4

Renegotiating the Social Contract for Use of Health Information

Lessons Learned from Newborn Screening and Implications for At-Home Digital Care

Jodyn Platt and Sharon Kardia

1 INTRODUCTION

At-home digital and diagnostic care has expanded in the wake of the COVID-19 pandemic. This change has set off a cascade of secondary effects including new pathways for information flows with an array of direct-to-consumer companies and products, alternative uses of information for health, and a renegotiation of space by shifting when, where, and how we interact with the health care system. This new landscape requires a reexamination of the implicit and explicit social contract between patients, clinicians, and the health delivery system. At-home digital care involves monitoring patients outside of the clinic walls and increased data sharing between traditional care providers and the private companies that build devices. For example, Cue Health offers testing for COVID-19, with the results sent to an app on a personal smartphone and to providers who can provide follow-up treatment.[1] The expansion of at-home digital care raises a number of ethical and policy questions: How is health information shared and with whom? What is the appropriate role of commercial companies? Are people who continue to receive care in clinical settings subject to the new norms of at-home care with respect to remote patient monitoring or data sharing?

Many of these questions have been raised before. Technology and circumstance have often driven change in health care, with policy playing a formative role. The electronic medical record, for example, was rapidly adopted as the American Recovery and Reinvestment Act of 2009 and the Health Information Technology for Economic and Clinical Health Act (HITECH) were passed in response to the 2009 financial crisis in the USA. These acts of legislation led to the investment of billions of dollars in health information infrastructure, and the widespread adoption of the electronic medical record meant that data could be collected, stored, and (ideally)

[1] Cue, *What Is the Cue Health Monitoring System?* (November 20, 2022), https://cuehealth.com/products/.

https://doi.org/10.1017/9781009373234.006 Published online by Cambridge University Press

readily shared to support learning, health care systems,[2] precision health,[3] and comparative effectiveness research.[4] Subsequent policies in the 21st Century Cures Act have continued this investment and commitment to incentivizing interoperability and data sharing.

In clinical research, the Human Genome Project similarly sparked innovation in research information infrastructure that enabled shared data and biospecimens, often in the context of biobanks. The number of large population biobanks housing millions of biological samples linked to individuals' health data has increased over the past decades in response to demand for the scientific and economic efficiencies that multi-use biobanks offer.[5] Technological advances have made it simpler, safer, and more inexpensive to measure vast arrays of molecular data (e.g., genome-wide chips for DNA, RNA, and methylation), as well as to catalogue and store sensitive health information (e.g., barcoding, robotic retrieval, encryption, and firewalls). In the United States, biobank repositories have emerged primarily from large health systems (e.g., Kaiser Permanente, Marshfield Clinic, Veterans Administration) and research institutions (e.g., Vanderbilt University) as natural extensions of the data collection and research already underway therein.[6]

The rapid adoption of new technologies impacts health care culture, care delivery pathways, payment, patient engagement, and, ultimately, the social contract between patients and the systems that care for them. In this chapter, we examine the emergence of the Michigan BioTrust for Health in 2009 as an instance of renegotiation of the social contract between stakeholders in response to new technologies and evolutionary changes in the scientific and health enterprises. Based on prior research on the ethical and policy implications for patients that were part of the legacy system (i.e., those being asked to make the change from old to new systems of care), we review the key findings on attitudes about informed consent, notification, and partnerships with commercial companies, and consider the implications for the governance of at-home digital health care.

II FROM NEWBORN SCREENING TO THE MICHIGAN BIOTRUST FOR HEALTH

With a century-long history of collecting, storing, and analyzing information for surveillance and monitoring community health, public health departments are

[2] Lynn M. Ethredge, A Rapid-Learning Health System, 26 *Health Affairs* W107–18 (2007).

[3] Francis S. Collins et al., A Vision for the Future of Genomics Research, 6934 Nature 422, 835–47 (2003).

[4] Jeremy Sugarman, Ethics and Regulatory Challenges and Opportunities in Patient-Centered Comparative Effectiveness Research, 4 Acad. Med.: J. Ass'n American Med. Colls. 91, 455–57 (2016).

[5] David Altshuler, Mark J. Daly, & Eric S. Lander, Genetic Mapping in Human Disease, 5903 Science 322, 881–88 (2008).

[6] Helen Swede, Carol L. Stone, and Alyssa R. Norwood, National Population-Based Biobanks for Genetic Research, 3 Genetics in Med. 9, 141–49 (2007).

potentially major contributors to the growing number of large population biobanks. For example, the residual newborn screening bloodspots that health departments collect and store are almost fully representative of a population, as they contain blood samples from ~99.9 percent of children born in a particular state. From an epidemiological perspective, this resource is the gold standard for population health assessment and research, given its completeness and lack of ascertainment bias. If made available or even marketed as public health biobanks, these repositories could contribute to robust population health studies when linked to a wide range of public health surveillance databases. And yet, the repurposing of newborn screening bloodspots to include research use challenges the expectations under which they were collected.

In 2009, the state of Michigan endeavored to pursue expanded uses of newborn screening bloodspots by opening the Michigan BioTrust for Health as a steward organization, tasked with navigating the data governance challenges inherent to the large-scale aggregation of medical information. Michigan's BioTrust for Health holds bloodspot cards for over four million children born in the state of Michigan and is one of the largest biobanks in the USA. The BioTrust is run through a nonprofit organization, the Michigan Neonatal Biobank, providing health researchers with access to de-identified samples and information, contingent on scientific review, institutional review board (IRB) approval, and payment. The biobank comprises a retrospective ("legacy") collection of approximately four million bloodspot cards stored from babies born in Michigan between July 1984 and April 2010 – before consent mechanisms were put in place – along with a prospective collection of dried bloodspots added to the biobank since its formal inception in Fall 2010, and included in the research pool only with a written consent.[7]

III CONSUMER PREFERENCES FOR THE USE OF NEWBORN SCREENING BLOODSPOTS AND HEALTH INFORMATION: IMPLICATIONS FOR DIGITAL HEALTH AT HOME

Over the course of approximately five years (2009–2015), we conducted several empirical studies assessing consumer perspectives on the uses of newborn screening bloodspots, including preferences for consent and notification to understand. This work focused on the so-called "legacy collection" of bloodspots held by the Michigan Department of Community Health (MDCH) and collected prior to policies being put in place for obtaining consent for research uses. There were approximately four million people with bloodspots in the BioTrust who fell into this group. We held ten community meetings across the state of Michigan (n = 393),[8] met with

[7] Daniel B. Thiel et al., Community Perspectives on Public Health Biobanking: An Analysis of Community Meetings on the Michigan BioTrust for Health, 2 J. Cmty. Genetics 5, 125–38 (2014).

[8] Id.

college students at 20 campuses (n = 2,010),[9] and conducted an online deliberative jury (n = 67).[10] We also conducted surveys, including three cohorts of the State of the State Survey (n = 2,618) and a simulated dynamic consent process (n = 187).[11] To try to reach a greater proportion of people in Michigan, we conducted a Facebook campaign that reached over 1.8 million people.[12] In this section of the chapter, we draw on the published work in this area, as well as our own reflections on it nearly ten years later, to describe what we learned about three key issues that are likely to shape ethical and policy assessments for at-home digital care: (1) Preferences for consent and notification, (2) relationships with commercial companies, and (3) trust and governance.

A *Consent and Notification*

Our findings with respect to expectations for consent and notification were consistent throughout our work on the BioTrust.[13] We found that a clear majority of people would like some form of notification. With respect to consent, preferences were divided. When offered a choice between providing a one-time "broad consent" that allows for unspecified future uses versus providing consent for each use of bloodspots, we found that about half of the people we interviewed or surveyed prefer a one-time notification and about half want to provide informed consent for specific uses of their information. These findings were consistent with other research on preferences for consent in similar activities, such as large-scale, longitudinal cohort studies.[14] We also found that feelings of respect and trust predicted preferences for broad versus specific consent. Specifically, those who see specific informed consent as important also see consent as an important sign of respect and may have less trust in the health system, while those who do not need to provide consent every time are more trusting of the health system.

[9] J.E. Platt et al., "Born in Michigan? You're in the Biobank": Engaging Population Biobank Participants through Facebook Advertisements, 4 Pub. Health Genomics 16, 145–58 (2013).

[10] Ann Mongoven et al., Negotiating Deliberative Ideals in Theory and Practice: A Case Study in "Hybrid Design," 1 J. Deliberative Democracy 12 (2016).

[11] Michigan State University Institute for Public Policy and Social Research, *State of the State Survey 63 (Fall 2012)* (2012), http://ippsr.msu.edu/soss/; Michigan State University Institute for Public Policy and Social Research, *State of the State Survey 66 (Fall 2013)* (2013), http://ippsr.msu.edu/soss/; Michigan State University Institute for Public Policy and Social Research, *State of the State Survey 67 (Winter 2014)* (2014), http://ippsr.msu.edu/soss/; Daniel B. Thiel et al., Testing an Online, Dynamic Consent Portal for Large Population Biobank Research, 1 Pub. Health Genomics 18, 26–39 (2015).

[12] Platt et al., supra note 9.

[13] Id.; Thiel et al., supra note 12; Tevah Platt et al., Engaging a State: Facebook Comments on a Large Population Biobank, 3 J. Cmty. Genetics 8, 183–97 (2017).

[14] Jodyn Platt et al., Public Preferences Regarding Informed Consent Models for Participation in Population-Based Genomic Research, 16 Genetics in Med. 1, 11–18 (2014).

Expectations for informed consent for the collection of data for research are well-established, while there are none for data used in the context of public health or quality improvement. Notification of data sharing is addressed in the Health Insurance Portability and Accountability Act (HIPAA) regulations, but, in practice, it is a blackbox for consumers. Developing, implementing, and maintaining consent for research is one of the greatest practical barriers in creating public health biobanks or repurposing the use of public health data and biological samples. Operationalizing consent depends on whether proposed research uses already-existing samples and databases, or if the research requires samples and data to be collected prospectively. For newborn screening, it would be impracticable for many states to obtain individual consent given the age of the data or the number of samples. In Michigan, the federal Office of Human Research Protections advised the MDCH that its storage and use of newborn screening bloodspots constituted human subjects research necessitating IRB review. The MDCH IRB stated that new samples would need documentation of consent. The existing four million samples could be issued a waiver of consent based on the impracticability of contacting subjects individually, contingent upon a good-faith effort to inform the public that the repository exists and that there are clear processes for those who choose to withdraw.

Digital health at home faces a similar quagmire of ethical and pragmatic challenges to implementing consent or notification. There are complex contingencies to the social license that purveyors of digital health face; trust in their services depends on the service being provided, their consumer base, the quality of the product, and the risk associated with faulty products.[15] At present, informed consent in digital applications is reduced to the notification of privacy policies. Cue Health, for example, which rapidly specialized in at-home COVID-19 testing and services, addresses the collection, use, sharing, and privacy of data gathered from patients participating in their website, app, and testing services.[16] Updates are posted on the website, meaning consumers need to check for updates rather than being notified directly. Consent is further complicated by the complex set of relationships required to deliver care and the limited responsibilities of any one actor. The Cue Health privacy policy (typical of this type of service and application) notes that they may link to outside websites and services for which they are not responsible. This leaves the responsibility for notification, in essence, up to consumers themselves to follow from one use and user to the next. Our experience with the BioTrust suggests this is not sufficient and that the future of digital health at home would benefit from greater levels of specificity and higher standards for quality of informed consent and notification that account for the full spectrum and scope of data sharing.

[15] Camille Nebeker, John Torous, & Rebecca J. Bartlett Ellis, Building the Case for Actionable Ethics in Digital Health Research Supported by Artificial Intelligence, 17 BMC Med. 1, 137 (2019).

[16] Cue, *Cue® Health Privacy Policy* (November 20, 2022), https://cuehealth.com/about/data-and-privacy/us/privacy-policy/.

https://doi.org/10.1017/9781009373234.006 Published online by Cambridge University Press

B *Comfort with Commercial Companies*

One factor that drove the expanded use of newborn screening bloodspots for research is the potential use of the resource by commercial companies. The use of newborn screening bloodspots for research was hailed as a goldmine.[17] Our research has revealed the desire for greater transparency about partnerships with commercial companies, calling for policies of "disclosure plus" that take extra measures to communicate about the commercial aspects of research.[18] In our qualitative work, we have found that many people are acutely aware of commercial partnerships as a reality of health systems in the United States. Beyond this common recognition, there were two attitudes about this aspect of the biomedical enterprise that often lay in tension with one another. First, there were those who already had a mistrust of the system and considered profit-seeking as evidence that the government and/or the medical community could not be trusted. Second, there were those who saw commercial partnerships as a benefit to society that should be an object of investment. For both groups, demonstrating the benefits of sharing health information, and to whom they accrue, is a way of being accountable to the trust given to the public health system as being good stewards of information. Our experience was consistent with the findings in contemporary literature on the issue of the commercialization of biobanks.[19]

For biobanks and, more recently, health care systems, the consequence of mingling the business aspects of information with expectations of responsible stewardship has been volatile. In managing public health information as a marketable biobank, the relationship of a health department to the public becomes a critical consideration. Accusations of the Texas Department of Health bartering with newborn screening bloodspots still resonate today.[20] The University of Chicago faced litigation after it partnered with Google to analyze health records to develop digital diagnostics.[21] Memorial Sloan Kettering entered a deal with Paige.AI to hold an exclusive license to tissue slides and pathology reports for twenty-five million

[17] Jennifer Couzin-Frankel, Science Gold Mine, Ethical Minefield, 5924 Science 324, 166–68 (2009).

[18] Kayte Spector-Bagdady et al., Encouraging Participation and Transparency in Biobank Research, 8 Health Affairs 37, 1313–20 (2018).

[19] Timothy Caulfield et al., A Review of the Key Issues Associated with the Commercialization of Biobanks, 1 J. Law Biosciences 1, 94–110 (2014); Christine Critchley, Dianne Nicol, & Margaret Otlowski, The Impact of Commercialisation and Genetic Data Sharing Arrangements on Public Trust and the Intention to Participate in Biobank Research, 3 Pub. Health Genomics 18, 160–72 (2015).

[20] Ellen Matloff, Your Baby's Newborn Screening Blood Sample Could Be Used To Convict You Of A Crime. It Just Happened In New Jersey, *Forbes* (November 21, 2022), www.forbes.com/sites/ellenmatloff/2022/09/22/your-babys-newborn-screening-blood-sample-could-be-used-to-convict-you-of-a-crime-it-just-happened-in-new-jersey/.

[21] Daisuke Wakabayashi, Google and the University of Chicago Are Sued Over Data Sharing, *The New York Times* (June 26, 2019), www.nytimes.com/2019/06/26/technology/google-university-chicago-data-sharing-lawsuit.html.

patients, causing an "uproar": Concerns over the commercialization of patient data – even if it is anonymized – renewed interest in the scope and significance of conflicts of interest.[22] Rational people could argue for both sides of each of these cases. The case against the University of Chicago, for example, was eventually dismissed, and Sloan Kettering issued a statement clarifying the relationship between the institution and Paige.AI.[23]

Each of these cases suggests that the risk of navigating in the "gray zone" is, at the minimum, a betrayal of trust as a harbinger of what may come for the companies and health systems moving out of the clinic and laboratory and into the home. Commercial companies are an integral part of the expansion of at-home care that is digital and diagnostic, but a policy of "disclosure plus" for at-home digital health is complicated given the nature of the digital health ecosystem and the lack of clear chains of accountability. Regulatory modernization will need to be a priority as partnerships become more ubiquitous. Novel strategies for licensing data, for example, might be pursued to give consumers greater control over how their health information is used and how profits are shared to promote the use of data as a public good. Novel policy regimes such as this can address the lack of transparency about commercial data use. They can also promote autonomy and respect for persons – the goal of informed consent – in an environment in which informed consent is not feasible or practicable.

C *Trust and Governance*

The use of newborn screening bloodspots for research demanded a shift in the terms of use. Such renegotiations have happened before – and will continue. Experience suggests that such shifts are motivated by a promise to improve public health and health care delivery systems, but they also raise questions of equity and challenge the public's trust in the biomedical enterprise. The seminal case settled by Arizona State University and the Havasupai Indian Tribe underscores the importance of communicating the scope and nature of the use of samples and data to research participants.[24] At issue was the secondary use of data and samples without the permission or knowledge of the participants, a fact that deeply offended tribal leaders, leading not only to a lawsuit, but also to an effective moratorium on medical research in that community and a rift in a partnership that had taken decades to build.[25] A distrust of

[22] Charles Ornstein & Katie Thomas, Sloan Kettering's Cozy Deal with Start-Up Ignites a New Uproar, *The New York Times* (September 20, 2018), www.nytimes.com/2018/09/20/health/memorial-sloan-kettering-cancer-paige-ai.html.

[23] Memorial Sloan Kettering Cancer Center, *Memorial Sloan Kettering and Paige.AI* (November 20, 2022), www.mskcc.org/news-releases/msk-and-paige-ai.

[24] Amy Harmon, Indian Tribe Wins Fight to Limit Research of Its DNA, *The New York Times* (April 21, 2010), www.nytimes.com/2010/04/22/us/22dna.html.

[25] Rex Dalton, When Two Tribes Go to War, 6999 Nature 430, 500–502 (2004).

research and public health continues for many in African American communities, where past public health programs, such as sickle cell screening in the 1970s, were implemented unjustly. A failure to invest in appropriate education about sickle cell anemia resulted in genetic discrimination in the form of discriminating and stigmatizing marriage laws.[26] In our work with communities in Michigan, we often heard skepticism that key stakeholders would be included: For example, "Can I truly trust you? African American people are always last to know. I want involvement and information." We also heard a concern about a slippery slope of hidden data collection and use: "What other lab specimens are being taken without the knowledge of the person being tested? This will end as a trust issue…."[27]

Public health biobanks that use newborn screening information and biospecimens are unique in their inclusivity, and yet the policies and practices that stem from the use of health information may be discriminatory and inequitable. At the same time, the collection of data when it is used for health often faces fewer barriers and is treated as exceptional when compared to other types of information. Public health data is often collected without consent, but as an activity of a public institution makes it accountable as such, expanding the use of data to include research and research institutions demands a new layer of accountability and a demonstration of the trustworthiness of both the stewards (i.e., public health bodies) and the users of health information.

The risk associated with the collection of information without ongoing governance to ensure fair use of the information longitudinally is exemplified by the 2009 *Beleno* v. *Texas Department of State Health Services* case, in which the Department of Health settled by agreeing to destroy their repository of five million bloodspots collected as a part of their newborn screening program.[28] Reporters reviewing nine years-worth of emails at the health department found evidence that the department suffered from a lack of guidance or policies to handle novel requests for biobanked data.[29]

Digital health operates as a market that lacks clear governance and ethical guidelines. Trustworthiness of the enterprise as a whole is a goal, but it is unclear who should be involved in oversight. The limitations to accountability for any one actor leaves consumers with the responsibility of tracking privacy policies from one user to the next. Innovation of traditional governance mechanisms is

[26] Neil A. Holtzman & Michael S. Watson (eds.) Promoting Safe and Effective Genetic Testing in the United States. Task Force on Genetic Testing. National Institutes of Health-Department of Energy (1997), www.genome.gov/10001733/genetic-testing-report.

[27] Daniel B. Thiel et al., Community Perspectives on Public Health Biobanking: An Analysis of Community Meetings on the Michigan BioTrust for Health, 2 J. Cmty. Genetics 5, 125–38 (2014).

[28] Richard Hughes IV, Spreeha Choudhury, & Alaap Shah, Newborn Screening Blood Spot Retention And Reuse: A Clash Of Public Health And Privacy Interests, *Health Affairs Forefront* (November 20, 2022), https://doi.org/10.1377/forefront.20221004.177058.

[29] Emily Ramshaw, DNA Deception, *The Texas Tribune* (February 22, 2010), www.texastribune.org/2010/02/22/dshs-turned-over-hundreds-of-dna-samples-to-feds/.

needed to temper special interests and meaningfully manage conflicts of interest. Obtaining meaningful community awareness would require an investment in outreach and education for large, diverse populations through novel governance structures that engage the range of stakeholders and actors in the digital health ecosystem. This provides an opportunity to apply principles that emphasize equity and inclusion such as "centering at the margins,"[30] that is, including minoritized people and interests.

IV CONCLUSION

The experience of biobanking residual newborn screening bloodspots matters not only because these repositories are vast, valuable, and politically volatile, but also because they are harbingers of the ethical and policy issues that will continue to arise in this new era of integrated health information technology and digital health at home. Learning from the public about data and biospecimen use in the context of the BioTrust suggests that the future of digital health at home would benefit from clear expectations and mechanisms for consent and notification. Those who prefer greater involvement in informed consent also see consent as an important sign of respect and may have less trust in the health system. Furthermore, demonstrating the benefits of sharing health information, and to whom they accrue, is a way of being accountable to the trust given to information systems – be they public or private – as being good stewards of information. Novel strategies for licensing data, for example, might be pursued to give consumers greater control over how their health information is used and how profits are shared to promote the use of data as a public good.

Both newborn screening and at-home digital health care are examples of data-generating activities that create information that is of potential value beyond its original intended use. For newborn screening, public health interests justified the original data collection, while research benefits justified the expanded use of those bloodspots. In the case of at-home digital health care, launching digital modalities involves a wider range of entities, including commercial consumer technology companies and a broad scope for data sharing. Public health biobanking has raised issues for consumers with respect to consent and notification, the role of commercial companies, and sustainable governance. Underlying these issues are questions of how to sufficiently notify consumers about the use of their data, how to negotiate the commercial interests in their data, and how to engage and empower the public as a key stakeholder. The issues raised around newborn screening biobanks presented in this chapter suggest that governance should include policies for access, conflicts of interest, and equity, while investing in outreach and education so that

[30] Chandra L. Ford & Collins O. Airhihenbuwa, The Public Health Critical Race Methodology: Praxis for Antiracism Research, 8 Social Science & Med. 71, 1390–98 (2010).

patients are informed and transparency is both meaningful and maintained. As a rapidly expanding area of health care, digital health at home has an opportunity to create new avenues for access and equity that may be honored first by assessing its guiding principles, and then by creating systems of governance and engagement that improve upon the current system of care.

https://doi.org/10.1017/9781009373234.006 Published online by Cambridge University Press