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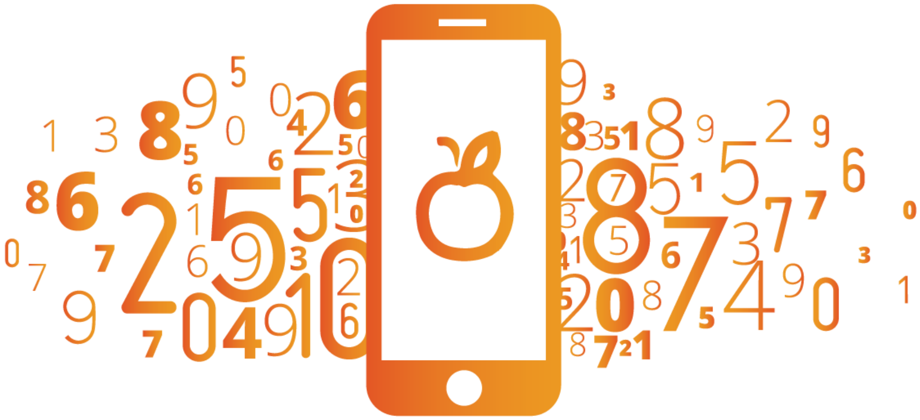
RESPONSIBILITY GUIDELINES FOR PERSONALIZED HEALTH TECHNOLOGY



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BACKGROUND INFORMATION

Why Responsibility Guidelines?

Personalized health technology – wearable tracking devices, smartwatches, and mobile applications – has emerged as a facilitator of healthy behavior change. This technology monitors users' health status by connecting them with a tracking device, a central data hub, and a broader social network. The potential of personalized health technology to improve health may be hindered by ethical, legal, and social challenges (see supporting White Paper). These challenges may have unanticipated or irrevocable consequences, which may lead to a lack of public acceptance and uptake of the technology. Responsibility guidelines provide a framework to proactively address ethical, legal, and social concerns associated with personalized health technology and personal health data.

Purpose and Goals of Responsibility Guidelines

Responsibility guidelines for personalized health technology aim to proactively address ethical, legal, and social implications associated with the technology and data. The guidelines will be measurable through concrete metrics, and will be a reference and a set of principles for the responsible stewardship of personalized health technology. The guidelines will be developed and piloted in collaboration with relevant stakeholders from the public and private sectors, which may include large health technology companies, data-driven enterprises, academic researchers, and policymakers.

Process of Responsibility Guidelines' Development

A systematic review and public consultation will inform the development of responsibility guidelines for personalized health technology. A global public consultation over a three-month period will provide feedback on a draft set of responsibility guidelines. In parallel, the Institute of Medicine (IOM) will convene a workshop on the Ethical, Legal, and Social Implications of Personalized Health Technology. The workshop will bring together a variety of stakeholders in public discourse and dialogue around personalized health technology. Outputs from the IOM workshop will inform responsibility guidelines for personalized health technology.

Importance of Responsibility Guidelines

Countless examples exist of innovations that are not accepted by civil society because of ethical or legal concerns or because of their failure to meet societal needs. Genetically modified organisms (GMOs) are one example. Ethical, legal, and social considerations were insufficiently identified and integrated into the design, development, and deployment of these innovations. Accounting for ethical, legal, and social implications of personalized health technology yields economic benefits and advances in health. Such issues are often seen as impediments, though may serve as drivers for new areas in research and innovation.

RESPONSIBILITY GUIDELINES FOR PERSONALIZED HEALTH TECHNOLOGY

Personalized health technology generates data on its users that can yield insights and advance the scientific evidence base when shared with researchers. Research with data from personalized health technology is in its infancy and requires validation to demonstrate long-term improvements to health. Data from personalized health technology has the potential to facilitate a better understanding of healthy behavior change. Ethical, legal, and social challenges prevail that may hinder uptake and acceptability. These concerns overlap in scope and variety, and inform solutions and recommendations for the implementation of personalized health technology. Selected challenges, solutions, and recommendations are areas for possible adaptation by companies engaged in the development and distribution of personalized health technology.

Engagement with Technology

The potential of personalized health technology to improve health is often hindered by low sustained engagement among users. A majority of individuals who purchase personalized health technology engage with the technology for a limited time. More than 50 percent of individuals who purchase a wearable tracking device terminate use, with a third doing so before six months.[1]

Behavioral science has emerged as a powerful discipline to promote sustained engagement with personalized health technology. Behavioral economic theory – one facet of behavioral science – suggests that individuals often engage in behaviors that are not in their self-interest. Within a behavioral economics purview, individuals are nudged to adopt and maintain healthier behaviors by combining personalized health technology with incentive and reward schemes so as to overcome engagement challenges. Behavior change research suggests that incentive approaches are most effective when frequent feedback is provided and when incentives are small and repeatedly provided once the activity has been completed.

Recommendation I: Ensure PHTs use principles of evidence-based approaches to health behavior improvement, such as behavior change techniques and behavioral economics.

Marginalized Populations

Poor health and low economic status are linked; individuals with poor financial health are often unhealthy. Personalized health technology, however, is primarily used by younger and more affluent individuals, though those who are older and less affluent would potentially benefit the most from engagement with the technology. Many individuals in low-income or marginalized communities often do not profit from personalized health technology because the technology is too expensive or not adapted to cultural nuances.

Creating personalized health technology that is culturally sensitive and affordable has potential to improve health for all populations. Personalized health technology should be designed for all income groups and incorporate principles of technology literacy so that users can understand how best to use the technology. Research should also be undertaken on various population subsets to identify effective technology interventions and to advance the health evidence base.

Recommendation II: Design PHTs with the aim of promoting utility and equitable accessibility across diverse populations.

Privacy of Data

Privacy for human research subjects in academic institutions requires researchers to obtain ethics approval from a federally mandated Institutional Review Board (IRB). Private sector companies are not bound to similar IRB approval processes. Instead, “notice and consent” is the most widely used strategy to maintain individual privacy, though individuals rarely read the details of a company’s online privacy policy.[2] This can result in personal health information being used in ways that may not accord with the expectations of users. Some companies, however, are shifting from a notice and consent model to one that integrates privacy into the design of new technologies. Privacy by design supports the inclusion of privacy considerations throughout the technology development process.[3]

Integrating privacy by design considerations throughout technology processes offers a promising foundation for responsibly engaging in research and innovation associated with personalized health technology. Companies engaged in the design and management of personalized health technology and supporting infrastructure and systems should seek to incorporate privacy and broader security features throughout the entire innovation process.

Recommendation III: Integrate approaches like privacy by design in the development and management of PHTs and supporting systems.

Interpretation of Health Information

Several populations may face difficulties when interpreting data from personalized health technology because they do not have appropriate health literacy. Individuals are health literate when they can understand health information and make informed decisions about their health.[4] Education, health services, and social and cultural factors, contribute to poor health literacy.[5] Those with little or no education or who speak a language not supported by the technology will be unlikely to engage with it. A mismatch exists between those seeking health information and the technology generating information.

Personalized health technology is often designed based on business objectives, feature maximization, or hardware or software capabilities. End-users are often excluded in designs. Instead of requiring users to adapt to existing personalized health technology, these technologies should be designed with them at their core. This is termed “user-centered design”. User-centered design incorporates needs, desires, and limitations of end users of personalized health technology at each stage of the design process. Designers develop technologies that are appropriate from health literacy and cultural perspectives so that data can be easily interpreted.

Recommendation IV: Advance user-centered design of PHTs.

Technology Validity

Governing bodies often propose guidance to represent current thinking on particular issues. The Food and Drug Administration (FDA) has proposed guidance for developers of mobile medical devices and pharmaceutical mobile applications, though no similar guidance exists for personalized health technology. Developers have discretion over the design of personalized health technology with no adherence to pre-defined guidelines, so the extent to which scientific evidence is integrated into the technology is the decision of the developer. Users of personalized health technology may subsequently be implicated if recommendations generated by the device are inconsistent with existing standards or if the technology does not operate as intended.

Technologies that integrate scientific evidence into their design and operate as intended can minimize harm to the individual and advance research on what works and does not work in chronic disease prevention. Designers of personalized health technology should be encouraged to undertake expert consultations to identify the best evidence and to understand how it can be leveraged for greater positive impact in technology design.

Recommendation V: Enable evidence on PHTs of validity, reliability, and other key performance metrics.

Data Stewardship

Data stewardship captures the possession and responsibility of personal health data. Uncertainty exists on who owns data from personalized technology – the user who generates the data or the company(ies) engaged in developing the technology, storing the data in web or cloud-based services, or other stakeholders. Many users would contend they should have access to – and own – their data. Companies often build features into technology that prohibit users from accessing their data. Conversely, research suggests individuals are willing to share personal health data with researchers in an anonymized format for analysis.[6] Data stewardship should extend to companies to share data with researchers for analysis to uncover broader insights on population health.

Recommendation VI: Facilitate transparency with respect to data stewardship.

ASSESSMENT AND MONITORING

A set of responsibility guidelines for personalized health technology to target ethical, legal, and social challenges appears well-suited. Critical to their development and pilot is the continuous assessment and monitoring undertaken by independent entities. Organizations engaged in developing and piloting responsibility guidelines will be independently assessed and monitored to ensure they remain accountable for their actions. Accountability will enable personalized health technology to generate its intended benefit as a facilitator and motivator for healthy behavior.

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