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Pan-creative patients
The use of DIY loop systems for automated insulin dosing in the case of type 1 diabetes

verfasst von | submitted by

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Abstract

What is good care? People living with chronic diseases are confronted with this question throughout their lives, constantly searching for an answer. The impairments associated with such illnesses are often experienced as a reduction in *quality of life*. Mitigating or overcoming these impairments is the goal of good *care*. A central component of this care are treatment technologies that align with patients' needs. One might assume that the strong regulation and powerful medical technology industry typically ensure this alignment. However, this research, using the example of Type 1 Diabetes (T1D), shows that this is not always the case.

T1D is a chronic metabolic disorder in which the pancreas is not able to produce insulin, a hormone essential for regulating blood glucose levels. For patients, this means navigating a highly demanding daily routine, especially in terms of manually regulating blood sugar levels by insulin injections. But what if there was a technical system that could imitate the function of the pancreas? This is precisely the idea pursued for over a decade by the patient activism movement OpenAPS. Its members hack conventional medical devices and reassemble them into a so-called *Artificial Pancreas System* (APS). These Loop systems allow for highly automated insulin delivery based on real-time glucose measurements. In this way, people with T1D become what one might call *pan-creative patients*: they address the chronic condition at the root of their illness with creative, innovative approaches.

Even though the medical industry has since followed by offering commercial systems for automated insulin dosing, there are still patients who use a DIY Loop instead of these commercial alternatives. Based on qualitative interviews with DIY Loop users in Germany, this research investigates two main questions: What motivates people with T1D to make this *choice*? And what specific challenges emerge from this choice, particularly in their interactions with other actors in the healthcare system? When opting for a DIY Loop, users continue to interact with for example healthcare professionals and insurance providers in context of their diabetes treatment.

This research draws on theoretical concepts from Science and Technology Studies. The Social Construction of Technology (SCOT) offers a technically oriented lens focused on the DIY Loop as a technological artifact. From this perspective, people with T1D are understood as a *relevant social group* with specific requirements. The DIY Loop can thus be interpreted in terms of its perceived functional advantages over commercial treatment devices. Moreover, from a SCOT viewpoint, DIY Loops prevent a premature closure of existing treatment technologies. DIY users demonstrate that alternative artifacts are still possible.

A second theoretical lens is offered by the *Logic of Care*, which critically interrogates the notion of "choice." The chosen technology does not exist as a *neutral tool* but is embedded in a complex socio-material constellation. The *Logic of Care* contradicts the assumption that patients merely have to choose the right device from a preexisting portfolio – especially in this case where appropriate commercial options do not exist or do not meet patients' criteria.

This study shows how people with chronic diseases articulate their needs for treatment technologies by creating them themselves, due to a lack of suitable options provided by the healthcare industry. The technologies they use serve as bridges toward an improved *quality of life* in the context of care. In doing so, DIY users show an alternative pathway outside of established structures of the healthcare system which does not offer adequate solutions. Users of DIY Loop systems thus also point to a new way of thinking – namely, a more individualized and patient-driven approach regarding care in technological terms. But by doing this, they confront new and previously unfamiliar challenges and responsibilities.

Abstract (German)

Was ist gute Sorge? Menschen mit chronischen Erkrankungen sind ihr Leben lang mit dieser Frage konfrontiert und ständig auf der Suche nach einer Antwort. Die mit solchen Erkrankungen einhergehenden Beeinträchtigungen werden häufig als Reduzierung der Lebensqualität empfunden. Diese Einschränkung zu reduzieren ist das Ziel von *guter Sorgearbeit*. Ein zentraler Bestandteil hierbei sind Behandlungstechnologien, die mit den Bedürfnissen der Patient:innen übereinstimmen. Man könnte annehmen, dass durch strenge Regulierungen und eine starke Industrie im Bereich der Medizintechnik genau diese Übereinstimmung sichergestellt wird. Dass dies nicht immer der Fall ist, zeigt diese Arbeit am Beispiel von Menschen mit Typ 1-Diabetes (T1D).

T1D ist eine chronische Stoffwechselerkrankung, bei welcher die Bauchspeicheldrüse nicht in der Lage ist, das Hormon Inuslin zu produzieren, welches zur Regulierung des Blutzuckerspiegels benötigt wird. Für Patient:innen bedeutet dies im Alltag ein hohes Maß an Herausforderungen, insbesondere durch die manuelle Regulierung des Blutzuckerspiegels durch Insulininjektionen. Was aber wäre, wenn es ein technisches System gäbe, welches die Funktion der Bauchspeicheldrüse imitiert? Genau diese Idee verfolgt seit gut einem Jahrzehnt die Patient:innen-Aktivismusgruppe „OpenAPS“. Ihre Mitglieder hacken konventionelle Medizingeräte und bauen daraus sogenannte Artificial Pancreas-Systeme (APS) zusammen. Diese auch „Loop“ genannten Systeme ermöglichen eine zum großen Teil automatisierte Insulindosierung auf Basis des aktuellen Blutzuckerspiegels. Menschen mit T1D werden gewissermaßen zu *pan-creative patients*: Sie begegnen ihrer chronischen Erkrankung mit kreativen Innovationen.

Obwohl die Medizintechnikindustrie inzwischen kommerzielle Systeme zur automatisierten Insulinabgabe anbietet, nutzen manche Patient:innen weiterhin ein DIY-Loop-System anstelle dieser kommerziellen Alternativen. Ausgehend von qualitativen Interviews mit DIY-Looper:innen in Deutschland untersucht diese Arbeit zwei zentrale Aspekte: Was motiviert Menschen mit T1D zu dieser Entscheidung? Und welche spezifischen Herausforderungen ergeben sich daraus – insbesondere in der Interaktion mit anderen Akteuren des Gesundheitssystems? Denn auch wenn sich Patient:innen für ein DIY-Loop entscheiden, stehen sie im Rahmen ihrer Diabetesbehandlung weiterhin in Kontakt mit beispielsweise Ärzt:innen oder Krankenkassen.

Diese Arbeit stützt sich auf theoretische Konzepte der *Science and Technology Studies*. Die *Social Construction of Technology* (SCOT) bietet eine technikorientierte Perspektive auf das DIY-Loop als technologisches Artefakt. Aus dieser Sichtweise werden Menschen mit T1D als relevante

soziale Gruppe mit spezifischen Anforderungen verstanden. Das DIY-Loop lässt sich somit im Hinblick auf seine wahrgenommenen funktionalen Vorteile gegenüber kommerziellen Geräten interpretieren. Darüber hinaus stellt das DIY-Loop aus SCOT-Perspektive eine Verhinderung eines verfrühten closure bestehender Behandlungstechnologien dar: DIY-User zeigen, dass alternative technologische Artefakte weiterhin möglich sind.

Ein zweiter theoretischer Zugang ergibt sich aus der *Logic of Care*, welche den Begriff der „Wahl" kritisch hinterfragt. Das verwendete Gerät ist kein neutrales Werkzeug, sondern eingebettet in eine komplexe soziomaterielle Konstellation. Die *Logic of Care* widerspricht der Annahme, dass Patient:innen lediglich das passende Gerät aus einem vorgegebenen Repertoire auswählen müssen – insbesondere in diesem Fell, in dem geeignete kommerzielle Optionen entweder nicht existieren oder nicht den Anforderungen der Patient:innen für eine gute Sorgearbeit entsprechen.

Diese Arbeit zeigt, wie Menschen mit chronischen Erkrankungen ihre technologischen Bedürfnisse artikulieren, indem sie mangels passender Angebote der Gesundheitsindustrie ihre eigenen Lösungen schaffen. Die von ihnen genutzten Technologien fungieren im Rahmen der Sorge um sich selbst als Brücken hin zu einer verbesserten Lebensqualität. Auf diese Weise zeigen DIY-Nutzer:innen einen alternativen Pfad jenseits der etablierten Strukturen des Gesundheitssystems auf, das ihnen aus ihrer Perspektive keine adäquaten Lösungen bieten kann. Hierdurch zeigen die Nutzenden eins DIY-Loops auch eine neue Denkweise auf, nämlich der eines individualisieren Ansatzes in der care von chronischen Krankheiten auf technologischer Ebene. Zugleich setzen sie sich hierbei aber auch neuen, bisher ungewohnten Herausforderungen und Aufgaben aus.

Acknowledgements

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Content

1. Diabetes: Towards the idea of an artificial pancreas

Imagine going to bed every night and having to worry about not waking up again. Dana Lewis, a type 1 diabetes patient from the USA, faced this potential danger every night. She was plagued by fears of experiencing low blood sugar levels at night because of her diabetes. While the constant glucose monitoring (CGM) system attached to her body had an alarm function for low blood sugar, the alarm sound was too quiet for Lewis, preventing her from waking up at night. When she reached out to the CGM manufacturer requesting a louder alarm, she was met with a lack of understanding. The company saw no need for such a feature and had no plans to improve the alarm function to meet Lewis' needs. But even if the manufacturer had been motivated to make improvements, the lengthy approval process by the Food and Drug Administration (FDA) for new medical devices in the U.S. would have meant several years before a new, improved device could become available.

In 2013, this circumstance led Lewis to hack her CGM, enabling her from that point onward to be awakened, when necessary, by a sufficiently loud alarm tone on her smartphone. This marked the birth of the so-called #WeAreNotWaiting movement (Hussain & Lewis, 2020; Martin, 2017). Using the hashtag – what can be seen as a call to action directed at medical device manufacturers and regulatory authorities – diabetes patients expressed their frustration and dissatisfaction on social media regarding existing medical devices and exchanged ideas. Rather than accepting what they saw as inadequate and slow-paced innovations, a spirit of self-reliance emerged.

The movement's activities lead to the development of a novel form of treatment technology not previously offered by commercial device manufacturers: the so-called Loop system for automated insulin delivery. Although commercial manufacturers have since followed suit and now offer comparable automated insulin delivery systems, a significant number of patients with type 1 diabetes continue to use DIY systems. This very circumstance forms the starting point of this research.

Before delving into this in greater detail, I will first outline the fundamentals of diabetes as a medical condition and its treatment by insulin therapy, with particular attention to the care routines this entails for patients. I will then describe the principles and basic functioning of a DIY Loop system, before presenting the specific focus of my research.

1.1. Diabetes type I as chronic disease and its' treatment

1.1.1. Insulin as treatment form for diabetes

Diabetes is a chronic metabolic disease in which the body is unable to properly regulate blood sugar levels (Knox, 2020; Rosenfeld, 2002). For regulation insulin is needed, a hormone which is in healthy state produced in the pancreas. When having nutritional intake, it ensures that the sugar is released from the blood to the cells in the human body, where it can be processed further. But if the pancreas is limited in its ability to produce any or sufficient levels of insulin (type 1 diabetes) – or if the body is resistant to the hormone and does not react appropriately (type 2 diabetes), your body is not able to release the sugar absorbed by nutrients into the bloodstream to the body's cells. If not treated properly, diabetes can lead even to death. Therefore, people with type 1 diabetes need to take insulin in the form of injections, while people with type 2 diabetes need to take other medications to regulate blood sugar levels (Knox, 2020). In this thesis, I will refer only to the former, type 1 diabetes (T1D). Even if, for the sake of simplicity, I only refer to diabetes without specifying a certain type, I mean type 1 in this work.

The cause of diabetes – the lack of insulin in the human body – was discovered in Canada in the 1920s by two researchers, Frederick Grant Banting and John James Rickard Macleod (Pannett & Roubein, 2022; Rosenfeld, 2002). Since then, mainly the way of producing insulin changed. In general, there are three types of insulin so far: human, animal and analog ones. The production method for animal insulin continued for a long time until a new form was established in the 1980s: human insulin is produced using recombinant DNA technology. In this process, the genes for human insulin are inserted into bacteria, which are then used to produce insulin (Knox, 2020).

1.1.2. Controlling blood glucose level

Despite the different forms of insulin, the treatment of T1D patients is essentially the same as it has been since the discovery of insulin a good hundred years ago. This is why the disease remains a daily challenge for patients still today, given the associated impairments in daily life and insulin management. "Management" respective "self-management", but also "chronic homework" as the literature calls it, are by no means exaggerated terms here, as will be visible in the following (Braune et al., 2022; Lucherini, 2016; Mattingly et al., 2011; Nicolucci et al., 2013; Nielsen et al., 2016).

Essentially, this so-called (self) management can be seen as a constant alternation between measuring the blood glucose level and injecting insulin to keep the blood glucose level within the target range. If the blood glucose level is too high, insulin must be injected, whereby the amount of insulin rises with the deviation of the blood glucose level from the target range. Otherwise, this

condition can lead to potentially fatal hyperglycemia to the patient. On the other side, it can also happen that the blood glucose level is too low: In this case, sugar must be taken in the form of nutrition to correct the blood sugar level upwards, otherwise there is a risk of hypoglycemia. Self-management therefore means continuously balancing the blood sugar level in the range between upper and lower limits by the surrounding activities. Insulin is used for downward correction, nutritional intake for upward correction. A distinction is made between two types of insulin dosage: There are the “basal rate” as a basic quantity distributed throughout the day and “bolus rates”. The basal rate covers the basic insulin demand, whereas the bolus rate is adjusted to the respective meal and is injected shortly beforehand to compensate for the sharp rise in blood glucose levels caused by the meal.

1.1.3. Evolution of diabetes technologies

The determination of the current blood sugar level is carried out using technical devices. For a long time, invasive testing was standard (Wiedemann, 2019). Here the patient had to stick their finger several times a day and check their blood glucose levels using test strips which were fed into a measurement device. The device then displayed the blood glucose level in one of the above-mentioned units (see Image 1).

Today, the invasive measuring by taking a drop of blood is still used, but other technologies had been established during the last decades. One of them is CGM. This is a sensor which gets invasively attached to the patient's skin where it then remains on the skin for several days to a few weeks before it gets replaced. It provides a current glucose level down to the minute, which can be displayed on a control unit or mobile phone (see Image 2). By that the patient can constantly access the current blood glucose level without pricking into one’s finger.

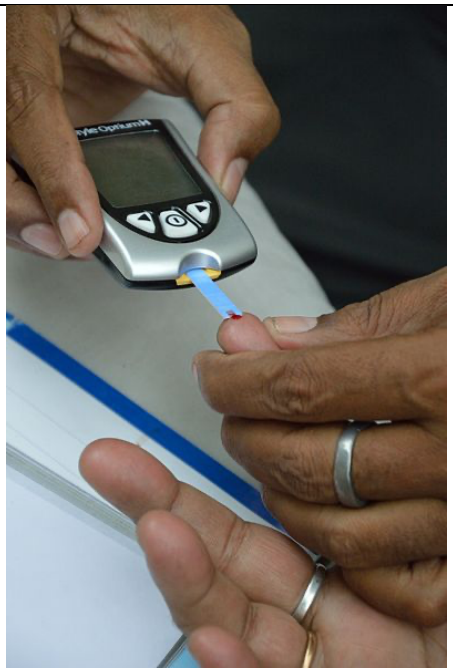


Image 1: Invasive measuring using a test stripe (Ganguly, 2015)

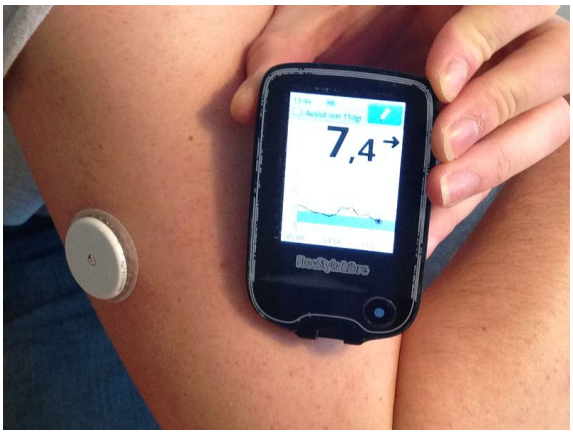


Image 2: Continuous Glucose Meter by the sensor on the skin and the display device (Sjö, 2016)

For administering insulin there are also different types of devices. The so-called insulin pen resembles a pen or fountain pen in shape and has a small needle, allowing insulin to be injected into the tissue by placing the pen against the skin (see Image 3). Alternatively, there are also insulin pumps, which are worn continuously on the body. The pump has a larger reservoir of insulin and delivers it into the patient's fatty tissue via a tube and needle. The amount of insulin can be adjusted using the pump's control device (see Image 4).

Image 3: Insulin pen (Wesalius, 2018)

Image 4: Insulin pump that can be attached to the body (Švec, 2014)

1.1.4. Diabetes management as constant care work

Even if the tasks as such can be regarded as routine for diabetes patients due to its regularity, the activity always requires close attention. This is because the quantities of needed insulin cannot be defined per se, but depend on a variety of factors, such as: What activities does a person do on a given day, what does the person eat and how quickly does the body process the nutrients contained in the food? How warm is it that day? Is the person possibly stressed?

This is because the human body's metabolism does not always work in the same way. Instead, it is influenced by internal and external factors. Stressful situations, for example, can also cause blood sugar levels to develop differently than usual. The same applies to particularly warm weather, for example. If you managed well on previous days with roughly the same amount of insulin, a particularly hot summer day or stress can cause enormous deviations today. The disease and treatment with insulin are therefore linked to a certain degree of unpredictability.

In addition, the time and duration of action of the injected insulin must be considered. This means that the blood glucose level is not immediately regulated once the injection has been given. Instead, insulin needs time to take effect and lasts for a certain amount of time, thus continuing to reduce the blood glucose level. Let's take the example of an insulin patient who wants to go for a run and has previously injected themselves a dose of insulin. The physical activity causes the blood glucose level to drop more than normal. In addition, the previously injected insulin continues to have an effect and causes the blood glucose level to drop. This overall sharp drop in blood glucose levels can lead to hypoglycemia in the patient. In this respect, the patient must already consider the planned run when injecting the insulin beforehand and use less insulin accordingly. You may also have to give up spontaneous runs because you simply didn't think about it when you injected insulin beforehand.

Due to the disease, people with T1D are in a continuous process of care work. The treatment of the condition demands attention that patients cannot escape from. Otherwise, there is a risk of potentially fatal consequences. The disease is also associated with the fundamental risk of secondary diseases, which are intensified by frequent and severe deviations in blood glucose levels. In this respect, not fulfilling this care work has enormous further health and even fatal consequences. Neither does this care work stop at the sleeping patient – or let's say the patient who wants to sleep – because blood glucose levels also need to be monitored at night. The previous evening meal, for example, can lead to nocturnal hyperglycemia. In this case, the patient not only has to inject insulin at night but is also troubled of intensified urge to urinate. The night's

rest is gone and with it the recovery the next morning, which in turn can have an impact on everyday life, work, private and social life.

1.1.5. Still today: Diabetes as challenge and source of risks for patients

The previous explanations already show: Diabetes patients are faced with a complex bundle of tasks to manage their chronic disease (Walsh et al., 2015). This is accompanied by a certain mental and psychological strain; these tasks mean constant stress and less flexibility coupled with the ongoing risk of incorrect dosages and health complications (Burnside et al., 2020; Omer, 2016). In this respect, diabetes is also a very personal disease in which one is largely left to one's own efforts, as day-to-day management is one's own responsibility (Heinemann & Lange, 2020). But at the same time, this disease-related care work is embedded in a socio-material constellation as it produces an intertwined network of human and technical-material actors, like for example the patients themselves, health professionals, body routines, economic situatedness, biomedical knowledge arrangements, social relationships, health insurances, medical law, daily routines and situations, emotions – and of course the used technology. All these layers and actors produce a complexity regarding the care work that may not be visible at the first glance (Wiedemann, 2019),

Not to be forgotten are the burdens caused by external factors, such as the stigmatization that often accompanies chronic diseases (Becker, 1994; Mattingly et al., 2011). For this reason, diabetes patients may well perceive their chronic disease as a constant challenge and reducing their quality of life (Braune et al., 2022). Basically, the tasks that the pancreas performs in a healthy person must now be actively performed by the patient themselves by “think[ing] like a pancreas” (Plotnick & Henderson, 1998) or “doing pancreas” (Wiedemann, 2019). The in a healthy state by the pancreas in a for the human not perceivable way performed process of managing the blood glucose level has to be externalized by diabetics to the outside from their body and be enacted as an active act by themselves. Although treatment devices have been improving and already simplified daily treatment compared to previous technologies, repetitive routine tasks remained for diabetes patients.

In this respect, any advancement in treatment modalities represents a potential improvement in the circumstances of affected individuals – coupled with a reduction of risk. This could mean: better health, less effort and stress, and an improvement in one's overall quality of life (Burnside et al., 2020; Heinemann & Lange, 2020; Kaziunas et al., 2018). This could be in the mere fact that the calculation of insulin dosage is primarily calculated automatically and thus the effort required for this is significantly reduced to the patients, they have a better night's sleep due to the

elimination of regular checking of their blood glucose levels and corresponding insulin dosages, and overall, a lower risk of hypoglycemia. In this respect, the question arises: Can the missing functions of the pancreas be imitated by a kind of artificial pancreas in order to relieve the patient of the tasks resulting from the disease?

1.2. The path towards a DIY Loop system

1.2.1. Hacking commercial Diabetes Technologies: OpenAPS

The idea of an artificial pancreas, which automatically doses insulin and regulates blood sugar levels, is not new; it has existed for several decades. However, in the early 2010s, it took concrete form as the Artificial Pancreas System (APS) – not by the healthcare industry, but through the patients themselves (Hussain & Lewis, 2020).

The case of Dana Lewis described at the beginning of my work, who was plagued by the fear of having a potential life-threatening hypoglycemic at night due to the insufficiently loud alarm of her commercial CGM and who hacked this very device to resolve this. This marked the beginning of the #WeAreNotWaiting movement which led to the open-source project OpenAPS.

The principle of OpenAPS is to create a system for automated insulin dosing using commercially available devices. The previously independent components of CGM and insulin pump are linked to each other so that insulin dosing by the pump can be automated based on the blood glucose measurements from the CGM (Hussain & Lewis, 2020). To achieve this, members of the OpenAPS community had to "hack" the devices – meaning they had to overcome the proprietary structure of the devices and create alternative access to its data and controls beyond the officially provided functions offered by the manufacturers (Delgado & Callén, 2017; Kaziunas et al., 2018). Using only the official functions, the recorded blood sugar values remained within the CGM or the compatible control devices and smartphone apps of the manufacturer. However, the collected data could not be further utilized and were thus limited to the functions provided by the manufacturer. Likewise, the insulin pump could only be controlled officially using its designated control device.

The OpenAPS community was able to access and use the blood sugar values from the CGM and control the insulin pump. However, a bridge had to be created between the CGM and the pump to facilitate communication between the two devices and calculate the required insulin dosage based on blood sugar measurements. Initially, a mini computer, known as a Raspberry Pi, was used for this purpose. It ran a program that calculated and initiated the necessary insulin dosage based on the measurements (West & Lewis, 2016). This application, the very core of the system,

was developed by the members of the OpenAPS community themselves (Litchman et al., 2020; Nightscout Foundation, n.d.). The mini computer has since been replaced by smartphones, and the application now runs as an app on these devices (see Image 5). As a result, two branches have emerged for Android and Apple smartphones: "Android APS" and "iOS Loop" (Crocket, 2020).

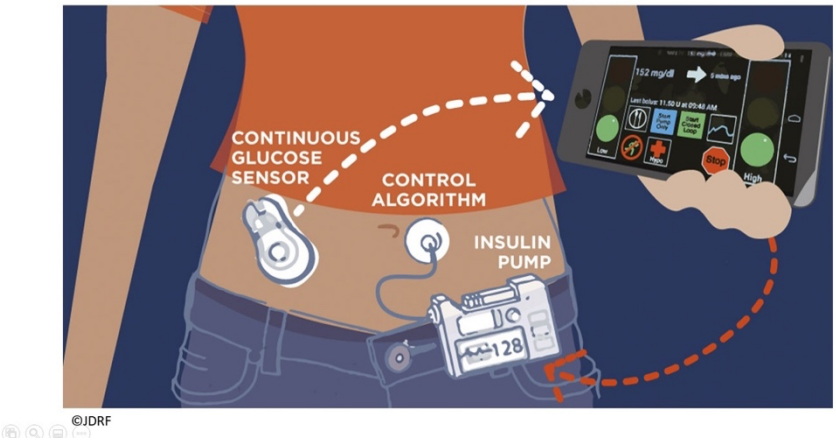


Image 5: The basic principle of an OpenAPS system: The CGM and the insulin pump are connected to the smartphone running the APS app. The APS app records the values from the CGM and calculates and initiates the insulin dosage using the pump based on this (JDRF, 2023)

Based on the blood sugar values measured by the CGM, the Loop system administers insulin to the patient via the pump, which in turn affects the patient's blood sugar levels. This setup is also referred to as a "hybrid Loop": The difference from a "full Loop" is that the user must still actively interact with the system for safety reasons. For example, they need to enter information about meals, meaning the APS does not function entirely without the patient's intervention (AndroidAPS, 2023).

Based on this setup, the #WeAreNotWaiting community made a significant step towards the idea of an artificial pancreas in technological terms. They could map the repetitive and entangled principle of measuring, calculating and dosing to an external technological device. It is noteworthy that the Loop system did not make the T1D-related care work disappear from the patients, but it met far better their needs than the commercially available diabetes management devices at the time.

1.2.2. Looping as activity of self-care

The term "Loop system" is synonymous with APS or OpenAPS. In the following sections of this work, I will primarily use the term Loop system. In my opinion, this term beautifully illustrates the interplay between the human body and the APS as an external entity. The human body and the

technology are intimately entangled (Forlano, 2016). They are in a constant dialogue and form a mutually influencing cycle – or a “symbiotic relationship” (Garfinkel, 2021). This interaction evokes the image of a cyborg, a fusion of biological and technological functions – very much in line with the concepts explored in Science Technology Studies (STS) by Haraway (Kaziunas et al., 2018). Such a cyborg extends a human being with the natural characteristics and abilities by additional ones through the functions of the machine (Haraway, 1994). Brantly also mentions this metaphor, but at the same time prefers the term "biotechnological organisms", i.e. the "dependency of the biological organism (human body) on biomedical technologies, their integration, and inseparability" (2023, p. 89).

Furthermore, I prefer the term "Loop" in my study because through my research and interviews I realized that the community predominantly uses "Loop" rather than "APS". I want to account for this terminology in my work, particularly from an STS perspective, considering the DIY APS community as a form of a thought collective (Fleck, 1979). This collective is also reflected in a shared language and, consequently, in the use of common terminology. Similarly, within the DIY Loop community, the term "Loop" is not only used to describe the system itself but also as a verb: "looping" to describe an activity. This shifts the focus from the Loop system as an artifact to a process. The patient is "looping", actively engaging in a practice with the help of the Loop system as part of the care work.

On one hand, this perspective once again highlights the interplay between the human actor and the Loop system. At the same time, it introduces a temporal perspective on the use of a Loop system: using a DIY Loop is not just about adopting an additional artifact within diabetes management. Instead, it leads to new, ongoing activities and relations in managing one’s condition. This perspective is also central to my research questions. For this reason, I will primarily use the terms “Loop system” and the activity of Looping throughout the rest of this work.

1.2.3. Building a Loop as individual task

For a Loop system, the commercial components – the insulin pump and CGM – are combined into a complete system by connecting them to a smartphone running the Loop app. However, this app is not available as a ready-to-use application in the Apple App Store or Google Play Store, as is common with regular apps. Instead, every user must build the app themselves and transfer it to their smartphone. The DIY Loop community provides the necessary source codes, which users can use to create the app on their own (Oliver et al., 2019). The reason for this lies in legal regulations: In its functionality, the Loop app for Android and iOS is classified as a medical device because it is directly involved in patient treatment. The app makes decisions about the amount of

insulin to be administered. This action could potentially be life-threatening, for example, if too much insulin was administered (Burnside et al., 2020). This raises liability questions, such as who would be responsible in the event of an incorrect treatment and resulting complications. If a fully functional app was distributed, the originators – meaning the members of the DIY community – would legally be considered distributors of a medical device and held accountable. Additionally, the distribution of medical devices requires regulatory approval (see 3.1). By providing only the source code instead of a ready-to-use app, this legal issue is avoided, as the source code itself is not classified as a medical device. Instead, each user, by compiling and installing the app, creates their own medical device in the legal sense.

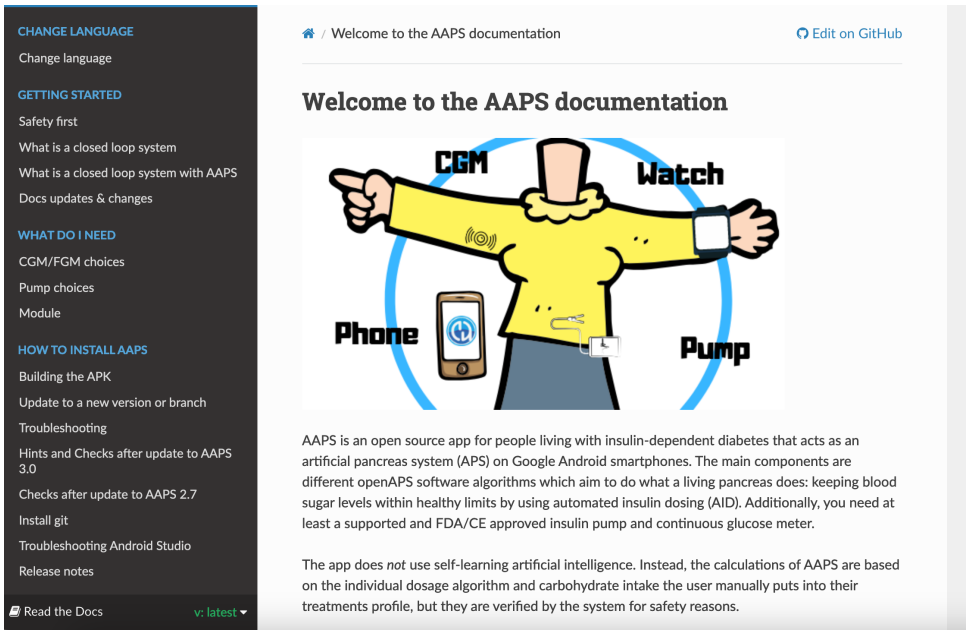


Image 6: The community provides detailed online documentation like this one for the Android APS system (AndroidAPS community, 2023)

For the process of building the Loop app and integrating the CGM and insulin pump, the community provides extensive documentation, including step-by-step guides that describe the entire setup process leading to a fully functional Loop system (see Image 6). These guides are tailored to different manufacturers and device models. Although I have generally referred to CGMs and insulin pumps as uniform categories, there is a wide variety of available devices. Not all of them can be integrated into a DIY Loop system, and depending on the specific model, different methods are required to connect them. For example, some devices cannot communicate directly with the smartphone via Bluetooth. In such cases, additional communication devices, known as transmitters, are needed to act as intermediaries between the smartphone and the CGM or pump (Heinemann & Lange, 2020; Litchman et al., 2020). A transmitter converts the Bluetooth signal from the smartphone into the specific wireless standard used by the device – and vice versa.

In addition to the provided documentation, users can also find support in online communities, such as dedicated Facebook groups (Brantly, 2023; Braune et al., 2021; Facebook, n.d.-a, n.d.-b; Hussain & Lewis, 2020; *Looped | Facebook*, n.d.). Within these groups, members exchange experiences about their use of the system and offer mutual support.

2. Research Topic: The usage of DIY Loops of T1D patients in Germany

2.1. DIY-Loops: Challenging the current state

Let's briefly go back to the origin of DIY Loops: Initially, it was the dissatisfaction with commercially available devices for diabetes management, as well as the lack of foreseeable improvements in this area, that led to the #WeAreNotWaiting movement of diabetes patients. The emergence of the community, its' infrastructures for information providing and communication and the development of an DIY Loop system can be seen as a response to the existing, but lacking commercially available insulin devices (Kaziunas et al., 2018). In addition, potential innovations in insulin devices could not be expected in the near future due to the regulations of regulatory agencies – in the U.S., this is the Food and Drug Administration (FDA) – as the approval process for new medical devices is lengthy (Heinemann & Lange, 2020; Kaziunas et al., 2018; Lewis, 2022; Walsh et al., 2015).

In this respect, the OpenAPS movement can be seen as helping patients to help themselves. Patients are moving away from being passive recipients of care to becoming active, contributing researchers. On the one hand, they define what they need and, at the same time, show what is technically possible (Lewis & Leibrand, 2016). In this context, Crocket (2020) speaks of the "disruptive character" of DIY devices, which paves new ways for innovation and, in particular, challenges classic processes and structures in healthcare. This is particularly interesting because the healthcare sector is generally a strictly regulated market in terms of medical devices (Faulkner, 2009b, 2009a). I will go into this in more detail in the state-of-the-art section (see 3).

However, it is important to note that the DIY APS community does not see their own devices as a fundamental alternative to commercial products. A large number of users of DIY devices as well as leading members of the movement express their willing of using commercially available products if they had the required innovations or improvements (Schipp et al., 2022). The DIY community does not necessarily see itself as a competitor to the medical industry or to healthcare providers, but would like to demonstrate alternative pathways of innovation (Omer, 2016). They also recognize strengths of commercial or weaknesses of its own DIY devices: Not every diabetes patient is able to assemble their own Loop device. A commercial product may therefore be more accessible in this respect. In addition, commercial products come with a warranty from the manufacturer and offer greater security in this regard.

This leads me to following perspective: Commercial products have made visible progress in recent years. Meanwhile, commercial providers also offer Loop systems for automated insulin dosing. The first such device was approved in the USA in 2017 and one year later in the European

Union (Medtronic, n.d.; Weinberger et al., 2023). In Germany, the first commercial Loop device have been available since 2021 (Matthes & Rau, 2021). Nevertheless, frustration remains among diabetes patients about the slow innovation process (Vallis & Holt, 2022). Because even if insulin devices today have the functions that have been demanded a few years ago, the requirements of the patients have evolved – and by this also the functions of DIY Loop devices, which can adapt new functions much more quickly (Brantly, 2023). In this respect, commercial systems for automated insulin dosing can be seen as lacking behind DIY devices – again. This is reflected in the ongoing demand by the DIY community for faster approval processes for medical innovations (Kaziunas et al., 2018; Walsh et al., 2015). So even though commercial manufacturers now offer devices for automated insulin dosing, the DIY Loop community is not satisfied with this status quo and favor the use of DIY devices instead of conventional options. Rather, their initial demands on diabetes treatment devices have evolved, not least because their DIY systems are constantly demonstrating what is even more technically possible.

The community proved in its initial origins that a Loop system for automated insulin dosing is technically feasible and applicable in everyday life. Studies have already shown that DIY Loop systems are effective, specifically leading to improved blood sugar levels in patients, better sleep and reducing their fear of hypoglycemia (Braune et al., 2021, 2022; Gawrecki et al., 2021).

Noteworthy in this context is the Citizen Science project "TeQfor1", which attests to the positive, perceivable effectiveness of DIY Loops in the treatment of T1D (Monecke, 2022; Weinberger et al., 2023). The study is based on self-reported outcomes from patients regarding measurable factors such as improved blood sugar levels, as well as subjective perceptions, such as a reduction in stress related to the disease. In this context, Gawrecki et al. (2021) also observed an improvement in glycemic control with increasing experience in using DIY Loops by both patients and medical professionals. Noteworthy is also the EU-funded research project “OPEN” which brought together scientists from different backgrounds and users of DIY Loop systems in order to build evidence on clinical outcomes and impacts on patient’s quality of life (Jansky, 2024; *The OPEN Project*, n.d.).

2.2. Research Focus: From the community towards the individual patient’s level

Within the DIY Loop community – understood as a form of activist movement led by individuals affected by a disease – it is important to distinguish between the community level, i.e., activist members driving the movement forward, and patients as individuals. Epstein (1995, 1996) highlighted this distinction in relation to the AIDS movement ACT UP. Similarly, Jansky (2024) differentiates between individual and collective forms of action in the context of a DIY Loop

system. Regarding the DIY Loop, I see two interconnected but distinct perspectives: one focusing on the community as a whole and the other on the individual patient. Although the DIY community initially emerged from individual diabetes patients, today's perspective requires viewing the individual patient under a different premise – especially the different availability of conventional diabetes technologies compared to time of the movements' formation. In the context of their individual care activities, today's patients have to – or respectively can – decide whether to use conventional technology or to build a DIY Loop system.

As part of my research, I investigate – in broader terms – the question of what leads diabetes patients to use a DIY Loop system. Why do people with T1D decide to use a DIY Loop instead of commercially available technologies? As simple as the question may sound, or as simple an answer as it may suggest, the reasons are complex and varied. Diabetes as a disease demands a high level of personal responsibility from those affected, as the majority of care work belongs to their own responsibility. Above all, they are driven by constant care for themselves (Wiedemann, 2019). What is the current blood glucose level, but also what will it be like in the future? Is it easy to control? And what difficulties are there? Stepping away from the care work as an isolated activity and seeing the DIY just as a tool therefor, I like to demonstrate a sensitivity to the very layers, processes and actors that surround the diabetes care in its socio-material constellation and which create a complexity that may not be visible at the first glance, also when raising the question about reasons for using a DIY Loop (Wiedemann, 2019).

2.3. Research Questions

In this context, I would like to move away from viewing "choice" as a singular moment and instead see it as part of a continuous care process. What (multifactorial) experiences with their illness led the patient to use a DIY Loop, and what does its use mean for the patient – both in terms of positive perceptions and specific challenges?

On the one hand, I focus on the concrete advantages of a DIY Loop as perceived by users compared to commercial alternatives. To what extent and why do DIY Loop systems better meet their needs? In this regard, I take a highly technical and functional perspective using SCOT (see 4). I see the users' choice for a DIY Loop as a classification of commercial devices as unsuitable for personal use. In this respect, the use of the alternative DIY system reflects the "interpretative flexibility" of the users as a relevant social group in the context of diabetes technologies (Bijker, 2010; T. J. Pinch & Bijker, 1984).

At the same time, I incorporate the sensibility of Mol's (2008) logic of care into this question, whereby I do not consider the choice of a DIY Loop as a singular step, rather embedded in the care

activities with the striving for the best possible life with the chronic condition. I see the actual use of the DIY Loop in the spirit of Mol: It is not just a neutral tool, but acts as an "inventive mediator" and its use is a "moral activity" (Mol, 2008). Therefore, I pose the question: What does it actually mean to use a DIY Loop? How do users perceive its use? With this in mind, I focus in particular on the tasks and maybe also kind of challenges associated with its use.

Closely linked to this, but to me an additional aspect to be considered in its own right, is the impact of this very use on patients' interaction with actors in the traditional healthcare system, which are part of the social-material constellation of care (Wiedemann, 2019). Particularly against the backdrop of the normally highly regulated market for medical devices and the unconventional character and associated legal uncertainties of DIY Loops, I am interested in whether and which effects my interview participants perceive on these interactions. At the same time, of course, this also shows which actors play a perceptible role here at all.

In this respect, the following three specific research questions arise for me:

- **What leads T1D patients in Germany to choose DIY systems for automated insulin dosing against the background of conventional alternatives?**
- **What are the consequences of the use of DIY systems for automated insulin dosing in terms of coping with the disease in everyday life?**
- **How does the use of DIY systems for automated insulin dosing affect diabetes therapy for patients regarding their interaction with actors of the traditional healthcare system?**

I explore these questions in Germany, which has a vibrant community of DIY Loopers. In the following to sections I will elaborate more on this specific national setting and why this focus makes sense to my research questions.

2.4. Research Focus on Germany

2.4.1. A vibrant community of DIY Loopers in Germany

Obtaining precise figures on the users of DIY Loops proved to be difficult for me. However, this is reasonable, as the very nature of the DIY system and the community behind it inherently lacks a central mechanism for collecting valid data on this topic. Nevertheless, it may be possible to estimate its scope. Braune (2022) estimated that there were more than 10,000 DIY Loop users worldwide, with 20 percent of them being children and adolescents under the age of 19. In Germany, the number of users was estimated to be several hundred five years ago (Heinemann &

Lange, 2020). In a survey, 102 out of 1,054 diabetes patients (1,027 of whom had T1D) reported using a DIY Loop system (Herzog et al., 2020), which corresponds to nearly ten percent.

As another reference point, I consider the Facebook groups of the German-speaking community that I used for my research. These groups consist of 2,700 members (Android Loopers) and 1,200 members (iOS Loopers) (Facebook, n.d.-b, n.d.-a). Of course, the limitations of this indicator must be taken into account, as no direct conclusions about the number of real users of a DIY Loop can be drawn from it. For example, some group members may not actually use a DIY Loop but are merely interested in the topic. Likewise, DIY Loop users are not necessarily members of these groups, as they may seek information and exchange ideas elsewhere or entirely refrain from participating in online communities.

A further insight into this can also be provided by the other side, so to speak, i.e. not the patients or Loopers themselves, but diabetologists as part of the medical professionals. According to a survey, two percent of patients with T1D used a DIY Loop system in 2023. In contrast, 21 percent used a commercial system for automated insulin dosing. Overall, it can also be noted that the number of users of both commercial systems (since 2019) and DIY systems (since 2018) has increased significantly, according to the report. However, the use of DIY Loop systems remains a niche, accounting for only ten percent of the users compared to those using conventional alternatives (diateam, 2024).

Given the 372,000 T1D patients in Germany (Deutsche Diabetes-Hilfe, 2022), it can be assumed that there are several thousand users of a DIY Loop – and in this sense a lively and still growing Looper community in Germany.

2.4.2. Germany as one specific healthcare setting

Against the backdrop of this lively DIY Loop community in Germany with its significant number of users I see Germany as suitable geographical setting to conduct my research.

A regional or national focus in examining my research interest is, in my view, of strong relevance due to national differences – especially in the structure of healthcare systems – and thus also in the sociopolitical context in which users of a DIY Loop navigate. Although DIY Loopers navigate within a global movement and their engagement cannot be solely limited to national borders (Beck, 2007), the national context still significantly shape the patients' experiences with a DIY Loop (Jansky, 2024; Jansky & Langstrup, 2023). For instance, the starting point for people in Germany differs fundamentally from that in the USA, the origin country of the DIY community, due to universal health coverage (Mattingly et al., 2011). Because of the different forms of health

insurance and the associated coverage of costs, access to conventional alternatives (Braune et al., 2022; Eitenberger & Wiedemann, 2022) and thus the role of DIY Loops as one option for automated insulin dosing can vary enormously. Legal frameworks and approval processes also differ significantly, which in turn affects the overall availability of conventional diabetes technologies (Braune et al., 2022). Even the European Union acknowledges inequalities between member states in the specific case of diabetes, namely regarding "access to care, education, autonomy, medicines, tools to monitor blood sugar levels, supplies and technologies and health outcomes" (Resolution on Prevention, Management and Better Care of Diabetes in the EU on the Occasion of World Diabetes Day, 2022). This was also evident in the later approval of the first commercial devices for automated insulin dosing in Germany compared to neighboring European countries (Matthes & Rau, 2021; Medtronic, n.d.; Weinberger et al., 2023). In general, Germany is considered relatively slow in adopting digital health infrastructure compared to other European countries (Bertelsmann Stiftung, 2019).

As previously mentioned, users of a DIY Loop remain embedded within the healthcare system, meaning that a DIY Loop can indeed influence those relationships as well. There are legal foundations or practice guidelines for physicians regarding this, which, however, vary by region (Braune et al., 2022; D+B Rechtsanwälte Berlin, 2018; Diabetes UK & Royal College of Nursing, 2020; Juvenile Diabetes Research Foundation UK, 2019; Steno Diabetes Center Copenhagen, 2019).

Because of these reasons for a national focus, I am concentrating my research specifically on Germany and have deliberately excluded the seemingly obvious option of including other German-speaking countries such as Austria or Switzerland.

3. State of the Art: Patient activism as response towards the healthcare regime of medical devices

What makes DIY Loop systems and their use such a compelling case from an STS perspective is their patient-oriented, bottom-up character: diabetes patients build their own devices to improve the treatment of their chronic condition. These actions, as well as the resulting technological artifacts, elude the normative framework and regulation of medical devices and the institutionally driven and controlled innovation processes. Only medical devices that emerge from this framework are considered normal in their use – DIY devices are not. At the same time, industrial, commercial manufacturers operate in the regulated area of medical devices, what significantly influence the innovation path and thus the available technologies.

But users of a DIY Loop system remain part of a healthcare system that has internalized this very normative framework. So, on the one hand, users of a DIY Loop move in an unconventional way within this normative structure; on the other hand, their activities are also a response to the framework's failure to produce adequate medical products – and thus underlying the formation of the DIY community as patient activism.

I view my case of DIY-Looping T1D patients as a concrete example that speaks to two strands of STS literature: the regulation and innovation processes of medical devices on the one hand, and patient activism on the other. The Looper community, as a form of patient activism, arises from diabetes patients' dissatisfaction with precisely these innovations and regulations. In this sense, my case offers a clear and specific illustration of how these two strands can be bridged.

In the following, I will first examine these two strands and then draw connections between them. To do so, I will begin with the regulation and innovation processes of conventional medical devices before turning to patient activism.

3.1. Conventional medical devices: A zone of innovation and regulation

3.1.1. The regulatory regime of medical devices

Medical devices are in general highly regulated, including in the European Union and Germany (French-Mowat & Burnett, 2012). This begins with the question of what type of technology is considered being a medical device. In this sense already a kind of a classification takes place (Bowker & Star, 2000) by defining medical devices and thus dividing the world into medical and non-medical devices (Faulkner, 2009a). Against this background, Faulkner calls medical technologies a regulatory regime in which a certain category of technologies is subject to a

specific set of regulations. These regulations define what they regulate themselves, namely what is considered a medical device. Hardware or software as such only becomes a medical device in this sense through the governmental process. The regulations turn the artefact into a medical device.

At the same time, it also defines the rules within this technological zone (Barry, 2006). This does not take place by limiting the authorisations within this zone post hoc, but rather by paving the pathways that must be followed and gateways which have to be passed by new medical devices and thus make innovation possible within this zone (Faulkner, 2009b, 2009a). In this respect, it is clear from the very beginning for manufacturers of potential new medical devices which regulatory paths must be taken to establish a new artifact within this technological zone.

The main aim of this regulation is to protect users from the potential risks of medical devices through institutionalized risk assessment (Faulkner, 2009a). However, this is not necessarily about an absolute exclusion of risks, but about balancing the benefits for the patient and the risks associated with the use of the medical devices, whereby the latter should of course be minimised (Bano et al., 2023). Medical devices thereby map the thought that we live in a "risk society" (Beck, 1998) because even if medical devices are intended to treat patients and thus fundamentally protect or improve their health, as a technology they must still be seen as a source of potential risks. It can therefore be assumed that medical devices available to patients have a certain level of safety or that the risks they pose are (sufficiently) low.

In this sense, the regulatory regime on medical devices also defines a standard in a different way: in the language of "medical devices", one can assume by default that corresponding artefacts passed the industrial and regulatory processes of this very regulatory regime. When I refer to devices of this kind in my work, I am talking about *official, classical or commercial medical devices* – what to be honest seems to be quite unusual. This is because this characteristic, which I have explicitly mentioned, is actually self-evident for medical devices that pass through the regulatory regime. However, the regulatory regime for medical devices does not see patients manufacturing their own devices to treat their illness as an option. In the world imagined here, there is no such category for DIY devices, and accordingly there is no term to distinguish between commercial medical devices and self-made devices. In this world, a medical device is inherently a commercial, industrial device. This shows how the health sector respective the regulatory regime is "ordering the world" (Bowker & Star, 2000) of medical devices and establishing different kind of standards.

3.1.2. Authorization process in Germany

Following the conceptual frame of “regulatory regime” from the previous section, I want to outline the practical implementation in the setting of Germany, which strongly bases on the European legal framework. I see this as relevant insofar as my research focuses on Germany.

In the European Union, the authorisation of medical devices is regulated by the European Medical Device Regulation (2017/745) (Wenner, 2024). It also applies directly in the member states, but is supplemented in Germany by additional laws and regulations (Bundesministerium für Gesundheit, 2024). In this sense, this regulatory regime of the European Union also represents a form of a geographical “technological zone” (Barry, 2006) as it creates common standards regarding technical practices and procedures.

In the European Union, “medical devices” are broadly defined "from the relatively simple e.g. sticking plasters and breast implants to the technically complex e.g. cardiac pacemakers and home blood glucose monitors" (Day & Bailey, 2012, p. 213). This broad spectrum of devices gets categorised into different risk groups. Looking on a Loop system for automated insulin dosing, it clearly belongs to the high-risk class as it automatically administers a drug to the human body. Additionally, two more aspects categorize the Loop system as high-risk as the regulation includes devices which use body measurements as basis for algorithm-based treatment decisions. This also applies to a Loop system, as it regulates the insulin dosage on the basis of the CGM's blood glucose measurement. The same assessment applies to software that provides information on the basis of which therapeutic treatment decisions are made, whereby these decisions could potentially result in irreversible damage, even death (Regulation on Medical Devices, 2017). This also applies to a Loop system, as incorrect insulin dosing can have serious, even fatal, health consequences (Bano et al., 2023).

Based on the classification, the approval process also varies, in which the safety and effectiveness of the devices must be demonstrated. While manufacturers can do this themselves for medical devices with a low-risk group while a nationally authorised "notified body" is required to carry out this review for high-risk products. The safety and performance must be proven by clinical data and a suitable benefit/risk ratio (Federal Ministry of Health, 2024; Day & Bailey, 2012). The approval of a medical device within the European Union therefore does not exclude risks in its use per se but primarily states that the positive treatment effects outweigh the potential risks to the patient from the device. Then a device is considered as being safe (Bano et al., 2023; Wenner, 2024). Medical devices that have successfully completed the European approval process receive the CE mark, the "Conformité Européenne" (Day & Bailey, 2012; European

Medicines Agency, n.d.). This is also affixed to the products themselves and is therefore also an indicator of the safety of a device for healthcare professionals and patients. Only with this CE marking, a medical device can get approval in Germany by the "Federal Institute for Drugs and Medical Devices" (Federal Ministry of Health, 2024).

These processes of approving medical devices via the CE mark reveal key aspects of the regulatory regime (Faulkner, 2009a) or – in other words – the “institutional logics” (Lenz, 2021; Thornton et al., 2012) in the European Union and Germany. The European regulation on medical devices defines the rules for the approval of medical devices and at the same time provides the industry with a transparent path of innovation within the field of medical devices. Forms of classification are also evident here (Bowker & Star, 2000) with regard to the question of what is considered a medical device, but also a subdivision of these by risk classes. The CE marking literally symbolises this process by affixing it to products that have successfully passed the process and is at the same time the linchpin of this process: the CE marking is essential for approval and is therefore the actual goal for the industry, as well as an essential orientation aid for patients and healthcare professionals. CE labelling stands for the successful institutional testing of a device and serves as an indicator of its safety. Patients should therefore be able to rely on the fact that a device with a CE mark is safe. Whereby "safe" is a relative term: In line with Beck's (1998) "risk society", risks are consciously seen as a component of new technologies. Even if the medical devices are actually intended to improve the health of patients or protect their lives, they can themselves pose risks to health and life (Bano et al., 2023). In the past, for example, breast implants caused a public stir due to the risk of sudden rupture caused by defective silicone. Complications with implantable cardioverter-defibrillators have also resulted in death. Both were CE-certified medical products (Day & Bailey, 2012).

In these processes of the regulatory regime and the understanding of the concept of the safety of medical devices, the form of national or supranational civic epistemology is also formed (Jasanoff, 2005). How is it tested whether a medical device is safe and what does safety mean? The CE marking stands for "institutionalised practices" (Jasanoff, 2005, p. 255) in the healthcare system of the European Union, as it is on the basis of this certification that authorities in Germany also grant national approval for medical devices. In addition, healthcare professionals, doctors and patients rely on this labelling.

3.1.3. Medical devices as market: Tensions between public health and commercial interests

In the previous two sections, I looked at the particularities of the market for medical devices regarding its regulatory characteristics. In doing so, I have first shown a theoretical, abstract level and finally a practical implementation of such a "regulatory regime" (Faulkner, 2009b) using the example of Germany and the European Union. In this chapter, I will discuss the leading mechanisms of the medical industry, which operates within this very regulatory regime.

In the case of diabetes technology, these industrial mechanisms strongly impact the development of available treatment technologies (Bennett, 2019). They follow fundamental different logics than maybe suggested by the institutional logics which I explained in the previous chapter – you might assume that this strictly regulated regime would lead to medical devices that optimally meet the needs of patients. For elaborating on the logics of industry, I first would like to look at the principles of innovation in the field of pharmacy: This is because here, too, an ambivalence of two opposing dynamics is key, namely the well-being of patients through improved medicine and thus better health – and the profit-oriented interests of these companies. Gaudilliere (2021) refers in this terms to the paradox between use value and exchange value in the context of drug development. The benefit for patients resulting from improvements and further development of drugs (use value) is set against the financial return for the pharmaceutical companies (exchange value). According to Gaudilliere, this constitutes the basis for an innovation crisis in the pharmaceutical sector. In the end, pharmaceutical companies are dependent on investors and their actions are aligned with generating returns. Expenditures in Research and Development (R&D) would reduce the profits and thus the return for the investors. The development of new drugs is a risky investment, which is why pharmaceutical companies prefer to profitably promote existing products in their portfolio instead of developing new forms of treatment or drugs. In other words, existing patents for drugs are exploited for as long as possible or are extended without major new innovations, for example through minimal modifications to existing drugs.

In the end, by hindering patent expiry, this prevents the production by other manufacturers, which could lead to competition with ultimately lower prices. To Gaudilliere (2021), the capitalist motives of the pharmaceutical companies outweigh the interests of the common good, namely the affordable health of patients. Instead of investing in cost-intensive and risky R&D processes for new drugs - or opening up the market to competition and lower prices - they choose the simpler and more financially profitable path for themselves and secure a constant income with significantly less investment.

In the context of diabetes treatment, the majority of patents by the pharmaceutical industry are no longer on the insulin products as such, but on the injection devices required for this (Schneider et al., 2022). These innovation steps are dedicatedly used for increasing dependency of devices on certain insulin products and creating a proprietary eco system of insulin technologies and the corresponding insulin. This is because the devices can only be used with insulins from certain manufacturers. Interoperability of the devices with other insulin manufacturers is thus deliberately excluded (Schneider et al., 2022). Crucial in this context is presumably the fact that patients would be less willing to switch to, for example, the insulin of another manufacturer, as this would then also be linked to the purchase of another device and thus to additional costs. In my view, this can be observed in particular in the area of insulin manufacturers, whose insulin pens, for example, can only be used with their own insulin. But it is not the case for dedicated device manufacturers who do not offer their own insulin products. In the case of corresponding pump models, the functionality with a variety of insulin products is even certainly emphasized.

Nevertheless, the mechanisms for creating a closed eco system also act here. The insulin delivery devices can only be used with components from the same manufacturer: For example, an insulin pump requires the corresponding control unit from the same manufacturer for controlling the pump (Jansky, 2024). In this way, however, device manufacturers tie their users to their own diabetes technology portfolio and make it for users difficult to switch to another technology or manufacturer.

Similar to Gaudilliere, Dumit (2012) sees capitalist mechanisms as the cause of a crisis in innovation in the healthcare sector. He also believes that the problem lies in the fact that these enterprises follow capitalistic rules by producing monetary value for their shareholders instead of being attached to the improvement of public health. This leads these enterprises to adapt their research and innovation processes towards higher revenue and profit. But in contrast to Gaudilliere, who focuses on the exploitation of existing patents, Dumit sheds light on the aspect of a capitalist-driven redefinition of health: Being healthy or reaching the state of health is in this sense not valuable. Rather, a redefinition of health towards continuous treatment is taking place (Dumit, 2012). The constant treatment of potentially sickness forms a profitable business model whereas the reaching of a healthy state would mean the end of a treatment and thereby the end of financial income for the company. In this sense, health is not a static state anymore, but much more a constant reducing risk of losing health. Or in the phrasing of Brantly, the “risk of the illness is treated as the illness itself” (2023, p. 98).

By this, another level gets visible: The state of being healthy is not a static one. What once may have been seen as a healthy state can change as being not healthy anymore. It is not the individual who defines being healthy or not. Rather, it is the publicly shaped and established perception of health by which individuals are assessed on (Petryna & Kleinman, 2020). As part of the healthcare system, the industry therefore also shapes the public perception of health in a broader sense. In the sense of Dumit health nowadays is not solely the absence of a concrete disease but much more the constant protection against a potential threat.

Even though Gaudilliere's (2021) remarks focus on the development of pharmaceuticals, Schneider (2022) clearly shows how strongly the development and use of pharmaceuticals can be interwoven with the corresponding medical devices, in the context of insulin treatment. The use of insulin by T1D patients today is inextricably linked to the medical devices used. This link is also evident in Dumit (2012), who not only refers to pharmaceuticals in his remarks, but also draws a connection to medical technologies. Based on this, Brantly (2023) also sees the development of diabetes technologies as being shaped by capitalist motives. For this reason, I see the aspects and explanations presented here as equally relevant to the role of commercial manufacturers in the innovation process of medical devices.

In this sense, the system in which the innovation of medical devices takes place must be critically scrutinized regarding its' outcome. What motives are driving this? Is it the well-being or recovery of patients, or do other motives dominate the development of new technologies?

3.1.4. Shaping technological normativity of diabetes treatment

Apart from the availability of medical technology or single artifacts it is crucial what is seen as standard by the actors of the medical healthcare sector. Health policies decide, for example, which medical devices or pharmaceuticals are financially covered by health insurance companies (Faulkner, 2009a). This also creates a certain form of normality: Which medical devices are reimbursed by health insurance, are thereby institutionally supported by the healthcare system and are thus more likely to be prescribed to a patient?

The manufacturers of medical devices for diabetes treatment are not only shaping the development of technologies (Bennett, 2019), but also play a decisive role in the process of establishing their devices in the healthcare sector because they not only act as pure manufacturers, but also rely on networks within the healthcare system.

For example, these companies train doctors in the use of medical devices and in the care of patients with them. As a result, medical staff are familiar with the specific devices and are

perhaps more inclined to recommend these familiar devices to their patients. In the context of pharmaceutical innovation, Sismondo (2018) brings up the concept of "assemblage marketing". This concept describes how companies try to actively control and manage markets, often in ways that are not immediately visible. To a large extent, pharmaceutical companies also influence what is written in scientific articles in medical journals, move the focus in medical and pharmaceutical research to areas with a vested interest, and in some cases also directly influence practicing physicians. In this context, Sismondo also speaks of a knowledge hegemony of the pharmaceutical industry over medical knowledge. They shape the view of medical professionals on symptoms, diseases and their treatment.

In my view, this view can be clearly transferred from the pharmaceutical sphere to the field of medical devices, since this aspect also became apparent during my participation on two diabetes conferences (see 5.2). I learnt from the speeches and individual talks to diabetologists that they mostly focus on just a few models or manufacturers, especially when it comes to the commercial devices for automated insulin dosing that are meanwhile available in Germany. In this respect, standards are also being set indirectly at the level of medical professionals. According to the event brochure, the first conference in particular, diatec, was sponsored by device manufacturers. In addition, the conference program was characterized by events and manufacturers' exhibition stands. The majority of visitors to the event were medical professionals. Especially with the statement in mind that most medical professionals focus on just a few device manufacturers or models, this event can be interpreted as kind of competition between device manufacturers to win over medical professionals.

3.1.5. Conclusion: Medical devices, its' regulations and innovations

This chapter gave an overview on the characteristic of the market for medical devices which is put into a regulatory frame of innovation paths and passage points. Its' purpose is to establish a portfolio of devices that patients can trust and rely on, because the institutionally hold processes aim to guarantee safety of these devices, whereby safety is a relative term. It is rather a kind of balancing of risks and benefits. But it must not be forgotten that the institutions which build and hold up this regulatory regime are not producing the medical devices themselves. Within the regulatory regime, commercial device manufacturers follow the paths of innovation and procure new artefacts. Of course, their motives can be questioned regarding fully concentrating on the health of patients or on their contrary capitalistic motives. This leads to the inevitable question: Does this highly regulated system of medical devices manage to create satisfying outcomes for users? In the case of diabetes technologies, this question must be denied, as the #WeAreNotWaiting movement explicitly expressed this dissatisfaction. Their actions can be seen

as a form of patient activism, which leads me to the second part of my literature review in the following section: What does STS Technology Studies say about patient activism?

3.2. Patient activism

In the sphere of STS Technology Studies, patient activism is a present topic that is lit up by different perspectives. One of the most known examples of patient activism is the “ACT UP” movement. It shows how lay people successfully engaged in and participated in a scientific discourse – or more specifically, how those affected by a disease can successfully influence medical discourses and processes (Epstein, 1995, 1996). In the 1980s, the ACT UP movement was formed in the USA to represent the interests of AIDS patients. They advocated for faster approval processes for new AIDS drugs and thus better access for sufferers to potentially helpful drugs – in backdrop of their life-threatening condition. Pinch and Collins (1998) suggest how, in this process, sufferers first acquired medical knowledge in order to raise their voices and be noticed. According to Epstein (1995), the activists achieved credibility in the discourse by mostly autodidactically learning the language of the researchers or acquiring "cultural competence" and were thus able to participate in the debate. There was a shift in the sovereignty of expertise about AIDS – away from actors such as academia and physicians to those affected. The latter were even considered to have a broader knowledge – they had a completely different insight into this due to their everyday dealings with the disease (Epstein, 1995; T. Pinch & Collins, 1998).

In the case of DIY Loops, a certain aspect comes into play, as the Loop system consists of commercial components for the pump and the CGM. However, these were “hacked” for use in the Loop system, i.e. the functions specified by the manufacturers were broken. This hacking as such is already a form of activism. At the same time, however, this action is a means of specific patient activism. Hacking medical devices is to be seen as a response to the current state of things, to show alternatives to it and at the same time a form of taking things into one's own hands. At the same time, this action makes the underlying problems – i.e. the lack of function of diabetes devices as well as the risky and nerve-racking life as a diabetes patient – visible (Delgado & Callén, 2017). In this sense, Rosental (2013) also speaks of hacking as a "mobilization apparatus”, as it paves the way for building and establishing new realities.

3.2.1. Patients as experts of their condition

The aspect of bringing in new perspectives into the scientific and medical discourse is an essential part of patient activism. Patient knowledge can build up new understandings of diseases and what it means to live with it, especially in the case of chronical conditions like Diabetes (Pols, 2013).

Living with a chronic disease means to live with the effects by the disease, especially impairments in daily life and in this respect also workload for the constant care work (Mattingly et al., 2011). This is particularly apparent in the case of T1D (Mol, 2008, 2009; Walsh et al., 2015). These disease-originated negative effects are perceived as a loss of "quality of life" what in turn causes a constant striving for improving the current state and recovering quality (Armstrong & Caldwell, 2004; Braune et al., 2022; Coolen et al., 2021; Nielsen et al., 2016; Wahlberg, 2017; Wahlberg & Rose, 2015). This striving gets mapped in the set of activities and knowledges of the patients.

This patient knowledge helps to change approaches on the question of what a good treatment is and regarding further medical innovation processes: It can lead the focus away from the question of how existing treatment methods can help into the perspective of what (other) treatment methods are actually needed to meet the patients' need (Thorne et al., 2000). In this sense it enables a way of outpacing established, traditional ways and approaches of medical innovation.

Basically to this discourse is the underlying understanding of who having a say at this stake, which is mostly linked to the attribution of expertise (Callon & Rabeharisoa, 2003). This very fundamental understanding of expertise defines the legitimization of as eligible seen actors in this discourse. Traditionally, expertise in the medical sphere is linked to health professionals or scientific actors. But Callon & Rabeharisoa see a remarkable knowledge hold by patients calling them "experts of experience". Through their everyday experience with the disease they have a very specific, practically framed set of knowledge, also called "experiential knowledge" (Arksey, 1994; Borkman, 1976; Rabeharisoa et al., 2014). In this context, Brown (2004) brings up another term, the so called "embodied experience". By using this term, he introduces yet another aspect: The experience of the disease is not a detached, abstract one, but a literally embodied experience of one's own body. Any experience of the patient or associated care activities in this context are always a form of interaction with one's own body. The body is the linchpin of the care activities designed for the illness. On the one hand, the activities are linked to the goal of ensuring or improving the condition of the body, but at the same time the body itself is also part of these activities. In the literature, the term "tinkering" is also used in this context (Jansky, 2024; Kaziunas et al., 2018; Mol, 2008). This includes actions and their variations with the aim of continuously improving care activities.

The disease is not only a constant companion of the patient, but an inseparable part of them. In this way, the term "embodied experience" also expresses a certain form of closeness to the illness that is perhaps hidden from purely professional expertise. Calling them "experts of experience", Callon & Rabeharisoa (2003) credential patients as legitimased voice. At the same

time, they do not classify expertise hold by medical professionals or scientists as competing to patient knowledge. Rather they see both sets of knowledge as complementing each other. This assumption is in line with Pols' (2013) view that patients can rather create a new, perhaps previously unconsidered perception of a disease.

3.2.2. Patients as a legitimate voice in the sense of a democratic healthcare system

In this context it is noteworthy to mention that not only by diseases affected patients hold this certain kind of expertise, but also caregivers. One of them holding it and contributing as kind of advocacy group is the case by Silverman (2012): During the 1960s to the 1980s, parents of children with autism significantly contributed to the development of behavioral therapy methods through advocacy, involvement in research, and self-education in therapeutic techniques. Their deep understanding of their children's unique symptoms and individual responses positioned them as experts. By demonstrating that children with autism could be educated and that this education could be grounded in theories of neurological differences and sensory atypicality – alongside interpretations of meaningful behavior – they laid the foundation for future advancements in the field.

Giving those affected by the disease the opportunity to participate in the discourse – whether patients themselves or their caregivers – is also seen in the literature as a form of democratization of the healthcare system as well as medical technologies (Landzelius, 2006; Laurent, 2011; Löfgren et al., 2011). Or seeing it in an even broader sense like Callon (2009), lay people's involvement in techno-sciences is a basis for democratizing democracy. Linking back to Epstein's (1995, 1996) case of AIDS activists, this kind of democratization is seen in the shifting role of patients: Instead of just being passive recipients in the context of AIDS treatment, the became an active part in the shaping of knowledge and thereby development of treatment forms. In this context, however, it is not only the mere possession of expertise recognized as such, but also, according to Epstein, credibility as a form of authority and the ability to legitimate one's arguments as authoritative knowledge. This means, for successful involvement in the public discourse, it is not only about the availability of relevant knowledge but also about performing this knowledge which means having agency.

Rabeharisoa et al. (2014) use the term "evidence-based activism" to describe how patient organizations actively engage in biomedical research, aiming to gain benefits for those affected. Evidence-based activism highlight the ways activists generate and contribute to new understandings of their conditions. These knowledge practices can influence and shape formal

biomedical knowledge, emphasizing the critical epistemic role patients play in the production of biomedical knowledge (Jansky, 2024).

One essential part of this engagement is a form of alliance-building with other actors in the medical and scientific sphere. Patient organizations rarely act solely but in a form of cooperation to bring their claims into public. Panofsky (2011) for example illustrates how patient groups build up close relationships with scientists and at the same time orchestrate them purposefully to strengthen their position within the discourse. In the end this alliance-building is a strategically form of claiming political power (Brown & Zavestoski, 2004; Callon & Rabeharisoa, 2003). At the same time, the patient organizations cannot be seen as a homogenous, singular group but rather as a fluid spectrum of more activistic individuals down to everyday patients, that do have a less active role in the movement. In this sense, patient organizations have a mediating role towards the patients, especially also regarding the interaction and cooperation with other actors in the discourse field (Epstein, 1995; Jansky, 2024; Thorne et al., 2000).

3.2.3. Patient activism regarding healthcare technologies

Nevertheless, patient activism not only addresses the disease as such, but also the medical complex in which one operates. Patient advocacy groups are inherently engaged in a politics of institutional design what defines and enacts narratives of inclusion, exclusion, fragmentation and legitimacy. They both reflect and co-constitute (often unevenly) emerging and dynamic forms of the public sphere in which processes of communication and negotiating take place (Milewa, 2011). Addressing technologies and treatment also means challenging the cultural authority of science and medicine.

One case of addressing and re-configuring of an established regime is given by Blume (1997). He outlines how deaf people refused a cochlear implant as a treatment technology for their condition. With the help of mass-media, the medical and scientific community had publicly presented the implant as an object of pioneering, the so-called “bionic ear”. They built up a rhetoric that strongly based on their assumptions on medical technology and deafness, ignoring the patient’s perspective which held a totally different view on their condition and its’ implications on daily life to those affected. It was merely assumed that deaf individuals see their condition the same way medical and audiological professionals did. This perceived ignorance of the medical community led to a counter-rhetoric by the patients focusing on the potential risks of the implant by undergoing a surgical intervention and a prolonged rehabilitation process.

Blume points out how deaf people as a patient group established themselves as a “relevant social group” (T. J. Pinch & Bijker, 1984) in the process of medical innovation. Confronted with the “bionic ear” presented as the ultimate solution, they gave themselves and their perspectives a say by arguing against this very technology. This case shows how the development of medical technologies can lead to active rejection if the intended patients are not involved. Callon & Rabeharisoa (2003) characterize this form of patient activism as so-called “opponent organizations”. In this case, the rejection of the implant is an expression of a larger refusal, namely the definition of their condition by the medical or scientific community. In the words of Callon & Rabeharisoa, the patients' “very identity as patients is at stake” (2003, p. 195). The deaf people felt ignored and that a perspective was projected onto them and the condition that they themselves did not share. This resulted in a refusal to let others speak for them and the associated decisions or technological developments, which ultimately affect the patients.

In the specific context of this research topic of DIY Loop systems, the affected T1D patients not only reject the available commercial systems but go one step further and create new technological artefacts based on them. Jansky & Langstrup (2023) put forward the concept of ‘device activism’. Here, the devices are the aim of activism on the one hand, but also the medium on the other. This is because their demands for suitable devices for T1D treatment are expressed directly through the creation of their own devices or the modification of commercial components. In terms of STS, the devices themselves are therefore central ‘matters of concern’ (Latour, 2004).

3.2.4. Patient activism as form of user-innovation

Putting the DIY Loop in broader context, it can also be seen as an example for needs-driven or user-generated innovation, which is a relevant topic in STS. Von Hippel (1988) shows that innovation often originates from users who develop their own solutions because existing commercial products fail to meet their specific needs. In particular, “lead users” experience needs earlier and more intensely than others, thereby driving innovation. In addition, von Hippel (2005) emphasizes that open-source communities and peer production enable needs to be collectively translated into new technical solutions outside commercial contexts. Both aspects are observable in the case of T1D patients using DIY Loops.

Oudshoorn and Pinch (2003) highlight the active role of users in the co-construction of technologies. It becomes clear that users such as people with disabilities adapt or develop devices and systems to meet specific everyday needs. These adaptations reflect a social practice in which needs and technologies emerge in a mutual relationship. While developers or manufacturers inscribe assumption into technologies, users can subvert or transform and “de-

scribe" them (Akrich, 1992). Needs-driven innovation show that technologies are not passively adopted but actively reshaped by its users.

These innovations often emerge without commercial intent. Needs-driven innovation thus appears as a social and collaborative process that extends classical innovation models by incorporating a user-centered perspective (Hippel, 2016).

3.3. Patient activism as a reaction to the status quo

As shown, patients are not only experts in their own rights regarding the treatment in form of care practices and how they make sense of their condition, but also regarding the question of what tools they need therefor, what functions these devices should cover to address and reduce the disease-related impairments which cause a reduced quality of life. Patients navigate both the material and epistemic dimensions of care practices, positioning them as central figures in the assemblage of healthcare technologies and build a new path of innovation.

In the subsequent sections of my work, I will examine these tensions in more detail. In doing so, I take into account the parallactic view on patient movements as collective movement or activist actors and normal users (Epstein, 1995, 1996; Jansky, 2024; Thorne et al., 2000) and focus on the perspectives of individual T1D patients. My focus here is on the individual motivations for using a DIY Loop as well as the perceived challenges, particularly in the context of use within the traditional healthcare system.

Through my research approach, I would like to contribute to the two strands of literature in STS through the individual insights of chronically ill patients who, due to dissatisfaction with the established regime for medical devices, create and use alternative, self-built options.

4. The usage of a DIY Loop from a theoretical angle of Science and Technology Studies

In the previous parts of my thesis, I explained my primary research interest and contextualized my research topic within the existing literature of STS. Before I explain my methodological approach, I will outline the theoretical concepts that I use for my research work and explain my choices.

For an adequate theoretical consideration of my research question, I apply a combined perspective of two theories. Therefore, I use the theories of Science-Technology-Studies SCOT (Social Construction of Science) (T. J. Pinch & Bijker, 1984) and Mol's (2008) logic of care. The combination of these two theories allows me to expand the two very specific perspectives into a larger, more holistic view and to build my research question on a stronger and more nuanced theoretical basis. At the same time, I overcome the respective limitations of each theory by linking them to the other. Before I go into these linkages and their significance for my specific case of DIY Loopers, I would first like to introduce two different theories. Here I will start with SCOT.

4.1. The Social Construction of Technology

> *"In deciding which problems are relevant a crucial role is played by the social groups concerned with the artefact, and by the meanings which those groups give to the artefact: a problem is only defined as such, when there is a social group for which it constitutes a 'problem'." (T. J. Pinch & Bijker, 1984, p. 414)*

SCOT states that technologies and their development and establishment are shaped by social processes and thus contradicts the concept of technological determinism, according to which a technology is free of social influences and the technology's availability ensures its use (Bijker, 2010; Brantly, 2023; T. J. Pinch & Bijker, 1984). According to SCOT, it is not only the influences on the technology that are diverse here, but also the technology itself. This is because a technology is represented by technological artifacts, which may well differ in their execution. Using the development of the bicycle as an example, Pinch and Bijker (1984) show that not all bicycles are the same: the early days of the bicycle were characterized by various designs of the vehicle that differed greatly in their shape and construction. Nevertheless, in terms of technology, we would speak of bicycles in all cases. What we nowadays consider being a bike does not come from nowhere, rather it is the result of previous developments based on social processes and actors. At the same time, SCOT here contradicts the linear innovation model: Instead of a straightforward evolutionary process of a technology, it consists of different variants as artifacts.

Regarding a technology, Bijker (2010) speaks of "relevant social groups". These are social actors who use the technology and expect it to solve their own problem in certain ways - or are otherwise

influenced by the technology. This results in an "interpretive flexibility" for technologies. How a technology or technological artifacts are perceived and interpreted varies between different social groups. While a technological artifact may meet the needs of one social group, another social group may not find its requirements met in the same artifact - or the use of the technological artifact may cause the latter group to face new problematics (Bijker, 2010; T. J. Pinch & Bijker, 1984). To stick with the example of bicycles: the design of certain bicycles and their wheels may have given racing cyclists the opportunity to achieve particularly fast speeds, but everyday cyclists struggled with the lack of riding comfort that this design entailed. Opposing technical demands – like the example mentioned – of social groups on a technology forms conflicts, which can be resolved by adaptive artifacts and lead to the acceptance of a technology. To this end, SCOT uses the terms "closure" and "stabilization": if the conflicts are resolved, an artifact can prevail and with it the technology (Bijker, 2010; Brantly, 2023). Social groups agree on the execution of a technology. It is used as well as the successful artifact is stabilized or adopted as the standard of this technology.

4.1.1. DIY Loop systems as preventing closure of diabetes technologies

SCOT theory provides an insightful perspective on DIY Loop devices in two ways: on the one hand, the DIY APS movement can be seen as a process that prevents closure in terms of insulin delivery technologies for diabetes patients. Instead of being satisfied with existing, commercially available technologies and devices and their functionalities, DIY Loopers demand new technologies with functions that meet their needs (Omer, 2016). Activists want to demonstrate that insulin devices could be different and show concrete alternatives or implement them directly (Delgado & Callén, 2017, p. 183). Thus, instead of just being dissatisfied with existing technologies and their functions, the DIY community proactively creates their own artifacts and uses them to make alternatives to existing commercial products. In doing so, they demonstrate that there is indeed greater scope with additional functions to the seemingly limited possibilities in insulin treatment - and claim them. In this sense, DIY devices can be seen as "mobilization apparatuses" (Rosental, 2013) to initiate this process - or to stop an early closure. Crocket (2020) even speaks of "disrupting the diabetes technology landscape".

Furthermore, SCOT allows us to see the DIY APS development as a new artifact (or even multiple artifacts) in insulin delivery technology. This artifact is embedded in a complex social context that is also highly institutionalized and regulated (Brantly, 2023; Burnside et al., 2020; Faulkner, 2009a; Heinemann & Lange, 2020; Vallis & Holt, 2022; Walsh et al., 2015). Relevant social groups in this context would be, for example, users and caregivers – but also explicit non-users (Brantly, 2023). Furthermore, the aspect "One Size Does Not Fit All" (Braune et al., 2021) should not be ignored:

Patients' requirements towards insulin delivery technologies are diverse and varying. That's why an interpretative flexibility also be taken into account here. The success of a technology or artifact is largely dependent on the acceptance of the individual social groups – and in this case also on the strict regulation of the medical market. Whether DIY Loop devices will be used in the future could be dependent on the traditional actors in the healthcare sector, i.e. physicians, health insurers and legislators, too. Their attitude towards DIY devices could significantly influence the use by patients.

These two perspectives that SCOT offers here, namely the prevention of the closure process and the creation of additional artifacts, are of particular relevance to my research work. For example, the initial #WeAreNotWaiting movement had repeatedly stated that they would not reject commercial devices in principle but would be willing to use them if they provided the required functions that were already covered by DIY devices (Schipp et al., 2022). This approach in particular underlines the attempt to prevent potential closure of diabetes technology. The insulin devices available to date were not sufficient for the members of the DIY movement or confronted them as a relevant social group with problems. The creation of DIY technologies, which offered the functionalities lacking in the commercial devices, showed in a very practical way that the end of innovation in diabetes technologies has not been reached, but that further developments are still possible. The activists were not satisfied with the current state of commercial technologies. However, from this point of view, the DIY artefacts can be seen as a practical illustration of this and break up a closure or stabilization of previously commercially available diabetes technologies.

4.1.2. DIY Loops as potential permanent artifacts

SCOT also offers an insightful view on the fact that commercial devices for automated insulin dosing are now available - including in Germany. Following the statements of the #WeAreNotWaiting movement, it could be assumed that this availability means that DIY devices are no longer necessary, and users are switching to commercial alternatives. However, this is not the case. Despite the availability of commercial alternatives, there is still a lively DIY community in Germany that uses self-built Loop systems. This (initially apparent) discrepancy is the basis of my research interest. Why do people with type 1 diabetes in Germany continue to use DIY systems for automated insulin dosing despite commercial alternatives - and the contradictory statements made by the movement in this regard? At this point, I am deliberately referring to an "initially apparent" discrepancy. This is because I would like to make the motives underlying this decision visible in the context of my work – and thereby make the "apparent" discrepancy explainable.

When we look at this further use of DIY technologies in context of the commercial alternatives that are now available, we can see the establishment of a new technological artefact from SCOT's perspective. DIY technologies are no longer just a practical illustration of alternatives (Delgado & Callén, 2017) to existing technologies with a temporary character. Rather, it can be seen as the establishment of permanently existing artifacts as an alternative to commercial devices.

It is precisely these two theoretical perspectives that SCOT offers me with regard to my research topic. The focus here is on the technology in the form of artifacts and functionalities. Although the users of the technologies are certainly of interest as relevant social groups, the focus here remains on their technology- and feature-specific needs and demands. SCOT does not allow a broader view of the larger context in which the technology and its users are embedded. In the context of diabetes technologies, this is particularly the healthcare system in which people with diabetes 1 are embedded in the treatment of their disease - and thus the technology they use for this purpose. For this perspective, I draw below on the feminism theory of science technology studies.

4.2. DIY Loop as a “choice”? The logics of care vs. choice

In addition to the previous theory of STS already presented and explained for my case, I now add a second approach to broaden my theoretical lens. To this end, I draw on Annemarie Mol's (2008) concept of the logics of care and choice. According to Mol, both logics offer different perspectives on patients in dealing with their condition, which she illustrates based on her own ethnographic observations of people with diabetes in a clinical context.

The logic of choice assumes that patients make rational, well-considered and well-informed decisions about the treatment of their disease in accordance with their individual. As Mol states, this approach is based on the idea of a libertarian and individualistic, patient-oriented form of care, which is particularly prevalent in Western healthcare systems and therefore also in Germany. According to this basic idea, patients can significantly influence their own care processes. This approach thus suggests freedom of choice for the patient through a spectrum of options for treating their own disease. The success of the treatment is subsequently possible with the right or a "better" choice – it is just about making the correct choice.

4.2.1. Logic of care: Taking into account the complexity and situatedness of care

According to Mol, however, this perspective neglects the complexity of the care networks in which patient find themselves, especially with a chronic disease. Rather, she calls for a shift towards a

perspective that considers the situatedness of the actors and activities surrounding the care activities. Accordingly, she sees care as embedded in specific contexts of actors and their interactions with each other, as well as processes and routines. Care and its activities are embedded in specific cultural, institutional and social contexts. Rather than the individual preferences and decisions of patients as individuals, it is precisely this situatedness of care that counts.

The question of good care is therefore not a question of an individual decision in a libertarian sense but depends on the specific arrangements in which it takes place. As a result, care should not be regarded as stable, but rather as fluid. The question of good care can have different answers depending on the evolving needs and framework conditions of the patient and the actors involved, such as the medical staff or caregivers.

While the logic of choice essentially reduces the care processes to one moment, namely the patient's choice, the logic of care emphasizes the character of care as an activity. The latter sees care as a collaborative process of interactions and negotiations between the various actors with a common endeavor – namely a living with the disease as good as possible (Wahlberg, 2017). The question of good care and thus its general design is therefore far more complex than the logic of choice might suggest. As simple as the choice appears to be, the attribution of blame in the event of treatment failure or complications is just as simple. According to the logic of choice, this is due to a wrong choice by the patient. Respectively the patient is blamed for complications. The current negative consequences could have been prevented – by making the right choice or a better one. This very individualistic perspective, which assumes decisions, places the freedom of the patient at the center and at the same time ascribes enormous responsibility for their own treatment to them.

This logic of choice also ignores the influence of the wider context on the decision-making process (Mol, 2008, 2009). Patients make – or have to make – decisions as part of their care. However, from an external perspective, these decisions may not initially appear rational in terms of correct, effective treatment. The therapeutic decisions and the associated actions of patients are significantly influenced by the situational context in which they find themselves. For example, diabetes patients may decide not to take a blood glucose test or postpone insulin dosing because it does not fit in with their current work schedule or because they are surrounded by other people in front of whom they do not want to take out their insulin pen and inject themselves (Wiedemann, 2019). The logic of choice would evaluate the respective decision of the patient with the view of

freedom of choice, but would neglect the underlying, significantly more complex basis for the decision (Chandwani & De', 2017).

4.2.2. Technologies as moral activity

In addition, Mol explicitly names the role of technologies in the treatment of a disease. In terms of the logic of choice, these are instruments, i.e. tools with specific functionalities. According to Mol, however, they are by no means just neutral tools: „Instead of being modest means, they are inventive mediators" (Mol, 2008, p. 50). The choice and use of a technology can, for example, have an influence on how you act as a patient and deal with your own disease and how you perceive it, but also how you interact with other actors in the context of care. It can also have an impact on the role one's own illness plays in social interactions or the space it is given. In this sense, Mol describes the use of technology as a "moral activity" (2008, p. 78). Technologies set a practical and moral framework. Just as, according to Mol, the extraction of insulin from the pancreases of animals had in some way legitimized the killing of these animals, the question must now be asked to what extent the hacking of medical devices and the production of a DIY Loop system are seen in a different light than before. In the case of the DIY Loop, you can also question at the individual level what justifies the challenges associated with the use of the DIY Loop, or, to put it vice versa: What are the users of the DIY Loop willing to do for the perceived benefits of the DIY Loop?

Going one step further, I would like to consider the consequences of using a DIY Loop system for patients regarding the treatment of their disease, their everyday lives and their perception of the surrounding care network. In the spirit of Mol, DIY technology is not a simple alternative tool to conventional Loop systems or other diabetes technologies in the broader sense. Its use is a moral act and has consequences. The character of tinkering with the body, technologies, knowledge and various actors is particularly evident here in DIY applications (Jansky, 2024; Kaziunas et al., 2018). Users of DIY Loop systems have already been part of an extensive care network due to their disease. Now they may be expanding this network by interacting with the DIY Looping community. Using a DIY system requires technological knowledge and, in addition to the initial construction of the system, updates and maintenance. Using a DIY system also puts diabetes patients in a position of legal uncertainty. It is still unclear, for example, who is liable in the event of incorrect dosing by the APS and the resulting complications and health consequences.

Following Mol's call for a change of perspective, I do not want to see the choice of DIY Loop systems by T1D patients as a singular, free and individual choice, whereby the technology is at the same time reduced to a purely technological tool for treating the disease which means that the decision can easily be dismissed as irrational against the backdrop of conventional, approved

systems, which could perhaps be considered safer or easier to use from the point of view of the traditional healthcare system.

Rather, I would like to pursue the question of why people with T1D decide to use a DIY Loop system – against the backdrop of commercial alternatives but paying attention to the complex context of the care networks. For me, the question of the extent to which we can speak of a "free decision" in favor of DIY technologies is particularly relevant in this respect. The spectrum of diabetes technologies is broad and diverse. What are the advantages of using a DIY-APS and why is it not a commercial device? Do the commercial devices perhaps still not cover required functions or is DIY technology perhaps even the only way to use an APS due to the healthcare system and access barriers to commercial variants? With all these questions, it is already difficult to reduce the use of a DIY system to a simple individualistic, free decision by the patient.

In addition, DIY technology is by no means a neutral entity as far as healthcare professionals as part of the care network are concerned. They are formally not allowed to support diabetes patients in the use of DIY systems due to legal ambiguities (D+B Rechtsanwälte Berlin, 2018). This raises the question of how doctors and other medical staff, but possibly also other traditional healthcare institutions, will behave towards users of DIY systems and how interactions will change. In a tight network of actors, institutions and interactions (Jansky, 2024; Kaziunas et al., 2018; Mol, 2008) around the patient, as is the case with T1D, changes within this network are obviously linked to the patient's perception of them and thus to a change in the reality of life with their own illness. These may change in a way that the users of DIY technologies do not have even suspected beforehand. At the same time, the question arises as to whether these changes are perceived positively or negatively – and perhaps even call into question the underlying DIY use.

4.3. A multi-theoretical view on DIY Loopers

In the previous sections, I have explained the two theoretical approaches that I use to look at my research interest. SCOT and the logic of care have very different approaches for shedding light on my research. While a single theory only allows me to take a very specific view, their combination enables me to take a broader view in order to build my complete research interest on a sound theoretical basis.

Even though the theories offer very different starting points and ways of looking at things, they complement each other well and complete the overall view. Mol's perspective by the logic of care in particular offers a deeply individual approach. This is because care and the associated activities and actors are strongly embedded in the setting the care work takes place – and are

therefore of course also dependent on the patient as an individual. This approach allows me to take a look at the complex motives for using a DIY system and the resulting consequences.

In contrast to this perspective, SCOT as the counterpart of my theoretical framework, offers a strong technology-centered focus on DIY technology or diabetes technologies in the broader sense. Essential here are the functions of the respective diabetes technologies and the DIY Loop as technology in particular. People with T1D and the DIY users among them as specific group play an essential role as a so-called relevant social group regarding the establishment of diabetes technologies. Users of DIY technologies thus demonstrate alternative technologies to conventional diabetes technologies and thereby prevent stabilization of the latter. This is particularly interesting in light of the fact that the #WeAreNotWaiting movement based its initial activities on the fact that conventional devices have not yet provided the required functions. With conventional devices for automated insulin dosing now available, it is important to consider how DIY technology will position itself in the diabetes technology landscape in the future.

In the sense of Mol (2008), SCOT offers a way of classifying various technologies for diabetes care in terms of their functionality as instruments. Although these instruments or artifacts are situated in the context of human actors, their use in often very complex and situated contexts is not taken into account.

In this chapter, I have outlined the theoretical framework within which my research work is based on. The two theories of STS, SCOT and the logic of care, form the theoretical foundation of my research questions and at the same time provide the perspective from which I initially approach my case. In line with my research question and the methodology I used, this forms the foundation of my work. As I had already explained my research interest and my specific research questions in the previous chapter, I will now outline my methodology in the following chapter.

5. Methodology

In the previous two chapters, I have already outlined my central research questions (see Chapter 2.2) as well as the theories that serve as analytical lenses for this study. In this chapter, I present the third component of my research framework: the methodology. The selection of an appropriate methodology, in alignment with the research questions and the theoretical foundations, constitutes the prerequisite for a research design that enables an adequate approach to the research interest (Jensen, 2016).

Already the phases of familiarization myself with the topic and the associated literature review were accompanied by a search for and formulation of a research perspective and the establishment of a theoretical framework in line with the methodology. However, these were not linear, sequential steps, rather an iterative process with gradual refinement and convergence to my current perspective.

Initially, I intended to focus in detail on how users of a DIY Loop perceive their interactions with their diabetologists – against the backdrop that a DIY Loop system is not an approved medical device, thereby placing both the patient and the physician in a sphere of legal uncertainty. However, this perspective shifted during my attendance with an ethnographic sense at two diabetes conferences in Berlin, where commercial systems for automated insulin delivery were particularly prominent (see xx). As a result, my primary research question evolved to focus on why diabetes patients prefer a DIY Loop over commercial systems, while retaining my original research approach – namely, to inquire into the potential challenges that arise from using a DIY Loop. Given this patient-oriented focus and my interest in the individual stories of DIY Loop users, qualitative interviews with these users emerged as an appropriate method (see Chapter xx).

In this sense my methodology includes Grounded Theory, which was developed by Barney G. Glaser and Anselm L. Strauss in 1967 (Glaser & Strauss, 1968). It is a set of "systematic, yet flexible guidelines for collecting and analyzing qualitative data" (Charmaz, 2006, p. 2). This is also reflected in the conduct and analysis of my qualitative interviews. While I principally relied on a predefined catalogue of questions, I also drew on the insights gained from previous interviews to adapt or specify questions accordingly (see xxx). By the iterative process of sorting, coding and memo-writing for identifying themes and setting them into relation, my theory rather derived from the collected data itself – and is in this sense "grounded" – instead of the use of a pre-existing grand theory.

5.1. First impression of the German Looper community: Access to social media groups

For initially getting in touch with the German Looper community and to get a first impression of it, I considered the social media channels through which the members of the community organize and exchange information (Braune et al., 2022; Jansky, 2024; Kaziunas et al., 2018) to be the primary means of access to this. I identified the platforms Twitter, Reddit and Facebook in particular. However, Facebook turned out to be the most useful one for me, as there are several closed groups for users of DIY Loop systems. Of particular relevance to me was the fact that there were also dedicated groups for users from Germany or German-speaking countries, namely a group for users of an Android-based Loop system and one for Apple iOS users. This geographical focus of the groups corresponded to my own research focus and would allow me to approach potential interview participants in a more targeted manner. In addition, both groups seemed to me to be sufficiently large with around 2,700 (Android Looper) and 1,200 users (iOS Looper). As the Facebook groups were closed ones, I first had to apply for access, whereby I stated my scientific research interest for the sake of transparency. Finally, I was given access to both groups and was able to get an initial impression of the ongoing topics and discussions in the group. The members primarily exchanged ideas on topics related to building and using the DIY Loop. Newcomers, for example, also asked questions about which components are best combined with one another or whether their previously conventionally used pump could be integrated into a DIY Loop. Through posts in the Facebook groups, I also became aware of two diabetes conferences, which I ultimately attended and where I was able to establish initial offline contact with the diabetes and Looper communities.

5.2. Entering the world of diabetes patients: Attending conferences with an ethnographic sense

At the end of January 2024, I attended these two conferences: One was the “Diatec” from January 25-27, a diabetes conference for diabetes technologies, which was particularly attended by medical professionals. This was followed the next day by T1Day, where people with T1D could exchange but also get in touch with medical professionals and medical device manufacturers. I attended both events with an ethnographic sense and tried to capture my impressions by writing them down in a notebook (Delamont, 2007). What were the main topics at the events, how did the participants interact with each other and – in particular – what presence did DIY Loop systems have here? Especially in light of the fact that commercial manufacturers presented their own Loop systems at Diatec.

Attending to the two conferences and talking to diabetes patients, healthcare professionals and representatives of commercial device manufacturers gave me a good initial overview on the medical sphere of T1D. I immediately wrote down my impressions in a notebook and noted down the key findings following informal discussions with participants at the event. I also kept an audio memory log at the end of each day of the event to capture my perceptions. Nevertheless, I have to admit that it was not always easy for me to attend the two conferences. Both conferences were characterized by groups of visitors who regularly attend the annual series of events and who therefore already knew each other. As an outsider, this made me feel like a kind of intruder entering this community. This feeling was reinforced when other participants asked me about my motivation after having outlined my research interest to them. Whether I was a T1D patient myself or had one in my family? When I answered in the negative, this was often immediately followed by the assumption that I must be a medical student. But I also had to deny this question and thus reveal that I did not belong to either of the two visitor groups – T1D patients or medical professionals.

In addition, I sometimes found it difficult to ask the T1D patients about their condition, as I had the feeling that I was touching on a very personal, even intimate area of privacy. Nevertheless, I also had some exciting conversations and insights during the conferences.

Three key aspects that left a particularly strong impression on me were, first, the division I perceived between physicians and patients – perhaps further accentuated by the split into an event for medical professionals and a separate format for patients. In any case, it was clear from my perspective how physicians exchanged views among themselves about their patients. Likewise, the diabetes patients present spoke with one another about their experiences with their physicians. This reinforced a theme I had already encountered in the literature: the individual responsibility of patients for managing their diabetes, and the physician's evaluation of these care activities on the basis of blood glucose levels. In one presentation, for example, a diabetologist remarked that one should be grateful if an adolescent at least measures their blood glucose once a day – prompting laughter from much of the professional audience. A joke, then, intended to express the carelessness in diabetes care resulting from adolescent obstinacy.

Image 7: Commercial device manufacturer's slogan saying "Spontaneity is a matter of mindset." (Source: Own illustration)

Secondly, a distinct position of DIY Loop users within the broader community of diabetes patients can be observed, not only in quantitative terms as a small subgroup, but also in how they are perceived by users of other treatment technologies. When I brought up DIY Loop systems in conversations, several diabetes patients were entirely unaware of the existence of such systems and responded with interest or surprise. Other patients, by contrast, were familiar with DIY Loops, but regarded the demands placed on users as exceptionally high or perceived DIY Loops as too complex for themselves.

Another interesting aspect was how manufacturers of commercial devices framed diabetes care in their marketing. One manufacturer, for example, prominently displayed the slogan “Spontaneity is a matter of mindset” at their booth (see Image 7) – a deliberate play on the German term “Einstellungssache”, which can be understood both as therapeutic adjustment and as mindset. Spontaneity, something that diabetes patients often miss because any activity must be considered and calculated as part of insulin management – thereby limiting flexibility in daily life – is thus portrayed as something that can easily be attained or regained by patients. All that is needed is the right mindset, or indeed the right device that enables adequate insulin therapy – and in doing so, restores spontaneity to the patient. I regarded this as a somewhat idealized view of the situation of diabetes patients, but I immediately recognized the “logic of choice” described by Mol (2008), according to which, from a libertarian perspective, the path to good diabetes care is simply a matter of making the right choice from among the options available on the market.

Even if this ethnographic recording is not the primary method for my research, I still do incorporate my impressions at appropriate points in this work in order to possibly complement certain observations from my interviews.

5.3. Capturing the individuals' experiences: Interviews with users of a DIY Loop

5.3.1. Acquisition of interview participants via Facebook groups

To be able to conduct my interviews, I first had to recruit T1D patients in Germany who use a DIY Loop system. At one of the conferences, "diatec", I made contact with a doctor who himself treats patients using DIY Loop systems and is downright euphoric about this technology. He had also offered to put me in touch with patients of his own. However, after considering this way of access to patients for a certain time, I postponed this path as backup option, as I might produce a certain bias in my research work through the mediation of a doctor who is very open-minded towards DIY technology, which of course could also impact the patients' view on the DIY usage. After all, a key aspect of my research interest is the impact of DIY use on the relationship with medical staff – and I might be more likely to have patients who have had positive experiences with it.

In addition, I got to know a diabetes self-help group at the conference, one of whose members was Looping. I messaged the person after the conference to ask for an interview, but never heard back. That is why I perceived the Facebook groups that I have already been member of as suitable. After several weeks in the two Facebook groups, I posted a call for participation (see Image 8) in both groups at the end of February after getting approval by the group administrators for this.

Image 8: Post of call for participation (Source: Own illustration)

The two posts were linked to a Google form, on which I provided more detailed information about my research interest and about the general conditions of the interview (see appendix). This essentially included the fact that participation in the interview is voluntary and can left anytime as well as that the data collected in the interview would be anonymized.

In the form, I first asked whether the following three characteristics apply to the person: The person is a T1D patient, uses a DIY Loop system for automated insulin dosing and lives in

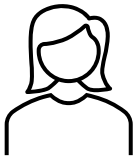
Germany. These were the principal selection criteria for me. In addition to the e-mail address for making contact and the name for addressing them, I asked about other aspects. These included the smartphone basis of the Loop (Android or Apple iOS), how long the DIY Loop system had already been used as well as age and gender (woman/man/diverse) of the person.

I was quite surprised by the high response to my calls as I had over 30 submissions within the first 24 hours and 45 in total over the following days. Of these, I sorted out a few persons because, for example, they do not live in Germany and therefore do not correspond to my target group. Similarly, some parents of children with T1D had also completed the form, but as caregivers of T1D patients they were not eligible for my research perspective. I first wrote to the remaining people by e-mail, thanked them for their interest and announced that I would select soon and contact them again. By selection I made sure to recruit users of both systems, AAPS and iOS Loop, as well as users with different lengths of use with the aim of perhaps more diverse stories. Since none of the registered persons indicated non-binary, I pursued a balanced selection between male and female participants only.

In the following, I emailed several qualified people again and asked whether they were still willing to be interviewed and provided more detailed information about the general conditions of the interview, such as the expected length of around one hour and the use of the Zoom video conferencing tool. I also proactively asked for suggested dates. In some cases, I received no answers or very delayed answers. However, I was able to conduct interviews with four of the candidates (see *Figure* 1).

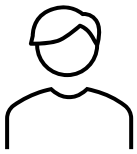
My interviewees were Petra, Thomas, Andrea and Markus (pseudonyms). I therefore had two female and two male participants aged between 38 and 45. Aware of this very specific age group, I also had my call for participation shared on Instagram by a T1D support group I met at a diabetes conference (see 5.2) in the hope of attracting younger participants in particular. However, this attempt remained unsuccessful. Nevertheless, I had four participants with different times of using a DIY Loop: As Petra and Markus have been using a DIY Loop already for several years, Andrea and Thomas just have started using it some months ago. All of them have been living with diabetes for several years so far and using a different diabetes technology before switching to a DIY Loop. Except Andrea, who uses an iPhone, all of them are using an Android-based Loop system.

Petra



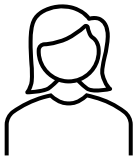
Age	44
Loop system	Android
Time of usage	For 5 years
Diabetes diagnosis	In adolescence
Interview	March 2024

Thomas



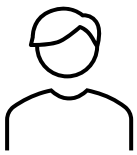
Age	38
Loop system	Android
Time of usage	Since October 2023
Diabetes diagnosis	May 2016
Interview	March 2024

Andrea



Age	45
Loop system	iOS
Time of usage	Since November 2023
Diabetes diagnosis	2010
Interview	April 2024

Markus



Age	41
Loop system	Android
Time of usage	For 4 years
Diabetes diagnosis	In adolescence
Interview	June 2024

Figure 1: Overview of the interviewees (Source: Own illustration)

With this insight, I would like to give an initial overview of my interview partners Markus, Andrea, Thomas and Petra, as they will play an important role in the rest of this work, and I will call them by their names (pseudonyms) from now on and tell their stories. In the following, I will go into more detail about how the interviews were conducted.

5.3.2. Conducting qualitative interviews

I used semi-structured interviews, which allowed me to take an explorative approach and gave me the flexibility to ask additional questions regarding aspects that were new to me or to adapt questions during the interview or for the next interview (Flick, 2021). My questions primarily based on open-ended 'what' and 'how' questions as well as a few close-ended questions and, if necessary, follow-up and probing questions to elaborate on underdeveloped answers and to

avoid misunderstandings (Jensen, 2016). In addition, this approach allows me to ask relevant aspects in an interview format in which my interviewees have enough space to tell their stories and – in particular – to emphasize aspects that are relevant from their point of view. By using this methodological framework, I also wanted to create an appropriate format with regard to sensitive topics, as my questions concern a very personal area of my interviewees and perhaps also touch on certain kinds of insecurities perceived by them.

This format of a personal conversation should also be reflected in the form of communication. As my four interviewees live in different regions of Germany, it was not possible for me to conduct face-to-face interviews on site. I therefore relied on interviews using the video call application Zoom. This allowed me to conduct the interviews with my interviewees remotely and with considerably more flexibility in terms of scheduling. In addition, it was possible for my interviewees to conduct the conversation at their preferred location, which in my view also had a positive effect on the well-being of my participants during the interview and may therefore also lead to a greater willingness to report on their own illness and use of a DIY Loop. Compared to a normal telephone call, the medium of video telephony also contributed to the participants being able to perceive me as an interviewer visually and perhaps gain more trust in me as a person. In addition, I was also able to incorporate the gestures and facial expressions of my interviewees into my perception or my interviewees could consciously illustrate something in the camera image or hold objects up to the camera (Jensen, 2016).

The first two interviews took place in March, followed by one each in April and June 2024 and have been carried out in German, but important quotations have been translated into English for this thesis by me with the support of the translation tool DeepL. Each interview setting began with a welcome from me and an informal exchange to get to know each other a little first, to at least reduce a potential feeling of strangeness. I then provided further information about the basic research interest and the interview process (see appendix) and gave the participants the opportunity to ask questions. I also emphasized once again the voluntary character of participation in the interview and the possibility for the interviewees to stop the interview at any time. After subsequent verbal consent, I started the recording of the interview. I had already obtained the Informed Consent for participation as well as for processing and use of the information collected during the previous e-mail communication (see appendix).

In line with the written consent, I once again explained how I would use and analyze the recorded and stored audio and video files of the interview, and that all information obtained and used would be anonymized. The recordings would subsequently be deleted. I also reiterated the voluntary

nature of participation and the possibility of ending the interview at any time or withdrawing consent.

To make the conversation as natural as possible, I also tried to incorporate my questions into the interview in a suitable way. To make this possible, I did not use a list of questions but had them visually clustered in front of me. This made it easier for me to simply eliminate any questions that had already been answered by the interviewee or, for example, to note down any new aspects that came up in a thematically appropriate way and pick them up in the course of the interview. I generally started with the question: “Can you describe your Loop system to me? What components does it consist of?” (original: “Kannst du mir dein Loop-System beschreiben? Aus welchen Komponenten besteht es?”). On the one hand, this question was of interest to me to understand the system and its components. At the same time, the question was intended as an easy introduction to the conversation, as it was primarily a straightforward description of the device structure. This initial question was followed by:

DIY Loop system as a “choice”	
• Kannst du mir erzählen, was dein erster Kontakt zum DIY-Loop war bzw. wie du davon erfahren hast? • Was hat dich dazu bewegt, ein DIY Loop zu nutzen?	• Can you tell me how you first came into contact with the DIY Loop or how you heard about it? • What motivated you to use a DIY Loop?
Building a DIY Loop system	
• Kannst du mir erklären, wie der Prozess des Bauens für dich aussah? • Woher stammt dein Wissen hierfür? • Wie viel Zeit hast du für den Prozess des Bauens benötigt?	• Could you please explain what the building process looked like for you? • Where did you acquire your knowledge for this? • How much time did you need for the building process?
Usage of a DIY Loop system	
• Wie wirkt sich die Nutzung des DIY Loops auf deinen Alltag aus? • Welche Auswirkung hat die Nutzung des DIY Loops auf deine Interaktion mit dem Arzt?	• How does using the DIY Loop affect your daily life? • What impact does using the DIY Loop have on your interactions with your doctor? • Do you notice any differences in your interactions with your health insurance or

• Nimmst du durch den DIY Loop Unterschiede in der Interaktion mit deiner Krankenkasse oder den Geräteherstellern von Pumpe oder CGM wahr? • Wie wirken sich eventuelle rechtliche Unsicherheiten hinsichtlich der Haftung auf dich aus? • Welche Aufgaben gehen für dich mit der Nutzung des DIY Loops einher? • Gibt es auch Momente, in welchen du lieber ein kommerzielles System nutzen wollen würdest?	the device manufacturers of your pump or CGM due to the DIY Loop? • How do any legal uncertainties regarding liability affect you? • What tasks are involved for you when using the DIY Loop? • Are there moments when you would prefer to use a commercial system instead?

Table 1: Interview questions in the original German as well as in the English translation

I used these questions as a general guide. I did not always use the exact wording or ask all the questions listed, as the interviewees may have already answered or touched on the question in their previous statements. In the latter case, I tended to pick up on the previous points again or asked about specific details. In addition, my interviewees' narratives brought up new aspects that I had not previously considered, and I then asked more in-depth questions about these.

Furthermore, the time gap between the interviews allowed me to carry out an initial analysis for each interview first and then to pick up on the findings in the subsequent interviews and perhaps also ask more in-depth questions of understanding. I also reflected on my own role in the interviews and adapted my questions and my interaction with the interview participants, for example. For instance, after the interview with Thomas in particular, I noticed that I was too quick to bridge moments of silence and move on to the next question, for example. In the following interviews, I consciously tried to avoid this.

Except one interview, which took 105 minutes, the other three interviews took around 80 minutes. This was roughly in line with my planning. I had announced that the interviews would take about an hour, whereby I had planned about 15 minutes for the welcome and the formal context and three quarters of an hour for the interview itself. However, at the end of the former exchange, which was characterized by my questions, I explicitly asked the interviewees again whether they had any other relevant aspects from their point of view. Even if the question was initially answered with “no” in some cases, this was followed by some very interesting insights for me. In this respect, the final part of the conversation turned out to be particularly valuable for me once again.

5.3.3. Towards narratives of using a DIY Loop: The process of coding

The interviews have been fully video-recorded and in the following transcribed verbatim. This kind of word-by-word transcription allows an authentic expression of the interviewees' statements for analysis as it includes for example pauses, repetitions, corrections and false starts (Paulus et al., 2014). Therefore, I used Microsoft Office Word for automated transcription. After this I went through the generated transcripts while listening to the recordings. Partially I had to correct the automatic transcript. Furthermore, this step of manual proving was a way of quickly familiarizing myself with the interviews. Once the transcription was complete, all video and audio files of the interviews were deleted.

For each interview, I did a first round of open-coding and formed first groups of categories (Jensen, 2016; Rivas, 2018). Therefore, I used the application Atlas.ti. After having coded all four interviews individually I went through the identified codes and categories with an comparative sense in order to find similarities as well as differences between the interviewees' perspectives (Jensen, 2016).

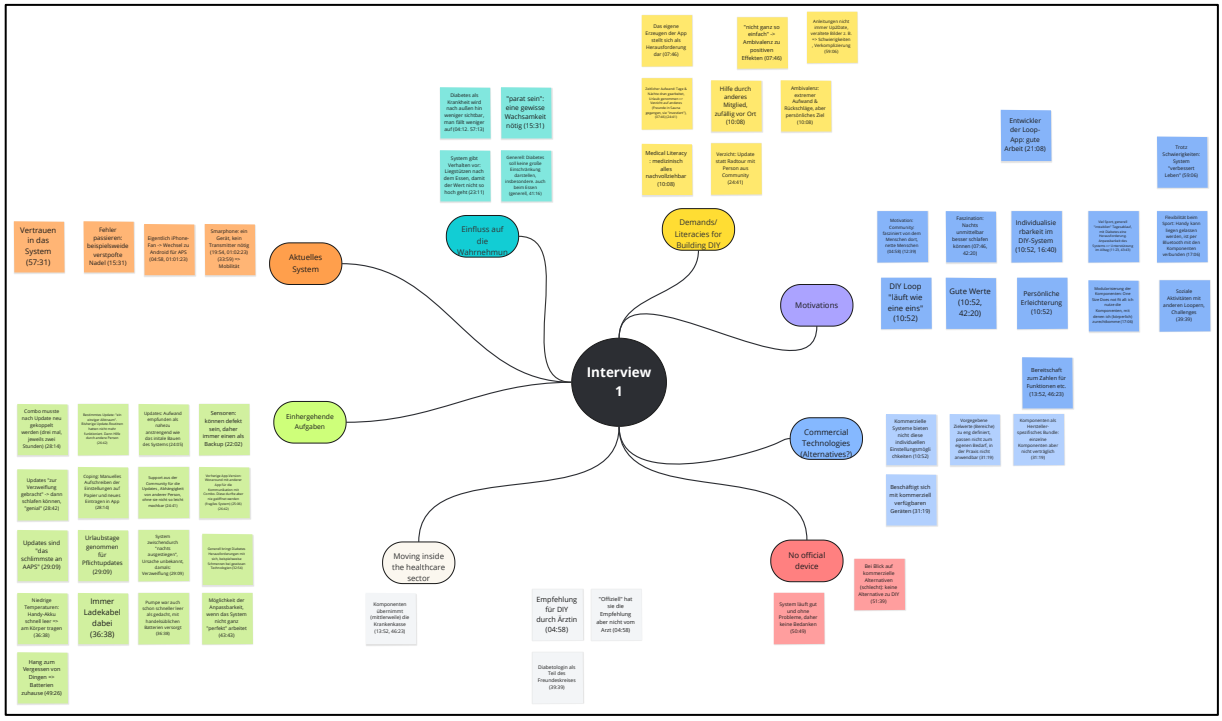


Figure 2: Miro board of categories and codes of the interview with Petra. The other three interviews' boards can be found in the appendix (Source: Own Illustration)

With the help of Miro, which made it easier for me to arrange and rearrange codes as well as to identify categories due to its visual nature, I created a separate board for each interview (see Figure 2), organizing the codes consistently according to first themes (Rivas, 2018). I could identify:

Themes (German)	Themes (English translation)
Aktuelles System	Current system
Motivationen	Motivations
Einfluss auf die Wahrnehmung der Krankheit	Influence on the perception of the disease
Anforderungen/Wissen zum Bauen des Loops	Demands/literacies for building Loop
Einhergehende Aufgaben	Associated tasks
Kommerzielle Technologien: Alternative?	Commercial Technologies: alternative?
Kein offizielles Medizingerät	Not an official medical device
Bewegen innerhalb des Gesundheitswesens	Moving inside healthcare sector

Table 2: Themes identified across interviews

This uniform yet interview-specific approach enabled me to work out the parallels and differences. In order to identify nuanced narratives based on the four usage stories of the DIY Loop, I arranged the codes from all four interviews together on an additional Miro board (see appendix), which I organized according to these narratives. The codes could still be assigned to the individual interviews by means of colour coding. This allowed me, for example, to break down the previously identified theme "Moving inside the healthcare sector" according to the relevant actors, namely the health insurance companies, device manufacturers, and the treating diabetologists.

Based on this, I built the empirical part of my thesis, consisting of Chapters 6-8, in which I trace the narratives from my interviews. Each of these three chapters serves as a response to one of my three specific research questions.

5.4. Technological setting of my interviewees

As already mentioned, various CGMs and insulin pumps can be used to build a DIY Loop. In this respect, the Loop systems of my interview participants differ not only in terms of the underlying system of iOS Loop or Android APS, but also in terms of the pump and the CGM. At this point, I will provide an overview of the different systems used by my interview participants (see Table 3).

The table reveals the modular structure of a DIY system. All Loop systems are based on the smartphone used and its operating system. Petra, Thomas, and Markus use an Android smartphone for this purpose, while Andrea uses an Apple iPhone with iOS.

A CGM sensor is required to measure blood glucose levels. Petra and Thomas use a Freestyle Libre 3 for this, while Andrea and Markus use a Dexcom G6. Both devices are worn on the skin and transmit their readings to the Loop app on the phone. As can be seen, both models are compatible with iOS and Android.

There is somewhat greater variation in the insulin pumps used: Petra uses an Accu-Chek Combo, which is a small device resembling a pager in shape and size, with a replaceable insulin reservoir. Insulin is delivered into the tissue via a needle connected to the device by a tube. The situation is different for the other three: Thomas and Andrea use an Omnipod Dash, and Markus uses an Omnipod EROS. Both are tubeless pumps, so-called patch pumps. In contrast to Petra's model, it does not consist of a device with an attached tube; instead, the pump and insulin reservoir are combined in a single small device that is adhered directly to the skin. The device sits directly on the body at the infusion site. When the insulin reservoir is empty, the whole device is removed from the body and replaced by a new one.

Both Petra's Accu-Chek Combo and the Omnipod Dash model used by Thomas and Andrea can communicate directly with the smartphone via Bluetooth. The latter can therefore control the pump's insulin dosing directly. The situation is different with the EROS model used by Markus, which cannot communicate directly with the smartphone. For this reason, his Loop system includes an additional component: a transmitter. This small device translates between the smartphone and the pump: it forwards data received via Bluetooth from the smartphone to the pump using a specific radio standard, and vice versa.

This overview thus also highlights a key principle of DIY Loops: it is essentially a modular system, in which certain components – smartphone, sensor, and pump – can be combined to form a complete Loop system.

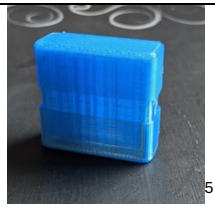
Interviewee	Smartphone OS	CGM Sensor		Insulin Pump		Transmitter	
Petra	Android	Freestyle Libre 3	 1	Accu Chek Combo	 2	none	
Thomas	Android						
Andrea	iOS	Dexcom G6	 4	Omnipod Dash Insulin Patch Pump	 3		
Markus	Android			Ominipod EROS		EmaLink	 5

Table 3: Settings and components of my interviewees' Loop systems

[1] https://www.freestyle.abbott/experience-fragments/adc/freestyle/ch-de/product/freestyle-libre-3-subscription/_jcr_content/root/productdetails_copy_/mediacarousel/image.coreimg.85.1024.png/1730129312661/02-01-02-fsl3-sensor.png on https://www.freestyle.abbott/ch-de/produkte/freestyle-libre-3.html. Last Accessed 6 December 2024

[2] https://mypump.co.uk/wp-content/uploads/2019/10/Accu-Chek-Combo-Pump.jpg on https://mypump.co.uk/accu-chek-combo-insulin-pump/. Last Accessed 6 December 2024

[3] https://www.omnipod.com/sites/default/files/2021-03/2col_pod-upright-grounded_omnipod-dash_1200x900x96_1.png on https://www.omnipod.com/de-at/was-ist-omnipod/omnipod-dash. Last Accessed 6 December 2024

[4] https://www.diabeticwarehouse.org/cdn/shop/products/dexcom-g6-transmitter_2048x2048.jpg?v=1626795029 on https://www.diabeticwarehouse.org/products/dexcom-g6-transmitter. Last Accessed 6 December 2024

[5] https://emalink.us/cdn/shop/products/PXL_20211023_135104206_940x.jpg?v=1634998873 on https://emalink.us/products/emalink-standard?variant=41147287961754. Last Accessed 6 December 2024

6. Reasons for using a DIY Loop system

In this and the following two chapters, I will present my empirical findings from my research. I will highlight some key aspects that became apparent in my interviews and that play an essential role in my interviewees' use of the DIY Loop. This chapter addresses the motivations behind the use of a DIY Loop, while the following chapter 7 examines the challenges associated with its use. This is followed by a focused perspective on how using a DIY Loop affects the experience of navigating the healthcare system as a patient (chapter 8).

Before turning to the perceived positive aspects of using a DIY Loop and their implications for diabetes care, I begin by exploring the initial moment when each of my four interview participants started looping. What led them to build a DIY Loop system in the first place – instead of opting for a commercial system?

6.1. How it got started: Commercial systems not as an option

6.1.1. Manufacturers and health insurances as gatekeepers: DIY as only pathway towards Loop technology

When Petra and Markus built their DIY Loop system, no commercial devices for automated insulin dosing were yet available in Germany. Accordingly, a DIY system represented the only access to this treatment technology at the time. The situation was different for Andrea and Thomas when they began Looping in November and October 2023, respectively. By then –unlike in Petra and Markus's case – commercial alternatives were already available in Germany. However, it is not the case that the two had not considered using a commercial system. In fact, that was initially their intention.

Andrea initially placed her hopes in a commercial Loop system. But the already available system with a tube-based pump was not an option for her, as it would have significantly restricted her in her physically demanding work as a waitress and in flexibility in her daily life – for example, to be able to spontaneously go swimming while wearing the pump. She therefore wanted to use a patch pump, which rests on the skin with an integrated insulin reservoir and thereby is less disruptive in daily life. She thus chose a patch pump that did not yet have Looping functionality, but which manufacturer had promised to deliver this function by a future update. However, the wait was in vain – the Looping function was never enabled, even though it was already available in the U.S. for that very pump model.

What made the situation even more frustrating for Andrea was that the manufacturer subsequently released a successor model of her pump in Germany, which *did* include automated

insulin delivery functionality. However, Andrea's application for this model was rejected by her health insurance provider on the grounds that the associated costs were too high. As a result, Andrea was left without the possibility of automated insulin delivery due to the manufacturer's unfulfilled promises and her health insurance's denial of coverage for the new model. She ultimately decided to turn the pump she was using into a Loop system herself.

6.1.2. Dissatisfaction with available commercial technologies

What led Thomas to try a DIY Loop was his negative experience with using commercial devices. Initially, he merely aimed to improve his blood glucose levels using an insulin pump and had no intention of using a system for automated insulin delivery from the outset. During an initial trial period with the pump, Thomas was able to test and familiarize himself with the device. However, the pump's control unit broke within the first 24 hours, rendering the pump unusable.

Due to what he perceived as the device's insufficient quality, commercial manufacturers, lost their role as guarantors or symbols of safety and reliability to him. The previously assumed dependability of commercial systems no longer held. This very circumstance simultaneously served as a form of legitimization for Thomas's decision to use a DIY Loop and to engage in the associated practices of hacking the pump: if a commercial device cannot provide adequate reliability, then such steps are necessary to access a good treatment technology. At the same time, this experience lowered Thomas's benchmark for evaluating a DIY system: from his perspective, building a DIY system that worked at least as reliably and effectively as a commercial product did not seem like a major challenge anymore.

6.1.3. Despite commercial alternatives: Sticking with the DIY Loop

Andrea, Markus, Petra, and Thomas – all four are aware of the (nowadays) available commercial alternatives. While they do not categorically rule out switching to a commercial system in the future, at present, none of them wishes to do so.

Of course, there was a moment for each of them when they initially built their Loop system. You could see this as the moment of choosing a DIY Loop. But just as much, their continued use of it can be understood as an ongoing decision in favor of the DIY Loop – and thus against a commercial system. This becomes evident throughout the course of my research: using a DIY Loop also entails continuously negotiating the use of a DIY Loop.

So, what motivates the four to continue using a DIY device? This is the question I address in this chapter. Taking the DIY Loop as a technological artifact in the sense of the SCOT approach, I begin

by examining the positively perceived functionalities that characterize a DIY Loop – and, conversely, are lacking in commercial systems.

6.2. One Size Does Not Fit All: The DIY Loop as blueprint for customizability

6.2.1. Options for combining components

> [00:33:08] Thomas
> And the pump that I have now is actually not intended for such a [commercial] Loop system but can of course be integrated here [into the DIY Loop]. And that, of course, is the freedom that you really have. And the programme that I'm using and that I've built also really allows - the vast majority of insulin pumps currently available on the market can be integrated. And really this freedom to choose which sensor I use, where do my values come from and which insulin pump do I actually use? No currently [commercially] available system on the market offers this to me.

The main advantage of a DIY Loop systems compared to commercially available systems is the high degree of customisation. All interview participants cited this aspect as an enormous advantage in relation to commercial Loop systems. The latter are limited to the ecosystem of the respective manufacturer: for example, if you get on well with the pump system from manufacturer A and want to use it, then you also have to use the CGM of this manufacturer and the associated control devices or apps on your mobile phone to use the Loop function. However, the fact that you get along well with the manufacturer's pump does not mean that you also find the corresponding CGM comfortable. Both components stick continuously to the body. Accordingly, the patient should feel comfortable wearing the devices. As already explained in the chapter regarding the disappointment by commercial alternatives, it was not an option for Andrea to use a tube-based pump system, as she saw this as a restriction in her everyday life, which is characterised by a lot of movement. However, the only commercial Loop system available at the time was based on a tube.

Petra, on the other hand, uses a Freestyle Libre 3 sensor for blood glucose monitoring, but had also tried a Dexcom sensor. The latter had caused her pain when wearing it, what made her decided against using it. In this respect, it would not be possible for Petra to use a Loop system of Dexcom, even if she got on well with the respective pump model, as the brand's own sensor was the limiting factor in this case. Instead, Petra uses a pump called “Accu Chek Combo”, an older pump model that is no longer available on the market, which she had used as a pure pump without a Loop function before. Markus, who also uses his already previously used pump for his Loop system, reports a similar situation. He justifies this step with the words "Never Touch A Running System" (06:15). He could stick to use his pump, which he had already used successfully before

and to which he got used to, was familiar with handling and had learnt how to operate it. If he used a commercial system, he would inevitably have to switch to a current pump model. This would mean that he would have to learn how to operate the system, get used to the new feeling of wearing it and not know exactly how the pump works or reacts. This change of pump system would be accompanied by a form of uncertainty for Markus, which he can avoid by keeping the pump he is already using.

The technical basis for this freedom in the choice of components is the inherent character of the modularisation of the DIY Loop system: the smartphone hosting the Loop app is the central element of the Loop system and is connected to the CGM on one side and to the pump system on the other. This flexibility on both sides results in many possible combinations of different pumps with sensors. Although not every available pump and CGM can be used in a Loop system, the system does cover a wide range of available devices. Android APS itself currently lists 12 compatible pump models as well as a few older models[6] . The list of compatible CGMs contains nine models[7] . On the iOS Loop side for users with an iPhone, there are nine pumps[8] and ten sensors[9] . In purely stochastic terms, there are more than a hundred possible combinations for Android users and 90 for iPhone users. The aspect of cross-manufacturer combinability in particular stands in contrast to commercial systems: While a wide range of components of different manufacturers can be used in a DIY Loop, only the significantly smaller pool of the manufacturer's own devices is available in commercial contexts – moreover with a reduced number of devices, as the manufacturers themselves do not necessarily allow their older pumps and sensors to be used in an official Loop system, but only the latest devices of their portfolio. Meanwhile, a DIY Loop also supports devices that are not even intended by the manufacturer for operating in a Loop system. My interviewees see this hardware-based flexibility as an enormous advantage over commercial alternatives.

6.2.2. Wide range of settings and automations

Using a DIY Loop therefore allows people with diabetes to choose the devices that are best suited to their individual needs. At the same time, if they have already been using a pure pump system, they do not necessarily have to give it up but can integrate it into the DIY Loop system. This view reflects the idea of "One Size Does Not Fit All" in the DIY Loop at hardware level.

[6] https://androidaps.readthedocs.io/de/latest/Getting-Started/Pump-Choices.html. Last Accessed 6 August 2024.
[7] https://androidaps.readthedocs.io/de/latest/Configuration/BG-Source.html. Last Accessed 6 August 2024.
[8] https://Loopkit.github.io/Loopdocs/build/pump/#next-step-compatible-cgm. Last Accessed 6 August 2024.
[9] https://Loopkit.github.io/Loopdocs/build/cgm/#next-step. Last Accessed 6 August 2024.

However, this credo can also be found regarding the software level, i.e. in the operation and control of the Loop system. Apart from the choice of components, the Loop app on the smartphone also offers a much greater degree of freedom in the settings than commercial systems. All my interviewees reported high degree of customisability, for example to set the target blood glucose levels to suit their own well-being and – in particular – their daily routine. Petra, for example, talks about being able to specify suitable target levels in the Loop application, especially in view of her many sport activities:

> [00:01:26] Petra
> My sugar levels are so much better; everything has become so much easier. And it's so great. And with this "do it yourself" system, you can set it to exactly the value that you ultimately need.

According to my interviewees, commercial devices are much more limited in this respect. Commercial devices only allow limited level ranges for the target definitions, which my interviewees perceive as too limiting. The ranges offered by commercial systems are not sufficient to adequately adjust their blood glucose levels to their daily routines and well-being.

Markus can also understand this restriction built into commercial systems to a certain extent. In his view, these limitations are for safety reasons built into official medical devices: the limited target values for blood glucose levels reduce the risk of complications. To him, these limitations by the manufacturers to protect against risks are a precondition for authorisation as a medical device and in this perspective understandable. He justifies this with the fact that anyone should be able to use a medical device, even if - as a person with diabetes - they have not yet dealt with the disease as intensively or are just fine with targets within the limited corridors by commercial devices. According to Markus, commercial systems are certainly justified, and their limitations are understandable for him – namely to give the *general public* access to automated insulin dosing. At the same time, however, he states that these same limitations are too strong for him and a use of a commercial system not possible to him - as well as for Petra, Andrea and Thomas. All my interview participants therefore see the use of a DIY Loop as an opportunity to leave this limited corridor marked out by commercial devices, simply because this corridor is too narrow for them and is not compatible with their needs for adequate treatment. Diabetes therapy itself already is based on corridors of values and nominal ranges (Wiedemann, 2019). However, the devices map these standards, maybe in a particularly strict way with regard to deviations. A DIY Loop therefore also offers the possibility of escaping these corridors.

Apart from these general setting options, which are nevertheless within the scope of nominal treatment in the context of quantified corridors, the Loop system enables treatment in a further

dimension: Markus reports a strong degree of automation and setting options. As he works partly from home, his daily routines also differ on his working days. Using an automation rule in the Loop app, the system doses an insulin bolus to him at lunchtime when he works at home. For this purpose, the Loop app checks whether Markus' smartphone is connected to his domestic Wi-Fi network on a weekday morning. If this is the case, the Loop system runs an automation, which is geared towards his daily routine in the home office. Of course, this makes things even easier for Markus. He does not have to report to the Loop system every time he works from home in time for lunch. At the same time, this form of automation integrates the Loop system - and therefore the human body - into a broader context. It is no longer just the human body and the Loop system that are in constant dialogue. The Loop system's blood glucose measurements and any additional input from the person to the system, which together influence the insulin dosage, are now enriched by the environment in which the user of the Loop system is located. In this case, it is the WIFI - namely electromagnetic waves - as an indicator of the geographical position of the person in combination with the temporal dimension, which influence the behaviour of the Loop system and thus the human body. This ability to incorporate environmental variables makes things even easier for Markus. This is a function that commercial systems do not offer.

6.3. Intrinsic motivations

In addition to the device-specific aspects already mentioned, a form of personal motivation also plays a special role. I call them intrinsic motives in the following. Apart from the circumstances resulting from the disease, a general interest in technology also plays a driving role. Almost all of my interviewees show a high affinity for technology, which is also reflected in their language. Some of them used very specific terms in the interview. For example, Andrea used the term "BIOS", a hardware-related programme with which standard computer users normally have little contact to. She also reported that she had been hacking devices since she was a child. Markus also sees himself as part of a generation that "grew up with personal computers" and therefore has a certain technical understanding of hardware and software.

Irrespective of their diabetes, the interview participants (apart from Petra, who describes herself being strongly dependent on the help of other community members for the technical realisation of the Loop system) showed a great interest in technology and enjoy or are interested in working or tinkering with technical, computer-controlled devices. Markus himself said that he enjoys getting faced up with unfamiliar technologies and systems and acquiring new knowledge through practical experimentation. He says that this interest was also part of his motivation for building the Loop system. During the 2020 coronavirus pandemic, he worked only from home and had

more free time, which he used to get familiar to the topic of DIY Loops and to build his own Loop system.

6.3.1. Self-care as a constant part of T1D

As I have already explained, dealing with diabetes as a chronic illness is a continuous care process that requires constant attention from the patient. Even if a way has been found to control blood glucose levels and a routine has been established for the patient, this does not rule out future complications. The possibility of blood sugar levels getting too high or too low cannot be eliminated. Neither can the risk of hypoglycaemia, hyperglycaemia or secondary diseases – people with diabetes live with these constant worries (Coolen et al., 2021). This concern was also evident in all my interviews. However, Markus also mentioned them explicitly as specific reasons for switching to a DIY Loop system. He was worried about his future in terms of his health. By using the DIY Loop, he is trying to reduce the risk of secondary diseases. The Loop system offers him a better control over his blood glucose level and thus also better values in the long term. At the same time, the Loop system enables him to do more sports again, which he had not done before – and thus also to improve his general state of health. These concerns about his future health are embedded in his family context. This is because Markus perceives a high degree of responsibility for his family and his children: he wants to be able to take care of them in the future and not be prevented from doing so by a health impairment.

At this point, it becomes clear once again how complex and multi-layered care activities are in relation to diabetes. The care network in which the activities take place not only influences what kind of activities are possible. Vice versa this care network also influences which activities or materiality take place. Markus is not just a diabetes patient who wants to treat his condition as well as possible by controlling his blood glucose levels. Markus sees himself also in the role of a father who wants to take care of his children and who perceives diabetes as a potential threat to this. In this case, it is primarily his sense as a father of duty that creates the will to maintain good health in the future, for which the DIY Loop system is a suitable tool.

6.3.2. Striving for good values

In the following chapter I will stick to the patient's motives of care, as the motives mentioned in the previous section led to what I call the *striving for good values*. A good blood glucose level within the target range – what means being neither too high nor too low - ensures a patient's physical well-being in the short term. Good values in the medium and long term demonstrate that you the patient has control over the diabetes, which means reducing the risk of secondary diseases for example. In this respect, striving for "good values" is reasonable. All my interviewees

stated that they reached "good values" with the DIY Loop or had switched to the DIY Loop with the aim of improving their values. But what are these "good values" that my interviewees are striving for? I would first like to make a small digression here.

Let's start with bloody measurement: Here, the patient had to stick their finger several times a day and check their blood glucose levels using test strips which were fed into a measurement instrument. This process was associated with specific actions, times of measurement, but for example also with physical pain and the visibility of blood through the pricking. A CGM takes a different approach: the device is invasively attached to the patient's skin. Okay, this step can also be painful but only takes place once the CGM is attached to the skin. There it remains for several days to a few weeks before it has to be replaced. It provides values every minute, which can be displayed on a control unit or mobile phone. Thanks to its more frequent measurements, the new technology provides more data in the form of metrics, which can now also be better correlated over time due to the higher intensity. Spectra and curves result from individual measuring points (Wiedemann, 2019). These spectra and curves now form kind of a norm – a corridor that needs to be achieved. In this respect, diabetes technologies also decide what is considered normality or good values – which diabetes patients strive for (Mol, 2000; Wiedemann, 2019). It is precisely this quantified and measurable value that represents a visible point of reference for diabetes patients to orientate themselves by. Have I reached this point or am I deviating? Am I doing a good job or is there potential for optimisation? And diabetes patients are certainly also assessed according to this frame of reference: Good values are also an expression of being a good patient. Failure to meet these targets is sometimes interpreted by doctors as a failure by the patient (Eitenberger & Wiedemann, 2022; Kjærulff et al., 2022). In this respect, these *good values* not only serve as a point of orientation for the patient themselves, but also as an external assessment of the patient's care work.

However, there is not just one value to orientate yourself by. Let's start with the snapshot, the current blood glucose level at the moment of measurement. A value as such that should already be within a certain corridor. With CGM devices, this value is usually supplemented by another value, the trend. This trend puts the current value into a temporal context and indicates whether the blood glucose level is rising or declining. Taking a look on a longer period of time and having a set of many values, you can determine the HbA1c value, which roughly speaking gives an indication of the average blood glucose level. It provides information on whether a patient has their blood sugar under control in the long term. As you can see, we are approaching Wiedemann's spectra and curves (2019). But that's not all. There is also the time in range (TIR): this value indicates the proportion of time in which the measured blood glucose values were within the

target range, relative to the measured time. This value is only made possible by the intensified measurement of the CGM's blood glucose level. There are no longer just a few, isolated values from blood measurements, but continuous values from the CGM at intervals of a few minutes. The TIR is sometimes considered to be a better value than HbA1c, as it provides a better indication of the patient's blood glucose development and insulin settings. This is because a patient with many upward and downward fluctuations in blood glucose could still have a good HbA1c value, as the high and low values balance each other out and the average value is well within the target range. In the TIR, however, the periods with the high and low values are cancelled out, the TIR deteriorates and better represents the many deviations from the target range. As you see, there is not only a set of different values, but also kind of a priority of values that diabetes patients face.

At this point, the aspect of the multiplicity of the disease (Mol, 2003) or its treatment becomes clear through the representation of the different values. What do the respective values represent and what aspect of the disease or treatment is reflected here? A patient can have a good HbA1c value and a poor time in range at the same time. On the other hand, a single measurement may be good within the current normal range but as a snapshot it says little about the long-term effectiveness of the treatment. At the same time, the example of the interplay between HbA1c and TIR shows that these values also represent a kind of black box (Latour, 1999). Good and bad values are each defined in their own evaluation category and can simultaneously come to different conclusions based on the same measurements, such as a good HbA1c value within the norm but a poor TIR.

Of course, Petra, Andrea, Markus and Thomas move within this environment of different categories, assessments, black boxes and multiplicities of values, too. They use the various values in their reports, such as a specific blood glucose value or range at a specific time – for example before eating. At the same time, they also categorise their values in the larger temporal context using HbA1c and TIR saying in particular how these values have improved with the use of the DIY Loop.

As mentioned in the interviews, gaining good or improving values were a motive for using a DIY Loop. At the same time, these good or improved values also serve to confirm that the DIY Loop therapy is effective and, of course, that the patients have made the "right" choice. In this respect, the HbA1c value and the TIR in particular serve them as a quantified evaluation option of the DIY Loop in order to summarise its advantages with regard to the treatment of their diabetes - on the one hand for themselves, but also to the outside world, where we would then be back to the "good patient".

6.4. Improvement of the patient's *quality of life*

A very prominent topic in the literature on diabetes I and its treatment is the 'quality of life' for those affected by the disease, in terms of its deterioration and the potential for improvement, for example through specific treatments or technologies (Braune et al., 2021; Heinemann & Lange, 2020; Lewis, 2022; Nielsen et al., 2016; Schipp et al., 2021; Sparring et al., 2013; Weinberger et al., 2023). As my work shows, this aspect also plays a strong role in DIY Loop systems. All the interview participants mentioned aspects of how their quality of life had improved through the use of the DIY system – and this, of course, as a motivating factor for using it. But before I go into these aspects in more detail in this chapter, I would first like to discuss the concept of 'quality of life'.

Nowadays, T1D diabetes is no longer a life-threatening condition for those affected, thanks to the possibility of continuous treatment with insulin. However, this form of treatment has only been possible since the discovery of insulin as an active ingredient at the beginning of the 20th century, i.e. for a good hundred years (Fischer & Rotella, 2015; Rosenfeld, 2002). This type of breakthrough was not only the case for diabetes, but also for other diseases: medical progress made it possible in principle to keep patients alive with a previously life-threatening disease through continuous medical treatment. This meant that fatal diseases became chronic diseases. This resulted in an increase in the number of chronically ill people – who, although they had a higher life expectancy and escaped death, now had to live with the symptoms of the disease. These symptoms and impairments – or in other words: loss of quality of life – thus became the focus of medical attention (Armstrong & Caldwell, 2004). According to Wahlberg, the term 'quality of life' developed during this period into 'something that can and should be measured, monitored, tested and improved in the medical field' (Wahlberg, 2017, p. 7). The aim here is to provide a normative value, a kind of ideal state: a person in perfect health and with all their faculties. In this sense, 'quality of life' becomes an indicator of the restrictions imposed on a person by an illness or the effectiveness of a treatment method to restore the ideal state. In this sense, quality of life can be seen as a deficit model: a chronic illness creates a deficit that needs to be compensated for. The goal here is the ideal state of the healthy self of a chronically ill person. The current level of medical quality of life is therefore also a relative value within a reference framework.

According to Armstrong & Caldwell (2004), this very same type of new thinking led to new approaches and goals in healthcare for cases in which a cure was unrealistic. Beyond the cure of diseases, the aim was now also to make life as pleasant as possible with a treatable but incurable disease. Similarly, forms of treatment could now also be thought of and evaluated in a new category, namely how they could best serve this very goal.

With regard to diabetes, Nielsen et al. (2016) speak of a specific loss of quality of life for people with diabetes in terms of their health compared to the 'general population'. This is reflected, for example, in an over-proportionately high number of sick leave days. Complications directly resulting from the disease or medical check-ups can in turn lead to a larger number of sick leave days. Apart from these quantitative values, which can easily be put into relation to the 'general population', other, perhaps more abstract aspects are also relevant: in addition to the immediate health consequences of the disease and possible physical limitations or even secondary diseases, the care activities associated with diabetes management create additional work and emotional stress. In particular, the fear of potential hypoglycaemia is a constant companion (Coolen et al., 2021). The reverse conclusion is that these also have a significant impact on the quality of life (or loss thereof) of diabetes patients in the sense of Wahlberg: without the diabetes, these people would not have these additional tasks, stress, fears or dangers at all.

In this respect, the aspects mentioned below also represent an essential form of quality-of-life improvement for the interview partners. The points mentioned concern areas of life that are positively influenced by the DIY Loop as a specific form of technology for diabetes treatment. It is precisely through this that the DIY Loop system gains a specific added value for the users, which confirms them in the use of the Loop system – and also in the retention of this technology.

In this area, I was able to identify four different aspects, namely better sleep, easier everyday life, regained spontaneity and greater flexibility in sports. In the following, I will explain them in more detail and show to what extent the interview participants see an improvement in quality of life here.

6.4.1. Improvement of sleep

All the interviewees address the aspect of night and sleep in relation to their T1D. As Markus himself explains, sleep is a fundamental challenge for diabetes patients in terms of the development of blood sugar levels. During the hours of sleep, the patient cannot measure blood sugar levels and react to them – which is contrary to the routine of regular measurements and injections during the day. In particular, previous meals and administered, after-effect insulin doses also have an effect on the blood sugar level during the period of sleep, which cannot be controlled and adjusted as required during this time. Accordingly, all interview participants reported sleep problems in the period before using the Loop. On the one hand, this was because they deliberately woke up at night to measure their blood sugar and inject insulin if necessary (interview with Andreas). On the other hand, it happened that they woke up, for example, due to hypoglycaemia and had to react to it acutely, for example by drinking sugary drinks (interview with

Andrea, Petra). Accordingly, the nights of all interview participants were restless before using the Loop. These nights were followed by days characterised by tiredness because they had not slept well. This nightly lack of control over blood sugar levels led directly to an unpleasant, exhausting night – and thus indirectly to a negative influence on the day. All four interview participants reported this – both when using pens and when using a normal pump system instead of the Loop. A significant perceived improvement for patients therefore arises from the fundamental character of the Loop system, the automated insulin delivery based on continuous blood glucose monitoring. The Loop system performs these two activities independently, without the need for action by the patient. The Loop system therefore fulfils a task that patients previously had to perform independently at night – thus enabling them to sleep better throughout the night and therefore have a better day.

The strong emphasis and mention of this aspect by all interview participants is not surprising, as it represents a significant improvement in their daily lives with diabetes. In line with Wahlberg (2017) , this can be seen as an improvement in quality of life. As explained in the previous section, Wahlberg defines the loss of quality of life due to a chronic illness as a deficit model – namely the difference between the potential abilities and freedoms that a healthy person would have without this illness. Before using the Loop, my interview partners were literally suffering from a lack of sleep and the associated tiredness and exhaustion during the day. Using the Loop system now enables them to sleep better – as if they were living without the disease. In this respect, this improvement represents an improvement in quality of life in Wahlberg's terms.

6.4.2. Reduction of workload regarding Diabetes-specific care work

In addition to the improved quality of sleep, all four interviewees also mentioned the aspect of personal workload with regard to the care work associated with their illness - or the positive effect of the Loop system, which relieves them of these tasks to a large extent. A significant part of the disease-related tasks consists of the regular measurement of blood glucose levels and the calculation and injection of the required amounts of insulin. A distinction is made here between the basal rate as a basic quantity distributed throughout the day and bolus rates, usually with fast-acting insulin. The latter are usually calculated and dosed individually for each meal. Even if the task as such can be regarded as routine for T1D patients due to its regularity, the activity always requires close attention. This is because the quantities of insulin required cannot be defined per se, but depend on a variety of factors, such as: What activities does a person do on a given day, what does the person eat and how quickly does the body process the nutrients contained in the food? How warm is it that day? Is the person possibly stressed? Markus reports on how many components are involved in the development of blood glucose levels, the effect of insulin and its

need. In this respect, the process of measuring, calculating and dosing is an essential aspect of the tasks associated with diabetes – and, of course, a need for time and attention for the patient. People with T1D have to imitate the missing function of their pancreas to produce (a sufficient level of) insulin with conventional forms of treatment. They take over the task of their organ 24/7, so to speak (Wiedemann, 2019). In this respect, it is a great advantage for those affected if they can delegate this task - at least to a large extent – to the Loop system. The Loop system - also known as the artificial pancreas system - enables the task of insulin dosing, which is initially delegated to the person and their external actions due to the disease, to be passed on to a further, third party. It is not possible to delegate the task back to the pancreas, as this would be tantamount to curing the disease. However, the Loop or APS system allows the disease-related burden of management to be passed on to an external, non-human entity, thus relieving the burden on the person with the disease.

All the interview participants rated this reduction in care work through the Loop system as a positive aspect. They now leave the tasks they previously performed themselves to the Loop system – and at the same time rely on its activities. Even though diabetes as such is not immediately visible or perceptible from the outside, the associated care work and the artefacts and routines associated with it certainly are. Whether it is the blood-soaked finger or the CGM attached to the body, calculating the required amount of insulin or injecting it into the body – all these activities and the objects required for them are part of the necessary care work for the treatment of diabetes – and make the latter visible as such. In this sense, the disease is inevitably performed – by the person with the disease themselves. However, the Loop system now performs largely on behalf of the patient – and gives the latter back the time and attention that the diabetes had previously claimed. Coming back to Wahlberg (2017) , we can also speak of an improvement in the quality of life here: the attention and time that care work demanded of patients due to their illness is now (at least in part) being returned to them. They can now use the time and attention they have regained for other activities in their daily lives.

However, this delegation of tasks and reliance on the Loop system also requires a minimum level of trust in the system. After all, the system administers insulin to the patient's body independently. An excessive or insufficient amount can lead to serious physical consequences, such as hyper- or hypoglycaemia. The use of the Loop system and the outsourcing of care work is based on the assumption or trust that the system will at least not make any major mistakes. Andrea expresses this trust in the system and the associated expectations as follows:

[00:14:09] Andrea
And I have to say, I really rely on it. One hundred per cent, of course. I'm completely blunt. So, I put the thing in my pocket and [the Loop] does the job. It has to fit.

Andrea very clearly expresses the aspects inherent in the delegation. The Loop system 'takes care of it', i.e. it takes over the essential tasks. At the same time, Andrea expresses the aspect of expectation and the associated trust in the system. At the same time, Andrea beautifully expresses the aspect of the visibility of the disease and the presence of the tasks: she puts 'the thing', i.e. the mobile phone as a control device for the Loop system, in her pocket. She puts it away and reduces its presence. The Loop system works in the background without Andrea having to become active or think about the tasks. In this respect, not only the care work that she previously had to perform and that the Loop system now takes over is reduced. Not only the care work as such, but also the underlying diabetes disease recedes into the background.

Thomas expresses the holistic perception of the DIY Loop in this context as follows:

[00:56:53] Thomas
So it [the Loop] makes actually everything easier and less complicated.

The perceived relief provided by the Loop system has a positive effect on Thomas' everyday life. He finds it easier to deal with the illness itself, as the care work involved is largely taken off his hands. At the same time, this has a positive effect on Thomas' everyday life as a whole: He can now concentrate more on other activities, for which he has more time and attention that he previously had to devote to the care work of his illness.

6.4.3. Re-Gaining flexibility in everyday life

The transfer of a significant part of the care work to the Loop system and the resulting relief for the users of the Loop system also means that they gain flexibility. To illustrate this aspect, I would like to start with a story from Andrea's everyday life:

[00:38:51] Interviewer
And do you have the feeling that the Loop system, since you now have the Loop system, has the same effect in your private life? So, are there situations where you notice a difference?
[00:39:09] Andrea
Nope. The fact that I really paid meticulous attention to it beforehand. It's ... well, no-one actually has anything to do with my sugar. It's really like this. I, I cook for everyone. I cook everything. We eat everything. There are simply no restrictions. So, it doesn't restrict me and it doesn't restrict my family at all.
[00:39:41] Interviewer

> But these restrictions didn't exist before? So, when you were still using pens or injections, when you were ...
> [00:39:51] Andrea
> Ah yes, yes. So, there was the problem when it was said, well, prime example, I think I'd just had it for three weeks. So, I had a drink after dinner, ate dinner and yes, great weather, went for a quick bike ride. It really backfired. Am I a diabetic? No, I'm not. I just set off, I've injected, it'll all work out, naive as you are. Yes, sometime in Timbuktu on a dirt track. Disaster alert. Hypoglycaemic, no sugar, no sweet drinks. So completely screwed, really screwed. Somehow sugar from ... I don't know what ... poo! Calling my husband: "You have to drive through the field now. Bring whatever you have. Coke, juice, I'll take it all". Then they came after me. So, with the pen, it was really difficult to say: 'So, I want to go cycling afterwards or this spontaneous thing: Hey, I've injected and I'm going to do sports now. Or even just swim in the pool. It's difficult. You have to plan something like that with Pen. So, if I inject now and say: All right, I'm going to do sport after all, I have to add twice as many carbohydrates on top. And in the Loop, it's like this: I press, I have 2 settings. One, for me it's not sport, for me it's work or sofa. These options are available, so for work it's 20 per cent and for sofa it's 120 per cent. Then I simply press work after eating, even if I've injected. And then it's reduced and then it doesn't happen that you somehow get into your spontaneous sport - or whatever - nothing happens. It's safe.

When asked how she perceives the impact of the Loop system in her private life, Andrea says that she did not perceive her illness as an obstacle in her family context even before using the Loop system. In particular, she emphasises at this point and at another point in the interview that she can eat the same things as her family members, who all do not have diabetes. Her illness is not reflected in the fact that, for example, she must eat something different from the rest of the family at family meals. When asked again about the use of the pen before the Loop system, she then tells of the case where she had dinner and then spontaneously went on a bike ride afterwards. However, since she had already injected a bolus dose of insulin before dinner and had not yet taken the sporting activity of cycling into account, the amount of insulin in combination with the spontaneous sporting activity was too high and Andrea suffered from hypoglycaemia. ‘You have to plan with a pen’: not only the current moment, but also the upcoming daily routine must be taken into account when calculating the amount of insulin – and that the effect of the injected insulin lasts for a certain time and has a delayed effect. This robs people with diabetes of a certain degree of flexibility in their everyday lives, as they cannot spontaneously engage in any other activities, but must first check whether this is compatible with the insulin dosage already taken.

With the Loop system the situation is different: Andrea can decide which activity she wants to do after eating, for example whether she wants to relax on the couch or whether she wants to do some sports – and she can do this by simply clicking on a button in the Loop app for the modes

she has previously defined. In this respect, Andrea also sees the Loop system as a relief, as it gives her back the flexibility, she did not have with the previous pen therapy.

From a technical point of view, the Loop system creates flexibility through the constant process of measuring and injecting. This is because the Loop system continuously measures the current blood sugar level, can thus read trends in this regard and react by administering the appropriate dose of insulin. In contrast to other diabetes technologies such as a pen or a normal insulin pump, the Loop system does not depend on user input from the patient for each injection. The Loop System can therefore deliver smaller doses more frequently, instead of larger doses over longer periods of time – and thus react faster and more flexibly to circumstances. By dividing the insulin into smaller doses, the amount of insulin currently acting in the body is also always lower. In the case of spontaneous exercise after dinner, a smaller amount of insulin is therefore released than with pen therapy, which enables the spontaneity Andrea mentioned.

In addition to Andrea, all the interview participants reported that the Loop System provided them with more flexible in terms of their activities. As Andrea also mentioned in her story, the function of the Loop system, which allows the basal rate to be dynamically adjusted to the current activity (40:14 Thomas, Markus 16:51, Petra 43:43), played a role here. Petra also mentioned the modular design of the Loop system as a specific advantage: for example, she can leave the mobile phone next to the track during a long-distance run in a stadium. Thanks to the wireless Bluetooth connection, the mobile phone remains connected to the CGM and pump components on the body as a Loop control unit so that the Loop system remains operational even during physical distance of the components. In this context, Petra's Loop system continues to work even if she is not carrying the mobile phone directly on her body.

In addition to the benefits of explicit exercise, the interviewees also reported a general sense of relief. Petra, through a very active lifestyle, Andrea through her work as a waitress and Thomas as a kindergarten teacher – they all have a very irregular daily routine and a lot of exercise. Andrea and Thomas reported frequent hypoglycaemia during working, when they were not yet using a Loop system. According to the two of them, this no longer happens.

The interviewees also reported a new flexibility regarding nutrition: they can eat food that previously caused problems for their insulin levels from now on without any problems:

> [00:14:31] Andrea
> Pizza ... has always been a problem. Eating pizza in the evening, going to bed: you can set whatever you want, you'll never get anywhere. With the Loop, it just works against it. I tell the Loop that I've eaten a pizza, that amount of carbohydrates. And then in the

following five hours it really controls it, it stays at - a miracle - 140, 160 and you have your peace.

All these aspects: According to my interviewees, daily routines as well as sport and nutrition as specific areas have regained flexibility thanks to the Loop system. Despite their diabetes, they can carry out their daily routines and activities with less planning than was necessary before using the Loop system. This relief in everyday life is a key motivator for using and retaining the Loop system as a diabetes technology.

6.5. The DIY Loop as an answer to the complex challenges of diabetes

In the previous sections, I explored the question of what motivates my interview partners using a self-built Loop system. First, I compared the DIY Loop to conventional alternatives regarding their functions and showed what advantages my interview participants see in a DIY Loop system. At the same time, these aspects can also be seen as weaknesses of the commercial systems. True to the motto "One Size Does Not Fit All", a DIY Loop enables a variety of combinations of different pumps and CGMs, even those models that are not intended for a closed Loop by the manufacturers. A DIY Loop also offers significantly more freedom in terms of settings and automation. While there were no conventional medical devices as an alternative to DIY Loops just a few years ago, my interviewees now see DIY Loops as functionally superior technology for diabetes treatment (see Table 4). None of my four interviewees categorically ruled out the use of a conventional device either, but they make the functional improvement of these a basic requirement for potential future use.

Positive perceived impact of DIY Loop on living with T1D: improved quality of life	Better sleep	Less workload of diabetes management	More flexibility in daily life	Less fear of hypo- & hyperglycemia
Technology-based benefits of DIY Loop in terms of SCOT	Individualization on software level like insulin dosing settings	Customizability on hardware level, like preferred components for better comfort	Superiority over commercial alternatives & reliability	Only way of access to automated insulin delivery
T1D-related motivations independent from technology	Good living with disease	Constant tinkering and striving for good values		Fears of complications or secondary diseases

Table 4: Multi-level and multi-factorial aspects leading to usage of a DIY Loop

Although this aspect did not play a major role for most of my interview participants, Andrea's account clearly highlights that health insurance providers and device manufacturers must be seen as obligatory passage points in accessing conventional alternatives. On the one hand, Andrea's health insurance provider refused to cover the costs of a new commercial device that supports automated insulin delivery, thereby denying her access to it. On the other hand, the conventional system Andrea was already using was approved for automated insulin delivery in the United States, but not in Germany. As a result, Andrea was unable to access the conventional application of this system and expanded the commercial device by integrating it into a DIY Loop to implement the functionalities that had been denied to her.

However, these functional, technical requirements and perceived advantages of the DIY Loop should not be viewed isolated, but as part of the socio-material constellation (Wiedemann, 2019) in which the care work of T1D patients takes place. On the one hand – independent from the specific diabetes treatment technology – there are the intrinsic motivations of patients with T1D. The associated activities and routines aim to make life with a chronic illness as manageable and pleasant as possible, or to minimize the impairments resulting from the condition and the risk of secondary diseases. This is characterized by a constant striving to improve care activities – a process referred to as *tinkering* (Jansky, 2024; Kaziunas et al., 2018). This is also reflected in a quantified form, namely in the striving for optimal blood glucose levels –whether in terms of acute readings at specific times or broader metrics such as Time in Range. As Wiedemann (2019) has shown, individuals with T1D operate within quantified corridors that simultaneously constitute a normative framework for their own treatment, as well as a basis for self-assessment and external evaluation, for example by healthcare professionals. A key objective is therefore to maintain as few deviations as possible outside these corridors. This ongoing self-care – embedded in continuous tinkering and reflected in the striving for good values – can be understood as a fundamental motivation for individuals with T1D to adapt their treatment approaches and the technologies involved, ultimately leading some to consider the usage of a DIY Loop system.

At the third level, I situate the perceived positive effects resulting from the use of a DIY Loop. How does the use of a DIY Loop ultimately impact daily life with T1D? This includes concrete, self-reported benefits such as a reduction in the workload associated with care work, increased flexibility in everyday life, and improved sleep quality. Limitations previously caused by the illness can—at least partially—be alleviated through the switch to a DIY Loop, and often more effectively so than with other diabetes technologies or conventional alternatives for automated insulin delivery. These improvements are also accompanied by a reduced fear of hypoglycemia.

Motivations for the usage of a DIY Loop are less singular factors and more about the sum of various, yet interdependent, elements. Likewise, it can be stated that the technology-based benefits of the DIY Loop form a bridge between T1D-related motivations that are independent of technology and the positively perceived impact of the DIY Loop on living with T1D. It is the DIY Loop, as a specific technological solution, that enables this pathway and thus facilitates the positively perceived influence attributed to its use.

7. The other side of the coin: Challenges of using a DIY Loop

In the previous section, I looked at the reasons for using a DIY Loop, i.e. the factors that lead to the "choice" of the DIY Loop or encourage users to do so. But the “choice” is not completed with the construction of the Loop; rather, the use of the DIY Loop is also characterised by a constant review of the suitability of the DIY Loop and thus also the validation of the initial step of switching to the DIY Loop. In the previous chapter, my focus was primarily on the positive aspects of the DIY Loop described by the interview participants, which get verified in their day-to-day use and which kind of legitimise and prove the initial step to the DIY Loop – the latter particularly in relation to the lack of approval as a medical device. However, as I have already mentioned, a DIY Loop does not make the tasks and challenges associated with diabetes disappear, it is by no means a miracle cure, it does not replace a human pancreas even if the term “Artificial Pancreas System” may suggest. Rather, there is an ongoing negotiation, a balancing of positive and negative aspects of the specific technology and its impact on the care work and control of one's condition. In this chapter, I will discuss the specific challenges associated with the use of a DIY Loop. What demands are placed on the user by its’ use and how does the DIY Loop influence the care work? Before I go into the findings from my interviews on this question, I would first like to provide an insight into relevant conceptual principles from Science Technology Studies.

Patients with T1D face the challenge of compensating for the lack of function of their pancreas to produce insulin. A biological process that takes place completely unconsciously in healthy people requires continuous action on the part of the person with diabetes. Wiedemann (2019) refers to this as "doing pancreas": imitating the functions of a pancreas is reflected in the patient's actions. Ultimately, all their care activities and the surrounding socio-material constellation are designed to imitate a healthy pancreas as effectively as possible. The disease as such is not immediately perceptible, but the linked care activities are. In this way, diabetes is enacted, a performative mobilisation takes place through situational practices (Wiedemann, 2019). This socio-material framework surrounding the practices includes people, devices, physical experiences and biomedical knowledge systems (Eitenberger & Wiedemann, 2022, p. 236). In this respect, a DIY Loop system is also part of this framework. However, it does not simply represent a neutral technological instance in relation to the enactment of diabetes or in the terms of my theoretical approach of the logic of choice: "Instead of being modest means, they are inventive mediators" (Mol, 2008, p. 50). A DIY Loop cannot be reduced to an instrument that automatically delivers insulin to the patient. Rather, it can be seen as an active entity that has an impact on the care network and care activities - possibly to an unforeseen extent.

In the previous chapter, I discussed the positive effects on the disease as perceived by the interviewees. But of course, there can also be negatively perceived effects of the DIY use. Diabetes technologies are not only a matter of the inscribed technological-biomedical function like producing numbers in case of a CGM or the shadowing, externalisation of these processes from the patient. There are also accompanying aspects that perhaps need to be weighed against this. In relation to a DIY Loop, this means: What function does a DIY Loop primarily offer to the patient and what added value do they derive from it as a user, but also, for example: What tasks or challenges are associated with its use? Kjærulff offers another way of expressing this (2022): New technologies for diabetes treatment can mean new freedoms for the patient, but at the same time also come with new responsibilities. This raises the question: If a DIY Loop gives better sleep back to me, what tasks do I have to face regarding the DIY Loop or what tasks do I have to accept? In the following sections, I will explain key aspects of the DIY Loop that my interviewees mentioned as associated challenges. To explain these, I will first show the chronological path with regard to the tasks that Loopers have to face. In the second part, I will then go into what these tasks demand of Loopers in terms of skills, knowledge and resources.

7.1. Path of tasks when using a DIY Loop

7.1.1. Building the DIY Loop

As already explained, the essential Looping app for controlling the DIY Loop is not available via a regular app marketplace such as the Apple App Store or the Google Playstore. It must be built by the user themselves and transferred to the smartphone. This is because of legal reasons: If an organisation or a private individual offered such a ready-made Loop app for download, this would legally constitute the distribution of a medical device and would therefore also result in liability on the part of the distributor (D+B Rechtsanwälte Berlin, 2018). To avoid these liability risks, no executable apps are made available within the Looper community, only the resources required for this, i.e. the source code of the application. This source code must be converted into an app by the individual users themselves so that it can run on the smartphone.

Petra talks about the initial use of her Loop system and expresses her enthusiasm for the system right at the beginning – but the next moment remembers the challenge of building it:

> [00:07:46] Petra
> The Freestyle Libre 1 and then this other component as a transmitter [...] and then the Combo, and my Xiaomi is the mobile phone I have, I have the Mi 9 there. And that went really well. Right at the beginning, I was immediately fascinated, really being able to sleep peacefully at night. Brilliant! (...) But it wasn't quite that easy. I really got to grips with it and these descriptions on the Internet are really great, that you can't download

> the system, this APK in general – this file first of all, you can't download it anywhere, you have to code it yourself so to say. And that's where I had real issues (laughs), even though I'm not actually a complete idiot. But purely with programming or something. Woah! That's also very difficult and it always looked different to the screenshots they showed there. And woah, I was really desperate, but I really wanted to do it. I had nights, I had days, I took extra holiday for it and so on. And I also went to sporting events and then tried to do it all in the evenings while the others went to the sauna and so on - and I really invested into it (laughs).
>
> I was always so close and thought: Maybe now it will work out. So, it was a matter of two weeks, yes. But it was dramatic for the fact that it was so important to me, it took a relatively long time. And normally it always has to go smoothly, I have the impression. But a person from the Stuttgart community agreed to do it. He somehow went on holiday anyway and drove through the place where I live - pure coincidence - and said he could come over and help me. And that was really, it was worth a mint.

I have chosen this quite longer quote by Petra at this point as it highlights several aspects of building a DIY Loop, which I will discuss in more detail below. In the beginning, Petra also beautifully expresses the ambivalence that can result from using a DIY Loop. Firstly, she talks directly about the positive side of the Loop system, namely that she can sleep better again, but then admits that building the system was associated with difficulties to her. In the previous chapter, I discussed the reasons for using a DIY Loop, which also included the positive effects of the system on everyday life with the disease as perceived by the users. In this chapter, I will discuss the specific challenges that arise when using a DIY Loop. In this respect, this chapter helps to illustrate this form of ambivalence, the negatively perceived aspects as an accompanying part of the positive aspects of the Loop system. Or to put it another way: a DIY Loop system is also a medal with two sides. The first side expresses the positive aspects, particularly the relief in dealing with T1D. The other side, however, consists of the – perhaps rather negatively perceived – challenges and tasks that inevitably go hand in hand with the use of the DIY Loop and make the positively perceived aspects possible in the first place.

As Petra reports, this process was both nerve-wracking and time-consuming to her. She spent two weeks building the app. She even used up her holiday and passed on leisure activities to make progress on building the app. Markus also reports such a challenging and time-consuming process not only for building the Loop but also for familiarising himself with the documentation and instructions of the DIY community beforehand. For him that was possible because he had more free time due to the coronavirus pandemic.

Only Thomas perceives the process of building in retrospect as not particularly challenging, but as easily doable, also thanks to good documentation from the community. However, he calls himself being technophile and having already familiarised himself intensively with the available documentation before building the Loop system.

Andrea's building process of her Loop was very challenging. In contrast to the other three, her Loop system is based on an iPhone and not an Android smartphone. While Android smartphones generally allow you to download and use a self-built app on your mobile phone without special restrictions, Apple requires a so-called developer account. This is subject to a fee and currently costs 99 dollars per year[10] . Although there is also a free developer account, self-built apps can then only be used on the iPhone for a maximum of one week when using this. And this is exactly what Andrea is struggling with: She initially created a paid developer account, but this was blocked by Apple without explanation and Apple's support was not able to help her. That's why Andrea helped herself by using the free account instead – with the consequences of the aforementioned time restriction of using the app:

> [00:06:43] Andrea
> And [I] now have a free developer account. So, every seven (...) yes, every seven days, I have to reinstall the whole thing and then I'm safe again.
> [00:06:57] Interviewer
> So, what exactly do you have to do every seven days?
> [00:07:00] Andrea
> I have to reinstall the app on my mobile phone. Because I have a free developer account. That means this app only runs for seven days and after seven days it says: App expired. And then I install it again on my mobile phone. Meanwhile, I no longer need two hours, just five minutes and I'm done.

Andrea was not able to build her Loop system just once in the past and then rely on it. Instead, Andrea must rebuild the Loop app and transfer it to her smartphone once a week. If she didn't do this, her Loop system would no longer be able to operate. Although the process of rebuilding meanwhile only takes her a few minutes to her, this task has become a weekly chore to her.

[10] https://developer.apple.com/de/support/compare-memberships/. Last Accessed 20 August 2024

7.1.2. Unlock functions of the Loop system

> [00:20:54] Thomas
> And once you have built this app, it does not let you go to the whole range of options. Instead, you really go through different goals and, depending on what I call the "unlocked goal", you only reach one of the next levels. So, you don't get the full range of the app after building the app, but you feel your way through it, you get to know yourself better, you get to know the diabetes settings. And of course, there really can be periods of time in this app, sometimes lasting 20 to 30 days, where you only ever get hints before the programme acts independently, for example, and are then really asked: "Should I adjust this - I'll say - temporary basal rate or not?". And that's where you learn something for a long time.

I use Thomas' explanation as an introduction to this section, because he summarises in an excellent way that once the Loop system has been built, the next task awaits the user. The Loop app cannot simply be configured so that the patient can sit back and let the Loop system do the work of insulin dosage. Instead, users must first activate functions within the app and thus increase the degree of automation of the Loop system incrementally. To do this, they are asked so-called objectives, i.e. questions in the form of a quiz with a set of answers (see Image 9 and Image 10), whereby the number of correct answers varies. These objectives include comprehension questions regarding the operating principle of the Loop system and how certain activities can affect the patient or their body values. Markus explained that if you answer the question incorrectly, you cannot immediately try the next answer option but may have to wait several hours. In addition, the answer options are varied for the same question, which, according to Markus, really requires you to familiarise yourself intensively with the topic in question in order to answer the questions correctly.

Within the Looper community, correct answers are not revealed to other members of the community. Instead, only the relevant resources in the community documentation are referred to. This is also intended to ensure within the community that users of the Looping app deal with the relevant topics and are therefore also familiar with the Loop app instead of using predetermined solutions to unlock the app's functions.

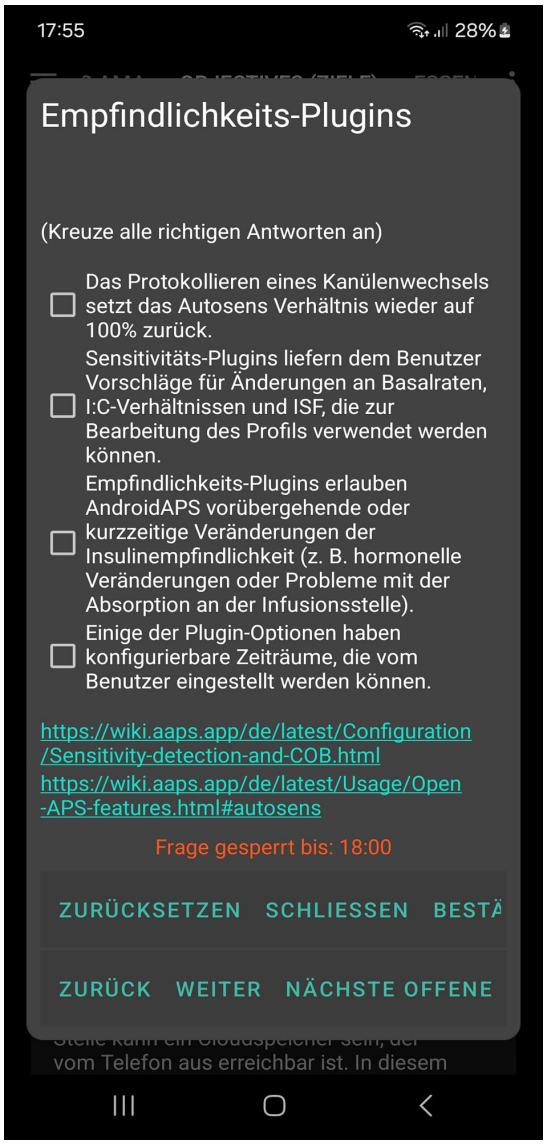


Image 9: One of the Objective in the Android Loop app (Source: Interview participant)

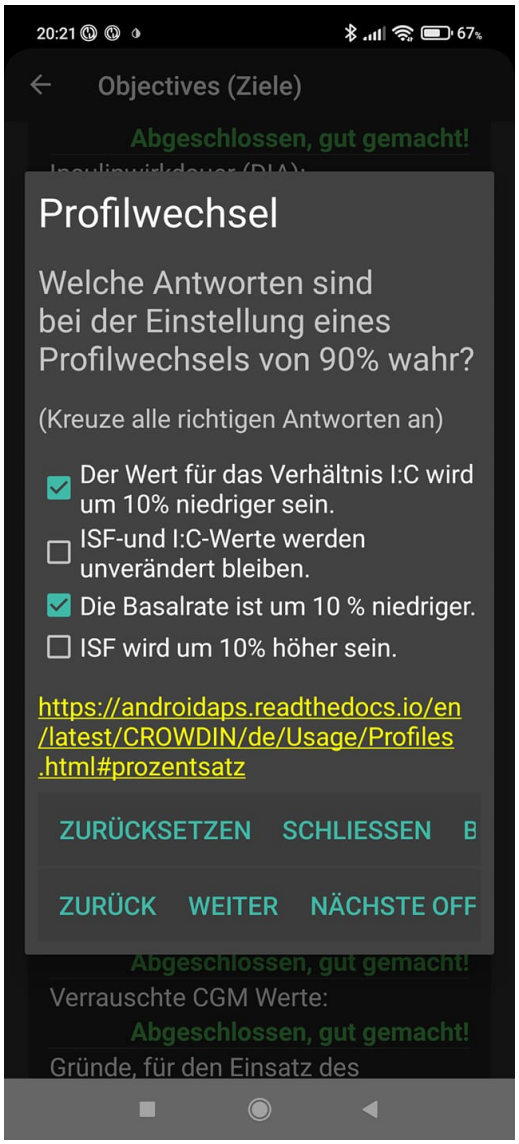


Image 10: Another Objective in the Android Loop app (Source: Interview participant)

Furthermore, according to Markus, confirmation of the individual activities of the Loop system is still required by the user in the early days. For example, the Loop system only suggests dosing a certain amount of insulin but the actual step of dosing as to be initiated by the user themselves. The system therefore does not yet work as a so-called closed Loop, which automatically administers insulin doses based on body measurements without patient's interaction. It only works as an open Loop so far, which means that all its' activities still must be confirmed by the user. The user is also given tasks to perform within the app. According to Markus, this can be, for example, the task to change a certain value within the app several times within a specified period of time. If the user does not carry out these tasks, they cannot unlock any further functions.

Markus and Thomas emphasise this aspect: the fact that they must deal with the functionality of the app in detail to a certain extent means that they familiarise themselves with the application, know their way around the app and can better assess how the Loop works. According to Petra, Thomas and Markus, this guided introduction to the app and the gradual activation of the self-operating Loop system meant that they were also able to quickly gain trust in the system, precisely because, for example, they initially had to approve the individual steps and decisions of the system but recognized that the Loop system had made reasonable suggestions in the process. In other words: They were slowly gaining the freedom within the Loop system in the first place, or conversely: the Loop system gained the freedom to act independently over time. According to Markus, it takes about two months to reach the closed Loop. Thomas attributes a further function to this phase, namely not only getting used to the Loop system, but also deciding for yourself whether the Loop system is something for you at all, i.e. whether you can cope with handing over the care activities, but also the control over them and your body, and whether you feel comfortable with this. It is therefore interesting that Petra, Markus and Thomas not only see this task as an obstacle but also see a positive purpose behind it.

Andrea has been completely left out in my explanations of how to unlock the functions of the Loop system. Using the Loop app on her iPhone instead of AAPS like the others, Andrea was able to use all of the app's functions right from the beginning:

> [00:51:38] Andrea
> No, no, with iOS you can really use every option right from the start. There was nothing that was somehow greyed out or that came later. It was open to everything right from the start. I played around with it at first. Because you first have to learn the functions to know where to play around inside. (...) Well, it's not easy, you can't just ... So, I was very careful there. In the meantime, I play around everywhere inside, but now I know what I'm doing.

In contrast to the AAPS app, Andrea's app does not have a mandatory introduction process with questions and tasks to be completed. Instead, Andrea reported that she had tried out the functions in the app on her own initiative to familiarise herself with its functionality. What is interesting in her explanation is the concept of "playing" within the app, which suggests a certain ease and fun when using the functions – while she is controlling an app that has an impact on her health and wellbeing. However, she immediately expresses this kind of awareness for keeping caution during these attempts. You could say that Andrea takes a rather free, playful approach to get to know the app, which is perhaps the intention of the app's programmers. At least her app does not offer a guided introduction as the AAPS app does. Petra, Thomas and Markus have to go through and successfully complete the guided learning process to use all the functions of the

Loop, whereby failure at the individual levels, such as answering questions incorrectly, is associated with penalties, i.e. an incorrect answer leads to a time ban, which means that achieving additional freedom within the app is even further away in terms of time. However, even if Andrea was not obliged by the design of the app to follow a programme to introduce the functions, she still imposed a kind of introduction to the app on herself.

7.1.3. Updating the Loop

Once the Loop app has been built and the users have achieved the freedom to use the system as a closed Loop, this does not mean that the users can finally leave the development environment for building the app behind them – or that the freedoms achieved within the app are permanently available to them. This is where updates to the Loop app come into play. Updates are a normal and familiar part of the life cycle of regular apps and usually take place on the smartphone without the user having to do much. Normally, it only takes one click to trigger an update on your smartphone, or the update even takes place completely in the background without any interaction with the user. But just as there are no ready-made apps to download for DIY Loop systems, no automatic updates are provided here either. Instead, users of the Loop app have to generate the corresponding updates themselves.

As with the initial construction of the app, the source files are also provided by the community, but the executable updated app must be created from them by the users themselves. In order to benefit from new functions or security updates, users of the Loop app must therefore create a new app using the development environment and then transfer it to their smartphone again. Both iOS Loop and AAPS have voluntary updates, only has also mandatory updates. For these mandatory updates, users are given a time limit of 60 days to update the app. After this time has elapsed, the functions gained at the start of use are lost again – the user would incrementally lose again the functions and thereby levels of freedom that they worked on before. Accordingly, Petra, Markus and Thomas must make these mandatory updates in order to continue using their autonomously operating Loop system.

Thomas does not see this task as a major challenge, but at the same time seems to recognise the challenge for other users. He says that these mandatory updates are not a way for developers to "nag" users, but are simply necessary due to the improvements, which are partly security related. Markus reports that he himself has no problems with building an app update and can usually do this within a few minutes but reports of another user who passed the time limit for updating and thus faced major challenges when the automations were not working anymore.

[00:29:09] Petra
Yes, and the [updating] really drives you to despair, I've thought about it a few times, whether I should switch to an official system, because it just takes so much of my time and energy.

Petra sometimes perceives the process of updating the Loop app as quite difficult. These mandatory updates are always a major challenge for her and are particularly time-consuming. For some of the past updates, Petra had to rely on the help of other people she knew from the DIY Loop community, who helped her updating the system. In Petra's opinion, these mandatory updates are actually the "worst thing about AAPS" and had already made her think several times about switching from the DIY system to a commercial system to escape from this effort. A statement that she clearly putted into context during the interview: These thoughts of switching were snapshots during this challenging process, but overall, she was very satisfied with the DIY system due to its advantages and was not considering switching to a commercial system. Nevertheless, in my view, this aspect of the Loop system also shows very dedicated that the associated tasks and challenges also represent a flip side to the perceived benefits and create a certain form of ambivalence to the users.

Although Andrea, as a user of the iPhone app, does not have any mandatory updates and there is no risk of losing functions, she also updates the app, but says that she regularly delays these updates out of fear that such an update will "destroy" her Loop, so that it will no longer work. However, when she does update the app, she integrates this process into her weekly routine of rebuilding the app on Saturday mornings and includes the update at this point.

It is precisely this task of updating that shows the very specific character of using a DIY device instead of a conventional system for insulin dosing. Using a DIY Loops are linked to continuous tasks, which have to be fulfilled for permanent use. The updates of the Looping app are one of these regularly recurring tasks that users must fulfil – especially due to the mandatory updates in the Android version - but also if they want to follow the recommendations of the community and use the latest versions for new functions and, in some cases, better safety mechanisms, as Andrea does.

7.2. Requirements for users of a DIY Loop

7.2.1. Sets of literacies

In the previous sections, I elaborated the main specific tasks that users of a self-built Loop have to complete. But what else does the DIY Loop demand of the user and what knowledge to master these tasks? Braune et al. (2022) have already stated that there is distinction between skillsets in

terms of utilisation and construction. I can certainly agree with this argument, but I would say that these two areas are difficult to separate. I will explain my point of view in more detail below.

Let's start with the use of the DIY Loop as a ready-made device: The user can use it for the intended purpose. The Loop automatically doses the insulin based on the closely timed blood glucose measurements and the user can interact with the system via the Loop app if required and, for example, view the current blood glucose level or the value of the time in range. They also can initiate an additional bolus rate by entering a meal in the app. These interactions of the user are based on basic knowledge and experience in dealing with diabetes as such. Regardless of the DIY Loop as a specific technology, the users already have what I would call *treatment literacy* through their experience with previously used technologies, through past experiences with the disease, through their body perceptions and also through the exchange with their doctor. Patients know "their" diabetes. Their actions are a response to the symptoms and impairments of their chronic disease. This is also reflected in all four of my interviews. In their stories, the four report on specific situations they have already experienced, as well as routines they have developed from them, for example to better prevent hypoglycaemia in the future. There is a fundamental need to understand how to deal with the disease in order to understand the corresponding values and functions in the DIY app itself.

However, the DIY system now adds a technology-specific dimension: Staying to the DIY Loop as a ready-made device, users must first learn how to use the DIY system. They develop a DIY-specific *device literacy*. Even if they have years of experience in dealing with their diabetes, they still have to build up knowledge about how to use the Loop system. This begins with the operation and settings within the Loop app but also extends to learning about the interplay between their own body and the Loop app as part of a closed Loop. As I pointed out earlier, the Android version of the Loop app has a mandatory introductory process for users to get to know the functions and to learn how to use the Loop app. The functions of the Loop system for automated insulin dosing are only gradually activated once this process has been successfully completed. However, this completion requires intensive knowledge acquisition, as Markus explained.

> [00:52:55] Thomas
> So, I could also eat something smaller in between without having to release insulin directly, but this Loop system intercepts this itself because it realises that the sugar levels are rising and it releases insulin on its own. And this has actually already led to negative aspects. After all, if you have a hypoglycaemic episode and take fast-acting glucose, you should of course tell the Loop: "I'm going to take something fast to counteract this impending hypoglycaemia." Because otherwise it will of course react to these rising glucose levels by releasing insulin and this will then lead to a kind of

> rollercoaster ride, where it really only goes up and down. But that's another thing you have to deal with. And I've included some things where I tell the system that if I have another rise in blood sugar at a certain sugar level, then please do nothing up to a blood sugar level of - let's say - 140 milligrams per decilitre. And only act if it's above this level in order to avoid this rollercoaster ride and this constant up and down. But I think that is, or was, another learning effect. Because to be able to act accordingly, it first has to be fed with this information.

Nonetheless, Thomas explained that minor complications could occur in the early stages of using the Loop: Thomas reported about a situation that he had taken glucose to stabilise his blood sugar level because he expected a potential hypoglycaemia. However, the immediate strong increase in blood sugar levels by the glucose caused the Loop system to automatically counteract this by releasing additional insulin, which in turn lowered the blood sugar level again. According to Thomas, this led to a 'rollercoaster ride' as his own actions to prevent hypoglycaemia and the activities of the Loop system counteracted each other. However, Thomas now knows that this can be prevented by telling the Loop system that he will be taking glucose in such a case. Since then, such wave effects have been prevented. However, in such cases, the patient must interact with the system accordingly, specifically by providing the system with information.

In this way, Thomas had to learn that he had to actively communicate his own actions, such as the conscious intake of fast-acting glucose to prevent hypoglycaemia, to the Loop system as another acting agent. This means that he had to enter his actions into the Loop app – or as he calls it: "feed" the Loop with information. The users of a Loop have a new actor in the treatment of their diabetes and must first learn how to use it, but also how to consciously interact with it. Through externalisation, the delegation of work and decisions to the Loop system, the users must also learn to communicate their own actions to the other actor. They now are in a constant dialogue with the Loop system regarding their diabetes care work and established a new actor in the socio-material network of care.

Apart from the use of the DIY Loop there is the essential part of initially building it. So, let's see the DIY Loop not in the state of an ready-made device anymore, but as device that first has to be assembled by the user themselves. In doing so, we obviously can identify a specific set of knowledge as basis for building the device as Braune et al. (2022) see it. The steps for building the require specific knowledge, which is provided to users by the community's online documentation. But as explained above, updating is a form of rebuilding the Loop app, which requires much of the same knowledge as building. But in my view, it is precisely at this point that the difficulty of

separating utilization and construction and the associated types of knowledges, as Braune et al. do, becomes apparent.

Of course, using and applying a DIY Loop requires other forms of knowledge than building and updating a Loop, but these phases are inevitably linked. If you want to use a Loop, you first have to build it yourself - as the name 'DIY Loop' suggests. The long-term, permanent use of the DIY Loop is also linked to updating, especially with the AAPS version. The use, building and updating of the Loop are therefore closely interwoven and are difficult to separate. Of course, there can be a clear separation between building and using, for example by separating personnel, so that one person builds it and onther one uses it. This could be the case, for example, when parents build a Loop system for their child with T1D as a caregiver. In my research work, however, I am focusing specifically on self-users. That's why I can certainly understand this separation of knowledge areas in terms of subject matter, but I see them as complementary components of an overall body of knowledge for users of a DIY Loop.

7.2.2. Time as an investment

The previously mentioned tasks, building and updating the Loop, activating the app's full range of functions, but also all of the forms of familiarisation and learnings that underlie these activities demand one thing in particular from the users: time. Of course, it can be said that a commercial system certainly also requires time to set up and maintain and requires users to familiarise themselves with its use to a certain extent, but the time required for a DIY system is definitely more – my interviewees are also aware of this. Markus, for example, reported that he spent about an hour every evening for two to three months familiarising himself with the system and reading the documentation on building the Loop. Andrea also said that she had to read a lot about the Loop system. To her explanation, Petra spent two weeks working intensively on building the Loop system and reported on this:

> [00:07:48] Petra
> And woah, I was really desperate. But I really wanted it, I had nights, I had days, I took extra holiday for it and so on. And then I also went to sporting events and then tried to do it all in the evenings while the others went to the sauna and so on - and I really invested into it (laughs).

She also talked about an update that had caused her particular difficulties because her pump system could no longer be coupled correctly:

> [00:24:41] Petra:
> The [other member of the Loop community] then spent hours doing this update together with me. So, I took holiday and he took the time to do it. That was really, really nice. We

had already said before that we want to go on a bike tour together or something like that. But instead of a bike tour we just did an update together (laughs).

For the building and for this update, which turned out to be particularly difficult, Petra had taken days off from her work to be able to work on the Loop system. In the case of the update, the helping friend from the Loop community also took the time to support her. What becomes particularly clear in both situations and what Petra herself describes as a form of investment: Working on the Loop system goes hand in hand with giving up other things, because in both cases Petra is giving up other activities. Instead of going to the sauna with others after sporting events, she worked on the Loop system. Instead of going on a planned bike tour with her friend from the Loop community, she and him worked together on the update for her Loop system. This means that working on the Loop system is mainly at the expense of her leisure activities and the socialising with other people.

The time spent on the activities and forms of knowledge acquisition associated with the Loop system can also be seen as a resource that is "invested" in the Loop system - and is therefore no longer available for other activities. Petra also reports that she took holiday leave from work to build and update the Loop. This reveals another way of looking at the time spent on the Loop system: if you consider this amount of time in a different, monetary category, the investment in the Loop system becomes attached to a financial category. Petra had used part of her holiday that she is entitled to as part of her paid work. The holiday to which she is entitled can be seen as paid time by her employer, which she receives for her labour in the remaining working hours. The days of leave used for the Loop system could therefore even be quantified in monetary terms, namely the salary corresponding to this time. During the interview Petra mentioned that she has a good income and that she is fine with this "investment" of her holiday. However, it is also clear that the time required for the Loop system should also be considered in financial terms. People who cannot afford such an investment of time in a DIY Loop system because they may not have a well-paid job and have to work as much of their time as possible in order to have enough money must also be kept in mind. Or they have other time commitments that they cannot simply give up.

Especially against this backdrop I believe that it is appropriate to see the time spent on the Loop system as a kind of resource that needs to be "invested". This aspect not only makes it clear what efforts users have to put into a DIY Loop, but also which persons might be excluded form a DIY Loop system because of the lack of these resources.

7.3. Constant Tinkering

In the previous parts I already mentioned tinkering as a strongly embedded part in care work. But what exactly does *tinkering* in this context mean? Jansky understands it as the activity of

"constantly adjusting, testing, and experimenting with bodies, selves, technological devices, or medication" (2024, p. 57). She also says that it "is not a linear translation process but a constant readjusting, refitting, and readapting of care practices" (2024, p. 57). Tinkering can therefore be seen as a measure to constantly optimise care activities in order to achieve the most effective care possible. In this respect, care activities in the sense of the logic of care (Mol, 2008) are not only designed to provide the best possible treatment for the patient at any given moment, but also to constantly reflect it regarding possible improvements.

Jansky (2024) identifies two variants of tinkering in the DIY Loop community. On the one hand there is the individual level, i.e. the diabetes patient using a DIY Loop to improve their quality of life, and on the other hand, a community level, also known as "collaborative tinkering". The latter describes the functions and processes of the Loop community, especially its knowledge practices and its criticism of the established healthcare system, i.e. in particular the manufacturers and medical products as well as health insurance companies and regulators, that is performed in this way. This "collaborative tinkering" facilitates individual tinkering in the first place, because without the provision of resources and knowledge transfer by the community, it would not even be possible for individuals to use a DIY Loop system or would at least mean an enormous personal effort and would therefore be extremely unlikely.

It was precisely this individual tinkering that could also be recognised in my interview participants when dealing with their Loop system. For example, Thomas talked about currently trying out a different, faster-acting insulin. Fast-acting insulins take effect in the human body very quickly, but do not last as long as slow-acting insulins. The option of different insulins therefore gives patients greater flexibility, particularly with regard to physical activity and meal planning (Knox, 2020). However, a Loop system only has one type of insulin, but it has the advantage over manual dosing such as with a pen, that it can split the insulin in several small doses. The use of an even faster-acting insulin provides the opportunity for a more time-sensitive effect on blood sugar levels and thus also for potentially more efficient regulation by the Loop system, as it can control blood sugar better with even more fine-tuned dosages. This also shows Thomas' desire to optimise his treatment - or quantified - get better blood glucose levels (see motivations for usage of DIY Loop).

Of course, tinkering can also be seen as an activity like the specific tasks from the previous chapter, such as building or updating the Loop, but I do not see tinkering as an action that can be completed – nor is it by definition, see above. Rather, it is a constant activity or a mode of acting – like the constant striving for good or better values. The care activities, including building and

updating the Loop, are part of this tinkering, as their intention is to create a form of treatment to improve the patient's quality of life.

Let’s go back to Thomas’ “rollercoaster ride”: He took fast-acting glucose to avoid the threat of hypoglycaemia, but the Loop counteracted this rapidly rising blood sugar level by releasing insulin. I see the negative experience here, the resulting learning process and the adjustment of the information that Thomas now provides to the Loop app to avoid such "rollercoaster rides" as part of the tinkering with the Loop system. Because there is constant adjusting, testing and experimenting with your own body and the Loop system as a specific technology. In Thomas' specific case, this means the harmonisation of his own actions and the activities of the Loop system. He realised that the Loop system could improve in regulating his blood sugar levels and avoid critical situations such as the "rollercoaster ride" when he provided the Loop system with sufficient information about his own actions. ‘Sufficient’ is a key factor here, as Thomas also points out that he does not enter small meals into the Loop system. He has therefore also negotiated how much information he needs to provide to the Loop system so that it can dose insulin in such a way that Thomas' blood glucose levels are within a good range and the risk of complications is minimised.

7.3.1. DIY Loop as blackbox

Andrea reported about her Loop app sometimes losing the connection to her pump during night and was therefore no longer working:

> [00:33:53] Andrea
> But in the meantime, with the Loop, it's like this when I wake up hypoglycaemic: Sometimes it loses the connection, for whatever reason. Maybe I was lying on the pump and suppressed Bluetooth. No, it's possible. Then I have a look. If necessary, I turn on the Loop again. I really rely on it now.

Andrea was able to correct this by pairing the pump with the mobile phone again using Bluetooth. However, there was still a certain lack of clarity, which is reflected in her statement: She assumes that she had been lying on the pump while sleeping and had thus deactivated its Bluetooth connection to the smartphone. However, she only sees this as a very probable cause, she does not seem to be completely sure. Petra's Loop system also stopped working at night for no clear reason. "And I still don't know what caused it. But now, fortunately, it always works perfectly again," she comments (Interview Petra, 00:29:01). Likewise, she does not know what caused the Loop system to stop working, even though this problem no longer seems to be an acute issue.

On the one hand, the elaborative tinkering of the DIY Loop community opens up the black box of traditional medical devices for patients through the knowledge practices it creates (Jansky, 2024; Kaziunas et al., 2018). To build the Loop system, they first have to acquire knowledge, which is made available to them in the DIY community through documentation and exchanges with other members. Building the Loop system and familiarising themselves with the components, their functions and how they interact with each other also represents a more intensive engagement with the device than with the normal use of a conventional device as a patient. In this respect, I definitely see this as a decisive step towards a more transparent device, but a DIY Loop system still can remain black-boxed in parts, as the specific examples of Andrea and Petra show. Even if the DIY Loop system lost opacity compared to a conventional medical device, the complexity of this system should not be underestimated. The very fact that the two modules of the Loop system, pump and CGM, are commercial devices also harbours the aspect of the black box attributed to conventional devices for the overall Loop system. And it is precisely this form of the Loop system's partial black box and the associated ambiguities and uncertainties on the part of the users that also influence their tinkering, as the resulting unpredictable situations force the users to take action, such as restoring the Bluetooth connection when it is interrupted at night. At the same time, the black box of the system also limits this action, because without knowing the exact reason for the failure of the Loop system, there is no way to solve this problem, but only to work around it when it occurs and hope that it may not occur again.

7.3.2. Development of coping strategies

Petra and Andrea's previous examples of their Loop system not working properly at night show that even a DIY Loop system does not always work smoothly. My interviewees mentioned common, recurring problems in dealing with the Loop system. Therefore, they have developed specific coping strategies or routines to deal with these errors or complications when they occur.

For example, Andrea talked about a perhaps somewhat bizarre situation during the interview: Sometimes her family tell her that she smells of insulin. “Its smell can not be compared to anything else; it just smells like insulin.” However, it is this smell that her family members are now familiar with, and which stems from the fact that the syringe of the insulin pump is blocked which means that the insulin runs over the skin instead of into the body tissue. As a result, Andrea's blood sugar levels are also too high because the regulating insulin has not reached her body. This means when someone tells her that she smells of insulin, Andrea knows that she needs to change her patch pump. This very specific example highlights an important aspect, namely that the Loop system is also prone to errors. However, the advantage of the modular system seen by users of the DIY Loop also means that its stability is based on that of the single modules. This means when

the pump or sensor stop working, the entire Loop system is no longer operational. Counting the smartphone, the sensor and the pump, there are at least three devices, and with a transmitter for communication between the pump and the smartphone, there may even be another one that could cause an error.

Petra and Thomas, for example, explained that they always try to keep an extra sensor as a backup with them, as they have experienced that the sensors can be faulty. Markus reports that he even tries to always have an additional pump with him. When he travels for a longer period of time, he even takes a whole set of backup technologies with him: In addition to additional components for his Loop system, he also takes the official operating devices for his Loop components with him, such as the control unit for his pump. This means that if his Loop system stops working, he still can operate the pump by the manufacturer's control unit and dose insulin manually. However, he even creates a further level of security by also taking a blood glucose meter with test strips for blood testing and his insulin pen with him. Even if the pump, replacement pump or meter were to fail, he would still be able to measure his blood glucose level manually and administer the insulin manually using the pen.

The operability of the Loop system also depends on the correct functioning of the smartphone. The most critical factor here is its battery. Regarding this, Petra told:

> [00:36:38] Petra
> Of course, you can always forget your charger. And it's always a bit more difficult to find a charger for an Android mobile phone than for an iPhone. (...) When riding on the horse in the Swabian Alb in winter, it can sometimes be double-digit temperatures below zero, so the batteries are naturally under extreme strain. I always have them in my trouser pocket or in my jacket pocket so that I try to generate a bit of heat so that the battery isn't quite that challenged, but of course that happens and yes, I always have my charging cable with me. So yes, I can also charge my mobile phone in the car.

When riding the horse in winter, Petra deliberately carries her smartphone close to her body to improve the battery capacity, which easily drops at low temperatures, and thus prevent the Loop system from failing due to an empty smartphone battery. However, if this takes place, she can recharge her mobile phone in the car. This problem of an empty mobile phone battery is very present among all four of my interviewees. Andrea even talks about this as "worst case", the failure of the Loop system, which must be prevented. All four said that they therefore always carry a charging cable, a power bank or both with them to be able to recharge their smartphone. Thomas reported that his mobile phone battery often ran out very quickly when he first started using the Loop. He therefore optimised the Loop app settings so that his blood glucose values

were only uploaded to the Nightscout cloud when his smartphone was connected to the charger. In addition, Markus and Andrea reported that they always have a backup smartphone available in case their current smartphone stops working.

However, there are also challenges that have been caused by “wrong” actions of the users: For example, Petra reported that in the early days of using Loop, the Loop app was unable to communicate directly with her Combo pump. Therefore, she needed an additional app on her smartphone, which acted as a kind of mediator between the pump and the Loop app. However, this construct was extremely unstable. According to Petra, if you opened this app on your smartphone, the Loop system immediately stopped working. She was therefore not allowed to open the app under any circumstances. To prevent herself opening this app by mistake, Petra had this app on a separate tab on her screen so that the possibility of accidentally opening the app could be avoided as far as possible. In this case, she took precautions to avoid the known problem as far as possible.

These narratives of my interviewees show that they are aware of a certain fragility of the DIY Loop and its components and may have already experienced this in the past. In this respect, they are aware of the risk that the Loop system could fail and thus also the necessary insulin dosage. They try to be prepared for this or to avoid such cases, for example by ensuring that their smartphone has sufficient battery capacity. This form of preparedness is particularly shown by Markus, who creates several levels of safety measures when he is away from home for long periods of time, so that he carries additional components for the Loop system with him, as well as the official control devices so that he can still deliver insulin manually with the pump if the Loop system fails. And as a further level of safety, he carries alternative diabetes technologies such as the measuring device with test strips and the insulin pen. All four of them developed coping strategies to avert these risks - or the "worst case" in Andrea's words - as efficiently as possible, in which the daily use of the DIY Loop is embedded. It is not only important to carry the Loop system as such, but also to be equipped with additional equipment such as a charging cable and power bank for maintaining this system.

7.4. The smartphone as the core of the Loop system: from a mundane to medical device

The smartphone running the Loop app is essentially the core of the Loop system. If it stops working, automated insulin dosing is no longer possible. However, this also changes the role of the smartphone as such, as all four of my interviewees do not use a dedicated smartphone for the Loop system, but their normal everyday device. In addition to the Loop app, the smartphone is

therefore also used for writing messages, making phone calls, surfing the internet or making phone calls, i.e. completely mundane activities. Or the other way round: the mundane smartphone as an everyday object suddenly becomes a medical device by hosting the Loop app which controls the user's vital medication. It now makes a considerable difference whether the battery is sufficiently charged, as there is now a fear that the necessary insulin dosage will not be administered. Previously, there might have been a fear of not being reachable or losing one's bearings due to the unavailability of a maps app. Using the Loop app on the smartphone therefore gives the smartphone a whole new significance. "It's my life insurance. I really look after my mobile phone because my mobile phone is my life" (00:42:36), as Andrea puts it. Markus also calls the Loop app the most important app on his mobile phone.

All four use their everyday smartphone for the Loop system for one reason: they don't want to have to carry an additional device with them. And why should you have to carry a second smartphone with you all the time if you always have your normal smartphone with you anyway? At the same time, however, this makes another perspective on the smartphone relevant, namely the role of the Android and iOS operating systems. Except for Petra, all interview participants used their existing smartphone for the Loop app. Petra previously used an Apple iPhone, but the Loop app for Android was recommended to her by the community. Petra followed this advice and switched her everyday activities from the iPhone to the Android phone. For Andrea, Markus and Thomas, on the other hand, their previously used smartphones were essential. Thomas, who says he has "never been an Apple person", therefore decided in favour of AAPS without much thought, but also because the Android version offered more setting options. Markus expressed a similar opinion. For Andrea, on the other hand, the question of an Android Loop did not arise at all: she has been an Apple user for years and her entire home automation system bases on Apple, so she could not simply bring in a "stranger" device into this setting. Her movement within the Apple device cosmos also became clear during our conversation: During the interview, she wore Apple headphones and operated her Apple smartwatch in between. And apart from the hardware-related focus on this one company, Andrea had been using her Apple account for 15 years at the time of building the Loop system. Her app purchases, which she had made over the years, were linked to this account. If she had switched to an Android smartphone, all her purchases would have been lost as she would not be able to use them on the Android operating system.

This clearly shows how previous smartphone use also has a direct impact on the Loop system. The binary division of the smartphone world into the two operating systems Android and iOS is a symbol of "platformisation" (van Dijck, 2021) by Google and Apple. As a smartphone user, you move in one of these worlds, which are characterised by different operating concepts or

marketplaces for apps, for example. Both platforms are also isolated from each other or incompatible with each other. Of course, this increases difficulties to switch platforms. Smartphone users are locked into a technology (David, 1985; Hughes, 1993), namely the platform their smartphone belongs to. In this respect, the choice of whether to use iOS Loop or Android APS is also a question of which of the two platforms you have used so far and how much effort you are willing to invest in a potential switch. And by remaining on the respective platform or ecosystem, this "locked in" can even intensify. This is particularly evident with Apple: as users of the DIY Loop have to build their app themselves and this is only possible for iPhone apps with an Apple computer, but not with a Windows or Linux system, Andrea bought an Apple computer - and belongs now to the Apple universe with another device as a result.

In the chapter on building the Loop app, I also reported on the problems Andrea faces here, as Apple had blocked her paid developer account for building apps, which means she can only use the free version. As a result, she can only use the app on her iPhone for a limited period of seven days and has to rebuild the Loop app every week before it expires. The enormous influence of the platforms and the companies behind becomes evident here: they become "obligatory passage points" (Callon, 1984) for the users of a Loop system by deciding whether or not someone gets access to a fully-fledged developer account. As Andrea said, Apple's customer support was not able to explain her why her account was blocked. In this respect, this position of Apple’s power is characterised by a lack of transparency towards the users. Even if this constellation concerns Apple in this case - none of the other three Android-using interviewees reported any problems in this regard - it nevertheless shows the enormous influence that the companies behind smartphone operating system have. The users of a DIY Loop are now also exposed to this influence, in some cases perhaps more so than users of a conventional medical device. If a manufacturer of a medical device offered a smartphone app for operation, the user would also move in one of the two smartphone worlds, but there would not be the problem with the developer account, as the user would not have to build their own app. The actions of DIY Loopers with the aim of reducing dependencies on institutionalised players - primarily the manufacturers of medical devices - also create new dependencies, this time on tech companies.

As I have shown, the role of the smartphone in the Loop system is not only functionally essential as a central control unit. It is also of central ontological importance. Its significance is changing from a mundane into a medical device.

7.5. Challenges of a DIY Loop as form of its performativity

In this chapter, I have provided an overview of the challenges faced by users of a DIY Loop. First, I outlined the specific tasks and actions that have to be carried out. This starts with building the Loop system. In contrast to a conventional medical device, users must build the system themselves, especially the Loop app as the core of the system. The system also requires updates from time to time, which essentially means rebuilding the app. For users of a Loop system based on an Android smartphone, there is the additional challenge of first activating the functions of the Loop system at the start of use. Users are thus only gradually introduced to a self-acting closed Loop system. I call this set *technology-based tasks*:

Challenges by using a DIY Loop	DIY Loop as a blackbox	Need for coping strategies	Smartphone: From a mundane towards a life-saving device
Technology-based tasks	Building DIY Loop	Updating DIY Loop	Gaining freedom and functionalities
Personal Requirements for usage of DIY Loop	Disease-related literacies	Technology-based literacies	Time as a resource

Table 5: Challenges resulting from using a DIY Loop

Apart from these specific activities, DIY Loops also demand fundamental requirements from users. This begins with specific forms of literacies. On the one hand, a basic medical understanding of diabetes is required to be able to understand and categorise the data and setting options within the Loop app. On the other hand, basic technical knowledge or a technical affinity is clearly beneficial for building and updating the app. And finally, the operating of the DIY Loop itself must be learnt. All of this, the activities as well as learning and familiarising oneself with the topic, requires time, which my interviewees lack elsewhere. They sometimes forgo other activities in order to devote themselves to the Loop system.

However, once built, this does not mean that a constant smooth usage is possible. Rather, my interview partners developed a mode of constant tinkering, continuous experimentation and adaptation of the interplay between the Loop and their own bodies as well as specific coping strategies. And even if the DIY Loop is far more open and comprehensible than commercial, proprietary alternatives, it sometimes remains a black box for the users in some facets. Last but not least, the smartphone plays an essential role within the Loop system as the host of the Loop

app. It mutates from a mundane device into a medical device. At the same time, users find themselves embedded in the platform economies dominated by Apple and Google.

In the spirit of Mol (2000, 2008) the performative character of the DIY Loop as a diabetes technology is evident here: it is not just a technology for treating diabetes, but also influences the context of its use, not least the patient's behaviour. This also includes the specific tasks and challenges for the patients as well as new dependencies into which they place themselves through its use.

8. The use of the DIY Loop in the context of institutionalised healthcare

8.1. Supporting or hindering: the specific role of the attending physician

All four of my interviewees have regular appointments with their diabetologists, usually every few months. It is obvious that the DIY Loop, as the diabetes treatment technology used, also has an impact on the interaction between patient and doctor. Andrea talked about this:

> [00:53:57] Interviewer
> And since you now have this Loop system, have you seen your diabetologist again?
> [00:53:58] Andrea
> Yes, she's just happy. She really celebrated it.
> [00:54:07] Interviewer
> So, in terms of the values or how did she express herself?
> [00:54:12] Andrea
> Yes, yes. Well, she also gave me all the tips, right. She gave me the websites where you can do that.
> [Doctor:] You didn't get that from me.
> I said: No.
> But I think I had the Loop running for six weeks when I was last there.
> She was totally fine. She was really like: "Yo, that's cool. And it should actually be possible for everyone to use it without having to tinker with it themselves".
> So, she supports it. Definitely.

Several aspects of this became apparent in Andrea's explanations: her diabetologist knows about the use of a DIY Loop, but she had even pointed out the possibility of a DIY Loop to Andrea and provided her with the relevant online sources where Andrea could find information about it. At the same time, Andrea echoes a very interesting statement from her doctor: "You didn't get that from me". The diabetologist asks Andrea to keep silence on the fact that she drew Andrea's attention to the DIY Loop system. This reveals the previously mentioned uncertainty for treating physicians regarding the counselling of DIY Loopers. This is a legal grey area, as the DIY Loop is not an officially approved medical device. Currently, only some advice from the German Diabetes Association can be seen as a point of reference, which discourages treating physicians from advising patients on DIY use, but rather to dehort them from the use, in order to remain on the legally safe side. Likewise, they should never make recommendations in favour of a DIY Loop (D+B Rechtsanwälte Berlin, 2018). It can be assumed that Andrea's doctor is aware of this legal uncertainty and is perhaps also aware of this recommended course of action. Nevertheless, she had advised Andrea to use a DIY Loop as part of her treatment.

Petra, who also received initial recommendation from her diabetologist, expressed a similar experience. She explained that her diabetologist is not allowed to give her any recommendations

regarding switching to a DIY Loop – followed by an obvious ironic statement that this of course had not happened. Regarding the recommendations for the Loop systems, Petra and Andrea were able to recognise a kind of consensual silence with their diabetologists: Their doctors seem to be aware of the legal uncertainty or problematic nature of the Loop system, yet they felt it was worth informing Andrea and Petra respectively about the DIY Loop. This step by the doctors could also be seen as kind of proof for Andrea and Petra that the DIY technology is suitable and safe for them. After all, if their doctors decide in favour of recommending the DIY Loop despite the legal uncertainties, this seems to be due to a certain form of conviction in favour of this technology. As healthcare professionals are an important source of trust for patients with regard to treatments (Hall et al., 2001), their recognisably strong conviction can contribute as a strong motivator for the use of a DIY Loop.

Returning to Andrea's quote, a second aspect of the medical role in relation to a DIY Loop becomes apparent here, too: After having used the Loop for six weeks, Andrea had another appointment with her diabetologist, who seemed to be convinced of the use and positive impact of the DIY Loop. She not only reiterated her support for Andrea but also demanded that DIY Loops should be accessible to everyone. This can primarily be understood to mean that access to the Loop system should be easier and should also be supported by the medical system, meaning that she may be able to make official recommendations for it in the future. At the same time, this statement should be seen as a confirmation for Andrea: If this technology should be accessible to the general public, then this statement also sends the message that this technology really works, i.e. that it is safe and effective. So, what takes place here in the diabetologist's treatment room is a kind of negotiation of the DIY Loop as a diabetes technology: Is it suitable for effective and safe diabetes treatment? In contrast to conventional medical devices, a DIY Loop is not officially authorized, it did not pass the regulatory regime and processes, it does not have a CE mark which patients and healthcare professionals can rely on. This basis of trust must be established in a different way. In this case, it takes place in the doctor's treatment room, who, as a trusted authority by the patient, also reflects these properties for the DIY Loop system. At the same time, however, this is embedded in a framework of consensual silence between doctor and patient. Due to the legal uncertainties, the essential process of negotiation, the doctor's advocacy as an authority of trust for the DIY Loop system, should not leave the space between the two. Through their recommendation, the doctor places themselves in a certain kind of dependency on the patient, as they trust the patient's silence. Perhaps this element of mutual dependence also strengthens the patient's trust in the doctor and their recommendation of the DIY Loop system.

In contrast to Andrea and Petra, Thomas and Markus did not receive their recommendation for the DIY Loop from their doctors, but from other people they know or from the diabetes community. Therefore, their doctors do not have the same special role in recommending the DIY Loop. Nevertheless, their doctors are aware of the use of the DIY Loop and they continue to advise them on diabetes treatment, but not specifically on the DIY Loop. However, they do make use of the data recorded by the Loop system, such as the progression of blood glucose levels, and use this for their counselling. Markus and Thomas also commented that their diabetologists perceive the use of the Loop system as positive due to the improved values achieved by the Loop system.

It is precisely these specific relationships between my four interviewees and their treating physicians that stand for themselves; no general rule can be derived here. This is shown by the differences in the role of the doctors between the four of them. Thomas also told a story of a child with T1D whose diabetologist refused further treatment because the child respective his parents were using a DIY Loop. Apparently there also seem to be doctors who rule out treatment with a DIY Loop. Users of a DIY Loop or patients considering using one should be aware of this. My interviewees may only use a DIY Loop because their diabetologist supports them or maybe even have drawn patient's attention to the DIY system first place – or at least tolerates its use. But it could also be different. Perhaps Andrea and Petra would never have learnt about the possibility of using a DIY Loop, perhaps other diabetologists would have discouraged Thomas and Markus from using it or they would have had to look for another diabetologist. The fact that it works well in these four cases does not mean that the medical support of diabetes I patients who use a DIY Loop generally works well. Rather, the personal attitude of the doctor plays a decisive role here.

8.2. Complicated support: manufacturers of pumps and CGMs

Perhaps not quite as obvious as health professionals is another group of actors, namely the manufacturers of medical devices. As I explained earlier, the main components of a DIY Loop consist of the Loop app on the smartphone as well as an insulin pump and a CGM, latter ones are both commercial devices. In the context of a DIY Loop, my interview partners do not use the official control devices or apps of the manufacturers, but the Loop app. This means that they use the pump and the CGM in a way not intended by the manufacturer, which in particular can limit the support provided by the manufacturer or void the device warranty (Braune et al., 2022). Especially the use of a patch pump, as used by Andrea, Markus and Thomas, sometimes causes the need to contact the manufacturer. In contrast to a tube-based pump, a patch pump essentially consists of an integrated reservoir for the insulin, which is usually sufficient for several days, and therefore needs to be changed regularly. Andrea, Markus and Thomas report that it can

happen that a new device my not work properly which means that they must contact the manufacturer to get a replacement pump.

When contacting, the usage of the components in the setting of a DIY Loop leads my interviewees to withhold information about this very unconventional usage of the components from the manufacturers. "If I complain about it, then not everyone has to know [how I use the pump]", states Andrea (48:10). This concealment from the manufacturers should reduce the risk of being immediately refused support due to the type of use in the DIY context. Nevertheless, there are further challenges in the interaction with the manufacturers. For example, manufacturers often require specific error codes that classify the type of error or defect. But in the case of insulin pumps, for example, these error codes are only visible via the manufacturer's own control unit. But as the pump in the DIY Loop is not connected to this device, DIY users do not have any error codes available that they can reference to the manufacturer. Therefore, my interviewees have developed strategies to avoid this problem. For example, they pretend on the phone that they don't have handy the control unit or smartphone with the manufacturer's official app and hope that their complaint will be accepted by the manufacturer despite the missing error code. Markus also reported that lists have been made available within the Looper community containing the possible error codes of the manufacturers. This means that a valid error code from the list can be used when calling or making an online complaint. The manufacturer can thus be made believe that the error code has just been red from the control unit. Markus's categorisation of this practice is also interesting. By the error code, only "one word" (44:28) is decisive for the support of the manufacturer. In this respect, the list of error codes can also be seen as a list of magic words, which is made available within the DIY community for mutual support in order to make it easier to get support by manufacturers, which became quite complex by the use of a DIY Loop.

And yet, despite the coping strategies to receive the necessary support from the device manufacturers, fears and feelings of insecurity are emerging. This is due to the limited or more complicated support provided by the device manufacturers and the associated higher level of individual liability. For the Loop system as a whole, the users have the role of a manufacturer themselves. There is no industrial manufacturer to turn to for support or a guarantee on the medical device. The DIY system also makes the support that is available for the commercial components of the CGM and pump more complex. Users have to rely strongly on support from the DIY community, as Markus explains. At the same time, he sees this as a personal consideration: The perceived benefits of the DIY system, which motivate users to use it, have to be weighed against the limited support from the institutional side, i.e. the manufacturer.

I think Thomas' categorisation of the DIY system in the following is definitely worth mentioning. In this context, he only mentions the DIY Loop as an alternative way of controlling the components. To him it is irrelevant whether he controls the pump and the CGM with the manufacturer's device or the DIY Loop. However, with his own Loop app, he just expands the possibilities of these components. In my view, this relativisation of the DIY Loop to an alternative way of controlling the commercial components reduces the complex system of the DIY Loop and also provides a certain justification for Thomas. Because it is of course correct that on a purely technological level, the components are simply controlled by the self-built app instead of the supplied control devices, an exchange that seems simple from this perspective. This perhaps also makes it easier for Thomas to claim support from the manufacturer – even if, as already mentioned, he does not explicitly mention DIY use. In addition, the faults in the components are independent of the type of control, as he says. These could also occur with the official control devices. In this respect, his words can be interpreted as: It does not really matter how the components are used, whether in the manufacturer's intended way or as part of a DIY Loop – he believes that he is entitled to appropriate support in any case. However, I think this statement is particularly interesting because Thomas is aware of the great advantages of the DIY Loop and mentioned them during the interview, which shows the extent and awareness of the complex impact of the DIY Loop on his care activities. At the same time, he reduces the DIY Loop to a kind of technical detail in the context of component manufacturers.

When considering DIY Loop use in relation to device manufacturers as part of the traditional, institutionalised healthcare system, two key aspects become apparent. First, if the Loop system is seen as one device, there is no device manufacturer in the role of giving support and warranty, which users normally can expect from authorised medical devices. Instead, the users themselves are the manufacturers of their Loop. In some cases, my interviewees consciously perceive this absence of a regularly available actor as a form of uncertainty and a form of inevitable autonomy. In the event of problems with the DIY Loop, they are left to their own and to the support of the community. For Markus, this aspect is particularly relevant regarding his own future: perhaps in later years he would rather switch to a commercial system due to a lack of time or possibly lost technical affinity.

On the other hand, the DIY Loop can be seen assemblage of components including commercial components like a CGM and insulin pump. These still can be seen as form of black-boxes that users need support by the manufacturers for if not working properly what – as explained above – creates a specific form of dependencies of the users on commercial manufacturers. This is not only characterised by the fact that, for example, the error codes required for support are not

available in the DIY Loop, but also by a feeling of insecurity among users that they may not receive any support or not the support they need. This can also be recognised by the fact that they try to withhold the use of the DIY from the manufacturers and thus preventively protect themselves from support restrictions.

Although the users of a DIY Loop decide against a conventional medical device, in particular because of the functional advantages and the positive effects on their quality of life, a dependency on the manufacturers of medical devices is also evident here in the context of the institutionalised healthcare system. The choice in favour of a DIY system is therefore not synonymous with complete independence from the medical device industry. Rather, there is a dependency on the industry, which also appears to be more complicated than the normal use of a conventional device.

8.3. Silence towards the health insurance company

In the two previous sections, I have already discussed how my interviewees perceive the role of doctors and device manufacturers in relation to their use of the DIY Loop. The latter two can be seen as institutionalised actors in the traditional healthcare system. Health insurance companies can be seen as additional actor in this context. Based on their underlying legislation, they play a key role in the establishment of conventional, authorised medical products (Faulkner, 2009a). The regulation by which medical devices are financially subsidised or fully covered is kind of an expression of which products are considered to be normal in their use and in this sense are hold by the healthcare system. A DIY Loop system itself cannot be subsidised at all under the current regulations, as it is not an approved and thereby CE-certified medical device originating from the existing regulatory regime. Nevertheless, health insurance also plays a more or less important role for my interview participants with a DIY Loop due to the conventional components of the pump and CGM contained in the DIY Loop. Although there were no direct monetary costs for my interview participants from using and building the DIY Loop – with the exception of Andrea, who bought an Apple laptop to build and rebuild the Loop app – the CGM and the pump meant that there was also a financial dependency on the health insurance company. The health insurance company had covered the costs of the CGM and the pump for all four of them, but this was based on the assumption of a "normal" use and not in the knowledge that they were using a self-built Loop system. All four of my interviewees stated that their health insurance company did not know how they were using the components provided. Like towards device manufacturers, they do not disclose the context of use of the commercial components in order to avoid potential reprisals. In contrast to the device manufacturers, here the basic financing of the required components is in question. This includes in particular the initial, one-off financing of the pump and the CGM, but

also components required for operation such as cannulas or even ongoing replacement patches in the case of a patch pump.

In the narratives of my interview partners, I can distinguish between two different processes: Andra, Petra and Markus already had the components they needed for the Loop system before they built it. The health insurance company had therefore already approved the devices so the three initially used them in the way intended by the manufacturers before they decided to use the components for their DIY Loop system. Thomas's path towards the Loop system was different. He was already interested into the topic of a self-built Loop system when he was still using an insulin pen. In the chapter on motivations for using a DIY Loop, I had already described Thomas' experiences and decisions in more detail, but essentially his disappointment of a commercial pump system led to his decision to use a DIY Loop: During a test phase to try out the pump, the associated control unit broke on the very first day of use. Thomas therefore just built a DIY Loop and used the respective pump for this – without the defective control unit. Satisfied with this system, Thomas wanted to continue using it, but the pump had first to be authorised by the health insurance company or medical service beyond the test period. According to Thomas, for obtaining permanent authorisation it must be proven that the use of the pump leads to an improvement in the values, i.e. that Thomas' blood glucose levels are better regulated than with the pen he was previously using. Proving takes place by a blood glucose diary of the CGM. Thomas really wanted to get approval for the pump and felt highly motivated to achieve good values during this phase, but at the same felt kind of stressed:

> [00:37:05] Thomas
> So now I'd say I'm even more relaxed about it anyway. But yes, this examination by the medical service was another sticking point for me, where I said I hope it goes through and nobody puts any obstacles in my way.

He was already convinced of the pump and its use within the Loop system but feared that he would not receive any funding for the pump. According to him, achieving good values was not a major problem here, but rather that the values could perhaps have been clearly too good. By the blood glucose diary, it was obvious that the pump was used in the context of a Loop system, as greater deviations in the measured values would have been inevitable if the pump had been operated in a conventional way. As the manufacturer of the pump did not provide an official Loop system, the use of a DIY Loop would also be evident and therefore the unconventional use would be visible. In principle, people with T1D who are hoping for approval of insulin pumps or commercial Loop systems are already under pressure to prove that they could optimise their values (Eitenberger & Wiedemann, 2022). It seems almost paradoxical that Thomas, who is

already using the pump to be approved within a DIY Loop during this test phase, has to fear that the values he had achieved could be too good and that the health insurance company will draw conclusions about DIY use and possibly refuse approval. This was precisely the fear that plagued Thomas during the authorisation process. Although he would have considered appealing a negative decision from the health insurance company, in retrospect he is very glad that the health insurance company approved the pump directly. Without the approval of the pump, Thomas would not have been able to continue using it – and therefore the Loop system as a whole – or would only have been able to do so at considerable expense to himself.

This illustrates the dependency of users of a DIY Loop on the health insurance companies as an institution of the traditional healthcare system. Although DIY Loopers decide against a conventional medical product, they are still dependent on the health insurance company. Primarily, a financial dependency of DIY users can be recognised here: By authorising and covering the costs of the components, the health insurance company enables the construction and use of the DIY Loop, which would otherwise be associated with high financial expenditure for the user. Here too, outside the area of conventional, authorised medical devices, the role of the health insurance company as a mediator with regard to the establishment of medical devices becomes apparent (Faulkner, 2009a) by supporting specific technologies – or not. During the approval process, Thomas feared that the health insurance company might recognise the unconventional use of the pump as part of a DIY Loop and therefore refuse to financially cover the pump. Thomas' awareness that he was not using a conventional medical device meant that he was already considering a rejection by the health insurance company. Even if his pump was finally approved, this awareness could perhaps also lead other people to prefer not to use the DIY Loop or to only use it strategically first after approval has been granted. There was a recognisable risk that the health insurance company, as an institution of the established healthcare system, could become aware of the use of the DIY Loop and that this could lead to negative consequences. In this respect, the health insurance not only guides the establishment of healthcare technologies, but also indirectly prevents or impedes the use of or access to alternative medical technologies outside the regulatory regime of healthcare (Faulkner, 2009a). However, it is not an explicit ban on technologies such as the DIY Loop, but rather the absence of the normally tightly meshed network of regulations within the healthcare sector, which normally provides a form of security and reliability. This absence creates an additional and yet unknown form of uncertainty for the users of a DIY Loop within this healthcare system and, as in the example of Thomas, leads to almost paradoxical situations: On the one hand, Thomas had to justify support for the pump on the basis

of good or improved values, while at the same time he feared that the values were in some way recognisably too good for the conventional way of using the insulin pump.

But it also became clear in Andrea's case how health insurances act as an obligatory passage point (Callon, 1984) towards patients for access to conventional medical devices. Andrea's application for approval of a different pump model, which already supports automated insulin dosing by the manufacturer's side, was rejected by her health insurance company. If Andrea had continued to use only conventional medical devices, she would have been denied access to automated insulin dosing technology. The pump system she was already using – at least when used in Europe – did not have the automatic dosing function. The use of a self-built Loop system also enabled her to benefit from automated insulin dosing using the same hardware - and therefore independently of her health insurance company.

8.4. New forms of navigation within the traditional healthcare system

In this chapter, I have shown what it means to be a user of a DIY Loop within the traditional healthcare system. The latter one bases on a regulatory regime for medical devices. For regular ones, there are clearly defined, institutionalised actors and practices in the European Union and Germany that regulate the approval process for new medical devices. The key element here is the CE mark, which is affixed to these devices and symbolises the successful passing of this processes. However, this regulatory regime for medical devices is reproduced by other players in the healthcare system. By financing medical devices, health insurance companies stabilise them and set standards at the same time: Which medical devices are financially supported by the healthcare system, meaning that their use by patients is also promoted and thus more easily established, and which are not? Health professionals also play a role here, as they courage – or maybe also discourage – patients on the choice of medical devices.

DIY Loop systems and their users, however, move partly outside this regulatory regime, as DIY Loops are not authorised medical devices and therefore cannot have a CE mark. However, the technological zone of medical devices, which provides highly regulated paths and processes for approval that on the other hand patients and health professionals can rely on, does not see DIY devices as possible category. Unlike using conventional devices, users of a DIY Loop find themselves in an environment of uncertainty in which they have to navigate.

With their DIY Loop, they move within an ambivalent context: on the one hand, their device as such is not an authorised medical device. At the same time, however, they are using the pump and the CGM as authorised medical devices, but in an unintended context. This means that my interviewees are still dependent on their health insurance provider for financing the components

and on the manufacturer for support for the devices. The response of my interviewees to this aggravated form of dependency is a form of strategic silence, not explicitly mentioning use in a DIY context to avoid any possible negative consequences.

The attending physicians take a special role, as they themselves face legal uncertainties when advising patients who use DIY Loops. In this respect, the role of doctors can vary greatly and is dependent on the individual's attitude. In some cases, they recommended the use of a DIY Loop to my interviewees themselves, or they at least know about its use and tolerate it. However, it can also happen that doctors refuse treatment when a DIY Loop is used. In this respect, the treating doctor also plays a potentially influential role by tolerating or even encouraging the use of a DIY Loop, or by making it more difficult to use or forcing the DIY user to look for another doctor.

I have summarised these new forms of navigation by the usage of a DIY Loop within the healthcare sector regarding the identified actors, namely attending physicians, health insurances and device manufacturers in the following table:

Attending physicians	Dependency on physicians' attitude towards DIY Loop	Potential source of initial information about DIY Loop technology (but consensual silencing)	Negotiating of safety and effectiveness of DIY Loop
Health insurance	Silence towards health insurance about using tools in DIY context	Obligatory passage point towards conventional technologies, but also for components for DIY Loop	Fear during applying process of getting rejected because of DIY usage could get visible
Manufacturers of Loop components	Silence towards manufacturers about using components in DIY context	Coping strategies for support	Less and strongly limited support by manufacturers and stronger self-reliance

Table 6: New forms of navigation in the interaction with actors of the classical healthcare system by the usage of a DIY Loop

Based on these three actors it becomes clear how the use of a DIY Loop opens up new, unfamiliar uncertainties within the traditional healthcare system. These uncertainties arise from the fact that the healthcare system and the regulatory regime do not think in terms of self-made medical devices; there is a clear regulatory gap. My interviewees developed specific coping strategies to overcome these uncertainties. For my interviewees, using a DIY Loop does not mean being able to escape the traditional healthcare system, but rather finding new ways to navigate it. This is a particular challenge when using a DIY Loop as it is also linked to new uncertainties and fears.

9. Discussion and Conclusion

9.1. DIY Looping as a shifting of tasks

In summary, the following general observation can be made: All of my interview participants expressed conviction regarding the use of a DIY Loop. Both the functions of the DIY Loop as a device and the positively perceived effects resulting from its use affirm my interviewees in their "choice". Nevertheless, the use of a DIY Loop system also entails specific challenges and demands on the user — not only in operating the device itself, but also consequently in navigating interactions with actors within the healthcare system.

Even though the idea of an artificial pancreas may suggest, an APS aka Loop does not make the underlying disease or the associated impairments disappear. While limitations previously perceived as burdensome may diminish, new tasks and challenges arise for users because of the Loop system respectively of looping as an activity. What becomes apparent is a shift away from tasks such as measuring blood glucose levels and calculating and injecting insulin that are now assumed by the Loop toward the challenges in operating the Loop.

What particularly surprised me when analyzing my interview results was the factor of time associated with the use of a DIY Loop system. As a present topic in literature, T1D is a particularly time-intensive condition (Mol, 2008, 2009; Walsh et al., 2015). This corresponds with broader discussions over patients reduction in quality of life (Wahlberg, 2017; Wahlberg & Rose, 2015). From the perspective of patients, effective treatment technologies should primarily support them in reducing this workload. And yet, from my perspective, my interviewees appear to invest enormous amounts of time in learning how to use a DIY Loop, in building it, and in maintaining it. Despite this considerable effort, the perceived positive effect of a DIY Loop still outweighs the use of a commercial alternative. If this substantial investment of time continues to be worthwhile because it ultimately results in less stress and greater flexibility in everyday life, this – at least for me – stresses the significant challenge that T1D poses in daily life.

9.2. How open is OpenAPS? Barriers towards a DIY Loop

What also became clear is that users of DIY Loops acquire or maybe already possess specific knowledge, skills, or resources – whether in the form of various literacies, general technical affinity, or socio-economic resources such as access to technology or, as just mentioned, time. These are essential prerequisites for the use of a DIY Loop system.

Moreover, users must also be able to manage uncertainties that arise from the usage of the DIY Loop when navigating through the healthcare context. I therefore consider these requirements as

potentially exclusionary factors for the usage of a DIY Loop. This perspective should be considered when evaluating DIY Loop systems as a principle technologically open alternative and path of accessing technology for automated insulin delivery.

It is also important to note that my research focuses specifically on the German healthcare setting. All of my interview participants had the components required for the Loop system covered by their health insurance, even though the approval process was, in some cases, associated with uncertainties. This coverage is a crucial factor in enabling access to automated insulin delivery technologies, as otherwise, the associated costs would be substantial for individuals. However, this socio-economic factor can vary significantly in other healthcare settings. Furthermore, the availability of commercial systems for automated insulin dosing depends on the national healthcare context. There may therefore indeed be contexts in which a DIY system remains the only means of access to automated insulin dosing. This is why my research in this respect is, by its very nature, limited to a certain extent.

9.3. Temporalities of good care and treatment technologies

Furthermore, my research illustrates the temporalities of patients' needs. A decade ago, when the #WeAreNotWaiting movement emerged, commercial devices for automated insulin dosing simply did not exist. In the meantime, such devices have become available, yet they still fail to meet the needs of some people with T1D. Even if today's commercial systems perhaps offer the functions that DIY Loops once provided, the functionalities of DIY Loops have continued to evolve in the meantime.

The activities of my interview participants show that even with a DIY Loop system, they are engaged in a constant process of tinkering (Jansky, 2024; Mol, 2008). They are in a state of ongoing optimization of their care work by adjusting the interplay between their body and the treatment technology. What was once perceived as good treatment may, in the meantime, have already been surpassed and further optimized. This definition of good care – or rather, of the best possible care – takes place through the patient as expert of their own condition and through their embodied experience (Brown et al., 2004). What happens here at the individual, embodied level also applies in a broader dimension: what enables good care and, in relation to technologies, what functions must a treatment device provide? As the logic of care (Mol, 2008) sensitizes for the complexity of care in the context of chronic diseases, this particularly also applies for treatment technology as part of this care. My work demonstrates how these aspects of good care are reflected in patients' requirements for the functionalities of appropriate treatment technologies. Good care – and good treatment technology – are by no means static or universal; it evolves over time. What is illustrated

here using the example of treatment devices for T1D certainly also applies to other chronic conditions.

9.4. Hacking for innovation: DIY Loopers as lead users

Using the terms of Akrich (1992), not only the immediately visible activity done with a treatment device, but also the broader context of improving the quality of life is an essential aspect that is *inscribed* by patients into good treatment devices. Whether a device is seen as an adequate device is dependent on the perceived improvement of quality of life by the patient. In this way, patients also attribute value to existing treatment technologies. As key users, they create and apply their own evaluation framework for these devices, which may differ to the evaluating metrics of other actor groups like for example device industry (Heuts & Mol, 2013). At the same time this evaluation of conventional diabetes technologies is performative, as it not just mirrors the status quo but creates something new, namely new artefacts (Asdal et al., 2024).

Just as in the case of the bionic ear, patients here reject the technology that is suggested to them as the appropriate solution through forms of organized patient activism (Blume, 1997). But in this case, patients go a step further by the production of socio-technical alternatives that address their needs, demonstrating the viability of user-driven innovation (Oudshoorn & Pinch, 2003). Based on the pancreas's inability to produce insulin as underlying impairment, this group of patients created a creative, new technological solution. One could call them pan-creative innovators.

While this innovative group represent only a small proportion of people with T1D, the majority rely on other diabetes treatment technologies. Similarly, in Germany, the number of users of commercial systems for automated insulin dosing is greater than those using DIY systems. As already mentioned, there is a perceivable distinct position of DIY Loop users from the perspective of the broader and considerably larger group of patients using other technologies. As became evident during my ethnographic attendance at two conferences, users of other systems often perceive the use of a DIY Loop as unusual or as too complex for themselves, or they had, in some cases, not even been aware of this option at all.

A key characteristic of members of the DIY community can be seen in a certain willingness – namely, a *hacking ethos* in the sense described by Delfanti (2013). Potential users of a DIY Loop need to have or to develop a positive attitude toward "hacking" as an approach that is widely regarded as unconventional by the general public. This is where Mol's perspective on medical devices becomes relevant: they are not merely neutral tools – their use is always also a „moral

activity“ (Mol, 2008). The pursuit of good care, and the technology required to achieve it in the form of a DIY Loop, may thus justify the unconventional step of hacking a medical device.

Despite its comparatively small size, the role of the DIY Loop community should not be marginalized, as it has demonstrated – both in the past and still today – that alternative treatment technologies are possible. Despite the now commercially available devices for automated insulin delivery, one may justifiably ask: Would this technology already exist today without the initiative of #WeAreNotWaiting or how would it look like? Or did people with diabetes first have to chart the path of innovation themselves by hacking?

Based on this assumption, non-users of DIY Loops who prefer commercial technologies benefit from the DIY community and thereby its individuals' activities. In terms of von Hippel (1988), DIY Loopers can be seen as "lead users" who show the path toward new technologies what non-users of DIY Loops can profit from, too. For this purpose, hacking emerges as a fundamental practice.

9.5. Need for re-adjustment commercial research and innovation towards patients' needs

In this case, the production of socio-technical alternatives represents an explicit contestation of the structural idleness and epistemic authority of regulatory institutions as well as the device industry. As Blume (1997) argues, the step of addressing a certain treatment form or technology is always also a form of challenging the contextual regime. This regulatory regime is intentionally designed to ensure access to safe and efficacious medical devices. My work exemplifies how this system can be misaligned with patient needs. In response, T1D patients assert their epistemic agency by fabricating and deploying their own devices, thereby actively reshaping biomedical infrastructures, whereby their innovations emerge without commercial intent (Hippel, 2016). Loopers also challenge the perspective of the logic of choice (Mol, 2008), according to which patients could simply select the right option from the portfolio of existing medical devices and thereby achieve good care. Likewise, they contradict the marketing claim I encountered at the event I attended to, which suggested that flexibility is merely a matter of attitude. The path to good care is, in fact, far more complex than adjusting dosage settings or simply changing one's attitude.

As a result, the DIY Loop community has taken on tasks that originally belong to medical device industry: Patients themselves develop and implement treatment technologies with new functionalities. Moreover, other aspects such as risk assessment and the classification of the device as effective and safe now fall onto the shoulders of patients who, by virtue of their chronic diabetes condition, are already exposed to considerable impairments. Precisely for this reason,

and against the backdrop of the access barriers to DIY Loops already discussed, this should not be regarded as the sole pathway to adequate treatment technologies for patients.

This aspect of my case illustrates in a good manner how the focus of industry in the healthcare sector lies more in its own capitalist interests than in public health (Dumit, 2012; Gaudilliere, 2021). T1D exemplifies the close interlinkage between pharmaceuticals and medical devices. Insulin and treatment devices are inseparably connected: they are mutually dependent and considered singularly without use. Since its discovery over 100 years ago, the therapy of T1D by insulin dosing has remained essentially the same – blood glucose level is measured and insulin is injected. We therefore find ourselves in a state that is indeed highly profitable for the healthcare industry: patients with T1D require continuous treatment with insulin, and for this, they also need suitable devices. A certain innovatory inertia within industry appears to be highly profitable for them.

To fulfil their task, device manufacturers would need to scale back their commercial interests and reorient their research and innovation processes toward the needs of patients – moving, in the words of Gaudilliere (2021), from *exchange value* to *use value*. A key step from the perspective of my interview participants would be to enable interoperability between device components from different manufacturers. The ability to freely combine components from various manufacturers is precisely what constitutes the central advantage of a DIY Loop and aligns with the idea that *one size does not fit all*. However, this principle runs counter to the manufacturers' interest in tying their users to the ecosystem of their own device portfolio.

Going one step further: T1D as a disease that was once fatal has become a chronic condition through continuous medical treatment (Armstrong & Caldwell, 2004), albeit with an associated reduction in quality of life (Wahlberg, 2017). Certainly, all of my interviewees report an improvement in quality of life through the use of a DIY Loop. But in the thinking of STS: Are there truly no alternatives to the current form of treatment? Pushed further: Might there even be possibilities for people with T1D to move beyond continuous treatment toward a cure, such that no external technological artifact would be required to imitate the pancreas? What I describe here in relation to T1D naturally also applies to other chronic conditions: Things could be different. The #WeAreNotWaiting movement not only reveals a concrete need, but also serves as an expression of a deeper, structural problem – the failure of the mechanisms behind medical devices.

9.6. Rethinking treatment-methods in the healthcare setting

Taking another perspective: What if the use of a DIY Loop system were no longer associated with the challenges identified by my interviewees and the focus could instead rest on its positive

effects? One of these challenges is the need to build and update the Loop system because the app, for legal reasons, cannot simply be offered for download. If, however, this app was easily downloadable and updatable via the Apple App Store or Google Play Store, a major challenge would be eliminated. At the same time, the regulatory level reveals that there is scarcely any thinking in terms of DIY treatment technologies in the first place, which further complicates the use of a DIY Loop. This form of patient activism, which emerged as a response to dissatisfaction with the healthcare system and sought to escape its innovation paradigms by creating an alternative path of innovation, nonetheless cannot fully free itself from the healthcare regime, as patients remain highly dependent on its actors. This, in turn, results in alternative ways of navigating the healthcare system. But what if the healthcare system, at both institutional and process levels, were to think in these terms – that is, that patients with T1D might use their DIY systems? The treatment of T1D is generally considered a highly individual challenge for which the patient bears primary responsibility. Would it not therefore make sense to think in these individualistic terms also regarding the used technology?

Studies have already shown that DIY Loop systems are effective, specifically improving blood glucose levels, enhancing sleep quality, and reducing fear of hypoglycemia (Braune et al., 2021, 2022; Gawrecki et al., 2021). My interviews also clearly highlight the predominance of positive effects from use. If taking conventional medical devices as a benchmark which approval and CE certification are based on a risk-benefit calculation (Bano et al., 2023; Beck, 1998): Why should the individual positive assessment by the patient not also legitimate a DIY Loop?

DIY Loopers not only demonstrate that they can envision a world in which patients use self-built treatment devices, they are already in the process of creating it. To some extent, their treating physicians are doing so as well. And yet, this form of use remains an exception within the national healthcare system as long as it is not supported institutionally and procedurally. This raises the question: Is it possible to build sociotechnical imaginaries (Jasanoff, 2015; Jasanoff & Kim, 2009) that are jointly shared with other actors in the healthcare system and that enable broadly accessible, patient-oriented treatment technologies in which good care for people with chronic illnesses is placed at the center?

A technological approach that could fit into such an imaginary is the app “Tidepool”, which the nonprofit company of the same name in the United States developed based on OpenAPS. In 2023, it received FDA approval as a medical device and is thus available for download via the relevant app stores in the U.S. One major challenge of building and updating the Loop system app oneself could therefore – at least for Loopers in the U.S. – be eliminated. However, there remains a direct

dependency on device manufacturers: Tidepool is reliant on manufacturers abandoning the proprietary character of their devices and making them easily compatible with the app so that these no longer need to be hacked.

In Germany, Tidepool currently plays no role. But perhaps Tidepool will show the path how diabetes technologies can develop just as OpenAPS once did – and how people with chronic diseases might once again find restful, worry-free sleep.

Literature

Akrich, M. (1992). The De-Scription of Technical Objects. In W. E. Bijker, Shaping Technology/Buidling Society. Studies in Sociotechnological Change (pp. 205–224). MIT Press.

AndroidAPS. (2023, August 31). Full Closed Loop—AndroidAPS 3.1 documentation. https://androidaps.readthedocs.io/en/latest/Usage/FullClosedLoop.html#. Last Accessed 8 September 2023

AndroidAPS community. (2023, August 31). Welcome to the AAPS documentation—AndroidAPS 3.1 documentation. https://androidaps.readthedocs.io/en/latest/. Last Accessed 5 September 2023

Arksey, H. (1994). Expert and lay participation in the construction of medical knowledge. Sociology of Health & Illness, 16, 468. https://doi.org/10.1111/1467-9566.ep11347516

Armstrong, D., & Caldwell, D. (2004). Origins of the Concept of Quality of Life in Health Care: A Rhetorical Solution to a Political Problem. Social Theory & Health, 2, 371. https://doi.org/10.1057/palgrave.sth.8700038

Asdal, K., Doganova, L., & Fochler, M. (2024). Valuation studies as a frame in STS (U. Felt & A. Irwin, Eds.; p. 86). https://doi.org/10.4337/9781800377998.ch08

Bano, A., Laimer, M., Wehrli, F., Kunzler, J., Rivero, T., Fraser, A. G., Stettler, C., Hovorka, R., & Bally, L. (2023). Clinical evidence for high-risk medical devices used to manage diabetes: Protocol for a systematic review and meta-analysis. BMJ Open, 13, e070672. https://doi.org/10.1136/bmjopen-2022-070672

Barry, A. (2006). Technological zones. European Journal of Social Theory, 9, 253. https://doi.org/10.1016/j.bbapap.2005.10.001

Beck, U. (1998). Risk society: Towards a new modernity (1. publ., repr.). Sage Publ. https://ubdata.univie.ac.at/AC02308000

Beck, U. (2007). The Cosmopolitan Condition: Why Methodological Nationalism Fails. Theory, Culture & Society, 24, 290. https://doi.org/10.1177/0263276407024007250

Becker, G. (1994). Metaphors in Disrupted Lives: Infertility and Cultural Constructions of Continuity. Medical Anthropology Quarterly, 8, 410. https://doi.org/10.1525/maq.1994.8.4.02a00040

Bennett, J. A. (2019). Managing Diabetes: The Cultural Politics of Disease. New York University Press,. https://www.degruyter.com/isbn/9781479821273

Bertelsmann Stiftung. (2019, March 28). #SmartHealthSystems. International comparison of digital strategies. Summary. https://www.bertelsmann-stiftung.de/fileadmin/files/Projekte/Der_digitale_Patient/VV_SHS-Studie_EN.pdf. Last Accessed 9 December 2023

Bijker, W. E. (2010). How is technology made?—That is the question. Cambridge Journal of Economics, 34, 76. https://doi.org/10.1093/cje/bep068

Blume, S. S. (1997). The Rhetoric and Counter-Rhetoric of a "Bionic" Technology. Sci Technol Human Values, 22, 56. https://doi.org/10.1177/016224399702200102

Borkman, T. (1976). Experiential Knowledge: A New Concept for the Analysis of Self-Help Groups. The Social Service Review (Chicago), 50, 456. https://doi.org/10.1086/643401

Bowker, G. C., & Star, S. L. (2000). Sorting Things Out: Classification and Its Consequences (1st ed.). https://doi.org/10.7551/mitpress/6352.001.0001

Brantly, N. D. (2023). Automating Health: The Promises and Perils of Biomedical Technologies for Diabetes Management [Virginia Polytechnic Institute and State University]. https://www.researchgate.net/profile/Nataliya-Brantly-2/publication/371120598_Automating_Health_The_Promises_and_Perils_of_Biomedical_Technologies_for_Diabetes_Management/links/64739aac59d5ad5f9c80406f/Automating-Health-The-Promises-and-Perils-of-Biomedical-Technologies-for-Diabetes-Management.pdf. Last Accessed 16 August 2023

Braune, K., Gajewska, K. A., 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 of Medical Internet Research, 23, e25409. https://doi.org/10.2196/25409

Braune, 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. (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

Brown, P., & Zavestoski, S. (2004). Social movements in health: An introduction. Sociol Health Illn, 26, 694. https://doi.org/10.1111/j.0141-9889.2004.00413.x

Brown, P., Zavestoski, S., McCormick, S., Mayer, B., Morello-Frosch, R., & Gasior Altman, R. (2004). Embodied health movements: New approaches to social movements in health. Sociol Health Illn, 26, 80. https://doi.org/10.1111/j.1467-9566.2004.00378.x

Bundesministerium für Gesundheit. (2024, February 19). Marktzugangsvoraussetzungen für Medizinprodukte. https://www.bundesgesundheitsministerium.de/themen/gesundheitswesen/medizinprodukte/marktzugangsvoraussetzungen. Last Accessed 13 September 2024

Burnside, M., Crocket, H., Mayo, M., Pickering, J., Tappe, A., & de Bock, M. (2020). Do-It-Yourself Automated Insulin Delivery: A Leading Example of the Democratization of Medicine. J Diabetes Sci Technol, 14, 882. https://doi.org/10.1177/1932296819890623

Callon, M. (1984). Some Elements of a Sociology of Translation: Domestication of the Scallops and the Fishermen of St Brieuc Bay. The Sociological Review (Keele), 32, 233. https://doi.org/10.1111/j.1467-954X.1984.tb00113.x

Callon, M. (2009). Acting in an uncertain world: An essay on technical democracy. MIT. https://ubdata.univie.ac.at/AC07681354

Callon, M., & Rabeharisoa, V. (2003). Research "in the wild" and the shaping of new social identities. Technology in Society, 25, 204. https://doi.org/10.1016/S0160-791X(03)00021-6

Chandwani, R., & De', R. (2017). Doctor-patient interaction in telemedicine: Logic of choice and logic of care perspectives. Information Systems Frontiers, 19, 968. https://doi.org/10.1007/s10796-016-9643-0

Charmaz, K. (2006). Constructing grounded theory: A practical guide through qualitative analysis (1. publ.). SAGE. https://ubdata.univie.ac.at/AC04827269

Coolen, M., Aalders, J., Broadley, M., Aanstoot, H., Hartman, E., Hendrieckx, C., Nefs, G., & Pouwer, F. (2021). Hypoglycaemia and diabetes-specific quality of life in adolescents with type 1 diabetes. Diabet Med, 38, n/a. https://doi.org/10.1111/dme.14565

Crocket, H. (2020). Peer Mentoring in the Do-it-Yourself Artificial Pancreas System Community. J Diabetes Sci Technol, 14, 1027. https://doi.org/10.1177/1932296819883876

D+B Rechtsanwälte Berlin. (2018, July 30). Gutachten "Looper." https://www.diabetes-technologie.de/download/3113/

David, P. A. (1985). Clio and the Economics of QWERTY. The American Economic Review, 75, 337.

Day, C., & Bailey, D. J. (2012). CE Marking and diabetes devices. The British Journal of Diabetes & Vascular Disease, 12, 215. https://doi.org/10.1177/1474651412466922

Delamont, S. (2007). Ethnography and Participant Observation. In C. Seale, G. Gobo, J. F. Gubrium, & D. Silverman (Eds.), Qualitative Research Practice (pp. 205–217). SAGE.

Delfanti, A. (2013). Biohackers: The politics of open science. Pluto Press.

Delgado, A., & Callén, B. (2017). Do-it-yourself biology and electronic waste hacking: A politics of demonstration in precarious times. Public Underst Sci, 26, 194. https://doi.org/10.1177/0963662516647348

Deutsche Diabetes-Hilfe. (2022). Diabetes in Zahlen. https://www.diabetesde.org/ueber_diabetes/was_ist_diabetes_/diabetes_in_zahlen. Last Accessed 13 March 2025

Diabetes UK & Royal College of Nursing. (2020, January 15). Do it yourself (DIY) closed loop for people living with Type 1 diabetes: Position Statement. https://www.diabetes.org.uk/resources-s3/2020-01/DIY%20closed%20looping%20for%20Type%201%20diabetes%20position%20statement.pdf. Last Accessed 8 November 2023

diateam. (2024, January 29). dt-report 2024—Diabetologen / Diabetologinnen Deutschland. https://dt-report.de/wordpress/wp-content/uploads/2024/08/dt_report-2024_Diabetologen_innen_deutschland.pdf. Last Accessed 1 June 2024

Dumit, J. (2012). Drugs for Life: How Pharmaceutical Companies Define Our Health. Duke University Press,. https://doi.org/10.1515/9780822393481

Eitenberger, M., & Wiedemann, L. (2022). Differences on display – Zur Digitalisierung diabetischer Sorgegeflechte. In C. Schubert, J. von Hayek, & A. Manzei-Gorsky (Eds.),

Digitalisierung und Gesundheit (1. Auflage 2022, pp. 233–261). Nomos Verlagsgesellschaft mbH & Co. KG. https://doi.org/10.5771/9783748922933

Epstein, S. (1995). The construction of lay expertise: AIDS activism and the Forging of Credibility in the Reform of Clinical Trials. Science, Technology, & Human Values, 20(408).

Epstein, Steven. (1996). Impure science: AIDS, activism, and the politics of knowledge. University of California Press.

European Medicines Agency. (n.d.). Medical devices. Retrieved August 10, 2024, from https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices

Facebook. (n.d.-a). AAPS users | Gruppen | Facebook. AAPS Users. Retrieved August 25, 2023, from https://www.facebook.com/groups/AndroidAPSUsers

Facebook. (n.d.-b). Looped-DE | Gruppen | Facebook. Retrieved August 25, 2023, from https://www.facebook.com/groups/loopedDE

Faulkner, A. (2009a). Medical technology into healthcare and society: A sociology of devices, innovation and governance (1. publ.). Palgrave Macmillan. https://ubdata.univie.ac.at/AC07509282

Faulkner, A. (2009b). Regulatory policy as innovation: Constructing rules of engagement for a technological zone of tissue engineering in the European Union. Research Policy, 38, 646. https://doi.org/10.1016/j.respol.2009.01.017

Fischer, J., & Rotella, D. P. (2015). Successful drug discovery.. Volume 1. Wiley-VCH Verlag,.

Fleck, L. (1979). Introduction to Thought Collectives. In Genesis and Development of a Scientific Fact (pp. 38–51).

Flick, U. (2021). Qualitative Sozialforschung: Eine Einführung (10. Auflage, völlig überarbeitete Neuauflage). Rowohlt Taschenbuch Verlag. https://ubdata.univie.ac.at/AC16419496

Forlano, L. (2016). Hacking the Feminist Disabled Body. Journal of Peer Production, Special Issue on "Feminist (Un)Hacking."

French-Mowat, E., & Burnett, J. (2012). How are medical devices regulated in the European Union? J R Soc Med, 105, 28. https://doi.org/10.1258/jrsm.2012.120036

Ganguly, B. (2015). Blood Glucose Check [Graphic]. https://commons.wikimedia.org/wiki/File:Blood_Glucose_Check_-_Howrah_-_2015-04-12_7550.JPG

Garfinkel, J. (2021, November 4). Diabetes as Illness and Metaphor: Stories from the Body-Technology. SCBE Seminar. https:// media space. stanf ord. edu/ media/t/ 1_ etfj9 5yq

Gaudilliere, J.-P. (2021). Pharmaceutical innovation and its crisis: Drug markets, screening, and the dialectics of value. BioSocieties, 16, 432. https://doi.org/10.1057/s41292-021-00235-7

Gawrecki, A., Zozulinska-Ziolkiewicz, D., Michalak, M. A., Adamska, A., Michalak, M., Frackowiak, U., Flotynska, J., Pietrzak, M., Czapla, S., Gehr, B., & Araszkiewicz, A. (2021). Safety and glycemic outcomes of do-it-yourself AndroidAPS hybrid closed-loop system in adults with type 1 diabetes. PLoS One, 16, e0248965. https://doi.org/10.1371/journal.pone.0248965

Glaser, B. G., & Strauss, A. L. (1968). The Discovery of grounded theory: Strategies for qualitative research (1. publ. in Great Britain). Weidenfeld & Nicolson. https://ubdata.univie.ac.at/AC04644079

Hall, M. A., Dugan, E., Zheng, B., & Mishra, A. K. (2001). Trust in Physicians and Medical Institutions: What Is It, Can It Be Measured, and Does It Matter? Milbank Q, 79, 639. https://doi.org/10.1111/1468-0009.00223

Haraway, D. (1994). A manifesto for cyborgs: Science, technology, and socialist feminism in the 1980s (p. 116). https://doi.org/10.1017/CBO9780511570940.007

Heinemann, L., & Lange, K. (2020). "Do It Yourself" (DIY)—Automated Insulin Delivery (AID) Systems: Current Status From a German Point of View. Journal of diabetes science and technology, 14, 1034. https://doi.org/10.1177/1932296819889641

Herzog, A. L., Busch, J., Wanner, C., & Von Jouanne-Diedrich, H. K. (2020). Survey about do-it-yourself closed loop systems in the treatment of diabetes in Germany. PLoS One, 15, e0243465. https://doi.org/10.1371/journal.pone.0243465

Heuts, F., & Mol, A. (2013). What Is a Good Tomato? A Case of Valuing in Practice. Valuation Studies, 1, 146. https://doi.org/10.3384/vs.2001-5992.1312125

Hippel, E. von. (1988). The sources of innovation. Oxford University Press,.

Hippel, E. von. (2016). Free Innovation. MIT Press.

Hughes, T. P. (1993). Networks of power: Electrification in Western society, 1880-1930 (Softshell books ed.). Johns Hopkins Univ. Press. https://ubdata.univie.ac.at/AC02007015

Hussain, S., & Lewis, D. (2020). Diabetes Podcast: Do It Yourself/Open Source Artificial Pancreas Systems: Part 1. Diabetes Therapy, 11, 1619. https://doi.org/10.1007/s13300-020-00827-9

Jansky, B. (2024). Digitized Patients: Elaborative Tinkering and Knowledge Practices in the Open-source Type 1 Diabetes "Looper Community." Science, Technology, & Human Values, 49(1), 53–77. https://doi.org/10.1177/01622439231170443

Jansky, B., & Langstrup, H. (2023). 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, 522. https://doi.org/10.1057/s41292-022-00278-4

Jasanoff, S. (2005). Designs on Nature: Science and Democracy in Europe and the United States. Princeton Univ. Press. https://ubdata.univie.ac.at/AC04841031

JDRF. (2023). Hybrid Clodes Loop [Graphic]. https://breakthrought1d.org.uk/news/nice-approves-hybrid-closed-loop-for-the-majority-of-people-living-with-type-1-diabetes-in-england-and-wales/. Last Accessed 27 February 2025

Jensen, E. (2016). Doing real research: A practical guide to social research. 14. SAGE Publications. https://app.talis.com/textbooks/9781473944299

Juvenile Diabetes Research Foundation UK. (2019, February 19). JDRF's UK position statement on type 1 diabetes 'DIY' technologies. https://jdrf.org.uk/about-jdrf-and-our-impact/about-jdrf/position-statements/jdrfs-uk-position-statement-on-type-1-diabetes-diy-technologies/. Last Accessed 8 November 2023

Kaziunas, E., Lindtner, S., Ackerman, M. S., & Lee, J. M. (2018). Lived Data: Tinkering With Bodies, Code, and Care Work. Human-Computer Interaction, 33, 92. https://doi.org/10.1080/07370024.2017.1307749

Kjærulff, E. M., Kingod, N., Tiemensma, M. D., & Wahlberg, A. (2022). Calibrating logics: How adolescents and young adults calibrate often-competing logics in their daily self-

management of type 1 diabetes. Health (London), 13634593221113211. https://doi.org/10.1177/13634593221113211

Knox, R. (2020). Insulin insulated: Barriers to competition and affordability in the United States insulin market. Journal of Law and the Biosciences, 7, lsaa061. https://doi.org/10.1093/jlb/lsaa061

Landzelius, K. (2006). Introduction: Patient organization movements and new metamorphoses in patienthood. Soc Sci Med, 62, 537. https://doi.org/10.1016/j.socscimed.2005.06.023

Latour, B. (1999). Pandora's hope: Essays on the reality of science studies. Harvard Univ. Press. https://ubdata.univie.ac.at/AC02601953

Latour, B. (2004). Why Has Critique Run out of Steam? From Matters of Fact to Matters of Concern. Critical Inquiry, 30, 248. https://doi.org/10.1086/421123

Laurent, B. (2011). Technologies of Democracy: Experiments and Demonstrations. Sci Eng Ethics, 17, 666. https://doi.org/10.1007/s11948-011-9303-1

Lenz, S. (2021). "More like a support tool": Ambivalences around digital health from medical developers' perspective. Big Data & Society, 8. https://doi.org/10.1177/2053951721996733

Lewis, D. (2022). Automated Insulin Delivery in Real Life (AID-IRL): Real-World User Perspectives on Commercial AID. J Diabetes Sci Technol, 16, 503. https://doi.org/10.1177/1932296820957360

Lewis, D., & Leibrand, S. (2016). Real-World Use of Open Source Artificial Pancreas Systems. J Diabetes Sci Technol, 10, 1411. https://doi.org/10.1177/1932296816665635

Litchman, 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 #WeAreNotWaiting and #OpenAPS Movements. J Diabetes Sci Technol, 14, 999. https://doi.org/10.1177/1932296820932928

Löfgren, H., 1953-, Leeuw, E. J. J. de, & Leahy, M. (2011). Democratizing health: Consumer groups in the policy process. Edward Elgar. https://ubdata.univie.ac.at/AC11586275

Looped | Facebook. (n.d.). Retrieved August 25, 2023, from https://www.facebook.com/groups/TheLoopedGroup/

Lucherini, M. (2016). Performing diabetes: Felt surveillance and discreet self-management. Surveillance & Society, 14, 276. https://doi.org/10.24908/ss.v14i2.5996

Martin, L. (2017, March 31). OpenAPS Offers Open Source Tools for Diabetes Management. Make: https://makezine.com/article/science/openaps/. Last Accessed 15 June 2025

Matthes, J., & Rau, M. (2021, September 21). Das MiniMedTM 780G Advanced-Hybrid-Closed-Loop System zur Behandlung von Typ-1-Diabetes ist jetzt in Deutschland verfügbar. Medtronic. https://www.medtronic.com/de-de/ueber/news/pressemitteilungen-medtronic-gmbh/minimed-780g-system.html

Mattingly, C., Grøn, L., & Meinert, L. (2011). Chronic Homework in Emerging Borderlands of Healthcare. Cult Med Psychiatry, 35, 375. https://doi.org/10.1007/s11013-011-9225-z

Medtronic. (n.d.). Medtronic erhält CE-Kennzeichnung für das MiniMed 670G System für Europa. Retrieved October 23, 2023, from https://www.medtronic.com/de-de/fachkreise/diabetes/produkte/670g-ce-zulassung.html

Milewa, T. (2011). Health activism in the age of governance. In H. Löfgren 1953-, E. J. J. de Leeuw, & M. Leahy, Democratizing health: Consumer groups in the policy process (pp. 15–29). Edward Elgar. https://ubdata.univie.ac.at/AC11586275

Mol, A. (2000). What diagnostic devices do: The case of blood sugar measurement. Theor Med Bioeth, 21, 22. https://doi.org/10.1023/A:1009999119586

Mol, A. (2003). The Body Multiple: Ontology in Medical Practice. Duke University Press. https://doi.org/10.1515/9780822384151

Mol, A. (2008). The logic of care: Health and the problem of patient choice. Routledge. https://ubdata.univie.ac.at/AC10717157

Mol, A. (2009). The art of medicine Living with diabetes: Care beyond choice and control. The Lancet (British Edition), 373, 1757. https://doi.org/10.1016/S0140-6736(09)60971-5

Monecke, A. (2022). Verbessern DIY-Systeme die Lebensqualität? Deutsche Diabetes Gesellschaft e.V. https://www.ddg.info/diabetes-zeitung/ddg-09/2022/verbessern-diy-systeme-die-lebensqualitaet. Last Accessed 20 October 2023

Nicolucci, A., Kovacs Burns, K., Holt, R. I. G., Comaschi, M., Hermanns, N., Ishii, H., Kokoszka, A., Pouwer, F., Skovlund, S. E., Stuckey, H., Tarkun, I., Vallis, M., Wens, J., & Peyrot, M. (2013).

Diabetes Attitudes, Wishes and Needs second study (DAWN2™): Cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet. Med, 30, 777. https://doi.org/10.1111/dme.12245

Nielsen, H. B., Ovesen, L. L., Mortensen, L. H., Lau, C. J., & Joensen, L. E. (2016). Type 1 diabetes, quality of life, occupational status and education level– a comparative population-based study. Diabetes Res Clin Pract, 121, 68. https://doi.org/10.1016/j.diabres.2016.08.021

Nightscout Foundation. (n.d.). Welcome to Nightscout—Nightscout Documentation documentation. Retrieved August 22, 2023, from https://nightscout.github.io/

Oliver, N., Reddy, M., Marriott, C., Walker, T., & Heinemann, L. (2019). Open source automated insulin delivery: Addressing the challenge. NPJ Digit Med, 2, 124. https://doi.org/10.1038/s41746-019-0202-1

Omer, T. (2016). Empowered citizen "health hackers" who are not waiting. BMC Med, 14, 118. https://doi.org/10.1186/s12916-016-0670-y

Oudshoorn, N., & Pinch, T. (2003). How Users Matter: The Co-Construction of Users and Technology (1st MIT press paperback ed.). https://doi.org/10.7551/mitpress/3592.001.0001

Pannett, R., & Roubein, R. (2022, August 9). The GOP blocked an insulin price cap: What it means for diabetics. Washington Post. https://www.washingtonpost.com/health/2022/08/08/insulin-price-cap-diabetes-senate-republicans/. Last Accessed 22 February 2023

Panofsky, A. (2011). Generating sociability to drive science: Patient advocacy organizations and genetics research. Soc Stud Sci, 41, 57. https://doi.org/10.1177/0306312710385852

Paulus, T., Lester, J., & Dempster, P. (2014). Transcribing Audio and Video Data. In pages 93-113 & pages 93-113, Digital Tools for Qualitative Research.

Petryna, A., & Kleinman, A. (2020). The Pharmaceutical Nexus (A. Petryna, A. Lakoff, & A. Kleinman, Eds.; p. 32). https://doi.org/10.1515/9780822387916-002

Pinch, T., & Collins, H. (1998). ACTing UP: AIDS cures and lay expertise. In T. Pinch & H. Collins (Eds.), The Golem at Large: What You Should Know About Technology (pp. 126–150). https://ubdata.univie.ac.at/AC05491295

Pinch, T. J., & Bijker, W. E. (1984). The Social Construction of Facts and Artefacts: Or How the Sociology of Science and the Sociology of Technology Might Benefit Each Other. Social Studies of Science, 14, 441. https://doi.org/10.1177/030631284014003004

Plotnick, L., & Henderson, R. (1998). Clinical Management of the Child and Teenager with Diabetes. JHU Press.

Pols, J. (2013). The patient 2.many: About diseases that remain and the different forms of knowledge to live with them. Science & Technology Studies (Tampere, Finland), 26, 97.

Rabeharisoa, V., Moreira, T., & Akrich, M. (2014). Evidence-based activism: Patients', users' and activists' groups in knowledge society. BioSocieties, 9, 128. https://doi.org/10.1057/biosoc.2014.2

Regulation on Medical Devices, Pub. L. No. 2017/745 (2017). https://eur-lex.europa.eu/legal-content/EN/TXT/%20PDF/?uri=CELEX:32017R0745&from=EN. Last Accessed 11 June 2024

Resolution on Prevention, Management and Better Care of Diabetes in the EU on the Occasion of World Diabetes Day (2022). https://www.europarl.europa.eu/doceo/document/TA-9-2022-0409_EN.html#def_1_25

Rivas, C. (2018). Finding themes in qualitative data. In Seale (Ed.), Researching Society and Culture (pp. 431–453). Sage.

Rosenfeld, L. (2002). Insulin: Discovery and Controversy. Clin Chem, 48, 2288. https://doi.org/10.1093/clinchem/48.12.2270

Rosental, C. (2013). Toward a Sociology of Public Demonstrations. Sociological Theory, 31, 365. https://doi.org/10.1177/0735275113513454

Schipp, J., Skinner, T. C., Holloway, E., Scibilia, R., Langstrup, H., Speight, J., & Hendrieckx, C. (2022). 'We're all on the same team'. Perspectives on the future of artificial pancreas systems by adults in Australia with type 1 diabetes using open-source technologies: A qualitative study. Diabet Med, 39, n/a. https://doi.org/10.1111/dme.14708

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 Technol Ther, 23, 554. https://doi.org/10.1089/dia.2020.0652

Schneider, T., Gomes, T., Hayes, K. N., Suda, K. J., & Tadrous, M. (2022). Comparisons of Insulin Spending and Price Between Canada and the United States. Mayo Clinic Proceedings, 97. https://doi.org/10.1016/jmayocp.2021.11.028

Silverman, C. (2012). Understanding Autism: Parents, Doctors, and the History of a Disorder. Princeton University Press.

Sismondo, S. (2018). Ghost-Managed Medicine: Big Pharma's Invisible Hands. Mattering Press,Mattering Press.

Sjö. (2016). Blood glucose meter [Graphic]. https://commons.wikimedia.org/wiki/File:BGM_twopart.JPG. Last Accessed 24 January 2025

Sparring, V., Nyström, L., Wahlström, R., Jonsson, P. M., Östman, J., & Burström, K. (2013). Diabetes duration and health-related quality of life in individuals with onset of diabetes in the age group 15—34 years—A Swedish population-based study using EQ-5D. BMC Public Health, 13, 377. https://doi.org/10.1186/1471-2458-13-377

Steno Diabetes Center Copenhagen. (2019, May 20). Guidelines for the use of unauthorized Do-It-Your-self (DIY) medical technologies for the treatment of diabetes. https://www.sdcc.dk/presse-og-nyheder/nyheder/Documents/SDCC%20guidelines%20for%20DIY%20medical%20systems-english-version-200519.pdf. Last Accessed 8 November 2023

Švec, T. (2014). Accu-Chek Combo [Graphic]. https://commons.wikimedia.org/wiki/File:Accu-Chek_Combo.png. Last Accessed 26 February 2025

The OPEN Project. (n.d.). The OPEN Project. Retrieved September 6, 2023, from https://www.open-diabetes.eu. Last Accessed 6 September 2023

Thorne, S. E., Ternulf Nyhlin, K., & Paterson, B. L. (2000). Attitudes toward patient expertise in chronic illness. Int J Nurs Stud, 37, 311. https://doi.org/10.1016/S0020-7489(00)00007-9

Thornton, P. H., Ocasio, W., & Lounsbury, M. (2012). The Institutional Logics Perspective: A New Approach to Culture, Structure and Process (1st ed., p. xiv). https://doi.org/10.1093/acprof:oso/9780199601936.001.0001

Vallis, M., & Holt, R. I. G. (2022). User-driven open-source artificial pancreas systems and patient-reported outcomes: A missed opportunity? Diabet Med, 39, n/a. https://doi.org/10.1111/dme.14797

van Dijck, J. (2021). Seeing the forest for the trees: Visualizing platformization and its governance. New Media & Society, 23, 2819. https://doi.org/10.1177/1461444820940293

Wahlberg, A. (2017). The Vitality of Disease. In M. Meloni, J. Cromby, D. Fitzgerald, & S. Lloyd (Eds.), The Palgrave Handbook of Biology and Society (pp. 727–748). Palgrave Macmillan.

Wahlberg, A., & Rose, N. (2015). The governmentalization of living: Calculating global health. Economy and Society, 44, 90. https://doi.org/10.1080/03085147.2014.983830

Walsh, J., Roberts, R., Morris, R., & Heinemann, L. (2015). Device Connectivity: The Next Big Wave in Diabetes. J Diabetes Sci Technol, 9, 705. https://doi.org/10.1177/1932296814568806

Weinberger, N., Pobiruchin, M., Fritsche, A., & Woll, S. (2023). "Do it yourself" therapy for type 1 diabetes; A Citizen Science project on the use of self-developed technologies for automated insulin delivery. Diabetologe, 19(2). https://doi.org/10.1007/s11428-022-00970-w

Wenner, H. (2024, March 1). Zulassung, Zertifizierung und CE-Kennzeichnung von Medizinprodukten. VDE Verband Der Elektrotechnik Elektronik Informationstechnik e.V. https://www.vde.com/topics-de/health/beratung/medizinprodukte-zulassung-zertifizierung-ce-kennzeichnung#. Last Accessed 12 June 2024

Wesalius. (2018). Insulin analog 100 IU/1ml pen [Graphic]. https://commons.wikimedia.org/wiki/File:Insulin_analog_100_IU-1ml_novomix_pen_white_background.jpg. Last Accessed 25 January 2025

West, B., & Lewis, D. (2016). Frequently Asked Questions—OpenAPS 0.0.0 documentation. https://bewest-openaps-docs.readthedocs.io/en/latest/docs/Resources/faq.html. Last Accessed 5 September 2023

Wiedemann, L. (2019). Self-Tracking: Vermessungspraktiken im Kontext von Quantified Self und Diabetes (1st ed. 2019). Springer Fachmedien Wiesbaden Imprint: Springer VS. https://doi.org/10.1007/978-3-658-27158-9

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Appendix

Accompanying text on registration form for participation

German (Original)

Vielen Dank für Ihr Interesse an einer Interviewteilnahme im Rahmen meiner Masterarbeit.

Forschungsthema und -ziel

Im Rahmen meiner Masterarbeit möchte ich die Nutzung von DIY Loop-Systemen in Deutschland aus einer wissenschaftlichen Perspektive betrachten. Hierfür suche ich nach aktiven DIY-Loopern, die mir in individuellen Interviews über ihre Erfahrungen hierzu berichten. Von besonderer Relevanz sind für mich dabei Ihre persönlichen Geschichten:

- Wie kamen Sie zur Wahl eines selbstgebauten (DIY) Loopsystems?
- Wie wirkt sich die Nutzung eines DIY-Loopsystems auf Ihren Alltag und den Umgang mit Ihrer Diabetes I-Erkrankung aus?

Dabei möchte ich die Bedeutung von selbstgebauten DIY-Technologien zur Diabetes Typ I-Behandlung als Alternative zu konventionellen Geräten herausstellen. Durch diese Patienten-orientierten Perspektive möchte ich auch eine Grundlage dafür bieten, das deutsche Gesundheitswesen PatientInnen-freundlicher gestalten zu können hinsichtlich der Diabetes I-Versorgung – aber vielleicht auch anderer chronischer Erkrankungen.

Teilnahme

Bitte füllen Sie vorab das folgende Formular aus. Dies ermöglicht mir zu prüfen, ob Sie der Zielgruppe für meine Forschungsfrage entsprechen. Im Anschluss melde ich mich bei Ihnen zurück.

Hinweis: Hierbei handelt sich um eine Vorabbefragung. Die eigentlichen Interviews finden separat und zu individuell vereinbarten Terminen statt, planmäßig per Videotelefonie. Alle im Interview erfassten Daten werden anonymisiert.

English (Translated)

Thank you very much for your interest in participating in an interview as part of my master's thesis.

Research topic and objective

As part of my master's thesis, I would like to examine the use of DIY Loop systems in Germany from a scientific perspective. For this, I am looking for active DIY Loopers who are willing to share their experiences in individual interviews. Your personal stories are of particular relevance to me:

- How did you come to choose a self-built (DIY) Loop system?
- How does using a DIY Loop system affect your everyday life and the management of your type 1 diabetes?

I aim to highlight the significance of self-built DIY technologies for the treatment of type 1 diabetes as an alternative to conventional devices. With this patient-centered perspective, I also hope to provide a basis for making the German healthcare system more patient-friendly in terms of type 1 diabetes care — and perhaps for other chronic illnesses as well.

Participation

Please fill out the following form in advance. This will allow me to check whether you fit the target group for my research question. I will then get back to you.

Note: This is a preliminary survey. The actual interviews will take place separately at individually agreed times, usually via video call. All data collected during the interview will be anonymized.

Informed Consent for Participation

Universität Wien
Fakultät für Sozialwissenschaften
Institut für Wissenschafts- und Technikforschung

universität wien

Einverständniserklärung

Zustimmung zu einem Interview und der Verwendung dieser Daten im Rahmen eines Forschungsprojekts

Projektziel: Zweck dieser Forschungsarbeit ist es, die Nutzung von selbstgebauten (DIY) Loop-Systemen zur automatisierten Insulindosierung durch Diabetes 1-Patienten zu erforschen. Von besonderem Interesse sind hierbei die Beweggründe der Diabetespatienten zur Nutzung der DIY-Technologie statt zugelassenen Medizinprodukten zur automatisierten Insulindosierung. Ebenso von besonderer Relevanz sind die Auswirkungen der Nutzung der DIY-Technologien im Alltag der Diabetes 1-PatientInnen, insbesondere um Umgang mit ihrer Krankheit.

Ich stimme hiermit zu, ein Interview zum Thema der Nutzung von DIY-Loop-Systemen zur automatisierten Insulindosierung durch Diabetes 1-Patienten zu geben. Die Teilnahme am Interview ist freiwillig.

Ich wurde darüber informiert, dass das Interview digital aufgezeichnet wird und bin damit einverstanden. Die Aufnahme wird von dem durchführenden Studenten bis zum Abschluss der Forschungsarbeit gespeichert. Im Rahmen dieser Forschungsarbeit am Institut für Wissenschafts- und Technikforschung wird die Aufnahme transkribiert und analysiert.

Die Aufnahme wird nur dem durchführenden Studenten zugänglich sein. Einige Aussagen können in studentischen Arbeiten und Berichten zitiert werden, die im Rahmen des abschließenden Master-Forschungsprojekts verfasst werden. Meine Aussagen werden hierbei anonymisiert, d. h. mein Name und meine Position werden im endgültigen Forschungsdokument nicht erscheinen. Die Ergebnisse der Studie werden veröffentlicht und im Archiv der Universität Wien gespeichert. Ebenso besteht eine Veröffentlichung der Forschungsergebnisse im Rahmen eines Beitrags, z. B. in der wissenschaftlichen Literatur oder im Rahmen einer Präsentation. Hierbei gelten ebenso die Prinzipien der Anonymisierung.

Mir ist bewusst, dass dieses Interview freiwillig stattfindet und ich daher jederzeit unterbrechen oder abbrechen kann. In solch einem Fall werden die mich betreffenden Daten, die bereits erhoben wurden, nur mit meiner expliziten Zustimmung verwendet. Mir ist bewusst, dass ich mein Einverständnis zur Benutzung meiner Daten auch künftig jederzeit widerrufen kann. Mir ist bewusst, dass zum Zeitpunkt eines Widerspruchs bereits erfolgte Veröffentlichungen nicht mehr rückgängig gemacht werden können, jedoch auf jegliche Weiterverwendung der in diesem Interview erhobenen Daten zukünftig verzichtet wird.

Name der interviewten Person:

E-Mail-Adresse:

Datum:

_____ _____

Unterschrift der interviewten Person Unterschrift Interviewer

Informed Consent for Usage of Shared Pictures/Screenshots

Universität Wien
Fakultät für Sozialwissenschaften
Institut für Wissenschafts- und Technikforschung

universität wien

Einverständniserklärung

Zustimmung zur Nutzung und Weiterverarbeitung von übermittelten Screenshots/Bilddateien

Projektziel: Zweck dieser Forschungsarbeit ist es, die Nutzung von selbstgebauten (DIY) Loop-Systemen zur automatisierten Insulindosierung durch Diabetes 1-Patienten zu erforschen. Von besonderem Interesse sind hierbei die Beweggründe der Diabetespatienten zur Nutzung der DIY-Technologie statt zugelassenen Medizinprodukten zur automatisierten Insulindosierung. Ebenso von besonderer Relevanz sind die Auswirkungen der Nutzung der DIY-Technologien im Alltag der Diabetes 1-PatientInnen, insbesondere um Umgang mit ihrer Krankheit.

Ich stimme hiermit zu, im Rahmen des Interviews entstandene Screenshots bzw. Bildschirmaufnahmen (Bild- oder Videodateien) zu erstellen. Diese Tätigkeit ist freiwillig. Die entstandenen Bild- und Videodateien kann ich an den Interviewführenden digital übermitteln.

Mit der Übermittlung der Bild- und Videodateien trete ich die Urheberrechte daran ab. Der Interviewführende kann diese Bild- und Videodateien im Rahmen seiner Forschungsarbeit nutzen. Eine Nennung meines Namens erfolgt auf Grundlage der Anonymisierung nicht. Eventuelle Elemente der Bild- oder Videodateien, welche eine Anonymisierung nicht möglich machen, werden entfernt bzw. unkenntlich gemacht.

Der Interviewführende darf die Bild- oder Videoaufnahmen im Rahmen seiner Forschungsarbeit und auch damit verbundenen Veröffentlichungen nutzen, insbesondere um im Rahmen des Interviews getroffene Aussagen zu illustrieren bzw. zu erklären.

Mir ist bewusst, dass ich mein Einverständnis zur Nutzung der Bild- und Videodateien jederzeit, auch künftig, widerrufen kann. Mir ist bewusst, dass zum Zeitpunkt eines Widerspruchs bereits erfolgte Veröffentlichungen nicht mehr rückgängig gemacht werden können, jedoch auf jegliche Weiterverwendung zukünftig verzichtet wird.

Name der interviewten Person:

E-Mail-Adresse:

Datum:

_____ _____

Unterschrift der interviewten Person Unterschrift Interviewer

Introduction of interviews

Welcome, Who am I?

- My name
- Master student in Science- and Technology Studies at University of Vienna
- About writing my master thesis

What is the interview about?

As part of my master's thesis, I would like to examine the use of DIY Loop systems in Germany from a scientific perspective. For this, I am looking for active DIY Loopers who are willing to share their experiences in individual interviews. Your personal stories are of particular relevance to me:

- How did you come to choose a self-built (DIY) Loop system?
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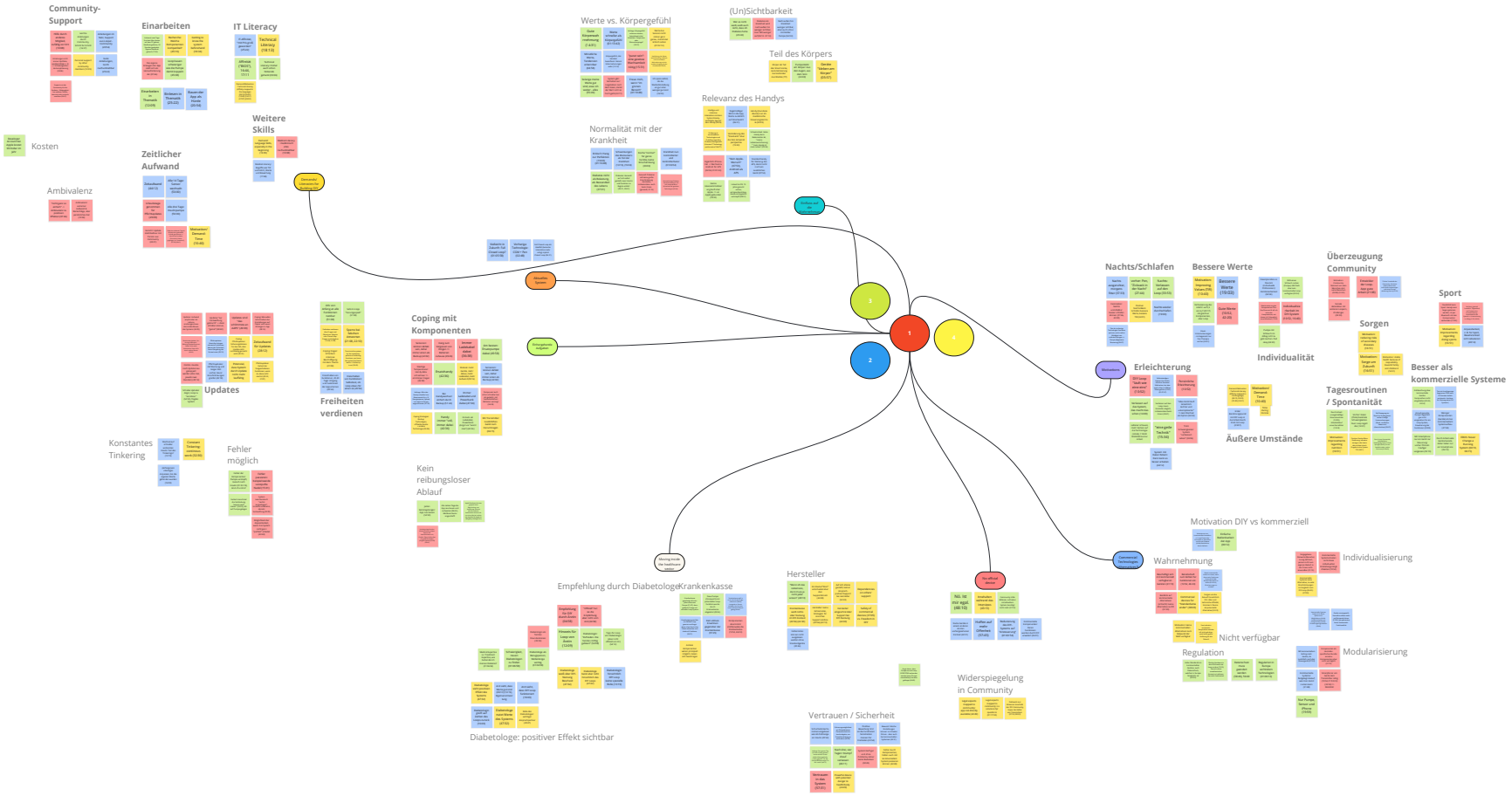
Structure of the interview

- About 45 minutes: Question catalogue
- Time left also for aspects, that the interviewee perceives as important but that I have not covered yet by my questions.
- Closing of the interview

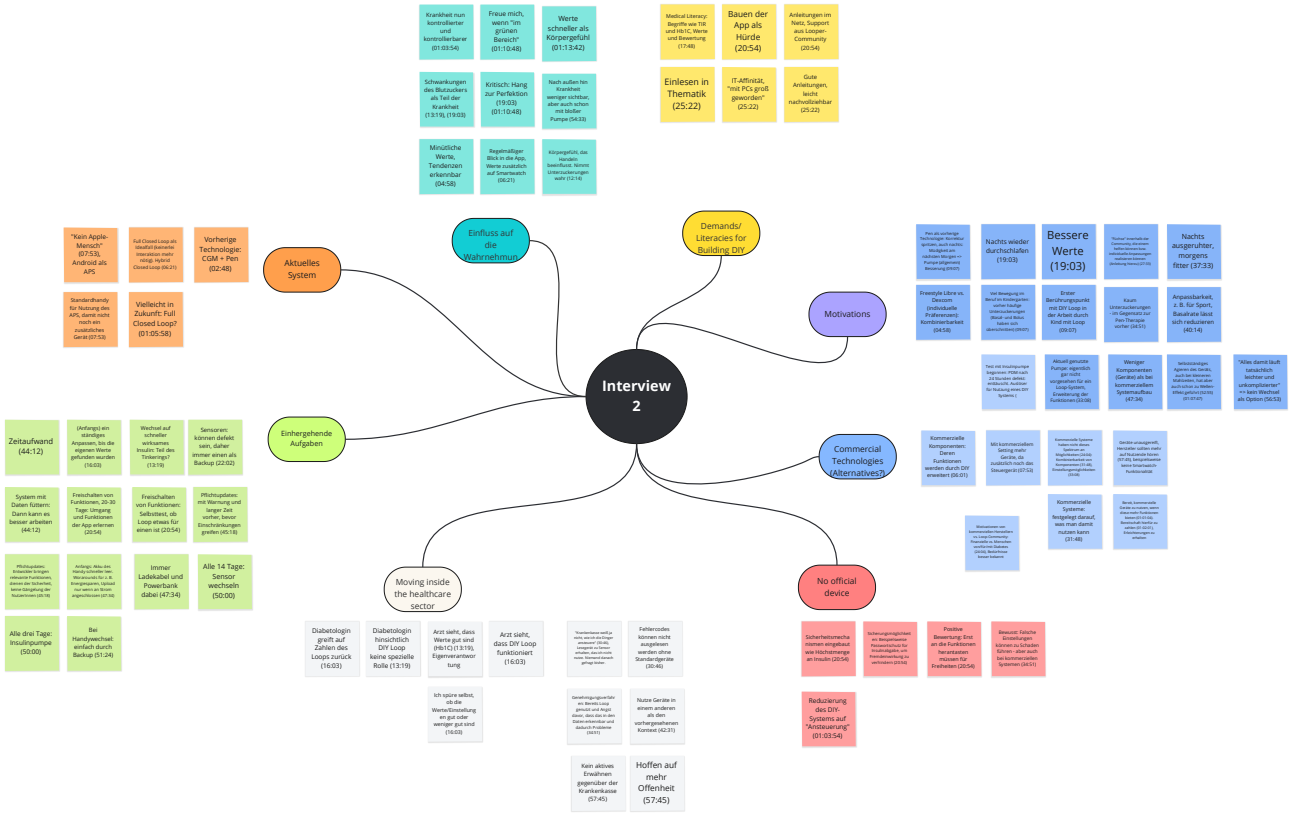
Consent

- Confirmation that I have already received written consent.
- Stressing voluntary character of participation and possibility to stop interview anytime.
- Asking again for verbal consent for recording and processing of interview.
- Start of recording

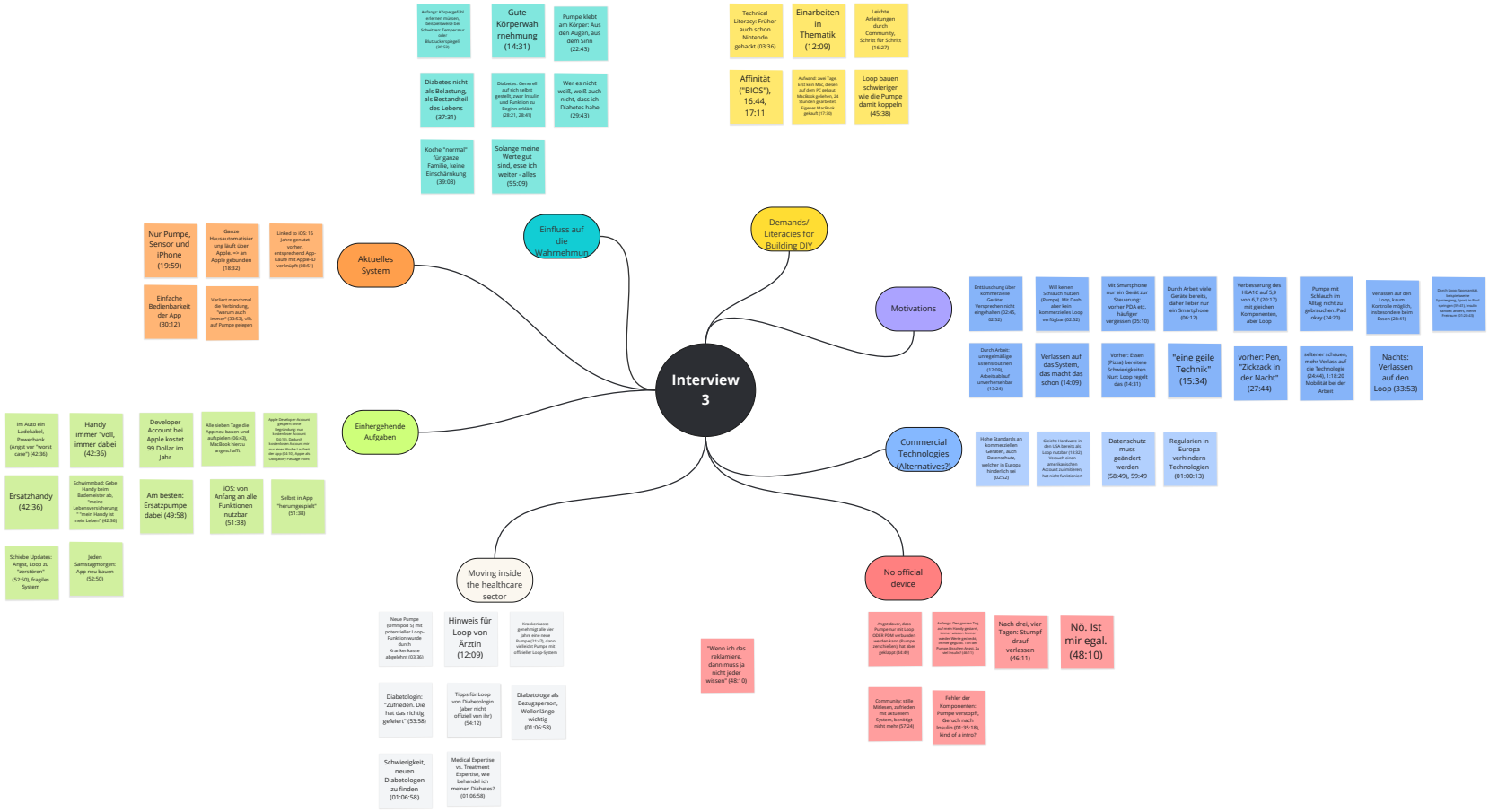
Coding Board: Merged Board



Coding Board: Thomas



Coding Board: Andrea



Coding Board: Markus