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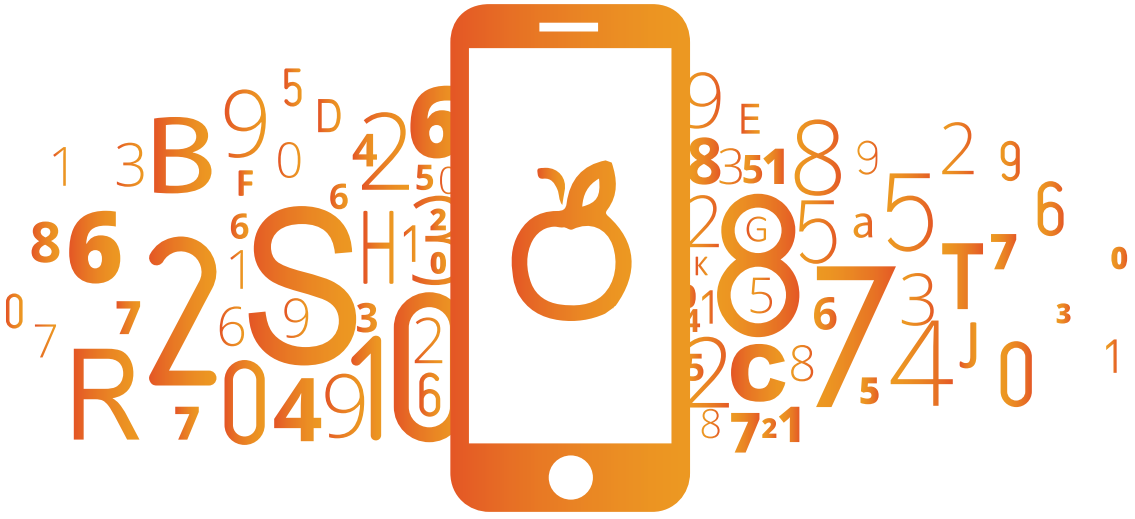

Ethical, Legal, and Social Implications of Personalized Health Technology

White Paper

Vitality™ INSTITUTE

About the Vitality Institute

The Vitality Institute is an evidence-driven and action-oriented research organization dedicated to health promotion and the prevention of chronic diseases to create a new culture of health. The Vitality Institute aims to unite leaders in the public and private sectors to transform evidence into action and create a healthier society. The Institute was founded in 2013 by the South African insurer, Discovery Limited, as part of its commitment to health promotion and well-being programs that advance social good.

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The authors are responsible for the content of this paper, which is intended to help inform and stimulate discussion.

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EXECUTIVE SUMMARY

Background Information

In June 2014, the Vitality Institute released research findings and recommendations from its *Commission on Health Promotion and the Prevention of Chronic Disease in Working-Age Americans* in the form of a report.[1] The Commission worked with stakeholders across sectors to place the power of prevention at the center of health policies and actions in the United States (US). It focused on major chronic diseases, which threaten the economic competitiveness and the vitality of our nation. At the Commission release, the Vitality Institute launched pledges to facilitate widespread progress. One commitment – under the recommendation "make markets work for health promotion and prevention" – was to work with the Institute of Medicine (IOM) to convene a workshop on the ethical, legal, and social implications of personalized health technology.

Opportunities for Health Using Personalized Technology

Personalized health technology, ranging from wearable tracking devices to smart pill bottles, offers potential to improve health. Individuals become empowered to self-quantify and modify their health status and behavior based on customized recommendations. These technologies provide contextual awareness of daily activities and facilitate the collection, transfer, and analysis of data to better understand health. It is estimated that there are 100,000 health, fitness, and medical mobile applications, a number that is expected to grow in coming decades.

Ethical, Legal, and Social Challenges and Solutions

While personalized health technology can advance health, the use of data generated by these technologies often entails ethical, legal, and social challenges, which often overlap in scope. Examples include:

1. **Ethical Challenges:** Developers of personalized health technology require access to data to identify behavioral insights and patterns. Conducting research also requires accessing and transferring data. The identification of personal health data, the role of human judgment, and equitable representation and fairness issues emerge with accessing and analyzing health data.
2. **Legal Challenges:** Personalized health technology often blurs health and medical information. Legal ramifications ensue because these data types are regulated differently – medical data in the US are covered by regulation, while health information is not. Challenges associated with privacy and consent and appropriately defining medical devices arise.
3. **Social Challenges:** Identifying the appropriateness, acceptability, and sustainability of personalized health technology necessitates the inclusion of public voices in discussions on data access and analysis. Education and training, new models of thinking, and adaptation of organizational structures are required to ensure data from personalized health technology provide equitable benefits across geographically, culturally, and socioeconomically diverse communities.

Potential solutions to ethical, legal, and social challenges of personalized health technology are included to stimulate discussion. Guiding questions are additionally posed to advance scientific inquiry and better inform solutions. Solutions will inform a set of responsibility guidelines for personalized health technology and associated data that will be piloted in leading health technology companies.

Sector and Global Guidance

Guidance on overcoming ethical, legal, and social implications of personalized health technology can be obtained from other sectors and countries. One example in healthcare is the Human Genome Project's Ethical, Legal and Social Implications Research Program. This program fostered basic and applied research on the ethical, legal, and social implications of genetic and genomic research. Legal and oversight systems in the US and other countries are also explored to identify best practices.

Conclusion

The Vitality Institute Commission presents pathways, and short- (2017); medium- (2020); and long- (2025) term measures of success. One short-term measure of success is the development of a framework that proactively addresses ethical, legal, and social issues with respect to data collected by personal prevention technologies, undertaken through a systematic review and extensive public consultation, and adopted across sectors. Outputs from the IOM workshop on the ethical, legal, and social implications of personalized health technology will contribute to the development of this framework, inclusive of responsibility guidelines.

INTRODUCTION

Vitality Institute Commission

In June 2014, the Vitality Institute released research findings and recommendations from its *Commission on Health Promotion and the Prevention of Chronic Disease in Working-Age Americans* in the form of a report.[1] The Commission worked with stakeholders across sectors to place the power of prevention at the center of health policies and actions in the United States (US). It focused on major chronic diseases, which threaten the economic competitiveness and the vitality of our nation. At the Commission release, the Vitality Institute launched pledges to facilitate widespread progress. One commitment – under the recommendation "make markets work for health promotion and prevention" – is to work with the Institute of Medicine (IOM) to convene a workshop on the ethical, legal, and social implications of personalized health technology.

Increasing Global Prevalence of Chronic Diseases

Chronic diseases, including cardiovascular and respiratory diseases, diabetes, and certain cancers, are a leading cause of death worldwide. They account for 36 million of the annual 57 million deaths globally.[2] Fortunately, a majority of chronic diseases are largely preventable by minimizing major risk factors. These include: eating a healthy diet, engaging in regular physical activity, avoiding tobacco use and excess alcohol intake, and adhering to chronic disease medications.

In most developed countries, the promotion of health and the prevention of chronic disease has resided within the domain of government. Governments develop and introduce regulatory, educational, and financial tools to improve the health of populations. Compulsory labeling on nutrition content in foods, health education programs and campaigns, and high taxes and age restrictions on the sale of tobacco and alcohol products are leading examples. These interventions have advanced health in many countries, though new technologies and tactics exist that should be leveraged to complement and scale up existing public health interventions.

Emergence of Personalized Health Technology

Personalized health technologies are rapidly being developed and deployed by the private sector. In 2013, private sector companies spent $13.8 billion on research and development to build digital enablers for health.[3]

What Is Personalized Health Technology?[4]

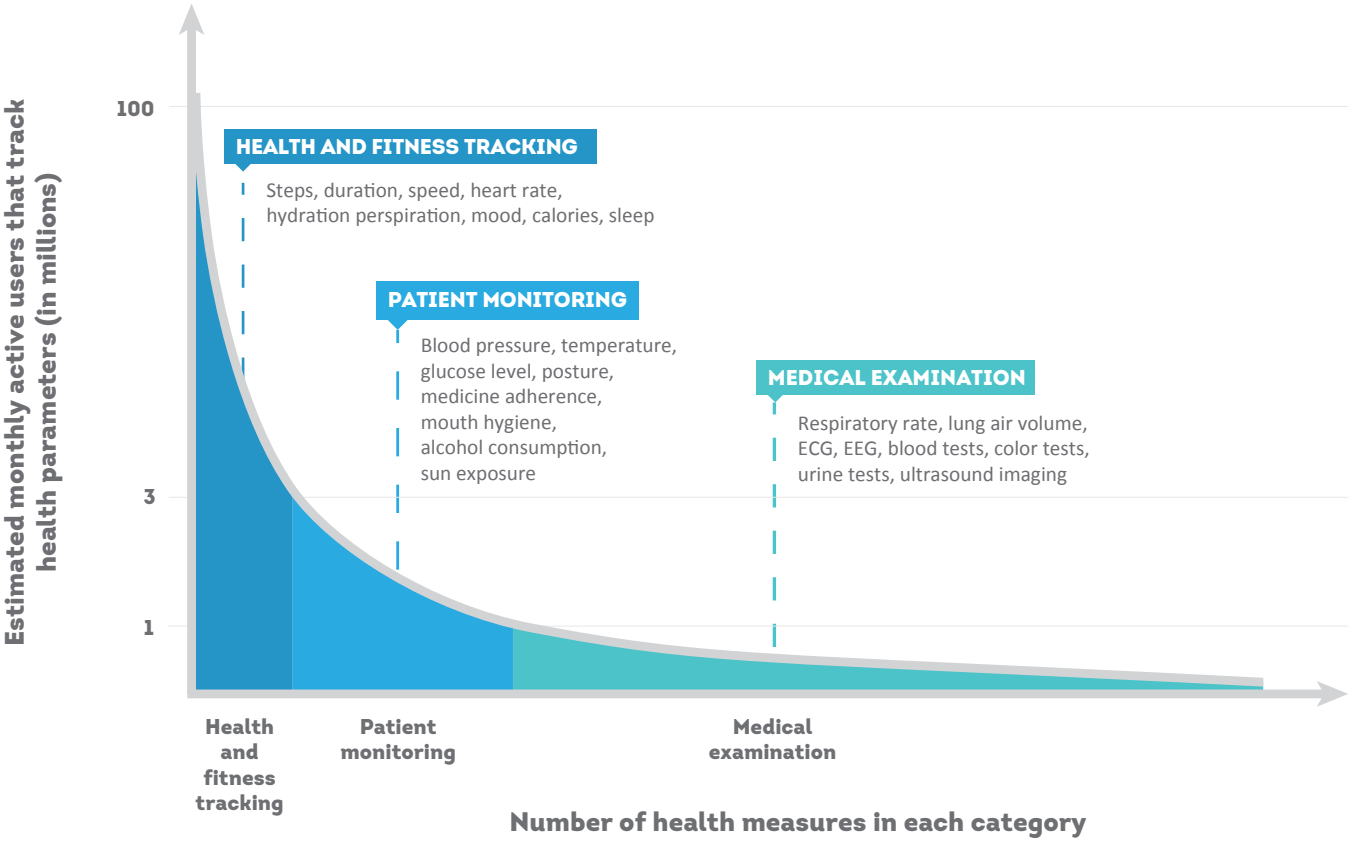
Personalized health technology wirelessly collects lifestyle information from multiple data sources by connecting the individual with a consumer device, a central data hub, others in a social network and at times a health professional. Data are integrated into a single, centralized platform and analyzed to provide the individual with a complete review of his or her health status with recommendations for improvement via a mobile phone.

Wearable tracking devices are an example of personalized health technology. These devices wirelessly track physical activity and sleep levels. Data on steps taken and hours slept are collected and analyzed to provide specific strategies for health improvement through a mobile phone. Other examples are automated pill boxes and smart watches.

The emergence of personalized health technology has been largely enabled by the proliferation of the mobile phone. The mobile phone is the most rapidly adopted consumer technology, with 91 percent of American adults owning one.[5] Mobile phones support mobile applications that can be used to track health. In 2013, it was estimated that there were 100,000 health, fitness, and medical mobile applications.[6] Tracking health and fitness information is the most popular use for mobile applications [Figure 1].

Personalized health technology has facilitated the expansion of the Quantified Self and the Internet of Things movements. The Quantified Self movement promises "self-knowledge through numbers" and is composed of members who are driven by the idea that collecting data can help individuals make better choices about their health and behavior. The Internet of Things similarly represents a movement toward developing objects embedded with sensors. These devices subsequently generate health, home, and global positioning system data, and can communicate with individuals and other technologies.[8, 9] In the future, it is expected that physical objects with accurate sensors that wirelessly communicate with users and coaches will be used as wearable devices, and will be placed in our environment. As algorithms become more personalized, digital coaches will become more responsive.

Figure 1: Health and Fitness Tracking is the Most Popular Type of Mobile Health Application[7]



Improving Health Using Personalized Technology and Behavioral Economics

Long-term engagement with personalized health technology has historically been low. The IMS Health Institute for Healthcare Informatics notes that 50 percent of mobile health applications receive less than 500 downloads. Only 2 percent are downloaded more than 100,000 times.[10] PricewaterhouseCoopers further estimates that two-thirds of individuals who download a mobile health application subsequently terminate use before the benefits of engagement become apparent.[7]

Combining personalized health technology with behavioral economics strategies that nudge individuals into engaging in specific actions has been shown to improve health. Recent studies have concluded that incentive-based health promotion programs that leverage personalized health technology are associated with lower probabilities of hospital admission and lower hospital costs in the following two years.[11]

Clinton Global Initiative: Reimagining Impact Using Big Data[14]

Ginni Rometty, Chairman, President, and CEO, IBM, on an opening panel for the Clinton Global Initiative's 2014 Annual Meeting, stated, "Big data will be the world's next natural resource, but like anything, only if you do something with it."

Generating Insights Using Big Data to Advance Health

Insights from big data from personalized health technology can be used to improve health. Big data is big in its ability to capture, aggregate, and analyze massive data *volume* and *variety* at high *velocity* (referred to as the "3Vs") as well as in the scale of analysis that can be applied to the data to identify patterns and inferences.[12, 13] Large quantities of health data generated by personalized health technology and mobile applications facilitate near ubiquitous data collection in real-time.

Big data generated by personalized health technology offers an opportunity to advance health by enabling the forecasting of future events using predictive analytics. Predictive analytics use electronic algorithms to identify patterns in data that might predict similar outcomes in the future.[15] Once data have been aggregated and cleansed (meaning that missing or incomplete records are completed or corrected) data mining is used to identify trends, patterns or relationships. This information is then used to develop a predictive model, which performs calculations on the data. The outputs of the model are used as predictors of future events or behaviors.[16]

Finally, big data may generate unrealized value for the healthcare system, potentially including lower healthcare costs. The US spends $2.7 trillion – or 17.9 percent of gross domestic product – each year on healthcare.[17] By forecasting future events and tailoring interventions using predictive analytics, it is estimated that big data can create an estimated $300-$450 billion per year in value to the healthcare sector.[12]

Example: Express Scripts Predicts Failures in Medication Adherence[7]

Express Scripts manages pharmacy benefits for 90 million members in the US and processes 1.4 billion prescriptions annually. It has scored data from doctors' offices, pharmacies, and laboratories to identify patterns that may notify physicians of possible adversarial drug reactions and interactions. Express Scripts now knows 12 months in advance – with a 98 percent accuracy rate – which individuals will not adhere to their medication regimen. Avoiding medication non-adherence could reduce the $317 billion that is spent annually in the US on unnecessary emergency room visits and inappropriate treatments.

Ethical, Legal, and Social Challenges

Data generated by personalized health technology raise ethical, legal, and social concerns. These may apply in different capacities depending on the technology under consideration. They will also apply differently to individuals generating the data, companies aggregating and managing the data, and researchers using the data to produce research results.

Clinton Global Initiative: Valuing What Matters[14]

A plenary session at the Clinton Global Initiative's Annual Meeting in September 2014 included a conversation between Jack Ma, CEO, Alibaba Group, and Darren Walker, CEO, Ford Foundation. Mr. Ma noted excitement regarding the proliferation of the Internet, while Mr. Walker indicated that "the dark side of the Internet is also problematic." He fears that we are "so enamored of, and excited by, the opportunity of the bright side [of the Internet] that we are not spending enough time as a society on the dark side."

Solutions to Ethical, Legal, and Social Challenges

Potential solutions to ethical, legal, and social challenges of personalized health technology are explored, recognizing that robust discourse and additional research will further contribute to solutions. Guiding questions are also included to advance scientific inquiry and better inform solutions. The potential solutions offered reflect existing research where available and integrate resolutions to big data concerns.
Alex "Sandy" Pentland's New Deal on Data, which rebalances data ownership in favor of the individual whose data is collected, is considered as a promising model.

Proposed solutions will inform voluntary guidelines to be adopted by companies across sectors to promote the responsible use of personalized health technology and health data. The guidelines will be measurable through concrete metrics, and will serve as a reference and a set of principles for the responsible stewardship of personalized health technology and health data. The guidelines will enable stakeholders, including governments, civil society, and other private sector organizations, to judge whether company actions constitute acceptable practices.

The Vitality Institute will encourage the piloting and implementation of guidelines in companies through public pledges. Companies will be held accountable for their integration of the guidelines through independent audits conducted by external organizations. Independent audits provide an objective evaluation on the company's stewardship of personalized health technology and health data.

Implementing voluntary guidelines for personalized health technology and health data will then be undertaken in regulatory environments that support innovation in areas where benefits may not be fully realized. The regulatory environment will direct change to prevent widespread abuses and misuses of personalized health technology or health data.

What is the New Deal on Data?

Suggested by Alex "Sandy" Pentland, Toshiba Professor of Media Arts and Sciences at MIT, the New Deal on Data offers principles and practices to define the ownership and control of data and its flow. Realizing the power of data and its potential for abuse, Pentland developed "a win for customers and citizens, a win for companies, and a win for government." The New Deal on Data enables users to appreciate what data is being collected, and offers an opt-in or opt-out solution for its collection. Despite many companies expressing concern for this model believing that it will render their business model inoperable, Pentland further indicates that in fact it would be beneficial for some businesses to disappear. When the relationship between individuals and companies is respectful and balanced, the economy will be healthier. People will share data only when they deem it is safe to do so.

Why Explore This Topic Now?

The rapid proliferation of personalized health technology and associated data has generated ethical, legal, and social challenges for individuals, policymakers, and public and private stakeholders. Exploring this topic now is particularly topical, given the series of related events and studies that have emerged in the preceding year.

The US government, for example, has ruled on cases that impact the extent to which personalized health technology may thrive. Chief Justice John G. Roberts Jr. of the US Supreme Court ruled in June 2014 that police will now require a warrant to search mobile phones of arrested individuals. This is because mobile phones have become "such a pervasive and insistent part of daily life that the proverbial visitor from Mars might conclude they were an important feature of human anatomy."[18]

Public awareness has also centered on the privacy of personal health data. The International Institute of Communications concluded that consumers are concerned about the privacy of health information though feel powerless to take action.[19] Pew Research similarly found that 54 percent of users of mobile applications have decided not to install an application because of the amount of personal information they would need to share, and 30 percent of users have uninstalled a mobile application because they learned it was collecting information they did not want to share.[20]

Young Voices on Fundamental Rights

In April 2014, 75 students in the United Kingdom debated and drafted a modern-day Magna Carta. Two of the five winning clauses incorporate issues associated with ethical implications of data:

(1) Everybody has the default right to be protected from explicit content in the media.

(2) The right to control the usage and storage of personal information on the Internet.

ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF PERSONALIZED HEALTH TECHNOLOGY

Ethical Challenges

Identification of Personal Health Data

An ethical challenge associated with personalized health technology is the identification of personal health data. While technology exists to remove personally identifiable information from an individual or device – a practice termed de-identification – equally powerful technology exists to re-identify information with a person or device.[13] The ability to re-identify previously de-identified data can entail personal privacy consequences for the individual.

While the impetus may not be strong to re-identify data, numerous studies demonstrate how it can be done. In one example, 241 of 1,130 de-identified participants who took part in a genomic surveillance survey could be re-identified. Using three sources of information – date of birth, gender, and ZIP code – combined with public records, researchers were provided with enough clues to re-identify the original individuals.[21] In a second personal genome study, surnames could be recovered using a triangulation process that included chromosome information and other types of metadata, including age and state.[22] Nonetheless, Cavoukian and Castro indicate that de-identification does work. They suggest that it is a "myth that de-identification is an ineffective tool to protect the privacy of individuals," and that the media and literature have overblown this issue.[23]

Solutions

Companies typically anonymize datasets by removing personally-identifiable information. It has been suggested, however, that personal information may be re-identified, particularly when multiple datasets are compared and analyzed for patterns and trends. Overcoming challenges associated with the re-identification of personal health data necessitates the use of the most sophisticated encryption technologies to profile, secure, present, and populate data. This may include using state-of-the-art data encryption algorithms that are difficult to crack but that do not restrict access to non-sensitive data, or securing data inclusive of personal information using multiple password protections.

Guiding Questions

- What safeguards are required for adequate confidence by consumers using personalized health technology?
- How can safeguards that ensure the confidence of consumers using personalized health technology be strengthened?
- To what extent can and should companies engaged in developing personalized health technology integrate data encryption technologies? Are there any downfalls associated with this?

Role of Human Judgment

Data from personalized health technology can also lead to tensions between relying on algorithms or human judgment to make decisions. On the one hand, McAfee and Brynjolfsson conclude that many decisions, predictions, diagnoses, and judgments should be made using algorithms that incorporate big data. They contend that when individual judgment is considered in addition to the analysis of a data-driven algorithm, they perform worse than the algorithm alone. The model in isolation performs better than when combined with individual judgment.[24]

On the other hand, Cattermole contends that big data still requires a human touch and that the power and value of big data will be minimized by relying solely on an algorithm. He believes that "big data is only as useful as the human decisions behind it." As more individuals and organizations become more dependent on big data, they risk applying solutions without considering common sense and human experience.[25]

Providing users with greater confidence in personalized health technology may require developing standards on the types of evidence that should be inputted into their design and development. In the case of community projects, the US Community Preventive Services Task Force has developed a Guide to Community Prevention Services. This community guide presents "information for decision-makers and stakeholders wanting to allocate resources effectively to protect and improve people's health; reduce future demand for healthcare spending that is driven by preventable disease and disability; and increase the productivity and competitiveness of the United States workforce." Developers of personalized health technology should have access to similar consultative services that provide guidance on what evidence to include or not include in the design and development of these technologies.[26]

IBM's Watson Wins Jeopardy![27]

In February 2011, IBM's Watson defeated two human opponents in *Jeopardy!*. IBM's Watson is a cognitive technology that understands natural language, generates hypotheses based on evidence, and incorporates dynamic learning. Watson is taught by users, learns from previous interactions, and is consistently presented with new information. It is thought that data generated by Watson can be used to make better decisions. In Jeopardy!, it used the knowledge it had amassed to compare possible answers, rank their confidence and accuracy, and respond within three seconds. The proliferation of dynamic learning tools such as Watson will raise ethical challenges on whether individuals should follow their own judgment or that of an algorithm.

Solutions

Consumers are unclear on the extent to which health decisions should be predicated on technology algorithms or human judgment. Developers of personalized health technology should be required to consult experts and existing references to effectively integrate relevant and credible scientific evidence into product design related algorithms. This may entail establishing meta-analyses of published studies, the outputs of which would subsequently be incorporated into technology designs. Recommendations generated by technology algorithms should be evidence-based and adhere to pre-defined standards or best practices developed by relevant, unbiased stakeholders. With confidence in the technology because of its robust evidence-base, consumer engagement may be advanced to improve health in the long-term.

Guiding Questions

- Under what circumstances does the consumer rely on technology algorithms versus human judgment when making health related decisions? Which behavioral economics approaches can improve adherence to recommendations generated by technology algorithms?
- What standards should be used to determine that algorithm-based recommendations are "evidence-based"? Who should be responsible for setting these standards?
- What stakeholders are necessary for widespread adoption of pre-defined standards or best practices for evidence? What considerations should be included in a set of pre-defined standards or best practices for personalized health technology?

Equitable Representation and Fairness

A final ethical challenge associated with personalized health technology is ensuring that forecasts from predictive analytics models include data that are representative of the entire population. There is a danger that algorithms can be used in a way that perpetuates stereotyping and bias because individuals representing certain minority populations may not use the same range of products and services that routinely collect electronic data.[28] This generates datasets that are unrepresentative of these populations.

While minorities have often been early adopters of technology, many people residing in low-income communities do not have access to or use personalized health technologies. They do not generate "data exhaust" or a "digital footprint" of health information.[29] As a consequence of being on the margins of society based on poverty, geography, lifestyle or cultural indicators, these people will continue to be marginalized by big data. The preferences and needs of those who are already marginalized are further neglected when governments and the private sector use big data to develop public policies.[30]

Solutions

The extent to which benefits from personalized health technology and data are realized varies by consumer groups. This is because variations in socioeconomic and demographic status among users persist. Targeting equitable representation and fairness requires developers of personalized health technology to design and market products to all populations, including high- and low-income segments, diverse racial, ethnic, social, and cultural groups, and older and younger generations. Adoption of personalized health technology should be supported by offering behavioral economics strategies customized to each target population to facilitate sustained engagement. Researchers engaged in studies requiring the analysis of data from personalized health technology should ensure that data is representative of the target population under consideration.

Guiding Questions

- What similarities and differences are there between population segments with regards to personalized health technology?
- How should personalized health technology be adapted for different populations based on socioeconomic and demographic variations?
- What insights can be derived from data from personalized health technology to benefit all populations and to benefit specific sub-populations?

Legal Challenges

Privacy and Consent

Within academic institutions, data privacy for human research subjects requires researchers to obtain ethics approval from a federally mandated Institutional Review Board (IRB). An IRB is a select group of individuals who are formally designated to ensure appropriate protection of the rights and welfare of human participants in research.

Private sector companies are not subject to the same IRB approval processes. In the private sector, the most widely used strategy to ensure consumer privacy is notice and consent, whereby individuals have to provide positive approval to personal data collection practices.[31] Nonetheless, the US President's Council of Advisors on Science and Technology concludes that "only in some fantasy world do users actually read these notices and understand their implications before clicking to indicate their consent."[32] One market survey similarly concluded that two-thirds of US consumers rarely read a company's online privacy policy.[33, 34] This model of consent places the burden of privacy on the individual, as the provider offers a take-it-or-leave-it set of conditions, which most users evaluate using minimal mental effort in a few seconds. This ultimately represents a market failure.[32]

Facebook's Experiment to Manipulate Emotions[35]

In January 2012, researchers manipulated the Facebook newsfeeds of approximately 689,000 users. The experiment investigated whether the emotional content of newsfeeds impacted the emotions of Facebook's users. The researchers concluded that emotional states can spread across social networks. Facebook's users agree to its Data Use Policy before creating an account, though no explicit informed consent was provided to users to engage in the research study. Users also did not have the option to opt out of the research study. In response, the digital rights group Electronic Privacy Information Center (EPIC) filed a formal complaint to the US Federal Trade Commission (FTC). EPIC indicated that Facebook had disobeyed ethical standards that govern human subjects. Facebook users may accept an online statement that gives them access to the site and their personal information, but in the public's view, this does not represent informed consent to conduct experiments. Later correspondence indicated that Facebook would train all its engineers in research ethics, though no outsiders will review Facebook's research projects.

Unlike medical information that is protected by Health Insurance Portability and Accountability Act (HIPAA), health data generated by personalized health technologies are not covered by existing laws. Unclear privacy and consent practices have led to many private sector companies sharing health information with third party vendors or across country borders, unbeknownst to the consumer. In one study, Evidon found that the top 20 mobile health applications, including MapMyFitness and WebMD Health, were transmitting information to approximately 70 third-party organizations.[36] The Executive Office of the President further notes that "personal health information of various kinds is shared with an array of firms, and even sold by state governments, in ways that might not accord with consumer expectations of the privacy of their medical data."[13]

Solutions

Widespread agreement exists on the need to overcome privacy and consent challenges associated with personalized health technology and health data. Solutions may entail companies offering a choice to consumers when asking for consent. When registering for a personalized health technology, companies should explicitly offer opt-in consent – in which health data is not shared unless consumers provide explicit consent otherwise – or opt-out consent – in which health data is shared unless consumers indicate a differing preference. Consumers should easily be able to modify their selections and should be notified of changes to company privacy policies that govern the use of health data. Providing explicit opt-in or opt-out consent enables consumers to decide on the distribution and disposal of their health data. Consumers thereby become the owners of their health data.

Guiding Questions

- To what extent do varying consent processes impact the uptake of and long-term engagement with personalized health technology? Does the language used to communicate privacy affect the adoption of technology?
- Do different consent models such as opt-in or opt-out affect consumers' willingness to share health data for research or other purposes?
- How can users of personalized health technology be better informed on how companies use health data?

Legal Definition of Medical Devices

Another legal challenge associated with personalized health technology is the legal definition of medical devices. If a technology is defined as a medical device, it produces medical data. Otherwise, the device produces health data. This has legal ramifications because medical data are covered by existing laws, while health data are not.

The US government has introduced various measures to adapt to the emergence of personalized health technology. In August 2013, the FDA released draft guidance recommending its intent to exempt certain medical devices from premarket notification requirements.[47, 48] This does not mean that the Food and Drug Administration (FDA) intends to exempt these devices from all other statutory and regulatory requirements. General controls still apply including registration and listing, labeling, and appropriate manufacturing practices.

In an attempt to provide clarity on the legal definition of medical devices, Representatives Tom Marino and Peter Defazio sent a letter to US Secretary of Health and Human Services (HHS) Sylvia Burwell asking her to assist with making HIPAA regulatory guidance for app developers clearer. The language of HIPAA, developers contend, makes it difficult for them to understand how the law applies to mobile applications.[50]

Apple's Health Product Launch: Apple Watch and HealthKit[50, 51, 52]

Health and medical data are currently collected and stored on numerous devices and platforms; they are not centrally stored. In June 2014, Apple announced HealthKit to overcome this problem. HealthKit combines data to enable individuals to take better care of their health. It offers a single dashboard that integrates health and medical information from third-party devices and mobile health applications. HealthKit syncs with the Apple Watch, Apple's first wearable tracking device of health and fitness data. Apple's HealthKit incorporates medical information from Electronic Health Records (EHRs) along with health and fitness data from personalized health technologies. While HealthKit does not permit developers to sell end-users' health information to advertising platforms, data brokers or information resellers, legal challenges associated with data ownership emerge. This is because medical record providers and Apple will may be required to abide by HIPAA.

Solutions

Personalized health technology often blurs health and medical data. This has ramifications because medical data are covered by existing regulations, while health data are not. Developers of personalized health technology may subsequently develop health devices understanding this distinction. This may assist in ensuring consumer protection and safety, and better promotion of technology innovation.

Guiding Questions

- What clarity is required on regulatory guidelines for technology developers to effectively create personalized health technology?
- Does a distinction between health and medical data constitute a valid separation?
- To what extent do existing laws on distinctions between health and medical data hamper innovation of personalized health technology?

Social Challenges

Inclusion of Public Voices

Ensuring the public's views and values are considered when using big data from personalized health technology requires approaches that include disparate voices. The Executive Office of the President recommends that the federal government's consumer protection and technology agencies should convene public workshops and develop reports on big data, particularly with regard to discriminatory practices.[14]

In healthcare, wider patient representation has been incorporated in the governance of organizations that develop and implement big data. In the case of biobanks, for example, a trust model is used. A trustee – either an individual or a group of people – is responsible for overseeing the use of specimens on behalf of donors and is involved in the organization's wider governance structure.[16]

Solutions

Public voices are often not included in discourse and dialogue on personalized health technology and associated data. Incorporating the public's views may entail convening public forums for relevant stakeholders to share knowledge and perspectives on personalized health technology. Stakeholders may include users of personalized health technology; developers of health devices; regulatory officials engaged in designing policies for personalized health technology; academic researchers undertaking analyses of health technology; and journalists writing and publishing on consumer perceptions and health devices. Outputs of public forums could inform the design of personalized health technology as well as data policies of companies developing health devices.

Guiding Questions

- How can the public's views on personalized health technology be assessed and subsequently incorporated into decisions by companies?
- How can trust between companies engaged in the development and application of personalized health technology and the broader public be aligned to support widespread adoption?
- To what extent can governance models be implemented in companies to include stakeholders' perspectives on personalized health technology and related data uses?

Risk Perceptions

Informing the public on risks associated with personalized health technology seems simple to attain in principle yet difficult to accomplish in practice. Perceived risks are different to every individual and are affected by multiple factors. Risk perceptions on personalized health technology may entail concerns on the safety of devices as well as how health data is stored, managed, and shared. Slovic (1986) presents four research findings on limitations of public understanding in relation to risk:[43]

1. **Perceptions of risk are often Inaccurate:** Risk perceptions are often influenced by individuals' memorability of past events and their ability to imagine future events. Recent disasters, media coverage, or films may taint perceptions of risk.

2. **Risk Information may Frighten and Frustrate the Public:** Merely mentioning possible consequences of innovative technologies may make risks seem more frightening.

3. **Strong Beliefs are Hard to Modify:** Individual beliefs change slowly and are difficult to modify even when they are presented with contrary evidence.

4. **Naïve Views are Easily Manipulated by Presentation Format:** Individuals with no strong opinions are affected by how information is presented. The communication of risks to the public can impact perceptions and subsequent decisions.

If the public's participation in discussions on perceptions of risk is to be meaningful, Slovic suggests that the public should be involved and informed at the outset. Risk communication efforts will fail unless a two-way process is embedded, in which experts and the public respect the insights and intelligence of the other.

Solutions

Stakeholders perceive and experience differing risks associated with personalized health technology and related data. Addressing perceptions of risk entails the development of a robust evidence base that demonstrates the effectiveness of personalized health technology. It also includes societal engagement, the dissemination of information to applicable stakeholders and to the broader public. Solutions should focus on optimal and iterative action to reduce risks as opposed to delaying action until risks are entirely understood.

Guiding Questions

- What are the leading consumer perceptions of risks that need to be considered and addressed to support the adoption of personalized health technology?
- What information is needed for consumers to be well informed about personalized health technology and associated data usages? What is the best approach to deliver this information to consumers?
- How can the public and the relevant stakeholder groups be informed and involved in identifying, understanding, and eliminating or mitigating risks associated with personalized health technology?

Education and Training

Another social challenge associated with personalized health technology is the development of education and training programs. This includes educating consumers on their health information, providing training to technology developers, and facilitating the integration of technology into health provider practices.

Messaging of Health Information to Consumers

Personalized health technology generates digital information on users' health status. Using advanced algorithms, behavioral recommendations further enable users to improve their health. Understanding information generated by personalized health technology requires a degree of health and technology literacy among users.[A1, A2] HHS estimates that 12 percent of Americans have proficient health literacy.[44] This is equivalent to nearly nine out of ten adults lacking the skills required to effectively manage their health and prevent disease. Similarly, it is estimated that 83 percent of individuals have difficulty using intelligent devices, including personalized health technology.[45] Insufficient uptake of messaging of health information via technology results in poor health outcomes among users, including higher rates of hospitalization and lower uses of preventive services.

Solutions

Interpreting results from personalized health technology may pose challenges for certain users of health devices. Solutions to address challenges associated with messaging of health information to consumers may include developers of personalized health technology designing devices with end-users in mind. This would require technology developers to better understand their target populations, including levels of health and technology literacy. Companies may further provide internal training on optimal technology design and data analytics as well as training on health and technology literacy to user groups to encourage adoption.

Guiding Questions

- What forms of messaging promote sustained uptake of personalized health technology? How can personalized health technology be simplified to encourage better understanding of health results?
- How and to what extent can customized messaging encourage the adoption of and long-term engagement with personalized health technology?
- How can companies better understand their target populations to design technology with end-users' needs and literacy levels in mind?

Skill Acquisition by Technology Developers

Companies interested in using big data for health promotion and chronic disease prevention most often require skilled workers with three types of talent:[46]

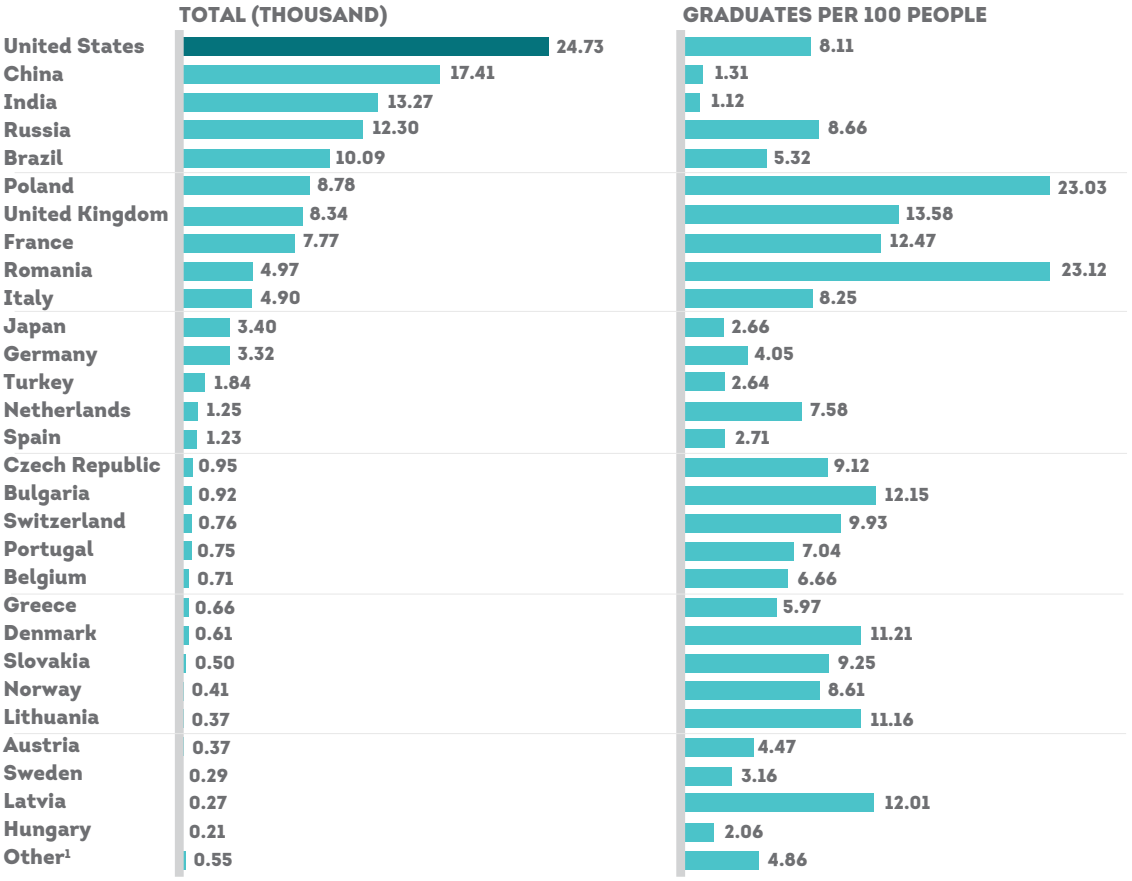
1. **Data Analysis:** Data analysis necessitates data scientists with deep analytical training. These employees have in-depth technical skills that are required to analyze large amounts of data to identify patterns and insights.

2. **Data Management:** Data managers understand the nuances of data. They pose the right questions, interpret and challenge results from data analysis, engage in decision making, and present findings.

3. **Systems Management:** Systems managers have the technological skills to create and manage big-data systems. They develop, implement, and maintain the hardware and software that underlies databases and analytic programs.

[A1] Health literacy is the degree to which individuals can gather, process, and comprehend health information required to make beneficial health decisions.
[A2] Technology literacy is the ability for individuals to use technology to access, manage, integrate, evaluate, create, and communicate information.

Figure 2: The United States Graduates the Largest Number of People with Deep Analytical Training Relative to Other Countries[46]



[1] Other includes Finland, Estonia, Croatia, Slovenia, Iceland, Cyprus, Macedonia, and Malta.

Source: Eurostat; Russia Statistics; Japan Ministry of Education; India Sat; NASSCOM Strategic Review 2005; China Statistical Yearbook; China Education News; IMF World Economic Outlook Database

With the most pressing needs in the first two categories in the US, the McKinsey Global Institute compared existing with required levels of data scientists and data managers projected through to 2018. For data scientists with deep analytical talent, the McKinsey Global Institute estimates that there are 300,000 individuals with this type of expertise. The US also graduates the largest number of people with deep analytical talent relative to peer countries [Figure 2]. Nonetheless, the demand for people with deep analytical talent could reach 440,000 to 490,000 in 2018. This represents a shortage of 140,000 to 190,000 data scientists by 2018.[46]

For data managers, the McKinsey Global Institute estimates that 4 million positions will require people with this skillset in 2018. Adding the number of existing workers with appropriate skills with the number of new graduates entering the market by 2018, 2.5 million people are reached by 2018. This represents a shortage of 1.5 million data managers. As a consequence, retraining the existing workforce will be needed with courses in statistics and experimental design.[46]

Solutions

Based on the amount of data generated by personalized health technology in coming decades, predictions suggest a shortage of skilled workers. For future data scientists and analysts, the potential shortage of skilled workers in the future requires academic institutions and companies to develop programs in big data and incentivize students to enroll in these programs. Policymakers could further incentivize academic tracks to increase the supply of data scientists. Finally, in medical education, clinicians will need to be trained to incorporate big data analytics in decision-making.

Guiding Questions

- What are the most pressing skills needed to effectively analyze and communicate information generated by personalized health technology?
- How can schools, universities, and companies support the skillset of developers of personalized health technology?
- How can gender imbalances be remedied to encourage interest in health technology?

Health Provider Integration with Technology

Concerns about the validity of data from health devices have led to doctors infrequently prescribing personalized health technology.[47] Many doctors have minimal time for, and interest in, leveraging health data from personalized technologies, in part because there is little evidence that consumer devices meet clinically acceptable levels. In addition, inclusion of health data has been met by physician resistance because of the training required to incorporate this information into their medical practice.[47]

Solutions

Many health providers have been apprehensive to prescribe personalized health technology to patients. This is because the efficacy of the technology and the validity of the data has yet to be verified. Encouraging health providers to support the adoption of personalized health technology requires the training of health providers on the potential of personalized health technology as well as on their associated evidence base.

Guiding Questions

- How can health providers integrate data from personalized health technology into their practices?
- What conditions are required for health providers to recommend the use of personalized health technology to patients?
- What incentives are required to support health providers in encouraging patients to use personalized health technology?

New Models of Thinking

Academic institutions and research funders will also have to shift priorities to incorporate new ways of thinking. In particular, analyses of big data from personalized health technology largely require departures from traditional statistics and hypothesis testing. Instead of producing new knowledge by testing theoretical hypotheses and answering single research questions, big data empirically analyzes large sets of data from real-world settings. Big data incorporates learning systems to reveal insights from the data, which are subsequently used in prediction and discovery. Outputs are highly reproducible and can be applied to numerous contexts.[48]

Studies that incorporate big data and that start with analyzing data are often considered to be inferior compared to those that formulate a hypothesis derived from an initial understanding of the phenomena.[48] Unlike traditional research programs which primarily focus on deductive reasoning, data science supports shifts between deductive and inductive reasoning.[B1] As a result, academic institutions and research funders should foster new knowledge generation that incorporates both deductive and inductive reasoning. This would account for analyses associated with big data.

Solutions

Misalignment in modes of thinking exists within public funding streams. Analyzing data from personalized health technology requires inductive thinking, while public funding programs require demonstrating results using deductive thinking. Offering grants for analyzing big data from personalized health technology may require the development of academic streams focused on device design and data analytics. Funding bodies, including the National Institutes of Health (NIH), should be encouraged to support inductive and deductive models of thinking to foster complementary research on big data.

Guiding Questions

- What skills are needed to conduct research using data from personalized health technology?
- How can public funding organizations adapt their funding model to support research involving personalized health technology?
- How can public funding bodies foster the development of academic streams to support research that uses inductive and deductive thinking?

[B1] What Is Inductive vs. Deductive Reasoning?

Deductive Reasoning: A logical process whereby a hypothesis is developed based on the theory, and observations are collected to test the hypothesis. Following data collection and analysis, the hypothesis is accepted or rejected, and the theory supported or unsupported, to arrive at a conclusion.

Inductive Reasoning: Inductive logic begins with specific observations, which are used to detect patterns and formulate tentative hypotheses. Eventually, hypotheses are explored and general conclusions or theories are developed.

Adaptation of Corporate Structures

A final social challenge with personalized health technology is the adaptation of corporate structures. Big data has potential to yield competitive advantage for companies, though many have yet to modify their existing structure to facilitate this. A study led by the MIT Center for Digital Business that interviewed 330 company executives concluded that the more the company perceived themselves as data-driven, the better they performed on financial and operational measures. Specifically, companies in the top third of their industry that had adopted data-driven approaches were 5 percent more productive and 6 percent more profitable than competitors.[49] Similarly, a 2013 survey conducted by the MIT Sloan Management Review and SAS Institute found that 67 percent of business executives indicated that their companies gained competitive advantage from using data analytics. This increased from 58 percent in 2012 and 37 percent in 2010.[49] With the increasing use of big data in predictive analytics, organizations will likely be required to adapt organizational structures and methods for managerial decision-making.

Solutions

The relative newness of big data has resulted in corporate structures not promoting appropriate management and analysis of data from personalized health technology. Leveraging the power of big data may require companies to create leadership positions in technology design and data analytics. Leaders would ensure that outputs from big data analyses are appropriately translated for non-experts and communicated within the company.

Guiding Questions

- How can companies maximize the potential of personalized health technology for improving workforce and community health?
- How can companies facilitate the sustained use of personalized health technology?
- What structures are required for the appropriate management of personal health data within companies?

LEARNING FROM OTHER SECTORS

Healthcare: Human Genome Project

One area where ethical, legal, and social challenges were effectively tackled at the outset was the Human Genome Project (HGP). HGP was officially launched in 1990 and was completed in 2003.[50] It aimed to understand and map all genes of human beings. Genes collectively are referred to as the genome.

The human genome contains an estimated 3 billion pairs of DNA strands, which reside in 46 chromosomes. The chromosomes contain genes, which carry the information to generate proteins. The production and functionality of these proteins dictate the functionality and health of the whole organism.[51]

HGP researchers uncovered the human genome using three phases:[52]

Phase 1: Determine the sequence of all the bases in our genome's DNA.

Phase 2: Develop maps that demonstrate locations of genes for major sections of chromosomes.

Phase 3: Produce linkage maps to highlight how inherited traits can be tracked over generations.

Before Phase 1 of the HGP was completed, a private biotechnology company, Celera Genomics Corporation led by Dr. Craig Venter, entered the race to sequence the human genome. Dr. Venter's team used a different approach to those being used by the HGP.[53] Eventual efforts to unite the HGP and Celera Genomics to complete the mapping of the human genome commenced in 1999. In March 2000, US President Bill Clinton and British Prime Minister Tony Blair made a joint declaration that genome information should be made publically and freely available. This resulted in Francis Collins – the then Director of the National Human Genome Research Institute (NHGRI) – and Craig Venter cooperating. In June 2000, Collins and Venter jointly announced that together they had deciphered all the genes in human DNA.[54]

Coordinated by the US NIH and the Department of Energy (DOE) with contributors from universities across the US and international partners, the HGP cost $2.7 billion in fiscal year 1991 and was completed more than two years ahead of the 15-year projected schedule.[51]

Ethical, Legal, and Social Challenges

Ethical, legal, and social implications from sequencing the human genome were recognized at the outset. As a result, NHGRI founded the Ethical, Legal and Social Implications (ELSI) Research Program in 1990. This program aimed to "foster basic and applied research on the ethical, legal and social implications of genetic and genomic research for individuals, families and communities."[55] The Research Program committee included a selected group of leaders in related fields, including bioethics, pediatrics, and the law.

The HGP's ELSI Research Program focused on the consequences of genomic research in four primary areas:[56]

1. Privacy and fairness in the use of genetic information, specifically in relation to genetic discrimination in employment and insurance.
2. The incorporation of new genetic technologies, including genetic testing, into the practice of clinical medicine.
3. Ethical concerns related to the design and conduct of genetic research with human subjects, including informed consent processes.
4. The education of healthcare professionals, policymakers, students, and the public about genetics and genomics.

Three percent of the total research budget for the HGP was allocated toward ELSI programs.[51] Today, 5 percent of the annual budget of NHGRI is allocated to exploring ethical, legal, and social implications related to human genome research, incorporating recommendations into the activities of NHGRI, and providing guidance to policymakers and the wider public.[51] The program's budget has increased from $1.57 million in fiscal year 1990 to $18 million in fiscal year 2013. Since its inception, the program has awarded $317 million in research support and funded more than 480 projects.[51]

Impact

A retrospective analysis published in August 2014 concluded that the NHGRI ELSI program had an impact in three areas:[57]

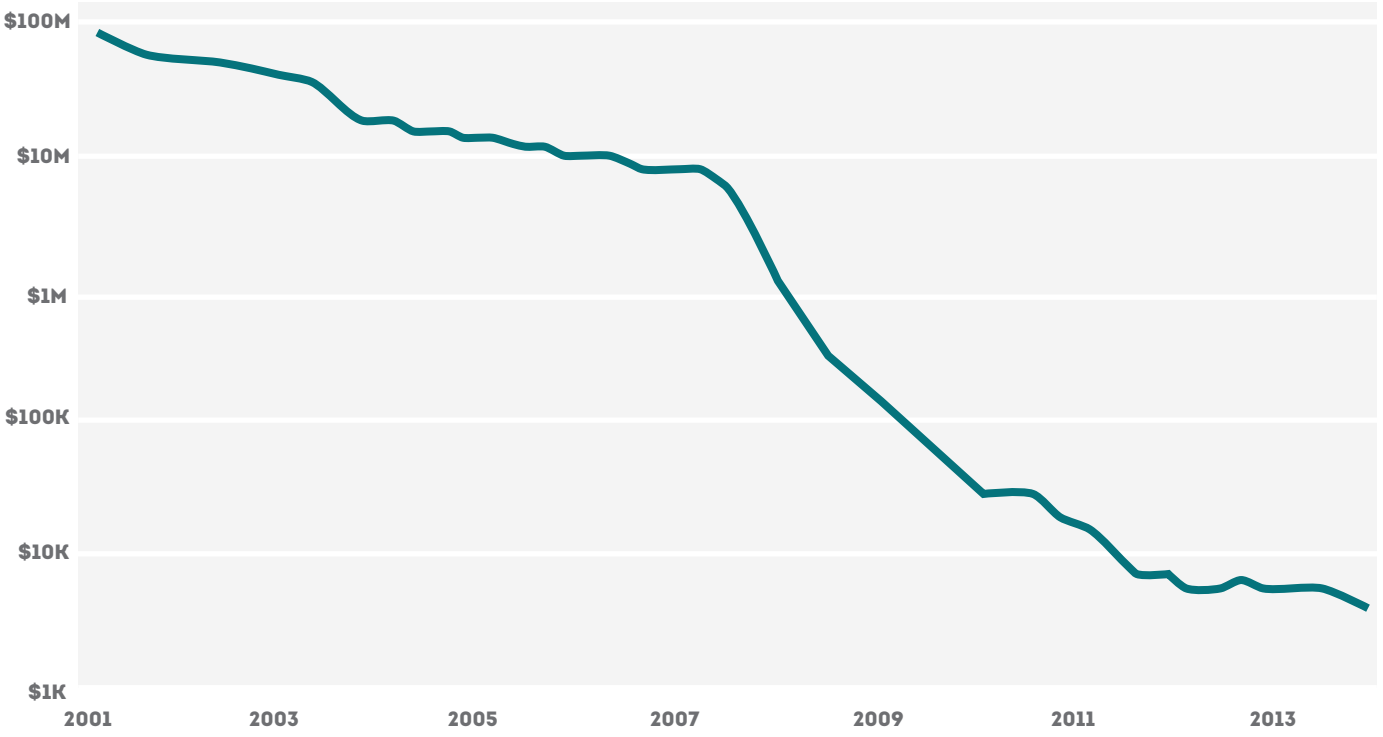
1. **Conduct of Genomics Research:** The impact of ELSI research has widely been viewed as most notable in policies related to the conduct of genomics research. One example is the evolution of approaches to informed consent for genetics and genomics research and testing, which has led to new models for simplifying and streamlining consent processes.

2. **Implementation of Genomic Medicine:** Numerous early funded research studies contributed to the development of documents, recommendations, and guideline statements by professional organizations. As new technologies emerge, this work continues to inform ongoing policy dialogue.

3. **Broader Legal and Societal Impact:** Many of the early normative and legal analyses contributed to policy changes, including the inclusion of a provision in HIPAA that prohibits group health insurers from excluding individuals from group coverage based on genetic predisposition, and the eventual passing of the Genetic Information Nondiscrimination Act of 2008, which prohibits genetic discrimination in health insurance and employment. The program has also sensitized members of the law enforcement community to the uses of DNA samples from people in the criminal justice system. Finally, analyses on the effects of gene patents and intellectual property protection have helped to inform policy development.

The advances made by the HGP have also ushered in an era of relatively inexpensive personal genome services that allows for earlier diagnoses of diseases and fueling the creation of new medicines [Figure 3].[8]

Figure 3: The Cost of Sequencing a Human Genome Has Dropped[8]



The Rise, Fall, and Resurrection of 23andMe[58, 59, 60]

23andMe is a privately held personal and biotechnology company that sells a relatively inexpensive direct-to-consumer personal genome service. The service analyzes key components of an individual's DNA to uncover genetic and ancestry information. In November 2013, 23andMe received a warning letter from the US FDA barring the company from marketing its service. The FDA indicated that 23andMe was selling a service with information on an individual's chances of contracting a disease and their likely response to various drugs. The FDA claimed that 23andMe was selling a medical device, which requires explicit approval, and which the company did not have. The FDA eventually permitted 23andMe to continue selling the service provided it did not include any information on disease. In July 2014, 23andMe received a grant from the NHGRI for approximately $1.4 million to continue developing its web-based database and research engine for genetic discovery.

Retail: Data and Analytics

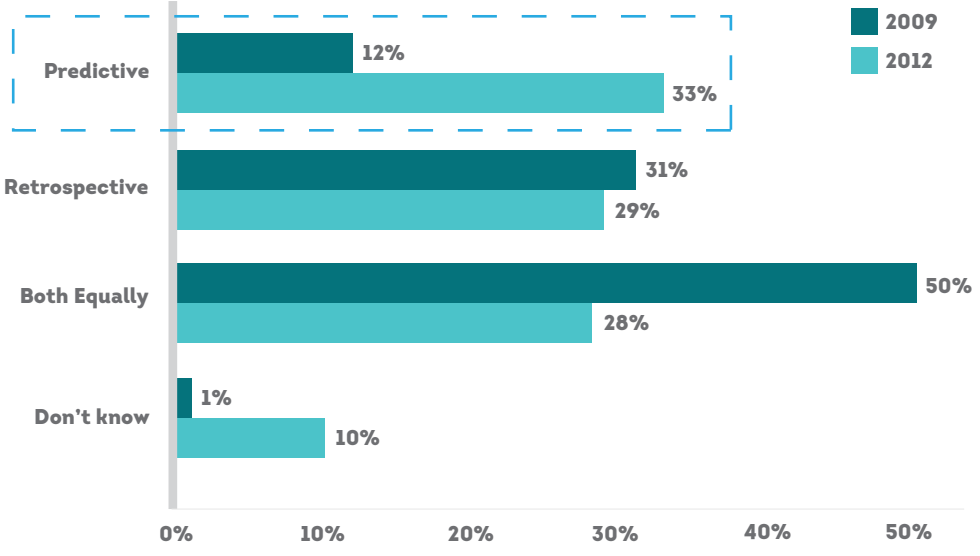
Retail is a second area where ethical, legal, and social challenges have emerged and key learnings can be derived. It is predicted that the retail analytics market will reach $4.40 billion by 2019 from $1.88 billion in 2014 and that "almost every major retailer, from grocery chains to investment banks to the US Postal Service, has a 'predictive analytics' department devoted to understanding not just consumers' shopping habits but also their personal habits, so as to more efficiently market to them."[61, 62]

Technology has enabled consumers to be more empowered. Consumers have vastly different and more sophisticated expectations of products, services, and value relative to a decade ago.[63] As a consequence, organizations need to adapt to a changing business environment. In one study conducted by Accenture of 600 director-level executives and managers in American and British companies, the company concluded that two out of three firms have appointed a senior figure such as a "Chief Data Officer" to lead data management. Seventy-one percent who do not have such a position expect to do so in the future. Thirty-three percent of organizations surveyed report that they are using analytics across the entire company.[64]

In 2009, Accenture concluded that only 12 percent of organizations surveyed were using predictive analytics. This had nearly tripled to 33 percent by 2012. This demonstrates the surge in predictive analytics to target consumers and yield business insights [Figure 4].

Canada: Privacy

Figure 4: The Surge in Predictive Analytics[65]



Ethical, Legal, and Social Challenges

While many retail organizations leverage the power of predictive analytics, the retail industry has not effectively overcome ethical, legal, and social challenges associated with big data. Many companies remain prone to public embarrassment and mistrust.[66] Target is one example.

Being responsible with big data requires moving beyond concerns with privacy. While the consequences of technology cannot always be foreseen, an open debate about what is principally right and wrong is required. A result of the ethical debate should be that business leaders develop a code of conduct for big data analytics.[66]

Impact

In an era when firms in many industries offer comparable products and use similar technologies, business processes are among the last remaining points of differentiation.[67] Personalizing services offered can yield smarter decision-making. Big data in predictive analytics has enabled firms to recognize each customer as a "market of one" and customize decisions accordingly. Successful implementation and execution of big data necessitates top leadership support to promote changes in culture, processes, behaviors, and skills for many employees.[67]

Target Predicts Pregnancy But Faces Public Embarrassment

Identifying pregnant mothers before a child is born allows for more targeted advertisements. Marketers at Target attempted to identify pregnant mothers in their second trimester instead of once the child was born. By assigning every customer a unique code inclusive of purchasing patterns and demographic information, Target was able to generate information and target advertisements on a personalized basis.

Target's ability to use predictive analytics made one customer particularly uncomfortable. Target found out before the father did that his teenage daughter was pregnant because the company sent promotional materials to her. While Target may be compliant with all federal and state laws, the question for Target became how to get information in consumers' hands without appearing as if they are spying on expectant mothers. Target overcame this challenge by mixing random advertisements with pregnancy products. It was believed that as long as the woman is not spooked, she will use Target's coupons.

GLOBAL GUIDANCE

Commissioner of Canada and Privacy Frameworks

Canada is one country tackling the ethical, legal, and social implications of personalized health technology. In particular, the Office of the Privacy Commissioner of Canada (OPC) has recently released three major documents related to personalized technology and its impact on the Privacy Act and the Personal Information Protection and Electronic Documents Act (PIPEDA):

1. **Predictive Analytics:** Presented in 2012, this research report outlines predictive analytics. Since predictive analytics is not a straightforward concept to define or describe, privacy implications can vary depending on its application. Inferences extend beyond retrospective pattern analysis to a result that is more prospective and anticipatory.

2. **Wearable Computing:** This research report provided to the OPC in January 2014 gave them a better understanding of privacy implications associated with wearable computing technologies. Following application of federal privacy laws, the report sets out specific wearable computing design considerations to enhance built-in privacy protections.

3. **Genetic Test Results:** The OPC issued a statement in July 2014 on the use of genetic test results by life and health insurance companies. It noted that no law exists in Canada that addresses this issue. The OPC thus urged the life and health insurance industry to expand its voluntary moratorium to refrain from requesting members to access existing genetic test results until they can be shown to be necessary and effective.

OPC was established in 1977 to advocate for privacy rights of Canadians. The Commissioner's powers include: investigating complaints, conducting audits and pursuing court action under two federal laws (the Privacy Act, which applies to the federal public sector, and PIPEDA, which applies to organizations engaged in commercial activities); publicly reporting on the personal information-handling practices of public and private sector organizations; supporting, undertaking, and publishing research into privacy issues; and promoting public awareness and understanding of privacy issues.

European Union: Adaptation of Existing Directives

A second example of countries addressing ethical, legal, and social challenges associated with personalized health technology is the European Union (EU). In 1995, the European Parliament introduced the EU Data Protection Directive, a regulatory framework to secure the free movement of personal data across national borders of EU member countries. It also introduced a standard of security for personal information when it is stored, transmitted, or processed.[68]

In 2009, the European Commission later launched a review of legal frameworks on data protection. Later in 2010, they released communications that presented revisions to the EU Data Protection Directive. This included a strategy to "protect individuals' data in all policy areas, including law enforcement, while reducing red tape for business and guaranteeing the free circulation of data in the EU."[68] 2012 marked the European Commission unveiling updates to the principles originally included in the 1995 Data Protection Directive. It incorporated two new legislative proposals: a Regulation that sets out a general EU framework for data protection, and a Directive on protecting personal data for the purposes of prevention, detection, investigation or prosecution of criminal offences, and related judicial activities. Key changes include: a single set of rules on data protection; easier access for the individual to access their own data and be able to transfer personal data from one service provider to another more easily; and a right to be forgotten online.[68]

At the global level, the Organisation of Economic Co-operation and Development (OECD) has called for greater transparency on the use of personalized data, rather than on preventing specific uses of the data. They contend that new and internationally recognized codes of conduct should be developed to prevent the abuse of personal data and to ensure that public support takes advantage of new forms of data.[69]

CONCLUSION

The Vitality Institute *Commission on Health Promotion and the Prevention of Chronic Disease in Working-Age Americans* that was released in June 2014 recommended "making markets work for health promotion and prevention." This Report outlined pathways, and short- (2017); medium- (2020); and long- (2025) term measures of success to ensure widespread progress. One short-term measure of success was the development of a framework that proactively addresses ethical, legal, and social issues with respect to data collected by personal prevention technologies. This would be undertaken through a systematic review and extensive public consultation, and adopted across sectors. If you are interested in learning more about this initiative, please contact Gillian Christie at gchristie@thevitalitygroup.com.

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APPENDIX

Summary of Ethical, Legal, and Social Challenges and Solutions of Personalized Health Technology

ETHICAL CHALLENGES, SOLUTIONS, AND GUIDING QUESTIONS			
Challenge	**Description**	**Solution(s)**	**Guiding Questions**
Identification of Personal Health Data	Consumers are uncertain about whether data from personalized health technology can be anonymized.	The best encryption and de-identification technologies are used by companies to anonymize data.	• What safeguards are required for adequate confidence by consumers using personalized health technology? • How can safeguards that ensure the confidence of consumers using personalized health technology be strengthened? • To what extent can and should companies engaged in developing personalized health technology integrate data encryption technologies? Are there any downfalls associated with this?
Role of Human Judgment	Consumers are uncertain whether to base decisions on technology algorithms or human judgment.	Relevant and credible scientific evidence is incorporated into product design algorithms.	• Under what circumstances does the consumer rely on technology algorithms versus human judgment when making health related decisions? Which behavioral economics approaches can improve adherence to recommendations generated by technology algorithms? • What standards should be used to determine that algorithm-based recommendations are “evidence-based”? Who should be responsible for setting these standards? • What stakeholders are necessary for widespread adoption of pre-defined standards or best practices for evidence? What considerations should be included in a set of pre-defined standards or best practices for personalized health technology?
Equitable Representation and Fairness	Consumers differ in the extent to which they benefit from personalized health technology and associated data because of socioeconomic and demographic status.	Developers of technology design and market products to all populations.	• What similarities and differences are there between population segments with regards to personalized health technology? • How should personalized health technology be adapted for different populations based on socioeconomic and demographic variations? • What insights can be derived from data from personalized health technology to benefit all populations and to benefit specific sub-populations?

LEGAL CHALLENGES, SOLUTIONS, AND GUIDING QUESTIONS			
Challenge	**Description**	**Solution(s)**	**Guiding Questions**
Privacy and Consent	Consumers are unclear on how data from personalized health technology is stored, shared, and managed because existing consent models are insufficient.	Opt-in or opt-out solutions are offered by companies so consumers can decide on the distribution and disposal of their data.	• To what extent do varying consent processes impact the uptake of and long-term engagement with personalized health technology? Does the language used to communicate privacy affect the adoption of technology? • Do different consent models such as opt-in or opt-out affect consumers’ willingness to share health data for research or other purposes? • How can users of personalized health technology be better informed on how companies use health data?
Legal Definition of Medical Devices	Personalized health technology often blurs health and medical data, which are regulated differently.	Guidelines clearly distinguish between health and medical data. Technology developers create personalized health technology products understanding the distinction.	• What clarity is required on regulatory guidelines for technology developers to effectively create personalized health technology? • Does a distinction between health and medical data constitute a valid separation? • To what extent do existing laws on distinctions between health and medical data hamper innovation of personalized health technology?

SOCIAL CHALLENGES, SOLUTIONS, AND GUIDING QUESTIONS			
Challenge	**Description**	**Solution(s)**	**Guiding Questions**
Inclusion of Public Voices	Public voices are often not included in discourse and dialogue on personalized health technology and associated data.	Public forums are convened to share knowledge and perspectives on technology design and data analysis. Outputs inform product design and data policies.	• How can the public's views on personalized health technology be apprehended and subsequently incorporated into decisions by companies? • How can trust between companies engaged in the development and application of personalized health technology and the broader public be aligned to support the adoption of personalized health technology? • To what extent can governance models be implemented in companies to include stakeholders' perspectives on personalized health technology and related data uses?
Risk Perceptions	Stakeholders perceive and experience differing risks associated with personalized health technology and related data.	Development of a robust evidence base that demonstrates the effectiveness of personalized health technology and the dissemination of information to applicable stakeholders and to the broader public.	• What are the leading consumer perceptions of risks that need to be considered and addressed to support the adoption of personalized health technology? • What information is needed for consumers to be well informed about personalized health technology and associated data usages? What is the best approach to deliver this information to consumers? • How can the public and the relevant stakeholder groups be informed and involved in identifying, understanding, and eliminating or mitigating risks associated with personalized health technology?
Education and Training			
Messaging of Health Information to Consumers	Interpreting results from personalized health technology may pose challenges for certain users of health devices.	Developers of personalized health technology design devices with end-users in mind.	• What forms of messaging promote sustained uptake of personalized health technology? How can personalized health technology be simplified to encourage better understanding of health results? • How and to what extent can customized messaging encourage the adoption of and long-term engagement with personalized health technology? • How can companies better understand their target populations to design technology with end-users' needs and literacy levels in mind?
Skill Acquisition by Technology Developers	Predictions suggest a shortage of skilled workers based on the amount of data generated by personalized health technology in coming decades.	Academic institutions and companies develop programs in big data and incentivize students to enroll in these programs.	• How can schools, universities, and companies support the skillset of developers of personalized health technology? • What are the most pressing skills needed to effectively analyze and communicate information generated by personalized health technology? • How can gender imbalances be remedied to encourage interest in health technology?
Health Provider Integration with Technology	Many health providers have been apprehensive to prescribe personalized health technology to patients because the efficacy of the technology and the validity of the data have yet to be verified.	Training of health providers on the potential of personalized health technology.	• How can health providers integrate data from personalized health technology into their practices? • What conditions are required for health providers to recommend the use of personalized health technology to patients? • What incentives are required to support health providers in encouraging patients to use personalized health technology?
New Models of Thinking	Analyzing data from personalized health technology requires inductive thinking, while funding programs require demonstrations of deductive thinking.	Training is provided by companies on optimal technology design and data analytics. Funding bodies are encouraged to support inductive and deductive models.	• What skills are needed to conduct research using data from personalized health technology? • How can public funding organizations adapt their funding model to support research involving personalized health technology? • How can public funding bodies foster the development of academic streams to support research that uses inductive and deductive thinking?
Adaptation of Organizational Structures	Organizational structures do not promote effective handling and analysis of data from personalized health technology.	Create leadership positions in technology design and data analytics.	• How can companies maximize the potential of personalized health technology for improving workforce and community health? • How can companies facilitate the sustained use of personalized health technology? • What structures are required for the appropriate management of personal health data within companies?


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