-cost curated app repository with explicit risk and quality criteria. |
| Beintner et al. 2019 (53) | 2019 | International | Journal citation | University | Not stated, but assume those developing reporting standards for trials of online interventions | To propose standards for measuring and reporting adherence to online interventions (Standards for reporting adherence) |
| Caulfield et al. 2019 (54) | 2019 | International | Journal citation | University | Researcher/clinicians interested in wearable devices | Evaluation framework for wearable devices for specific applications |
| UK Dept Health & Social Care 2019 (55) | 2019 | United Kingdom | Website | Government agency | Developers, deployers, and users of data-driven technologies | Principles for data-driven technologies (Code of conduct for data-driven health and care technology) |
| HAS 2019 (23) | 2019 | France | Website | HTA agency | Manufacturers or operators of CMDs applying for individual funding by the French health insurance scheme | (Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement) |
| Draft HAS 2019 (56) | 2019 | France | Website | HTA agency | Industrialists, patient associations, national professional colleges, but also developers of IT solutions, researchers, Interdisciplinary Artificial Intelligence Institutes, etc | Consult on complementary analysis grid for the evaluation of AI-based medical devices for health insurance reimbursement |
| Huckvale et al. 2019c (31) | 2019 | International | Journal citation | University | Health care professionals | Provides a contemporary assessment of the privacy practices of popular apps for depression and smoking cessation by critically evaluating privacy policy content and, specifically, comparing disclosures regarding third-party data transmission to actual behavior. |
| UK NICE 2019 (2) | 2019 | United Kingdom | Website/ Standard | HTA agency | Technology developers and evaluators | Standards for the evidence of effectiveness and economic impact relative to the financial risk (Evidence standards framework for digital health technologies) |
| NHS Digital 2019 (57) | 2019 | United Kingdom | Website | HTA agency | Guidance for health app developers, commissioners, and assessors | To make sure that only safe and secure apps and digital tools are published on the NHS Apps Library (Digital assessment questions (DAQ)) |
| Rajan et al. 2019 (58) | 2019 | International | Journal citation | University | Policymakers | Policy implications for facilitating the further deployment of telemedicine in the care of chronically ill patients |
| Draft Australian commission on safety and quality in health care (CSQHC) 2020 (21) | 2020 | Australia | Website/ Draft standard | Government agency | Consumers and carers, clinicians, service providers, developers, and any other interested stakeholders | To improve the quality of digital mental health service provision and to protect service users from harm |
| Dick et al. 2020 (59) | 2020 | International | Journal citation | University | System developers | A qualitative review of system developers’ experiences of evaluating mHealth interventions in the context of a developing country |
| Draft Federal Ministry of Health Germany 2020 (60) | 2020 | Germany | Website/ Draft bill | Government agency | Manufacturers | (Requirements for testing the eligibility for reimbursement of digital health applications) |
| Health Information and Quality Authority (HIQA) Ireland 2020 (61) | 2020 | Ireland | Website/ Report | Government agency | Not stated but assume Government decision-makers | To review national and international evidence and best practice in relation to models for the collection, use, and sharing of personal health information for the development of recommendation for Ireland |
| Draft Aust. Medical Services Advisory Committee MSAC 2020c (62) | 2020 | Australia | Website/ Draft guideline | HTA agency | Applicants and assessment groups requesting public funding through MSAC | Guidelines providing advice on the HTA methods used throughout the MSAC assessment pathway for requests for public funding (Draft Guidelines for Preparing Assessment Reports for the  Medical Services Advisory Committee) |
| Moshi et al. 2020 (63) | 2020 | Australia | Journal citation | University | HTA evaluation framework developers | To propose a module which could be used to facilitate the assessment of mobile medical applications (MMA) for regulatory and reimbursement purposes |

HTA, Health Technology Assessment; NGO, Non-government organization

a Country/region for which the framework is intended

b While this paper does not strictly meet the evaluation framework inclusion criteria, it provides DHT specific content on data privacy relevant to the Safety and Ethical Analysis domains

c Note this is a draft version of the technical guidelines for MSAC applications that includes DHT specific content. There exist two in-force technical guidelines: One for investigative and one for therapeutic technologies that do not include digital specific content

Supplementary Table 5: Digital health technology (DHT) specific content by HTA Core Model(19) domains from frameworks in review

| **Digital health technology (DHT) specific content from frameworks in review**  **Issues of *Topic***  *Issue (Assessment element ID from HTA Core Model or DHT prefix if new)* | | |
| --- | --- | --- |
| **Domain 1: Health problem and current use of technology (CUR)**  ***Topics not in HTA Core Model:*** *None* | | |
| ***Issues of Utilization***  *Is the technology a new, innovative mode of care, an add-on to, or modification of a standard mode of care, or a replacement of a standard mode of care? (F0001)*  Describe inputs (i.e., image, physiological status, symptoms, etc.), algorithms (i.e., equations, analysis engine model logic, algorithm, etc.), and outputs (i.e., inform, treat, diagnose) of the DHT(63) | *How much are the technologies utilized? (A0011) & What kind of variations in use are there across countries/regions/settings? (A0012)*   * Do health workers/patients invest in personal digital technologies (e.g., hardware, operating systems, platforms) required to use the DHT? (32) Are these personal devices costly or difficult to support? (32) * Is the DHT limited in terms of platforms and languages? (32) * Is network connectivity or digital literacy a problem? (32) * Is data on DHT usage collected ongoing to share with decision-makers? (2) | |
| **Domain 2: Health problem and current use of technology (CUR)**  ***Topics not in HTA Core Model:*** *None* | | |
| **Issues of *Features of the technology***  *How well do the technology and its comparators perform in overcoming technical barriers? (DHT01)*   * How well do the technology and its comparators perform in interoperability(20, 21, 23, 32, 41, 48, 49, 51, 55, 57, 63), data quality and technical reliability(21, 48, 51, 55), standardization of access and extraction mechanisms, including the ability to extract raw data(48, 54), data visualization and feedback(54)   **Issues of *Investments and tool required to use the technology***  *What material investments are needed to use the technology? (B0007)*   * Consider devicedimensions, battery life and charging methods, calibration requirements, operational system compatibility, connectivity requirements (e.g., wired, Wi-Fi, Bluetooth), data access and storage, data security, technical and data support(20, 35, 41, 49, 54, 57, 63) | **Issues of *Training and information needed to use the technology***  *What kinds of skills and training characteristics and information are needed for the personnel/caregivers using this technology? (B0013)*   * Is training required/provided for personal data handling and digital skills? (32, 48, 63)   *What kind of training resources and information should be provided to the patient who uses the technology, or for his family? (B0014)*   * Is training required/provided for digital health literacy and digital skills? (32, 48, 63) * Is there provision of technical support? (49) | |
| **Domain 3: Safety (SAF)**  ***Topics not in HTA Core Model:*** *Quality and safeguarding (2, 21, 31, 35, 36, 41, 43, 48, 51, 55-57, 63), Technical safety (technical reliability & stability) (2, 20, 21, 41, 56, 57, 60, 63), Communicating for safety* (21, 36) | | |
| **Issues of *Quality and safeguarding(New)***  *How are data security and privacy managed? (DHT02)*   * Does the DHT comply with data protection legislation/standards and allow users to manage access to their data?(21, 41, 48, 51, 55, 57) * Has the DHT been regularly audited for actual data transmissions to third parties? (31) * Does the DHT employ authentication, encryption, and threat analysis to avoid unauthorized access to personal data?(21, 41, 48, 51, 55, 57) * Is there safeguarding around peer-to-peer and other communications within DHT platforms? (2)   *How well is the interoperability of the technology designed and data quality managed? (DHT03)*   * Does the DHT have processes to support the creation and maintenance of accurate healthcare records that can be integrated with multiple information systems using the relevant patient/ provider identifiers and standard terminologies?(21, 41, 48, 55, 57)   *How transparent are the risks of the technology to the user? (DHT04)*   * Does the DHT provide users with accurate information on how their data is collected, used, protected, and shared?(21, 41, 48, 55) * Is there clear identification of the DHT’s owners, contact information, funding sources, promotion and sponsorship, and any other possible conflicts of interest? (35, 36, 41, 63)   *How well is the technology and comparator(s) designed for usability and accessibility? (DHT05)*   * Is the DHT designed to minimize the barriers associated with hardware, software, data requirements, and platform services, or the language/location, age, culture and ability of users”?(21) * Are services are compatible with commonly used assistive technologies and do they meet relevant web page or web application standards? (21, 36, 57) * Are there processes to collect and act on user feedback? (21)   *Is there adequate information on algorithms employed in the technology to evaluate their risk? (DHT06)*   * Has data quality been validated prior to building and employing algorithms? (23) Are data quality checks built programmatically into artificial intelligence algorithms to avoid harm? (55) | | * Does the developer/manufacturer clearly state the limitations of the data used, algorithms deployed, especially any learning algorithms, and how outcomes are validated to users? (56) For learning algorithms, is there adequate disclosure of the characteristics of the training, test, and validation data, the model, and the algorithms to understand how the algorithm controls the clinical decision-making process? (57)   **Issues of *Technical safety (technical reliability & stability) (New)***  *How technically reliable and stable is the technology and comparator(s)? (DHT07)*   * Is there evidence of accurate and reliable transmission of unbiased data? (2, 20, 63) Does the DHT alert the user when working suboptimally or experiencing interference, e.g., low or no network connectivity? (21, 41) Does it perform well outside the laboratory(41), and is it validated for use on multiple platforms? (41) * Is it resilient to erroneous data inputs, errors of precision, hardware problems, inappropriate use of devices, changes in other applications, and other interruptions? (21, 41, 56, 57, 60, 63)   *How well are continuity and updates of the technology managed? (DHT08)*   * Is there evidence that platform and operating system updates and patches, service continuity, backup, and recovery mechanisms are well managed? (21, 63) Is there effective communication to users about service changes or interruptions? (21, 63)   **Issues of *Communicating for safety (New)***  *Are there processes for the user to communicate critical risk information to the provider? (DHT09)*   * Does the DHT allow the user to communicate to the provider critical information about changes in their condition or information on risks(21) of the DHT? Is there a contact mechanism for technical support with a fixed response time? (36)   *Does the technology have processes for the correct identification of users? (DHT10)*   * Are there processes for correctly identifying users to match them with appropriate care and provide accurate health records, protecting anonymity where necessary? (21)   *Does the technology have processes to communicate changes to or transfer of a patient’s care? (DHT11)*Are there processes for the service provider to communicate when a user’s care emerges or changes, or when all or part of a user’s care is transferred? (21) |
| **Domain 4: Clinical Effectiveness (EFF)**  ***Topics not in HTA Core Model:*** *Demonstrating effectiveness(2, 22, 23, 35, 39, 43, 44, 46, 47, 50, 53), Reliable information content(2, 20, 21, 35, 36, 41, 51, 60, 63), Use of appropriate Behavior change techniques(2, 35, 39, 41, 43, 44, 47, 51), External validity/generalizability(20, 35, 44, 47, 59), Patient satisfaction(20, 41, 46, 49, 51, 54, 57, 59)* | | |
| **Issues of *Demonstrating effectiveness (New)***  *Is the study design appropriate for demonstrating effectiveness for these technologies? (DHT12)*   * Is it clear whether any changes were made to the DHT during the trial (e.g., major bug fixes or changes in the functionality or content)? (35, 39) * Was digital literacy an implicit eligibility criterion? (35) * Have accepted methods been used to overcome common methodological problems for DHT in performing RCTs, e.g., achieving blinding, biases from informed consent procedures? (22, 23, 35)   *Is the choice of comparator appropriate for these technologies? (DHT13)*   * Was the comparator group restricted in the DHT to which they had access? (44, 47)   *Do the outcome measures capture the unique benefits of the technology and are the methods for their collection robust? (DHT14)*   * Have DHT specific outcome measures been collected, i.e., metrics of use, the intensity of use (dose, exposure), adherence, attrition(35, 53), user satisfaction, and engagement? (2) * Are these metrics and their methods of collection described in adequate detail? (35, 53) * If surveys of health outcomes are completed online, are they validated for online use? (35, 50) * If data collection is embedded within the DHT, may it have created systematic bias or confounding? (44, 47)   *Is the reporting of effectiveness studies transparent and tailored for the technology? (*DHT15)  Is the reporting of the RCT in accordance with CONSORT E-HEALTH or a similar effectiveness reporting standard designed for DHT interventions? (46, 50) | | **Issues of *Reliable information content (New)***  *Is the health information provided by the technology accurate, valid, up to date, and sufficiently comprehensive?(DHT16)*  Is there evidence that the health information provided by the DHT is accurate, valid, up to date, sufficiently comprehensive, clear, tailored to the users' diversity, and that there are quality assurance processes in place?(2, 20, 21, 35, 36, 41, 51, 60, 63)  **Issues of *Use of appropriate Behavior change (New)***  *(If applicable) Does the technology use appropriate and best practice behavior change techniques? (DHT17)*   * Are appropriate and best practice behavior change techniques used in the technology? (2, 35, 39, 41, 43, 44, 47, 51) Is the targeted behavior change apparent to the user, is the mechanism is credible, are the appropriate supports in place, and it is relevant for the target population? (2, 35, 39, 41, 43, 44, 47, 51)   **Issues of *External validity/generalizability (New)***  *Are the conditions during the trial realistic in practice? (DHT18)*   * Have the actions taken to enhance the trial's internal validity, such as participant identity validation and obtaining off-line contact details to promote good follow-up rates, skewed participant populations, and jeopardized external validity? (44, 47)   *Can the results be transferred to other patient groups/settings/regions? (DHT19)*   * Are the results generalizable to the general internet population, to the general patient population, or other organizations? (35) Will it work in regions where telecommunication infrastructure is poor, or there is low network connectivity? (20, 59)   **Issues of *Patient satisfaction***  *Were patients satisfied with the technology? (D0017)*   * Is it usable and accessible for a diverse range of users, including those with disabilities or limited technical ability? (20, 41, 46, 49, 51, 57, 59). Are there obvious design issues hindering usability, e.g., washable, durable, causes skin allergies? (54) |
| **Domain 5: Costs and economic evaluation (ECO)**  ***Topics not in HTA Core Model:*** *None* | | |
| **Issues of *Resource utilization***  *What types and amounts of resources are used when delivering the assessed technology and its comparators (resource-use identification)? (E0001& E0002)*  *What were the measured and/or estimated costs of the assessed technology and its comparator(s) (resource-use valuation)? (E0009)*   * Have the costs of supporting health care providers in using the DHT, such as costs of training, help desks, and change management, been included? (20, 29) * Have costs of the system, platform, licensing, attachable hardware, and versions of DHT that would be used in the health system been included? (63) * Have the costs of the DHT, including the need for additional or recurrent purchases, shipping fees, or technical support subscription charges, as well as relevant supply information, such as availability in the target country and minimum order requirements, been considered? (54) | | **Issues of *Validity of the model(s)***  *Are within-trial collected costs and outcomes externally valid? (DHT20)*   * Are changes in fixed costs for scaling up the DHT known? Is the cost function per patient smooth or stepped? (20)   **Issues of *Measurement and estimation of outcomes***  *What is (are) the measured and/or estimated health-related outcome(s) of the assessed technology and its comparator(s) (outcome identification, measurement and valuation)? (E0005)*   * Have DHT specific outcomes been considered and measured where possible, e.g., improved access to health information and services (20), reduced waiting time, less burdensome travels, a feeling of security, transfer of skills (29), better-managed care through self-management and digitally connected healthcare professionals? (48) * Given all the functionalities of DHTs may not be used, and many people may not use the DHT from the outset, are the estimated benefits of the DHT realistic? (32) |
| **Domain 6: Ethical analysis (ETH)**  ***Topics not in HTA Core Model:*** *None* | | |
| ***Issues of Benefit-harm balance***  *What are the benefits and harms of the technology for relatives, other patients, organizations, commercial entities, society, etc.? (F0011)*   * Is the DHT designed and used for clearly defined purposes that uphold the health system's social values or society’s values? Does it enable fair access to its benefits by all social groups, realize the value of patient data created by the DHT (not to be used for commercial activities), and depending on its purpose, preserve and enhance direct contact between healthcare professionals and patients, enable safe and effective health care, support people to manage their own health, and enable research and innovation? (52)   *Are there any other hidden or unintended consequences of the technology and its applications for patients/users, relatives, other patients, organizations, commercial entities, society, etc.? (F0003)*   * Where are alerts about a patient’s health reported? Is real-time data securely transmitted? How does the DHT affect the participant’s safety and welfare? Could patients have a false sense of security if their DHT is collecting real-time data and not being contacted by physicians? Are there harms from the patient having access to the data without someone's assistance to help them interpret what it means? (45) | | * Have there been any perceived or real privacy breaches, technical problems, unexpected/unintended incidents created by the DHT? (35)   **Issues of *Autonomy***  *Is the technology used for individuals that are especially vulnerable? (F0005)*   * Does the DHT use understandable and straightforward language, with clear and short messages, adapted to the target user profile for style and comprehension level? (41)   *Does the implementation or use of the technology affect the patient´s capability and possibility to exercise autonomy? (F0004)*   * Is there potential for the DHT to influence a person’s behavior for commercial purposes when they are most susceptible? E.g., The DHT has access to a large amount of personal data, behavioral-economic insights, algorithmic predictive analyses, and can communicate with the patient continuously? (30) What controls are in place to limit this risk? * Does the DHT enable the user to make independent and authentic decisions and give an adequate range of options for that decision making? (30) |
| *Is there a need for any specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used? (F0006)*   * Does the DHT clearly identify all collaborators in the development of the DHT? Is there sufficient information on funding sources, promotion and sponsorship of the DHT?(41, 63) * Is there concise information on the procedures used to select the DHT’s contents, and does it clearly identify who is responsible for the content? (41) * Is informed consent language is clear about what type of data is collected by the DHT, how the data is used, and which data is available to subjects? (45)   **Issues of *Respect for persons***  *Does the technology invade the sphere of privacy of the patient/user? (F0101)*   * Does the DHT clearly identify who holds any personal data? Is the supplier’s cookie policy stated and clear? (41) * Only data necessary for a particular treatment is shared with the doctor and only after explicit consent, which the patient can revoke. Can patients opt-out if they are not able or unwilling to manage their data? (48) | | * Data sharing with third parties that includes linkable identifiers is prevalent and difficult to detect in DHTs.(31). Are users informed of this risk by the DHT? * Does the DHT provider have privacy policies that are easy to understand, uphold users’ rights and choices, and are readily available to users before and while using the DHT, compliant with privacy laws, privacy principles, and best practices? Are changes to privacy policies communicated to users in a timely way? (21)   ***Issues of Justice and Equity***  *Are there factors that could prevent a group or person from gaining access to the technology? (H0012)*   * Patients with a lack of economic resources to have a proper infrastructure to access DHTs, or patients and practitioners with low IT skills or digital health literacy can be prevented from using DHTs? How does the DHT overcome these barriers? (48, 63) * Is the DHT compatible with common assistive technologies and available in a wide number of languages and platforms? (21, 63) |
| **Domain 7: Organisational aspects (ORG)**  ***Topics not in HTA Core Model:*** *Contextual issues for barriers and enablers to implementation(32-34)* | | |
| ***Issues in Health delivery process***  *How does the technology affect the current work processes? (G0100)*   * What are the impacts on work methods and interactions between medical staff, patients, and their carers from removing distance constraints and offering shared access to the patient’s data to medical staff? (23)   *What kind of involvement has to be mobilized for patients/participants and important others and/or caregivers? (G0002)*   * Consider digital health literacy training and educating patients and caregivers in using the DHT(63)   *What kind of process ensures proper education and training of staff? (G0003)*   * Digital health literacy training and continual professional development (CPD) courses for using and recommending the DHT in clinical practice(48, 63)   *What kinds of co-operation and communication of activities have to be mobilized? (G0004)*   * Consider changes to the amount of electronic communication, information and reporting systems, the number of face-to-face patient consultations, the way medical staff communicate and work together(20) | | ***Issues in Structure of the health system***  *What are the processes ensuring access to the new technology for patients/participants? (G0101)*   * Refer to *How well is the technology and comparator(s) designed for usability and accessibility? (\*)* under ***Quality and safeguarding*** in SAF   ***Issues in Contextual issues for barriers and enablers to implementation***  *What are the contextual issues that are barriers and enablers to implementation? (DHT21)*   * Consider barriers: Lack of information technology infrastructure, uncertainty around information governance, lack of incentives to prioritize interoperability, lack of accountability within the commercial sector, and a market perceived as challenging to navigate, a lack of capital for start-up costs, a lack of experience and knowledge in operational details, a lack of high-quality training, need for better algorithms to identify patients with the greatest need for reducing expenditures (32-34) * Consider enablers: clinical endorsement, champions who promote digital health, and public and professional willingness, supplemental payments to help with start-up costs, close collaboration between all providers caring for patients (32-34) |
| **Domain 8: Patient and social aspects (SOC)**  ***Topics not in HTA Core Model:*** *None* | | |
| ***Issues of social group aspects***  *Are there groups of patients who currently don’t have good access to available therapies? (H0201)*   * Consider the ability of the wearable solution to improve interpersonal connectivity (among healthcare team members and the patient) and access to patients as part of the remote health care model (49) | | ***Issues of Communication aspects***  *What specific issues may need to be communicated to patients to improve adherence? (H0203)*   * The DHT provider provides service users with clear and transparent information on the: a. Direct costs to access the service, b. Estimated data usage requirements for using the service (21, 32-34) |
| **Domain 9: Legal aspects (LEG)**  ***Topics not in HTA Core Model:*** *None* | | |
| **Issues of *Privacy of the patient***  *Is there a possibility that the use of the technology produces additional information that is not directly related to the current care of the patient and may violate their right to respect for privacy? (I0007) What do laws/binding rules require with regard to appropriate measures for securing patient data and how should this be addressed when implementing the technology? (I0009)*   * Does the DHT comply with the GDPR principles of data minimization, data protection by default, and data protection by design? Does the service provider need a data protection officer?(41, 51) * Other aspects to consider are data accountability, governance, transparency, and consent requirements(41) * Also, refer to  *How are data security and privacy managed? (\*)* under ***Quality and safeguarding*** in SAF | | **Issues of *Ownership and liability***  *Professional liability (DHT22)*   * Clarifying the party(s): Responsible for medical advice; responsible for monitoring and reviewing patient data; and that own the data related to the DHT(63) * Clarify litigation risks to the healthcare practitioners using or recommending the DHT, how insurance(s) (i.e., professional indemnity, life, health, income) and professional registrations could be affected through use or recommendation of the DHT(63) |

| **Existing health technology assessment (HTA) content common to DHT and non DHTs from frameworks in review**  **Issues of *Topic***  *Issue (Assessment element ID from HTA Core Model)* |
| --- |
| **Domain 1: Health problem and current use of technology (CUR)**  ***Issues of******Current management of the condition***  *What are the other typical or common alternatives to the current technology? (A0018)*   * What DHT do those with the condition already have available them? (55) |
| **Domain 2: Health problem and current use of technology (CUR)**  **Issues of *Features of the technology***  *What is the phase of development and implementation of the technology and the comparator(s)? (B0003)*   * Is there evidence that the DHT is relevant to the health care system and can perform successfully to the expected number of users (e.g., server size adequate)? (2) * As DHT often develop rapidly, is the DHT is in a steady-state to enable a robust economic analysis to be performed? (20) |
| **Domain 3: Safety (SAF)**  **Issues of *Safety risk management***  *Are there processes for recognizing and responding to the patient’s acute deterioration? (C0062)*  Does the DHT have defined parameters to identify a patient’s acute deterioration that requires care to be escalated(21), criteria for calling for emergency assistance(21), and systems to respond to users showing signs of acute deterioration? (21) |
| **Domain 4: Clinical Effectiveness (EFF)**  **Issues of *Patient satisfaction***  *Were patients satisfied with the technology? (D0017)*   * Is there evidence to show relevant stakeholders were involved in the design and satisfied with the DHT? (2, 21, 35, 36, 43, 59, 62) * Is there ongoing data collected on user satisfaction that will be acted upon and available to decision-makers? (2,21) * Has qualitative data been collected and analyzed to evaluate the mode of action, differences between recipients and sites (44,59), and identify barriers to uptake or implementation? (20, 21, 41, 44, 48, 51, 57) * Does the DHT create additional burdens on the patient or caregiver, which may affect uptake or adherence? (44, 59) |
| **Domain 5: Costs and economic evaluation (ECO)** None noted |
| **Domain 6: Ethical analysis (ETH)**  ***Issues of Benefit-harm balance***  *Are there any other hidden or unintended consequences of the technology and its applications for patients/users, relatives, other patients, organizations, commercial entities, society, etc.? (F0003)*   * What will be done with any incidental findings? (45)   **Issues of *Autonomy***  *Is the technology used for individuals that are especially vulnerable? (F0005)*   * Does the DHT provider identify the diversity of service users and groups of users at higher risk of harm and incorporate this information into the planning and delivery of the service? Does the DHT provider have systems to minimize the risk for children and young people to be harmed? (21)   ***Issues of Justice and Equity***  *Are there factors that could prevent a group or person from gaining access to the technology? (H0012)*   * Show evidence of the DHT being used in hard-to-reach populations (2) |
| **Domain 7: Organisational aspects (ORG)**  ***Issues in Health delivery process***  *How does the technology affect the current work processes? (G0100)*   * Describe the steps in the proposed new care pathway or pathways incorporating the DHT intervention for the relevant population and setting. Detail any infrastructure and service-level changes needed to existing pathways and associated systems to implement, operate and maintain the new pathway (2, 62)   ***Issues in Culture***  *How is the technology accepted? (G0010)*   * Does the DHT have credibility with health care professionals? Is there published or publicly available evidence documenting the relevant health care experts' role in the design, development, testing, or sign-off of the DHT? (2, 21, 60) |
| **Domain 8: Patient and social aspects (SOC)** None noted |
| **Domain 9: Legal aspects (LEG)** None noted |

Supplementary Figure 1 Preferred reporting items for systematic reviews and meta-analysis (PRISMA) flow diagram for framework study selection

**Additional records identified through grey literature**

*(grey literature n=68)*

*(Search of articles in reference lists n=12)*

**Frameworks included in systemic review**

*(n=44)*

**Records after duplicates removed**

*(n=9,238)*

**Studies included in systemic review**

*(n=44 frameworks; 45 papers)*

*=9,238)*

**Records excluded**

*(n=9,123)*

**Full text articles excluded, with reasons**

*(Excluded n=79)*

Abstract only 10

For clinical trial 2

Lifestyle & wellbeing focus 6

Not specific to digital 5

No HTA evaluation framework 23

Regulatory purpose 22

For system implementation 11

**Full text articles assessed for eligibility**

*(n=115)*

**Records screened**

*(n=9,238)*

**Additional frameworks from pearling**

*(n=8)*

Identifictaion

Screening

Eligibility

Included

**Records identified through database searching**

**(MEDLINE, Embase, Econlit,**

**CINAHL, Cochrane)**

*(n=11,824)*

1. Searches modified for Embase, Econolit, CINAHL, Cochrane [↑](#footnote-ref-1)
2. (1) Search terms used to identify e-Health, m-Health and digital health modes of health delivery (2) Terms used to identify decision making, funding and health evaluation studies (3) Terms to identify economic evaluation studies (4) Terms used to identify Randomised Controlled Trials (5) Terms used to identify observational studies (6) Terms used to identify Health Technology Assessments (7) Terms used to search for animal not human studies [↑](#footnote-ref-2)
3. All terms were searched using multipurpose (.mp) [↑](#footnote-ref-3)
4. All terms were searched using text words (.tw)

   Search string: Limit yr="2015 - Current" ( (1) AND ((2) OR (3)) AND ((4) OR ((5) NOT (4)) OR (6) NOT ((4) OR ((5) NOT (4))))NOT (7)); Medline/Embase search conducted on 20 March 2020; CINAHL/Econolit search conducted on 22 March 2020. [↑](#footnote-ref-4)