A Value Framework to Assess Patient-facing Digital Health Technologies for Chronic Disease Management

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Unique Challenges of Digital Health Technologies (DHTs)

• There are very different economic considerations for DHTs than for pharmaceuticals and traditional medical devices

  *Why?*
  • Pace of Innovation
  • Evidence standards
  • Method of treatment (personalisation)
  • Data & Analytics

• At the same time, lack of clear evidence assessment guidance makes it difficult for innovators to understand specific evidentiary requirements and may hinder the pace of digital innovation.

• HTA methods for DHTs need to evolve to account for real world evidence (RWE), ongoing software updates and adaptive AI, integration into the daily lives of patients, and data governance concerns, among others.
Methodology

- Study countries: UK, USA, Germany
- Literature Review
- web-Delphi Panel
  - Conducted online using Welphi
  - Thematic analysis using Nvivo
  - Decision context: patient-facing DHTs
- Statistical analysis to test for stability and consensus

**Round 1:**
Participants are given the starting framework, make comments, and can add new value statements.

**Round 2:**
After feedback is incorporated, participants judge value statements on a Likert scale (1-5) in two decision contexts: a user-facing and system-facing technology.

**Round 3:**
Participants are shown the distribution of responses across all participants for each construct and given an opportunity to change their answer.
Participating stakeholder groups

**Patient users:** patients, caregivers and patient advocates

**Health care professionals:** doctors, nurses, pharmacists, care coordinators etc.

**Supply side actors:** representatives of the pharmaceutical industry, medical devices, health tech start-ups etc.

**Decision makers:** purchasers, payers, budget-holders, individuals who have acted as an advisor to formal decision-makers in a health system

**Influencers:** academics, HTA bodies, policy experts, independent consultants, etc.
Results

• 34 indicators proposed from the literature review, amended to 45 based on thematic analysis, refined to 33 stable indicators with consensus

• Value domains: Clinical characteristics, economic characteristics, data rights and governance, technical and security, and user preferences

• Number of participants invited (n=129)
  • Retention rate through Round 3 (61%, n=79)
Unstable Indicators – No conclusions

According to Delphi methodology, conclusions about consensus cannot be drawn for indicators with instability.

**Note:** For all indicators with instability, responses shifted towards higher positivity ratings and do not present a threat to the results.

<table>
<thead>
<tr>
<th>Value domain</th>
<th>Indicator</th>
<th>Stakeholder group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data rights and governance</td>
<td>Sharing of identifiable data to outside commercial entities is not permissible</td>
<td>Influencer, Supply Side Actor</td>
</tr>
<tr>
<td>Technical and security</td>
<td>Sustainable data architecture</td>
<td>Supply Side Actor</td>
</tr>
<tr>
<td>Clinical characteristics</td>
<td>Where applicable, improves quality of life for patients and carers</td>
<td>Influencer</td>
</tr>
<tr>
<td>Economic characteristics</td>
<td>Long-term cost effectiveness to the system</td>
<td>Influencer</td>
</tr>
<tr>
<td>User preferences</td>
<td>Relevance of the solution to the targeted user group</td>
<td>Supply Side Actor</td>
</tr>
<tr>
<td></td>
<td>Ease of adoption and use with minimal training</td>
<td>Supply Side Actor</td>
</tr>
<tr>
<td></td>
<td>Technology is offered in multiple languages</td>
<td>Influencer</td>
</tr>
<tr>
<td></td>
<td><strong>Value domain</strong></td>
<td><strong>Indicator</strong></td>
</tr>
<tr>
<td>Data rights and governance</td>
<td>Upon discontinuation of use, methods of de-registering and deleting data are clearly communicated to the user and are not difficult to achieve.</td>
<td>United States, United Kingdom</td>
</tr>
<tr>
<td>Technical and security</td>
<td>Processes in place to prevent unauthorised access to patient and outcomes data</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Economic characteristics</td>
<td>Long-term cost effectiveness to the system</td>
<td>Germany</td>
</tr>
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</tr>
</tbody>
</table>
“Important” Indicators with Agreement

Clinical Characteristics:
• Improves patient adherence to treatment
• Clinical risk management in place
• Clinical benefit based on patient-centred endpoints
• Improves patient engagement
• Integrates with and improves clinical processes
• Improves communication and information sharing
• Supports and sustains lifestyle changes
• **Utilises real world data for proof of benefit.**

Data governance:
• **Data is user owned**
• Adheres to strong information governance standards, including **processes for data protection violations**
• Policies on data privacy, sharing, collection and commercialisation are clearly communicated to all users
• The storage and processing of data corresponds to the regional legal requirements for data privacy
• **Systems are in place for health data (RWD) and its analytics (RWI) to contribute to Real World Evidence (RWE) generation while adhering to privacy standards. (Including post-marketing approval)**

Economic Characteristics:
• Affordability to the patient
• Affordability to the system
• Pre-marketing approval, innovation incentives exist for supply-side actors, such as opportunities for managed entry and risk-sharing agreements
“Important” Indicators with Agreement (cont.)

Technical and Security
• Complies with local data protection regulations
• **Data has a high degree of integrity and credible provenance.**
• **Where applicable, ability for patient users to input data**
• Security specifications are simply and transparently communicated to all users, including detailed information about updates.
• Systems are in place for continued product development and security updating after product release
• Uses multi-factor authentication
• Where applicable, convenient and sustainable device consumables.
• Capable of working and storing data offline and then syncing when internet restored, where clinically appropriate.
• **Data is interoperable**

User Preferences:
• Technical and user support
• **Where relevant, offers customisable integration with other solutions to facilitate management of multiple co-occurring conditions.**
• Provides an attractive/engaging experience for the end-user
• User is able to choose communication method as a result of personal preferences
• **Connection to peer support where appropriate.**

Health Inequalities:
• **Does not exacerbate existing health inequalities**
• Supports Digital Literacy
• Helps reduce socioeconomic health inequalities
Indicators with disagreement

• No significant disagreements between stakeholder groups were found for any indicators.

• Significant disagreements were found between country groups:
  “Ease of adoption and use with minimal training”
  British (91% VI) disagree with Americans (53% VI)
  “Integrates with and improves clinical processes”
  Germans (38% VI) disagree with British (73% VI)

• 3 Indicators had dissensus across all participants (due to high rates of neutrality)
  “Adheres to value-based care methodology”
  “Sustainable system improvements through resource optimisation”
  “Multi-stakeholder design, development and implementation”
How these findings compare with pharmaceutical HTA

• HTAs for DHTs need a strong focus on data governance: DHTs raise data management issues pharmaceuticals do not and proving value will rely on RWE.

• Delphi participants suggested indicators that assess aspects of value for DHTs that go not only beyond traditional HTA indicators, but also beyond those included in the study countries’ frameworks

• Eg. “Data is user owned”

• Currently, data collected from DHTs is not actually owned by the data subject. Patients have little say in how their data is managed and no opportunity to participate in profit-sharing. New technologies, such as web 3.0, are starting to change this.
Key Takeaways

- HTA for DHT is challenging due to the pace of innovation, difficulty meeting evidence standards, and data governance concerns, among others.
- There is an inherent difference between HTA for pharmaceuticals and for DHTs due to the ongoing collection and analysis of RWD.
- Value domains: Economic characteristics, Clinical characteristics, Data governance, Technical and security, and User preferences
- Participants suggested value indicators that go beyond current regulatory and HTA frameworks
- E.g., issues of data ownership, the ability to input data, and connect to peer support.
Thank You!

Any Questions?

- Look for our upcoming open access paper!
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