Automating Health: The Promises and Perils of Biomedical Technologies for Diabetes Management

Nataliya Dubchak Brantly

Dissertation submitted to the faculty of the Virginia Polytechnic Institute and State University in partial fulfillment of the requirements for the degree of

Doctor of Philosophy
In
Science and Technology Studies

Rebecca J. Hester
Janet Abbate,
Monique DuFour
Ashley S. Shew

April 24, 2023
Blacksburg, VA

Keywords: Automation, Diabetes, Risk, SCOT, Disability, STS

Automating Health: The Promises and Perils of Biomedical Technologies for Diabetes Management

Nataliya Dubchak Brantly

ABSTRACT

Type 1 Diabetes (T1D) is an irreversible chronic autoimmune disease that affects millions in the United States. Individuals with T1D rely on biomedical technologies to manage their disability and to stay alive. The increased use of and reliance on automated technologies creates complex entanglements between human bodies, technologies and external factors including digital infrastructures creating what I term as "biotechnological organism." This U.S.-based study focuses on the most advanced biomedical technology used to manage T1D today, the Artificial Pancreas System (APS), to demonstrate how seemingly liberating automated biomedical technologies can entangle, subjugate, and confine those they aim to free. This study features the analysis of two distinct social groups by focusing on their risk discourses and risk reduction efforts. The first group is a community of regulatory experts represented by the American Diabetes Association (ADA). It provides an important perspective grounded in evidence-based science, established norms, and professional standards of medicine, healthcare, and research. The second group is the Do-It-Yourself (DIY) biological community represented by DIY innovators, patients, caregivers, and advocates. It provides a different but equally important perspective shaped by affective dimensions that reflect a phenomenological experience with biomedical technologies. The combination of these two perspectives along with the improved understanding of this disability, the complexity of entanglements between humans and machines, differing approaches to health automation and knowledge production practices elucidates important social, economic, and political issues. The significance of this work lies in its examination of how the improved understanding of health automation efforts can help inform policy and healthcare decisions.

Automating Health: The Promises and Perils of
Biomedical Technologies for Diabetes Management

Nataliya Dubchak Brantly

GENERAL AUDIENCE ABSTRACT

Type 1 Diabetes (T1D) is a chronic condition when the pancreas does not make enough insulin necessary for the body to allow blood glucose (blood sugar) to enter cells and produce energy. This disability affects millions in the United States. Individuals with T1D rely on biomedical technologies to manage their blood glucose levels and need to inject insulin to stay alive. The increased use of and reliance on automated technologies is encouraged to reduce the risks of health complications and reduce the demands of T1D management. But automated biomedical technologies also pose additional burdens related to technological use, maintenance, data overload, decision-making, and risk. This U.S.-based study focuses on the most advanced biomedical technology used to manage T1D today, the Artificial Pancreas System (APS). I coin the term "biotechnological organism" to describe the complex relationship between humans and biomedical technologies. The study demonstrates how seemingly liberating automated biomedical technologies can burden those they aim to free from the demands of disease. This study features the analysis of two distinct groups by focusing on their risk perceptions and risk reduction efforts. The first group is regulatory experts represented by the American Diabetes Association (ADA). This group provides an important perspective grounded in evidence-based science, established norms, and professional standards of medicine, healthcare, and research. The second group is the Do-It-Yourself (DIY) biological community, which includes DIY innovators, patients, caregivers, and advocates. This group provides a different but equally important perspective shaped by the diverse lived experiences of people using biomedical technologies. The improved understanding of differing approaches to health automation and knowledge production practices within these two groups elucidates important social, economic, and political issues. This work aims to understand how health automation efforts can help inform policy and healthcare decisions.

Dedication

I dedicate this dissertation to my husband Aaron, our three sons Andrew, Daniel, and Oliver (the motivation for my research), for their unwavering support, encouragement, and love.

Acknowledgements

I would like to acknowledge and express my sincere gratitude to my in-laws Mark L. Brantly, M.D. and July F. Lew, M.D. for their generosity, support, and pride in my academic and professional accomplishments. I will forever be grateful for their kindness.

I would also like to express my gratitude to my amazing dissertation committee members for their advice, shared time, valuable recommendations, and constructive feedback. A special thank you goes to my dissertation committee chair Dr. Rebecca J. Hester for reviewing my drafts countless times, for understanding, motivating, and advising, for sharing her scholarly acumen as well as for her patience throughout the entire process. Thank you for agreeing to serve on my dissertation committee Dr. Janet Abbate, Dr. Monique DuFour, Dr. Rebecca J. Hester and Dr. Ashley S. Shew.

I would also like to thank STS staff and faculty for their support throughout my Ph.D. adventure.

Table of Contents

List of Abbreviations

ADA – American Diabetes Association
AGP – Ambulatory Glucose Profile
AID System – Automated Insulin Delivery System
APP – Artificial Pancreas Project
APS – Artificial Pancreas System
BG – Blood Glucose
BGM – Blood Glucose Meter
CF – Correction Factor
CGM – Continuous Glucose Monitor
CSII – Continuous Subcutaneous Insulin Infusion
DIY – Do It Yourself
EHR – Electronic Health Record
GMI – Glucose Management Indicator
HbA1c - Hemoglobin A1C or Glycated Hemoglobin
ICR – Insulin Correction Ratio
FDA – U.S. Food and Drug Administration
HPC – Healthcare Provider
JDRF - Juvenile Diabetes Research Foundation
PPC – ADA's Professional Practice Committee
SCOT – Social Construction of Technology
SNS – Strategic National Stockpile
STS – Science and Technologies Studies
TAR – Time Above Range
TBR – Time Below Range
TIR – Time In Range
T1D – Type 1 Diabetes
T2D – Type 2 Diabetes
U.S. – United States of America
WHO – World Health Organization
%CV – Coefficient of Variability

Chapter 1. Automating Health: Technological Change and the Emergence of the Artificial Pancreas System (APS).

Introduction

In late 2019, the New York Times reported the story of John, a ten-year-old who experienced a life-threatening incident due to the malfunction of his diabetes monitor.[1] John has type 1 diabetes and relies on Dexcom, a continuous blood glucose monitor (CGM), to monitor his health and make decisions regarding insulin injections and food consumption. At night, when John goes to sleep, his parents rely on Dexcom and its share application for alerts of blood glucose deviations on their phones. With the help of such alerts, John's parents can administer insulin or feed John carbohydrates, such as juice or candy, to help balance his blood glucose. His parents also rely on Dexcom to sleep in peace, knowing that if there is an issue, Dexcom will alert them.

At around midnight on Friday after Thanksgiving 2019, Dexcom suffered a "major server outage"[2] which left John's parents, and thousands like them, without the critical information they rely on daily, "leaving them unaware of potentially dangerous problems."[3] In the morning John's parents woke up to find John in distress, experiencing hypoglycemia, critically low blood glucose, which can lead to a diabetic coma and death. This dangerous situation was immediately treated by John's parents. Individuals with

[1] O'Connor, Anahad. 2019. In Weekend Outage, Diabetes Monitors Fail to Send Crucial Alerts. The New York Times. https://www.nytimes.com/2019/12/02/well/live/Dexcom-G6-diabetes-monitor-outage.html.
[2] Pedersen, Amanda. 2019. Dexcom Fesses Up About Its Communication Mess Up. Medical Device and Diagnostic Industry (MD+DI). https://www.mddionline.com/diabetes/dexcom-fesses-about-its-communication-mess.
[3] Farr, Christina. 2019. Dexcom glitch kept parents of children with diabetes in the dark over their conditions this weekend. CNBC. https://www.cnbc.com/2019/12/02/dexcom-tech-went-down-keeping-diabetes-patients-from-getting-readings.html.

type 1 diabetes (T1D), just like John, require intensive monitoring 24 hours a day. Nighttime over the Thanksgiving holiday weekend, during the period when people travel, visit family, and consume holiday foods, might have already required greater vigilance without technological malfunction.[4] While the Dexcom service was fully restored by the following Monday, it left many questioning Dexcom and biomedical technologies like it.

Due to its promise to reduce the burden of disease management, many patients, young and old, describe Dexcom as "life-changing," "freeing," and a "God-send,"[5] as it offers users "a huge sense of security and peace of mind,"[6] and helps reduce the risks of disease. It relieves the burden of multiple daily finger pricks with a needle to draw blood to check blood glucose levels including overnight. Nevertheless, the 2019 Dexcom outage emphasized the need for a backup plan as biomedical technologies, like CGM, might offer a false sense of freedom and, thus, cannot be fully trusted. As John's case showed, biomedical technologies are not immune to failure. While they decrease some burdens of daily disease management, they increase the technological burden people experience, and they entangle human bodies with outside systems upon which they become dependent.

Biomedical technologies like Dexcom reduce some of the risks of T1D for patients' health, but they also introduce new ones. While the company actively promotes

[4] Mukherjee, Sy. 2019. Parents of Children With Diabetes Are Furious Following the Blackout of a Major Blood Sugar Monitoring Software. https://fortune.com/2019/12/02/dexcom-outage-blackout-diabetes-patients-blood-sugar-monitor/.

[5] Parmar, Arundhati. 2019. Dexcom's IT outage shows fabulous device maker floundering with patient communication. MedCityNews. https://medcitynews.com/2019/12/dexcoms-it-outage-shows-fabulous-device-maker-floundering-with-patient-communication/.

[6] Salomon, Sheryl Huggins. 2020. When CGM Service Fails: 5 Tips for a Creating a Backup Plan. Everyday Health. https://www.everydayhealth.com/type-1-diabetes/dexcom-cgm-app-outage-what-to-do-if-service-fails/.

that Dexcom makes finger pricks a thing of the past,[7] it also clearly indicates instances where inaccuracies occur in Dexcom's outputs. Some of these inaccuracies occur in the first 24 hours of newly inserted sensors or when blood glucose (BG) is quickly changing (dropping or rising) or when something is pressing on the CGM sensor, such as one's body while sleeping at night,[8] additionally there are no BG readings for the first two hours of new sensor warmup or when sensor experiences performance failure.[9] In all these instances when Dexcom is not working or is not working properly, finger pricks to draw blood are required for BG checking with an alternative method. Therefore, technological promises do not always match the outcomes of the technologies in use.

In the management of T1D biomedical technologies play a central role. Patients rely on them daily, yet they rarely stop to consider in what ways these technologies entangle them, influencing their thoughts and actions. While the 2019 Dexcom CGM outage was the biggest outage to date, it was also a complete surprise not only to users and caregivers but also to the Dexcom company itself.[10] The intimate nature of biomedical technologies, such as Dexcom CGM attached to John's body, is contrasted with the digital infrastructure entanglements and hostile networks such as the internet, the power grid, corporate servers, and the general infrastructure of medical and technological procurement. As human lives become more interconnected and as different technologies

[7] Dexcom. 2018. Dexcom CGM — For People with Diabetes, Finally, Dexcom Makes Fingersticks a Thing of the Past. https://www.youtube.com/watch?v=A1NU5ivC5Og.
[8] Dexcom. 2022. Is my Dexcom sensor accurate? https://www.dexcom.com/faqs/is-my-dexcom-sensor-accurate.
[9] Dexcom. 2022. What can I do if my Dexcom G6 sensor fails during the 2-hour warmup period? https://www.dexcom.com/faqs/what-to-do-if-dexcom-g6-sensor-fails-during-warmup.
[10] Farr, Christina. 2019. Dexcom says the outage that kept diabetes patients from tracking blood sugar was a 'complete surprise'. CNBC. https://www.cnbc.com/2019/12/03/dexcom-cto-our-biggest-ever-glitch-was-a-big-surprise.html.

integrate into our lives in more ways than we perceive, the likelihood of experiencing additional "surprises" with biomedical technologies increases.

This work focuses on a single health condition, type 1 diabetes, a condition inseparable from its therapeutic tools, and a single biomedical technology, the Artificial Pancreas System (APS), as the most advanced technology available today to manage T1D, to provide a better understanding of the entanglements implicating human bodies that are reliant on biomedical technologies. This research applies a self-coined term "biotechnological organism" to reflect on the integration of individuals and biomedical technologies where a human body exists in a symbiotic relationship with technology, or a system of technologies. The biotechnological organism as a theoretical concept allows for the analysis of the complexity around T1D care and the conceptualization of health automation for individuals living with a chronic health condition. This work argues that in T1D care human lives are more entangled than commonly recognized with important implications for all stakeholders, from individual patients, health and medical service providers to policymakers, healthcare systems, and commercial entities. The purpose of this study, therefore, is not only to demystify biomedical technology but also to explain how the seemingly liberating nature of technology can subjugate and confine those it is aimed to free.

This analysis features two distinct but related groups to assess how they view health automation and how they perceive biotechnological organisms in ontological and epistemological ways. The first group is a community of regulatory experts represented by the American Diabetes Association (ADA). This group provides an important perspective grounded in evidence-based science, normative base, and professional

standards upheld within the fields of medicine, healthcare, and research. The second group is a community of Do-It-Yourself (DIY) innovators represented by patients, caregivers, and advocates who work together to make open-source and DIY solutions for individuals with T1D without waiting for commercial entities to decide to innovate. This group provides a different but equally important perspective shaped by affective dimensions that reflect phenomenological experience with biomedical technologies. Paying particular attention to the concept of risk and risk reduction efforts, this study aims to understand the logics of health automation within these two groups in relation to the biotechnological organism as well as the risks of automating biotechnological organisms. This analysis demonstrates how biomedical technologies, as exemplified by the APS, are socially constructed and how the knowledge production practices within these groups can provide new understandings of health practices, especially in relation to biotechnological organisms.

T1D is not simply a biological reality centered around a single faulty organ, namely the pancreas, or the human body not working as intended. T1D is a complex health condition with political, economic, and social dimensions. As this research demonstrates, life with T1D does not exist without the use of biomedical technologies. Therefore, T1D and its therapeutic technologies are inextricable and exist at the tension of these dimensions and realities. This study offers a different perspective than those celebrating novelty, innovation, and technological progression. Rather, it aims to elucidate a deeper understanding of the social, economic, and political issues related to biotechnological organisms and efforts of health automation. The idea of a

biotechnological organism is particularly important in this understanding due to the interconnected nature of biomedical technologies and human bodies.

Individuals with T1D are encouraged to use and depend on increasingly complex biomedical technologies for insulin injection and blood glucose (BG) monitoring. Thus, it is important to understand the consequences of this dependence, especially considering the high level of automation of these technologies. This work explores the tensions that arise when people become reliant on biomedical technologies that are touted as neutral, healthy, and helpful. The significance of this study lies not only in the understanding of what a biotechnological organism is but also in the examination of how the knowledge of entanglements of bodies and technologies can help inform policy, healthcare, and innovation decisions.

Diabetes today is a significant public health issue, extensively studied and discussed. Studies of T1D and disease management strategies pertaining to the improvement of clinical outcomes and technological efficacy rarely address the everyday challenges faced by patients and the risks that arise from the nonstop use of biomedical technologies, as well as how these challenges and risks influence one's life, one's health, one's relationships and the society at large. These studies do not address how biomedical devices modify users' bodies and how they are perceived within society. Nor do they address how users impact, interact with, and modify technologies for their own needs. Contemporary perceptions of T1D lead to misunderstandings, not only because of the differences between diabetes types but also because the perception of automation and technological solutions points overwhelmingly toward a condition considered resolved. The majority of the public believes diabetes has been cured or "at least tamed" with the

utilization of biomedical technologies, but health statistics globally present a very different picture.[11] As John's story above highlights, this is not the case. In addition to not being resolved, the complicated relationships of patients, technologies, and outside factors create numerous tensions unseen or overlooked by the general population.

This study interrogates the ways in which the APS promises to mitigate the risks of living with a chronic condition and shows where they might fail to live up to that promise. It asks who contributes to the knowledge production that informs automated technologies for diabetes management and how. While the efforts in the automation of health are generative, they do not develop in isolation within the scientific community. Knowledge production is an iterative process rooted in the work of scientists, physicians, philosophers, policymakers, patients, and others. The investigation of how the APS makes T1D a visible condition and how it might create new burdens, new restrictions, and additional concerns also demonstrates new forms of freedom, new ways of practicing health, and new communities built around the development and promotion of the APS. This research applies the social construction of technology (SCOT) theory to study the relationship between the APS, an emerging and still evolving technology at the leading edge of diabetes management, and society.

This study of health automation is significant not only because it pertains to diabetes, a condition of national and global importance to the lives and livelihoods of a vast number of individuals, but also because it focuses on the associated biomedical technologies that have a major economic impact on the fields of medicine, biomedical research and by extension the U.S. economy. Furthermore, the focus on biotechnological

[11] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.

organisms allows for a close cross-disciplinary examination of complex entanglements within health automation that extend beyond technological advances, progress, and technological determinism.

The primary audience for this dissertation is first and foremost scholars and students within the field of science and technology studies (STS). Additionally, this research is aimed at public health and medical professionals, policymakers and regulatory experts involved in the regulation of biomedical technologies. This work contributes to STS understandings of technology by addressing biomedical technology as knowledge which highlights the relationship between science, technology, and medicine. It adds to the studies of the social construction of technology theory (SCOT) with the application of SCOT to the study of the Artificial Pancreas System and society. Finally, this research adds to the studies of risk and expertise in contemporary society by examining the relationship between risk and expertise.

The Drive for Diabetes Automation

In 2006 the United Nations General Assembly recognized diabetes as "a chronic, debilitating, and costly disease associated with severe complications, which poses severe risks for families, Member States, and the entire world."[12] The only and best available solution offered to patients today is through the utilization of biomedical technologies to help individuals improve their blood health, reduce the possibility of extreme blood glucose fluctuations and reduce the risk of complications. Today, chronic disease care, as well as the field of medicine at large, have become so intertwined with biomedical

[12] United Nations General Assembly. 2006. Resolution Adopted by the General Assembly – 61/225. World Diabetes Day, New York: US General Assembly.

technology that it is difficult to imagine the non-technological practice of medicine. On the surface, progress toward the improved treatment and care of patients through the use of biomedical technologies is an inherently forward-leaning endeavor. Yet, this progress is built on a historical record not only of achievement but also of failure,[13] on tensions and transformations influenced by all those involved in the process.

The efforts of health automation support enhanced efficiency in various aspects of health and medical services through the use of distinct biomedical technologies, including software and hardware products. Some of these technologies are used solely by medical providers and some by patients, caregivers, and other stakeholders. Biomedical technologies allow services such as patient portals for the exchange of health information,[14] telemedicine or telehealth for remote health care,[15] electronic health record (EHR) systems for the digitized patient chart for improved provider decision-making, and automated, as well as streamlined, provider workflow.[16] Numerous biomedical technologies are used by patients on a daily basis. Some are integral to supporting human life and can cause severe harm if used improperly or fail to function as intended. For instance, insulin pumps for subcutaneous delivery of insulin, pacemakers for heart

---

[13] Furdell, Elizabeth Lane. 2009. Fatal Thirst: Diabetes in Britain until Insulin, (Leiden, The Netherlands: Brill, 2009) Stretton, Antony O. W. The First Sequence: Fred Sanger and Insulin. Genetics. 2002. 162 (2): 527-532 https://www.genetics.org/content/162/2/527.
Feudtner, Chris. 1995. The Want of Control: Ideas, Innovations, and Ideals in the Modern Management of Diabetes Mellitus. Bulletin of the History of Medicine 69, no. 1 (1995): 66-90. http://www.jstor.org.ezproxy.lib.vt.edu/stable/44444508.
Bliss, Michael. 1982. The Discovery of Insulin. Chicago: University of Chicago Press.
Starr, Paul. 1982. The Social Transformation of American Medicine. New York: Basic Books.
[14] HealthIT.gov. 2019. What is a patient portal? The Office of the National Coordinator for Health Information Technology (ONC). Accessed 12.03.22. https://www.healthit.gov/faq/what-patient-portal.
[15] HealthIT.gov. 2019. What is telehealth? How is telehealth different from telemedicine? The Office of the National Coordinator for Health Information Technology (ONC). Accessed 12.03.22. https://www.healthit.gov/faq/what-telehealth-how-telehealth-different-telemedicine.
[16] HealthIT.gov. 2019. Frequently Asked Questions: Electronic Health Record. The Office of the National Coordinator for Health Information Technology (ONC). Accessed 12.03.22. https://www.healthit.gov/faq/what-electronic-health-record-ehr.

arrhythmia, vascular stents for peripheral arterial disease (PAD), and Cochlear implants for those with severe hearing loss are all Class III medical devices considered to be high-risk technologies because they are crucial to maintaining health and sustaining life.[17]

The drive for automation in T1D management can be seen as a result of the failure of other methods, such as organ transplantation, stem cell research, insulin-producing cell injections, and implantable patches that require immunosuppression. Risk considerations are at the core of solution-seeking for diabetes. Alternative methods of approaching T1D did not gain mainstream acceptance due to higher risk concerns compared to the requirements of T1D management using the APS or other biomedical technologies. The risk continues to be a primary consideration in the quest for T1D automation as well as the primary guiding principle of therapeutic decisions in diabetes care.

The risk appears to be a constant in the studies of health and biomedical technologies. This is evident in historical studies of diabetes that highlight the risks associated with the human body and the environment,[18] as well as The Nobel Prize awards marking the achievements of great scientists who worked to mitigate risks through the use of biomedical technologies.[19] Additionally, individuals with T1D are

---

[17] Brantly, Nataliya D. 2021. Homefront to Battlefield: Why the U.S. Military Should Care About Biomedical Cybersecurity. The Cyber Defense Review 6, no. 2 (2021): 93–110. https://www.jstor.org/stable/27021378.

[18] Fletcher, James. 1745. A mechanical enquiry into the nature, causes, seat, and cure of the diabetes. With an explication of the most remarkable symptoms. Oxford. Eighteenth Century Collections Online. Gale. Virginia Tech.
Girdlestone, Thomas. A case of diabetes, with an historical sketch of that disease. By Thomas Girdlestone, M.D. Yarmouth, 1799. Eighteenth Century Collections Online. Gale. Virginia Tech.

[19] Banting, Frederick G. 1923. The Nobel Prize in Physiology of Medicine in 1923 lecture - for discovery of insulin. https://www.nobelprize.org/prizes/medicine/1923/banting/lecture/.
Macleod, John. 1923. The Nobel Prize in Physiology of Medicine in 1923 lecture. John Macleod - for discovery of insulin. https://www.nobelprize.org/prizes/medicine/1923/macleod/lecture/.

considered to be members of an "at-risk population," immunocompromised, with increased susceptibility to other diseases and health complications. Their "at-risk" status necessitates stringent disease control. Patients' expectations and their desire for control over their condition are influenced by regulatory expert opinions, norms, and the promotion of biomedical technologies. Health automation allows for new ways to intervene in people's lives and manage disease in the name of risk reduction, health, safety, and security. New practices of patient and population control fuel the drive for more automation and further expand the purview of regulatory experts and biomedical technologies toward preventative interventions to keep individuals free from future risks. Therefore, the drive for diabetes automation is risk-based and entails explicit as well as concealed levers of control of disease, individual patients, populations, and their future.

The matter of diabetes automation falls at the crossroads of commercial interest, regulatory authorities, professional priorities of health and medical professionals, and the needs of those with T1D. The U.S. Food and Drug Administration (FDA) is the primary regulatory body for biomedical technologies in the United States. Yet, there are numerous unregulated, Do-It-Yourself (DIY), and open-source biomedical technologies created, modified, and used by patients today. This is particularly evident within type 1 diabetes care with a growing and thriving community of DIY innovators, users, and advocates. These unregulated technologies seem to exist on a different plane, outside of policy and regulatory controls, discouraged, frowned upon, and unwelcome by regulatory experts,[20]

KAROLINSKA INSTITUTET. 1977. The Nobel Prize in Physiology or Medicine 1977 - Roger Guillemin, Andrew V. Schally and Rosalyn Yalow. https://www.nobelprize.org/prizes/medicine/1977/press-release/.

[20] FDA. 2019. FDA Warns Against the Use of Unauthorized Devices for Diabetes Management. FDA News Release. https://www.fda.gov/news-events/press-announcements/fda-warns-against-use-unauthorized-devices-diabetes-management.

yet still developed, used, promoted, and supported by DIY innovators. Efforts toward health automation within and by the patient population indicate a level of dissatisfaction with available FDA-approved regulated technologies and a discrepancy between the provided healthcare and that desired by those with T1D.

This divergence within the regulatory environment as well as within the healthcare provision is creating an important outcome: the disconnect between efforts of health automation and contemporary approaches to healthcare. On one side are highly regulated and corporate biomedical technologies championed and celebrated by the regulatory expert community with authority, expertise, and professionalization of medical and health service providers. On the other side are the unregulated biomedical technologies, represented by DIY and open-source technologies, focused on individuals' unaddressed needs and reflect dissatisfaction with regulated biomedical technologies. These two sides represent different approaches to addressing the issue of diabetes through health automation. They line up with the two groups examined in this research with the regulatory expert community primarily supporting regulated biomedical technologies and the DIY community innovating and sharing technologies that are unregulated. Since the drive for diabetes automation, both regulated and unregulated, originates within these two communities, they require closer inspection.

Despite the proliferation of biomedical technologies within the practice of medicine, within the health services provision, and among patients, health automation is not included as a consideration within the leading public health models and approaches such as One Health and Whole Health. One Health approach promotes "achieving optimal health outcomes recognizing the interconnection between people, animals, plants,

and their shared environment" in a collaborative, multisectoral, and transdisciplinary way across local, regional, national, and global levels.[21] This approach does not consider the interconnection of technologies and people, the harm that biomedical technologies can cause, and the risks they introduce to patient well-being, and their mental and physical health. The Whole Health approach is a relatively new initiative centered on what matters to the patient, not what is the matter with the patient.[22] This approach focuses on the patient and their purpose, on risk identification and its minimization. It promotes health optimization, skills building, and partnership within the healthcare team. Yet, this approach does not consider biomedical technologies and their impact on a person's health, especially for chronic disease management.

The drive for diabetes automation is evident through the development and availability of complex biomedical technologies and the demand as well as the reliance of individuals with T1D on such technologies. Both of the above health approaches do not directly incorporate the whole dimension of health automation and how it impacts our "shared environment," how it changes the provision of health care, and how it impacts patients' health, well-being, and risk considerations. How can contemporary efforts to reconfigure the healthcare system, to create more effective, equitable, and accessible health services, as well as efforts to address the growing issue of diabetes, be successful while health automation is omitted as a crucial consideration in these efforts? Therefore, it is important to examine biotechnological organisms not only to demonstrate the dependency of patients on technologies but also to highlight that public health models

[21] CDC. 2022. One Health Basics. Centers for Disease Control and Prevention. Accessed 12.03.22. https://www.cdc.gov/onehealth/basics/index.html.
[22] VA. 2022. Whole Health. U.S. Department of Veteran's Affairs. Accessed 12.03.22. https://www.va.gov/WHOLEHEALTH/veteran-resources/whole-health-basics.asp.

that ignore biotechnological organisms also ignore the consequences of technological entanglements.

T1D is considered to be an invisible disease as the diagnosis does not carry with it any visible physical signs of disease or disability. T1D is not a new health condition. As the below brief historical review indicates the human population has been wrestling with it for centuries. Today biomedical technologies used to manage T1D seem to be integral to the modern understanding of T1D, yet they are omitted from the prominent healthcare approaches. Simply the knowledge of one's blood glucose places individuals in a biological category of diabetes. This categorization and everything that it entails is not possible without the use of biomedical technologies and the data outputs they provide. Biotechnological organisms are categorized, optimized, standardized, monitored, and controlled within the healthcare system that does not seem to recognize or acknowledge them. How can the healthcare system care for individuals reliant on biomedical technologies if it does not even acknowledge them for what they are, namely biotechnological organisms?

Efforts of T1D automation exist at the tension of political, economic, and social dimensions. The political dimension is shaped by norms, standards, and regulatory expert assumptions guiding legal, policy, and regulatory implications of T1D and biomedical technologies. It is reductive in nature as it reduces not only what is perceived as risky, but also what success looks like in T1D management. The economic dimension is guided by profit-seeking efforts, commercialization, commodification, affordability, and other economic forces. The social dimension is concerned with accessibility, affordability, equality, the nuanced nature of the disease, and the diversity of needs among those with

T1D. It considers both real and intangible risks of living with a chronic disease and their influence on the welfare of the individual and the population. It is important to include these dimensions when analyzing biotechnological organisms and the complex entanglements around diabetes automation situated at the cross-section of two distinct communities.

False Promise of Technological Miracle

The groundbreaking cure for T1D as well as the complete prevention of the disease onset has remained at the ever-moving target of being "on the verge of being achieved since the 1980s."[23] Since the discovery of insulin, the treatment of T1D and associated complications today have been dominated by powerful drug and technology companies. These entities are in a race for the development of new drugs and technologies for their growing population of consumers. While a number of drugs have been developed to reduce the risk of complications and further development of disease, populations today are sicker than ever. There is a growing number of individuals with diabetes, including T1D, with worsening health outcomes. All the modern biomedical technologies and modern clinical approaches are not sufficient to effectively address the complexity of the health condition. Therefore, there is a need for research like this one that extends beyond the clinical setting or the laboratory bench.

The Artificial Pancreas System automates basal (background) insulin delivery in response to the blood glucose data reported by the CGM. It consists of four main components. The first component is a CGM which provides blood glucose (BG) readings

[23] Tattersall, Robert. 2009. Diabetes : The Biography. Biographies of Disease. Oxford: Oxford University Press.

every five minutes. The second is an insulin pump that administers insulin to its user subcutaneously. The third is a computational component that automates insulin delivery in response to BG data. The fourth is the user, the patient, or the caregiver. The APS is still in the process of development, improvement, and integration of additional functionality to not only reduce its size or make it integrated into a single wearable device but also to make it more closely aligned with the role the actual human pancreas plays in the regulation of blood glucose. The value of such biomedical technologies arises from automation, and the associated sense of stability, risk reduction, and relief from the demand for constant human attention and care which is substituted with digital outputs. It is important to note that a failure of one component within the system is a failure of the entire system. Thus, when the CGM ceases to function or provides inaccurate outputs, the APS has no way to automatically administer the correct amount of insulin. APS users rely on the continuous functionality of all components. Lost functionality even for a part of the day might have significant negative repercussions.

The Juvenile Diabetes Research Foundation (JDRF), a nonprofit organization supporting T1D research and advocacy, has invested over $116 million USD in the past decade in artificial pancreas research projects.[24] Biomedical technologies like the APS have medically and technologically altered T1D "by tapping into people's fears, desires and convictions to embrace technologies as best solutions to people's problems" in what Feudtner refers to as the technological ethos.[25] Likewise, the majority of scientific studies evaluating T1D treatment options, biomedical technology efficacy, or new approaches to

[24] JDRF. 2016. JDRF Celebrates FDA Approval of Artificial Pancreas System. https://www.jdrf.org/press-releases/jdrf-celebrates-fda-approval-of-artificial-pancreas-system/.
[25] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.

patient care, review a very narrow aspect of one's health. Yet, contemporary society embraces technological solutions like the APS with a misleading understanding that the health condition has been "solved" requiring no further attention or effort.

Regulatory experts promote automated diabetes management technologies to patients with the promise of relief from the burdens of disease, the promise of increased lifespan longevity, and the promise of freedom through automation. These promises obscure the risks associated with automation and promote absolute trust in technological solutions. Scientific studies of T1D, investigations of T1D causes, prevention methods, or suggestions of new treatments, primarily have a limiting view of the disease focusing on the genetic characteristics, molecular biology, or technological components. Interconnectivity and increases in the use of biomedical devices create new and alternative challenges including the potential for malicious actor manipulations of life-sustaining technologies that might affect users' health. This is evidenced in cybersecurity risk assessments of pacemakers, and biomedical devices used for irregular heart rhythm management.[26] Researchers at the 2012 Black Hat security conference also demonstrated hacking vulnerabilities in pacemakers by delivering a deadly 830-volt pacemaker shock at a distance of 50 feet using a laptop computer.[27] Likewise, insulin pumps were found to have cybersecurity risks with vulnerabilities for unauthorized access, possibilities for device disabling, or delivery of a modified amount of insulin including the delivery of a lethal dose of the medication.[28] There is no way back from today's high-tech world.

---

[26] Daniel Clery. 2015. Could your pacemaker be hackable?" Science, 347, no. 6221, (AAAS, 2015): 499, https://science.science- mag.org/content/sci/347/6221/499.full.pdf.

[27] Mandeep Khera. 2016. Think Like a Hacker. Journal of Diabetes Science and Technology, 11, no. 2, (2016): 207-212, doi:10.1177/1932296816677576.

[28] David Klonoff. 2015. Cybersecurity for Connected Diabetes Devices. Journal of Diabetes Science and Technology, 9, no. 5 (2015): 1143-1147, https://doi.org/10.1177/1932296815583334.

Further automation will create more technological intrusions into the patients' lives. In such cases, the risk of technological failures can lead to inaccurate outputs, incorrect dosing, and potentially grave consequences.

The rest of this chapter will address changing understandings of type 1 diabetes and the biomedical technologies used to manage it. This brief historical overview accounts for the technological change leading up to the emergence of Artificial Pancreas Systems. The analysis of risk and risk mitigation approaches can help in explaining technological change over time and among different groups in contemporary society and can challenge narratives of technological progress. This work argues that looking into the history of T1D and juxtaposing it with today's disease-management technologies can be the means to a greater understanding of the purpose, meaning, and impact of automated technologies on the human condition.

Type 1 Diabetes Today and Throughout History

The first mention of diabetes is believed to have originated in 1552 B.C.[29] in the Papyrus Ebers, the earliest medical record in existence,[30] with a description of a polyuric syndrome believed to be diabetes.[31] Frequent urination, excessive thirst, and rapid weight loss are some of the primary symptoms of diabetes noted in historical medical texts. The sweetness of one's urine, due to the excess of glucose in the body, was used as a

---

Brantly, Nataliya D. 2021. Homefront to Battlefield: Why the U.S. Military Should Care About Biomedical Cybersecurity. The Cyber Defense Review 6, no. 2 (2021): 93–110. https://www.jstor.org/stable/27021378.

[29] Kilgour, Frederick G. 1993. Locating Information in an Egyptian Text of the 17th Century B.C. Journal of the American Society for Information Science 44 (5): 292–97. doi:10.1002/(SICI)1097-4571(199306)44:5<292::AID-ASI4>3.0.CO;2-V.

[30] Bolton, H Carrington. 1884. Papyrus Ebers, the Earliest Medical Work Extant. Weekly Drug News Press, 1–19. https://hdl.handle.net/2027/uiug.30112000670197.

[31] Ahmed, Awad M. 2007. History of Diabetes Mellitus. Saudi Medical Journal 23 (4): 373–78.

diagnostic measure[32] and a feature that allowed one to distinguish and classify diabetes as different from other conditions with similar symptoms. Since prior beliefs about the human body, health, and disease were driven by the prevailing medical and religious theories of the time,[33] the nature and treatment of diabetes were not well understood before 1889 when the pancreas was identified as the origin of diabetes.[34] T1D, as a separate condition, first became known only in the early 18th century, which also brought the recognition that only patients having a combination of all symptoms attributed to the disease should be considered as having it.[35] The condition was further established by the use of chemistry as a diagnostic tool in the late 18th century followed by the emergence of endocrinology, the field of study and practice concerned with endocrine glands and hormones, as a formal discipline.[36]

Throughout history doctors "developed imaginative regimens and therapies for their patients to follow" in an effort to help their patients deal with this fatal disease.[37] Diverse types of potions, dietary manipulations, and regimens were tried to prolong the patient's existence. Allen F.M. and Joslin E.P. were considered the most prominent specialists in T1D in the early 20th century. They believed that diets based on "repeated fasting and prolonged undernourishment" (severe calorie restriction known as starvation

---

[32] Lakhtakia, Ritu. 2013. The History of Diabetes Mellitus. Sultan Qaboos University Medical Journal 13 (3): 368–70.

[33] Fletcher, James. A mechanical enquiry into the nature, causes, seat, and cure of the diabetes. With an explication of the most remarkable symptoms. Oxford, 1745. Eighteenth Century Collections Online. Gale. Virginia Tech. 8 Oct. 2019

[34] Karamanou M, Protogerou A, Tsoucalas G, Androutsos G, Poulakou-Rebelakou E. 2016. Milestones in the history of diabetes mellitus: The main contributors. World Journal of Diabetes. 2016;7(1):1–7. doi:10.4239/wjd.v7.i1.1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4707300/.

[35] Girdlestone, Thomas. 1799. A case of diabetes, with an historical sketch of that disease. By Thomas Girdlestone, M.D. Yarmouth. Eighteenth Century Collections Online. Gale. Virginia Tech. 8 Oct. 2019

[36] Ahmed, Awad M. 2007. History of Diabetes Mellitus." Saudi Medical Journal 23 (4): 373–78.

[37] Furdell, Elizabeth Lane. 2009. Fatal Thirst: Diabetes in Britain until Insulin. Leiden The Netherlands: Brill.

diets) was “the most advanced treatment” of T1D and led to symptom relief and the “maximum extension of life.”[38] Every new improvement for patients, in this case slightly prolonged lifespan, came with its own concerns. Restrictive diets introduced new issues such as death from starvation and stunted growth in children.[39] With strict dietary restrictions, patients could live about 4 years after the diagnosis with some patients reporting living up to 14 years.[40] However, every patient’s story ended the same regardless of the regimen - suffering, complications, and death.[41]

Despite the attention of medical professionals to diabetes throughout history, it was not until 1921 that more modern medical treatments were achieved and provided long-term life-sustaining solutions to those with T1D. The discovery of insulin in 1921 was a result of groundbreaking medical research which forever changed the treatment of diabetes, contributed to a better understanding of the disease, and saved millions of lives. The discovery of insulin was a pivotal point in the history of T1D and created a visible dividing line in the perception of the disease before and after insulin. Nevertheless, with the discovery and use of insulin, new complications came to light. As individuals started living longer with the disease, they started developing peripheral artery disease leading to amputations, cardiovascular disease, nerve damage, poor wound healing, and vision and hearing damage. These complications are a result of high blood glucose (hyperglycemia) over a period of time. Too much insulin in the body can lead to low blood glucose (hypoglycemia) causing confusion, loss of coordination, impaired vision, diabetic coma,

[38] Mazur A. 2011. Why were "starvation diets" promoted for diabetes in the pre-insulin period? Nutrition Journal 10:23. doi:10.1186/1475-2891-10-23 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3062586/.
[39] Ibid.
[40] Brostoff, J.M., Keen, H. & Brostoff, J. 2007. A diabetic life before and after the insulin era. Diabetologia. 50: 1351. https://doi.org/10.1007/s00125-007-0641-0.
[41] Ibid.

and death as a result of an insufficient supply of glucose for the brain to function properly. Thus, diabetes is a multi-system disease that affects all organs within the body.[42] It is a generally accepted belief that good glycemic control, with blood glucose levels reaching those of healthy individuals as closely as possible, can prevent and/or delay the onset of complications. However, it is a tremendously complex and very challenging task to regulate what is typically a well-functioning internal self-regulatory feedback system in a human body from the outside.[43]

The story of T1D is not linear, rather it is full of discoveries and re-discoveries. Yet, one of the greatest achievements in medicine, the discovery of insulin, celebrated along with its acclaimed scientists from the University of Toronto (Banting, Best, Macleod, and Collip) is seen as linear, sequential, progressive, and merit-based. The miracle of insulin not only steadily increased the global number of individuals with diabetes due to prolonged life and their ability to procreate, but also led to the fact that "diabetes posed more medical problems after the discovery of insulin than before" due to the difficulties of disease management and a large number of risk factors.[44] However, insulin discovery is still disputed today as other researchers were able to produce pancreatic extracts before 1921, such as Nicolas Paulesco's "Pancreine,"[45] but it was the University of Toronto group that made insulin a suitable therapeutic treatment for diabetes.[46] Additionally, alternative anti-diabetic extracts were also researched, including "glucokinin" made from onion greens which seemed to work better than insulin, and

[42] Wilson, Val. 2013. Diabetes: From the Ebers Papyrus to Cell Technology. Teneo Press.
[43] Mol, Annemarie. 2008. The logic of care: health and the problem of patient choice. London: Routledge.
[44] Bliss, Michael. 1982. The Discovery of Insulin. Chicago: University of Chicago Press.
[45] Rosenfeld, Louis. 2002. Insulin: Discovery and Controversy, Clinical Chemistry, Vol. 48, Issue 12, pp. 2270–2288, https://doi.org/10.1093/clinchem/48.12.2270.
[46] Majumdar, Sisir K. 2002. Glimpses of the history of insulin. Bull Indian Inst Hist Med Hyderabad 31, no. 1: 57-70. http://www.ccras.nic.in/sites/default/files/viewpdf/jimh/BIIHM_2001/57%20to%2070.pdf.

those made from fish, clams, rice, beetroot, yeast, and even grass clippings which also lowered blood glucose experimentally.[47] Thus, innovation and progress in T1D treatment is not an orderly and straightforward process, but a complicated entanglement of alternative solutions, successes, and failures with the involvement of multiple individuals across the globe.

Today it is estimated that there are over 37.3 million individuals in the United States living with diabetes.[48] Only about 5-10% of them have T1D, while 90-95% have type 2 diabetes (T2D). The difference between these two conditions is that T1D is an irreversible autoimmune condition that can start at any age, but is commonly diagnosed in childhood. Patients with T1D have to manage complex requirements to stay alive and healthy, including subcutaneous injections of insulin for life, dietary management, and round-the-clock supervision of blood glucose. T2D is considered to be a generally preventable and reversible lifestyle condition that develops over time due to increasing internal resistance to insulin produced within the body. T2D can be managed with diet and exercise, oral drugs, and, in some cases, insulin. The difference between the two types of diabetes was identified in 1935 by a British diabetologist who observed that the disease could be caused by either the lack of insulin in the human body (T1D) or the lack of sensitivity to insulin already present in the body (T2D).[49] Individuals with T1D do not produce a sufficient amount of insulin to meet the needs of their bodies and individuals with T2D produce more insulin than their body needs due to insulin resistance which leads to overtasking of insulin-producing cells causing their deterioration.

[47] Bliss, Michael. 1982. The Discovery of Insulin. Chicago: University of Chicago Press.
[48] CDC. 2021. Diabetes Basics. https://www.cdc.gov/diabetes/basics/index.html.
[49] Wilson, Val. 2013. Diabetes: From the Ebers Papyrus to Cell Technology. Teneo Press.

Historically, the distinction between these two types of diabetes was not clearly defined. Before the discovery of insulin, the majority of patients most likely had T2D as it is more common, and individuals with T1D did not live very long. Therefore, efforts were often focused on nutritional aspects of the disease as patients and doctors could see significant improvements in patients with diabetes with improved diets. Even today, with clear definitions and understandings of the differences between the two, there is remaining confusion in which many people commonly misunderstand what causes and how to treat these two conditions. Of the two, T1D remains a minority, often misunderstood and misjudged. Both types of diabetes are deadly if not treated and can lead to debilitating complications even if treated well, leaving patients very vulnerable even with all the pharmaceutical advances and biomedical technologies currently available.[50]

Diabetes (T1D, T2D, and gestational diabetes) is one of the top ten leading causes of death in the United States.[51] it is a significant global issue with a growing number of affected individuals. The global diabetes population is estimated to have increased from 108 million in 1980 to 422 million in 2014 and impacts both low- and middle-income countries as well as high-income countries.[52] Type 1 diabetes today is known to be a chronic autoimmune disease caused by the inability of the pancreas to secrete a sufficient amount of insulin to regulate the level of glucose in the blood. Due to the excess of glucose in the patient's blood, individuals with T1D have an increased risk of severe irreversible complications that can impede T1D self-management. These include lower-

[50] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[51] Leading Causes of Death. 2022. National Center for Health Statistics. CDC. https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm
[52] WHO. 2021. Diabetes: Key Facts. https://www.who.int/news-room/fact-sheets/detail/diabetes.

limb amputations, heart disease, retinopathy, kidney disease, diabetic neuropathy, dental issues, psychological problems, and other complications.

Diabetes is also a costly disease,[53] with further increasing costs, especially for those who developed complications. The costs of medical care are estimated to be on average 2.3 times higher than those of individuals without diabetes. Due to technological advances, patients today have a number of options to consider when monitoring blood glucose and administering insulin. Today patients should be able to live active and productive lives, if they practice meticulous T1D management, even though the development of insulin and new technologies brings with them new and unexpected consequences.[54]

Health is a universal human need. It defines one's quality of life, and one's ability to work, study, experience the world, and contribute to society. Health is desired by all, often not appreciated, but always valued when compromised. The onset of T1D leaves the affected individuals little choice. Today the exact causes of T1D still remain unknown,[55] with some studies indicating an infectious cause, some strongly suggesting environmental factors, exposure to cow's milk, family predisposition, or even the hygiene hypothesis pointing to the negative effects of the sterile environment on the immune system.[56] There is no consensus or clear data to indicate the cause for possible prevention approaches. Further, T1D has no cure, but standardization of insulin and diabetes care along with new tools and technologies available to both practitioners and patients, allow

[53] ADA. 2020. Statistics About Diabetes. https://www.diabetes.org/resources/statistics/statistics-about-diabetes.
[54] Mol, Annemarie. 2008. The logic of care: health and the problem of patient choice. London: Routledge.
[55] Wang, Z., Xie, Z., Lu, Q. et al. "Beyond Genetics: What Causes Type 1 Diabete" Clinical Reviews in Allergy & Immunology. 2017. 52 (2): 273–286 https://doi.org/10.1007/s12016-016-8592-1.
[56] Tattersall, Robert. 2009. Diabetes: The Biography. Biographies of Disease. Oxford: Oxford University Press.

for improved disease management with the possibility of a higher quality of life achieved by more individuals.

The Impact of Historical T1D Transformation

The modern history of T1D coincides with the emergence of experimental medicine. With the increased use of the experimental method, witnessing, confirmation of results and experimental reproducibility played an important role.[57] Thus, the views of T1D transitioned from primarily philosophical to experimentally verifiable. Insulin discovery along with the use of experimentation driving human curiosity were game changers not only for patients with T1D but also for doctors, for the field of endocrinology, and for the growth of industry surrounding insulin production and the development of biomedical technology. This discovery led to a scientific revolution.[58] Insulin saved millions of lives,[59] at the same time as it opened up new avenues that required attention for all those T1D patients now living with a chronic disease, such as how to improve the lives of T1D patients (provision of medication, better insulin delivery methods, improved blood glucose testing methods, improved technology, development of T1D complication therapies), how to cure T1D (Beta Cell research, immunotherapy, T1D prevention)[60] and how to resolve issues related to the increased burden from patients with diabetes on the healthcare system.

[57] Steven Shapin and Simon Schaffer. 1989. Leviathan and the Air-Pump. Princeton.
[58] Kuhn, Thomas S. 1962. The Structure of Scientific Revolutions. 4th ed. 2012 [1962]. Chicago, University of Chicago Press.
[59] ADA. 2019. The History of a Wonderful Thing We Call Insulin. American Diabetes Association. https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin.
[60] JDRF. Type 1 Diabetes Research. Accessed 12/15/19. https://www.jdrf.org/impact/research/.

The development of new technologies affected the way science was conducted and created new possibilities within the scientific field. The process of health automation calls for further advances and more innovation as new issues arise as a result of automation. However, T1D and biomedical technologies used in its management did not develop unidirectionally. The disease and related technologies do not just shape us, we shape them. We shape technologies by using or refusing to use them, by modifying and tinkering with them, by devising new unintended uses for existing technologies as well as by creating new technologies as exemplified by the DIY innovators. Technologies shape us by influencing how we see ourselves, for example through technologically derived metrics. Biomedical technologies, such as the APS, also shape individual's actions by requiring user time for technological input and user effort for technological maintenance. They influence users' appearance by entangling them into a network of computers, devices, and networks. They also influence users' behavior guiding what activities to engage in or not to engage in. Today's culture sets technology apart and above human affairs as objective and impartial.[61] Progress and technological innovation might seem impersonal and inevitable but technological change is a product of complex interactions among different stakeholders, "funding agencies, government policies, ideologies, and cultural frames."[62]

Diabetes is often referred to as an emergency in slow motion. In addition to life-long dependency on insulin, increasing costs of care, and T1D complications, patients have elevated risks of adverse health outcomes due to comorbidities associated with other unrelated ailments, one's lifestyle, and genetic predispositions. Clinical approaches to

[61] David Noble. 1986. Forces of Production: A Social History of Industrial Automation.
[62] Edwards, Paul N., 1996. The Closed World: Computers and the Politics of Discourse in Cold War America. Cambridge, MA: MIT Press.

care that define disease in terms of numerical thresholds[63] focused on medication intake and biomedical technology use, rarely pay particular attention to other factors that impact a person's health. For example, one's blood glucose (BG) is also affected by stress, trauma, exercise, dehydration, illness, puberty, alcohol consumption, and the weather to name a few. The impact of outside factors on BG was experimentally demonstrated in the 17th century when, to induce hyperglycemia (high blood glucose), patients were subjected to "emotional or physical upset."[64] This showed the complexity of the condition and its interconnection with the patient's lived experiences, settings, and environment surrounding them. Additionally, mental health issues might develop as diabetes complications, becoming a barrier and inhibitor to one's ability to manage their condition effectively.

The history of T1D tells a story of disagreements, creativity, mistakes, new opportunities, and inspired ingenuity. It is a story of pain, suffering, curiosity, and change in research methods[65] and approaches to care with increased utilization of technology. T1D is not just a disease, a number on a spreadsheet, or a statistic. It has a large human dimension to it with social complexity, full of paradoxes and dilemmas. Even today patients still wrestle with the stringent demands of T1D to stay alive. Researchers are still seeking a cure for the disease by employing a full arsenal of technological innovations and new research methods. In the management of T1D, rigorous investigation and experimentation are used on biomedical technologies that would ease the burdens of disease. These efforts are particularly focused on glucose monitoring, insulin delivery,

[63] Greene, Jeremy. 2008. Prescribing by Numbers: Drugs and the Definition of Disease. Johns Hopkins.
[64] Wilson, Val. 2013. Diabetes: From the Ebers Papyrus to Cell Technology. Teneo Press.
[65] PICKERING GW. 1949. The place of the experimental method in medicine. Proc R Soc Med. 42(4):229–234. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2081184/?page=1.

and, advanced automation that assists in, if not takes over, decision-making, imitating the function of a healthy human pancreas.

Technological Change in T1D Management

Since the discovery of insulin, diabetes has typically been viewed as a "biomedical problem requiring a biomedical solution."[66] These biomedical solutions are pharmaceuticals including oral drugs, different types of insulin, and Glucagon, as an emergency medicine to treat severe hypoglycemia, as well as various devices designed for drug delivery and blood glucose monitoring. There are numerous other biomedical solutions developed to target a variety of diabetes complications to ease the burden of disease and prevent further deterioration of one's quality of life. The biomedical view of disease utilizes genetic test results, numerical measures, laboratory examination outcomes, scans, images, and other tools to create an objective reality of a patient. This offers a limited perception of a patient and their illness and omits the social complexity of the disease and the associated technologies. Since T1D is a multi-system disease affected by a variety of factors including those outside of the patient's body, biomedical technologies used in disease management cannot be understood solely within the biomedical or technological dimension.

Biomedical technologies, just like any technologies in modern society, are perceived as neutral, objective, error-proof, labor and cost-saving, efficient, and inherently good. However, as Eubanks demonstrates, efforts to improve efficiency, and

[66] Schillinger, Dea, 2021. Recommendations of the 2021 Federal Diabetes Commission: Translating the socio-ecologic model into policy, and global health implications. https://globalhealthsciences.ucsf.edu/event/recommendations-2021-federal-diabetes-commission-translating-socio-ecologic-model-policy-and.

reduce administrative costs and fraud in automated decision-making technologies used in public services lead to technologies that have inherent inequalities, discrimination, and surveillance for social sorting built into them.[67] Benjamin highlights how technological fixes, promoted as objective, progressive, and benevolent, "often hide, speed up, and even deepen discrimination" in comparison to prior eras.[68] Further, technologies are capable of producing a "more objective reflection of reality" unlike comparable results produced by humans.[69] Yet, as this chapter demonstrates, biomedical technologies for T1D are useless without human input and judgment. Therefore, human interpretation of reality (perception of one's well-being and feeling of blood glucose raise or fall) in this case should take precedence over the outputs of error-prone biomedical technologies full of inherent risks and vulnerabilities. Users as an integral component of the APS are essential to ensuring biomedical technology success. Biomedical systems like the APS cannot function properly without human agency.

Diabetes entails work. It requires exhausting and burdensome work to manage the complexity of a disease blurred between the self and biomedical technologies used in its management.[70] The type of work involved has changed over time transforming from strictly dietary requirements and urine testing for glucose to the use of syringes to inject insulin, blood glucose testing technologies with increased frequency of testing and improved accuracy, new ways, and new biomedical technologies to automate the

---

[67] Eubanks, Virginia. 2018. Automating Inequality : How High-Tech Tools Profile, Police, and Punish the Poor First ed. New York, NY: St. Martin's Press.
[68] Ruha, Benjamin. 2019. Race After Technology : Abolitionist Tools for the New Jim Code. Cambridge, UK: Polity.
[69] Ibid.
[70] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. Accessed May 13, 2021. http://www.jstor.org/stable/j.ctv12fw5z8.

administration of insulin.[71] Today T1D requires a significant level of self-management that involves not only the injection of insulin but also dietary management, exercise, blood glucose monitoring, and significant effort in learning and understanding T1D to be able to take appropriate actions.[72] Technological changes in the management of T1D have also shifted the responsibility for disease and its outcomes from the medical professional to the patient.

At the same time, biomedical technologies have transformed the disease itself. Biomedical technologies are often viewed in isolation from the affected individual for their purpose, action, and success or failure. However, these technologies have been integrated into users' lives, their families, school, workplaces, communities, networks of people, and places.[73] They have altered patients' bodies visually with the presence of devices, rashes, and scars left behind, as well as functionally, by altering how bodies interact with the outside world in intimate and public ways.[74] Every place where users exist has been modified by the presence of biomedical technologies. But users are not passive in their interaction with technology. Users also transform technologies and modify them to fit their needs, preferences, and goals. In the care of T1D today, medicine

---

[71] Tattersall, Robert. 2009. Diabetes : The Biography. Biographies of Disease. Oxford: Oxford University Press.
Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. Accessed May 13, 2021. http://www.jstor.org/stable/j.ctv12fw5z8.
Wilson, Val. 2013. Diabetes: From the Ebers Papyrus to Cell Technology. Teneo Press.
Feudtner, John Christopher. 2003. Bittersweet : Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[72] Horrocks, Stephen K. 2020. Insulin Pump Use and Type 1 Diabetes: Connecting Bodies, Identities, and Technologies. PhD diss., Purdue University Graduate School.
[73] Ibid.
[74] Forlano, Laura. 2016. Hacking the Feminist Disabled Body. Journal of Peer Production. Issue 8. Feminism and (un)hacking. http://peerproduction.net/issues/issue-8-feminism-and-unhacking-2/peer-reviewed-papers/issue-8-feminism-and-unhackingpeer-reviewed-papers-2hacking-the-feminist-disabled-body/.

has a lot to offer with a variety of tools and solutions, but it also demands a lot of the patient.

Technologically sophisticated healthcare prolongs life but also dehumanizes life within the narrow perspective of health, a limited view of what is possible and desirable.[75] Since "disease thought is inextricably bound to social thought and social relations" Wailoo, an award-winning author and a renowned historian of medicine, is encouraging all to study this relationship and to "assess the meaning of technology in modern medicine."[76] The below brief review of biomedical technologies used in T1D management focuses on insulin pump therapy, blood glucose monitoring, and the emergence of the APS. It captures not only technological change but also highlights the associated complexities and challenges.

Insulin Pump Therapy

Insulin has transformed T1D from a death sentence to a chronic condition. It has offered millions of affected individuals and their families rescue, hope, an opportunity to plan for a future, and the possibility of experiencing the happily ever after they seek. It did this by subjecting patients to a lifetime of injections without which they could expect certain death. Insulin has meant life to them. Along with the development of different forms of insulin, including short and long-acting insulin, and the transition from animal-derived insulin to human insulin produced in a laboratory using recombinant DNA technology, there was a need to develop improved methods of insulin delivery for

[75] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[76] Wailoo, Keith. 1999. Drawing Blood: Technology and Disease Identity in the Twentieth-Century America. Baltimore: Johns Hopkins University Press.

accuracy, reliability, and ease of use. These methods range from new and improved insulin syringes to insulin pens, automated insulin pumps, and other complex connected systems. In the late 1970s, the idea of automated insulin therapy was explored with an effort to mimic the function of the human pancreas from the outside of the body as closely as possible by providing continuous insulin infusion via a needle or a cannula.[77]

The first insulin pump was quite large and bulky. It had to be strapped to one's back like a backpack. Through a continuous effort of inquiry, development, and improvement, insulin delivery devices got smaller. Today individuals have a number of available options that range in size similar to an average smartphone to a size close to a small box of matches. For example, Omnipod®, a tubeless, waterproof insulin pump, provides non-stop insulin delivery for three days with no multiple daily injections.[78] It is attached directly to the body with an adhesive and delivers insulin via a cannula, a very thin tube. Some other insulin pumps are carried along the body and connected through tubing that leads to a needle or a cannula which can be attached to one's abdomen arms, thighs, or lower back. The two figures below illustrate the first insulin pump designs followed by the two most popular insulin pump designs in the United States.

[77] Wilson, Val. 2013. Diabetes: From the Ebers Papyrus to Cell Technology. Teneo Press.
[78] Onmipod. 2022. Omnipod® gives you more with less. https://www.omnipod.com.

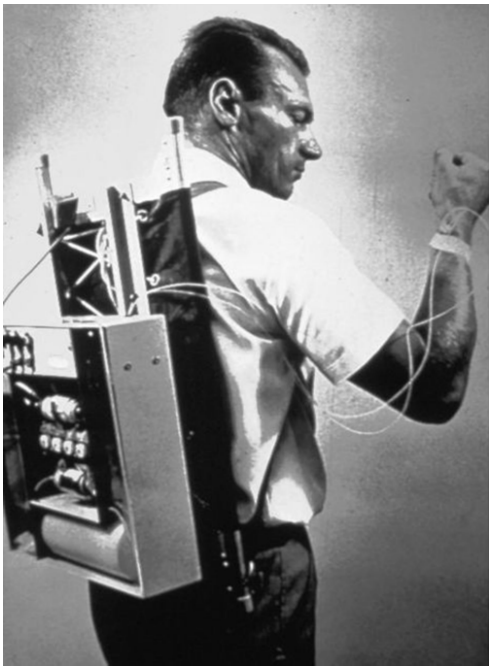


Figure 1. First insulin pump, Kadish's device (1963).[79]

[79] Alsaleh, Fatemah M., Fraser J. Smith, Simon Keady, and Kevin MG Taylor. 2010. Insulin pumps: from inception to the present and toward the future. Journal of clinical pharmacy and therapeutics 35, no. 2: 127-138.

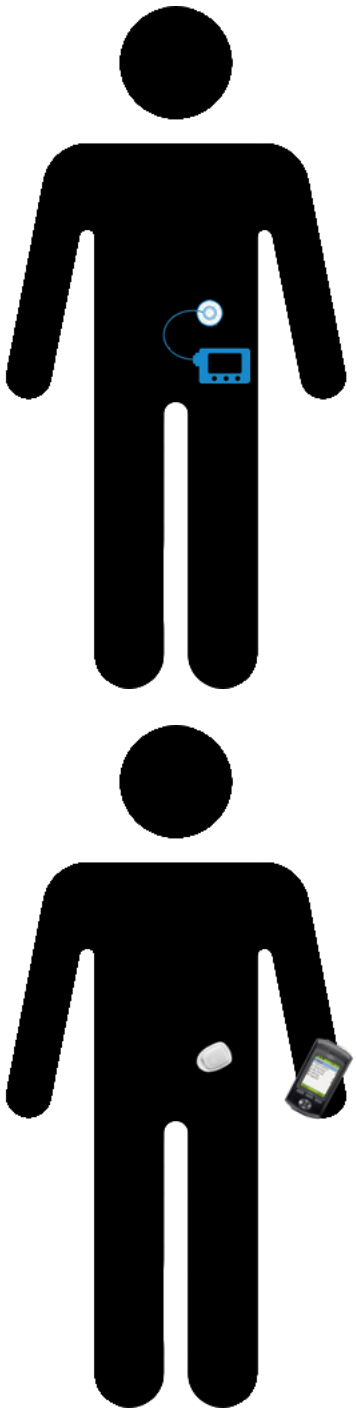


Figure 2. Illustration an insulin pump with a cannula[80] (top) and a wireless insulin pump illustration of Omnipod DASH[81] (bottom).

[80] Smith A, Harris C. 2018. Type 1 Diabetes: Management Strategies. Am Fam Physician. 98(3):154-162. PMID: 30215903. https://www.aafp.org/pubs/afp/issues/2018/0801/p154.html.
[81] Omnipod. 2011. Simplify Life™ with Omnipod DASH®. https://www.omnipod.com/en-gb.

An insulin pump is not a permanent device and it does not work without human input. For example, an Omnipod pump lasts up to 3 days before it has to be replaced. There are a number of risks associated with insulin pump use such as skin irritation, rash, pain, scar tissue development, thus requiring a new site for the pump, accidental pump removal due to contact sports, or peeling due to sweat to name just a few. Additionally, a variety of accessories were developed to help mitigate those issues and improve the look and usability of the technology. These include a variety of adhesives, 3D-printed covers, belts, and pockets. Each pump has a limit of the volume of insulin it can carry and insulin therapy, also known as continued subcutaneous insulin infusion, differs among individuals as bodies differ, dosage differs and so does the sensitivity to insulin and its absorption rate. While the pump might last the full duration of its useful life (3 days) for a child, for an adult it might need to be changed more often as the insulin capacity is used up faster.

Blood Glucose Monitoring

The oversight and management of one's blood glucose on a continual basis is an integral part of T1D management, a necessity not only for the calculation of insulin dose, but also to see how illness, exercise, and other life events affect one's insulin sensitivity and glucose absorption. Significant improvements in techniques of measuring blood glucose happened in 1910 and 1920 with the reduction in the amount of blood needed to identify one's blood glucose from 20 ccs. or more of blood to 0.2 ccs.[82] This allowed for blood to be drawn from the fingertip, not the vein, increasing the possible frequency of

[82] Myers, Victor C, and Cameron V Bailey. 1916. The Lewis and Benedict Method for the Estimation of Blood Sugar, with Some Observations Obtained in Disease. Journal of Biological Chemistry 24 (2): 147–61. https://doi.org/10.1016/S0021-9258(18)87566-4.

testing and patient comfort level. Blood testing at the time required special laboratory equipment and special training. In 1957 measuring blood glucose in the laboratory setting became easier and more accurate with the Technicon AutoAnalyzer which allowed for hundreds of measurements a day, though results were not available in real-time.[83] The first instant glucose meter was invented in 1964 and used with Dextrostix, the first blood glucose test strip with a color indicator, which had poor precision and accuracy.[84] In 1970 the Ames Reflectance Meter became the first meter used outside of the laboratory.[85] The early glucose meters were available in the physician's office and would provide an approximate reading with a swinging needle mechanism.[86] It was also used primarily in the emergency department of hospitals to differentiate between patients with T1D in a coma and individuals unconscious for other reasons.[87] Subsequently, this technology was developed for individual patient use with the launch of Dextrometer, a BG meter with a digital display using Dextrostix.[88]

Today every individual with T1D uses a small portable testing meter which requires a small drop of blood, usually from a fingertip, to test their blood glucose as frequently as they desire. An examples of a glucose meter is illustrated in figure 3 below. Even when users have other more complex biomedical technologies for measuring blood

---

[83] Tattersall, Robert. 2009. Diabetes: The Biography. Biographies of Disease. Oxford: Oxford University Press.

[84] Irl B. Hirsch. 2018. Introduction: History of Glucose Monitoring. ADA Clinical Compendia. 2018 (1): 1. https://doi.org/10.2337/db20181-1.

[85] Tattersall, Robert. 2009. Diabetes: The Biography. Biographies of Disease. Oxford: Oxford University Press.

[86] Tonyushkina, Ksenia, James H Nichols. 2009. Glucose meters: a review of technical challenges to obtaining accurate results. Journal of diabetes science and technology vol. 3,4 971-80. doi:10.1177/193229680900300446.

[87] Wilson, Val. 2013. Diabetes: From the Ebers Papyrus to Cell Technology. Teneo Press.

[88] Tonyushkina, Ksenia, James H Nichols. 2009. Glucose meters: a review of technical challenges to obtaining accurate results. Journal of diabetes science and technology vol. 3,4 971-80. doi:10.1177/193229680900300446.

glucose, a small meter is frequently used as a backup option. A simple glucose meter is not only light and portable to carry, but it is also affordable. Today it is a starter device in the care kit for every newly diagnosed patient with T1D. A blood glucose meter typically requires a test strip which is inserted into the meter. A lancet with one sharp edge is inserted into the lancing device which is set on top of a clean finger. With a press of a button, the sharp edge of the lancet is released to prick the finger. A drop of blood is then placed on the test strip. The screen of the meter shortly after gives an output of a blood glucose reading.

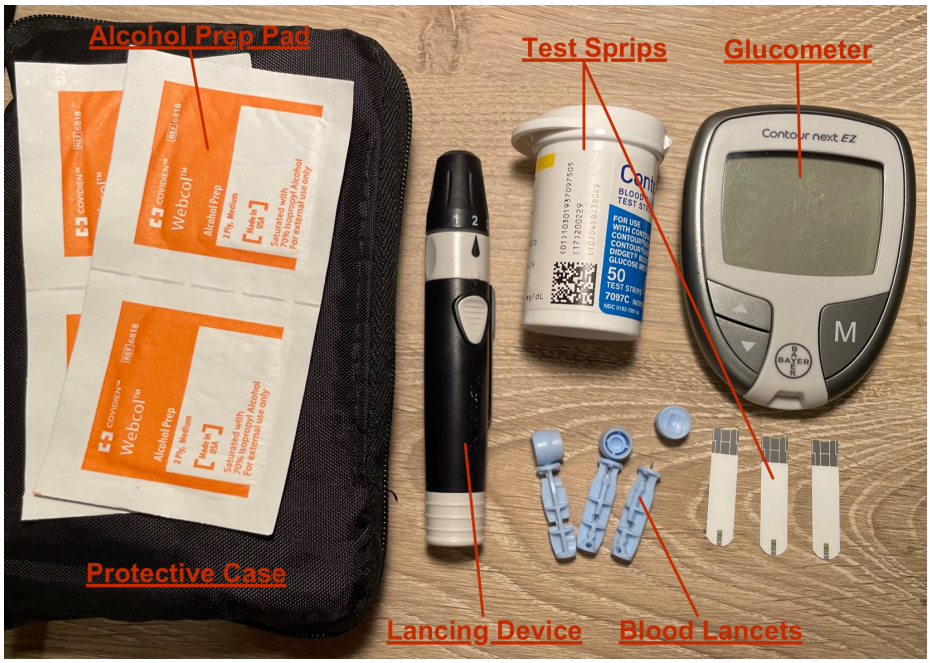


Figure 3. A small portable blood glucose meter (Glucometer) with test strips and a lancing device with lancets.

Some people report feeling symptoms of low blood glucose (hypoglycemia) such as shaking, sweating, anxiety, irritability, confusion, dizziness, and hunger, as well as symptoms of high blood glucose (hyperglycemia) such as thirst, tiredness, blurry vision,

dry mouth, frequent urination, headache, and stomach pain.[89] Some report that they don't experience any symptoms of blood glucose fluctuations at all. This is called glycemic unawareness. A particularly worrisome situation is when one's blood glucose drops dangerously low and the individual is not aware. In this case, individuals are recommended to frequently test their blood glucose or use a continuous blood glucose monitor (CGM). CGMs, such as Dexcom, are devices that look like small patches and use a very thin sensor inserted under the skin to measure blood glucose readings every five minutes. Dexcom returns BG readings to the receiver or a smartphone app via a transmitter that is connected to the sensor, as illustrated in Figure 4.

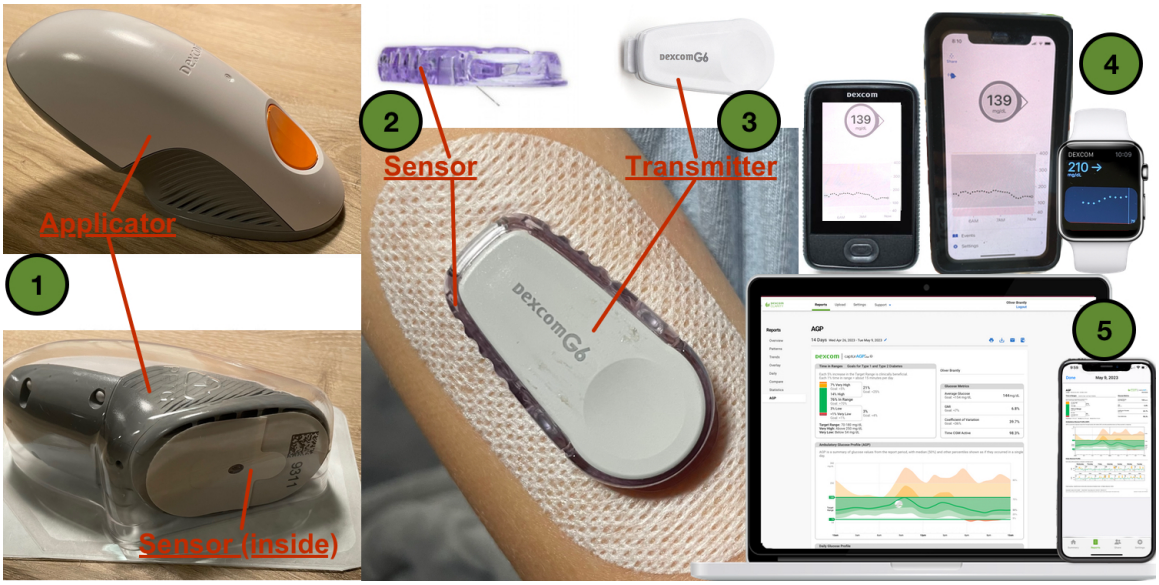


Figure 4. Dexcom CGM components.[90]

[89] CDC. 2021. Living With Diabetes: Manage Blood Sugar. https://www.cdc.gov/diabetes/managing/manage-blood-sugar.html.
[90] Dexcom Inc. 2023. Dexcom G6 Pro. Accessed 2.19.23. https://provider.dexcom.com/products/dexcom-g6-pro.

1. The one-touch auto-applicator allows for simple sensor insertion right underneath the skin. The sensor is located inside the applicator.
2. The sensor monitors interstitial glucose levels through a small wire inserted just underneath the skin, sending a signal to the transmitter.
3. The transmitter snaps into the sensor and sends real-time glucose readings wirelessly to a compatible receiver via Bluetooth.
4. The receiver can be a smartphone, smartwatch, and/or a separate receiver device. It displays glucose information on the screen, alerts the user of the blood glucose trajectory, and alarms the user of pending highs and lows.
5. Reader and Dexcom CLARITY applications are primarily for physician use as they do not display any real-time CGM data. They allow healthcare providers (HCPs) and patients to view blood glucose patterns, trends, and statistics via a range of interactive reports.

The first "professional" CGM was approved by the U.S. Food and Drug Administration in 1999.[91] Since then, there were a number of new such devices, slightly smaller with expanded functionality and reliability, requiring less effort in maintenance and improved ease of use. It is a generally accepted fact among medical professionals that CGMs help prevent risky blood sugar swings before they happen and help improve overall blood health. Just like insulin pumps, CGMs are not permanent devices. For example, Dexcom G6 CGM has to be replaced every 10 days. Despite occasional

[91] Didyuk, Olesya, Nicolas Econom, Angelica Guardia, Kelsey Livingston, and Ulrike Klueh. 2021. Continuous Glucose Monitoring Devices: Past, Present, and Future Focus on the History and Evolution of Technological Innovation. Journal of Diabetes Science and Technology 15, no. 3: 676–83. https://doi.org/10.1177/1932296819899394.

outages, skin irritations, inaccuracies, device failures, high costs, and other frustrations, CGMs have significantly changed diabetes management. They not only offered users the freedom of choice and an opportunity for constant data flow but also minimized the need for healthcare provider involvement in patient monitoring and care.

Numerous clinical studies indicate that tight blood glucose management leads to better health outcomes and reduced incidence of complications. Yet, doctors considered the use of biomedical devices by patients as irresponsible and dangerous before 1975.[92] It was only in the late 1970s that the self-monitoring of blood glucose became possible, which allowed individuals using insulin to feel safe and avoid hypoglycemia, and the Hemoglobin A1c (HbA1c) test provided a measure of assessment of one's blood glucose management over the period of 3 months. Patients who were able to test their BG received an opportunity to better understand T1D and their bodies. Those who wanted to maintain BG levels close to the healthy person's range had to have visibility over the fluctuations in their BG, so self-management of BG became essential. Even before the discovery of insulin, many physicians in the United States considered patient education to be an integral part of treatment and patient handbooks were widely used.[93]

Diabetes is not just a glucose disease, it is a "disorder of such infinite variety that it becomes impossible to say that this always occurs or that never happens."[94] This definition was provided by John Malins, a physician, in his 1968 textbook. This is also true today as individuals with T1D have very different insulin regimens, doses, diets, and biomedical technologies used. Robert Tattersall in his book "Diabetes: The Biography"

[92] Tattersall, Robert. 2009. Diabetes: The Biography. Biographies of Disease. Oxford: Oxford University Press.
[93] Ibid.
[94] J.M. Malins. 1968. Clinical Diabetes Mellitus. London.

wrote a story about Herbert, a young man diagnosed with T1D at the age of 12, who was put on a prescribed regimen of insulin and a specified diet. In 1939 at the age of 22, he was told not to return to his doctor again as "you know how to take care of yourself."[95] Two years later the young man got married and with the help of his spouse and "The Diabetic ABC" patient handbook, he was able to live 50 years with no complications. The variability of the disease, just like the variability of patients, and the challenges of disease management cannot be easily standardized into a single approach to care. However, as Herbert's story demonstrates, patients are capable of self-care and proper assessment of their needs and their bodies. Patient input is necessary for both the effective management of disease and effective medical care.

The Emergence of the APS

The first attempts at automated glucose-responsive insulin delivery systems were made about 50 years ago.[96] Biostar, a bedside computer-controlled closed-loop insulin pump, was developed in 1974 by Miles Laboratory Inc.[97] It was designed to simulate the function of healthy pancreatic cells and consisted of a pump for withdrawal and mixing of blood; a blood glucose analyzer; "a computer programmed with a set of algorithms to calculate the amount of insulin or dextrose to be infused based on blood glucose level; a computer-operated infusion pump for insulin or dextrose delivery," and a printer/plotter

[95] Tattersall, Robert. 2009. Diabetes : The Biography. Biographies of Disease. Oxford: Oxford University Press.
[96] J.V. Santiago, A.H. Clemens, W.L. Clarke, et al. 1979. Closed-loop and open-loop devices for blood glucose control in normal and diabetic subjects Diabetes, 28 (1), pp. 71-84.
[97] Schaaf, Tracy. 2018. 'In MedTech History' - Diabetes Technology - Part 1. MedTech Strategist. https://www.mystrategist.com/blog/article/diabetes-part-1.

for continual blood glucose recording.[98] However, the use of such devices was limited due to algorithm simplicity, large size, the need for intravenous access, and greater wastage of blood.[99] The disadvantages of such systems far outweighed their advantages, not only because of the cost of about $55,000 in 1982 but also because the patient had to be confined to a bed or a chair with non-stop supervision, with frequent device calibrations and malfunctions.[100] This technology did not gain much traction because of the need for more computing power at first and then the need for continuous glucose sensors which was produced only in 1999. As biomedical technologies for T1D management have improved over time, decreasing in size and improving accuracy, the idea of the closed-loop system was revitalized in part due to the growing interest in "closing the loop" between the insulin pump and CGM.[101]

In 2006 the Juvenile Diabetes Research Foundation (JDRF) launched the Artificial Pancreas Project (APP) initiative with the intent to accelerate progress toward closed-loop Artificial Pancreas Systems.[102] In September of 2016, the U.S. Food and Drug Administration (FDA) approved the first Artificial Pancreas System (APS) Medtronic's MiniMed 670G hybrid closed-looped system for individuals with T1D over the age of 14.[103] This system was intended to provide automated basal (background)

---

[98] Ibid.

[99] Klemen Dovc, Tadej Battelino. 2020. Evolution of Diabetes Technology, Endocrinology and Metabolism Clinics of North America, Vol. 49, Issue 1, pp 1-18. https://doi.org/10.1016/j.ecl.2019.10.009.

[100] Tattersall, Robert. 2009. Diabetes: The Biography. Biographies of Disease. p.151. Oxford: Oxford University Press.

[101] T. Battelino, M. Phillip. 2004. The first meeting of the loop club. J Pediatr Endocrinol Metab, 17 (3). 10.1515/JPEM.2004.17.3.375.

[102] Kowalski, Aaron. 2015. Pathway to Artificial Pancreas Systems Revisited: Moving Downstream. Diabetes Care. 38 (6): 1036–1043. https://doi.org/10.2337/dc15-0364.

[103] FDA. 2018. Press Release: FDA approves first automated insulin delivery device for type 1 diabetes. https://www.fda.gov/news-events/press-announcements/fda-approves-first-automated-insulin-delivery-device-type-1-diabetes.

insulin delivery in response to blood glucose fluctuations. The image of such system components is shown in Figure 5. The MiniMed 670G system has since been discontinued effective February 1, 2021, and replaced by a more advanced MiniMed ™ 770G system[104] now FDA-approved for users over the age of two.[105] There are a number of other similar systems in development.

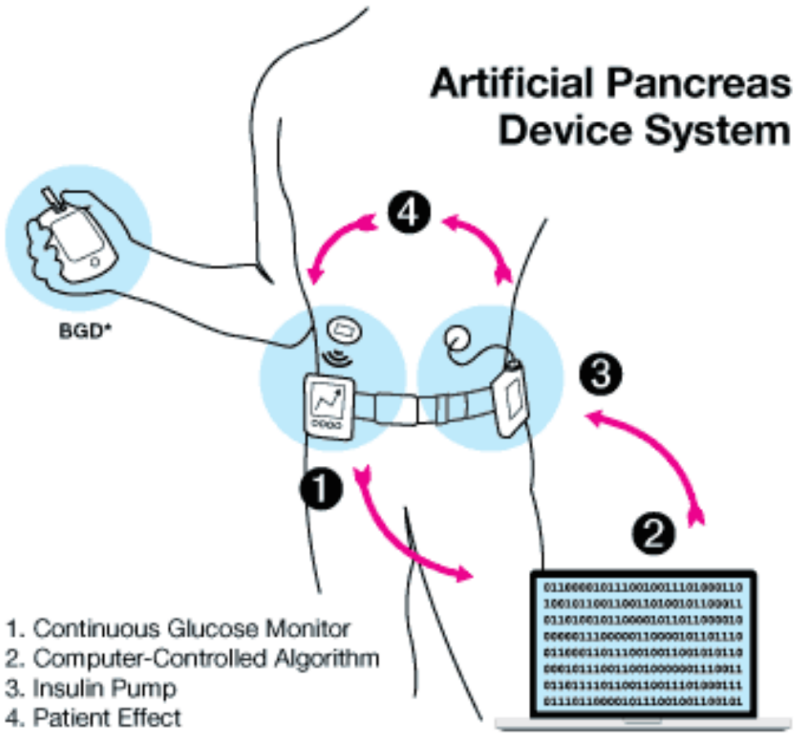


Figure 5. The Artificial Pancreas System components.[106]

In the APS, the core of the system consists of a computational control algorithm that receives blood glucose data from the CGM, calculates the amount of insulin the user

[104] Medtronic. 2021. MINIMED™ 670G system discontinuation of new sales. https://www.medtronicdiabetes.com/products/minimed-670g-insulin-pump-system.
[105] Medtronic. 2022. Learn more about how the MINIMED™ 770G system can help children living with diabetes. https://www.medtronicdiabetes.com/minimed-770g-system-kids/.
[106] FDA. 2018. What is the pancreas? What is an artificial pancreas device system? https://www.fda.gov/medical-devices/artificial-pancreas-device-system/what-pancreas-what-artificial-pancreas-device-system.

needs, if any, and instructs the insulin pump to deliver it on a continual basis throughout the day and night. Additional technological components of the APS are a CGM device and an insulin pump. The APS measures the increase in the patient's blood glucose and triggers the incremental release of insulin, similar to the way that the human pancreas does it. However, user input is still required to administer insulin for the carbohydrates consumed. Insulin pump therapy in combination with continuous glucose monitoring (CGM) is associated with efficacy, a better quality of life, improved health outcomes, and better decision-making regarding T1D care.[107] Artificial pancreas closed-loop system, also called glucose-responsive automated insulin delivery, with a combination of CGM, an insulin pump, and a computational element is believed to "improve long-term outcomes with less disease burden."[108] In 2018, the APS was named "the most disruptive medical technology in healthcare" with further advances planned for the upcoming years to include improved longevity of system components, better accuracy, and functionality.[109]

In addition to the FDA-approved closed-loop systems, there is a growing community of users who support the do-it-yourself approach with open-source APS. This thriving "patient-driven ecosystem"[110] offers openly shared data, instructions, and tutorials via open-source platforms to help others with T1D gain access to do-it-yourself

---

[107] Dovc K, Battelino T. 2019. Evolution of Diabetes Technology. Endocrinol Metab Clin North Am. 2020 Mar;49(1):1-18. doi: 10.1016/j.ecl.2019.10.009. Epub. PMID: 31980111.
[108] Ibid.
[109] Didyuk, Olesya, Nicolas Econom, Angelica Guardia, Kelsey Livingston, and Ulrike Klueh. 2021. Continuous Glucose Monitoring Devices: Past, Present, and Future Focus on the History and Evolution of Technological Innovation. Journal of Diabetes Science and Technology 15, no. 3: 676–83. https://doi.org/10.1177/1932296819899394.
[110] Klemen Dovc, Tadej Battelino. 2020. Evolution of Diabetes Technology, Endocrinology and Metabolism Clinics of North America, Vol. 49, Issue 1, pp 1-18. https://doi.org/10.1016/j.ecl.2019.10.009.

artificial pancreas systems (DIY APS), gain better access to their data and use it in innovative ways as well as gain additional functionality of biomedical technologies they use. The analysis of self-reported clinical outcomes of children and adolescents using DIY APS found improved glycemic outcomes across all pediatric age groups, including very young children, which is in line with clinical trial results from commercially developed closed-loop systems.[111] In 2019 JDRF reported that Aaron Kowalski, Ph.D., president and CEO of JDRF, as well as Jeremy Pettus, M.D., an endocrinologist from the University of California San Diego and a JDRF grantee, both use a DIY artificial pancreas system.[112] JDRF openly supports the development of commercial and DIY biomedical technologies to hopefully have patients choose what works best for them, and to have cross-compatibility between different technologies, so users can "mix and match what they prefer" until a permanent cure is found.[113]

Biomedical devices for diabetes management are becoming increasingly sophisticated with more automation and ease of use. In January 2022 the FDA approved the first tubeless APS Insulet's Omnipod 5 automated insulin dosing (AID) system (aka closed-loop or artificial pancreas system) for individuals with T1D six years of age and older.[114] This is the first and only FDA-approved patch pump system that sits directly on the skin without tubing and can be controlled with a smartphone. Omnipod 5 system consists of three components: the Pod, a tubeless insulin pump with APS SmartAdjust™

---

[111] Braune, Katarina, Shane O'Donnell, Bryan Cleal, Dana Lewis, Adrian Tappe, Ingrid Willaing, Bastian Hauck, and Klemens Raile. 2019. Real-World Use of Do-It-Yourself Artificial Pancreas Systems in Children and Adolescents with Type 1 Diabetes: Online Survey and Analysis of Self-Reported Clinical Outcomes. Jmir Mhealth and Uhealth 7 (7): 14087. https://doi.org/10.2196/14087.

[112] JDRF. 2019. A DIY Approach to Artificial Pancreas Technology. https://www.jdrf.org/blog/2019/05/02/diy-approach-artificial-pancreas-technology/.

[113] Ibid.

[114] Jackson, Lala. 2022. OMNIPOD 5 receives FDA approval. Beyond Type 1. https://beyondtype1.org/omnipod-5-fda-approved/.

algorithm embedded inside, a Dexcom G6 CGM, and a smartphone app that allows users to have full control over both basal and bolus rates for the system. Figure 6 illustrates the system's components contrasted with the DIY APS analog. The Pod has to be replaced every 3 days and Dexcom CGM every 10 days. While there are still a number of other shortcomings, this system is considered to be "a life-changing technology" that is a "simple-to-use, elegant system, designed to deliver unmatched freedom and to greatly simplify insulin management and improve glucose control."[115]

[115] Insulet Corporation. 2022. Insulet Announces FDA Clearance of its Omnipod® 5 Automated Insulin Delivery System, First Tubeless System with Smartphone Control. https://investor.insulet.com/news-releases/news-release-details/insulet-announces-fda-clearance-its-omnipodr-5-automated-insulin.

Figure 6. Omnipod 5 APS components (top) with computing algorithm embedded inside the Pod and DIY APS components (bottom) with OrangeLink Pro device which links all components within the DIY system.

Only four Artificial Pancreas Systems have been FDA-approved as of August 2022: The Medtronic 670G (approved in 2016 and discontinued in 2021),[116] the Tandem Control-IQ™ (approved in 2019),[117] Medtronic 770G (approved in 2020),[118] and Omnipod 5 as discussed above. Each system works under the same premise: if the blood glucose is predicted to be high, the pump increases basal insulin delivery and when blood glucose is predicted to be low, the pump decreases or stops basal insulin delivery. Some individuals have been successfully using DIY APS with integrated tubeless Omnipod and a Dexcom CGM since April 2019.[119] The FDA claims the Artificial Pancreas device system "closely mimics the glucose regulating function of a healthy pancreas" by automating insulin delivery.[120] However, the above statement by the FDA obscures other impacts such as the interference of the APS in people's lives in new ways driven by its technological complexity and new risks created for the users as detailed in the following chapters. With a number of FDA-approved APS, the community of DIY diabetes

[116] Medtronic. 2021. MINIMED™ 670G system discontinuation of new sales. https://www.medtronicdiabetes.com/products/minimed-670g-insulin-pump-system.
[117] Tandem Diabetes Care. 2022. CONTROL-IQ TECHNOLOGY Predicts and helps prevent highs and lows. https://www.tandemdiabetes.com/products/t-slim-x2-insulin-pump/control-iq.
Mulvey, Alexandra. 2019. FDA Authorizes a Second Artificial Pancreas System. JDRF. https://www.jdrf.org/blog/2019/12/13/jdrf-reports-fda-authorizes-second-artificial-pancreas-system/.
[118] JDRF. 2020. FDA Approves First-of-its-Kind Automated Insulin Delivery and Monitoring System for Use in Young Pediatric Patients.
[119] Boudreaux, Todd. 2019. DIY lop now compatible with OMNIPOD. Beyond Type 1. https://beyondtype1.org/omnipod-diy-loop/.
[120] FDA. 2018. What is the pancreas? What is an artificial pancreas device system? https://www.fda.gov/medical-devices/artificial-pancreas-device-system/what-pancreas-what-artificial-pancreas-device-system.

technology is still growing. The analysis of the biotechnological organism conducted in the following chapters across two distinct communities allows for a closer examination of the reason for this divergence.

Conclusion

The opening story of the Dexcom outage is just a single example of many ways biomedical technologies for diabetes management can fail. It demonstrates that health automation is not an inherently positive development due to risks, tradeoffs, and shortcomings presented through automation. Yet, individuals are left with little choice and a lot of pressure to embrace technological innovations such as the APS to improve their health outcomes. Even when trying to understand the disease and historical approaches to treatment, the search for the meaning or cause of disease within modern medical practice operates from an increasingly reductive approach, moving from body to organs, cells, and molecules to genes. Biomedical definitions of disease are reductive as the meanings of disease always transcend biology.[121]

Individuals with diabetes are much more than a combination of biological processes, and our understanding of T1D should extend beyond the medical practice and beyond the biomedical technologies in use. T1D, or any disease for that matter, does not exist as an independent entity without people. The disease is not an independent entity with a natural history and a predictable course, people have a hand in shaping disease, life, and death. Likewise, biomedical technologies do not exist without people, they are designed, utilized, shaped, and transformed by all those that interact with them. The user,

[121] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.

the patient or the caregiver is an essential component of the APS, therefore, users are integral to technological success.[122] Users also embed their values in technological systems. For instance, DIY innovators embed a sense of urgency and flexibility into the open-source systems they create, whereas the regulatory expert community seeks standardization and uniform measurement in regulated biomedical technologies. These values are reflected in the kinds of Artificial Pancreas Systems they make.

As the review of T1D history and associated technologies demonstrates, patients had to juggle an ever-changing regimen of new types of insulin along with the demands of new and improved biomedical technologies. The rapid technological change since the discovery of insulin in 1921 and still ongoing, combined with the opening story of the 2019 Dexcom outage indicates that the drive for automation is fostering new biomedical technologies that are not only sophisticated but also elevate the risk considerations that impact individuals with T1D and their communities. Biomedical technologies in use relieve some risks associated with T1D but create new challenges, new requirements of the users, and new entanglements. As new devices proliferate among patients, they require user trust, continual training, and responsibility for not only proper wear and carrying, but also for procuring parts and accessories, troubleshooting, constantly interacting with and still planning for a plan B in case the technology fails. T1D management today is a never-ending process demanding effort, time, and attention. Technological advances make it easier to manage the disease and improve glycemic control. However, due to the increased use of technology, there is also an increased reliance and dependency on such technologies.

[122] FDA. 2018. What is the pancreas? What is an artificial pancreas device system? https://www.fda.gov/medical-devices/artificial-pancreas-device-system/what-pancreas-what-artificial-pancreas-device-system.

As this chapter demonstrates, the historical risks of disease were not eliminated with automation. They exist today even with advanced technological innovations and pharmaceuticals available and used by patients. Patients are still vulnerable and still concerned about suffering from adverse health outcomes. Technological advances have relieved some burdens of disease but also created new ones such as risks of technological malfunction, failure, and data overload as well as the challenges and demands of technological maintenance to name just a few. This indicates not a reduction of risk or the effort it takes to manage a chronic condition but a shift from where these risks and efforts emerge. The history of T1D reveals complex human consequences of medical innovations and technologically intensive therapy. This complexity must be examined more to bring forth the details of the contemporary consequences of health automation and today's realities of living with T1D using biomedical technologies.

This work proceeds in four chapters. The second chapter reviews the literature pertaining to risk, automation, and the commodification surrounding the transformation of diabetes care and biomedical technologies used for T1D management. Risk is a prevalent theme in discussions of any health condition. Thus, this research uses the lens of risk throughout the chapters. The second chapter focuses on theorizing the technological management of T1D, outlining the research gap, and addressing the methodological approach for the research. Particularly chapter 2 explains how looking at two distinct knowledge-producing communities, the community of regulatory experts and the DIY biological community, through the analysis of two types of technology, regulated and unregulated APS, helps understand the drive for and approaches to health automation, as well as helps narrow the research gap.

The third chapter analyzes how communities of regulatory experts views health automation through the lens of risk. This chapter focuses on risk perception and risk reduction efforts pertaining to both the regulated FDA-approved APS and the DIY open-source APS within the regulatory expert community. This social group is represented by the American Diabetes Association (ADA). It provides an important perspective grounded in evidence-based science, established norms and professional standards upheld within the fields of medicine, healthcare, and research. The regulatory experts this work refers to include medical professionals, public health leaders, government officials, as well as policymakers. The term "regulatory experts" includes individuals directly involved in the formation of regulations regarding T1D care as well as individuals bound by regulations in their professional status. This research uses the term regulatory expert to differentiate from another form of expertise evident among DIY biological community. In the review of the regulatory community of experts this chapter focuses on two primary sources. The first one is the ADA-established "Standards of Medical Care in Diabetes" 2022 created to provide the most current evidence-based guidelines for diabetes care. The second one is the professional development course designed by regulatory experts for regulatory experts titled "Making Diabetes Technology Work."

The fourth chapter analyzes risk discourses within the DIY biological community. This chapter focuses on the patient-driven ecosystem of innovators united under the #WeAreNotWaiting movement to understand the drive for health automation and knowledge production practices. This community is represented by patients, caregivers, and advocates who work together to make open-source and DIY solutions for individuals with T1D without waiting for commercial entities to innovate technical solutions. This

social group provides a different but equally important perspective shaped by affective dimensions that reflect the phenomenological experience of patients living with biomedical technologies. This chapter also addresses regulated and unregulated technologies from the perspective of the DIY biological community. It explains how users are reshaping, adapting, reframing, reimagining, and changing biomedical technologies to fit their needs and how this, in aggregate, constitutes the formation of a biological community formed around DIY biomedical technologies. In the review of the DIY biological community this chapter focuses on comparable primary sources to include technological set up documentation, training materials related to OpenAPS and related diabetes technologies.

Both chapters 3 and 4 address risk within the context of the technological complexity that stems from its design, use, maintenance, and knowledge production from different vantage points of two different communities. The reviews conducted in these chapters allow for the analysis of how biotechnological organisms are perceived within these communities and in relation to the logics of health automation. The analysis conducted within these two distinct, but related social groups is not to compare or contrast the accuracy of the two perspectives on risk, on T1D, or on biomedical technologies, but to understand efforts to automate health technologies, the ways in which knowledge is constructed through these efforts, how risk discourses influence biomedical innovations, and how perceptions of risk acquire authority.

The fifth and final chapter returns to the concept of biotechnological organism introduced earlier in this work to summarize the entanglements and the consequences of technological dependence for those living with T1D. It evaluates these entanglements and

consequences through the lens of risk. It addresses the ideas of biotechnological organisms in relation to the two logics of health automation: techno-deterministic logic, exemplified by the regulatory expert community, and integrative logic, exemplified by the DYI biological community. This chapter addressed the economic, political, and social consequences of health automation in T1D care by focusing on the risk perceptions, tensions, and entanglements impacting the automation of biotechnological organisms. It does so by addressing normalization, commodification, and knowledge production practices in T1D automation. Lastly, this chapter concludes the work through a reflection on how this research itself can provide new understandings of health practices, especially those pertaining to chronic disease, biological communities, disability studies, and biotechnological organisms.

Chapter 2. Risk, Automation, and Commodification: Theorizing the Technological Management of Type 1 Diabetes.

The previous chapter offered a brief overview of historical shifts in understanding type 1 diabetes (T1D) and the biomedical technologies used in its management. It demonstrated the increasing complexities and nuanced nature of the chronic disease brought about by the technological change leading up to the emergence of Artificial Pancreas Systems (APS). The consequences of technological change as well as the historical changes in medical theories pertaining to T1D are further addressed in this chapter. Drawing from the Science and Technology Studies (STS) literature, this chapter theorizes the consequences of those shifts on how we think about chronic disease and its management. Specifically, it addresses what contributions have already been made to the study of biomedical technology, technological use, automation of health, and risk perception within the field of STS and STS-adjacent fields like Sociology. The primary aim of this chapter is not only to situate this study within the broader literature of STS but also to discuss the methodological approach aimed at improving our understanding of health automation and expanding the scope of analysis beyond biological processes by examining the risks and entanglements of automating biotechnological organisms.

Biomedical technologies for diabetes management in the U.S. are promoted to patients by regulatory expert communities of physicians, specialists, and public health officials as well as direct-to-consumer marketing from corporations that produce and profit from the increased sale and continued use of such technologies. However, there is an overall lack of data pertaining to the exact number of users with insulin pumps,

continuous glucose monitors (CGMs), and closed-loop systems (APS). The uncertainty in user data and the lack of information on failure types and frequencies are important to recognize because "it is difficult to estimate the rates of malfunction and user error when the denominator is unknown."[123] The lack of information demonstrating the levels of malfunctions, faulty hardware, and a variety of other issues related to biomedical technologies obscures the entanglements and risks of biomedical technologies in use and calls for alternative approaches to analyses as provided by this research.

The study of biomedical technologies can produce the knowledge needed to improve our understanding of disease and human health, especially for chronic conditions reliant on the continued use of technologies. The idea of technology as knowledge has well-established scholarship in STS. Ann Johnson wrote that technology is the knowledge that "has affects and is affected by society" on at least two levels: internalist and externalist.[124] The internalist approach requires the examination of social groups involved in knowledge construction. The externalist approach includes the examination of interactions of technology with users and non-users. Both approaches demonstrate that technology is not just an artifact, a physical form of scientific expression, or an application of prior scientific knowledge. Technological knowledge is not universal but has a local dimension, which differs based on different social, cultural, economic, and other contexts.[125]

[123] Chaplin, S. 2016. Insulin pump risks and benefits: an analysis of the EASD/ADA joint statement. Pract Diab, 33: 90-92a. https://doi.org/10.1002/pdi.2010.
[124] Johnson, Ann. 2006. Revisiting Technology As Knowledge. Perspectives on Science 13 (4): 554–73.
[125] Ibid.

Technology as knowledge sets up parallels between science and technology.[126] Biomedical technology as knowledge, thus, parallels not only science and technology but also medicine. However, STS scholarship pertaining to technology as knowledge does not specifically address biomedical technologies. Therefore, this research aims to adopt the STS approach to studying technology as knowledge toward the study of biomedical technology as knowledge. One way to do so is through the investigation of technological knowledge communities which expand beyond the regulatory experts and figures of authority towards biological communities. In Johnson's analysis of three books concerned with the state of technology as knowledge,[127] the author concluded that the focus on the nature of knowledge communities, actors involved, social relations, knowledge production, and exchange practices were instrumental in conceptualizing qualities of technology as knowledge. Similarly, this research applies the internalist approach by focusing on two social groups, the community of regulatory experts and the community of Do-It-Yourself (DIY) innovators, both of which are knowledge communities. These two groups are closely related to the biotechnological organism by not only producing and exchanging knowledge that impacts it but also by influencing health outcomes, well-being, social relations, and T1D care practices.

A prominent theory within the field of STS called the social construction of technology (SCOT) focuses on epistemological dimensions of technologies and examines

[126] Layton, Edwin. 1971. Mirror-Image Twins: The Communities of Science and Technology in 19th-Century America. Technology and Culture 12 (4): 562–80.
Layton, Edwin. 1974. Technology As Knowledge. Technology and Culture 15 (1): 31–41.
[127] Slaton, Amy E. 2001. Reinforced Concrete and the Modernization of American Building, 1900-1930. Johns Hopkins Studies in the History of Technology. Baltimore: Johns Hopkins University Press.
Thompson, Emily Ann. 2002. The Soundscape of Modernity: Architectural Acoustics and the Culture of Listening in America, 1900-1933. Cambridge, Mass.: MIT Press.
Wermiel, Sarah. 2000. The Fireproof Building: Technology and Public Safety in the Nineteenth-Century American City. Baltimore: JHU Press.

the influence of technology on society and social influences on technology.[128] The impact of technology on society has been widely addressed and extensively studied. It is clear and pronounced. The influence of society on technology is more subtle. The SCOT theory emphasizes the need to study technology from multiple perspectives including technical, social, economic, and political to explain technological change and human agency in shaping technology. This theory is particularly appropriate to the examination of the relationship between society and technology focused on technology as knowledge with socially determined content.[129] The Artificial Pancreas System has not yet been studied through the use of the SCOT theory.

This research uses SCOT theory to study the social groups involved in the development and promotion of the APS, including regulatory experts and lay experts involved in a do-it-yourself movement, as well as the ways in which users have adapted biomedical technology for their own purposes. By combining SCOT with an internalist approach, the study aims to illuminate the consequences of a reductionist approach used by manufacturers of biomedical technologies for diabetes management. Against such a narrow approach, this study advocates embracing the cultural and social complexity of knowledge production, the complexity surrounding the disease, and the complexity of the human body. This work adds to the understanding of disease and biomedical technologies by looking at the APS through the lens of biomedical technology as knowledge, examining social groups and their knowledge production and exchange practices, as well as risk reduction efforts. This research fills an important gap in scholarship adding not

[128] Bijker, Wiebe E., Thomas P. Hughes and Trevor Pinch. [1987] 1989. The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology. Cambridge, MA: MIT.
[129] Ibid.

only to reinforce the idea of biomedical technology as knowledge but also to improve our understanding of T1D and health automation through the social construction of technology lens.

This research views the human body as a complex system, prone to accidents, as defined by Downer,[130] further complicated by biomedical technologies that create additional risk considerations. Human bodies are more than organs wrapped in skin with a clear barrier between the self and the outside. As the historical review from the previous chapter demonstrates, there are inherent risks for bodies due to the autoimmune nature of T1D[131] and technological risks due to the chronic use of biomedical technologies that repeatedly and continuously pierce the skin. In T1D care life without the use of biomedical technologies does not exist. This integration of patients and biomedical technologies can be viewed as a form of a biotechnological organism. An organism is made up of a human body and a computer, or a system of computers. The integration between the two can be both a symbiotic relationship and a frustrating reality, but it requires the best performance from each side to achieve success. This biotechnological organism exists within a rule-based and data-driven world acted upon from multiple directions, from all aspects of human life, digital networks, and from within the body. Individuals who aspire to gain a bit of freedom from the rules they are expected to follow and from the world they are expected to inhabit, such as by using unregulated biomedical technologies, have to justify their choices, their reasons, and their successes or failures. Yet, absolute freedom cannot be achieved, because, at the most basic level, each such

[130] Downer, John. 2011. "737-Cabriolet" The Limits of Knowledge and the Sociology of Inevitable Failure. American Journal of Sociology 117 (3): 725-762.
[131] Anderson, Warwick, and Ian R Mackay. 2014. Intolerant Bodies: A Short History of Autoimmunity. Johns Hopkins Biographies of Disease. Baltimore, Maryland: Johns Hopkins University Press.

biotechnological organism requires insulin to live, and insulin can be obtained only through the rule-, data- and norms-based world. Therefore, to have T1D means becoming abnormal in the eyes of society and finding one's way in life as a reconstructed biotechnological organism, a human body kept alive by biomedical technologies in a contentious symbiotic relationship.

This work defines automation as the use of technologies to reduce risk and ease human efforts in managing a complex health condition. For example, a continuous glucose monitor (CGM) automates blood glucose tracking. It reduces the need to draw blood multiple times a day to get blood glucose readings. Through the process of automation, a user of a CGM device, such as Dexcom, gets blood glucose readings every five minutes, 24 hours a day for ten days before the technology must be replaced. Likewise, an insulin pump automates the delivery of insulin. An Artificial Pancreas System automates blood glucose management through the automation of insulin delivery in response to fluctuations in blood glucose. Before automation, individuals with diabetes or their caregivers had to draw blood and inject insulin using a syringe multiple times a day and night. With an Artificial Pancreas System, the multiple daily pricks are reduced, but users carry multiple devices, two of which are physically attached to their bodies, and are responsible for the regular procurement of parts and the management of devices. Before automation, patients had to listen to their bodies for signs of low or high blood glucose to make diabetes management decisions. After automation, they rely on technological outputs for decision-making. The outsourcing of blood glucose monitoring to automated biomedical technologies is taking place at the same time as the outsourcing of diabetes care is shifting from primarily doctor-led to self-managed by patients.

The consequences of historical shifts and automation discussed in this chapter build the foundational base for the risk discourses analyses addressed in the following chapters. This work challenges technological determinism by documenting the social construction of Artificial Pancreas Systems, both FDA-regulated and approved, as well as DIY open-source ones. It analyzes the efforts of risk reduction and knowledge production in two social groups to understand what risks are associated with health automation and biotechnological organisms. This chapter theorizes the technological management of type 1 diabetes by analyzing risk, efforts of automation, and commodification.

Terminology Use

This research uses a number of terms and abbreviations that require clarification. The health condition in question, type 1 diabetes, is referred to throughout scientific and social studies by a number of different names. These include type 1 diabetes mellitus (T1DM), juvenile diabetes, juvenile-onset diabetes, insulin-dependent diabetes mellitus, and insulin-dependent diabetes. This work uses the term type 1 diabetes (T1D) as the most commonly used term and the one that best identifies the autoimmune condition. T1D, while commonly diagnosed in childhood, can in fact be diagnosed at any age. Therefore, the term juvenile, referring to young individuals, is not accurate. Likewise, the term referring to insulin dependency is confusing as there are numerous individuals with type 2 diabetes who depend on insulin. In a social setting, in oral or written communication, individuals at times refer to type 1 diabetes as type 1 or T1D.

When referring to individuals with T1D, this work does not use the term "diabetic." This term is stigmatized and is considered socially unacceptable. The word

diabetic is still used as an adjective to describe health conditions such as diabetic neuropathy, diabetic retinopathy, diabetic ketoacidosis, or products used by those with diabetes, such as diabetic supplies. A "diabetic" definition of a person labels that person by a disease they have. It is acceptable to acknowledge that a person comes first and then comes the illness or disorder. A person with diabetes is commonly used in literature with the abbreviation of PWD. This research chooses to use "individual with T1D" or "person with diabetes" in their full form even though it takes longer to say or write. It is done deliberately with the primary reason not to hide an individual behind an abbreviation, but to deliberately and respectfully acknowledge the person.

This research, as an alternative to "individuals with T1D", uses the term "patients." On one hand, it is a helpful term when referring to persons with T1D from a medical, pharmaceutical, and healthcare perspective. Others might argue that individuals with T1D are patients only when interacting with a physician, or being physically located in a hospital or any other clinical setting. This research argues that individuals with T1D never stop being patients. A large part of this consideration is the round-the-clock connectivity and the constant stream of data which is often accessible to healthcare providers, such as endocrinologists. In the relation to the use of biomedical technologies, individuals with T1D are referred to as users.

When referring to biomedical technologies for T1D management, there are multiple names used for each. For example, an insulin pump in scientistic literature can be referred to as Continuous Subcutaneous Insulin Therapy or Continuous Subcutaneous Insulin Infusion (CSII). The Artificial Pancreas System is also referred to as Artificial Pancreas Device System, automated insulin delivery system, closed-loop system, and

hybrid closed-loop technology. For ease of reference, this research primarily uses the term Artificial Pancreas System (APS), interchangeable with the term closed-loop system used seldomly.

Transformation of Diabetes Care: Literature Review

Historical Studies of T1D

Type 1 diabetes is addressed in historical studies with a review of biomedical technologies used in its diagnosis, management, and treatment. The discovery of insulin in 1921 is a pivot event often addressed in the literature. It is remarked not only because it led to the transformation of disease from acute to chronic, but also because it made T1D inseparable from pharmaceuticals and other biomedical technologies used in its management. However, insulin, just like numerous biomedical technologies used today, did not emerge from a vacuum. Rather, it was the result of many years of work by many researchers across many nations. This is demonstrated well by Michael Bliss in "The Discovery of Insulin," where the author describes the complexity of relationships with those involved, the error-prone process full of setbacks, tensions, struggles, and challenges, and the significant effort of many professionals that was necessary to bring insulin to patients who needed it.[132] Just like Thomas Kuhn challenges the accepted progressive accumulation of knowledge in the historiography of science,[133] Bliss illustrates how the road to the discovery of insulin was paved with regressions, competing approaches, and conflicting ideas.

[132] Bliss, Michael. 1982. The Discovery of Insulin. Chicago: University of Chicago Press.
[133] Kuhn, Thomas S. 1996. The Structure of Scientific Revolutions. 3rd edition. Chicago, IL: University of Chicago Press.

Even with the general availability of insulin to the public, the process of administering and absorbing it was not without complications.[134] Too much insulin can be lethal, and too little insulin leads to significant adverse health complications. While these risks are better than the certainty of death, "insulin did not free diabetics from careful dietary control and self-discipline" required on a daily basis.[135] Bliss tells the story of insulin discovery and highlights how new issues arise with each new attempt at further discovery and innovation. Even now new and effective treatments for diabetes call for continued improvement. This drive for innovation parallels David Nobles' work pertaining to the industrial revolution and the effort of automation post-WWII.[136] There Noble describes how efforts of automation result in even more automation as new issues arise and require action.[137] Following Noble, and drawing from the work of Ruth Cowan, I conceptualize this below as "more work for patients."

Insulin, just like many biomedical technologies available today, was considered miraculous. Images of patients before and after insulin use provided a striking difference in the appearance of patients' health. Images of young children were particularly startling showing a transformation of children from emaciated to plump. These images offered hope for a better future and further emphasized the importance of the wonder drug. Insulin inspired many medical and scientific achievements that followed, strengthening the religious view[138] of scientists' ability to produce powerful and effective biomedical solutions for every illness. Even with demonstrated positive changes due to insulin use,

[134] Bliss, Michael. 1982. The Discovery of Insulin. Chicago: University of Chicago Press.
[135] Ibid.
[136] Noble, David F. 1984. Forces of Production: A Social History of Industrial Automation. 1st ed. New York: Knopf.
[137] Ibid.
[138] The phrase "religious view" refers to the unwavering belief and the worship-like faith in the abilities of scientists or produce effective solutions for any ailment.

prolonged lifespan, and improved health, the proliferation of insulin was not immediate as a number of doctors remained skeptical.

Medical understanding of T1D today is reductive, peering through the patient, often through the use of biomedical technologies, towards "some essential, objective, solid reality" yet, in the process loses the sense of the patient as a person.[139] Feudtner posits that focusing the retelling of T1D history on the wonder drug, such as insulin, or life-changing biomedical technologies as symbols of scientific progress, distracts from "the human realities of living with diabetes" as well as all the problems that still exist or new ones created as a result of "transmuted" disease.[140] Biomedical technologies have utility, but the narrow understanding of disease places a lot of value in precise scientific knowledge and technological data outputs to the detriment of comprehending the affected individual as subjective, complex, a result of unique experiences. This is demonstrated well by Joseph Dumit who postulates how pharmacological intervention focuses on data-driven, statistically significant, and risk-reduction practices which lead to a numerical representation of the patient and chronic use of pharmaceuticals.[141] Today's technological advances in T1D management did not eliminate users' vulnerabilities and risks such as hyperglycemia, hypoglycemia, and a variety of health complications. They might have shifted the points of concern slightly as they took the core place in T1D health considerations. The prominent role of biomedical technologies in today's society requires further research and critical study for better understanding.

---

[139] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[140] Ibid.
[141] Dumit, Joseph. 2012. Drugs for life: how pharmaceutical companies define our health. Duke University Press.

A significant challenge with the discovery of the first and all the subsequent versions of insulin was the ability to coordinate the supply of insulin to match the needs of the body as effectively as the human pancreas does it.[142] The innovation of insulin resulted in a variety of insulin types, offering different working times, and adding flexibility for different routines and lifestyles. However, with this innovation arose a need for a better insulin injection technology and further discoveries to address the new and emerging needs caused by the technologies in use. Managing T1D became a chore that required relentless attention every day and every night for a lifetime not only to manage the body but also the biomedical technologies used. For a long time, patients as well as researchers were hoping for a solution, such as an APS or a transplant with insulin-producing cells, that would reduce the burden of disease and ease or eliminate disease management requirements.[143] Thus, the drive for automation of blood glucose monitoring and insulin injection started with the eventual combination of the two to automate insulin injection in response to one's blood glucose. Combining these two technologies is the first step in achieving complete automation as well as redefining the search for a "cure" to T1D from biological to technological.[144]

In 1968 Professor Samuel Rahbar discovered that patients with diabetes had an abnormally increased amount of glycated hemoglobin (HbA1c) in their blood.[145] New methods of measuring HbA1c, implemented clinically (1977) and commercially (1991),

---

[142] Bliss, Michael. 1982. The Discovery of Insulin. Chicago: University of Chicago Press.
[143] Tattersall, Robert. 2009. Diabetes: The Biography. Biographies of Disease. Oxford: Oxford University Press.
[144] Pettus, J., Von Herrath, M. 2018. The shifting paradigm of a "cure" for type 1 diabetes: is technology replacing immune-based therapies? Acta Diabetol 55, 117–120. https://doi.org/10.1007/s00592-017-1069-8.
[145] Azizi, Mohammad Hossein, Moslem Bahadori, and Farzaneh Azizi. 2013. Breakthrough Discovery of Hba1c by Professor Samuel Rahbar in 1968. Archives of Iranian Medicine 16 (12): 743–45. https://doi.org/0131612/AIM.0013.

are now standardized and commonly used around the world.[146] The test called hemoglobin A1C or simply A1C is used to measure average glucose levels or blood health (blood glucose concentration) over the period of about 3 months (estimated life of red blood cells). This test is widely used today to assess the quality of one's blood glucose (BG) management and the effectiveness of biomedical technologies in the management of one's T1D. With the use of this test, scientists were able to determine that intense diabetes management with close monitoring and the use of biomedical devices was effective in preventing complications and maintaining BG levels close to those in healthy individuals. The HbA1c test presents an additional data point to represent the individual by and to quantify the disease. As Tattersall writes, while individuals with T1D need effective tools, the management of diabetes is much more involved than the use of the newest biomedical technologies.[147] Since BG is affected by a variety of factors external to the human body, as addressed in the previous chapter, the numerical, pharmaceutical, or technological view of disease provides a limiting view of the quality of one's health management. Such understanding often neglects to consider the individual responsible for the use of biomedical technologies and that individual's lived experiences.

Feudtner calls for us to move beyond the technological ethos and to seek a better balance between the acknowledgment of the benefits of biomedical technologies and understanding of the "incompleteness" and often harmful consequences of technological "solutions."[148] The introduction of new diabetes biomedical technologies was

[146] Ibid.
[147] Tattersall, Robert. 2009. Diabetes: The Biography. Biographies of Disease. Oxford: Oxford University Press.
[148] Ibid.

accompanied by the tension between progress and frustration. The progress part is clear as the drive for and trust in continual innovation resulted in the emergence of novel therapeutic solutions. There is tension in progress itself as new concerns appear with innovation, and efforts are made to enable further innovation. The balance of power itself is tipped toward regulatory experts and those driving the innovation efforts. The frustration part comes along with the progress which reshapes patient and caregiver experiences, exchanging old concerns for new ones, including complications, side effects, responsibilities, biomedical technologies, health care, and patient choices. Feudtner explains that "people with diabetes are more than a compilation of biological mechanisms."[149] Their experience with T1D has been uniquely influenced by different social circumstances, personal background, and their own interactions with the biomedical technologies they use to manage their disease. These experiences shape how patients interact with technologies and how patients shape technologies.

Historical studies demonstrate not only that T1D is inseparable from biomedical technologies used in its management, but also that T1D today is a technologically altered disease of high complexity. This complexity stems from the complexity of the human body, biomedical technology, human interactions, sociopolitical factors, challenges of self-management, and much more. Looking back in history allows one to see that the transformation of disease is due to this complexity not merely a result of the innovative achievements of a select few who lead humanity's progress toward miraculous technological solutions. The contemporary drive for innovation supports technological determinism and the linear model of beliefs pertaining to the historiography of

[149] Ibid. p.25.

technology where technology is equated with progress.[150] However, studies truly focused on the history of technological innovation would be primarily histories of failure.[151] Our innovation-obsessed society often disregards the "technology-in-use"[152] responsibility which, in a biomedical context, lies with the individual patients and their caregivers. The role of the user, a patient or a caregiver, in the automation of health should not be underestimated as users are involved in shaping technologies, maintaining them, modifying, educating, and disposing of them.[153] Exploring biomedical technology in society can offer a depth of understanding unachievable via standard scientific analyses. In order to assess a particular technology, it is important to look at the interplay of not only doctors and patients, but also of experts, communities, society, tools, bodies, and diseases.[154] Analyzing these complex interplays is daunting, yet they should not be ignored.

T1D as a Case Study

Diabetes is often used as a case study in anthropological works, studies of healthcare systems and treatment practices, as well as discussions of the biomedicalization of society. For example, Annemarie Mol uses the case of type 1 diabetes to compare the logic of care with the logic of choice. She reviews treatment practices and illustrates life with T1D in her ethnographic scholarship. Individuals with

[150] Edgerton, David. 2010. Innovation, Technology, or History: What Is the Historiography of Technology About? Technology and Culture 51(3): 680-697.
[151] Ibid.
[152] Russell A.L, and Vinsel L. 2018. After Innovation, Turn to Maintenance. Technology and Culture 59 (1): 1–25. https://doi.org/10.1353/tech.2018.0004.
[153] Bijker et al, eds., The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology. Cambridge, MA: MIT Press, 1987.
[154] Wailoo, Keith. 1999. Drawing Blood: Technology and Disease Identity in the Twentieth-Century America. Baltimore: Johns Hopkins University Press.

diabetes rely on and "depend on modern technologies for their survival" at the same time as the treatment of and life with T1D are synonymous as there is no life without treatment and individuals with T1D have no life without biomedical technologies.[155] This further emphasizes the inseparability of disease and the technologies used in its management. Mol explains just how involved the care of T1D is where chronic disease requires chronic care which is interactive, open-ended, and constantly reshaped based on results and patient's needs.[156]

In today's clinical care and scientific research, patients' success with T1D is measured by their ability to control their bodies and exercise control over their disease. The idea of control is further enforced by the established norms of T1D care which establish frames for individual capacity to govern themselves for the purposes of "optimizing the well-being of the population" and making it potentially more "productive."[157] Norms are used as control levers though the responsibility for control is shifted to the patient. Such norms are used to "encourage individuals to engage voluntarily in self-regulation."[158] Norms are set, for example, for blood glucose and HbA1c levels which have fixed target ranges and require biomedical technologies not only for data output but also for maintaining the required level of monitoring, self-regulation, and self-discipline. In fact, diabetes control is a widely used term in scientific literature erroneously indicating that is it possible to control something unpredictable and variable.[159] This also applies to biomedical technologies which are identified in scientific

[155] Mol, Annemarie. 2008. The Logic of Care: Health and the Problem of Patient Choice. Myilibrary. London: Routledge.
[156] Ibid.
[157] Mckee, Kim. 2009. Post-Foucauldian Governmentality: What Does It Offer Critical Social Policy Analysis? Critical Social Policy 29, no. 3: 465–86. https://doi.org/10.1177/0261018309105180.a
[158] Lupton, Deborah. 1999. Risk (Key Ideas). New York: Routledge (Chapter 2)
[159] Ibid.

literature as important for reaching better control over T1D, but in practice are not an assurance of success. Technologies are not as obedient or easily controlled, and they often have unexpected side effects.

"The key weapon available against the potentially devastating effects of diabetes is the individual's ability to achieve near-normal control of their blood glucose levels."[160] Val Wilson, a Ph.D. in Health Education, wrote in her 2013 book on diabetes. This statement stands out as it does not refer to clinical recommendations, medical expertise, or the miracle of biomedical technologies. It does not call for the superiority of regulatory experts or biomedical solutions. It places the power in the patient's (or caregiver's) hands, the patient's ability to self-manage their health, care for their diabetes, and educate themselves about their body and all the tools available to them. With this power comes the burden of responsibility for failures, lack of improvement, or less-than-desirable outcomes. However, one's ability to achieve near-normal control of their blood glucose is not an assurance of success as control is not something that can be achieved. It is not a state that once achieved can be permanent. It is a constant effort of managing, maintaining, and relentless work, which, even if performed the same way, can lead to different results. Since T1D as a chronic disease requires chronic use of biomedical technologies, the matter of maintenance gains particular importance. Technological maintenance is defined as "all of the work that goes into preserving technical and physical orders."[161] Thus, attention to maintenance is essential not only to the effort of gaining control over disease and ensuring stability and continuity of biomedical

[160] Wilson, Val. 2013. Diabetes: From the Ebers Papyrus to Cell Technology. Teneo Press.
[161] Russell A.L, and Vinsel L. 2018. After Innovation, Turn to Maintenance. Technology and Culture 59 (1): 1–25. https://doi.org/10.1353/tech.2018.0004.

technology but also to elevating the role of the user and drawing attention to the power users hold in shaping technologies.[162]

Warwick and Mackay wrote about T1D, as one of four conditions in their study of autoimmunity.[163] The ideas of autoimmunity are a rich source of metaphors to describe not only how the confrontation with autoimmune disease transforms bodies, but also how it changes one's sense of worth, relationships, families, and society.[164] The addition of biomedical technologies to the "complicated and productive entanglements" of autoimmunity further contributes to the "unsettling of identity" where T1D as a chronic disease can induce uncertainty and fear from technological malfunction. It can lead to social isolation where others shy away from interaction with those wearing T1D biomedical technologies. It can even cause stress and anxiety from too much data provided as the output of biomedical technologies. Through the analysis of autoimmunity, as presented by Warwick and Mackay, we can see that T1D is a multidimensional disease that requires situated approaches to study.

Biomedical technologies themselves are used to create meaning, construct disease, and form medical knowledge. As Keith Wailoo wrote, "doctors have learned to think and act through their technologies" which play an important role in assigning disease identification and legitimizing medical attitudes.[165] Their technological understanding of disease allows for the "depersonalization" of medicine and the

---

[162] Long, Pamela O. 2018. Engineering the Eternal City: Infrastructure, Topography, and the Culture of Knowledge in Late Sixteenth-Century Rome. Chicago: University of Chicago Press.
Russell A.L, and Vinsel L. 2018. After Innovation, Turn to Maintenance. Technology and Culture 59 (1): 1–25. https://doi.org/10.1353/tech.2018.0004.
[163] Anderson, Warwick, and Ian R Mackay. 2014. Intolerant Bodies: A Short History of Autoimmunity. Johns Hopkins Biographies of Disease. Baltimore, Maryland: Johns Hopkins University Press.
[164] Ibid.
[165] Wailoo, Keith. 1999. Drawing Blood: Technology and Disease Identity in the Twentieth-Century America. Baltimore: Johns Hopkins University Press.

structuring of their thoughts, discussions, and conclusions.[166] It is still believed that biomedical technologies, perceived as powerful, have the ability to uncover the truths of one's health status. This is also the case with T1D as biomedical technologies take a central stage in medical care, clinical interactions, and disease management.

T1D often has contradictory, confusing, and even at times deceptive representations in U.S. culture as demonstrated by Bennett.[167] On one side it is represented as a lethal condition, on the other side, it is represented as "a condition that is effortlessly mastered" with the help of biomedical technologies.[168] Bennett pays particular attention to how diabetes is represented in contemporary U.S. culture and demonstrates that the management of T1D is not only clinical but also cultural. He wrote that "the ways we communicate about disease and illness have a direct effect on how we act upon them."[169] The way T1D is represented in the public sphere has the power to influence not only one's experience with the disease but also influence policy and the practice of medicine. This parallels Ian Hacking's idea of "representing as intervening," meaning the way we represent things in the world influences what those things do in the world.[170] Contemporary representations of T1D skillfully cultivate hope for a technological solution to diabetes with unwavering faith in the promise of scientific expertise to eliminate all suffering related to T1D.[171]

---

[166] Ibid.
[167] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. http://www.jstor.org/stable/j.ctv12fw5z8.
[168] Ibid.
[169] Ibid.
[170] Hacking, I. 1983. Representing and Intervening: Introductory Topics in the Philosophy of Natural Science. Cambridge: Cambridge University Press. doi:10.1017/CBO9780511814563.
[171] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. p.44. http://www.jstor.org/stable/j.ctv12fw5z8.

Biomedical technologies add complexity at different levels of analysis. Technological complexity combined with the demands of the disease can create conditions that impede one's ability to effectively manage their health, thus counteracting the purpose of these technologies. Biomedical technologies, perceived as depersonalized and objective, are celebrated in media and among regulatory experts for their potential and promise (more in Chapter 3). Challenges associated with T1D and technological use are not sexy or exciting, thus, do not warrant the attention and media coverage they deserve. Even trauma due to diabetes, causing lost limbs, blindness, or other irreversible health complications, is not considered all that traumatic due to the slow nature of disease progression.[172] Bennett argues for more research to improve our understanding of T1D as without deeper understanding there cannot be a better treatment. The use of T1D as a case study in research further emphasizes the entanglements of T1D with biomedical technologies, care practices, cultural representations, power structures, health outcomes, and more. There is a need to add a variety of perspectives and approaches to the study of biomedical technologies and T1D to not only improve our understanding of disease and health but also to move toward more effective ways of care and treatment.

More Work for Patients

Technological change in T1D management modified the requirements and responsibilities of patients. In a number of ways, patients today have better tools to manage their T1D with more data to work with and more devices with higher accuracy. However, the technological ways to manage T1D require "unremitting labor" and

[172] Moran-Thomas, Amy. 2019. Traveling with Sugar: Chronicles of a Global Epidemic. Oakland, California: University of California Press.

"perpetual vigilance."[173] Individuals with T1D have to "manage not only their disease but also the work that this management system has created for themselves and the effects of this self-care work on their relationships with others."[174] This draws parallels with Cowan's study of household technologies that led to the transformation of the home and led the "industrialization" of housework.[175] Just like housework today does not exist in isolation from economic and social systems, biomedical technologies for diabetes management, such as the Artificial Pancreas Systems, do not stand in isolation. As the SCOT theory indicates, technologies are shaped by a variety of social factors including relevant social groups such as users, caregivers, and even non-users, which are those who refuse the technology altogether.[176] Further, the APS cannot function without a power source, replacement parts, Bluetooth connection, all its components, insulin, and the healthcare system.

The uptake of technology is not universal. Just like with household technology, the adoption of biomedical technology for T1D management lacks consistency or homogeneity. This is observed across the levels of socioeconomic status, education, and ethnicity. Cowan's approach can be used to better understand the shifting burden of responsibility in T1D care and the impact of biomedical technologies on everyone involved, directly and indirectly, in patient care and technological change. There is a general lack of comprehensive studies taking on this perspective, especially with the

---

[173] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[174] Ibid. p.65.
[175] Cowan, Ruth Schwartz, 1983. More Work for Mother: The Ironies of Household Technology from the Open Hearth to the Microwave. New York: Basic Books.
[176] Oudshoorn, Nelly and Trevor Pinch (eds). 2003. How Users Matter: The Co-Construction of Users and Technologies. Cambridge, Mass.: MIT Press.
Bijker, Wiebe E., Thomas P. Hughes and Trevor Pinch. [1987] 1989. The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology. Cambridge, MA: MIT.

increasing standards of care and more stringent expectations of patients. However, emerging scholars like Stephen Horrocks, are starting to explore the complicated entanglements around T1D and the roles biomedical technologies play in U.S. culture in twenty-first-century medical care, chronic disease management, and user well-being.[177]

Advertising and marketing efforts in the 20th century emphasized the role of women in the household with the use of household technologies.[178] Similar efforts are made by pharmaceutical and biotechnological companies who try to define people's health as well as the roles and responsibilities of patients with biomedical technologies. As the SCOT theory indicated, technologies have "interpretive flexibility", meaning they are open to multiple and at times radically different interpretations by different social groups.[179] This also means that even biomedical technologies can be understood differently by different subgroups within the population. The "one size fits all" approach to biomedical technologies and technological users cannot be successfully applied.

Biomedical technologies for T1D management have inherent risks built in based on technological malfunction and the need for alternative disease care options as discussed in the previous chapter. Hinchliffe, Bingham, Allen, and Carter state in their work, "making life safe always risks the very thing it seeks to protect."[180] Likewise, efforts of automation and risk reduction to make T1D patients "healthier" might

[177] Horrocks, S. 2019. Materializing datafied body doubles: Insulin pumps, blood glucose testing, and the production of usable bodies. Catalyst: Feminism, Theory, Technoscience, 5(1), 1-26.
Horrocks, Stephen and Horrocks, Melissa. 2022. Bread and Chronic Illness. Diabredic. Accessed 07.10.2022. https://www.diabreadic.com.
[178] Cowan, Ruth Schwartz. 1983. More Work for Mother: The Ironies of Household Technology from the Open Hearth to the Microwave. New York: Basic Books.
[179] Bijker, Wiebe E., Thomas P. Hughes and Trevor Pinch. [1987] 1989. The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology. Cambridge, MA: MIT.
[180] Hinchliffe, S., Bingham, N., Allen, J., & Carter, S. 2016. Pathological Lives: Disease, Space and Biopolitics, John Wiley and Sons.

contribute to adverse health outcomes. While the authors examine the efforts of optimization in farming, similar thinking can be applied to the study of biomedical technology designed for the population with significant risk factors internal and external to individuals' bodies. In fact, as some scholars indicate, our lives are surrounded by risks coming from multiple directions,[181] including an unquantifiable amount of risk under the current global health security regime.[182] Yet, efforts are made to optimize, standardize, and quantify disease with the promise to reduce risks.[183] Quantification and risk mitigation efforts fail to address patient health and well-being within the socio-technical-scientific complexities. For example, David Fonte and his co-authors address well-being among T1D adolescents but do not incorporate technology as an important factor affecting patient well-being.[184] Similarly, contemporary public health approaches for improved population health do not directly incorporate considerations of biomedical technologies and health automation on patients' health, provision of medical services, and their impact on patients' well-being.

Biomedical technologies for diabetes management themselves are products of complex interactions among different groups within society. Emily Martin wrote about human immunity and how in the late 20th century the human body was thought of as a complex system. It was a way to conceptualize the world around us. The complex systems view of the human body, human immunity, and/or biomedical technological

[181] Lakoff, A., & Collier, S. J. (Eds.). 2008. Biosecurity interventions: global health and security in question. Columbia University Press.
[182] Lakoff, A. 2017. Unprepared: Global Health in a time of emergency, UC Press.
[183] Greene, Jeremy. 2008. Prescribing by Numbers: Drugs and the Definition of Disease. Johns Hopkins.
[184] David Fonte, Sébastien Colson, José Côté, Rachel Reynaud, Marie-Claude Lagouanelle- Simeoni, Thémis Apostolidis 2019. Representations and experiences of well-being among diabetic adolescents: Relational, normative, and identity tensions in diabetes self-management. Journal of Health Psychology: An Interdisciplinary, International Journal Volume: 24 Issue 14 (2019) ISSN: 1359-1053 Online ISSN: 1461-7277.

systems such as the APS can be a helpful venue for analysis. Just like the outcome of HIV/AIDS infection depends on the state of the immune system before and after HIV exposure, the outcome of biomedical technology use for someone with T1D depends on a number of variables, one of which is the state of the immune system but extends further to include variables that can and cannot be easily influenced. T1D, just like other autoimmune diseases, should be thought of as multifactorial. Martin's analysis of immunity is also applicable to T1D. Especially her concept of empowered powerlessness, which indicates that even if an individual is feeling responsible and capable of "controlling" their own health, they come to the realization of just how wide the circle is and all that it encompasses that impacts their health including but not limited to family, work, community, and more.[185] This can lead to stress and anxiety in healthy individuals with more significant implications for someone with health concerns.[186] The scale of disease management, especially autoimmune disease, and everything that it entails can easily become overwhelming.

A number of STS scholars have demonstrated that superiority is granted to novelty and innovation in studies of technology. Biomedical technologies for diabetes management are no exception. Technological design and manufacturing apply narrowly defined, and constricted views of the world or the problem scientists are trying to address. This is evident in historical studies of production that challenge technological determinism, studies of use to demonstrate how users and technologies are co-

[185] Martin, Emily. 1994. Flexible Bodies: Tracking Immunity in American Culture from the Days of Polio to the Age of Aids. Boston: Beacon Press.
[186] Ibid.

constructed, and studies of maintenance to "dethrone" innovation.[187] U.S. culture objectifies as well as fetishizes technology and places it above and apart from human affairs.[188] In many ways, technology is viewed as a problem within society as well as the solution to societal problems, such as in environmental studies. However, technological determinism guides individuals with a strong faith in technological solutions, absolving them from the responsibility to be proactive in life, strive to achieve fulfillment and take action to make desired changes without waiting for future technologies to make those desired outcomes possible for them.[189] As Noble writes, technological determinism and the denial of the full potential of people, which carries with it experiences, tacit knowledge, creativity, and skills, establish "a severely impoverished realization of the existing possibilities."[190] Yet, the expression of the full potential of people is frowned upon, especially if it goes beyond the norms and expectations established by regulatory experts, especially in relation to human health.

In some cases, technological innovation does not improve people's lives for the better as individuals have to be aware of technologies, have access to them, and have to engage with them to even get close to receiving any benefits.[191] Furthermore, individual users play a role in the development of technologies through consumption, modification, creative use, design, and resistance.[192] Users of technologies today are not just passive recipients, they are active participants as exemplified by the DIY movement to provide an

[187] Noble, David F. 1984. Forces of Production: A Social History of Industrial Automation. 1st ed. New York: Knopf.
[188] Ibid.
[189] Ibid.
[190] Ibid.
[191] Petrick, Elizabeth R. 2015. Making Computers Accessible: Disability Rights and Digital Technology. History of Science, Technology, and Medicine. Baltimore: Johns Hopkins University Press.
[192] Oudshoorn, Nelly and Trevor Pinch (eds). 2003. How Users Matter: The Co-Construction of Users and Technologies. Cambridge, Mass.: MIT Press

open-source solution to patients by patients marked by the hashtag #WeAreNotWaiting.[193] Biomedical technologies for diabetes management require user engagement otherwise those technologies can't and won't fulfill their promise. Their utility fully depends on users. Additionally, the role of the user is elevated within the technological marketplace where human identities are increasingly defined by consumption, not production, thus users might have more power than producers.[194] Technologies might be used as tools to shape relationships, make status claims and express one's lifestyle to others.[195] Therefore, the role of users should not be ignored in the analysis of biomedical technologies.

Users of technologies as well as the maintenance they perform are often underrepresented in technological studies as important factors that contribute to technological success. While Pamela Long does not write about biomedical technologies, her study of major projects of engineering and urban design of late 16th century Rome highlights important aspects of technological maintenance.[196] Technological maintenance within T1D as well as the questions of technological obsolescence which emphasizes issues of disposal[197] become the primary responsibilities of users. We live in a society "obsessed with novelty."[198] Historical studies of technology demonstrate how technological design is prioritized over production, production over consumption, with

[193] Healthline. 2019. The #WeAreNotWaiting Diabetes DIY Movement. Accessed 9/5/22. https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting#About-the-#WeAreNotWaiting-Movement.
[194] Oudshoorn, Nelly and Trevor Pinch (eds). 2003. How Users Matter: The Co-Construction of Users and Technologies. Cambridge, Mass.: MIT Press.
[195] Ibid.
[196] Long, Pamela O. 2018. Engineering the Eternal City: Infrastructure, Topography, and the Culture of Knowledge in Late Sixteenth-Century Rome. Chicago: University of Chicago Press.
[197] Mika, Marissa. "The Half-Life of Radiotherapy and Other Transferred Technologies." Technology and Culture, Volume 61, Number 2 Supplement, April 2020, pp. S135-S157.
[198] Russell A.L, and Vinsel L. 2018. After Innovation, Turn to Maintenance. Technology and Culture 59 (1): 1–25. https://doi.org/10.1353/tech.2018.0004.

maintenance or disposal barely considered at all.[199] Scientific studies of biomedical technologies rarely venture past the innovation, design, new technology implementation, and the focus on progress, towards what happens "after", when technologies have to be used daily, maintained, and disposed of.

The maintenance of biomedical technologies is closely related to T1D management as it is performed during use. Technological maintenance, while not directly affecting health outcomes, ensures biomedical technologies are functioning as intended. The maintenance is often overlooked, but it adds substantial work for patients and impacts risk considerations. Risks of technological failure or malfunction, and as a result risks of adverse health outcomes, increase with improper or insufficient maintenance. The issues of maintenance are particularly important in T1D care with biomedical technologies that intimately interact with users' bodies and influence their health and well-being. The contemporary medical system lacks a nuanced view of T1D care as the primary focus is aimed at the medical management of T1D. Since T1D is a multisystem disease with increasing intensity of care, it affects the patient in a multitude of ways. Including just the medical aspect in the understanding of T1D provides a limited view, omits the demands of care that burden users of biomedical technologies, and obscures the risks associated with biomedical technologies.

Automation of Diabetes Care

Automation is perceived as the reduction of work required of patients and the drive towards automation historically was focused on the reduction of labor. As a chronic disease with a growing customer base, diabetes has become the target of automation in a

[199] Ibid.

race for better biomedical technologies. T1D is a complex condition and requires a complexity of management. In T1D management the drive for automation was focused not only on labor reduction but also on the reduction of risks associated with adverse health outcomes for users. The automation of diabetes entangles the patient with the digital infrastructure and associated expertise. Since "experts perceive risk differently from other members of the public,"[200] the automation of T1D might act as the foil to the goals of automated diabetes management.

Achievements of biomedicine and biomedical technologies are celebrated in society for their past, current, and future contributions to the knowledge pertaining to the human body and the world around it. The scale and complexity of biomedical devices, which have increased over time, have created a gap between biomedical specialists and the general public, and between doctors and their patients. Thomas Hughes describes this phenomenon in his 1998 book “Rescuing Prometheus.”[201] Even though Hughes describes large-scale R&D projects, some of his thinking can be applied here as well. The larger the gap between the public and biomedical technology engineers and specialists, the more challenging it will be to ensure the traditional checks and balances with such high complexity and high automation of medical practice.[202] Based on Hughes, automation of complex systems today is no longer the product of a single inventor, but of multiple technologies, sources of research, production, and funding, all of which require management and coordination. Biological communities and the DIY movement in this context are positioned in the domain which aims to close the gap between regulatory experts and users.

[200] Jasanoff, Sheila. 1993. Bridging the Two Cultures of Risk Analysis Actions. Risk Analysis 12: 123-129.
[201] Hughes, Thomas, 1998. Rescuing Prometheus. 1st ed. New York: Pantheon Books.
[202] Ibid.

Similarly, David Noble presented automation technologies as political tools used to maintain control and create a large gap between management and labor in order to keep managers in positions of power and retain a high level of their authority.[203] The gap serves as a reason to enforce public trust in biomedicine and increase the authority tied to biomedical technologies. It is no surprise that biomedical technologies are not only connected with the conditions of modern politics but also in themselves have political properties.[204] David Noble argues that industrial automation is a social process that reflects very real divisions and pressures within our society. In his book, Noble explains how technology is often spurred and shaped by the military, corporations, universities, and other institutions. Interestingly, his work demonstrates how automation led to the shortage of skilled workers which in turn created the need for more automation. Automation creates issues that call for further automation. The author describes how decisions to automate had a positive influence on the industry, the speed, and the quality of production, but a negative effect on labor. The labor-saving technologies of post-WWII automation did not lower the burden of working individuals, but eliminated working people "for narrow economic ends but still in the name of improving the human condition."[205] Automation has led to labor-displacing technologies that reduced people's livelihoods and tarnished their identities.[206] Similar questions arise about what negative effects are hidden behind the positive impacts of biomedical technologies. Should automation be encouraged without limitations or constraints due to technological and scientific advances which are viewed as positive developments for society?

---

[203] Noble, David F. 1984. Forces of Production: A Social History of Industrial Automation. 1st ed. New York: Knopf.
[204] Winner, Langdon. 1980. Do Artifacts Have Politics? Daedalus 109(1): 121-136.
[205] Hughes, Thomas, 1998. Rescuing Prometheus. 1st ed. p.58. New York: Pantheon Books.
[206] Ibid.

Efforts have been made to automate many aspects of human health to improve health outcomes, enhance health monitoring, increase the data outputs pertaining to one's health, as well as develop a number of lifesaving and life-sustaining biomedical technologies. The automation of health through biomedical technologies is celebrated as progress and advancement under the sheath of neutrality. Keith Wailoo demonstrated how experts were "uncovering the truths" through the use of biomedical technologies, thus claiming professional authority and validity via the perception of scientific and technological neutrality.[207] Ruha Benjamin has argued that automation itself appears neutral because the data are perceived as neutral, the technology is viewed as impartial and, the algorithms incorporated in technologies are seen as solely mathematical formulations.[208] The drive for automation in T1D management is very prominent along with the perception of technological neutrality.

Automated diabetes management also increases patients' dependence on such technologies, an outcome that contrasts sharply with the assurances of freedom that automation promises. This is evidenced by limitations imposed by insurance companies where only certain brands and types of biomedical technologies can be used for a defined period of time. This limits the patient's ability to switch to a more desirable and better-suitable technology for that particular patient. It also makes switching technologies very costly. Further, users are burdened not only by managing and requesting prescriptions from their doctors, and procuring the technology and related supplies, but also by managing malfunctions, skin irritations, infections, and other issues that arise due to

[207] Wailoo, Keith. 1999. Drawing Blood: Technology and Disease Identity in the Twentieth-Century America. Baltimore: Johns Hopkins University Press.
[208] Benjamin, Ruha. 2019. Race After Technology: Abolitionist Tools for the New Jim Code. Cambridge, UK: Polity.

technological use. It is rarely discussed that a simple BG meter requires separate prescriptions for test strips and lancets as well as a supply of batteries. Components and supplies for a more complex APS make even more demands on the user's time, effort, and wallet.

Automation is often viewed as labor-saving and long-term cost-saving. However, whose labor and costs is automation saving? Despite the insulin patent being sold for $1 (USD) shortly after insulin discovery, the cost of insulin remains high today. The blood glucose meters were considered affordable, yet the parts they required, such as branded test strips, were expensive. Treating complications of diabetes is also costly. Biomedical technologies do not always work properly or last the full duration of their useful life. This further increases the costs of care. The U.S. medical system offers a vast number of pharmaceuticals and biomedical technologies but it also asks for a lot in return as reflected by the raising costs of healthcare that might impede access to and the quality of care.[209] This is particularly evident with the management of T1D. Yet the increasing costs of pharmaceuticals and biomedical technologies combined with a rush of new innovations and new systems make it prohibitively expensive for some to access and leave little to no time to consider the quality of medical care, to train health care providers to acquire the necessary skills and to improve access for those who were left behind. Financial constraints might limit one's ability to effectively manage their T1D. The burden of medical care along with the burden of medical costs are associated with lower aggregate lifetime earnings and fewer job prospects for those with T1D than those

[209] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.

without it.[210] Thus, automated technologies in the management of T1D can lead to financial concerns due to the cost of technologies and can increase risk due to financial limitations, increasing costs of medical care, of the health condition itself.

As historical studies of diabetes indicate, the faith in technological solutions from the 20th century has the majority of the population believe that most if not all problems related to diabetes have been solved or are about to be solved by technological solutions. Technological innovations were viewed as powerful, altruistic, miraculous, and a blessing to be treasured. Biomedical technologies present a lot of value to the individual, to the clinical practice, for society, and for global security. However, biomedical science and the technological lens it is viewed through does not always consider cultural ideas, professional tensions, disability, human suffering, mental health, and the complexity of the world we live in. This is most likely due to the narrow scientific view of technologies. Biomedical technologies support the automation of decision-making in the practice of medicine, where the reliance on technologies overshadows the reliance on patient feedback or a doctor's intuition based on experience. Technology itself is not a definitive guide to understanding the human body and the human condition. Furthermore, the politics surrounding biomedical technologies and the field of biomedicine reveal concerns with the ideas of life enhancement and the pursuit of perfection with "growing capacities to control, manage, engineer, reshape, and modulate the very vital capacities of

[210] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. Accessed May 13, 2021.

human beings as living creatures."[211] The politics of life today are inseparable from biomedical considerations of life and associated technological interventions.[212]

Shifting Responsibilities and Risks of Care

One significant benefit of new biomedical technologies, which decreased in size and improved in functionality over the years, was the shift of technological use from that limited to clinics, hospitals, and laboratories to individual patients. This in turn increased patient and caregiver education, as well as improved awareness of patients about their bodies, their blood glucose, and their disease. This increased patient involvement in self-management of T1D reinforced by essential information such as one's blood glucose reading led to increased interest and involvement of patients in technology modification and design of new ones to address patient-specific concerns.

Allen Joslin, a prominent diabetologist, advocated for patient education, and increased self-management so that patients could attain increasing mastery over their health even before the first administration of insulin in 1922.[213] Today, a global community of patients is involved in designing, educating, and sharing modern biomedical technologies in an open-source format. The shift in patient education and disease self-management points towards patients as potential sources of knowledge production and expertise. One way to examine this is to follow the #WeAreNotWaiting movement and the community of DIY open-source innovators (addressed in detail in

[211] Rose, Nikolas. 2009. The politics of life itself: Biomedicine, power, and subjectivity in the twenty-first century. p.3. Princeton: Princeton University Press.
[212] Ibid.
[213] Feudtner, C. 1995. The Want of Control: Ideas, Innovations, and Ideals in the Modern Management of Diabetes Mellitus. Bulletin of the History of Medicine 69 (1): 66–66.

chapter 4) where patients and their advocates gather to be proactive in finding solutions to their lived problems without the profit-driven motivations and barriers.

Further, technological developments throughout history have contributed to the shift of responsibilities and risks of T1D. On one side the shift towards increased self-management also increased the responsibility of patients for their bodies, for technologically driven disease management, and for the outcomes of that management. In addition to the intimacy of T1D self-management, this shift imposed industrial agendas on one's biological and social processes, mediating, surveilling, and interfering with them.[214] Patients became further intertwined with the systems of industrial procurement, health insurance transactions, corporate health systems, and outside networks. Patients are also the ones responsible for maintaining these relationships to ensure sufficient supplies are on hand, resolve health insurance issues, keep up with the need for prescriptions, and handle the connectivity of technologies for proper functionality.

On the other side, the increasing demands of care have also increased the risks associated with T1D self-management. Laura Forlano, a scholar with T1D, wrote: "*It is almost ironic that the system that has nearly eliminated the frequent episodes of extremely low blood sugar that woke me in the middle of the night almost a decade ago has enforced another form of sleep interruption and depravation."*[215] Forlano refers to technological demands for calibration, frequent alarms, and other disruptions. She said: "my body is networked and dependent on a system of technologies that is fragile,

[214] Forlano, Laura. 2017. Data Rituals in Intimate Infrastructures: Crip Time and the Disabled Cyborg Body as an Epistemic Site of Feminist Science. Catalyst. Vol. 3 No. 2 (2017): Science Out of Feminist Theory. https://catalystjournal.org/index.php/catalyst/article/view/28843.
[215] Forlano, Laura. 2023. Living Intimately with Machines: Can AI Be Disabled? Association for Computing Machinery. Vol. 30/1. pp.24-29. https://doi.org/10.1145/3572808.

vulnerable, and prone to breaking down."[216] This indicates not only that risks of T1D have a significant technological component, but also that biotechnological organisms are dependent on industrial agendas that introduce interruptions, depravations, vulnerabilities, and risks.

Laura Forlano self identifies as a cyborg. While cyborg is a concept that is widely used in disability studies and STS, this research consciously avoids the term and instead uses the term biotechnological organism. The reason for this is threefold. The first reason is the clarity of terminology. "Cyborg" is widely used in science fiction literature and filmography. Since the audience for this dissertation is, among others, regulatory experts, I seek to avoid any confusion among non-STS readers about what I mean. The second reason is the multitude of uses of "cyborg" within the STS literature. This term is discussed and described in a variety of ways ranging from the intimate nature of one's identity as in Forlano's case and cybernetically extended or enhanced organisms, "organism extended by means of cybernetic technology" [217] to a positive feminist metaphor of cyborg[218] and the everyday cyborg by choice.[219] This research aims to carve out a very specific use that is akin to cyborg but approached from a different side. Although the literature is more nuanced and many ideas discussed in this dissertation have also been discussed in the cyborg literature, the term "biotechnological organism" is not as laden and provides more analytical clarity for this analysis. Lastly, this research

[216] Forlano, Laura. 2017. Data Rituals in Intimate Infrastructures: Crip Time and the Disabled Cyborg Body as an Epistemic Site of Feminist Science. Catalyst. Vol. 3 No. 2 (2017): Science Out of Feminist Theory. https://catalystjournal.org/index.php/catalyst/article/view/28843.
[217] Kline, Ronald. 2009. Where Are the Cyborgs in Cybernetics? Social Studies of Science 39 (3): 331–62.
[218] Haraway, Donna. 1991. A Cyborg Manifesto: Science, Technology, and Socialist-Feminism in the Late Twentieth Century, in: Simians, Cyborgs and Women: The Reinvention of Nature, pp. 149–181. New York: Routledge.
[219] Haddow, Gill, Emma King, Ian Kunkler, and Duncan McLaren. 2015. Cyborgs in the Everyday: Masculinity and Biosensing Prostate Cancer. Science As Culture 24 (4): 484–506. https://doi.org/10.1080/09505431.2015.1063597.

aims to place the individual before the disease and before the technology. This is done visually and rhetorically while discussing T1D and referring to individuals with T1D and people with disability instead of diabetic and disabled individuals. The same idea is applied to the relationship between the individual and technology. Therefore, this research prefers to use biotechnological organism instead of cyborg or cybernetic organism.

Biotechnological organisms include not only biomedical technologies in the form of digital devices, computers, or systems of computers, as in the case of the APS but also pharmaceutical technologies, such as insulin. In this context, the term biotechnological organism highlights the dependency of the biological organism (human body) on biomedical technologies, their integration, and inseparability. Since life with a chronic condition requires involvement in the process of continuous breakdown and repair,[220] biotechnological organisms are constantly in flux, balancing the demands between the body, technology, and outside factors such as industrial agendas. The shifting responsibilities and risks of T1D due to automation have a direct impact on biotechnological organisms by complicating, reconfiguring, and entangling life instead of simplifying it.

Normalization

The concepts of normalcy within U.S. society since the introduction of injectable insulin placed a lot of pressure on those living with a chronic disease. As individuals with

[220] Forlano, Laura. 2016. Hacking the Feminist Disabled Body. Journal of Peer Production. Issue 8. Feminism and (un)hacking. http://peerproduction.net/issues/issue-8-feminism-and-unhacking-2/peer-reviewed-papers/issue-8-feminism-and-unhackingpeer-reviewed-papers-2hacking-the-feminist-disabled-body/.

T1D deal with the challenges of managing their health and the use of biomedical technologies, they can often feel estranged from the "archetypal normal," the prevailing vision of who the ideal Americans should be.[221] However, patients have been increasingly involved in defining what this normalization means to them. Feudtner reported accounts of patients tinkering with the insulin dosage backing in 1936.[222] Patients' involvement in self-education and proactive solution-seeking contributes to the shift of the power structure and influences what "normal" should be in modern society.

Joseph Dumit wrote "[t]o be normal, therefore, is to be insecure" as one's perception of health might be defined by ignorance.[223] Health as a concept "is starting to disappear in pharmaceutical reports."[224] It is no longer a meaningful and achievable target. As medicine began relying on statistics in the 1950s, the population became increasingly considered in terms of risk, and "risk became the target of medical interventions."[225] Pharmaceuticals or biomedical technologies, accompanied by tests and screenings, became essential in the efforts to reduce risks. Therefore, "health" today is replaced with "healthier" which is accomplished through the ingestion of preventative pharmaceuticals and the use of biomedical technologies in order to reduce the risks of adverse health outcomes.

Biomedical technologies and software products for T1D management, even when used continuously with repetitive practices, do not lead to identical outcomes, resulting in

[221] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[222] Ibid.
[223] Dumit, Joseph. 2012. Drugs for life: how pharmaceutical companies define our health. Duke University Press.
[224] Ibid.
[225] Ibid.

the “failure of individuals to exercise self-discipline,” not technological failure.[226] However, “failure is not a lack but rather what it means to live with disability and what it means to live with machines”[227] as Forlano posits. For those with T1D, technological failure is normal, a regularly occurring state. People are flawed and so are biomedical technologies. When looking at the biotechnological organism, the flaws of the body and the technology are merged and inseparable. They both require attention for the biotechnological organism to live.

Individuals with T1D live with substantial lifelong risks, intimately connected with biomedical technologies in an effort to reduce risks. Biomedical technologies for diabetes management are designed to relieve the burdens of disease and mitigate the risks of adverse health outcomes. Thus, efforts are made to regulate and normalize T1D patients by federal agencies and by medical professionals who have been delegated the responsibility of keeping their patients in line with the established norms. The automation of biomedical technologies for diabetes management contributes to the quantification of patients' health and disease as well as to the increased need for control over all aspects of a patient's life. Deborah Lupton links efforts on the part of the state through the mechanism of biopolitics to affect the "idealized" citizen.[228] Lupton's analysis of a woman's body during pregnancy can similarly be applied to the body of a T1D patient. These include efforts to surveil, advise and regulate bodies considered to be at high

[226] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. Accessed May 13, 2021.
[227] Forlano, Laura. 2023. Living Intimately with Machines: Can AI Be Disabled? Association for Computing Machinery. Vol. 30/1. pp.24-29. https://doi.org/10.1145/3572808.
[228] Lupton, Deborah. 1999. Risk and the Ontology of Pregnant Embodiment In Risk and Sociocultural Theory: New Directions and Perspectives, edited by D. Lupton. Cambridge, UK, New York & Melbourne, Cambridge University Press, 59-85.

risk.[229] The quality of T1D management is assessed based on biomedical technology outputs and emphasized by the need for control of the "at-risk population" of patients with T1D. Patients are immunocompromised and at risk of health complications,[230] including the increased risk of mental health problems that can impede T1D self-management.[231] If the risk is the probability of bad outcomes,[232] then T1D patients are living lives full of risk in everything they do.

Normalization is the method of identifying, measuring, and monitoring norms of one's health status or one's behavior within a target population. The concept of normalization is closely related to the theory of governmentality as it allows for population comparison and efforts of conformity to established norms in order to increase productivity and compliance. Risk is essential in the process of normalization since "risk is problematized, rendered calculable and governable" and allows for interventions and specific expert forms of knowledge.[233] Regulated biomedical technologies are used as tools of normalization, helping to quantify risk and compare it against the established norms. Thus, one can be found "normal" or acceptable in comparison to norms, or "abnormal" and in need of interventions and monitoring. Deviations from the currently set norms are understood as risky, requiring new biomedical technologies, new pharmaceuticals, and more medicalization.

---

[229] Ibid.
[230] CDC 2020. Diabetes: Prevent Complications. Accessed 4/20/20 https://www.cdc.gov/diabetes/managing/problems.html.
[231] Clarke, Janine, Judy Proudfoot, Veronica Vatiliotis, Charles Verge, Deborah J Holmes Walker, Lesley Campbell, Kay Wilhelm, Catherine Moravac, Pillaveetil S Indu, and Madeleine Bridgett. 2018. Attitudes Towards Mental Health, Mental Health Research and Digital Interventions by Young Adults with Type 1 Diabetes: a Qualitative Analysis. Health Expectations 21 (3). John Wiley & Sons, Ltd (10.1111): 668–77. doi:10.1111/hex.12662.
[232] Jasanoff, Sheila. 1993. Bridging the Two Cultures of Risk Analysis Actions. Risk Analysis 12: 123-129.
[233] Lupton, Deborah. 1999. Risk. New York: Routledge.

Medicalization

Patients receiving health advice from their doctors are responsible to navigate this information by understanding it, making decisions, and accepting responsibility for it. Commercials, publications, and other similar public relations approaches to increase patient awareness are used as tools of communication directly to consumers, often generating concern and anxiety about a possible complaint turning into treatable entities. This is referred to as medicalization where non-medical states become medical and treatable, including moral, social, and legal issues such as drug abuse, crime, obesity, aging, and alcoholism to name a few. Since the theory of medicalization was insufficient to some at explaining the contemporary state of medicine and human health, this led to the emergence of biomedicalization theory which includes "old and new social arrangements that implement biomedical, computer, and information sciences and technologies to intervene in health, illness, healing, the organization of medical care, and how we think about and live "life itself."[234] Thus, one no longer requires the presence of physical symptoms of disease to be considered ill.

While the medicalization theory was suitable for explaining the changes in clinical practice and the expansion of authority within medical care,[235] the shift to biomedicalization is apparent due to the changes in "the medical gaze" from strictly clinical to molecular, to include technoscientific interventions not only for treatment but also for enhancement.[236] Advances in biomedical technologies enable further developments and extensions of biomedicine. Clarke and her colleagues emphasize the

[234] Clarke, Adele, Laura Mamo, Jennifer Ruth Fosket, Jennifer R. Fishman, and Janet K. Shim, eds. 2010. Biomedicalization: Technoscience, Health, and Illness in the U.S. Durham, NC: Duke University Press.
[235] Starr, Paul. 1982. The Social Transformation of American Medicine. New York: Basic Books.
[236] Clarke, Adele, Laura Mamo, Jennifer Ruth Fosket, Jennifer R. Fishman, and Janet K. Shim, eds. 2010. Biomedicalization: Technoscience, Health, and Illness in the U.S. Durham, NC: Duke University Press.

stratification of biomedicalization with unequal access to medicines across the population due to social inequalities. Similarly, access to biomedical technologies for T1D management is highly stratified. The authors also attest that the biomedicalization strategy aims to prevent disease through the ingestion of synthetic compounds by individuals to prevent and reduce risks already in existence within us.[237] This is in stark contrast to the efforts of improving the environmental, social, and economic conditions individuals live in to achieve disease prevention, risk reduction, and reversal of symptoms. The population-level interventions to identify and actively strive to remove illness-causing agents have been replaced with choice, education, and responsibility at the individual level. Instead of focusing on creating our surroundings to be more supportive of an active lifestyle and creating conditions where only healthy meal options are available, the burden of responsibility lies with individuals to control themselves, and live a healthy lifestyle amidst the surroundings full of temptations that entice people to move less and eat more poor-quality foods. Our environment driven by corporate interest is creating conditions that promote a lifestyle that leads to the development of T1D complications, thus increasing risks for patients.

Biomedical Citizenship

Particularly interesting engagements are taking place through biomedicalization at the population level where patients are changing the possibilities and creating new opportunities as individuals, communities, and biological citizens. For example, Petryna wrote how Chornobyl victims in Ukraine claimed their rights to healthcare services and

[237] Ibid.

social support for survival, suffering, and well-being.[238] The author described how individuals gained their entry into the status of biological citizenship based on their exposure to radiation, based on numbers, measurements, and medical reports, thus harmfully exposed and deserving of compensation.[239] The levels of exposure and with it the biological citizenship status fluctuated along the changing norms of radiation safety as none were clearly defined or strictly adhered to at the time.[240] The concept of biological citizenship is often discussed in terms of a certain health condition, but more research is needed to evaluate how biomedical technologies might facilitate knowledge production and the inclusion of one into the biological citizenship status.

DNA biomarkers can be used to define biomedical citizenship in terms of Native American DNA as demonstrated by Kim Tallbear.[241] The author described how biomedical genetic technologies are used to settle disputes regarding Native American ancestry and tribal membership.[242] Results of DNA testing can help an individual make a claim to Native American land and resources.[243] For decades now efforts have been undertaken to identify risk factors such as susceptible genes, protein expression changes, and cellular changes, which serve as biomarkers predictive of T1D.[244] Tallbear wrote how DNA testing has become a strange hybrid of science and corporate marketing.

---

[238] Petryna, Adriana. 2013. Life exposed: biological citizens after Chernobyl. Princeton, NJ: Princeton University Press.
[239] Ibid.
[240] Ibid.
[241] TallBear, Kimberly. 2013. Native American DNA: Tribal belonging and the false promise of genetic science. Minneapolis: University of Minnesota Press.
[242] Ibid.
[243] Ibid.
[244] Purohit S, She JX. 2008. Biomarkers for type 1 diabetes. Int J Clin Exp Med. 2008;1(2):98-116. Epub PMID: 19079665; PMCID: PMC2596319.
Mathieu, C., Lahesmaa, R., Bonifacio, E. et al. 2018. Immunological biomarkers for the development and progression of type 1 diabetes. Diabetologia 61, 2252–2258. https://doi.org/10.1007/s00125-018-4726-8.
Ezio Bonifacio. 2015. Predicting Type 1 Diabetes Using Biomarkers. Diabetes Care. 38 (6): 989–996. https://doi.org/10.2337/dc15-0101.

Similarly, biomedical technologies for diabetes management with marketing efforts of corporations that promote medical technology use create biological communities. The utilization of such technologies allows for patient categorization and a way to order life driven by data and technological outputs. Just like genetic memory can refer to a sense of ancestral memory, the data repository of numerical outputs and associated data analysis can serve as digital memory of T1D belonging and quality of self-management. Yet, there is a need to further evaluate how this "digital memory" is used and how it influences biological communities.

Commodification

Biomedical technologies used in medical care can be considered tools for screening, testing, monitoring, and management in order to reduce risks. "[S]cience has become a key resource in the management of risk."[245] The concept of risk reduction to achieve a "healthier" state encourages the use and production of new pharmaceuticals and new biomedical technologies that can improve statistical odds of less risk. However, this also encourages companies to engage in research that will cover the largest proportion of the consumer market, which does not necessarily lead to better health outcomes or improved patient well-being.[246]

Bennet highlights how technological innovations have reshaped diabetes and diabetes management. The author recognizes that biomedical innovations while offering some incremental utility to the patient, have also fueled significant commercial profits.

[245] Petryna, Adriana. 2013. Life exposed: biological citizens after Chernobyl. Princeton, NJ: Princeton University Press.
[246] Dumit, Joseph. 2012. Drugs for life: how pharmaceutical companies define our health. Duke University Press.

Individuals with T1D are entangled "in a network of power relations articulated to laborious surveillance and laissez-faire consumerism."[247] Commercial interests that drive innovation have priorities that lay contrary to those of individuals with T1D. Those include prioritization of profit over patient wellness, investing in customer base growth over disease cure, and focusing on the treatment of risk for the future disease over the elimination of suffering happening today. Significant concerns for the future of global health due to current trends of diabetes create a worrisome image of the future. While worrisome to global populations, this future is profitable to large corporations.

Dumit wrote how commercial approaches to research and the introduction of new solutions for risk reduction in the population's health might seem counterintuitive. The health industry is designing drugs and technologies to reduce the risk of sickness in the population, yet the population in the United States has never been sicker than it is today. The reason for this is that pharmaceutical and biotechnological companies are for-profit entities interested in growing profits, recouping their investments, growing their market shares, and increasing the mass consumption of pharmaceuticals.[248] This is counter to the idea of improving people's health, offering the best possible therapy, curing illness, and eradicating disease. Thus, patient health becomes secondary to corporate profits. Dumit also writes that each medical specialty favors its own approach. This further emphasizes and explains why technological solutions to illness are held as superior at a time when pharmaceutical and corporations are funding and directing innovation in medical care and driving the prevailing narratives about risk-reducing solutions to illness.

---

[247] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. p.185 http://www.jstor.org/stable/j.ctv12fw5z8.

[248] Dumit, Joseph. 2012. Drugs for life: how pharmaceutical companies define our health. Duke University Press.

Biomedical Technologies are valued for their implications on society in terms of new employment opportunities, economic benefits, scientific education, national security, and global health. Rajan questions the economic benefit of biomedicine to society and states that "biotechnology is a form of enterprise inextricable from contemporary capitalism."[249] He argues that biomedicine represents a new phase of capitalism. The author confirms just how intertwined biomedical technologies are with the market forces: not designed to help the public as much as intended to enrich a select few. He describes biomedical research as a corporation. This view expands our understanding of values and expectations from biomedicine as a field. The commodification of biomedicine expands its customer base from clinicians to States and even to the public, creating the impression that health, identity, and status can be purchased.

The concept of chronic disease has been transformed into chronic efforts of risk reduction. This change from a healthy body to a chronically risky body, where the risk of illness is treated as the illness itself, often requiring lifelong treatment, can be considered a paradigm shift[250] in considerations of health and disease. With that, the reach of pharmaceutical companies goes beyond medicines to treat disease. The state of risk reduction is located somewhere between health and disease, where treatment might be undertaken to prevent an illness that does not manifest itself yet.[251] Risk reduction requires continuous attention to life as new risks might emerge at any moment.

[249] Rajan, Kaushik Sunder. 2006. Biocapital: The constitution of postgenomic life. Duke University Press.
[250] Kuhn, Thomas S. 1996. The Structure of Scientific Revolutions. 3rd edition. Chicago, IL: University of Chicago Press.
[251] Dumit, Joseph. 2012. Drugs for life: how pharmaceutical companies define our health. Duke University Press.

Establishing Scholarship Gap

As the above sections have shown, STS scholarship helps illuminate some of the tensions and risks at work in the use of biomedical technologies. Major themes that emerge from the literature review indicate not only that automation of diabetes entails entangled complexity aimed at risk reduction, but also that commercial approaches to research, medical care, technological design, biomedicalization within society, and public representation of T1D in U.S. culture obscure our understanding of disease and biomedical technologies used in its management. Following Dumit's recommendation, one of two primary ways of understanding a chronic disease is through risk. Yet, T1D and associated biomedical technologies are generally absent from comprehensive STS risk studies. This work aims to fill this gap in the following chapters by examining risk discourses pertaining to one specific biomedical technology, the Artificial Pancreas System. The prevalence of risk-mitigating practices in narratives around T1D and efforts of risk reduction in chronic disease management as the prevailing motivation for more automation of health services is an ample source for analysis and further research.

In addition to the scholarship gap established above, there is a policy gap at the intersection of the two social groups analyzed in this research. This is evident in the co-existence of regulated FDA-approved and unregulated DIY biomedical technologies. It is evident from the tension present between the regulatory experts and DIY innovators pertaining to expertise, authority, therapeutic decision-making, and biomedical technology use. The DIY biological community is posing a fundamental challenge to the regulatory function of the state as it pertains to health automation. It challenges the official regulatory function by offering an effective alternative to biomedical technologies

as evidenced by the growing and thriving community of DIY innovators, users, and advocates (discussed in more detail in chapter four). The two types of APS, FDA-approved and DIY one, demonstrate there is a policy window for shifting perceptions of risk in diabetes care. Through the STS lens, this policy window creates a reconceptualization of how we think about health automation and technologically burdened healthcare (discussed in more detail in chapter five). This work argues that the policy gap can be narrowed through the effort of addressing the scholarship gap. As a result, this research has the potential to impact not only policymaking but also the contemporary approaches to healthcare.

Documentary Analysis[252]

The documentary analysis approach is used to set the stage and the "backstory" for the historical development of automation within diabetes. It includes primary sources and archival documents pertaining to diabetes technology to understand the historical technological change and how the perceptions of risk mitigation have changed over time. This methodological approach is used to gain a general understanding of the push toward automation in the modern history of biomedical technologies for diabetes management. The aim is not to provide an exhaustive historical analysis but highlight a number of primary historical developments in diabetes research since the discovery of insulin in 1921. The focus of this work is primarily on technologies measuring blood glucose such as Continuous Glucose Monitors (CGMs), automation of insulin injection such as insulin

[252] Scott, John. 1990. A Matter of Record: Documentary Sources in Social Research. Cambridge, Mass., USA: Polity Press in association with B. Blackwell.

pumps, and the early efforts of autonomous T1D management via complex systems such as DIY APS and FDA-approved APS.

Risk Discourse Analysis

The analysis of the social construction of the Artificial Pancreas Systems is used as an effort to understand how new forms of knowledge are produced, how health practices are understood, and how new biological communities are created within the area of health automation. The analysis of risk and risk mitigation approaches is a constructive venue for the analysis. The risk appears to be a constant consideration in the studies of human health and biomedical technologies. The automation of health as well as the automation within T1D care are intimately connected with the efforts of risk reduction. This work looks at regulatory experts and commercial discourses to understand the ways in which the APS promises to mitigate the risks of living with a chronic condition. It also analyzes the narratives around open-source APS to understand where promises of risk reduction might fail to alleviate suffering and lessen the burdens of disease.

Individuals with diabetes are recipients of direct and indirect communications from a number of regulatory experts and expert entities. Such communications highlight a variety of risks associated with T1D and biomedical technologies, as well as shape the perceptions of promises and expectations regarding biomedical technologies for diabetes management. These regulatory experts include primary care physicians, medical specialists, such as endocrinologists, public health leaders, such as representatives of local and state health departments, government officials, as well as representatives of

leading organizations in diabetes research and advocacy. This research analyzes regulatory expert discourses and practices pertaining to risk to better understand what information and perceptions of automated biomedical technology are communicated among regulatory experts to individuals with T1D, and to the public.

This research analyzes the community of regulatory experts represented by the American Diabetes Association (ADA) focusing on two primary sources. The first source is the ADA-established "Standards of Medical Care in Diabetes," created to provide "the most authoritative source for current guidelines for diabetes care."[253] These standards of diabetes care are published annually and are continuously updated as new evidence-based research emerges. The second source is the professional development course designed by regulatory experts for regulatory experts titled "Making Diabetes Technology Work." The course is openly available via the ADA professional online portal. This work analyzed regulatory expert discourses and practices to understand the perceptions of risk and the approach to risk reduction among regulatory experts and expert entities.

In the review of the DIY biological community, this work focused on the Open APS and related software products. The DIY biological community is a community of patients, caregivers, and advocates who work together to make open-source and DIY solutions for individuals with T1D without waiting for commercial entities to decide to innovate. This work focuses on comparable sources such as publicly available technological setup documentation and training materials related to Open APS and other DIY diabetes technologies. This research reviews publicly available presentations, primary literature, video presentations, recorded interviews, press releases, instructional

[253] American Diabetes Association. 2022. Introduction: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S1–S2. https://doi.org/10.2337/dc22-Sint.

and legal documents, as well as other publicly available materials pertaining to the use of related biomedical technologies. The data collected were qualitatively analyzed for major themes and risk thinking within the regulatory expert and DIY biological communities, what they communicate about biomedical technologies, what promises they make, and what images they relay in analyzed sources.

This research fills the research gap by analyzing not only the FDA-approved biomedical technology but also the open-source Artificial Pancreas System. It considers how the APS shapes biological citizenship[254] and the formation of new societies around efforts to mitigate the risks both of T1D and of the technologies developed to manage it. It includes the analysis of writings, publications, and public speeches within the diabetes DIY community including the #WeAreNotWaiting movement. It particularly focuses on the three co-founders of the open-source APS, Dana Lewis and Ben West, and other contributors to the APS development with reliance on print and digital sources.

Limitations of the Study

The presence of disease impacts the social relationships and cognitive function of patients, providers, and society more broadly. The COVID-19 pandemic, which immobilized the world in 2020 and sent nations into a global recession, is but the most recent and most visible representation of the effects of disease on society. Similarly, T1D influences every aspect of a patient's life with implications of disease that extend beyond

[254] Rose, Nikolas. 2009. The politics of life itself: Biomedicine, power, and subjectivity in the twenty-first century. Princeton: Princeton University Press.
Petryna, Adriana. 2013. Life exposed: biological citizens after Chernobyl. Princeton, NJ: Princeton University Press.
TallBear, Kimberly. 2013. Native American DNA: Tribal belonging and the false promise of genetic science. Minneapolis: University of Minnesota Press.

the patient to a patient's family, community, and society. While T1D is an equal opportunity disease and affects individuals regardless of race, gender, geography, socioeconomic status, or beliefs, the biomedical technology associated with diabetes care is not distributed equitably among nations, subpopulations, or different social groups. Therefore, technological use and related health outcomes of T1D management are stratified.

This research proceeds with a full awareness that individuals with T1D using biomedical technologies such as the Artificial Pancreas System are most likely to be white and within the higher socioeconomic status. Disparities in biomedical technology use exist in the United States just like those in the healthcare system. Disparities in care are important to consider and further research, especially in the relation to biomedical technologies as treatment. Some believe that prescribing Artificial Pancreas Systems in primary care to individuals with T1D could reduce care disparities.[255] This research disagrees with this perspective as will be addressed later (chapter 3). This study will not be addressing the abovementioned disparities but urges further research to address this important subject.

The decision to use the Artificial Pancreases System as the primary technology to study was deliberate. On one hand, it is considered to be the best technological solution provided to individuals with T1D today. It is an advanced and complex technology, still in development, but already gaining traction among regulatory experts and users alike. Numerous scientific studies support the use of APS for optimal T1D health outcomes emphasizing the need for and aid the proliferation of APS. On the other hand, this

[255] Rosenberg, Jaime. 2021. Uptake of Artificial Pancreas Systems in Primary Care Could Reduce Care Disparities. AJMC. Accessed 7/12/22/ https://www.ajmc.com/view/uptake-of-artificial-pancreas-systems-in-primary-care-could-reduce-care-disparities.

technology has alternatives within the DIY community. This offers an interesting case study for the analysis of biomedical technology as knowledge as there are biological communities involved in the automation of T1D on par with the FDA-approved APS, automation at the highest level of complexity and risk. The use of the APS as the main biomedical technology to study can be viewed as a limitation as well as a strength.

The automation of diabetes care is not only meant to reduce risks associated with diabetes, and simplify and streamline glucose monitoring and the dispensing of insulin for patients, but it is also meant to make the health management process more efficient and effective for physicians and anyone else involved in collecting and analyzing patient data. Whether this objective is achieved in practice is one of the areas of inquiry informing this research project. Lessons learned from this analysis might be applicable to other medical conditions reliant on biomedical technologies to manage patients' health.

Langdon Winner in his article titled "Upon opening the black box and finding it empty: social constructivism and the philosophy of technology" highlighted the limitations of the theoretical approach used in this research. Winner wrote that while the general attitude towards the SCOT approach indicates that it is sufficient in explaining technological development, it falls short due to its narrow research program and lack of definite position regarding "the social and technological patterns under study."[256] This work will include not only the application of SCOT to the analysis of the APS but also an expansion of the SCOT methodology necessary to address some of its limitations highlighted by Winner. In addressing the consequences of the APS in the broader context, including who is affected by this technology, and what cultural, intellectual, and

[256] Winner, Langdon. 1993. Upon Opening the Black Box and Finding It Empty: Social Constructivism and the Philosophy of Technology. Science, Technology, & Human Values. 18 (3): 362–78. https://doi.org/10.1177/016224399301800306.

economic forces affected its construction this work sheds light on the interplay of actors, values, technologies, and disease. As a result, this research aims to provide a valuable and generative contribution to the social study of technology literature.

Today T1D management includes the use of multiple devices and complex systems such as the APS (closed loop or hybrid systems). The APS is still a new technology and not as widely adopted as some. While this low technological proliferation can be a limitation of the research, it also can be a strength in telling a story of what is to come and what to expect from the APS, and similar biomedical technologies, with further automation. While the proliferation of biomedical technologies in the United States might be high compared to other countries, this research proceeds with awareness of disparities that exist not only in the utilization of biomedical technologies but also in the healthcare system across the board among individuals with T1D and those with other health conditions.

Chapter 3. Regulatory Expert Risk Discourse Analysis

> "… habits of common medical language and practice are too impoverished to capture the range of experiences with chronic illness, and thus are too limited when physicians talk with patients about what has happened, what is likely to happen, and what they should do."
>
> *Chris Feudtner, MD, Ph.D., MPH (2003)*[257]

Introduction

It is difficult to find any type 1 diabetes (T1D) related analysis that does not mention the risks of living with and managing the disease. This is evident from historical studies and T1D as a case study analysis, as described in the previous chapter. Risk is a particularly prevalent theme in discussions of T1D where every individual the disease is considered to be within the "at-risk population," susceptible to significant health complications and at increased risk for severe illness due to exposure to communicable diseases such as COVID-19.[258] Many risks are related to biological processes within the body since T1D is a multisystem disease, as established previously. These risks pertain to the state of one's health before T1D diagnosis, and current health status with related or unrelated medical conditions burdening the individual. Yet, diabetes carries with it not only biological risks related to a single organ, namely the pancreas, or the human body due to the autoimmune nature of the disease. T1D also has significant technological and

[257] Feudtner, John Christopher. 2003. Bittersweet : Diabetes, Insulin, and the Transformation of Illness. P.167. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[258] CDC. 2022. COVID-19: People with Certain Medical Conditions. Accessed 12.30.22. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. CDC. 2022. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals. Accessed 12.30.22. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html.

financial risks that influence one's ability to access the necessary tools of care and effectively use them.

Risk is defined as exposure to danger or dangerous situations that increase the likelihood of harm.[259] This definition of risk primarily refers to physical harm to one's body, material possessions, or one's physical surroundings. This work defines risk as the increased likelihood of adverse outcomes. These outcomes might take different forms including but not limited to physical, emotional, mental, intellectual, and technological. An individual with T1D is at the center of these risk considerations. The individual is acted upon by the outside forces that create the most common perceptions of disease, risk-prone bodies, and biomedical solutions. Regulatory experts interact with patients, caregivers, health insurance providers, pharmaceutical and biomedical technology companies. Through these interactions, regulatory experts influence policies and regulations as well as impact the prevailing views of disease and biomedical technologies within the general population.

This work defines regulatory experts as those in the position of authority to influence normative therapeutic standards and policymaking regarding diabetes management and biomedical technologies in use. Thus, regulatory experts are medical and healthcare professionals, including but not limited to primary care physicians, endocrinologists, certified diabetes educators, and registered dietitians. They also include policymakers who rely on the expertise of medical and healthcare professionals to guide regulatory and policy decisions. The term "regulatory experts" includes individuals directly involved in the formation of regulations regarding T1D care as well as

[259] Merriam-Webster. 2023. Dicrionary. Accessed 2.24.23. https://www.merriam-webster.com/dictionary/risk.

individuals bound by regulations in their professional status. This work uses the term regulatory expert to differentiate from another form of expertise discussed in the following chapter.

This chapter analyzes how regulatory experts shape discourses around risk regarding health automation and T1D management. The traditional model of medical practice called the biomedical or the medical model conceptualizes "disease as deviation from normal biological functioning owing to biological determinants" and focused on the biomedical view of disease based on statistics, risk, and scientific evidence.[260] The medical model of the disease strongly appeals to most medical and health professionals as their education and practice are concerned with the strict criteria of what falls under the term disease.[261] It points not only to the assumption that doctors have specific knowledge and expertise but also that they are increasingly led by guidelines, norms, and scientific evidence to "advise on, coordinate or deliver interventions for health improvement."[262] The medical model views disease detection and subsequent treatment recommendations as possible primarily via standard accepted procedures such as medical examinations, and tests within a defined set of symptoms.[263] However, since the concept of health as such is disappearing, replaced by "less-risky" or "healthier" states of being,

[260] Fuller, Jonathan. 2017. The New Medical Model: A Renewed Challenge for Biomedicine. Cmaj : Canadian Medical Association Journal = Journal De L'association Medicale Canadienne 189 (17): 641. https://doi.org/10.1503/cmaj.160627.
[261] Hofmann, Bjørn. 2005. Simplified Models of the Relationship between Health and Disease. Theoretical Medicine and Bioethics: Philosophy of Medical Research and Practice 26 (5): 355–77. https://doi.org/10.1007/s11017-005-7914-8.
[262] Shah, Premal, and Deborah Mountain. 2007. The Medical Model Is Dead – Long Live the Medical Model. British Journal of Psychiatry 191 (5): 375–77. https://doi.org/10.1192/bjp.bp.107.037242.
[263] Swaine, Zoë. 2011. Medical Model. In: Kreutzer, J.S., DeLuca, J., Caplan, B. (eds) Encyclopedia of Clinical Neuropsychology. Springer, New York, NY. https://doi.org/10.1007/978-0-387-79948-3_2131.

within the comprehensive and expanding idea of risk in health care, risk, and risk factors became the primary target within the medical field and under the medical model.[264]

Risk discourse analysis serves as the gateway to a deeper understanding of automated health within T1D management. Greene wrote that the foundation of mainstream U.S. medical practice lies at the "complex nexus of drugs and disease, risk and diagnosis, medicine and marketplace."[265] This chapter expands on the perception of risk in health considerations from that limited to biological bodies and, increasingly, biomedical devices. The above excerpt from Feudtner's book indicates that regulatory expert language and practices are too narrow to capture the full scope of factors influencing one's experiences, perceptions, and expectations in regard to chronic illness. With this perception of regulatory expert practices, it is important to not only understand what regulatory expert discourses claim regarding risk but also expand on them. This chapter reviews regulatory expert risk discourses pertaining to biomedical technologies for diabetes management with a focus on Artificial Pancreas Systems, both the FDA-approved and the Open-Source Do-It-Yourself (DIY) ones.

In the analysis of regulatory expert discourses pertaining to diabetes technologies, this work uses the case of the American Diabetes Association (ADA). The case of the ADA is representative of regulatory expert views not only because the organization strives to "present activities that are independent, balanced, objective and scientifically rigorous" or provide "content that is free of commercial bias," but also because the ADA produces content that is used and referred to by medical professionals in their practice for

[264] Hofmann, Bjørn. 2005. Simplified Models of the Relationship between Health and Disease. Theoretical Medicine and Bioethics: Philosophy of Medical Research and Practice 26 (5): 355–77. https://doi.org/10.1007/s11017-005-7914-8.
[265] Greene, Jeremy. 2008. Prescribing by Numbers: Drugs and the Definition of Disease. Johns Hopkins.

information and decision making,[266] by researchers and policymakers.[267] Even the Centers for Disease Control and Prevention (CDC), the leading United States service organization in public health protection[268] and "the major operating components of the Department of Health and Human Services,"[269] refers to the ADA's reports, publications, and data.

Further, the ADA is one of two organizations authorized by the U.S. Centers for Medicare & Medicaid Services (CMS) to grant accreditation or recognition for Diabetes Self-Management Education and Support (DSMES) services.[270] The ADA produces a large amount of information related to diabetes in addition to the continuously updated standards of care outlining diabetes clinical guidelines. These include a monthly *Diabetes* journal published since 1952 containing ADA-authored articles and other original research, a monthly *Diabetes Care* journal for healthcare practitioners established in 1978, a quarterly *Clinical Diabetes* journal for primary care clinicians established in 1983, a quarterly *Diabetes Spectrum* journal launched in 1988 for the healthcare professionals to "optimize patient outcomes", as well as professional books.[271] The ADA

[266] ADA. 2021. How to Thrive with Diabetes. https://professionaleducation.diabetes.org/Public/Catalog/Main.aspx.
[267] National Clinical Care Commission. 2021. Report to Congress on Leveraging Federal Programs to Prevent and Control Diabetes and Its Complications. https://health.gov/sites/default/files/2022-01/NCCC%20Report%20to%20Congress.pdf.
[268] CDC. 2022. About CDC: CDC 24/7. Accessed 09.17.22. https://www.cdc.gov/about/.
[269] CDC. 2021. About CDC: CDC Organization. Accessed 09.17.22. https://www.cdc.gov/about/organization/cio.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fabout%2Forganization%2Findex.html.
[270] Joni Beck, Deborah A. Greenwood, Lori Blanton, Sandra T. Bollinger, Marcene K. Butcher, Jo Ellen Condon, Marjorie Cypress, Priscilla Faulkner, Amy Hess Fischl, Theresa Francis, Leslie E. Kolb, Jodi M. Lavin-Tompkins, Janice MacLeod, Melinda Maryniuk, Carolé Mensing, Eric A. Orzeck, David D. Pope, Jodi L. Pulizzi, Ardis A. Reed, Andrew S. Rhinehart, Linda Siminerio, Jing Wang; on behalf of the 2017 Standards Revision Task Force, 2017 National Standards for Diabetes Self-Management Education and Support. Diabetes Care 1 October 2017; 40 (10): 1409–1419. https://doi.org/10.2337/dci17-0025.
CDC. 2022. National Standards for DSMES. https://www.cdc.gov/diabetes/dsmes-toolkit/accreditation-recognition/index.html.
[271] ADA. 2022. Professional Journals. Accessed 09.19.22. https://diabetesjournals.org/journals.

also holds "the world's largest scientific meeting focused on diabetes research, prevention, and care,"[272] publishes Clinical Compendia,[273] creates monthly audio podcasts, and circulates diabetes-related news and resources.

This chapter is based on the analysis of ADA's publicly available resources. One such resource is the professional education offerings which provide a view into how regulatory experts communicate, what they prioritize, and how they view biomedical technologies and the risks associated with such technologies. Another resource is the ADA-established "Standards of Medical Care in Diabetes," also called the standards of care, created with an intent to ensure health and medical experts, policymakers, researchers and other individuals have a reliable and "the most authoritative source for current guidelines for diabetes care."[274] These standards of care that include screening, diagnostic, and therapeutic norms, if followed, are believed to reduce the risks of T1D and provide positive health outcomes for the patient population. The norms established by the ADA act as tools to set treatment goals and evaluate the quality of T1D care, including those affecting biomedical technologies like the APS.

The essential question this chapter aims to answer is how does an examination of risk discourses help us to better understand the contemporary drive for automated health? This in turn helps with a better understanding of the relationship between technology, body, and disease. In an effort to answer this question, this chapter examines approaches to risk thinking as exemplified by the ADA in four primary sections. The first section

[272] ADA. 2019. The iLet Bionic Pancreas Increased Time in Range for Adults with Type 1 Diabetes. ADA's Scientific Sessions. https://diabetes.org/newsroom/press-releases/2019/the-ilet-bionic-pancreas.
[273] ADA.2022. Clinical Compendia: Comprehensive Diabetes Information. Accessed 09/06/22. https://diabetesjournals.org/compendia.
[274] American Diabetes Association. 2022. Introduction: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S1–S2. https://doi.org/10.2337/dc22-Sint.

briefly reviews the established normative base for T1D care. This includes the 2022 standards of medical care in diabetes which are embraced, promoted, and enforced by regulatory experts as well as mandated for patients to adhere to. Norms are a direct response by regulatory experts to the perceptions of risks in medical care. The second section examines regulatory expert risk discourses through the analysis of the ADA's nine-part accredited continuing education series for healthcare professionals titled "Making diabetes technology work"[275] and other publicly available sources. The third section analyzes the difference in risk considerations between the FDA-approved APS and the DIY APS along with approaches to increased patient engagement and reduced existing barriers. Lastly, this chapter concludes with a summary of the findings and how they support the goals of this research.

This chapter demonstrates the regulatory community of experts is primarily data driven, reliant on established norms and standards of diabetes care where patients are represented through a variety of metrics, numbers, and technologically derived measures. With heavy reliance on data, the patients become hidden behind graphs, charts, trendlines, statistics, and measures. Thus, the patient's lived experiences, their unique T1D requirement, their individualistic health needs, and everyday relationships become secondary. With the help of norms and standards established within the community of regulatory experts, patients are expected to avoid harmful behaviors, to become disciplined in T1D self-management and to become productive citizens.

This community supports the top-down approach to care viewing patient as the primary problem to adverse health outcomes. As this analysis shows, regulatory experts

[275] ADA. 2021. Professional Education: Making Diabetes Technology Work. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.

view biomedical technologies as a solution to T1D under the misleading notion of "technology will set you free"[276]. Thus, regulatory experts support and enhance the promises of further automation through a risk-based approach concerned with safety and regulation. Such views of biomedical technology highlight the need for increased physician's oversight and increased utilization of more advanced automated technologies for diabetes care to reduce the risks of human fallacies such as human errors, literacy and numeracy problems. However, how can we reconcile the fact that the APS user is an integral part of a system that requires user input while at the same time operating from the belief that users are the problem because they are incapable of effective T1D self-management?

The community of regulatory experts provides an important perspective on health automation grounded in evidence-based science, established norms and professional standards upheld within the fields of medicine, healthcare, and research. However, there seems to be a disconnect between the normative disease controls embraced by the regulatory expert community and the aspects of a patient's health and well-being that cannot be easily quantified and measured, such as patient's lived experiences, challenges with disease management and anxieties associated with the stringent demands of this disability. This chapter demonstrates that while regulatory experts acknowledge biological, technological, and financial risks, their professional purview, steeped in quantitative measurements and logics, guides their focus primarily toward biological risks in diabetes automation. Therefore, the disconnect observed within the regulatory

[276] Sargent, Jennifer. 2021. Technology will set you free. Nature Portfolio. Accessed 1.16.23. https://www.nature.com/articles/d42859-021-00024-z.

community is likely the result of the way this community understands and defines risk in T1D care.

This chapter draws from the risk in contemporary culture literature with a particular focus on the works of Deborah Lupton, Ulrich Beck, Mary Douglas, and Aaron Wildavsky. It focuses on the theories of governmentality and subjectivity. A discourse is a combination of language, metaphors, practices, techniques, and technologies for the production of power and knowledge.[277] Therefore, this discourse analysis draws from the risk in contemporary culture literature to help elucidate the disconnect between regulated and unregulated biomedical technologies from the regulatory expert perspective as well as gain a better understanding regarding the role of biomedical technologies in T1D management. This chapter contributes to the literature by analyzing the case study of the APS and the field of diabetes care where risks are complicated and highly personal for the affected individuals making normative compliance very enticing as well as highly demanding.

Normative Base for T1D Management

T1D is quantified and regulated via the measures established as target norms that are calculated for every patient throughout the patient's life. Norms are set, for example, for blood glucose (BG) testing frequencies, BG levels, and Hemoglobin A1c (HbA1c or A1C) levels which have fixed target ranges and thus indicate the patient's deviation from the norm. A "fasting blood sugar level of 99 mg/dL or lower is normal, 100 to 125 mg/dL

[277] Edwards, Paul N., 1996. The Closed World: Computers and the Politics of Discourse in Cold War America. Cambridge, MA: MIT Press.

indicates you have prediabetes, and 126 mg/dL or higher indicates you have diabetes."[278] The A1C test measures one's average blood glucose level over the past 3 months, with an A1C below 5.7% as normal, between 5.7 and 6.4% indicating prediabetes, and 6.5% or higher indicating diabetes.[279] The ADA promotes achieving A1C targets of <7% in adults with T1D to reduce the risk of complications.[280] The norms established by the ADA are used as tools to encourage "more stringent" glycemic control to reduce risks of the development and progression of microvascular complications, increase life expectancy, reduce comorbidities, and reduce the risks of hypoglycemia.[281]

Additional measures are used to indicate an individual's sensitivity to insulin and to the carbohydrates consumed. These are the Insulin Correction Ratio (ICR), indicating how much insulin one must take per gram of carbohydrates consumed, and the Correction Factor (CF), indicating how much insulin is needed to lower BG to the desired level. T1D patients are also encouraged to complete regular laboratory blood tests for deviations from the norm and markers of potential risks and health complications. These measures are carefully established, tracked, and compared against the established standards by the regulatory expert community. They also add to the normative base for T1D management.

Norms are believed to help patients become productive citizens and avoid harmful behaviors. Norms are also viewed as the tool to exercise power by institutions through procedures and discourses that discipline and normalize individuals and conform them to

---

[278] CDC 2022. Diabetes: Getting Tested. Accessed 7/28/22 https://www.cdc.gov/diabetes/basics/getting-tested.html.
American Diabetes Association Professional Practice Committee. 2022. 2. Classification and diagnosis of diabetes: Standards of Care in Diabetes—2022. Diabetes Care 2022;45(Suppl. 1):S17–S38. https://diabetesjournals.org/care/article/45/Supplement_1/S17/138925/2-Classification-and-Diagnosis-of-Diabetes.
[279] Ibid.
[280] American Diabetes Association Professional Practice Committee. 2022. 6. Glycemic targets: Standards of Medical Care in Diabetes—2022. Diabetes Care 2022; 45(Suppl. 1):S83–S96.
[281] Ibid.

be productive citizens. This perception of norms is addressed by Foucault's theory of Governmentality.[282] Norms are usually internalized by the target population as individuals feel obliged to conform. Norms are used to "encourage individuals to engage voluntarily in self-regulation," while allowing those in the position of authority to monitor, regulate, discipline, and manage the population.[283] Since T1D is a multisystem disease, patients' bodies are subjected to careful oversight that extends beyond glycemic control into control of other bodily systems, patients' lifestyles, behaviors, and biomedical technologies.

Lupton wrote "[g]overnmentality is the approach to social regulation and control" which extends beyond the individual towards the population and towards the society. [284] When discussing the theory of governmentality, it is important to note that the risk perceptions within health automation are not simply about glycemic control, individual patient compliance, or the control of the patient's body. They extend further into the control of populations as a mechanism to achieve desired control over the health of a social body "requiring intervention, management, and protection so as to maximize wealth, welfare and productivity."[285] The health of the individual as well as the health of the population, thus, becomes the agent of these established statistics, norms, measures, and variables. Expert knowledge plays a crucial role in governmentality as a strategy and rationale, by establishing standards, advice, and guidelines for population comparison, monitoring, surveyance, and training to conform to norms for improved productivity.

[282] Foucault, Michel. 1991. Governmentality Actions. In The Foucault Effect: Studies in Governmentality, edited by G. Burchell, C. Gordon, and P. Miller. Chicago, University of Chicago Press, 87-104.
[283] Lupton, Deborah. 1999. Risk (Key Ideas). New York: Routledge.
[284] Ibid.
[285] Ibid.

Risk becomes a tool and a strategy of the government in its regulatory power to manage the population via a diverse network of actors, organizations, practices, and knowledges. [286] Lupton defines risk in science and medicine as "an objective reality that can be measured, controlled and managed" via the use of "mathematical models to measure and predict risk," where lay individuals are often represented as unscientific, unsophisticated and inferior in their responses to risk.[287] The regulatory expert community of health and medical professionals, policymakers, scientists and researchers collects, analyzes, and problematizes risk in a never-ending process to identify those "at risk" that require special expertise, specific interventions, and further monitoring. Thus, biomedical technologies that collect, calculate and process data regarding patients are at the core of governmentality as they enable the process of normalization, comparison against acceptable standards, and assessment of deviations from desirable. Perceived future risks suggest how one should act today. In Risk Society, Beck writes: "We become active today in order to prevent, alleviate or take precautions against the problems and crises of tomorrow and the day after tomorrow…"[288] Since risk is not a current reality but a future potentiality, the government's risk-based regulation indicates a desire to calculate, monitor, and control the future to discipline citizens and minimize potential future adverse outcomes.

Beck wrote: "Risks only suggest what should not be done, not what should be done." [289] In the case of T1D risk suggests both what should and should not be done. This is evident with blood glucose (BG) management to avoid the risk of severe BG

[286] Ibid.
[287] Ibid.
[288] Beck, Ulrich. 1992. Risk Society: Towards a New Modernity. London: Sage Publications.
[289] Beck, Ulrich. 1999. Risk Society Revisited: Theory, Politics, Critiques and Research Programmes. In World Risk Society. Cambridge et al.: Polity Press/Blackwell, 133-152.

fluctuations. For example, individuals with T1D are recommended to exercise regularly because exercise can lower BG levels, at the same time as they are recommended not to exercise if blood glucose (BG) is high (over 300 mg/dL) because "the stress of exercise can drive blood sugar [BG] levels even higher."[290] The perceptions of risk are used in attempts to exude control over the individual's health, body, practices, thoughts, and actions. Further, the categorization of T1D patients as "at-risk" individuals positions them as weak, vulnerable, powerless, passive, and in need of additional surveillance as a sub-group within the population. [291] As Lupton wrote, the "at-risk" designation "serves to reinforce the marginalized or powerless status of individuals."[292] Patients are placed in the position of a victim with a T1D diagnosis over which they have no control, at the same time as they are blamed for the outcomes of disease management for which they are expected to have full control. Patients are blamed for increasing their risk through their own actions or inactions when expected to act in a certain way.

For the past 30 years, the ADA has been updating the standards of care with the help of the ADA's Professional Practice Committee (PPC), supplemented by clinical diabetes literature, and input from ADA staff and the medical community at large.[293] The ADA's PPC is a "multidisciplinary expert committee," yet its members consist exclusively of health and medical professionals including physicians, diabetes care and education specialists, endocrinologists, epidemiologists, public health professionals, and

[290] UPMC. 2023. Exercise for Diabetes Patients. Accessed 2.24.23. https://www.chp.edu/our-services/endocrinology/resources/exercise
[291] Ibid.
[292] Lupton, Deborah. 1999. Risk (Key Ideas). New York: Routledge.
[293] American Diabetes Association. 2022. Introduction: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S1–S2. https://doi.org/10.2337/dc22-Sint.

biomedical technologists.[294] Turning back to Feudtner's point made above, when only clinical literature is taken into consideration and only the medical community is consulted in the matter of establishing and maintaining the standards of care for T1D, the resulting standards are likely to be too narrow to capture the full scope of factors influencing the success of one's T1D management. The professional dominance, disposition, interests, and preferential approaches to defining the standards of care by regulatory experts are not surprising.[295] Yet, the connection between norms and risks in T1D management is undeniable. The impoverished language and practice of medicine as well as the limited "multidisciplinary" inclusion in decision-making regarding the standards of care indicate a narrow lens used by regulatory experts to view risk, T1D, and biomedical technologies used in its management.

Individual targets are set for patients to encourage them to strive for stringent control to reduce risks associated with disease, reduce vascular complications, improve life expectancy, and reduce comorbidities (the presence of other health conditions). In order to achieve such control, based on the above ADA figure, patients must be highly motivated and capable of excellent self-care, in addition to having readily available resources and support systems.[296] The above-established norms imposed on T1D patients are reinforced by biomedical technologies. Additionally, biomedical technologies have

[294] American Diabetes Association. 2022. Professional Practice Committee: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S3. https://doi.org/10.2337/dc22-Sppc.
[295] Starr, Paul. 1982. The Social Transformation of American Medicine. New York: Basic Books. Navarro, V. 1984. Medical History As Justification Rather Than Explanation: A Critique of Starr's the Social Transformation of American Medicine. International Journal of Health Services: Planning, Administration, Evaluation 14 (4): 511–28.
[296] ADA. 2021. Professional Education: Making Diabetes Technology Work. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.

enabled the creation of new norms of care and new ways of measuring T1D as discussed below.

Risk-based information collected and communicated by the regulatory expert community is used in advising parents, caregivers, and their families regarding how to conduct their lives, how to interact with their bodies, biomedical technologies, and their surroundings. These risk discourses and narratives influence how patients perceive themselves and how others perceive patients. Through the use of practices and regulated technologies, these discourses impact a person's subjectivity, or selfhood, influencing a person's desire to alter themselves in order to attain a certain level of the desired and expected perfection. This is evident by how patients rely on the preventative capacity of biomedical technologies to reduce future risks: "I love the fact that it [CGM] tells me I'm going to be low [experience low BG] before I even feel it so I can prepare" or their capacity to correct body's deficiencies such glycemic unawareness to detect unsafe BG ranges: "My blood sugar [BG] could be 50 [mg/dL] or below and I'm not feeling it. I don't get shaky or have any of the symptoms until I'm, like, in the 40s. So CGM…helps me to stay in that safe range [70-180 mg/dL]."[297] Thus, biomedical technologies become an integral part of self to ensure a safer future, to correct one's deficiencies as well as to monitor self and loved ones.[298] "As expert knowledge about risk proliferated in late modernity, the various strategies which individuals are required to practice upon

[297] ADA. 2022. CGMs – The benefits of this life changing diabetes technology. American Diabetes Association. YouTube. Accessed 2.24.23. https://www.youtube.com/watch?v=SSrDxGInHXo.
[298] ADA. 2022. Continuous Glucose Monitors (CGMs) and Me; The Beauty of Technology. American Diabetes Association. YouTube. Accessed 2.24.23. https://www.youtube.com/watch?v=w_Locm5JSrs.

themselves to avoid risk have equally proliferated."[299] Thus, individuals seek advice and guidance from those with regulatory expert knowledge.

Quantitative and normative disease management is also a form of subjectivization in which the patient and the caregiver start to aspire to achieve a level of control over disease guided by specific numerical values and normative expectations that include not only glycemic control but also good health and lifestyle management. Patients with T1D are surrounded by expert and lay advice directed at how they should behave, how to engage or not to engage in certain practices, and what they should and should not eat or drink. When a patient suffers health complications or experiences challenges with T1D management, that individual is expected to adhere to even more stringent self-controls, behavior monitoring, intake of additional pharmaceuticals, and seek out more regulatory expert advice, additional oversight, and more frequent medical examinations. Patients are also encouraged to self-educate and seek out authorized as well as certified diabetes educators for the best information, practices, and education.

Regulatory expert discourses within the normative base of T1D management suggest that it is the patient's responsibility to ensure their health and to adhere to regulatory expert recommendations. This requires constant work from the patient. If health outcomes are not as desired, then patients are blamed for their failed self-management for not learning enough, and for not doing enough. Patients are eager to embrace regulatory expert recommendations as they themselves want to reduce and avoid the risks brought about by the disease. The regulation of patients' bodies is done through directives intended for the patients to direct themselves. Risk-avoiding practices are viewed as moral and necessary for "self-control, self-knowledge, and self-

[299] Lupton, Deborah. 1999. Risk (Key Ideas). New York: Routledge.

improvement."[300] Since one can never achieve an absolute lack of risk, the process of self-control requires constant vigilance and is lifelong and never-ending. Yet, how are patients expected to adhere to these attributes when good health management also carries social, economic, and political consequences? How can normative disease control account for other aspects of a patient's health and well-being that cannot be quantified and measured, especially those based on the patient's phenomenological experience with the health condition?

Beck wrote that the concept of risk has changed the relationship between past, present, and future, where the past loses its power to determine the present."[301] With T1D management, did we in the process trade off the lessons of the past and the needs and wants of the present for something non-existent, imagined, fabricated, and fictitious? As the below examination of regulatory expert discourses on risk demonstrates, regulatory experts help shape patients who voluntarily take up governmental and regulatory expert imperatives. Risk discourses focused on future-centric risk reduction influence a person's desire to ensure a healthier future via technological use. Therefore, risk discourses influence not only the assemblage within the biotechnological organism, the balance between the body and the technology, but also the desired, expected, and imagined future, and the actions necessary to achieve it. However, due to perceived or real barriers to constructing the biotechnological organism needed to achieve the desired future, patients might seek to obtain alternative forms of expertise as addressed in the following chapter. Norms, statistics, measures, and variables reinforce regulatory expert imperatives across medical specialties with authority and strong professional identity to

[300] Ibid.
[301] Beck, Ulrich. 1999. Risk Society Revisited: Theory, Politics, Critiques and Research Programmes. In World Risk Society. Cambridge et al.: Polity Press/Blackwell, 133-152.

achieve a future state of reduced risk. As a result, regulatory experts and expert organizations, as represented by the ADA, are primarily focusing on the imagined future not on the state of affairs around T1D as they are today, not on contemporary health system shortcomings or current barriers for individual patients and different subpopulations.

Regulatory Expert Discourses on Risk

The ADA provides free continuing education series titled "Making Diabetes Technology Work" created by medical and health professionals for medical and health care providers, such as primary care physicians, physician assistants, nurses, nurse practitioners, dietitians, pharmacists, and other health care professionals who manage patients with diabetes. The 2022 series are evidence-based, meaning they apply the most current scientific research findings to the course design, content, and recommendations. The series not only provide 6.75 credits towards continuing education at no cost but also includes nine modules covering a range of technology-related subjects as stated below. This section of the chapter analyses the course modules for their content and for the narratives toward risk and views on biomedical technologies.

> **Module 1:** Diabetes Technology Today: An Overview of the Latest Devices to Help People with Diabetes Optimize Glycemic Management and Improve Outcomes.
> **Module 2:** Why Using Diabetes Technology Is More Important Than Ever.
> **Module 3:** Beyond A1C: Understanding Time in Range, a New Continuous Glucose Monitoring–Derived Metric for Assessing Glycemia.
> **Module 4:** How to Select the Best Diabetes Technology Options for Each Patient's Needs.
> **Module 5:** Basics of Therapeutic Decision-Making in Diabetes Using Continuous Glucose Monitoring Data.

Module 6: Deploying Diabetes Technologies Effectively in Complex Type 2 Diabetes Cases.
Module 7: Connecting the Dots: Efficiently Managing Workflow and Logistics for Remote Monitoring of Patients with Diabetes.
Module 8: Improved Diabetes Care? There Are Apps for That!
Module 9: Engaged and Empowered: How Technologies Can Encourage Involvement, Increase Motivation, and Improve Outcomes for People with Diabetes.[302]

The use of biomedical technologies in diabetes care is increasing along with the increasing number of affected individuals. This is widely acknowledged by regulatory experts.[303] While the increase in the proliferation of biomedical technologies is celebrated, the increased prevalence of diabetes is viewed as troubling. Yet, the focus of health interventions has not changed over the past decades with primary efforts of risk reduction via improved patient self-control through the use of established statistics, norms, measures, and variables. The ultimate outcome of biomedical technology use is the optimization of glycemic management and improved health outcomes. For this optimization, the regulatory experts use several existing measures and established norms of care. The constant stream of data available using biomedical technologies reinforces governmentality. Stephen Farrow MD said: "The more information that I can receive over a 24-hour period as to how diet and medications affect the patient's blood sugar [BG], the better I can adjust medical nutrition therapy and medications to help achieve a

[302] ADA. 2021. Professional Education: Making Diabetes Technology Work. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[303] Fontecha, J., González, I., Barragán, A., & Lim, T. 2022. Use and Trends of Diabetes Self-Management Technologies: A Correlation-Based Study. Journal of diabetes research, 2022, 5962001. https://doi.org/10.1155/2022/5962001.
Agarwal, S., Simmonds, I., & Myers, A. K. 2022. The Use of Diabetes Technology to Address Inequity in Health Outcomes: Limitations and Opportunities. Current diabetes reports, 22(7), 275–281. https://doi.org/10.1007/s11892-022-01470-3.

better blood sugar [BG] control."[304] Dr. Farrow and many like him place data, data trends, and biomedical technologies that produce data on a pedestal high above the phenomenological experiences of patients. The vast production of data necessitated the development of new technologically-derived metrics. In particular, with the increased use of the CGM, which is an essential component of the APS, a new measure to manage BG was introduced - Time In Range (TIR). It is the measure of the amount of time an individual spends in the target BG range. The desired norm for TIR is "between 70 and 180 mg/dL for most people."[305] TIR has become a highly used measure to understand BG highs and lows, allowing the doctor to be better equipped in prescribing medications and making adjustments to other aspects of T1D management.

The previously mentioned A1C measure is "the current gold standard for determining diabetes management."[306] However, with the proliferation of continuous glucose monitoring, the A1C became an insufficient measure for treatment decisions, so it is primarily used as a predictive measure to assess one's prediabetes or diabetes status, risk of complications, and as the snapshot of one's diabetes management. In addition to the TIR, new metrics were introduced to assess glycemic control. These include Time Above Range (TAR), Time Below Range (TBR), Glycemic Variability (%CV), and Glucose Management Indicator (GMI). Targets for all these new metrics are summarized below in Table 1 and are used as norms for assessing the quality of T1D self-management through the use of biomedical technologies. The targets set for these metrics are adjusted based on the risk factors and risk assessment done by the physician based on

[304] ADA. 2022. Continuous Glucose Monitors (CGMs) and Me; The Beauty of Technology. American Diabetes Association. YouTube. Accessed 2.24.23. https://www.youtube.com/watch?v=w_Locm5JSrs.
[305] ADA. 2022. CGM & Time in Range. Accessed 11.15.22. https://diabetes.org/tools-support/devices-technology/cgm-time-in-range.
[306] Ibid.

the patient's age, pregnancy status, or expert-identified high-risk health status and other potential concerns.

Metric	BG Target Range (mg/dL)	Duration (% of the time)
Time in Range (TIR)	70-180	>70%
Time above Range (TAR) Level 1 Level 2	 >180 >250	 <25% <5%
Time below range (TBR) Level 1 Level 2	 54–69 <54	 <4% <1%
Coefficient of Variation (%CV): ≤36% Glucose Management Indicator (GMI): <7% (ADA)		

Table 1. CGM-derived BG metrics with established BG target ranges and expected percent-time spent within the desired range.

These metrics are presented in a standardized report called the Ambulatory Glucose Profile (AGP) as shown in Figure 7. The AGP is used by doctors to guide therapeutic decision-making. It displays all the measures identified above (TIR, TAR, TBR) along with GMI, equivalent to an estimated A1C value based on BG data, and %CV, which indicates glycemic variability of BG readings. The AGP presents a visual representation of blood glucose levels which are "processed, plotted, and analyzed in terms of treatment-relevant factors."[307] Patient data on the AGP is compared against the established norm for each measure to help doctors make recommendations regarding insulin dose adjustments, dietary changes, physical activity, different technologies, adjustments to technological settings, and other care optimization efforts.

[307] Kröger J, Reichel A, Siegmund T, Ziegler R. 2020. Clinical Recommendations for the Use of the Ambulatory Glucose Profile in Diabetes Care. J Diabetes Sci Technol. 14(3):586-594. doi: 10.1177/1932296819883032. Epub 2019 Nov 13. PMID: 31718268; PMCID: PMC7576939.

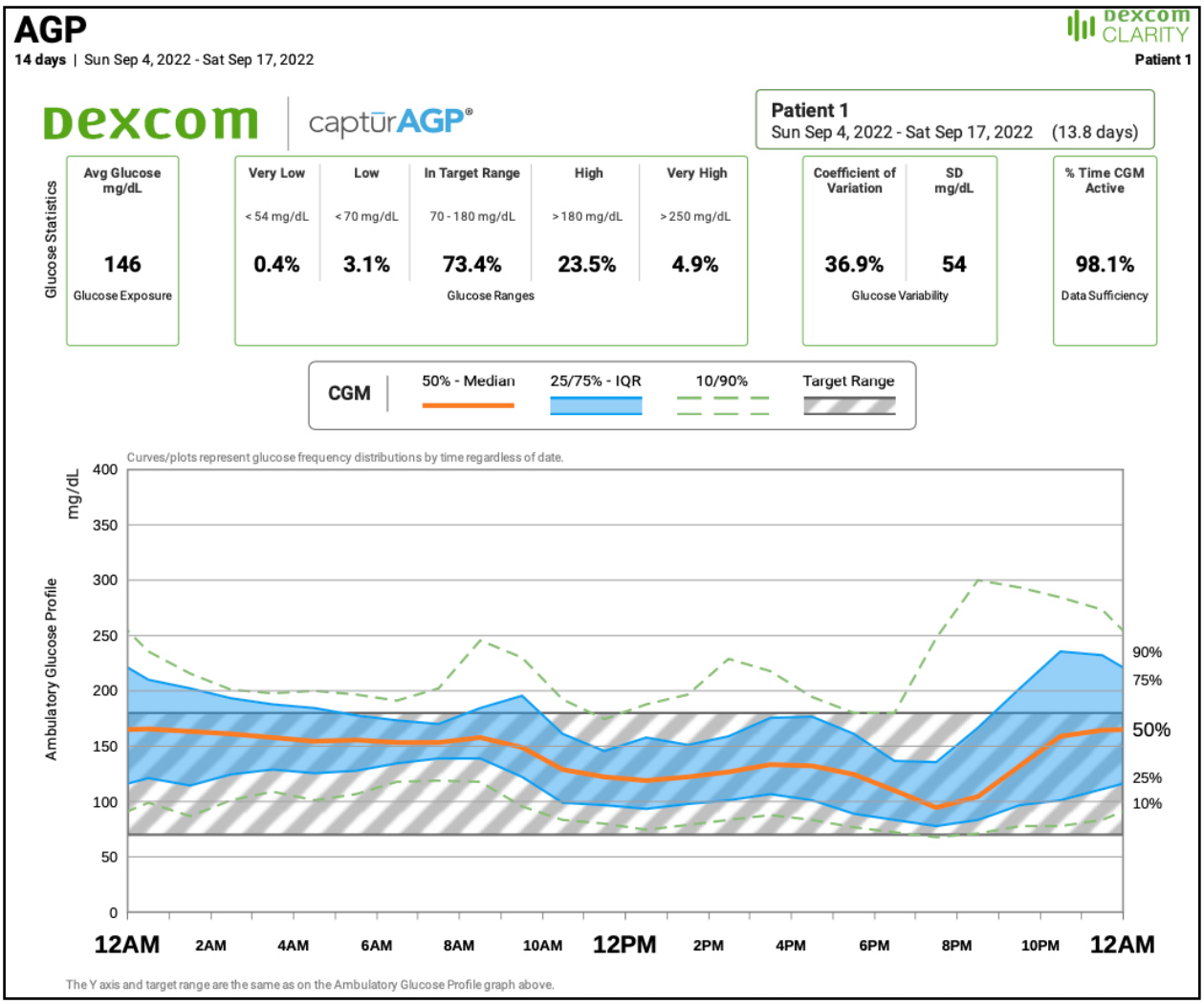
During the educational course, regulatory experts reviewed multiple case studies to compare and contrast patients' health outcomes, as well as to make therapeutic recommendations based solely on displayed data as represented in the AGP. During the training Sean M. Oser, MD described how the standardized metrics and data on the AGP report are used to assess patient cases:

"Let's look at Janice first. We see that she has a GMI that matches her A1c, and not surprisingly, she doesn't meet the target for time in range. However, she has almost no hypoglycemia, and, as expected, a affair amount of time above range, hence the average glucose or GMI, being above target. Looking at her variability, though, it's pretty low. She tends to run above average, consistently with little variability. And now let's look at Brenda, whose average glucose and A1c, at least in her GMI, are the same as Janice's. But Brenda spends much less time in range, Much more time below range, and much more time above range, especially in that higher tier of time above 250 mg/dL. She has a significant amount of time below 54 and time above 250, not just below 70 and above 180. Her variability is far higher. Her path is not so steady, like Janice's path is. Brenda's is all over, from very high to very low and everything in between. For Janice then, she might benefit from treatment adjustment that would shift everything a little lower in order to bring her average glucose, and her GMI down towards target, which would increase her time in range, and decrease her time above range. She doesn't experience much hypoglycemia, so we could probably do this pretty comfortably. For Brenda, though, it would be more dangerous to simply lower her glucoses across-the-board in order to get her GMI her A1c to target. Doing that would increase her already high frequency of hyperglycemia, and we'd increase its severity too. So she is going to require a very different approach. But without CGM, these two ladies would have looked very similar from a glycemia standpoint, because all we would have known is that both of them have A1c levels that are not at target, and which should be lower. ***CGM here is absolutely the key to informing our therapeutic approach.*** *I like to think that looking at an A1c level is like finding your location on a map, and this can be extremely useful. But CGM is more like GPS. It can show you the location on the map in much the same way, but it can also show you where are you headed, how fast, and how you got to where you are now, whether it was a meandering and frantic trip to where you are, like Brenda, or a slower and steadier, and more direct route there, like Janice."*[308] [emphasis added]

This indicates not only that what regulatory experts consider "treatment-relevant factors" is limited to data, metrics, identified patterns, graphs, and trends, but also that

[308] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 5. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.

patient input was not required for regulatory experts to make therapeutic decisions and lifestyle change recommendations. Such an approach to care emphasizes the prioritization of biological factors and risks over other impacts of disease on human health. In the process of healthcare standardization and the transformation of T1D management with biomedical technologies, the patients and their lived experiences are often reduced to data points. This reductionist and regulated approach to care in the process is losing the sense of the patient as a person. As the above quote demonstrates, during the case analysis for Brenda and Janice, CGM data was "the key" for therapeutic decision-making and for the assessment of the quality of the patient's glycemic management. With heavy reliance on data, the patient becomes hidden behind graphs, charts, trendlines, statistics, and measures. Thus, the patient's lived experiences, their unique T1D requirement, their individualistic health needs, and everyday relationships become secondary.


AGP
14 days | Sun Sep 4, 2022 - Sat Sep 17, 2022
dexcom CLARITY
Patient 1
dexcom
captūrAGP®
Patient 1
Sun Sep 4, 2022 - Sat Sep 17, 2022 (13.8 days)
Glucose Statistics
Avg Glucose mg/dL
146
Glucose Exposure
Very Low
< 54 mg/dL
0.4%
Low
< 70 mg/dL
3.1%
In Target Range
70 - 180 mg/dL
73.4%
High
> 180 mg/dL
23.5%
Very High
> 250 mg/dL
4.9%
Glucose Ranges
Coefficient of Variation
36.9%
SD mg/dL
54
Glucose Variability
% Time CGM Active
98.1%
Data Sufficiency
CGM
50% - Median
25/75% - IQR
10/90%
Target Range
Curves/plots represent glucose frequency distributions by time regardless of date.
Ambulatory Glucose Profile
mg/dL
400
350
300
250
200
150
100
50
0
90%
75%
50%
25%
10%
12AM
2AM
4AM
6AM
8AM
10AM
12PM
2PM
4PM
6PM
8PM
10PM
12AM
The Y axis and target range are the same as on the Ambulatory Glucose Profile graph above.

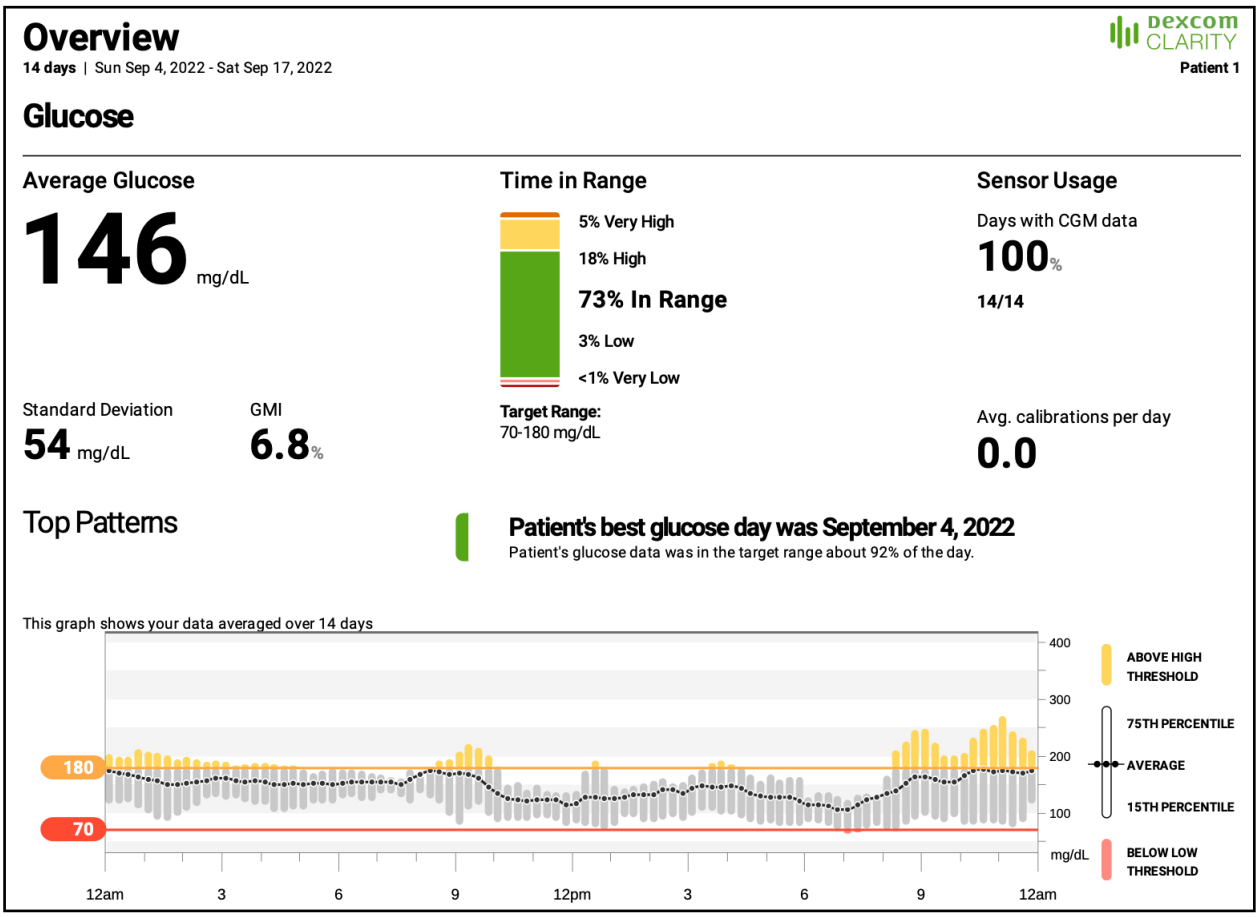


Figure 7. Partial sample Ambulatory Glucose Profile (AGP) from Dexcom G6 CGM user with T1D followed by a partial sample of the overview glucose report.

The ADA praises biomedical technologies for their advancing automation and for the availability of these new metrics to guide T1D care and management. However, from the continuing education course, a dilemma stands out. On one side patients are presented as illiterate and incapable of disease self-management. “An estimated 2/3 of adults have difficulty with simple arithmetic, 25% are unable to identify their BG targets, 56% can’t count carbohydrate grams while using a food label, 59% are unable to accurately

calculate insulin dose based on grams of carbohydrates and current blood glucose."[309] These statistics indicate not only that the majority of patients are likely to harm themselves during self-care, but also that greater physician oversight is required. Automated biomedical technologies for diabetes care are presented as a solution to the problem of patient illiteracy that should work for both the patient and the physician. Thus, patients are asked to rely on technology to do the math for them. On the other side, all biomedical technologies available today require patient input. Since patients as users are an integral component of the APS,[310] they are essential to biomedical technology effectiveness and success. How do we reconcile the role of the patient in making biomedical technology work, which already involves arithmetic, data entry and complex decision-making, with regulatory expert claims that such technologies negate issues of literacy and numeracy challenges?

Regulatory expert risk discourses reveal a tension between how patients are perceived, as illiterate and incapable of disease self-management, and what is expected of patients in terms of self-control, self-knowledge, and self-improvement. Biomedical technologies seem to transcend the barrier between the two. Health automation via the use of biomedical technologies mitigates not only biological risks of disease but also risks of human ineptitude, inadequacy, and deficiency. Automation is set to reduce risk, enhance efficiency, and ease human efforts in managing T1D. The assumption that the process of automation will reduce the risk of human error applies not only with the APS

[309] ADA. 2021. Professional Education: Making Diabetes Technology Work. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[310] FDA. 2018. What is the pancreas? What is an artificial pancreas device system? https://www.fda.gov/medical-devices/artificial-pancreas-device-system/what-pancreas-what-artificial-pancreas-device-system.

or in T1D care. It is also evident with autonomous driving, where a self-driving car takes control of the vehicle since the majority of traffic accidents are caused by human error[311] or automation of human cognition via Artificial Intelligence (AI) and research on the computerized mind due to human cognitive shortcomings.[312] Thus, the drive for automation in contemporary society is aimed at reducing the risk of human elements across different aspects of human life and health automation is no exception.

Additional challenges and risks are experienced by individuals who have difficulty managing multiple daily injections of insulin or multiple blood glucose checks, and who suffer from impaired vision, hand tremors, and other disabilities. During the course endocrinologist Mansur Shomali, MD, analyzed a case study of Mateo, a 57-year-old man with T1D who developed retinopathy (impaired vision) and nephropathy (deterioration of kidney function).[313] Dr. Shomali expressed concern with Mateo's self-management, his forgetfulness to administer insulin, and signs of diabetes distress as Mateo "gets frustrated easily by his erratic glucose patterns."[314] Dr. Shomali proceeded by prescribing Automated Insulin Delivery (APS) to "prevent the progression of diabetes complications."[315] Biomedical technologies are offered as solutions not only to T1D, or one's glycemic management but also to halt health complications and help with mental health concerns.

---

[311] Brell, Teresa, Ralf Philipsen, and Martina Ziefle. 2019. sCARy! Risk Perceptions in Autonomous Driving. The Influence of Experience on Perceived Benefits and Barriers. Risk Analysis 39 (2): 342-357.
[312] Edwards, Paul N., 1996. The Closed World: Computers and the Politics of Discourse in Cold War America. Cambridge, MA: MIT Press.
[313] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 2. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[314] Ibid.
[315] Ibid.

Automated biomedical technologies are remarked as effective in improving quantitative measures associated with T1D, such as A1C, GMI, TIR, TBR, TAR, and %CV, as well as patient confidence and quality of patient life. Dr. Shomali concluded: "With the use of this automated insulin delivery device [APS], Mateo now has improved his glucose profile. His time in range has increased to 71%. And the GMI, which approximates A1C is now 6.6%. Wow, what a difference!"[316] The excitement for the promises of further health automation is celebrated by regulatory experts for its positive impact not only on the patient and the medical practice efficiency but also on the increased range of services medical experts can bill for and for associated growing reimbursements. Eric L. Johnson, MD encouraged the remote monitoring of patients with diabetes: "You might also do virtual technology demonstration. It's even possible to incorporate how-to demonstrations for diabetes devices…This might be a first look or it might be a refresher."[317] Eden Miller, DO, continued: "Now don't forget we can bill for remote monitoring of CGM…Many CGM's are not even downloaded let alone reviewed at the encounter with the patient. I urge you to do that because we can bill for those time and those services."[318] Biomedical technologies help to further focus clinical care on reaching target norms as the main approach while helping strengthen the professional standing of regulatory experts and providing monetary incentives.

[316] Ibid.
[317] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 7. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[318] Ibid.

The regulatory experts claim the use of diabetes technologies is "more important than ever" for a number of reasons.[319] Technologies optimize patient health outcomes as well as reduce the clinical burden. Further, the regulatory experts are calling to realize the full potential of the technologies which help patients live healthier lives. For example, in addition to using biomedical technologies for diabetes management, regulatory experts are calling for the utilization of clinical technologies, such as the electronic health record (EHR) systems, for data mining of patient records to identify individuals or subpopulations for monitoring and additional interventions. Data generated by diabetes technologies (TIR, A1C, BG etc.) together with other patient data, such as socioeconomic status, age, race, sex, ethnicity, health insurance data, BMI, mental health status, level of education, zip code and a range of behavior factors (frequency of doctor or emergency room (ER) visits) can be used for mining. This clinical data collection, sorting and analysis further reinforces governmentality. This is exemplified by Eden Miller's, DO, quote below.

"The electronic health record has a really underappreciated use. We can do clinic data mining via the EHR system. It really is a powerful use of technology on the provider-facing side. ***We can actually identify at-risk populations****. It is this population-level data tool set. It kind of allows us to* ***sort for meaningful parameters. It can also identify other subpopulations for interventions.*** *You can see how this could be a way for the use of technology to* ***identify individuals that you want to bring back in to overcome therapeutic inertia or to try to recapture some of their ongoing care****."*[320] [emphasis added]

[319] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 2. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.

[320] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 7. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.

Biomedical technologies come to the rescue, especially for patients with T1D who are recommended to use more advanced biomedical technologies. For example, the ADA recommends the use of CGM while performing critical tasks such as driving.[321] In the case of hypoglycemia (low BG) onset while driving, individuals with T1D can experience blurry vision or fainting, putting the individual and those around them at risk of harm. The CGM or the APS can prevent hypoglycemia by alerting the individual of danger. A constant need to pay attention to alerts and to always be ready to take action can be exhausting. As a result, increased reliance on biomedical technologies increases individual's trust in these technologies. The ADA recommends APS to all adults with T1D who are able to safely manage the device. However, the ADA does not specify what that management entails. Regulatory experts say even people with complex needs such as developmental challenges and incarceration, and those with movement disorders can benefit from diabetes technology. Joseph Aloi, MD, said, "I think sometimes technology is viewed as something that's complex and that you have to have technical skills, but people with intellectual impairments such as severe autism and or down syndrome and others with neurobehavioral challenges can also benefit."[322] Yet it does not address the specific challenges these subpopulations experience. Samar Hafida, MD, continued:

"[I]t's really ***important that we close the disparity gap here and think about our most vulnerable populations and offer technology to them****. A lot of people don't think that they are worthy enough or having these incredible devices are extraordinarily expensive, but they're, you know, they're just as needy of them as anybody else. And also that includes our incarcerated people who have type 1 diabetes and type 2 diabetes and other vulnerable groups in society."*[323] [emphasis added]

---

[321] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 2. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[322] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 6. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[323] Ibid.

The above quote supports technological solutionism and highlights the belief among regulatory experts that biomedical technologies for diabetes management are capable of addressing social disparities and vulnerabilities within the population that extend beyond diabetes. Such beliefs disregard the user's role in diabetes management and the challenges of technological maintenance for which users carry primary responsibility.

The ADA recognized a number of risk factors associated with biomedical technologies. The most prominent risk factor identified during the course is hypoglycemia (low BG). The APS helps reduce this acute risk. Other risks such as hyperglycemia (high BG), and irreversible complication of T1D, as discussed in previous chapters, are all believed to be mitigated through the effective use of biomedical technologies with the guidance of target metrics for TIR, GMI, TIR, TBR, TAR, and %CV. Additional risks include data overload, when patients are overwhelmed with the constant inflow of data, and increased distress from the use of biomedical technologies. A number of patient-specific factors can add complexity to the use of biomedical technologies. These include complex comorbidities, social determinants of health, behavioral barriers, and diabetes burnout. These challenges are acknowledged, but very little is provided in terms of detailing what these issues are or engaging with the patients regarding how to deal with such issues since regulatory experts are primarily focused on risks associated with biological processes of the human body. Michael Cronyn, physician assistant and assistant professor at AdventHealth University, spoke about the benefits of biomedical technologies: "diabetes can be overwhelming, and patients who have trouble

coping could get more overwhelmed by more data. On the other hand, technology can ease the burden so it could improve diabetes related distress."[324]

Human error is a significant risk factor identified by regulatory experts in biomedical technology use and disease management. Individuals with T1D are already burdened with the demands of the disease not to mention the need to function in the world outside of T1D. Mistakes happen and one such error can be related to the mathematics of disease management. The calculation of carbohydrates consumed the calculation of insulin dose and the estimation of activities in relation to insulin and food intake. The possibility of mathematical errors further emphasizes the need to automate T1D management. The presentation of the iLet Bionic Pancreas trial at the ADA's 82nd Scientific Sessions in 2022 spurred a number of articles highlighting how the Bionic Pancreas, a technology that "mimics the glucose regulating the function of a healthy pancreas,"[325] also "removes math from diabetes."[326] Dr. Shomali said: "Many Americans have trouble doing the arithmetic necessary to calculate an insulin dose. Many people with diabetes…have numeracy challenges. Why not let the apps do the math?"[327] This further demonstrates that automation proliferates move automation and that technologies are sought as solutions for disease, suffering, and users' intellectual shortcomings.

[324] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 4. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[325] ADA. 2019. The iLet Bionic Pancreas Increased Time in Range for Adults with Type 1 Diabetes. ADA's Scientific Sessions. https://diabetes.org/newsroom/press-releases/2019/the-ilet-bionic-pancreas.
[326] McDermid Eleanor. 2022. Bionic pancreas removes math from diabetes. ADA 2022 Conference coverage. Medicine Matters – Diabetes. https://diabetes.medicinematters.com/ada-2022/artificial-pancreas-systems/bionic-pancreas-removes-math-from-diabetes/23127798.
[327] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 2. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.

ADA's standards of care were updated since the course was originally published in 2021. The 2021 language indicating that "CGM could "replace" BGM" (blood glucose meter) was updated to "People using continuous glucose monitoring devices must have access to blood glucose monitoring at all times."[328] The CGM, despite being built and promoted as a solution to BG monitoring that operates on a continuum, in actuality is adding steps for the user rather than taking them away as exemplified by the need for BGM access with CGM use. This change in the perception of the CGM and the APS means that the risk perception of biomedical technologies has since increased accounting for situations when technology is not working or is not functioning properly, necessitating a backup plan for BG monitoring. However, the issue still remains with commercial narratives that promise such as "Dexcom makes fingersticks a thing of the past."[329] Such narratives influence public perception of biomedical technologies indicating that life with T1D is easy.

Per ADA diabetes is a growing "nationwide epidemic" with growing national annual costs of diagnosed diabetes from $245 billion in 2012 to $327 billion in 2017.[330] The cost of diabetes has increased by 26% from 2012 to 2017.[331] Individuals with diabetes on average are paying about 2.3 times more in medical expenses compared to individuals without diabetes.[332] This data highlights how burdensome diabetes is not only to the patients but also to society at large. The availability of different biomedical technologies, scientifically proven to be effective in reducing some burdens of disease,

[328] ADA. 2022. Making Diabetes Technology Work. ADA Professional Education. Accessed 9.13.22. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[329] Dexcom. 2018. Dexcom CGM — For People with Diabetes, Finally, Dexcom Makes Fingersticks a Thing of the Past. YouTube. https://www.youtube.com/watch?v=A1NU5ivC5Og.
[330] ADA. 2022. Statistics: Examine the Facts. https://www.diabetes.org/about-us/statistics.
[331] ADA. 2022. The cost of diabetes. https://diabetes.org/about-us/statistics/cost-diabetes.
[332] Ibid.

does not mean accessibility or affordability. The increased variety, complexity, and automation of biomedical technologies in diabetes care does not reflect positive population-level health outcomes. Cost remains to be a significant risk and a barrier for patients even with health insurance. Insurance limitations as well as the high cost of insulin and diabetes technologies become barriers to patients' ability to obtain the needed therapeutic tools to manage T1D. The ADA further confirms that diabetes carries with it intangible burdens "from pain and suffering."[333] While regulatory experts acknowledge biological, some technological, and financial risks, their professional purview guides their focus primarily toward biological risks. Increasing costs, challenges with access and affordability as well as tangible and intangible burdens of T1D lead to increased social risks, such as loss of employment, poverty, and social isolation to name just a few.

Artificial Pancreas Systems, Patient's Engagement, and Barriers

In the introductory video to the ADA's educational series "Making Diabetes Technology Work," Joseph Alio, MD, says: "Incorporating technology into the care of people with diabetes has been as impactful as the isolation of insulin 100 years ago."[334] He continues to say that "these technologies have forever changed the landscape of diabetes care" and greatly enhanced the ability of doctors to help patients, improve the quality of life for patients and improve patient engagement in their own care.[335] This is high praise for biomedical technologies indicating a paradigm shift on par with the

[333] ADA. 2022. The cost of diabetes. https://diabetes.org/about-us/statistics/cost-diabetes.
[334] ADA. 2022. Making Diabetes Technology Work Bundle. ADA Professional Education. Accessed 10.15.22. https://professionaleducation.diabetes.org/Users/LearningActivity/LearningActivityDetail.aspx?LearningActivityID=q2ZftMXYXt2c4xOSzX%2BrVA%3D%3D&tab=1.
[335] Ibid.

discovery of insulin. The ADA encourages the use of the APS, also called Automated Insulin Delivery Systems (AID systems) or hybrid closed-loop systems, which "approximate physiologic insulin delivery" to reduce A1C levels, improve time in range (TIR) of desired blood glucose levels, lower the risk of exercise-related hypoglycemia, provide "psychosocial benefits."[336] Thus, the APS is believed to be a solution to not only BG management, but also to the social, mental and emotional effects of type 1 diabetes. The ADA is promoting the use of biomedical technologies under the oversight, direction, and recommendation of healthcare professionals. It recommends the use of only FDA-approved technologies since they underwent proper quality, safety, and usability testing.

The ADA acknowledges the use of Do-It-Yourself Closed-Loop Systems (DIY APS) by patients despite it not being approved by the FDA. While it acknowledges that thousands of patients use DIY APS, it emphasizes multiple times throughout the course that DIY APS is not cleared by the FDA. Since great value is assigned to evidence-based and peer-reviewed clinical data as well as regulatory expert opinions, DIY APS is considered risky. The ADA recommends health care providers, while they cannot prescribe the use of DIY APS, to "assist in diabetes management to ensure patient safety" for patients who are using DIY APS.[337] Interestingly, part of the assurance of safety is to devise a backup plan in case of CGM failure as demonstrated by the opening story in the first chapter. The same assurances of safety are not specified or emphasized by the ADA for the FDA-approved APS, despite the same need for alternative care during that system's failure. This suggests a bias in the risk assessment between the two systems.

[336] American Diabetes Association Professional Practice Committee. 2022. 7. Diabetes technology: Standards of Medical Care in Diabetes—2022. Diabetes Care 2022;45 (Suppl. 1):S97–S112.
[337] Ibid.

The APS has reportedly taken the center stage at the 2022 ADA annual meeting.[338] This is not surprising since it is the most advanced technology available to patients with T1D today. It promises to automate T1D management without requiring much input from the user, to adjust the amount of insulin administered to the patient, "so you don't have to think about it as much."[339] Despite the promises of the APS, regulatory experts expressed and identified concerns regarding the barriers to effective T1D care and issues of patient engagement preventing users from safe use of biomedical technology to its full potential, including but not limited to complex comorbidities, social determinants of health, costs of care, availability of health insurance and behavioral barriers.

The DIY APS was briefly mentioned during the professional education course to highlight that there are thousands of patients using it and that the FDA deems it to be risky, unsafe, and injury-prone.[340] Every mention of the DIY APS was accompanied by mentioning that it is not FDA-approved without describing how the system works or how it differs from the FDA-approved one. How can health and medical professionals "assist in diabetes management to ensure patient safety"[341] if there is no education provided on the specifics of the systems so many patients use? Further, the ADA does not include the DIY APS in the "Devices and Technologies" section of its online resource[342] or the ADA's "Consumer Guide" which was created "to inform both consumers and

[338] Park, Andrea. 2022. ADA: Beta Bionics' automated insulin pump slashes glucose levels, diabetes distress in Type 1 patients. https://www.fiercebiotech.com/medtech/ada-beta-bionics-automated-insulin-pump-slashes-glucose-levels-diabetes-distress-type-1.
[339] ADA. 2022. Devices & Technology. Better blood glucose meters and more. Accessed 09.18.22. https://diabetes.org/tools-support/devices-technology.
[340] U.S. Food and Drug Administration. 2019. FDA Warns Against the Use of Unauthorized Devices for Diabetes Management. FDA safety communication. Accessed 01/09/22. www.fda.gov/medical-devices/safety-communications/fda-warns-people-diabetes-and-health-care-providers-against-use-devices-diabetes-management-not.
[341] American Diabetes Association Professional Practice Committee. 2022. 7. Diabetes technology: Standards of Medical Care in Diabetes—2022. Diabetes Care 2022;45 (Suppl. 1):S97–S112.
[342] ADA. 2022. Devices & Technology. Better blood glucose meters and more. Accessed 09.18.22. https://diabetes.org/tools-support/devices-technology.

professionals about technology and medications available to treat diabetes."[343] The ADA wants a "life free of diabetes and all its burdens" and sets a mission to not only prevent and cure diabetes but also "to improve the lives of all people affected by diabetes."[344] How can patients' lives be improved if they do not know of all the options available to them or how to safely engage with such options and get quality support from their medical team? One reason for not including DIY biomedical technologies in the ADA's list of technological options available to users might be the fact that we live is a litigious society with significant legal risks of a possible lawsuit. Another reason might be the perception of DIY APS as inferior, unsafe, and risky. However, the matter of DIY APS use, as presented by the regulatory expert community, seems to default with a normative view of technology based on assumptions, assigned values, and predefined judgement, not an objective view guided by data, evidence and scientifically presented user experience.

Patient Engagement

Patient engagement was a common theme throughout the professional education course. Patient engagement is both a process and a behavior that is shaped by patients, providers, their relationship and "the environment in which healthcare delivery takes place."[345] It is one's "desire and capability to actively choose to participate in care in a way uniquely appropriate to the individual, in cooperation with a healthcare provider or institution, for the purposes of maximizing outcomes or improving experiences of

[343] ADA. 2022. Consumer Guide: Products. Accessed 09.18.22. https://consumerguide.diabetes.org.
[344] ADA. 2022. About Us: Who We Are https://diabetes.org/about-us.
[345] Higgins, T., Larson, E., & Schnall, R. 2017. Unraveling the meaning of patient engagement: A concept analysis. Patient education and counseling, 100(1), 30–36. https://doi.org/10.1016/j.pec.2016.09.002.

care."[346] Regulatory experts perceive low patient engagement as a risk factor. A few approaches were suggested to increase patient engagement to allow patients to get the most out of the technologies they use. These approaches include patient education, enhanced personal experiences, and optimization of glycemic control. Regulatory experts emphasize patient engagement as important because it is believed to have a positive impact on patient's clinical outcomes (A1C, TIR,%CV, etc.), mental health outcomes (perception of disease severity and patient distress), and patient quality of life outcomes. Since biomedical technology use is believed to have a strong potential to influence patient engagement in a positive way, medical and health professionals are instructed to help patients overcome the barriers associated with biomedical technology use and strive to achieve positive outcomes. Endocrinologist Janise Wong, MD, said: "Technology can influence engagement in either a positive or a negative way and that's why we really need to focus on how we can help patients overcome barriers to technology so that we can actually help them achieve all these idea outcomes."[347] Most patients are not "coerced through disciplinary means to accede to expert advice."[348] They are encouraged to rely on biomedical technologies to achieve the best possible health outcomes.

The course identified patient education as essential to ensure patients know how to use biomedical technologies and can benefit from health automation. Janise Wong, MD, discussed one of the recommendations to increase patient engagement is to

[346] Ibid.
[347] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 9. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[348] Lupton, Deborah. 1999. Risk (Key Ideas). New York: Routledge.

"normalize devices and technology with education."[349] However, who is responsible for providing this education? The professional education course reviewed for this chapter is available for medical and healthcare professionals at no cost, online, at their convenience with educational credits for their continued education. There are multiple such courses available via ADA's online portal on a variety of subjects related to diabetes. On the other hand, patients only have the option to attend Diabetes Self-Management Education and Support (DSMES) programs which require their physical presence, physician's referral, health insurance, funds, transportation, and time away from work.[350] The ADA aims "to improve the lives of all people affected by diabetes"[351] as well as identifies patient education as essential to patient success in T1D self-management. Yet, patient education and educational resources are not made accessible on par with those provided to the regulatory expert community considering costs, flexibility, and convenience.

If the strategy of governmentality is to configure an autonomous and self-regulating subject who "voluntarily takes up government imperatives"[352] then the above exemplifies the role of regulatory experts in influencing patients' voluntary compliance. The widely used term noncompliance, indicating an active refusal or failure by the patient to comply with the prescribed regimen, is slowly replaced by the term nonadherence, or

[349] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 9. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[350] Jody Davis, Amy Hess Fischl, Joni Beck, Lillian Browning, Amy Carter, Jo Ellen Condon, Michelle Dennison, Terri Francis, Peter J. Hughes, Stephen Jaime, Ka Hei Karen Lau, Teresa McArthur, Karen McAvoy, Michelle Magee, Olivia Newby, Stephen W. Ponder, Uzma Quraishi, Kelly Rawlings, Julia Socke, Michelle Stancil, Sacha Uelmen, Suzanne Villalobos. 2022 National Standards for Diabetes Self-Management Education and Support. Diabetes Care 1 February 2022; 45 (2): 484–494. https://doi.org/10.2337/dc21-2396.
[351] ADA. 2022. About Us: Who We Are https://diabetes.org/about-us.
[352] Lupton, Deborah. 1999. Risk (Key Ideas). New York: Routledge.

inertia, indicating passive and unintentional refusal by the patient.[353] This change in terms indicates a shift in the role of the medical provider from authoritarian to an advisory. It also indicates the shift in the way patients should be perceived, from passionate, rebellious, troubled, and demanding to overwhelmed, helpless, concerned, and confused.[354] The language matters. Here, the question regarding access to educational resources stands at tension. On one side nonadherent patients require regulatory expert guidance to encourage self-regulation within the established framework of population and information controls. Therefore, there is no need to provide external educational resources to patients since regulatory experts educate patients at their discretion. On the other side, the need for autonomous patients striving for self-control, self-knowledge, and self-improvement, necessitates greater access to educational resources. It is likely that this tension is strengthened by regulatory experts' desire to claim expertise and guard their professional identity.[355]

The community of regulatory experts emphasizes the need for more diabetes education specialists, behavioral health specialists, and others to help patients manage their disease. They encourage and prioritize the growth of the field and the increase in the number of specialists to educate patients by physician's referral, instead of providing readily available and accessible resources to patients directly. Thus, patients depend on the regulatory expert's judgment regarding their capabilities, risk status, vulnerabilities, barriers, suitable biomedical technologies, referrals, and technology prescriptions.

---

[353] Anderson, Jim. 2021. Why Word Choice Matters When Describing Patients Who Do Not Follow Medical Advice. The Clinical Advisor. https://www.clinicaladvisor.com/home/the-waiting-room/word-choice-describe-patients-do-not-listen-to-medical-advice/.
[354] Jones, Sue. 2016. The Noncompliant vs The Non-adherent Patient. Cooperative of American Physicians. https://www.capphysicians.com/articles/noncompliant-vs-non-adherent-patient.
[355] Starr, Paul. 1982. The Social Transformation of American Medicine. New York: Basic Books.

During the course, regulatory experts identified biomedical technologies with a higher level of automation, such as a CGM, as effective not only for BG monitoring but also for increasing patient engagement. This is attributed to patients learning how physical activities and food intake impact their BG levels through the use of such technologies. Therefore, the personal experiences of patients with biomedical technologies can be powerful venues for learning. Regulatory experts acknowledge potential qualitative and behavioral benefits of biomedical technology use without specifying them. Yet, their gaze is primarily focused on quantitative measures and efforts of optimization in response to established norms and metrics of care.

The shifting role of regulatory experts from authoritative to advisory emphasizes the shift of the burden and blame for glycemic management. Both doctors and patients influence efforts of "glycemic control." Doctors remain as ultimate authorities in patient care, by defining glycemic targets, adjusting medical regimens, and prescribing biomedical technologies to optimize "glycemic control." Patients have no ability to obtain FDA-approved biomedical technologies without a doctor's approval, even if they desire to. Doctors make judgments and assess patient readiness to engage with more advanced biomedical technologies since patients can be viewed as easily overwhelmed by the data and can experience increased levels of anxiety. Mark Heyman, Ph.D., diabetes psychologist, demonstrated the challenges of patient engagement with a review of a case study of a 24-year-old female with T1D: "Katherine feels overwhelmed by the data she gets from her CGM. She was used to checking her blood sugar every couple of hours then having those blips of data. But now that she has a CGM, she feels deluged by that data, which is increasing her anxiety and making things challenging in her quality of

life."[356] Overwhelmed and anxious patients are likely to be nonadherent patients. Yet, the judgment and the ultimate decision remain with the medical and health provider.

The engaged patient is a compliant and adherent patient. Regulatory experts see biomedical technologies as a solution to the problem of patient engagement with opportunities and barriers. This is exemplified by the following statements made by Mark Heyman, Ph.D., diabetes psychologist, in his address to the question regarding what patients need to do to be engaged:

"Patients want to have the tools they need to manage their diabetes. And so ***giving them the tools that they need and the technologies that they need can help patients be engaged****. They also want to see their diabetes management behavior actually matters, and the* ***technology can help them to be engaged because it can show them how their behavior impacts the blood sugars [BG] in real time****. And finally, patients need to feel confident they can manage diabetes and t****echnology gives them a tool they can use to feel more confident*** *in their diabetes management and be more successful in glycemic control."*[357] [emphasis added]

Opportunities include improved glycemic management increased oversight and monitoring of the patient. Biomedical technologies are expected to increase not only patients' knowledge about T1D and self-care, but also improve their motivation, well-being, and general quality of life. Barriers include patient literacy and technological hesitancy. Regulatory experts indicate barriers can be overcome via discussions of short-term and long-term risks and benefits of automation, via regularly scheduled visits with a diabetes care provider, communicating with the diabetes team between visits, getting laboratory tests as well as establishing a supportive environment with family and friends.

[356] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 9. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[357] Ibid.

An engaged patient is also a patient who uses biomedical technologies in the way instructed by regulatory experts.

Historian Paul Edwards wrote about the development of the computer industry that "[p]eople who think they are being watched tend to do what they think they are supposed to do, even when they are not."[358] Likewise, individuals with T1D who rely on computers (biomedical technologies) and presume they are under constant supervision by a healthcare provider due to the real-time continuous glucose monitoring data sharing are believed to be more engaged and compliant.[359] That is the reason why more frequent and regular interactions between patients and healthcare providers are encouraged, especially for those who experience health complications or challenges with T1D self-management. Biomedical technologies become one of the tools of monitoring and surveillance, allowing regulatory experts to see patients' blood glucose data even without direct interaction with the patient. This mirrors the impact of computerized recordkeeping on the increased regulatory expert ability to "control people without touching them, using the subtle pressures of internalized discipline," making modern power generate "active compliance rather than passive obedience."[360] The power to make patients actively adherent determines what can count as truth and knowledge in contemporary society. Thus, the perception of true knowledge is guided by established norms by those in the position of authority.

[358] Edwards, Paul N., 1996. The Closed World: Computers and the Politics of Discourse in Cold War America. Cambridge, MA: MIT Press.
[359] Polonsky, W. H., & Fortmann, A. L. 2021. Impact of real-time continuous glucose monitoring data sharing on quality of life and health outcomes in adults with type 1 diabetes. Diabetes technology & therapeutics, 23(3), 195-202.
[360] Ibid.

Barriers to Effective T1D Care

The course identified a number of barriers that impact T1D management and the effective use of biomedical technologies. These include not only disparities in biomedical technology use among different ethnic minorities and socioeconomic and behavioral factors, but also cost barriers to technology adoption and barriers to obtaining knowledge. A physician has the power to determine what biomedical technology a patient is prescribed based on their assessment. However, the ability of the patient to obtain such technology is limited by insurance authorization, and their ability to pay and handle the work that technology requires. Further barriers can be caused by complex comorbidities, social determinants of health, and behavioral barriers.

Cost remains to be a significant barrier for many individuals with T1D. This issue extends from the cost of insulin, with over 1 million U.S. residents rationing insulin because they can't afford it,[361] to the cost of biomedical technologies and supplies which are prohibitively expensive for many.[362] As of 2020 an estimated 8.6 percent of the U.S. population, or 28 million individuals, did not have health insurance at any point during the year.[363] Insurance access in the United States is not universal and an individual's ability to pay often impacts the quality of T1D management. It is difficult to stay motivated about biomedical technologies when the basic needs of patients, such as the availability of insulin, are not addressed. The above factors define what biomedical technologies, if any, are accessible to the patient. Accessibility also differs between

[361] Norton, Amy. 2022. Over a Million Americans Are Rationing Insulin Due to High Cost. U.S. News & World Report. https://www.usnews.com/news/health-news/articles/2022-10-18/over-a-million-americans-are-rationing-insulin-due-to-high-cost.
[362] ADA. 2023. The Cost of Access to Diabetes Technologies. Accessed 01.04.23. https://diabetes.org/advocacy/cost-access-diabetes-technologies.
[363] Keisler-Starkey, Katherine; Bunch, Lisa N. 2021. Health Insurance Coverage in the United States: 2020. U.S. Census Bureau. Report #P60-274. https://www.census.gov/library/publications/2021/demo/p60-274.html.

different states. For example, Medicaid coverage for CGM has great variability among states. Some states have no coverage for CGM under Medicaid, some only cover pediatrics, or only eligible T1D patients, and some cover CGM for both T1D and T2D patients.[364]

Since technologies are believed to increase engagement in diabetes care, regulatory experts recommend telehealth options to increase visit attendance and improve access to providers. This way patients will not have to worry about transportation costs and will help maintain continuity of care. Biomedical technologies provide new opportunities for remote monitoring, and remote access to patient statistics and reports, such as the AGP. Another recommendation is to use patient portals to facilitate communication with the diabetes care team. Online health portals offer flexible communication and allow for the delivery of information and educational materials. Additional recommendations for cost saving include the use of mobile applications that help people find an affordable price for pharmaceuticals.

The regulatory experts remark that increased patient engagement leads to positive outcomes for clinical care and increased use of biomedical technologies by patients. As one physician said during the diabetes technology training, "COVID-19 and expanding use of technology has improved reimbursements."[365] Clinical care outcomes include increased income from increased use of biomedical technologies, increased variety of services provided and billed for as well as increases in staff and patient satisfaction. For example, to enable telehealth services more patients opted for real-time blood glucose

[364] Yan, Karena. 2022. Medicaid and CGM: Who's Covered? diaTribe Learn: Making Sense of Diabetes. https://diatribe.org/medicaid-and-cgm-whos-covered.
[365] ADA. 2021. Professional Education: Making Diabetes Technology Work. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.

monitoring by sharing their biomedical technology data in real time with their medical professionals. Clinics can now bill for remote patient data monitoring, the application of technologies to the patients, and patient education. Additionally, electronic health record systems (EHR) can be used for clinical data mining and population data sorting by parameters such as diabetes control, frequency of visits, and comorbidities to identify subpopulations of patients for additional interventions. Such data research can pinpoint regulatory expert efforts in further increasing patient engagement and reducing barriers to effective T1D care.

Regulatory experts view biomedical technologies for diabetes management not only as a solution facilitating effective T1D care but also as a barrier. For instance, the complexity of technology and the rapid changes in the technological landscape might create a barrier to implementing technology in clinical practice and among patients. The APS provides a constant stream of data, alarms, technical concerns of changing devices and troubleshooting, as well as the need to manage prescription and procurement of supplies that can overwhelm the patient. Even diabetes technologies deemed beneficial can sometimes have a detrimental impact on a patient's quality of life. Some regulatory experts report that biomedical technologies make T1D, an otherwise invisible disease to outsiders, very visible. This includes a visual display of devices on the patient's skin, possible constraints experienced by patients while playing with sports and engaging in other activities, and visible skin irritations, redness, rashes, and scarring caused by the use of such devices. Dr. Heyman said that patients might "worry that other people will notice them of they're there [devices] and they want to keep diabetes to themselves and keep their condition invisible to others…Diabetes for many people is an invisible

condition and they want to keep it that way and having a device on their body reminds them every day that they have diabetes."[366] T1D as well as biomedical technologies used in its management are a lot of work and a constant reminder of the disease. Further, biomedical technologies might violate patients' privacy by exposing their health issues to the public.

The Cacophony of Risks Quantified

The transformation effort of medical and public health practice via the introduction of new approaches to care such as One Health or Whole Health indicates a shift in understanding that the medical model of disease and the medical language are too insufficient and impoverished to address the complexities of a chronic condition such as T1D. However, this understanding also requires action, a change in policies and regulations, as well as a change in the way medical and health services are provided. Further, with the increased use of biomedical technologies by both patients and physicians, clinical practice is experiencing increased technological demands and a higher technological burden. The way we communicate about a disease is the way we understand it and get to know it.[367] Yet, the default way of communication by regulatory experts is quantitative, statistical, measured, and standardized.

Based on the risk discourses research conducted for this chapter, regulatory experts communicate about T1D via quantitative representation of risk perceived to be more scientific, objective, standardized, rigorous, and impersonal because it is "evidence-

[366] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 9. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[367] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press.

based" as exemplified by the ADA-established and maintained "Standards of Medical Care in Diabetes". Quantitative risk discourses prioritize numerical representation of complications, issues, successes, technologies, and patients. They allow regulatory experts to make decisions about treatment, biomedical technology use, and adjustments to patient's lifestyles based on data represented by a number of normative metrics (A1C, GMI, TIR, TBR, TAR, %CV, ICR, CF, etc.) collected through biomedical technologies and those reported by patients (carbohydrate count, minutes of daily exercise, etc.). Quantitative risk discourses create a perception of validity and truth. They carry with them embedded value since the regulatory expert community views quantification, biomedical technologies, and health automation as the best way to mitigate risks and make the biggest positive impact on patient health outcomes.

Quantitative risk discourses morph into a quantitative and technology-driven perception of barriers to effective T1D self-management and hurdles to increased patient engagement. Regulatory experts are working to understand these barriers through quantitative approaches to analyzing population data, such as via Electronic Health Record Systems (EHR), to infer individual-level challenges via statistical measures of significance and probability. Medical professionals heavily rely on biomedical technologies and the numerical outputs such technologies produce.

Health automation also seems to reduce the need for patient input, since data and reports, such as AGP, can be used to make therapeutic decisions. However, the patient's input is required for the effective use of biomedical technologies and disease self-management outside the doctor's office. Regulatory experts rely on quantitative approaches to care and on evidence-based research prioritizing quantitative methods

since qualitative research is not well understood or accepted within the scientific community.[368] Medical and health experts emphasize quantitative research as the best and most effective. This begs the question: automating diabetes care is best and more effective for whom?

A quantitative view of risk and approach to care distances the regulatory expert from the patient. It is highly structured, organized, disciplined, refined, and reduced. Since patients are complex beings with complex needs and complex social circumstances, quantitative approaches to care are not sufficient to capture patients' needs and patient-specific barriers to a higher level of engagement with their health and associated biomedical technologies. Reliance on quantification avoids deeper and more cumbersome issues of patient lived experiences. Further, the practice of medicine is focused not only on patients and standards of practice but also on billing, reimbursements, profits, efficiency, cost-effectiveness, and increasing technological demands. There is seemingly very little space, if any, left for detailed patient interactions, so regulatory experts focus on data mining EHR, systematic reviews, and quantitative studies to get the biggest return on their invested time and efforts.

Examination of risk within the regulatory expert community reveals that quantification accompanied by automated health demands more quantitative data gathering in order to gain more accurate truths about how to reduce risk and remove barriers to patient engagement. Quantification coupled with automation serves as a remedy to the risks of human fallibility originated by the regulatory community. Health automation allows the regulatory expert to employ new ways of quantitative analysis with

[368] Anderson C. 2010. Presenting and Evaluating Qualitative Research. American Journal of Pharmaceutical Education. 74 (8) 141; DOI: 10.5688/aj7408141.

a more varied and higher volume of data. Thus, automation of quantification allows for greater population-level analysis to influence not only the patient population but also individual patients in the doctor's office. The discrepancy in educational resources between health professionals and patients, as demonstrated above, the professional authority of medical providers to prescribe pharmaceuticals and biomedical technologies, as well as their authority to assess, monitor, regulate and discipline patients indicate that health automation can be viewed as a political tool used to maintain control and create a large gap between regulatory experts and patients in order to maintain control and a level of authority. Health automation becomes the solution not only to one's health or effective BG management but also to one's engagement, confidence, the perceived value of self, reduction of barriers to effective T1D care, and higher quality of life.

Regulatory experts claim that biomedical technology-derived data can inform patient-centered health care.[369] Patient-centered care itself means that decision-making and quality measurements in medical care should be driven by patient-specific health needs and patient-desired health outcomes, where treatment is provided from emotional, mental, spiritual, social, and financial perspectives on the level of partnership between patient and health care providers.[370] Dr. James Rickert, a highly respected medical professional and a big proponent of patient-centered care stated "one of the basic tenets of patient-centered care is the idea that patients know best how well their health providers are meeting their needs, and it is the patient's view of his or her health care delivery that

[369] ADA. 2021. Professional Education: Making Diabetes Technology Work. Module 5. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
[370] NEJM Catalyst. 2017. What Is Patient-Centered Care? https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0559.

correlates with outcome or satisfaction."[371] In this case, technology-derived data is unable to accurately inform patient-centered health care, because most patients do not communicate in quantitative terminology. Any perception of patients as illiterate, nonadherent, or unable to handle biomedical technologies would indicate patients are not able to participate in patient-centered care. This is counter to the idea of what patient-centered care is.

Conclusion

Douglas and Wildavsky wrote: "Our techniques for finding new dangers have run ahead of our ability to discriminate among them."[372] The speed of health automation does not allow sufficient time to experience biomedical technologies and assess their challenges and influences. Health automation, quantitative measures, and norms cannot guarantee success not only because human bodies and systems are volatile with a chronic autoimmune disease, but also because there is no guarantee that no complications or health problems will develop even with biomedical technology use or once a patient achieves "optimal control". Automation aims to reduce the burdens of disease and reduce human effort and human error. However, how can automation mitigate the risk of human error or human inadequacy if the human is an essential component of the automated system?

[371] Rickert, James. 2012. Patient-Centered Care: What It Means And How To Get There. https://www.healthaffairs.org/do/10.1377/forefront.20120124.016506.
[372] Douglas, Mary, and Aaron B Wildavsky. 1982. Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers. Berkeley: University of California Press.

Risk itself is a movable boundary.[373] It is not objectively identifiable, it cannot be objectively measured in a neutral and justifiable way.[374] The capacity of governmentality as a strategy is restricted to the viewpoints, interests, and positions of regulatory experts in its ability to have a lasting positive impact on individual patients and patient populations due to clashing interests, priorities, and motivations. However, in an effort to ensure a safer and less-risky future via quantification, and due to the demands of clinical care, regulatory experts are losing the sense of the patient as an individual with situated needs and priorities. Based on Beck's writing "those who endanger the public well-being and those charged to protect it may well be identical."[375] How can regulatory experts ensure a desired less-risky future for patients if patients are so much more than their disease or what biomedical technologies were designed to offer?

Regulatory experts recommend patients avoid stress, yet this often overlooks the burdens of biomedical technologies and how they can be stress and anxiety-inducing. Regulatory experts recommend patients sleep well, yet the constant data flow and alarms from biomedical technologies, while beneficial, might cause sleepless or restless nights. Patients are expected to control every aspect affecting T1D, but it is impossible as certain parameters are not under one's control. Biomedical technologies for T1D management promise to relieve the burdens of disease and improve users' quality of life, but the burdens brought on by these technologies are rarely discussed by regulatory experts. An individual's quality of life cannot be simply measured with numerical data outputs,

[373] Ibid.
[374] Ibid.
[375] Beck, Ulrich. 1999. Risk Society Revisited: Theory, Politics, Critiques and Research Programmes. In World Risk Society. Cambridge et al.: Polity Press/Blackwell, 133-152.

reports, graphs, or satisfaction with the availability of biomedical devices as it cannot be reduced to what technologies and data can offer.

The perception of risk and risk reduction efforts by regulatory experts influence technological change. It emphasizes the need for more quantification, more data accuracy, and more automation. The drive for health automation, as viewed through the regulatory expert risk discourses, recognizes some entanglements associated with the human body, biomedical technologies in use, and the outside entanglements that influence and impact the assemblage of body and technology, but the default view on health automaton is via technological solutionism and quantification of care perspective. This perspective is important to understand as it shapes regulatory expert risk thinking, influences doctor-patient interactions, and sets up the analysis of the biotechnological organism that follows in chapter five.

It is important to recognize that regulated biomedical technologies as well as the quantitative methods of T1D care are helpful and beneficial for many individuals with T1D. Regulatory experts and their risk discourses play an important role in contemporary medical care, especially in an effort to set up safety standards to safeguard patients from harm, ensure quality standards, and help with patient support and accountability. However, since "experts perceive risk differently from other members of the public,"[376] there is a need to incorporate the views of those outside of the regulatory expert community. Biomedical technology cannot be truly understood through a single perspective or a single vintage point, therefore, the following chapter addresses risk discourse analysis of the lay community of patients, caregivers, and advocates, united under the #WeAreNotWaiting movement.

[376] Jasanoff, Sheila. 1993. Bridging the Two Cultures of Risk Analysis Actions. Risk Analysis 12: 123-129.

Chapter 4. Biological Community and Risk

> "…most patients and their families want not only to acquire information regarding their diseases and treatment options but also to be understood by those caring for them, to have their social circumstances recognized, their cultural values respected, their fears and anxieties, aspirations and dreams acknowledged."
>
> *Chris Feudtner, MD, Ph.D., MPH*[377]

Introduction

The American Diabetes Association (ADA), analyzed in the previous chapter, was established by medical professionals and researchers professionally interested in diabetes. The ADA "took as its primary concern a paternalistic responsibility toward the diabetic patient" where discipline and "right living" were central to disease management.[378] The discovery of insulin, thought to be a miracle cure for diabetes, was feared by some to have a negative effect on the professional identity of diabetologists. Yet, it turned out that insulin, insulin syringes, and all the subsequently introduced biomedical technologies increased the "moral architecture" of diabetes care bound to life-long full-time discipline and compliance.[379] Regulatory experts still report significant concerns with "suboptimal adherence" or compliance among individuals with type 1 diabetes (T1D)[380] indicating the need for more discipline, monitoring, reinforcement, and behavioral interventions.

---

[377] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. P.167. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[378] Greene, Jeremy. 2008. Prescribing by Numbers: Drugs and the Definition of Disease. Johns Hopkins.
[379] Ibid.
[380] Delamater, M. Alan. 2006. Improving Patient Adherence. Clin Diabetes 1 April 2006; 24 (2): 71–77. https://doi.org/10.2337/diaclin.24.2.71.

The issue of patient non-compliance arises when two or more individuals are working towards different goals. Experts, who include medical and health professionals, as well as patients generally desire similar outcomes, namely positive health outcomes and good quality of life for patients. Yet, regulatory experts aim to achieve medical goals, via medical means guided by the medical model of disease, by norms, standards, and measures, as established in the previous chapter. Patients, by contrast, are guided by other goals and priorities that include but are not limited to physical and mental health concerns, family demands, education, employment, safety, comfort, personal worries, and individual barriers. Since patients are responsible for over 95% of their diabetes care,[381] patients' goals and priorities should be at the center of the interactions about disease management as their health outcomes depend on it.

Patients are more than passive recipients of medical expertise as evident in T1D self-management. Therefore, regulatory expert-directed, compliance-oriented care is not an effective approach for all as it discounts patients' experience with disease management and patient-generated knowledge about their needs, priorities, and challenges. This is also evident from a growing and thriving community of Do-It-Yourself (DIY) diabetes innovators who continue to challenge the status quo in health automation. Patients and their caregivers felt disappointed with the regulated biomedical technologies available to them desiring more choice, customization, open connectivity, and open standards without

---

Gandhi, K., Vu, B. K., Eshtehardi, S. S., Wasserman, R. M., & Hilliard, M. E. 2015. Adherence in adolescents with Type 1 diabetes: strategies and considerations for assessment in research and practice. Diabetes management (London, England), 5(6), 485–498. https://doi.org/10.2217/dmt.15.41.
Datye, K.A., Moore, D.J., Russell, W.E. et al. 2015. A Review of Adolescent Adherence in Type 1 Diabetes and the Untapped Potential of Diabetes Providers to Improve Outcomes. Curr Diab Rep 15, 51 (2015). https://doi.org/10.1007/s11892-015-0621-6.

[381] Funnell MM, Anderson RM. 2000. The Problem With Compliance in Diabetes. JAMA. 284(13):1709. doi:10.1001/jama.284.13.1709-JMS1004-6-1.

the assumption that all patients are the same and have the same needs.[382] This disappointment, guided by patients' individual needs, led to the emergence and growth of the DIY biological community. The DIY community is disrupting the traditional ways of healthcare provision, conventional approaches to research, and ways of commodification within the pharmaceutical industry.

This chapter focuses on this distinct, patient-driven biological community with the primary aim to gain a better understanding of DIY automated biomedical technologies and their entangled complexity aimed at risk reduction. It proceeds with an examination of risk discourses pertaining to DIY biomedical technologies from the perspective of the T1D biological community united under the #WeAreNotWaiting movement. This is a community of patients, caregivers, and advocates who work together to make open-source and DIY solutions for individuals with T1D without waiting for commercial entities to decide to innovate. The primary focus here is on the Artificial Pancreas Systems (APS) and its technological subcomponents: continuous glucose monitor (CGM), insulin pump, and the APS computational component, as well as on the monitoring software solutions used for tracking blood glucose (BG) data. This chapter scrutinizes how DIY APS is viewed through the lens of risk within the context of technological complexity that stems from design, use, maintenance, and knowledge production with an effort to answer the following questions. How does the perception of risk within the community drive innovation? How are the tensions and risks perceived by the DIY community reflected in the DIY APS? How does the DIY T1D technology

[382] Rodriguez Fernandez, Clara. 2019. How the DIY Diabetes Community Made the Artificial Pancreas Possible. Labiotech.eu. https://www.labiotech.eu/in-depth/diy-diabetes-community-artificial-pancreas/.

produce and reinforce knowledge? Lastly, how does the examination of DIY community risk discourses help us better understand the contemporary drive for health automation?

This chapter demonstrates the community of DIY innovators is experience driven, based on individual's particular needs. In contrast to the regulatory community that views technology users as the problem, the DIY community views unmet patient needs as the primary problem that needs to be address through automation. These needs extend beyond the biological needs and include technological, financial, and social needs. This is a patient-driven ecosystem of innovation which supports open access to data, interoperability of different biomedical technologies, flexibility of use, increased speed of automation and increased level of customization to address a greater number of needs among a greater number of individuals. "Your diabetes may vary" is a phrase often used within the DIY community. This pushback against standardization and homogenization, is used to emphasize the diversity of experiences, bodies, needs, preferences among those with T1D and a variety of approaches to T1D management. This group provides a different but equally important perspective than that offered by the regulatory experts. One shaped by affective dimensions that reflect the phenomenological experiences of the users of these biomedical technologies.

As the analysis reveals, the community of DIY innovators views biomedical technologies as one of the tools of care, not an absolute solution. For them, the APS system is a useful and flawed tool. Such views highlight user agency and individual superiority over technology. This community supports the bottom-up approach to care as well as the open access to diabetes education and resources for all. It empowers patients to be proactive in self-care, to gain expertise and to stop waiting for others to address

their personal needs. Individuals within this community are ultimately making decisions regarding where to start with DIY biomedical technologies and judgments about what approach to care works best for them. This community stands in tension with the community of regulatory experts especially in terms of normalization and standardization of T1D care since it is difficult to standardize something so varied as differing insulin requirements and insulin sensitivity among different individuals with T1D. The DIY community brings to the forefront human realities of living with a chronic disease with the urgency, drive, and attention it deserves.

Significant disagreement exists regarding what is considered risky, how risky it is, and what should be done about it.[383] Feudtner writes, as quoted above, that patients and their caregivers care not only about the information pertaining to disease but also about being understood, respected, and acknowledged. Since patients' concerns go beyond medical care, their risk considerations likely do so as well. Patients live with T1D through a variety of life circumstances and events such as puberty, transition to adulthood, employment, parenting, love, and loss to name just a few. Regulatory experts are guided by regulations, standards of care, norms, and scientific evidence. The vantage points differ between patients and regulatory experts as do their priorities and needs. When we add complex biomedical technologies into this consideration, the possible disconnect between the care provided and the care desired grows larger. In the case of T1D, this would indicate the increased demands of disease management, now heavily dependent on biomedical technologies, increase the need for support, understanding, recognition, respect, and acknowledgment. The higher complexity of care with growing

[383] Douglas, Mary, and Aaron B Wildavsky. 1982. Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers. Berkeley: University of California Press.

demands places greater pressure on individual patients' time, resources, and physical and mental capacity with increased responsibility for biomedical technology use, maintenance, procurement, and disposal.

In the cultural studies of risk "[t]he ways in which individuals – including experts – interpret risks can instead be seen as an expression of socially located beliefs and world views that to a large extent stem from the individual's situated position and experiences within social hierarchies, institutions, and groups."[384] This work argues that a cultural approach to risk might not be sufficient for recognizing the diversity of experiences, situations, and practices influencing risk perceptions where the dynamic of risk construction might be changing fast along with the rapid rate of health automation. The social constructionist position might be more suitable for addressing the risk that is not static but is "constantly negotiated as part of the network of social interaction and the formation of meaning."[385] Therefore, the perception of risk within the DIY biological community is the product of social, cultural, historical, financial, political, and other influences and understandings.

Improved understanding of patient motivations and risk perceptions, via the examination of the DIY biological community, can bring to the forefront the intricate and nuanced nature of living with a chronic disease heavily reliant on and inextricable from biomedical technology used. As addressed in the previous chapter, the regulatory expert community is recognizing and acknowledging the use of DIY technologies by many patients. It might be an achievement on its own for the DIY community to have FDA and medical professionals speak openly about it, even to just warn the population of the risks

[384] Summerton, Jane, and Boel Berner. 2003. Constructing Risk and Safety in Technological Practice. Routledge Advances in Sociology, 4. London: Routledge.
[385] Lupton, Deborah. 1999. Risk. New York: Routledge.

associated with unauthorized technology use.[386] The DIY T1D technologies are also recognized in training materials of the American Diabetes Association (ADA) and the Standards of Diabetes Care with warnings and expressed concerns.[387] Despite the warnings and concerns, the community of citizen scientists developing DIY biomedical technologies continues to innovate, educate, and openly share data. As this chapter demonstrates the continued drive for DIY innovation does not originate from ignorance of regulatory expert views, but from the way in which risk perceptions are constructed and acted upon by those directly affected by chronic disease. If risk perceptions lead to certain actions,[388] then it is the risks of unmet healthcare needs, in the broad sense, and technological shortfalls that lead to DIY innovation.

This chapter argues that the DIY biological community's unique perspective of the complexity of risk is the driving force behind the #WeAreNotWaiting movement. Patients and their caregivers live with the disease and are affected by it in profound and intimate ways. They have a firsthand perspective on how disease, different lived experiences, and biomedical technologies affect their bodies, their well-being, their mental health, and their disease burdens. The successes of DIY APS[389] demonstrate that patients are not ambivalent about the importance of biomedical technologies, quantitative views of risks, data, metrics, and measures of T1D success. Additionally, it shows that patients are capable and carry a large volume of expertise for their individualized care, technological use, and maintenance. This comes in stark opposition to the way the

[386] U.S. Food and Drug Administration. FDA warns people with diabetes and health care providers against the use of devices for diabetes management not authorized for sale in the United States: FDA safety communication. Available from www.fda.gov/medical-devices/safety-communications/fda-warns-people-diabetes-and-health-care-providers-against-use-devices-diabetes-management-not. Accessed 01/09/22.
[387] American Diabetes Association. 2022. Introduction: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S1–S2. https://doi.org/10.2337/dc22-Sint.
[388] Lupton, Deborah. 1999. Risk. New York: Routledge.
[389] OpenAPS. 2022. OpenAPS Outcomes. Accessed 10.25.22. https://openaps.org/outcomes/.

regulatory expert community portrays patients as incapable and illiterate, as discussed in the previous chapter.

Biological citizenship is a form of belonging recognized by the state on the basis of an individual's physiological difficulties arising from an "abnormal" biological condition.[390] A condition that deviates from the conventional normal and/or healthy biological state. This work defines biological citizenship not only by the diagnosis of T1D but also by biomedical technology use. When looking at the biological community studied here it is important to acknowledge that the definition of a biological community is constrained and expanded at the same time in relation to the definition of biological citizenship. It is constrained because of the understanding that not every individual with T1D engages with DIY technologies. Thus, simply having the diagnosis of T1D does not make one a part of the DIY community. It is expanded, because some individuals within the community might not have the T1D diagnosis themselves but might be caregivers and advocates personally touched by T1D. The belonging, in this case, means not only the fact of use, contribution to, or support of DIY T1D technologies, but also means the will to reclaim autonomy, power, and control over one's life, one's therapies, data, and devices.

The term biological citizenship as defined by Petryna portrays an individual's health as a political project, reflective of political and scientific failures to address and account for human welfare, vulnerabilities, and practices of survival.[391] Biological DIY community, or simply the community, is a complex term reflective of bureaucracy,

[390] Benton, Adia. 2015. HIV Exceptionalism: Development through Disease in Sierra Leone. Minneapolis: University of Minnesota Press.
[391] Petryna, Adriana. 2013. Life exposed: biological citizens after Chernobyl. Princeton, NJ: Princeton University Press.

policy shortcomings, healthcare failures, commodification letdowns, and "compounding vulnerability for citizens whose practices of survival" do not fit neatly in the efforts to conceptualize them.[392] The community members are changing what is possible while creating new opportunities as technology users and biological citizens. The membership within the community is not static, it might fluctuate along the lines of commercial and DIY biomedical innovations as well as along the changing perceptions of risk since the risk is a movable boundary.[393] The inclusion of one into the DIY community might also be defined by knowledge production practices, such as the creation, sharing, education, and raising awareness of DIY technologies, as well as associated with the rebellious and unconventional approaches to biomedical technologies.

Jeremy Greene, MD, Ph.D., historian of medicine wrote: "The locus of disease definition has shifted away from the intimate space of doctor and patient to be deliberated within wider and more abstract arenas of policy, guidelines, and markets, simultaneously distanced from the level of human experience by the very small (molecular diagnosis) and the very large (massive long-term population studies)."[394] The definition of disease distanced from human experiences means that human experiences do not influence the onset of disease or one's health outcomes. That is simply not true as personal experiences, social circumstances, and community issues influence how people experience health, illness, healthcare, and risk as well as how they perceive self and others.[395] This indicates the need to not only understand how the perception of risk and

[392] Ibid.
[393] Douglas, Mary, and Aaron B Wildavsky. 1982. Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers. Berkeley: University of California Press.
[394] Greene, Jeremy. 2008. Prescribing by Numbers: Drugs and the Definition of Disease. Johns Hopkins.
[395] Wolf JA, Niederhauser V, Marshburn D, LaVela SL. 2021. Reexamining "Defining Patient Experience": The human experience in healthcare. Patient Experience Journal. Vol. 8(1):16-29. doi: 10.35680/2372-0247.1594.

risk categories have changed from the perspective of those in the position of authority but also to understand how the human experience defines risk. One such way is to examine the DIY biological community as represented by lay scientists, patient innovators, and DIY technology proponents. From the constructionist perspective, knowledge about risk is generated within the sociocultural context where regulatory expert and lay knowledges are in a relationship, making risk a product of continuously constructed and negotiated social interactions.[396]

The previous chapter looked at how risk is constructed within the regulatory expert community via norms, standards, regulations, measures, and metrics with the help of biomedical technologies often used as additional levers of control over the health of individual patients or patient populations for their own benefit. This chapter looks at the construction of risk within the DIY biomedical community, and how the perception of risk is part of an individual's lived experiences, perspectives, phenomenological needs, and social interactions. The idea of studying the two communities is not to compare or contrast the accuracy of the two perspectives on risk, on T1D, or on biomedical technologies, but to understand the efforts of health automation, the ways in which knowledge is constructed, how risk discourses influence biomedical innovation and how perceptions of risk acquire authority.

This chapter consists of five primary sections. The first section addresses the primary DIY biomedical technologies and the emergence of the #WeAreNotWaiting movement. It examines the disruptive nature of the movement and how it fits within the contemporary provision of care. Here it aims to understand the primary motivations for joining and contributing to the community. The second section highlights a number of

[396] Lupton, Deborah. 1999. Risk. New York: Routledge.

select primary innovators within the community to understand their motivations, expertise, and views on DIY and FDA-approved technologies. This section addresses the community's risk discourses starting with some of the main contributors to the #WeAreNotWaiting movement. The third section explores the concepts of trust and intimacy with biomedical technology use. Further, this section analyses the commercial APS as the black box technology contrasted with the DIY APS to better understand the drive for innovation. The fourth section focuses on pedagogy within the biological DIY community to demonstrate how risk discourses influence patient engagement and barriers to effective T1D care. The final section summarizes the chapter and explains how the wide range of risks experienced by patients and caregivers influences DIY innovations and knowledge-production practices.

This chapter relies on publicly available resources pertaining to DIY technologies. This includes DIY APS documentation, training, and setup guidance openly provided to all individuals within the community and those outside of it. These documents provide details about biomedical technology, DIY APS components, monitoring solutions, and risks associated with technological design, use, maintenance, and disposal. These documents, web resources, and presentations are used as a comparable representation of training efforts within the DIY community equivalent to the regulatory expert community's training on "Making Diabetes Technology Work."[397] These resources were created by DIY technology users for DIY technology users and do not call for specialized technical knowledge to comprehend them. They are available at no cost and without the need to register or provide one's affiliation. In order to understand the desired standards

[397] ADA. 2021. Professional Education: Making Diabetes Technology Work. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.

of care within the DIY community, this work reviewed publicly available video presentations and articles by Dana Lewis and Ben West, two prominent contributors to the DIY APS. All resources were also analyzed for risk discourses with a particular focus on biological, technological, and financial risks originating from the DIY community perspective.

DIY Biomedical Technologies: What #WeAreNotWaiting for?

The fragility of human bodies is put into sharp relief with a diagnosis such as T1D. Those that live with a chronic autoimmune disease are constantly reminded of how vulnerable they are due to significant risks of adverse health outcomes, and chronic reliance on pharmaceuticals and biomedical technologies, which in and of themselves contain risks and vulnerabilities. Reminders of vulnerabilities are prominent in labeling individuals with T1D as an "at-risk population" in public health campaigns, promotions of pharmaceuticals and biomedical technologies as well in public regulatory expert discourses as highlighted in the previous chapter. Many challenges of T1D are represented in modern culture, however, these representations are not always accurate.[398] For example, patients are often viewed as overindulgent in consuming sugary drinks and high-calorie meals, thus seen as guilty and responsible for their health condition or adverse health outcomes. Even insulin, a stability-promoting miracle drug required for "glycemic control," can bring about hypoglycemia (low BG) and cause harm since "hypoglycemia is something that transpires because of control not in spite of it."[399] Thus,

[398] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. Accessed May 13, 2021. http://www.jstor.org/stable/j.ctv12fw5z8.
[399] Mol, Annemarie, and John Law. 2004. "Embodied Action, Enacted Bodies: The Example of Hypoglycaemia." Body & Society 10 (2-3): 43–62.

insulin, created to prevent death and harm from T1D, can itself cause death and harm. A chronic disease might involve chronic pain, persistent discomfort, and constant awareness of risks to one's health and well-being. It might be consuming of time, energy, and effort on the part of the patient since patients are responsible for over 95% of their diabetes care.[400]

The challenges associated with T1D management lead patients to feel disillusioned with the promise that one day soon their issues will be resolved because of revolutionary biomedical technologies.[401] Scott Hanselman, a person with T1D, a programmer, and a teacher said "it cannot be overstated that your experience and my experience, and I think 99% of type 1 diabetics' experiences, are absolutely the same in that we were told this [T1D] will be cured in 5 years and I've been told every year for 30 years "5 more years."[402] For those living with a chronic disease, every day might be a challenge, so waiting for regulatory medical experts and corporations to solve one's pressing issues and offer such technologies did not seem adequate. Regulatory experts and corporate actors have to abide by regulations, established policies, and laws, but the fact that these do not include DIY devices results in an "almost complete lack of ethical or regulatory guidance for clinicians who provide care to patients using DIY systems".[403] Patients do not have the same responsibilities and concerns. Within the contemporary U.S. healthcare system patients are perceived as empowered to choose how to care for

[400] Funnell MM, Anderson RM. 2000. The Problem With Compliance in Diabetes. JAMA. 284(13):1709. doi:10.1001/jama.284.13.1709-JMS1004-6-1.
[401] Thomas, Johnson. 2015. Endo Apps: The DIY Artificial Pancreas. Accessed 09.27.22. https://www.medpagetoday.com/endocrinology/type1diabetes/50839.
[402] Hanselman, Jason. 2023. Ben West is not waiting for Diabetes Tech to catch up. Show #875. The HANSELMINUTES Podcast. Accessed 2.26.23. https://www.hanselminutes.com/875/ben-west-is-not-waiting-for-diabetes-tech-to-catch-up.
[403] Roberts, J. T. F., Moore, V., & Quigley, M. 2021. Prescribing unapproved medical devices? The case of DIY artificial pancreas systems. Medical law international, 21(1), 42–68. https://doi.org/10.1177/0968533221997510.

their bodies and what biomedical technologies to use within a framework of health politics outlining what can be prescribed and who carries the responsibility for it.[404]

DIY biomedical technologies exist outside of the regulatory framework. They coexist along with FDA-approved technologies as an option and a choice for patients to use, without obligations, constraints, or coercion. With regulated biomedical technologies the "provider is the gate-keeper to the ability to obtain the management tools."[405] This is not the case for DIY biomedical technologies. Additionally, the DIY community does not have institutionally or geographically established borders. It is an interventional community that exists and functions across borders in the digital plane defined by social media interactions, peer support, and user needs. Therefore, DIY biomedical technologies are influencing user experiences across the globe and are creating a global network of innovators as well as DIY technology users all united under the #WeAreNotWaiting movement.

The #WeAreNotWaiting movement was born in November 2013[406] at the DiabetesMine D-Data ExChange.[407] During the event Howard Look, co-host and CEO of Tidepool, a 501(c)(3) nonprofit organization working "to make diabetes data more accessible, actionable, and meaningful for people with diabetes,"[408] as well as a father to a child with T1D led a group discussion attempting to summarize "the sentiments of the

[404] Mol, Annemarie. 2008. The Logic of Care: Health and the Problem of Patient Choice. Myilibrary. London: Routledge.
[405] Duke, M. D., & Fredlock, A. A. 2020. Do-It-Yourself (DIY) Systems in Diabetes: A Family and Provider Perspective. Journal of diabetes science and technology, 14(5), 917–921. https://doi.org/10.1177/1932296820906204.
[406] Healthline. 2019. The #WeAreNotWaiting Diabetes DIY Movement. Accessed 09.27.22. https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting.
[407] DiabetesMine.com. 2013. The DiabetesMine D-Data ExChange - Nov 2013. Accessed 09.22.22. https://www.facebook.com/media/set/?set=a.10151790075828008.1073741829.56695563007&type=3.
[408] Tidepool. 2023. About Tidepool. Accessed 4.16.23. https://www.tidepool.org/about.

diabetes do-it-yourselfers and entrepreneurs taking charge."[409] This group discussion with patients, advocates, data experts and others led to the creation of the motto and the movement. The primary aim of the movement is to make diabetes data more accessible, intuitive, and actionable to reduce the risks of T1D and achieve improved blood glucose (BG) outcomes.[410] An example of data discrepancy between FDA-approved and DIY technology (Dexcom vs Nightscout application) is provided later in this chapter in the section titled "Intimacy with a Black Box Technology." The movement has since grown, gained mainstream recognition, and produced numerous DIY innovations for the T1D community. The most notable ones are Nightscout, OpenAPS, and Loop.

Nightscout, also called the continuous glucose monitor (CGM) in the Cloud, was developed to "allow remote monitoring of a T1D's glucose level using existing monitoring devices."[411] It is a software solution that also provides browser- and application-based visualization, storage, and sharing of data from CGM in real time for OpenAPS users and Loop users. Nightscout continues to be developed, maintained, and supported by volunteers. OpenAPS, which stands for open-source artificial pancreas system, is an effort to make a safe and effective DIY APS design used to dose basal (background) insulin via an insulin pump in response to CGM data "in order to keep BG levels inside a safe range overnight and between meals."[412] OpenAPS utilizes FDA-approved biomedical technologies (CGM, Insulin Pump), commodity hardware (Intel

[409] Healthline. 2019. The #WeAreNotWaiting Diabetes DIY Movement. Accessed 09.27.22. https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting.
[410] Ibid.
[411] The Nightscout Project. 2022. What is the Nightscout project? Accessed 10.19.22. http://www.nightscout.info.
[412] OpenAPS. 2022. What is #OpenAPS? #WeAreNotWaiting to reduce the burden of Type 1 diabetes. https://openaps.org.

Edison or Raspberry Pi), and open-source software.[413] It is estimated as of July 5, 2022, there are over 2,720 individuals globally with various types of DIY closed-loop implementations.[414] Lastly, Loop is a DIY closed-loop algorithm for iPhone users. It is used with RileyLink compatible devices, a separate small device such as OrangeLink,[415] which is a communication protocol allowing for the CGM and the insulin pump to interact. The Loop app, just like other DIY solutions, is not available for purchase and requires users to build it themselves using open-source code and detailed instructions.

None of the above efforts are profit-seeking endeavors. All three solutions are available to anyone within the community and outside of it. They are offered openly with step-by-step setup instructions with Nightscout documentation,[416] OpenAPS documentation,[417] and LoopDocs[418] with no special skills required to be able to accomplish set up. The technological complexity of these DIY solutions is explained in detail with illustrations, images, and video tutorials. Since there is no corporate customer support for these solutions, support and troubleshooting are offered within the community through the utilization of social media, forums, and peers.

The #WeAreNotWaiting movement started from frustration and disillusionment with the promises originating from regulatory experts. First, the frustration originated with concerns for "data dysfunction" and issues of "data interoperability" indicating "the lack of standards and formats for health data that are captured electronically to work

[413] OpenAPS. 2023. Principles of an Open Artificial Pancreas System (OpenAPS). OpenAPS Reference Design. https://openaps.org/reference-design/.
[414] OpenAPS. 2022. OpenAPS Outcomes. https://openaps.org/outcomes/.
[415] GetRileyLink. 2022. OrangeLink Pro. https://getrileylink.org/product/orangelink.
[416] Nightscount. 2022. Welcome to Nightscout. Accessed 10.7.22. https://nightscout.github.io.
[417] OpenAPS. 2022. Welcome to OpenAPS's documentation! Accessed 10.21.22. https://openaps.readthedocs.io/en/latest/index.html.
[418] LoopDocs. 2022. Welcome to LoopDocs. Accessed 10.21.22. https://loopkit.github.io/loopdocs/.

seamlessly within the life of a patient with a chronic condition."[419] The health data collected by regulated biomedical technologies also lacked transparency regarding its use, leaving little to no room for users to engage with the data and devices beyond proscribed functionality.[420] For instance, users have no knowledge about where their data is stored and who has access to it since they themselves "do not have full authority to access, view, download, and use data as they wish."[421]

Second, the frustration reflects the perceptions of patients as incapable, not as equal stakeholders, and the power asymmetry between patients and professionals providing care. Nora Williams, a Princeton and Harvard-educated person with T1D wrote about her medical encounters of "being treated as though I just couldn't be very smart" and "I've wished I'd brought my diplomas with me to many a first visit with a clinician."[422] Williams wondered: "Is it that few modern physicians have time to deal with the complexities of the disease and find it easier to treat us as simpletons?" [423] This frustrating reality of associating expertise with professionals such as "health care providers, IT, medical device companies, pharma, and the government" discounts the view of "patients as experts and innovators" and patients' efforts of "engaging and designing and developing and doing research and science."[424] Third, the frustration resides with the FDA which is optimized for corporations and regulators without a

[419] Munro Dan. 2014. The View Of Digital Health From An 'Engaged Patient'. Forbes Healthcare. https://www.forbes.com/sites/danmunro/2014/03/09/the-view-of-digital-health-from-an-engaged-patient/?sh=378fad282b79.
[420] Jansky, B., Langstrup, H. 2022. Device activism and material participation in healthcare: retracing forms of engagement in the #WeAreNotWaiting movement for open-source closed-loop systems in type 1 diabetes self-care. BioSocieties. https://doi.org/10.1057/s41292-022-00278-4.
[421] Ibid.
[422] Williams, Nora. 2017. Fifty Years of Living With Type 1 Diabetes. Clin Diabetes. 35 (5): 331–332. https://doi.org/10.2337/cd17-0089.
[423] Ibid.
[424] Patton, Mary Anne. 2018. Dana Lewis – patients are experts. MyArtificialPancreas.net. Accessed 01.08.23. https://myartificialpancreas.net/2018/08/23/dana-lewis-at-hic18/.

pathway for DIY biomedical technologies to be approved as authorized and legitimate.[425] Science and technology policy favors regulatory expert organizations and corporations. FDA approval of biomedical technologies requires large financial investment and is prohibitive for DIY innovators. Providing a way for DIY biomedical technologies to gain FDA approval would help promote safety and encourage others to develop and apply skills to address a variety of health issues.

Anna McCollister-Slipp, a person with T1D and advocate for health data democratization, said: "patient needs are nowhere in sight for manufacturers or policymakers."[426] While there is a general recognition of biomedical technologies reducing the risks associated with the disease, patients' drive for innovation is fueled by constant reminders of demands, implications, and risks of the disease that seem to dissolve patients' autonomy and disrupt time.[427] The decision-making demands of T1D alone can be draining for the patient, thus, biomedical technologies are seen as burden-reducing solutions. However, the demands of the disease, experience living with it as well as patients' efforts in balancing insulin intake with all their needs help patients "progressively acquire both experience and knowledge of their condition."[428]

What is the DIY community not waiting for? The following powerful list was provided by individuals involved in establishing the movement and can be summarized as follows. #WeAreNotWaiting to bridge disconnected data islands and to ease access to

[425] Rao, Ankita & Cunnane, Megan. 2016. Diabetes Hacking 101. Only Human. WNYC Studios. Accessed 01.08.23. https://www.wnycstudios.org/podcasts/onlyhuman/articles/diabetes-hacking-with-ben-west.
[426] Healthline. 2019. The #WeAreNotWaiting Diabetes DIY Movement. Accessed 9/5/22. https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting#About-the-#WeAreNotWaiting-Movement.
[427] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[428] Cordier, Jean-François. 2014. The expert patient: towards a novel definition. European Respiratory Journal. 44 (4) 853-857; DOI: 10.1183/09031936.00027414.

patient's own data, to gain the freedom of choice and to gain peace of mind, to get some decent sleep, to live safely, not waiting for the cure.[429] #WeAreNotWaiting for competitors, regulators, manufacturers, and insurance companies, "for others to decide if, when, and how we access and use data from our own bodies," to pull talent from around the world to innovate for the benefit of individuals with diabetes who have lost their patience with regulatory expert promises.[430] This movement is a grassroots initiative guided by the urgency and priorities of patients who are not willing to wait for corporate, policy, and regulatory cycles to play themselves out to satisfy patient's needs since a few years can make a difference between improved living and going blind or dying in one's sleep.[431] The risks of disease are understood, feared, and personalized. They drive DIY health automation.

The promises of automated diabetes with a fully functional bionic pancreas are capturing the imagination of patients and non-patients alike. While the DIY community is welcoming of such innovations, it is being cautiously optimistic, prioritizing access to technologies today and relying on its own skills, talent, and efforts for further T1D automation. Particularly, the community works to improve current DIY technologies and available commercial products. It recognizes flaws of all types of biomedical technologies along with the fact that T1D technologies fill an important gap in patient care. Ben West, a person with T1D and DIY innovator said, "it was really obvious to me that there's this mismatch in terms of the things that were possible and the things that

[429]Healthline. 2019. The #WeAreNotWaiting Diabetes DIY Movement. Accessed 09.27.22. https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting.
[430] Ibid.
[431] Munro, Dan. 2014. The View Of Digital Health From An 'Engaged Patient'. Forbes Healthcare. https://www.forbes.com/sites/danmunro/2014/03/09/the-view-of-digital-health-from-an-engaged-patient/?sh=378fad282b79.

people expected and yet the things that people were actually doing in practice especially when it came to the application of technology to diabetes."[432] The DIY movement is disrupting the power dynamic claiming expertise in T1D management, patient-driven health care, and technological innovation. The community is challenging the medical model of disease which highlights the reliance on standardly accepted procedures, such as medical examinations and tests, as well as on the prescribed use of approved biomedical technologies in favor of patient empowerment, individual abilities and strengths, and the holistic view of patients and their needs.[433]

The community is claiming expertise not only over the health condition but also over the biomedical technologies used in its management. "Many DIY APS users maintain that diabetes is inherently a DIY condition even with the various technologies that are available."[434] Renza Scibilia, a person with T1D wrote: "ALL diabetes is DIY. It is 24/7 and we do it ourselves for day to day. Call it what you want – DIY or off-label diabetes – it's just diabetes. And we have no choice other than doing it ourselves."[435] Current DIY technology users can be represented as a cohort of 'experts' in T1D.[436] Since no one is born an expert and expertise is acquired via practice, experience, learning with effort, perceptiveness, and communication, any patient has the potential to acquire

[432] Hanselman, Jason. 2023. Ben West is not waiting for Diabetes Tech to catch up. Show #875. The HANSELMINUTES Podcast. Accessed 2.26.23. https://www.hanselminutes.com/875/ben-west-is-not-waiting-for-diabetes-tech-to-catch-up.
[433] Swaine, Z. (2011). Medical Model. In: Kreutzer, J.S., DeLuca, J., Caplan, B. (eds) Encyclopedia of Clinical Neuropsychology. Springer, New York, NY. https://doi.org/10.1007/978-0-387-79948-3_2131.
[434] Shepard, J. A., Breton, M., Nimri, R., Roberts, J. T. F., Street, T., Klonoff, D., & Barnard-Kelly, K. 2022. User and Healthcare Professional Perspectives on Do-It-Yourself Artificial Pancreas Systems: A Need for Guidelines. Journal of diabetes science and technology, 16(1), 224–227. https://doi.org/10.1177/1932296820957728.
[435] Scibilia, Renza. 2019. The spectrum of DIY diabetes. Diabetogenic. Accessed 1.10.23. https://diabetogenic.blog/2019/05/21/the-spectrum-of-diy-diabetes/.
[436] Crabtree, Thomas; McLay, Alasdair; Wilmot, Emma. 2019. DIY artificial pancreas systems: here to stay? Practical Diabetes. https://doi.org/10.1002/pdi.2216.

expertise.[437] The redefinition of the terms "expert" and "expertise" can be perceived as medical disobedience as well as the "process of discovery and trust in one's own knowledge that has the potential to cultivate an alternative identity that could be productively used for other types of social change on a large scale."[438] This has a profound impact on how we view risk and health automation by shifting the lens from medical-industrial complex and regulatory experts to biotechnological organisms and experts with phenomenological experience.

The DIY community united under the #WeAreNotWaiting is a thriving "patient-driven ecosystem,"[439] a community of citizen scientists. This community demonstrates that patients and biomedical technology users are not just passive recipients, they are active participants in diabetes management and technological innovation, working to provide an open-source solution for patients created by patients.[440] Behind the community's drive to innovate and encourage access to innovations for more people is hidden the reality of suffering, individual fears, risks, and the inevitability of disease-causing harm. These realities are not prominent within the regulatory expert community but are important within the DIY community.

Biomedical technologies in use stand in stark contrast to the novel and innovative technologies that dominate the public view. The public view is exemplified by images

[437] Cordier, Jean-François. 2014. The expert patient: towards a novel definition. European Respiratory Journal. 44 (4) 853-857; DOI: 10.1183/09031936.00027414.
[438] Forlano, Laura. 2016. Hacking the Feminist Disabled Body. Journal of Peer Production. Issue 8. Feminism and (un)hacking. http://peerproduction.net/issues/issue-8-feminism-and-unhacking-2/peer-reviewed-papers/issue-8-feminism-and-unhackingpeer-reviewed-papers-2hacking-the-feminist-disabled-body/.
[439] Klemen Dovc, Tadej Battelino. 2020. Evolution of Diabetes Technology, Endocrinology and Metabolism Clinics of North America, Vol. 49, Issue 1, pp 1-18. https://doi.org/10.1016/j.ecl.2019.10.009.
[440] Healthline. 2019. The #WeAreNotWaiting Diabetes DIY Movement. Accessed 9/5/22. https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting#About-the-#WeAreNotWaiting-Movement.

4.1. and 4.2. of Dexcom advertisements[441] promising the elimination of fingersticks with Dexcom G6 CGM and the management of diabetes with zero fingersticks to draw blood for testing. Despite being promoted as a solution to BG monitoring, the CGM operates on a continuous basis that adds steps to BG monitoring rather than taking them away. This is evident by the need for BGM access to draw blood for testing even with CGM use. Most individuals rarely read the small script contradicting claims in the advertisement itself: "Fingersticks required for diabetes treatment decisions if symptoms or expectations do not match readings." Dexcom Inc, promises that fingersticks are a thing of the past,[442] yet it specifies multiple instances when fingersticks are required to measure blood glucose with an alternative method.[443] The DIY community has no monetary or other incentives to misrepresent technological demands and burdens.

[441] Dexcom. 2019. Manage Diabetes with Zero Fingersticks. YouTube. Accessed 1.17.23. https://www.youtube.com/watch?v=DbOToLqYLvU.
[442] Dexcom. 2018. Dexcom CGM — For People with Diabetes, Finally, Dexcom Makes Fingersticks a Thing of the Past. https://www.youtube.com/watch?v=A1NU5ivC5Og.
[443] Dexcom. 2022. Is my Dexcom sensor accurate? https://www.dexcom.com/faqs/is-my-dexcom-sensor-accurate.
Dexcom. 2022. What can I do if my Dexcom G6 sensor fails during the 2-hour warmup period? https://www.dexcom.com/faqs/what-to-do-if-dexcom-g6-sensor-fails-during-warmup.

Figure 8. Dexcom Inc. advertisement for Dexcom G6 CGM "Manage Diabetes with Zero Fingersticks."

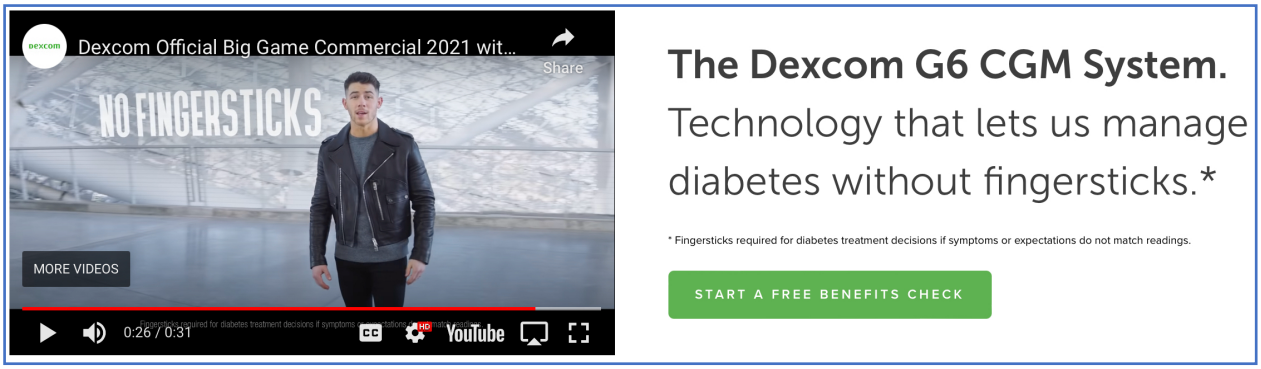


Figure 9. Dexcom Inc. commercial for Dexcom G6 CGM at the Big Game 2021.[444]

[444] Dexcom Inc. 2023. The Dexcom G6 CGM System. Accessed 1.17.23. https://www.dexcom.com/get-started-cgm/119?sfc=701f30000018vibAAA&gclsrc=aw.ds&gclid=EAIaIQobChMI3M2g6L_P_AIVn4JaBR07ewLtEAAYASAAEgK-pPD_BwE.

Most importantly, DIY community members recognize themselves as users of biomedical technologies, ultimately responsible for technological procurement, maintenance, and disposal. They recognize that coders and manufacturers of commercial biomedical technologies might have little experience with the challenges and complexities of T1D management. Therefore, they support the idea of innovation based on existing technologies, lived experiences, and patients' unique needs. Ben West said, "as patients, because these devices are connected to us, and because our only other alternative is to suffer some of the symptoms of the disease … the options are to do something or do nothing, and a lot of us are choosing to do something as much as we possibly can."[445] The release and testing of biomedical technologies in real-time might be the best approach to speed up innovation without the burden of regulation. The aim of the #WeAreNotWaiting movement is not to cause disruptions or rebel, but to raise awareness, provide equitable and humane solutions, to innovate without barriers. Rather, the disruptions caused by the movement are a byproduct of its efforts.[446]

DIY Innovators and Risk

Life with T1D forces patients to become tinkerers, experimenters, and scientists. For example, David Burren with a team of individuals with T1D is modifying biomedical technologies like the Dexcom G6 CGM transmitter to include the following: user-replaceable battery (not offered by Dexcom, Inc.), 180-day transmitter useful life (compared to Dexcom, Inc.-supported 100/110 days) and no sensor restart detection

[445] Nighscout Foundation. 2016. KCGM-TV OpenAPS & the FDA with Ben West, Ep2. https://www.youtube.com/watch?v=c98TwesRkeQ.
[446] Simms, Stacey. 2021. Ben West: Using Diabetes Tech to Relieve the "Onus to Bolus". Diabetes Connections with Stacey Simms. Podcast. Accessed 2.26.23. https://diabetes-connections.com/ben-west-using-diabetes-tech-to-relieve-the-onus-to-bolus/.

(preset time limit for sensor use) which allows to expend sensor life past the Dexcom, Inc.-supported 10 days.[447] Additionally, patients test out and learn of their body's reaction to foods and exercise, they evaluate what works and what doesn't with their particular needs. Biomedical technologies have become just another aspect of T1D care that patients can experiment with. These experiments might include better site selection, prevention of adverse skin reactions from technological object use, and adjusting device settings independently without expert advice, just to name a few. Diabetes care requires decision-making, arithmetic, and significant effort with daily disruptions that add up and take away focus from life, school, and work.[448] Biomedical technologies like the APS, both FDA-approved and open-source one, might help recapture and reclaim some of the lost time of manual T1D management and disrupted sleep hours, improving sleep, daily, and focus, reducing distractions and constant worry due to automation. Andrew Calabrese, a father whose son has T1D, said: "Diabetes is dangerous anyway. Insulin is dangerous. I think what we are doing [constructing and using OpenAPS] is actually improving that and lowering the risk."[449] Many individuals might not even recognize their personal creative contributions to their own care along the lines of their own concerns and priorities.

The strength, perseverance, and great personal characteristics of patients are exemplified by how President Barack Obama described Supreme Court Justice Sonia Sotomayor's management of T1D as prudent, self-disciplined, courageous, and

[447] Burren, David. 2021. Anubis – the G6 reborn! Project Anubis. Bionic Wookiee. https://bionicwookiee.com/2021/04/02/anubis-the-g6-reborn/.
[448] Lewis, Dana. 2018. Open Artificial Pancreas System. TEDxFHKufstein. https://www.youtube.com/watch?v=kgu-AYSnyZ8.
[449] Linebaugh, Kate. 2016. Tech-Savvy Families Use Home-Built Diabetes Device. WSJ. Accessed 1.12.23. https://www.wsj.com/articles/tech-savvy-families-use-home-built-diabetes-device-1462728637.

triumphant over hardship.[450] In this instance, the qualities of an individual with T1D are celebrated and add credibility to professional aspirations. When looking at DIY innovations these personal qualities are overlooked since the DIY community stands on the outside of established regulations and accepted norms. The FDA's strong recommendation not to share or distribute DIY APS code, which equated to distributing unauthorized medical devices, placed additional risk consideration on DIY innovators.[451] These additional risk considerations include potential litigation, fines, or imprisonment for sharing unauthorized medical devices.[452] The FDA describes an FDA-approved APS as an innovative device, an "automated insulin delivery" system with safety standards.[453] It views the DIY APS as inherently unsafe and risky. The DIY community, on the other hand, is claiming the DIY APS design is safety-focused with safety as the priority.[454] In fact, the DIY APS, with the knowledge that technology is prone to failure, was designed to fail safely.[455] This means that safety principles are built into the OpenAPS Reference Design[456] accounting for limitations of hardware and software components to account for "missing or faulty CGM data and loss of communication with the pump."[457] This is exemplified with an excerpt from the OpenAPS Reference Design below:

---

[450] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. http://www.jstor.org/stable/j.ctv12fw5z8.
[451] Lewis, Dana. 2019. Automated Insulin Delivery: How artificial pancreas "closed loop" systems can aid you in living with diabetes.
[452] FDA. 2022. Types of FDA Enforcement Actions. Accessed 2.26.23. https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions.
[453] FDA. 2018. The Artificial Pancreas Device System: FDA's Efforts to Advance Artificial Pancreas Device Systems. https://www.fda.gov/medical-devices/consumer-products/artificial-pancreas-device-system
[454] OpenAPS. 2022. OpenAPS Is Designed For Safety. Accessed 10.21.22. https://openaps.org.
[455] Lewis, Dana. 2019. Automated Insulin Delivery: How artificial pancreas "closed loop" systems can aid you in living with diabetes.
[456] OpenAPS. 2021. Principles of an Open Artificial Pancreas System (OpenAPS). Accessed 01.08.23. https://openaps.org/reference-design/.
[457] Lewis D. 2019. History and Perspective on DIY Closed Looping. Journal of diabetes science and technology, 13(4), 790–793. https://doi.org/10.1177/1932296818808307.

"OpenAPS is designed to simply and safely fall back to the patient's pre-programmed basal therapy whenever it receives conflicting information about what the appropriate course of action is (or when required information is missing). For example, if BG is predicted to eventually go low but is actually rising at that moment, OpenAPS can cancel any temporary basals and wait to see whether BG continues rising or begins to fall, and only then begin issuing the appropriate temporary basal commands. Additionally, OpenAPS further ensures safety by falling back to traditional "low glucose suspend" behavior when current BG is below a configured threshold and falling or not rising fast enough. This ensures that insulin infusion is completely withheld while BG remains low for any reason, until it starts to recover, which maximizes the ability to recover from hypoglycemia."[458]

Risk can be viewed as a collective construct with "all the asymmetries that stem from actor's differential access to power and authority."[459] However, this view might disregard the significance of individual agency in defining risk, especially in chronic disease management. The collective, community, or organization exercises influence over the individual, but it is that individual's risk determination that guides their decision-making. On one side, DIY community members might be seen as individuals reclaiming power and authority over their T1D care and therapeutic decision-making. They are gaining expertise and investing personal time to innovate, promote, support, and/or use DIY biomedical technologies. On the other side, community members are likely to give

[458] OpenAPS. 2023. Principles of an Open Artificial Pancreas System (OpenAPS). OpenAPS Reference Design. https://openaps.org/reference-design/.
[459] Summerton, Jane, and Boel Berner. 2003. Constructing Risk and Safety in Technological Practice. Routledge Advances in Sociology, 4. London: Routledge.

up any power and authority related to T1D if a comprehensive solution to T1D is offered by the experts. A solution that either cures the disease or makes the management of it an afterthought requires no effort, physical or mental. Both of these sides are guided by individual risk perception, not by access to power and authority. While the former side is a current likelihood, the latter is a hopeful eventuality. The reclaiming of power and authority is the outcome of DIY innovation and use, rather than the primary goal or incentive for it.

The boundaries drawn by this work between the two communities studied are artificial. It is done so deliberately to engage understanding of risk and health automation. However, it is important to acknowledge this is not a binary distinction among different groups, but a range with fluctuating and changing affinity for DIY technology use due to changing individual risk perceptions. DIY biomedical technologies are a choice. Every day patients have to make that choice willingly without or despite the outside influence of clinicians, insurance companies, or corporations. This choice is based on real and perceived barriers, ability and comfort levels, willingness, time, and resources to learn and try.[460] Patients recognize the significant biological and financial risks, as well as those brought about by biomedical technologies, including but not limited to cybersecurity risks, software and hardware malfunction, alarm fatigue, and notification overload. One such instance is the 2022 FDA warning regarding possible unauthorized

[460] Lewis, Dana. 2019. History and Perspective on DIY Closed Looping. Journal of diabetes science and technology, 13(4), 790–793. https://doi.org/10.1177/1932296818808307.

access to certain Medtronic insulin pumps and unauthorized insulin dosage adjustments.[461] It highlights a cybersecurity risk with fatal consequences.

Decision-making regarding the use or non-use of DIY T1D technologies is an individual choice where the risks of disease, financial and other risks are evaluated against technological risks and benefits. For example, Dana Lewis, a co-founder of the DIY Artificial Pancreas System OpenAPS, highlights the vulnerabilities of T1D and the DIY biomedical technology but also emphasizes that "…an automated insulin delivery system introduces many new risks…However, the calculation *also* must include the everyday risks of living with type 1 diabetes."[462] Lewis started innovating because of her fear of sleeping through a hypoglycemic (low blood glucose) episode at night. She started with a single problem: insufficient volume in sound presets on her T1D device. If she is not able to hear the alarm of dangerously low BG while sleeping, she might die in her sleep. Lewis ended up co-creating a hybrid closed-loop DIY APS with the help of her partner Scott Leibrand. Many others have since contributed to the effort of expanding APS functionality and features. Lewis did not monetize the innovation but shared it openly so others could also benefit from it.

It often takes about 17 years between when research results are published and when those results might be implemented into patient care.[463] FDA-approved biomedical technologies are designed years before they become available to the public due to testing,

---

[461] Roy, Mrinalika. 2022. FDA warns of cybersecurity risk with certain Medtronic insulin pumps. Reuters. Accessed 01.11.23. https://www.reuters.com/business/healthcare-pharmaceuticals/fda-warns-cybersecurity-risk-with-certain-medtronic-insulin-pumps-2022-09-20/.
FDA. 2022. Cybersecurity. Accessed 1.11.23. https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity.

[462] Lewis, Dana. 2019. Automated Insulin Delivery: How artificial pancreas "closed loop" systems can aid you in living with diabetes.

[463] Vieira, Ginger. 2022. DiabetesMine Innovation Summit Unveils New Tech & Products for Type 1 Diabetes. T1D Exchange. Accessed 1.11.23. https://t1dexchange.org/diabetes-mine-summit-2022/.

verification, and regulatory requirements. Making changes to technologies based on patient needs and preferences is also time-consuming. This might be the reason why so many people around the globe have embraced the DIY APS, its availability, and customization. Individuals with T1D make about 180 health-related decisions daily regarding BG monitoring, insulin intake, food, and exercise in addition to everything else in life.[464] As the DIY community shows, the burdens of constant decision-making can be relieved through automation. "Without automated insulin delivery, people overdose or underdose on insulin multiple times a day, causing adverse effects and bad outcomes and decreasing their quality of life."[465] A 17-year gap between research and practice is a frustrating reality, a risk on its own. Thus, the risks of DIY technologies are evaluated against the risks of disease, the need for constant decision-making, and the shortcomings of regulated biomedical technologies.

Risks are everywhere, even with life-saving insulin and groundbreaking biomedical technologies. Ben West said: "What's interesting with the risk is that [traditionally] we're given a bunch of insulin and we're told to take it. We hold people responsible for getting it right. That's not a humane thing, there's no way you're going to be able to balance insulin with all your needs."[466] The DIY community does not hide or shy away from openly and clearly proclaiming technological risks and potential issues due to the interconnected nature of such technologies. For example, in Figure 10 shows a safety message for the Nightscout application highlighting risks of unexpected failure, the

[464] Mungmode, Ann. 2022. Emboldened to Innovate: Supporting All People Living with Diabetes. T1D Exchange. Accessed 1.11.23. https://t1dexchange.org/diabetes-mine-summitt-2022-researcher/.
[465] Lewis, Dana. 2022. We Have Changed the Standards of Care for People With Diabetes. DIYPS.org. Accessed 01.08.23. https://diyps.org/tag/wearenotwaiting/.
[466] Rao, Ankita & Cunnane, Megan. 2016. Diabetes Hacking 101. Only Human. WNYC Studios. Accessed 01.08.23. https://www.wnycstudios.org/podcasts/onlyhuman/articles/diabetes-hacking-with-ben-west.

need for an alternative method of care, and the need for an internet connection for this technology to work. DIY biomedical technologies are not "out of the box" technologies ready for immediate use. They also require time, effort, patience, and a steep learning curve. The FDA-approved APS is a ready-to-use technology that does not require as much effort to set up and learn how to use. The APS from Medtronic Inc. costs in the range of 5,000-8,000 USD or more per year out of pocket after health insurance payments,[467] while the Open APS DIY system costs from 150 USD to several hundred dollars per year out of pocket.[468] The DIY APS costs less and provides more functionality for its users. But it also has less support from the medical community.

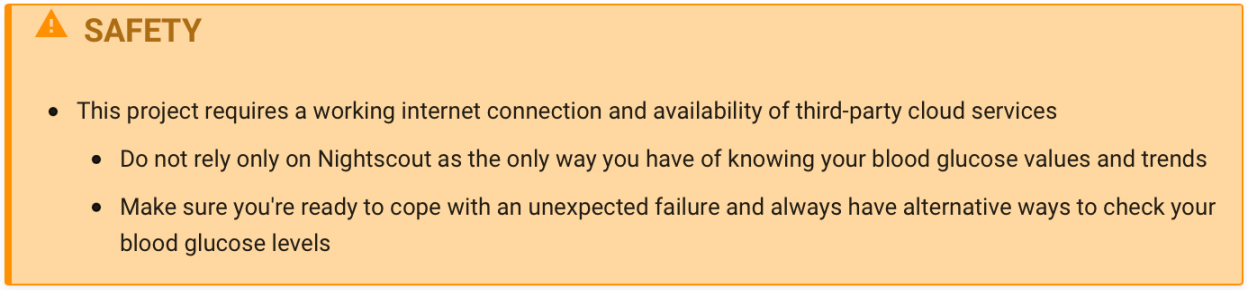


Figure 10. Nightscout safety message.

Users and individuals interested in learning about DIY T1D technology have convenient and free access to documentation for OpenAPS,[469] Nightscout[470] , and

[467] Kelly, Clint. 2020. What is an Artificial Pancreas – Who Makes it and the Cost. Prescription Hope, Inc. Accessed 1.11.23. https://prescriptionhope.com/blog-what-is-an-artificial-pancreas/.
[468] OpenAPS. 2019. Frequently Asked Questions. Accessed 1.11.23. https://openaps.org/frequently-asked-questions/.
[469] OpenAPS. 2022. Welcome to OpenAPS's documentation! Accessed 10.21.22. https://openaps.readthedocs.io/en/latest/index.html.
[470] Nightscount. 2022. New Nightscout Users. Accessed 10.21.22. https://nightscout.github.io/nightscout/new_user/.

Loop[471] covering everything from functionality, setup to use, and troubleshooting. Prospective users are encouraged to build their DIY technologies themselves for full understanding and their own safety. The documentation is well-organized, and intuitive, and does not require specialized skills. It provides step-by-step instructions, guidance as well as directions where one can get support. It also provides important disclaimers regarding risk and responsibility as illustrated in Figure 11 below. DIY projects are not supported by companies and are not regulated. Thus, users take full responsibility for building and using DIY technologies at their own risk without corporate customer support. Users' choice of DIY biomedical technologies is an act of reclaiming the power of the individual over health outcomes, personal data, one's body, and one's future. It transcends governmentality and serves as an example of medical disobedience as patients go beyond the established standards of T1D care by disobeying norms, guidelines, and expectations.

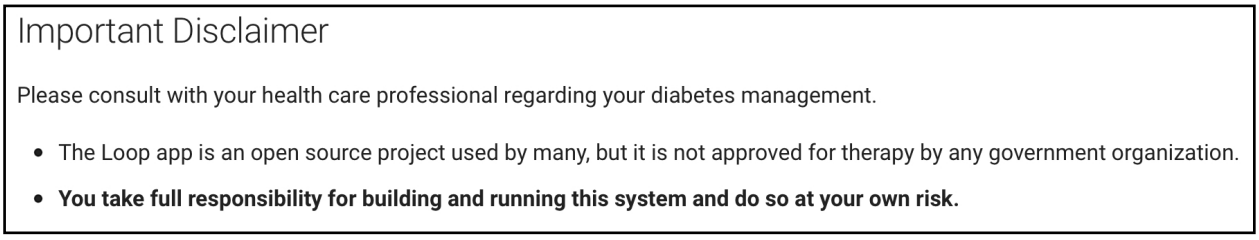


Figure 11. LoopDocs disclaimer for the Loop App users.

If T1D is a life sentence for those affected by it, then increased control over automated technologies might not only be beneficial but also necessary considering that the overwhelming majority of care is done by patients and caregivers. However, it has

[471] LoopDocs. 2022. Welcome to LoopDocs. Accessed 10.21.22. https://loopkit.github.io/loopdocs/.

equally important technological risks, shortcomings, and safety concerns. Technological failure might happen due to heavy use, accident, connectivity issues, faulty parts, or user errors to name just a few. This can happen with any of the components of the APS including the insulin pump.[472] The DIY community recognizes this and creates no illusion that DIY APS is somehow safer and more reliable or that FDA-approved APS is risk-free. Regulated technologies carry significant risks as well. Simply looking back at the numerous recalls placed by the FDA one can see some of the risks and vulnerabilities of regulated technologies. Just in 2021, Medtronic recalled MiniMed Insulin Pumps for incorrect insulin dosing in a Class I recall, the most serious type of recall for devices that may cause serious injuries or death.[473] This insulin pump was a part of the first FDA-approved APS, Medtronic MiniMed 670G hybrid closed-loop system. It was deemed dangerous, potentially with "life-threatening effects," linked to 26,421 consumer complaints, 2,175 injuries, and one death.[474]

A published peer-reviewed 2018 study concluded there were no significant side effects due to using DIY APS in addition to demonstrating a significant decrease in A1C, increased TIR, and decrease for both TAR and TBR.[475] Similar findings for improved

[472] Ouellet Valérie, Adhopia Vik, Culbert Andrew. 2018. Insulin pumps linked to more reports of injury and death than any other medical device, records show. CBC News. https://www.cbc.ca/news/health/implant-files-insulin-pumps-1.4915491.
[473] FDA. 2021. Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing. https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-minimed-insulin-pumps-incorrect-insulin-dosing.
[474] Meyers, Flowers. 2021. FDA Expands Recall of Medtronic Minimed Insulin Pump. Meters & Flowers Trial Attorneys. https://www.meyers-flowers.com/our-firm/news-room/fda-expands-recall-of-medtronic-minimed-insulin-pump/.
[475] Choi, Soo Bong, Eun Shil Hong, and Yun Hee Noh. 2018. Open artificial pancreas system reduced hypoglycemia and improved glycemic control in patients with type 1 diabetes. Diabetes 67, no. Supplement_1.
Lewis, Dana M., Richard S. Swain, and Thomas W. Donner. 2018. Improvements in A1C and time-in-range in DIY closed-loop (OpenAPS) users. Diabetes 67, no. Supplement_1.

glycemic control are documented in other peer-reviewed studies in 2019,[476] 2020,[477] and 2022.[478] These studies were published in the monthly ADA publication *Diabetes*. Yet the regulatory expert community does not use these evidence-based studies to elevate the importance of DIY APS in the Standards of Diabetes Care[479] or in its biomedical technology-focused professional education courses.[480] Recently another study was published in the New England Journal of Medicine stating that open-source APS system use resulted in a significantly higher percentage of time in the target glucose range than the use of a sensor-augmented insulin pump at 24 weeks.[481] It appears that having evidence-based data is not sufficient for regulatory experts to promote and/or support DIY APS since it lacks FDA approval. However, without a pathway to gain FDA approval for these innovations not driven by profit, proliferation will remain limited.

---

[476] Braune, Katarina, S. H. A. N. E. O'DONNELL, Bryan Cleal, Dana M. Lewis, Adrian Tappe, Bastian Hauck, Ingrid Willaing et al. "117-LB: DIWHY: factors influencing motivation, barriers, and duration of DIY artificial pancreas system use among real-world users." Diabetes 68, no. Supplement_1. https://doi.org/10.2337/db19-117-LB.
ANDREAS MELMER, THOMAS ZÜGER, DANA M. LEWIS, SCOTT M. LEIBRAND, MARKUS LAIMER; 76-OR: In-Depth Review of Glycemic Control and Glycemic Variability in People with Type 1 Diabetes Using Open Source Artificial Pancreas Systems. Diabetes 1 June 2019; 68 (Supplement_1): 76–OR. https://doi.org/10.2337/db19-76-OR.
EMMA G. WILMOT, LINN LANGELAND, ALASDAIR MCLAY, NICOLA TAYLOR, ISKANDAR RAUF IDRIS; 1067-P: Open Source Artificial Pancreas System (APS) vs. Combination Insulin Pump with Flash Glucose Monitoring in Adults with Type 1 Diabetes: An Observational Study. Diabetes 1 June 2019; 68 (Supplement_1): 1067–P. https://doi.org/10.2337/db19-1067-P.
[477] JENNIFER ZABINSKY, HALEY HOWELL, ALIREZA GHEZAVATI, DANA M. LEWIS, ANDREW NGUYEN, JENISE C. WONG; 988-P: Do-It-Yourself Artificial Pancreas Systems for Type 1 Diabetes Reduce Hyperglycemia without Increasing Hypoglycemia. Diabetes 1 June 2020; 69 (Supplement_1): 988–P. https://doi.org/10.2337/db20-988-P.
[478] SANDRA AMUEDO, MARÍA ANTEQUERA, SHARONA AZRIEL; 800-P: Real-World Use of Do-It-Yourself Artificial Pancreas Systems in Adults with Type 1 Diabetes. Diabetes 1 June 2022; 71 (Supplement_1): 800–P. https://doi.org/10.2337/db22-800-P.
[479] ADA. 2022. Introduction: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S1–S2. https://doi.org/10.2337/dc22-Sint.
[480] ADA. 2021. Making Diabetes Technology Work. Professional Education. Accessed 09.27.22. https://professionaleducation.diabetes.org/Public/Catalog/Main.aspx.
[481] Burnside, Mercedes J, Dana M Lewis, Hamish R Crocket, Renee A Meier, Jonathan A Williman, Olivia J Sanders, Craig A Jefferies, et al. 2022. "Open-Source Automated Insulin Delivery in Type 1 Diabetes." The New England Journal of Medicine 387 (10): 869–81. https://doi.org/10.1056/NEJMoa2203913.

The important role of biomedical technologies, regulated or unregulated, cannot be dismissed despite the abovementioned risks, concerns, and technological burdens. A life shaped by insulin injections and blood glucose monitoring leaves little choice for the one impacted to ignore biomedical technologies since life without them does not exist. As Cowan writes "our tools are not always at our beck and call. The less we know about them, the more likely it is that they will command us, rather than the other way around."[482] Biomedical technologies are tools of diabetes management and DIY innovations are striving to improve the quality of life, not just extend its duration of it. However, the quality of one's life is not a standard measure fit for all. It cannot be easily assessed without understanding one's individual needs, priorities, and choices. Dana Lewis wrote: "No matter their choice of tools or technologies, people with diabetes SHOULD be supported in THEIR choices. Not choices limited by healthcare providers, who might only suggest specific tools that they (healthcare providers) have been trained on or are familiar with – but the choices of the patient."[483] Biomedical technologies increase the intensity of T1D care becoming not simply a part of patients' health or health management routines, but an integral part of their lives. Thus, these tools of care require continuous learning, understanding of risks, cautious trust, alternatives of care, and increased self-awareness and they would benefit from the supportive care of healthcare providers.

[482] Cowan, Ruth Schwartz, 1983. More Work for Mother: The Ironies of Household Technology from the Open Hearth to the Microwave. New York: Basic Books.
[483] Lewis, Dana. 2022. We Have Changed the Standards of Care for People With Diabetes. DIYPS.org. Accessed 01.08.23. https://diyps.org/tag/wearenotwaiting/.

Intimacy with a Black Box Technology

Biomedical technologies for T1D management are described as liberating not only by the regulatory expert community, as addressed in the previous chapter, but also by the DIY community.[484] Along with the positive aspects of health automation, there are negative attributes related to new risk considerations and an understanding that biomedical technology use alone is not an assurance of success. Dana Lewis wrote: "I was "just" the patient and the "user" or "consumer" of the device, with no option to change medical device to better suit my needs."[485] Patients as technological users recognize T1D as a data-intensive risk-prone disease with no set regimen that would universally work for all individuals. Varying requirements of T1D also mean that technological requirements to successfully manage the disease must vary. This recognition was one of the driving forces behind the DIY community to reverse engineer commercially available devices to get to the data and work to create solutions that increase customization and provide more information for users' decision-making.[486]

Some media sources celebrate the relentless, driven, dedicated, tech-savvy, and motivated community of caregivers and patient innovators.[487] Other media sources portray the DIY community as "a loose network of "aggressive patients" who have been exploiting security flaws in some of the pumps to make them automatically estimate

[484] Nighscout Foundation. 2016. KCGM-TV OpenAPS & the FDA with Ben West, Ep2. https://www.youtube.com/watch?v=c98TwesRkeQ.
[485] Lewis, Dana. 2019. Automated Insulin Delivery: How artificial pancreas "closed loop" systems can aid you in living with diabetes.
[486] Stanford Medicine X. 2017. Ben West: Linking Medical Devices. Accessed 10/19/22. https://www.youtube.com/watch?v=CXTxRyG34tA.
[487] Linebaugh, Kate. 2016. Tech-Savvy Families Use Home-Built Diabetes Device. WSJ. Accessed 1.12.23. https://www.wsj.com/articles/tech-savvy-families-use-home-built-diabetes-device-1462728637.

blood glucose levels and adjust insulin levels accordingly."[488] Claiming that thousands of people are breaking into their medical devices because they "don't want to wait for the FDA to approve something from the usual stream of regulation"[489] is a problematic statement conflicting with the ideas within the DIY community that emphasize the need for both DIY and regulated diabetes technologies to offer options to address a variety of patient needs. More regulated technologies are welcome so long as they provide patients with more choices. The primary motivation behind the DIY community is data transparency, the complexity of patient needs, and the desire to fill the gap "until there's something commercially available"[490] or until there is a complete cure for T1D.

The regulatory experts and the media rarely address the close relationship patients have with the technologies they use and how these technologies affect users' bodies. Patients are expected to trust commercially available technologies, but for many trustworthiness cannot be easily offered simply because biomedical technologies have the FDA's stamp of approval. Further, the intimate connection of biomedical technologies to patient bodies is contrasted with the hostile networks these technologies function within, raising questions about safety, security, and risk.[491] When users can verify claims made by corporations through open data, trust in technologies is likely to grow as it ensures higher fidelity via checks and balances.

---

[488] SA Today. 2019. Hacking Diabetes: People Break Into Insulin Pumps as an Alternative to Delayed Innovations. https://cacm.acm.org/news/237406-hacking-diabetes-people-break-into-insulin-pumps-as-an-alternative-to-delayed-innovations/fulltext?mobile=false.
[489] Ibid.
[490] Brown, Dalvin. 2019. USA Today. Hacking diabetes: People break into insulin pumps as an alternative to delayed innovations. https://www.usatoday.com/story/tech/2019/06/05/diabetics-forgoing-new-tech-hacking-into-insulin-pumps/1256667001/.
[491] Stanford Medicine X. 2017. Ben West: Linking Medical Devices. Accessed 10/19/22. https://www.youtube.com/watch?v=CXTxRyG34tA.

Ben West, a key contributor within the DIY community for both Nightscout and OpenAPS, a person with T1D himself, had publicly spoken about the matter of intimacy that patients feel with the technologies they carry.[492] When looking at the current FDA-approved APS, there are two devices within the system directly attached to one's body. They both penetrate the skin, the body's primary defense system,[493] to deliver insulin subcutaneously and measure glucose levels via a sensor inserted under one's skin. West recognizes that each device within the APS is a computer in its own right, a computer that is physically attached to one's body like "a thorn in one's side."[494] Therefore, the relationship between the person and the technology is very personal and intimate. This relationship between the body and computers can make one feel as if one is under constant supervision and continuous medical intervention, like a patient always connected and never leaving the medical practice. Through constant technological demands and data flows, technologies continually are acted upon and themselves act on the body, "screaming" alarms, alerting of the need to reset, change a device or fix connectivity issues. Therefore, this highly personal and intimate relationship with biomedical technologies can also be disruptive and intrusive.

The matter of intimacy with biomedical technologies is reflected in the integration of the patient's body and diabetes devices or systems of devices in the form of a biotechnological organism. This integration between the two, on one side, is mutually beneficial since individuals with T1D require biomedical technologies to live and

---

[492] Ibid.
[493] Brodell, Lindsey; Rosenthal, Kenneth S. 2008. Skin Structure and Function: The Body's Primary Defense Against Infection. Infectious Diseases in Clinical Practice: Vol. 16. Issue 2. pp. 113-117 doi: 10.1097/IPC.0b013e3181660bf4.
[494] Stanford Medicine X. 2017. Ben West: Linking Medical Devices. Accessed 10/19/22. https://www.youtube.com/watch?v=CXTxRyG34tA.

technologies require individuals to function. On the other side, this integration can be viewed as a frustrating reality due to risks, possible dysfunctions, dependency, and constraints within the assemblage of body and technology. Further, the entanglements due to outside factors contribute to this frustrating reality. Since the biotechnological organism exists within a rule-based and data-driven world acted upon from multiple directions, from all aspects of human life, digital networks, and from within the body. Individuals who aspire to gain a bit of freedom from the rules they are expected to follow and from the world they are expected to inhabit, have to justify their choices, their reasons, and their successes or failures. Yet, absolute freedom cannot be achieved, because, at the most basic level, each such biotechnological organism requires insulin to live, and insulin can be obtained only through the rule-, data- and norms-based world.

Computers are programmed by people who are flawed and prone to mistakes. Thus, the technologies they create are also flawed and prone to mistakes. This is applicable to both FDA-approved and DIY technologies. Some of these flaws are inherent to biomedical technologies and some are due to the networks and other surroundings the technology exists within.[495] However, even with technological limitations of coded functions, data outputs, hardware, and connectivity, they encompass and shift "both the practical and the moral frameworks of our existence."[496] T1D biomedical technologies are not representative of the full range of patient demands and

[495] Ibid.
[496] Mol, Annemarie. 2008. The Logic of Care : Health and the Problem of Patient Choice. Myilibrary. London: Routledge.

care needs since they and the data outputs they provide are not experienced by all users in the same way.[497]

As Noble writes, systems efficiency depends not on the complexity of the system, its design, or cost, not even on engineers or programmers, but on those who operate them.[498] Both regulated and unregulated biomedical technologies for T1D management are operated by patients or caregivers. However, there is a question of data ownership for data generated via these technologies. Do patients as users have the right to access their health data and do they have the right to know how and who uses their data?[499] For commercially available and FDA-approved technologies the ownership of data and the responsibility for compliance is with the corporation, since users do not have access to or visibility on the data. However, for DIY biomedical technologies data ownership and the responsibility for compliance is with the user. This represents a different form of biomedical data ownership which necessitates a new model of "FDA rulemaking," for a pathway to gain FDA approval, as highlighted below:

> *"The developers of the open-sourced software Nightscout have met with the FDA numerous times to determine the best way to fit Nightscout into the FDA charter. Nightscout represents a novel application of FDA rulemaking in that it is "open-sourced" having a* ***distributed model of ownership and/or responsibility for compliance*** *with various medical device, treatment, and research overseers."*[500] [emphasis added]

Even with greater visibility and access to their data, DIY community members are still at the whim of regulatory experts, corporations and outside networks such as the internet,

---

[497] Eubanks, Virginia. 2018. Automating Inequality: How High-Tech Tools Profile, Police, and Punish the Poor First ed. New York, NY: St. Martin's Press.
[498] Noble, David F. 1984. Forces of Production: A Social History of Industrial Automation. 1st ed. New York: Knopf.
[499] Stanford Medicine X. 2017. Ben West: Linking Medical Devices. Accessed 10/19/22. https://www.youtube.com/watch?v=CXTxRyG34tA.
[500] T1Pal. 2023. Frequently Asked Questions. Is T1Pal or the Nightscout software cleared by the FDA? Accessed 2.27.23. https://www.t1pal.com/legal/faq_8_18_2020_13_38.

which pose risks and entanglements. DIY innovators are stuck in the no man's land, not able to gain positive FDA recognition to be embraced by the regulatory experts and not able to gain freedom from the rule-, data- and norms-based world to ensure absolute independence.

West argues that patients have the right to access their own data and their own device protocols to verify the device's trustworthiness.[501] Biomedical technology might seem less risky if one trusts the people who made it and/or can verify that technology does what it was designed to do. Commercial biomedical technologies in this case can be described as black boxes with selected allowable functions, closed off, inaccessible for patient customization, as intellectual property of a corporation. Black Box is a metaphor used in STS to explain how the social production of science and technology is hidden from view.[502] For example, when looking at the proprietary Dexcom CGM application (Figure 12) and the DIY Nightscout application (Figure 13) for the same patient at the same time, one can see how much more knowledge is produced and offered for patient's consumption via the DIY application. The Dexcom CGM application offers some information predetermined based on what features and data are believed to be most desired by users, without customization, and what constraining information the consumer is able to process so as to not overwhelm the "illiterate and incapable" patient-user.[503] With the DIY application, the user has full access to the code in contrast to the commercial application. If the FDA-approved APS is a closed black box, then the DIY

[501] Ben West. 2022. Building Higher Fidelity Technology - The Quest to Better Treat Type 1 Diabetes. The Data Binge Podcast. https://poddtoppen.se/podcast/1355543236/the-data-binge/ben-west-building-higher-fidelity-technology-the-quest-to-better-treat-type-1-diabetes.
[502] Ruha, Benjamin. 2019. Race After Technology : Abolitionist Tools for the New Jim Code. Cambridge, UK: Polity.
[503] ADA. 2021. Professional Education: Making Diabetes Technology Work. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.

APS is an open box offering users full access, full control, and a full range of functionality.

The additional options and data points portrayed in Figure 13 make T1D decision-making more informed but also offer an option for full customization. More options, data, and customization can be daunting, increasing possible risk considerations at the same time as being beneficial in reducing risks via informed decision-making. For example, the IOB measure (insulin on board) in Figure 13 informs the user how much insulin is currently in their system before they administer more. Too much or too little insulin might require action depending on the user's activities such as a work event, participation in sports, or a lengthy road trip. The PUMP data indicates the number of units of insulin remaining in the insulin pump reservoir. This is particularly relevant for patients with high insulin usage where a single pump reservoir is not sufficient. The screen lock override feature allows users to display the app continuously on their iPhone without the need to open the device, enter a password, and open the app before viewing the BG data. This might be particularly beneficial at night. The rate of change measured at -3mg/dL indicates that blood glucose reading decreased by three points from the last reading. This is important to know since blood glucose is actually slowly dropping despite Dexcom applications indicating BG is stable (horizontal arrow) at 123 mg/dL without providing any additional information. These and many other features are not available with the Dexcom App.

Figure 12. Dexcom Application

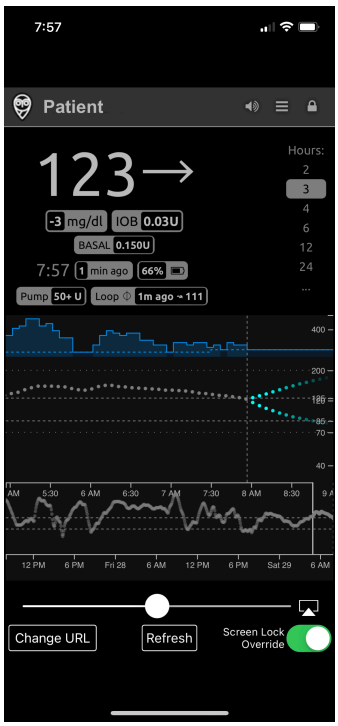


Figure 13. Nightscout Application

The focus on and the opportunity with the DIY technologies lie within the ability for customization, personalization, and precision medicine where DIY community members are encouraged to safely try and fail at medical intervention.[504] Knowledge is power and DIY technologies appear to offer more knowledge for decision-making. Reverse engineering and decoding one's care might be the best way to not only develop trust in biomedical technologies but also to learn and make improvements in the technologies used. As West explains, risks in T1D care increase due to using biomedical technologies for therapy, not due to the disease itself.[505] However, risks associated with trial and potential failure, with multiple choices and possibilities, as well as high demands of care might present a challenge and a barrier to DIY technology adoption.

[504] Stanford Medicine X. 2017. Ben West: Linking Medical Devices. Accessed 10/19/22. https://www.youtube.com/watch?v=CXTxRyG34tA.
[505] Ibid.

Pedagogy within Biological DIY Community

Unlike the formal professionally designed educational course analyzed in the previous chapter, The DIY community's educational materials and resources are produced and shared with reliance on social media, online sources, podcasts, and presentations where innovators and users share their own experiences, struggles, challenges, and successes. These include YouTube videos, Twitter feeds, Facebook groups, and a number of blogs to name a few. Pedagogy within the DIY biological community is conducted within free and public online sources and via the word of mouth among peers. These unofficial sources of information created within the DIY community exist on the outskirts of the formal and authorized information presented to patients by the regulatory expert community.

Innovation in diabetes technology has the ability to significantly impact individuals with T1D, "but innovations are decidedly not limited to technology and product development." [506] Additional innovations can be accomplished in approaches to pedagogy and the DIY community is a good example. This global community not only provides valuable resources to DIY technology users but also does it in a way that necessitates user participation in all aspects of technological design from learning the basic concepts to coding and setting up technological components of the system. Each DIY biomedical technology user is an engineer, a coder, a developer, a scientist, and a health provider through technology self-development and empowered decision-making. The "Do-it-yourself" approach to biomedical technologies and pedagogy might not work for most individuals and especially for those that would like to minimize their

[506] Vieira, GingeR. 2022. DiabetesMine Innovation Summit Unveils New Tech & Products for Type 1 Diabetes. T1D Exchange. Accessed 1.11.23. https://t1dexchange.org/diabetes-mine-summit-2022/.

involvement with devices. This is the reason why it is important for individuals to have options that include regulated biomedical technologies and why representatives of the DIY community are developing simplified organized solutions such as T1Pal, a newly managed Nightscout service which is "Nightscout software without the barriers of DIY."[507] Ben West, who now is the CEO of Medical Data Networks, LLC which has launched T1 Pal, said:

"So we want to offer Nightscout as a service and reduce the barrier to entry, make the entire experience much more reliable, predictable, and consistent. And we want to increase the benefits of remote monitoring for everyone, whether that's caretakers and parents or temporary guardians, or whether it's just people that just want to find their Dia-buddy [friend with diabetes] on social media and share it with them… So T1Pal is our first product from medical data networks. And it leverages all the experience that we had building Nightscout. So T1Pal is Nightscout as a service. So you can think of it as the easy way, it's a new way to get started with Nightscout. And it eliminates all of the server and database administration and DIY craft. So it makes it as easy as any other platform where you simply sign up, you pay for your subscription, and you have access to all of the benefits that Nightscout brings."

The requirement for DIY systems to be self-built is in itself a learning process where one creates by doing not just by listening or reading. The community encourages users to build their own technology so they understand it, can troubleshoot it, and use it more effectively. Learning is an integral part of using and managing DIY technologies, as without learning this would be impossible. In addition to the documentation and set-up files for DIY technologies, there are resources focused on patient learning. For example, the diaTribe online publication with an annual readership of 3.5 million people,[508] as part of the diaTribe Foundation, provides patient-focused actionable information about

[507] T1Pal. 2023. Medical Data Networks, LLC. https://www.t1pal.com.
[508] The diaTribe Foundation. 2022. Our Mission. Accessed 10.31.22. https://diatribe.org/foundation/about-us/our-mission.

"Making Sense of Diabetes."[509] Just looking at a single page explaining Time in Range (TIR) one can see the comprehensive review of TIR freely available to all.[510] This stands in stark contrast to a similar TIR explanation by the ADA, which is promoted to professionals and requires login to access.[511]

The availability of FDA-approved technologies does not simultaneously indicate affordability and accessibility. Many individuals are not able to access these biomedical technologies through the barriers that exist including cost, health insurance, and access to quality healthcare. The DIY community is aware of this and places great emphasis on education not only about T1D or the benefits of DIY technologies but also on biological, technological, and financial risks to improve patient awareness, knowledge base, and self-care. The DIY community is functioning outside of the conventional and the learning resources it provides are not conventional, either.

Dana Lewis said: "you don't know what you can do until you try" since anything is better than nothing and there are endless possibilities for what one can accomplish when one decides to stop waiting for someone else to do it for them.[512] The community members seek a creative approach to biomedical devices which reduces the dependency of users on corporations. "Your diabetes may vary" is a phrase often used within the DIY community. Individuals within the community are ultimately making decisions regarding where to start with DIY biomedical technologies and judgments about what approach to care works best for them. There is no pressure to commit to a single approach or a single

[509] diaTribe Learn. 2022. About diaTribea: Making Sense of Diabetes. Accessed 10.31.22. https://diatribe.org/about-diatribe.
[510] diaTribe Learn. 2022. Time in Range. Accessed 10.31.22. https://diatribe.org/time-range.
[511] ADA. 2022. Time in Range: More Than Just a Number. Accessed 10.31.22. https://professional.diabetes.org/content-page/time-range.
[512] Lewis, Dana. 2018. Open Artificial Pancreas System. TEDxFHKufstein. https://www.youtube.com/watch?v=kgu-AYSnyZ8.

technology. Users are empowered to discontinue use if they desire, to switch technology and components of the system. Individuals within the community might even switch between different types of closed-loop systems depending on their needs."[513] Users are encouraged to maintain reasonable expectations and develop a good plan for technological failure to manage their risks.

"*While patients have shared with physicians and other members of society some common notions of how to live with the disease, diabetics have formed their own opinions regarding how to manage their disease, what represents good control, and how they are responsible for their condition. These opinions have resonated with the circumstances of that patient's life and developed as the patient grew older."*[514]

The above-quoted text from Feudtner's writing on diabetes points to the importance of patient-users agency and how their opinions, priorities, needs, and views of T1D, risk, and biomedical technologies might change with age and life experiences. Technological demands as well as the need for learning might change as well. Patients continue to share with physicians and other members of society the challenges and benefits of DIY biomedical technologies they use. This exchange of knowledge is necessary so that health and medical providers can learn and be able to better assist patients since this knowledge is not taught in medical schools.[515] Improved education has the potential to reduce not only patients' burdens of self-care but also medical professionals' burdens of helping all of their patients.

[513] DiabetTech. 2022. How to get started with DIY "Artificial Pancreas" systems. Accessed 10.30.22. https://www.diabettech.com/looping-a-guide/.
[514] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[515] Lewis, Dana. 2018. Open Artificial Pancreas System. TEDxFHKufstein. https://www.youtube.com/watch?v=kgu-AYSnyZ8.

Howard Brody, a family physician, wrote: "Patients did not tell us their stories; instead we took their medical histories."[516] In his book, *Stories of Sickness* Brody argues that storytelling should be viewed as a process of healing where individuals are able to share their experiences within the context of their life story.[517] Medical and health professionals are able to understand how it feels to have a chronic disease for that individual and how it is to live as a biotechnological organism in contemporary society only through discussions, stories, and sharing of knowledge by the patient. Such situated knowledge can be instrumental not only in our understanding of risks, risks of living as a biotechnological organism, and risks due to the multitude of entanglements but also in our understanding of health automation (discussed in greater detail in the following chapter).

Patient-driven innovation is not a new concept in or outside of T1D care. In this case, patient-driven innovation is ahead of corporate innovation, as exemplified by the APS. Unfortunately, this lag is also reflected in policymaking and education. For now, patients using DIY technologies are engaging in self-advocacy, self-education, and self-promotion with the understanding of healthcare provider limitations. However, the educational efforts within the DIY community directed at individuals with T1D and at the regulatory expert community have the potential to further disrupt commercial innovation cycles and approaches by energizing patient-driven innovation. Therefore, risk thinking within the DIY community as the force for innovation and pedagogy has the potential to influence not only patient engagement and barriers to effective T1D care but also medical approaches to patient care and corporate approaches to innovation.

---

[516] Brody, Howard. 1987. Stories of Sickness. New Haven: Yale University Press.
[517] Ibid.

Conclusion: **The Cacophony of Risks Experienced**

What does it mean to have T1D and experience a cacophony of risks described in this work? It means a lifetime of chronic disease management, a lifetime of biomedical technology use, and a lifetime of elevated risk. The community of DIY innovators deviates from the ideas of accepted norms of care and standards of biomedical technology use. Yet, it exists within the U.S. healthcare system and is influenced by health and medical professionals in ways that cannot be discounted. T1D and other chronic conditions are disruptive for the affected individual and impact their identity in ways necessitating the reconstruction and the rethinking of life as a patient and biomedical technology user. This leads to new priorities, new risks, and new personal needs. To have T1D means becoming abnormal in the eyes of society and finding one's way in life as a reconstructed biotechnological organism, a human body kept alive by biomedical technologies in a contentious symbiotic relationship.

The DIY biological community organized around the #WeAreNotWaiting movement perceives risks beyond biological risks or the malfunction or failure of technological components of biomedical technologies. Risk perception expands to technological use, management, monitoring, and procurement reflecting the requirements of never-ending chronic disease management that entangle users into outside systems, networks, and services. Most importantly, it is the understanding of different patient needs and demands of disease that highlight there is no universal preset therapy for T1D. T1D differs among patients, including but not limited to different insulin needs, insulin sensitivity, metabolism, internal hormonal levels, biomedical technology used, etc. As T1D needs differ, risk perceptions differ as well. It is also important to recognize that the

DIY community is also a knowledge community with expertise that reflects the phenomenological experience of those with the disease. This understanding distinguishes the DIY community from the regulatory experts and regulatory agencies and creates an opportunity to learn about health automation at the nexus of the two.

Risk is the driving force for DIY innovations and DIY biomedical technology use. In the rule-based, data-driven, and norm-based provision of care and society that holds medical and health professionals as the ultimate authorities in T1D care, the DIY community is carving a place for itself and forcing its voice to be heard by empowering patients to take charge of their data, their health, and their biomedical technologies. The community is replacing the idea of technological solutionism, that biomedical technologies as a solution to T1D, with the idea that biomedical technologies can be effective tools of care that require continuous learning.

The perception of risk within the DIY community drives innovation in a number of ways including via the need for transparency, education, and accessibility. Transparency goes along with the matters of trust and intimacy. Trust is called for with FDA-approved technologies as if the stamp of FDA approval alleviates all risks, concerns, and technological issues during use. Trust should not be easily given due to the close and intimate connections within the biotechnological organism. A single instance of broken trust, exemplified by the 2019 Dexcom outage,[518] can force those affected to become cautious about the technologies they use and fearful of possible future shortfalls of the critical technologies they rely on to live. Patients are prone to errors and so are biomedical technologies, both DFA-approved and DIY ones. This basic understanding

[518] O'Connor, Anahad. 2019. In Weekend Outage, Diabetes Monitors Fail to Send Crucial Alerts. The New York Times. https://www.nytimes.com/2019/12/02/well/live/Dexcom-G6-diabetes-monitor-outage.html.

should persuade corporations not to sell trust as one of the features of regulated technologies because of reliability issues. The DIY community members see transparency regarding diabetes automation as a basic need since biomedical technologies are connected to and penetrate human bodies creating a greater need for improved technological understanding.

When healthcare providers are unable to provide support and proper care to those using DIY technologies, continual patient education reduces the need and reliance on a regulatory expert community. In this case, patients and their caregivers are gaining expertise in patient individualized care. The DIY community members are tired of maintaining hope for the eventual cure "just 3-5 years away." Instead of hoping, they are learning and doing today what they can without waiting for what the future might or might not bring. They want better health now and they are willing to put in the time, effort, and resources so they and many like them can benefit.

Access to biomedical technologies and healthcare services remains a significant issue in the United States. However, the DIY community is trying to narrow the gap between patients, needed therapies, and knowledge. The DIY community is working to reduce barriers not only to biomedical technology accessibility but also to further T1D innovations. Within the community, the matters of access and innovation are time-sensitive matters requiring action now. The community members are willing to take on the risks of new DIY technologies today in order to have their care needs addressed without waiting years for future commercially produced technology to become available. Every day counts as every day brings significant risks to the patient, their well-being, and those they care for.

The DIY community does not reject the quantitative way of seeing disease and approaching care. In fact, the community adds to technological and quantitative views of disease by emphasizing the importance of transparency, education, and access. They do not see a problem with a data-driven treatment of T1D, but in order to truly impact patients' quality of life, focusing on technologies and data is insufficient. The DIY APS is a good example of how risk perceptions are incorporated into biomedical technologies. The DIY APS is fully transparent, from the code used in its design to the educational materials and set-up instructions available and open to all. DIY innovators are also exerting pressure on policymakers, regulators, and commercial innovators to keep pushing them to develop faster ways to bring more adaptive, usable systems to market.[519] Due to the DIY community's work, many more individuals were able to access and use DIY technologies. Unfortunately, "the successful fruits of technological innovation have not been enjoyed by all."[520] The DIY biological community through DIY biomedical technologies is working to change that.

[519] Patton, Mary Anne. 2020. Ben West – fixing diabetes, changing the conversation. MyArtificialPancreas.net. Accessed 01.08.23. https://myartificialpancreas.net/2020/04/01/ben-west-fixing-diabetes-changing-the-conversation/.
[520] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.

Chapter 5. Co-Production of Automated Health

> "If the patterns established during the past century persist, then we should anticipate that diabetes care in the future will be more intense and have a wider purview, focused less on immediate or short-term problems and more on primary prevention and the long-term enhancement of quality of life for people with diabetes."
>
> *Chris Feudtner, MD, Ph.D., MPH*[521]

Introduction

The promises of biomedical technologies in diabetes management are inspiring hope, dreams, creativity, success, enthusiasm, and drive for further automation. These promises are contrasted with fears, concerns, struggles, disillusionment, and the "just-out-of-reach capacity of science to radically reconfigure lives."[522] Even the Artificial Pancreas System (APS), the most advanced biomedical technology used for Type 1 Diabetes (T1D) management today, is wedged in between praise for outstanding achievement and concerns for technological demands, new risk considerations, issues of affordability, access, and transparency. The fully automated technological solution to T1D, in the form of a technological reproduction of the biological human pancreas, that would offer worry-free and risk-free care remains an ever-elusive target. A fully bionic pancreas for T1D or increased automation to address other health conditions can be transformative, but it raises several questions that should be considered to not only gain a better understanding of risks in chronic disease care but also help conceptualize the logics of heath automation that drive innovation, influence policymaking and impact healthcare. This research has

[521] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. P.167. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.
[522] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. Accessed May 13, 2021. http://www.jstor.org/stable/j.ctv12fw5z8.

asked: How do risk considerations impact health automation? Who is benefiting from health automation and who is being left behind? How does automated health influence the provision of health services and the power dynamic between providers and users? What are the risks and the logics of health automation in relationship to the entanglements implicating human bodies that are reliant on biomedical technologies?

To address these questions this research featured the review of two distinct social groups: the community of regulatory experts represented by the American Diabetes Association (ADA) and the Do-It-Yourself (DIY) biological community represented by DIY innovators, patients, caregivers, and advocates. The first group provided an important perspective grounded in evidence-based science, normative base, and professional standards upheld within the fields of medicine, healthcare, and research. The second group provided an equally important perspective grounded in phenomenological experience with biomedical technologies. The primary goal of this chapter is to recap the analyses and reviews done so far into a summary of findings and discuss their implications for health automation.

The words of Feudtner cited above were published 20 years ago, yet they ring true today. Diabetes care has not only intensified and widened its purview but also became increasingly technologically dependent with the growing complexity of automated technologies used to reduce disease burdens and improve the quality of patients' lives. This is particularly evident through the historical review conducted in the first chapter that demonstrated the increasing complexity of T1D care with biomedical technologies. Historical changes in treatments and approaches to T1D care demonstrated how advances in therapies introduced new risks. In an effort to maximize life extension, life with T1D

came at a cost of new risks and life-long reliance on biomedical technologies. The inseparability of disease and its therapeutic tools is not unique to T1D as it is also observed with heart conditions requiring a pacemaker, chronic kidney disease (CKD) requiring dialysis, mobility impairments requiring prosthetics, wheelchairs, or other assistive devices as well as numerous other conditions. The importance of biomedical technologies for patients' care and their sustained and prolonged lives cannot be ignored. As the review of the two social groups shows, there is no objection to health automation per se, the challenge lies in how automation is carried out and who has the right to automate.

The complexity of entanglements in T1D is multidirectional. The biological complexity of T1D, as a multi-system disease that affects all organs within the body, is visible throughout history which reveals the complex human consequences of medical innovations and technologically intensive therapy (Chapter 1). Technological complexity is evident through increased automation that makes T1D management more intense instead of simplified and streamlined. It further highlights the integration of biomedical technologies into the lives of individuals with T1D, into a biotechnological organism, indicating inseparability, symbiosis, and, simultaneously, tension (Chapter 2). The transformative nature of biomedical technologies comes into question through the analyses of risk discourses that highlight the introduction of new risks due to increased automation that redefined the success of T1D care through technologically derived metrics and standards (Chapters 3 and 4). This complexity is also visible in the intensification of healthcare through automation which has created new opportunities and threats to the effective provision of diabetes care and to the transformation of the U.S.

healthcare system to one that promotes access, affordability, transparency, trust, and balance. This final chapter aims to highlight related social, political, and economic issues resulting from this complexity of entanglements as well as bring to the surface important tensions manifested in risk discourses, differing approaches to automation, and knowledge production.

The significance of this work lies in the examination of how the knowledge of entanglements of bodies, technologies, and outside factors can help inform policy, healthcare, and decisions to automate in the field of human health. One way to do so is through the understanding of what a biotechnological organism is, with a recognition that risk perception, as the driving force within health automation, is multi-dimensional. Recognizing and accounting for the multi-directionality of entanglements in T1D as well as the multidimensionality of risk has important implications for all stakeholders, from individual patients, health and medical service providers to policymakers, healthcare systems, and commercial entities, with a potential to improve access, affordability, transparency, trust, and balance within the U.S. healthcare system as well as address the disconnect between efforts of health automation and contemporary approaches to healthcare. Positive changes can start with a recognition that the seemingly liberating nature of biomedical technologies can also entangle, subjugate, and confine those it is aimed to free. Positive changes can continue with the understanding of the consequences of these entanglements, dependencies, and tensions. While this chapter is not intended to be an exhaustive analysis, it aims to tie together the threads raised in the previous chapters and include relevant questions to spur further research.

It is important to recognize that the historical risks of T1D are not eliminated through automation. They exist today despite advanced technological innovations and pharmaceuticals available and used by patients. Patients are still vulnerable and still concerned about suffering from adverse health outcomes. Technological advances have relieved some burdens of disease but also created new ones such as risks associated with technological malfunction, failure, and data overload, as well as the challenges and demands of technological maintenance. This indicates not an elimination of risk or the effort it takes to manage a chronic condition but a shift in where these risks and efforts emerge. The perception of risk between the two social groups analyzed in this work differs. The community of regulatory experts views the APS as a solution, while the DIY biological community views it as a "net risk reduction."[523] However, risk reduction does not mean risk-free.[524]

This chapter is positioned at the crossroads of two communities and two distinct logics of health automation. It demonstrates how examining the small-scale view, based on a single disease (T1D) and a single biomedical technology (APS), can help advance the understanding of large-scale issues. The promises of life-changing and utilitarian biomedical technologies viewed through the perspective of risk discourses and risk thinking are contrasted with the perils of such technologies. Similarly, the intimate nature of biomedical technologies is contrasted with the digital infrastructure entanglements and hostile networks such as the internet, the power grid, corporate servers, and the general infrastructure of medical and technological procurement. A further understanding of

[523] The Quantified Self Symposia. 2016. We're Not Waiting for Our Automatic Pancreas System. Quantified Self Public Health. Accessed 1.15.23. https://medium.com/quantified-self-public-health/were-not-waiting-for-our-automatic-pancreas-system-888162fcde2b.
[524] Greene, Jeremy. 2008. Prescribing by Numbers: Drugs and the Definition of Disease. Johns Hopkins.

these entanglements in relation to the social construction of biomedical technologies, such as the APS, in the past and present, produces new forms of knowledge which can help inform policy decisions. This work further facilitates the contextualization of biomedical technologies as knowledge and biological communities as knowledge communities.

Douglas and Wildavsky wrote: "Risk should be seen as a joint product of knowledge about the future and consent about the most desirable prospects." [525] This quote contextualizes risk and enables us to put the problem into perspective. In the case of T1D, knowledge is not static and certain. As the volume of research studies increases and as new studies are published, evidence regarding the disease (T1D) and biomedical technologies constituting scientific knowledge is changing and adapting. This is evident in the ADA-established "Standards of Medical Care in Diabetes" which are regularly updated to reflect new scientific evidence.[526] Changing knowledge, ideas regarding consent, and notions of desirability prospects for certain therapies result in changing perceptions of risk. The DIY biological community is gaining increasing recognition for DIY innovations and expertise, and increasingly influences narratives around risk. Therefore, the contemporary understanding of whose knowledge and perspective should be considered is changing, especially when identifying risk and putting problems into perspective, as well as when innovating in the field of human health.

The biological DIY community, through the creation of its own open-source biomedical technologies, is opening a policy window that pushes the regulatory and

[525] Douglas, Mary, and Aaron B Wildavsky. 1982. Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers. Berkeley: University of California Press.
[526] American Diabetes Association. 2022. Introduction: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S1–S2. https://doi.org/10.2337/dc22-Sint.

expert communities to acknowledge new modalities of knowledge creation and pressure these communities to adapt. The U.S. Food and Drug Administration (FDA) is taking note of DIY biomedical technologies[527] and the regulatory expert community is acknowledging the need to know about DIY technologies to help patients who use them.[528] The difference in risk perception through the risk discourse analysis demonstrates a divergence between the policies advocated by the FDA and the American Diabetes Association (ADA) and practices within the DIY community related to transparency, access, affordability, customization, and technological functionality.

The APS is a Class III medical device considered to be a high-risk technology, crucial to maintaining health and sustaining life.[529] Therefore, a failure or malfunction of such biomedical technology carries a risk of severe impairment, injury, or even death. The FDA's classification of medical devices is risk-based, and the Class III designation includes devices with the greatest level of risk.[530] The DIY community is pushing for regulatory, policy, and care changes for biomedical technology at the highest classification of risk and the highest level of automation in diabetes management, as exemplified by the below quote. The DIY community is creating and openly sharing knowledge to encourage both open-source and commercial/proprietary biomedical technology production. However, patient-led innovations are not only challenging the

[527] FDA. 2019. FDA Warns Against the Use of Unauthorized Devices for Diabetes Management. FDA NEWS RELEASE. Accessed 11.12.22. https://www.fda.gov/news-events/press-announcements/fda-warns-against-use-unauthorized-devices-diabetes-management.
[528] ADA. 2021. Professional Education: Making Diabetes Technology Work. https://professionaleducation.diabetes.org/Public/Catalog/Details.aspx?id=q2ZftMXYXt2c4xOSzX%2brVA%3d%3d.
American Diabetes Association. 2022. Introduction: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S1–S2. https://doi.org/10.2337/dc22-Sint.
[529] Brantly, Nataliya D. 2021. Homefront to Battlefield: Why the U.S. Military Should Care About Biomedical Cybersecurity. The Cyber Defense Review 6, no. 2 (2021): 93–110. https://www.jstor.org/stable/27021378.
[530] FDA. 2020. Classify Your Medical Device. https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.

conventional practices of care, but they also further increase the gap between what is commercially available and what is needed by patients.

> *"We [at the Open Artificial Pancreas System project (#OpenAPS)] believe that **we can make safe and effective APS technology available more quickly, to more people, rather than just waiting for current APS efforts to complete clinical trials and be FDA-approved and commercialized through traditional processes**. And in the process, we believe we can engage the untapped potential of dozens or possibly hundreds of patient innovators and independent researchers and also make APS technology available to hundreds or thousands of people willing to participate as subjects in clinical trials… We believe this will in turn allow manufacturers (and the academic research teams they work with) to turn more of their attention to designing and testing more advanced APS systems, and thereby **accelerate the pace of innovation** toward new and improved Type 1 diabetes treatments, and eventually a cure. Please note that OpenAPS community efforts will be open source and free for use for other people, open source projects, researchers, and non-profits to use, and **available on an open and non-discriminatory basis for all** commercial manufacturers to use in proprietary products if desired."*[531] [emphasis added]

The technologically dependent provision of diabetes care in contemporary society is contingent on commercially available and FDA-approved technologies. These technologies are based on the knowledge produced by the regulatory expert community, the normative base, and the established standards of care. Within the top-down provision of care model, patient-produced knowledge is not a primary consideration. Patients are the recipients not participants in health care systems. If the DIY community's patient-led innovations are an expression of need and a call for change, then this perspective is important to consider. This discrepancy demonstrates a clear power differential between the two communities. This differential exists between healthcare providers and patients and arises from the tension between the two logics of health automation. The first logic is techno-deterministic. It is exemplified by the regulatory expert community as an outcome of the analysis conducted in Chapter 3. The techno-deterministic logic is shaped by

[531] OpenAPS. 2023. What is #OpenAPS? Accessed 2.28.23. https://openaps.org.

norms, professionalization, and a regulated market system. This logic is based on a regulatory and proprietary social dynamic closely aligned with the capitalist, profit-driven economy.

The second logic of health automation is integrative logic. This logic is exemplified by the DIY biological community as an outcome of the analysis conducted in Chapter 4. The integrative logic is shaped by efforts to merge knowledge production and proactive innovation in partnership with all stakeholders to build skills, openly share knowledge, improve accessibility, and empower patients as active participants in their health care in an effort to achieve improved T1D treatments and, eventually, a complete cure. The integrative logic runs counter to the top-down approaches to health care by empowering patients to be proactive in self-care, to self-educate, and innovate. It is shaped by affective dimensions that reflect phenomenological experience with biomedical technologies. This logic is based on an economy of exchange, mutual aid, and reciprocity as well as embodied needs.

As this work demonstrates, biomedical innovation based solely on the medical view of disease is not sufficient to meet the complexity of human needs and nuanced disease management therapies. Yet, biotechnological organisms are situated at the intersection of these two logics of health automation between the top-down and bottom-up efforts of T1D care that include the medical view of disease but extend beyond it. Some advocate for the creation of universal but modifiable (within safe operating limits) biomedical technologies which add flexibility and customization to fit diverse patient needs and address differences in disease presentation and management requirements.[532]

[532] Petrick, Elizabeth R. 2015. Making Computers Accessible : Disability Rights and Digital Technology. History of Science, Technology, and Medicine. Baltimore: Johns Hopkins University Press.

Regardless of where the health automation will take T1D care next, it is important to consider a variety of expertise, including those originating from nontraditional sources, such as the DIY community. With the knowledge contributed by this research, it is possible that the optimal approach to automation and health care resides between the techno-deterministic and the integrative logics.

Technologically dependent provision of diabetes care places demands on patients, physicians, industry, and society at large. This chapter returns to the concept of biotechnological organisms introduced earlier in this work to summarize the entanglements and the consequences of this technological dependence through the lens of risk perception. This chapter proceeds in five sections. The first section addresses biotechnological organisms in relation to the logics of health automation. This section focuses on the risks, tensions, and entanglements impacting the automation of biotechnological organisms. The second section addresses normalization in T1D and health automation. This section focuses on how automated health influences the provision of health services and the power dynamic between providers and users. The third section addresses the commodification and regulation of T1D. The fourth section addresses knowledge production practices in T1D automation. Lastly, this work concludes with a brief conclusion.

This work was conducted with the recognition that DIY technology is not for everybody. Not everybody is comfortable using it considering the lack of FDA approvals and formal regulatory processes to verify safety. In fact, individuals that use DIY biomedical technologies are a minority among those with T1D. There are numerous barriers to the use of both regulated and unregulated technologies. However, since this is

the study of health automation in diabetes care, it was crucial to review the alternative source of automation to the conventional regulated and commercially available biomedical technologies. Many individuals with T1D closely follow the recommendations of their medical doctors regarding insulin and biomedical technology use. Many do not, for a variety of reasons. This adds to the variability of therapeutic regimens and patient needs, as well as to the complexity inherent within each social group studied. This work focused on a single aspect of this complexity and more studies are needed to further the research. It is also important to point out that even with the DIY community innovating or with patients starting to use DIY technologies, there are costs associated with the DIY approach. Even though the DIY community is pushing the regulatory agencies to create new pathways of approval for DIY technologies, it takes time to automate, test and learn about how to innovate on your own terms. It might also require a certain comfort level with technology and quantification. Many are already working to reduce the "barrier to entry" for both regulated and unregulated technologies.

Biotechnological Organism and Logics of Health Automation

The quest for fully automated T1D is inspiring bionic and cybernetic dreams where individual responsibility for chronic disease management and the relentless demands of disease are passed on to a fully autonomous machine.[533] These machines are universal, code-based, standardized, normalized, and regulated. They reinforce the top-down normalization of care and seek to return the individual to some notion, often regulatory expert-driven, of what normal is. When looking at the biotechnological

[533] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. http://www.jstor.org/stable/j.ctv12fw5z8.

organism, the notions of machines shift on par with the ideas of the human body. The term biotechnological organism does not prioritize one over the other but highlights the assemblage and the dependency between the two. Biotechnological organisms are not clones or even the ideal combination of bio- and tech-. They are messy, living in a contentious symbiotic relationship between the body with T1D and biomedical technologies used to manage the disease and keep the body alive. This assemblage, in addition to the symbiotic relationship, exists at a tension, a frustrating reality that reflects risks, burdens, and numerous internal and external entanglements.

Within the biotechnological organism, both the body and the technology are essential for the successful function of the organism. Managing the internal tensions present within the organism are essential for this success. These include, but are not limited to human error, technological malfunction, or failure, data overload, mental health issues, rashes and infections, sleep disruptions, health complications, etc. Some of these internal tensions are related to the biological organism, some to biomedical technology, and some to both. Internal tensions reflect all the risks highlighted in this research from the analysis of the two social groups to emphasize the complexity and the nuanced range of risks and their implications on successful blood glucose (BG) and lifestyle management to achieve optimal health outcomes. Many of the internal tensions, if become prominent enough and severe, can lead to a fatal outcome for the biotechnological organism. Internal tensions are constant and vary in intensity and their severity differs among biological organisms.

In addition to the internal tension, biotechnological organisms experience external tensions or entanglements due to digital infrastructures, such as the internet, corporate

servers, the power grid, and the infrastructure of medical and technological procurement. External tensions reflect external risks highlighted in this research related to patients' ability to function with and within the outside systems. These include connectivity interruptions, medical supply disruptions, and health insurance demands to name just a few. Life with a chronic condition is demanding, chaotic, and full of continuous breakdown and repair.[534] Therefore, biotechnological organisms are constantly in flux, balancing the demands between the body, technology, and outside factors such as industrial agendas that introduce interruptions, deprivations, vulnerabilities, and risks. The shifting responsibilities and risks of T1D due to automation have a direct impact on biotechnological organisms by complicating, reconfiguring, and entangling life instead of simplifying it.

Biotechnological organisms cannot avoid these internal or external tensions. They cannot function outside of them because biotechnological organism exists within a rule-based and data-driven world acted upon from multiple directions. Absolute freedom from internal and external entanglements cannot be achieved because biotechnological organisms require pharmaceuticals (insulin), technological components (parts), and connected systems (Bluetooth, internet, corporate systems of exchange) to live which can be obtained only through the rule-, data- and norms-based world. Therefore, to have T1D means becoming abnormal, becoming a biotechnological organism, a body dependent on biomedical technologies for life, with internal and external tensions important to be able to live.

[534] Forlano, Laura. 2016. Hacking the Feminist Disabled Body. Journal of Peer Production. Issue 8. Feminism and (un)hacking. http://peerproduction.net/issues/issue-8-feminism-and-unhacking-2/peer-reviewed-papers/issue-8-feminism-and-unhackingpeer-reviewed-papers-2hacking-the-feminist-disabled-body/.

Using biotechnological organisms as a vantage point for health automation reveals that within the techno-deterministic logic of health automation, the primary focus lies on the technological component. In this case efforts of automation are not preoccupied with internal tensions, that include both concerns for the body and the technology but focus on the proper functionality and safety of technology to do the job it was programmed to do, to address the deficiency within the body, namely a faulty pancreas, the technology was designed to address. Under this logic, technology is viewed as separate from the body, designed to help return the body to normal functionality. Such a view ignores the dependency between the body and technology, the continued use required, and the issues that arise along the way. The integrative logic of health automation, since it is shaped by affective dimensions that reflect phenomenological experience with biomedical technologies, recognizes internal tensions within the biotechnological organism to a greater degree. DIY technologies are designed to address a variety of needs reflected by internal tensions to enhance the flexibility of use and customization. Integrative logic is concerned with embodied needs and, thus, might be better positioned to address the internal and external entanglements of the biotechnological organism.

The two social groups reviewed are closely related to the biotechnological organism not only by producing and exchanging knowledge that impacts it but also by influencing T1D care practices. However, the biotechnological organism is perceived differently between the two. Within the community of regulatory experts that exemplified the techno-deterministic logic, the biotechnological organism is not seen as an assemblage. Instead, the human body is perceived as an independent, autonomous entity.

Biomedical technologies are seen as separate as well. And so, the human body is perceived to come together with technology for a particular purpose (BG monitoring or insulin administration or both), which ignores the complexity of impacts, entanglements, and risks within the assemblage that extend beyond T1D management into other aspects of life (home, school, work, travel, etc.). Here internal tensions are not that important, they are considered to be the responsibility of the individual not a concern for biomedical technology. External tensions are considered for as long as they might interfere with the proper functionality of technology. The consequences of health automation that does not perceive biotechnological organisms include a limited focus on health automation due to a limited range of entanglements to consider when designing new biomedical technologies. This results in biomedical technologies with limited scope likely to cause additional disruptions in already challenging life with a chronic disease.

When contemporary efforts of health automation start recognizing they are automating a biotechnological organism, the consequences of health automation will have to address both the internal and the external entanglements, not piecemeal, but together. This has important implications for the leading approaches to healthcare and policymaking with the potential to address the disconnect between regulation and healthcare models. Public health models that ignore biotechnological organisms and biomedical technologies also ignore the consequences of technological entanglements that have a direct impact on health outcomes. There are risks of automating biotechnological organisms, but the idea of integrating more nuanced considerations in diabetes innovations increases the likelihood of health automation driven not only by

biological risks but also by verification of needs and a range of issues stemming from internal and external entanglements of biotechnological organisms.

Biotechnological organisms become visible in the eyes of society through biomedical technologies. This visibility, which starts with the knowledge of one's blood glucose, placing the human body in the category of diseased, allows for further categorization of biotechnological organisms. Biotechnological organisms are categorized, optimized, standardized, monitored, and controlled within the healthcare system that does not seem to recognize or acknowledge the assemblage. Patients are expected to control their bodies and control technologies. On the other hand, technologies are trusted to do their job and do what they were designed to do. With the understanding that both bodies and technologies are flawed, the idea of a biotechnological organism removes the need to shift blame from one or the other part of the assemblage. It is a futile and counterproductive effort. Therefore, it might be beneficial to shift the perception of patients towards biotechnological organisms to highlight the tensions within that might need help managing. Such a change in perspective might be more beneficial when dealing with an unpredictable disease in an unpredictable body.

Within the techno-deterministic logic, the body should surrender control to the machine because of the machine's perceived superior objective and precise decision-making. Further efforts of automation within the regulatory expert community often indicate the need to automate to remove the human element altogether and thereby reduce human errors, risks of T1D, and human fallacy. This is evident through the perception of patients as illiterate and with numeracy challenges. Yet, when we look at the

biotechnological organism, there is a continuous balancing act between the body and technology, both parts are equally important, and no part is neutral and precise.

Within the integrative logic, the DIY community challenges technological superiority by demonstrating that biomedical technologies are integral tools of care, not absolute solutions, and require user knowledge and subsequently input to function properly. Thus, the biomedical system cannot function properly without the agency of the human with whom it creates a biotechnological organism. The DIY community demonstrates that individuals with T1D have an important role to play in managing the symbiotic relationship and the assemblage within the biotechnological organism. First, individuals choose what biomedical technologies to use or not to use, how to use them, and when. Biomedical technologies are recipients of the user's commands and influence the user's actions. This demonstrates that the assemblage itself within the biotechnological organism is not passive.

The DIY community illustrates that the individual patient's agency can be liberated from the restricted constraints of regulated biomedical technologies in a number of ways. Some of the ways the patient is liberated extend beyond the internal tension within the biotechnological organism and include social, economic, and political attributes inclusive of health insurance restrictions, individual economic capacity, regional technological availability, medical service provider knowledge of T1D, and more. For instance, DIY biomedical technologies can relieve some of the issues of working with health insurance such as eligibility, when a doctor determines a patient meets eligibility criteria for a prescription of a particular biomedical technology, as well as procurement and cost. Additionally, many regulated systems often constrain an

individual to a system for a period of time within the confines of insurance policy guidelines or financial constraints, such as Dexcom G6 GCM receiver prescription for 12 months, refilled once a year, without the option for insurance coverage if change is desired.[535] These restrictions can persist well beyond the shelf life of a technology. The patient's ability to choose and change biomedical technologies is limited. For example, one APS insurance policy states: "[r]eplacement or upgrade of existing, properly functioning equipment, even if the warranty has expired, is considered not medically necessary" and both CGM and external insulin pump must meet medical criteria for coverage.[536] Only medical professionals are authorized to determine what is medically necessary and who meets the medical criteria for coverage. This determination is guided solely by biological and socioeconomic factors.

Patients' agency can also be restricted with DIY technologies in a number of ways, such as during any issues with technology setup and troubleshooting. There is no legally responsible person or entity that should be involved in assisting the user. Support within the DIY community is based on the goodwill of peers and the availability of written resources. If regulated biomedical technologies are black box technologies with minimized descriptions, functionality, and customization, then DIY biomedical technologies are open boxes with full transparency, both within the code being used to operate the device and within the data collected, transmitted, and stored by the devices,

[535] Dexcom, Inc. 2023. Learn how to fill a Dexcom G6 pharmacy prescription for you and your patients. Accessed 2.28.23. https://provider.dexcom.com/education-research/clinic-resources/prescribing-info/learn-how-fill-dexcom-g6-pharmacy-prescription.
[536] Blue Cross and Blue Shield Association. 2022. Artificial Pancreas Device Systems. Policy Number: MP-636. Blue Cross and Blue Shield of Alabama. Accessed 1.16.23. https://al-policies.exploremyplan.com/portal/web/al-policies/home/-/asset_publisher/gvKEs0SDu27L/content/mp-636/78515.

and their affiliated systems. Full transparency can be a burden and a restriction in itself overwhelming individuals with too much data.

Biotechnological organisms cannot exist in isolation. At the very basic level, they have to interact with medical professionals to obtain the necessary supplies to live. They are surrounded by expertise and commercial and regulatory forces. The history of medical treatments is replete with scammers who peddled medical treatments for profit. The market for medical care eventually gave rise to regulatory oversights to control the commodification of treatments and associated technologies. The result is a dynamic interplay of market and regulatory forces that in the process of protecting the individual, by some part of necessity removes the individual as a focal point of medical care and insists on standardization and normalization. The term biogeotechnological organism aims to emphasize and bring to the fore the individual not only within T1D management, but also within the important interactions with medical doctors, healthcare providers, regulators, and commercial entities. Efforts of health automation that works for and with biotechnological organisms within the emerging markets and regulatory forces are better positioned to address the complexity of entanglements experiences in chronic disease management.

Normalization of Health Automation

As Chapter 3 demonstrates, efforts of normalization continue to take place in contemporary medical care driven by health automation. These efforts are directed toward patients with T1D and are led by the regulatory expert community involved in establishing and maintaining norms. These efforts are targeting patients with the intent to

direct them toward achieving a state of "normalcy" defined by the prevailing vision of what a "normal" and "healthy" individual should look, act, and behave like. These efforts are enhanced by biomedical technologies used in T1D care with additional technologically-derived metrics, measures, and norms. Furthermore, the strategy of governmentality plays well into the efforts of patient population normalization. Governmentality as an approach and as a strategy of social regulation and control enhances and expands normalization from an individual patient to the population.

While health automation furthers normalization, it also hinders it. Normalization can be viewed as an effort of bringing one to the "normal" and "healthy" state of being according to the generally accepted norms of blood glucose data, A1C test results, or one's lifestyle. Normalization can also be viewed as a physical and behavioral appearance of "normal" and "healthy" according to the prevailing vision of who the ideal Americans should be.[537] However, biomedical technologies used in T1D management move the patient away from a "normal" or "healthy" state in a number of ways. The physical appearance of biomedical technologies physically attached to one's body moves that individual away from the conventional "normal" unencumbered body to a hybrid body constituting a biotechnological organization. The need for close interaction of the user with technology and the need for constant attention to maintain the technology adds to the "abnormality" of that individual in a behavioral sense, a sense that is reinforced by an auditory and physical cue from the biomedical system. The resultant biotechnological organism constructed through the close interconnection and symbiosis between the

[537] Feudtner, John Christopher. 2003. Bittersweet: Diabetes, Insulin, and the Transformation of Illness. Studies in Social Medicine. Chapel Hill: University of North Carolina Press.

patient's body and the machine does not fit the standard American notion of the "normal."

Moving beyond physical appearance, achieving constant "normal" BG levels for individuals with T1D is not an attainable state. First, there are numerous variable factors of everyday life that influence an individual's BG that are beyond reasonable control. Some of these variables include puberty, menstruation, stress levels, and even changes in weather (temperature, humidity, etc.). Second, the very notion of achieving "normal" BG levels goes against the definition of T1D which defines individuals with diabetes as having non-normal A1C. Even individuals managing their daily BG with extreme attention to detail are generally unable to achieve anywhere near prediabetic, let alone normal, A1C levels. Individuals with normal BG do not have any form of diabetes and therefore do not require normalization. However, the autoimmune status of T1D indicates there is a constant internal struggle where one's immune system mistakenly attacks healthy tissues of the pancreas. Therefore, "abnormality" comes from within the body in a process that cannot with current biomedical technologies be halted without severe side effects. Third, the normalization of individuals categorized as an "at-risk" population by definition sets them apart from the "normal" since they are always in the position to deviate further from the norm. Additional invisible and visible deviations from the norm induced by T1D include but are not limited to severe BG fluctuations, internal organ damage, blindness, and limb amputations.

The idea of the disappearing concept of health[538] points to the concepts of "normal" and "healthy" as spectrums rather than absolutes. Health is no longer an

[538] Dumit, Joseph. 2012. Drugs for life: how pharmaceutical companies define our health. Duke University Press.

achievable target and is now replaced by risk mitigation as the primary target of medical interventions. Health is being replaced by the idea of "healthier" where efforts are aimed at innovations in technologies and pharmaceuticals that reduce the risks of current or future diseases.[539] Simultaneously, "normal" was replaced with the idea of "as close to normal as possible." Thus, one's normality in contemporary technologically-dependent medical care is defined and assessed based on risk perception and statistical measurements standardized across populations. Biomedical technologies play a central role in T1D normalization with efforts of risk prevention, reduction, and measuring. Biomedical technology use itself is becoming normalized. For instance, within the current state of T1D automation, the biotechnological organism necessitates visual abnormality of technological use to achieve a state "as close to normal as possible" and to prevent further visible or invisible deviations from the norm. Risk prevention is the focus of health automation and normalization in contemporary medical care. The vast number of risks and entanglements associated with biotechnological organisms indicate a state of abnormality as the norm. It might be better to accept abnormality as the norm in health automation than increase user distress in an effort to automate something or someone who cannot be normalized in the traditional sense of the term.

The use of regulated biomedical technologies further determines the roles and responsibilities of different actors in contemporary society. Patients are viewed as victims of a relentless disease, in need of guidance and care. Medical professionals are viewed as figures of authority and a source of expertise. Governmentality theory in risk management offers a view on the distribution of power dynamics within T1D care,

[539] Dumit, Joseph. 2012. Drugs for life: how pharmaceutical companies define our health. Duke University Press.

disease management, and the establishment of norms. Governmentality, as an approach to political rule for social regulation and control, supports individual rights and freedoms "against the excessive intervention of the state."[540] However, the logic of social regulation and control views the population as a body in need of management, intervention, and protection to increase and maximize health, wealth, and productivity.[541] Thus, members within the population are compared against established norms and determined to be acceptable or "at-risk." The "at-risk" status of every individual with T1D necessitates additional interventions, monitoring, and other control measures.

Regulated biomedical technologies and health automation at large can be considered political tools used to maintain control, to categorize patients and experts to create a gap between those expected to have the expertise to steer the patient to the best possible health outcomes and those who are expected to accept prescribed regimens and follow directions. Such political controls are established to keep those with authority in positions of power and maintain professional boundaries established to safeguard recognized regulatory experts through implicit behavioral norms. Patients are expected to be engaged, but not rebellious. They are expected to follow expert recommendations, but not proactively modify prescribed regimens or tinker with biomedical technologies. Patients are expected to follow the preestablished standards of care without challenging them.

The DIY community is proactively challenging the status quo, by emphasizing technologically-derived risks and concerns. The community points to the need for increased diversity of actors involved in biomedical technology innovation. While this

[540] Lupton, Deborah. 1999. Risk. New York: Routledge.
[541] Ibid.

can create additional challenges and tensions that must be overcome, it is likely to result in biomedical technologies that better meet the needs of their intended users. Even the FDA cannot ensure risk-free biomedical technologies as evidenced by prior recalls of T1D technologies.[542] FDA approval means the best acceptable judgment of safety based on available data and evidence, not an absolute mark of safety. Further, biomedical technologies are not designed to fit every user, but the majority of users or the average user – i.e. the norm. Since everyone's diabetes differs, standardization and optimization of biomedical technologies ultimately leave some patients behind. Moreover, the increasing complexity of biomedical innovation obfuscates normalization. It obscures the checks and balances to guarantee safety, security, trust, and transparency. The norm is no longer patient-based but code-based embedded in biomedical systems designed to return the average person to a normal BG level.

Chapter 4 demonstrated the increasing involvement of patients as technological users in the DIY biomedical community that is influencing the formulation of the Standards of Diabetes Care[543] and redefining what "normal" means. According to the DIY community, normal means patients can be empowered to make therapeutic decisions that affect their health. It means patients can be proactive solution-seekers that self-educate and embrace their increasing responsibilities with T1D self-management. It means allowing patients the power to recognize they do not fit the "norm" and can and should be able to modify their treatments to better fit their needs. In the process of creating the OpenAPS the DIY community is redefining what "normal" patients' roles or

[542] ADA. 2021. American Diabetes Association Elevates Resources on Medtronic Recalls. Accessed 11.28.22. https://diabetes.org/newsroom/official-statement/2021/american-diabetes-association-elevates-resources-medtronic-recalls.
[543] Lewis, Dana. 2022. We Have Changed the Standards of Care for People With Diabetes. DIYPS.org https://diyps.org/2022/12/23/we-have-changed-the-standards-of-care-for-people-with-diabetes/.

behaviors should be in their health care by inadvertently facilitating a shift in the current power structure that is altering the perception of what the normalization of automation looks like. The DIY innovators through their advocacy and their close interactions with medical professionals, policymakers, and the global community of patients, caregivers, and advocates are demonstrating not only capability and skills but also providing a significant contribution to the reconceptualization of what normal health automation in diabetes management is and should be.

T1D, considered to be an invisible disease, is made visible through biomedical technologies. This visibility is outside the expected norms for the "idealized" citizen.[544] Yet, the DIY community is redefining what this citizenship entails by taking more control over their health, biomedical technologies, and associated risks. The community is also taking control over their data outputs, data ownership, biomedical technology customization, and knowledge production by pulling together resources from the global #WeAreNotWaiting movement and by openly sharing them to improve accessibility and affordability. The co-construction of biomedical technologies through increasing patient involvement in diabetes care and technological innovation is shifting roles, perceptions, and norms closer to align them with patients' phenomenological experiences and patient-specific needs. This is both breaking patients out of established norms and facilitating a nuanced approach to T1D care.

[544] Lupton, Deborah. 1999. Risk and the Ontology of Pregnant Embodiment In Risk and Sociocultural Theory: New Directions and Perspectives, edited by D. Lupton. Cambridge, UK, New York & Melbourne, Cambridge University Press, 59-85.

Commodification and Regulation of T1D

The drive for the APS and further automation in T1D management can be seen as a result of the failure of other methods, such as organ transplantation,[545] stem cell research, insulin-producing cell injections, and implantable patches that require immunosuppression.[546] Technological mimicry of biological processes to solve problems with disease and disability is not a new concept. As this research demonstrates, the risk is at the core of biomedical technologies and other efforts to solve diabetes. Alternative methods of approaching T1D did not gain mainstream acceptance due to higher risk concerns compared to the requirements of T1D management with the APS and other devices. The risk continues to be a primary consideration in the quest for T1D automation as well as the primary guiding principle of therapeutic decisions. Additionally, risk remains a tool used by those in the position of authority as the main lever in the efforts of patient population control.

The future of health automation and the state of the population's health is uncertain, insecure, and risky. The COVID-19 (SARS-CoV-2) pandemic, which started in late 2019, is an example of the power of disease to disrupt the present and destabilize the future. Power influences the ability to intervene in the present and to shape the future. The drive for health automation is fueled by efforts to make the future less uncertain, less insecure, and less risky at the individual, national, and global levels. These efforts range from expanding the use of T1D technologies among patients to reduce the risks of health

[545] Stratta R. J. 1998. Immunosuppression in pancreas transplantation: progress, problems and perspective. Transplant immunology, 6(2), 69–77. https://doi.org/10.1016/s0966-3274(98)80020-8.
[546] Rother, K. I., & Harlan, D. M. 2004. Challenges facing islet transplantation for the treatment of type 1 diabetes mellitus. The Journal of clinical investigation, 114(7), 877–883. https://doi.org/10.1172/JCI23235.

complications[547] to Strategic National Stockpiling (SNS) of supplies, medicines, and biomedical technologies to protect against future health threats[548] and the global health emergency preparedness and prevention efforts led by the World Health Organization (WHO) "to strengthen and expand systems to rapidly detect, investigate and assess potential threats to public health; and to respond immediately and systematically to manage acute emergencies."[549]

Health automation is seen as a solution to address not only an individual's blood glucose management issues but also to address a regional, national, and global health crisis. Biomedical technologies, in addition to addressing T1D, also allow for care optimization, monitoring, and surveillance to achieve the best possible future for all those involved. Rose argues that "we are seeing the emergence of a novel somatic ethics, imposing obligations yet imbued with hope, oriented to the future yet demanding action in the present."[550] This is evident in the management of T1D and beyond. Health automation allows for new ways to intervene in people's lives and manage disease in the name of health, safety, and security. New practices of patient and population control further expand the purview of regulatory experts and biomedical technologies toward preventative interventions to keep individuals free from future risks.

The concept of health automation facilitates the visualization of an effort-free state of health with less work for patients, caregivers, doctors, public health professionals, students, and others engaged in the provision, regulation, and/or receipt of health

[547] Foster NC, Beck RW, Miller KM, et al. 2019. State of type 1 diabetes management and outcomes from the T1D Exchange in 2016–2018. Diabetes Technology & Therapeutics. pp.66-72. http://doi.org/10.1089/dia.2018.0384.
[548] ASRP. 2023. Strategic National Stockpile. HHS, Administration for Strategic Preparedness and Response (ASPR). https://aspr.hhs.gov/SNS/Pages/default.aspx.
[549] WHO. 2023. Health emergencies. https://www.who.int/our-work/health-emergencies.
[550] Rose, Nikolas. 2009. The politics of life itself: Biomedicine, power, and subjectivity in the twenty-first century. Princeton: Princeton University Press.

services. However, the notion that "technology will set you free"[551] is misleading on multiple accounts. First, it removes the patient's role in the process of grappling with the challenges of disease and self-care. It removed patients' independent capability to act and influence their bodies and their will. Second, it provides a simplified understanding of how T1D affects the body by narrowing it to selected biological problems, such as blood glucose (BG) regulation, and disregarding psychological, social, economic, and other issues that influence one's health and well-being. Third, biomedical technologies can be constraining, not freeing, in a number of ways. For instance, they often require continuous user input and effort for maintenance, repairs, and use. Further, the APS itself visually wraps (quite literally with tubed devices) its user's body in a tangled network of computers, devices, and pharmaceuticals. Thus, users become freed from some burdens of BG regulation but become increasingly burdened by the work that these technologies require as well as by the entanglements of their bodies with devices, outside systems, organizations, and hostile networks upon which they become dependent.

Cutter wrote: "The technological complexity and interdependence of many of our transportation, power, utility, and economic systems mean that failure in one cascades to disruptions and failures in another."[552] Cutter's statement rings true, more so today than ever before. The United States is growing in complexity and interdependence within and beyond the provision of medicine, with more systems joining the "grid" of connectivity now to include all levels of the government, financial system, commercial entities, and the healthcare system. On one side there is the connectivity to the digital networks and

[551] Sargent, Jennifer. 2021. Technology will set you free. Nature Portfolio. Accessed 1.16.23. https://www.nature.com/articles/d42859-021-00024-z.
[552] Cutter, Susan L. 2003. The Vulnerability of Science and the Science of Vulnerability Actions. Annals of the Association of American Geographers 93 (1): 1-12.

the transfer of information between the systems. On the other side, there is physical connectivity across sectors, all interconnected and interdependent. This includes medical supplies, international logistics, transportation, the federal government, tourism, travel, pandemic, and unemployment, to name a few. Every system is vulnerable in its own right, but the stakes are high when one's health is tied to the strengths and weaknesses of the grid.

Contemporary society objectifies technology. Technology is viewed as the application of science. Subsequently, scientific objectivity is transferred to technologies. This also applies to biomedical technologies which are often perceived as neutral. This neutrality is evident in Wailoo's writing of medical technology considered to be a neutral artifact of history,[553] as this work demonstrates this is not the case due to the harms and other impacts of technology. Biomedical technologies are used both to clarify disease, by generating additional data for decision-making and to obscure the understanding of the disease, by adding complexity and entangling the user in a network of devices and the digital infrastructure. Biomedical technologies have the potential to free its user from some burdens of blood glucose management at the same time as it has the potential to constrain the user with the burdens of technological management, maintenance, and additional entanglements.

Through risk discourse analysis this work redraws the boundaries of market-based healthcare, where corporations and clinics are working to gain a greater share of the consumer pie, to community-based healthcare, where the biological community is working to spare everyone from the risks of disease in whichever form they come and

[553] Wailoo, Keith. 1999. Drawing Blood: Technology and Disease Identity in the Twentieth-Century America. Baltimore: Johns Hopkins University Press.

however these risks are perceived. The two communities analyzed demonstrate different social dynamics with similar objectives to reduce the burdens of disease, but different ways to solve it. Therapeutic innovations inextricably entangle individuals with T1D "in a network of power relations articulated to laborious surveillance and laissez-faire consumerism."[554] This previous quote highlights the power differentials between the two communities and the drivers of medicalization, consumerism, and marketization of healthcare and society.[555] While biomedical innovations offer some incremental utility to the patient, they have also fueled significant commercial profits.

The DIY biological community, represented to a greater degree by technological users, is disturbing the balance of established healthcare practices and the directionality of healthcare provision. Techno-deterministic logic of health automation relieves the responsibility of individuals to change and impact technologies and leaves them hopeful that technologies will themselves develop in a way projected by those in the position of authority. The indisputable faith in biomedical technologies negates the need for human fulfillment, the search for social equality, and the struggle that drives innovation.[556] Daily struggles with the disease are reflected within the DIY community. This struggle, combined with the need to increase access, affordability, and social equality drives the DIY community. Without this drive, the community of users would have no motivation to innovate and spend personal time and resources to make a difference in disease management for themselves and so many others.

---

[554] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. P.185. http://www.jstor.org/stable/j.ctv12fw5z8.
[555] Clarke, Adele, Laura Mamo, Jennifer Ruth Fosket, Jennifer R. Fishman, and Janet K. Shim, eds. 2010. Biomedicalization: Technoscience, Health, and Illness in the U.S. Durham, NC: Duke University Press.
[556] Noble, David. 1986. Forces of Production: A Social History of Industrial Automation.

Access to novel commercial biomedical technologies can involve a lengthy process of approval, evaluation, manufacturing, and prescription. The DIY community is disillusioned with the belief that manufacturers or policymakers keep patient needs in mind or understand the true urgency and priorities of T1D.[557] Since the FDA takes a "risk-based approach" to biomedical technologies, the DIY community of citizen scientists undertakes a "release-and-repair approach" typical of Silicon Valley.[558] The FDA is concerned with safety and regulation to mitigate the potential harms resident in monetized health care practices, while the DIY community is concerned with the speed of innovation not typically characteristic of biomedicine due to liability, regulators, and risks.[559]

Regulated biomedical technologies are seen as the answer and the solution to the problem of diabetes within the regulatory expert community. Techno-deterministic logic views health automation as the reproduction of expertise among scientists and medical professionals. Commodified medicine is structured to safeguard against deliberate wrongdoing, error, fraud, or manipulations occurring from incentives arising from or during the commodification of healthcare solutions. However, despite regulation and control mechanisms to create "safe" products, it is not uncommon for FDA-approved devices to lead to injury, cause harm, or provide incorrect outputs. In many ways, the regulatory processes enhance perceptions of safety surrounding commercial health

[557] Munro Dan. 2014. The View Of Digital Health From An 'Engaged Patient'. Forbes Healthcare. https://www.forbes.com/sites/danmunro/2014/03/09/the-view-of-digital-health-from-an-engaged-patient/?sh=378fad282b79.
[558] Linebaugh, Kate. 2014. Citizen Hackers Tinker With Medical Devices. Accessed 09.27.22. http://online.wsj.com/articles/citizen-hackers-concoct-upgrades-for-medical-devices-1411762843?reflink=desktopwebshare_permalink.
[559] Linebaugh, Kate. 2014. Citizen Hackers Tinker With Medical Devices. Accessed 09.27.22. http://online.wsj.com/articles/citizen-hackers-concoct-upgrades-for-medical-devices-1411762843?reflink=desktopwebshare_permalink.

solutions. Regulation and regulatory approvals of biomedical technologies provide security for technologies that were vetted, verified, and tested. Trust in biomedical technologies that made their way through regulatory oversight and are subsequently approved for use in the practice of medicine subvert the art of medicine rooted in doctor-patient relationships. The science verified through regulatory processes is accepted, translated into standards, and implemented on passive patients given limited insight into the processes by which the standards were derived, and the technologies approved. Science is valuable. It informs the practice of medicine. But when it is implemented in a manner that subsumes the patient into the standard and judges them against the norm it inadvertently commodifies them. Overreliance on science and technology in the practice of medicine shifts attention away from the patients, patients' particular needs, their experience, and priorities as well as their unique technological requirements.

Decisions regarding therapeutic recommendations or health automation based solely on ADA, FDA, or other regulatory standards are based on a single perspective that constitutes one piece of the broader puzzle of patient care. The patient becomes a product to be shaped into a defined mold. A mold which in the case of many diseases and T1D in particular is often ill-fitting. When the mold becomes flexible, as is the case in the DIY community, the result is the decommodification and humanization of the patient. The standards of care remain, but the patient now has an expanded voice because they are a part of the process of care provided through the creation of the DIY APS and its implementation. The DIY innovators are also able to enforce a new relationship, one predicated not on an abstract regulated biomedical device, but rather on a customized system tailored to their unique needs. They interject into the rigid mold a degree of

flexibility that is both beneficial for them as a patient and forces commercial entities and regulatory bodies to speed up innovation and open new approaches to democratize health automation in new and more humane ways.

Commodification within T1D goes hand in hand with biomedicalization. It is an effort to expand, standardize and metricize the customer base for new pharmaceuticals and technological solutions, creating the impression that health, normalcy, and risk-free status can be purchased. Commodification in T1D care is risk-based. It expands to include not only BG regulation but also related complications, skin conditions, comorbidities (presence of two or more diseases), and mental health issues as separate treatable states. This also applies to symptomatic and asymptomatic conditions. Commodification encourages companies to engage in big data research and statistical analysis to find possible new treatment categories. Regulated systems become a source of commodities such as data available to device producers, medical researchers, and commercial firms producing ancillary products and services.

Commercial interests drive health innovation in ways that alter priorities in contrast with those directly affected by T1D. The profit-seeking motive, the commodification of health, makes the products and provision of services distinctly different from non-commodified DIY approaches. The DIY community demonstrates that the top-down approach to care is not working for many providers and patients. It shows that commodification has its limits. Those limits can and do undermine the health and well-being of T1D patients. Generally, this finding is represented in the ever-worsening U.S. national-level data on mortality and diabetes management health outcomes. Additionally, the growth of the #WeAreNotWaiting movement indicates a strong

dissatisfaction among patients and caregivers. Normalization and commodification do not prioritize the individual. They prioritize and focus on the population, statistical measures, and on economic benefits.

Commodification in health automation influences how users see themselves and what they expect from biomedical technologies. Failures of commodification are reflected in the DIY community and the #WeAreNotWaiting movement. DIY APS changes how patients view their care with transparency and choice, as part of the biological community, empowered and motivated. The patient ceases to be a customer and becomes an innovator, free to choose, customize care, and change technologies. DIY technologies can also be considered a burden to patients who do not feel comfortable with biomedical technologies and who might feel forced to be a DIY because of the inaccessibility of other regulated technologies. Patients as technology users gain clarity about their therapeutic tools and their risks outside of the distorted presentations of miraculous biomedical technologies or misrepresented risks to entice more individuals to buy into them.

Knowledge Production in T1D Automation

Individuals with T1D, members of the DIY community, have lived experience and technical knowledge. This experience is an essential reason why the #WeAreNotWaiting movement has gained prominence and why the community of DIY innovators is growing and thriving. Despite the daily requirements of managing T1D, maintaining biomedical technologies, and overseeing food intake and exercise, individuals with T1D approach their disease in highly creative and varied ways through

the "tactics of material participation."[560] These tactics indicate that the community and the movement around which it is centered is not abstract, but an entangled participant or community embodying a range of health practices, biomedical technology engagements, efforts of patient activism, and advocacy. Living with a chronic disease such as T1D requires biomedical technologies, but engagements with technologies among patients differ. Moreover, there is an expectation within the DIY community for technological variability due to the variability of patients and their needs.

Kline and Pinch refer to technologies appropriated and redesigned by non-expert groups, such as farmers or in this case patients, as "agents of technological change."[561] Placing the power of technological change with the patient helps to free the movement for innovation and knowledge production from strictly regulatory expert-driven towards patient-driven, need-based, and contextual innovation. When patients become innovators, they not only help in addressing their own needs but also help to close the gaps in commercial innovations. "The economic reality is that commercial producers and medical service providers are unlikely to be able to deliver everything patients need."[562] Therefore, patients as biomedical technology users, have an important role to fulfill, and the sooner they stop waiting for others to do it, the sooner new solutions will become available to address a wide range of health concerns.

---

[560] Jansky, B., Langstrup, H. 2022. Device activism and material participation in healthcare: retracing forms of engagement in the #WeAreNotWaiting movement for open-source closed-loop systems in type 1 diabetes self-care. BioSocieties. https://doi.org/10.1057/s41292-022-00278-4.

[561] Kline, Ronald, and Trevor Pinch. 1996. Users as Agents of Technological Change: The Social Construction of the Automobile in the Rural United States. Technology and Culture 37, no. 4 (1996): 763–95. https://doi.org/10.2307/3107097.

[562] Demonaco, H., Oliveira, P., Torrance, A., von Hippel, C., von Hippel, E. 2020. When patients become innovators. In: Tiwari, R., Buse, S. (eds) Managing Innovation in a Global and Digital World. Springer Gabler, Wiesbaden. https://doi.org/10.1007/978-3-658-27241-8_9.

The freedom to innovate allows for greater complementarity between DIY and regulated commercial innovations where more health conditions and more health concerns are likely to be addressed. Regulated biomedical technologies envision and devise an average user with common needs to maximize the number of suitable users in order to ensure a return on investment for corporations producing biomedical technologies. Such a conception of the user, based on statistical significance, is not a universal representation of all patients and by definition, most patients will and do deviate from norms. DIY biomedical technologies, based on the variable user needs, emphasize the need for customization and universality. Universal design accounts for the needs of more users so that technology can be used by as many individuals as possible.[563] The freedom to innovate shifts the conceptualization of users from passive recipients to active participants. This shift better frames and articulates the risks associated with T1D management.

Since there is great complementarity between regulated and unregulated technologies in terms of fulfilling a variety of patient needs, this begs a question of who has the right to contribute to transformative biomedical technologies? The answer to this question seems obvious since everyone benefits in a society that has more health conditions addressed and/or addressed more efficiently. Everyone should be allowed to innovate and apply their expertise to better their lives and those around them. However, when it comes to health innovation, not everyone is recognized as an expert due to preestablished criteria, formal education, certification, and professional status. Further, not everyone is authorized to implement innovative health technologies due to regulatory

[563] Petrick, Elizabeth R. 2015. Making Computers Accessible: Disability Rights and Digital Technology. History of Science, Technology, and Medicine. Baltimore: Johns Hopkins University Press.

restrictions, policies, and procedures. The tension between patient needs and the ability to innovate by a variety of individuals with expertise should be relieved by removing regulatory barriers. Health regulation should be modified to create a pathway for lay experts, especially those not seeking profitability, to innovate in healthcare in a way that still upholds user safety without being prohibitively discouraging.

The techno-deterministic logic of health automation exemplified by the regulatory expert community consists of a future of health that is determined by intense efforts aimed at innovation and automation to ensure profitability and progress. However, since technology is not a self-evolving entity, it requires input from multiple different actors and is influenced by a variety of economic, political, cultural, and social factors. The DIY community demonstrates an ability to understand biomedical technologies and modify and maintain them, despite experiencing a host of issues related to legality, safety, and lack of support. This opens a new perspective on situated knowledge production.

Brody, a medical doctor and a philosopher of medicine asserts that in chronic disease management individual patients' perspectives, experiences, and stories become unique tools and essential instruments in the process of making therapeutic recommendations and clinical decisions.[564] "A successful outcome from the visit is a coauthored, mutually negotiated story, not a physician-imposed story."[565] The perspectives of the DIY biological community are essential to telling the story of patients as technological users in the coauthored policies, regulations, and future innovations as a direct response to patients' needs. Patient's storytelling and knowledge production is reflected in the work of DIY community members who innovate, educate and advocate.

[564] Brody, Howard. 1987. Stories of Sickness. New Haven: Yale University Press.
[565] Ibid.

These stories are changing common perceptions of patients' roles in their care. They are changing who has the right to innovate and impact the regulatory environment.

While technology is considered to be more than a mere artifact, neither fully under the purview of science nor fully outside of it,[566] biomedical technology is interconnected with science, medicine, and social, cultural, political, and economic forces guiding innovation. "What makes the phenomenon of #WeAreNotWaiting distinct, within this context, is that code, data, and (digital) devices are their shared concern and the means through which loopers[567] engage individually and collectively."[568] Biomedical technologies are tools of engagement and knowledge production. This knowledge pertains not only to technologically derived data but also to the influences different factors have on the biotechnological organism as discussed previously.

David Noble, in his analysis of post-WWII industrial automation, examines how "technological possibilities have been delimited by social constraints."[569] He describes how decisions to automate had a positive influence on industry, speed, and quality of production, but also had negative effects, such as means of production including labor. Biomedical technologies for diabetes management also have positive and negative impacts and effects. For example, the APS offers users and healthcare providers additional metrics, and historical and real-time data regarding the patient's state of health and blood glucose management. It allows users to have greater oversight over their bodies and the impact of outside factors on their health. As this work demonstrates,

---

[566] Johnson, Ann. 2006. "Revisiting Technology As Knowledge." Perspectives on Science 13 (4): 554–73.
[567] Loopers is the term used for individuals with T1D who use the Loop application, a DIY closed-loop algorithm, for their DIY APS on their iPhone to manage T1D and administer insulin in response to the CGM data.
[568] Jansky, B., Langstrup, H. 2022. Device activism and material participation in healthcare: retracing forms of engagement in the #WeAreNotWaiting movement for open-source closed-loop systems in type 1 diabetes self-care. BioSocieties. https://doi.org/10.1057/s41292-022-00278-4.
[569] Noble, David. 1986. Forces of Production: A Social History of Industrial Automation.

biomedical technologies can also cause harm, and stress and increase risks of adverse health outcomes. Thus, automation is not inherently good, and efforts of innovation should consider both positive and negative impacts as well as both users and non-users to reduce risks and increase accessibility. Emphasizing the duality of biomedical technologies and their positive and negative effects on patients' lives provides a more informed perspective for all stakeholders.

Many of the technologies discussed by Noble in the automation of the machine-tool industry were often a replacement of skilled labor thus "de-skilling" the labor. Interestingly, the de-skilling of individuals is also pertinent to biomedical technologies. The more individuals rely on and trust biomedical technologies to take over the function previously conducted by users or medical professionals, the more performing these skills manually become secondary or unnecessary. Deskilling is not universal across the population because the use of advanced technologies like the APS is not universal. However, increased reliance on and trust in biomedical technologies to do what they were promoted to do, might leave many individuals vulnerable especially during technological failure, such as the 2019 Dexcom failure,[570] where one incident can lead to a fatal outcome.

The true consequences of further automation of diabetes care are not known, but the more control machines are allowed to have over human health the more severe the consequences of error, malfunction, or technological failure might be. Current biomedical technologies, such as the APS, require an attentive and active user, not one who is indifferent to self-care. Will biomedical technologies remain freeing if users surrender

[570] O'Connor, Anahad. 2019. In Weekend Outage, Diabetes Monitors Fail to Send Crucial Alerts. The New York Times. https://www.nytimes.com/2019/12/02/well/live/Dexcom-G6-diabetes-monitor-outage.html.

their responsibility to a machine? The promise of greater control over disease through automation should enhance consciousness, not erode it.[571] The DIY community's efforts to facilitate data accessibility and transparency, combined with encouraging users to be attentive and active, are changing the population of individuals with T1D cautiously surrendering their responsibility to machines. The DIY community encourages enhancing consciousness with greater awareness of risk and a greater focus on self-education, greater engagement with biomedical technologies, and more informed therapeutic decision-making.

The knowledge produced within the DIY community has a sense of urgency where risks of living with a chronic disease are internalized and bring the need to take action, innovate, learn, and address the immediate pressing risks of disease and of technologies used in its management. This knowledge is essential for the individualistic approach to healthcare in what Mol calls the logic of care, targeting specific needs, calling for adaptability of care, perseverance, and tenacity without imposing guilt.[572] This knowledge is also important to consider efforts to improve contemporary approaches to medical and health services provision where success is defined not only by clinical outcomes but also by business interests, professional needs, and regulatory requirements. This knowledge requires consideration in a balancing act with all the other requirements and pressures of modern healthcare.

The DIY community is changing the standards of care for people with diabetes by increasing their presence and significance in the ADA-published document and peer-

[571] Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press. http://www.jstor.org/stable/j.ctv12fw5z8.
[572] Mol, Annemarie. 2008. The logic of care: health and the problem of patient choice. London: Routledge.

reviewed journals.[573] Additionally, the Juvenile Diabetes Research Foundation (JDRF) has created the Open Protocols Initiative "to establish clear financial, regulatory and legal frameworks" in support of patient innovation and to "forge pathways to make devices compatible and enable open-protocol systems."[574] These efforts are aimed at helping overcome some of the challenges of the use and implementation of open-protocol systems.

Since T1D is managed mostly by patients, diabetes education should be made accessible and the importance of knowledge production by patients should be normalized. DIY innovators not only take the means of production into their own hands but also challenge expertise and knowledge practices in biomedicine. Variations between individuals and their needs are not an impairment, but an opportunity to provide customized or universal technologies and medical therapies that fit more patients. Ruha Benjamin wrote: "[u]ltimately we must demand that tech designers and decision-makers become accountable stewards of technology, able to advance social welfare."[575] One way to do so is to provide customized therapy and focus on personalized and precision medicine.[576] If biomedical technologies are designed to reduce risks, then certain populations are living riskier lives than others. For instance, those able to afford biomedical technologies and pharmaceuticals, are able to purchase "safety and freedom from risk."[577]

---

[573] Lewis, Dana. 2022. We Have Changed the Standards of Care for People With Diabetes. DIYPS.org https://diyps.org/2022/12/23/we-have-changed-the-standards-of-care-for-people-with-diabetes/.
[574] JDRF. 2017. Open-Protocol Automated Insulin Delivery System Initiative. Accessed 1.20.23. https://grantcenter.jdrf.org/rfa/open-protocol-automated-insulin-delivery-system-initiative/.
[575] Ruha, Benjamin. 2019. Race After Technology: Abolitionist Tools for the New Jim Code. Cambridge, UK: Polity.
[576] Stanford Medicine X. 2017. Ben West: Linking Medical Devices. Accessed 10/19/22. https://www.youtube.com/watch?v=CXTxRyG34tA.
[577] Beck, Ulrich. 1992. Risk Society: Towards a New Modernity. London: Sage Publications.

Who determines how this knowledge is used and what knowledge matters? The quantitative risk thinking that dominates the discourse within the regulatory expert community relies on statistically significant metrics, measures, and data. However, patients do not live within a quantitative risk reality. "No doctor can control a host of patients on an assembly-line basis"[578] and achieve quantification, optimization, and standardization. Therefore, the DIY community members are innovating, and they are doing it differently with a set of values and priorities that diverge from the capitalistic culture of the regulatory expert community toward an open and inclusive culture. Automation should not only address the disease but also lower the amount of responsibility placed on the patient to continuously manage the disease and the technologies in use. One should not change their lifestyle to fit the technology, the technology should be designed to fit one's lifestyle or a multitude of lifestyles. Making technology open and inclusive allows others to audit, verify and debug it making it fairer and more inclusive.

Conclusion: Are We There Yet?

The quest for health automation is not an orderly and straightforward process. It reflects a complicated relationship of alternative solutions, successes, failures, and the interactions of a multitude of actors. The story of T1D automation is full of suffering, challenges, overcoming difficulties, adaptation, change, and the drive of human curiosity. While the role of the individuals with T1D and their contribution towards human curiosity and innovation is often overlooked, this work adds the story of T1D by

[578] Tattersall, Robert. 2009. Diabetes: The Biography. Biographies of Disease. Oxford: Oxford University Press.

elevating DIY innovators in their capacity to learn, share, create and contribute to defining the trajectory of T1D care and possible future medical advances. The body of evidence presented here, while limited in many ways, offers an opportunity to view a different approach to health innovation with redefined priorities of chronic disease care and a fundamentally different power dynamic between all stakeholders involved in chronic disease management.

T1D affects millions of individuals in the United States. This is a chronic disease of national and global importance with a significant economic impact on the fields of medicine, biomedical research, and the U.S. economy. Within the limitations of this narrow study, this work demonstrates that the existing risk discourses pertaining to the top-down regulatory controls and techno-deterministic functions of biomedical technologies are lacking the human element. The medical understanding of disease supported by the regulatory expert community is regulated and reductive. Medical practice views patients through their devices and seeks out an objective reality based on metrics and statistical measures. What they claim is an objective reality is anything but. It is the representation of what programmers and device designers think best represents the standards of care and norms to which patients should adhere. In attempting to view an objective reality, they are losing sight of patients as individuals. By contrast, the DIY community is bringing to the foreground the human element, the human realities of living with a chronic disease with the urgency, drive, and attention that resides at the individual level of each patient. The DIY community empowers individuals and gives them a voice and the freedom to choose.

The disease of T1D and the modern dependency of patients on biomedical technologies constitute an area of shared concern between the techno-deterministic and integrative logics of health automation. Both logics and the communities they represent have similar missions to improve the lives of all with diabetes and to cure the disease. While generally, they are focused on the same goal, their position within the healthcare innovation and provision ecosystems generates different forms of risk thinking and different approaches to health automation. When considering the concept of a biotechnological organism, the questions is no longer what technology is better, regulated or DIY, but how can health automation better address the tensions within the biotechnological organism? There are many unfulfilled medical needs and there is space for all kinds of innovators that should have a "seat at the table" to encourage knowledge development by all, skill building, and patient empowerment for a more comprehensive approach to policymaking. There is a need for regulatory pathways of health automation for a variety of innovators that together can coauthor the future of T1D by joining expertise to create the best possible future reducing suffering from this relentless disease.

Bibliography

Agarwal, S., Simmonds, I., & Myers, A. K. 2022. The Use of Diabetes Technology to Address Inequity in Health Outcomes: Limitations and Opportunities. Current diabetes reports, 22(7), 275–281. <https://doi.org/10.1007/s11892-022-01470-3>.

Ahmed, Awad M. 2007. History of Diabetes Mellitus. Saudi Medical Journal 23 (4): 373–78.

Alsaleh, Fatemah M., Fraser J. Smith, Simon Keady, and Kevin MG Taylor. 2010. Insulin pumps: from inception to the present and toward the future. Journal of clinical pharmacy and therapeutics 35, no. 2: 127-138.

American Diabetes Association Professional Practice Committee. 2022. 2. Classification and diagnosis of diabetes: Standards of Care in Diabetes—2022. Diabetes Care 2022. 45(Suppl. 1):S17–S38.

American Diabetes Association Professional Practice Committee. 2022. 6. Glycemic Targets: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S83–S96. <https://doi.org/10.2337/dc22-S006>.

American Diabetes Association Professional Practice Committee. 2022. 7. Diabetes technology: Standards of Medical Care in Diabetes—2022. Diabetes Care 2022. 45 (Suppl. 1):S97–S112.

American Diabetes Association. 2023. The Cost of Access to Diabetes Technologies. <https://diabetes.org/advocacy/cost-access-diabetes-technologies>.

American Diabetes Association. 2022. Introduction: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S1–S2. <https://doi.org/10.2337/dc22-Sint>.

American Diabetes Association. 2022. Professional Practice Committee: Standards of Medical Care in Diabetes—2022. Diabetes Care. 45 (Supplement_1): S3. <https://doi.org/10.2337/dc22-Sppc>.

American Diabetes Association. 2022. Statistics: Examine the Facts. <https://www.diabetes.org/about-us/statistics>.

American Diabetes Association. 2022. Clinical Compendia: Comprehensive Diabetes Information. <https://diabetesjournals.org/compendia>.

American Diabetes Association. 2022. The cost of diabetes. <https://diabetes.org/about-us/statistics/cost-diabetes>.

American Diabetes Association. 2022. Time in Range: More Than Just a Number. <https://professional.diabetes.org/content-page/time-range>.

American Diabetes Association. 2022. About Us: Who We Are. <https://diabetes.org/about-us>.

American Diabetes Association. 2022. CGM & Time in Range. <https://diabetes.org/tools-support/devices-technology/cgm-time-in-range>.

American Diabetes Association. 2022. Devices & Technology. Better blood glucose meters and more. < https://diabetes.org/tools-support/devices-technology>.

American Diabetes Association. 2022. CGMs – The benefits of this life changing diabetes technology. American Diabetes Association. YouTube. <https://www.youtube.com/watch?v=SSrDxGInHXo>.

American Diabetes Association. 2022. Consumer Guide: Products. <https://consumerguide.diabetes.org>.

American Diabetes Association. 2022. Continuous Glucose Monitors (CGMs) and Me;The Beauty of Technology. American Diabetes Association. YouTube. <https://www.youtube.com/watch?v=w_Locm5JSrs>.

American Diabetes Association. 2022. Professional Journals. <https://diabetesjournals.org/journals>.

American Diabetes Association. 2021. American Diabetes Association Elevates Resources on Medtronic Recalls. <https://diabetes.org/newsroom/official-statement/2021/american-diabetes-association-elevates-resources-medtronic-recalls>.

American Diabetes Association. 2021. How to Thrive with Diabetes. <https://professionaleducation.diabetes.org/Public/Catalog/Main.aspx>.

American Diabetes Association. 2021. Making Diabetes Technology Work. Professional Education. <https://professionaleducation.diabetes.org/Public/Catalog/Main.aspx>.

American Diabetes Association. 2020. Statistics About Diabetes. <https://www.diabetes.org/resources/statistics/statistics-about-diabetes>.

American Diabetes Association. 2019. The iLet Bionic Pancreas Increased Time in Range for Adults with Type 1 Diabetes. ADA's Scientific Sessions. <https://diabetes.org/newsroom/press-releases/2019/the-ilet-bionic-pancreas>.

American Diabetes Association. 2019. The History of a Wonderful Thing We Call Insulin. ADA. <https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin>.

Anderson C. 2010. Presenting and Evaluating Qualitative Research. American Journal of Pharmaceutical Education. 74 (8) 141; DOI: 10.5688/aj7408141.

Anderson, Jim. 2021. Why Word Choice Matters When Describing Patients Who Do Not Follow Medical Advice. The Clinical Advisor. <https://www.clinicaladvisor.com/home/the-waiting-room/word-choice-describe-patients-do-not-listen-to-medical-advice/>.

Anderson, Warwick, and Ian R Mackay. 2014. Intolerant Bodies: A Short History of Autoimmunity. Johns Hopkins Biographies of Disease. Baltimore, Maryland: Johns Hopkins University Press.

Melmer, Andreas, Thomas ZÜGER, Dana M. Lewis, Scott M. Leibrand, and Markus Laimer. 2019. 76-OR: in-depth review of glycemic control and glycemic

variability in people with type 1 diabetes using open source artificial pancreas systems. Diabetes 68, no. Supplement_1.

ASRP. 2023. Strategic National Stockpile. HHS, Administration for Strategic Preparedness and Response (ASPR). <https://aspr.hhs.gov/SNS/Pages/default.aspx>.

Azizi, Mohammad Hossein, Moslem Bahadori, and Farzaneh Azizi. 2013. Breakthrough Discovery of Hba1c by Professor Samuel Rahbar in 1968. Archives of Iranian Medicine 16 (12): 743–45. <https://doi.org/0131612/AIM.0013>.

Banting, Frederick G. 1923. The Nobel Prize in Physiology of Medicine in 1923 lecture - for discovery of insulin. <https://www.nobelprize.org/prizes/medicine/1923/banting/lecture/>.

Beck, Ulrich. 1992. Risk Society: Towards a New Modernity. London: Sage Publications.

Beck, Ulrich. 1999. Risk Society Revisited: Theory, Politics, Critiques and Research Programmes. In World Risk Society. Cambridge et al.: Polity Press/Blackwell, 133-152.

West, Ben. 2022. Building Higher Fidelity Technology - The Quest to Better Treat Type 1 Diabetes. The Data Binge Podcast. <https://poddtoppen.se/podcast/1355543236/the-data-binge/ben-west-building-higher-fidelity-technology-the-quest-to-better-treat-type-1-diabetes>.

Benjamin, Ruha. 2019. Race After Technology: Abolitionist Tools for the New Jim Code. Cambridge, UK: Polity.

Bennett, Jeffrey A. 2019. Managing Diabetes: The Cultural Politics of Disease. New York: NYU Press.

Benton, Adia. 2015. HIV Exceptionalism: Development through Disease in Sierra Leone. Minneapolis: University of Minnesota Press.

Bijker, Wiebe E., Thomas P. Hughes and Trevor Pinch. [1987] 1989. The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology. Cambridge, MA: MIT.

Bliss, Michael. 1982. The Discovery of Insulin. Chicago: University of Chicago Press.

Blue Cross and Blue Shield Association. 2022. Artificial Pancreas Device Systems. Policy Number: MP-636. Blue Cross and Blue Shield of Alabama. <https://al-policies.exploremyplan.com/portal/web/al-policies/home/-/asset_publisher/gvKEs0SDu27L/content/mp-636/78515>.

Bolton, H Carrington. 1884. Papyrus Ebers, the Earliest Medical Work Extant. Weekly Drug News Press, 1–19. <https://hdl.handle.net/2027/uiug.30112000670197>.

Boudreaux, Todd. 2019. DIY lop now compatible with OMNIPOD. Beyond Type 1. <https://beyondtype1.org/omnipod-diy-loop/>.

Brantly, Nataliya D. 2021. Homefront to Battlefield: Why the U.S. Military Should Care About Biomedical Cybersecurity. The Cyber Defense Review 6, no. 2 (2021): 93–110. <https://www.jstor.org/stable/27021378>.

Brantly, Nataliya D. 2021. Homefront to Battlefield: Why the U.S. Military Should Care About Biomedical Cybersecurity. The Cyber Defense Review 6, no. 2 (2021): 93–110. https://www.jstor.org/stable/27021378.

Braune, Katarina, Shane O'Donnell, Bryan Cleal, Dana Lewis, Adrian Tappe, Ingrid Willaing, Bastian Hauck, and Klemens Raile. 2019. Real-World Use of Do-It-Yourself Artificial Pancreas Systems in Children and Adolescents with Type 1 Diabetes: Online Survey and Analysis of Self-Reported Clinical Outcomes. Jmir Mhealth and Uhealth 7 (7): 14087. <https://doi.org/10.2196/14087>.

Brell, Teresa, Ralf Philipsen, and Martina Ziefle. 2019. sCARy! Risk Perceptions in Autonomous Driving. The Influence of Experience on Perceived Benefits and Barriers. Risk Analysis 39 (2): 342-357.

Brodell, Lindsey; Rosenthal, Kenneth S. 2008. Skin Structure and Function: The Body's Primary Defense Against Infection. Infectious Diseases in Clinical Practice: Vol. 16. Issue 2. pp. 113-117 doi: 10.1097/IPC.0b013e3181660bf4.

Brody, Howard. 1987. Stories of Sickness. New Haven: Yale University Press.

Brostoff, J.M., Keen, H. & Brostoff, J. 2007. A diabetic life before and after the insulin era. Diabetologia. 50: 1351. <https://doi.org/10.1007/s00125-007-0641-0>.

Brown, Dalvin. 2019. USA Today. Hacking diabetes: People break into insulin pumps as an alternative to delayed innovations. <https://www.usatoday.com/story/tech/2019/06/05/diabetics-forgoing-new-tech-hacking-into-insulin-pumps/1256667001/>.

Burnside, Mercedes J, Dana M Lewis, Hamish R Crocket, Renee A Meier, Jonathan A Williman, Olivia J Sanders, Craig A Jefferies, et al. 2022. Open-Source Automated Insulin Delivery in Type 1 Diabetes. The New England Journal of Medicine 387 (10): 869–81. <https://doi.org/10.1056/NEJMoa2203913>.

Burren, David. 2021. Anubis – the G6 reborn! Project Anubis. Bionic Wookiee. <https://bionicwookiee.com/2021/04/02/anubis-the-g6-reborn/>.

CDC. 2022. Diabetes: Getting Tested. <https://www.cdc.gov/diabetes/basics/getting-tested.html>.

CDC. 2022. Leading Causes of Death. National Center for Health Statistics. <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>.

CDC. 2022. About CDC: CDC 24/7. < https://www.cdc.gov/about/>.

CDC. 2022. National Standards for DSMES. <https://www.cdc.gov/diabetes/dsmes-toolkit/accreditation-recognition/index.html>.

CDC. 2022. One Health Basics. Centers for Disease Control and Prevention. <https://www.cdc.gov/onehealth/basics/index.html>.

CDC. 2022. COVID-19: People with Certain Medical Conditions. <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

CDC. 2022. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html>.

CDC. 2021. About CDC: CDC Organization. <https://www.cdc.gov/about/organization/cio.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fabout%2Forganization%2Findex.html>.

CDC. 2021. Diabetes Basics. <https://www.cdc.gov/diabetes/basics/index.html>.

CDC. 2021. Living With Diabetes: Manage Blood Sugar. <https://www.cdc.gov/diabetes/managing/manage-blood-sugar.html>.

CDC 2020. Diabetes: Prevent Complications. <https://www.cdc.gov/diabetes/managing/problems.html>.

Chaplin, S. 2016. Insulin pump risks and benefits: an analysis of the EASD/ADA joint statement. Pract Diab, 33: 90-92a. <https://doi.org/10.1002/pdi.2010>.

Clarke, Adele, Laura Mamo, Jennifer Ruth Fosket, Jennifer R. Fishman, and Janet K. Shim, eds. 2010. Biomedicalization: Technoscience, Health, and Illness in the U.S. Durham, NC: Duke University Press.

Clarke, Janine, Judy Proudfoot, Veronica Vatiliotis, Charles Verge, Deborah J Holmes Walker, Lesley Campbell, Kay Wilhelm, Catherine Moravac, Pillaveetil S Indu, and Madeleine Bridgett. 2018. Attitudes Towards Mental Health, Mental Health Research and Digital Interventions by Young Adults with Type 1 Diabetes: a Qualitative Analysis. Health Expectations 21 (3). John Wiley & Sons, Ltd (10.1111): 668–77. doi:10.1111/hex.12662.

Cordier, Jean-François. 2014. The expert patient: towards a novel definition. European Respiratory Journal. 44 (4) 853-857; DOI: 10.1183/09031936.00027414.

Cowan, Ruth Schwartz, 1983. More Work for Mother: The Ironies of Household Technology from the Open Hearth to the Microwave. New York: Basic Books.

Crabtree, Thomas, McLay, Alasdair,Wilmot, Emma. 2019. DIY artificial pancreas systems: here to stay? Practical Diabetes. <https://doi.org/10.1002/pdi.2216>.

Cutter, Susan L. 2003. The Vulnerability of Science and the Science of Vulnerability Actions. Annals of the Association of American Geographers 93 (1): 1-12.

Lewis, Dana M., Richard S. Swain, and Thomas W. Donner. 2018. Improvements in A1C and time-in-range in DIY closed-loop (OpenAPS) users. Diabetes 67, no. Supplement_1.

Daniel Clery. 2015. Could your pacemaker be hackable? Science, 347, no. 6221, (AAAS, 2015): 499, <https://science.science- mag.org/content/sci/347/6221/499.full.pdf>.

Datye, K.A., Moore, D.J., Russell, W.E. et al. 2015. A Review of Adolescent Adherence in Type 1 Diabetes and the Untapped Potential of Diabetes Providers to Improve Outcomes. Curr Diab Rep 15, 51. <https://doi.org/10.1007/s11892-015-0621-6>.

David Fonte, Sébastien Colson, José Côté, Rachel Reynaud, Marie-Claude Lagouanelle-Simeoni, Thémis Apostolidis. 2019. Representations and experiences of well-being among diabetic adolescents: Relational, normative, and identity tensions in diabetes self-management. Journal of Health Psychology: An Interdisciplinary, International Journal Volume: 24 Issue 14 (2019) ISSN: 1359-1053 Online ISSN: 1461-7277.

David Klonoff. 2015. Cybersecurity for Connected Diabetes Devices. Journal of Diabetes Science and Technology, 9, no. 5 (2015): 1143-1147. <https://doi.org/10.1177/1932296815583334>.

David Noble. 1986. Forces of Production: A Social History of Industrial Automation.

Delamater, M. Alan. 2006. Improving Patient Adherence. Clin Diabetes 1 April 2006; 24 (2): 71–77. <https://doi.org/10.2337/diaclin.24.2.71>.

Demonaco, H., Oliveira, P., Torrance, A., von Hippel, C., von Hippel, E. 2020. When patients become innovators. In: Tiwari, R., Buse, S. (eds) Managing Innovation in a Global and Digital World. Springer Gabler, Wiesbaden. <https://doi.org/10.1007/978-3-658-27241-8_9>.

Dexcom Inc. 2023. Dexcom G6 Pro. <https://provider.dexcom.com/products/dexcom-g6-pro>.

Dexcom Inc. 2023. The Dexcom G6 CGM System. <https://www.dexcom.com/get-started-cgm/119?sfc=701f30000018vibAAA&gclsrc=aw.ds&gclid=EAIaIQobChMI3M2g6L_P_AIVn4JaBR07ewLtEAAYASAAEgK-pPD_BwE>.

Dexcom. 2023. Learn how to fill a Dexcom G6 pharmacy prescription for you and your patients. <https://provider.dexcom.com/education-research/clinic-resources/prescribing-info/learn-how-fill-dexcom-g6-pharmacy-prescription>.

Dexcom. 2022. What can I do if my Dexcom G6 sensor fails during the 2-hour warmup period? <https://www.dexcom.com/faqs/what-to-do-if-dexcom-g6-sensor-fails-during-warmup>.

Dexcom. 2022. The Tubeless Omnipod® 5 Automated Insulin Delivery System. <https://www.dexcom.com/g6/integrations-and-compatibility>.

Dexcom. 2022. Is my Dexcom sensor accurate? <https://www.dexcom.com/faqs/is-my-dexcom-sensor-accurate>.

Dexcom. 2019. Manage Diabetes with Zero Fingersticks. YouTube. <https://www.youtube.com/watch?v=DbOToLqYLvU>.

Dexcom. 2018. Dexcom CGM — For People with Diabetes, Finally, Dexcom Makes Fingersticks a Thing of the Past. YouTube. <https://www.youtube.com/watch?v=A1NU5ivC5Og>.

DiabetesMine.com. 2013. The DiabetesMine D-Data ExChange - Nov 2013. <https://www.facebook.com/media/set/?set=a.10151790075828008.1073741829.56695563007&type=3>.

DiabetTech. 2022. How to get started with DIY “Artificial Pancreas” systems. <https://www.diabettech.com/looping-a-guide/>.

diaTribe Learn. 2022. About diaTribea: Making Sense of Diabetes. <https://diatribe.org/about-diatribe>.

diaTribe Learn. 2022. Time in Range. <https://diatribe.org/time-range>.

Didyuk, Olesya, Nicolas Econom, Angelica Guardia, Kelsey Livingston, and Ulrike Klueh. 2021. Continuous Glucose Monitoring Devices: Past, Present, and Future Focus on the History and Evolution of Technological Innovation. Journal of Diabetes Science and Technology 15, no. 3: 676–83. <https://doi.org/10.1177/1932296819899394>.

Douglas, Mary, and Aaron B Wildavsky. 1982. Risk and Culture : An Essay on the Selection of Technical and Environmental Dangers. Berkeley: University of California Press.

Dovc K, Battelino T. 2019. Evolution of Diabetes Technology. Endocrinol Metab Clin North Am. 2020 Mar;49(1):1-18. doi: 10.1016/j.ecl.2019.10.009. Epub. PMID: 31980111.

Downer, John. 2011. “737-Cabriolet” The Limits of Knowledge and the Sociology of Inevitable Failure. American Journal of Sociology 117 (3): 725-762.

Duke, M. D., & Fredlock, A. A. 2020. Do-It-Yourself (DIY) Systems in Diabetes: A Family and Provider Perspective. Journal of diabetes science and technology, 14(5), 917–921. <https://doi.org/10.1177/1932296820906204>.

Dumit, Joseph. 2012. Drugs for life: how pharmaceutical companies define our health. Duke University Press.

Edgerton, David. 2010. Innovation, Technology, or History: What Is the Historiography of Technology About? Technology and Culture 51(3): 680-697.

Edwards, Paul N., 1996. The Closed World: Computers and the Politics of Discourse in Cold War America. Cambridge, MA: MIT Press.

Wilmot, Emma G., Linn Langeland, Alasdair Mclay, Nicola Taylor, and Iskandar Rauf Idris. 2019. 1067-P: open source artificial pancreas system (APS) vs. combination insulin pump with flash glucose monitoring in adults with type 1 diabetes: an observational study. Diabetes 68, no. Supplement_1.

Eubanks, Virginia. 2018. Automating Inequality: How High-Tech Tools Profile, Police, and Punish the Poor First ed. New York, NY: St. Martin's Press.

Ezio Bonifacio. 2015. Predicting Type 1 Diabetes Using Biomarkers. Diabetes Care. 38 (6): 989–996. <https://doi.org/10.2337/dc15-0101>.

Farr, Christina. 2019. Dexcom glitch kept parents of children with diabetes in the dark over their conditions this weekend. CNBC.

<https://www.cnbc.com/2019/12/02/dexcom-tech-went-down-keeping-diabetes-patients-from-getting-readings.html>.

Farr, Christina. 2019. Dexcom says the outage that kept diabetes patients from tracking blood sugar was a 'complete surprise'. CNBC. <https://www.cnbc.com/2019/12/03/dexcom-cto-our-biggest-ever-glitch-was-a-big-surprise.html>.

FDA. 2022. Cybersecurity. <https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity>.

FDA. 2022. Types of FDA Enforcement Actions. <https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions.>

FDA. 2021. Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing. <https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-minimed-insulin-pumps-incorrect-insulin-dosing>.

FDA. 2020. FDA Approves First-of-its-Kind Automated Insulin Delivery and Monitoring System for Use in Young Pediatric Patients. < https://www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-automated-insulin-delivery-and-monitoring-system-use-young-pediatric>.

FDA. 2020. Classify Your Medical Device. < https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>.

FDA. 2022. FDA Warns Against the Use of Unauthorized Devices for Diabetes Management. FDA News Release. <https://www.fda.gov/news-events/press-announcements/fda-warns-against-use-unauthorized-devices-diabetes-management>.

FDA. 2018. Press Release: FDA approves first automated insulin delivery device for type 1 diabetes. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-automated-insulin-delivery-device-type-1-diabetes>.

FDA. 2018. The Artificial Pancreas Device System: FDA's Efforts to Advance Artificial Pancreas Device Systems. <https://www.fda.gov/medical-devices/consumer-products/artificial-pancreas-device-system>.

FDA. 2018. What is the pancreas? What is an artificial pancreas device system? <https://www.fda.gov/medical-devices/artificial-pancreas-device-system/what-pancreas-what-artificial-pancreas-device-system>.

Feudtner, Chris. 1995. The Want of Control: Ideas, Innovations, and Ideals in the Modern Management of Diabetes Mellitus. Bulletin of the History of Medicine 69 (1): 66–66.

Feudtner, John Christopher. 2003. Bittersweet: diabetes, insulin, and the transformation of illness. Univ of North Carolina Press.

Fletcher, James. 1745. A mechanical enquiry into the nature, causes, seat, and cure of the diabetes. With an explication of the most remarkable symptoms. Oxford. Eighteenth Century Collections Online. Gale. Virginia Tech.

Fontecha, J., González, I., Barragán, A., & Lim, T. 2022. Use and Trends of Diabetes Self-Management Technologies: A Correlation-Based Study. Journal of diabetes research, 2022, 5962001. <https://doi.org/10.1155/2022/5962001>.

Forlano, Laura. 2023. Living Intimately with Machines: Can AI Be Disabled? Association for Computing Machinery. Vol. 30/1. pp.24-29. <https://doi.org/10.1145/3572808>.

Forlano, Laura. 2017. Data Rituals in Intimate Infrastructures: Crip Time and the Disabled Cyborg Body as an Epistemic Site of Feminist Science. Catalyst. Vol. 3 No. 2: Science Out of Feminist Theory. <https://catalystjournal.org/index.php/catalyst/article/view/28843>.

Forlano, Laura. 2016. Hacking the Feminist Disabled Body. Journal of Peer Production. Issue 8. Feminism and (un)hacking. <http://peerproduction.net/issues/issue-8-feminism-and-unhacking-2/peer-reviewed-papers/issue-8-feminism-and-unhackingpeer-reviewed-papers-2hacking-the-feminist-disabled-body/>.

Foster NC, Beck RW, Miller KM, et al. 2019. State of type 1 diabetes management and outcomes from the T1D Exchange in 2016–2018. Diabetes Technology & Therapeutics. pp.66-72. <http://doi.org/10.1089/dia.2018.0384>.

Foucault, Michel. 1991. Governmentality Actions. In The Foucault Effect: Studies in Governmentality, edited by G. Burchell, C. Gordon, and P. Miller. Chicago, University of Chicago Press, 87-104.

Fuller, Jonathan. 2017. The New Medical Model: A Renewed Challenge for Biomedicine. Cmaj : Canadian Medical Association Journal = Journal De L'association Medicale Canadienne 189 (17): 641. <https://doi.org/10.1503/cmaj.160627>.

Funnell MM, Anderson RM. 2000. The Problem With Compliance in Diabetes. JAMA. 284(13):1709. doi:10.1001/jama.284.13.1709-JMS1004-6-1.

Furdell, Elizabeth Lane. 2009. Fatal Thirst: Diabetes in Britain until Insulin, (Leiden, The Netherlands: Brill. Stretton, Antony O. W. The First Sequence: Fred Sanger and Insulin. Genetics. 2002. 162 (2): 527-532 <https://www.genetics.org/content/162/2/527>.

Gandhi, K., Vu, B. K., Eshtehardi, S. S., Wasserman, R. M., & Hilliard, M. E. 2015. Adherence in adolescents with Type 1 diabetes: strategies and considerations for assessment in research and practice. Diabetes management (London, England), 5(6), 485–498. <https://doi.org/10.2217/dmt.15.41>.

GetRileyLink. 2022. OrangeLink Pro. <https://getrileylink.org/product/orangelink>.

Girdlestone, Thomas. 1799. A case of diabetes, with an historical sketch of that disease. By Thomas Girdlestone, M.D. Yarmouth. Eighteenth Century Collections Online. Gale. Virginia Tech.

Greene, Jeremy. 2008. Prescribing by Numbers: Drugs and the Definition of Disease. Johns Hopkins.

Hacking, I. 1983. Representing and Intervening: Introductory Topics in the Philosophy of Natural Science. Cambridge: Cambridge University Press. doi:10.1017/CBO9780511814563

Haddow, Gill, Emma King, Ian Kunkler, and Duncan McLaren. 2015. Cyborgs in the Everyday: Masculinity and Biosensing Prostate Cancer. Science As Culture 24 (4): 484–506. <https://doi.org/10.1080/09505431.2015.1063597>.

Hanselman, Jason. 2023. Ben West is not waiting for Diabetes Tech to catch up. Show #875. The HANSELMINUTES Podcast. <https://www.hanselminutes.com/875/ben-west-is-not-waiting-for-diabetes-tech-to-catch-up>.

Haraway, Donna. 1991. A Cyborg Manifesto: Science, Technology, and Socialist-Feminism in the Late Twentieth Century, in: Simians, Cyborgs and Women: The Reinvention of Nature, pp. 149–181. New York: Routledge.

HealthIT.gov. 2019. Frequently Asked Questions: Electronic Health Record. The Office of the National Coordinator for Health Information Technology (ONC). <https://www.healthit.gov/faq/what-electronic-health-record-ehr>.

HealthIT.gov. 2019. What is a patient portal? The Office of the National Coordinator for Health Information Technology (ONC). <https://www.healthit.gov/faq/what-patient-portal>.

HealthIT.gov. 2019. What is telehealth? How is telehealth different from telemedicine? The Office of the National Coordinator for Health Information Technology (ONC). <https://www.healthit.gov/faq/what-telehealth-how-telehealth-different-telemedicine>.

Healthline. 2019. The #WeAreNotWaiting Diabetes DIY Movement. <https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting#About-the-#WeAreNotWaiting-Movement>.

Healthline. 2019. The #WeAreNotWaiting Diabetes DIY Movement. <https://www.healthline.com/health/diabetesmine/innovation/we-are-not-waiting>.

Higgins, T., Larson, E., & Schnall, R. 2017. Unraveling the meaning of patient engagement: A concept analysis. Patient education and counseling, 100(1), 30–36. <https://doi.org/10.1016/j.pec.2016.09.002>.

Hinchliffe, S., Bingham, N., Allen, J., & Carter, S. 2016. Pathological Lives: Disease, Space and Biopolitics, John Wiley and Sons.

Hofmann, Bjørn. 2005. Simplified Models of the Relationship between Health and Disease. Theoretical Medicine and Bioethics: Philosophy of Medical Research and Practice 26 (5): 355–77. <https://doi.org/10.1007/s11017-005-7914-8>.

Horrocks, Stephen and Horrocks, Melissa. 2022. Bread and Chronic Illness. Diabredic. <https://www.diabreadic.com>.

Horrocks, Stephen K. 2020. Insulin Pump Use and Type 1 Diabetes: Connecting Bodies, Identities, and Technologies. PhD diss., Purdue University Graduate School.

Horrocks, S. 2019. Materializing datafied body doubles: Insulin pumps, blood glucose testing, and the production of usable bodies. Catalyst: Feminism, Theory, Technoscience, 5(1), 1-26.

Hughes, Thomas, 1998. Rescuing Prometheus. 1st ed. New York: Pantheon Books.

Insulet Corporation. 2022. Insulet Announces FDA Clearance of its Omnipod® 5 Automated Insulin Delivery System, First Tubeless System with Smartphone Control. <https://investor.insulet.com/news-releases/news-release-details/insulet-announces-fda-clearance-its-omnipodr-5-automated-insulin>.

Irl B. Hirsch. 2018. Introduction: History of Glucose Monitoring. ADA Clinical Compendia. 2018 (1): 1. <https://doi.org/10.2337/db20181-1>.

J.M. Malins. 1968. Clinical Diabetes Mellitus. London.

J.V. Santiago, A.H. Clemens, W.L. Clarke, et al. 1979. Closed-loop and open-loop devices for blood glucose control in normal and diabetic subjects Diabetes, 28 (1), pp. 71-84.

Jackson, Lala. 2022. OMNIPOD 5 receives FDA approval. Beyond Type 1. <https://beyondtype1.org/omnipod-5-fda-approved/>.

Jansky, B., Langstrup, H. 2022. Device activism and material participation in healthcare: retracing forms of engagement in the #WeAreNotWaiting movement for open-source closed-loop systems in type 1 diabetes self-care. BioSocieties. <https://doi.org/10.1057/s41292-022-00278-4>.

Jasanoff, Sheila. 1993. Bridging the Two Cultures of Risk Analysis Actions. Risk Analysis 12: 123-129.

JDRF. 2019. A DIY Approach to Artificial Pancreas Technology. <https://www.jdrf.org/blog/2019/05/02/diy-approach-artificial-pancreas-technology/>.

JDRF. 2019. Type 1 Diabetes Research. <https://www.jdrf.org/impact/research/>.

JDRF. 2017. Open-Protocol Automated Insulin Delivery System Initiative. <https://grantcenter.jdrf.org/rfa/open-protocol-automated-insulin-delivery-system-initiative/>.

JDRF. 2016. JDRF Celebrates FDA Approval of Artificial Pancreas System. <https://www.jdrf.org/press-releases/jdrf-celebrates-fda-approval-of-artificial-pancreas-system/>.

Zabinsky, Jennifer, Haley Howell, Alireza Ghezavati, Dana M. Lewis, Andrew Nguyen, and Jenise C. Wong. 2020. 988-P: Do-it-yourself artificial pancreas systems for type 1 diabetes reduce hyperglycemia without increasing hypoglycemia. Diabetes 69, no. Supplement_1. <https://doi.org/10.2337/db20-988-P>.

Jody Davis, Amy Hess Fischl, Joni Beck, Lillian Browning, Amy Carter, Jo Ellen Condon, Michelle Dennison, Terri Francis, Peter J. Hughes, Stephen Jaime, Ka Hei Karen Lau, Teresa McArthur, Karen McAvoy, Michelle Magee, Olivia Newby, Stephen W. Ponder, Uzma Quraishi, Kelly Rawlings, Julia Socke,

Michelle Stancil, Sacha Uelmen, Suzanne Villalobos. 2022. National Standards for Diabetes Self-Management Education and Support. Diabetes Care .45 (2): 484–494. <https://doi.org/10.2337/dc21-2396>.

Johnson, Ann. 2006. Revisiting Technology As Knowledge. Perspectives on Science 13 (4): 554–73.

Jones, Sue. 2016. The Noncompliant vs The Non-adherent Patient. Cooperative of American Physicians. <https://www.capphysicians.com/articles/noncompliant-vs-non-adherent-patient>.

Joni Beck, Deborah A. Greenwood, Lori Blanton, Sandra T. Bollinger, Marcene K. Butcher, Jo Ellen Condon, Marjorie Cypress, Priscilla Faulkner, Amy Hess Fischl, Theresa Francis, Leslie E. Kolb, Jodi M. Lavin-Tompkins, Janice MacLeod, Melinda Maryniuk, Carolé Mensing, Eric A. Orzeck, David D. Pope, Jodi L. Pulizzi, Ardis A. Reed, Andrew S. Rhinehart, Linda Siminerio, Jing Wang. 2017. on behalf of the 2017 Standards Revision Task Force, 2017 National Standards for Diabetes Self-Management Education and Support. Diabetes Care. 40 (10): 1409–1419. <https://doi.org/10.2337/dci17-0025>.

Karamanou M, Protogerou A, Tsoucalas G, Androutsos G, Poulakou-Rebelakou E. 2016. Milestones in the history of diabetes mellitus: The main contributors. World Journal of Diabetes. 2016;7(1):1–7. doi:10.4239/wjd.v7.i1.1 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4707300/>.

KAROLINSKA INSTITUTET. 1977. The Nobel Prize in Physiology or Medicine 1977 - Roger Guillemin, Andrew V. Schally and Rosalyn Yalow. <https://www.nobelprize.org/prizes/medicine/1977/press-release/>.

Braune, Katarina, S. H. A. N. E. O'DONNELL, Bryan Cleal, Dana M. Lewis, Adrian Tappe, Bastian Hauck, Ingrid Willaing et al. 117-LB: DIWHY: factors influencing motivation, barriers, and duration of DIY artificial pancreas system use among real-world users. Diabetes 68, no. Supplement_1. <https://doi.org/10.2337/db19-117-LB>.

Keisler-Starkey, Katherine; Bunch, Lisa N. 2021. Health Insurance Coverage in the United States: 2020. U.S. Census Bureau. Report #P60-274. https://www.census.gov/library/publications/2021/demo/p60-274.html.

Kelly, Clint. 2020. What is an Artificial Pancreas – Who Makes it and the Cost. Prescription Hope, Inc. <https://prescriptionhope.com/blog-what-is-an-artificial-pancreas/>.

Kilgour, Frederick G. 1993. Locating Information in an Egyptian Text of the 17th Century B.C. Journal of the American Society for Information Science 44 (5): 292–97. doi:10.1002/(SICI)1097-4571(199306)44:5<292::AID-ASI4>3.0.CO;2-V.

Klemen Dovc, Tadej Battelino. 2020. Evolution of Diabetes Technology, Endocrinology and Metabolism Clinics of North America, Vol. 49, Issue 1, pp 1-18. <https://doi.org/10.1016/j.ecl.2019.10.009>.

Kline, Ronald, and Trevor Pinch. 1996. Users as Agents of Technological Change: The Social Construction of the Automobile in the Rural United States. Technology and Culture 37, no. 4 (1996): 763–95. <https://doi.org/10.2307/3107097>.

Kline, Ronald. 2009. Where Are the Cyborgs in Cybernetics? Social Studies of Science 39 (3): 331–62.

Kowalski, Aaron. 2015. Pathway to Artificial Pancreas Systems Revisited: Moving Downstream. Diabetes Care. 38 (6): 1036–1043. <https://doi.org/10.2337/dc15-0364>.

Kröger J, Reichel A, Siegmund T, Ziegler R. 2020. Clinical Recommendations for the Use of the Ambulatory Glucose Profile in Diabetes Care. J Diabetes Sci Technol. 14(3):586-594. doi: 10.1177/1932296819883032. Epub 2019 Nov 13. PMID: 31718268; PMCID: PMC7576939.

Kuhn, Thomas S. 1996. The Structure of Scientific Revolutions. 3rd edition. Chicago, IL: University of Chicago Press.

Lakhtakia, Ritu. 2013. The History of Diabetes Mellitus. Sultan Qaboos University Medical Journal 13 (3): 368–70.

Lakoff, A. 2017. Unprepared: Global Health in a time of emergency, UC Press.

Lakoff, A., & Collier, S. J. (Eds.). 2008. Biosecurity interventions: global health and security in question. Columbia University Press.

Layton, Edwin. 1974. Technology As Knowledge. Technology and Culture 15 (1): 31–41.

Layton, Edwin. 1971. Mirror-Image Twins: The Communities of Science and Technology in 19th-Century America. Technology and Culture 12 (4): 562–80.

Lewis, Dana. 2022. We Have Changed the Standards of Care for People With Diabetes. DIYPS.org. <https://diyps.org/2022/12/23/we-have-changed-the-standards-of-care-for-people-with-diabetes/>.

Lewis Dana. 2019. History and Perspective on DIY Closed Looping. Journal of diabetes science and technology, 13(4), 790–793. <https://doi.org/10.1177/1932296818808307>.

Lewis, Dana. 2019. History and Perspective on DIY Closed Looping. Journal of diabetes science and technology, 13(4), 790–793. <https://doi.org/10.1177/1932296818808307>.

Lewis, Dana. 2019. Automated Insulin Delivery: How artificial pancreas “closed loop” systems can aid you in living with diabetes.

Lewis, Dana. 2018. Open Artificial Pancreas System. TEDxFHKufstein. <https://www.youtube.com/watch?v=kgu-AYSnyZ8>.

Linebaugh, Kate. 2014. Citizen Hackers Tinker With Medical Devices. <http://online.wsj.com/articles/citizen-hackers-concoct-upgrades-for-medical-devices-1411762843?reflink=desktopwebshare_permalink>.

Linebaugh, Kate. 2016. Tech-Savvy Families Use Home-Built Diabetes Device. WSJ. <https://www.wsj.com/articles/tech-savvy-families-use-home-built-diabetes-device-1462728637>.

Long, Pamela O. 2018. Engineering the Eternal City : Infrastructure, Topography, and the Culture of Knowledge in Late Sixteenth-Century Rome. Chicago: University of Chicago Press.

LoopDocs. 2022. Welcome to LoopDocs. < https://loopkit.github.io/loopdocs/>.

Lupton, Deborah. 1999. Risk (Key Ideas). New York: Routledge

Lupton, Deborah. 1999. Risk and the Ontology of Pregnant Embodiment In Risk and Sociocultural Theory: New Directions and Perspectives, edited by D. Lupton. Cambridge, UK, New York & Melbourne, Cambridge University Press, 59-85.

Macleod, John. 1923. The Nobel Prize in Physiology of Medicine in 1923 lecture. John Macleod - for discovery of insulin. <https://www.nobelprize.org/prizes/medicine/1923/macleod/lecture/>.

Majumdar, Sisir K. 2002. Glimpses of the history of insulin. Bull Indian Inst Hist Med Hyderabad 31, no. 1: 57-70. <http://www.ccras.nic.in/sites/default/files/viewpdf/jimh/BIIHM_2001/57%20to%2070.pdf>.

Mandeep Khera. 2016. Think Like a Hacker. Journal of Diabetes Science and Technology, 11, no. 2: 207-212, doi:10.1177/1932296816677576.

Martin, Emily. 1994. Flexible Bodies: Tracking Immunity in American Culture from the Days of Polio to the Age of Aids. Boston: Beacon Press.

Mathieu, C., Lahesmaa, R., Bonifacio, E. et al. 2018. Immunological biomarkers for the development and progression of type 1 diabetes. Diabetologia 61, 2252–2258. https://doi.org/10.1007/s00125-018-4726-8.

Mazur A. 2011. Why were "starvation diets" promoted for diabetes in the pre-insulin period? Nutrition Journal 10:23. doi:10.1186/1475-2891-10-23 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3062586/>.

McDermid Eleanor. 2022. Bionic pancreas removes math from diabetes. ADA 2022 Conference coverage. Medicine Matters – Diabetes. <https://diabetes.medicinematters.com/ada-2022/artificial-pancreas-systems/bionic-pancreas-removes-math-from-diabetes/23127798>.

Mckee, Kim. 2009. Post-Foucauldian Governmentality: What Does It Offer Critical Social Policy Analysis? Critical Social Policy 29, no. 3: 465–86. <https://doi.org/10.1177/0261018309105180.a>.

Medrtonic. 2022. The MINIMED™ system components. <https://www.medtronicdiabetes.com/products/minimed-770g-insulin-pump-system/virtual-brochure>.

Medtronic. 2022. Learn more about how the MINIMED™ 770G system can help children living with diabetes. <https://www.medtronicdiabetes.com/minimed-770g-system-kids/>.

Medtronic. 2021. MINIMED™ 670G system discontinuation of new sales. <https://www.medtronicdiabetes.com/products/minimed-670g-insulin-pump-system>.

Merriam-Webster. 2023. Dicrionary. <https://www.merriam-webster.com/dictionary/risk>.

Meyers, Flowers. 2021. FDA Expands Recall of Medtronic Minimed Insulin Pump. Meters & Flowers Trial Attorneys. <https://www.meyers-flowers.com/our-firm/news-room/fda-expands-recall-of-medtronic-minimed-insulin-pump/>.

Mika, Marissa. 2020. The Half-Life of Radiotherapy and Other Transferred Technologies. Technology and Culture, Volume 61, Number 2 Supplement, April 2020, pp. S135-S157

Mol, Annemarie, and John Law. 2004. Embodied Action, Enacted Bodies: The Example of Hypoglycaemia. Body & Society 10 (2-3): 43–62.

Mol, Annemarie. 2008. The Logic of Care : Health and the Problem of Patient Choice. Myilibrary. London: Routledge.

Moran-Thomas, Amy. 2019. Traveling with Sugar: Chronicles of a Global Epidemic. Oakland, California: University of California Press.

Mukherjee, Sy. 2019. Parents of Children With Diabetes Are Furious Following the Blackout of a Major Blood Sugar Monitoring Software. <https://fortune.com/2019/12/02/dexcom-outage-blackout-diabetes-patients-blood-sugar-monitor/>.

Mulvey, Alexandra. 2019. FDA Authorizes a Second Artificial Pancreas System. JDRF. <https://www.jdrf.org/blog/2019/12/13/jdrf-reports-fda-authorizes-second-artificial-pancreas-system/>.

Mungmode, Ann. 2022. Emboldened to Innovate: Supporting All People Living with Diabetes. T1D Exchange. <https://t1dexchange.org/diabetes-mine-summitt-2022-researcher/>.

Munro Dan. 2014. The View Of Digital Health From An 'Engaged Patient'. Forbes Healthcare. <https://www.forbes.com/sites/danmunro/2014/03/09/the-view-of-digital-health-from-an-engaged-patient/?sh=378fad282b79>.

Myers, Victor C, and Cameron V Bailey. 1916. The Lewis and Benedict Method for the Estimation of Blood Sugar, with Some Observations Obtained in Disease. Journal of Biological Chemistry 24 (2): 147–61. <https://doi.org/10.1016/S0021-9258(18)87566-4>.

National Clinical Care Commission. 2021. Report to Congress on Leveraging Federal Programs to Prevent and Control Diabetes and Its Complications. <https://health.gov/sites/default/files/2022-01/NCCC%20Report%20to%20Congress.pdf>.

Navarro, V. 1984. Medical History As Justification Rather Than Explanation: A Critique of Starr's the Social Transformation of American Medicine. International Journal of Health Services : Planning, Administration, Evaluation 14 (4): 511–28.

NEJM Catalyst. 2017. What Is Patient-Centered Care? <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0559>.

Nightscount. 2022. New Nightscout Users. <https://nightscout.github.io/nightscout/new_user/>.

Nightscount. 2022. Welcome to Nightscout. <https://nightscout.github.io>.

Nighscout Foundation. 2016. KCGM-TV OpenAPS & the FDA with Ben West, Ep2. <https://www.youtube.com/watch?v=c98TwesRkeQ>.

Noble, David F. 1984. Forces of Production : A Social History of Industrial Automation. 1st ed. New York: Knopf.

Norton, Amy. 2022. Over a Million Americans Are Rationing Insulin Due to High Cost. U.S. News & World Report. <https://www.usnews.com/news/health-news/articles/2022-10-18/over-a-million-americans-are-rationing-insulin-due-to-high-cost>.

O'Connor, Anahad. 2019. In Weekend Outage, Diabetes Monitors Fail to Send Crucial Alerts. The New York Times. <https://www.nytimes.com/2019/12/02/well/live/Dexcom-G6-diabetes-monitor-outage.html>.

OpenAPS. 2022. OpenAPS Is Designed For Safety. <https://openaps.org>.

OpenAPS. 2022. OpenAPS Outcomes. <https://openaps.org/outcomes/>.

OpenAPS. 2022. Welcome to OpenAPS's documentation! <https://openaps.readthedocs.io/en/latest/index.html>.

OpenAPS. 2022. What is #OpenAPS? #WeAreNotWaiting to reduce the burden of Type 1 diabetes. <https://openaps.org>.

Onmipod. 2022. Omnipod® gives you more with less. <https://www.omnipod.com>.

Omnipod. 2021. Simplify Life™ with Omnipod DASH®. <https://www.omnipod.com/en-gb>.

OpenAPS. 2021. Principles of an Open Artificial Pancreas System (OpenAPS). <https://openaps.org/reference-design/>.

OpenAPS. 2019. Frequently Asked Questions. <https://openaps.org/frequently-asked-questions/>.

Oudshoorn, Nelly and Trevor Pinch (eds). 2003. How Users Matter: The Co-Construction of Users and Technologies. Cambridge, Mass.: MIT Press.

Ouellet Valérie, Adhopia Vik, Culbert Andrew. 2018. Insulin pumps linked to more reports of injury and death than any other medical device, records show. CBC News. <https://www.cbc.ca/news/health/implant-files-insulin-pumps-1.4915491>.

Park, Andrea. 2022. ADA: Beta Bionics' automated insulin pump slashes glucose levels, diabetes distress in Type 1 patients. <https://www.fiercebiotech.com/medtech/ada-beta-bionics-automated-insulin-pump-slashes-glucose-levels-diabetes-distress-type-1>.

Parmar, Arundhati. 2019. Dexcom's IT outage shows fabulous device maker floundering with patient communication. MedCityNews. <https://medcitynews.com/2019/12/dexcoms-it-outage-shows-fabulous-device-maker-floundering-with-patient-communication/>.

Patton, Mary Anne. 2018. Dana Lewis – patients are experts. MyArtificialPancreas.net. <https://myartificialpancreas.net/2018/08/23/dana-lewis-at-hic18/>.

Patton, Mary Anne. 2020. Ben West – fixing diabetes, changing the conversation. MyArtificialPancreas.net. <https://myartificialpancreas.net/2020/04/01/ben-west-fixing-diabetes-changing-the-conversation/>.

Pedersen, Amanda. 2019. Dexcom Fesses Up About Its Communication Mess Up. Medical Device and Diagnostic Industry (MD+DI). <https://www.mddionline.com/diabetes/dexcom-fesses-about-its-communication-mess>.

Petrick, Elizabeth R. 2015. Making Computers Accessible: Disability Rights and Digital Technology. History of Science, Technology, and Medicine. Baltimore: Johns Hopkins University Press.

Petryna, Adriana. 2013. Life exposed: biological citizens after Chernobyl. Princeton, NJ: Princeton University Press.

Pettus, J., Von Herrath, M. 2018. The shifting paradigm of a "cure" for type 1 diabetes: is technology replacing immune-based therapies?. Acta Diabetol 55, 117–120. <https://doi.org/10.1007/s00592-017-1069-8>.

Pickering, G. W. 1949. The Place of the Experimental Method in Medicine: President's Address. 229-234. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2081184/?page=1>.

Polonsky, W. H., & Fortmann, A. L. 2021. Impact of real-time continuous glucose monitoring data sharing on quality of life and health outcomes in adults with type 1 diabetes. Diabetes technology & therapeutics, 23(3), 195-202.

Purohit S, She JX. 2008. Biomarkers for type 1 diabetes. Int J Clin Exp Med. 2008;1(2):98-116. Epub PMID: 19079665; PMCID: PMC2596319.

Rajan, Kaushik Sunder. 2006. Biocapital: The constitution of postgenomic life. Duke University Press.

Rao, Ankita & Cunnane, Megan. 2016. Diabetes Hacking 101. Only Human. WNYC Studios. <https://www.wnycstudios.org/podcasts/onlyhuman/articles/diabetes-hacking-with-ben-west>.

Rickert, James. 2012. Patient-Centered Care: What It Means And How To Get There. <https://www.healthaffairs.org/do/10.1377/forefront.20120124.016506>.

Roberts, J. T. F., Moore, V., & Quigley, M. 2021. Prescribing unapproved medical devices? The case of DIY artificial pancreas systems. Medical law international, 21(1), 42–68. <https://doi.org/10.1177/0968533221997510>.

Rodriguez Fernandez, Clara. 2019. How the DIY Diabetes Community Made the Artificial Pancreas Possible. Labiotech.eu. <https://www.labiotech.eu/in-depth/diy-diabetes-community-artificial-pancreas/>.

Rose, Nikolas. 2009. The politics of life itself: Biomedicine, power, and subjectivity in the twenty-first century. p.3. Princeton: Princeton University Press.

Rosenberg, Jaime. 2021. Uptake of Artificial Pancreas Systems in Primary Care Could Reduce Care Disparities. AJMC. <https://www.ajmc.com/view/uptake-of-artificial-pancreas-systems-in-primary-care-could-reduce-care-disparities>.

Rosenfeld, Louis. 2002. Insulin: Discovery and Controversy, Clinical Chemistry, Vol. 48, Issue 12, pp. 2270–2288, <https://doi.org/10.1093/clinchem/48.12.2270>.

Rother, K. I., & Harlan, D. M. 2004. Challenges facing islet transplantation for the treatment of type 1 diabetes mellitus. The Journal of clinical investigation, 114(7), 877–883. <https://doi.org/10.1172/JCI23235>.

Roy, Mrinalika. 2022. FDA warns of cybersecurity risk with certain Medtronic insulin pumps. Reuters. <https://www.reuters.com/business/healthcare-pharmaceuticals/fda-warns-cybersecurity-risk-with-certain-medtronic-insulin-pumps-2022-09-20/>.

Ruha, Benjamin. 2019. Race After Technology : Abolitionist Tools for the New Jim Code. Cambridge, UK: Polity.

Russell A.L, and Vinsel L. 2018. After Innovation, Turn to Maintenance. Technology and Culture 59 (1): 1–25. <https://doi.org/10.1353/tech.2018.0004>.

SA Today. 2019. Hacking Diabetes: People Break Into Insulin Pumps as an Alternative to Delayed Innovations. <https://cacm.acm.org/news/237406-hacking-diabetes-people-break-into-insulin-pumps-as-an-alternative-to-delayed-innovations/fulltext?mobile=false>.

Salomon, Sheryl Huggins. 2020. When CGM Service Fails: 5 Tips for a Creating a Backup Plan. Everyday Health. <https://www.everydayhealth.com/type-1-diabetes/dexcom-cgm-app-outage-what-to-do-if-service-fails/>.

Amuedo, Sandra., Antequera, Maria., Azriel, Sharona. 2022. 800-P: Real-World Use of Do-It-Yourself Artificial Pancreas Systems in Adults with Type 1 Diabetes. Diabetes. 71 (Supplement_1): 800–P. <https://doi.org/10.2337/db22-800-P>.

Sargent, Jennifer. 2021. Technology will set you free. Nature Portfolio. <https://www.nature.com/articles/d42859-021-00024-z>.

Schaaf, Tracy. 2018. 'In MedTech History' - Diabetes Technology - Part 1. MedTech Strategist. <https://www.mystrategist.com/blog/article/diabetes-part-1>.

Schillinger, Dea. 2021. Recommendations of the 2021 Federal Diabetes Commission: Translating the socio-ecologic model into policy, and global health implications.

<https://globalhealthsciences.ucsf.edu/event/recommendations-2021-federal-diabetes-commission-translating-socio-ecologic-model-policy-and>.

Scibilia, Renza. 2019. The spectrum of DIY diabetes. Diabetogenic. <https://diabetogenic.blog/2019/05/21/the-spectrum-of-diy-diabetes/>.

Scott, John. 1990. A Matter of Record : Documentary Sources in Social Research. Cambridge, Mass., USA: Polity Press in association with B. Blackwell.

Shah, Premal, and Deborah Mountain. 2007. The Medical Model Is Dead – Long Live the Medical Model. British Journal of Psychiatry 191 (5): 375–77. <https://doi.org/10.1192/bjp.bp.107.037242>.

Shepard, J. A., Breton, M., Nimri, R., Roberts, J. T. F., Street, T., Klonoff, D., & Barnard-Kelly, K. 2022. User and Healthcare Professional Perspectives on Do-It-Yourself Artificial Pancreas Systems: A Need for Guidelines. Journal of diabetes science and technology, 16(1), 224–227. <https://doi.org/10.1177/1932296820957728>.

Simms, Stacey. 2021. Ben West: Using Diabetes Tech to Relieve the "Onus to Bolus". Diabetes Connections with Stacey Simms. Podcast. < https://diabetes-connections.com/ben-west-using-diabetes-tech-to-relieve-the-onus-to-bolus/>.

Slaton, Amy E. 2001. Reinforced Concrete and the Modernization of American Building, 1900-1930. Johns Hopkins Studies in the History of Technology. Baltimore: Johns Hopkins University Press.

Smith A, Harris C. 2018. Type 1 Diabetes: Management Strategies. Am Fam Physician. 98(3):154-162. PMID: 30215903. <https://www.aafp.org/pubs/afp/issues/2018/0801/p154.html>.

Choi, Soo Bong, Eun Shil Hong, and Yun Hee Noh. 2018. Open artificial pancreas system reduced hypoglycemia and improved glycemic control in patients with type 1 diabetes. Diabetes 67, no. Supplement_1.

Stanford Medicine X. 2017. Ben West: Linking Medical Devices. <https://www.youtube.com/watch?v=CXTxRyG34tA>.

Starr, Paul. 1982. The Social Transformation of American Medicine. New York: Basic Books.

Steven Shapin and Simon Schaffer. 1989. Leviathan and the Air-Pump. Princeton.

Stratta R. J. 1998. Immunosuppression in pancreas transplantation: progress, problems and perspective. Transplant immunology, 6(2), 69–77. <https://doi.org/10.1016/s0966-3274(98)80020-8>.

Summerton, Jane, and Boel Berner. 2003. Constructing Risk and Safety in Technological Practice. Routledge Advances in Sociology, 4. London: Routledge.

Swaine, Zoë. 2011. Medical Model. In: Kreutzer, J.S., DeLuca, J., Caplan, B. (eds) Encyclopedia of Clinical Neuropsychology. Springer, New York, NY. <https://doi.org/10.1007/978-0-387-79948-3_2131>.

T. Battelino, M. Phillip. 2004. The first meeting of the loop club. J Pediatr Endocrinol Metab, 17 (3). 10.1515/JPEM.2004.17.3.375

T1Pal. 2023. Frequently Asked Questions. Is T1Pal or the Nightscout software cleared by the FDA? <https://www.t1pal.com/legal/faq_8_18_2020_13_38>.

T1Pal. 2023. Medical Data Networks, LLC. <https://www.t1pal.com>.

TallBear, Kimberly. 2013. Native American DNA: Tribal belonging and the false promise of genetic science. Minneapolis: University of Minnesota Press.

Tandem Diabetes Care. 2022. CONTROL-IQ TECHNOLOGY Predicts and helps prevent highs and lows. <https://www.tandemdiabetes.com/products/t-slim-x2-insulin-pump/control-iq>.

Tattersall, Robert. 2009. Diabetes: The Biography. Biographies of Disease. Oxford: Oxford University Press.

The diaTribe Foundation. 2022. Our Mission. <https://diatribe.org/foundation/about-us/our-mission>.

The Nightscout Project. 2022. What is the Nightscout project? <http://www.nightscout.info>.

The Quantified Self Symposia. 2016. We're Not Waiting for Our Automatic Pancreas System. Quantified Self Public Health. <https://medium.com/quantified-self-public-health/were-not-waiting-for-our-automatic-pancreas-system-888162fcde2b>.

Thomas, Johnson. 2015. Endo Apps: The DIY Artificial Pancreas. <https://www.medpagetoday.com/endocrinology/type1diabetes/50839>.

Thompson, Emily Ann. 2002. The Soundscape of Modernity: Architectural Acoustics and the Culture of Listening in America, 1900-1933. Cambridge, Mass.: MIT Press.

Tidepool. 2023. About Tidepool. <https://www.tidepool.org/about>.

Tonyushkina, Ksenia, James H Nichols. 2009. Glucose meters: a review of technical challenges to obtaining accurate results. Journal of diabetes science and technology vol. 3,4 971-80. doi:10.1177/193229680900300446.

United Nations General Assembly. 2006. Resolution Adopted by the General Assembly – 61/225. World Diabetes Day, New York: US General Assembly.

UPMC. 2023. Exercise for Diabetes Patients. <https://www.chp.edu/our-services/endocrinology/resources/exercise>.

VA. 2022. Whole Health. <https://www.va.gov/WHOLEHEALTH/veteran-resources/whole-health-basics.asp>.

Vieira, Ginger. 2022. DiabetesMine Innovation Summit Unveils New Tech & Products for Type 1 Diabetes. T1D Exchange. <https://t1dexchange.org/diabetes-mine-summit-2022/>.

Wailoo, Keith. 1999. Drawing Blood: Technology and Disease Identity in the Twentieth-Century America. Baltimore: Johns Hopkins University Press.

Wang, Z., Xie, Z., Lu, Q. et al. 2017. Beyond Genetics: What Causes Type 1 Diabete. Clinical Reviews in Allergy & Immunology. 2017. 52 (2): 273–286 <https://doi.org/10.1007/s12016-016-8592-1>.

Wermiel, Sarah. 2000. The Fireproof Building: Technology and Public Safety in the Nineteenth-Century American City. Baltimore: JHU Press.

WHO. 2023. Health emergencies. <https://www.who.int/our-work/health-emergencies>.

WHO. 2021. Diabetes: Key Facts. <https://www.who.int/news-room/fact-sheets/detail/diabetes>.

Williams, Nora. 2017. Fifty Years of Living With Type 1 Diabetes. Clin Diabetes. 35 (5): 331–332. <https://doi.org/10.2337/cd17-0089>.

Wilson, Val. 2013. Diabetes: From the Ebers Papyrus to Cell Technology. Teneo Press.

Winner, Langdon. 1980. Do Artifacts Have Politics? Daedalus 109(1): 121-136.

Winner, Langdon. 1993. Upon Opening the Black Box and Finding It Empty: Social Constructivism and the Philosophy of Technology. Science, Technology, & Human Values. 18 (3): 362–78. <https://doi.org/10.1177/016224399301800306>.

Wolf JA, Niederhauser V, Marshburn D, LaVela SL. 2021. Reexamining "Defining Patient Experience": The human experience in healthcare. Patient Experience Journal. Vol. 8(1):16-29. doi: 10.35680/2372-0247.1594.

Yan, Karena. 2022. Medicaid and CGM: Who's Covered? diaTribe Learn: Making Sense of Diabetes. <https://diatribe.org/medicaid-and-cgm-whos-covered>.