Technology-Driven Disruption of Healthcare and 'UI Layer' Privacy-by-Design

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Marcelo Corrales Compagnucci,[*] *Mark Fenwick,*[**] *Helena Haapio,*[***] *Timo Minssen*[****] *& Erik P.M. Vermeulen*[*****]

Abstract The use of digital technologies in healthcare is changing how medical treatments are developed by researchers, applied/practiced by medical professionals and experienced by patients. This article argues that a defining feature of this disruption is the emergence of new medical "apps" that leverage algorithm-based AI systems. As the use of such apps and AI wearables goes mainstream and new players—notably "Super Platforms" with digital rather than a medical expertise—enter the healthcare sector, the traditional means of providing medical services will be further transformed.

These developments pose several challenges for regulators and other policymakers, most obviously, in the context of privacy and data protection. Here, we examine how the emerging field of Legal Design can provide a more transparent infrastructure that embeds relevant legal protections in the user interfaces of healthcare products and services. Such a user interface (UI) focused Privacy-by-Design approach offers a number of advantages, most obviously greater transparency, accountability and (consequently) human choice. The article offers several real-world examples of design patterns that illustrate the value of UI focused Privacy-by-Design in protecting individuals' sensitive information, enabling people to make choices and retain control of their personal data. The article concludes with some examples and reflects on the challenges specific to implementing Legal Design in an eHealth context.

Keywords AI, Algorithms, Apps, Data Protection, Design Patterns, GDPR, Healthcare, Legal Design, Privacy, Super Platforms, UI Layer Privacy-by-Design

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1 Introduction

The use of digital technologies in healthcare—most obviously in hospitals and research facilities—is changing how medical treatments are developed by researchers, delivered by medical professionals and experienced by patients. Central to this disruption is the use of algorithm-based AI systems to analyse massive amounts of medical data, better understand medical conditions and their causes, and make highly accurate diagnoses. As the use of mobile apps and medical wearables goes mainstream and the capacities of new technologies further develop, this disruption seems certain to continue. The traditional means of providing medical services will be further transformed as new players—notably "Super Platforms" with a digital, rather than a conventional medical, expertise (Apple or Tencent, for instance)—enter the healthcare space.

These developments are already influencing the work of medical professionals and researchers. Adapting to this new environment is now crucial for all stakeholders, but such adaptation is not always easy. After all, new technologies create an unprecedented combination of ethical dilemmas and technological challenges and existing "best practice" offers little assistance in identifying the way forward. But the ongoing disruption of healthcare also creates several complex legal challenges for regulators and other policy makers. Many of these challenges are a result of the processing of deeply personal and highly sensitive data that is crucial to emerging healthcare models. Finding effective and transparent solutions to these regulatory issues is a key challenge in ensuring public confidence in healthcare providers, both old and new. Moreover, given the importance of medical information to individuals, effectively addressing these policy challenges is crucial in ensuring public confidence in the capacity of governments to navigate the Digital Revolution, more generally.

While opening a new world of possibilities, the application of new digital technologies in a healthcare context can be likened to a "Black Box," involving, as it does, a number of complex issues that create serious doubts and uncertainties about current legal arrangements. Most obviously, there are the privacy concerns and the suggestion that the use of such technologies can run counter to the consent of individuals. This is because new forms of healthcare involve the collection, processing and transfer of sensitive personal data in unanticipated ways and often without adequate opportunities for truly informed consent.

Everyone seems to agree about the general principles for dealing with these regulatory challenges. A respect for human autonomy and dignity is at the core of all discussion. Personal data collected by data systems should also be secure and commentators also underscore the importance of "transparency." Data and algorithms used to create digital systems should be accessible and the traceability of data should be guaranteed. In other words, operators should be able to explain all decisions that computer systems make involving private data. As such, there is a broad consensus that data systems should empower human beings, allowing individuals to make informed decisions and—ultimately—retain full control over their personal information.

However, operationalizing these principles has proved much more difficult. In part, this reflects reasonable disagreement as to the appropriate level of regulation and the specific formulation of relevant rights. But, difficulties in identifying an appropriate regulatory

response also reflect the reality that lawyers and the law do not enjoy a good reputation when it comes to transparency, clarity and the empowerment of "ordinary" people (i.e., those unfamiliar with the law). There is currently an enormous amount of public mistrust of "the law"—particularly in a privacy context—and recent scandals involving Facebook have merely fed such concerns. Moreover, legal issues are often confounded with organizational and ethical issues. As such, any regulatory response has to overcome legitimacy concerns before being able to establish credibility amongst the public.

In this piece, we therefore make an argument for a "Legal Design"-based approach to privacy that we present as an example of Privacy-by-Design. Legal Design is an interdisciplinary approach to apply human-centred design principles to prevent or address legal problems. It prioritizes the point of view of ordinary people as the "users" of law, i.e., citizens, consumers, business people, rather than legal professionals. It builds on the vision of a legal system that is more straightforward, more engaging, and more user-friendly. Crucially, this includes how information is presented, as well as how processes are set up and how policies are established. In the broadest sense, Legal Design can be situated in the Access to Justice movement in that it focuses on opening up access to legal information and protections. In a narrower sense, it is bringing a design-focus to legal information, products, or services. The overall goal is to improve how lawyers communicate, deliver services, and how rules and policies are made—all with the aim of enhancing the experience, comprehension, and empowerment of law's users.[1]

As indicated, privacy represents a broad variety of concerns including autonomy, accountability, transparency and security. The traditional Privacy-by-Design approach focused on anticipating such concerns early in the software development process. That is, the architectural design of the computer software—or its "code layer."[2] But translating these concerns to the end users has proven more difficult. Therefore, the approach taken here is to emphasize accessible communication of relevant information and interactive design—and, in particular, to focus on the "user-interface" (UI) layer. In that respect, the examples provided in this work come mainly from (legal) information design, i.e., patterns that aim to improve the communication and comprehension of legal information. Such "design patterns" can provide this approach with a more universal set of tools. For architects, interaction designers, and software engineers, design patterns and pattern libraries are a common way to share transferable solutions to commonly occurring problems. In a legal context, design patterns were first applied to contract communications.[3] In recent years, however, the development of prototypes of design patterns and pattern libraries has developed rapidly in different contexts.

In a healthcare-privacy context, Legal Design can therefore provide a reliable and transparent infrastructure for embedding relevant legal protections in the user interfaces of healthcare products and services. Such a UI-focused Privacy-by-Design approach offers a number of advantages, most obviously greater transparency, accountability and (consequently) human choice. The paper is structured as follows. Section 2 introduces the claim that digital technologies are disrupting healthcare. We focus on the emergence of new healthcare apps and

[1] "What is Legal Design?" in Legal Design Alliance, n.d.
[2] See e.g., the privacy patterns available at https://privacypatterns.org and https://privacypatterns.eu.
[3] See Haapio & Hagan, 2016, and Haapio et al., 2018.

the trend for "Super Platforms" to move into this space, often via the acquisition of start-ups. These developments raise a number of legal issues, particularly in the context of recent developments in privacy and data protection. Section 3 introduces the main argument, namely that the emerging field of Legal Design can play a crucial role in ensuring better privacy protection by providing more open and accessible infrastructures that embed relevant legal requirements in user-friendly interfaces for healthcare products and services. The article offers several real-world examples of such "UI layer" design patterns to illustrate how Privacy-by-Design can be implemented by helping participants better understand their choices, rights and the types and uses of data that are being collected. Section 4 provides some of the challenges and examples of implementing Legal Design in the digital healthcare sector. Section 5 concludes.

2 Technology-Driven Disruption of Healthcare, "Super Platforms" & Evolving Privacy Law

This section makes three claims. Firstly, in the healthcare sector multiple start-ups, as well as traditional healthcare providers are developing new and innovative apps—often powered by AI and algorithm solutions—to improve healthcare services (Section 2.1). Secondly, what we here refer to as "Super Platforms"—such as Tencent and Apple—see the healthcare sector as a potentially lucrative market and are now moving into the space, often via the acquisition of the above-mentioned start-ups (Section 2.2). Finally, these two developments involve the collection, processing and transfer of personal and highly sensitive data in unanticipated ways and often without adequate opportunities for truly informed consent. Given the sensitivity of the information and public concerns around Super Platforms, this is a worrying trend. Some of the resulting legal challenges are introduced via a discussion of EU developments, namely the EU General Data Protection Regulation (GDPR)[4] and Ethics Guidelines for Trustworthy AI[5] (Section 2.3).[6]

2.1 Technology-Driven Disruption of Healthcare

Digital innovation has impacted all sectors of the economy and society. Some industries—such as retail, travel, and entertainment—have experienced fast change, whereas the disruption of other sectors—such as healthcare—has proceeded more slowly. This presents something of a paradox. While life-changing technological breakthroughs can develop at a rapid pace,

[4] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
[5] European Commission High-Level Expert Group on Artificial Intelligence, 2019.
[6] During the time of writing this paper there were other initiatives released in the context of AI, data protection and ethics and the safety and liability implications of AI, such as the European Commission's Report on Safety and Liability Implications of AI, the Internet of Things and Robotics (European Commission, 2020a) and the Commission's White Paper on Artificial Intelligence: A European Approach to Excellence and Trust (European Commission, 2020b).

improvements in the way healthcare is delivered are often deployed more slowly.[7] One of the reasons for this slower adoption of digital technologies in healthcare contexts is the heavily regulated nature of this sector. Stringent rules for safety and quality control often stifle the dissemination of new products and services.[8] Sweeping technological advances are posing challenging legal questions and the preeminent question is always how to balance the protection of consumers / patients and at the same time foster innovation and economic growth.[9]

Nevertheless, in spite of this structural obstacle, different types of technological enablers, business models, and value networks seem to have facilitated a digital transformation. A recent systematic study by Hermann et al., surveyed the 2017 Forbes 2000 data from an annual ranking of the top 2000 companies in the world. A search query of the terms "digital health," "digital medicine," "eHealth," "health care," "mHealth, "outcomes-based reimbursement," and "value-based care" were used to identify the 100 leading companies. Furthermore, the 100 most successful technology, life science and start-ups active in the healthcare sector were scrutinized based on the amount of funding they received according to the CB insights database.[10]

A further analysis revealed more than 400 projects and collaborations, identifying emerging patterns that differentiate corporations within the healthcare sector with respect to their strategies in the context of the digital transformation in healthcare. The results of the study revealed that established companies show strengths in improving the traditional business model they have been pursuing before. In contrast, start-ups seem to be more agile and flexible to explore new market segments moving towards new forms of collaboration and disruptive innovations. Since the healthcare sector is heavily regulated, established companies with a better understanding of its regulatory framework appear to have clear advantages. However, start-ups seem to be getting better at meeting this challenge.[11]

Start-ups with their agile corporate culture and innovative technology and life science companies with their regulatory experience should partner together to drive the digital transformation of the healthcare sector. By engaging in collaborative projects, large companies can lower their costs, while addressing all patient needs. This will also allow them to innovate in new products and services and to quickly adapt when a disruptive business model emerges.[12]

Against this backdrop, the new digitally driven healthcare sector will crucially disrupt the healthcare services by providing consumers (patients, researchers and physicians) with more choice, access, transparency, curation of medical information, and discovery, with information being more focused and analytic-driven.[13] This is largely due to the democratization of healthcare which has opened up the opportunity for start-ups to disrupt the industry.[14]

According to the Stanford Medicine 2018 Health Trends Report,[15] the democratization of healthcare is characterized by two major components: i) the distribution of data, and; ii) the

[7] Murphy & Jain, 2018.
[8] Herrmann et al., 2018.
[9] Eggers, Turley & Kishnani, 2018.
[10] Herrmann et al., 2018.
[11] Herrmann et al., 2018.
[12] Herrmann et al., 2018.
[13] Landi, 2018.
[14] See Paine, 2017.
[15] Stanford Medicine, 2018.

ability to generate and scale up insights. Data is growing exponentially—and flowing more freely—across our healthcare system faster than ever before. Historically, the healthcare system has operated as a closed ecosystem, having the hospital or research institution as a main hub and primary gatekeepers of medical information. Information flow was hierarchical and linear, *from* the expert physician *to* the patient. But now—again, largely due to digitization—information flow has become much more ubiquitous and "flatter." Data is constantly generated and patients are now experiencing a much more diverse healthcare system and more complex forms of information sharing relationships.[16]

This transformation is challenging the healthcare sector to adapt. New tools are now available that can interpret data more accurately and patients are now experiencing a new digital healthcare system. A growing number of healthcare providers and other firms—often tech-driven start-ups—are leveraging the above-mentioned developments to create different kinds of apps to provide better services to patients. They use AI solutions and algorithms to improve personalized medicine, genetic research, clinical trials, mental health, drug discovery, data analytics, medical records, communication with patients, etc.[17] The availability of large amounts of data from multiple modes of information, combined with AI, machine learning (ML) and other expert systems, has the potential to transform the healthcare system.

Patient-oriented medical "chatbots" and conversational AI technology are good examples of these solutions. Chatbots are computer programs designed to simulate human conversations and learn directly from such communication. These chatbots interact with potential patients visiting the website online, helping them to schedule appointments, find a doctor and even receive a first consultation based on the symptoms. Florence[18] is, for instance, a chatbot designed for older patients that reminds them to take their pills on a regular basis and Izzy[19] helps women better track their menstrual cycle and can also work as a reminder for the birth control pill.[20] Efficient diagnosis assistant systems such as Your.Md[21] and CitizenDoc[22] are other examples of chatbots based on such expert systems. They were developed to help patients find a solution to the most common symptoms through AI.[23]

The market for AI wearable devices (smart watches, fitness trackers, connected headsets, smart glasses, wrist bands and other forms of smart wearable devices) is also increasing steadily.[24] Among the wide range of wearable devices now available, wrist wearables such as smart watches and wrist bands—commonly used in fitness and sport activities—seem to have become mainstream. Such wearable devices include a number of sensors providing continuous real-time valuable data about users' vital signs (e.g., heart rate, skin temperature) and environmental variables (e.g., movements) that can be used for many different purposes.[25]

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[16] Stanford Medicine, 2018.
[17] See e.g., Rijcken, 2019, 127–128.
[18] See Florence, n.d.
[19] See Izzy Care, n.d.
[20] Peyrou, Vignaux & André, 2019, 30–31.
[21] Your.MD is a free service that uses AI to help patients find health related information and improve their choices. See Your.MD, n.d.
[22] See CitizenDoc, n.d.
[23] Peyrou, Vignaux & André, 2019, 30–31.
[24] Luxton et al., 2016, 139.
[25] De Arriba-Pérez, Caeiro-Rodríguez & Santos-Gago, 2016, 1538.

What is particularly significant, however, is that these new healthcare products and services have attracted the attention of some of the largest companies in the world, and these companies are now starting to expand their healthcare operations. A disruptive challenge for both the start-ups and life science companies is the strong focus of Big Tech companies to establish the emerging platform business model and assume the necessary negotiating power to appropriate the value created as will be explained in the following section.[26]

2.2 "Super Platforms"

A major development in the global economy over the last two decades has been the emergence of businesses that organize and define themselves as "platforms."[27] By platform, we refer to any organization that uses digital and other emerging technologies to create value by facilitating connections between two or more groups of users. Obvious examples of such companies are Amazon, Facebook, or Uber. The type of connection facilitated by different platforms varies depending on the platform. Some platforms facilitate connections between the buyer and seller of goods (e.g., Amazon); some facilitate connections between those wanting a service and those willing to provide it (e.g., Airbnb or Uber); and others simply facilitate connections (information exchange) between friends (e.g., Facebook).[28] What is common to all platforms, however, is that they make connections between "creators" and "extractors" of value and the platform generates a profit from making these connections, either by taking a commission or through advertising.[29] What is interesting, however, is the speed with which these platform-oriented businesses have evolved into what is sometimes referred to as "Big Tech" or what we would call here "Super Platforms." Here, we first describe Super Platforms and then show how they are moving into the healthcare space.

a) Super Platforms have a huge global user-base and enormous market power and cultural influence

A cursory look at any list of the world's largest companies illustrates the speed of growth of platforms such as Amazon, Facebook or Uber. In the 2000s, none of the biggest companies in the world were platforms. Now, you could make the argument that over half of the world's ten largest companies are organized as platforms or, at least, derive a significant slice of their income from platform operations. The emergence and growth of Super Platforms is a significant event, not least because such platforms have become a routinized feature of everyday life within such a short period.[30] To illustrate this rise, consider that it took the radio 38 years to reach 50 million users. It took television 13 years to achieve the same degree of market penetration. Facebook, however, "only" needed two years to gain the same number of users. Now it has an active user base of over 2 billion. As such, Super Platforms enjoy enormous economic and cultural influence. They are capable of influencing and shaping nearly

[26] Herrmann et al., 2018.
[27] See e.g., generally, Codagnonce, Karatzogianni & Matthews, 2019.
[28] See Fenwick, McCahery & Vermeulen, 2019.
[29] Parker, Van Alsyne & Choudary, 2016.
[30] Parker, Van Alsyne & Choudary, 2016.

every aspect of life, from consumers' shopping behaviour to voting choices (consider the 2016 US Presidential Election and Brexit Referendum).[31] It is this power that has triggered regulators into action and regulating "Big Tech" is now one of the main political challenges of the Digital Age.[32]

b) Super Platforms have disrupted incumbents across all sectors of the economy

In the same way that industrial companies transformed how business was conducted in the context of the Industrial Revolution, technology-driven Super Platforms have completely changed the contemporary business landscape. In a business context, technologies have offered new opportunities for entrepreneurs and consumers to develop and enjoy previously unimagined products and services. The rapid growth of Super Platforms has compelled incumbents to re-visit their business models. Traditional retailers, for example, have been forced to shifting their distribution channels for their products from "stores" to online platforms. For example, big industrial giants, such as General Electric, are attempting to transform themselves from industrial manufacturers into data science companies that utilize platforms, software, applications, and Big Data.[33] Also, as new Fintech firms are moving into the financial services space, many banks are thinking about how to add platform services to their operations.[34] In fact, every organization—including healthcare providers—are obliged to integrate platform ideas and experience into their operations.

c) Super Platforms are algorithm and AI-driven

The of use platforms has obviously been made possible by the development and proliferation of digital technologies—most obviously, PCs and smartphones, the Internet, algorithms, and cloud computing. In particular, they leverage a combination of global networks, massive amounts of data, and AI/algorithms analytics. ML and expert systems—such as the abovementioned medical chatbots that simulate human conversation—are obvious examples that illustrate this phenomenon. ML and other related expert systems are based on a relatively new subfield of computer science. It is seen as a new subset of AI and refers to the scientific study of algorithms and statistical models that computer systems utilize to effectively perform certain tasks without employing explicit instructions.[35]

d) Super-Platforms have evolved into global "ecosystems" & are moving into the healthcare space

The above features have allowed Super Platforms to leverage their platform operations in order to support the development of a global business "ecosystem."[36] An ecosystem is defined in

[31] Corning, 2018.
[32] See Galloway, 2017.
[33] See GE Digital, n.d.
[34] Ernst & Young, 2018; Gulamhuseinwala, 2017; Pollari, 2018.
[35] See e.g., Alpaydin, 2016.
[36] See Fenwick, McCahery & Vermeulen, 2019.

biology as a community of living organisms existing in conjunction with the non-living components of their environment, interacting as a system. In a business context, we might think of an ecosystem as a combination of business entities co-existing and working in close partnership. They constitute an online-to-online (O2O) infrastructure, which spans a vast audience including different sectors of economic activity. Super Platforms provide different types of tools, resources, products and services to both businesses and consumers. They operate in a uniform, standardized, and highly interconnected fashion.[37] Apple is a good example of such a technology-driven ecosystem comprising connected, interoperable, and seamlessly interacting products/devices (iMac, iPad, iPhone, Apple Watch, AirPods, iPod devices)[38]. As mentioned, a key challenge today facing regulators—and governments more generally—is to find the necessary mechanisms to promote innovative *and* socially responsible global ecosystems. All too often, such ecosystems become mired in controversy over their business practices.

In particular, there are concerns around the business model that such Super-Platforms have developed. At first, these firms promised a more decentralized, efficient, and less formal economy and society. However, as these tech businesses scaled into some of the largest businesses in history ("Super Platforms"), they have become shrouded in controversy and are now widely seen as hugely problematic. A specific concern involves how such firms collect data, analyze that data, and then sell targeted advertising to anyone willing to pay. Critics of this model suggest that it represents a new form of "surveillance capitalism" that needs to be urgently addressed.[39] Understanding these difficulties and finding an appropriate regulatory response is particularly pressing, especially as Super Platforms expand their operations into new and socially sensitive sectors, such as healthcare.

Given that the healthcare market has become a highly dynamic sector of the economy, Super Platforms see healthcare as a potentially lucrative market and are moving into the space often via the acquisition of healthcare-focused start-ups. Tencent and Apple, for example, have already started to invest in the automation of healthcare and scientific research.

One of the best examples of this is Chinese tech giant Tencent, which has become the largest e-health platform in China. Before penetrating the healthcare sector, Tencent was already the owner of "WeChat," an app used for "Everything-as-a-Service" (XaaS).[40] WeChat is basically a combination of WhatsApp, Facebook, Paypal, Uber and more, including services such as text messaging, shopping, ride hailing, food delivery, money transfers, and payments for all kinds of consumers services.[41] Tencent was already considered to be a Super Platform in its own right. In 2014 Tencent started to provide healthcare services and became one of the most important Super Platforms in the healthcare industry. Tencent provides services such as online consultations, medical appointments with doctors, payments for medicine and services at hospitals, etc. Today, there are over 38,000 medical institutions able to deliver integrated

[37] Corning, 2018.
[38] iMac, iPad, iPhone, Apple Watch, AirPods and iPod are trademarks of Apple Inc., registered in the U.S. and other countries.
[39] Zuboff, 2019.
[40] Everything-as-a-Service (XaaS) refers to a variety of services, including, platforms, IT infrastructure, software, databases and other IT resources. See Nanos, Manthou & Androutsou, 2019, 129.
[41] Buvailo, 2018.

healthcare services using Tencent's open platform[42] and applications through a wide range of channels.[43] Tencent recently partnered with Babylon Health, a British start-up developing online healthcare assistant apps. This new cooperation enables users to get immediate access to online medical consultation by just messaging their symptoms. Tencent also entered into a recent collaboration with iCarbonX, a Chinese AI-driven healthcare unicorn which attempts to create a complete digital representation of one's biological self by using genetic data, epigenetics and other factors, allowing for a truly personalized medicine to emerge.[44]

Another example of this trend for Super Platforms to move into healthcare is offered by Apple. Its Health app consolidates data from different devices (iPhone, Apple Watch and third-party apps), enabling individuals to view a wide range of their health and "wellness" metrics (such as daily step counts, weight, calories use, heart rate, etc.) in one place and follow their daily details, progress and long-term trends.[45] In November 2019 Apple launched its Research app with three health studies using information from the iPhone and Apple Watch.[46] Apple's "Kits" offer app developers frameworks they can use to develop apps. HealthKit is a repository for health and fitness data that allows developers and researchers to feed information to and from the Health app, allowing apps to work with Apple Health and each other.[47] CareKit[48] and ResearchKit.[49] are open-source software frameworks for building apps: ResearchKit for researchers and CareKit for helping people to manage their medical conditions, track their symptoms and medications and share the information with their care team. Since the frameworks work seamlessly together, researchers can get access to even more robust data for their studies.[50]

2.3 New Legal Risk: The EU GDPR & Guidelines

Healthcare apps—often powered by AI and algorithm solutions—record and process granular and real-time sensitive data. These developments have sparked a debate on the many risks posed to the privacy and data protection of individuals. Not surprisingly, these radical changes in the traditional way of providing health care services and treatment, have significant consequences. While harnessing many benefits, this use of private information raises multiple legal challenges and these developments have been one factor pushing policy makers into a re-evaluation of privacy laws.

Here we take the EU as an illustration of a more general regulatory trend to introduce new and stricter requirements that impact upon any business or organization that handles personal and sensitive data. The new compliance challenge is how to operationalize these requirements and to embed them effectively in the design of products and services in a way that affords

[42] See Tencent, n.d.
[43] Buvailo, 2018.
[44] Buvailo, 2018.
[45] See Apple Health app, n.d.
[46] See Apple Research app, n.d.
[47] See Apple HealthKit Developer, n.d.
[48] See Apple CareKit, n.d. and Apple CareKit Developer, n.d..
[49] See Apple ResearchKit, n.d. CareKit, HealthKit and ResearchKit are trademarks of Apple Inc., registered in the U.S. and other countries.
[50] Mehmood, Faisal & Altowaijri, 2015, 535.

meaningful protection of the relevant interests. To give some sense of the complexity of the legal challenge, we consider two recent developments, the GDPR and the recent EU Ethics Guidelines for Trustworthy AI.

The GDPR was adopted on 27 April 2016 and after a two-year transition period it came into force on 25 May 2018. The GDPR replaced the previous European Data Protection Directive[51] and was designed to strengthen and unify data protection and privacy for all EU citizens and to empower individuals by granting them more control and certainty over their data when using Internet services.[52] The GDPR has been generally welcomed for updating some of the rules of the previous data protection regime and has triggered regulatory action around the world. However, it has clearly created a new degree of legal risk for all firms and healthcare providers. The most significant changes can be briefly summarized as follows:

- *International Data Transfers*: The GDPR imposes more stringent rules for the transfer of personal data to third countries and international organizations outside the EU. This change was designed to ensure an adequate level of protection in a globally connected world;[53]
- *Extra-Territorial Scope*: The GDPR expands its territorial scope of protection (extra-territorial applicability) to data controllers and processors established in the EU and *outside* of the EU territory with regard to the processing of personal data of European citizens;[54]
- *Consent*: The GDPR strengthened the definition of consent as follows: "consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data…".[55] It is no longer acceptable for companies to hide crucial privacy information somewhere in the middle of long terms and conditions full of legalese;[56]
- *Transparency:* The GDPR highlights transparency as one of its fundamental requirements, noting that the principle of transparency requires "that any information addressed to the public or to the data subject be concise, easily accessible and easy to understand, and that clear and plain language and, additionally, where appropriate, visualisation be used";[57]
- *Breach Notification*: Data breach notifications are mandatory. Data controllers must notify the breach immediately (within 72 hours) to their supervisory authority, whereas data processors must report the breach to the controllers;[58]

[51] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. OJ 1995 No. L281, 23 November 1995, 31–50.
[52] See e.g., McNealy & Flowers, 2015, 199, and Gjermundrød, Dionysiou & Costa, 2016, 4.
[53] Article 46 of the GDPR, Voigt & von dem Bussche, 2017, 120.
[54] See Article 3 of the GDPR, Svantesson, 2013, 89 and Hijmans, 2016, 497.
[55] See Article 32 of the GDPR.
[56] Article 7 (4) of the GDPR and Wisman, 2017, 357.
[57] Recital 58 of the GDPR. According to the Article 29 Data Protection Working Party, 2018, 5 "[t]he concept of transparency in the GDPR is user-centric rather than legalistic." This highlights the central role of the comprehensibility and presentation of the information.
[58] See Article 33 of the GDPR.

- *Access Rights*: Data subjects have more rights to get access and control regarding their data. This allows them the right to request the data controller whether personal data concerning them is being processed, where and for what purpose;[59]
- *Right to be Forgotten (data erasure)*: This right endows data subjects to have the controller delete their personal data and stop further processing and dissemination of data from third parties;[60]
- *Data Portability*: The GDPR creates a new right to data portability. This right allows data subjects to receive personal data concerning them—which they have previously submitted to the data controller—in a "structured, commonly used and machine-readable format," and to send those data to another controller;[61]
- *Privacy by Design and by Default*: The Privacy by Design and by Default approach[62] entails the notion of embedding privacy and data protection requirements directly into the architecture design of information technologies and related systems. Data controllers and processors must adopt this approach by default, making an explicit reference to "data minimization"[63] and the possible use of "pseudonymization."[64]

Even a cursory review of the main features of the GDPR highlights the legal risk confronting any firm handling personal medical information.

Such risk is compounded by a second development worth mentioning, namely the new legal and ethical requirements relating to AI. In this context, the European Commission released a new set of guidelines[65] to encourage the development of trustworthy and ethical AI. The guidelines—although they are "soft law" and not yet legally binding—address some of the diffuse problems that AI will bring to society as we integrate it in sectors such as healthcare, education, and consumer technology. The guidelines focus on how governments, companies, and other organizations should develop ethical applications of AI. According to the guidelines, AI systems should be accountable, explainable, and unbiased. To help achieve this goal, the EU recommends using an assessment list of seven fundamental areas that AI systems should meet in order to be deemed trustworthy.[66] Again, this has clear implications for any firm that uses AI systems to analyse the personal information it collects and compiles.

In summary, the expansion of Super Platforms into the healthcare sector is triggering a growth of new products and services. As a result, the healthcare sector is offering various kinds of apps for medical treatment, patient's control and research. This sector is growing exponentially ranging from large-scale systems to more moderate micro-services including apps of different kinds. Researchers are increasingly developing apps and other tools that process personal and sensitive data often powered by AI and algorithm solutions. This

[59] See Articles 12–14 of the GDPR and Quelle, 2016, 143.
[60] See Article 17 of the GDPR, and Sobkow, 2016, 36.
[61] See Article 20 of the GDPR; see also Article 29 Data Protection Working Party, 2017.
[62] The Privacy by Design approach was first introduced by the Information and Privacy Commissioner of Ontario and has existed as a general concept ever since. However, the GDPR introduced, for the first time, the Privacy by Design (and Privacy by Default) as a legal obligation.
[63] See Article 5 (1) (c) of the GDPR; Lynskey, 2015, 206; Thouvenin, 2017, 218.
[64] See Article 25 (1) of the GDPR; see also D'Acquisto et al., 2015, Voigt & von dem Bussche, 2017, 62.
[65] See European Commission High-Level Expert Group on Artificial Intelligence, 2019.
[66] See European Commission High-Level Expert Group on Artificial Intelligence, 2019.

complexity at the level of technology is matched by a parallel new complexity in regulatory schemes. Anyone handling personal and sensitive data is obliged to manage a high degree of legal risk, particularly if that information is affected by AI.

3 "UI Layer" Privacy-By-Design

As noted above, the emergence of new healthcare products and services, as well as the intervention of Super Platforms in a healthcare context poses obvious challenges concerning the processing of personal and sensitive data. Here we introduce the claim that the emerging field of Legal Design can play a crucial role in ensuring better privacy protection by providing more open and accessible infrastructures that embed relevant legal requirements in user-friendly interfaces for healthcare products and services (Section 3.1). To substantiate this claim, we offer several real-world examples of design patterns to illustrate the centrality of UI-focused Privacy-by-Design in protecting the most sensitive information of individuals who provide their data. (Section 3.2).

3.1 Legal Design

Legal Design is an emerging inter-disciplinary approach to apply human-centred design thinking in order to prevent and address legal problems. It prioritizes the point of view of the "users" of law, i.e., citizens, consumers, and business people, rather than legal professionals, and builds on a vision of a legal system that is more straightforward, more engaging, and more user-friendly.[67] Design thinking seems particularly timely in the context of the Digital Revolution. As was the case during the Industrial Revolution, business, governments and other organizations are scrambling to take advantage of these technological advancements, but they are also concerned about the direction and speed of change. The Digital Revolution will certainly benefit people in myriad ways, but it can also create a lot of harm if we do not think ahead to potential problems that we may have.

The healthcare industry is one of the sectors that will benefit the most. It will inevitably become more digital and "smart." It will also become more efficient and more accurate. And like all "Revolutions" this coming benefit is welcome, but we have to be aware of the potential problems that these new technologies can bring. AI will reorganize the way we live, work and interact socially due to the sudden amount of data available in the things we use. Therefore, in this section we argue that we need to improve the design of new products and services in the healthcare sector.

In order to understand how to design better AI apps, we should first understand the essence of design thinking. The first principle of design is simplicity. John Maeda, in his book The Laws of Simplicity explains that the world is full of complex technologies and products. It is, however, simple design that allows a particular product or service to differentiate itself from rivals. It is therefore crucial for all companies to understand how to balance complex technologies with simple design if they want to develop innovative and successful products.[68]

[67] "What is Legal Design?" in Legal Design Alliance, n.d.
[68] Maeda, 2006.

But how to achieve simplicity in a world full of complex technology? According to John Maeda, simplicity is all about "subtracting the obvious, and adding the meaningful." Think of Apple products such as the iPod player. The reason why they became so widely popular is because they were simple to use, and their design was appealing to consumers. There is no functional difference between an iPod player and an MP3 player. But the iPod player took all the obvious complex design functions away—such as the various buttons for every function which were found in other MP3 players—and added the round control pad which was much easier to use.[69]

In addition, the iPod player was the first product to be connected to an online music store such as iTunes which let customers quickly find, purchase and download music without subscription fees. The simplicity, usefulness and user-friendly design of the software and hardware of both the iPod player and iTunes store together is what led these products to disrupt the market.[70]

David Rose has similarly explained the important role design plays in the development of personal technology.[71] According to Rose, it is time for us to move away from screen-based devices toward a world of more intuitive, useful and efficient devices, designed for a specific purpose, or as he ably puts it, through "enlightened design." Rose asked himself the following question: "what will technology look like in the future?" One idea that could shape our future lives are "enchanted objects."[72] That is, technology that is not there to distract us but to offer information at a glance. The problem with screen-based devices such as smart phones is that they require your full attention as you read and respond to messages.[73]

The same holds true with regard to reading the terms and conditions of those apps. The clauses of user agreements are usually too long and difficult to be understood by the layperson. When we use our smartphones, the text is even too small to be read properly, and a considerable amount of mental effort is required. The problem with user agreements is that they are too difficult to understand even for lawyers. The importance of this has been examined by the House of Commons Science and Technology Committee in the UK. They found out that consumers usually just sign up without really reading and knowing what they are actually signing up to. They were particularly critical of the complexities surrounding terms and conditions, describing them as "more complex than Shakespeare."[74]

To demonstrate what reading those terms actually entails, the Norwegian Consumer Council downloaded and read aloud, word by word, all the 33 app terms and conditions on an average Norwegian's mobile phone. This "read-a-thon," which took more than 30 hours, was streamed live online. It revealed that the current state of terms and conditions for digital services is "bordering on the absurd. Their scope, length and complexity mean it is virtually impossible to make good and informed decisions."[75]

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[69] Maeda, 2006.
[70] Breen, 2004. iPod and iTunes are trademarks of Apple Inc., registered in the U.S. and other countries.
[71] Rose, 2015.
[72] Rose, 2015.
[73] Raisinghani et al., 2015, 188.
[74] Anderson, 2015, 159; see also Corrales, Jurčys & Kousiouris, 2019, 195.
[75] Schumacher, 2016, citing Council Digital Policy Director Finn Myrstad.

According to Gillian Hadfield, the "avalanche" of "click to agree" boxes, in response to the GDPR, is an example of the low and poor impact regulatory tools have on user privacy and control because people still don't know what they are agreeing to. It will be difficult for consumers to monitor what these companies are actually doing with their data.[76]

As discussed earlier, it is overwhelming for patients and participants to read and understand the terms and conditions of their medical apps and to fully understand what they are asked to consent to with regard to the processing of their personal data. Legal designers can help to change this, by developing better interfaces to empower both medical professionals and patients.

Designers know that if people do not read the information, find what they need or understand what they find, inadvertent non-compliance will occur, and readers' (and non-readers') problems easily become writers' problems: complexity causes unnecessary risks. So, designers seek to simplify the user experience. As illustrated in Figure 1, there are three main building blocks to simpler communication: 1) empathize with the users' needs and expectations; 2) distil the communication, boil it down to its essence; and 3) clarify.

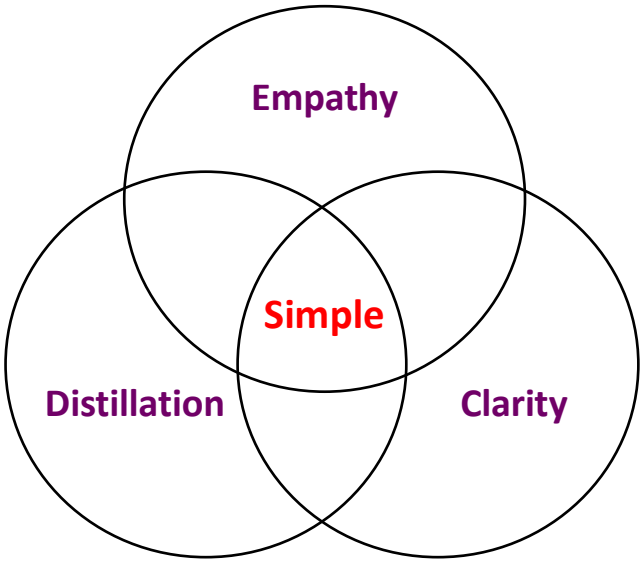


Figure 1: The Three Building Blocks of Simpler Communication.[77]

When the goal is clear communication, it is important not to overwhelm the audience with too much information. Instead, readers should be guided through the text, making sure they can skim through and find content and explanations, when needed. Procedures can be shown in a step-by-step fashion, with the help of charts and explanatory diagrams. Clear and visible headings can be shown to answer typical questions, and so on. These information design techniques need not be reinvented – they can be identified, shared, and reused as *design patterns*.

[76] Hadfield, 2018.

[77] Image by Helena Haapio. Used with permission. The image originally appeared in Spanish in Haapio, Siedel & Bernal Fandiño, 2016. The three building blocks and the idea of the image are adapted from Siegel & Etzkorn, 2013.

3.2 Design Patterns: from Architecture to Contracts, Privacy and Beyond

Design patterns offer a systematic way to identify, collect, and share good practices. In essence, design patterns are reusable solutions to a commonly occurring problem—something that practitioners can develop, collect, and share. The original idea stems from Christopher Alexander et al.,[78] who collected reusable architectural and design solutions. The idea was later applied to the digital world and gained widespread acceptance with Erich Gamma et al.[79] Since then, design patterns have been extensively used in many other fields, including computer science and interface and UX design. Over the last few years, they have even made their way to contract design,[80] privacy design,[81] and Legal Design.[82]

Even before the emergence of Legal Design,[83] early pioneers promoted better and simpler presentation of legal information with user-centred design, simplification, and visualization. Several projects looked into the simplification of online terms & conditions, end-user licenses, and privacy policies, for example through the use of icons.[84] EU-wide and country-specific guidance was developed to help organizations incorporate GDPR and other requirements within their consent processes. For example in the UK, the Information Commissioner's Office (ICO) shared examples of good (and bad) privacy notices and provided guidance on how to make privacy notices more engaging and effective for individuals while emphasizing the importance of greater choice and control over what is done with their data.[85] Despite all the guidance, making *privacy-by-design* a reality proved difficult. Lawyers and developers alike were wondering how to best convert "lawyer speak" into "engineering speak" and how to anticipate and prevent problems early in the development process.[86]

By collecting, naming, and describing *design patterns* and showing examples it is possible to systematize and share knowledge and create a common language for experts and novices alike, irrespective of their discipline or professional background. To enable users to interact with the information, the selection of patterns needs to be based on what is suited to express the particular information to the particular user group in a particular context. For those in charge of producing information, the focus changes from clear and concise *writing* or *drafting* to *designing communication* with and for multiple user groups. This also involves responding to and balancing different needs and requirements.[87] Our contention is that such design patterns are particularly relevant and have enormous potential in a healthcare context.

In recent years, *pattern libraries* – collections or catalogues of design patterns - have been launched that help those in charge of preparing information engage and empower its targeted

[78] Alexander et al., 1977.
[79] Gamma et al., 1995.
[80] Haapio & Hagan, 2016, Haapio & Passera, in press.
[81] Haapio et al., 2018, Rossi, 2019, Rossi & Lenzini, 2020 and Rossi & Haapio, in press.
[82] For an overview of legal design patterns, see e.g. Rossi et al., 2019a, and the resources mentioned in notes 80-81.
[83] Hagan, 2018.
[84] For a summary, see Haapio, 2013, with references, and Lannerö, 2013. See also Rossi, 2019.
[85] See, e.g., ICO, 2016. - The ICO is the UK's independent body set up to uphold information rights.
[86] Privacypatterns.org, n.d..
[87] Rossi & Haapio, in press.

users. After the development of prototype collections,[88] a number of pattern libraries now exist. As regards contracts, the International Association for Contract and Commercial Management (IACCM) offers a collection of design patterns that help organize and communicate contracts and terms and conditions more clearly so that they are read, understood, and acted upon.[89] Research organizations and technology studios, too, have opened access to their privacy toolkits, data permissions catalogues, and pattern libraries for others to use and be inspired by. For example, Sage Bionetworks has developed a multi-media approach to addressing transparency and comprehension within electronic informed consent (eConsent) for app-mediated research studies.[90] They offer an open-access toolkit of design tools and patterns with accompanying use cases to assist researchers in using the appropriate patterns in their applications.[91] Another valuable resource is offered by IF: a curated catalogue of patterns for sharing data.[92] These resources can help developers and researchers make decisions about how and when to collect and use data about people and effectively communicate their related messages.

3.3 Examples of "UI Layer" Design Patterns for Privacy Communication

To show how design patterns can transform the communication of complex privacy-related messages, let us take some examples. There is compelling evidence that people typically just click "Accept" when confronted with a privacy policy—telling what is known as "the biggest lie on the Internet."[93] Most people using platforms or consuming Internet services just want fast access to whatever service or product they are looking for. As regards policies and terms, anything goes. People feel overwhelmed by the resulting "wall of text."

Such a "wall of text" is a well-known and widely acknowledged issue in the field of contracts, privacy policies, and legal documents.[94] The result is that finding information is hard, due to the opaque and undifferentiated text that provides no highlights or navigational aids. All the information is presented in the same monochromatic, text-only manner, making it difficult to search and find or read key information. It is impossible to skim-read the text to find answers to specific questions or concerns. And when the text seems too long or complex, very few people will actually take the trouble of reading it. They just give up.

In the following sections, we introduce some examples of UI-layer design patterns and pattern families that have been effectively used in overcoming the "wall of text" challenge. The following examples illustrate how this can be and has been done in the context of privacy

[88] See Contract Design Pattern Library, Privacy Design Pattern Library and Know Your Rights Pattern Library at http://www.legaltechdesign.com/communication-design/?s=pattern. For pioneering Privacy Pattern Libraries, see also https://privacypatterns.eu and https://privacypatterns.org.
[89] IACCM, Passera & Haapio, n.d.(a).
[90] Doerr, Suver & Wilbanks, 2016.
[91] For Sage Bionetworks' Privacy Toolkit, see Sage Bionetworks, n.d.(a) and (d) and Moore & Doerr, 2020.
[92] For IF's Data Patterns Catalogue, see IF, n.d.(a)
[93] Obar & Oeldorf-Hirsch, 2016.
[94] For contracts, see Passera, 2017. For privacy policies, see Rossi et al., 2019a, Rossi et al., 2019b and Rossi & Lenzini, 2020, 5, where the authors list the "wall of text" among eight main problems that preclude effective legal-technical communication, leading to impenetrable text where "details are lost in a sea of text".

communication and health data sharing. The patterns complement each other, and their goal is to foster the clarity, findability, transparency, and comprehensibility of the information.

a) Privacy FAQs and FAQ-Style Heading Patterns

Privacy-related "frequently asked questions" (FAQs) can be used to provide easy-to-read explanations about the most frequently asked privacy-related questions and the most relevant data practices. In addition to the problem of "wall of text," they can be used to respond to a number of other communication challenges, including the complexity of language, excessive length, and public lack of familiarity with key concepts and terms. Many organizations present Privacy FAQs on their website.[95] Users can click on each question and a box opens up with a short paragraph explaining key privacy and data protection policies. The FAQs make it easier for users to find answers to specific personal data related questions they might have.

FAQ-style headings, in turn, is a design pattern where headings are shown as questions that readers frequently ask the experts. The following example (Figure 2) shows how Juro uses FAQ-style headings in their privacy policy as a way to present the topics from the point of view of the reader and to pre-emptively anticipate questions with regard to their data security and data retention policies.

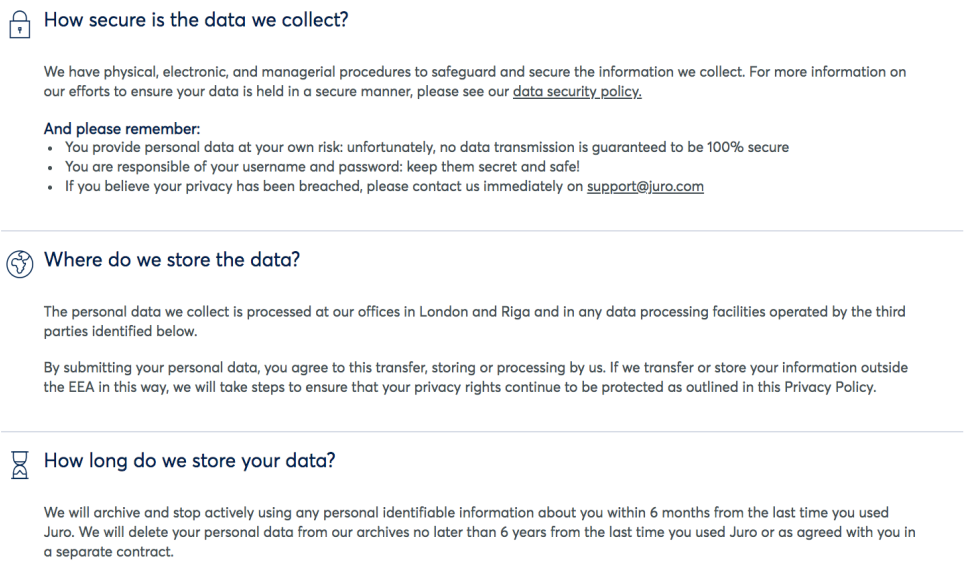


Figure 2: FAQ-style headings used in the Juro Privacy Policy[96]

FAQ-based patterns are useful, because users often skim-read to find answers to specific questions or to assess if the text is relevant and worth their time. They may stop to read details

[95] See, for example, Health Data Coalition Privacy FAQs at https://hdcbc.ca/privacy-faqs/, Privacy for Your AncestryDNA Test at https://www.ancestry.com/cs/legal/PrivacyForAncestryDNATesting, Aetna Health Care Privacy FAQs at https://www.aetna.com/faqs-health-insurance/about-us-privacy-faqs.html and Privacy FAQs at Sony UK Privacy Centre, https://www.sony.co.uk/eu/pages/privacy/en_GB/privacy_faq.html.

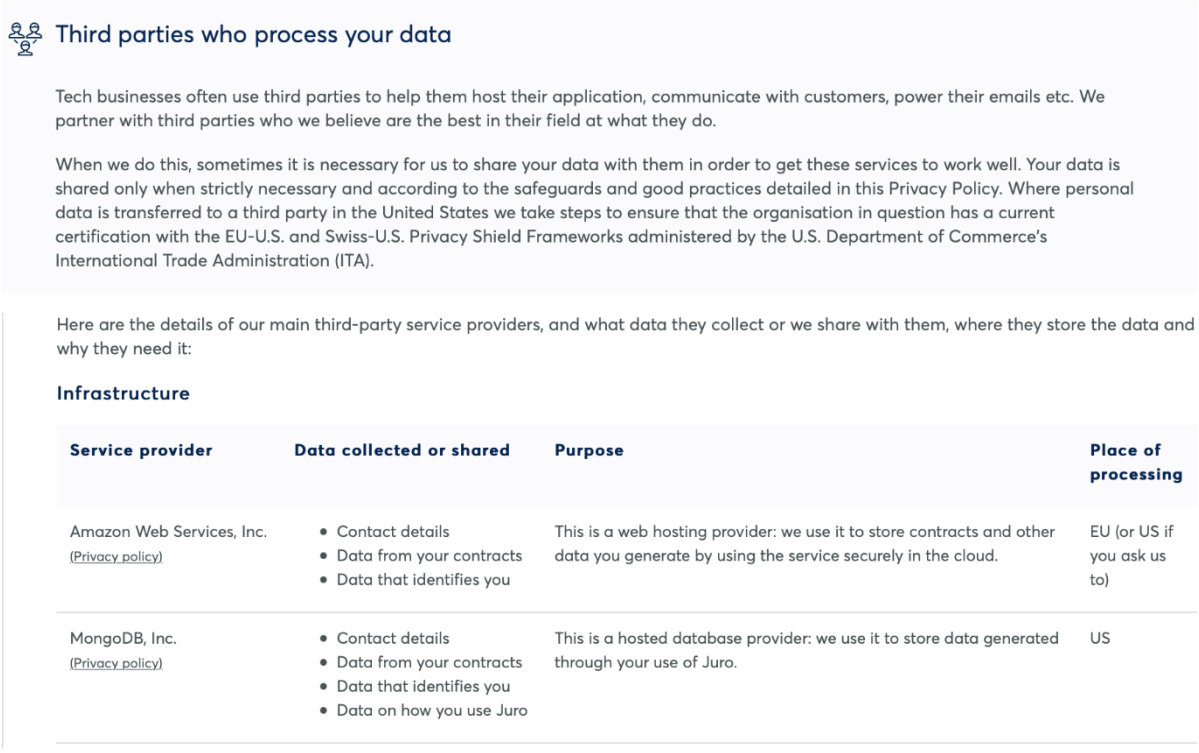
[96] Juro Privacy Policy, n.d.. © Juro Online Limited. Image used with permission. Original at www.juro.com. - The FAQ-style headings pattern can also be used in contracts and terms and conditions. For examples, see IACCM, Passera & Haapio, 2019a. For research consents, see Moore & Doerr, 2020, 36.

only when they think that they are relevant. Questions help reframe the topics from the point of view of the readers, increasing the chances that they will recognize the content as relevant and actually stop to read it.

b) Organization and Navigation Patterns

Organization and navigation patterns help readers find their way through the information and find what they need. They help structure the content so that it is logical, meaningful and relevant to the readers. Used together, the patterns help present information in a way that maximizes its clarity and understandability. They facilitate skim-reading and ease of use. Ideally, they offer a visual and logical access structure, with visible and well-organized headings, sections, pages, cross-references, as well as indexes, tables of contents, and menus.[97]

A table pattern can be used when there is a need to structure information so that readers can skim and process a lot of information at a glance: tables can be read very rapidly. They can also be used to facilitate comparison and choice between different elements. Tables offer a systematic way to arrange information in rows and columns. This allows readers to search and read the information more easily and break down the "wall of text". The example below (Figure 3), explains the reasons why and how a person's data may be shared with third parties. The information is broken down in order to depict it in a clear and consistent manner.



Third parties who process your data

Tech businesses often use third parties to help them host their application, communicate with customers, power their emails etc. We partner with third parties who we believe are the best in their field at what they do.

When we do this, sometimes it is necessary for us to share your data with them in order to get these services to work well. Your data is shared only when strictly necessary and according to the safeguards and good practices detailed in this Privacy Policy. Where personal data is transferred to a third party in the United States we take steps to ensure that the organisation in question has a current certification with the EU-U.S. and Swiss-U.S. Privacy Shield Frameworks administered by the U.S. Department of Commerce's International Trade Administration (ITA).

Here are the details of our main third-party service providers, and what data they collect or we share with them, where they store the data and why they need it:

Infrastructure

Service provider	Data collected or shared	Purpose	Place of processing
Amazon Web Services, Inc. (Privacy policy)	• Contact details • Data from your contracts • Data that identifies you	This is a web hosting provider: we use it to store contracts and other data you generate by using the service securely in the cloud.	EU (or US if you ask us to)
MongoDB, Inc. (Privacy policy)	• Contact details • Data from your contracts • Data that identifies you • Data on how you use Juro	This is a hosted database provider: we use it to store data generated through your use of Juro.	US

Figure 3: Table pattern used in the Juro Privacy Policy[98]

[97] See IACCM, Passera & Haapio, n.d. (c) and (d).
[98] Juro Privacy Policy, n.d.. © Juro Online Limited. Image used with permission. Original at http://www.juro.com.

It is not always practical to use words only. Most readers are busy and need the information to be presented in a simple and straightforward fashion. Timeline patterns may allow them to contextualize and understand at a glance the information according to their own experience.[99] Timelines represent time or duration, a series of steps, tasks or processes taking place within a given timeframe, or a sequence of events.[100] Timeline patterns may help to explain the course of actions and requirements that need to be taken in a chronological order. Figure 4 below illustrates an example of a privacy timeline showing the data collection process. The graphic shows the exact moments when data is collected, making the process more tangible and transparent. Different outcomes are set out, and different colours indicate the data collection process from both the user and the company experience.[101]

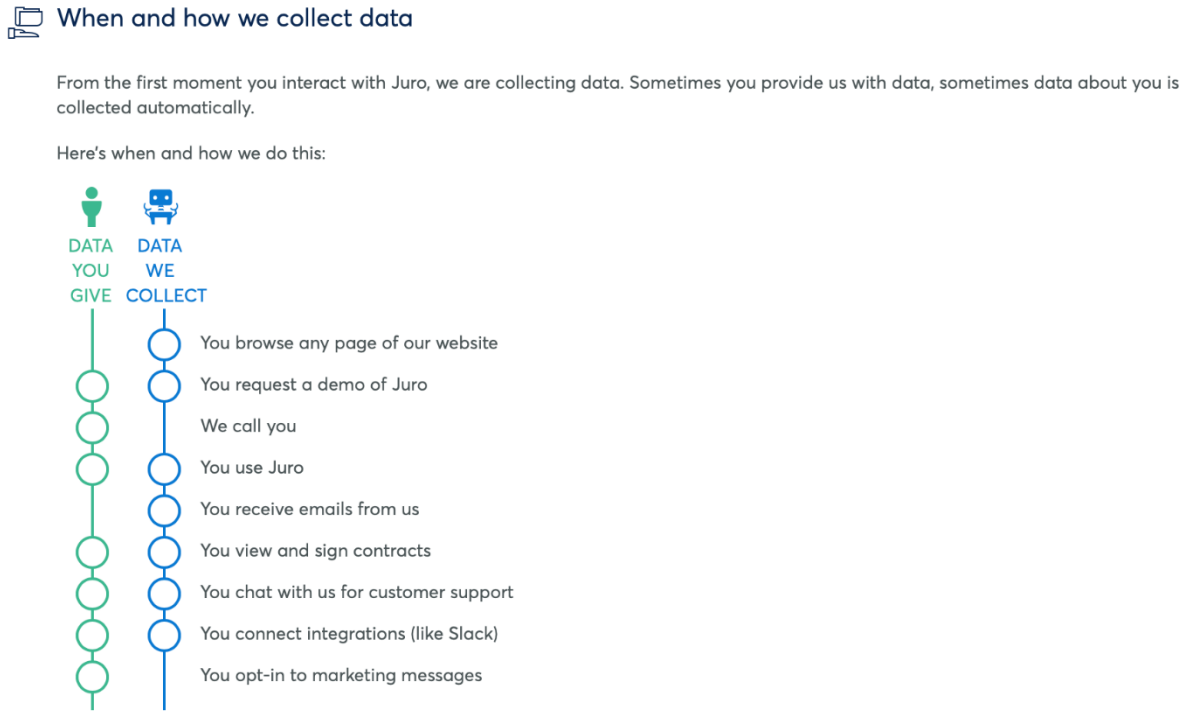


Figure 4: Timeline pattern showing the data collection process in the Juro Privacy Policy[102]

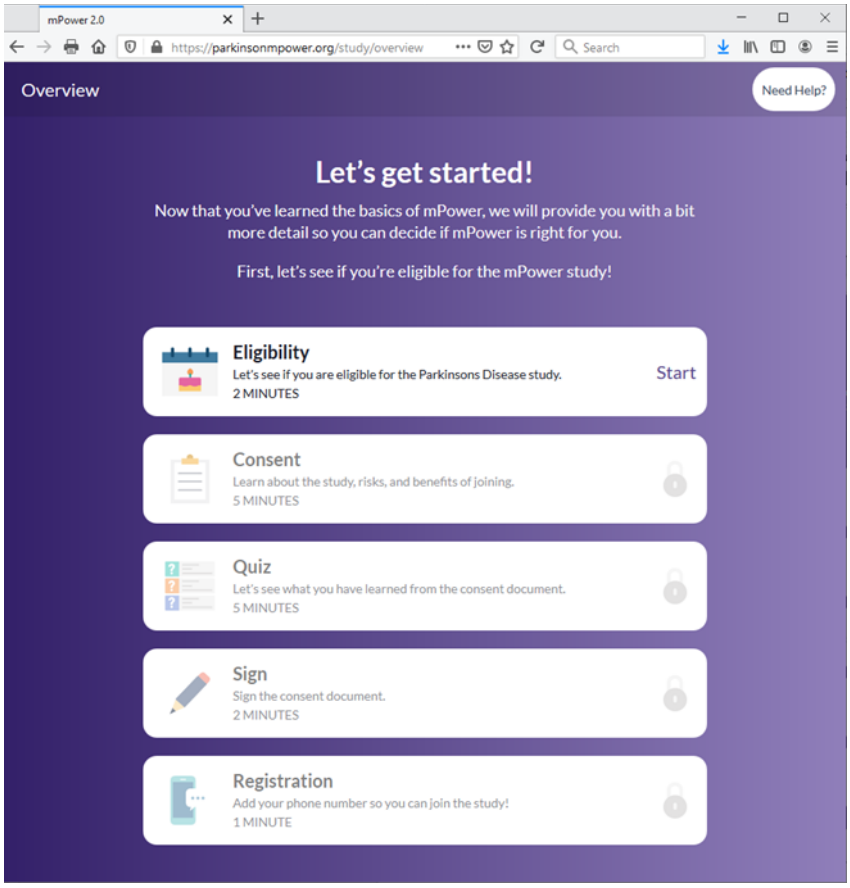
In addition to helping organize the content of complex communication in a way meaningful for the reader, navigation patterns can also be used to show information at the time when it matters. By using design patterns at the appropriate time, participants are helped to understand the types of data that are being collected and other aspects, for example how they have the ability to change their data sharing permission.[103]

Consider a person who has heard about a study from recruitment materials and is looking for additional information on the purpose of the study, eligibility criteria, and requirements of

[99] Haapio & Passera, in press, 16-19.
[100] See IACCM, Passera & Haapio, 2019b.
[101] Haapio & Passera, in press.
[102] Juro Privacy Policy, n.d.. © Juro Online Limited. Image used with permission. Original at http://www.juro.com.
[103] Barone et al., 2019.

participation.[104] Different information matters at different stages of the person's journey. Before being able to make her data available for the study, she is required to provide informed consent via a dedicated mobile application. She needs to prove that she has understood the reason why and by whom her data will be analyzed, the benefits and risks and her rights as a participant and a data owner. This process can be long and the related information, if everything is presented at one time, can be overwhelming.

Providing the information at stages and turning the process into an easy-to-navigate experience helps guide the participant to a choice that can be genuinely described as informed. The following example (Figure 5) helps break down the consent process, gives an overview of the various steps, and combines simple text with images. Videos, comics, or other visual means can be added to support comprehension in each phase. Navigation is supported through the different stages until the person lands on the options for data use authorization. A quiz and an assessment of her understanding can be made a precondition before activating the possibility to grant consent.[105]



[104] The following two examples and pattern descriptions are adapted from Rossi & Haapio, in press, exploring design patterns as a means to bring proactive Legal Design to practice and to promote transparency and trust in health data sharing.

[105] Rossi & Haapio, in press. For quizzes and assessments, see Moore & Doerr, 2020, 27–28. For comics, see Botes, 2017; see a portion in Rossi & Lenzini, 2020, 12–13.

Figure 5: Navigable eConsent process: steps for participation in a research study on Parkinson's disease[106]

In conventional consent and permission models, information about possible data uses is provided at a single point in time, often at registration or when installing an app. At that time, participants may not understand the options or may not have time to consider the implications of what they are agreeing to. Permission options that are not relevant for the task at hand may alienate people from participation or nudge them to refuse permission.[107] The following example (Figure 6) illustrates a dynamic, just-in-time consent pattern that helps provide participants with relevant information at the moment when they need to authorize or refuse the collection of data. It enables participants to receive notifications, engage them in the provision of granular authorizations for specific research activities and update their preferences about data access by certain organizations.[108]

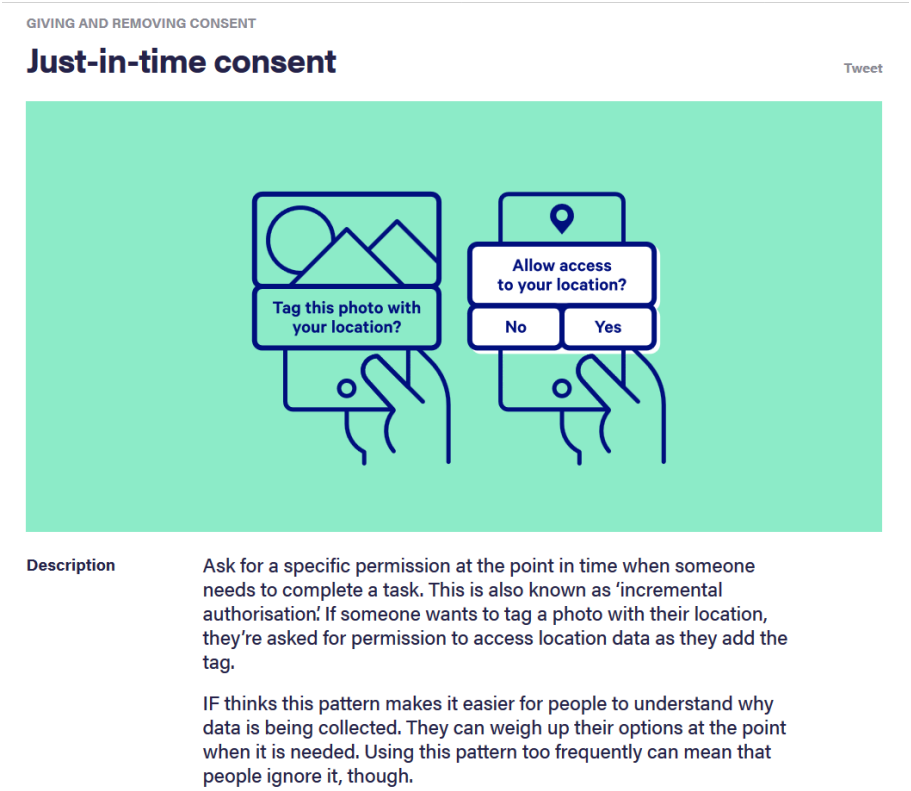


Figure 6: Just-in-time consent pattern shown in IF's Data Patterns Catalogue[109]

c) Layering Patterns: Overview First, Details on Demand

Full privacy notices are often very long and complex. Readers have to scroll down, which can be tedious, particularly in mobile apps. Summarizing and layering refer to pattern families which seek to help users get an overview and find the most relevant information easily, without

[106] Sage Bionetworks, n.d.(c). Image used with permission.
[107] Rossi & Haapio, in press; Sage Bionetworks, n.d.(b).
[108] Rossi & Haapio, in press; Budin-Ljøsne et al., 2017, 3. For dynamic-informed consent in the context of population genomics, see also Dankar et al., 2020.
[109] IF, n.d.(b). Licenced under CC BY 4.0, https://creativecommons.org/licenses/by/4.0/.

being overwhelmed with details they do not need.[110] Easy-to-read summaries can be placed next to the original text throughout the document or at the beginning of the document to help accommodate the needs of both those who only want to get the main idea and those who want to be informed in depth.

The following example (Figure 7) shows the first layer of Juro's Privacy Policy, Your-privacy-at-a-glance summary, shown when a user lands on the main page. Users can click through to the full policy, if they want to read more. Further information is made available in manageable bits using a design pattern known as accordion: key information is presented at the top which, when clicked, displays further details inside expandable panels. This example also shows the use of further design patterns, such as companion icons.[111]

Figure 7: The first layer of the Juro Privacy Policy: overview first, details on demand[112]

The examples given above indicate that a number of solutions already exist that help break down the wall of text. There are many other challenges in legal communication, of course—and many design patterns to respond to them. As practitioners and researchers collect and share more design patterns, we envision a number of new and better ways to promote transparency and informed consent and to translate regulatory requirements and abstract Privacy-by-Design principles into applicable solutions.[113]

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[110] IACCM, Passera & Haapio, n.d. (b), (e) and (f). For examples of using a layered approach in the context of research consents, see Moore & Doerr, 2020, 33-34.

[111] For a more detailed description of the patterns used and the project, see https://stefaniapassera.com/portfolio/juro/.

[112] Juro Privacy Policy, n.d.. © Juro Online Limited. Image used with permission. Original at http://www.juro.com.

[113] For further examples, see e.g., Rossi et al., 2019a, Rossi et al., 2019b and Rossi & Lenzini, 2020. For contract design patterns, see also IACCM, Passera & Haapio, n.d.(a). For informed consent for research, see Moore & Doerr, 2020, with references.

4 Legal Design in Digital Health: Examples & Challenges

Sharing data and keeping privacy may seem like conflicting goals. Medical institutions, developers and technology companies around the world have started to look for ways to respond to the needs of individuals and to the challenges faced by healthcare professionals and medical researchers. Solutions already exist that allow individuals to share their health data with the apps of their choice, while keeping control over their data and choosing how they want it to be shared, and open access tools are available for researchers and developers to create such apps.[114] For example, the ResearchKit, an open source framework introduced by Apple, allows researchers and developers to create apps for medical research, offering tools to create visual consent flows, real-time dynamic active tasks, and surveys using customizable modules to build on and share.[115]

We envision platforms that provide a user-friendly interface for everyone, both health care professionals and the people who want to manage and maintain their health. In addition, we envision open-access *toolkits of toolkits*: resources that include design patterns and other tools helping developers and researchers create apps that enable users to better understand and manage their health and their data. Such platforms and toolkits can be built on existing technology, with the goal of being smart at the back, but seeming simple, intuitive, and clear at the front.[116]

However, the uniqueness of the healthcare sector brings about specific challenges of implementing Legal Design in the digital health context. Preventive and therapeutic care will soon be driven by disruptive technologies such as AI, machine learning, wearable devices, Internet of Things (IoT), cloud computing and big data predictive analytics. Besides collecting medical data at the point of care, the technology behind Super Platforms will allow engineers and scientists to work with large amounts of data from mobile and wearable devices in unprecedented ways.[117]

To better illustrate this challenge, one may think of it from two different layer perspectives: (i) the underlying infrastructure enabling technology (such as cloud computing and IoT); and, (ii) the data-analytics framework (such as AI and ML), which focuses on the smart algorithms that help doctors and patients make more data-driven and informed decisions.[118]

The first layer framework is usually composed of three main elements, namely edge node(s), a cloud aggregator, and a back-end data-analytics engine.[119]

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[114] See, e.g., Apple CareKit, n.d. and Apple CareKit Developer, n.d.. According to the accompanying Human Interface Guidelines (Apple Developer, n.d.), "[n]othing is more important than protecting people's privacy and safeguarding the extremely sensitive data your CareKit app collects and stores".
[115] See Apple ResearchKit, n.d.. See also Apple Research & Care, n.d.: "We've put together all the content, code, and support you need to get started on your ResearchKit or CareKit app." Both Kits come with Human Interface Guidelines and other UI resources.
[116] "Be simple on the front, and smart at the back" is principle 5 in Hagan, 2016; we are indebted to Margaret Hagan for this phrase.
[117] Ananthan, 2017.
[118] Ananthan, 2017.
[119] Ananthan, 2017.

Edge nodes collect all kinds of raw physiological health data through various sensors. Most of the wearable devices developed by Big Tech companies described in the Super Platforms context are good examples of such edge nodes. These include some proprietary FDA-regulated devices such as blood-glucose sensors (inserted under the patient's skin to measure glucose levels) and electrocardiogram (ECG) monitors (used to scan and analyse heart's rhythm and detect cardiac issues).[120]

A cloud aggregator is a gateway that can stream data from the edge nodes and take advantage of cloud-based computational resources. With the right signal or image-processing technologies, it is possible to collect signal features and transfer them to the cloud. The cloud infrastructure allows to reduce bandwidth requirements and improve the computational power of these wearable devices.[121]

Back-end data-analytics engine allows the data collected to be processed and analysed to extract meaningful information from the aggregated data (for analysing patterns, trends, anomaly detection, etc.).[122]

The second layer framework which helps us to understand this landscape is the data-analytics framework, including AI and ML algorithms that add intelligence into this entire operating system. This helps physicians and patients to transform data into actionable insights. These smart algorithms allow healthcare professionals to analyse large amounts of data to amplify and accelerate diagnostic capabilities.[123]

This second layer involves the communication between physicians and patients which is crucial for the informed consent and decision-making process. In this phase, doctors need to translate and explain the accrued information back to the patient. One example of this is the integration into electronic health records (EMR) and patient guidance. EMR is a digital version of the conventional paper-based medical record for a patient. Implementing EMR solutions has been known to improve medical practices' productivity as well as the quality of care provided to patients.[124]

One example that illustrates all the phases of this challenging landscape very well are so-called "ingestible electronic sensors" (IES), also known as "smart pills." IES are small electronic devices – roughly the size of a medicine pill – composed of biocompatible and non-invasive materials, which have the ability to telecommunicate relevant information for the monitoring and diagnosis of disease in the healthcare sector.[125]

IES is a disruptive technology that works through wearable sensors and microprocessors. Once the smart pill is ingested into the human body – either with medicine or as an embedded part of a drug – the sensors and microprocessors are capable of storing and collecting all sorts of valuable data such as medication intake or behavioural and physiological metrics. The wearable sensors and microprocessors then transfer the collected data to a connected

[120] Ananthan, 2017.
[121] Ananthan, 2017.
[122] Ananthan, 2017.
[123] Ananthan, 2017.
[124] For a more detailed description of the infographics used in electronic health records (EHR), see https://www.capterra.com/infographics/top-emr-software
[125] Gerke et al., 2019, 329.

computing device such as a smart phone or a tablet, which then displays the information to a user interface.[126]

IES have already entered the mainstream market in the United States and Europe, and it is expected that more products will be launched soon. Examples include Proteus Discover, Abilify MyCite, Atmo Gas-Sensing Capsule and an ingestible bacterial-electronic sensor designed by MIT School of Engineering, which can communicate with your gastrointestinal track and the wireless transmitters can send and share the information outside the body through the patient's mobile phone.[127]

IES are a promising technology for improving health outcomes and making health care more effective, since they allow to monitor the interaction of drugs with the human body and allow to control drug administration. Yet, IES also raise a great variety of ethical and legal challenges. On the ethical side, there are key challenges for IES relating to patients, physicians, and society more generally and in particular with regard to autonomy and informed consent, ownership rights of data collected by IES products, including the question of the doctor–patient privilege and the related issue of medical confidentiality.[128]

On the legal side, it is important to consider the regulatory frameworks for the approval of such devices; furthermore, intellectual property rights, privacy protection, international data transfer regimes, cybersecurity, accountability, transparency, explainability, fairness, and robustness are of crucial importance.[129] However, regulatory frameworks often face the challenge to keep apace of technology and the regulatory landscape is always changing.

This is where UI-focused Privacy-by-Design can contribute to the new "Super Platforms" emerging ecosystem in the health care sector. If the goal is that digital health apps should be broadly accepted and trusted by society, patients and markets, it is of vital importance for developers to address and consider such issues at the earliest stages of the product development process.

The UI-layer Privacy-by-Design applied to the digital health context can guide the patients/end users through all the phases of this process where challenges seem to be more acute due to: (i) the sensitivity, richness and uncertain limits of the information collected by the "edge nodes"; (ii) the complexity of the processes by which that information is acquired; and, (iii) the need for an interface to translate and explain the informed consent process and accrued information back to the patient.

When preparing a platform or a solution, designers and builders need a common language so they can convey their messages among the team members, for example from subject matter experts to lawyers to coders and vice versa – and then ensuring that the output makes sense for the users, patients and professionals alike. As regards the output, whether displayed on a screen or printed documents, design patterns can help them do so: graphic elements such as tables, bullet lists, or diagrams can be used to make the content clearer and easier to navigate. The use of timelines, swim lanes, or other visual design patterns can help the reader and make the information easier to find.

[126] Fernandez, 2019; Gerke et al., 2019, 329–330.
[127] Gerke et al., 2019, 329.
[128] Gerke et al., 2019, 332–333.
[129] Gerke et al., 2019, 333.

We hope that our vision and examples can contribute to digital health platforms and apps adopting new and more transparent ways of conveying complex legal messages, including privacy communication, in the near future. A user-friendly interface can hide the complexity, simplifying and improving the user experience of the platform and apps. The toolkit for developers, as we envision it, would include "UI layer" design patterns.

5 Conclusion

The Digital Revolution has triggered the emergence of new business models, new products and new services. As a result, the healthcare sector is radically changing the traditional way of providing medical services and treatment. Hospitals, clinics, pharmaceuticals and medical research centres are all now partnering with start-ups and Big Tech companies, creating new online decentralized structures or ecosystems that we here labelled "Super Platforms."

This opens the way for a new data-driven healthcare market and the development of a wide range of specialized software apps powered by historically unprecedented AI and algorithm capabilities. It is clear that Super Platforms will inevitably emerge and benefit the healthcare and pharmaceutical industry. However, this new trend also brings a number of legal and ethical concerns as these apps and other online tools have important implications for privacy rights, in particular.

Here, we have taken the view that in a healthcare context, Legal Design can provide a reliable and transparent infrastructure for embedding relevant legal protections in the user interfaces, privacy policies, and terms of use of healthcare products and services. Legal Design is about putting the user in the centre and finding the right balance between simplicity and ease of use on the one hand and compliance with the applicable legal requirements on the other. Such a UI-focused Privacy-by-Design approach offers a number of advantages, most obviously greater transparency, accountability and (consequently) human choice. For such an approach to be truly effective, however, it requires further efforts to be applied to the practical challenge of developing design patterns that can be deployed in diverse real-world settings.

With the development of design patterns and pattern libraries, it becomes easier for legal technologists, privacy professionals, and legal designers to co-create better AI products and provide better legal communications, systems, and solutions. Recent research and practice illustrate how UI layer design patterns can help transform dysfunctional disclosures, legal notices, and data processing information into useful and usable communication that works for (rather than against) their intended audience.

And of course, it is important to note that the law is only one factor amongst a myriad of factors which will impact upon how much choice users have in this context. There needs to be "buy-in" from the technology companies developing these apps and from companies using the data and making accessing apps/platforms contingent upon users surrendering their data for other purposes. How much choice users will ultimately have in determining data uses will be as reliant upon the app platform hosts as it is on the legal infrastructure.

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