



**POSITION STATEMENT AND CALL TO ACTION:**

# Ethics and Law as Essential to e-Mental Health

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(VERSION 1.0)



# About eMHIC

eMHIC is a group of global subject matter experts, collaborating and sharing knowledge on all topics related to eMental Health. We serve as a single international point of reference for key eMental Health leaders and associated sectors who can improve and support the conditions for mental health and addiction. eMHIC's mission is simple: supporting meaningful collaboration and knowledge exchange to foster global best practice in eMental Health.

Our global community are working towards a future where all populations have access to safe and effective, digitally enabled mental health promotion, prevention, screening, treatment and social support. Through enabling support and recovery at a time and place of a person's choosing, such initiatives are a vehicle to promote and achieve population wellbeing and prevention of mental ill-health or distress.

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**eMHIC would like to stress that this Position Statement and Call to Action is important and urgent for improving the quality of services enabled by new and emerging technology throughout the world, including in low-, middle-, and high-income countries.**

eMHIC views this Position Statement, which has involved the consultation at the 2021 eMHIC Congress, as the beginning of an ongoing process that will require continued engagement with eMHIC members, people with lived experience, as well as members of the public who may participate in direct-to-consumer wellness and mental health programmes, families, industry representatives, legal and policy makers, Government regulators and eMHIC partners globally.

It was developed to set direction and a practical basis for action. Specific engagement has been sought from eMHIC partners from government and the legal sector to ensure the Position Statement informs and, in turn, is informed by emerging regulatory and legal frameworks. The Position Statement aims to encourage and support adherence to the highest ethical standards in the design, development and use of e-mental health technologies.

E-mental health initiatives, as eMHIC has noted, are extremely varied and wide-ranging. Diverse technologies bring an equally diverse set of ethical and legal issues—whether they concern online counselling, therapeutic chatbots, online peer support forums, an array of apps concerning mental health and wellbeing, biometric monitoring technologies, electronic mental health records, and more. It may not be clear whether and, if so, to what extent, such initiatives have been subject to ethical scrutiny, or whether there are any legal issues of concern, particularly where regulatory frameworks may be unclear.

Several ethical principles and frameworks could be used to evaluate the potential benefits and harms of e-mental health initiatives, such as:

- **The classic bioethics principles** described by Thomas Beauchamp and James Childress in 1979, which concern autonomy, beneficence (promoting welfare), non-maleficence (harming welfare) and justice.
- **An 'ethics of care' approach** may be taken which prioritises the quality of therapeutic and supportive relationships.
- **A utilitarian or consequentialist analysis**, which is perhaps the most common approach in public policy, could help to weigh the goals and benefits of a particular technological practice against risks.

At the same time, this statement takes into account a deontological (or rule-based) approach, to ensure diverse interests would be safeguarded and advanced, particularly in the global context of international human rights law.

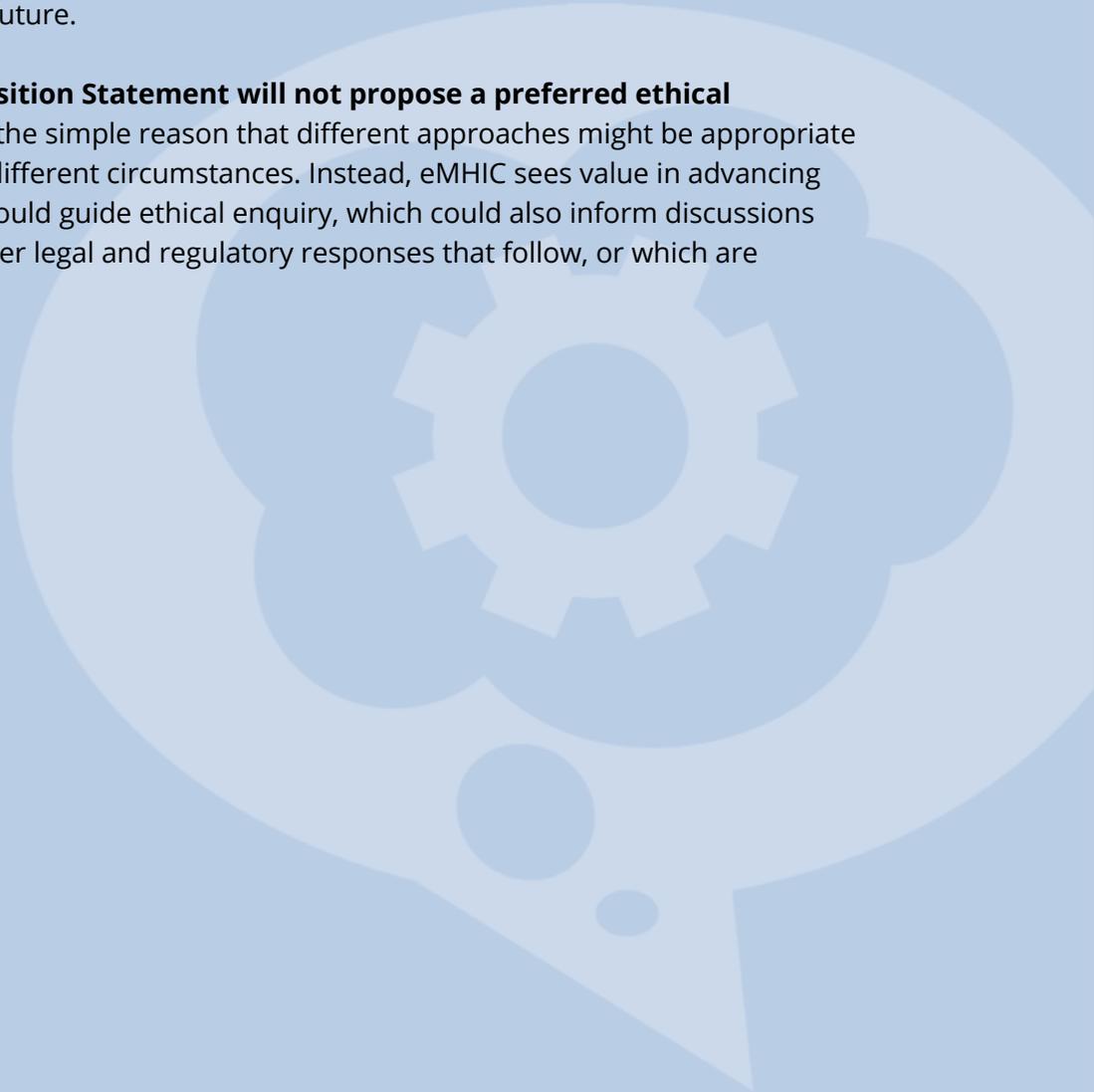
The classic bioethics principles are likely to be commonly understood in mental health systems. Yet, this approach may not always be the most appropriate lens through which to evaluate and view a particular e-mental health initiative. The increased attention and use of e-mental health tools in workplaces and education settings, means that the range of groups delivering e-mental health services

appears to be expanding beyond health and social services. Additionally, rearrangements in healthcare financing and reconfigurations in delivery may have the effect of transferring responsibilities and duties from traditional healthcare providers to institutions, organisations (both public and private), and individuals who are creating online, mental health-related initiatives.

Changing roles, relationships, and service contexts that extend beyond conventional therapeutic and professional settings, can lead to circumstances demanding new ethico-legal considerations. For example, is there a duty to intervene in emergencies during online therapeutic encounters and, if so, what are the legal or ethical limits to this duty? What are the legal requirements and ethical responsibilities for ensuring e-mental health service providers have the competency to support people's needs? What are the professional duties, regulatory responsibilities, or legal liabilities in relation to the consent and health literacy of patients, consumers, or users of commercialised products, particularly when those products are offered directly online?

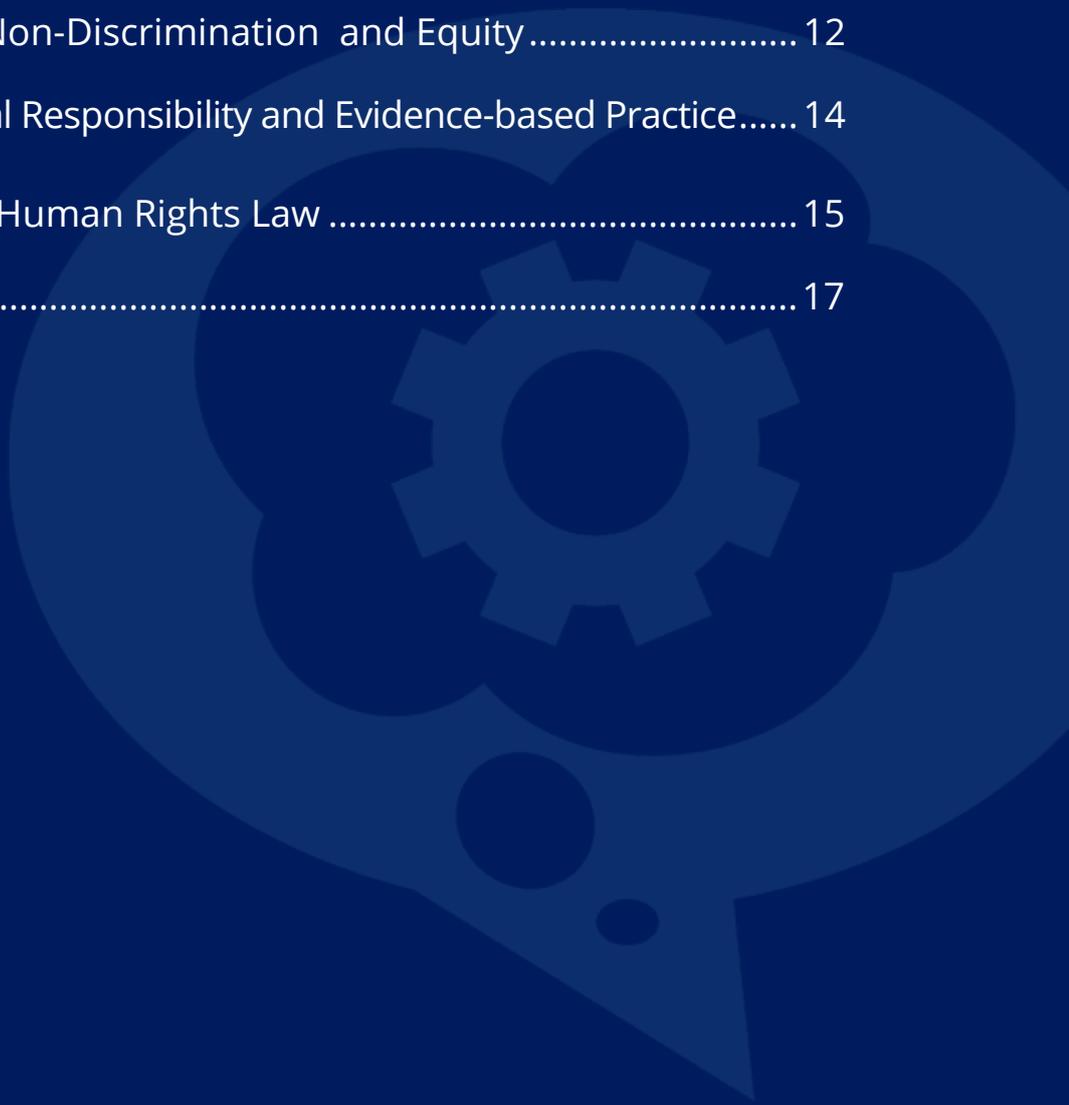
Rather than attempt to directly answer these questions, and in recognition of the diverse and evolving nature of e-mental health activities, this Position Statement seeks to encourage consideration of new and existing ethical and legal frameworks, together with practices and practice guidelines that are likely to be required in the future.

As such, **this Position Statement will not propose a preferred ethical framework** for the simple reason that different approaches might be appropriate or preferred in different circumstances. Instead, eMHIC sees value in advancing principles that could guide ethical enquiry, which could also inform discussions about the broader legal and regulatory responses that follow, or which are required.



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# Principles

There are several principles that may help guide emerging e-mental health practices in relation to ethical frameworks – from pre-development as well as initial work in testing an idea and deciding whether to proceed, through to design, development, implementation, ongoing maintenance, and even winding down particular systems.

These principles should be considered 'living principles', in so far that they are likely to evolve as the e-mental health field evolves. They are:<sup>1</sup>

- **partnership and active involvement of people with 'lived experience'**
- **privacy**
- **accountability**
- **safety and security**
- **transparency and explainability**
- **fairness, non-discrimination, and equity**
- **professional responsibility and evidence-based practice**

The purpose of this document is to set out key principles at a high level of generality. Future iterations of this Position Statement may include more detailed material. For example, additional details that are specifically relevant to particular types of e-mental health initiatives could be developed under each of the principles noted above.

**The purpose of this document is to set out key principles at a high level of generality.**

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In addition to the above principles, there has been a growing appreciation for the relevance of **international human rights law** to both the governance of new and emerging technologies and to policy, practice and laws related to mental health and distress. We will briefly discuss human rights at the end of the document.

Finally, before describing the principles, it is worth reiterating that they are presented here as an initial step to stimulate discussion and consideration. These principles and the accompanying material may be amended following feedback from eMHIC members, and following further consultation with practitioners, lived experience organisations, members of the public, policymakers, professional bodies, and other groups.



# Partnership and Active Involvement of People with ‘Lived Experience’

The Special Interest Group wishes to emphasise the importance of partnership and active involvement of people with lived experience of profound psychological distress,

experience in the design, development and use of e-mental health technologies as an overarching expectation and requirement. This need relates to

## **Partnership can also mean less intense forms of involvement.**

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mental health conditions, mental health services and interventions, and those who are imagined as end beneficiaries of various e-mental health practices.

several principles noted below, including Accountability, Transparency, Privacy, Fairness, Non-discrimination and Equity, and Professional Responsibility.

eMHIC recognises the need for partnership with people with lived

There is a range of ways ‘partnership’ may occur, from thoughtful

consultation that allows for meaningful input through to 'gold-standard' forms of co-design, and technological initiatives led by people with lived experience and the groups they represent. A one-size-fits-all process.

people with lived experience need to be involved in planning and shaping the systems meant to support them. Nothing about us without us."<sup>4</sup> This participatory ethos is increasingly considered standard practice in mental health-related policy and

## Diverse perspectives across socio-economic status are also crucial.

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A one-size-fits-all approach to active involvement of people with lived experience will not work, and precisely what the relevant 'lived experience' is for a particular e-mental health initiative will differ between practices (for example, grief and loss services, trauma support, LGBTQ+ services, culturally specific support, and so on).

Partnership can also mean less intense forms of involvement, and partners help determine the level of involvement before projects commence. An example of prioritising lived experience input at the policy level is the Australian National Safety and Quality Digital Mental Health Standards ('DMH Standards'), which promotes a 'partnering with consumers standard.'<sup>2</sup> The DMH Standards require digital mental health service providers to 'develop, implement and maintain systems to partner with service users and their support people'. Partnerships may relate to 'planning, design, delivery, measurement, review and evaluation of digital mental health services.'<sup>3</sup>

Jonah Bossewitch puts it succinctly when he writes that creating "technology to help support people better... starts with inclusive design –

practice. According to Dainus Pūras, professor of psychiatry and social paediatrics and the former UN Special Rapporteur on the Right to the Highest Quality Physical and Mental Health:

*participation of persons with mental health conditions, including persons with disabilities, in the planning, monitoring and evaluation of services, in system strengthening and in research, is now more widely recognized as a way to improve the quality, accessibility and availability of services and the strengthening of mental health systems.*<sup>5</sup>

According to 40 psychiatrist authors of a report for the *World Psychiatric Association-Lancet Commission on the Future of Psychiatry*, the involvement of patients, service users, families and carers, and their representative groups, is generally agreed to increase the likelihood of 'viable and effective—rather than disruptive and short-lived—advances' in digital technologies in the mental health context.<sup>6</sup> These aims also appear to align to some degree with popular user design methods.<sup>7</sup>

Participatory methods also align with human rights standards to actively involve and partner with persons with disabilities in decisions about

the policy and programming that concerns them.<sup>8</sup> Despite this, there is some evidence that lived experience perspectives are not necessarily prioritised in research concerning e-mental health.<sup>9</sup>

Further, given the international purview of eMHIC members, it is vital

that diversities in language and culture are represented in lived experience input. Diverse perspectives across socio-economic status are also crucial. (These points concerning social equity are elaborated below under the principle of Fairness, Non-Discrimination and Equity)

**ACTION >** Processes for partnership and active involvement of persons with lived experience, as well as the views of support people, must be developed, implemented, and maintained in relation to the planning, design, delivery, measurement, review, evaluation and regulation of e-mental health tools and services

# Privacy

Long established in international human rights law, the right to privacy protects a citizen from unlawful interference with their private life and correspondence. At a minimum, basic privacy principles must be upheld in e-mental health practices. As an example, Article 5(1) of the European Union General Data Protection Regulations sets out six privacy principles that are integrated throughout the Regulations. These principles elaborate on established privacy standards. They are:

1. **Lawfulness, Fairness, and Transparency.** Data controllers must process data lawfully, fairly, and in a transparent manner in
4. **Accuracy of Data.** Data controllers must maintain the integrity of data, ensuring it is: accurate; where necessary, kept up to date; and, erased or rectified without delay where personal data is inaccurate.
5. **Data Storage Limits.** The data should be deleted once no longer needed for the purpose for which it was collected.
6. **Integrity and Confidentiality.** Appropriate security of personal data is required, including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage.

## At a minimum, basic privacy principles must be upheld in e-mental health practices.

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- relation to the data subject.
2. **Limitations on Purposes of Collection, Processing, and Storage.** Data must be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.
  3. **Data Minimisation.** The personal information collected should be limited to the minimum necessary to achieve a legitimate purpose.

These are basic minimum standards to uphold privacy that draw from longstanding privacy provisions, and hence they are broadly similar worldwide. In the e-mental health context, these principles will be key to creating trustworthy services and practices. More robust privacy protections may be required in some circumstances, and it is likely that privacy principles and practices will evolve with the expansion of the complex communication ecosystem.

**ACTION >** E-mental health practices should be harmonised with exemplary privacy and data protection standards, recognising that these are likely to continue evolving.



# Accountability

Proper mechanisms of accountability are required for all e-mental health initiatives and will be vital to ensuring public trust in technologically enabled responses to mental distress. Accountability includes creating opportunities to examine the objectives, outcomes and any potential trade-offs involved in using e-mental health systems compared to traditional support services, or compared to no services. (This principle links closely to the principle of Transparency, discussed below).

Different forms of accountability may be required for different stages of e-

mental health activities, including design, monitoring during use, and redress in the event of harm.

At a fundamental level, accountability should be addressed by appropriate governance of the e-mental health tool or service. This governance should extend to the domains of organisational, clinical, technical, and lived experience governance, but with an over-arching perspective that is captured in documented frameworks of accountability which describes the roles and responsibilities of those involved in developing and delivering e-mental health.

**ACTION >** To foster public trust and confidence, organisations and individuals involved in e-mental health should adopt robust frameworks and processes to achieve high levels of accountability and oversight in the use e-mental health.



## Safety and Security

E-mental health initiatives must be safe and secure.<sup>10</sup> 'Safety' typically refers to ensuring the technology avoids unintended harms and functions as intended. 'Security' tends to refer to addressing external threats to data-driven systems, and often relates to privacy and data protection.

incorporating systems that monitor clinical and personal outcomes of users, and monitoring service users' experience of using the tools/systems that are involved, as well as providing options about what to do when serious risks exist. Other safety measures may concern maintaining professional boundaries

### **Safety encompasses being both 'reactive' and 'proactive' to minimise harm.**

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**Safety** measures taken by e-mental health providers include safety planning for service users, particularly those who face higher risks (for example, where suicide is a risk, or where a person faces disadvantage, whether economic, social, cultural, etc). In the clinical context, safety considerations include

in the virtual space, developing protocol for crisis responses, or promoting the protection of data concerning the mental health of individuals or groups.

A key point concerning safety is '**harm minimisation**'. Safety encompasses being both 'reactive' and 'proactive' to minimise harm. All

mental health interventions may have the potential to cause harm. The core principle of beneficence includes maximising possible benefits and minimising possible

manufacturers, or service providers and 'end users'.<sup>11</sup>

Data protection authorities, technology companies, professional

## Privacy engineering approaches might include encryption and role-based limits to data access.

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harms (non-maleficence).

Regarding **security**, one common strategy to protect data is to seek to anonymise, de-identify, or aggregate data where possible. Privacy engineering approaches might include encryption and role-based limits to data access. Other strategies, in keeping with privacy principles, is to ensure data minimisation and limitations on purposes of collection, processing, and storage (see above). Another strategy is to make clear the specific content of rights and obligations for technology developers, product

associations, and organisations representing people with lived experience place high importance on safety and security in fostering trust in digital systems.<sup>12</sup>

Any initiative concerned with collecting data relating to people's mental health, distress and disability should provide sufficient details of safety and security measures to address questions and concerns, which could extend to clarifying who monitors compliance. These details should be included in the informed consent process for those engaging with e-mental health initiatives.

**ACTION** > E-mental health initiatives should demonstrate evidence of safety and security, including ensuring consent processes include explicit details of data security measures.



# Transparency and Explainability

**Transparency** is defined in various ways but essentially refers to the importance of technological systems being designed and implemented so that oversight and external evaluation are possible. In the e-mental health context, transparency

informed consent, as we will discuss below). Transparent information is also essential for individuals and services that refer individuals to e-mental health practices. Transparency could also extend to publicly available information about

## **Explainability is particularly crucial for systems with potential to cause harm or significantly impact individuals**

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is required for achieving informed consent, to ensure that those using e-mental health are aware of how the systems they are engaging with are designed to work, and how the data generated by their interaction with that system will be used. (Transparency is but one element of

outcomes of e-mental health practices.

Transparency is therefore closely linked to accountability. It could extend to matters such as the data that are generated in a particular setting, the system that processes

the data, and (where relevant) the business model that makes use of them.<sup>13</sup> As an example, Til Wykes and Stephen Schueller have proposed a transparency governance method for apps concerning health.<sup>14</sup> The 'Transparency for Trust (T4T) Principles of Responsible Health App' provides a list of questions that can be asked to reveal key matters concerning privacy, security, feasibility, and so on. Wykes and Schueller promote the use of the T4T principles by app stores and for presentation 'in a simple form so that all consumers can understand them.'<sup>15</sup>

The related concept of **explainability**, which is a key term and concept in artificial intelligence (AI), refers to 'the translation of technical concepts and decision outputs into intelligible, comprehensible formats suitable for evaluation'.<sup>16</sup> Explainability seems particularly important for AI-based systems,<sup>17</sup> although it should be

noted that at this stage, AI is used in a small (but growing) proportion of e-mental health initiatives.

Explainability is particularly crucial for systems with potential to cause harm or significantly impact individuals. It is often linked to promoting non-discrimination given that the more comprehensible a system is, the more likely discrimination, bias or error can be identified, prevented and rectified.<sup>18</sup>

**Transparency and explainability** support an important element of informed consent by helping to ensure that appropriate standards of information disclosure are met. Other essential elements of informed consent that need to be addressed include decision-making capacity (the ability to make decisions), competence (the ability to perform actions needed to put decisions into effect) and voluntariness, as well as best practices for recording or documenting consent.

**ACTION >** E-mental health initiatives should seek to achieve high levels of transparency, explainability and key elements of informed consent in order to build trust, and to uphold the highest standards of responsible practice.

# Fairness, Non-Discrimination and Equity

Global discussions about governance of online technologies have increasingly focused on ensuring fairness, non-discrimination and equity, and these issues are beginning to be discussed in the e-mental health context.

E-mental health technologies must be designed in a way to avoid perpetuating discrimination by encoding negative social attitudes and relations into digital initiatives. E-mental health tools and services should speak to people of different cultures and be culturally safe.

discrimination and bias. In addition, partnership with or active involvement of diverse linguistic and cultural groups, and those facing low socio-economic conditions will promote equitable (and likely more effective) e-mental health initiatives.<sup>19</sup>

Accessibility is a key equity issue in e-mental health initiatives. Lack of access to digital technologies or infrastructure, low digital literacy, lack of availability of linguistically or culturally appropriate interventions will limit access. How e-mental health

## **Access to technology is increasingly important to societal wellbeing and is often reflected in concerns with a growing 'digital divide'.**

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Such initiatives must also be developed with care and attention to the inequalities in existing mental health services. Psychological distress and mental health issues do not occur equally across society: those who are poorer, from disadvantaged, marginalised and vulnerable groups are more likely to experience distress, mental health conditions and psychosocial disabilities.

Elevating persons with psychosocial disabilities and mental health conditions as domain experts in the design, research, and development of algorithmic technologies in the mental health context can help guard against the potential for

practice address these issues are critical to achieving fairness and non-discrimination. Access to technology is increasingly important to societal wellbeing and is often reflected in concerns with a growing 'digital divide'.

Digital inclusion strategies – such as subsidising the purchase of equipment, internet billing support, education to improve digital literacy, and so on – may be required to prevent people becoming excluded from both digitised health and social services and from society in general. According to one recent inquiry, governments can assist by “enabl[ing] mental health and

wellbeing services to offer people living with mental illness or psychological distress access to devices, data, and digital literacy

support, where it is their preference to use digital services, but they are otherwise unable to do so.”<sup>20</sup>

**ACTION >** All actors, public and private, involved in the design, development and use of e-mental health initiatives must seek to prevent and mitigate against discrimination risks, promoting e-mental health initiatives that are socially, culturally, and economically equitable.

# Professional Responsibility and Evidence-based Practice

This principle is mainly aimed at individuals and groups who are responsible for designing, developing, or deploying e-mental health technologies. The actions of these individuals and groups have direct influence on the ethical, legal, and social dimensions of technology being used in the mental health context.

Adequate research and evaluation of e-mental health practices must be carefully implemented to enable evidence-based delivery of e-mental health initiatives. Scientific integrity and the testing of claims should be of

need to be part of the decision about what is the evidence.

Opportunities, resources, and initiatives should be created to develop or support awareness, education and training of mental health and crisis support workforce for ethics in the context of e-mental health services. Individuals and groups involved in developing and delivering e-mental health initiatives should be cognisant of their personal and professional responsibilities to ensure that their initiatives positively contribute to the wellbeing of the

## **...digital technology requires systems for ensuring that evaluations are conducted in ways consistent with the highest standards of scientific practice.**

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paramount concern of e-mental health initiatives. Creating high quality services that are enabled by digital technology requires systems for ensuring that evaluations are conducted in ways consistent with the highest standards of scientific practice. Lived experience partners

service users, patients, groups, and so on, for whom they are designed.

This extends to recognising situations when professionals may lack the skills to support consumers and taking action to support those service users, consumers, and so on, to access appropriate care.

**ACTION >** Training and continuing education programmes should be developed and made available to assist mental health practitioners and crisis support professionals in understanding and adapting to use of e-mental health practices, as well as to consider evidence-based practice and to maintain high professional standards.



# International Human Rights Law

International human rights law is a governance regime with significant potential relevance to the growth of e-mental health practices.

## E-mental health initiatives have much to offer in promoting and protecting human rights worldwide.

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E-mental health practices can enhance human rights, promoting the right to the enjoyment of the highest attainable standard of physical and mental health and other rights.

However, there is a risk that some digital approaches to mental healthcare could threaten human rights.<sup>21</sup>

Guidance to ensure world-leading standards in e-mental health that benefit people and work towards achieving societal goals, can be found in specific human rights documents such as the Universal Declaration of Human Rights (UDHR), International Covenant on Civil and Political Rights (ICCPR), UN Declaration on the Rights

of Indigenous People (UNDRIP), Convention on the Rights of Persons with Disabilities (CRPD), United Nations Guiding Principles on Business & Human Rights, and United Nations Sustainable Development Goals. E-mental health initiatives have much to offer in promoting and protecting human rights worldwide.

Care is required to follow the evolving interpretation and protection of human rights in the digital context generally, and the mental health care context particularly, which will include precise adjudication of standards like 'privacy' and 'fairness' as standards change overtime.

**ACTION >** Human rights obligations must be met by those who fund, design, regulate or use e-mental health technologies.

# Conclusion

E-Mental health initiatives have the potential to improve mental health care services comprehensively. Yet, there are ethical concerns and legal issues that will need to be addressed as digital technology develops.

The mental health and wellbeing of service users, patients and consumers must remain central to these considerations. Organisations, groups, or individuals who are developing and implementing e-mental health practices need to be in partnership with service users, patients, and consumers, and to consider key ethical issues.

All seven principles discussed here offer a starting point to establish foundational requirements for e-mental health initiatives that are ethical, and respectful of international law. The true challenge arises in applying these high-level concepts in the real world. Law will evolve with new legislation, judicial decisions, and other regulations, as well as with the emergence of new technological capabilities.

Subsequent developments will require ongoing conversation about principles for achieving e-mental health practices that promote societal aims and bring about the highest standards of care, support, and well-being. And these efforts will be informed both through top-down efforts, such as dialogues at the intergovernmental level, as well as bottom-up approaches, including at the service level, and among people most impacted by e-mental health initiatives and the organisations who represent them.

These conversations will build upon the hard work of the many individuals and organisations who have aspired to create the highest quality e-mental health initiatives. eMHIC takes the lead in helping generate awareness and discussions in this area for all to be involved.

**END**

\*This Position Statement arises from the work of the eMHIC Special Interest Group on Ethics and Law ('Special Interest Group'), which was established in accordance with the aims of the eMHIC Board in January 2021. The Special Interest Group is co-chaired by Dr Piers Gooding and Mr Richman Wee, who benefited greatly from the advice of Prof Nick Titov. The group would also like to acknowledge the valuable feedback provided by A/Prof Nicole Martinez-Martin, Ms Lene Søvold, Ms Mary O'Hagan, Prof Chee Ng, Adj Prof Wong Kim Eng, Adj Assoc Prof Daniel Fung, eMHIC Executive Director Anil Thapliyal, and by the eMHIC Board. The Special Interest Group presented a draft version of this Statement to the November 2021 eMHIC Congress and sought feedback from eMHIC members and several independent, expert advisors. The feedback received, as well as wider consultation, informed this finalised **Position Statement (Version 1)** which will be launched with a webinar in March 2022. Comments are welcome to inform refinements of the Policy Statement for the future. Please email: [admin@emhicglobal.com](mailto:admin@emhicglobal.com)

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<sup>1</sup> These principles draw on work by the Berkman Klein Center for Internet and Society at Harvard University, which compared the contents of thirty-six prominent artificial intelligence (AI) principles documents side-by-side. Although eMHIC's scope extends beyond AI to a range of computerised and data-driven technologies, the Special Interest Group drew on these principles to link our discussion to emerging areas of consensus in what can otherwise be a fractured global conversation on digital technologies and the contemporary communications ecosystem. See Jessica Fjeld et al, *Principled Artificial Intelligence: Mapping Consensus in Ethical and Rights-Based Approaches to Principles for AI* (SSRN Scholarly Paper No ID 3518482, Social Science Research Network, 15 January 2020) <<https://papers.ssrn.com/abstract=3518482>> ('Principled Artificial Intelligence').

<sup>2</sup> National Safety and Quality Digital Mental Health Standards established in 2020 by the Australian Commission on Safety and Quality in Healthcare. ACSQHC. National Safety and Quality Digital Mental Health Standards <<https://www.safetyandquality.gov.au/standards/national-safety-and-quality-digital-mental-health-standards/partnering-consumers-standard>> (accessed 23/09/21).

<sup>3</sup> Ibid.

<sup>4</sup> Jonah Bossewitch, 'Brave New Apps: The Arrival of Surveillance Psychiatry', *Mad In America* (9 August 2019) <<https://www.madinamerica.com/2019/08/brave-new-apps-the-arrival-of-surveillance-psychiatry/>> ('Brave New Apps').  
<sup>5</sup> Human Rights Council. (2020). *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (A/HRC/44/48)* [Data set]. United Nations, para 13.

<sup>6</sup> Dinesh Bhugra et al, 'The WPA-Lancet Psychiatry Commission on the Future of Psychiatry' (2017) 4(10) *The Lancet Psychiatry* 775.

<sup>7</sup> Rex Hartson and Pardha Pyla, *The UX Book: Process and Guidelines for Ensuring a Quality User Experience* (Elsevier, 2012) ('*The UX Book*').

<sup>8</sup> United Nations Convention on the Rights of Persons with Disabilities, 2006, Preamble 15.

<sup>9</sup> Piers Gooding and Tim Kariotis, 'Ethics and Law in Research on Algorithmic and Data-Driven Technology in Mental Healthcare: Scoping Review' (2021) 8(6) *JMIR – Mental Health* e24668.

<sup>10</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>11</sup> Standard Administration of China and Paul Triolo, 'White Paper on Artificial Intelligence Standardization' excerpts in English published by New America (January 2018) (See Principle 3.3.1.).

<sup>12</sup> See e.g. World Economic Forum in collaboration with Deloitte, *Global Governance Toolkit for Digital Mental Health: Building Trust in Disruptive Technology for Mental Health* (April 2021) <<https://www.weforum.org/whitepapers/global-governance-toolkit-for-digital-mental-health/>>.

<sup>13</sup> European Commission High-Level Expert Group on Artificial Intelligence (n 135) p.18

<sup>14</sup> Til Wykes and Stephen Schueller, 'Why Reviewing Apps Is Not Enough: Transparency for Trust (T4T) Principles of Responsible Health App Marketplaces' (2019) 21(5) *Journal of Medical Internet Research* e12390 ('Why Reviewing Apps Is Not Enough').

<sup>15</sup> Ibid.

<sup>16</sup> Fjeld et al (n 8) pp.42-43.

<sup>17</sup> Julia Amann et al, 'Explainability for Artificial Intelligence in Healthcare: A Multidisciplinary Perspective' (2020) 20(1) *BMC Medical Informatics and Decision Making* 310 ('Explainability for Artificial Intelligence in Healthcare').

<sup>18</sup> Fjeld et al (n 8) p.43.

<sup>19</sup> Martinez-Martin, Nicole, Henry T Greely and Mildred K Cho, 'Ethical Development of Digital Phenotyping Tools for Mental Health Applications: Delphi Study' (2021) 9(7) *JMIR mHealth and uHealth* e27343

<sup>20</sup> Recommendation 60, Royal Commission into Victorian Mental Health Services. Victorian Government, Australia <https://finalreport.rcvmhs.vic.gov.au/recommendations/>

<sup>21</sup> World Health Organization, *Ethics and Governance of Artificial Intelligence for Health* (World Health Organization, 28 June 2021) xi; Piers Gooding, 'Mapping the Rise of Digital Mental Health Technologies: Emerging Issues for Law and Society' (2019) 67 *International Journal of Law and Psychiatry* 101498 ('Mapping the Rise of Digital Mental Health Technologies').