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Mind the gaps: Assessing and enhancing the trustworthiness of mental health apps

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MIND THE GAPS

Assessing and Enhancing the Trustworthiness of Mental Health Apps

Mental health apps including artificial intelligence ("AI")-powered apps and chatbots have raised serious concerns relating to safety, efficacy and privacy. This article assesses their trustworthiness based on lego-regulatory, ethical and technological measures in addressing the abovementioned concerns. Focusing on applications to mental health apps, it examines Singapore laws, regulations and guidelines relating to software-based and AI medical devices, data protection, consumer protection, advertising and medical negligence. Additionally, upon taking into account other non-binding ethical guidelines, certification standards and technological measures targeted at app developers, a few recommendations are offered for enhancing trust in mental health apps.

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I. Introduction

1 The COVID-19 pandemic has seriously impacted the mental health of residents in Singapore not least due to the imposed restrictions on movement and social distancing rules[2] and consequently, increased isolation. A majority of respondents from various countries including Singapore have reported adverse effects of the pandemic on their sleep

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2 COVID-19 (Temporary Measures) Act 2020 (Act 14 of 2020); COVID-19 (Temporary Measures) (Control Order) Regulations 2020 (S 254/2020).

quality.[3] The National University Health System's Mind Science Centre's survey disclosed that 61% of individuals working from home reported feeling stressed in 2020.[4] Major sources of stress during this period were the possibility of family members being infected with COVID-19, financial loss and unemployment.[5] Of particular concern was the increase in suicide rates in Singapore in 2020 compared to the previous year.[6] Apart from working adults, the pandemic has also taken a mental toll on migrant workers,[7] school-going children and adolescents.[8] The dire situation has called for the provision of psychological first aid and support to affected persons.[9]

2 A study by the Institute of Mental Health during the pandemic disclosed the proportions of the surveyed Singapore population which met the criteria for clinical depression (8.7%), anxiety (9.4%) and mild to severe stress (9.3%).[10] The government ministries, social services agencies, corporate and charitable organisations have been providing support for mental health amongst the general population and vulnerable segments. The COVID-19 Mental Wellness Taskforce that was established in October 2020 has transitioned into the Interagency Taskforce on Mental Health and Well-Being to deal with mental health issues in the longer

3 *Seeking Solutions: How COVID-19 Changed Sleep Around the World* (Koninklijke Philips NV, 2021) <https://www.usa.philips.com/c-dam/b2c/master/experience/smartsleep/world-sleep-day/2021/philips-world-sleep-day-2021-report.pdf> (accessed 24 March 2022).

4 Joyce Teo, "More working from home feel stressed than those on Covid-19 front line: Survey" *The Straits Times* (19 August 2020).

5 *COVID-19 Mental Wellness Taskforce Report* (Ministry of Health Singapore & Institute of Mental Health, 2020) at p 8 <https://www.moh.gov.sg/resources-statistics/reports/covid-19-mental-wellness-taskforce-report> (accessed 24 March 2022).

6 "Singapore Reported 452 Suicide Deaths in 2020: Number of Elderly Suicide Deaths Highest Recorded Since 1991" *Samaritans of Singapore* (July 2021) <https://www.sos.org.sg/pressroom/singapore-reported-452-suicide-deaths-in-2020-number-of-elderly-suicide-deaths-highest-recorded-since-1991> (accessed 25 March 2022).

7 Lai Gwen Chan & Benjamin Kuan, "Mental Health and Holistic Care of Migrant Workers in Singapore During the COVID-19 Pandemic" (2020) 10(2) *Journal of Global Health* 1.

8 Vidhya Renjan & Daniel S S Fung, "Debate: COVID-19 to the under 19 – A Singapore School Mental Health Response" (2020) 25(4) *Child and Adolescent Mental Health* 260.

9 Hui Shan Sim & Choon How How, "Mental Health and Psychosocial Support During Healthcare Emergencies – COVID-19 Pandemic" (2020) 61(7) *Singapore Medical Journal* 357.

10 *COVID-19 Mental Wellness Taskforce Report* (Ministry of Health Singapore & Institute of Mental Health, 2020) at para 5 <https://www.moh.gov.sg/resources-statistics/reports/covid-19-mental-wellness-taskforce-report> (accessed 24 March 2022). See also *Novel Coronavirus, Population Well-being and Resilience: A Cross-Sectional Study* (Institute of Mental Health & The University of Hong Kong, 2021).

term[11] with a more recent proposal for setting up a permanent national mental health office on the table.[12]

3 Digital health services provide an avenue for patients and affected individuals in isolation to obtain assistance during the pandemic. A survey conducted by Accenture revealed that the percentage of respondents who were more likely to use remote or tele-monitoring devices had increased from 2016 (48%) to 2019 (75%).[13] The use of digital health facilitates the inputs of health data by patients and clinicians, the monitoring of treatments and allows for tele-consultations by therapists.[14]

4 Mental health digital use, including apps, enables users to obtain health-related information and receive needed support through self-help measures, peer support tools and activities, and educational programs.[15] A mental health app may be utilised in conjunction with medication, face-to-face visits by therapists where feasible, or used on its own. It includes wellness apps that encourage people to adopt healthy habits.[16]

5 Artificial intelligence can play a role in mental health through chatbots, natural language processing and wearables for monitoring mental health conditions.[17] Certain apps incorporate chatbots such as Wysa and Woebot as "conversational AI" or "conversational agents" that provide therapeutic guidance for mental health such as Cognitive Behavioural Therapy ("CBT"). Mental health apps can be personalised through natural language processes using social media content to make inferences about the emotions or mental health of the authors.[18] Certain apps track the user's symptoms and moods (ecological momentary

11 *COVID-19 Mental Wellness Taskforce Report* (Ministry of Health Singapore & Institute of Mental Health, 2020) at para 16 <https://www.moh.gov.sg/resources-statistics/reports/covid-19-mental-wellness-taskforce-report> (accessed 24 March 2022).

12 This proposal emerged during the Budget debate in March 2022. See Timothy Goh, "Call for more to be done to plug mental health gaps" *The Straits Times* (21 March 2022).

13 Kaveh Safavi & Brian Kalis, *How Can Leaders Make Recent Digital Health Gains Last?* (*Accenture*, August 2020) at p 8 <https://www.accenture.com/us-en/insights/health/leaders-make-recent-digital-health-gains-last> (accessed 25 March 2022).

14 Jimmy Lee, Nawal Roy & Benjamin Seet, "Electric dreams – The future of mental healthcare is digital" *The Straits Times* (8 February 2021).

15 Ilaria Montagni *et al*, "Mental Health-Related Digital Use by University Students: A Systematic Review" (2020) 26(2) *Telemedicine and e-Health* 131.

16 Janice Tan, "SG Govt Partners Apple for Bespoke Health App, Kicks Off New Campaign" *Marketing-Interative* (16 September 2020) <https://www.marketing-interactive.com/sg-govt-partners-apple-for-bespoke-health-tech-app-kicks-off-new-campaign> (accessed 25 March 2022).

17 Simon D'Alfonso, "AI in Mental Health" (2020) 36 *Current Opinion in Psychology* 112.

18 Rafael A Calvo *et al*, "Natural Language Processing in Mental Health Applications Using Non-Clinical Texts" (2017) 23(5) *Natural Language Engineering* 1.

assessment) or obtain passive location data (geographical momentary assessment).[19] Smartphone apps have been utilised in conjunction with wearables to obtain objective data that can help psychiatrists infer a patient's mental state and behaviour and the presence of mental disorders.[20] Patients' daily activities may be monitored using Android-based smartphones and an Android platform-based mobile application that accessed hardware sensors (*eg*, accelerometer, GPS and gyroscope) in order to measure the level of depression.[21]

6 In addition to the various actors in the field of mental health apps – namely the app developers, app stores, medical and healthcare professionals, regulators and the consumers – public and patient involvement in AI development[22] can help drive innovations in (mental) healthcare. Singapore start-ups have developed apps for those with mental disorders,[23] which provide peer support[24] and connections between users and healthcare professionals.[25] During the pandemic, mental health resources comprising information, self-help tools and support services[26] were delivered via Internet platforms.[27] Government agencies[28] have also

19 Steven Chan *et al*, "Review of Use and Integration of Mobile Apps into Psychiatric Treatments" (2017) 19 *Current Psychiatry Report* 96.

20 Sunil Patel & Kate E A Saunders, "Apps and Wearables in the Monitoring of Mental Health Disorders" (2018) 79(12) *British Journal of Hospital Medicine* 672.

21 Mohammed T Masud *et al*, "Unobtrusive Monitoring of Behavior and Movement Patterns to Detect Clinical Depression Severity Level via Smartphone" (2020) 103 *Journal of Biomedical Informatics* 1.

22 Sarah Carr, "'AI Gone Mental': Engagement and Ethics in Data-driven Technology for Mental Health" (2020) 29(2) *Journal of Mental Health* 125.

23 *Eg*, Singapore-based firm Holmusk developed mConnect for persons with major depressive disorder: See Kelly Ng, "Rethinking mental health: Wellness startups and apps on the upswing" *The Business Times* (16 January 2021) <https://www.businesstimes.com.sg/brunch/rethinking-mental-health-wellness-startups-and-apps-on-the-upswing> (accessed 25 March 2022).

24 *Eg*, CARA Unmask. See also Kelly Ng, "Rethinking mental health: Wellness startups and apps on the upswing" *The Business Times* (16 January 2021) <https://www.businesstimes.com.sg/brunch/rethinking-mental-health-wellness-startups-and-apps-on-the-upswing> (accessed 25 March 2022).

25 *Eg*, mental health apps by Intellect: See Catherine Shu, "Singapore-based mental Health App intellect Reaches One Million Users, Closes Seed Funding" *TechCrunch* (1 December 2020) <https://techcrunch.com/2020/11/30/singapore-based-mental-health-app-intellect-reaches-one-million-users-closes-seed-funding/> (accessed 25 March 2022).

26 Singapore Parl Debates; Vol 95; [4 September 2020]; and Singapore Parl Debates; Vol 95; [11 May 2021].

27 See mindline.sg website <https://www.mindline.sg/> (accessed 25 March 2022).

28 The Ministry of Health Office for Healthcare Transformation, Ministry of Social and Family Development, National Council of Social Service and Institute of Mental Health.

partnered a private tech firm to launch the chatbot platform Wysa during the pandemic.[29]

7 Mental health apps, in providing accessibility to users on a 24/7 basis, can alleviate the shortage of mental health professionals[30] attending to patients with less serious conditions. It was reported in 2020 that the median waiting time for a new appointment with a psychiatrist or psychologist for subsidised consultation in public hospitals was 27 to 28 days.[31] Those who experienced social stigma associated with mental health and who might have been deterred from consulting therapists for treatment[32] would at least benefit from anonymity as well as access to information and support from the apps to cope with their mental health challenges.

8 Nevertheless, with the widespread use and easy access to a wide array of mental health apps in the marketplace, there are potential knowledge gaps and risks. To what extent would the mental health app be able to treat a mental disorder as intended? Will its use introduce adverse effects to the consumer or patient? For a mental health app that seeks to implement an established psychotherapy such as CBT, is the app intervention as efficacious as face-to-face delivery? Would the privacy and security of users' health data be protected or compromised?

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29 Goh Yan Han, "New 'emotionally intelligent' chatbot to help Singaporean stressed by pandemic" *The Straits Times* (22 October 2020) <https://www.straitstimes.com/singapore/community/new-emotionally-intelligent-chatbot-to-help-singaporeans-stressed-by-pandemic> (accessed 25 March 2022).

30 There were 254 psychiatrists registered with the Singapore Medical Council (see *Singapore Medical Council Annual Report 2019* <https://www.healthprofessionals.gov.sg/docs/librariesprovider2/publications-newsroom/smc-annual-reports/smc-annual-report-2019.pdf> (accessed 5 September 2022)) and 504 psychologists on the Singapore Psychological Society register (see Singapore Register of Psychologists website, maintained by the Singapore Psychological Society: <https://singaporepsychologicalsociety.org/singapore-register-of-psychologists/> (accessed 17 August 2022)). This translates to about 4.5 psychiatrists and 8.9 psychologists per population of 100,000: see Singapore Parl Debates; Vol 95; [11 May 2021]. There were no reported figures on psychotherapists and counsellors.

31 Timothy Ong, "Parliament: Urgent need to improve affordability, accessibility and quality of mental healthcare, says NMP Andrea Ong" *The Straits Times* (27 February 2020) <https://www.straitstimes.com/singapore/health/urgent-need-to-improve-affordability-accessibility-and-quality-of-mental-healthcare> (accessed 25 March 2022).

32 The treatment gap for people with mood, anxiety and alcohol use disorder in Singapore may be due to the financial status and lack of awareness of individuals and cultural factors including stigma: see Mythily Subramaniam *et al*, "Minding the Treatment Gap: Results of the Singapore Mental Health Study" (2020) 55(11) *Social Psychiatry and Psychiatric Epidemiology* 1415.

9 Underlying the abovementioned questions is a key issue: can we trust mental health apps? We will examine this issue through the combined lenses of law, ethics and technology in order to assess how they can better address the knowledge gaps and risks and deliver on the benefits afforded by mental health apps. Part II will assess mental health apps by focusing on safety, efficacy and privacy concerns. In response to these concerns, we will discuss in Part III the existing laws and regulations (and related guidelines from regulators) in Singapore and the extent to which they may govern mental health apps. The discussion will cover the regulation of medical devices, data protection, consumer protection, advertising and tort of negligence including the potential gaps and ambiguities in the scope of application. Apart from the Singapore laws, regulations and associated guidelines, this article will discuss in Part IV the roles of non-binding ethical guidelines and standards, guidance documents by regulators, the certification of apps, and the technological measures targeted at app developers that are either global in scope or applicable to selected foreign jurisdictions. Part V concludes with suggestions to enhance trust in mental health apps.

II. Assessment of mental health apps: Safety, efficacy and data privacy and security

10 Three main concerns for consumers and users have arisen with respect to mental health apps: (i) safety – do the apps cause harm?; (ii) efficacy – do the apps work as intended?; and (iii) data privacy and security – do the apps infringe rights to privacy and security of data? Perhaps not surprisingly, there are variations amongst the different mental health apps in the abovementioned aspects. The author's overall assessment of mental health apps from existing literature is that, notwithstanding their potential benefits, there remain gaps in terms of safety, efficacy and privacy. Nevertheless, the presence of risks *per se* does not foreclose trust entirely. The measures to deal with these concerns, which we will discuss in subsequent Parts of the article, will be equally pertinent to the concept of trust. Other challenges such as bias from the use of natural language processing in mental health assessments at the expense of certain groups,[33] global (in)equity in accessing digital mental health, youth dependency on technology and anonymity issues,[34] though important, are outside the focus of this paper.

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33 *Eg*, Isabel Straw & Chris Callison-Burch, "Artificial Intelligence in Mental Health and the Biases of Language Based Models" (2020) 15(12) *PLoS ONE 2020* 1.

34 Blanche Wies, Constantin Landers & Marcello Ienca, "Digital Mental Health for Young People: A Scoping Review of Ethical Promises and Challenges" (2021) 3 *Frontiers of Digital Health* 1.

A. Safety

11 Many mental health apps are well-equipped to help consumers or users cope with mental health issues and pose low or minimal risks. However, mental health apps that are not properly designed to deal with the targeted mental disorders or serious mental health problems such as suicidal ideation or self-harm[35] are risky. These risks are exacerbated by the failure to attend to clinical standards. It was found that 93% of the mobile apps for suicide prevention and depression management did not take account of all the six suicide prevention strategies that are typically found in international clinical guidelines.[36]

12 A review of apps for anxiety relief found in app stores reported that a majority did not provide information regarding the intervention approach or its efficacy for the intended use.[37] It was also found that the apps for bipolar disorder did not refer and adhere to clinical practice guidelines or established self-management tools.[38] In another study on apps to help Indian Android phone users deal with depression, only a small percentage explicitly stated the scope of use (9%), provided an initial screening tool of users for suitability (3%), or offered targeted guidance on managing suicidal crises (12%).[39]

13 For unvalidated mental health apps which purport to provide clinical diagnosis or treatments, the use of the apps may cause users to delay seeking the necessary and proper professional help from psychiatrists and psychologists.[40] In assessing the safety of mental health apps, more attention should be paid to users who are particularly vulnerable due to their mental health conditions or susceptibilities (*eg*, cognitive impairments and affective disorders).

14 Chatbot errors can result in harm to users when utilised without medical or professional supervision. A study was conducted to assess the

35 *Eg*, The Calm Harm app seeks to minimise thoughts of self-harm using dialectical behaviour therapy.

36 Laura Martinengo *et al*, "Suicide Prevention and Depression Apps' Suicide Risk Assessment and Management: A Systematic Assessment of Adherence to Clinical Guidelines" (2019) 17(1) *BMC Medicine* 231.

37 Madalina Sucala *et al*, "Anxiety: There is an App for That. A Systematic Review of Anxiety Apps" (2017) 34(6) *Depress Anxiety* 518.

38 Jennifer Nicholas, *et al*, "Mobile Apps for Bipolar Disorder: A Systematic Review of Features and Content Quality" (2015) 17(8) *Journal of Medical Internet Research* 198.

39 Satish Kumar & Semma Mehrotra, "Free Mobile Apps on Depression for Indian Users: A Brief Overview and Critique" (2017) 28 *Asian Journal of Psychiatry* 124.

40 Michael Bauer *et al*, "Ethical Perspectives on Recommending Digital Technology for Patients with Mental Illness" (2017) 5(1) *International Journal of Bipolar Disorders* 6.

abilities of general-purpose conversational assistants[41] in responding to medical questions (medical queries, medication tasks and emergency tasks) from laypersons. Based on the researchers' computations, the errors by conversational agents in responding to the medical questions that could have led the subject participants to take actions (*eg*, taking the wrong medication) that would likely result in harm (12.4%) or death (6.9%) was not insignificant.[42]

B. Efficacy

15 The gold standard for assessing the effectiveness of a face-to-face psychological intervention is the use of randomised controlled trials ("RCTs") which can be applied to assess interventions via mobile health apps. The apps vary in terms of the targeted audience, types of mental disorders or mental health conditions, the mode and content of delivery. As we will see below, there is ample evidence that mental health apps can generate benefits for users though evidence may be lacking for certain targeted groups or mental disorders. From the outset, it should be highlighted that the fact that a particular psychotherapy has been proved to be effective for specific mental disorders does not necessarily mean that the app version of the psychotherapy would be equally efficacious.[43]

16 A meta-analysis of studies involving 18 RCTs of 22 mental health interventions delivered via smartphone devices to a total of 3,414 participants revealed that smartphone apps reduced depressive symptoms significantly compared to control conditions.[44] Psychological interventions delivered via smartphone devices were shown to reduce anxiety in another study, though the authors acknowledged that more research would be needed to compare the efficacy of such digital interventions to standard face-to-face psychological care.[45] A subsequent meta-analysis not only affirmed the effects of smartphone interventions on depressive and anxiety symptoms, but also indicated significant

41 The study selected Siri, Alexa and Google Assistant.

42 Timothy W Bickmore *et al*, "Patient and Consumer Safety Risks When Using Conversational Assistants for Medical Information: An Observational Study of Siri, Alexa, and Google Assistant" (2018) 20(9) *Journal of Medical Internet Research* 1.

43 Claire Hill *et al*, "Navigating the Challenges of Digital Health Innovation: Considerations and Solutions in Developing Online and Smartphone-application-based Interventions for Mental Health Disorders" (2017) 211(2) *The British Journal of Psychiatry* 65 at 66.

44 Joseph Firth *et al*, "The Efficacy of Smartphone-based Mental Health Interventions for Depressive Symptoms: A Meta-analysis of Randomized Controlled Trials" (2017) 16(3) *World Psychiatry* 287.

45 Joseph Firth *et al*, "Can Smartphone Mental Health Interventions Reduce Symptoms of Anxiety? A Meta-analysis of Randomized Controlled Trials" (2017) 218 *Journal of Affective Disorders* 15.

positive effects on stress levels, quality of life, general psychiatric distress and social anxiety symptoms as compared to controls.[46] However, a meta-analysis of 7 RCTs and 10 apps did not show any significant effect of smartphone applications on borderline personality disorders with symptoms such as emotional dysregulation, suicidality, or self-harm compared to in-person treatments or a waitlist control.[47]

17 Human-computer interactions continue to fascinate, conjuring images of "AI therapists" of the future. One interesting experiment focused on the interviews between the conversational agent Ellie and two groups of participants who were informed either that the conversation agent was a computer or that it was controlled by a human. It turned out that the second group of participants were more concerned about self-disclosure, indicating a certain distrust of human control or judgment, as compared to the first group.[48] Conversely, the first group of participants were more honest and open in their disclosures to the conversational agent.

18 The delivery of psychotherapies via chatbots have generally yielded positive outcomes for mental health. In a study, participants with depression symptoms were randomly assigned to receive self-help content based on CBT principles with a text-based conversational agent Woebot over two weeks. The Woebot possessed some "therapeutic process-oriented features" such as empathic responses, goal-setting, motivation, encouragement and reflection. As a result, the participants' symptoms decreased significantly relative to the information-only control group provided with an e-book on depression.[49] In a separate study, participants who were allocated to chat with Tess, an AI chatbot, via an instant messenger app, experienced reductions in depression as compared to the control group.[50] A review of several studies indicated that mental health outcomes improved significantly following synchronous text-based interventions (chats) which could be delivered via SMS text messaging,

46 Jake Linardon *et al*, "The Efficacy of App-supported Smartphone Interventions for Mental Health Problems: A Meta-analysis of Randomized Controlled Trials" (2019) 18 *World Psychiatry* 325.

47 Gabrielle S Ilagan *et al*, "Smartphone Applications Targeting Borderline Personality Disorder Symptoms: A Systematic Review and Meta-analysis" (2020) 7 *Borderline Personality Disorder and Emotion Dysregulation* 12.

48 Gale M Lucas *et al*, "It's Only a Computer: Virtual Humans Increase Willingness to Disclose" (2014) 37 *Computer and Human Behaviour* 94.

49 Kathleen Kara Fitzpatrick, Alison Darcy & Molly Vierhile, "Delivering Cognitive Behaviour Therapy to Young Adults with Symptoms of Depression and Anxiety Using a Fully Automated Conversational Agent (Woebot): A Randomized Controlled Trial" (2017) 4(2) *JMIR Mental Health* 19.

50 Russell Fulmer *et al*, "Using Psychological Artificial Intelligence (Tess) to Relieve Symptoms of Depression and Anxiety: Randomized Controlled Trial" (2018) 5(4) *JMIR Mental Health* 64.

mobile phone apps, or websites though it also acknowledged the limited use of RCT evaluations of the interventions.[51]

19 The popular mindfulness-based smartphone app, Headspace, comprising daily guided meditations has generated significant positive impact on irritability, affect and stress resulting from external pressure as compared to active controls.[52] It also produced positive effects on healthy adult participants in terms of stress and resilience compared to a waitlist control group.[53] Postpartum women with moderate to moderately severe depressive symptoms who used the app for only 10 to 20 minutes per day for 6 weeks experienced significant improvements in depressive symptoms, perceived stress and sleep quality.[54] A RCT-designed study demonstrated significant increases in positive affect and reduced depressive symptoms with smartphone-based mindfulness interventions, albeit without significant differences in satisfaction with life, flourishing or negative affect relative to the control group.[55]

20 The use of mindfulness app "Calm" was associated with significant gains in wellbeing measured by the Short Warwick-Edinburgh Mental Well-Being Scale.[56] However, with regard to mindfulness interventions for suicidality with Asian youths, papers published in peer-reviewed journals from 2007 to 2017 have not disclosed sufficient evidence of their effectiveness.[57]

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51 This is based on the 25-item Mobile Agnew Relationship Measure (*eg*, "I feel friendly towards the app" and "The app is supportive"): see Simon Hoermann *et al*, "Application of Synchronous Text-Based Dialogue Systems in Mental Health Interventions: Systematic Review" (2017) 19(8) *Journal of Medical Internet Research* 267.

52 The active control consisted of excerpts from the audiobook The Headspace Guide to Meditation and Mindfulness: see Marcos Economides *et al*, "Improvements in Stress, Affect, and Irritability Following Brief Use of a Mindfulness-based Smartphone App: A Randomized Controlled Trial" (2018) 9 *Mindfulness* 1584.

53 Louise Champion, Marcos Economides & Chris Chandler, "The Efficacy of a Brief App-based Mindfulness Intervention on Psychosocial Outcomes in Healthy Adults: A Pilot Randomised Controlled Trial" (2018) 13(12) *PLoS ONE 2018* 1.

54 Lyndsay A Avalos *et al*, "A Mobile Health Mindfulness Intervention for Women with Moderate to Moderately Severe Postpartum Depressive Symptoms: Feasibility Study" (2020) 7(11) *JMIR Mental Health* 1.

55 Annika Howells, Itai Ivtzan & Francisco Jose Eiroa-Orosa, "Putting the 'App' in Happiness: A Randomised Controlled Trial of a Smartphone-Based Mindfulness Intervention to Enhance Wellbeing" (2014) 17 *Journal of Happiness Studies* 163.

56 Joseph Clarke & Steve Draper, "Intermittent Mindfulness Practice can be Beneficial, and Daily Practice can be Harmful. An in depth, Mixed Methods Study of the 'Calm' App's (Mostly Positive) Effects" (2020) 19 *Internet Interventions* 1.

57 Carol C Choo & André AD Burton, "Smartphone Apps for Mindfulness Interventions for Suicidality in Asian Youths: Literature Review" (2018) 6(6) JMIR Mhealth Uhealth 139.

21 CBT is an established psychotherapy designed to improve an individual's behaviour through effecting changes in his or her negative cognitive schema consisting of irrational core beliefs and thoughts.[58] The use of mental health apps incorporating CBT principles was effective at least in the short-term for certain mental health problems such as insomnia and depression.[59] A smartphone-based CBT app acting as an adjunct to medication change among patients with major depression who were unresponsive to prior antidepressant treatments was shown to be more effective than treatment by medication change alone, and it also decreased the overall side-effect burden of the pharmacotherapy.[60] A study conducted on a combined mobile app-based mindfulness program and cognitive behavioural psychoeducation program over four weeks revealed significant improvements in mental well-being and reduced psychological distress among participants in Hong Kong even three months after the study.[61]

22 With respect to the specific target audience, a review of publications between January 2008 and July 2016 covering 15 mental health apps showed there was inadequate evidence of the efficacy of mental health apps for children, preadolescents, and adolescents with mental health problems.[62] Amongst them, only two small RCTs were found but they did not generate significant effects of outcomes with respect to depression or body image. The youngest participant in the trials was nine years old which meant there was no study applicable to children below that age. For older patients with mild cognitive impairment and/or mild-to-moderate dementia, mobile phone apps can be customised to facilitate their daily activities and to help them stay socially engaged.[63]

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58 See generally, Aaron T Beck, "Thinking and Depression: II. Theory and Therapy" (1964) 10 *Archives of General Psychiatry* 561.

59 Amy Leigh Rathbone, Laura Clarry & Juli Prescott, "Assessing the Efficacy of Mobile Health Apps using the Basic Principles of Cognitive Behavioral Therapy: Systematic Review" (2017) 19 *Journal of Medical Internet Research* 399.

60 Akio Mantani *et al*, "Smartphone Cognitive Behavioral Therapy as an Adjunct to Pharmacotherapy for Refractory Depression: Randomized Controlled Trial" (2017) 19(11) *Journal Medical Internet Research* 373.

61 Winnie W S Mak *et al*, "Efficacy and Moderation of Mobile App–Based Programs for Mindfulness-Based Training, Self-Compassion Training, and Cognitive Behavioral Psychoeducation on Mental Health: Randomized Controlled Noninferiority Trial" (2018) 5(4) *JMIR Mental Health* 60.

62 Rebecca Grist, Joanna Porter & Stallard Paul, "Mental Health Mobile Apps for Preadolescents and Adolescents: A Systematic Review" (2017) 19(5) *Journal of Medical Internet Research* 176.

63 Blanka Klimova, "Mobile Phone Apps in the Management and Assessment of Mild Cognitive Impairment and/or Mild-to-Moderate Dementia: An Opinion Article on Recent Findings" (2017) 11 *Frontiers of Human Neuroscience* 461.

23 Overall, there is evidence of the potential benefits of mental health apps for certain mental disorders such as depression though more attention should be paid to the target groups and effects of specific treatment modalities delivered through apps that are also dependent on the extent of adherence to such treatment modalities.[64] Another factor to consider is "digital therapeutic alliance", *ie*, the relationship between the user and the mental health app that conduces to the therapeutic benefits of the user. Here, the issue is whether the alliance can be enhanced by suitable features in human–computer interactions. It was proposed that an assessment scale consisting of relevant items (*eg*, whether the human feels friendly towards the app, his or her willingness to share personal information, and level of confidence or disappointment with the app) may be applied to mental health apps. [65]

C. Privacy and security of data

24 Privacy infringements can exacerbate the problem of stigma and mental harms associated with individuals with mental health conditions. There is also the need to safeguard the health data of users from cyberattacks and malicious hackers given that data security breaches involving the health sector are potentially sensitive and massive[66] and may contribute to identity theft and health system fraud.

25 A lack of sensitivity to privacy concerns can give rise to public backlash. The app launched by a suicide prevention group – the Samaritans – scanned the Twitter feed of users in order to make suggestions of depression and suicidal ideation of people whom the users follow. Though the developers might have thought that the app function would encourage early detection of such symptoms, its design, perhaps unwittingly, violated the privacy rights of users with mental health conditions. In view of the negative public responses, the app was eventually withdrawn.[67]

26 An assessment of 79 health apps in July 2013 available on both Android and iOS platforms, and certified as safe and trustworthy by the UK NHS Health Apps Library, revealed that the stored personal

64 Kit Huckvale *et al*, "Smartphone Apps for the Treatment of Mental Health Conditions: Status and Considerations" (2020) 36 *Current Opinion in Psychology* 65.

65 Simon D'Alfonso *et al*, "The Digital Therapeutic Alliance and Human-Computer Interaction" (2020) 7(12) *JMIR Mental Health* 1.

66 *Re Singapore Health Services Pte Ltd* [2019] SGPDPC 3.

67 Jamie Orme, "Samaritans pulls 'suicide watch' Radar app over privacy concerns" *The Guardian* (7 November 2014) <https://www.theguardian.com/society/2014/nov/07/samaritans-radar-app-suicide-watch-privacy-twitter-users> (accessed 25 March 2022).

information in the apps were not encrypted, two-thirds of the apps had transmitted identifying information via the Internet without encryption, and one-third of them did not have privacy policies.[68] In a review of 36 apps for depression and smoking cessation on Android and iOS in the US and Australia in 2018, a material discrepancy was found between the disclosures in the apps and the actual behaviour concerning the transmission of data to third parties. Whilst 81% of the apps transmitted data for advertising and marketing purposes or analytics to Google and Facebook, a smaller proportion of them[69] had disclosed this information to users.[70]

27 With regard to screen privacy, health apps may contain notifications (*eg*, reminders to record thoughts for a specific therapy) and widgets (*ie*, the embedded miniature app views that provide quick information without opening the app) relating to the user's personal health information that may be visible to a third party with access to the user's smartphone.[71]

III. Existing laws, regulations and associated guidelines and their relevance to mental health apps

28 Given the potential benefits, risks and gaps in knowledge and evidence concerning mental health apps, it is pertinent to ask if they are indeed trustworthy. The trustworthiness of technology is dependent, amongst others, on the trustor's knowledge and perceptions regarding its positive and negative characteristics and susceptibility to errors, and the relevant stakeholders associated with the technology and its use.[72] In the context of mental health apps, as mentioned above, the stakeholders may include app developers, apps stores, the medical profession and the regulators. The users' and consumers' knowledge and perceptions of the measures are based on a trifecta of technological, ethical and lego-

68 Kit Huckvale *et al*, "Unaddressed Privacy Risks in Accredited Health and Wellness Apps: A Cross-Sectional Systematic Assessment" (2015) 13(1) *BMC Medicine* 214.

69 43% of apps transmitting data to Google and 50% transmitting data to Facebook.

70 Kit Huckvale, John Torous & Mark E Larsen, "Assessment of the Data Sharing and Privacy Practices of Smartphone Apps for Depression and Smoking Cessation" (2019) 2(4) *JAMA Network Open* 1.

71 Nick Jones & Matthew Moffitt, "Ethical Guidelines for Mobile App Development Within Health and Mental Health Fields" (2016) 47(2) *Professional Psychology: Research and Practice* 155 at 157.

72 Gary Chan Kok Yew & Man Yip, "AI, Data and Private Law: The Theory-Practice Interface" in *AI, Data and Private Law: Translating Theory into Practice* (Gary Chan Kok Yew & Man Yip eds) (Hart Publishing, 2021) at p 6.

regulatory dimensions,[73] which aim to address the perceived negative aspects of the technology and would be particularly apposite to trust. To plug the knowledge gaps and build trust, the communication to and the education of consumers, users and app developers on the potential risks and measures would also be important. To that end, we will examine the relevant Singapore laws, regulations and associated guidelines relating to mental health apps. This will be followed by a discussion of the ethical guidelines and technological measures employed globally and in specific jurisdictions to enhance the trust and acceptability of mental health apps. As we will see below, the regulatory landscape for mental health apps is delineated by a combination of public regulation (top-down approach), private regulation (bottom-up approach) and co-regulatory approaches.[74]

29 There is no omnibus set of laws, regulations and guidelines that govern mental health apps. Instead, we would have to traverse a wide sweep of legal and regulatory instruments that are dispersed across several legal domains and which are enforced or regulated by different authorities: medical devices (by the Health Sciences Authority), data protection (by the Personal Data Protection Commission), consumer protection (by the Competition and Consumer Commission of Singapore and Consumers' Association of Singapore), advertising (by the Advertising Standards Authority of Singapore) and the tort of negligence (by the courts). In addition, there are several guidelines associated with the abovementioned laws and regulations that do not have legal effect. The task at hand highlights the need for the government, policy-makers and experts in different sectors to work together to develop an overarching regulatory framework for health apps.[75]

A. Medical devices, telehealth and software applications

30 The main regulatory body in Singapore in respect of medical devices is the Health Sciences Authority[76] ("HSA") which promulgated the Health Product (Medical Devices) Regulations 2010 pursuant to the Health

73 See Pouyan Esmaeilzadeh, "Use of AI-Based Tools for Healthcare Purposes: A Survey Study from Consumers' Perspectives" (2020) 20 *BMC Medical Informatics and Decision Making* 170.

74 See generally, Roger Brownsword, "The Regulatory Environment" in *Law, Technology and Society* (Routledge, 2019) at pp 39–62.

75 Lisa Parker *et al*, "The 'Hot Potato' of Mental Health App Regulation: A Critical Case Study of the Australian Policy Arena" (2019) 8(3) *International Journal Health Policy Management* 168.

76 "Digital Health" *Health Sciences Authority* (7 March 2022) <https://www.hsa.gov.sg/medical-devices/digital-health> (accessed 25 March 2022).

Products Act.[77] A digital health device intended for medical purposes, *ie*, the investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process, would be classified as a medical device.[78] This should be read in conjunction with the Regulatory Guidelines for Telehealth Products: Medical Devices Branch 2019 ("Telehealth Guidelines 2019") that define "telehealth products" as instruments, apparatus, machines or software (including *mobile applications*) that are involved in the provision of healthcare services over physically separate environments via infocomm technologies including *mobile technology*. The risk classifications of medical devices in the Telehealth Guidelines 2019 refer mainly to examples of devices for physiological health rather than medical devices to be used in respect of mental health conditions. There is, however, one notable example of risk A classification for a mobile app that is intended to collect and measure the degree of tremor in patients with Parkinson's disease via the smartphone inbuilt accelerometer.

31 More specific to mental health apps, the Telehealth Guidelines 2019 cover the Standalone Mobile Applications, *ie*, R2.0 – a software and/or mobile application that is intended to function by itself and is not intended for use to control or affect the operation of other hardware medical devices. In this regard, apps distributed in Singapore through the local online platforms are within the HSA's regulatory purview. Not all mental health apps will fall within the scope of a "medical device" to be regulated by the HSA. Wellness apps and apps that facilitate the administrative planning of hospital psychiatric appointments, for example, will not be regarded as medical devices under the regulations.

32 The determination of "medical purpose" is not always straightforward. A mental health app may be originally intended to measure and regulate the stress levels of individuals. Such an intended use does not in itself render the app as a medical device. However, stress levels may become excessive or toxic and over time lead to physiological problems and increased risks of mental disorders such as depression. If this is taken into account, an app that alerts the user to such high stress levels might qualify as a medical device. Moreover, with regard to approvals under the Immediate Registration Pathway for Standalone Software and Mobile Applications (discussed below), there are different ways to determine intended use whether by reference to labelled use for

77 The definition of "medical device" is contained in the First Schedule to the Health Products Act (Cap 122D, 2008 Rev Ed), now the Health Products Act 2007 (2020 Rev Ed).

78 "Digital Health" *Health Sciences Authority* (7 March 2022) <https://www.hsa.gov.sg/medical-devices/digital-health> (accessed 25 March 2022).

marketing (*eg*, for health promotion) or use as intended by the product owner which can give rise to different responses.

33 The HSA employs the Immediate Registration Pathway for Standalone Software and Mobile Applications that was implemented in 2018 to leverage the regulatory review and approvals from certain regulatory agencies in Australia, Canada, the EU, Japan and the US. Where a Standalone Medical Mobile application has been registered by one of HSA's reference agencies and its clinical utility has been reviewed by the agency, it may qualify for the Immediate Registration Route. For example, in 2020, the Singapore HSA approved an app known as "reSET" as a clinical intervention (CBT) for substance use disorder in lieu of a pill or injection. The app was approved by the US Food and Drug Administration ("FDA") in 2017.[79] A randomised trial of the app had been conducted, which revealed an improvement in abstinence from certain substance uses[80] for those individuals who had used the app and received standard counselling compared to persons who had only received counselling.[81]

34 Medical devices are categorised into four classes based on the level of risks.[82] A Class B standalone medical mobile application, for example, may qualify for registration if it fulfils the following conditions at the point of submission:[83]

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79 "Pear Therapeutics Announces Market Authorization of reset from the Health Science Authority in Singapore for the Treatment of Adults with Substance Use Disorder" *BusinessWire* (18 June 200) <https://www.businesswire.com/news/home/20200618005459/en/Pear-Therapeutics-Announces-Market-Authorization-of-reSET%C2%AE-from-the-Health-Science-Authority-in-Singapore-for-the-Treatment-of-Adults-with-Substance-Use-Disorder> (accessed 25 March 2022). See also an app approved by the HSA for pain assessment and monitoring of older persons including those with dementia: Dean Koh, "PainCek receives Singapore Regulatory Clearance and Signs Agreement with Allium Healthcare" *Mobi Health News* (6 August 2019) <https://www.mobihealthnews.com/news/apac/painchek-receives-singapore-regulatory-clearance-and-signs-agreement-allium-healthcare> (accessed 25 March 2022).

80 The substances were alcohol, cocaine, marijuana and stimulants.

81 "FDA Permits Marketing of Mobile Medical Application for Substance Use Disorder" *US Food & Drug Administration* (14 September 2017) <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-mobile-medical-application-substance-use-disorder> (accessed 25 March 2022).

82 There are four classes, A to D, from the lowest to the highest risk. Class A medical devices which pose the lowest risk are exempt from product registration though they are subject to other requirements such as safety and performance: see *Medical Device Guidance – GN-15: Guidance on Medical Device Product Registration* (Health Sciences Authority, August 2021) at para 3.1.

83 See *Medical Device Guidance – GN-15: Guidance on Medical Device Product Registration* (Health Sciences Authority, August 2021) at para 4.1.

(a) Approval by at least one of HSA's independent reference agencies for a labelled use identical to that intended for marketing in Singapore. The HSA's independent reference regulatory agencies are (i) Health Canada; (ii) Japan's Ministry of Health, Labour and Welfare; (iii) US Food and Drug Administration; (iv) Australian Therapeutic Goods Administration; and (v) EU Notified Bodies and the corresponding approvals listed.

(b) No safety issues globally associated with the use of the medical device(s) when used as intended by the product owner, in the last three years or since market introduction of the medical device(s) globally, defined as:

(i) no reported deaths;

(ii) no reported serious deterioration in the state of health[84] of any person; and

(iii) no open field safety corrective actions (including recalls) at the point of submission.

(c) No prior rejection/withdrawal of the medical device by/from any reference regulatory agency/foreign jurisdiction(s) or HSA/Singapore due to quality, performance/efficacy or safety issues.[85]

35 In addition, other standard regulatory controls (*ie*, Dealers' Licence and Post-Market obligations) apply to standalone mobile applications as medical devices. Given the abovementioned reference agencies' participation in the International Medical Device Regulators Forum's (IMDRF") Artificial Intelligence Medical Devices Working Group, it is not surprising that there are common features in their approaches albeit with some variations:

(a) Regulating mental health apps as software medical devices that are intended to be used for medical purposes.[86]

84 Serious deteriorations in the state of health in relation to a person means: (a) a life-threatening illness or injury suffered by that person; (b) a permanent impairment of a bodily function of that person; (c) any permanent damage to any part of that person's body; or (d) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

85 This includes non-registration such as refusal to register specific models in an application.

86 *Eg*, the Therapeutic Goods Act 1989 (No 21 of 1990) (Aus) s 41BD; the Food and Drugs Act (RSC, 1985, c F-27) (Can); the Medical Devices Regulations (SOR/98-282) (Can); and Japan's Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No 145 of August 10, 1960) (Japan) Art 2(4).

(b) Classifications of medical devices based on risks though there may be different tiers applicable in each jurisdiction.[87]

(c) The importance of safety and performance requirements of the medical devices in the regulatory process including the impact of artificial intelligence-driven medical devices that possess the capacity for continuous learning from interactions with the real-world environment.[88]

(d) The extent of discretion exercised by regulators such as in the US in the enforcement of regulations (*eg*, for software medical devices that pose a lower risk to the public)[89] and alleviating unnecessary regulatory burden by not regulating products where there is no significant risk to safety as in Australia.[90]

36 With respect to Artificial Intelligence-Medical Devices ("AI-MD") specifically,[91] the Regulatory Guidelines for Software Medical Devices 2020 "reflect HSA's current thinking and practice" and are "not [to] be misconstrued as a new regulatory control on software medical devices".[92] One major objective of the Regulatory Guidelines for Software Medical Devices 2020 is to ensure, as part of its quality management system, the "safety, quality and effectiveness of software medical devices".[93]

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87 *Eg*, the Medical Devices Regulations (SOR/98-282) (Can); and the European Medical Devices Regulations, *ie*, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

88 *Eg*, the US FDA's "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan" (US Food & Drug Administration, January 2021) <https://www.fda.gov/media/145022/download> (accessed 18 August 2022).

89 "Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff" *US Food & Drug Administration* (27 September 2019) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications> (accessed 25 March 2022). See also Avril D McCarthy & Patricia V Lawford, "Standalone Medical Device Software: The Evolving Regulatory Framework" (2015) 39(7) *Journal of Medical Engineering & Technology* 441.

90 *Regulatory Changes for Software Based Medical Devices* (Commonwealth of Australia, 2021) at p 4 <https://www.tga.gov.au/sites/default/files/regulatory-changes-software-based-medical-devices.pdf> (accessed 25 March 2022).

91 This is defined as an "artificial intelligence application intended to be used for medical purposes, such as investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process".

92 *Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach* (Health Sciences Authority, April 2020) <https://www.hsa.gov.sg/docs/default-source/hprg-mdb/gudiance-documents-for-medical-devices/regulatory-guidelines-for-software-medical-devices---a-life-cycle-approach.pdf> (accessed 25 March 2022) at para 1.1.

93 *Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach* (Health Sciences Authority, April 2020) <https://www.hsa.gov.sg/docs/default-source/

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In line with the approach in the Singapore Model Artificial Intelligence Governance Framework 2020,[94] there should be regular monitoring and reviews of AI-MD post-deployment in "real-world" conditions given their capacity for "continuous learning".[95]

37 The medical device lego-regulatory framework comprising parent and subsidiary legislation, the approaches of the relevant foreign reference agencies, guidance documents pertaining to the definitions of medical devices and their risk classifications as well as more recent guidelines on AI-MD, can appear convoluted and daunting to developers of mental health apps. In this regard, there are schemes for consultations with the HSA during the development of the apps or prior to submission for approvals.[96] This reflects the rapidly evolving state of affairs in this space.

38 Indeed, in July 2021, the HSA issued draft Regulatory Guidelines for Classification of Standalone Medical Mobile Applications ("SaMD") and Qualification of Clinical Decision Support Software for public consultation.[97] Similar to the Regulatory Guidelines for Software Medical Devices 2020, the draft guidelines stated specifically that they merely represent "HSA's current policy stance and practice" and are *not* "new regulatory controls". The proposed risk classification framework was based on the framework for SaMD drawn up by the IMDRF. The proposed draft also highlighted the risks classification for software "intended for healthcare professionals to provide cognitive behaviour therapy as an adjunct to a contingency management system, for patients with substance use disorder" which appears to be an implicit reference to the approved

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hprg-mdb/gudiance-documents-for-medical-devices/regulatory-guidelines-for-software-medical-devices---a-life-cycle-approach.pdf> (accessed 25 March 2022) at para 2.

94 *Model Artificial Intelligence Governance Framework* (Infocomm Media Development Authority & Personal Data Protection Commission Singapore, 2nd Ed, 2020) <https://www.pdpc.gov.sg/-/media/files/pdpc/pdf-files/resource-for-organisation/ai/sgmodelaigovframework2.pdf> (accessed 25 March 2022).

95 *Model Artificial Intelligence Governance Framework* (Infocomm Media Development Authority & Personal Data Protection Commission Singapore, 2nd Ed, 2020) at paras 8.2 and 8.3 <https://www.pdpc.gov.sg/-/media/files/pdpc/pdf-files/resource-for-organisation/ai/sgmodelaigovframework2.pdf> (accessed 25 March 2022).

96 "Consultation Schemes" *Health Sciences Authority* (27 February 2020) <https://www.hsa.gov.sg/medical-devices/consultation-schemes> (accessed 25 March 2022).

97 "Consultation on Regulatory Guidelines for Classification of Standalone Medical Mobile Application (SaMD) and Qualification of Clinical Decision Support Software (CDSS)" *Health Sciences Authority* (19 July 2021) <https://www.hsa.gov.sg/announcements/regulatory-updates/consultation-on-regulatory-guidelines-for-classification-of-standalone-medical-mobile-applications-(samd)-and-qualification-of-clinical-decision-support-software-(cdss)> (accessed 25 March 2022).

ReSet app mentioned above. This was followed shortly by the Artificial Intelligence in Healthcare Guidelines[98] ("AIHGle") in October 2021. The aims of AIHGle, co-developed by the Ministry of Health, the HSA, and the Integrated Health Information Systems, are the "safe development and implementation" of AI-MD and "other AI implemented in healthcare settings", and "complementing HSA's AI-MD registration requirements".

39 In addition to medical device regulations and guidelines, a pertinent issue is how mental health apps ought to be used in conjunction with the delivery of telemedicine services[99] by healthcare professionals and organisations. In Singapore, at present, telemedicine services are provided by general practitioners[100] and more recently, also by government polyclinics and restructured hospitals. In this regard, the Ministry of Health's National Telemedicine Guidelines ("NTGs") issued in January 2015 had not fully envisaged the use of (mental) health apps in the provisions of healthcare services. Superficially, telemedicine – defined as the "systematic provision of healthcare services over physically separate environments via Information and Communications Technology (ICT)" – appears broad enough to cover the use of mental health apps. Though there was no specific mention of mental health apps in the NTGs, they stated that one of the four main dimensions or domains of Telemedicine was tele-treatment including tele-psychiatry. Further, telemedicine covers the "exchange of information for clinical purposes between healthcare provider and patient over the telephone, through text messaging (SMS) or other similar application (*eg*, iMessage, WhatsApp)".

40 Assuming that the NTGs are applicable to mental health apps in telemedicine, their use must not compromise the overall standard of care towards the patient through non-Telemedicine care delivery.[101] This principle on standard of care is similarly highlighted in the Singapore Medical Council ("SMC") Ethical Code and Ethical Guidelines 2016[102] together with the need for the patient's informed consent to telemedicine and the confidentiality of information shared through the technology. The SMC has adopted the position that it is empowered to take disciplinary

98 "Artificial Intelligence in Healthcare" *Ministry of Health Singapore* <https://www.moh.gov.sg/licensing-and-regulation/artificial-intelligence-in-healthcare> (accessed 5 September 2022).

99 It is a "licensable healthcare service" under the recently enacted Healthcare Services Act 2020 (Act 3 of 2020).

100 *Eg*, Doctor Anywhere and WhiteCoat.

101 *Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach* (Health Sciences Authority, April 2020) <https://www.hsa.gov.sg/docs/default-source/hprg-mdb/gudiance-documents-for-medical-devices/regulatory-guidelines-for-software-medical-devices---a-life-cycle-approach.pdf> (accessed 25 March 2022) at para 1.2.

102 Section A6(1).

action against registered medical doctors in respect of misconduct arising from telemedicine taking place overseas.[103]

B. Other laws, regulations and guidelines

41 Aside from the regime for medical devices, we will consider whether laws, regulations and guidelines related to the other domains of consumer protection, advertising, personal data protection and the tort of negligence will be relevant to regulate the use of mental health apps generally including those apps that do not qualify as medical devices.

(1) Consumer protection

42 According to the Singapore Consumer Protection (Fair Trading) Act[104] ("CPFTA"), a supplier's unfair practices – deceiving and misleading a consumer, making a false claim, and taking advantage of the consumer[105] – will be met with sanctions to protect consumers. This is reinforced by prohibitions against specified conduct, *eg*, "[m]aking a false or misleading representation concerning the need for any goods or services" and concealing material facts from or misleading a consumer as to material facts in connection with the supply of services.[106] If an unfair practice is established, the consumer may claim for monetary compensation subject to the prescribed limit,[107] and apply for an

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103 *Explanatory Notes – Principles of Revised ECEG* (Singapore Medical Council, 13 September 2016) <https://www.healthprofessionals.gov.sg/smc/guidelines/smc-ethical-code-and-ethical-guidelines-(2002-and-2016-editions)-and-handbook-on-medical-ethics-(2016-edition)> at para 19.

104 Cap 52A, 2009 Rev Ed. Now, the Consumer Protection (Fair Trading) Act 2003 (2020 Rev Ed).

105 Section 4 reads: It is an unfair practice for a supplier, in relation to a consumer transaction —

(*a*) to do or say anything, or omit to do or say anything, if as a result a consumer might reasonably be deceived or misled;

(*b*) to make a false claim;

(*c*) to take advantage of a consumer if the supplier knows or ought reasonably to know that the consumer —

(i) is not in a position to protect his own interests; or

(ii) is not reasonably able to understand the character, nature, language or effect of the transaction or any matter related to the transaction; or

(*d*) without limiting the generality of paragraphs (*a*), (*b*) and (*c*), to do anything specified in the Second Schedule.

See also *Freely Pte Ltd v Ong Kaili* [2010] 2 SLR 1065.

106 Consumer Protection (Fair Trading) Act 2003 (2020 Rev Ed) Second Schedule, at paras 3 and 23.

107 Consumer Protection (Fair Trading) Act 2003 (2020 Rev Ed) s 6(2). The prescribed limit is currently $30,000: see s 6(6).

injunction to restrain the supplier from engaging in the unfair practice.[108] Alternatively, consumers may lodge complaints to the Consumers Association of Singapore[109] ("CASE"). The Competition and Consumer Commission of Singapore is empowered to conduct investigations and enforcements and to submit applications for injunctions against errant businesses under the statute.[110]

43 Does the statute apply to mental health apps to begin with? The definition of a "consumer transaction" which refers to the supply of goods[111] and services is broad.[112] It further states that it does not include any transaction specified in the First Schedule,[113] and in this respect, transactions relating to the provision of mental health services have not been excluded in the First Schedule.

44 The ambiguity lies with the definition of "services" in the CPFTA. *Prima facie*, the word should be wide enough to encompass professional services including health services.[114] The statute does not define "services" but states what the term "includes".[115] Mental health services have neither been specifically incorporated in nor excluded by the definition of "services". If the word "includes" is limited to the explicitly stated items in the definition of "services",[116] then it is likely that the statute does not govern mental health apps.

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108 Consumer Protection (Fair Trading) Act 2003 (2020 Rev Ed) s 9.

109 See CASE website <https://www.case.org.sg/> (accessed 25 March 2022).

110 Parts 3A and 3B respectively and ss 9–10. These responsibilities came under the purview of the Standards, Productivity and Innovation Board prior to 2 April 2018: see s 44.

111 The CPFTA has been applied to the sale of health supplements: see "Case Studies for June 2012" *Consumers Association of Singapore* <https://www.case.org.sg/consumer_guides_casestudies_archive.aspx?month=June&year=2012> (accessed 25 March 2022).

112 A "consumer transaction" means: (a) the supply of goods or services by a supplier to a consumer as a result of a purchase, lease, gift, contest or other arrangement; or (b) an agreement between a supplier and a consumer, as a result of a purchase, lease, gift, contest or other arrangement, in which the supplier is to supply goods or services to the consumer or to another consumer specified in the agreement.

113 Consumer Protection (Fair Trading) Act 2003 (2020 Rev Ed) s 2.

114 See Ravi Chandran, "Consumer Protection (Fair Trading) Act" [2004] 1 SJLS 192.

115 The term "services" includes (a) a service offered or provided that involves the addition to or maintenance, repair or alteration of goods or any residential property; (b) a membership in any club or organisation if the club or organisation is a business formed to make a profit for its owners; (c) the right to use time share accommodation under a time share contract; and (d) financial services: Consumer Protection (Fair Trading) Act 2003 (2020 Rev Ed) s 2.

116 See *Swee Hong Investment Pte Ltd v Swee Hong Exim Pte Ltd* [1994] 3 SLR(R) 259 at [38]–[39] (that with regard to the use of the word "includes" in s 7(2) of the Government Proceedings Act, which stated that "[f]or the purposes of

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45 However, this interpretation may not be conclusive. The word "includes" may have a more expanded meaning that is in line with the statutory purpose. The Minister, in a response to queries from Members of Parliament during the parliamentary debates, had envisaged the statute to apply to online and e-commerce retailers.[117] This is not unexpected considering the prevalence of online transactions involving goods and services. Yet, the statute does not explicitly refer to "online", "electronic" or "e-commerce" transactions. Analogising to health apps, such an online mode may be intended to be covered under the statute even if it is not specifically mentioned. Nevertheless, amendments would be welcome to clarify if the statute is indeed intended to cover online transactions including the use of health apps.

(2) Advertising

46 In so far as claims or representations made in mental health apps are concerned, they may be governed by advertising regulations and standards. Consumers may have recourse to the Singapore Code of Advertising Practice issued by the Advertising Standards Authority of Singapore[118] which is an Advisory Council to the CASE. Due to online purchases during the COVID-19 pandemic, there was increased exposure to advertisements on apps, websites and social media.[119] The CASE received complaints and requests for advertising advice relating to health which was one of the top five industries that attracted feedback in 2020.

47 For licensed healthcare establishments, the Healthcare Services (Advertisement) Regulations 2021 apply to advertisements published by them or other authorised persons[120] by any means or in any form or medium; and that has a Singapore link.[121] An advertisement is regarded as having a Singapore link if: (a) a person who is physically present in Singapore is capable of having access to the advertisement; or (b) the advertisement is addressed to a person or class of persons who the

subsection (1), 'exercise of public duties' *includes*" a list of four categories of public works, the enumerated categories of works were exhaustive of the definition).

117 Singapore Parl Debates; Vol 94; [13 September 2016].

118 "Code" *Advertising Standards Authority of Singapore* <https://asas.org.sg/About/Code> (accessed 25 March 2022).

119 *2020 COVID-19 Ad Complaints Contribute to Increase in Feedback* (Advertising Standards Authority of Singapore, 7 June 2021) <https://asas.org.sg/Portals/0/ASAS%20Media%20Release%20on%202020%20Feedback.pdf> (accessed 25 March 2022).

120 Authorised persons include: Any person appointed as an agent to advertise healthcare services on behalf of licensees (*eg*, employees of the licensee, third party advertising agents or third-party administrators): see reg 2.

121 Healthcare Services (Advertisement) Regulations 2021 (S 1033/2021) reg 3.

licensee or authorised person knows or has reason to believe is physically present in Singapore. In addition to the abovementioned regulations on advertising, medical practitioners in Singapore would have to pay heed to the ethical standards of medical advertising in the Singapore Medical Council's Ethical Code and Ethical Guidelines which apply regardless of the "platform of advertising".[122]

48 For apps that qualify as medical devices, the Health Products (Medical Devices) Regulations 2010[123] stipulate rules on advertisements that emphasise the safety and efficacy of the medical devices. The advertisements cannot contain any statement concerning the intended use and efficacy of the medical device unless such statement has been verified by objective evidence;[124] any statement, assertion or feature of uniqueness or prominence differentiating the medical device from any other competing or similar medical device must be substantiated by facts or evidence;[125] and an advertisement relating to a medical device shall not expressly or implicitly claim that the medical device will prevent, alleviate or cure any disease or condition specified in the Second Schedule[126] which includes epilepsy or fits, hypertension and insanity. Additional principles found in the regulator's guidance document[127] require advertisements to truthfully state the nature, quality and properties of the medical device and not mislead by ambiguity, exaggeration, omission or otherwise; claims in advertisements must be substantiated with scientific studies;[128] and there should not be any claim or implication that the medical device is 100% safe, has no side effects and that their use will not cause harm.

122 *Ethical Code and Ethical Guidelines* (Singapore Medical Council, 2016 Edition) at Section G3.

123 Health Products (Medical Devices) Regulations 2010 (S 436/2010) Pt V.

124 Healthcare Services (Advertisement) Regulations 2021 (S 1033/2021) reg 19.

125 Healthcare Services (Advertisement) Regulations 2021 (S 1033/2021) reg 20.

126 Healthcare Services (Advertisement) Regulations 2021 (S 1033/2021) reg 22.

127 *Medical Device Guidance – GN-08: Guidance on Medical Device Advertisements and Sales Promotion* (Health Sciences Authority, Revision 2, June 2018).

128 In the US, in the case of *FTC v Lumos Labs, Inc*, the creator of Lumosity, a brain training app, was fined by the Federal Trade Commission for claiming that the app could, amongst others, protect against dementia and Alzheimer's disease: see "Lumos Labs, Inc (Lumosity Mobile and Online Cognitive Game) *Federal Trade Commission* (5 January 2016) <https://www.ftc.gov/enforcement/cases-proceedings/132-3212/lumos-labs-inc-lumosity-mobile-online-cognitive-game> (accessed 25 March 2022). Evidence from at least one RCT-based study was required to adequately substantiate claims about the product's efficacy in treating and preventing specific diseases: see "POM Wonderful LLC, et al" *Federal Trade Commission* (2 May 2016) <https://www.ftc.gov/enforcement/cases-proceedings/pom-wonderful-llc-et-al> (accessed 25 March 2022).

(3) Personal data protection, data security and protection of confidentiality

49 The mental health app may collect various types of patient and consumer data including physiological data (*eg*, heart rate), behavioural and emotional data (*eg*, anxiety and depression) and even location data. Apps may also analyse the patient's speech and voice and make predictions of mental disorders based on symptoms.[129]

50 With respect to privacy concerns relating to health-related data, the Singapore Personal Data Protection Act 2012[130] ("PDPA") – a law that governs the collection, use and disclosure of personal data by organisations – obliges the app developers to comply with the statutory duties including the notification of purposes, protecting the personal data from unauthorised access, collection, use, disclosure and loss of the storage medium, ensuring accuracy of data and retention limit obligations. The ambit of "organisation" is wide and includes any individual, company, association or body of persons, corporate or unincorporated, whether or not formed, recognised by Singapore law or resident in Singapore, but excludes "any individual acting in a personal or domestic capacity".[131] This statute would therefore cover a corporate entity or an individual app developer if it designed or used the mental health app in a business capacity.[132] It does not, however, impose the abovementioned statutory obligations on any public agency including the government.[133]

51 The transfer of personal data to a country or territory outside Singapore is prohibited unless the country or territory concerned adheres to comparable data protection standards.[134] To that end, the transferring organisation must take steps to ensure that the recipient of the personal data is bound by "legally enforceable obligations" (such as contracts and binding corporate rules).[135] The app developer cannot collect, use or disclose the mental health app data unless the individual concerned

129 Nicole Martinez-Martin & Karola Kreitmair, "Ethical Issues for Direct-to-Consumer Digital Psychotherapy Apps: Addressing Accountability, Data Protection, and Consent" (2018) 5(2) *JMIR Mental Health* 32.

130 2020 Rev Ed.

131 Personal Data Protection Act 2012 (2020 Rev Ed) s 4(1)(*a*).

132 See *Re Sharon Assya Qadriyah Tang* [2018] SGPDPC 1; *Re Neo Yong Xiang* [2021] SGPDPC 12; and "Mobile App Developers to Comply with Personal Data Protection Act" *Personal Data Protection Commission Singapore* (7 December 2015) <https://www.pdpc.gov.sg/news-and-events/press-room/2015/12/mobile-app-developers-to-comply-with-personal-data-protection-act> (accessed 25 March 2022).

133 Personal Data Protection Act 2012 (2020 Rev Ed) s 4(1)(*c*) read with s 2.

134 Personal Data Protection Act 2012 (2020 Rev Ed) s 26.

135 Personal Data Protection Regulations 2021 (S 63/2021) regs 10 and 11.

has given consent or was deemed to have given consent under the law[136] or there are exceptional circumstances allowing disclosure without consent.[137] By way of recent amendments, the statute has introduced the "legitimate interests" exception[138] and permitted "deemed consent by notification".[139] For the latter, the app developer must conduct an assessment to determine that there is no likely adverse effect on users with respect to their personal data, and has taken reasonable steps to ensure adequate notification.[140]

52 To address the consequences of data breaches, the app developer is required to notify the Personal Data Protection Commission ("PDPC") and affected individuals as soon as practicable of a data breach if the latter results or is likely to result in significant harm for the affected individual or is likely to be of significant scale.[141] The PDPC ensures compliance of statutory rules through issuing mandatory orders and imposing financial penalties for non-compliance with data security obligations.[142] A recent case involved a mobile app developer's lack of oversight with respect to the deployment of a security code fix into the app.[143] Tort claims for breach of statutory duties may be pursued by users and consumers provided loss or damage was suffered as a direct result of the statutory contravention.[144]

53 The data collected by the app may reveal other aspects of the patient's behaviour including erratic conduct or physical assaults and abuse that harmed others. Such information obtained by healthcare professionals should be kept confidential under the equitable action of breach of confidence.[145] The scope of confidentiality is subject to overriding

136 Personal Data Protection Act 2012 (2020 Rev Ed) s 15.

137 See Personal Data Protection Act 2012 (2020 Rev Ed) Second, Third and Fourth Schedules.

138 Personal Data Protection Act 2012 (2020 Rev Ed) First Schedule, Pt 3.

139 Personal Data Protection Act 2012 (2020 Rev Ed) s 15A.

140 See illustration of a health app company that collects, uses and discloses personal data relating to individuals' lifestyle and wellness in *Advisory Guidelines on Key Concepts in the Personal Data Protection Act* (Personal Data Protection Commission Singapore, 1 October 2021) at pp 47–48 <https://www.pdpc.gov.sg/-/media/Files/PDPC/PDF-Files/Advisory-Guidelines/AG-on-Key-Concepts/Advisory-Guidelines-on-Key-Concepts-in-the-PDPA-1-Oct-2021.pdf?la=en> (accessed 25 March 2022).

141 Personal Data Protection Act 2012 (2020 Rev Ed) ss 26B and 26D.

142 Personal Data Protection Act 2012 (2020 Rev Ed) s 24. See *Singapore Health Services Pte Ltd* [2019] SGPDPC 3.

143 *Iapps Pte Ltd* [2021] SGPDPC 1.

144 See Personal Data Protection Act 2012 (2020 Rev Ed) s 32; and *Bellingham, Alex v Reed, Michael* [2021] SGHC 125 at [93] (that "loss or damage" is limited to the "heads of loss or damage under common law and does not include distress or loss of control over personal data").

145 *I-Admin (Singapore) Pte Ltd v Hong Ying Ting* [2020] 1 SLR 1130.

public interests for disclosure such as the prevention of serious harms to the patient or members of the community[146] and mandatory requirements under judicial orders and written laws. The confidentiality principles are generally consistent with the ethical codes for medical doctors,[147] allied health professionals,[148] and other mental health professionals such as psychologists,[149] psychotherapists and counsellors[150] in Singapore.

54 Where medical practitioners (including psychiatrists) or healthcare organisations recommend the use of a mental health app to their patients for which they have specifically contracted with the app developer to collect patient data, the doctor's duty to respect patient confidentiality should extend to the confidential information received by the doctor via the mental health app.[151] Whether the app developer is acting as a data intermediary would depend on whether it is processing the personal data on behalf of a healthcare organisation.[152] If so, the data intermediary is also under an obligation to notify the PDPC of a data breach.[153]

55 Alternatively, the doctor may recommend a mental health app owned by a third party which collects the personal data. In such a scenario, the third party rather than the doctor would owe statutory duties to the data subject. The same applies to apps used by the patient independently of the doctor's advice.

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146 See *W v Egdell* [1990] Ch 359; *Lion Laboratories Ltd v Evans* [1984] 2 All ER 417.

147 *Ethical Code and Ethical Guidelines* (Singapore Medical Council, 2016 Edition) at Guideline 2b; *Singapore Medical Council v Soo Shuenn Chiang* [2020] 3 SLR 1129 at [55].

148 *Allied Health Professions Council Code of Professional Conduct (2013)* (Allied Health Professions Council, 2013) at para 2 <https://www.healthprofessionals.gov.sg/ahpc/information-for-registered-allied-health-professionals/code-of-professional-conduct> (accessed 25 March 2022).

149 *Singapore Psychological Society Code of Ethics 2019* (Singapore Psychological Society, July 2019) Guideline 1 <https://singaporepsychologicalsociety.org/sps-code-of-ethics/> (accessed 25 March 2022).

150 "Standards of Ethics & Conduct" (Association of Psychotherapists and Counsellors, 2022) <https://apacs.org.sg/about-us/standards-of-ethics-conduct/> (accessed 25 March 2022).

151 This is provided in the information "has the necessary quality of confidence about it" and has been "imparted in circumstances importing an obligation of confidence"; an obligation of confidence will also arise where confidential information has been accessed or acquired without a plaintiff's knowledge or consent: see *I-Admin (Singapore) Pte Ltd v Hong Ying Ting* [2020] 1 SLR 1130.

152 Personal Data Protection Act 2012 (2020 Rev Ed) s 2; and *Iapps Pte Ltd* [2021] SGPDPC 1 at [14].

153 Personal Data Protection Act 2012 (2020 Rev Ed) s 26C, unless the data intermediary is processing personal data on behalf of a public agency under s 26E.

(4) Negligence

56 In contrast to the *ex ante* regulation of health apps as medical devices, the tort of negligence considers *ex post* the legal liabilities of the app developers and healthcare professionals who use the apps in delivering medical services to patients.

57 Should the mental health app provide a wrong recommendation to patients, would the medical practitioners who used the app be legally responsible to their patients for any resulting physical or mental harms? This would depend on the level of the doctor's foreseeable risk of such harms arising. Furthermore, the fact that the mental health apps have been approved by the HSA should be relevant in ascertaining whether there has been reasonable use or reliance on the app or authority though it should not, on its own, absolve the doctor's responsibility under the tort of negligence.[154] The medical practitioner or healthcare professional who intends to recommend a mental health app should independently evaluate its safety and efficacy with respect to the patient.[155]

58 Where the doctor recommends a mental health app as a psychotherapeutic intervention that is unsafe or unsupported by empirical testing, the doctor may be liable for negligent treatment itself in the event that the patient suffers harm from the app use.[156] In so far as mental health apps have been used as part of the medical treatment advised by the doctor, the latter should disclose material information relating to the patient's health conditions in connection with the app usage so as to allow the patient to make an informed decision on his health matters.[157]

59 We should also consider patients' responses, *eg*, whether a patient could have contributed to his own damage by not providing relevant information of his or her health conditions as requested by the app which led to the misdiagnosis or mistreatment of his mental health condition. Alternatively, he may be partially at fault for accepting the

154 *TV Media Pte Ltd v De Cruz Andrea Heidi* [2004] 3 SLR(R) 543.

155 On the evaluation of health apps, see Edwin D Boudreaux *et al*, "Evaluating and Selecting Mobile Health Apps: Strategies for Healthcare Providers and Healthcare Organizations" (2014) 4(4) *Translational Behavioural Medicine* 363.

156 See James Armontrout *et al*, "Mobile Mental Health: Navigating New Rules and Regulations for Digital Tools" (2016) 18 *Current Psychiatry Report* 91.

157 The information to be disclosed is dependent on the practice accepted by peer professional opinion to the extent the opinion is based on logic: see s 37 of the Civil Law Act 1909 (2020 Rev Ed).

recommendation made by the mental health app where that was, to the patient's knowledge, contrary to the doctor's prior advice or indications.[158]

60 Aside from negligence claims against medical doctors, app developers which have negligently designed mental health apps for a purported treatment which turned out to be inefficacious may be liable for causing harm to users if it is demonstrated that the users were diverted from proper mental health services or treatment that they would otherwise have received.

61 In summary, the laws and regulations governing mental health apps is dispersed over a wide spectrum touching on disparate topics such as medical devices, data protection, advertising, negligence and possibly consumer protection. There are also a number of non-binding guidelines on telemedicine and software medical devices. The spread of information located in different places can be quite bewildering for the average consumer, app developer and user. One notable exception is the HSA's website on Digital Health[159] which consolidates information on medical devices pertaining to mobile health apps. Nonetheless, the predominant focus of the medical devices regulations is health apps generally. In comparison, there is negligible reference to the unique features of mental health apps to deal with certain mental disorders and the associated social stigma and apps purporting to deliver psychotherapies and to protect against potentially serious risks (*eg*, suicide ideation and severe depression).

IV. Non-binding ethical guidelines and technological measures for mental health apps

62 Apart from the existing laws, regulations and associated guidelines governing mental health apps, what might be the relevance of ethical and technological measures and standards relating to health apps that are targeted at consumers, users and/or app developers but do not impose any legal sanctions for non-compliance? The Singapore laws and regulations have limited coverage over transactions undertaken and entities established outside Singapore. As we have discussed above, the advertising and consumer protection statutes only cover scenarios or transactions that involve Singapore connections or links. Moreover, even if court judgements are obtained, they cannot be enforced against app developers or related parties which do not have any presence in

158 For failure to follow doctor's advice, see *Crossman v Stewart* (1997) 82 DLR (3d) 677 at [32]–[34]; and *Pidgeon v Doncaster Health Authority* [2002] Lloyd's Rep Med 130.

159 "Digital Health" *Health Sciences Authority* (7 March 2022) <https://www.hsa.gov.sg/medical-devices/digital-health> (accessed 25 March 2022).

Singapore.[160] There is therefore a need to consider how initiatives relating to mental health apps taking place outside Singapore's jurisdiction can indirectly affect its use in Singapore. These initiatives may also prompt or encourage the implementation of additional measures in Singapore so as to mitigate the concerns of safety, efficacy and data privacy and security.

63 We will briefly survey the range of voluntary measures pertaining to mental health apps undertaken in several jurisdictions and globally. Some of the voluntary ethical guidelines and best practices are targeted at mental health apps whilst others cover wider areas relating to health apps or digital (mental) health generally.[161] Beyond these, there are also best practices on chatbots such as the framework recently issued by the World Economic Forum[162] that may apply to the design of apps generally. The framework is based on ten ethical principles including safety or non-maleficence, efficacy and data protection, which we have discussed, and recommends actions that can be taken by developers, providers and regulators to implement each principle in three stages (*ie*, develop, deploy and scale).

A. Self-regulation by medical profession and allied professions

64 With regard to mental health apps used by medical doctors in clinical practice, one consideration is whether there should be professional guidelines to regulate its use and the conduct of its members. The Canadian Medical Association's Guiding Principles for Physicians Recommending Mobile Health Applications to Patients (2015)[163] includes principles relating to the physician's considerations (*eg*, the patient's abilities, comfort level, access to technology) prior to recommending a mobile health application, and the communications and advice to patients if the mobile health application will be used for continued monitoring of the patient's conditions. In addition, the guidelines laid out some characteristics of a safe and effective mobile health application, the usability of the app, privacy and security concerns, and evidence of its impact on patient health outcomes.

160 See Singapore Parl Debates; Vol 94; [13 September 2016].

161 See generally, *Global Governance Toolkit for Digital Mental Health: Building Trust in Disruptive Technology for Mental Health* (World Economic Forum in collaboration with Deloitte, April 2021).

162 *Chatbots RESET: A Framework for Governing Responsible Use of Conversational AI in Healthcare* (World Economic Forum in collaboration with Mitsubishi Chemical Holdings Corporation, December 2020).

163 It was stated that the guiding principles build on the Canadian Medical Association's Physician Guidelines for Online Communication with Patients.

65 In contrast, the Singapore Medical Council's Ethical Code and Ethical Guidelines 2016[164] do not provide any specific ethical guidelines for medical practitioners on the use of mental health apps or health apps generally. The diffusion of mobile mental health apps usage extends to the work of other mental health professionals such as psychologists, counsellors and social workers in Singapore but there are as yet no specific codes of ethics or guidelines on the use or impact of health apps for the allied professions. Though the existing basic guidelines on informed consent and confidentiality would apply generally, more specific guidelines on the usage of health apps would be useful for members of the medical and allied healthcare professions as they deliver healthcare services in tandem with the enabling technology.

B. Issuance of digital health service standards

66 The Australian Commission on Safety and Quality in Health Care[165] has, together with service users, consumers, carers, clinicians, service providers and technical experts, developed the National Safety and Quality Digital Mental Health Standards[166] to improve the quality of digital mental health service provision (*eg*, providing information, counselling services, treatment and peer-to-peer support services) including mobile health applications. The Clinical and Technical Governance Standard is focused on maintaining and improving the reliability, safety and quality of care, protecting the privacy of users and transparency in data use, whilst the Model of Care Standard requires service providers to minimise harm to service users and others. In the UK, the Care Quality Commission has also issued guidance for digital health care providers focusing on safety.[167]

C. Guidance on best practices, laws and policies for app developers

67 The UK, US, Europe and Australia have, to varying degrees, developed guidance documents on best practices, relevant laws and/or policies which are targeted at health app developers. The National Institute

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164 *Ethical Code and Ethical Guidelines* (Singapore Medical Council, 2016 Edition).

165 "National Safety and Quality Digital Mental Health Standards" *Australian Commission on Safety and Quality in Health Care* <https://www.safetyandquality.gov.au/our-work/safety-in-e-health/certification-framework-for-digital-mental-health-services/> (accessed 18 August 2022).

166 Published in November 2020.

167 See *Clarification of Regulatory Methodology: PMS Digital Healthcare Providers* (Care Quality Commission, March 2017) <https://www.cqc.org.uk/file/1295582> (accessed 18 August 2022).

for Health Research in the UK has developed the mHabitat framework for the effectiveness evaluation of mobile (mental) health tools as a way of guiding app developers towards best practices in producing mental health apps.[168] The framework provides pointers for app developers to obtain data on the potential usage, target audience and anticipated benefits (and possible harms) of the app at the planning and developmental stages of a health app, and to also measure and report post-use the clinical effects on users' health and wellbeing. The US FTC has issued a "best practice" guidance in 2016 for mobile health app developers to build privacy and security into their apps including a section on applicable laws.[169]

68 In August 2021, the European Committee for Standardization published technical guidelines entitled "Health software – Part 2: Health and wellness apps – Quality and reliability"[170] to assess the quality, safety and effectiveness of health apps.[171] It provides quality criteria for the entire app's project life cycle from the development, testing, releasing to the updating of an app. One useful resource in the Australian context is a tool developed by The Australian Communications Consumer Action Network in co-operation with the University of Sydney – the App Developer's Guide to Law and Policy[172] – to guide app developers on a range of legal and regulatory issues on health apps.

D. Guidelines by app stores for app developers

69 The adoption of apps that are typically based on user ratings and reviews might not necessarily be consistent with the objectives of ensuring their safety and efficacy. It has been found that the ratings and reviews of anxiety apps found on app stores were positively correlated with the number of anxiety app downloads whilst the price of the apps

168 Victoria Betton *et al*, *mHabitat: Framework for the Effectiveness Evaluation of Mobile (Mental) Health Tools* (National Health Service, 2017).

169 "Mobile Health App Developers: FTC Best Practices" *Federal Trade Commission* (April 2016) <https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices#keep> (accessed 18 August 2022).

170 ISO/TS 82304-2:2021.

171 "CEN has Published New Guidelines on Health and Wellness Apps to Help to Sort the Best from the Rest" *CENELEC* (30 August 2021) <https://www.cencenelec.eu/news-and-events/news/2021/eninthespotlight/2021-08-30-cen-iso-ts-82304-2-guidelines-health-and-wellness-apps/> (accessed 18 August 2022).

172 See "Developing a Health or Wellbeing App?" *App Developer's Guide to Law and Policy* (2017) <http://accan.org.au/files/Grants/PeaceofMind/index.html> (accessed 18 August 2022); and Lisa Parker *et al*, "A Health App Developer's Guide to Law and Policy: A Multi-Sector Policy Analysis" (2017) 17 *BMC Medical Informatics and Decision Making* 141.

and labelling of apps in connection with symptoms were negatively correlated with downloads.[173]

70 App stores play a role akin to a gatekeeper of apps seeking entry into the market. If the app developers do not comply with the rules and guidelines of the app stores, their apps may be excluded. In reality, the level of enforcement of app store rules are also tied to financial incentives to accept and monetise the apps through targeted advertising.[174] Hence, there needs to be continuous monitoring to ensure adequate protection for consumers.

71 Nonetheless, there have been developments in the app stores' policy and guidelines. The Google Developer Program Policy mandates the inclusion of a data privacy and security section for every app that encompasses the collection, use and sharing of personal and sensitive user data. This includes disclosing information on the types of personal and sensitive data the app accesses, collects, uses and shares; and any parties with which any personal or sensitive user data is shared, secure data handling procedures for personal and sensitive user data and the developer's data retention and deletion policy. In the section on "Misleading Claims", the policy specifically prohibits "[a]pps that feature medical or health-related content or functionalities that are misleading or potentially harmful". There is also ongoing work on developing ways for app developers to share with users the safety aspects in the use of the apps.[175]

72 The App store review guidelines state that "[m]edical apps that could provide inaccurate data or information, or that could be used for diagnosing or treating patients may be reviewed with greater scrutiny".[176] There are specific instructions on ensuring that the apps disclose data and methodology to support accuracy claims relating to health measurements (*eg*, blood pressure). Other instructions exhort users to check with a doctor in addition to using the app before making medical

173 Huang Hsiao-Ying & Masooda Bashir "Users' Adoption of Mental Health Apps: Examining the Impact of Information Cues (2017) 5(6) JMIR Mhealth Uhealth 83.

174 Lisa Parker *et al*, "How Private is Your Mental Health App Data? An Empirical Study of Mental Health App Privacy Policies and Practices" (2019) 64 *International Journal of Law and Psychiatry* 198.

175 "Preparing for Google Play's New Safety Section" *Android Developers Blog* (28 July 2021) <https://android-developers.googleblog.com/2021/07/new-google-play-safety-section.html> (accessed 18 August 2022).

176 "App Store Review Guidelines" *Apple Developer* (6 June 2022) at para 1.4.1 <https://developer.apple.com/app-store/review/guidelines/#safety> (accessed 18 August 2022).

decisions,[177] and contain sections on data use and security including the privacy of health-related information[178] and data for health, fitness and medical research.[179]

E. Assessments and certifications of mental health apps

73 Ground-up initiatives contribute to the external assessment and certification of digital health apps by private organisations such as The Organisation for the Review of Care and Health Apps ("ORCHA") in the UK.[180] The accreditation of apps has been carried out by national health bodies (*eg*, the NHS) and in partnership with ORCHA. The NHS has applied the Digital Technology Assessment Criteria for health and social care to the development of digital health tools based on specific standards relating to clinical safety, data protection, technical security, interoperability and usability and accessibility.[181] These apps are highlighted on publicly accessible NHS websites. Other repositories of apps may require app developers to respond to queries on app safety and quality, *eg*, AppScript and MyHealthApps or to include patient reviews, *eg*, MyHealthApps.[182]

74 The approach to assessing health apps may be based on objective standards derived from professional bodies (*eg*, the American Psychiatric Association) applied to a database of health apps set up by a

177 "App Store Review Guidelines" *Apple Developer* (6 June 2022) <https://developer.apple.com/app-store/review/guidelines/#safety> (accessed 18 August 2022).

178 "App Store Review Guidelines" *Apple Developer* (6 June 2022) at para 5.1.2 <https://developer.apple.com/app-store/review/guidelines/#safety> (accessed 18 August 2022).

179 "App Store Review Guidelines" *Apple Developer* (6 June 2022) at para 5.1.3 <https://developer.apple.com/app-store/review/guidelines/#safety> (accessed 18 August 2022).

180 *Eg*, The Organisation for the Review of Care and Health Apps ("ORCHA") operates in the UK and several other countries: see ORCHA website at <https://orchahealth.com/about-us/> (accessed 18 August 2022). Assessments are based on Clinical Assurance, Data Privacy, and User Experience. ORCHA's services are mainly aimed at helping health professionals prescribe and monitor usage of health apps and for app developers to build better health apps.

181 "Digital Technology Assessment Criteria (DTAC)" *NHS* <https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/> (accessed 18 August 2022).

182 Clarence Baxter *et al*, "Assessment of Mobile Health Apps Using Built-In Smartphone Sensors for Diagnosis and Treatment: Systematic Survey of Apps Listed in International Curated Health App Libraries" (2020) 8(2) JMIR Mhealth Uhealth 1.

US university.[183] PsyberGuide,[184] a US-based website, is based on reviews by mental health professionals of the apps albeit without a scientific evaluation of the apps' efficacy.

75 Another resource is the certification of information on health-related websites based on an ethical code. For example, Health on the Net stated on its website that it is for readers to "know the source and purpose of the information they are reading" but "[i]t does not seek to rate the medical accuracy, validity or appropriateness of the information itself".[185] The code principles relate to aspects such as the authoritative[186] nature of the information, privacy of data,[187] attribution to sources,[188] justifiability by evidence[189] and transparency.[190]

76 Given the wide accessibility of online mental health apps, consumers in Singapore using such apps may indirectly benefit from the effects of these ethical and technological measures. Collectively, the above ethical and technological measures, though non legally-binding in Singapore, can contribute towards the mitigation of risks and the promotion of appropriate standards and practices in the use of mental health apps generally. In particular, the existing initiatives relating to the inclusion of specific guidelines on mental health apps in the ethical codes of the medical profession and the provision of more information on the potential risks as well as laws, regulations and guidelines governing mental health apps for the benefit of app developers, users and consumers merit serious consideration.

183 John Torous, "Matching Mental Health Apps with Trust and Transparency" *Psychology Today* (21 April 2020) <https://www.psychologytoday.com/sg/blog/digital-mental-health/202004/matching-mental-health-apps-trust-and-transparency> (accessed 18 August 2022).

184 See One Mind PsyberGuide website: <https://psyberguide.org/> (accessed 18 August 2022).

185 "Methodology" *HONcode* (2 May 2017) <https://www.hon.ch/HONcode/Patients/method.html> (accessed 24 August 2021).

186 "Any medical or health advice provided and hosted on this site will only be given by medically trained and qualified professionals."

187 "Confidentiality of data relating to individual patients and visitors to a medical/health Web site, including their identity, is respected by this Web site …".

188 "Where appropriate, information contained on this site will be supported by clear references to source data and, where possible, have specific HTML links to that data."

189 "Any claims relating to the benefits/performance of a specific treatment, commercial product or service will be supported by appropriate, balanced evidence …".

190 See Health on the Net website: <https://www.hon.ch/cgi-bin/HONcode/principles.pl?English> (accessed 24 August 2021).

V. Concluding remarks: Recommendations for enhancing trust in mental health apps

77 The trust and acceptability of mental health apps may be assessed by reference to lego-regulatory, ethical and technological benchmarks. In this regard, there is an array of Singapore laws, regulations and guidelines governing the use of mental health apps as medical devices and which regulate the users' data privacy and security, the content of advertisements on apps, claims against negligent doctors and healthcare professionals who utilise apps that result in harm to patients, and possibly protect against unfair practices *vis-à-vis* consumers. In addition, we can leverage self-regulatory professional and ethical codes, best practices and guidance targeted at app developers, app store guidelines for inclusion of conforming apps, and independent and objective certifications and assessments of health apps by private and public organisations to enhance trust whether directly or indirectly in the use of mental health apps.

78 The applicable laws, regulations, ethical guidelines and technological measures for mental health apps are spread across multiple domain areas catering to the main concerns of safety, efficacy and data privacy and security. They apply to a wide range of target audiences including the app developers and medical practitioners and other healthcare professionals who use apps as well as the consumers or patients (the potential beneficiaries of the regulations). The consumers or patients can be further differentiated according to their mental health concerns, age and the types of assistance or interventions they are seeking. Due to the wide-ranging domains and target groups, finding the relevant principles and norms may require an inordinate amount of time and resources for the layperson.

79 There are some gaps and ambiguities as to the scope of the laws and regulations. The applicability of consumer protection laws and National Telemedicine Guidelines to mental health apps is presently uncertain and should be clarified. Furthermore, more attention may be paid to incorporate in the professional codes of ethics for medical doctors and mental health professionals specific guidelines on the use of mental health apps.

80 As mentioned in Part I, the Singapore Government has worked with partners to set up websites containing resources on mental health during the COVID-19 pandemic for the members of the public. The HSA separately publishes information on regulations for medical devices

including mobile health apps.[191] Another example is the Australian Federal Government's Head to Health website[192] which provides resources on common mental health conditions and digital mental health to consumers and health professionals including a list of recommended mental health apps.

81 At present, there is no consolidated database on laws, regulations and ethical guidelines and codes on mental health apps in Singapore that addresses the safety, efficacy and privacy concerns relating to the development and use of mental health apps in Singapore. To facilitate access to relevant information on the laws, regulations and guidelines, it is recommended that a centralised repository of documents be developed to consolidate all relevant Singapore laws, regulations and guidelines governing mental health apps. The COVID-19 Mental Health Taskforce in Singapore has recommended setting up an online portal containing mental health resources.[193] In tandem with the proposed online portal, a microsite on lego-regulatory resources would be a useful addition.

82 The information should be targeted at app developers, healthcare professionals and potential consumers. Hence, they should be communicated in a simple and accessible manner to these target groups. It is important for informed consumers to serve as a check on potentially errant app developers or healthcare professionals by raising legitimate complaints or queries to relevant agencies (or better, a dedicated agency) in charge of health apps particularly where material risks of harms or breaches of the laws and regulations are involved.

83 App developers should make publicly available certain information about apps to protect consumers. Wykes and Schueller proposed the Transparency for Trust principles[194] comprising four types of information to be made available to consumers at the point of downloading the app: (a) privacy and security (*eg*, where personal data is stored and who will be able to access them?); (b) development characteristics concerning the app (*eg*, how were target users involved in the initial design or usability evaluations?); (c) feasibility (*eg*, what adverse events occurred and the frequency?); and (d) benefits (*eg*, what

191 "Digital Health" *Health Sciences Authority* (7 March 2022) <https://www.hsa.gov.sg/medical-devices/digital-health> (accessed 25 March 2022).

192 See Head to Health website: <https://headtohealth.gov.au/> (accessed 18 August 2022).

193 Timothy Goh, "Task force flags pandemic's impact on mental health" *The Straits Times* (24 August 2021).

194 Til Wykes & Stephen Schueller, "Why Reviewing Apps is Not Enough: Transparency for Trust (T4T) Principles of Responsible Health App Marketplaces" (2019) 21(5) J Med Internet Res 1.

is the impact on health?). In line with promoting transparency, it is proposed that mental health apps should provide information relating to the key aspects of safety, efficacy and privacy. Whilst information on development characteristics would be welcomed, they are not absolutely necessary to protect consumers. Questions on feasibility and benefits in the Transparency for Trust principles overlap with the criteria of safety and efficacy.

84 As mentioned, the Google and App store guidelines have recently paid more attention to the content on health apps. Other important information is proposed here. In terms of safety, mental health apps should state clearly the targeted audience and scope of the services it can provide. Where applicable, the groups of people or mental health conditions that the app is not meant to target should be highlighted in the app and users should be advised to seek the professional help of psychiatrists or mental health professionals in appropriate circumstances. Where particular mental disorders are stated to be outside the app's scope, the app should refrain from providing any information relating to such disorders to avoid the user mistakenly treating the information as advice or a recommendation.

85 To mitigate the problem of the users' over-reliance on chatbots, the apps should, in the interests of safety, encourage users especially the young to consider other activities that involve human interactions or to give prompts for users to end the conversation with chatbots after a sufficiently long period.[195] The chatbot "Tess", for example, would provide contact numbers of the national suicide prevention hotline if it detects users with suicidal or homicidal ideation, and would encourage the user to end the conversation and seek professional assistance.[196]

86 With a view to educating the consumer who may be unaware, apps should state clearly that professional ethics pertaining to doctors and therapists would not apply for apps provided directly to consumers.[197] It is suggested that the above guidelines on disclosure of information on the apps be incorporated as part of a set of voluntary national guidelines

195 Kira Kretzschmar *et al*, "Can Your Phone Be Your Therapist? Young People's Ethical Perspectives on the Use of Fully Automated Conversational Agents (Chatbots) in Mental Health Support" (2019) 11 *Biomedical Informatics* 1.

196 Russell Fulmer *et al*, "Using Psychological Artificial Intelligence (Tess) to Relieve Symptoms of Depression and Anxiety: Randomized Controlled Trial" (2018) 5(4) *JMIR Mental Health* 64.

197 Nicole Martinez-Martin & Karola Kreitmair, "Ethical Issues for Direct-to-Consumer Digital Psychotherapy Apps: Addressing Accountability, Data Protection, and Consent" (2018) 5(2) *JMIR Mental Health* 32.

addressed to app developers and in psychoeducation materials to educate users and consumers.

87 Furthermore, certain information as to the efficacy of mental health apps should be provided. Evidence as to whether the mental health app was assessed by RCTs would be material information for users and consumers to make an informed choice. To mitigate the risks of apps being ineffective, there is a need for greater involvement of clinicians in app development which will in turn encourage greater buy-in by the medical and healthcare professionals to use mental health apps for their patients.[198] This is especially important for the development of mental health apps relating to mental disorders that entail material risks to life and personal injuries (*eg*, suicide prevention).

88 Finally, the views of patients and service users, including those with specific mental disorders, may be integrated at the design stage to enhance trust.[199] The apps may be co-designed, for example, with inputs from youths with depression, suicidal ideation including those who self-harm, as well as clinicians in order to develop useful apps for self-monitoring of symptoms in between face-to-face clinical appointments and communications with their clinicians.[200]

198 Jamie M Marshall, Debra A Dunstan & Warren Bartik, "Clinical or Gimmickal: The Use and Effectiveness of Mobile Mental Health Apps for Treating Anxiety and Depression" (2020) 54(1) *Australian & New Zealand Journal of Psychiatry* 20.

199 Emil Chiauzzi & Amy Newell, "Mental Health Apps in Psychiatric Treatment: A Patient Perspective on Real World Technology Usage" (2019) 6(4) *JMIR Mental Health* 1.

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