



## Growing Digital Ecosystems for Mental Health Support for People and Society: Understanding the Role of EU Law and Policy

Summary report of a knowledge exchange workshop

### Executive summary

This workshop brought together 14 experts, including mental health service user and survivor advocates, service providers, policymakers, and researchers, to discuss the law and regulation of digital approaches to mental health care and crisis support in the EU. Well-designed digital technologies that offer high degrees of public involvement can be used to promote good mental health and crisis support in communities. They can be employed safely, reliably and in a trustworthy way, including to help build relationships, allocate resources and promote human flourishing. On the other hand, there is clear potential for harm, and the list of ‘data harms’ in the mental health context is growing longer. ‘Data harms’ is used here to mean situations in which people are in worse shape than they would be had the activity not occurred.<sup>1</sup>

The workshop sought to partially survey the EU legal and regulatory landscape that helps govern the digitalisation of mental health services and crisis support. Secondly, we sought to list some of the major unresolved legal and policy issues in the field, and confirm with speakers whether these were indeed issues of concern to those working in the field.

Digital technology – variously referred to as ‘data-driven’, ‘online’, ‘computational’, ‘algorithmic’ technologies, and so on – has become an increasing part of people’s lives in the EU and throughout the world. Increasingly, digital technologies have been applied to mental health policies and practices. This trend has been amplified by the COVID-19 pandemic, as service users and providers searched for ways to access and deliver mental health care amid social restrictions.

Digitalisation (in the form of tele-health, mental health apps, data sharing among service users and professionals, the use of techniques like virtual reality, machine learning, and so on) brings opportunities. However, it also has the potential to perpetuate and perhaps even amplify human rights pitfalls that already appear in the mental health field.

For example, some digital approaches like mental health apps focus heavily on the individual and present them as needing “to be fixed”, which can reinforce individualistic views of mental health and make socio-economic determinants of mental health invisible. The privacy of app users is also a major concern, particularly with sensitive personal data concerning mental health.

<sup>1</sup> See Jonah Bossewitch, Lydia X. Z. Brown, Piers Gooding, Leah Harris, James Horton, Simon Katterl, Keris Myrick, Kelechi Ubozoh and Alberto Vasquez, *Digital Futures in Mind: Reflecting on Technological Experiments in Mental Health & Crisis Support* (University of Melbourne, 2022) <<https://automatingmentalhealth.cc/>> (accessed 9/1/23).

Digitalising mental health support and care may also reduce the human connection and compassion that are indispensable to providing and experiencing support, care and healing. Digital mental health care services can also create new inequalities or strengthen existing ones when structural inequalities and biases are built into data science processes, software engineering and so on.

Debate about whether techniques like artificial intelligence ('AI') and machine learning are politically and morally *neutral*, or whether they embed certain political and moral values within them, is likely to continue.<sup>2</sup> For the purposes of this workshop, we were interested in a broad discussion about how to sway the balance towards beneficial outcomes. It was agreed by all participants that doing so will depend on how technologies are implemented, managed and regulated, but that these activities are poorly understood in the mental health context among a range of affected groups, including service users, survivors, mental health and crisis support practitioners, advocacy groups and policymakers.

This workshop was premised on the view that it is vital for countries and the EU to make policies and regulations that enhance the 'equalising opportunities' digitalisation brings and reduce the risks, especially for groups that already face marginalisation and disadvantage.

Mental Health Europe has promoted themes of 'Safety & Quality', 'Equity' and 'Going beyond technology: framing mental health in a bigger picture' as key priorities in the EU, national policies and regulations. These themes were echoed in the workshop discussion. Quality and equity concerns centre on the call for service users to be meaningfully engaged in the development, design, and implementation of technology – as well as its governance. Precisely what this governance should look like was left as an open question, but it was agreed that at a minimum, existing advocacy organisations – whether user/survivor and patient advocacy organisations, or civil society organisations like Mental Health Europe – had a key role to play. Existing frameworks for mental health system re-design, such as international human rights law, and instruments like the Convention on the Rights of Persons with Disabilities (CRPD), were seen as an important safeguard to ensure that digital technologies are used not just because they are feasible but because they respond to a real need.

### In memoriam

The authors of this report wish to pay our sincere respects to the memory of the beloved and incredible activist, the late Jolijn Santegoeds who participated in this workshop. Ms Santegoeds was a staunch human rights defender and a powerful figure in the global movement of psychiatric user and survivors, and disabled people. A tribute to Ms Santegoeds by the European Disability Forum can be read here: <https://www.edf-feph.org/we-mourn-the-loss-of-jolijn-santegoeds-disability-activist-and-voice-for-people-with-psychosocial-disabilities/> (accessed 30/05/2023).

## Workshop Details

On 11 January 2023, Mental Health Europe and Dr Piers Gooding, a Senior Research Fellow at the Melbourne Law School, University of Melbourne, hosted a 'knowledge exchange meeting' on the role of EU law and policy in digitalised online mental health care and crisis support. The workshop brought

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<sup>2</sup> Langdon Winner, 'Do Artifacts Have Politics?' (1980) 109(1) *Daedalus* 121.

together a broad range of stakeholders: including members of EU institutions, people with lived experience and mental health advocates, researchers, and service providers from different European countries. The variety of expertise in the room guaranteed a fruitful and enriching experience.

## Research questions

The workshop aimed to answer and discuss the following questions:

- What is the EU landscape of law and policy concerning digitalised mental health care?
- What are user survivor advocacy organisations hearing about experiences with digital mental health service provision and other digital responses to distress and crises? Are advocacy priorities well formed? If so, what are they? If not, why is this? Is digitalisation of health and social services even a priority for user survivor advocacy organisations or is it simply one component of broader advocacy concerning services in general (whether digital or face to face)?
- Are the existing laws and regulations fit for purpose? Do they address key issues in the mental health context? Is more work needed to apply these general laws to the mental health context? If so, in what way?
- Are service providers indicating that the EU regulatory landscape is conducive to the use of digital/online technologies in their work, including supporting innovative research and development? Do services that are pursuing digital approaches appear to be aware of their obligations under these rules?

## Background

### *The legal and policy landscape*

Three important pieces of legislation in the EU regulating e-mental health tools – like mental health apps, the use of sensor technologies in hospital settings, telehealth website interfaces – include the [General Data Protection Regulation \(GDPR\)](#), [Medical Devices Regulation \(MDR\)](#) and the draft [Artificial Intelligence Act \(AIA\)](#). The relevance of each instrument will be outlined below.

Legislation covering digital services, such as large-scale teletherapy platforms that connect ‘users’ and therapists, are also relevant in some instances. The European Commission introduced two key laws to upgrade rules governing digital services in the EU: the [Digital Services Act](#) and the [Digital Markets Act](#).<sup>3</sup>

The Digital Services Act and Digital Markets Act have two main goals:

1. to create a safer digital space in which the fundamental rights of all users of digital services are protected;
2. to establish a level playing field to foster innovation, growth, and competitiveness, both in the European Single Market and globally.

The EU [General Product Safety Directive](#) is also relevant as it aims to ensure all products available on the EU market meet minimum safety standards. The updated Directive aims to bring digital products into scope, thereby covering any products (such as games or connected devices) that are not covered by higher safety requirements under laws such as the Digital Services Act and the AIA.

The GDPR is an extensive regulation which, among other things, provides protections for ‘data concerning health’, including mental health data (Art 4(15)). As a genre of ‘sensitive data’ (Art 9(1)), mental health

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<sup>3</sup> The Digital Markets Act entered into force on 1 November 2022 and the Digital Services Act entered into force on 16 November 2022.

data attracts the highest level of protection under GDPR, requiring explicit consent to obtain rather than normal consent.

The GDPR further concerns the use automated profiling, which it defines as ‘any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person’s performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.’<sup>4</sup> Article 22 of the GDPR provides that ‘the data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her.’ Legal scholar, Bernadette McSherry, has noted that predicting aspects of a person’s mental health (whether accurate or not) appears likely to fall within the ambit of this Article.<sup>5</sup>

A key development in the EU regulatory scheme is the [Artificial Intelligence Act](#) (AIA), a proposed European law on artificial intelligence (AI). It is the first law on AI by a major regulator anywhere. The law assigns applications of AI to three risk categories. First, applications and systems that create an unacceptable risk (such as government-run social scoring) are banned. Second, high-risk applications (such as a CV-scanning tool that ranks job applicants) are subject to specific legal requirements. Lastly, applications not explicitly banned or listed as high-risk are largely left unregulated.

Finally, another important current development on the EU level is the [European Commission’s proposal to implement a European Health Data Space](#) (EHDS). The main goal of the EHDS is to organise data, by specifying who can access them, and for what purpose.

The EHDS aims to:

- Empower people with regards to access to and control over their personal health data.
- Facilitate the EU-wide use and exchange of health data for research, innovation, policy-making and regulatory activities, to improve quality of health care, policies and innovations.
- Foster a genuine single market for electronic health record systems, relevant medical devices - including wellness apps- and high-risk AI systems.

To achieve these goals, the European Health Data Space provides infrastructures, rules, common standards and practices and a governance framework, stimulating and safeguarding the primary use (on a case level) and secondary use (on a population level) of health data.

It is important to note that the EHDS is about data *exchange*, not about data *storage*. There will not be a European system that stores all Europe’s health data. Instead, the EHDS provides an infrastructure to exchange data safely between stakeholders. Primary data are only exchanged when service users and healthcare professionals agree with the request. Secondary data are only exchanged in a pseudonymized, encrypted, highly secured form.

### *Unresolved issues of law and policy*

In 2021, the European Commission released a report on ‘The State of Health in the EU’, which took a **healthcare** lens to the question: what unresolved issues of law and policy remain for digital health? The report focuses on general (rather than mental) health, but the issues remain relevant and include the following.

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<sup>4</sup> Regulation (EU) 2016/679 of the European Parliament and 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) [2016]

<sup>5</sup> Bernadette McSherry, ‘Computational Modelling, Social Media and Health-Related Datasets: Consent and Privacy Issues’ (2018) 25(4) *Journal of Law and Medicine* 894.

- 1) **Policy and regulatory changes during the pandemic promoted the uptake of digital health tools: What to retain? What to discard? What to build upon?**
- 2) **Addressing health inequality and digital exclusion**
- 3) **Standardisation of electronic health records and databases**
- 4) **Reimbursement pathways for digital health technologies, and assessing evidence**
- 5) **Product liability and applicable regulatory regimes**
- 6) **Human rights issues**

These issues were explored in the workshop and will be discussed further in the following sections. Further background notes on The European Commission's 'The State of Health in the EU' Report can be found in **Appendix 1**.

## Discussion

### Legislation

In relation to the legislative developments presented above, it was noted that they try to address three concerns related to digital advancements (and their application in health care):

- 1) Need to access and share data (in order to develop a product, to do research, provide and improve services, and so on).
- 2) Legal issues related to safety of digital products and services (trustworthiness) and to liability considerations (i.e., who is accountable if something goes wrong).
- 3) Ethical issues, related to the need not to leave anybody behind (for instance by addressing the digital divide).

The European Commission has proceeded with horizontal initiatives, addressing safety of AI in general (not just in health care). The AI Act goal is to ensure that AI systems are trustworthy. The focus is on data quality and liability. The main issue in relation to liability consists in defining when AI systems are defective and when – if one is harmed – one can claim liability. This requires a balancing act between innovation and security. Among others focuses, the AI Act sets requirements for algorithm transparency, human oversight, and system robustness. It also puts some obligations on the users of high-risk systems (article 29 AI Act).

### Service Users

Some representatives of service users expressed positive expectations in relation to digital technologies. They acknowledged that digitalisation is here to stay, hence it is inevitable to have it also in the mental health care field. Yet, laws and regulations should address the following concerns:

- 1) **Data safety.** There was a general concern about the possibility for data to be collected or shared without the person's consent. Formal mental health care records can be accessed by an unknown number of people and there are concerns about who can make changes to the file, including whether electronic records will improve patients or service users' ability to rectify medical notes they feel are wrong. Once information is in a digital medical record, it can be difficult to challenge it and can 'follow' a person through health systems, and potentially other government agencies, such as criminal legal and welfare systems. Some clinical or social work files concerning mental health may be structured in such a way to emphasise the most shocking episode in a person's

encounters with mental health services, which strongly and sometimes negatively affects the way other services interact with that person. Records held by mental health services, and other services that collect mental health-related data, are not necessarily designed for persons and their family members, so can be hard to engage with and – if need be – to challenge. This difficulty can strengthen the stigma individuals' and families experience. One participant was concerned that files can be filtered by key words (danger, threat), which can also lead to increased stigma.

- 2) **Transparency.** Concerns about trustworthy systems are particularly amplified in the case of mental health digital systems. One participant raised concerns about cases of people being hospitalised in the EU against their consent and their data being accessed by counterterrorist agencies or border control agencies. Regardless, the possibility for data transfer (without consent) heightens the possibility of discrimination, amplifies stigma and may create fear among service users about interacting with mental health services in the first place. Without trustworthy digital systems there is the potential that efforts to improve efficiency and expand the accessibility of services to more people, may – perversely – frighten people into *not* engaging with services for fear of data harms.
- 3) **Surveillance.** Services users experience anxiety in relation to potential if not already existing applications of digital systems. For instance, the possibility for digital systems to ensure adherence to treatment is felt by users as a limitation of their freedom, given that the decision on taking or discontinuing a medicament should be entirely up to them. Similarly, crisis intervention algorithms can be activated by the wrong triggers.

It was stressed that the above concerns can be prevented. In order to do so, it is crucial to **involve users in design and control of digital systems** and to consider digital technologies as a complementary component to, **not a substitute for, human support** (as no AI can replace the value of human support).

Participants with lived experience and experience in user/survivor advocacy roles emphasised another concern: digital technologies can strengthen a narrow understanding of mental health. In other words, efforts to digitalise services and make them 'scalable' typically requires formulaic approaches, which can be reductive and highly individualistic and medicalised. Mental health becomes something presented as an individual matter: the person experiencing mental health problems needs to fix themselves and only then can they be included in society. Yet, **mental health is societal** and the psychosocial dimensions and broader socio-economic context need to be taken in consideration. The example was made of apps designed to reduce fear, which can't go very far in helping the concerned person, if s/he is fearful because s/he lives in the same household as an abuser. On the other hand, apps that are more responsive to social context, which are connected to local support services, could be greatly beneficial.

Other service users who took part in the informal knowledge exchange were less optimistic, highlighting **that digital technologies have the potential to amplify many of the human rights pitfalls** already existing in the mental health field and to take current challenges to a whole new level. Possibilities such as biometric monitoring (e.g., analysing speech patterns and making a diagnosis out of it) were singled out as highly concerning, as they bring the risk of classifying individuals en masse in ways that lead to discrimination, or more subtly, reductive accounts about people's inner worlds based on proxy measurements of their behaviour (such as how they type on their phone, the modulation of their voice, evaluation of their texting and typing, which are all examples presented by researchers as being able to 'reveal' a person's mental health condition). Regardless of the scientific validity of claims that this is possible, this type of personal, behavioural data can fuel discrimination. It was pointed out that these are not new challenges. Some participants went as far as saying that the mental health system is broken and it needs to be transformed, and that digital technologies are neither the cause nor the solution to that need.

It was observed that mental health systems, as part of health, already have extensive regulations in place, whereas the use of digital technologies in this field may be comparatively under-regulated or unregulated. Hence, a call for very robust regulatory framework and governmental scrutiny was put forward. This is a permanent challenge, because markets and technology evolve on a continuous basis and in a globalised way. It is crucial to **define solutions to protect human rights in digital contexts**. The participation of people with lived experience is a key step in this direction.

## Research

Two main concerns were identified by researchers in relation to e-mental health:

- 1) **Lack of clinical validation** of mental health digital devices and apps
- 2) **Poor data protection practices**

It was stressed that any policy approach should address at least these two main concerns.

From a legal point of view, these concerns can be addressed with two different forms of legislation: product safety laws and data protection laws, respectively.

In relation to clinical validation, the first question to address is whether the specific device is a medical device or a wellness device. If the purpose of the device – as stated by the manufacturer – is a medical one (as defined by the Medical Devices Regulation, MDR), then it is a medical device and it falls in the scope of the MDR. On the other hand, if the intended purpose of the device is not medical, the applicable regime is completely different, and consists of the general law that covers all consumer products (the General Product Safety Directive). The General Product Safety Directive does not require any evaluation of clinical evidence, pre-market assessment, or oversight by the sectoral control mechanism. Only medical devices, regulated by the MDR, require an evaluation of clinical evidence. The level of clinical evidence required depends on level of risk.

In the previous Medical Devices Directive there were no classification rules for software. Most manufacturers of mental health devices classified their device under risk Class I. This lower risk categorisation corresponded with less onerous registration requirements, as would be the case with a clinical evaluation based on self-assessment, with no need for third party involvement.

The current MDR introduced an entirely new section to the classification rules dedicated to software. Rule 11 Annex VIII MDR provides that:

Software intended to provide information which is used to **take decisions with diagnosis or therapeutic purposes** is classified as class IIa, except if such decisions have an impact that may cause:

- Death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- Serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software are classified as class I. (emphasis added)

In theory, the option still exists of categorising software such as mental health apps under Class I. However, in practice, the current wording of the provision appears to be understood in a very broad manner by manufacturers and notified bodies. If a broad understanding is taken of the terms '*information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa*', then practically all mental health apps would appear to fall – at a minimum – in risk Class IIa.

The Risk II category involves lengthier procedures, additional bodies requiring notification, and more onerous registration requirements on registrants. Hence, under the current legislation, manufacturers have no incentive to self-classify their app as a 'medical device' – the registration process is lengthy, costly and inconvenient. As a result, they may forgo registration by stating the purpose of their device as *non-medical*. Therefore, no clinical evaluation is performed, which among other risks can jeopardise the quality of the care provided.

A possible solution is to encourage manufacturers to admit their product as a medical device. This would require reforms of the MDR to remove registration requirements that are perceived as disproportionate by the manufacturers and to either reopen the Risk I class, or create exemptions for certain devices. (Some jurisdictions, such as Australia, have provided exemptions for most mental health apps, although this does not extend to apps deemed to sit in a higher risk category, such as where an app is based on experimental forms of 'digital phenotyping'). Arguably, incentives should be provided to encourage manufacturers to admit their products as medical devices. To put it simply, the existing classification rules have resulted in a greater number of manufacturers choosing to bypass certification entirely. The effect is that more devices end up in the consumer health market, which is a far less regulated realm, which lacks mandatory clinical evaluation or proof of efficacy.

There was some discussion in the workshop about the aims of some user survivor organisations to de-medicalise responses to mental health crises. How this broader debate about the (de-)medicalisation of distress, mental health crises, and disability, fits within these discussions about the potential safeguarding provided by medical regulation, and the appropriate boundaries of medical versus consumer product regulation, is unclear at this stage but warrants further consideration.

In relation to data protection concerns, the GDPR was generally considered by the participants to be robust. However, problems lie in implementation. Hence, careful reflection is needed on how to increase compliance of digital technologies with GDPR.

The health system – faulted as it can be – does provide a regulatory structure than the general market does not. Yet, there are some gaps in the regulatory structure, as clinical evaluation doesn't leave room to approaches delivered by people with lived experience for people with lived experience.

Another aspect highlighted by researchers pertains to human rights concerns, in particular in relation to **health equity and digital inclusion**. Digital technologies can create new inequalities and strengthen existing ones, with a negative impact particularly on vulnerable groups. The potential for algorithmic bias or discrimination is well-documented: some digital mental health technologies are powered by machine learning models, which can perpetuate existing biases and present risks of algorithmic discrimination. This is mainly due to unrepresentative datasets and the fact that **structural inequalities (on the basis of race, gender, disability, etc.) permeate data science process**. If we rethink our datasets, we can challenge unequal power structures and rather value multiple forms of knowledge and perspectives. The workshop recommended raising awareness of the human rights issues behind AI and digital technologies and acknowledging the specificities of their application in the health sector: people's health is at stake, people in need of healthcare are in a vulnerable position and collection of health data is historically biased. It was



stressed that a meaningful **involvement of the users of digital technologies in all the phases of the process is key to guaranteeing fairness and equity.**

### Service providers

From the perspective of service providers, three important developments were identified:

- 1) The Medical Device Regulation (MDR) made it more difficult for apps to obtain safety clearance, which leads to increased costs and an onerous procedure in research with apps under the MDR. As discussed earlier, the disadvantage of having more devices not admitted as medical devices is that no form of mandatory proof of efficacy or clinical evaluation is required for them (contrary to medical devices, which all have to provide clinical evidence pursuant to Article 61 MDR).
- 2) Covid-19. With the outburst of the pandemic, all psychiatric services faced the challenge on how to keep in contact with users. There was a boost in tele-therapy (not so much of apps, because of safety concerns and technical aspects). Changes to local and national regulations in Germany enabled providers to provide teletherapy services, by linking those services to (public) remuneration.
- 3) Germany's Digital Health Act (Digitale-Versorgung-Gesetz; DIGA). This reform dated two years ago was intended to accelerate the use of digital health tools. It allowed doctors to prescribe digital mental health apps, and for insurance companies to reimburse the costs related to the purchase of these apps. Companies were required to submit evidence of the safety and efficacy of their apps before they were allowed to receive government reimbursement via medical insurers. Some debate arose whether clinical efficacy and safety had been tested sufficiently given that a fast track for apps was made possible with short-term, but preliminary clearance. Medical doctors and psychologists need training in using such apps. Clinical staff have many questions regarding liability and clinical efficacy issues. In the framework of the [eMEN project](#) (e-mental health innovation and transnational implementation platform North West Europe), such education to psychiatrists was provided.

In relation to the boost of teletherapy during Covid-19, it was highlighted that the regulatory approaches were relaxed. For instance, service providers and users were allowed to use platforms like Zoom or WhatsApp for telehealth. Many of these platforms are not compliant with GDPR data security requirements. As the sanitary emergency is over, the easiest solution would consist in getting rid of these platforms that are not compliant with data protection regulations. In this sense, a user-friendly mapping of the GDPR compliance of the different platforms could be a useful resource to help service providers choose among them to meet data security requirements. Yet, broader considerations are at stake. Indeed, in the case of **marginalised communities** (e.g., people living in homelessness, refugees) the platforms they use – and where they can be contacted – are often those which would have to be disregarded for data protection issues. Here a delicate exercise of **reconciling** the reality – and **the needs of users, especially those from vulnerable groups – with the strict requirements of the GDPR** needs to be performed. When regulating on digital mental health, it is important to have a clear overview of the different types of digital tools available, the stakeholders involved and what each tool does.

It was pointed out that European countries perform very differently in relation to the different applications of digital technologies to the health field, such as electronic health records, e-prescriptions, telemedicine, e-Health applications. Policymakers should be open to innovation.

It was stressed that digitalisation should never be a substitute of human connections and care and should not be considered as an end in itself. The goal should always be to improve people's welfare and wellbeing. Also, from the service providers there was a call for users' participation, considered as a key element to ensure that digital technologies can be of benefit to humanity.

## Conclusions and next steps

For digital technologies to strengthen opportunities for good mental health across the population, governments need to invest in **safety** and **quality**, and to ensure **accountability** when these are not provided. Attention should not turn to focusing on the technology itself, but rather on those who design, develop, and deploy it. The appropriate attribution of **responsibility** and clear pathways for **redress** when things go wrong is vital not only for individuals, but also for maintaining public trust in technology-driven solutions.

Moreover, **'fairness'** and **equity** need to be considered. Avoiding the exacerbation of socio-economic inequalities via digital tools is a paramount requirement for the ethically aligned deployment of these technologies. **Active involvement of those most impacted** by algorithmic and data-driven technologies should not be seen merely as a required step of 'stakeholder engagement', but rather as an ethical necessity. This way digital technologies will be applied not just because they are feasible, but because they respond to a real need.

The discussion in this workshop was very much needed, but it did not presume to provide answers to all possible questions in relation to digital mental health. The complexities of the issues at stake, the fact that there are different actors with competing interests, and the different speeds at which technological advancements and law-making processes occur make it impossible to address all the nuances in a two-hour discussion. Yet, it was clear to all stakeholders that **digital technologies should be viewed as a means to an end rather than an end in and of itself**—the ends to which they should be directed is to allow people to flourish and fully enjoy their human rights. In order to do so, it is crucial to hear the voice of all the interested actors, particularly people with lived experience. A human rights framework, a psychosocial model of understanding mental health, and the co-creation approach should be the compass to solve any current or future dilemmas.

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## Mental Health Europe

[Mental Health Europe](#) (MHE) is the largest European independent network organisation representing mental health users, their families and carers, health professionals and service providers in over 30 countries across Europe. MHE has been working for over 35 years to promote positive mental health, prevent mental health problems and advocate for social inclusion and the protection of the rights of persons with psychosocial disabilities. MHE subscribes to the psychosocial model of mental health, according to which mental health is shaped by a variety of factors including wider socio-economic and environmental issues. MHE's work is underlined and guided by key international and European frameworks such as the UN Convention on the Rights of Persons with Disabilities. At MHE we recognise that no policy or service will effectively tackle mental health without the insight and expertise provided by people with lived experience and their supporters and their meaningful involvement.

## Dr Piers Gooding

Dr Piers Gooding is a Senior Research Fellow at the Melbourne Law School at the University of Melbourne Law School. He is a socio-legal researcher who examines disability and mental health-related law and policy. Dr Gooding has acted as a board member and advisor for a range of local, national and international bodies working on the rights of disabled people, including advising the UN Special Rapporteur for the Rights of People with Disabilities, the UN Special Rapporteur on the right to physical and mental health, the UN Economic and Social Commission for Asia and the Pacific, and the World Psychiatric Association.

## Melbourne Law School

Melbourne Law School is one of the professional graduate schools of the University of Melbourne. Melbourne Law School is Australia's oldest law school, and offers J.D., LL.M, Ph.D, and LL.D degrees. In 2021-22, Times Higher Education World University Rankings ranked the law school as 5th best in the world and first both in Australia and Asia-Pacific.

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**Appendix 1 – Further Notes on the European Commission, *The State of Health in the EU: Companion Report 2021***

What unresolved issues for law and policy remain? Taking a **healthcare lens**, the European Commission addresses this question in its recent 'State of Health in the EU' report.<sup>6</sup> The report focuses on general (rather than mental) health but the issues remain relevant and include the following.

### 1) **Policy and regulatory changes during the pandemic promoted the uptake of digital health tools: What to retain? What to discard? What to build upon?**

During the pandemic, new national policies were developed to support the rapid uptake of digital health tools. This included:<sup>7</sup>

- Relaxed thresholds on the volume of remote telehealth consultations (e.g. Germany);
- Teleconsultations for first-visit patients allowed (e.g. France and Belgium)
- Remote renewal allowed for repeat prescriptions (e.g. Italy, Austria and Malta). Data show a sizeable increase in the use of remote prescriptions in the EU overall.
- Reimbursement rates adjusted for remote consultations, or the creation of COVID-19-specific tariffs (most countries). According to the European Commission, 'most countries have increased reimbursement levels for remote patient consultations closer or even up to those normally paid for standard face-to-face ones' with the aim of 'incentivi[sing] the provision of telehealth, as well as to offset physicians' loss of income from the temporary reduction in the volume of face-to-face consultations'.<sup>8</sup>

Several EU countries allocated additional resources to digitalising healthcare, including via EU's Recovery and Resilience Facility. For example, Belgium allocated EUR 40 million to expand eHealth services that will extend e-prescription capabilities, develop digital clinical decision-making support systems and increase telehealth.<sup>9</sup>

According to the European Commission, 'evidence suggests that important enablers of [the increased use of digital health technologies] during the pandemic *consisted in changes to the rules that governed their use by health workers*'.<sup>10</sup> More research is required to understand the views of 'health workers and patients who have used digital health tools during the pandemic... with a view to evaluate their effectiveness and devise adequate financial and regulatory provisions'.<sup>11</sup>

### 2) **Addressing health inequality and digital exclusion**

Risks of exclusion from health services that become digitalised in various ways exist for certain groups (for example, people with cognitive disabilities and indeed, people with psychosocial disabilities).<sup>12</sup> This also extends, as the European Commission pointed out, to 'a large share of the population who either have never had access to the internet (10% of the EU's population in 2019) or have not developed digital skills and material requirements to use it (29%)'.<sup>13</sup>

### 3) **Standardisation of electronic health records and databases**

There has been no regional effort (to the authors knowledge) to define data quality management to 'ensure integrity, completeness and security of the data sources'.<sup>14</sup> for electronic health records in the mental health context; nor a public discussion of issues of concern or interest to persons with psychosocial disabilities, advocates and so on. Mental Health Europe is undertaking work in this area presently, and a report that addresses this and other topics concerning mental health and the digitalisation of European society more generally, is imminent.

### 4) **Reimbursement pathways for digital health technologies, and assessing evidence**

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<sup>6</sup> European Commission, *The State of Health in the EU: Companion Report 2021*. Luxembourg: Publications Office of the European Union, 2022 [https://health.ec.europa.eu/state-health-eu/companion-report\\_en](https://health.ec.europa.eu/state-health-eu/companion-report_en).

<sup>7</sup> Ibid pp 22-26.

<sup>8</sup> Ibid 24.

<sup>9</sup> Ibid.

<sup>10</sup> Ibid. (emphasis added).

<sup>11</sup> Ibid 25.

<sup>12</sup> See Liam Ennis et al, 'Can't Surf, Won't Surf: The Digital Divide in Mental Health' (2012) 21(4) *Journal of Mental Health* 395; Murielle Girard, Philippe Nubukpo and Dominique Malauzat, 'Snapshot of the Supports of Communication Used by Patients at a French Psychiatric Hospital: A Digital or Social Division?' (2017) 26(1) *Journal of Mental Health* 8.

<sup>13</sup> Ibid 26.

<sup>14</sup> Ibid.

Approaches to reimbursement for the use of digital health technologies varies. In the UK, the National Institute for Health and Care Excellence, *Evidence standards framework for digital health technologies* are designed to ‘assist innovators and commissioners in understanding what good levels of evidence for digital health technologies would look like,’ with the aim of clinical efficacy and economic value.<sup>15</sup> Germany’s *Digital Health Act (Digitale-Versorgung-Gesetz)* was intended to accelerate the use of digital health tools during the Covid-19 pandemic and requires companies to submit evidence of safety and efficacy before they are allowed to receive government reimbursement. According to Nicole Martinez-Martin and colleagues, similar ‘regulation could help to provide a more consistent system for evaluation of digital [mental] health tools and ensure that users have access to safe products’.<sup>16</sup>

## 5) Product liability and applicable regulatory regimes

Concerns have been raised that that ‘the distinction between products and services have been blurred in the context of digitalisation and AI.’<sup>17</sup> The European Commission has indicated that the product liability rules (in the Product Liability Directive 1985 (*Directive 85/374/EEC*) noted previously) need to be adapted to the digital era, in ways that seek to balance ‘user’ protection while promoting innovation. In June 2021 the European Commission published a policy document which identified that the new rules should seek:<sup>18</sup>

- (a) to provide legal certainty to companies about the risk they take in the course of their business;
- (b) to encourage the prevention of damage and
- (c) to ensure injured parties are compensated.

Another key issue arising from the blurring of healthcare intervention and commercial product, is that it creates ambiguity about which regulatory regime is applicable. For example, if an app is pitched by a manufacturer as a ‘wellbeing app’ it is not subject to the same restrictions as medical devices, with its strict oversight of software that functions as medical device. The EU adheres to a strict distinction between medical devices and consumer health products but some are concerned that this arrangement risks overlooking the grey zone between them, particularly in the mental health context.<sup>19</sup> Further, onerous regulatory requirements in the Medical Devices Regulation, which appear to be designed more for physical health- rather than mental health-related devices, will incentivise manufacturers to pitch their software as ‘wellbeing’ or ‘wellness’ products—that is, a consumer health product, which attracts substantially lower legal protections for those who use them. This power to determine the applicable regulatory regime appears to lie with manufacturers because article 2 of the MDR ‘as intended by the manufacturer’.

## 6) Human rights issues

According to the World Health Organisation, ‘[t]here are ... potential serious negative consequences if ethical principles and human rights obligations are not prioritized by those who fund, design, regulate or use AI technologies for health’.<sup>20</sup> This Brief goes beyond AI but the point here remains relevant: many people and organisations have supported international human rights law as a basis for regulating data-driven technologies,<sup>21</sup> including in the mental health context.<sup>22</sup> For example, an upcoming report by Mental Health Europe states:

A value-based human rights approach should be used as central guideline. We have to look at ways for technologies to promote and protect, rather than threaten, human rights (such as: prohibition of discrimination, the right to privacy, freedom of expression, the right to health, the right to a fair trial and the right to an effective remedy). Co-creation is of essence: research that actively involves users in the development, design and implementation of technology – as well as its governance – will help to ensure technology is enabling rather than disabling.<sup>23</sup>

This comment refers to the digitalisation of society more generally, but the point is particularly relevant to digitalised mental health care and crisis support services. Yet, in many public documents celebrating the positive potential of

<sup>15</sup> Ibid. Harriet Unsworth et al, ‘The NICE Evidence Standards Framework for Digital Health and Care Technologies – Developing and Maintaining an Innovative Evidence Framework with Global Impact’ (2021) 7 *Digital Health* 20552076211018616.

<sup>16</sup> Nicole Martinez-Martin et al, ‘Ethics of Digital Mental Health During COVID-19: Crisis and Opportunities’ (2020) 7(12) *JMIR Mental Health* e23776.

<sup>17</sup> ICLG.com (n Error! Bookmark not defined.)

<sup>18</sup> European Commission, Inception impact assessment - Adapting liability rules to the digital age and circular economy, Ref. Ares(2021)4266516, 30/06/2021 ([https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Product-Liability-Directive-Adapting-liability-rules-to-the-digital-age-circular-economy-and-global-value-chains\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Product-Liability-Directive-Adapting-liability-rules-to-the-digital-age-circular-economy-and-global-value-chains_en)).

<sup>19</sup> I am grateful to Dr Elisabeth Steindl for sharing a working paper on this topic, whose ideas have informed this section of the discussion brief. Her paper on this matter is forthcoming.

<sup>20</sup> Ethics and governance of artificial intelligence for health: WHO guidance. Executive summary. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO, xi.

<sup>21</sup> See e.g. Lorna McGregor, Daragh Murray and Vivian Ng, ‘International Human Rights Law as a Framework for Algorithmic Accountability’ (2019) 68(2) *International & Comparative Law Quarterly* 309; *Algorithm Charter for Aotearoa New Zealand 2020*.

<sup>22</sup> Bossewitsch et al (n1).

<sup>23</sup> Mental Health Europe, ‘Mental health in the digital age: Applying a human rights framework as compass’ (forthcoming).

digital technologies in mental healthcare, there is a concerning lack of partnership with people with firsthand experience of mental health services and their representative organisations.<sup>24</sup>

The Convention on the Rights of Persons with Disabilities is perhaps the most relevant international human rights instrument, given its role in applying established human rights norms to the disability context, and given the strong involvement of people with first-hand experience of lived experience and psychosocial disability in its development—but more work is required to apply it to the digital context. Toward this aim, the Convention underscores the importance of ‘co-creation’, to use the term of Mental Health Europe, and requires the active involvement of persons with disabilities in the development of laws, policies and programmes that impact them (art 4(3) CRPD).

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<sup>24</sup> See eg. Sarah Carr, “‘AI Gone Mental’”: Engagement and Ethics in Data-Driven Technology for Mental Health’ (2020) 0(0) *Journal of Mental Health* 1; Til Wykes, ‘Racing towards a Digital Paradise or a Digital Hell?’ (2019) 28(1) *Journal of Mental Health* 1.

## **Appendix 2 – Participant Biographies**

### **Mr Yiannos Toliás, Legal Officer, European Commission, DG SANTE**

Mr Toliás is a lawyer in DG SANTE (Health and Food Safety) in the European Commission. He is in the team working on AI liability in Healthcare, Digital Health and Health Data. He was a Senior Emile Noel Fellow at New York University Law School working on a project on machine learning in medicine and law. Prior to joining the European Commission he was an Assistant Professor of EU law at the Universities of Edinburgh and Dundee. He holds a Ph.D. in EU Constitutional law from the University of Edinburgh and was a Post-doctoral Research Fellow at the Institute for Advanced Studies in the Humanities (Edinburgh University).

### **Ms Olga Kalina, Chair, ENUSP**

Olga Kalina is a human rights activist in the disability and mental health fields. After being diagnosed with paranoid schizophrenia in 2005, she joined the non-governmental organization, Partnership for Equal Rights promoting rights of people with mental health problems. Since then she has been involved in trainings, advocacy activities and projects related to human rights in the mental health sphere. She has an MD in Biology (Georgia), received in between of the two de facto involuntary hospitalizations. Since 2014, Olga Kalina is Chair of the European Network of (Ex-)Users and Survivors of Psychiatry (ENUSP) and a member of the monitoring team of the National Preventive Mechanism, Georgia. Olga has been involved in monitoring of houses for elderly people, prisons and psychiatric institutions. In 2019 she participated in the monitoring process based on Quality Rights monitoring methodology. Was involved in the drafting of the Georgian Mental Health Strategy 2020-2030. She is also founding Board member for the organization of women with disabilities “Platform for the New Opportunities” and a member of the National Network of women with disabilities.

### **Ms Jolijn Santegoeds, Board member, ENUSP**

The late Jolijn Santegoeds was a European Disability Forum board member on behalf of the European Network of (Ex-)Users and Survivors of Psychiatry (ENUSP); Co-Chair, World Network of Users and Survivors of Psychiatry (WNUSP). For more information Ms Santegoeds’ enormous contribution to advancing human rights, please see the European Disability Forum tribute for her here: <https://www.edf-feph.org/we-mourn-the-loss-of-jolijn-santegoeds-disability-activist-and-voice-for-people-with-psychosocial-disabilities/> (accessed 30/05/2022).

### **Mr Alberto Vásquez Encalada, Senior Advisor at the Center for Inclusive Policy (CIP) and consultant on disability rights and mental health law**

Alberto Vásquez Encalada is a Senior Advisor at the Center for Inclusive Policy (CIP) and a consultant on disability rights and mental health law. He is a lawyer and holds an LL.M in International and Comparative Disability Law and Policy from the National University of Ireland, Galway. He has served as a consultant to various UN agencies and worked as Research Coordinator at the Office of the UN Special Rapporteur on the rights of persons with disabilities from 2015 to 2020. In Peru, he is actively involved in the drafting, advocacy and monitoring of laws and policies relating to persons with disabilities, and worked at the Ombudsperson Office and the Peruvian Congress. He is the president of Sociedad and Discapacidad - SODIS, a board member of the Disability Rights Fund (DRF) and the Bank Information Center (BIC), and a proud member of the Redesfera Latinoamericana de la Diversidad Psicosocial (Latin American Network of Psychosocial Diversity).

### **Dr Elisabeth Steindl, Research Associate, Department of Innovation and Digitalisation in Law, University of Vienna**

Elisabeth Steindl has a multifaceted academic background, primarily in law and the arts. She works at the Department of Innovation and Digitalisation in Law as well as working as a member of the platform, Governance of Digital Practices, both at the University of Vienna. Her research on data protection and

privacy aspects takes a special interest in the field of e-mental health and emerging technologies of the mind, such as emotion recognition and neuro technology. Her work focuses on questions of legal policy, legal ethics, and legal comparison at the intersection with the humanities and social sciences.

Elisabeth is a member of the Competency Group for Public Mental Health of the Austrian Society for Public Health (ÖGPH), and of the Institute of Electrical and Electronics Engineers Standards Association Sub-Committee on Ethical Assurance of Data-Driven Technologies for Mental Healthcare.

**A/Prof Pin Lean Lau, Lecturer (Assistant Professor) in Bio-Law, General Manager, Centre for Artificial Intelligence: Social & Digital Innovations, Brunel University London**

Assistant Professor Pin Lean Lau is a Lecturer in Bio-Law at Brunel Law School London. A former practising barrister and solicitor, she was previously an attorney on secondment with the Legal Services Team in the General Counsel's Organization of American Express International, where she was a key senior legal counsel for the Asia-Pacific region.

Pin Lean is the General Manager of the Centre for Artificial Intelligence: Social & Digital Innovations. She is an active member of the Brunel International Law Research Group, and the Human Rights, Society and the Arts Research Group, and Reproduction Research Group. Externally, she is, among other things, a member of the European Association of Health Law (EAHL), and a General Manager of the Interest Group on Supranational Bio-Law of the EAHL. She has held visiting fellowships with the Centre for Health, Law and Emerging Technologies (HeLEX), University of Oxford; the Centre for Ethics and Law in the Life Sciences (CELLS) at the University of Hannover, Germany; and participated in the Centre for Ethics and Law in Biomedicine (CELAB) in Central European University, Hungary.

**Prof Jürgen Zielasek (E-Mental Health Innovation and Transnational Implementation Platform Northwest Europe (eMEN))**

Prof Zielesak is a psychiatrist and neurologist. He works as the Scientific Coordinator of the LVR-Institute of Healthcare Research (LVR-IVF) in Cologne. His main interests are in mental healthcare services research with a focus on development, implementation and evaluation of innovative healthcare processes, and in statistical modelling of mental healthcare. He is also involved in a project to implement an e-mental health app for refugees in inpatient mental healthcare: [I-REACH](#).

**Mr Kevin Cullen, director of WRC, the Dublin-based independent health and social research centre**

Mr Kevin Cullen is a founding director of WRC, the Dublin-based independent health and social research centre. His work focuses especially on policy-support research at Irish and European levels, including health & social care system innovation, mental health, eHealth, older people, disability, supportive housing, and carers and caring. He has also carried out a large body of work on technology assessment in these fields.

**Ms Anna Keller, Project Manager at Pfalzlinikum für Psychiatrie und Neurologie**

Anna Keller is the project manager for digitalisation and digital transformation at Pfalzlinikum für Psychiatrie und Neurologie in the south-west of Germany – MHE member. She is responsible for the strategic and conceptional development of Pfalzlinikum digitalisation projects and information exchange on national and federal level regarding governmental support law. Her goal is to empower the digitalisation within the psychosocial field to improve health care and furthermore self-determination. For a long-lasting assurance of care quality but especially for the reason to give the user the possibility to become an expert in him/herself.

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