

In collaboration with
Deloitte



Governance Frameworks in Digital Mental Health

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Foreword



Stephanie Allen
Leader, Global and Australia
Healthcare Sector, Deloitte,
Australia



Shyam Bishen
Head, Platform for
Shaping the Future of
Health and Healthcare,
World Economic Forum

In 2018, the World Economic Forum's Global Future Council on Neurotechnologies set out to understand the potential uses and ethical implications of digital tools for the treatment of mental ill health. This work¹ surfaced two insights:

- Technology holds the potential to fundamentally change the way mental well-being is addressed.
- A paucity of frameworks and roadmaps grapple with their ethical deployment.

Subsequently, the World Economic Forum has collaborated with Deloitte to identify the gaps in governance surrounding mental health digital tools. It was felt that without appropriate regulation, the potential benefit of these technologies would not be realized because consumers, funders and providers lack confidence in their ability to select safe, high-quality tools.

As the COVID-19 pandemic spread, the need for governance in this space became more urgent – rates of depression and anxiety were spiking around the world, lockdowns were preventing in-person meetings with providers, and innovative,

digital-first solutions looked more essential than ever. After analysing nearly 200 examples of novel technology use in mental health with at least 10,000 users/downloads and interviewing thought leaders around the world, the Forum published the "[Global Governance Toolkit for Digital Mental Health](#)" in collaboration with Deloitte in April 2021. The toolkit, piloted with the New Zealand Ministry of Health, was designed to equip governments, regulators and independent assurance bodies with a roadmap of what "good" looks like in digital mental health and to "improve the accessibility, quality and safety of services that support all members of society to meet their desired emotional, social and psychological potential".

Four years after this journey began, the world looks profoundly different: COVID-19, greater attention from regulators and an ever-evolving innovation landscape have altered what we know and what should be done. Recognizing this, we have returned to the work to assess these changes and shed light on the current state of digital mental health regulation via interviews with those who piloted the toolkit, those crafting their own policies and mental health innovators.

Executive summary

Globally, mental health concerns are both common and undertreated. Accessing mental health services is not a simple demand and supply curve. For individuals who live in areas with mental health clinicians, barriers to accessing mental health care remain. These barriers include, but are not limited to, stigma, cost or access to reimbursement models, privacy concerns, a preference for dealing with problems independently and time constraints.

Digital mental health services, such as those delivered by mobile phone or web-based platforms, have the promise of delivering more affordable care, expanding the reach and accessibility of services and designing new treatment models that meet the needs of the current and future generations. But digital mental health is not straightforward, and new technology is substantially disrupting approaches to how mental health conditions are identified, diagnosed, treated and supported.

Telemedicine is offering care whenever and wherever it is needed through phone, video, email, chatbots and even gaming. Cognitive artificial intelligence (AI) is creating supportive digital interaction. Big data is unearthing a new understanding of the biopsychosocial factors. And brain-machine interfaces, which directly connect human consciousness with computers, are all promising to push the boundaries of what is possible.

A dramatic increase in the creation of digital mental health services has occurred in the past 10 years. At the same time, governments, clinicians, large corporations and consumers have been expressing concerns about the safety, quality, efficacy, privacy and application of AI in these services and the extent to which they are safe.

In 2018, the World Economic Forum's Global Future Council on Neurotechnologies set out to understand the potential uses and ethical

implications of digital tools for the treatment of mental ill health and collaborated with Deloitte to design a Global Governance Toolkit for Digital Mental Health.

The COVID-19 pandemic created a mental health crisis of unprecedented scale, triggered by social isolation, widespread unemployment, worries over contracting the virus, insomnia, social media exposure and the rising death toll. This accelerated the move towards the adoption and implementation of digital tools for mental healthcare. It also created a renewed urgency to develop and implement governance and regulatory frameworks to deliver clinical efficacy, access, privacy and data protection, as well as fairness, transparency and accountability.

The toolkit, published in 2021, was designed to outline a way forward and provide recommendations for policy-makers, funders, developers, service providers and users. It became a fundamental resource that countries could lean on to start building their digital mental health roadmap.

The work on the state of digital mental health regulation continues today, via interviews with those who piloted the toolkit, those crafting their own policies and mental health innovators. This White Paper sheds light on the current regulation and highlights four case studies of entities that are leading the way in regulating the tools. Their emerging standards provide much-needed guidance for service developers and providers to incorporate privacy policies, data transparency and health information security in digital mental health frameworks and applications.

This is only the beginning of the digital mental health journey. The regulatory structures of the future must be as dynamic and flexible as the advances they govern.

1

Introduction

The life expectancy of individuals living with mental ill health across the globe is significantly reduced compared to those living without a mental ill health condition.

For the estimated 1 billion people living with mental ill health, such as depression, anxiety, personality disorders, schizophrenia and substance abuse, life expectancy is 10 to 30 years² lower than that of individuals with typical neurological development and functioning.³ This statistic is further exacerbated by suicide, which the World Health Organization (WHO) has estimated as taking one life every 40 seconds.⁴ Half of mental illnesses begin by the age of 14 and 75% by the mid-20s, drastically impacting early stages of social and emotional development, health, education and employment.⁵

Tragically, these numbers are drawn from pre-COVID-19 data, which may have pushed the prevalence of the two most common conditions – depression and anxiety – up by 25% globally.⁶ This toll is not only personal, but economic: the direct and indirect costs of mental ill health are estimated at 4-6% of global GDP (gross domestic product), more than the combined burden of cancer, diabetes and respiratory disease. The Lancet Commission on mental health has estimated that by 2030, the worldwide cost of mental illness will reach more than \$16 trillion annually as a result of lost or low output.⁷

Mental ill health is undoubtedly a global challenge of our time. Current models of care, care pathways and supporting systems are inadequate to address the growing burden. The way mental ill health is addressed must be radically rethought to ensure every person in need can access support that is safe, high quality, affordable and appropriate to their circumstances. In every society, without

exception, the gaps in access to affordable quality treatment and care are significant. This ranges from approximately 10 to 48 mental health professionals for every 100,000 citizens in high-income countries to 0.26 to 2 for every 100,000 citizens in low-income countries.⁸ Despite the disparity, everywhere in the world today, there simply is insufficient mental health support available to those in need.

While COVID has undoubtedly had a detrimental effect on global health and well-being, there have been some silver linings. These include a global increase in attention to the importance of mental health along with an explosion of innovative solutions backed by an unprecedented level of funding. Governments took emergency measures to loosen regulation on the delivery of telemedicine and e-health, maintaining and increasing access to mental health support. In addition, governments and large employers now offer new services designed to build resilience and protect the well-being of citizens. Yet these heralded changes also raise concerns. As the number of digital tools rapidly increases in an environment without sound regulation, it has become more difficult for consumers to know what “good” looks like. In the current paradigm, low-quality digital tools may advertise false claims without evidence of clinical efficacy, or cut corners when it comes to data protection and privacy. Not only does this create an unsafe experience for the user, it also damages the entire ecosystem by undermining trust in credible solutions.

Recognizing this, the World Economic Forum Disruptive Technologies in Mental Health project developed the “[Global Governance Toolkit for Digital Mental Health](#)”. The toolkit was designed to outline a way forward and provide recommendations for policy-makers, funders, developers, service providers and users to answer several questions:

- What disruptive technologies offer the promise to augment, supplement and scale behavioural models of care, and bridge gaps in the access to care?
- What principles and standards underpin the decision to call a product clinically effective, safe and ethical? Who is best positioned to make these decisions?
- How can these products be regulated responsibly without stifling innovation?

Four years after this journey began, the toolkit has been revisited, interviews with those piloting standards have been conducted, and work with a new tranche of innovators from around the world has been undertaken to understand what good governance comprises in practice and what is on the horizon. Several new insights came out of this work:

- Increased attention and decreased stigmatization of mental ill health has been a windfall, but short funding cycles and changing political priorities can make systems unsustainable without significant foresight and longer-term commitment.

- Governments are dedicating far more resources to ensuring digital connectivity is universal, helping to abate concerns about digital inequity for the most vulnerable populations.
- Digital literacy and readiness must be considered not only for users, but for clinicians and funders who may be sceptical of changing long-established practices.
- Regulatory bodies do not necessarily have to be government-owned; excellent examples of not-for-profit bodies doing the same work now exist.
- Comprehensive regulation and rigorous standards can be detrimental for new entrants into the market who may not have the expertise, time or resources to meet all requirements. Tiered standards in line with entrant size and proposed service should be considered.
- Solutions must be designed with equity in mind. Innovations are commonly developed with only a single language, excluding immigrants and already marginalized populations. People with lived experience should be central to the entire design–build–test–operate process. The adoption of equitable design principles and a robust adherence to them are critical.

1

Governance frameworks in digital mental health

Digital mental health governance frameworks exist in several jurisdictions and, in some instances, have been implemented across entire countries.

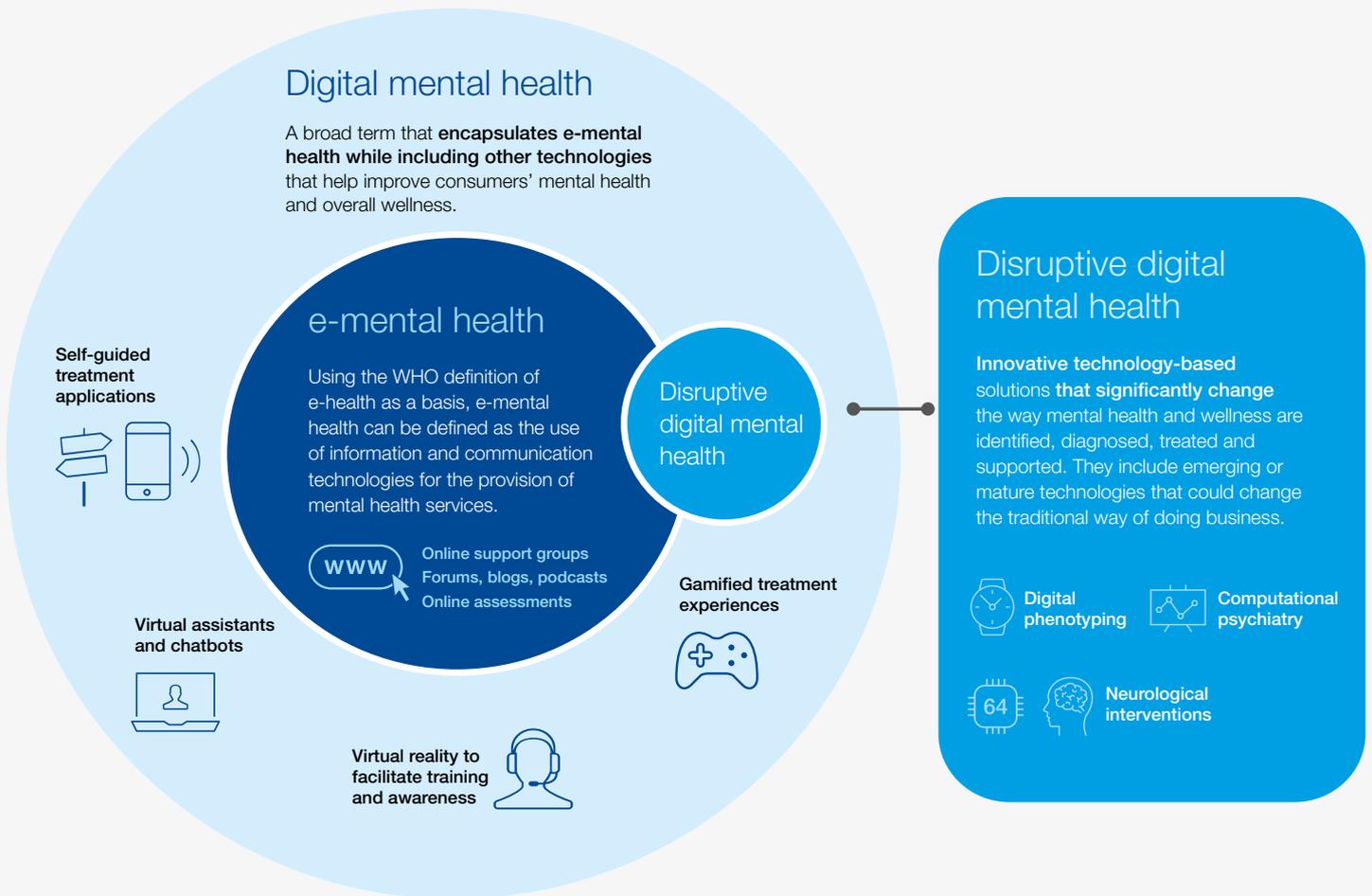


Even as their level of maturity and stage of implementation vary, keeping up with the pace of digital mental health innovations has been a ubiquitous challenge. This is further exacerbated by difficulty understanding whose purview these digital mental tools and their governance arrangements fall under. They incorporate elements of health data, medical devices, consumer goods, artificial intelligence (AI) and information technology. In addition, they frequently

operate without constraint, in various countries with different legal jurisdictions and policy frameworks.

To address some of these challenges, frameworks for digital mental health need to be equipped with a robust policy foundation and must be purpose-driven, evidence-based, goal-oriented and adaptable to provide assurance of the safety, quality and efficacy of the service without stifling innovation.

BOX 1 **What is digital mental health?**



Source: Deloitte

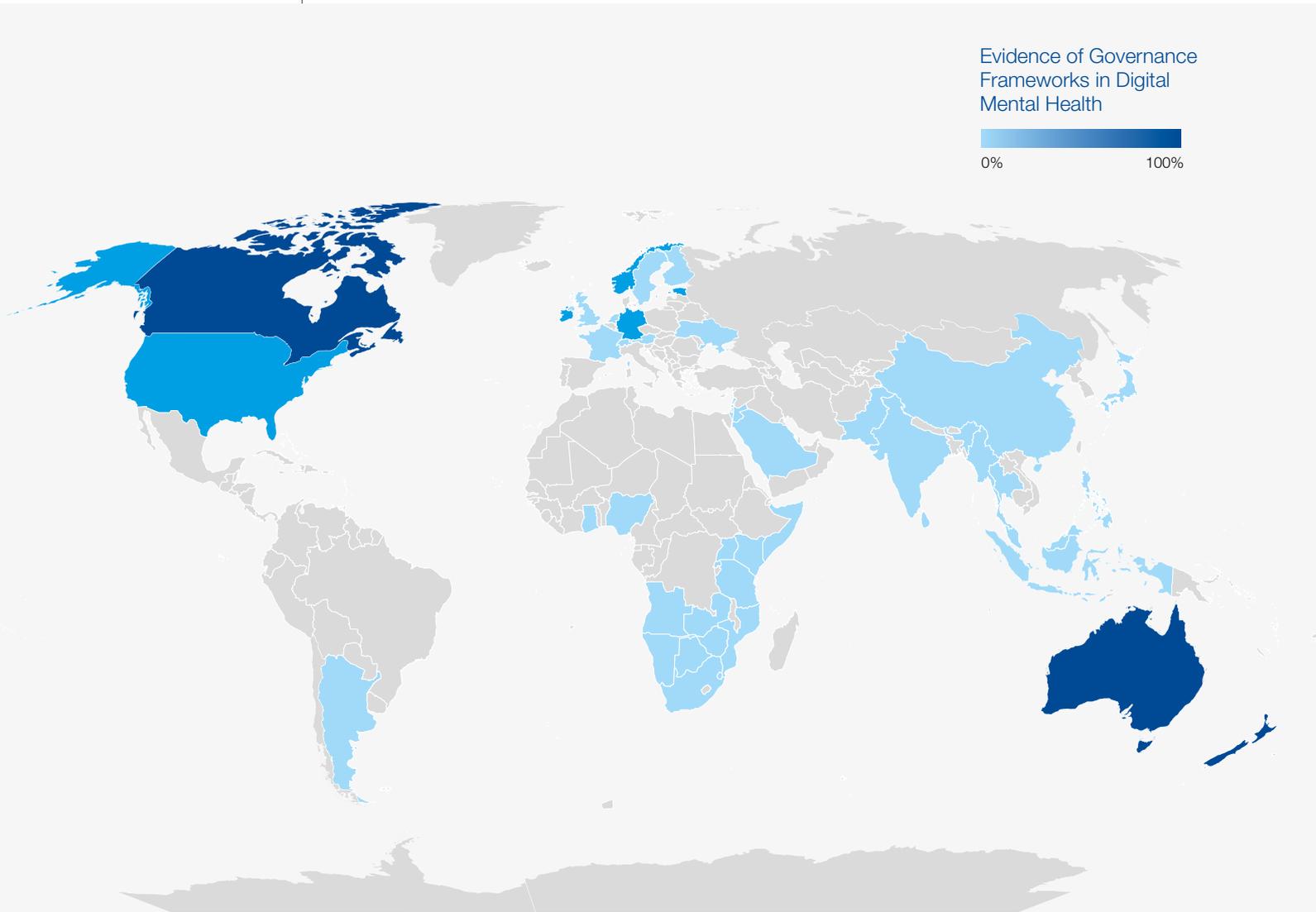
Understanding what digital mental health is, and is not, has also been the topic of much debate. Digital mental health encompasses any services, accessed through a digital platform, that aim to prevent or treat mental health disorders or promote the well-being of people. It encapsulates e-mental health while including other technologies that help improve consumers' mental health and overall wellness. These can include self-guided treatment applications, virtual assistants and chatbots, virtual reality facilitation and gamified treatment experiences.

Disruptive technologies in mental health are innovative technology-based solutions that significantly change the way mental health and wellness are identified, diagnosed, treated and supported. They can include digital phenotyping, computational psychiatry and neurological interventions. They are powered by innovation in the cloud, cognitive AI, big data, internet of things, blockchain, digital reality, robotics and quantum computing.

While many good examples of digital mental health frameworks or standards exist around the world

(Figure 1), it appears that many still fail to account for the unique ethical challenges of AI in psychology.

FIGURE 1 Digital mental health frameworks worldwide, 2022



Source: Deloitte with Australian Bureau of Statistics, GeoNames, Microsoft, NavInfo, OpenStreetMap and TomTom input

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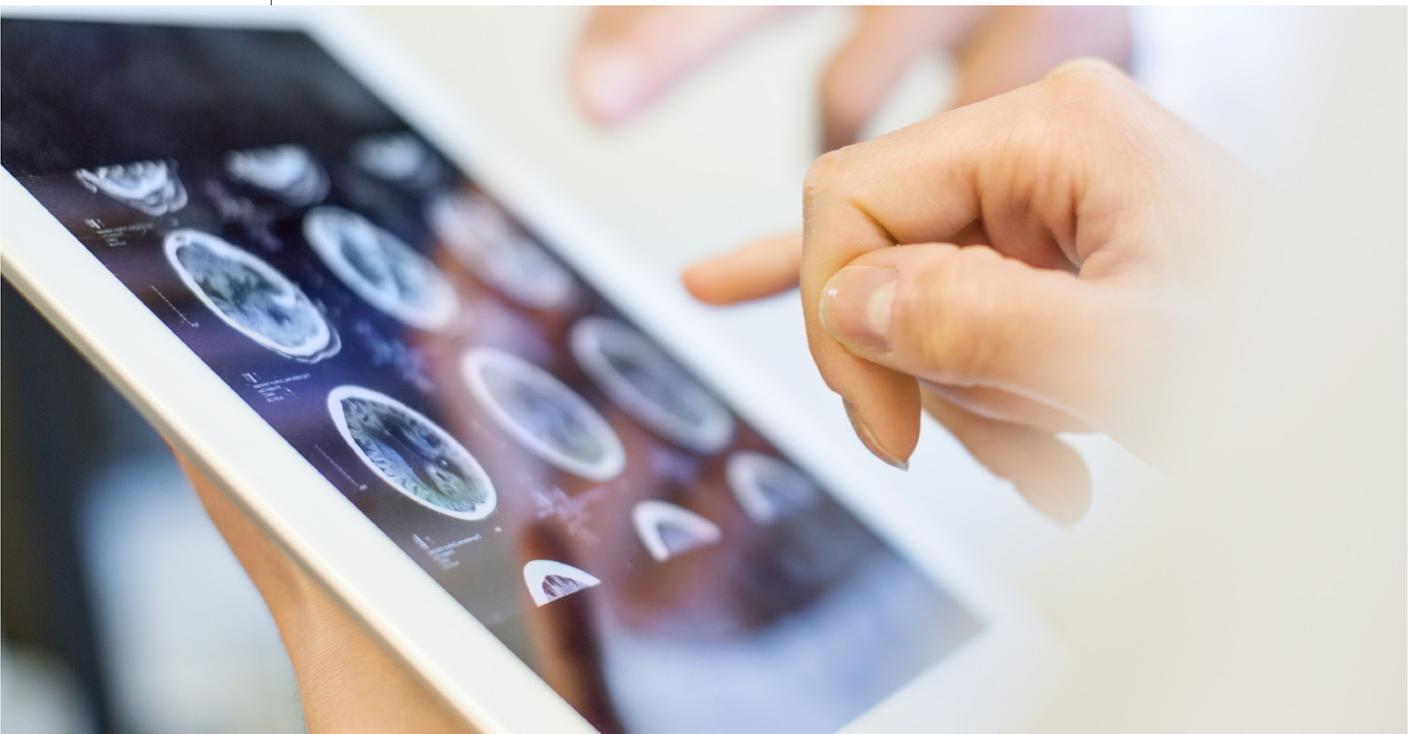
Implementer insights

To go beyond frameworks and understand what deployment looks like on the ground, a series of interviews were conducted with four entities that are leading the way in regulating digital mental health tools:

1. One Mind PsyberGuide, USA
2. Mental Health Commission of Canada
3. Australian Commission on Safety and Quality in Health Care
4. New Zealand Ministry of Health

These conversations sought to understand:

- What mental health services are provided
- How they have implemented digital mental health governance frameworks
- What they have learned to date





CASE STUDY 1

One Mind PsyberGuide, USA

Mental health system overview

Mental illnesses are a prevailing burden of disease in the United States, affecting about 50 million adults in 2020, with only just over 46% receiving treatment and/or support.⁹ The US health system is comprised of providers of healthcare, insurance companies and patients. The types of providers within the mental healthcare ecosystem can include highly trained professional providers (e.g. psychiatrist), generalists (e.g. general practitioners), social service providers, advocates, a support network of caregivers, employers and community members.

The US public health system is understandably complex to navigate due to the fragmented nature of its ecosystem, and consumers often struggle to access the mental health treatment they require. As with many countries with the onset of the pandemic, the United States faced a sharp increase in mental ill health along with the demand for psychological services. The US Government will invest \$300 million for youth mental services,¹⁰ integrating mental health and substance abuse treatment into primary care settings and investing in several programmes for providers to pursue behavioural health, including providing training and access to scholarships.

One Mind

One Mind is a global brain health not-for-profit organization based in northern California that accelerates collaborative research to enable all individuals facing brain health challenges to lead healthy, productive lives. It funds and supports scientific research to accelerate tools for diagnosis, prevention and treatment. One Mind established One Mind at Work in 2017 to help business leaders develop best-in-class workplace mental health programmes that enable both employees and companies to thrive.

One Mind PsyberGuide

In 2017, One Mind launched PsyberGuide and provided funding, a clear focus on the end user and guidance to progress its development. One Mind also provided connections with its users and with One Mind at Work to amplify and increase the reach of PsyberGuide in the community and workplaces. Initially started as a research endeavour, PsyberGuide developed an accessible, digestible and bite-sized framework as a resource for general consumers attempting to navigate the proliferation of mental health apps and solutions.

The One Mind PsyberGuide is aimed at both clinicians and consumers who can access the not-for-profit website, which evaluates digital mental health apps and provides a publicly accessible pre-assessed library of apps.

How does One Mind PsyberGuide work?

- PsyberGuide provides information on digital mental health products to help consumers make informed decisions on the self-management of their mental health.
- The health apps have been assessed for their credibility, transparency and user experience (using the Mobile App Rating Scale), taking into consideration professional narrative reviews.
- The framework behind PsyberGuide includes clear guidelines on evaluating app objectives and efficacy, and ensuring strong privacy policies are established.
- PsyberGuide provides both app assessments and a pre-approved library.
- The products reviewed by PsyberGuide do not include endorsements; some products can score high or low in certain areas of assessment.
- PsyberGuide also provides resources on mental health and digital mental health for consumers.

Advice for other jurisdictions

An important realization is that digital mental health tools are but one solution. They are important innovations that can address access issues. But thought should be given also to other barriers to access (e.g. cultural, language), structural changes, equity and the broad cultural context. One Mind at Work has been engaging employers at all levels from diverse regulatory and cultural environments, in both the public and private sectors. The conversation about mental health needs to be elevated so people feel comfortable seeking the care they need when appropriate. Digital mental health is a segment of healthcare but is not comprehensive.

Accreditation

- The current digital mental health app assessment process is based on publicly available information.
- PsyberGuide provides recommendations and guidance but has not yet put in place a mechanism for audit verifications of its findings.



CASE STUDY 2

Mental Health Commission of Canada

Mental health system overview

Mental illness is a leading cause of disability in Canada, affecting 1 in 5 Canadians in any given year.¹¹ The economic burden of mental illness in the country is estimated to be over \$50 billion per year.¹² The Canadian health system is funded by the federal Government, which distributes the funding to the provinces and territories. The amount to each region differs, but this funding is not sufficient to cover mental health services in general. The cost remains an increasingly substantial barrier to access the required supports and treatments for those living in Canada.¹³

Mental health support services are available to individuals through primary healthcare providers (e.g. general practitioners) who offer referrals to psychiatrists, psychologists and therapists; through services provided by their employer (e.g. employee assistance programmes, insurance programmes for private cover); or through community groups. As in most countries, Canada's mental health system has been overwhelmed by the growing demand for mental health services largely driven by the pandemic. The shift from triage response to understanding prevention and sustainability in the long term is noticeable.

Current state

- The Mental Health Commission of Canada (MHCC) recently launched E-Mental Health Implementation learning modules,¹⁴ developed from its “Toolkit for e-Mental Health Implementation”, to support the teachings and establishment of e-mental health programmes.¹⁵
- The toolkit echoes information gathered from the knowledge and experiences of practitioners and research groups, and includes an environmental scan and review of existing literature, interviews conducted with key informants in Canada and internationally, peer-reviewed research, templates and case studies.¹⁶
- The online learning modules are free, self-directed and “designed to give mental health providers, managers and leaders the knowledge and skills they need to integrate e-mental health into daily practice and support effective, person-centred e-mental health projects”.¹⁷
- The e-Mental Health team has published several e-mental resources available on the MHCC website and recommended for immediate use.¹⁸
- At the onset of the pandemic, the Canadian Government funded and developed Wellness Together Canada (WTC), a free online resource for those living in Canada to access mental health services online 24/7, including crisis response.
- The WTC portal connects those living in Canada seeking mental health and substance use aid to “peer support workers, social workers, psychologists and other health professionals”.¹⁹

- The portal also provides evidence-based information to help address mental health and substance use issues.
- Stepped Care 2.0²⁰ underlines the WTC portal, a mental health framework in partnership with Stepped Care Solutions across provinces in Canada.²¹
- In 2021, the MHCC and the Canadian Agency for Drugs and Technologies in Health released reports on the uses and trends of AI in mental health.
- The MHCC is currently developing the first e-mental health strategy for Canada.
- An assessment framework for mental health apps in Canada has been finalized, aligned to the eMental Health International Collaborative's (eMHIC) “Ethics and Law as Essential to e-Mental Health” position statement.²²
- An application standardization approach was taken, ensuring a suite of high-quality mental health apps are available to consumers.

Key strengths and challenges of the mental health system

- The MHCC completed an extensive two-year project on recommendations to increase the access to psychotherapy in Canada.
- Canada has a “decentralized, universal, publicly funded health system called Canadian Medicare” where “healthcare is funded and administered primarily by the country's 13 provinces and territories. Each has its own insurance plan, and each receives cash assistance from the federal Government on a per-capita basis.”²³
- Services are slowly being tailored for people from different cultural and/or linguistic backgrounds to ensure they can access appropriate support for their mental health and well-being (e.g. the Centre for Addiction and Mental Health focuses on culturally adapted cognitive behavioural therapy, which has had good results).

Assessment framework for mental health apps in Canada

- The framework encompasses over 450 criteria based on seven standards: 1) data and privacy; 2) clinic evidence; 3) clinical safety; 4) usability and accessibility; 5) security and technical stability; 6) cultural safety, social responsibility and equity; and 7) enhanced data sovereignty.
- In particular, the “Cultural Safety, Social Responsibility and Equity” standard includes content on key topics such as Indigenous data security and privacy, gender equity, representation from the Black, Indigenous and people of colour community in app content and visuals, usability and accessibility, and lived experience involvement in app development.

- The framework underwent a one-month public consultation period and was developed with 200 Canadian and international stakeholders from diverse backgrounds, including those with lived and living experience, policy-makers, government officials, app developers and designers, academic researchers and mental health service providers.
- The public review was conducted to reach a wider audience and provide transparency.
- With the final version completed, the MHCC aims to turn the assessment framework into an app review engine for app developers to assess their apps with the framework more easily; it will also develop public and provider platforms where the Canadian public and providers can go to access safe, quality and effective mental health apps.

Barriers to implementation

- Not all provinces have the same coverage in terms of broadband/network support and some need to establish better network infrastructure to support digital mental health.
- Marketing and PR for digital mental health tools are critical to ensure the public, clinicians and practitioner know where to go to access services and resources.
- E-mental health service quality is currently lacking.
- Both consumers and service providers presently lack sufficient digital literacy.
- Providers need training to ensure they are comfortable providing a particular digital mental health tool.

Overall design decisions

Key design decisions within the framework/toolkit were taken to ensure that it does not:

- Stifle innovation and is balanced for grassroots players as well as large players/providers
- Penalize small/grassroots developers in small communities or rural settings

Evidence-based approach to the design of the digital mental health framework

- Baseline criteria were leveraged with the Organisation for the Review of Care and Health Apps (ORCHA, implemented in the United Kingdom's digital health programme for the National Health Service (NHS), Ireland and the Netherlands) and the National Institute for Health and Care Excellence (NICE) Evaluation and Assessment for the Improving Access to Psychological Therapies programme; both of these frameworks are robust and have been validated and implemented in similar jurisdictions to those in Canada.
- Lessons were learned from the United Kingdom in terms of legislation adoption and general data protection regulation to ensure consumer data is sensitively managed in alignment with robust policies/regulation on data consent for privacy.
- The ORCHA assessment was further tailored to the needs of the people in Canada to ensure that the diversity of community voices included Indigenous populations and that the lived experience testimonies were incorporated into the development of the framework.
- The framework was aligned to equivalent regulations and terms in Canada (e.g. the Pan-Canadian Health Data Strategy and the Medical Devices Regulations) to ensure the strategic visions for digital health correspond with mental health.

Lessons learned

- Lived experiences should be incorporated; consultants/clinicians should receive training to understand that lived experience is expert advice.
- Broad consultation must take place with diverse stakeholders and with other jurisdictions (e.g. Australia, Denmark, Ireland, Israel, New Zealand and the United Kingdom) to share and learn from other experiences from which improvements can be made.
- Standardization should be ensured (where possible) at the national level.

Accreditation

- The assessment framework for mental health apps in Canada has been finalized.
- An accreditation process for service providers is advisable now that the assessment framework for mental health apps in Canada has been developed.



CASE STUDY 3

Australian Commission on Safety and Quality in Health Care

Mental health system overview

Over 40% of Australians aged 16-85 (about 8.6 million people) have experienced a mental health illness at some point during their life, and 20% of the population has experienced a mental disorder in the previous 12 months.²⁴ In 2020, a rise in psychological distress coincided with the COVID-19 pandemic.²⁵ Within the Australian health sector, most mental health referrals are provided by a general practitioner to a mental health clinician, including psychiatrists and psychologists. These services may attract a subsidy under the Medicare Benefits Schedule. The Australian Government and state and territory governments deliver a range of mental health services that provide specialist care for people experiencing mental ill health. The Government funds a range of programmes and services, including income, social and community support, disability services, workforce participation programmes, and housing to people experiencing mental ill health.²⁶ In February 2021, the final report of the Royal Commission into Victoria's Mental Health System handed down recommendations for a 10-year reform programme for mental health, focusing on a recovery-oriented approach to delivering mental health and well-being services.²⁷

Current state

- The 2019-2020 bushfires across Australia were described as unprecedented, affecting the lives, land, houses and livelihoods of thousands of people.²⁸ It is well established that bushfires and other natural disasters have long-term psychological effects on the communities they impact.²⁹
- The Taking the Pulse of the Nation survey showed psychological distress pre-pandemic at 6.3% of the population, rising to 17.7% after the first wave of the pandemic (July 2020).³⁰
- Digital mental health (DMH) tools over the past decade have evolved rapidly and the number of options in the Australian market have increased substantially in recent years.
- These tools have the potential to reach communities with reduced access to healthcare. The onset of the pandemic, among other factors, accelerated the uptake of these digital health tools.
- Until recently, no formal accreditation process for DMH services existed to assess against safety and quality standards, although mental health standards have existed for over 20 years.
- The Australian Commission on Safety and Quality in Health Care (ACSQHC) was tasked with developing standards for DMH services to support the safe and high-quality delivery of these services.

Digital mental health framework

- The Australian Government Department of Health and Aged Care engaged the ACSQHC to develop safety and quality standards for DMH service provision. This includes supporting providers to ensure their services meet the expectations of service users and their support people.
- The ACSQHC has been working on the National Safety and Quality Digital Mental Health (NSQDMH) Standards since 2017, recognizing the importance of using technology as an adjunct to traditional models of care.
- In 2019, the National Mental Health Commission (NMHC) released “Vision 2030”, setting out the “blueprint for a successful, connected mental health and suicide prevention system” that delivers better outcomes for the mental health of all Australians.³¹
- The ACSQHC partnered with service users, consumers, carers, families, clinicians, service providers and technical experts to develop the NSQDMH Standards, which were released in November 2020.
- The NSQDMH Standards include requirements for clinical and technical governance, partnering with consumers and models of care.³²

Key strengths and challenges of the mental health system

- The ACSQHC was established in 2006 “to lead and coordinate national improvements in the safety and quality of healthcare”.³³
- The NMHC was established in 2012 “to monitor and report on investment in mental health and suicide prevention initiatives [and] provide evidence-based policy advice to Government”.³⁴
- Both New South Wales and Victoria have seen record investments in mental health delivery; Victoria's investment was realized after the final report of the Royal Commission into Victoria's Mental Health System.
- The Australian Government is investing \$391.7 million, which builds on the historic \$2.3 billion funding, in response to the Productivity Commission's inquiry report on mental health and national suicide prevention.³⁵ This funding aims to improve access to high-quality mental health, suicide prevention, and social and emotional well-being services for Aboriginal and Torres Strait Islander peoples and culturally and linguistically diverse (CALD) communities.³⁶
- There is significant variability in the delivery of quality mental healthcare; in some regions, mental healthcare can be financially, geographically and/or physically inaccessible.³⁷

- In some locations, access to DMH services is limited due to inadequate telecommunications infrastructure. This is particularly the case in rural and remote locations in Australia (e.g. related to 4G and 5G coverage and internet connection stability to support virtual consultations or web-based services).

National Safety and Quality Digital Mental Health Standards

- The NSQDMH Standards aim to improve the safety and quality of DMH service provision, and protect service users and their support people from harm.
- The Standards “address key safety and quality risks for DMH service users”.³⁸
- They serve as a best practice guideline for service providers and developers to support quality assurance for DMH services.
- Providers include non-governmental, public or private organizations or individuals who provide DMH services.
- Implementing the NSQDMH Standards is voluntary for DMH providers but service providers are encouraged to use them to reduce the risk of harm to service users.
- A pilot study to validate the Standards was undertaken in 2021, involving DMH service providers implementing the standards and an independent external assessment to test the assessment and accreditation framework.

Evidence-based approach to the design of the NSQDMH

- The NSQDMH Standards were informed by experts and service users and modelled on the National Safety and Quality Health Service (NSQHS) Standards.
- Technical requirements were included in the Standards in acknowledgement of the digital environment in which they will operate.
- The Therapeutic Goods Administration (TGA) was engaged in the development of the Standards.

- The TGA regulates software as a medical device (SaMD) and has developed an exemption process for DMH tools that are evidenced by established clinical guidelines.³⁹
- DMH tools falling outside TGA regulation may be appropriate for accreditation to the NSQDMH Standards.

Lessons learned

- Standards should focus on addressing improvements in the safety and quality of systems.
- Privacy and protecting service users from harm are essential elements in the Standards.
- The ACSQHC determined that several technical actions in the NSQDMH Standards were challenging for a range of service providers to implement, regardless of their size and service delivery model. A comprehensive implementation strategy that includes specific resources and guidance for services may address many of these challenges.
- Service delivery for DMH should be research- and evidence-based and should have systems and processes in place to reduce the risk of harm, protect privacy and increase confidence and assurance in the safety and quality of DMH tools.

Accreditation

- The assessment of service providers to the NSQDMH Standards will commence in November 2022.
- Accrediting agencies approved by the ACSQHC will conduct assessments of the NSQDMH Standards. Providers that meet the requirements will be awarded accreditation.
- Service providers that receive accreditation will be authorized to display an accreditation badge.
- This accreditation badge will ensure consumers can identify DMH service providers that have met the expected standards for safety and quality.



CASE STUDY 4

New Zealand Ministry of Health

Mental health system overview

According to WHO-Five Well-Being Index (WHO-5) results at the end of 2020, 1 in 4 adults in New Zealand had poor levels of mental well-being.⁴⁰ New Zealand follows the same trends in mental health as other OECD countries. Individuals seeking mental health support are referred by their general practitioner or family doctor to a psychologist or psychiatrist. During the pandemic (2020-2021), 3.7% of the population accessed specialist mental health or addiction services.⁴¹ The Government boosted mental health funding in 2019 but, despite this investment, the mental health system's reform has been difficult. In 2020, in collaboration with the World Economic Forum and Deloitte, the New Zealand Ministry of Health developed an initial Digital Mental Health & Addiction Services evaluation framework as part of its response to the *He Ara Oranga report* (a government inquiry into mental health and addiction) and the drive for mental health services presented by the COVID-19 pandemic. The initial standard was redesigned in collaboration with the eMHIC to develop the Digital Mental Health & Addiction Tool (DMHAT), which was released in 2021.

Current state

- New Zealand's Digital Mental Health Strategy was guided by This Way Up (implemented at St Vincent's Hospital, Sydney, Australia).
- A hybrid model of care that included face-to-face as well as virtual/telehealth was considered vital.
- New Zealand is promoting the use of digital tools as complementary to mental health support.
- The Government is integrating primary/acute care services with digital mental health tools and strengthening community-based support.
- Tihei Mauri Ora – a Māori phrase expressing the “vital breath of life” – guided the Ministry of Health's thinking throughout the process of developing the standards for e-mental health.

Key strengths and challenges of the mental health system

- The Government is strongly committed to providing health services and establishing telehealth services, including phone-based services to meet a high volume of services for the population.
- Major system reconfiguration inside the Ministry of Health limited private health service delivery, particularly in the areas of mental health and addiction.
- Digital mental health tools have been used widely within the Māori community (for those under the age of 65).
- The lack of funding for implementation has been a barrier.

Development of the digital mental health framework

- Detailed standards were developed in collaboration with the World Economic Forum and Deloitte.
- The core components of the standards were piloted with a range of stakeholders, including developers, clinicians, people with lived experience, Indigenous peoples and consumers.
- The ORCHA framework was leveraged.
- The initial standard was redesigned in collaboration with the eMHIC to develop the DMHAT, which was released in 2021.
- The DMHAT covers specific issues related to equity, data, privacy, security, clinical governance, user experience, acceptance and cultural safety.
- The assessment is an actively managed, self-assessment process.

Evidence-based approach to the design of the digital mental framework

- The framework design incorporates health equity, local needs, data sovereignty and data management.
- It is aligned to the ORCHA framework.
- It was developed with the Aotearoa New Zealand context (recognizing the Indigenous name of the country) and Tihei Mauri Ora concept in mind.
- It comprises two components: the first sets out baseline standards expected of e-mental health tools and the second is a self-assessment tool for the designers and developers of these e-mental health tools.⁴²

Digital Mental Health & Addiction Tool

- The DMHAT covers mobile apps and online tools and was driven by guiding principles and goals intended to reflect the needs of all consumers in New Zealand.
- The initial draft assessment approach was to form 55 wide-ranging individual standards that reflected the needs of consumers and clinicians for safe, trusted, ethical, sustainable and effective solutions.
- The initial standard was redesigned in collaboration with the eMHIC to develop a lightweight assessment across four levels with a risk-based hierarchy to determine the appropriate assessment requirements for each digital tool.⁴³
- These standards were grouped into mandatory questions, for all services, which set out baseline standards expected of the e-mental health tools, and supplementary questions, which depended on the functional scope, data collected, therapeutic claims and service workforce.

- Each standard individually contained an objective that had to be met, with evidence indicating whether a vendor had met the standard or with examples of not meeting it.
- The four levels were well-being, general health, condition management, and integration with health records or medical devices.
- The second component caters to designers and developers of e-mental health tools concerned with the user experience, clinical safety and quality, data privacy and security, technical security and stability.⁴⁴
- Enhanced review criteria are also included specific to the Aotearoa New Zealand context, related to advertising, social responsibility and equity, cultural safety, user experience responsiveness and data sovereignty.⁴⁵

Lessons learned

- The DMHAT can be leveraged by similar-sized jurisdictions.
- It is important to secure sufficient funding – from the development of the toolkit to implementation and the establishment of an accreditation process – for the entire process.
- It is best not to develop a toolkit during a pandemic as that creates its own set of obstacles.
- Diverse stakeholders should be consulted, including engaging local Indigenous communities and lived experience consumers, from the beginning of the process.

Accreditation

- These standards provide the potential for a more formal accreditation pathway.
- The DMHAT was released in November 2021 as a beta version and the toolkit is open to refinement.

Accreditation: The way forward

This analysis shows that Australia is currently leading the way by establishing a national accreditation process. In November 2022, Australia will form an independent accrediting agency approved by the Australian Commission on Safety and Quality in Health Care.

The accreditation process will be voluntary. The intention is to provide much-needed guidance to consumers, clinicians and funders to better support their selection of safe and efficacious digital mental health tools.

It is a powerful signal to the market. It provides “guard rails” creating a shared understanding of what “good” looks like. It will encourage both established service providers and new innovators to comply. Moreover, it will enable clinicians to confidently recommend and prescribe tools to their patients, and will encourage public and private funders to reimburse their use.

Germany has adopted a slightly different model but with the same outcomes in mind. With the DiGA or digital health applications that are available on prescription,⁴⁶ the country has implemented an accelerated evaluation and reimbursement approach for digital health apps from the European Union. It has recently approved 11 mental health apps⁴⁷ that are prescribed and can be reimbursed through its statutory health system.⁴⁸

Although much progress has already been made, this is only the beginning of a journey that is evolving. Real progress comes with substantial increases in access to high-quality and affordable mental health services. This future will allow consumers to choose how and when they access services and to select models of care that offer in-person, augmented and fully digital services that meet their preferences and requirements. The need for an ethical and regulatory framework to guide this journey ahead has never been more compelling.

3

UpLink innovators in youth mental health

Most mental ill health occurs during youth (between 15 and 24 years of age).



Mental ill health, especially during youth, drastically impacts the early stages of social and emotional development, health education and employment. It also coincides with a period of heavy technology

use and access, potentially providing the opportunity to empower young people to address their mental health needs.

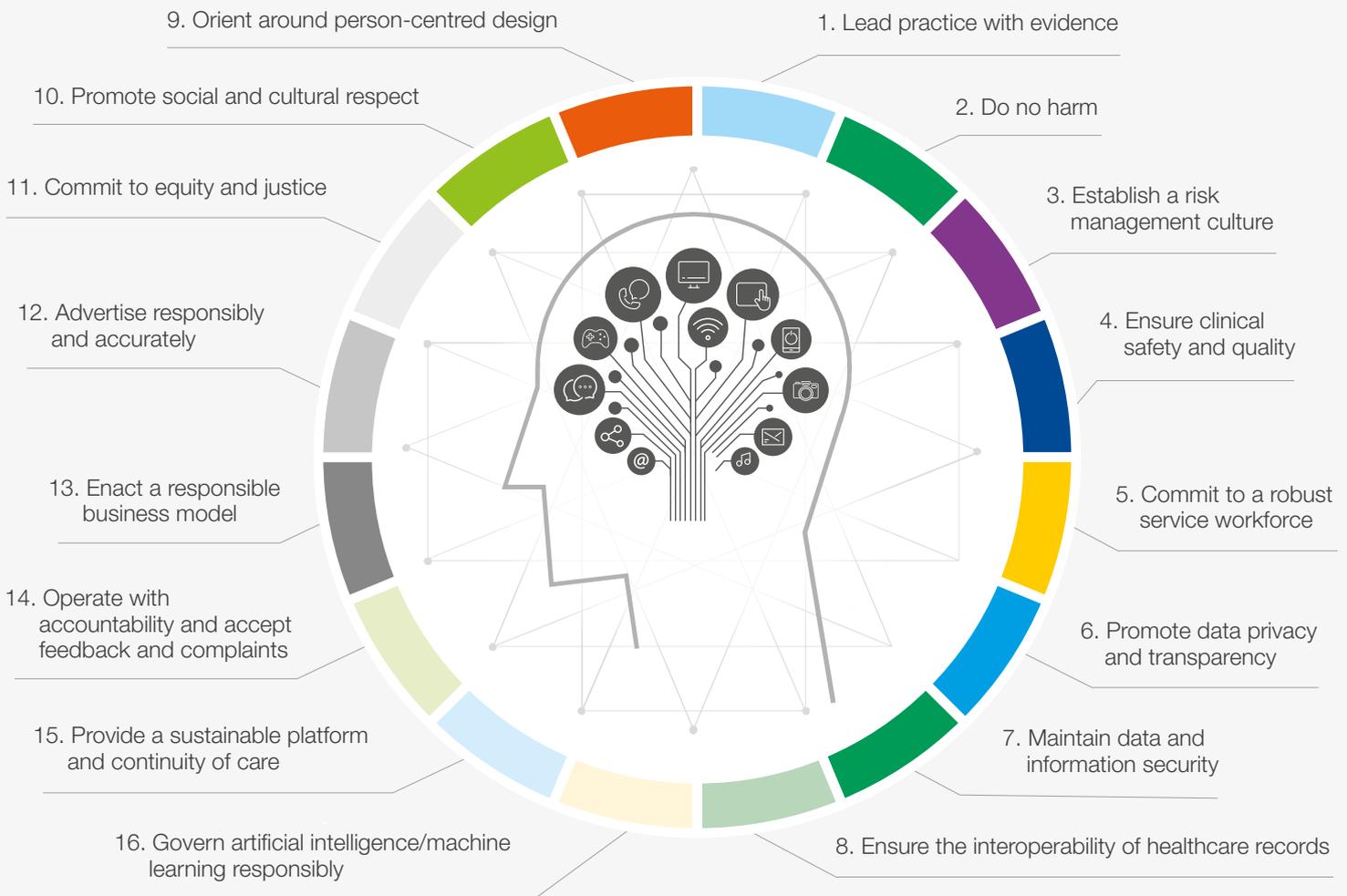
World Economic Forum UpLink Youth Mental Health Challenge

Just as the regulation of digital mental health is rapidly evolving, so too is innovation. Much of it has been driven worldwide by young people eager to improve their lives and their communities. To spotlight some of the many excellent solutions being built, the project team collaborated with UpLink, an open platform for innovation, launched by the World Economic Forum in 2020, centred on specific challenges supporting the UN Sustainable Development Goals that seeks to source innovative solutions and connect them to resources to expand.⁴⁹

The aim of the Forum's Youth Mental Health Challenge was to find start-ups led by young people that provide innovative evidence-based solutions to reduce the stigmatization of mental health and improve well-being.⁵⁰

The UpLink platform provides a bridge for start-ups to work with entrepreneurs, investors, corporate partners, experts and organizations to help them develop. A total of 119 submissions were received from around the globe, 75 of which met the criteria for evidence-based solutions in mental health. The top 14 innovators were selected. The assessment criteria leveraged insights from the 16 standards (Figure 2) for digital mental health outlined in the “[Global Governance Toolkit for Digital Mental Health](#)”. Using the criteria listed in Table 1, 14 of the top submissions (Figure 3) were selected and invited to join the UpLink Innovation Network Programme. This programme is facilitated by the Forum and its partners to help increase and advance sustainability and impact.

FIGURE 2 Standards for digital mental health



Note: Adapted from the “[Global Governance Toolkit for Digital Mental Health](#)” to audit and govern digital mental health services and provide assurance of their safety, quality and efficacy.

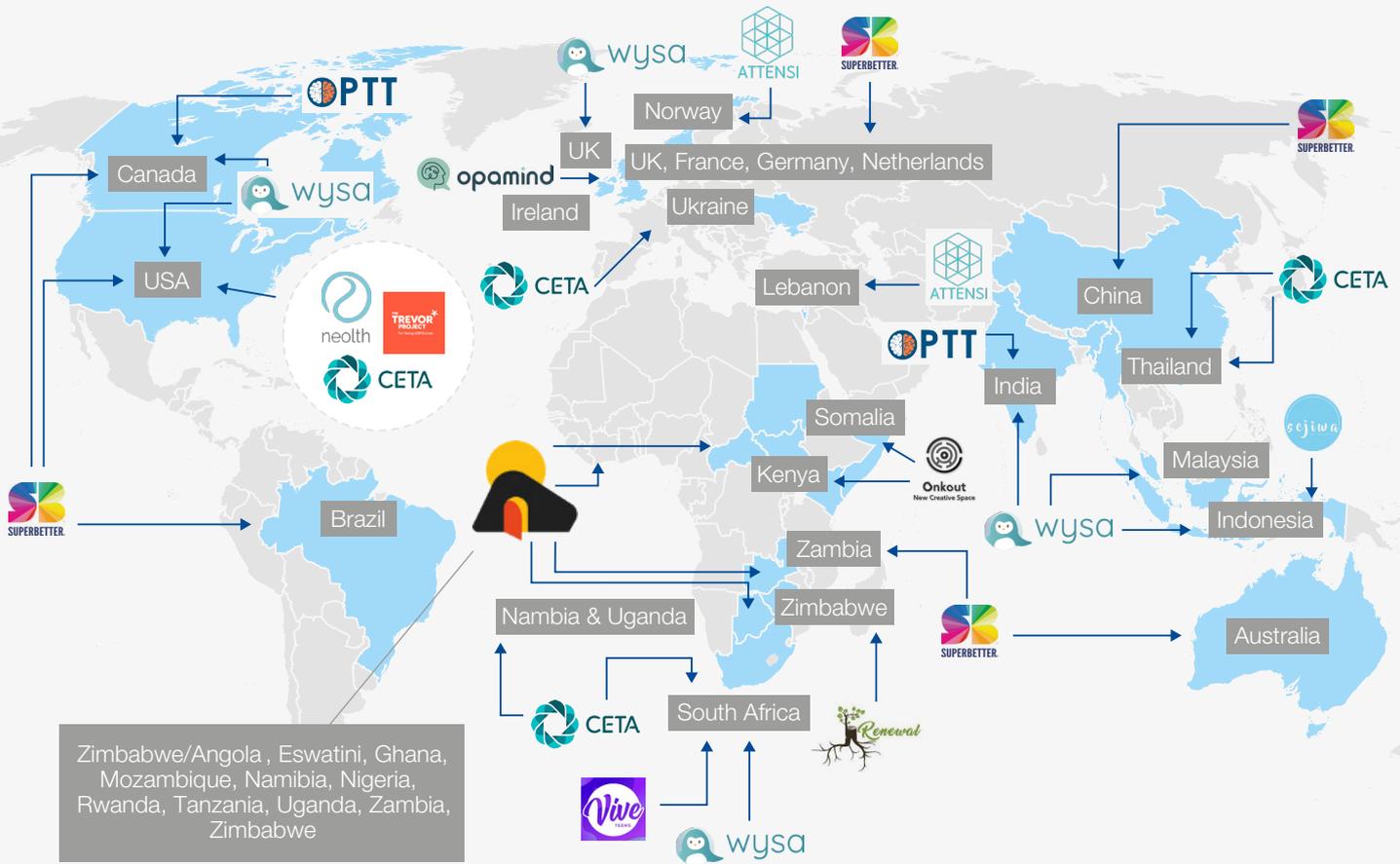
Source: Deloitte

TABLE 1 Assessment criteria for submissions for the UpLink Youth Mental Health Challenge⁵¹

 <p>Financially viable business mode</p>	<p>Solutions need to demonstrate a sustainable business model and approach to revenue and represent investable opportunities for investors or philanthropic funders.</p>
 <p>Effective impact</p>	<p>Solutions need to show a positive impact on youth mental health and well-being.</p>
 <p>Ethical</p>	<p>Solutions need to be aligned with youths' interests and demands, ensuring tools and/or services are ethical and transparent in terms of their purpose, models of care, use of data and technology, and integration into health systems.</p>
 <p>Equitable and inclusive</p>	<p>Solutions need to contribute to reducing an identified gap, such as geography, economics, gender, age, disability, affordability, technical skills and digital literacy. Solutions will be accessible, appropriate and free from discrimination, for those who will need them most.</p>
 <p>Safe</p>	<p>Solutions need to be safe to use for the intended purpose and incorporate processes to do no harm. Solutions will show a commitment to responsibly stewarding the data collected, stored and prepared, shared, analysed and used.</p>
 <p>Sustainable</p>	<p>Solutions should support the mental health infrastructure long term, strengthening it through capacity building, supporting re-/upskilling and task shifting/task sharing innovations.</p>
 <p>Socio-ecological</p>	<p>Solutions that encompass a joint, rather than individualistic, approach are encouraged; this can mean involving communities, family units, neighbourhoods or peers to support positive mental health and well-being.</p>
 <p>Measurement and standards verification</p>	<p>Solutions should demonstrate a clear impact monitoring and evaluation framework. The metrics and indicators should be tracked transparently; relevant robust standards are referenced and applied; and independent credentialing and third-party verification received.</p>
 <p>Governance, team and operating models</p>	<p>Solutions should have a legal entity attached to the project or technology and a diverse leadership team with the right capacity and skill set to deliver on the project's mission. The operating model should show the extent to which the project has achieved financial viability and sustainable revenue streams or has a vision and plan for achieving it.</p>

Note: Youth-led submissions were strongly considered, provided they met the criteria for assessment.
Source: UpLink

FIGURE 3 | 14 top innovators representing innovative solutions in youth mental health, also aligned with the standards for digital mental health



Source: Deloitte

Conclusion

The goal of a governance framework for digital mental ill health is to incentivize the growth of safe, ethical, trusted and strategic innovation in mental health without stifling innovation.

The Fourth Industrial Revolution is defined by an ever-increasing rate of innovation across and between technological domains. With every passing year, technology becomes more powerful, yet the governance structures and regulatory mechanisms underpinning them have changed little. There are no easy answers or quick fixes, and the problem is doubly challenging when disruptive technologies intersect with a topic that is as deeply personal as mental ill health. This is truly an unprecedented moment in human history, yet it is also a moment of great uncertainty: if the urge to “move fast and break things” is not coupled with a deep consideration of the consequences, mankind runs the risk of missing an opportunity to truly improve the well-being of people everywhere.

The regulation of digital mental health tools is fragmented. These tools operate in several jurisdictions and a large variety of settings, such as schools and workplaces, or direct-to-consumer, etc., as well as in the more traditional medical arenas. Each setting has its own standards, policies and frameworks. This makes the need for an overarching digital mental health accreditation process and regulatory framework critical.

Data sharing, privacy and cybersecurity concerns still envelop the plethora of digital mental health tools in the market. These tools are collecting sensitive information on consumer-reported data to do with mood, journaling, medication adherence and guided psychological interventions, providing mental health stories and histories and evaluating symptoms. Yet the lines of informed consent for mental health information remain blurred.

A review of commonly used health apps available for iOS and Android devices indicated that only 30.5% had privacy policies and two-thirds of these policies were not specific to the app itself.⁵² Technological capabilities, such as zero-knowledge encryption, that ensure data is kept secure and that the app developer does not have access to the data, are one potential solution.

As the case studies in this paper have shown, emerging standards and frameworks provide much-needed guidance for service developers and providers to incorporate privacy policies, data transparency and health information security in digital mental health tools. A stringent accreditation process that identifies and endorses the tools that meet these defined standards builds confidence and reassures all the stakeholders in the ecosystem. This is especially important when considering the urgent need to continue to develop the sector as well as the role of investors and employers in delivering this ambition. The investment in mental health services^{53,54,55} and digital mental health services^{56,57} in recent years has been unprecedented.

Also evident is employers increasing the scope of services offered to their employees. For example, the Deloitte Mental Health and Well-Being in the Workplace 2022 survey found significant investment in raising awareness, extending the employee benefits programme, and initiating training programmes for leadership with a focus on how to identify and support staff experiencing mental distress.⁵⁸ Sustaining this much-needed growth in service provision would not be possible in the absence of an ethical regulatory framework.

But this work is certainly not yet finished. To grapple with this new reality and build radically new models of governance, it is necessary to first recognize that this is a rapidly changing landscape. What is considered “best practice” today will continually need to be refreshed or will quickly become obsolete.

When this work began four years ago, the idea that a global pandemic could upend the world and supercharge the need for disruptive technology for mental health was unthinkable. The concept of the “metaverse” had not entered the cultural lexicon. Interest in applications of blockchain and cryptocurrencies for mental health were nascent but had not yet been matched with the investments now seen. This is the beginning of the journey. The regulatory structures of the future must be as dynamic and flexible as the advances they govern.

Contributors

Lead authors

Stephanie Allen

Leader, Global and Australia Healthcare Sector, Deloitte, Australia

Aminath Azhan

Fellow, Disruptive Technologies in Mental Health, World Economic Forum;
Senior Consultant, Deloitte, Australia

Cameron Fox

Lead, Health and Healthcare, World Economic Forum LLC

Clare Medhurst

Fellow, Disruptive Technologies in Mental Health, World Economic Forum;
Specialist Director, Deloitte, Australia

Acknowledgements

Maureen Abbott

Manager, Access to Quality Mental Health Services,
Mental Health Commission, Canada

Margaret Banks

Director, Australian Commission on Safety and Quality
in Health Care, Australia

Christopher Boyd-Skinner

Program Manager, Digital Mental Health, Australian
Commission on Safety and Quality in Health Care,
Australia

Jennifer Caspari

Senior Manager, Deloitte, USA

Arran Culver

Acting Deputy Director-General, Mental Health and
Addictions, Ministry of Health, New Zealand

Philip Grady

Acting Deputy Director-General, Mental Health and
Addictions, Ministry of Health, New Zealand

Christina McCarthy

Executive Director, One Mind at Work, USA

David Rabinowitz

Senior Manager, Monitor Deloitte, USA

Sandra Rigby

Project Officer, Digital Mental Health, Australian
Commission on Safety and Quality in Health Care,
Australia

Victor Storm

Senior Clinical Adviser, Digital Mental Health, Australian
Commission on Safety and Quality in Health Care,
Australia

Sapna Wadhawan

Program Manager, Access to Quality Mental Health
Services, Mental Health Commission, Canada

Sylvia Yan

Associate Director, Deloitte, New Zealand

World Economic Forum

Shyam Bishen

Head, Platform for Shaping the Future of Health and Healthcare

Anna Huber

Impact Lead, Water and Development

Bonnie Rowe

Fellow, Disruptive Technologies in Mental Health;
Director, Deloitte, Australia

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World Economic Forum
91–93 route de la Capite
CH-1223 Cologny/Geneva
Switzerland

Tel.: +41 (0) 22 869 1212
Fax: +41 (0) 22 786 2744
contact@weforum.org
www.weforum.org