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Technology assessment framework for precision health applications

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Abstract

Objective. Established and emerging technologies—such as wearable sensors, smartphones, mobile apps, and artificial intelligence—are shaping positive healthcare models and patient outcomes. These technologies have the potential to become precision health (PH) innovations. However, not all innovations meet regulatory standards or have the required scientific evidence to be used for health applications. In response, an assessment framework was developed to facilitate and standardize the assessment of innovations deemed suitable for PH.

Methods. A scoping literature review undertaken through PubMed and Google Scholar identified approximately 100 relevant articles. These were then shortlisted ($n = 12$) to those that included specific metrics, criteria, or frameworks for assessing technologies that could be applied to the PH context.

Results. The proposed framework identified nine core criteria with subcriteria and grouped them into four categories for assessment: technical, clinical, human factors, and implementation. Guiding statements with response options and recommendations were used as metrics against each criterion.

Conclusion. The proposed framework supports health services, health technology innovators, and researchers in leveraging current and emerging technologies for PH innovations. It covers a comprehensive set of criteria as part of the assessment process of these technologies.

Assessment

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Introduction

The world has a rapidly ageing population. Associated with an ageing population is an increased prevalence of injuries, health conditions, and diseases. Furthermore, across the age spectrum, an estimated 20 percent of the world's population experiences difficulties with physical, cognitive, or sensory functioning, mental health, or behavioral health (1;2). These experiences may be temporary or permanent, acute or chronic, and may change throughout one's life span. If left unchecked, trends in chronic disease risk factors—combined with an ageing population—suggest that the delivery of affordable, timely, and quality care may become unsustainable. Preventative care models show potential as an alternative and proactive approach that aims to maintain the health of individuals by providing timely intervention prior to the onset of evident signs of ailment. Precision health (PH) is such a preventative health strategy that aims to support and maintain the health and well-being of individuals through the provision of predictive and personalized care (3;4). PH requires a holistic understanding of an individual's health beyond their clinical physiological status including genome, lifestyle, and mental health factors. PH-based models of care have the potential to be more efficient and cost-effective to the healthcare system, because the nature of care provision is preventative, rather than reactive once an individual has already experienced an ailment (5;6).

A range of health technologies exist that aim to assess, prevent, treat, and manage health conditions to promote better health and well-being (7). Through leveraging existing and emerging technologies—such as wearable sensors, smartphones, mobile applications (apps), internet-of-things (IoT), and artificial intelligence (AI)—new opportunities are positively shaping healthcare models and patient outcomes (8). To this end, there is a growing number of emerging technologies with a diverse range of functionalities and forms that have the potential to become PH innovations, including hardware (e.g., sensors), software (e.g., mobile and web platforms with data integration), and data analytics techniques (e.g., predictive models) to assess, diagnose, and manage health and well-being.

One of the main challenges of integrating emerging technologies into a PH solution is that most technologies do not have the required scientific evidence to support their claims and do not meet regulatory standards to be PH solutions—regardless of whether they were intended for health or designed for a PH context. With these factors in mind, a framework that supports a standardized approach for identifying and implementing PH products is essential. In response, we propose a framework in the form of health technology assessment (HTA), which can be used to accommodate a large range of products, technologies, and innovations for PH applications.

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HTA and Opportunities for PH

HTA is the systematic evaluation of technology properties and their associated impact on health care (7). It encompasses a multidisciplinary decision-making process to determine the value of technology at different points across its lifecycle (9). Global (e.g., World Health Organization) and national (e.g., FDA, Australian TGA, and Department of Health) health agencies engage in HTA and provide guidelines for the assessment of technologies in health care (7;10). These guidelines may cover criteria to assess the justification and rationale (e.g., clinical evidence, impact on efficiency and effectiveness), service provision (e.g., patient pathway and care model, safety requirements, and conflict of interests), and monitoring and evaluation of new technologies (10). Examples of assessment outcomes may include: out of scope, still in research, seek further advice, not recommended or recommended.

Although available frameworks provide an effective tool to assess a wide range of technologies in health care, the rapid emergence and quickly evolving nature of digital health technologies has attracted academic research and international agencies to develop new assessment guidelines and frameworks specific to digital health (11;12). The basis of these frameworks consists of indicators that guide the assessment of digital health technologies to reach a recommendation of suitability for their use in health care. HTA frameworks in digital health generally include assessments related to technical requirements and functionalities; clinical, economic, organizational, ethical, and legal factors; and healthcare system characteristics and stakeholder determinants (13).

Digital health frameworks can be classified into (i) staged, which apply a sequential approach for assessing measures relevant to the development phase of a technology service; (ii) dimensional, which contain a set of assessment measures grouped according to the expected impact of technology services, irrespective of the development phase; (iii) hybrid, which combine a sequential phased development approach and the impact of a technology service, and apply a varying set of criteria in a particular order for the assessment; and (iv) business modeling, which include an assessment of technology services in the context of economic viability and business models (13).

Despite the availability of assessment frameworks for digital health, there is a growing demand for more specific guidelines and metrics to identify and assess current and emerging digital technologies. Of particular interest are sensing devices and related technologies that have potential in PH applications (4), even if their original purpose was not related to PH. Most work in this area has been in the form of siloed approaches largely focused on specific attributes (e.g., compliance to patient safety) grounded by technical, physical, and operational factors (14–25). The literature in terms of assessment measures to PH innovations is sparse. Existing assessment frameworks can provide guidelines on health-related technologies in their complete form (e.g., Ref. 7), but they are not necessarily effective when assessing technologies that were not originally intended for health care.

A lack of agreed measures poses challenges in ensuring whether a specific innovation aimed for PH is appropriate. Assessment models, such as the GRASP framework (26), were developed to cover tools that recommend actions and decisions of specific clinical implementations, but they do not cover their potential as digital health technologies or innovations for PH. The proposed framework goes beyond the assessment of a technology for implementation. It provides advice to guide a decision maker toward including a piece of technology within a product and the impacts this may have. It can be used by a variety of stakeholders (e.g., innovators, software developers, clinicians, and researchers) working on PH solutions that require emerging technologies in the form of hardware, software, or data analytics techniques.

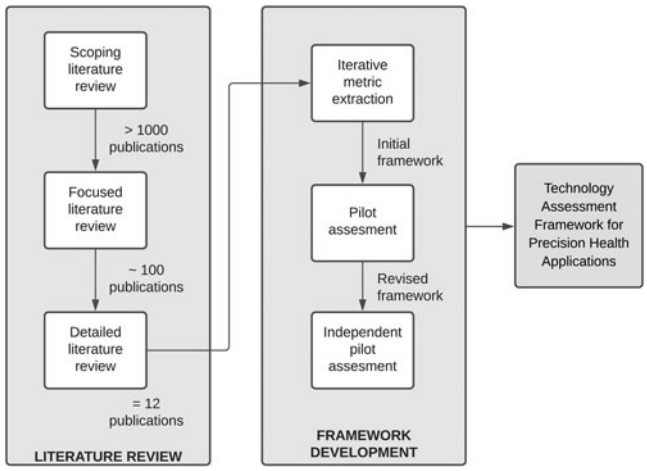


Figure 1. Framework development flowchart.

The fundamental novelty of this framework lies with its intend of use for PH applications, including preventative care models that go beyond traditional clinical care settings (e.g., home care monitoring and personalized/adaptive intervention). If such applications become part of an individual's care, there are technical aspects—such as accuracy of measures, safety, privacy, regulatory compliance—that need special consideration and are not captured comprehensively in the scope of existing health assessment frameworks, which impacts their utility for such purposes. As a wave of digital technologies enter the health domain, with specific potential for PH, this framework aims to empower an array of stakeholders with the ability to assess, evaluate, and implement digital innovations (including technologies repurposed to be used in PH applications) based on the suitability and impact they may have on the target application.

In line with previous work, the proposed framework aims to provide guidance on a standardized approach to support an improved implementation process of PH innovations, ensuring their suitability, compatibility, performance, reliability, interoperability, quality, and safety among a range of key considerations.

Methodology

A scoping review was undertaken of available academic literature (between the years 2005 and 2018) through PubMed and Google Scholar to identify articles that included general health informatics terms (i.e., telemedicine, medical innovations, eHealth, mHealth, and medicine) and keywords related to technology assessment or evaluation (i.e., technology, assessment, evaluation, criteria, decision, and framework) within paper titles. The search returned numerous articles across these databases (>1,000 in total). Duplicates of the retrieved studies, from both databases, were removed first. Then, studies were screened for relevance by one researcher, based on their titles and abstracts. Approximately 100 articles relevant to this work were shortlisted. A closer examination throughout the full text of the shortlisted articles identified those ($n = 10$) that included specific metrics, criteria, or frameworks for assessing or evaluating products, technologies, and health innovations applicable

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Table 1. Technical assessment metrics and guidelines for PH innovations

	Subcriteria	Metrics	Recommendation
Novelty	Uniqueness (e.g., is it one of its kind?)	Unique over similar innovations	Optional
	Value addition (e.g., value creation for targeted stakeholders)	Aims to improve on existing innovations Informs on other potential further improvements	Optional Optional
	Cost and effort implications	Informs on costs and effort needed (e.g., purchase and license) for its basic setup and functionality Informs on cost and effort needed (e.g., API and server setup) to set up and integrate with other products or technologies needed for the target use case	Encouraged Encouraged
	Technology readiness (e.g., prototype, established, commercially valuable)	Readily available and ATUC Fits the description provided Informs on its accessibility	Mandatory Mandatory Mandatory
Adaptability	Interoperability and interchangeability (adaptable to new information, tools, frameworks, platforms, *etc.*)	Usable with other products or technologies Usable for the target use case Information is available on alternative products or technologies	Encouraged Mandatory Optional
	Scalability (e.g., agility in adapting to innovation needs, such as expanding its use from one to multiple hospitals)	Capacity to function under an increased workload as a result of changes in size or volume	Encouraged
	Integrability (e.g., ability to incorporate and be incorporated into other innovations)	Integrates with other products or technologies	Encouraged
	Compatibility (e.g., with legacy systems)	Compatible with other products or technologies	Encouraged
	Augmentability (e.g., expanding the characteristics and utility of an innovation beyond its original purpose)	Capacity to expand beyond its current features or capabilities to support the target use case	Optional
Information management	Data collection (sensors, wearables, self-reporting, *etc.*)	Informs on data collection methods Data collection methods are ATUC	Mandatory Mandatory
	Data transaction, storage, and handling (e.g., between app, server/cloud and/or sensors)	Data transaction methods are ATUC Data access methods are ATUC Data storage is ATUC Use of proprietary data within the innovation is ATUC Use of external data (e.g., third-party services) is ATUC	Mandatory Mandatory Mandatory Mandatory Mandatory
	Privacy measures (e.g., how patient data are managed and stored and who has access)	Strategies to protect data privacy are ATUC	Mandatory
	Security measures (e.g., cybersecurity implications)	Data security measures are ATUC Strategies to handle cyber security risks and breaches are ATUC Strategies for long-term maintenance of data security are ATUC	Mandatory Mandatory Mandatory
Performance	Precision and specificity, accuracy, and sensitivity of measurements	Outcome measures captured are ATUC Precision of measurements is ATUC Specificity of measurements is ATUC Accuracy of measurements is ATUC Sensitivity of measurements is ATUC	Mandatory Mandatory Mandatory Mandatory Mandatory
	Implementation of codes of practice (e.g., ISO Standards)	Has been certified to comply with codes of practice during design and development Codes of practice implemented are ATUC	Encouraged Mandatory

to the PH context. During this process, two additional articles (dated 1986 and 1995) were identified from references of the short-listed articles and were included due to their suitability for the scope of this work. The final set of articles ($n = 12$, Supplementary Appendix 1) were then used to inform the development of the proposed framework.

In consolidating available frameworks for technology assessments and evaluations in health care, key metrics were extracted by one of the authors to develop a comprehensive process for assessing potential products, technologies, and innovations for PH. This was then revised and confirmed by the two other authors in an iterative process. Using the revised information, we designed an initial version of the framework and applied it to assess three different PH innovations: a wearable device, a mobile app, and a predictive algorithm. A revised version of the framework was then used by two independent researchers (with expertise in the development and implementation of digital health solutions) to assess emerging technologies with potential for PH (e.g., a novel sensor to monitor sleep patterns). Their feedback and recommendations were incorporated into the final framework. Figure 1 shows the flowchart of the technology assessment framework for PH applications.

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Table 2. Clinical assessment metrics and guidelines for PH innovations

	Subcriteria	Metrics	Recommendation
End-to-end intervention	Health information and assessment (e.g., information relating to the condition, illness, disease, as well as how it is diagnosed)	Informs on the health conditions targeted by the innovation	Optional
		Informs on how target health conditions or diseases are assessed by the innovation	Optional
	Patient outcome measures (e.g., objective and subjective measures related to conditions)	The outcome measures provided by the innovation are ATUC	Mandatory
	Lifestyle assessment (e.g., information on lifestyle and habits such as diet, exercise, smoking, and drinking)	Supports data collection or assessment of environmental and lifestyle factors	Encouraged
		Collection or assessment of environmental or lifestyle data is ATUC	Mandatory
	Clinical intervention (e.g., treatment and recommendation)	Clinical intervention provided by the innovation is ATUC	Mandatory
	Intended use in practice (e.g., how, when the innovation should be used, and for what)	Use cases in a clinical setting are ATUC	Mandatory
	Multi-stakeholder involvement (patient-clinician platforms, clinical care team platforms, *etc.*)	Engages multiple end users	Optional
		Informs on the user type (e.g., patient and clinicians) and the expectations of their involvement	Optional
Quality assurance	Precision and specificity, accuracy, and sensitivity of interventions/assessments	Intervention/assessment delivered is ATUC	Mandatory
		Precision of the intervention/assessment delivered is clinically ATUC	Mandatory
		Specificity of the intervention/assessment delivered is clinically ATUC	Mandatory
		Accuracy of the intervention/assessment delivered is clinically ATUC	Mandatory
		Sensitivity of the intervention/assessment delivered is clinically ATUC	Mandatory
	Safety	Safety standards are ATUC	Mandatory

Results

This section presents our health technology assessment framework for PH applications. The framework follows a *hybrid framework* approach that encompasses both: (i) a single piece of digital technology (e.g., a predictive algorithm, a biosensor, or a wearable sensor) and (ii) several integrated digital technologies. The framework identifies nine core criteria with subcriteria and groups them into four categories based on whether the criteria are related to *technical*, *clinical*, *human* (i.e., interaction), and *implementation* aspects. For each of the four groups, the framework provides a comprehensive list of metrics with suggested recommendations (Optional, Encouraged, Mandatory) to be considered when assessing PH innovations—referred to as the "technology or product."

Not all aspects of the framework need to be considered when evaluating a product or technology; thus, the suitability of the core criteria, sub-criteria, and metrics will depend on the application and use case intended by the assessor. This will be referred to as *appropriate for the target use case* (ATUC).

Technical Assessment

Technical assessments cover *Novelty*, *Adaptability*, *Information Management*, and *Performance* aspects of the innovation (Table 1). *Novelty* refers to the value proposition, uniqueness, status, and readiness of the innovation. *Adaptability* considers criteria relating to the innovation's ability to be used with other innovations and/or expanded beyond its original purpose. Data collection and its handling by technical components fall under *Information Management,* whereas the standard of quality of the innovation is covered by *Performance*. These measures can be used to assess innovations that may or may not be complete PH solutions.

Clinical Assessment

Several factors can influence the appropriateness of an innovation when operated within clinical settings and environments or with existing clinical innovations. The clinical assessment of the framework (Table 2) covers *End-to-end Intervention* (aspects of intervention delivered by the innovation, including health assessment tools) and *Quality Assurance* (quality measures of clinical interventions, including health assessment tools). These measures can be used to assess the appropriateness and impact of an innovation when incorporated into clinical settings.

Human Factors' Assessment

This section covers all aspects of user experience, including usability, interactivity, and engagement with the innovation (Table 3). These measures can be used to assess products and technologies that are directly used by people. These innovations may or may not be a final PH solution.

Implementation

Implementation of innovations in health requires careful considerations of their efficacy, effectiveness, and implications on healthcare practice. *Evidence-based*, and *Registration and Compliance,* cover aspects regarding an innovation's assertion of

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Table 3. Human factors and implementation assessment metrics and guidelines for PH innovations

	Subcriteria	Metrics	Recommendation
Human factors			
User experience	Usability	Acceptable and ATUC and population. Informs on essential features, their purpose, and the expected use cases. Uses methods to encourage user interactivity and engagement (reminders, notifications, *etc.*)	Mandatory Encouraged Optional
	Accessibility	Designed and developed with passive and active accessibility measures (to ensure equality to all users) Supports accessibility to a wide audience	Encouraged Encouraged
	Ease of use, training, and support	Provides training or informs on how to use Provides technical support Supports end users' feedback collection (e.g., user experience)	Optional Optional Optional
	Personalization	Supports customization and personalization to end users Provides customization and personalization instructions to suit end-user needs	Encouraged Encouraged
	User testing	Undergone user testing during its design and development Informs on the outcomes and extent of user testing Outcomes of user testing are ATUC and population	Encouraged Encouraged Mandatory
Implementation			
Evidence-based	Efficacy and effectiveness (experimental studies, clinical trials, *etc.*)	Undergone evaluation studies and informs on efficacy and effectiveness outcomes Evaluation outcomes are ATUC	Mandatory Mandatory
	Implications for use outside of intended purpose (e.g., if innovation has been adapted or augmented beyond its original purpose)	Informs on alternative uses outside of its intended purpose Informs on implications of use outside of its intended purpose	Optional Encouraged
	Implications and impact on health services and users (political, social, and organizational effects, access to care, *etc.*)	Implications on the impact and influences to health services and other health-related entities are appropriate Implications on the impact and influences to end users are appropriate	Mandatory Mandatory
Registration and compliance	Regulatory compliance (e.g., certification provided by a regulator, such as TGA and FDA)	Has regulatory certifications Regulatory certification is ATUC	Mandatory Mandatory
	Discoverability (e.g., information can be found about the innovation and compliance)	Can be found in registries or public repositories Discoverable information is up to date	Optional Optional

its intended purpose and its availability and discoverability in the public domain (Table 3). This should be used to assess innovations that are close to a final PH solution.

Framework Implementation and Use Cases

This PH Innovation Assessment Framework is intended to be used by innovators and researchers developing or implementing PH solutions when leveraging current and emerging technologies in the form of hardware, software, or data analytics techniques. The framework aims to cover a comprehensive set of criteria as part of the assessment process of these technologies. For each of the criterion in the framework, guiding statements (or metrics in Tables 1–3) are used to complete the assessment using the following responses:

- True: The information is available, and the assessment is valid.
- False: The information is available, but the assessment is not valid.
- Unavailable: The information is not available.
- Partial: The information is incomplete or partially available.
- Not Applicable. The criterion is not applicable for the target use case

Only a subset of the criteria in Tables 1–3 may be appropriate based on an innovation's scope, intended use, development phase or maturity of the technology, and the health system requirements as part of the implementation (13). From the overarching categories perspective, *technical* and *clinical* factors are essential. In most cases, the *technical* and *clinical* criteria should be assessed before an innovation is considered suitable for PH. Then, criteria related to *human factors* should be assessed for innovations that involve human

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interaction. Finally, *implementation* criteria should guide decisions when an innovation is to be incorporated into real-world settings.

Not every innovation put through the framework will successfully adhere to the full set of suggested criteria. This does not necessarily mean that an innovation should be excluded from its intended use, but may require careful consideration before implementation in practice. Thus, in this framework, recommendations are organized using three levels:

- Mandatory: Required to respond "True" pertaining to the guided statement; responding "False," "Unavailable," or "Partial" may indicate that an innovation is inappropriate for an intended use case.
- Encouraged: "True" response is recommended pertaining to the guided statements. Alternatively, proceed cautiously or conduct in-house evaluations for "False," "Partial," or "Unavailable" responses.
- Optional: The response should not inhibit the adoption of an innovation.

If an innovation is deemed unfit for use, contacting the developer or sponsor of the innovation may help validate the suggested recommendations against the core criteria and subcriteria in the assessment framework. Where possible, based on the use case and complexity of the innovation, additional development and/or evaluation might be considered as an alternative (22).

Conclusion

Technologies and innovations targeting PH solutions will play a fundamental role in shaping future healthcare models and supporting personal health, well-being, and patient outcomes. With the wave of established and emerging technologies showing the potential to support healthcare delivery through PH solutions, researchers and innovators need to consider safety regulatory standards and evidence-based implications, among many factors, associated with their innovation. Thus, a technology assessment framework for PH applications is essential to support the appropriate implementation of these innovations.

In this paper, we collated the components required during the assessment of PH innovations. We believe that the grounding of the assessment framework, formed from previous works, will be flexible and adaptable to a variety of PH applications, which will play a foundational role in supporting the growth of innovations in PH. Although the focus of this framework is on PH, the framework could be applicable to health technologies in general, particularly those where user data are collected and used to support decision making (e.g., medical assessment).

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