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Patient-led innovation and global health justice: Open-source digital health technology for type 1 diabetes care

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Abstract

Health innovation is mainly envisioned in direct connection to medical research institutions or pharmaceutical and technology companies. Yet, these types of innovation often do not meet the needs and expectations of individuals affected by health conditions. With the emergence of digital health technologies and social media, we can observe a shift, which involves people living with illness modifying and improving medical and health devices outside of the formal research and development sector, figuring both as users and innovators. This patient-led innovation has been celebrated in innovation studies and economics as a “bottom-up” type of innovation. In this article, we take a closer look at open-source patient-led innovation in the context of type 1 diabetes care. In our inquiry, we pay particular attention to the social and ethical dimensions of this innovation, building on empirical material. Upon exploring the notion of patient-led innovation and its socio-political context through the lens of intersectional and global health justice, we argue that a proactive strategy is needed to ensure that open-source patient-led innovation will be more globally accessible, center the health needs of the most underserved populations, as well as facilitate equitable and just health benefits. To support this aim, we provide a range of examples of different initiatives addressing the persistent inequalities that have so far inhibited patient-led innovation from more fully materializing its innovative potential.

KEYWORDS

digital health, empirical bioethics, health justice, mHealth, open-source, patient-led innovation

1 | INTRODUCTION

I was living with the problem then, that day, that night, and every night for the rest of my life. And what could I do about it? Nothing. I was “just” the patient and the

“user” or “consumer” of the device, with no option to change medical devices to better suit my needs.¹

¹Lewis, D. M. (2019). *Automated insulin delivery: How artificial pancreas closed loop systems can aid you in living with diabetes* (p. 4). Independently published by Dana M. Lewis.

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Enabled by technology, social media, and a keen desire to find solutions aligned with their own needs, consumers of all kinds are designing new products for themselves.²

Health innovation is predominantly conceptualized in direct connection to institutionalized settings, such as academia or pharmaceutical and technology companies. Often, these types of innovation do not meet the needs and expectations of people affected by illnesses or healthcare professionals.³ Despite of this, pharmaceutical companies and medical device manufacturers continue to hold great power over user data, interoperability of technologies, and access and pricing. At the same time, we can observe a shift with the emergence of digital health technologies and social media. This shift involves people affected by different health conditions,⁴ and their family members, who, outside of the traditional medical research and development sector, are modifying and further improving medical and health devices and the services offered through them. With this, they also challenge the authorities of device manufacturers and the pharmaceutical industry. It is important to recognize that innovation put forward by people who are affected by illness are largely motivated by frustration with the political economics of innovation in various healthcare contexts. Their efforts are driven by dissatisfaction with commercial actors, who are not providing the necessary care tools, as well as the lack of access to (their own) data or transparency about what happens to the data in these commercial products.⁵ These efforts, which recently led to the invention of open-source ventilators in the COVID-19 pandemic,⁶ are driven by people

with health conditions, responding to the failure of healthcare systems and commercial manufacturers to deliver much-needed healthcare.

The practice of finding solutions for oneself and then sharing them with others (online) once they have been proven to be effective has been named by economists and scholars of innovation studies as “patient-led/driven innovation” (in relation to the concept of “user-led innovation”).⁷ Some celebrate this type of innovation as “bottom-up” innovation, challenging the traditional top-down innovation process. Since the 1970s, Eric von Hippel and other researchers in innovation studies have emphasized that users are not only important in the innovation process but that they can also create and drive innovation.⁸ In the context of patient-led innovation, the scholars emphasize that manufacturers “will never be able to deliver everything patients need.”⁹ “Patients”—with appropriate support structures—can fill these gaps. In addition, they underline the fact that patient-led innovations are beneficial for companies that “produce and sell medical devices and services,”¹⁰ as they can function as “free R&D [research & development] that informs and amplifies in-house development efforts”¹¹ for commercial manufacturers. According to this view, patient-led innovation has the potential to solve many issues and hurdles in healthcare: it can enable “patients” to solve their own problems as well as speed up the development of commercially manufactured tools, as companies benefit from having individuals affected by illness conduct research and development for them.

However, the broader social context and structural underpinning of these innovative practices have not been sufficiently considered in conceptualizations of patient-led innovation. It is important to note that patient-led innovation “is not practiced in a vacuum independent of political, social, or economic forces.”¹² This article aims to use an intersectional theoretical framework and insights from Science and Technology Studies (STS)¹³ to explore the global social structures and power inequities that shape health care and health innovation, which are currently underexplored in the scholarly discourse around patient-led innovation. With this approach, our ethical analysis is not focused on the consideration of individual-level factors while

²Demonaco, H. O., Torrance, A., von Hippel, C., & von Hippel, E. (2019). When patients become innovators. *Mitsloan Management Review*, 60(3), 15, p. 82f.

³Poncette, A. S., Rojas, P. D., Hofferbert, J., Valera Sosa, A., Balzer, F., & Braune, K. (2020). Hackathons as stepping stones in health care innovation: Case study with systematic recommendations. *Journal of Medical Internet Research*, 22(3), e17004. <https://doi.org/10.2196/17004>

⁴In this article, we will carefully use the term “patient” only in relation to the theoretical concepts that we are building upon, and not to describe the individuals in our researched case. Language matters, and as we will be talking about individuals with a chronic health condition, the term “patient” does not do justice to their experiences of having to live with this condition every day. See Schicktanz, S. (2015). The ethical legitimacy of patient organizations' involvement in politics and knowledge production: Epistemic justice as conceptual basis. In P. Wehling, W. Viehöver, & S. Keonen (Eds.), *The public shaping of medical research* (pp. 246–265). Routledge; Dickinson, J. K., Guzman, S. J., Maryniuk, M. D., O'Brian, C. A., Kadohiro, J. K., Jackson, R. A., D'Hondt, N., Montgomery, B., Close, K. L., & Funnell, M. M. (2017). The use of language in diabetes care and education. *The Diabetes Educator*, 43(6), 551–564.

⁵Braune, K., Gajewska, K., Thieffry, A., Lewis, D. M., Froment, T., O'Donnell, S., Speight, J., Hendrieckx, C., Schipp, J., Skinner, T., Langstrup, H., Tappe, A., Raile, K., & Cleal, B. (2021). Why #WeAreNotWaiting—motivations and self-reported outcomes among users of open-source automated insulin delivery systems: Multinational survey. *Journal for Medical Internet Research*, 23(6), 25409; Schipp, J., Skinner, T., Holloway, E., Scibilia, R., Langstrup, H., Speight, J., & Hendrieckx, C. (2021). How adults with type 1 diabetes are navigating the challenges of open-source artificial pancreas systems: A qualitative study. *Diabetes Technology Therapy*, 23(8), 546–554; Kazianus, E., Ackerman, M. S., Lindtner, S., & Lee, J. M. (2017). Caring through data: Attending to the social and emotional experiences of health datafication. In *Proceedings of the 2017 ACM Conference on Computer Supported Cooperative Work and Social Computing* (pp. 2260–2272). Association for Computing Machinery; Kazianus, E. (2018). *Designing for lived health: Engaging the sociotechnical complexity of care work* [PhD dissertation, University of Michigan]; Forlano, L. (2016). Hacking the feminist disabled body. *Journal of Peer Production*. Special Issue on “Feminist (Un)Hacking.”

⁶Pearce, J. (2020). A review of open source ventilators for COVID-19 and future pandemics. *Research*, 9(218), 57–89; Richterich, A. (2020). When open source design is vital: Critical making of DIY healthcare equipment during the COVID-19 pandemic. *Health Sociology Review*, 29(2), 158–167.

⁷Von Hippel, E. (1976). The dominant role of users in the scientific instrument innovation process. *Research Policy*, 5(3), 212–239.

⁸ibid.

⁹Demonaco, H. O., et al., op. cit. note 2.

¹⁰ibid: 81.

¹¹ibid.

¹²O'Kane, A. (2016). DIY health and wellbeing: The hackers and makers outpacing manufacturers and researchers. *Proceedings of the 2016 CHI Conference Extended Abstracts on Human Factors in Computing Systems* (Vol. 25, pp. 477–501). <https://doi.org/10.3389/conf.fpubh.2016.01.00080>

¹³Oudshoorn, N., Rommes, E., & Stienstra, M. (2004). Configuring the user as everybody: Gender and design cultures in information and communication technologies. *Science, Technology, & Human Values*, 29(1), 30–63; Akrich, M. (1992). The description of technical objects. In W. E. Bijker & J. Law (Eds.), *Shaping technology/building society, studies in socio technical change* (pp. 205–224). MIT Press.; Akrich, M. (1995). User representations: Practices, methods and sociology. In A. Rip, T. J. Misa, & J. Schot (Eds.), *Managing technology in society: The approach of constructive technology assessment* (pp. 167–184). Pinter Publishers. While we build on (feminist) STS approaches in our exploration of inequalities in the context of patient-led innovation, we also want to acknowledge the persistent legacy of white male domination on STS itself (Mascarenhas, M. (2018). White space and dark matter: Prying open the black box of STS. *Science, Technology, & Human Values*, 43(2), 151–170).

critiquing individuals engaging in innovative approaches to their care. Instead, our critique aims at systemic- and structural-level factors that shape patient-led innovation, its infrastructure, and communities. These include national healthcare systems shaped by local and global structural inequalities, a common lack of infrastructure for engagement between public and private healthcare sectors, innovation monopolies of commercial and pharmaceutical companies, and issues of inaccessible health data, which often inhibit the development of or access to life-saving technologies, but also global and local socio-political and economic inequalities.

A large number of studies on social determinants of health and illness¹⁴ show that structural socio-political and economic inequalities shape the capability to be healthy. Many of these unequal health outcomes stem from the ongoing legacy of colonialism and intersecting racial, gender, and class inequalities. These inequalities have not only undermined the health and well-being of structurally oppressed and vulnerable populations through maintenance of unequal access to various resources but also through their shaping of medicine, healthcare, and research.¹⁵ As medical therapies and technologies, including digital health, have been developed in an unequal socio-political environment, they have also produced unequal health outcomes and at times even exacerbated health inequalities.¹⁶ Patient-led innovation is situated and embedded within this uneven local and global socio-political context, to which it both responds and is simultaneously also shaped by.¹⁷ It is thus crucial to explore innovation in this broader context and sociopolitical conditions.

Patient-led innovation typically starts with someone identifying a therapeutic gap or problem, followed by an—often collective—development of a solution. In the case of open-source innovation, the technological solution is shared online, without any intellectual property licensing, on open-source platforms.¹⁸ Through this collective engagement, open-source patient-led innovation can be an opportunity to make health technology more tailored to the needs of affected people and more easily accessible and widely beneficial to various populations. It is crucial for users of medical technologies to be part of the research and development process. Indeed, individuals

whose lives are affected by particular health conditions have vital and crucial insights into what they as affected people need. As such, patient-led design can pave the way toward the development of technologies and technically advanced solutions tailored to the needs of affected people. Some of us have previously emphasised in our research that, direct involvement is especially crucial in populations whose health concerns and needs have been neglected in medical research and practice, owing to structural socio-economic, gender, racial and colonial inequalities, locally and globally.¹⁹ Moreover, medicine has a long and troubling history of systematically excluding affected people from knowledge production. Especially in chronic healthcare, it is crucial to acknowledge the lived experiences and experience-based expertise of people affected by (chronic) health conditions as primary decision-makers and not use terms such as compliance or adherence to describe their care practices.²⁰

The integration of the health needs of historically oppressed populations is essential to foster equity in the healthcare system and generate technologies that can facilitate intersectional health benefits. Intersectionality is a theoretical framework²¹ that enables us to examine how categories of social (dis)advantage and power, such as gender and race, intersect with other social categories, such as class or citizenship status, impacting one's position within society, access to resources, and capabilities to be healthy.²² Scholars have argued²³ that it is crucial to implement an intersectional perspective in the digital health context, in order to assess the social and ethical implications of each technology and its impact on the user population. Every such population is heterogeneous and various users (and their bodies) can have different health needs. Some of the authors of this paper have previously argued²⁴ that this necessitates an intersectional approach to health benefits, reflecting on the specific needs of digital health users from different population groups. A growing pool of research has demonstrated that medicine and healthcare have historically excluded and neglected negatively racialized people and their health. In particular, populations of Black and Indigenous women and fellow negatively racialized people who are simultaneously marginalized on gender grounds have been disproportionately neglected and thus now

¹⁴Marmot, M. G., & Wilkinson, R. G. (2006). *Social determinants of health*. Oxford University Press; Powers, M., & Faden, R. R. (2006). *Social justice: The moral foundations of public health and health policy*. Oxford University Press; Venkatapuram, S. (2020). Global justice and the social determinants of health. *Ethics & International Affairs*, 24(2), 119–130; Chung, R. (2021). Structural health vulnerability: Health inequalities, structural and epistemic injustice. *Journal of Social Philosophy*. p.12393.

¹⁵Hendl, T., Jansky, B., & Wild, V. (2020). From design to data handling: Why mHealth needs a feminist perspective. In J. Loh & M. Coeckelbergh (Eds.), *Feminist philosophy of technology* (pp. 77–103). J.B. Metzler; Liao, S. Y., & Carbonell, V. (2022). Materialized oppression in medical tools and technologies. *American Journal of Bioethics*, 21(9), 16–18; Hatch, A. (2016). *Blood sugar. Racial pharmacology and food justice in Black America*. University of Minnesota Press; O'Donnell, S. (2020). 'Your wealth is your health': The fundamental causes of inequalities in diabetes management outcomes: A qualitative analysis. *Sociology of Health and Illness*, 42, 1626–1641; Sherwood, J. (2013). Colonisation—It's bad for your health: The context of Aboriginal health. *Contemporary Nurse*, 46(1), 28–40.

¹⁶ibid; Criado-Perez, C. (2019). *Invisible women: Exposing data bias in a world designed for men*. Penguin.

¹⁷Wajcman, J., & MacKenzie, D. A. (1999). *The social shaping of technology*. Open University Press; Bijker, W., Hughes, T. P., & Pinch, T. (1987). *The social construction of technological systems*. MIT Press; Jasanoff, S., Markle, G., Petersen, J., & Pinch, T. (Eds.) (1995). *Handbook of science and technology studies*. Sage Publications.

¹⁸Kelty, C. (2008). *Two bits: The cultural significance of free software*. Duke University Press.

¹⁹Hendl, T., & Jansky, B. (2021). Tales of self-empowerment through digital health technologies: A closer look at 'Femtech.' *Review of Social Economy*, 80(1), 29–57. <https://doi.org/10.1080/00346764.2021.2018027>; Hendl, T., & Roxanne, T. (2022). Digital surveillance in a pandemic-response: What bioethics ought to learn from indigenous perspectives. *Bioethics*, 36(3), 305–312.

²⁰Anderson, R., & Funnell, M. (2000). Compliance and adherence are dysfunctional concepts in diabetes care. *The Diabetes Educator*, 26(4), 597–604.

²¹Crenshaw, K. (1991). Mapping the margins: Intersectionality, identity politics, and violence against women of color. *Stanford Law Review*, 43(6), 1241–1299; Collins, P. H. (2019). *Intersectionality as critical social theory*. Duke University Press; Collins, P. H., & Bilge, S. (2016). *Intersectionality*. Polity Press; Kóczé, A. (2009). *Missing intersectionality race/ethnicity, gender, and class in current research and policies on Romani women in Europe*. In *Policy studies series* (pp. 1–70). Central European University.

²²Venkatapuram, S. (2011). *Health justice: An argument from the capabilities approach*. Polity Press.

²³Figueroa, C. A., Luo, T., Aguilera, A., & Lyles, C. R. (2021). The need for feminist intersectionality in digital health. *The Lancet Digital Health*, 3(8), e526–e533. [https://doi.org/10.1016/S2589-7500\(21\)00118-7](https://doi.org/10.1016/S2589-7500(21)00118-7); Hendl, T., et al., op. cit. note 15; Hendl, T., Jansky, B., Shukla, A., Seeliger, V., & Wild, V. (2023). Ethical aspects of mHealth technologies: Challenges and opportunities In R. Huss (Ed.), *Digital medicine* (pp. 101–128). Jenny Stanford Publisher.

²⁴Hendl, T., et al., op. cit. note 15.

require specific and affirmative attention in the health context, in order for them to receive adequate healthcare and equitable health outcomes.²⁵ To achieve this, we have argued²⁶ that an intersectional approach to digital health is warranted at all stages of the development and use of these technologies. On our account, such an approach should involve an intersectional design of digital health, maintenance of quality control and testing across various sub-populations within the target population, and scientific proof that each digital health technology will facilitate intersectional user health benefits, and as such, provide high-quality health services to as diverse a population as possible.

In this article, we take a closer look at patient-led innovation in the context of type 1 diabetes (T1D) and explore the social conditions and global inequalities that shape this innovation. We build on the STS literature on technology development and scholarship on intersectional equity and justice in health and healthcare.²⁷ Our inquiry focuses both on the way in which social identity relates to power and the way through which socio-political and economic conditions shape health, including the opportunity to participate in health innovation to improve one's health outcomes. Building on empirical research on open-source technology development in T1D, we explore the potential of open-source patient-led innovation to bridge social and health disparities and provide people living with T1D with much-needed and life-saving technologies for improved health, which could relieve some of the burdens associated with the management of the chronic health condition on a global level. To our knowledge, this is the first article examining open-source automated insulin delivery systems from a global health justice perspective.²⁸

In the following sections, we first introduce the case of patient-led innovation that we will focus on. We then lay out our methodological approach and describe how we combine an empirical and normative analysis. In the following section we discuss the main social and ethical aspects of patient-led innovation, building on scholarship on intersectional equity and justice in patient-led innovation and healthcare.²⁹ We conclude this article by offering examples of different initiatives that are addressing the persisting inequalities in T1D that have so far inhibited the notion of patient-led innovation to more fully materialize its innovative potential.

2 | CASE: OPEN-SOURCE AUTOMATED INSULIN DELIVERY SYSTEMS IN T1D CARE

T1D occurs because of autoimmune destruction of the pancreatic insulin-producing cells.³⁰ This chronic health condition has no relation to the lifestyle of individuals and external factors. T1D is associated with "reduced quality of life, serious long-term complications, shortened life expectancy, and substantial costs for individuals and healthcare systems."³¹ A growing body of literature suggests that in impoverished countries, where access to healthcare and T1D self-care devices is limited, complications and early mortality are exceptionally high.³² Furthermore, research has shown that negatively racialized people with T1D globally have poorer health outcomes.³³ In her ethnographic study on Diabetes in Belize, Amy Moran-Thomas urgently points out that "Diabetes takes specific shape in each life, family, and nation [and it is] causing unevenly patterned injuries and deaths in nearly all countries in the world."³⁴

Even though T1D technologies have become increasingly sophisticated,³⁵ people living with T1D are still expected to act as their "own nurse, doctor's assistant and chemist."³⁶ T1D is characterized by a demanding regime of self-care for the affected: they are responsible for measuring their glucose levels multiple times a day and, according to these measurements, manually administer insulin.³⁷ If the chronic health condition is not well managed, severe immediate- and long-term health consequences might occur.³⁸ People living with T1D often have to deal with stigma surrounding

³⁰Atkinson, M. A., Eisenbarth, G. S., & Michels, A. W. (2014). Type 1 diabetes. *Lancet*, 383(9911), 69–82. [https://doi.org/10.1016/S0140-6736\(13\)60591-7](https://doi.org/10.1016/S0140-6736(13)60591-7)

³¹Gregory, G. A., Robinson, T. I. G., Linklater, S. E., Wang, F., Colagiuri, S., de Beaufort, C., Donaghue, K. C., International Diabetes Federation Diabetes Atlas Type 1 Diabetes in Adults Special Interest Group, & Magliano, D. J. (2022). Global incidence, prevalence, and mortality of type 1 diabetes in 2021 with projection to 2040: A modelling study. *The Lancet Diabetes & Endocrinology*, 10(10), 714.

³²Chan J., Lim, L., Wareham, N., Shaw, J. E., Orchard, T. J., Zhang, P., Lau, E. S. H., Eliasson, B., Kong, A. P. S., Ezzati, M., Aguilar-Salinas, C. A., McGill, M., Levitt, N. S., Ning, G., So, W. Y., Adams, J., Bracco, P., Forouhi, N. G., Gregory, G. A., ... Gregg, E. W. (2021). The Lancet Commission on diabetes: Using data to transform diabetes care and patient lives. *Lancet*, 396, 2019–2082; Atun, R., Davies, J. I., Gale, E. A. M., Bärnighausen, T., Beran, D., Kengne, A. P., Levitt, N. S., Mangugu, F. W., Nyirenda, M. J., Ogle, G. D., Ramaiya, K., Sewankambo, N. K., Sobngwi, E., Tesfaye, S., Yudkin, J. S., Basu, S., Bommer, C., Heesemann, E., Manne-Goehler, J., ... Werfalli, M. (2017). Diabetes in sub-Saharan Africa: From clinical care to health policy. *Lancet Diabetes Endocrinology*, 5, 622–676; Marshall, S. L., Edidin, D. V., Arena, V. C., Becker, D. J., Bunker, C. H., Gishoma, C., Gishoma, F., LaPorte, R. E., Kaberuka, V., Ogle, G., Rubanzana, W., Sibomana, L., & Orchard, T. J. (2017). Mortality and natural progression of type 1 diabetes patients enrolled in the Rwanda LFAC program from 2004 to 2012. *International Journal of Diabetes in Developing Countries*, 37, 507–515.

³³Zuidwijk, C. S., Cuerden, M., & Mahmud, F. H. (2013). Social determinants of health on glycemic control in pediatric type 1 diabetes. *Journal of Pediatrics*, 162(4), 730–735.

³⁴Moran-Thomas, A. (2019). *Traveling with sugar: Chronicles of a global epidemic (first)* (p. 7). University of California Press.

³⁵Gottlieb, S. D. (2021). The fantastical empowered patient. In S. Geiger (Ed.), *Healthcare activism: Markets, morals, and the collective good* (pp. 198–223). Oxford University Press.

³⁶Joslin E. P. (1929). *A diabetic manual for the use of doctor and patients*. Lea & Febiger.

³⁷Mathieu-Fritz, A., & Guillot, C. (2017). Diabetes self-monitoring devices and transformations in "patient work". New forms of temporality, reflexivity and self-knowledge relating to the experience of chronic illness. *Revue d'anthropologie des Connaissances*, 11(4), 1–32; Bruni, A., & Rizzi, C. (2013). Looking for data in diabetes healthcare: Patient 2.0 and the reengineering of clinical encounters. *Science & Technology Studies*, 26(1), 29–43; Danesi, G., Pralong, M., Panese, F., Burnand, B., & Grossen, M. (2020). Techno-social reconfigurations in diabetes (self-) care. *Social Studies of Science*, 50(2), 1–23.

³⁸Plotnick, L., & Henderson, R. (1998). *Clinical management of the child and teenager with diabetes*. JHU Press.

²⁵Krieger, N. (2019). Measures of racism, sexism, heterosexism, and gender binarism for health equity research: From structural injustice to embodied harm—An ecosocial analysis. *Annual Review of Public Health*, 41, 37–62; Hendl, T., & T. K. Browne. (2022). Gender: Ongoing debates and future directions. In W. Rogers, S. Carter, V. Entwistle, C. Mills, & J. Leach Scully (Eds.), *Routledge handbook of feminist bioethics* (pp. 151–166). Routledge.

²⁶Hendl, T., et al., op. cit. note 15; Hendl, T., et al., op. cit. note 23.

²⁷Chung, op. cit. note 14; Venkatapuram, op. cit. note 22. Hendl, T., et al., op. cit. note 23.

²⁸So far, there has been little academic research, exploring open-source patient-led innovation from an ethical perspective. Most publications focus on liability issues for clinicians and their perspectives on the system (see, e.g., Shaw, D., Crabtree, T. S. J., Hammond, P., McLay, A., & Wilmot, E. G. (2020). The DIY artificial pancreas system: an ethical dilemma for doctors. *Diabetic Medicine*, 37(11), 1951–1953. <https://doi.org/10.1111/dme.14270>). Only one publication focuses on the perspective of the users (Quintal, A., Messier, V., Rabasa-Lhoret, R., & Racine, E. (2020). A qualitative study of the views of individuals with type 1 diabetes on the ethical considerations raised by the artificial pancreas. *Narrative Inquiry in Bioethics*, 10(3), 237–261. <https://doi.org/10.1353/nib.2020.0072>) and includes concerns of justice, but from an individual rather than a public health or global health perspective.

²⁹Hendl & Roxanne, op. cit. note 19; Venkatapuram, op. cit. note 14; Samra, R., & Hankivsky, O. (2021). Adopting an intersectionality framework to address power and equity in medicine. *The Lancet*, 397(10277), 857–859.

the chronic health condition, and the aspect of high self-reliance is associated with mental distress, which is referred to as diabetes distress in social-psychology.³⁹ At the same time, they often have to deal with shaming if they do not follow healthcare professionals' advice, and are labeled as "non-compliant."⁴⁰ Overall, T1D is a health condition that completely changes a person's life.

For over 60 years, researchers, as well as people living with T1D, have been envisioning how to automate some of the care practices to reduce the burden related to managing this health condition.⁴¹ With the emergence of mobile health technologies, this idea became more attainable.⁴² Some even started to talk about the vision of a "technical cure,"⁴³ which eventually led to the idea of a closed-loop system⁴⁴ for insulin delivery, also referred to as an automated insulin delivery system. In such a system, a pre-programmed control algorithm would enable a continuous glucose monitoring device and an insulin pump to communicate. This algorithm makes minor adjustments to insulin dosages every few minutes to respond automatically to changing glucose concentrations to maintain glucose levels in a predefined target range, based on the values that the sensor-based glucose monitoring device has registered.⁴⁵

While a few commercial systems for automated insulin delivery have recently entered the healthcare market, the development and implementation of these devices have been slow.⁴⁶ Even when these tools are formally accessible, it is often difficult and expensive to acquire these systems. Owing to the lack of commercial technology, a community of people with T1D is developing open-source versions and sharing the instructions and source codes online.⁴⁷ In 2013,⁴⁸ Dana Lewis, a person with T1D based in the United States, and her partner started to work on an open-source version, and in 2015, they⁴⁹ shared their innovation online on social media under the hashtag #WeAreNotWaiting and initiated a global movement and community.

These open-source systems "benefit from a fast innovation cycle"⁵⁰ as well as transparent, open-source customizable algorithms. However, they are not yet authorized by regulatory bodies and need to be self-implemented by every user.⁵¹ This means that the self-care practices of people with T1D using such systems are changing considerably. Individuals with T1D utilizing open-source automated insulin delivery systems can no longer rely on the support of pharmaceutical companies, device manufacturers or healthcare professionals and might thus become even more self-reliant. It is important to note that creating these systems has been "a collective effort to improve the lives of people living with diabetes whose needs were not sufficiently being met by industry, even though the technology to make change existed."⁵²

This innovation spawned a radical shift not only in T1D therapy but also in healthcare in general,⁵³ as "anyone with the compatible diabetes devices and motivation, [could] learn how to build such a system for themselves."⁵⁴ Especially amongst the scholars of innovation studies, whose work we have discussed in the introduction, this movement has gained wide popularity as one of the examples for "bottom-up" user innovations, challenging the notion that "[v]aluable improvements in health and patient care should come from experts in the pharmaceutical, medical device, and related industries."⁵⁵ Some even refer to these open-source endeavors as "low-cost clinical trials by and for patients."⁵⁶

There is increasing interest in open-source automated insulin delivery systems and the innovator community, both from academia and industry. Therefore, in 2022, a group of clinicians published an international consensus statement on the use of open-source automated insulin delivery systems, which provided practical guidelines for clinicians.⁵⁷ Also, just recently, in 2023, the nonprofit organization Tidepool, which emerged due to the patient-led innovation, received an FDA 510(k) clearance.⁵⁸ Despite these efforts, many people with T1D who use open-source systems face

³⁹Fisher, L., Polonsky, W. H., Hessler, D. M., Masharani, U., Blumer, I., Peters, A. L., Strycker, L. A., & Bowyer, V. (2015). Understanding the sources of diabetes distress in adults with type 1 diabetes. *Journal of Diabetes and its Complications*, 29(4), 572–577. <https://doi.org/10.1016/j.jdiacomp.2015.01.012>

⁴⁰Gottlieb, op. cit. note 35.

⁴¹Hovorka, R. (2006). Continuous glucose monitoring and closed-loop systems. *Diabetic Medicine*, 23, 1–12. <https://doi.org/10.1111/j.1464-5491.2005.01672.x>, p. 1

⁴²De Vries, G., & Blachman, J. (2020). *The patient equation: The data-driven future of precision medicine and the business of healthcare*. Wiley.

⁴³Heinemann, L. (2017). Rolle der Diabetes-Technologie in der Diabetestherapie. In Deutsche Diabetes Gesellschaft (Ed.), *Deutscher Gesundheitsbericht. Diabetes 2017. Bestandesaufnahme* (pp. 226–239). Kirchheim Verlag.

⁴⁴The term "closed-loop system" refers to systems that are "designed to automatically achieve and maintain the desired output condition by comparing it with the actual condition [...] a 'closed-loop system' is a fully automatic control system in which its control action being dependent on the output in some way." (<https://www.electronics-tutorials.ws/systems/closed-loop-system.html>, latest access: 13.11.2019). There is no fully closed-loop system that is "able to replicate islet function in the form of a fully automated, multihormonal blood glucose control device" Weaver, K., & Hirsch, I. (2018). The hybrid closed-loop system: Evolution and practical applications. *Diabetes Technology & Therapeutics*, 20(2), 216–223, 16.

⁴⁵Weaver & Hirsch, op. cit. note 44.

⁴⁶When they first shared the instructions for this technology, there was no such system commercially available.

⁴⁷Schipp, J., et al., op. cit. note 5; Lewis, op. cit. note 1; Boughton, C. K., & Hovorka, R. (2019). Is an artificial pancreas (closed-loop system) for Type 1 diabetes effective? *Diabetic Medicine*, 36(3), 279–286.

⁴⁸Lewis, op. cit. note 1.

⁴⁹Ibid.

⁵⁰Boughton & Hovorka, op. cit. note 47.

⁵¹From a legal perspective, Quigley and Ayihongbe (2018) also point out the question of responsibility and ownership of medical devices that are attached to the bodies of their users. Quigley, M., & Ayihongbe, S. (2018). Everyday cyborgs: On integrated persons and integrated goods. *Medical Law Review*, 26(2), 276–308. <https://doi.org/10.1093/medlaw/fwy003>

⁵²<https://www.youtube.com/watch?v=sxvJoakmyY> (latest access: 15.02.2023).

⁵³Gottlieb, S. D., & Cluck, J. (2019). "Going Rogue" re-coding resistance with type 1 diabetes. *Culture & Society*, 4(2), 137–155; Gottlieb, op. cit. note 35; 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*, 18(3), 498–522. https://link.springer.com/article/10.1057/s41292-022-00278-4#Section_7

⁵⁴Mesko, B. (2016). *Interview with Dana Lewis: What is living with an artificial pancreas like?* <https://medicalfuturist.com/living-with-an-artificial-pancreas/> (latest access: 11.08.2023).

⁵⁵Demonaco, H., & von Hippel, E. (2019). Patient-innovators fill gaps that industry hasn't addressed—or can't. *Stat News*, 15, 7–8.

⁵⁶Demonaco, H. O., et al., op. cit. note 2, p. 86.

⁵⁷Braune, K., Lal, R. A., Petruželková, L., Scheiner, G., Winterdijk, P., Schmidt, S., Raimond, L., Hood, K. K., Riddell, M. C., Skinner, T. C., Raile, K., Hussain, S., & OPEN International Healthcare Professional Network and OPEN Legal Advisory Group. (2022). Open-source automated insulin delivery: International consensus statement and practical guidance for health-care professionals. *The Lancet. Diabetes & Endocrinology*, 10(1), 58–74. [https://doi.org/10.1016/S2213-8587\(21\)00267-9](https://doi.org/10.1016/S2213-8587(21)00267-9)

⁵⁸<https://www.tidepool.org/blog/tidepool-loop-has-received-fda-clearance> (latest access: 16.02.2023).

skepticism from clinicians, which is why many still do not disclose the use of open-source systems to their clinicians at all.⁵⁹

To summarize, the open-source community significantly impacted the T1D technology industry. This community pushed for shifts in legal and institutional arrangements and accomplished something that the industry and academia have been attempting since the middle of the 20th century.⁶⁰ At the same time, the psychological and medical benefits of these open-source systems are currently being researched in numerous studies, showing better self-reported clinical outcomes⁶¹ and an overall improvement in quality of life⁶² in people with T1D using the open-source system. Furthermore, the movement demonstrated that while individuals with T1D should be “diagnostic agents”⁶³ in their care, they do not have the full authority and control over what happens to their health data.⁶⁴ This in turn clearly shows the powerful position of pharmaceutical and device manufacturing industries in the contemporary healthcare ecosystem.

3 | METHODOLOGY

In this paper, we combine empirical sociological approaches with normative ethical analysis. The inquiry results from an interdisciplinary collaboration of a sociologist with expertise in medical STS and qualitative methodology, a sociologist with expertise in intersectional inequalities and decolonial theory, and a scholar with expertise in decolonial feminist philosophy, normative, and public health ethics. This cross-disciplinary collaboration allows us to provide a more in-depth normative analysis. In practice, this means that we are looking at the empirical material through the lens of normative ethics to interrogate the public health and ethical issues related to patient-led innovation and opportunities for effective responses.

The empirical study at the core of this paper is located in Germany and our inquiry is primarily grounded in the German healthcare context. Germany is a high-income Western European country with universal healthcare coverage. However, the country tends to have a conservative approach to the adoption of digital health technologies and infrastructures.⁶⁵ For example, Germany only recently introduced a variety of digital tools into the healthcare setting.⁶⁶ While our empirical data are German-based, and some of

our findings might be rather specific and relevant to the particular regional context, there are substantial observations that can inform debates on health innovation more broadly around the world.⁶⁷ The German T1D open-source community is one of the largest groups globally engaged in this patient-led innovation,⁶⁸ and thus has a significant influence in the global innovation process in open-source technology. Hence, some of the implications of the regional study reach far beyond Germany.

For our analysis, we build on 28 problem-centered in-depth⁶⁹ interviews⁷⁰ with members of the T1D open-source community, their relatives, and healthcare professionals, as well as media articles, and instructions and publications of regulatory bodies; we further incorporate results of quantitative empirical analyses of other scholars working on T1D open-source technologies. This combination of qualitative (focused on local experiences) and quantitative (focused on global and broader issues) aspects provides a more in-depth understanding of the empirical case.

3.1 | Limitations

We want to acknowledge that we do not have direct lived experiences of T1D and are not part of the patient-led innovation community (one of the authors of this article has a parent with T1D). Writing about (chronic) health conditions without having embodied knowledge is not an unproblematic practice,⁷¹ especially given that medicine has historically largely disregarded the experiences and realities of those living every day with a chronic health condition and favored “those who study it from a distance.”⁷² We are aware that our ethical analysis is not a “view from nowhere”⁷³ and it is crucial to reflect on this. At the same time, we believe that our “view from somewhere” can shed light on the ethical and social challenges of patient-led innovation, especially as we take an approach that reaches beyond much explored issues of safety and liability and focuses on concerns and opportunities of structural issues of equity and justice in the context of open-source innovations. In this endeavor, we build on the conceptualization of ethics of accountability developed by Kim TallBear,⁷⁴ who builds on feminist standpoint

⁵⁹Gottlieb, & Cluck, op. cit. note 53; Jansky, B. (2023). Digitized patients: Elaborative tinkering and knowledge practices in the open-source Type 1 diabetes “Looper Community”. *Science, Technology & Human Values*, online first, p. 8. <https://doi.org/10.1057/s41292-022-00278-4>

⁶⁰Hovorka, op. cit. note 41.

⁶¹Braune, K., et al., op. cit. note 5.

⁶²Schipp, J., et al., op. cit. note 5.

⁶³Oudshoorn, N. (2008). Diagnosis at a distance: The invisible work of patients and healthcare professionals in cardiac telemonitoring technology. *Sociology of Health and Illness*, 30(2), 272–288.

⁶⁴Forlano, op. cit. note 5; Kaziunas, op. cit. note 5; Kaziunas, E., et al., op. cit. note 5.

⁶⁵BertelsmannStiftung. (2019). #SmartHealthSystems. *International comparison of digital strategies*.

⁶⁶DiGA. *Verzeichnis für digitale Gesundheitsanwendung*. Retrieved June 22, 2022, from <https://diga.bfarm.de/de>

⁶⁷Liboiron, M. (2021). *Pollution is colonialism* (p. 29). Duke University Press.

⁶⁸Braune, K., et al., op. cit. note 5.

⁶⁹Reiter, H., & Witzel, A. (2012). *The problem-centred interview*. Sage.

⁷⁰The interviews lasted from approximately 20 min to 2 h. Out of the interviewed participants, 12 were women and 16 were men. Their ages ranged from 22 to 81 years. Six participants were healthcare professionals, of whom two did not have T1D. The interviews were conducted in German. There were two exceptions in which the interviews were conducted in English. The interviews were recorded and later transcribed verbatim.

⁷¹Richards, R. (2008). Writing the othered self: Autoethnography and the problem of objectification in writing about illness and disability. *Qualitative Health Research*, 18(12), 1717–1728. <https://doi.org/10.1177/1049732308325866>, p. 1726.

⁷²ibid: 1720.

⁷³Haraway, D. (1988). Situated knowledges: The science question in feminism and the privilege of partial perspective. *Feminist Studies*, 14(3), 575–599. <https://doi.org/10.2307/3178066>

⁷⁴TallBear, K. (2014). Standing with and speaking as faith: A feminist-indigenous approach to inquiry [Research note]. *Journal of Research Practice*, 10(2), Article no. 17. Retrieved from <http://jrp.icaap.org/index.php/jrp/article/view/405/371>

theory and emphasizes the need for researchers to shift from a standpoint of disinterested and disembodied agents toward accountability for the implications of our study and theorization. In this article, our accountability begins with the recognition that we are writing about a group of people living with T1D, that is, those facing a difficult and challenging situation, which not only involves struggle for necessary life-saving technologies but also defense of the epistemic legitimacy of their practices. In order to be accountable and to recognize and reflect on our limitations as scholars without T1D, we have sought and obtained feedback for this article from academics working in the patient-led innovation space, individuals living with T1D, and carers. Their input has immensely helped us to go beyond our limited knowledge and to understand the phenomenon of patient-led innovation in its complexity and situatedness.

In light of the reflective writing process, which has been made more insightful and detailed thanks to the feedback provided by people affected by the chronic health condition that our inquiry focuses on, we wish to clarify that in our discussion below, we do not aim to criticize any patient-led innovation efforts. Rather, we wish to point to the structural underpinnings of patient-led innovation and the challenges and opportunities that become clear once an intersectional and global health justice perspective is applied to patient-led innovation and its broader and fundamentally unequal socio-political context. We hope that our writing can contribute to debates and innovation practices that will make the means and design of patient-led innovation, the resulting life-saving T1D technology, and its health benefits accessible and beneficial to a wider cohort of people living with T1D around the world.

4 | EMPIRICAL ANALYSIS

4.1 | The burden of living with T1D: What motivates patient-led innovation

Everybody seems to think that it's OK to wait another two or three years for this process to play itself out. In terms of the business or policy cycles that's the current trajectory, but for those of us who live with this data dysfunction, two or three years can make the difference between going blind or dying in our sleep. It's purely an issue of priorities and urgency and despite glowing rhetoric to the contrary—patient needs are nowhere in sight for manufacturers or policymakers.⁷⁵

There are various motivations for people to leave behind commercial devices recommended to them by their healthcare provider and engage in an unregulated open-source endeavor.

Among the major ones are the burdensome data work that is involved in the care of T1D, the responsibility associated with it, and crucially, the improvement of one's quality of life when insulin delivery can be partly automated.⁷⁶

As indicated in the quote above, people with T1D feel overlooked by the pharmaceutical and device industry. Jakob, a father of a young child with T1D,⁷⁷ explains this as follows:

As a computer scientist, I was frustrated by the amount of manual management required for diabetes, how many simple calculations you have to make every day, and how high the probability of errors is when you have to make these calculations yourself on paper. [...] and we were somewhat frustrated as to why we have to do this ourselves—the data is all there, the pump has the data, the sensor has the data.

While Jacob has almost real-time access to the data that the glucose-monitoring device is creating about the metabolism of his child, he states that being almost constantly in the “loop” of insulin delivery seems to be an unnecessary as well as an error-prone practice. For many of the interviewed people living with this chronic health condition, using an automated insulin delivery system completely changed their lives. For example, Lisa, a young woman living with T1D, describes it as follows:

I think when I closed the loop I talked to my mom on the phone after three days and when she asked how it was going, I said: “oh Mom I think I'm cured”⁷⁸ So the first few days it was really fantastic, I didn't expect [...] it just worked immediately.

People living with T1D and their caretakers have to make high-risk decisions about when to intervene and administer insulin on an everyday basis. Using a semi-automated system can help to improve the quality of life considerably as it relieves one from constantly managing one's health condition. We use the quotes by Jacob and Lisa, and the sense of necessity evident in their narratives of the daily practices of self-care in T1D as a backdrop in order to gain a deeper understanding of why one would go beyond the recommended technologies and venture into the unknown and opt for using an unauthorized system. While in many other sectors, innovation cycles are much faster and the automation of repetitive processes is

⁷⁵Lewis, D., Braune, K., Gajewska, K., Thieffry, A., Lewis, D. M., Froment, T., O'Donnell, S., Speight, J., Hendrieckx, C., Schipp, J., Skinner, T., Langstrup, H., Tappe, A., Raile, K., & Cleal, B. (2021). Why #WeAreNotWaiting-motivations and self-reported outcomes among users of open-source automated insulin delivery systems: Multinational survey. *Journal for Medical Internet Research*, 23(6), 25409.

⁷⁷Jakob's case is rather specific as he is looping for his child. As such, there are further ethical implications involved, including the health impact on another person - in this case, a dependent minor; however, we do not have the space to discuss them in detail in this article.

⁷⁸It is important to note here that this is her experience of relief and it shows how fundamentally it changed her relationship with T1D, but an open-source automated insulin delivery system is not the end-solution to deal with the burden of T1D.

⁷⁵<https://www.forbes.com/sites/danmunro/2014/03/09/the-view-of-digital-health-from-an-engaged-patient/> (latest access 14.10.2022).

advanced, in the field of medical technology, progress has been slower. This has left people living with T1D feeling frustrated and ignored by the industry.⁷⁹ For our analysis of the social and ethical implications of open-source patient-led innovation from a global health justice perspective, people's motivation, their frustration with the lack of commercial development, and the necessity of innovations are important to understand. It is crucial not to lose sight of the fact that these systems are life-saving technologies that can change and are changing the lives of people with T1D considerably.⁸⁰

4.2 | Access to devices

Devices, such as insulin pumps and CGMs, are significant and life-sustaining technologies for "practical cyborgs with T1D."⁸¹ This is the first aspect that needs to be acknowledged when looking at open-source automated insulin delivery systems. While discussions around mHealth technologies sometimes emphasize digitalization, with apps and software somewhere in the "cloud," the material aspect of living with devices in, on, and with their bodies is at the center of this innovation.⁸² Only with access to these devices can one engage in this movement in the first place.

O'Donnell et al. (2023) point out that on a structural level, people with T1D report that the most significant barrier that holds them back from engaging in and using an open-source automated insulin delivery system is "sourcing of compatible insulin pumps and access to CGM systems."⁸³ The fact that individuals were already in possession of devices that would work to create an automated insulin delivery system was a necessary precondition for many of the participants to initiate open-source endeavors⁸⁴:

It was actually a coincidence that I was prescribed the right pump. And that this step towards this first loop attempt was actually a very small one because I didn't actually need any new hardware.

This shows that the opportunity to access the necessary technological devices is a fundamental precondition to be able to engage in patient-led innovation. Such findings also fit with the results of a recent quantitative study conducted with nonusers,

⁷⁹The lack of commercial systems is also related to liability and cost issues for commercial actors. If commercial manufacturers were to offer automated insulin delivery systems that are as advanced as the open-source ones that are currently available, costly and time-intensive clinical trials will be required and a liability would occur if something adverse were to happen to the users.

⁸⁰Weaver & Hirsch, op. cit. note 44.

⁸¹Garfinkel, J. (2021). *Diabetes as Illness and Metaphor: Stories from the Body-Technology*. SCBE Seminar. Retrieved November 29, 2021, from https://mediaspace.stanford.edu/media/t/1_etfj95yq

⁸²Jansky & Langstrup, op. cit. note 53.

⁸³O'Donnell, S., Cooper, D., Chen, Y., Ballhausen, H., Lewis, D. M., Froment, T., Anna Gajewska, K., Tappe, A., Skinner, T., Cleal, B., & Braune, K. (2023). Barriers to uptake of Open-Source automated insulin delivery Systems: Analysis of socioeconomic factors and perceived challenges of adults with type 1 diabetes from the OPEN survey. *Diabetes Research and Clinical Practice*, 197, 110235.

⁸⁴ibid.

where almost one third of the participants stated that a barrier to developing the system was that the technical components were too expensive.⁸⁵ The majority of people in the T1D innovation community are located in countries in the global North, that is in socio-economically better positioned spaces and conditions⁸⁶ which enable access to these expensive health devices required for innovating. While the hashtag that initiated the movement is being used globally, the actual practice of engaging in open-source endeavors is influenced by global and local socio-economic inequalities, which can have further implications for local and global disparities in health outcomes. Access to the devices necessary to set up an open-source automated insulin delivery system is far from easy: these devices are not only expensive but also hard to access in many national healthcare contexts or within some health insurance systems. It is already difficult to obtain and benefit from the diabetes devices for individuals with T1D in high-income countries without universal healthcare coverage.⁸⁷ Litchman and colleagues pointed out that the high cost of devices and medications places a huge burden on individuals living with diabetes, which results in people turning to "an underground exchange to obtain necessary medications and supplies."⁸⁸ Amidst these inequalities in access to urgently needed T1D devices, reports have emerged about a new alarming health and wellness trend that involves people without Diabetes using glucose sensors for "fun" to experiment with their bodies and food intake,⁸⁹ and in some instances, using the devices for weight loss.⁹⁰

Overall, access to the devices is more difficult for individuals in impoverished countries owing to the high prices that pharmaceutical and device companies charge. Moreover, in countries without universal health coverage, these devices have to be bought privately, and because of the very high cost of direct purchase of these devices, most people cannot afford to buy these. The innovator community is very much aware of this. For example, Kim, a person with T1D and a physician, criticizes the device industry:

Many medical device manufacturers don't even have this [access to technologies in impoverished countries] on their radar. It's additional labor for them, so they do FDA [U.S. Food and Drug Administration] approval and CE Marking [conformité européenne] and then it's really done for them, and I think that's very sad. Open-source offers the potential to bring closed-loop technologies to countries of the world that are otherwise certainly not on any agenda of the industry.

⁸⁵Ibid: 3.

⁸⁶Hatch, op. cit. note 15; Jansky & Langstrup, op. cit. note 53.

⁸⁷Schipp, J., et al., op. cit. note 5.

⁸⁸Litchman, M. L., Oser, T. K., Wawrzynski, S. E., Walker, H. R., & Oser, S. (2020). The underground exchange of diabetes medications and supplies: Donating, trading, and borrowing, oh my!. *Journal of Diabetes Science and Technology*, 14(6), 1000–1009.

⁸⁹See: <https://www.telegraph.co.uk/health-fitness/body/wore-glucose-tracker-two-weeks-bad-news-favourite-breakfast/>, <https://diabetogenic.blog/2022/07/27/unoriginal-biohacking/>.

⁹⁰See: <https://diabetogenic.blog/2021/06/20/cgm-as-a-weight-loss-tool/> (latest access: 14.02.2023).

But also for this you need the components. [...] Someone has now developed an insulin pump for 15 dollars from India. We need more of these products because if no one gets a pump then they get no closed-loop system.

Kim's observation reflects on the potential that open-source innovation has to solve lack of access to standard healthcare. However, it also indicates that one can only have an automated insulin delivery system with access to the right hardware. This, for example, also fits with the increase of open-source approaches to T1D technologies in India, where T1D technologies are often unattainable for many within the privatized system, as this Indian blogger describes:

In India, CGM [continuous glucose monitoring] devices stay highly unaffordable for regular use till date. With no proper health insurance plans for people living with T1D the economic burden of the cost of a CGM is too much for most of the T1Ds. This didn't stop the T1s from finding a jugaad (makeshift alternative) for that.⁹¹

This narrative again shows how access to the actual material devices is the prerequisite to one's engagement with the innovative process. While the source codes and instructions become rapidly available worldwide, the fact is that open-source systems are based on expensive and hard to access devices, which are primarily accessible to those who are socio-economically well-positioned and can afford to engage in innovation.

4.3 | (Online) community building, power asymmetries, and sense of belonging

While access is the first important barrier to patient-led innovation, active participation in the (online) community is also crucial not only to use the technology but also to play an active role in shaping it. Christian describes the community as follows:

This community, it's the reason I started looping. I have never experienced so much solidarity, so much support and so much willingness to selflessly give something to others, to do something good, to support other people. I have a problem today and tomorrow I have three answers [...] that's completely different than when I compare it with any problems I have commercially; [...] so that's why I did that because I realized nothing can happen to you.

Due to limited support networks outside of peer-to-peer support, the community is building their own support structures, which the first author refers to elsewhere as "adjunct structures of support and care."⁹² Similar to Christian, Julia explains how she can get help at any time of the day through community support:

Because you can get help 24 hours a day, really quickly. Even at night you can ask anyone a question. Or, yesterday for example, there was a message going around: "People watch out, do an update [...] because there's a bug in it and we should update it urgently." Really, it passes through WhatsApp and you get the messages twice and three times.

However, not everyone experiences this in the same way. Most of the participants interviewed by the leading author, Bianca Jansky, had only positive experiences with the community. However, she also interviewed three individuals who stopped using the system (briefly or completely), and some who were using the system, but did not feel as included in the (online) community.

For example, Christina, who has no IT background, explains that she has never felt that she was part of the community and even stopped using the system:

Honestly, I never felt like a part of it. [...] I always thought, "Okay, I'm watching this." I was in that Facebook group, but I really didn't dare to post there, but rather thought, "Okay, I'm watching now." I was like peeping at the window, I had the feeling. I observe that.

Christina elaborates that even while she was using the open-source system, she had difficulties situating herself as part of the community and not just as someone observing the practice from the outside. In the interview sample, especially women and people without an IT or medical background pointed out that they were hesitant to actively participate in the online discussions. Even though there is no palpable gender disparity in the composition of the community, and many of the most vocal people in the public discourse are women, often it was women who reported in the interviews that they were not very active in the online discussions surrounding the open-source technology.

Similarly, Thorsten, who had no higher educational background, described his difficulties with self-identifying as part of the community:

Now I always feel like this: (...) I kind of cheated my way into it or something. Because, of course, I'm aware of my computer knowledge and, of course, that's not really there.

⁹¹See: <https://www.t1dfindia.org/post/looping-101-an-india-perspective> (latest access: 15.02.2023).

⁹²Jansky, op. cit. note 59, p. 11.

Thorsten refers to his lack of “computer knowledge,” which leads him to question his skills and place in the community. This is a recurring theme in many of the interviews conducted with people without an IT background, an issue that has also been highlighted in recent discussions about the #WeAreNotWaiting community.⁹³

While the T1D open-source innovation community places emphasis on solidarity and community building—and the majority of interlocutors reported feeling included—the interviewees who reported that they were struggling with belonging to or identifying with the community were also those who did not fit the normative expectations of someone engaging in the open-source sphere: women, people without IT knowledge/background, and individuals from a lower socioeconomic background.

While our qualitative data are not representative of the global community, a quantitative survey by Braune et al. provides further evidence of the largely homogeneous composition of the community.⁹⁴ The survey identifies stark disparities around the globe and socio-economically, with results showing that 77% of the users of open-source automated insulin delivery systems are from Europe and 14% are from North America; ca. 83% of adults involved in this community have a university degree or higher and 26% have an IT background and 19% work in the healthcare sector, with 25% having a household income over U.S. \$100,000 per year and 82% disclosing that they had “out-of-pocket expenses, with an average of US \$530 and a maximum of US \$1000 per year.”⁹⁵ The survey does not report major gender disparities in community membership and the researchers did not seek information about the ethnic/racial background of the participants.⁹⁶ Similarly, a recent study⁹⁷ exploring the discontinuation of the use of the Apple version of the open-source automated insulin delivery system “loop” shows that 72.1% of the people who continued using the system had a household income of over U.S. \$100,000. The researchers obtained data on race/ethnicity, and the majority of people in both groups (discontinuing use and continuing use), over 90%, reported to be white. Similar to Braune et al., the authors did not identify a major gender disparity in the sample.⁹⁸ However, a study from 2023 shows that significantly more women than men report barriers that hold them back from engaging in the use of an open-source automated insulin delivery system.⁹⁹

To summarize, there is quantitative evidence that the T1D open-source patient-led innovation community on a global level is relatively homogeneous in terms of class, nationality, and race. In the interviews of the Germany-based community, the majority of participants reported experiencing solidarity and inclusion. However, some struggled to find their place in the open-source community and described various ways to deal with this struggle. Some stopped using the system and others described that they did not contribute to the online debates.

4.4 | The additional costs of open-source innovation and voluntary labor

It is important to note that open-source innovation is a labor-intensive practice. As we have discussed above, much of the community support is provided as voluntary online peer-to-peer guidance. Most of the people interviewed had regular day jobs and engaged in the open-source community after work and on the weekends. Without support from commercial manufacturers, the innovators had to build their own support structures.¹⁰⁰ For Marcel, who was actively involved in the early stages of the community, the involvement became so labor intensive that he described experiencing burnout:

And then there was this burnt-out feeling, more related to my family. The fact that I saw that I don't do anything with my family anymore and only hang out in front of the computer or somehow have a phone in my hand and chat.

Marcel's engagement in the open-source sphere was so time-consuming that he even went through conflicts with his family, which is why he decided to withdraw from his close engagement with the community. While the open-source system is providing relief to individuals living with T1D from the mental distress of constantly having to manually manage their health condition, being part of the innovation process can also create new kinds of distress for the people involved in community-based peer-to-peer support.¹⁰¹

A lot of “hidden work”¹⁰² goes into developing the systems in an open-source manner. As Marcel pointed out, people sacrificed their leisure time, family life, plus their own savings, and they also experimented with their own bodies and had to tackle legal issues owing to the fact that the systems are unauthorized.¹⁰³ Kaziunas and colleagues point out that this cost of being part of the open-source innovation process “points to how, to a much larger degree, the promotion of self-empowerment and DIY making brings with it

⁹³Garfinkel, op. cit. note 81 we refer to a comment made by philosopher and person with T1D Aude Bandini and the following discussion starting from minute 31:25; Hatch, op. cit. note 15.

⁹⁴As with all online communities, it is difficult to define membership. For this survey, the criteria for inclusion of participants were “adults (aged >18 years), living with diabetes (type 1, 2, or other), or being caregivers of a child or an adolescent with diabetes using an open-source AID system.” Braune, K., et al., op. cit. note 5. Participants were then recruited online through announcements of the OPEN project and in the two largest international Facebook groups dedicated to open-source automated insulin delivery systems.

⁹⁵Braune, K., et al., op. cit. note 5.

⁹⁶ibid.

⁹⁷Wong, J. J., Suttiratana, S. C., Lal, R. A., Lum, J. W., Lanning, M. S., Dunlap, A., Arbiter, B., Hanes, S. J., Bailey, R. J., Hood, K. K., & Naranjo, D. (2022). Discontinued use of the loop insulin dosing system: A mixed-methods investigation. *Diabetes Technology & Therapeutics*, 24(4), 241–248. <https://doi.org/10.1089/dia.2021.0362>

⁹⁸ibid: pp. 241–248.

⁹⁹O'Donnell, S., et al., op. cit. note 83, p. 3.

¹⁰⁰Crocket, H. (2020). Peer mentoring in the do-it-yourself artificial pancreas system community. *Journal of Diabetes Science and Technology*, 14(6), 1022–1027; Jansky, op. cit. note 58, p. 11.

¹⁰¹This is, for example, a blog post about a mother with T1D looking into commercial options because she does not have the “brain-space” to engage in the open-source endeavor: <https://bittersweetdiagnosis.com/2022/10/18/chasing-d-tech/> (latest access 28.10.2022).

¹⁰²Kaziunas, E., et al., op. cit. note 5, pp. 2260–2272, pp. 2257.

¹⁰³ibid: 2257.

the demand to take on the work that used to be performed by the state and health care system.”¹⁰⁴

5 | SOCIAL AND ETHICAL ASPECTS OF PATIENT-LED INNOVATION FROM A GLOBAL HEALTH JUSTICE PERSPECTIVE

Engaging in an open-source endeavor to improve current T1D therapy and also advance the technology provided by the national healthcare system entails complex challenges. It is in many ways admirable to take production into one's own hands and develop technological solutions outside of the traditional research and development context, and also to challenge large pharmaceutical and technological commercial corporations. However, it needs to be recognized that patient-led innovation actually refers to a range of activities in response to underfunded national healthcare systems that co-create conditions in which pharmaceutical companies and medical device manufacturers profit from peoples' health needs¹⁰⁵ without safeguarding often life-saving healthcare technologies. This socio-political context shapes the frustration of individuals with the current conditions of their healthcare. Such issues also point to the persistent problem of lack of allocated funding of health care for people with chronic health conditions.¹⁰⁶

Patient-led innovation, especially in T1D, has been widely discussed in diabetology and other healthcare disciplines. Most of the discussions regarding ethical, legal, and societal issues have been focusing on safety risks¹⁰⁷ or liability issues.¹⁰⁸ There is, however, a growing body of literature addressing the issue that management of T1D with insulin always involves risks and that the community of innovators is already doing a lot to ensure the safety of the technology. Some of the strategies involve built-in safety regulations in algorithms.¹⁰⁹ There has also been an increase in whitepapers and statements on how to mitigate risk as much as possible when using an open-source automated insulin delivery system, stimulating a collaborative approach with clinicians.¹¹⁰ In the last few years, there has also been an increase in clinical evidence regarding the benefits of these systems (clinical and socio-psychological).¹¹¹

From an ethical perspective, it is crucial to broaden the focus of discussions on patient-led innovation beyond the risk and safety concerns and also integrate concerns of health justice on individual, social, and global levels. The notion of patient-led innovation needs to be examined in the context of structural inequalities and hierarchies within national and global healthcare environments. As we have discussed above, medicine and healthcare have an ongoing legacy of exclusion and harm to people structurally disadvantaged and oppressed on the grounds of intersectional gender, racial, colonial, and class inequalities. The populations most affected by this legacy are from (post)colonized and peripheralized societies, from which wealth and resources have systemically been extracted.¹¹²

Chronic autoimmune health conditions, such as T1D, place an especially huge burden on people who are already structurally disadvantaged. A lot of discussions on T1D reflect on the fact that this chronic health condition is a major public health concern globally and a rapid increase in cases is expected especially in impoverished countries.¹¹³ While there are people engaged in T1D patient-led innovation all over the world,¹¹⁴ the population that is most vocal and publicly engaged is not representative of the diversity of people affected by T1D globally or the needs of structurally impoverished populations. This raises a multitude of social and ethical questions regarding the potential of T1D open-source innovation to ensure health benefits for people living with T1D all around the globe as well as concerns over the egalitarian and democratizing character of the innovation.

We believe that the structural conditions of open-source patient-led innovation, which shape access to technology and the opportunity to participate in the innovation process, need to be accounted for in an ethics analysis. In our case, two infrastructures are particularly significant: 1. the global open-source sphere, in which the majority of the technical innovation is conducted, and 2. (in relation to this empirical case) the German healthcare system and its socio-political context.

An increasing number of studies on open-source innovation discuss concerns of structural inequalities that shape the innovation process, particularly those regarding gender, sexuality, and race/ethnicity. For example, Dunbar-Hester points out the following in her research on diversity in open-source contexts: “[...] social context and position, including gender, matter greatly as we consider who participates in technical practices and who possesses agency with regard to technology, both historically and in the present.”¹¹⁵ There are many hurdles that people face on the path to engagement in the

¹⁰⁴ibid.

¹⁰⁵This is clearly documented by pharmaceutical companies charging high prices for insulin.

¹⁰⁶Holman, H. R. (2020). The relation of the chronic disease epidemic to the health care crisis. *ACR Open Rheumatology*, 2(3), 167–173. <https://doi.org/10.1002/acr2.11114>

¹⁰⁷Ceylan, B. (2021). *Evaluating APS ecosystem security: Novel IoT enabled medical platform for diabetes patients* [PhD thesis]. <https://www.diva-portal.org/smash/get/diva2:1543769/FULLTEXT02.pdf>

¹⁰⁸Oliver, N., Reddy, M., Marriott, C., Walker, T., & Heinemann, L. (2019). Open source automated insulin delivery: addressing the challenge. *NPJ Digital Medicine*, 2, 124. <https://doi.org/10.1038/s41746-019-0202-1>. Currently, there is only one short conference proceeding specifically looking at open-source automated insulin delivery systems from a principlism medical ethics perspective: Braune, K., Hussain, S. S., Quigley, M., Petruzelkova, L., Scheiner, G., Winterdijk, P., Schmidt, S., Raimond, L. H., Hood, K. K., Riddell, M., Skinner, T. C., Raile, K., Johnston, C., & Lal, R. (2021). 712-P: International Consensus on the Ethics of Open-Source Automated Insulin Delivery. *Diabetes*, 70(Suppl. 1). <https://doi.org/10.2337/db21-712-p>

¹⁰⁹<https://androidaps.readthedocs.io/de/latest/> (latest access: 16.02.2023).

¹¹⁰Braune, K., et al., op. cit. note 57.

¹¹¹Schipp, J., et al., op. cit. note 5; Braune, K., et al., op. cit. note 57.

¹¹²These countries have commonly been clustered under “low- and middle-income countries” (LMICs), but scholars have critiqued this category in particular as it conceals and depoliticizes how the countries have been systematically impoverished and by whom. See: Khan, T., Abimbola, S., Kyobutungi, C., & Pai, M. (2022). How we classify countries and people—And why it matters. *BMJ Global Health*, 7(6), e009704.

¹¹³Atkinson, M. A., et al., op. cit. note 30; Gregory, G. A., et al., op. cit. note 31.

¹¹⁴Kesavadev, J., Saboo, B., Kar, P., & Sethi, J. (2021). DIY artificial pancreas: A narrative of the first patient and the physicians' experiences from India. *Diabetes & Metabolic Syndrome*, 15(2), 615–620. <https://doi.org/10.1016/j.dsx.2021.02.033>; <https://www.t1dfindia.org/post/looping-101-an-india-perspective> (latest access: May 22, 2023).

¹¹⁵Dunbar-Hester, C. (2019). *Hacking diversity. The politics of inclusion in open technology cultures* (p. 83). Princeton University Press.

open-source community.¹¹⁶ These issues point to structural limitations and socio-political and economic constraints to participation in open-source innovation. As some have pointed out, the openness in open source is predominantly practiced and realized in intellectual property arrangements, rather than the community itself.¹¹⁷ Others, such as Hatch et al.,¹¹⁸ have emphasized that the fact that the exclusionary character of patient-led innovation is largely unintended does not change the material reality of stark disparities in the open-source context: “while it seems that exclusion is certainly not a goal of this movement, without reflecting that not everyone can just get involved, exclusion is a problem that the movement reproduces nonetheless.” Indeed, contemplating on global socio-economic inequalities, the difficulty of gaining access to expensive devices indicates that while people in socioeconomically privileged places in the world “cannot wait” for the commercial actors to deliver life-saving self-care tools, others in structurally disadvantaged regions also cannot wait but are left without viable options, as they do not have the means to gain access to the devices required for open-source innovation. These are indeed the populations that would need the benefits of health innovation the most as the ongoing legacy of colonialism and global socio-economic inequalities has had a detrimental impact on their health and the systematic extraction of wealth and resources from their environment has deprived them of well-equipped healthcare systems and infrastructures.¹¹⁹

While the structural barriers constraining participation in patient-led innovation have not been put in place by the open-source movement, they still considerably affect innovation. Unequal access has real-life implications for the open-source community and its innovative output. Participation in innovation communities, and the health needs that innovators prioritize shape the innovation infrastructures, the generated technologies, and their social and health impacts and accessibility. Criado-Perez¹²⁰ has argued that the lack of equitable participation in design or research is a form of data gap as the health requirements, needs, and concerns of structurally marginalized populations are not integrated into the designed products and solutions. Others¹²¹ have also emphasized the need for innovation processes to be led, shaped and driven by the agency and needs of socio-historically excluded populations, so that novel technologies

can stand a chance to improve the health of the most structurally vulnerable populations in the health context, including those affected by structural racism in medicine and healthcare.

In light of this, to ensure genuinely intersectional and population-wide health benefits from a potentially life-saving open-source technology, innovation ought to be shaped by the experiences and health needs of as diverse a population as possible and structurally vulnerable population groups in particular.¹²² The current underrepresentation of socio-economically disadvantaged, negatively racialized, migrant, and other intersectionally marginalized and oppressed population groups in the T1D innovation community (i.e., the same population groups who are also most structurally vulnerable in the health context¹²³) warrants attention and proactive measures that can mitigate the obstacles limiting participation. Such measures will make open-source digital health more globally beneficial, especially in currently underserved communities. Different sub-populations have different and specific health needs and structurally disadvantaged and oppressed populations urgently require accessible, rigorously designed, and affordable health technologies that will suit their needs.

As we have stated above, the German community is currently one of the biggest communities working on the open-source system. The German socio-political structures, health priorities, and strategies for addressing them will be incorporated into the design of the technologies that the community will develop, and the technology might focus less on the needs of different communities, including those who more urgently need affordable healthcare. Currently, debates about public health and structural inequalities—and racial inequalities in particular—are less advanced in Germany than in other countries, such as the United Kingdom or United States.¹²⁴ Yet, just like the majority of societies, the German society is inherently racialized and everyone is assigned a racial identity within its racially hierarchical social structures.¹²⁵ While the idea of biological racial phenotypes has been scientifically debunked, the social practice of racializing people and the consequent racial disparities and inequalities that stem from it still remain.¹²⁶ This has real-life social and

¹¹⁶Izquierdo, D., Huesman, N., Serebrenik, A., & Robles, G. (2019). OpenStack gender diversity report. *IEEE Software*, 36(1), 28–33. <https://doi.org/10.1109/MS.2018.2874322>; Bosu, A., & Sultana, K. Z. (2019). Diversity and inclusion in Open Source software (OSS) projects: Where do we stand? *ACM/IEEE International Symposium on Empirical Software Engineering and Measurement (ESEM)*, 2019, 1–11. <https://doi.org/10.1109/ESEM.2019.8870179>; Dunbar-Hester, op. cit. note 115.

¹¹⁷Prainsack, B. (2017). *Personalized medicine: Empowered patients in the 21st century* (p. 125). New York University Press; Taylor, A. (2014, April 10). *Open systems and glass ceilings*. Le Monde Diplomatique. Retrieved February 14, 2023, from <https://mondediplo.com/openpage/open-systems-and-glass-ceilings>

¹¹⁸Hatch, op. cit. note 15, p. 11.

¹¹⁹Sherwood, op. cit. note 15; Khan, M., Abimbola, F., Aloudat, T., Capobianco, E., Hawkes, S., & Rahman-Shepherd, A. (2021). Decolonising global health in 2021: A roadmap to move from rhetoric to reform. *BMJ Global Health*, 6(3), e005604.

¹²⁰Criado-Perez, op. cit. note 16.

¹²¹Krishnan, A., Abdilla, A., Moon, A. J., Souza, C. A., Adamson, C., Lach, E. M., Ghazal, F., Fjeld, J., Taylor, J., Havens, J. C., Jayaram, M., Morrow, M., Rizk, N., Quijano, P. R., Çetin, R. B., Chatila, R., Dotan, R., Mhlambi, S., Jordan, S., & Rosenstock, S. (2021). *Decolonial AI Manifesto*. <https://manyfesto.ai/>; Hendl & Roxanne, op. cit. note 19.

¹²²Hendl, T., et al., op. cit. note 23.

¹²³Durocher, E., Chung, R., Rochon, C., & Hunt, M. (2016). Understanding and addressing vulnerability following the 2010 Haiti earthquake: Applying a feminist lens to examine perspectives of Haitian and expatriate health care providers and decision-makers. *Journal of Human Rights Practice*, 8(2), 219–238. <https://doi.org/10.1093/jhuman/huw000>; Rogers, W., Mackenzie, C., & Dodds, S. (2012). Why bioethics needs a concept of vulnerability. *International Journal of Feminist Approaches to Bioethics*, 5(2), 11–38. <https://doi.org/10.3138/ijfab.5.2.11>; Hendl, T., Chung, R., & Wild, V. (2020). Pandemic surveillance and racialized subpopulations: Mitigating vulnerabilities in COVID-19 apps. *Journal of Bioethical Inquiry*, 17(4), 829–834.

¹²⁴Krieger, op. cit. note 25; Hendl, T., et al., op. cit. note 123; Carbonell, op. cit. note 15; Argueza, B. R., Saenz, S. R., & McBride, D. (2021). From diversity and inclusion to antiracism in medical training institutions. *Academic Medicine*, 96(6), 798–801. <https://rat-fuer-migration.de/2022/10/28/wer-zaehlt-in-amtlichen-statistiken-zur-begriffsethik-von-migrationshintergrund/>

¹²⁵Hamed, S., Thapar-Björkert, S., Bradby, H., & Ahlberg, B. M. (2020). Racism in European health care: Structural violence and beyond. *Qualitative Health Research*, 30(11), 1662–1673; Lewicki, A. (2022) The material effects of Whiteness: Institutional racism in the German welfare state. *The Sociological Review*, 70(5), 916–934, p. 916.

¹²⁶Hamed, S., et al., op. cit. note 125; Lewicki, op. cit. note 125; Plümecke, T., Supik, L., & Will, A.-K. (2021). *Rassismus der Pandemie. Unterschiedliche Sterberaten im Zusammenhang mit COVID-19*. Mediendienst Integration. https://mediendienst-integration.de/fileadmin/Daten/Expertise_Rassismus_Uebersterblichkeit_Covid_19_Will_Supik_Pluemecke_FINAL.pdf

economic impacts, conferring benefits and privileges to some and withholding them from others.¹²⁷ For example, sociologist Aleksandra Lewicki points out that in Germany, white individuals receive better access to healthcare services as well as better-quality healthcare services, while groups racialized as “Other,” notably “Black,” “Muslim,” or “Eastern European,” receiving poorer-quality treatment in the welfare state.¹²⁸ Similarly, sociologist Gurminder K. Bhambra introduces the concept of methodological whiteness to emphasize the significance of not using the category “class” as a neutral or objective concept independently from “race” for studies of structural inequalities. Rather, social scientists need to acknowledge the “imperial and colonial histories that shape most current Western national polities”¹²⁹ to adequately understand injustice.

Given the unequally structured social context, a approach to innovation that does not address the social practice of racialization, the inequalities that it produces, and their impact in the health(care) context will only allow these inequalities to remain and potentially increase through digital health. The design of truly innovative technologies that can bridge inequalities and provide better health care to a wider cohort will require conscious consideration and tackling of the inequalities currently in place and in a manner that will intentionally eliminate them.¹³⁰ A crucial step toward implementing an approach that will actively mitigate structural inequalities is the integration of people who have been affected by these inequalities into innovation communities. However, mere ‘inclusion’ is not enough; scholars have emphasized the need to incorporate the perspectives and health needs of people from structurally marginalized communities in ways that will ensure that they will be able to drive, lead and shape patient-led innovation processes.¹³¹ This will not only increase the likelihood that the generated technologies will serve the health needs of currently underserved population groups but also that they will not harm them and instead provide substantial health benefits.

An increasing number of studies in the STS literature on I-methodology¹³² and gender script¹³³ show why it is so crucial to consider *who* develops technologies. In development processes, designers and developers most commonly think of themselves as the standard users (I-methodology) and as such, they inscribe themselves into future technology.¹³⁴ Feminist STS scholars, such as Donna Haraway and Sandra Harding, point out that it is crucial to acknowledge the “standpoints” from which people produce

knowledge, as the idea of neutrality is an illusion. At present, much of the digital health technology has been proven to benefit white and male populations the most, also given that these are the populations who are currently in charge of and engaged in designing most technologies and on whom the technologies are also disproportionately tested.¹³⁵ As a consequence, much of the empirical evidence shows that various digital health technologies fail to serve BIPOC users and that patients from these population groups are often undiagnosed, misdiagnosed, or overdiagnosed based on training data obtained from clinical studies that exclude them.¹³⁶ Remarkably, structural inequalities have not been sufficiently addressed in research, medicine, and healthcare and the automation of health care delivery can exacerbate such inequalities through algorithmic discrimination.¹³⁷ Many health technologies are also intersectionally more risky for BIPOC women because these tools have been disproportionately tested on white male population samples and calibrated to the average size and needs of the white male body.¹³⁸ With inequalities inscribed into design, there is growing empirical evidence that technologies perpetuate harm and fall short of benefitting whole population groups.

Given the persistent inequalities permeating society and healthcare, conscious efforts need to be made to design health technologies that will not replicate and exacerbate problems and disparities. The need to find solutions for existing problems is crucial in patient-led innovation, especially to foster genuinely innovative potential. To fully realize the potential of innovation, communities, procedures, and products need to be driven by innovators from underserved communities, led from their perspectives and by their own healthcare needs. Indigenous feminist STS scholar Kim TallBear¹³⁹ has argued that hypotheses and analyses need to start with the lived experiences of marginalized populations and only through consideration of their standpoints can knowledge production become more rigorous.

Crucially, the driving of innovation by the agency and healthcare needs of structurally vulnerable, marginalized, and underserved populations is fundamental for fostering a truly “bottom-up” kind of innovation. Raman et al.¹⁴⁰ emphasize that minority groups can engage in science and innovation in “ways that allow alternative visions of the public interest to become temporarily visible and

¹³⁵Criado-Perez, op. cit. note 16; Figueroa, C. A., op. cit. note 23; Hendl, T., et al., op. cit. note 15; Hendl, T., et al., op. cit. note 23.

¹³⁶Sjoding, M. W., Dickson, R. P., Iwashyna, T. J., Gay, S. E., & Valley, T. S. (2020). Racial bias in pulse oximetry measurement. *New England Journal of Medicine*, 383(25), 2477–2478; Larrazabal, Nieto, N., Peterson, V., Milone, D. H., & Ferrante, E. (2020). Gender imbalance in medical imaging datasets produces biased classifiers for computer-aided diagnosis. *Proceedings of the National Academy of Sciences of the United States of America*, 117(23), 12592–12594; Daneshjou, R., Smith, M. P., Sun, M. D., Rotemberg, V., & Zou, J. (2021). Lack of transparency and potential bias in artificial intelligence data sets and algorithms: A scoping review. *JAMA Dermatology*, 157(11), 1362–1369; Liao & Carbonell, op. cit. note 15; Hendl, T., et al., op. cit. note 23.

¹³⁷Noble, S. U. (2018). *Algorithms of oppression: how search engines reinforce racism*. New York University Press; Hendl, T., et al., op. cit. note 15.

¹³⁸Hendl, T., et al., op. cit. note 23.

¹³⁹TallBear, op. cit. note 74.

¹⁴⁰Raman, S., Hobson-West, P., Lam, M. E., & Millar, K. (2018). ‘Science Matters’ and the public interest: The role of minority engagement. In B. Nerlich, S. Hartley, S. Raman, & A. Smith (Eds.), *Science and the politics of openness: Here be monsters* (1st ed., pp. 230–252). Manchester University Press, p. 231.

¹²⁷Kelly, N. (2021). *Rassismus. Strukturelle Probleme brauchen strukturelle Lösungen!* Altrium Verlag. <https://www.degruyter.com/document/doi/10.1515/9780804779722/html>

¹²⁸Lewicki, op. cit. note 125.

¹²⁹Bhambra, G. K. (2017). Brexit, Trump, and ‘methodological whiteness’: On the misrecognition of race and class. *The British Journal of Sociology*, 68(1), 227.

¹³⁰Benjamin, R. (2019). *Race after technology*. Polity Press.

¹³¹Criado-Perez, op. cit. note 16; Turner, K., Wood, D., & D’Ignazio, C. (2021). The abuse and misogyny playbook. In A. Gupta, A. Royer, C. Wright, F. A. Khan, V. Heath, E. Galinkin, R. Khurana, M. Bergamaschi Ganapini, M. Fancy, M. Sweidan, M. Akif, & R. Butalid (Eds.), *State of AI ethics report* (pp. 15–34). Montreal Ethics Institute; Hendl & Roxanne, op. cit. note 19.

¹³²Oudshoorn et al. 2004 op. cit. note 13.

¹³³Akrich, op. cit. note 13.

¹³⁴Amrute, S. (2019). Of techno-ethics and techno-affects. *Feminist Review*, 123(1), 56–73. <https://doi.org/10.1177/0141778919879744>

potentially compelling.” In light of this, innovation communities that include and are dominated by members of socio-economically better-positioned population groups represent a “top-of-the-bottom” kind of innovation. As such, a conscious strategy that will assess and mitigate possible obstacles to more equitable participation and leadership in innovation is needed, integrative of an approach to design and distribution of open-source technology that will aim to foster just health outcomes for all.¹⁴¹ Such an approach is warranted in order to unlock the full potential of patient-led innovation for improving public health outcomes locally and globally.

5.1 | How can open-source innovation mitigate inequalities in healthcare?

From the perspective of justice in terms of healthcare for all, perhaps the best part of open-source patient-led innovation is that it starts with someone identifying a health(care) problem and responding by (re)designing a technological solution and sharing it with others without commercializing the idea. This ethos of open-source innovation is vital, especially to ensure that potentially life-saving health technology is more accessible to underserved population groups. Next, we will discuss ideas on how to maximize this potential.

As discussed above, much of patient-led innovation is currently inhibited owing to socioeconomic inequalities. These inequalities limit access to both the opportunity for innovating and the material innovation technologies, even when there are no formal or intended restrictions on access or participation. The disparities in participation impact how innovation is done, whose perspectives and health needs inform the process, to whom the products are tailored, and therefore whom they will benefit the most.

How then to approach and address these structural issues and mitigate their consequences? As we have noted, widening the innovation community and including members from underserved communities in leadership roles are crucial steps to this endeavor. Yet, how to do this in ways that will genuinely benefit currently under-represented individuals and population groups? It might seem viable to simply call for larger inclusion and involvement of structurally disadvantaged and under-represented population groups in patient-led open-source innovation. However, if engagement is not sought under just and affirmative conditions, such an approach could place additional burdens on already disadvantaged population groups.

For example, an approach that would seek to diversify a community by including members from marginalized population groups and assigning them responsibility for solving the problems stemming from their previous exclusion would seem unfair.¹⁴² Moreover, the involvement of disadvantaged and socio-economically worse-off population groups might place further strain on these communities. As we have discussed, innovation is costly, and besides expensive

devices, patient-led innovation is conducted based on unpaid labor, mostly done in one's spare time. Hence, without subsidies, the involvement of structurally impoverished population groups could involve extra costs, fewer opportunities for paid work, or time required to rest and attend to their health needs. As such, this involvement could make already disadvantaged population groups even more unwell. Financial support might need to be facilitated through affirmative remuneration strategies, such as grants or fellowships for innovators from underserved and socio-economically marginalized populations.

The topic of affirmative remuneration also relates to issues of commercialization and profit. While empirical evidence shows that most people engaged in patient-led innovation do this labor without any remuneration, companies can capitalize on patient-led innovation because open-source involves no intellectual property arrangements.¹⁴³ This means that corporations can access the outputs of patient-led innovation and use them to manufacture technologies for their own financial profit. As such, patient-led innovation infrastructure can involve fundamental inequalities between unpaid innovators and companies benefiting from their labor, if these companies commercialize innovation, while innovators bear the costs of innovating (which we should not forget involves experimentation with their own bodies). Such costs weigh more heavily on intersectionally disadvantaged population groups, who already have limited access to socio-economic and healthcare resources. These issues should prompt follow-up discussions on the role and responsibilities of medical technology manufacturers and corporations, the digital health sector, and the national healthcare and regulatory systems that they are embedded within, including financial support for innovators.¹⁴⁴

Similarly essential to the creation of conditions under which innovators from underserved population groups might want to participate in innovating is the restructuring of innovation communities in ways that will be welcoming to so far under-represented innovators, enabling them to be heard and have influence within these communities. Researchers who have investigated how gender and racial inequalities manifest in the technology industry have critiqued the tokenizing and continuous dismissal of under-represented and marginalized population groups, such as women of color.¹⁴⁵ These observations are also relevant to patient-led innovation communities. A crucial part of innovating and fostering equitable innovation benefits is enabling members of under-represented and underserved population groups to hold leadership positions and power to shape innovation processes.¹⁴⁶ This requires the maintenance of innovation communities in ways that will be inclusive, welcoming, and appreciative of so far

¹⁴³When our paper was read by members of the innovation community and carers, it was pointed out that many people with T1D have a particularly strong desire to gain access to better products faster, which will ensure better health with less risk, effort, and so forth.

¹⁴⁴In relation to financial reimbursement, it is also important to point out that financial support is often provided by the pharmaceutical industry (see, e.g., #dedoc voices). This could then also create issues of dependency and conflict of interest between the needs of affected individuals and the profit of pharmaceutical corporations. As such, it is not only crucial to think about financial reimbursement but also about who is paying.

¹⁴⁵Turner, K., et al., op. cit. note 131.

¹⁴⁶Argueza, B. R., et al., op. cit. note 124; Ganguli-Mitra, A. (2023). Power and feminist bioethics. In W. Rogers, S. Carter, V. Entwistle, C. Mills, & J. Leach Scully (Eds.), *Routledge handbook of feminist bioethics* (pp. 58–70). Routledge.

¹⁴¹Benjamin, op. cit. note 130; Liao & Carbonell, op. cit. note 15. Hendl, T., et al., op. cit. note 23.

¹⁴²Argueza, B. R., et al., op. cit. note 124.

excluded members and encourage them to play key roles in setting agendas and having them implemented.¹⁴⁷ This is particularly relevant to participation in (online) peer-to-peer support groups but also meetings and socializing events, which are all spaces where experiences with innovation and its challenges are discussed.¹⁴⁸ In order to facilitate more inclusive, diverse, and egalitarian innovation communities, intentional actions will need to be taken toward creating and maintaining welcoming and equitable community infrastructures, which will seek and value input and leadership from historically under-represented groups. Further debates and research are warranted to explore how this can be achieved in patient-led innovation in various local contexts as well as viable strategies to foster and support more diverse participation globally.

While we do not have substantial answers to complex questions regarding how patient-led innovation can bridge and mitigate global inequalities in healthcare, we will provide some examples of how patient-led innovation can foster more equitable participation on a global scale. The first and possibly easiest strategy involves carefully and fairly executed hackathons. Hackathons are already an integral part of the patient-led innovation infrastructures.¹⁴⁹ They can also be used to boost the participation of under-represented population groups.¹⁵⁰ Ideally, especially participants from currently under-represented and structurally and socio-economically marginalized population groups ought to be paid for their labor.¹⁵¹ There are already some examples of good practice to balance up the predominance of white and male voices in open-source technology development, for example, the “heart of code” feminist hackerspace in Berlin and the “at the root” project which fosters actively anti-racist open-source technologies.¹⁵² Collaborations between these initiatives and patient-led innovation communities could benefit innovation spaces, all the while without requiring brand-new strategies. Hackathons have already been conducted as part of open-source patient-led innovation in T1D and an integration of intersectional concerns of gender and racial justice could advance them.

Another example of good practice in bridging health inequalities is the international organization #dedoc° for and by people with diabetes, which supports and amplifies diabetes advocates around the globe. The #dedoc° voices¹⁵³ initiative brings together people living with diabetes to share their experiences and the industry funds their

participation¹⁵⁴ at academic conferences to ensure the representation of the voices and perspectives of those affected. An emphasis is placed on diverse representation and global reach as well as the elevation of “patient” voices and the democratization of debates on diabetes. Too often, people with chronic health conditions are seen primarily as only “important epistemic factors”¹⁵⁵ within medical knowledge production. #dedoc° challenges these notions and supports and amplifies the voices and demands of people living with diabetes in various social groups and contexts, so that they can guide diabetes research. One recent example is Hubban Khan,¹⁵⁶ a #dedoc° voices participant from Pakistan, who used his #dedoc° voices role to draw attention to the fact that during disastrous floods that Pakistan has faced, the mental health problems of people living with diabetes in Pakistan have significantly increased and need to be addressed. The #dedoc° organization, their global connectivity, and support networks could be used as an inspiration to bring voices from under-served communities to the forefront and amplify them in patient-led innovation.

The third example involves the OPEN project, designed mostly by academics with T1D, who have engaged in open-source patient-led innovation and applied for an EU grant to produce empirical evidence about open-source automated insulin delivery systems. Situated at different universities and research centers around Europe, the United States, and Australia, the project facilitates cooperation between people with T1D, academia, industry, and the patient-led innovation community. It aims to “create patient-centric innovation and reduce disease burden”¹⁵⁷ in a communal way. The conduct of patient-led innovation within scientific research and its standards and regulations also produces more rigorously conducted, evidence-based, tested, and regulated innovation, without it being tied to commercial pharmaceutical actors. Unlike citizen science in this project, people with T1D are not only invited to participate, but they are at the center of all steps of the research project. The project also advances research on so far neglected aspects of T1D, such as the relationship between automated insulin delivery systems and users’ menstrual cycle, exploring how digital technologies might work differently for women and fellow people with uteruses in terms of menstruation,¹⁵⁸ which is an understudied area of diabetology¹⁵⁹ and medicine in general.¹⁶⁰ Notably, the OPEN project

¹⁵⁴It is important to note that #dedoc is financially supported by stakeholders of the pharmaceutical industry. This entanglement points to the complexities of the relations in this context, where finding sponsorship by nonprofit organizations and governmental agencies would be vital in order to minimize socio-ethical harms and concerns and conflicts of interest.

¹⁵⁵Falke, O. (2018). Der Patient als epistemische Größe. *Praktisches Wissen und Selbsttechniken in der Diabetestherapie 1922-1960. Medizinhistorisches Journal*, 53(1), 36-58.

¹⁵⁶https://twitter.com/khan_hubban/status/1626500179837825026/photo/1 (latest access: 14.02.2023).

¹⁵⁷O'Donnell, S., Lewis, D., Marchante Fernández, M., Wäldchen, M., Cleal, B., Skinner, T., Raile, K., Tappe, A., Ubben, T., Willaig, I., Hauck, B., Wolf, S., & Braune, K. (2019). Evidence on user-led innovation in diabetes technology (the OPEN Project): Protocol for a mixed methods study. *JMIR Research Protocols*, 8(11), e15368. <https://doi.org/10.2196/15368>

¹⁵⁸Mewes, D., Wäldchen, M., Knoll, C., Raile, K., & Braune, K. (2022). Variability of glycemic outcomes and insulin requirements throughout the menstrual cycle: A qualitative study on women with type 1 diabetes using an open-source automated insulin delivery system. *Journal of Diabetes Science and Technology*. <https://doi.org/10.1177/19322968221080199>

¹⁵⁹Mewes, D., et al., op. cit. note 158. p. 2.

¹⁶⁰Hendl, T., et al., op. cit. note 23.

¹⁴⁷Argueza, B. R., et al., op. cit. note 124.

¹⁴⁸Jansky, op. cit. note 58; Jansky, B. (2023). *Device activism. An ethnography of patient activism and the intersection of chronic (self)care and open-source innovation in Type 1 Diabetes* [PhD dissertation, Ludwig-Maximilians-University, Munich].

¹⁴⁹Jansky, op. cit. note 148.

¹⁵⁰Beltrán, H. (2020). The first latina hackathon. *Catalyst: Feminism, Theory, Technoscience*, 6(2), 1-30. <https://doi.org/10.28968/cfft.v1i001.32904>; Wuschitz, S. (2022). A feminist hacklab's resilience towards anti-democratic forces. *Feminist Theory*, 23(2), 150-170. <https://doi.org/10.1177/14647001221082298>

¹⁵¹Ideally, all innovators would be paid for their labor. Yet, in a racially unequal society, it is particularly crucial to financially compensate socio-economically marginalized innovators from under-served population groups.

¹⁵²We, however, could not find information regarding how these organizations deal with reimbursement of the labor of members of under-represented, structurally, and socio-economically marginalized population groups.

¹⁵³<https://www.dedoc.org/> (latest access: 14.02.2023).

also enables the collection and analysis of data about the users of open-source automated insulin delivery systems. In particular, the data on the distribution of users of open-source automated insulin delivery systems show that there are users outside of Europe, Australia, and North America who are, however, not as prominently included and focused on in public debates around patient-led innovation. For example, an analysis of Twitter data revealed that as many people in India and South Africa as in Europe, Australia, and North America were tweeting about the innovation; yet, how people with T1D in these regions were engaging in this innovation has not been traced yet.¹⁶¹ A similar research project is the CREATE Trial,¹⁶² which is a randomized-controlled clinical trial of the open-source technology based in New Zealand. One of the first publications stemming out of this project is an interview study on the experiences of Māori people with T1D using the open-source technology using a “by Māori, for Māori” approach.¹⁶³ More transnational research projects led by people with T1D from under-served population groups are needed to explore and foster global participation to the benefit of structurally marginalized communities, including in impoverished and decolonizing countries.¹⁶⁴

A good example of an initiative that provides access to innovative technologies without diminishing the open-source ethos of patient-led innovation is the nonprofit organization “Tidepool,” founded by people with diabetes and carers. Tidepool’s website states that “Inequality and exclusion are the defaults of software development and medical device industries. Without intentional effort to address barriers to access, we inherit those failings and worsen the problem.”¹⁶⁵ The NGO offers structures and technologies for “empowering the next generation of innovations in diabetes management” without a fee and focuses on eliminating “The default of exclusion” in the medical device industry. In January 2023, Tidepool received 510(k) clearance for their modified AID system controller, representing a regulatory clearance for technology developed by the community.¹⁶⁶ Communities inspired by this and

other examples discussed above, who would like to extend their views on social and health justice, do not need to start from scratch. There are resources that can help them further their endeavor, such as the “Digital Health Social Justice tool kit.”¹⁶⁷ This resource was compiled for developers of various digital health technologies but can be integrated into the open-source patient-led innovation sphere. Other resources, such as Anti-racist community citizen science courses, are also increasingly being introduced.¹⁶⁸

While there are many other examples, initiatives, and strategies for improving the infrastructure and conditions of open-source patient-led innovation, we would like to end this section by acknowledging that individuals’ use of T1D open-source technologies can often be met with challenging responses from clinicians. In particular, some clinicians might disapprove of T1D patient-led innovation, for example, because they might fear legal liabilities when their patients use open-source tools.¹⁶⁹ This can discourage individuals living with T1D from visiting a doctor or being open about their use of open-source technologies.¹⁷⁰ O’Donnell et al. (2023) report in their studies on barriers to engaging in using an open-source automated insulin delivery system that individuals with T1D fear losing the support of their healthcare providers.¹⁷¹ Such discouraging contexts can limit the range of health services and technologies that one can use and, through this, undermine the quality of healthcare and health of disadvantaged individuals living with T1D, who already might be struggling to access much-needed healthcare services. Recently, Hussain et al. (2022) pointed out in a *Lancet* commentary that developments of open-source automated insulin delivery systems have been met with resistance from the academic medical community. The authors have noted that the hesitation was not necessarily aligned with objective evidence or widespread consensus¹⁷² concerning the benefit of open-source automated insulin delivery systems. These issues thus raise broader questions about the challenges to integrating much-needed technologies into clinical practice and the healthcare system.

There have already been some vital initiatives to develop guidelines and position statements from different national diabetology associations¹⁷³ and an international consensus statement from clinicians on open-source automated insulin delivery

¹⁶¹Litchman, M. L., Walker, H. R., Fitzgerald, C., Gomez Hoyos, M., Lewis, D., & Gee, P. M. (2020). Patient-driven diabetes technologies: Sentiment and personas of the #WeAreNot-Waiting and #OpenAPS Movements. *Journal of Diabetes Science and Technology*, 14(6), 990–999. <https://doi.org/10.1177/1932296820932928>

¹⁶²<https://www.otago.ac.nz/christchurch/departments/paediatrics/research/otago717634.html> (last access: 04.05.2023).

¹⁶³Burnside, M., Haitana, T., Crocket, H., Lewis, D., Meier, R., Sanders, O., Jefferies, C., Faherty, A., Paul, R., Lever, C., Price, S., Frewen, C., Jones, S., Gunn, T., Wheeler, B. J., Pitama, S., de Bock, M., & Lacey, C. (2023). Interviews with Indigenous Māori with type 1 diabetes using open-source automated insulin delivery in the CREATE randomised trial. *Journal of Diabetes & Metabolic Disorders*, 22(1), 861–871. <https://doi.org/10.1007/s40200-023-01215-3>

¹⁶⁴The fact that many nations have had resources systematically extracted from them also raises concerns about the socio-economic capital required for innovating. Global health scholar Seye Abimbola recently emphasized that knowledge from the global South is located in the global South and that it is much more crucial to support, build, and foster knowledge platforms in the global South than to include global South voices in global North platforms. The same can be said about innovation. Thus, important questions remain to be answered about how to achieve such support in patient-led innovation in epistemically just ways and in accordance with the needs of decolonizing societies. This is particularly important in order to eliminate the inequalities between under-represented innovators ‘invited’ to already existing Western platforms that have been established and shaped without them and innovators in places from which resources have systematically been extracted by the West. See: Abimbola, S. (2023). Knowledge from the global South is in the global South. *Journal of Medical Ethics*, 49(5), 337–338. <https://doi.org/10.1136/jme-2023-109089>

¹⁶⁵<https://www.tidepool.org/about> (latest access: 05.10.2022).

¹⁶⁶<https://www.tidepool.org/tidepool-loop> (latest access: 15.02.2023).

¹⁶⁷Figuerola, C. A., Murayama, H., Amorim, P. C., White, A., Quiterio, A., Luo, T., Aguilera, A., Smith, A. D. R., Lyles, C. R., Robinson, V., & Von Vacano, C. (2022). Applying the digital health social justice guide. *Frontiers in Digital Health*, 4, 1–12. <https://doi.org/10.3389/fdgth.2022.807886>

¹⁶⁸<https://citizenscience.org/2023/01/12/anti-racist-community-citizen-science-course/> (latest access: 14.02.2023).

¹⁶⁹Raimond, L. H., O’Donnell, S., Bøggild-Damkvi, T., Filges, T., & Lomborg, K. (2022). Open-source automated insulin delivery systems and formal healthcare: A qualitative study of challenges in the interaction between service-users with type 1 diabetes and healthcare professionals. *Chronic Illness*. <https://doi.org/10.1177/17423953221142341>; Shaw, D., op. cit. note 28.

¹⁷⁰Gottlieb & Cluck, op. cit. note 53; Schipp, J., et al., op. cit. note 5; Jansky, op. cit. note 59.

¹⁷¹O’Donnell, S., et al., op. cit. note 83, p. 3.

¹⁷²Hussain, S., Rayhan, A.L., & Braune, K. (2022). Open-source automated insulin delivery in type 1 diabetes—The evidence is out there. *The Lancet Diabetes & Endocrinology*, 10(12), 835–836.

¹⁷³SDCC guidelines for DIY medical systems-english-version (2019); Position Statement | Diabetes Australia. (2019). *UK position statement*. <https://www.diabetes.org.uk/professionals/position-statements-reports/do-it-yourself-closed-loop>

systems.¹⁷⁴ More such initiatives and their context-sensitive implementation could improve the health status of individuals with T1D.¹⁷⁵ For people living with T1D to be able to use open-source technologies and consult their clinicians, health professionals need to take such technologies into consideration, refrain from denying care to their patients who use these technologies, and be informed on the limits of their liability. Socio-economically disadvantaged individuals with T1D, who are disproportionately affected by limited opportunities and exclusion, might have even less motivation to engage in patient-led innovation, should this complicate access to healthcare or in case their clinicians disapprove. If one has reasons to worry that their engagement in the open-source community will result in them receiving worse healthcare or less supportive treatment from clinicians, they might not engage in patient-led innovation, even with community support. Hence, there seems to be a need for specific training for clinicians on the use and importance of T1D open-source technologies and their greater integration into healthcare.¹⁷⁶

6 | CONCLUSION

While the open-source community paved the way for faster development of commercial automated insulin delivery systems, members of the community are also in a precarious situation. Patient-led innovation can be perceived and experienced as empowering, while at the same time, it is also illustrative of an increasing shift of health responsibilities onto the individual. Indeed, in a chronic health condition where most of the illness-related management is already been carried out by the affected individual. Open-source patient-led innovation has initiated a push for the development of new digital technologies for managing T1D. The initiative contributed toward raising awareness about the issue of slow innovation cycles in T1D technology development and the constant burden associated with living with T1D (even with digital aids), and paved the way toward more rapid development of commercial health technologies. The movement has also highlighted that in contemporary digitized and personalized healthcare settings, individuals living with chronic health conditions often function as “digitally engaged patients”¹⁷⁷ in their digitized self-care regime, but without any real say in what happens to their health data.¹⁷⁸ As

such, the T1D open-source community and their work do not represent an elitist or niche engagement with self-care technologies. This community highlights and challenges the relative power of the pharmaceutical industry in contemporary digitized and personalized healthcare systems, including data monopolies, extractivism, and insufficient user engagement. However, from an intersectional global justice perspective, we also see that currently, the most under-served population groups and their health needs are not prominently present in these debates. Patient-led innovation is commonly described as a “bottom-up” innovation; yet, a closer look shows a more complicated picture. While patient-led innovation involves the subverting of some traditional power asymmetries and hierarchies in the biomedical sphere and disrupts the concentration of expertise and innovation in the hands of physicians and medical technology manufacturers, it still replicates many socio-political and economic inequalities. As such, can inadvertently contribute to the maintenance and perhaps even exacerbation of health inequalities. To better serve the needs of all people living with T1D, especially the health interests of the most underserved population groups, patient-led innovation needs to integrate, center, and prioritize the voices, agency, and health needs of so far excluded, marginalized, vulnerable, and underserved individuals living with T1D.

The T1D patient-led innovation community has created technologies that have considerably improved the lives of people living with the burdensome chronic health condition and enabled collective sharing of the process. Nevertheless, there still remains scope for improving patient-led innovation infrastructures locally and globally. It is crucial to recognize that patient-led innovation responds to the shortcomings and gaps in standard healthcare systems as well as the large (data) monopoly that commercial digital health technology manufacturers have. At the same time, it is ethically important to grasp and interrogate whose voices, ideas, and health needs are shaping patient-led innovation infrastructures, communities, processes, and the resulting technologies. Because we acknowledge that automating some of the burden involved in self-managing a chronic health condition can improve many lives, we see the need to reflect on who might be left behind or out. This seems especially urgent from a global health justice perspective, which recognizes that people in countries and communities from which resources have systematically been extracted particularly need innovative open-source technologies.¹⁷⁹ At the same time, scholars of global and Indigenous health, such as Seye Abimbola and Krystal Tsosie and her colleagues,¹⁸⁰ have emphasized the need for nonextractivist and epistemically just approaches to knowledge. This approach also needs to be integrated into open-source innovation and innovative infrastructures. Follow-up and epistemically just research could help find effective ways to address and mitigate disparities and

¹⁷⁴Braune, K., et al., op. cit. note 57.

¹⁷⁵Raimond LH, et al., op. cit. note 169, p. 9.

¹⁷⁶Braune, K., et al., op. cit. note 57.

¹⁷⁷Lupton, D. (2013). The digitally engaged patient: Self-monitoring and self-care in the digital health era. *Social Theory & Health*, 11, 256–270. <https://doi.org/10.1057/sth.2013.10>

¹⁷⁸It is however also relevant to note here, that in a qualitative interview study with users of sensor-based glucose monitoring devices, the interlocutors stated that they are not worried about their data being used by pharmaceutical companies, as long as it is used for improving the system; Jansky, B. (2021). Warum stechen, wenn man Scannen kann? Zum Einsatz sensorbasierter Glukosemesssysteme in der Typ 1 Diabetestherapie. In I. Julia, & S. Rudolf (Eds.), *Digitale Patientenversorgung: zur Computerisierung von Diagnostik, Therapie und Pflege*. Bielefeld: transcript (pp. 127–148). <https://doi.org/10.14361/978383839449189-007>; From an ethical perspective it is however still relevant to think about the harm that these data monopolies can entail for the users, even if the users might not necessarily disapprove.

¹⁷⁹Kesavadev, J., et al., op. cit. note 114; <https://www.t1dfindia.org/post/looping-101-an-india-perspective> (latest access: May 22, 2023).

¹⁸⁰Abimbola, op. cit. note 164; Tsosie, K. T., Krystal S., Yracheta, J. M., Kolopenuk, J. A., & Geary, J. (2021). We have “gifted” enough: Indigenous genomic data sovereignty in precision medicine. *American Journal of Bioethics*, 21(4), 72–75.

inequalities in patient-led open-source innovation within the broader context of a largely privatized digital health market, local healthcare systems, the global health data economy, and the health needs as defined by experts from structurally vulnerable and decolonizing societies and population groups.

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