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Regulation and accreditation of addictive behaviour applications—navigating the landscape

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ABSTRACT

Background mHealth applications (apps) for addictive behaviours offer widespread provision of digital support, with particular benefits for stigmatized groups and those with poor access to treatment services. Regulation and accreditation may encourage the uptake and use of evidence-based addictive behaviour apps, yet this is a complex and confusing landscape. We navigate international regulatory and accreditation guidance, explore some of the implementation challenges and provide implications for app developers, health-care professionals and app users. **Analysis** We explore the classification of health and wellbeing, blended support and clinical therapy apps as medical devices by country to help readers navigate the complexity of the guidance. We describe an addictive behaviour app classified as a medical device and explore the innovative approaches to regulation that are currently emerging. We discuss the use of curated on-line app libraries that adhere to thresholds for characteristics such as quality, user satisfaction or effectiveness, which we hope will become the starting-point in the search for suitable apps, rather than commercial app stores. We also explore the ethical concerns associated with apps and how curated libraries address these. **Conclusions** International regulation of applications as medical devices varies across countries and would benefit from standardization in a simple, usable and transparent format. Efforts to provide accreditation of non-medical device applications are also variable, and public bodies provide mixed messages concerning endorsement. Health-care professionals and users are encouraged to use accredited applications for addictive behaviours where they exist, or explore other forms of digital intervention with a stronger evidence base.

Keywords Addiction, app accreditation, app regulation, digital health, medical device, mHealth.

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INTRODUCTION

mHealth applications (apps), defined as medical and public health practice supported by mobile devices [1], are often hailed as a scalable approach to delivering screening and intervention for addictive behaviours. Their scalability comes from their reach; approximately one-third of the global population has access to a smartphone (2.5 billion people in 2019 [2]), and in the United States almost 60% of people use their smartphones to access health apps [3]. More than 325 000 health and wellbeing apps have been developed [4], and nearly one-third of disease-specific apps have a mental health focus, which include addictive behaviours [5]. As such, there is potential for widespread provision of digital support, with particular benefits for stigmatized groups and those with poor access to treatment services. Apps for addictive behaviours cover the spectrum of severity, from stand-alone self-monitoring apps to adjuncts to pharmacological treatment and fully independent therapy, such as computerized cognitive behavioural therapy (cCBT) and relapse prevention. There is a small yet emerging evidence-base for apps to reduce alcohol consumption [6], promote smoking cessation [7–9] and prevent relapse to illicit drugs [10–12]. However, the most popular apps are those without effectiveness data; only two of the top 50 ranked smoking cessation apps identified in one study had any evidence of effectiveness [13]. Furthermore, profit-making apps that promote addictive behaviours also benefit from access to this mass market of consumers. This 'free ride' may be challenged by regulation and accreditation that encourages use of effective clinical innovations —a recognized implementation strategy to promote uptake and sustained use [14]. However, the regulation and accreditation of apps is complex and, at times, confusing.

The COVID-19 pandemic has accelerated the adoption and normalization of digital technologies by health services throughout the world at an unprecedented pace [15]. Without clear guidance on which apps are of high quality, effective and safe to use, patients are at risk of substituting effective therapeutic approaches for an app that does not support behaviour change, puts their privacy at risk and may ultimately result in the development of a problem or relapse to an addictive behaviour.

This opinion piece aims to navigate two strategies that can influence the uptake and use of evidence-based addictive behaviour (i.e. smoking, alcohol consumption and illicit drug use) apps: (1) classifying an app as a medical device and (2) receiving accreditation of an app by a public body [e.g. National Health Service (NHS)]. We explore some of the implementation challenges of this approach and provide implications for app developers, researchers, health-care professionals, patients and the public.

Apps as medical devices

A medical device undergoes a rigorous assessment process to determine its quality, effectiveness and safety. The classification of an app as a medical device in principle awards it a definitive stamp of approval, enabling health professionals to refer or prescribe the app to patients. The World Health Organization (WHO) defines a 'medical device' as any device, including software, intended by the developer to be used, in isolation or in combination, for a range of specific medical purposes in humans, including: diagnosis, prevention, monitoring, treatment or alleviation of disease [16]. This definition is sufficiently broad and opaque that it incorporates the spectrum of addictive behaviour apps. App developers can seek more nuanced categorization guidance from their country's own regulatory agency. To help readers navigate this complex and confusing landscape, we have compared the criteria, features and key characteristics of addictive behaviour apps that would class as a medical device according to: (1) the Food and Drug Administration (FDA, USA) [17], (2) the Medicines and Healthcare products Regulatory Agency (MHRA, UK) [18], 3) the Therapeutic Goods Administration (TDA, Australia), (4) Health Canada and (5) the European Medicines Agency (EMA). For comparative purposes, we have broadly categorized addictive behaviour apps into three categories: (1) health and wellbeing apps (or self-help apps)—designed to help people change an addictive behaviour to improve their own health and wellbeing without any person-orientated support, (2) blended support apps—combine self-help components with person-orientated support, which could range from help navigating an app to the delivery of therapeutic support, for people without a diagnosed substance use disorder or not receiving formal clinical therapy and (3) clinical therapy apps—designed as an adjunct to formal dependence treatment for people with a substance use disorder. We acknowledge that addictive behaviour apps do not fall neatly into each of these categories and, as with in-person intervention approaches, they constitute a continuum.

All regulatory agencies agree that health and wellbeing apps used as self-help resources as we have defined them are not considered medical devices, providing they do not claim to directly prevent ill health. Blended apps are not explicitly mentioned in regulatory guidance, although promising effectiveness data to support a blended approach will potentially influence future guidance [19,20]. Clinical therapy apps, often referred to as digital therapeutics, are less clear cut. FDA and MHRA classify these as medical devices, EMA would consider these as medical devices if the app creates a 'hazardous situation' (see Table 1), whereas Health Canada does not consider therapeutic apps as medical devices and TDA guidance is unclear. To the best of our knowledge, only one addictive behaviour app has been formally classified as a medical device. In 2018, the FDA announced approval of its first and only mHealth app, reSET, to treat substance use disorders [21]. reSET provides cognitive behavioural therapy, in combination with contingency management, for patients currently enrolled in outpatient treatment under the supervision of a clinician, and is available on prescription in the United States. There has been some criticism of the evidence that supports the reSET app; namely, that the app has only been found to be efficacious in combination with contingency management, an evidence-based implementation strategy [14], and the effects of the app alone are not known. Further, the FDA approval relies upon efficacy evidence; there are no pragmatic/Phase III effectiveness trials to support its use, therefore it may not be effective in real-world settings.

Recent innovation in regulatory processes

In 2017, the FDA launched a new approach to app regulation that focuses primarily upon the credibility of the developer. The FDA pre-certification programme approves developers with a credible reputation for software development [22]. Apps developed by pre-certified developers are automatically FDA-approved, without the standard review process. This innovative approach to app regulation is thought to speed up the availability of apps and thus the benefit to patients, health professionals and developers. Efforts to address the complex regulatory criteria for apps are slowly emerging, but cross-country consensus on quality standards is needed; apps are global products, and therefore need international standardization [23,24]. While therapeutic apps may benefit some patients with substance use disorders, the majority of apps for addictive behaviours are classified as health and wellbeing apps. The FDA has been criticized for not regulating health and wellbeing

Table 1 Regulatory guidance and application to addictive behaviour applications (apps).

Regulator	*Relevant part of definition for apps as medical devices*	*Addictive behaviour apps*		
		Health and wellbeing (self-help app) e.g. smoking cessation, or alcohol reduction app (early intervention)	Blended support app (enhanced intervention)	Clinical therapy app (intensive intervention)
		An app that provides information and behavioural support, such as risk information, motivational and practical support (e.g. NHS Drink Free Days)	An app that combines support beyond early intervention, such as connection to facilitators or health professionals, with self-help support (e.g. NIH sober grid, nomo sobriety clocks)	A therapeutic app designed to be used with existing dependence treatment services (e.g. Pear Therapeutics reSET; Chess Health CHESS)
Medicines and Healthcare Products Regulatory Agency (MHRA)—UK	'An instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application which is intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease' [18]	Would only be classed as a medical device if the app provides an indication of future risk, e.g. 'people with the same risk factors as you have an X% chance of heart disease or claims the app would directly reduce the risk of disease	Would only be classed as a medical device if the app provides an indication of future risk, e.g. 'people with the same risk factors as you have an X% chance of heart disease' or claims the app would directly reduce the risk of disease	'Apps intended to automate the treatment pathway for an individual patient' [18]
Therapeutic Goods Administration (TDA)—Australia	'Many mobile apps are simply sources of information, or tools to manage a healthy lifestyle. The TGA does not regulate health and lifestyle apps and software that do not meet the definition of a medical device' [43]	Not a medical device	Not a medical device	Unclear
Food and Drug Administration (FDA)—USA	'When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device'…'We intend to apply this oversight authority only to those software applications whose functionality could pose a risk to a patient's safety if the software applications were to not function as intended' [44]	Not a medical device	Not a medical device	A medical device

(***Continues***)

Table 1. (Continued)

Regulator	*Relevant part of definition for apps as medical devices*	*Addictive behaviour apps*		
Health Canada	Not considered a medical device: 'Software intended for maintaining or encouraging a healthy lifestyle, such as general wellness apps… Software that is only intended to support a health care professional, patient or non healthcare professional caregiver in making decisions about prevention, diagnosis, or treatment of a disease or condition' [45]	Not a medical device	Not a medical device	Not a medical device
European Medicines Agency (EMA)	The EMA has yet to issue regulation procedure. A second draft of guidelines on assessment of the reliability of mobile health applications was published in 2016 [46]	Not a medical device	Not a medical device	'Where "health apps" may create a hazardous situation, they are treated —in terms of development scrutiny, documentation, verification and validation for instance, in a similar manner to medical devices' [46]

apps. It is argued that they have an ethical duty to prevent harm to the public, a duty that precariously lies with the developers and the app stores [25].

Germany has recently adopted a Digital Healthcare Act (Digitale-Versorgung-Gesetz; DVG), which entitles recipients of state-funded health insurance to apps classified as lower-risk medical devices [26]. These are devices that support monitoring, detection, relief or treatment of illnesses. A register of eligible apps has been developed which meet criteria on safety, functionality, quality, data protection, data security and positive effects on care (demonstrated by expert opinion through to experimental studies). However, the scope of eligible apps is currently limited. Health and wellbeing apps and potentially blended support apps are excluded, as they are not considered medical devices by the EMA (Medical Device Regulation [27]). On one hand, this approach is a step forward in providing widespread access to effective apps with transparent assessment procedures, but on the other hand it might restrict access to or devalue apps that have not or do not need to be classified as medical devices.

We now consider the use of accreditation as an alternative to regulation for health and wellbeing and blended support apps for determining quality, safety and effectiveness.

Accreditation of apps

While many countries are developing robust procedures for regulating digital health technologies, there is less progress in providing accreditation and access to these technologies for patients/consumers or health professionals via curated on-line libraries or 'portals'. A lack of formal accreditation or recommendation of addictive behaviour apps could have implications for supporting behaviour change. Most apps are discovered through commercial app store searches [3,28]. The order in which apps are presented after searching a commercial app store ('display rank') strongly influences which apps are selected, with people rarely going beyond the first few apps in search results, as found with general search engines. Display rank is determined by uptake (downloads, rate of downloads over time) and popularity (ratings). Evidence from the uptake of alcohol and smoking cessation apps on app stores find that app ratings and rankings are only weakly associated with assessed clinical quality and use of behaviour change techniques [29,30]. Top-ranking addiction-orientated apps of low clinical quality will, therefore, probably remain top-ranking apps and impede people motivated to change their addictive behaviour from installing those apps that are more likely to be clinically effective. This is due in part to the

dominant entrepreneurial model of app development that applies 'agile development' principles, where apps are developed and made available early with the intention to enhance them continuously based on user feedback, supported by their income stream [29]. However, most apps are developed by those outside the health and addiction field and so lack access to expertise to develop their evidence-base. Furthermore, often due to financial pressures, they are not enhanced much after their launch.

Other approaches that can be used by consumers to identify apps for addictive behaviours, instead of commercial app stores, are slowly growing in number. Curated on-line app libraries are one such approach. These services, usually websites, can provide information to users, health professionals and potentially commissioners to help identify apps that serve a specific purpose. In some cases, these app libraries provide a form of accreditation, such as only including apps that adhere to thresholds for characteristics such as quality, user satisfaction or effectiveness. In England, for example, the second launch of the NHS apps library in 2017 requires app developers to adhere to specified criteria to ensure quality. These criteria include some evidence of effectiveness, as defined by the National Institute for Health and Care Excellence (NICE) Evidence Standards Framework [31], regulatory approval obtained if necessary, demonstration of clinical safety, adherence to legal and security standards for data privacy, adherence to the Web Content Accessibility Guidelines and a commitment to ensure technical stability over the app's life-time, although this is soon to be replaced by the Digital Technology Assessment Criteria (DTAC). Other examples include the Alberta Health Services Addiction and Mental Health Mobile Application Directory [32], which includes apps with 'supporting evidence' such as research articles or positive expert reviews, although they also include apps from a 'known reliable source' without supporting evidence. Competitive industry app libraries are more varied in the information provided on their criteria for inclusion. Libraries such as AppScript and ORCHA provide no clear information on inclusion criteria or scoring and others, such as MyHealthApps, refer to recommendations from consumers and health-care communities and the provision of app information by the developer on aspects such as contact details, app pricing, funding source and involvement of medical advisers for listing an app. As with regulatory procedures, we need closer international agreement on the level of evidence required for accreditation. Where the level of evidence differs across countries there should be strong justification. In turn, we need greater investment in evaluations of addictive behaviour apps. Further, evidence on the opportunity cost of using an ineffective or poor clinical quality app compared with effective apps or other therapeutic approaches and subsequent health benefits should be required for regulation and accreditation [33].

With the vast majority of apps for addictive behaviours not classified as medical devices, and accreditation not compulsory, there are ethical concerns over their use. Capon *et al.* [34] conducted a review of apps for addictive behaviours used in research studies and identified ethical concerns around data storage and transfer, data ownership, third-party access, user anonymity, informed consent, equality of access, communication of clinically relevant results, evidence of safety and effectiveness and regulation. Data protection was found to be the greatest ethical concern with apps for addictive behaviours which target sensitive and possibly illicit behaviours, such as drug use. This concern is not unfounded. In 2013–14, Huckvale *et al.* conducted a cross-sectional assessment of 79 health and wellbeing apps on the NHS apps library. They found that two-thirds of apps did not encrypt identifying information sent over the internet, some apps lacked privacy policies and most did not describe the nature of personal information included in transmissions. Furthermore, four apps transmitted both identifying and health information without encryption [35]. The NHS apps library has since been revamped, with these data protection failures addressed, but this illustrates the complexity of accrediting apps and the real and potentially incriminating risks faced by their users, where law enforcement agencies can subpoena data on illegal drug use in most countries [36]. Accreditation bodies, as with federal agencies, have an ethical duty to ensure technical safeguards are in place to prevent data protection breaches and build confidence in the security of personal data.

Pitfalls with public body endorsement

In addition to the NHS apps library in the England, Public Health England (PHE) offer their own suite of apps to promote healthy behaviours, which include SmokeFree and Drink Free Days for smoking cessation and reducing alcohol intake, respectively. A challenge for public bodies such as PHE is that they are expected to provide support tools prior to demonstrating any evidence of effectiveness, as is the case with the SmokeFree and Drink Free Days apps. However, these apps are widely publicized over multimedia channels, they have inherent credibility for being delivered by PHE and, as such, they are likely to be endorsed by health professionals. We believe this sets a potentially worrying precedent that a public body, such as PHE, can develop and disseminate an unevaluated intervention, which does not meet the criteria to be included in the NHS apps library.

A current limitation with most existing curated app libraries is that there are only a limited number or no apps available at all to specifically address addictive behaviours. A partial exception is the Alberta Health Services Addiction and Mental Health Mobile Application Directory. This

includes eight apps focused on alcohol behaviour change (two with some connected research but not effectiveness evidence; six with expert review only), two smoking cessation apps (both with some evidence of effectiveness) and four focused on opioid misuse (one with some connected research but not effectiveness evidence; two with expert review; one developed by a 'known reliable source'). The NHS apps library has no apps that primarily aim to change addictive behaviours. Public Health England have a curated library with one smoking cessation and one alcohol reduction app although, as mentioned above, neither have evidence of effectiveness. MyHealthApps includes four smoking cessation (one with evidence of effectiveness; unclear if the other three have evidence of effectiveness) and two alcohol reduction apps (unclear if there is evidence of effectiveness). AppScript include no addictive behaviour apps. While accreditation by public bodies is needed for health and wellbeing and blended support apps for addictive behaviours, their availability is lacking. Another limitation with apps listed on app libraries is that most are only available for a single operating system (i.e. iOS or Android) [37], reducing access further.

The lack of available addictive behaviour apps on current curated app libraries is, in part, a symptom of accreditation. App developers or owners may not meet all requirements of an accreditation or assessment process, or if they do they may not see the value in doing so or have the knowledge or resources to do so. Most addictive behaviour apps also lack research evidence to support their use and there is a more general issue that most of the apps that have been evaluated are not available in app stores [6]. For health apps as a whole, curated app libraries and third-party websites are estimated to account for between 17 and 21% of health app discoveries [3,28], although more up-to-date studies are needed. The extent to which this is true for addictive behaviour apps is unknown. Providing a greater choice of addictive behaviour apps may be an important factor for increasing uptake on such platforms, with evidence that people looking for addiction-related apps have varied preferences based on the look, description and available features of the app [38]. Given the large number of addictive behaviour apps found on app stores, relative to curated app libraries, it is of no surprise that the identification of apps is predominantly directly through these services. For example, reviews searching for smoking cessation apps found 400 relevant apps [39], and 91 alcohol reduction apps in the first 800 alcohol-related apps identified [30], although there are still few apps focused on managing use of opioids or other substances [10].

Putting aside the current limited choice of addictive behaviour apps, there are benefits to curated app libraries that include accreditation. A European Union-wide study reported that having a health-care system evaluate the quality of an app would encourage 15% of adults to use health apps more often [40]. Such quality evaluation would probably circumvent some of the current barriers to app uptake, such as accuracy and data privacy concerns. A further benefit would be the potential for practitioners in health-care and community settings to promote use of the app library to increase the absolute uptake of evidence-based apps among the public, where trust in the practitioners was high. Unlike app stores' current approach, curated app libraries can provide systematic descriptions of app features, user guidance and provide uptake recommendations, all of which are associated with app uptake [41]. We hope that, in time, curated app libraries will become the starting-point for users and health professionals in the search for suitable apps, rather than the app stores.

IMPLICATIONS

Apps are complementary to other digital treatment approaches. Computerized CBT is a long-established evidence-based treatment approach in mental health, which is routinely delivered for addictive behaviours in many health-care systems, such as in Sweden and the Netherlands. A platform of multi-modal evidence-based technologies should be available to patients and the public, without sole reliance upon apps. It is important to recognize the speed at which digital technology becomes obsolete. Just as we begin to establish an evidence-base for apps, the popularity of wearables and other sensory devices is gaining pace. For patients and the public who wish to track more than one health behaviour, having multiple apps can be burdensome and users primarily focused on improving other health behaviours, such as physical activity, may be deterred from also downloading an addictive behaviour app. Apps intended to integrate with existing health services must consider other health service priorities, such as efforts to link primary, secondary and tertiary care data sources and beyond, such as criminal justice and social service databases.

This opinion piece has focused upon regulated and accredited apps, but with few addictive behaviour apps available as either medical devices or accredited by national bodies, researchers, health professionals and patients/public can assess their quality using a range of different quality rating systems [33,42]. For app developers and researchers who do wish to gain regulatory approval and accreditation for their apps, in the United States they may benefit from partnering with FDA-approved developers to accelerate the creation and regulation of therapeutic apps. In the United Kingdom, Academic Health Science Networks (AHSNs), a partnership between the NHS, academia and the private sector, facilitate the way the NHS identifies, develops and adopts new technologies.

Digital Health London was born from the South London AHSN (Health Innovation Network) and was established specifically to help developers navigate the complex regulatory landscape. Further, app developers and researchers are encouraged to produce pragmatic evidence to demonstrate the impact of their app in real-world settings.

CONCLUSION

The popularity of apps will undoubtedly continue to accelerate, due to the rapid adoption of digital health technologies, which has been further catalysed by the COVID-19 pandemic. International regulation of apps as medical devices is slowly evolving to address the need for high quality, safe and effective apps, although criteria vary across countries and would benefit from standardization in a simple, usable and transparent format. Efforts to provide accreditation of non-medical device apps are variable and public bodies provide mixed messages around endorsement. App developers and researchers are encouraged to work more closely with pre-certified developers or local Academic Health Science Networks, who have a good grasp of this complex regulatory landscape. Health professionals and patients are encouraged to use accredited apps for addictive behaviours, where they exist, or explore other forms of digital intervention with a stronger evidence-base, although they will need help to do this until there are appropriate facilities fully embedded within the digital environment.

Declaration of interests

None.

Author contributions

Zarnie Khadjesari: Conceptualization; data curation; project administration. **Tracey Brown:** Data curation. **Felix Naughton:** Conceptualization; data curation.

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