Finding Peace of Mind

Navigating the Marketplace of Mental Health Apps
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Quinn Grundy, Lisa Parker, Melissa Raven, Donna Gillies, Barbara Mintzes, Jon Jureidini and Lisa Bero

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Finding peace of mind: Navigating the marketplace of mental health apps

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Executive Summary

Background

Mental health is a burgeoning smartphone app market and is projected to be a core market for impact and growth in Australia (Andria, 2015; Farr, 2016). The Australian Government has recently prioritised implementation of digital mental health services including apps as an accessible and cost-effective alternative or adjunct to face-to-face care (Australian Government, 2015). About one in five Australians experiences a mental disorder in any given year (Australian Bureau of Statistics (ABS), 2008). Thus, a large consumer group may increasingly be required to navigate the mental health app marketplace.

However, the market for mental health apps is largely unregulated, falling between several regulatory domains including telecommunications, privacy, therapeutic goods, media and advertising (Therapeutic Goods Administration (TGA), 2013). App developers must meet the ‘quality’ criteria for their app store of choice (e.g. Google Play, Apple iTunes), which refer predominantly to the performance, functionality and stability of the software program (Apple Inc., 2015; Google Play, 2015). However, there is little or no oversight of consumer protection concerns such as privacy, security or deceptive advertising prior to market entry. Anyone can develop and distribute a mental health app, but app authorship and sponsorship are rarely transparent; this makes it difficult for consumers to detect bias, find an accountable party, or assess the trustworthiness of the app (Jutel & Lupton, 2015).

App technologies may enable wider and more inclusive access to mental health supports, but unless adequate consumer protections are in place it is not clear that this will deliver more benefit than harm. The purpose of this project was to identify salient consumer issues related to the mental health app market and to inform advocacy efforts towards promoting the safety and quality of mental health apps.

Methods

Using a critical, qualitative approach, we analysed the promotional materials of prominent mental health apps commercially available in Australia. In consultation with a team of researchers who specialise in mental health, commercial influences on health, and bias in research, we identified key consumer issues that might arise from the distribution or use of this sample of apps. We concurrently analysed the policy environment, identifying relevant laws, regulations, industry codes, and post-market evaluations that pertain to the oversight of mental health apps in order to cover both the telecommunications and health consumer concerns.

Results

Content analysis

We identified 61 mental health apps, published by 45 unique developers, that were rated by iTunes or Google Play as within the “Top 100”, or were endorsed by a national organisation.
**Mental health apps are commercial entities.** The majority of apps were commercial enterprises, developed by private companies or individuals. The promotion of related apps, products and services suggested a commercialised space, which was reflected in the promotional messages targeted at consumers. Apps used a range of monetization strategies from paid downloads to subscription models to external investors. Apps’ business models were sometimes misleading, lacked transparency or were potentially predatory.

**Authorship of app content was not transparent.** Only half of the sampled apps named an author or content advisor in their promotional materials. Very few of the developers were authors of original content, but instead drew from various psychotherapy approaches (e.g. ‘Cognitive Behavioural Therapy’), spiritual practices (e.g. ‘Buddhism’) or referred to clinical experience or input from scientific experts.

**Apps lacked transparency about the collection, retention, sharing and use of consumers’ personal data.** Nearly half of the sampled apps did not have a privacy policy. For the majority of apps that did have a privacy policy, the policy failed to meet the minimum standards set of the Office of the Australian Information Commissioner or were difficult to find or read. Few of the privacy policies had features that would facilitate user engagement. Only one of the sampled app’s privacy policies met all of the Australian Government’s minimum standards for privacy policies for mobile apps. Overall, only half of sampled apps met any single criterion. Android apps requested, on average, a total of five ‘permissions’, which Android developers use to disclose the way the app interacts with a consumer’s smartphone and the types of consumer data collected. Most commonly, apps requested internet access and ability to read and write to the device’s memory. Some apps appeared to request more consumer data than seemed necessary for the app’s function, and the accompanying privacy policy failed to explain this discrepancy.

**Claims to easily and rapidly improving mental health were not supported by evidence and were undermined by disclaimers.** Developers frequently claimed that consumers could easily and rapidly achieve mental health and wellbeing through use of their product. Even if prospective consumers were sceptical about these claims and the benefits promised, developers encouraged consumers to adopt a ‘nothing to lose’ attitude. Developers claimed credibility in a number of ways, including using scientific authority, highlighting the app’s popularity, and displaying testimonials. Very few provided evidence that would allow consumers to verify the accuracy of claims.

**Apps contained disclaimers that negated claims to improving mental health outcomes and shifted responsibility for harms to consumers.** Half of the apps in our sample posted a disclaimer in the store description, on their website, or in their legal documents. Most disclaimers asserted that the app provided information or guidance that was ‘general in nature’ and not intended as a substitute for ‘professional’ or ‘medical’ advice. Some disclaimers served to distance developers from any suggestion that the app was providing a medical service, which has regulatory implications since apps with a medical function may fall under the oversight of medical device legislation (TGA, 2013). This suggests that developers may be aware of the regulation around medical software and are actively trying to position their apps outside of its purview. Disclaimers treated adverse events or the possibility of harm in a very oblique manner, largely omitting discussion of harm at all.
Mental health apps largely addressed mild anxiety and provided relaxation strategies. There was a lack of diversity in the strategies apps employed in pursuit of promised mental health outcomes. Consistent with the dominant focus on anxiety and stress, the most common approach was to facilitate relaxation (30/61, 49%) via tools such as guided audio recordings, hypnosis, breathing exercises and mindfulness.

App descriptors suggested that mental health apps are for everyone. Most apps were targeted at a general audience (52/61, 85%). Developers’ advice to a general audience implied that everyone needs assistance to maximise their personal potential and achieve ‘peak performance’, prevent mental illness through the pursuit of ‘mental fitness’, and manage the symptoms of mental distress that arise in daily life. Reflecting the aim of targeting as large a consumer market as possible, app store descriptions characterised ‘symptoms’ of mental illness as synonymous with the challenges of ‘everyday living’.

Apps were largely based on the idea that individuals could – and should – successfully self-manage their mental health. Terms such as ‘empowerment’ and ‘self-improvement’ were common, and consumers were encouraged to work on their mental wellbeing just as they would go to a gym to improve their physical fitness. Consumers were repeatedly told that they could manage their symptoms themselves.

Policy analysis
We identified 29 policies that related to one or more of the five principal regulatory sectors: privacy, medical device, marketing, digital content and finance. Policies shape the app market by operating at different levels along the trajectory of health app development that runs from inspiration to distribution and then selection for use. We characterized policies as regulatory, related to distribution, or market evaluation depending on where they provided oversight along the app distribution trajectory.

Policy authors framed the problem of oversight of mental health apps in a range of ways, with some kinds of problems promoted much more prominently than others. The main problems represented were: a lack of regulatory clarity and overburden, barriers to commercial success, and difficulty with consumer choice. Few policies framed the problem of health app oversight as one of protecting consumers – either in terms of privacy or their health and wellbeing. Instead, regulators treated the problem of app oversight as a ‘hot potato,’ largely seeking to clarify what they would not regulate and shifting the responsibility to app developers and ultimately, consumers.

Conclusions
Consumer interests may be well served by health apps, but they may also be compromised. Despite clear risk of harm, our findings show that consumers are not well served by existing regulation. Many of the current regulatory policies focus predominantly on problems other than consumer protection. Secondly, the set of regulatory policies that do provide consumer protection are not easy for app developers to identify or use. Policies are scattered throughout a range of separate sectors, and developers may not be aware of all the relevant legislation and guidance. Additionally, the regulations themselves are not necessarily easy to interpret in the context of health apps.
Our analysis of mental health apps indicated that there were significant issues with content, privacy, security and promotion that precludes endorsing particular apps, or to suggest that a ‘safe’ space exists in the commercial mental health app market for consumers. We are not the first to face the difficulty of providing assistance to consumers in this manner. For example, the National Health Service (NHS) in the UK recently closed their pilot Health Apps Library, which provided consumers a curated set of evidence-based health apps, when researchers discovered that 66% sent unencrypted identifying information over the internet (Huckvale, Prieto, Tilney, Benghozi, & Car, 2015).

To begin addressing these consumer protection issues, we have developed a tool to help developers navigate the policy environment and create safe, quality and legally-compliant mental health apps (see Appendix 1 – A health app developer’s guide to law and policy). Since the existing patchwork of regulation (including legislation, industry codes of conduct and post-market evaluation programs) that delivers consumer protection is complex, siloed and difficult to navigate, app developers may not adhere to good practices at least partly because of lack of knowledge rather than intent.

**Recommendations**

Ensuring the quality, safety and privacy of apps in the mental health app marketplace requires the cooperation of a number of key stakeholders. We present opportunities for action for each of these stakeholder groups in this report. The priority recommendations that will help move toward ‘Peace of Mind’ for mental health app consumers are –

- Innovate in the area of transparency and accountability, for example, raising the bar for transparency around consumer data collection and sharing and innovating in the area of cybersecurity and privacy.
- Prohibit or limit in-app purchases and in-app advertising in apps targeted at children and vulnerable adults (e.g. mental health consumers) (Australian Communications and Media Authority, 2016).
- Require in-store reporting of permissions and explain permissions in lay language.
- Require publicly accessible research evidence to back up any claims that an app will improve mental health.
- Develop quality assurance standards specific to the use of mental health apps in practice that pertain to patient safety, privacy and security (Department of Health and Ageing, 2012)
- Assess community standards for acceptable practices associated with mental health apps, relating to topics such as privacy practices, uses of consumer data, advertising, marketing to vulnerable audiences, and overdiagnosis.
- Place an immediate and high priority on supporting innovation in app security (Huckvale et al., 2015).
- Create a simple, digital mechanism for consumer notification about all adverse events or concerns with mental health apps, with a single, centralised body to receive and investigate reports (Medicines and Healthcare products Regulatory Agency, 2017).
- Apply greater regulatory focus onto app stores and other commercial partners within the mobile ecosystem.
Introduction

Australians are highly connected to their smartphones – of the 84% of Australian smartphone owners, half will check their phones within 15 minutes of waking (Drumm, White, & Swiegers, 2016). Smartphones are now part of many aspects of our lives, including health. At a global level there are more than 200,000 health apps currently available for smartphone users, from over 45,000 different developers, with market revenues in the billions of dollars (Godfrey, Bernard, & Miller, 2016; research2guidance, 2016).

Apps focused on mental health and wellbeing occupy a large and expanding part of the market (Aitken & Gauntlett, 2013; Giota & Kleftaras, 2014; Seko, Kidd, Wiljer, & McKenzie, 2014). Mental health is predicted to be one of the core markets for digital technology in Australia over the next few years (Andria, 2015). The Australian Government has recently prioritised implementation of digital mental health services including apps as an alternative or adjunct to face-to-face care (Australian Government, 2015). As about one in five Australians experience a mental disorder in a given year (Australian Bureau of Statistics (ABS), 2008) this represents a large consumer group which may increasingly be required to navigate the mental health app marketplace.

While there is widespread enthusiasm for mental health apps and optimism that they might transform mental health care, others have urged caution. There is limited evidence for the effectiveness of mental health apps (Donker et al., 2013; Gaggioli & Riva, 2013; Hollis et al., 2015; Leigh & Flatt, 2015; Price et al., 2014). Few mental health apps remain commercially available long enough to be properly evaluated (Larsen, Nicholas, & Christensen, 2016) and there is potential for real harm to consumers resulting, for example, from loss of privacy (Donker et al., 2013; Gaggioli & Riva, 2013; Hollis et al., 2015) or exacerbation of mental health symptoms (Firth & Torous, 2015). These issues are especially relevant to mental health apps because consumers choose these apps when they are experiencing distress and may be particularly vulnerable to discrimination on account of their mental health condition (Hollis et al., 2015).

In order to explore possible risks associated with the rapidly growing availability and use of mental health apps, we sought to perform a critical analysis of currently available apps and the regulatory environment. Through these analyses, we sought to identify salient consumer issues and to inform advocacy efforts towards ensuring the safety and quality of mental health apps. This report describes our findings and recommendations.

What is a mental health app?

Digital technologies used in healthcare are collectively known as eHealth. Apps are one type of digital technology used for healthcare purposes; others include computer-based websites, electronic health records and electronic prescribing. Health apps may also be known as: medical apps, mobile health, mobile medical apps, mHealth and m-health.

In this report we use the term ‘health app’ to mean software focused on health and/or wellness that is designed to be downloaded onto a smartphone, tablet computer, or other mobile platform and run with or without internet availability (Torous & Powell, 2015). Health apps are available via free
or at-cost download, or by subscription. They are usually accessed through one or more of the web-based commercial app stores, with Google Inc. and Apple Inc. dominating the app market with their respective stores, Google Play and iTunes. Apps in these stores are designed for the companies’ unique smartphone operating systems. The Android platform, Google’s operating system, dominates the global market share and serves most Australian consumers (e.g. via Samsung, Nokia or HTC hardware). Apple’s iOS platform claims only 15% of the global market share, although 43% of Australians own an Apple device, making it a significant player in our local context (Drumm et al., 2016).

The definition of a ‘mental health app’ is not clear-cut. In this report we use it to mean an app that addresses one or more of a wide range of concerns ranging from mental illness (such as major depression or anxiety) to mental wellness (such as mindfulness) (Christensen & Petrie, 2013). Mental health apps can be classified according to their main purpose (Giota & Kleftaras, 2014; Gravenhorst et al., 2015; Hollis et al., 2015; Olla & Shimskey, 2015) –

- Assessment or diagnosis of ill-health (e.g. via a questionnaire, diary entries)
- Treatment of ill-health (e.g. via Cognitive Behavioural Therapy)
- Monitoring of health status (e.g. tracking mood or anxiety levels)
- Health promotion (e.g. relaxation exercises)
- Education (e.g. information about mental health conditions)
- Reminders and scheduling (e.g. appointments or medications)
- Peer support (e.g. social networks of users)

Many health apps collect health-related and other personal data from the user. Data collection can be active, requiring user participation (e.g. recording of subjective experiences, typing diary entries) or passive and automatic (e.g. through sensors or permissions requested) (Torous & Powell, 2015). Of 1000 app developers surveyed at the 2016 Congress of the Application Developers Alliance, 90% collected some form of user data, 80% retained data indefinitely or “for several years”, and 75% agreed that “efforts by policymakers to limit data retention are concerning” (Application Developers Alliance, 2016).

The Congress report reflected the near unanimous view that collection of user data is an integral part of an app developer’s business model, characterising data as the ‘lifeblood’ of mobile app companies. The collection of user data allows app developers to identify consumer needs and create products to fill them, generate advertising revenue and monetize the data itself (Application Developers Alliance, 2016).

**A mental health app boom**

Tens of thousands of mental health apps are available (Coulon, Monroe, & West, 2016); many focus on mental well-being, but also offer treatment for specific mental illnesses (Aitken & Gauntlett, 2013). Mental health apps are popular with the public (Donker et al., 2013) and routinely feature in the top-selling lists of iTunes and Google Play.

Mental health apps are also popular with health professionals, particularly in Australia where clinicians and researchers are highly active in the use and study of web-based and mobile technologies for mental illness (Christensen & Petrie, 2013; Perry, Werner-Seidler, Calear, &
Christensen, 2016; Proudfoot et al., 2013). The Australian Government is prioritising the use of digital mental health services (Australian Government, 2015), alongside other countries such as Sweden and the United Kingdom (UK) (Christensen, Batterham, & Calear, 2014; Hollis et al., 2015; NHS Choices, 2015). Policymakers’ enthusiasm for mental health apps is driven by the hope that such apps will deliver substantial benefits to individuals and to society by:

- **Increasing the availability and accessibility of mental health care.** Young people tend to be poor users of clinical services and heavy users of apps (Burns, Davenport, Durkin, Luscombe, & Hickie, 2010; Mani, Kavanagh, Hides, & Stoyanov, 2015; Perry et al., 2016) and people in rural and remote areas struggle with physical access to mental healthcare services (Giota & Kleftaras, 2014; Proudfoot et al., 2013).

- **Enhancing the confidentiality of mental health care.** Confidentiality may be important to young people (Perry et al., 2016) and to those in small, highly connected communities where it is difficult to access face-to-face services anonymously (Proudfoot et al., 2013).

- **Making mental health care more effective.** Due to their functionality, mental health apps might be able to recognize early warning signs of mental health decline or crisis, alerting patients, carers or clinicians (Hollis et al., 2015).

- **Improving the cost-effectiveness of healthcare.** Digitally-delivered mental health services, including apps, may be cheaper than – and just as effective as – face-to-face clinical services (Hollis et al., 2015).

**Consumer issues**

Despite the potential benefits listed above, much of this promise is hypothetical, with limited evidence for benefit associated with mental health app use (Donker et al., 2013; Gaggioli & Riva, 2013; Hollis et al., 2015; Price et al., 2014). The mobile platform has unique functionality but creates additional risks to consumers compared with other digital health interventions.

**Loss of privacy**

Loss of consumer privacy may arise through routine (although often covert) commercial data collection practices or from malign ‘hacking’ of poorly secured data. Apps are known to routinely collect and store personal consumer data including phone and email contacts, call and internet usage histories, calendar data, photographs, phone location, and unique phone identifiers (Office of the Information Commissioner Queensland, 2014). Mobile phone numbers, for example, are an easily attainable and unique digital identifier that can be used to link a consumer’s personal data held by multiple companies including social networking sites, health apps and credit agencies (Lohr, 2016). Personal information about consumers may be shared or sold by the app developer: the US Federal Trade Commission analysed twelve popular health and fitness apps and found they shared data such as usernames, names, email addresses, postal codes, geo-location, and exercise and diet habits with 76 third parties (Kaye, 2014).

Privacy and security are particularly important when it comes to personal health data. Loss of privacy about personal health status may result in employment, housing or financial discrimination (Pasquale, 2015). For example, an employer who has access to health data about job applicants may discriminate against those with certain health issues, even if those issues are not current, or not
relevant to the prospective employee’s performance, or the information is incorrect. Given that mental illness remains a highly stigmatised condition, loss of privacy around mental health may leave consumers particularly vulnerable to discrimination of this kind (Hollis et al., 2015). Loss of health data can also lead to fraud and identity theft (Giota & Kleftaras, 2014). Electronic health records have become a valuable item for hackers because health fraud is lucrative and difficult to detect (Humer & Finkle, 2014).

Standard government guidelines (Office of the Australian Information Commissioner, 2014) for the protection of consumer privacy in relation to apps include:

- Seeking consent before collecting or sharing personal data
- Collecting only data that are strictly necessary for the function of the app
- Defining a reasonable time of data retention
- Deleting expired data (Aitken & Gauntlett, 2013).

Most health apps fail to operate in line with these standard principles (Huckvale et al., 2015; Sunyaev, Dehling, Taylor, & Mandl, 2014). Apps also may have weak security standards. For example, the United Kingdom’s National Health Service shut down their pilot Health Apps Library after researchers discovered that 89% of the endorsed apps transmitted information to online services and 66% sent unencrypted identifying information over the Internet (Huckvale et al., 2015). Few health apps enable users to erase data in the event that the phone is lost or stolen (Giota & Kleftaras, 2014).

**Lack of transparency**

There is a widespread lack of transparency in mental health apps relating to privacy policies, authorship, commercial interests and data sharing practices.

Health apps do not always provide consumers with an accessible privacy policy; of those that do, some provide policies that are out of date, insufficient or require a high-level reading ability (Aitken & Gauntlett, 2013). For example, in a study about privacy policies in the 300 most frequently rated health apps in each of the Apple and Google Play app stores, researchers found only 31% had a privacy policy. Two-thirds of these policies were generic company documents that did not specifically focus on the app itself (Dehling, Gao, Schneider, & Sunyaev, 2015).

The vast majority of apps are developed by commercial entities (research2guidance, 2015). Anyone can develop and distribute a mental health app, and app authorship and sponsorship are rarely transparent. This means it is difficult for consumers to detect bias, find an accountable party, or assess the trustworthiness of the app (Jutel & Lupton, 2015; Lewis, 2013; Lupton, 2014; Shen et al., 2015). Health apps are largely created by non-clinical developers without health professional input (Lewis & Wyatt, 2014; research2guidance, 2015; Shen et al., 2015). Few health apps provide references for app resources and content (Coulon et al., 2016).

There is only limited knowledge about the variety of possible uses for consumer data from sources such as mobile apps. For example, this kind of data may be used to populate predictive algorithms that are used as tools by governments, insurance companies and employers to plan for preferred outcomes, in much the same way as a credit score enables financial institutions to determine lending practices (Pasquale, 2015). Algorithms are proprietary, thus consumers cannot challenge the

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accuracy of algorithmic decisions and policymakers are unable to scrutinise their processes, though they have been linked to discriminatory practices such as racial bias (Pasquale, 2015).

**Coercion**

There is growing enthusiasm for the use of mental health apps in the workplace amongst employers including the Australian Army (Chen, 2016), which regards apps as a means of improving employee health and wellbeing, and reducing absenteeism (Incubate, 2015; Mack, 2016). Some commentators are concerned that individuals may be coerced by employers, insurance companies or even governments to use health apps (Fox, 2015; Krieger, 2013) and that it represents an unacceptable invasion of personal privacy (Gal, 2017).

**Health inequity**

Apps represent an approach to the prevention and management of mental illness that is heavily focused on individual action. Researchers have critiqued apps for focusing on personal responsibility for health because it seemingly ignores or draws attention away from important social determinants of health such as income, education opportunities, adequate housing, and healthy neighbourhoods (Lupton, 2015; Seko et al., 2014; Till, 2014). The rise of apps as health solutions shifts the responsibility for health and well-being onto individuals, and away from governments, employers and others who have the power to create healthy environments and support individuals who have limited and unequal abilities to attain good mental health (Seko et al., 2014).

Even free apps exist in a highly commercialized space where consumers must buy a smartphone and a data plan, and must use a credit card to access an app store (Millington, 2014). The rise of health apps may therefore reinforce health inequities by focusing on the “white, worried and well” who are ideal marketing targets, but not necessarily the ones who could most benefit (McInerney, 2016). Governments which promote apps as the preferred – or mandated – first point of access for mental health services may find that those who are most in need have the least ability to obtain help (Australian Government, 2015).

**Unproven benefits**

There is limited evidence that mental health apps improve mental health outcomes: the vast majority have not been formally tested (Donker et al., 2013; Giota & Kleftaras, 2014; Hollis et al., 2015; Seko et al., 2014). The few scientific trials of mental health apps have been small, with short follow-up periods (Proudfoot et al., 2013). The lack of evidence is not unexpected: health app development is a new and rapidly expanding field and the number of available health apps has risen dramatically over the last five years. Many apps are only available in stores for short periods of time, and those that persist may be frequently updated and altered (Larsen et al., 2016). For example, researchers found that 50% of the search results in Google Play changed after 130 days (for key word ‘depression’), 195 days (for key words ‘bipolar disorder’), and 115 days (for key word ‘suicide’) (Larsen et al., 2016).

Despite the lack of evidence, some clinicians and researchers are optimistic about the effectiveness of mental health apps where they are based on online mental health interventions, which have strong evidence of effectiveness, particularly those offering cognitive behavioural therapy.
(Christensen et al., 2014; Christensen & Petrie, 2013; Mayo-Wilson & Montgomery, 2013). There is less confidence in the usefulness of health apps to assess or diagnose consumers (Abroms, Padmanabhan, Thaweethai, & Phillips, 2011; Coulon et al., 2016) particularly as most are developed without input from health professionals (Lewis & Wyatt, 2014; research2guidance, 2015; Shen et al., 2015).

Possible health harms

On the other hand, consumers might be harmed by using mental health apps. Few people have studied the harms of using health apps, so it is not clear how frequently harms occur, whether consumers are aware of harms, or under what circumstances the benefits of mental health app use are likely – or unlikely – to outweigh harms.

Some health apps promise to diagnose mental health conditions. If an app provides an incorrect diagnosis, a consumer may go on to receive unnecessary or incorrect treatment, or may experience a delay in treatment with negative health consequences (Shen et al., 2015). In addition, mental health apps could paradoxically exacerbate a consumer’s symptoms. For example, some apps allow users to track their mood or other symptoms. Consumers might feel excessive pressure to self-monitor or shame and guilt if unable to self-monitor effectively (Seko et al., 2014). Others may experience an exacerbation of psychotic symptoms (Firth & Torous, 2015). Many apps offer social networking opportunities or user forums, and researchers have raised the possibility that participation in these could normalise self-harm behaviours, enable cyber-bullying, encourage suicidal acts, discourage help-seeking, or provide conflicting recommendations (Juarascio, Manasse, Goldstein, Forman, & Butryn, 2015; Perry et al., 2016).

Commercial interests may use mental health apps to expand consumer markets. For example, encouraging large proportions of the population to self-diagnose for depression may increase the demand for treatments (Moynihan, Doust, & Henry, 2012). This practice of predatory overdiagnosis occurs when consumers with very minor, self-limiting or non-progressive mental health conditions are encouraged to self-diagnose and are directed to particular treatments in a cycle that does not deliver any benefit to the consumer involved but engenders commercial profit (Carter et al., 2015; Jutel & Lupton, 2015; Mackey & Liang, 2015). Overdiagnosis can negatively affect a person’s identity and behaviour and subject them to side-effects, financial burden, and distress that are not offset by any treatment benefit. It can also unnecessarily increase the burden on the healthcare system because more people with minor complaints who will not benefit from treatment are prompted to seek assessment (Welch, Schwartz, & Woloshin, 2011). This means that, far from ameliorating existing loads on the mental health system, promotion of mental health app use may unnecessarily and unhelpfully exacerbate demand.

Summary

Consumers with mental health concerns are particularly vulnerable to flaws in the health apps market as the impetus for seeking a mental health app is typically mental distress. Our analysis of mental health apps will explore the possibilities for harm and benefit from the use of mental health apps to understand the implications for this group of consumers. Particularly, there has been little discussion of conflicts of interest or commercial interests in relation to mobile apps (Krieger, 2013; Lupton & Jutel, 2015). Consulting firms have published studies of the health app marketplace, but
these reports are only available to the public at a high cost and these do not come from a consumer focus (Andria, 2015).

'The ‘Wild West’: Apps and regulation

Despite the array of potential consumer harms resulting from the use of mental health apps, this sector is under-regulated. The Huffington Post recently described the current situation as “the Wild West phase” of using apps to treat mental illness (Gregoire, 2017). Legislators around the world have released formal guidance on the development and dissemination of health apps (European Commission, 2014; Medicines and Healthcare products Regulatory Agency, 2016; TGA, 2013; US Food and Drug Administration (FDA), 2015, 2016). However, a number of these publications were notable for outlining what they intended to omit from their regulatory scope. For example, the US FDA, under whose purview fall medicines and medical devices, produced guidance stating that it does not intend to exercise any regulatory oversight of apps that could be classified as ‘general wellness’ products, including apps marketed towards mental wellbeing (US FDA, 2016).

Oversight of mental health apps occurs through a mix of government regulation, industry self-regulation, and direct education of consumers and practitioners. This combination of oversight mechanisms is not well studied (Boulos, Brewer, Karimkhani, Buller, & Dellavalle, 2014) and there is no consensus on what, if anything, should be done about the regulation of health apps (Powell, Landman, & Bates, 2014). Some stakeholders argue for stricter regulation to reduce the risk of consumer harms (Hollis et al., 2015). Others warn that this may stifle innovation (Buijink, Visser, & Marshall, 2013; Castro, 2011), suggesting that developers may decide against creating health apps if medical device law means that the development and distribution of these products is slow and unprofitable (Yetisen et al., 2014). Many writers endorse more frequent and comprehensive expert reviews of health apps (Chan, Torous, Hinton, & Yellowlees, 2015; Giota & Kleftaras, 2014; Powell, Landman, & Bates, 2014b), but others suggest this is unrealistic in the face of a rapidly expanding and changing health app market (Boudreaux et al., 2014; Boulos et al., 2014; Lewis & Wyatt, 2014).

There is a growing literature exploring, explaining and critiquing the policy environment surrounding health apps (Censi, Mattei, Triventi, & Calcagnini, 2015; d4, 2012; Daly, 2015; Lupton, 2014; Smith, 2016). In brief, government oversight resides in five sectors:

- Privacy, governing the collection and use of individual user’s personal data and health data;
- Medical devices, addressing the efficacy, safety and advertising of apps that provide medical diagnosis or treatment;
- Advertising, outlawing false or misleading promotion of an app;
- Media, setting standards for acceptable content of apps; and
- Commerce, overseeing the system of electronic payments associated with apps.

Regulation may apply to a particular health app depending on the app’s intended function, whether it collects or accesses the health data, and who owns or distributes the app. The separate regulations tend to reside within different government agencies, and vary between jurisdictions, meaning that government oversight is often siloed (Fernando, 2012), creating the potential for both gaps and duplication of effort. Some writers suggest that current legislation is not fit for purpose because it does not provide enough protection for app users. For example, there is little regulatory oversight of health apps that do not come under medical device laws, even though these apps may
deliver harms to consumer health (Kamerow, 2013; van Kerkhof, van der Laar, de Jong, Weda, & Hegger, 2016). Similarly, privacy laws, which have largely been written prior to the explosion of the app market and the era of ‘big data’, may not provide enough protection for consumer’s sensitive personal information (Martinez-Perez 2015).

There are also publications describing non-legislative mechanisms for oversight of health apps (Australian Communications and Media Authority, 2013; Boulos et al., 2014; Powell et al., 2014b), but none that we could find that systematically document or analyse these policies. We undertook to study policies relevant to the regulation of health apps in order to report on the range of policy actors and mechanisms of app oversight, to better understand the process of policy development, and to comment on any problem areas.
Literature Review

The development and use of apps, including mental health apps, is a relatively new phenomenon. The empirical research reflects this: the earliest published evaluation of a health app dates from 2010 (Coulon et al., 2016; Rao, Hou, Golnik, Flaherty, & Vu, 2010). Thus far, empirical investigations of mental health apps have been largely either clinical trials of the efficacy and usability of apps, or content analyses of the functionality and content quality.

Our review of the literature suggests that there are two broad groups of mental health apps, which have little overlap:

- Apps developed and tested by clinical researchers, which are often not available for public download; and
- Apps developed by commercial entities, which are little studied, and are commercially available through app stores.

We identified four reviews that exclusively included clinical trials of individual mental health apps (Donker et al., 2013; Firth & Torous, 2015; Plaza, Demarzo, Herrera-Mercadal, & García-Campayo, 2013; Torous & Powell, 2015). These reviews included 31 trials evaluating 24 different apps. Most trials were small, short-term pilot studies conducted by the app developer, who was typically also a scientific or clinical researcher. Many of the tested apps were not available commercially and were only available to trial participants (de la Vega & Miro, 2014; Donker et al., 2013). Reviewers concluded that, although mental health apps are widely accepted and easily used by consumers, there is little, if any, credible evidence that they work to improve mental health outcomes (Donker et al., 2013; Firth & Torous, 2015; Plaza et al., 2013; Torous & Powell, 2015).

A 2016 systematic review of studies that evaluated the content of commercially available health-related apps identified 91 studies published since 2010 (Grundy, Wang, & Bero, 2016). These studies largely took a descriptive, instrumental approach, and used one-dimensional or surrogate measures for the quality of apps’ content (Grundy et al., 2016). Six of the included studies were focused on mental health apps, including apps for depression, bipolar disorder, eating disorders, stress, and mindfulness meditation (Coulon et al., 2016; Juarascio et al., 2015; Mani et al., 2015; Nicholas, Larsen, Proudfoot, & Christensen, 2015; Plaza et al., 2013; Shen et al., 2015). These analyses suggest a worrying picture:

- Mental health apps are not evidence-based nor in line with best-practice guidelines (Coulon et al., 2016; Juarascio et al., 2015; Mani et al., 2015; Nicholas et al., 2015);
- App store descriptors of mental health apps are often inaccurate (Coulon et al., 2016; Mani et al., 2015; Shen et al., 2015); and
- Mental health apps are not transparent in relation to information about developers, content sources, and privacy practices (Coulon et al., 2016; Nicholas et al., 2015; Shen et al., 2015).

Some authors concluded that app store consumers will struggle to identify credible and reliable mental health apps (Coulon et al., 2016; Nicholas et al., 2015; Shen et al., 2015).
Methodology

A critical approach

The overarching methodology for this project was a critical, interpretive qualitative approach. We sought to understand mental health apps as social objects that can change the way that consumers understand themselves and their mental health (Lupton, 2014). Apps can also serve political purposes by serving as a means for interest groups to establish authority and to change the way that information is controlled and shared (Lupton, 2014). The project was encouraged and supported by the Australian Communications Consumer Action Network, who worked with the researchers throughout the design and dissemination of the study to facilitate research translation. However, the researchers had full autonomy over study design, data collection, analysis and publication. None of the report authors are involved in the development of mental health apps and have no other conflicts of interest to declare.

The purpose of this project was to identify salient consumer issues related to the mental health app market and to inform advocacy efforts towards ensuring the safety and quality of mental health apps. The goals of this project were to provide consumer and app developer guidance related to safe and quality mental health apps and to identify existing policy options, key gaps and policy development priorities.

Specific aims

This project had three specific aims:

- To identify salient consumer issues related to prominent mental health apps;
- To analyse issues and gaps in the current regulation of mental health apps; and
- To create a tool to help developers identify and comply with relevant regulation.

Study design

This project occurred in two phases. We first performed a descriptive and interpretive content analysis of the promotional materials of prominent mental health apps available on the Australian market. Secondly, we undertook a critical policy analysis of relevant Australian regulation, industry codes and post-market evaluations and influential policy from overseas jurisdictions.

Content analysis

To identify salient consumer issues and to highlight potential means to mitigate harm to consumers, we conducted an in-depth content analysis of prominent mental health apps in the Australian marketplace.

Sampling

App stores differ by country, their search algorithms are proprietary, personalized and localized, and the population of apps changes rapidly (Grundy et al., 2016). Thus, we combined two purposive
sampling strategies to identify widely used and promoted mental health apps available to Australian consumers: (1) sampling based on endorsement, and (2) an app store ‘crawling’ program.

From 18 August to 9 September 2016, we sampled any mental health app that was covered in the mainstream media (The New York Times, BBC and The Guardian), digital health blogs (MobiHealth news and RockHealth weekly) or social media (Twitter), or was endorsed by the Australian Government (Department of Veterans’ Affairs), or public health and mental health organisations in Australia (ReachOut, beyondblue, Black Dog Institute, Young and Well CRC).

We also ran a ‘crawling’ program, which interacted directly with the iTunes and Google Play app stores’ application programming interface (API) and extracted the meta-data on the top-rated 100 Health and Fitness and Medical apps in Australia, the United States, the United Kingdom and Canada. We ran this program weekly, and included apps that were present in the top 100 for at least two out of four of the sampled weeks in any country or any store.

One researcher screened the combined results of the crawling program extractions and included any app that might be mental health-related. Two researchers then independently screened 105 apps for inclusion according to the following criteria –

- Available to consumers in Australia.
- Designed for a mobile platform.
- English language promotional materials (e.g. store description, website).
- Explicitly pertained to a mental health diagnosis (e.g. depression); a mental health symptom (e.g. suicidal ideation); or behaviours that directly related to mental health (e.g. meditation, mindfulness) AND:
  - Provided diagnosis, guidance or a recommendation (e.g. following a program); OR
  - Allowed for monitoring, tracking and/or recording of health biometrics or user-generated data; OR
  - Made a mental health claim.

We excluded apps that related exclusively to addiction (including alcohol, drugs, smoking cessation, gambling, sex or pornography), although this will be an important topic for future study.

Finally, we did not consider ‘reducing stress’ to be a mental health claim on its own, but did include those apps that sought to alleviate ‘anxiety’. Figure 1 details the sampling approach.
**Figure 1 – Selection of mental health app samples**

**Data collection**

We designed an instrument to collect data on the app, developer and funder characteristics; privacy and security features; and the key messages, claims, and scientific basis. This instrument was based upon previous study of health and fitness apps (Grundy et al., 2016), the Mobile Apps Rating Scale (Stoyanov et al., 2015) and a systematic review of methods for studying the quality of mobile health apps (Grundy et al., 2016).

We collected data between 1 October 2016 and 1 February 2017 from the app store description, linked websites and privacy policies, from Crunchbase, a web-based database of company investors and acquisitions, and targeted Google searches. The collected data included app, developer and funder characteristics, and privacy and security features. Each app was further evaluated by two researchers working independently, who responded to open-ended questions related to the app’s health claims, messages about mental health, scientific claims and evidence, and any disclaimers presented. This data was collated and any discrepancies were discussed and resolved systematically within a team workshop.

**Data analysis**

We calculated descriptive statistics using SPSS (IBM Corporation, 2012) for app, developer and privacy characteristics. We inductively coded the open-ended responses using NVivo (QSR International Pty Ltd., 2012), wrote interpretive memos on each code and generated a preliminary list of themes. During an all-day analysis meeting, the research team reviewed these emerging themes, discussed relationships among the themes, and discussed the range of mental health apps, noting key differences. Following the analysis meeting, these insights were developed into interpretive memos, which were again reviewed by the team. Key messages to include in a consumer information sheet were identified and discussed.
Critical policy analysis

We conducted a critical policy analysis to identify the broad array of policies that govern apps and guide consumers and developers; to identify the key policy making bodies and stakeholders that are providing or influencing the oversight of health apps; and to analyse gaps.

In light of regulators’ published guidance regarding their intention not to regulate most health apps (US FDA, 2016), we sought to determine who else might be active and influential within the policy arena. We wanted to look beyond regulators, and see what other entities might be playing a role. Therefore, for the purposes of this project, we broadly define policy as: “written or unwritten set of goals, objectives and means that create a framework for activity” (Mays, Buse, & Walt, 2012). We expected that this would include: government legislation, regulatory documents, industry self-regulation (for example, app store guidelines or industry codes of conduct); and post-market certification or evaluation programs. Policies could be directed towards apps in general, those that provide medical assistance, or those apps targeting health and wellbeing.

Sampling

We identified policies relevant to the oversight of health apps using a multi-step strategy. We looked for policy as providing control, regulatory oversight or guidance about mental health app development, distribution or selection for use by consumers. Although our focus was the Australian policy environment, we also included policy from international jurisdictions which influenced or informed the Australian context. We used a combination of sampling strategies:

1. Purposive searching through the websites of Australian government departments, peak organisations for industry, consumers, and people living with mental illness;
2. Medline and Google searches;
3. Hand searching through references and links in policies identified via steps 1 and 2; and
4. Consultations with ACCAN and the Australian Digital Health Agency.

To be included, the policy needed to cover all of the following –

- Addresses app development, distribution or selection for use.
- Addresses apps on the mobile platform.
- Applies to apps that provide information, diagnosis, monitoring, treatment, or support related to mental health.
- Produced by an active, prominent entity defined as: a government; major university, hospital or mental healthcare institution; multinational corporation; or a national organisation, including peak bodies and not-for-profit organisations.
- Published in the last 10 years.
Data collection and analysis

We used qualitative methods to analyse our data, informed by theories of the policy process including Bacchi’s ‘what’s the problem represented to be?’ approach (Bacchi, 2009).

We began by categorising policies according to the locus of regulatory intervention along the pathway of app development from inspiration through to consumer selection. We then systematically analysed policies in the data set by identifying the problems implicitly defined by policy ‘solutions’ and their underlying tacit assumptions and judgements.

Analysis proceeded by first reading the policies in detail and then coding each policy using an instrument designed to capture information about policy content, impacts, target population, and underlying suppositions. A representative selection of policies was double-coded. We wrote interpretive memos on each of the categories, identifying themes and contrasts.
Results – Content analysis

We identified 61 mental health apps (see Appendix 2 – Mental health apps included in this study) using the two sampling strategies: 66% (40/61) were identified via the app store crawling program, and 38% (23/61) were identified from the websites of not-for-profit and government organisations. Only six apps were identified through both sampling methods, suggesting that there is a gap between the apps that are popular in the commercial app stores and those that governments and health organisations seek to promote.

The majority of apps were available in both Google Play and iTunes (45/61 or 74%), with 84% (51/61) available for the Android platform in Google Play and 90% (55/61) available for iOS in iTunes. In the past 12 months, 59% (30/51) of the apps available in Google Play and 71% (39/55) of the apps available in iTunes had been updated.

Who are the developers of mental health apps?

The majority of apps are designed for-profit. The majority of apps were for-profit enterprises, developed by private companies or individuals that marketed the apps to generate revenue (see Figure 2). The promotion of related apps, products and services suggested a commercialized space, which was reflected in the promotional messages targeted at consumers. Even not-for-profit developers adopted language like ‘innovation’, ‘leveraging technology’, and ‘optimizing’ health, suggesting that commercial influences work to shape messages about mental health and the kinds of claims that developers make.

Figure 2 – Number of apps per developer type

The 61 apps were published by 45 unique developers, as identified by the app store. Developers represented a range of different entities including individuals, companies, and public institutions. The majority of developers were for-profit, marketing their apps to generate revenue. Sixty-two percent (28/45) of developers offered more than one app in stores, with an average of nine other
About half of developers were based in North America (23/45 or 51%); others were based in Europe (9/45 or 20%) and Australia or New Zealand (13/45 or 29%).

Developers’ expertise drew from a range of backgrounds including psychologists, entrepreneurs and hypnotherapists (see Table 1). We could find no information about three developers beyond the name listed in the app store – they provided no contact information beyond a Gmail account, did not have a developer’s website and we could not find additional information through Google searches.

Table 1 – Characterising developer expertise

<table>
<thead>
<tr>
<th>Developer background</th>
<th>n developers (Total = 45)</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lay (non-professional)</td>
<td>13</td>
<td>Tech entrepreneurs; people living with mental illness; psychology students</td>
</tr>
<tr>
<td>Not-for-profit organisation</td>
<td>10</td>
<td>University-based research group; mental health advocacy organisation; social enterprises</td>
</tr>
<tr>
<td>Health professional</td>
<td>10</td>
<td>Practicing psychologist; psychotherapist</td>
</tr>
<tr>
<td>Hypnotherapy</td>
<td>4</td>
<td>Certified hypnotherapist</td>
</tr>
<tr>
<td>Mixed</td>
<td>3</td>
<td>Person living with panic disorder and psychologist</td>
</tr>
<tr>
<td>Government</td>
<td>2</td>
<td>Departments of Defence and Veterans’ Affairs</td>
</tr>
<tr>
<td>No information</td>
<td>3</td>
<td>Unable to find any information beyond name listed in store</td>
</tr>
</tbody>
</table>

Authorship of app content was not transparent. Only half the apps named an author or content advisor in their promotional materials (31/61 or 52%). Very few of the developers were authors of original content, but instead drew from various psychotherapy approaches (e.g. ‘Cognitive Behavioural Therapy’), philosophies or spiritual practices (e.g. ‘Buddhism’) or referred to their clinical experience or input from scientific experts.

Reuben Lowe, the developer of Mindful Creation, explains, “Much of my work is influenced by contextual psychology, but not all. I am also deeply interested in Buddhist teachings and non-denominational psycho-spiritual approaches that share a similar approach of using mindfulness and acceptance.” Similarly, the developer of Anorexia Bulimia Binge Eating Test, by PocketShrink, claims an ‘amalgamation’ of scientific evidence for the app’s content: “PocketShrink™ is based on an amalgamation of the best research, clinical experience and currently accepted diagnostic criteria. It has been developed by a qualified, registered psychologist with a doctorate in Neuroscience.” Nowhere in the app store or on the PocketShrink website is the “qualified, registered psychologist” named; consumers cannot verify this claim of scientific and clinical expertise.

Developer identity – Consumer implications and recommendations

- Select apps where you can clearly identify the developer (by name or company name), and a means to contact them (including an email address, telephone number and physical location) in the event of a concern about, for example, poor functionality.
- Research the developer and ensure that their credentials and experience match the service or content they are offering.
- If the developer is not responsible for the app’s content, make sure you can identify who is.
How do mental health apps generate revenue?

Apps in our sample drew from a wide variety of strategies to generate revenue (see Box 1 – “Try it for free. Forever!”).

- **Paid downloads**: 41% (25/61) of sampled apps were available for purchase. The average price of the paid apps was AUD$4.64 (SD=AUD$3.03), with a minimum price of AUD$1.39 and a maximum price of AUD$14.99. Some developers, who exclusively offered paid apps, also offered a suite of related apps, which collectively accounted for millions of downloads (e.g. the Andrew Johnson apps and Kim Fleckenstein apps).

- **In-app purchases**: 79% (48/61) of sampled apps offered in-app purchases. Most in-app purchases arose as additional costs within a paid app, but some free apps (10/36 or 28%) offered extra content for a cost. These apps are examples of the ‘freemium’ model, where apps are advertised as free to download, but most content and functionality requires the consumer to make in-app purchases.

- **Subscription model**: Several apps offered access to full content on a subscription model. For example, Headspace offers a yearly subscription rate at USD$7.99/month, which auto-renews via the consumer’s credit card on file with the app store, unless cancelled by the consumer.

- **Ad-supported**: Hosting ads within the app generates revenue for the developer in lieu of charging the consumer upfront. Unlike in-app purchases, which are disclosed in the app store, it is impossible to discern which apps host advertising prior to downloading. We detected in-app advertising in a few of the apps as banner ads were captured in the screen shots displayed in the promotional materials.

- **External funding**: Four apps, all privately-held companies, relied on external investment in the form of venture capital as a ‘start-up’ business model, with the aim of acquisition. Two apps were publicly-traded companies with shareholders. The ten non-commercial developers (22%) had external funding from sources such as governments, commercial sponsors, community foundations and universities.

- **Employer/corporate programs**: A few developers marketed their app as a program or service targeted at employers, health insurers or other corporate clients (in addition to offering a consumer-facing app).

- **Links to other products or services**: 18 apps prominently offered a related product or service for sale on the developer’s website. These included: self-help books, CDs, mp3 downloads, podcasts, links to other (paid) apps, and links to merchandise.

Privacy policies or app terms and conditions further characterized consumer personal information as a business asset. While we were unable to discern whether developers sold consumer data to third parties to generate revenue, some developers informed consumers that their personal information would be transferred in the event of a merger or acquisition. For example, Breathing Zone’s privacy policy states:

“If BreathingZone, or substantially all of its assets, were acquired, or in the unlikely event that Breathing Zone goes out of business or enters bankruptcy, user information would be one of the assets that is transferred or acquired by a third party.”
Monetisation strategies were frequently misleading, lacked transparency or were potentially predatory.

Both Google Play and iTunes require developers to report up front whether the app offers in-app purchases. In-app purchases can be required for full functionality and can even be addictive, particularly in the context of games, and consumers may end up spending much more than they intended (Commonwealth Consumer Affairs Advisory Council (CCAAC), 2013). Consumers who wish to avoid apps with in-app purchases may be misled by app descriptors that heavily emphasise the free version in their promotional text, with little or no information about in-app purchases. One app, OMG. I Can Meditate!, which offers in-app purchases for full functionality, encourages users to: “Try it for free. Forever! Yes – it’s free! This app has free meditations you can use forever. And you don’t even have to sign up, so go ahead and download the app!”

Similarly, several apps that monetised via a subscription model promoted themselves as being free to download. Subscription models are inherently problematic, as regular payments will continue to be deducted from the consumer even if the app is no longer being used: the strategy is thus seemingly taking advantage of the need for phone users to leave their credit card details in the app store, in order to retain access to any of the store’s products.

Developers do not control the content of advertising libraries that they choose to embed in their apps. When a consumer starts up an app, the embedded ad library connects to ad network servers and requests ads for display, sometimes sending information about the consumer to the network. The ad network pays the developer on an ongoing basis based on the amount of exposure the ad gets through the app.

However, data-driven, targeted advertising may be predatory, especially for vulnerable consumers (Grace, Zhou, Jiang, & Sadeghi, 2012). Targeted advertising may serve to undermine the purpose of the app itself. For example, Worry Box is deliberately aimed at consumers with anxiety, but the promotional screen shot showed a banner ad for LAP-BAND weight loss surgery. Ad libraries can also introduce privacy and security threats. Researchers who studied 100 ad libraries that are embedded in over 50,000 Android apps found that ad libraries sometimes accessed information about the consumer that was not directly relevant to targeted advertising, but could be correlated to discover the consumer’s identity. For example, some ad libraries transmitted the consumer’s call history or a list of other apps on their phone to other parties across the internet (Grace et al., 2012).

User costs – Consumer implications and recommendations

- Free apps may cost you in other ways such as in-app purchases or targeted advertising.
- Consider whether paid apps without in-app purchases might actually cost you less over time than apps with no up-front charge.
- Monitor your credit cards for auto-renewals if you subscribe to an app, and remember to be pro-active about cancelling subscriptions you no longer need.

Box 1 – “Try it for free. Forever!”

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How private is your phone?

Apps lacked transparency about the collection, retention, sharing and use of consumers’ information. Nearly half of the sampled apps did not have a privacy policy (41% or 25/61). Apps published by for-profit developers had privacy policies most frequently (86% or 19/22 private and publicly-traded companies), whereas less than half of the apps published by individuals (45% or 11/24) and public or not-for-profit developers (40% or 6/15) had a privacy policy. None of the four apps published by governments (all Departments of Defence/Veterans’ Affairs) had a privacy policy available. Box 2 – What is your personal data used for? details some of the uses for consumer data generated through mobile apps.

Box 2 – What is your personal data used for?

There are a variety of uses for consumer data that is collected through an app (Pasquale, 2015). Some of these are part of the app function, or provide at least some benefit to the consumer. Others are solely for the benefit of the app developer. Apps should be transparent about how they are collecting, sharing and using consumer data, and should ensure that neither they nor their commercial partners engage in practices that contravene community expectations of acceptable uses for data. Examples of possible uses for collected consumer data are given below. Arguably the latter two uses (building individual and population group profiles) would be considered unacceptable by community standards, and should be avoided.

App function: An app may collect real-time location information from the consumer in order to deliver information about local services. For example, Calm Down Now by June Tomaso-Wood provides information to consumers about mental health practitioners that work nearby.

Targeted advertising: Information on consumer preferences and consumer location may be used to deliver targeted ads. Behavioural advertising uses a consumer’s web viewing history to identify their likely interests (e.g. stress relief, sleep assistance) and deliver ads that target those interests (Federal Trade Commission (FTC), 2009). Location-based advertising uses a consumer’s recent or current location to infer likely interests, or for the timely delivery of local ads (e.g. for nearby coffee shops or massage therapists) (Fair, 2016).

Building individual consumer profiles: Information about an individual consumer may be collected and cross-linked from a variety of sources (e.g. apps, social media accounts, official sources) and used to build an individual consumer profile. This profile may be used by commercial entities to populate algorithms that deliver predictive information on, for example, employability, insurability, and credit rating (Pasquale, 2015).

Building population group profiles: Information about individual consumers may be aggregated with data on other consumers to build profiles of sub-population groups. For example, postcode data may be used to generate pricing for luxury products, and ethnicity data may be used to generate pricing for educational services, based on algorithms that predict the level of interest in these goods and services amongst population sub-groups (Pasquale, 2015).
For the majority of apps, privacy policies failed to meet the minimum standards, were difficult to find or read, or were non-existent. On average, privacy policies were just over 1000 words long (mean=1038 words, SD 1269 words) and ranged from seven words (e.g. “No data from this application is collected”) to 5254 words. Few of the privacy policies had features that would facilitate user engagement: for example, only three (5%) contained a summary with key points, and only four (7%) were judged to use lay language. The link to the privacy policy was easy to find for less than half of sampled apps (43% or 26/61), and a minority used headings to facilitate navigation through the policy (41% or 25/61).

The Australian Government specifies minimum standards for privacy policies for mobile apps (Office of the Australian Information Commissioner, 2014). Only one app’s privacy policy met all of these requirements (RR Eating Disorder Management by Recovery Record). Overall, only half of sampled apps met any single criterion (see Figure 3).

![Frequency of privacy policy assurances](image)

**Figure 3 – Frequency of mandated privacy policy assurances (n apps = 61)**

Most failed to provide information about where and how to complain about an app’s privacy practices, with at least one app, Rise Up: Eating Disorder Help by Recovery Warriors, suggesting that consumers were responsible for securing their own information:

“You are responsible for maintaining the security of your Health-Related Information derived from your use of Recovery Warriors Services. We have secured you with reasonable technical safeguards such as a security PIN. We are not responsible for any third-party’s access of your Health Related Information that you entered through the use of the Recovery Warriors Services.”

No information could be obtained by which to test the security claims made by this product.
‘Permissions’ requested

The Google Play store allows developers to self-report the way the app interacts with the device and personal data in the form of ‘permissions’ (iTunes currently does not). Of the 51 apps available in Google Play, 50 (98%) reported permissions requested. At the time of data collection, apps requested, on average, a total of five permissions, ranging from 0 to 14 (Figure 4). Most commonly, apps requested internet access (e.g. full network access or view Wi-Fi connections), and ability to read and write to the device’s memory (e.g. read, modify and delete USB storage) (Figure 5).

Figure 4 – Number of permissions requested (n = 61)

Google differentiates between ‘normal’ permissions, which pose little risk to a consumer’s privacy or the operation of other apps, and ‘dangerous’ permissions, which may involve the consumer’s personal information or the ability to interfere with other apps (Android Developers, 2016). Apps requested, on average, two dangerous permissions, ranging from 0 to 7. On average, government and university-based developers requested more dangerous permissions than the overall mean number of permissions (5 and 4, respectively). The most common dangerous permission requested was the ability to read (37/51 or 73%) and modify or delete USB storage (also 37/51 or 73%), where the consumer’s personal information and information from other apps is also stored. Dangerous permissions requested are highlighted in Figure 6. A full description of the permissions that developers requested is provided in Appendix 3 – Explanation of ‘dangerous’ permissions.
Figure 5 – Types of permissions requested
Some apps appeared to request more user data than seemed necessary for the app’s function and the accompanying privacy policy failed to explain this discrepancy. For example, Happify advertises its offering as “science-based activities and games to elevate happiness”, including audio guides to “conquer negative thoughts” and “reduce stress & anxiety through relaxation/meditation”, and self-reflection tasks.

At the time of data collection Happify requested 13 permissions including: find accounts on the device; read your contacts; read and receive text messages; read phone status and identity; read, modify and delete the contents of your USB storage; take pictures and videos; view Wi-Fi connections (location data); plus other ‘normal’ permissions. The privacy policy acknowledged these requests, but provided little additional explanation as to why this data was required or, more importantly, what the developer would do with it. For example, granting permission to view Wi-Fi connections also allows the developer to determine a consumer’s location from known data on Wi-Fi service location. The privacy policy stated:

“When you use the Site, Happify™ Offerings, the Services, or Promotions, we may collect location information either provided by a mobile device interacting with our Site or one of our applications, or associated with your IP address, where we are permitted by law to process this information.”

At the time of writing, the number of permissions requested had risen to 17, reflecting the fact that developers may edit these requests at any point – and continued use of the app signifies the consumer’s consent.
The value of sharing

At the same time, promotional messages about consumer interactions via the app (either anonymously or identifiably through social media) were common in the sampled apps store descriptions. Developers actively encouraged consumers to share personal mental health data, such as completion of app-based activities, through the app and described the ability to share as a valuable feature (Box 3 – Debating the value of sharing). For example, MoodKit by Thriveport, LLC listed app “highlights” as including “Email, text, & Facebook sharing of activities.” Other apps advertised the creation of user communities with which users could share their experiences, portraying it as a safer space, emotionally and privacy-wise, than traditional social media: “Forums! Talk with people that may be feeling just like you from all around the planet, without worrying about the like/dislike system” (What’s Up, by Jackson Tempra).

Analysis of the ‘fine print’ contrasted with promotional messages about the value of ‘sharing’ consumer personal information. As noted above in Box 2 – What is your personal data used for?, many apps described consumer information as a business asset, and absolved themselves from responsibility of any harm that might result from loss of personal privacy.

Box 3 – Debating the value of sharing

Mental health apps and other digital health services have been promoted by health services and researchers partly because they appear to offer a discreet, accessible and affordable alternative to face-to-face therapy (Australian Government, 2015; Cotton, Irwin, Wilkins, & Young, 2014; Proudfoot, 2013). However, our findings suggest that the mobile phone is not a particularly private or secure place.

Consumers might not be sufficiently aware of the risks of harm associated with publicising personal mental health data (e.g. employment, insurance, financial discrimination). Embedded ad libraries are granted all the same permissions as the developers, and some share the information they collect with ad networks and advertisers (Grace et al., 2012). Consumers who are aware, and prefer to remain anonymous, might not realise that their apparently unidentified entries in closed or public forums may be traceable (Huckvale et al., 2015). An unmediated forum for sharing of ideas about mental health and illness may be harmful, especially to those with a serious mental illness (Perry et al., 2016). Consequently, it is not clear to us that advice to consumers about sharing news and ideas about their mental health is sound.

Phone privacy – Consumer implications and recommendations

- Choose apps that have clear, understandable privacy policies and take accountability for your privacy and security
- Be aware that some data sharing may be hidden and that the way an app shares your data could change at any time
- Beware of apps that request more permissions than is needed for the app’s function
- The Android and iOS platforms now offer ways for consumers to switch the permissions associated with individual apps on and off. Instructions on how to do so can be found here:
  - Android: https://support.google.com/googleplay/answer/6270602?hl=en
  - iOS: https://support.apple.com/en-au/HT203033
What do mental health apps claim to do?

Mental health apps largely addressed mild anxiety and provided relaxation strategies. Apps predominantly claimed to offer benefit in relation to control of anxiety, panic and stress (34/61 or 56%) and/or mood disorders (16/61 or 26%) as shown in Figure 7.

![Frequency of app focus*](image)

* Note: Apps may have had more than one mental health focus.

**Figure 7 – Mental health focus of sampled apps**

There was a lack of diversity in the strategies apps employed in pursuit of promised mental health outcomes (see Table 2). Consistent with the dominant focus on anxiety and stress, the most common approach was to facilitate relaxation (30/61 or 49%) via tools such as guided audio recordings, hypnosis, breathing exercises and mindfulness. A second dominant approach was to educate consumers in overcoming negative thoughts and emotions using techniques such as cognitive exercises or skills training (24/61 or 39%).

About one quarter of the app sample billed themselves as being based upon ‘Cognitive Behavioural Therapy’ or variations of this evidence-based therapy approach. Finally, other apps used a logging and monitoring approach. These apps provided consumers with tools to track their symptoms over time, and encouraged consumers to share their symptoms and progress with friends, clinicians and/or with other anonymous app users (13/61 or 21%). There was minimal use of interactive functionalities such as tailored feedback, and none of the apps were complemented by a wearable or other smart technology.
Table 2 – Strategies used in apps to address mental health concerns

<table>
<thead>
<tr>
<th>Approach</th>
<th>Strategies</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relaxation (30/61 or 49%)</td>
<td>Guided audio recordings</td>
<td>Hypnosis, meditation, mindfulness, guided breathing</td>
</tr>
<tr>
<td>Distraction</td>
<td>Flash cards</td>
<td>‘Soothing colours’ Music</td>
</tr>
<tr>
<td>‘Treatment’ for anxiety</td>
<td>Eye Movement Desensitisation Reprocessing (EMDR) Hypnosis Mindfulness Diaphragmatic breathing</td>
<td></td>
</tr>
<tr>
<td>‘Overcoming’ negative thoughts and feelings (24/61 or 39%)</td>
<td>Exercises</td>
<td>CBT, DBT and/or ACT exercises* ‘Brain-training’ Positive psychology exercises Journaling/worry boxes Thought challenges Goal setting Tracking positive experiences</td>
</tr>
<tr>
<td>Gamification</td>
<td>‘Take control of a snake as you seek out food’ (distraction technique) “Complete Quests, activate PowerUps and battle Bad Guys each day”</td>
<td></td>
</tr>
<tr>
<td>Track, share and compare (13/61 or 21%)</td>
<td>Self-assessment, self-diagnosis</td>
<td>Diagnostic questionnaires Traffic light system to grade mood Graph of anxiety level over time Log of symptoms</td>
</tr>
<tr>
<td>Compare</td>
<td>To ‘normal’</td>
<td>To ‘population data’</td>
</tr>
<tr>
<td>Share</td>
<td>With social media</td>
<td>Support network</td>
</tr>
<tr>
<td></td>
<td>To other anonymous users</td>
<td>Clinicians</td>
</tr>
<tr>
<td></td>
<td>To self over time</td>
<td>User communities (anonymous)</td>
</tr>
</tbody>
</table>

*CBT = Cognitive Behavioural Therapy; DBT = Dialectical Behaviour Therapy; ACT = Acceptance and Commitment Therapy

Developer claims to easily and rapidly improve consumer mental health were not supported by evidence, and were undermined by disclaimers. Developers frequently claimed that consumers could easily and rapidly achieve mental health and wellbeing through use of their products. For example, Mark Grant, a psychologist and the developer of Anxiety Release based on EMDR (short for Eye Movement Desensitization & Reprocessing), advertises that consumers can “release anxious thoughts and feelings naturally, by harnessing the power of your brain,” explaining that this is easy:

“Because bilateral stimulation appeals to the unconscious, sensing part of the brain, there is no need for effortful thinking or struggling with feelings. All you have to do is LISTEN and your brain will do the rest!”
Thus, consumers were promised improvements in their mental health symptoms without any effort or the discomfort of confronting difficult emotions. Another developer, Dr Monica Frank of Excel At Life, also a psychologist, advertises that her app, Qi Gong Meditation Relaxation, will help consumers achieve health benefits, and that they can circumvent the “years of training” typically required: “Qi Gong is a basic form of Tai Chi where you can experience the health benefits of Tai Chi without the years of training.”

Even if prospective consumers were sceptical about these claims and the benefits promised, developers encouraged consumers to adopt a ‘nothing to lose’ attitude. Surf City Apps promotes their app Anxiety Relief Hypnosis on their website by stating, “Because the apps are free to try, there is nothing to lose.”

**Very few developers provided evidence to support their claims.** Developers claimed credibility in a number of ways, including scientific authority, app validity or popularity, and personal testimonials. Very few provided evidence that would allow consumers to verify the accuracy of these claims.

- **Scientific claims:** About two thirds (37/61 or 61%) of the apps made some sort of claim to scientific authority within their promotional materials. This was particularly common in apps from not-for-profit, government, university-based, and clinician developers, but was not restricted to this sample. Very few scientific claims were backed up with relevant academic citations. The types of scientific claims included:
  - **Explicit reference to academic research:** Developers implied that the app had been empirically tested, or was based on scientific evidence, by using phrases such as: ‘clinically proven’, ‘studies show’, or ‘empirically-based.’ Very few provided citations for these statements, although there were a few exceptions, where apps had been tested in qualitative pilot evaluations, where evaluations were in progress, or where scientific studies of the app were cited.
  - **Use of a well-known, ‘evidence-based’ approach:** Developers branded their apps as using well-known and established forms of psychological treatment methods such as ‘CBT’ or ‘positive psychology’. A few apps provided scientific citations that gave general support for their approach but fell short of providing evidence that was specific to their app or apps in general.
  - **Name-dropping of scientific partnerships or affiliations:** Some apps mentioned research partnerships or working with clinicians or scientists to develop an evidence base around their app, e.g. Happify advertised, “We’re currently working with several academic institutions to conduct and publish studies in peer-reviewed journals.”

- **App validity:** Some apps claimed credibility by claiming that they understood the needs and experiences of consumers with mental health concerns, stating, for example, that the app was developed by ‘young people’, ‘clinicians’ or “someone who has lived with panic for many years and understands how frightening these attacks are” (Beat Panic, by Jane Anderson-Hawke). Although information like this is an indication that an app’s content might be valid, or in other words, that it addresses what is important to mental health consumers, it is not evidence for an app’s effectiveness, and does not provide any proof that the app will actually work to improve mental health outcomes.

- **App popularity:** Apps advertised how popular their app was in terms of the number of downloads, the media coverage it had received or naming prominent corporate clients. They
used this information to suggest that their app was of high quality, e.g. Andrew Johnson’s website advertises that with “over 10 million downloads to date, Andrew’s recordings are the best-selling ‘Self-help’ recordings on the Apple and Android App stores.”

- **Testimonials**: Testimonials by consumers or health professionals were used in apps’ promotional materials. Rather than relying on in-store user review systems, developers selected and placed testimonials in the store description. This was despite the fact that Google Play bans the practice of user testimonials in store descriptions. For example, Mindfulness Daily by Inward Inc, available in iTunes uses testimonials to highlight the value of the app in lieu of a description by the developer:

  “This app is like my best friend. I feel like it asks me how I’m doing? How am I feeling? What mood am I in?... The alerts, the reminders, the pauses [let] you be still for a moment. Very highly recommend this app!” – Joeykcmo (iTunes review)

  “I am bipolar and anxiety is a constant struggle for me. I started mindfulness a few months ago after my new therapist recommended it & found the breathing exercises helpful but really easy to forget or ignore...” – PookusJ (iTunes review)

**Apps contained disclaimers that negated claims to improving mental health outcomes.** Half of the apps in our sample posted a disclaimer in the store description, on their website, or in their legal documents (30/61 or 49%) that could be easily found within twenty minutes. Most disclaimers asserted that the app provided information or guidance that was “general in nature” and not intended as a substitute for professional or medical advice.

An example from Optimism Apps reflects a standard wording: “The Optimism app is not intended as a substitute for professional medical advice, diagnosis, or treatment.” Similarly, Surf City Apps disclaims in a number of its app products that “the content and services provided by this Application are for educational purposes only”.

Some disclaimers served to distance developers from any suggestion that the app was providing a medical service, which has regulatory implications because apps with a medical function may fall under the oversight of medical device legislation (TGA, 2013). This suggests that developers may be aware of the regulation around medical software, and actively trying to position their apps outside of its purview: for example, the apps in our sample offered ‘self-assessment’ and ‘aid’ rather than ‘diagnosis’ or ‘treatment.’ Anxiety Test by MoodTools disclaimed, “This self-test is not meant to be a diagnosis for your anxiety” and “this application will only aid you on your path to recovery from depression or anxiety.” It was not always clear that these distinctions reflected any real difference in function, particularly as apps such as Anxiety Test used questionnaires that would also be used in clinical practice.

Disclaimers treated adverse events or the possibility of harm in a very oblique manner, largely omitting discussion of harm at all. Only BeyondNow, an app developed by the not-for-profit organisation beyondblue and targeting people at risk for suicide, provided explicit directions about who to call in the case of self-harm or suicidal ideation. Three developers stated conditions under which the app could not be used safely (e.g. using a relaxation app while driving; need for medical supervision for people with neurological conditions). One app, ReachOutBreathe, acknowledged the possibility for adverse effects (e.g. light-headedness and hyperventilation) during use. Other
disclaimers more explicitly absolved the developer from legal responsibility for any consumer harms resulting from app use. For example, Pacifica Labs disclaimed in their Terms of Services:

“We are not liable or responsible for any actions taken due to your having read or been told about such advice or other materials. In particular, to the fullest extent permitted by law, we give no representation or warranties about the accuracy, completeness, or suitability for any purpose advice, other materials and information published on or through the Services.”

A handful of apps disclaimed that the app might not be effective, typically making a bland statement about it not being the thing for everybody or disclaiming the efficacy of the app under particular conditions (e.g. use while under the influence of drugs and alcohol, PTSD app). For example, Reuben Lowe, the developer of Mindfulness, The Art of Being, explains:

“I am not suggesting that this material is the only way to live a mindful life of meaning and purpose. However, if it relates to your experience, then you may be able to benefit from it and use it to make changes in your life.”

This type of disclaimer worked to soften health promises, possibly aiming to minimise any legal liability from misleading claims. However, it also has the effect of implying to consumers that the individual user is the reason for an app’s lack of efficacy, possibly leading to further consumer distress or anxiety.

Performance claims – Consumer implications and recommendations

- Seek out apps that are realistic and cautious about what they promise to do, and are open about possible harms.
- Look for apps that cite, reference or quote independent evidence that they are effective. The best studies will have a control group, have longer follow up periods and will be conducted by researchers who are independent of the developer and their funding.
Who are mental health apps for?

Developers sought to reach a wide audience by targeting their apps to a general audience. Most apps were targeted at a general audience (52/61 or 85%). However, we found a few apps that specifically mentioned children (4/61 or 7%), adolescents (4/61 or 7%), young adults (4/61 or 7%), and veterans or defence personnel (6/61 or 10%).

App descriptors suggested that mental health apps are for everyone. Developers’ advice to their targeted (general) audience implied that everyone needs assistance to maximise their personal potential and achieve ‘peak performance’, prevent mental illness through the pursuit of ‘mental fitness’, and manage the symptoms of mental distress that arise in daily life.

Reflecting the aim of targeting as large a consumer market as possible, app store descriptions characterised ‘symptoms’ of mental illness as synonymous with the challenges of ‘everyday living’. For example, Smiling Mind targets a general audience, explaining, “Our programs are designed to assist people in dealing with the pressure, stress and challenges of daily life.” In Hand, an app targeted at young people, suggested that everyone could benefit from their app because, “Life ain’t easy. Some days are good. Some days are bad. Some are just fine. We understand this.” Similarly, apps suggested that everyone was likely to have mental health issues and require assistance, even if they were not aware of this (see Box 4 – Too much medicine). For example, a testimonial excerpted from Cosmopolitan magazine and embedded in the store description for the app Stop, Breathe & Think by Tools for Peace urged consumers to “Use meditation app Stop, Breathe & Think for the daily zen tune up you might not even realize you needed.”

Personal responsibility for health

Apps were largely based on the idea that individuals could – and should – successfully self-manage their mental health. Terms such as ‘empowerment’ and ‘self-improvement’ were common and consumers were encouraged to work on their mental wellbeing, just as they would go to a gym to improve their physical fitness. Consumers were definitively told that symptoms could be managed by themselves. For example, Beat Panic by Jane Anderson-Hawke said, “Panic is very treatable and you can learn to control the symptoms.” The website for Mindfulness Daily by Inward Inc told its readers that “Individuals practice Creating Space to choose their response rather than mindlessly reacting.” A user testimonial posted by the developer in the MindFit app store description stated that the app “helps you help yourself. It is what you make it but if you utilize it then it works well.” There was frequently a moral overtone to this imperative.

For example, SAM, or Self-Help Anxiety Management, developed by the University of the West of England, presented itself to consumers as, “a friendly app that offers a range of self-help methods for people who are serious about learning to manage their anxiety.” Consumers who do not derive the promised benefit from these apps may perceive that they only have themselves to blame.

Some apps conflated mental health and wellbeing with success in life more generally. For example, the Happify store description states:

“Struggling with everyday challenges and being gripped by negativity is toxic to your emotional and physical wellbeing, your relationships, your performance at work. So when you start to turn the
corner, and begin to learn the new habits of successful engagement with life, everything starts to look brighter and better.”

The combination of extrapolating mental wellbeing to success in every aspect of life, plus personal responsibility for mental health, implies that consumers who are unable to achieve “brighter and better” in everything are personally to blame for their own failure. This does not seem to be a helpful suggestion, and is particularly inappropriate for an audience that may already be suffering symptoms of mental distress.

Box 4 – Too much medicine

When the challenges of everyday life are labelled as mental health ‘symptoms’, or when consumers are encouraged to engage in constant self-monitoring or particular treatments, they may be subject to ‘too much medicine.’ This occurs when people who do not require intervention are tested, then labelled as sick or at risk, given unnecessary treatments, told to live differently, or are monitored regularly; it can result in complications or exacerbate mental health symptoms (Carter et al., 2015).

The personal harms and burdens of ‘too much medicine’ in this context may include:

1. Psychological harms of having a false label of mental illness;
2. Financial harms associated with app use, or seeking professional diagnosis and treatment;
3. Burdens and harms associated with app use (e.g. time; loss of privacy).

Rather than decreasing the stigma associated with mental health, apps that promote personal responsibility for mental well-being might paradoxically make it worse. These apps imply that individuals who are not successful at improving their mental health and are suffering mentally or physically only have themselves to blame. It may also be harmful advice to suggest that individuals focus on managing their negative emotions if they are faced with social situations that are harmful to their mental health, such as being in an abusive relationship.

A focus on individuals and self-responsibility for mental well-being may also detract from the social factors that contribute to mental health and the responsibility of governments, health services and communities to invest in mental health services and health public policy (Lupton, 2015). These findings also support the critique that mobile health may reinforce health inequalities by focusing on the “white, worried and well” who are ideal marketing targets, but not necessarily the ones who could most benefit (McInerney, 2016).

App applicability – Consumer implications and recommendations

- Beware apps that claim to provide a mental health diagnosis or allow for ‘self-assessment’ as this is beyond their legal scope.
- If you are under the care of a health professional, consider choosing an app with their input.
- If mental symptoms do not improve, this is not likely to be because of some ‘failure’ of consumers, but rather because the app does not deliver what is promised.
Results – Critical policy analysis

We identified 29 policies, including legislative acts, regulatory guidance, industry codes of conduct and post-market app evaluation programs. The included policies are listed in Appendix 4 – List of policies applicable to apps. Each of these policies related to one or more of the five principal regulatory sectors: privacy, medical device, marketing, digital content and finance.

A framework for policy action

Policies shape the app market in different locations (see Table 3) –

- Governments provide legislation and accompanying explanatory guidelines (that may or may not be legally binding) in an attempt to regulate the kinds of apps that are developed.
- Major app stores provide guidelines to developers about the kinds of apps they will and will not distribute in their stores.
- Post-market efforts provide recommendations and guidance for consumers about app selection.

Table 3 – Framework for location of health app policy oversight

<table>
<thead>
<tr>
<th>Policy location</th>
<th>Mechanism and location of oversight</th>
</tr>
</thead>
</table>
| Regulatory                  | • Defines and oversees the pool of legally compliant apps.  
• Enacted by legislators and implemented by regulators.  
• Includes legislation and regulatory guidance, which may not be legally binding but carry the influence of the regulator. |
| Distribution                | • Defines the pool of apps that are commercially available to consumers.  
• Due to the smartphone market dominance of Apple and Google, in practice this includes the iTunes and Google Play app store guidelines.  
• Although compliance is voluntary, developers must submit their apps for review before they can be commercially distributed through these stores. |
| Market recommendation       | • Seeks to identify high-quality apps on the market as a signal to consumers.  
• Achieves this through curation, endorsement, certification programs, or adherence to best practices.  
• Compliance is voluntary and there are no formal consequences for non-compliance. |

In certain sectors, ‘regulatory’ mechanisms are absent or emergent, and ‘distribution’ or even ‘market recommendation’ mechanisms are sometimes the first point where health apps are subject to oversight. For example, the Therapeutic Goods Administration, which regulates medical devices, has signalled that it does not intend to regulate mental health apps, thus providing little government oversight of health safety or health-related promotional claims. The commercial app stores provide...
limited comments on health-related apps, but do not provide details of their review criteria. For example, Apple’s review guidelines state: “Medical apps that could provide inaccurate data or information, or that could be used for diagnosing or treating patients may be reviewed with greater scrutiny” (Apple Inc., 2015).

How problematic is the oversight of mental health apps?

We identified a range of ‘problems’ that mental health app policies were implicitly seeking to correct with their policy ‘solutions’ (Bacchi, 2009); some problems were represented much more prominently than others. The main problems represented were: a lack of regulatory clarity, barriers to commercial success, and difficulty with consumer choice. Very few framed the problem of app oversight as a problem of harms to consumers.

- **Regulatory problem:** Several government policies presented themselves as solutions to a problem of confusing regulation (Australian Communications and Media Authority, 2013; European Commission, 2014; US FDA, 2016). They sought to remedy uncertainty by “provid[ing] clarity to industry and [agency] staff”, noting that the latter “regularly receive inquiries” about legislation (US FDA, 2016). This clarity sometimes centred on defining health apps, with the result that health apps were defined outside of the regulatory agency’s mandate (US FDA, 2015).

- **Commercial problem:** Many policies identified threats to the commercial success of the health app industry, and provided solutions aimed at the commercial sustainability of the mobile industry. For example, the app store policies justified their review guidelines as necessary to maintain their reputations as a “trustworthy ecosystem” in the eyes of consumers (Apple Inc., 2015). Other policies delivered advice to app developers about protecting consumer privacy, presenting this as a solution to the problem associated with loss of “consumer confidence” in the product (Federal Trade Commission, 2016; Office of the Australian Information Commissioner, 2014). Policy advice about ensuring appropriateness of content was also delivered as a solution to a potential business problem, in this case, the problem of attracting “costly” fines for “violations” of the law (Federal Trade Commission (FTC), 2013).

- **App selection problem:** Numerous policies described the problem of consumer choice, suggesting that, “with thousands of different mobile applications (apps) out there, trying to choose ones that are reliable and effective can be a daunting task” (Navy and Marine Corps Public Health Center, 2014). We identified several downstream solutions to the problem of identifying high quality apps such as curated app libraries, a post-market evaluation and certification program, and careful guidance and education for those selecting app products (Agencia de Calidad Sanitaria de Andalucía, 2012; Stoyanov et al., 2015; TRUSTe, 2016; VicHealth, 2015b).

Few policies framed the problem of health app oversight as one of protecting consumers – either in terms of privacy or their health and wellbeing. We did not find any policies that explicitly described loss of consumer privacy as being a consumer problem (rather than a commercial problem). Only one policy alluded to the possibility of apps causing harm to consumers’ health, noting that “it is not yet clear if and to what extent lifestyle and wellbeing apps could pose a risk to citizens’ health” (European Commission, 2014). However, the dominant problem identified in this policy was the lack
of regulatory clarity around which apps would come under the purview of medical device legislation, and proposed only a solution to the latter. In contrast, other policies generally assumed that health apps were low risk and not in need of regulatory oversight.

For example, the agency:

“...does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements.” (US FDA, 2016)

Further details on the three kinds of problems described in policies are provided in Table 4, Table 5, and Table 6 respectively.

Table 4 – Illustrative examples of policies for DOMINANT problem representations

<table>
<thead>
<tr>
<th>Type of problem</th>
<th>Explanation of problem: “This policy is needed because...”</th>
<th>Illustrative quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory</td>
<td>...the application of existing regulation to mental health apps is hard to understand ...app developers are ignorant of regulatory requirements ...regulation is out-of-date for new app technologies</td>
<td>“The FDA is issuing this guidance document to provide clarity to industry and FDA staff” (US FDA, 2016) “CDRH regularly receives inquiries about whether particular products are devices as defined by the FD&amp;C Act” (US FDA, 2016) “App developers, unaware of the data protection requirements, may create unwanted threats to the privacy and reputation of users of smart devices” (European Commission, 2014) “[Apps have] introduced business models and business practices that did not exist when measures covering personal information and consumer protection were developed” (Australian Communications and Media Authority, 2013)</td>
</tr>
<tr>
<td>Commercial</td>
<td>...apps with poor quality or privacy practices threaten the reputation of the app store ...apps with poor privacy practices will not be commercially successful ...apps with offensive or misleading content might attract expensive fines</td>
<td>“We work hard to make the App store a trustworthy ecosystem and expect our app developers to follow suit” (Apple Inc., 2015) “Apps which fail to protect user privacy lose user confidence and gain negative publicity” (Office of the Australian Information Commissioner, 2014) “When developing a health app, sound privacy and security practices are key to consumer confidence” (Federal Trade Commission, 2016) “Laws ... apply to you, too, and violations can be costly.” (Federal Trade Commission, 2013)</td>
</tr>
</tbody>
</table>
### Table 5 – Illustrative examples of policies for MINOR problem representations

<table>
<thead>
<tr>
<th>Type of problem</th>
<th>Explanation of problem: “This policy is needed because...”</th>
<th>Illustrative quotes</th>
</tr>
</thead>
</table>
| App selection           | ...choosing an app can be very time consuming...consumers do not have the knowledge to identify high quality apps             | “More and more people are looking to their mobile devices for health information and tracking. However, with thousands of different mobile applications (apps) out there, trying to choose ones that are reliable and effective can be a daunting task” (Navy and Marine Corps Public Health Center, 2014)  
|                         |                                                                                                                                 | “[With the] rapid proliferation of smart phone apps, it is increasingly difficult for users, health professionals, and researchers to readily identify and assess high quality apps (Stoyanov et al., 2015) |
| Consumer privacy        | ... apps can pose a threat to consumer privacy                                                                               | “[T]hird party services such as advertising are developing rapidly, which, if integrated by an app developer without due regard [they] may disclose significant amounts of personal data” (Article 29, Data Protection Working Party, 2013)  
|                         |                                                                                                                                 | “The OAIC has developed this guide to help ... app developers embed better privacy practice in their products and services” (Office of the Australian Information Commissioner, 2014) |
Table 6 – Illustrative examples of policies for RARE problem representations

<table>
<thead>
<tr>
<th>Type of problem</th>
<th>Explanation of problem: “This policy is needed because...”</th>
<th>Illustrative quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer health safety</td>
<td>... apps may pose a threat to consumer health</td>
<td>“It is not yet clear if and to what extent lifestyle and wellbeing apps could pose a risk to citizens’ health. However, when placing an app on the market, an app developer needs to know whether he has to comply with any Union safety requirements” (European Commission, 2014)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FC&amp;C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements” (US FDA, 2016)</td>
</tr>
</tbody>
</table>

Discussion – Policy analysis

Our results identified considerable interest and activity in policies influencing health app development, distribution and selection for use. Current policies derive from a range of sectors (medical device, privacy, advertising, finance and content) and a variety of stakeholders (governments, industry groups, app stores, app library curators and consumer groups). The dominant regulatory concerns were to clarify and contain the reach of existing legislation, to facilitate commercial profits, and to reduce the time required for selection of a suitable app. There was little regulatory interest in protecting consumers, either against loss of personal privacy or against harm to health. Instead, regulators treated the problem of app oversight as a ‘hot potato,’ largely seeking to clarify what they would not regulate and shifting the responsibility to app developers and ultimately, consumers.

Consumer interests may be well served by health apps, but they may also be compromised and risk harm. Firstly, many of the current regulatory policies focus predominantly on problems other than consumer protection. They are framed instead as commercial incentives for app developers through preserving brand image or as a means to make certain apps stand out from the crowd. Secondly, the set of regulatory policies that do provide consumer protection is not easy for app developers to identify or use. Policies are scattered throughout a range of separate sectors, and developers may not be aware of all the relevant legislation and guidance. Further, the regulations themselves are not necessarily easy to interpret in the context of health apps. For example, despite the growth of guidance documents, medical device regulation is complex and app developers may not know if or how they should act to ensure that their health app meets safety and efficacy standards (Daly, 2015; US FDA, 2015). There is little or no enforcement of regulation, with some regulatory bodies actively distancing themselves from the majority of products in the health app market, effectively treating health app regulation like a ‘hot potato’ (US FDA, 2016).
In practice, the most influential regulators for the mental health app market are the multinational technology companies that operate the dominant app stores. Compliance with app store guidelines is the only way developers can access the dominant app distribution outlets. The policies are only partially aligned with consumer interests, and do not have a health focus. However, as yet, these gatekeepers are not the focus of regulatory action, despite their influence and position within the app market. Similarly, the commercial entities within the mobile ecosystem that buy and process consumer data have escaped regulatory scrutiny, though their business practices may inherently conflict with the protection of consumer privacy.

The existing regulatory landscape places less emphasis on consumer interests than is warranted. While consumer education related to the selection of quality apps and safety of use is essential, this should not be the dominant or only consumer protection strategy, as this group has relatively little opportunity to affect change. Rather, further work is needed to facilitate cross-sector conversations among consumer advocacy organisations, peak associations and regulators, to bridge silos and address gaps in the oversight of mental health apps.
Conclusions

One of our original aims for this project was to create a toolkit that would help consumers navigate the marketplace to find safe and effective mental health apps. Our findings, however, indicated that there were significant issues with content, privacy, security and promotion that did not allow us to endorse particular apps, or to suggest that a ‘safe’ space exists in the commercial mental health app market. We are not the first to face the difficulty of providing assistance to consumers in this manner; for example, the NHS Health Apps Library in the UK closed when it could not guarantee apps’ security, but could only indicate whether app content was high quality (Huckvale et al., 2015). Therefore, instead of providing guidance for consumers related to selecting quality apps, we have taken a more circumspect approach. We have developed a tool for consumers that highlights some of the key issues and alerts consumers to the safety issues they face when downloading or using mental health apps. This tool is available through ACCAN (www.accan.org.au).

In addition, we developed a more upstream solution: a tool that aims to help developers navigate the policy environment and create safe, quality and legally-compliant mental health apps. Since the existing patchwork of policy (including regulation, industry codes of conduct and post-market evaluation programs) that delivers consumer protection is complex, siloed and difficult to navigate, app developers may not adhere to good practices, at least partly because of lack of knowledge rather than intent.

We used the policy data to identify key elements of mental health apps that attract regulatory oversight, and organised our developer-focused tool around these domains. We made further use of policy data to provide information in each domain about legal requirements and ‘best practices’, (we use the term ‘best practice’ here to mean non-legally binding guidance contained within policies identified using the above process) and about how to comply. We annotated the tool with further information that we thought might help developers to understand why they should comply with the described legislation and best practice guidance. This included, for example, references to recent legal cases against app developers who had not complied with legislation, and notes on why consumers might post negative reviews about non-compliant apps. During this work, we drew on the expertise of our research team, which included: a lawyer specialising in privacy law; several clinicians including mental health practitioners; academics with experience in commercial bias; and a telecommunications consumer group. A draft was circulated to industry stakeholders, including individual app developers, and was refined in response to their feedback on the usability and helpfulness of the tool.

The tool we have developed, the ‘App developer’s guide to law and policy: Creating quality mental health apps’ can be accessed in \textit{Appendix 1 – A health app developer’s guide to law and policy}. 

\textit{APPENDIX 1 – A health app developer’s guide to law and policy}
Ensuring the quality, safety and privacy of apps in the mental health app marketplace requires the cooperation of a number of key stakeholders. We present the options for action, including doing nothing, for each of these stakeholder groups, and present the available evidence. We highlight recommended options that will move toward ‘Peace of Mind’ for mental health app consumers.

Options for app developers and associations

- Do nothing. Allow market mechanisms to distinguish credible, effective and safe mental health apps such that popularity will be the proxy for quality.
- Further develop and promote standards for professionalism within the tech industry. For example, create a professional body with a code of conduct and strong enforcement system to encourage compliance (Weckert & Lucas, 2013).
- **Recommended:** Extend the self-regulatory policy that prohibits or limits in-app purchases in apps targeted at children to include vulnerable adults (e.g. mental health consumers) (Australian Communications and Media Authority, 2016).
- **Recommended:** Innovate in the area of transparency and accountability, including raising the bar for transparency around consumer data collection and sharing, and innovating in the area of cybersecurity and privacy. For example, developers could experiment with ways to enhance consumer access to privacy policies and practices (Flick, 2013) or give consumers greater control over their own data.

Options for commercial app stores

- Do nothing. Allow market mechanisms to distinguish credible, effective and safe mental health apps such that popularity will be the proxy for quality.
- Create a separate medical category with higher standards; do not give the label ‘health’ to apps that do not meet these criteria.
- **Recommended:** Incorporate evidence for safety and effectiveness into app review processes (or make transparent which evidence is available).
- **Recommended:** Prohibit or limit in-app purchases and in-app advertising in apps targeted at children and vulnerable adults, e.g. mental health consumers (Australian Communications and Media Authority, 2016).
- **Recommended:** Enforce the in-store reporting of permissions and explain permissions in lay language.

Options for health services and professionals

- Do nothing. Rely on post-market evaluation schemes to identify credible, effective and safe mental health apps to incorporate into health services or to recommend to patients.
- Create reputable curated app libraries or post-market badging programs (Agencia de Calidad Sanitaria de Andalucía, 2012) taking particular care to examine privacy and security practices as well as the quality of app content (Huckvale et al., 2015).
• Partner with app developers to inform evidence-based content and messages that promote mental health, while ensuring independence and managing conflicts of interest.
• Open electronic health records to third party app development, while ensuring high standards for cybersecurity, privacy and content quality (e.g. prohibit targeted advertising, monitor the use of dangerous permissions, ensure data encryption etc).
• **Recommended:** Develop quality assurance standards specific to the use of mental health apps in practice that pertain to patient safety, privacy and security (Department of Health and Ageing, 2012).
• **Recommended:** Advocate for stronger regulation of mental health apps at the national level.

**Options for consumers and consumer organisations**

• **Do nothing.** Allow market mechanisms to distinguish credible, effective and safe mental health apps such that popularity will be the proxy for quality.
• Follow available guidance on making wise choices about mental health apps and keeping personal information private, knowing that this is unlikely to provide adequate protection against harm to personal health or reputation.
• **Recommended:** Lobby governments and industries to invest funds in sufficient regulation for mental health apps.
• **Recommended:** Undertake and support research into benefits and harms associated with mental health apps.
• **Recommended:** Assess community standards for acceptable practices associated with mental health apps, relating to topics such as privacy practices, uses of consumer data, advertising, marketing to vulnerable audiences, and predatory overdiagnosis.

**Options for the Australian Digital Health Agency**

• **Do nothing.** Mental health apps will continue to develop outside of the ADHA mandate.
• **Recommended:** Place an immediate and high priority on supporting innovation in app security (Huckvale et al., 2015).
• **Recommended:** Create a simple, digital mechanism for consumer notification about all adverse events or concerns with mental health apps, with a single, centralised body to receive and investigate reports (Medicines and Healthcare products Regulatory Agency, 2017).
• **Recommended:** Undertake and support research into benefits and harms associated with mental health apps.

**Options for government regulators**

• Opt for no changes to existing structures and processes.
• **Recommended:** Place an immediate and high priority on supporting innovation in app security (Huckvale et al., 2015; science.gov.au, 2017).
• **Recommended:** Create a simple, digital mechanism for consumer notification about all adverse events or concerns with mental health apps, with a single, centralised body to receive and investigate reports (Medicines and Healthcare Products Regulatory Agency, 2017).
• **Recommended:** Apply greater regulatory focus onto app stores and other commercial partners within the mobile ecosystem

• **Recommended:** Improve and enforce systems that aim to create transparency over the collection and use of health app data and enable consumer correction of ‘bad’ data. For example, adopt precedents set up within electronic health record programs (i.e. that enable citizens to access and correct any mistakes in their electronic health records) and in medical research (i.e. that ensure acceptable use of identifiable and de-identified personal information) (Pasquale, 2015).
Authors

This project was a collaboration between researchers at the Charles Perkins Centre (The University of Sydney), the Critical and Ethical Mental Health research group (The University of Adelaide), and NSW Health Western Sydney Mental Health Network.

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Professor Bero is a researcher in evidence-based health care who is internationally renowned for her studies on the integrity of clinical research evidence used to influence health policy and communicated to consumers. She is the Chair for Health Outcomes and Medicines Use at the Charles Perkins Centre, and co-chairs the Cochrane Collaboration (which synthesises health evidence for clinicians and consumers).
Appendices

Appendix 1 – A health app developer’s guide to law and policy

This Appendix illustrates the sequence of screens that will be displayed to users of the App developer’s guide to law and policy: Creating quality mental health apps on-line tool that was developed as part of this project. The tool itself can be accessed at www.accan.org.au

App developer’s guide to law and policy:
Creating quality mental health apps

Produced in cooperation with The University of Sydney and the Australian Communications Consumer Action Network (ACCAN).
Developing a mental health or wellbeing app?

Find out which laws and standards apply to you. This tool:

- Helps you identify which Australian laws apply to your app
- Suggests best practices to promote consumer confidence in your app

While this is not legal advice, it will point you in the direction of resources to help ensure your health app is legally compliant and in line with industry and community standards.

This tool will cover six areas of the law: privacy, security, content, advertising, financial, and medical device. But it also provides a checklist to ensure your app meets the highest standards of professionalism.
Privacy

Health information is one of the most sensitive types of personal information. For this reason, the law requires extra protections when handling health information. Most health apps are covered by the Privacy Principles of the Privacy Act https://www.oaic.gov.au/privacy-law/privacy-act/australian-privacy-principles. Answer these questions to find out how it applies to you:

1.1 Does the app collect, use, disclose or hold any personal information?

YES  Go to Question 1.2

NO   You do not need to comply with any privacy legislation.

1.2 What kind of developer are you?

An individual or entity conducting a commercial activity

Go to Question 1.3.

A federal public entity

You must comply with the Australian Privacy Principles

A State or Territory public sector entity

Your app is covered by your State or Territory’s privacy legislation and you must comply with their Privacy Principles

An individual

You are not required by law to comply with privacy legislation unless you are conducting commercial activity. However, you should build privacy into your app’s design. Here’s how: https://www.oaic.gov.au/agencies-and-organisations/guides/guide-for-mobile-app-developers

1.3 Has your business had an annual turnover of more than $3,000,000 in any financial year since 2002?

• YES  You must comply with the Australian Privacy Principles

• NO   Go to Question 1.4.
1.4 Does the app do, or claim to do, ANY of the following in ANY way?

- Assess, maintain or improve a person's physical or mental health, fitness or wellbeing?
- Manage a person's condition, disability or disease?
- Diagnose or treat a person's illness or disability, or injury?
- Record a person's health information?


**NO** You are not required by law to comply with privacy legislation. However, you should aim for privacy by design. Here’s how: https://www.oaic.gov.au/agencies-and-organisations/guides/guide-for-mobile-app-developers

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**PRIVACY BOX**

The Australian Privacy Principles outline how to collect, use and manage personal information. You must:

- Manage personal information in an open and transparent way (this includes having a clearly expressed Privacy Policy)
- Adhere to principles about how personal information can be collected, used and shared
- Take measures to maintain the quality of personal information
  - Keep personal information secure
- Ensure people can access and correct their personal information

Security

If your app is subject to the Privacy Act, then you must take reasonable steps to protect the personal information you collect, store or share. Even if your app is exempt from the Privacy Act, you should ensure the app is secure.

There is no specific security law that app developers must follow. Instead, developers should use a risk-based approach to decide on the most appropriate level of security. The more sensitive the personal information collected, the stronger your security should be. Health information is highly sensitive, so apps that collect, store or share health information should adopt the strongest security measures.

**WHY SECURITY MATTERS**

The FTC recently found that 12 popular health apps transmitted personal data [http://adage.com/article/privacy-and-regulation/ftc-signals-focus-health-fitness-data-privacy/293080/](http://adage.com/article/privacy-and-regulation/ftc-signals-focus-health-fitness-data-privacy/293080/) including names, email addresses and unique device IDs to 76 third parties. Some third parties received personal data from more than one app, allowing them to put together a more complete picture of the user. This could greatly affect a consumer’s insurance premiums, for example, if this data is then sold.

Here’s how you can ensure your app is secure:

Content

The law prohibits offensive online material, including offensive content in smartphone apps. In particular, your app **must not** expose children to offensive or unsuitable material. See if these rules apply to your app:

3.1 Does your app contain ANY of the following?

- Images of child sexual abuse or instructions in paedophilia
- Depictions of gratuitous or exploitative violence including sexual violence
- Depictions of actual or exploitative sexual practices including bestiality or incest
- Detailed instruction in or promotion of crime or violence including the use of illicit drugs or terrorist acts

**YES** Your app is **prohibited** by law and **must not** be available for download in Australia. Distribution, promotion or possession of this kind of app is a criminal offence [https://www.acorn.gov.au/learn-about-cybercrime/prohibited-offensive-and-illegal-content](https://www.acorn.gov.au/learn-about-cybercrime/prohibited-offensive-and-illegal-content) Offensive content in your promotional materials is also prohibited.

**NO** Check your social media channels regularly. If offensive material is posted by users in relation to your app, you **must** remove this promptly. Go to Question 3.2.

3.2 Your app must have an appropriate age-classification


**YES** You **must** ensure the app store implements access restrictions [https://www.legislation.gov.au/Details/F2014L01757](https://www.legislation.gov.au/Details/F2014L01757) to prevent under-age viewing. This also applies to how your app is promoted. Go to Advertising.

**NO** Go to Advertising.
Advertising

Australian Consumer Law covers how an app is advertised. Promotional materials:

- That are deceptive or misleading are **prohibited**
- **Should not** be offensive and should be age-appropriate
- **Should** provide information about financial costs associated with buying and using the app
- For medical devices have further restrictions

**WHAT ARE PROMOTIONAL MATERIALS?**

Promotional materials are any information provided about an app to the public including: app store description; app store category; and information about the app on the developer’s website, media releases, multimedia or social media channels. This **includes** testimonials, quotes and user reviews that have been copied by the app developer into promotional material but **excludes** user reviews posted directly onto an app store, and information written and disseminated by a third party. External postings about the app on an app developer’s social media channels are also **excluded**, although these **should** be regularly monitored by the app developer and corrected if misleading. They **must** be removed if offensive.

41. Do the app’s promotional materials accurately reflect what the app provides?


Go to Question 4.2.


4.2 Is the promotional material likely to be seen by an audience that includes children?

**YES** You **should** adhere to the industry standards [http://aana.com.au/content/uploads/2014/05/AANA-Code-For-Marketing-Advertising-Communications-To-Children.pdf](http://aana.com.au/content/uploads/2014/05/AANA-Code-For-Marketing-Advertising-Communications-To-Children.pdf) for advertising to children. If this is an app for adults, it should not be promoted in places where children will see it.

4.3 Are there any up-front or in-app charges associated with downloading or using the app?

YES  You must be clear and transparent in your advertising about the cost of the app, including whether in-app purchases are required for full functionality.

NO  Go to Question 4.4.

4.4 Does downloading or usage of the app require extraordinary amounts of data?

YES  You should provide information upfront about data usage.

NO  Go to Question 4.5.

4.5 Does your app and related material act as a proxy advertisement for a health practitioner who is subject to regulation under the Australian Health Practitioner Regulation Agency (AHPRA)?


NO  Go to Financial.
Financial

Some developers choose to make their app available to consumers for free, others for a price. Some apps also include in-app purchases, which allow consumers to upgrade or access extra content or buy subscriptions. You should provide information about in-app purchases in promotional materials and in the app. This information should be easily accessible and readily understood. If your app is targeted at potentially vulnerable users such as children or people living with mental illness, you should not repeatedly offer users in-app purchases.

5.1 Does your app contain in-app purchases?

YES  You should provide information about in-app purchases in promotional materials and in the app. You must indicate whether in-app purchases are required for full functionality.

NO   Go to Medical Devices.

5.2 Do you sell your app directly to consumers (e.g. via your own website)?

YES  You should have an obvious and accessible process http://asic.gov.au/for-consumers/codes-of-conduct/epayments-code for refunding consumers the costs of downloading or using the app if it fails to meet consumer guarantees.

NO   The app store where you sell your app should have an obvious and accessible process for refunding consumers the costs of downloading or using the app if it fails to meet consumer guarantees.
Medical Device

Some apps fit the legal definition of a “medical device.” Whether apps are covered by medical device laws depends on how likely use of the app will result in consumer harm. See whether your app is a “medical device” and what this means for you.

IS MY APP A MEDICAL DEVICE?

User-generated data is any information entered into the app that comes from the user. This includes numbers or text entered directly by the user, active measuring or sampling of biological information, and passive entries from wearables. Apps may rely on user-generated data to generate tailored messages to users. Messages could be generated by algorithms, calculators, coaches or other means. If an app delivers health messages, it may be classified as a medical device. Example health messages include:

- Diagnosis: e.g. The user has...
- Prognosis: e.g. The user is at risk of ...
- Monitoring: e.g. The user’s disease is getting better / worse, or is stable / unstable
- Advisory, including specific advice on how to alleviate or prevent a specific disease or modify a physiological process (“treatment” or “prevention”): e.g. The user should pursue a particular behaviour or use a product or service in a particular way (e.g. specifying dose or timing)

An app is unlikely to be classified as a medical device, if the app only ever:

- Indicates the risk that a population group has of developing a disease
- Provides general advice about a “healthy lifestyle” (such as limiting smoking and alcohol use, getting sufficient exercise)
- Provides links to support groups Gives generic advice to “seek help”
- Provides education about disease, anatomy or physiology Reminds users to take medications
- Monitors general health, fitness, wellbeing or the menstrual cycle (except if it investigates a specific physiological process)
- Stores user-generated data for later review by a health professional

Remember apps are defined as health-related more broadly when it comes to privacy than medical device law. Go to Privacy.
6.1 Is the focus of the app ANY of the following?

- A specific disease, injury or disability? This DOES include medical diagnoses and conditions (e.g. depression, eating disorder). It does NOT include symptoms or conditions that are not classified as a medical disease (e.g. stress, trouble concentrating, difficulty sleeping)
- An anatomical or physiological process? This DOES include things like the sleep cycle. It does NOT include general well-being
- Control of conception

**YES** Go to Question 6.2.

**NO** It is unlikely that your app is a medical device. Go to Professionalism.

6.2 Does the app claim that the output from the device can prevent or treat a specific disease, injury or disability or directly influence an anatomical or physiological process?


**NO** Go to question 6.3

6.3 Does the app collect user-generated data?

**YES** Go to question 6.4

**NO** It is unlikely your app is a medical device. Go to Professionalism.

6.4 Does the app deliver individualised health messages on the basis of user-generated data?

**YES** Your app may be classified as a medical device, sometimes called “medical device software”, a “mobile medical app” or “SAMD: software as a medical device.” Your app will be subject to the Therapeutic Goods Administration (TGA) Medical Device regulation. For more information, go here: [https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd](https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd) Go to Question 6.5.

**NO** It is unlikely your app is a medical device. Go to Professionalism.

6.5 Does the app allow direct diagnosis or monitor a vital physiological process?

**YES** Your app is likely a Class Ila (low-medium risk), Class Iib (medium-high risk) or Class III (high risk) medical device. All of these apps must be assessed by the Therapeutic Goods Administration [https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-](https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-).
devices-argmd or must hold an equivalent certificate from a European Notified Body.

**NO** Your app is likely a Class I (low risk) medical device. You must conform to the Therapeutic Goods Administration's Essential Principles [https://www.tga.gov.au/form/essential-principles-checklist-medical-devices](https://www.tga.gov.au/form/essential-principles-checklist-medical-devices) for safety and performance but unless your app has a direct measuring function (e.g. wearables) your app does not require external assessment by the TGA. You must be able to provide evidence of conformity to the TGA upon request. Apps with a measuring function must undergo external assessment.

---

**NEXT STEPS**

Your app is considered a medical device. Here’s what to do next:

- Apply to the TGA to enter the app into the Australian Register of Therapeutic Goods: [https://www.tga.gov.au/australian-register-therapeutic-goods](https://www.tga.gov.au/australian-register-therapeutic-goods)

For more information, you should contact the Therapeutic Goods Administration [https://www.tga.gov.au](https://www.tga.gov.au)
Professionalism

Health apps are an emerging and increasingly competitive market. There are standards of professionalism that set some health apps apart. Here’s a checklist to see if your app can compete:

- I have identified myself as the developer and provided contact information in the app, in store and on promotional materials.

- I have identified the authors of the app content by:
  - Disclosing authorship, and providing author credentials
  - Citing all sources
  - Attributing all intellectual property

- I have disclosed all funding sources for the app, including commercial partners:
  - In the promotional materials
  - In the app itself

- I have disclosed (https://www.adma.com.au/compliance/code-of-practice) my business model (for example, up-front pricing, in-app purchases, subscription model, selling of personal information to third parties or commercial data collation) so consumers understand how they are paying for the service.

- I have provided scientific evidence to support the claims about what the app can do.
  - If I’m making a health claim, I have provided clinical evidence

- I have provided an easily accessible and understandable privacy policy

- I have obtained consumers’ fully informed consent

- I have carefully selected third party partners
  http://digitaladvertisingalliance.org/principles so that I only work with partners that are transparent and accountable about how they collect, store and share user data.

- I have designed my apps to be usable https://www.w3.org/WAI/mobile/ by all consumers including people with specific user needs such as those people with vision, hearing or dexterity impairments.
What are the Laws and Standards?

Privacy


Security


Content


Advertising


Association for Data-driven Marketing & Advertising (ADMA) Code of Practice

Financial


Australian Communications and Media Authority Mobile apps: Occasional paper 1

Medical Device


Therapeutic Goods Administration (TGA) Therapeutic Goods Advertising Code


Therapeutic Goods Administration (TGA) Conformity Assessment Certificates

Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods

Accessibility

World Wide Web Consortium (W3C) Mobile Accessibility Guidelines
https://www.w3.org/WAI/mobile/
## Appendix 2 – Mental health apps included in this study

<table>
<thead>
<tr>
<th>App name (Google Play)</th>
<th>App name (iTunes)</th>
<th>Developer name (Google Play)</th>
<th>Developer name (iTunes)</th>
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**APPENDIX 2:** Mental health apps included in this study.
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## Appendix 3 – Explanation of ‘dangerous’ permissions

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<td>Read the contents of your USB storage</td>
<td>Read the phone’s memory and Secure Digital (SD) card</td>
</tr>
<tr>
<td>Modify or delete the contents of your USB storage</td>
<td>Write to the phone’s memory and SD card</td>
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<td>Find accounts on the device</td>
<td>Get the list of accounts known by the device, including those created by other installed apps</td>
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<tr>
<td>Read phone status and identity</td>
<td>Determine the phone number and device IDs, whether a call is active, and the remote number connected by a call</td>
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<td>Precise location (GPS and network-based)</td>
<td>Use the Global Positioning System (GPS) or cell towers and Wi-Fi to determine location; user must turn location services on</td>
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<tr>
<td>Approximate location (network-based)</td>
<td>Use network location sources such as cell towers and Wi-Fi to determine location; user must turn on location services</td>
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<tr>
<td>Take pictures and videos</td>
<td>Use the camera at any time without user confirmation</td>
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<tr>
<td>Use accounts on the device</td>
<td>Request authentication tokens to access other services and possibly external data</td>
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<tr>
<td>Read your contacts</td>
<td>Read data about user contacts stored on the phone, including the frequency of calls, emails or other communication with specific individuals; save user contact data</td>
</tr>
<tr>
<td>Record audio</td>
<td>Record audio with the microphone at any time without confirmation</td>
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<tr>
<td>Add or remove accounts</td>
<td>Add and remove accounts and delete their password</td>
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<tr>
<td>Create accounts and set passwords</td>
<td>Use the account authenticator capabilities of the AccountManager including creating accounts and getting and setting their passwords</td>
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<td>Read sensitive log data</td>
<td>Read from the systems various log files; contains general information about use of device including personal or private information</td>
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<td>Directly call phone numbers</td>
<td>Call any phone number, including emergency numbers, without user intervention</td>
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<td><strong>Add or modify calendar events and send email to guests without owners’ knowledge</strong></td>
<td>Add, remove, or change events that user can modify including bookmarking those of friends or co-workers; can send messages that appear to come from calendar owners or modify events without owners’ knowledge</td>
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<tr>
<td><strong>Read calendar events plus confidential information</strong></td>
<td>Read all calendar events stored on device including those of friends or co-workers; share or save your calendar data regardless of confidentiality or sensitivity</td>
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<tr>
<td><strong>Receive text messages (SMS)</strong></td>
<td>Receive and process SMS messages; can monitor or delete messages without showing user</td>
</tr>
<tr>
<td><strong>Read your text messages (SMS or MMS)</strong></td>
<td>Read SMS messages stored on device or SIM card regardless of content or confidentiality</td>
</tr>
<tr>
<td><strong>Read call log</strong></td>
<td>Read call log, including data about incoming and outgoing calls; can save or share call log data without user knowledge</td>
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</tbody>
</table>

* Adapted from “Google Play Store Apps Permissions” by Pew Research Center: [http://www.pewinternet.org/interactives/apps-permissions/]
## Appendix 4 – List of policies applicable to apps

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<td>Software as a Medical Device (SaMD) (International Medical Device Regulators Forum, 2013 2014 2015)</td>
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<td>General Wellness: Policy for Low Risk Devices (US FDA, 2016)</td>
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<td>Marketing Your Mobile App: Get it Right from the Start (Federal Trade Commission, 2013)</td>
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<td>Opinion 02/2013 on Apps on Smart Devices (Article 29, Data Protection Working Party, 2013)</td>
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<td>Europe</td>
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<td>Mobile Health App Developers: FTC Best Practices (and accompanying Mobile Health Apps Interactive Tool) (Federal Trade Commission, 2016)</td>
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<td>Guidance: Medical Device Stand-alone Software Including Apps (including IVDMDs) (Medicines and Healthcare products Regulatory Agency, 2016)</td>
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<td>Stay Smart Online: Mobile Devices (Attorney-General’s Department, 2017)</td>
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<td>A Guide to Apps &amp; In-app Purchases</td>
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<td>(Stoyanov et al., 2015)</td>
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References


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Smith, M. (2016). A legal and practical guide to developing mobile medical applications (‘apps’): navigating a potential minefield. *Journal of Mobile Technology in Medicine, 5*(1), 52-61. doi:10.7309/jmtm.5.1.8


Finding Peace of Mind
Navigating the Marketplace of Mental Health Apps