Canadian Journal of Health Technologies

CADTH

February 2022 Volume 2 Issue 2

CADTH Horizon Scan

An Overview of Smartphone Apps

CADTH

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ISSN: 2563-6596

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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Key Messages

- Health-based mobile applications (mHealth) are downloadable applications on a smartphone or similar device for use in health care, either by the person directly or by a health care provider. This Horizon Scan summarizes the available information and provides an overview of health apps on smartphones that are not connected to specialized medical equipment, describing examples of emerging apps in different clinical areas, who they might benefit, and their operational issues.
- There are over 350,000 mobile applications available for download in app stores, used for a variety of disease areas. These areas include chronic disease, stress, mental health, fitness, sleeping problems, general medication adherence and tracking, and vital sign measurements.
- The scan identified that health apps often fall into 1 of 4 categories: informational applications, diagnostic applications, disease management applications, and fitness tracking applications.
- Numerous apps were identified that are available for use by people in Canada. Health apps offer the potential to provide convenience, flexibility, accessibility, and personalized health information. However, the majority of health apps that require evidence of benefit for users have not been assessed in appropriately designed studies that examine their clinical efficacy, or safety. The apps that have been tested in some research studies may have numerous shortcomings in areas such as app design, user engagement, user satisfaction, and retention.
- This scan describes some operational considerations for apps that relate to their lack of evidence-base, concerns about biases in app design, and the need for equity focused app development. It was noted in the literature that many apps do not provide appropriate privacy and confidentiality for consumers, which may put people at risk of data breaches or inappropriate use of personal data.

Purpose

The purpose of this Horizon Scan is to present health care stakeholders in Canada with an overview of information related to emerging smartphone mobile applications for health care, a description of some of the published studies, and a summary of some important considerations related to the potential implementation of the technology, should emerging evidence demonstrate value. This report is not a systematic review, does not involve critical appraisal, and does not include a detailed summary of study findings. It is not intended to provide recommendations for or against the use of the technology or to endorse any applications.

Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the international HTA database, the websites of Canadian and major international health technology agencies, the US National Institutes of Health trials registry (clinicaltrials.gov) as well as a focused internet

search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were mobile apps, post-traumatic stress disorder (PTSD), chronic inflammatory lung disease (COPD), substance use disorder, and vital signs. No filters were used to limit retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2018 and September 27, 2021.

Regular alerts updated the search until project completion; only citations retrieved before December 16, 2021 were incorporated into the report.

One author screened the literature search results and reviewed the full text of all potentially relevant studies. Studies were considered for inclusion if the information was regarding smart phone applications (i.e., not web-only or computer only interventions), was not an education only intervention (i.e., applications with only learning material), or if the application was reasonably accessible (e.g., downloadable on app stores, available through clinicians, or not discontinued). The Canadian context was the focus of this report, but applications originating from other countries were considered if available for use in Canada. Conference abstracts and grey literature were included when they provided additional information to that available in the published studies.

Peer Review

A draft version of this bulletin was reviewed by 1 clinical expert with expertise in family medicine, health informatics, and mobile health.

Background

Data from Statistics Canada shows that[1] 88% of individuals 15 years of age or older own a smartphone, and it is estimated that half of smartphone users have downloaded at least 1 health-based application.[2,3] Smartphone users therefore represent a large market of individuals that can be reached with the use of mobile-based digital health technologies (mHealth) – interest in tapping into the mHealth market has only expanded with the COVID-19 pandemic, increasing the adoption of technologies to communicate and access care through digital health. Over the past decade, the number of mobile-based health apps have increased substantially, with over 350,000 mHealth apps being available to the public for download. These apps mostly consist of general wellness and fitness apps, as well as condition-specific apps for mental health, diabetes, and cardiovascular diseases.[4] A survey in 2017 found that for individuals who frequently use mobile health apps, 64% monitor physical activity, 41% monitor nutrition, 36% monitor weight, 36% monitor sleep, and 19% monitor sport performance.[5]

Scope of this Bulletin

The number of apps available and the number of apps being released each year precludes a detailed explanation of every health-related apps available in Canada. Therefore, the scope of the current bulletin is limited to a general overview of apps and some examples of emerging apps that may be beneficial to inform the Canadian health care context, are endorsed

or recommended by a evidence-based health care or technology agencies, or have been assessed in limited research settings. Apps that connect to specialized medical equipment (e.g., remote monitoring devices) are not covered by this bulletin. The inclusion of specific apps are not endorsements of said applications. The scope of the bulletin was determined through CADTH's scan of upcoming health technology trends; it is not a comprehensive overview of all available apps and disease areas.[6]

The Technology

What Are Mobile Apps?

Health-based mobile apps are downloadable software that can use data collected by smartphones for health functions (e.g., diagnosis, monitoring, treatment). Health Canada defines software as a medical device (SAMD, which includes all computing platforms), as only software that are intended to be used as a medical device and that do not require a hardware medical device.[7] Specific to mobile devices, the FDA defines mobile medical apps as a mobile-based software that can be used as an accessory to an already regulated medical device, or that intends to transform the mobile device into a regulated medical device.[8]

Smartphones can collect data related to fitness (e.g., number of steps walked, or flights of stairs climbed), weight, breathing, heart rate, and location. Some phones have built-in or pre-downloaded health apps (e.g., Apple health, Samsung health, Google fit), and as mobile technology improves, smartphones are being equipped with more built-in, tracking features. For example, starting in 2021, Google Pixel phones have the capability to measure a user's heart rate and respiration using the phone's camera.[9]

Some mobile apps require additional non-medical device wearables to function or provide increased capabilities. For example, fitness trackers such as Fitbits, Garmin watches, Samsung watches, and Apple watches can measure heart rate and heart rate variability, blood oxygen saturation levels, activity levels, sleep quality and quantity, electrodermal activity, and skin temperature, which then feed the data into specific apps for tracking. The difference in accuracy of certain data between wearable trackers and phone-only trackers (such as the number of steps taken) is disputed,[10] but wearable trackers can often provide greater functionality for collecting different types of health data. However, the use of wearable technology can be cost-prohibitive for many people, and so phone-based tracking may be a viable solution for many individuals. Other apps do not automatically collect health data, but may require a person to fill in data manually into the app.

What Types of Apps Are There?

mHealth apps can fall into broadly defined categories, but some may also have diverse functions that fall into multiple categories. The Center for Democracy and Technology[11] (Washington, DC) proposed 4 main categories of health apps:

- Health reference (i.e., looking up health information)
- Fitness tracking
- Diagnostic
- Disease management.

Some applications may fall into multiple categories — for example, some apps contain both a disease management component and a health reference or education component.

What Health Conditions Can Apps Manage or Monitor?

There is a wide variety of diagnosed or suspected health conditions and health tracking that mobile apps are being developed for. These include:

- general health such as vital sign measurements,[12,13] and stress reduction[14]
- mental health[15,16] and substance use[3,17-20]
- chronic conditions[21] such as chronic obstructive pulmonary disease (COPD)[22] or diabetes[23-25]
- pain conditions[26]
- cardiovascular disease[27]
- headache[28]
- sleeping problems[29-31]
- general medication adherence and tracking.[32]

Many free health apps do not require an official diagnosis of a condition and are available for anyone aiming to support their health and wellbeing. These apps may be related to stress management, fitness, or mental health.

Availability

The availability of mobile health apps in Canada is widespread. As mobile health apps are not regulated in the same way that traditional medical devices are, it means that apps can be created by any entity and can be available for anyone in Canada to download from their phone's app store. Health Canada has issued draft guidance for SAMD in 2019, but there are challenges with regulating this type of software for use in Canada as app stores contain hundreds of thousands of apps (i.e., requiring validation of every app on the market for the Canadian audience), and it may be possible for an individual to use certain apps outside of their intended use or purpose (i.e., the person may use the app in a particular manner despite developers not intending it as such).[2]

It is also common for apps to be available on either Android or iOS smartphones, but not both. This restricted availability may limit options for people who do not have access to 1 of these operating systems or phones. There were also a number of apps that were identified in the literature, but did not appear to be available anymore.[33]

Some identified apps are not available in Canada in general — these apps frequently require a prescription as they are connected to a specific clinical intervention or therapeutic program, and therefore are not publicly available on app stores. Examples such apps include those for problem drinking prescribed after residential care and apps for opioid use disorder in outpatient clinics.[34,35] Limited information about the future availability of these apps in Canada was identified, and it is unclear how research assessing their effectiveness translates to Canada's population and health care context.

Cost

Most available apps are free from the app stores (either Android or iOS). Some apps may run advertisements to cover operating costs or are funded through public health groups.

Some apps are free to download and come equipped with base features but may offer additional features at an additional cost (e.g., Fitbit). These apps are usually provided as a monthly subscription costing between approximately CA$5 and $20 per month. Other apps, such as DynamiCare (a substance use recovery app) offer plans with different features, costing between US$20 and US$50 per week.[34]

Apps that require wearable fitness devices require an additional monetary investment — their cost ranges based on the device and its features, but they commonly cost $100 to $400 per wearable.

One of the potential benefits of mobile health devices may be the cost-savings to people and health care systems they could provide. For example, digital coaching and at-home monitoring of symptoms may reduce the need for a patient to visit their doctor in person, which could translate to cost-savings in time, transportation, and parking. More consistent tracking of health behaviour could lead to an individual exercising more, eating better, using relaxation exercises, and therefore generally improving their overall health.[36] However, there is a need for apps to demonstrate clear clinical benefit before assessing their potential economic benefits. Additionally, if costs for mobile health (e.g., phone bills, internet bills, app store prices) are moved from the health care system to individuals, will this place additional inequity on individual who may not be able to afford the premium versions of apps?

Who Might Benefit?

Individuals and groups of people with diverse life circumstances and experiences may benefit from the convenience, flexibility, and capability apps could provide to improve people's health and wellbeing. For example, should certain mHealth apps demonstrate clinical effectiveness, they may help complement therapies and clinical interventions for people who:

- cannot afford costly treatment options[37]
- are self-managing their conditions,[38] especially chronic conditions[21]
- face stigma due to their health condition or life circumstance[20]
- wish to remain anonymous in treatment[20]
- live in rural or remote areas with less access to specialized services[39]
- cannot afford the time requirements of certain treatments (e.g., taking time off work, travel time)[20]
- face structural barriers to accessing treatment.[15]

Clinical Areas for mHealth Apps

General Health and Wellbeing

Vital Sign Measurement and Wearable Trackers

Phone-based heart rate monitoring is not a new concept. Wearable devices that use photoplethysmography (i.e., using an infrared light source and photo detector to measure heart rate) have been around for years, with the wearable technology market reaching US$116.2 billion in 2021 and projected to increase to US$265.4 billion within 5 years.[40] Wristwear, which includes smartwatches and fitness trackers was estimated to be valued at US$77.9 billion in 2021.[40] Wearable technology that specifically monitors health statistics are also growing in popularity, and the technology has improved beyond just heart rate monitoring to heart rate variability, sleep tracking, and blood pressure. The wearable trackers offer an alternative to much heavier and bulkier electrocardiograms and are often lower cost.[41] Companies offering wearable technology that pairs with a smart phone app include Fitbit, Amazon, Samsung, Apple, and Garmin. Of note, these apps and these wearable technologies are not considered medical devices under Health Canada's definition for SAMD and are not subject to the same regulations as standard SAMDs.[7]

Most of the higher-end (i.e., newer, and more expensive) fitness trackers include step counting, heart rate and heart rate variability monitoring, blood oxygen level monitoring, menstruation trackers, skin temperature readings, electrodermal activity readings, sleep quality measurements, calories burned, and many of the apps include built-in workouts and educational content. A 2017 survey by Canada Health Infoway reported that 77% of individuals who use smart connected devices (including fitness trackers) found them useful in their lives, with 69% stating that they had maintained or improved their health through their use.[5]

The Amazon Halo wearable includes an app-based measurement of body fat composition using the phone camera and 3-D rendering. One study of 134 participants funded by Amazon found that the scanner was as accurate as some other body fat composition methods, when compared to the gold standard of dual-energy X-ray absorptiometry.[42] The feature includes a slider for users to see what their 3-D modelled body would look like at different body fat compositions. The feature has been criticized for not differentiating between different kinds of fat (i.e., visceral and subcutaneous) and for creating the potential for triggering body dysmorphia in susceptible users.[43]

There are several ongoing studies involving wearable trackers, such as a partnership with Apple and the Ted Rogers Centre for Heart Research and Peter Munk Cardiac Centre in Toronto exploring how blood oxygen levels can assist with heart failure management.[44] Additionally, Apple is working with the Brotman Baty Institute for Precision Medicine (Seattle, US) to explore how heart rate and blood oxygen can serve as markers of early respiratory infection.[44]

Stress Management

General stress management was a common application purpose in the literature. Stress management apps were either combined with mental health treatments or were standalone apps. Common methods of stress reduction included mindfulness and meditation.

Mindfulness, stress management, and meditation apps included:

- Calm,[45] a guided general meditation app with stories for sleep
- Mindfulness Coach,[46] a National Center for Post-Traumatic Stress Disorder (NCPTSD) endorsed mindfulness app
- Headspace, a meditation app[47]
- COVID Coach, an application endorsed by NCPTSD for addressing stress related to COVID-19. It is designed as a self-management app that provide coping skills and tracking.[16]

There were several other mindfulness apps identified in a systematic review by Mani et al. (2015),[14] but they did not include any effectiveness studies or proof of efficacy.

Mental Health and Substance Use Disorders

Mental health is a promising clinical area for apps. Apps offer an opportunity to provide at-home self-management of mental health conditions and can be used in conjunction with traditional mental health services.[38] There is preliminary evidence from an overview of meta-analyses that mobile apps may help with some mental health conditions such as depression and anxiety,[48] and they can provide an avenue for patients to access services that may be inaccessible to them ordinarily, due to financial or geographical reasons.[38] For example, there is a plethora of apps available to support people looking to reduce consumption of harmful substances including opioids,[19] alcohol, cannabis, and tobacco. Many individuals with substance abuse issues do not seek traditional or formal treatment options.[20] This group may especially benefit from mobile-based treatment options, as apps may allow more flexibility in treatment options and timing, and users may feel they provide more anonymity than traditional in-person treatments.

Alberta Health Services[38] published a directory of addiction and mental health related apps in 2021. The directory covered apps focused on neurodevelopmental disorders (i.e., autism spectrum disorder, ADHD, and motor disorders such as Tourette syndrome), schizophrenia and psychotic disorders, depression, anxiety, obsessive-compulsive disorder, PTSD, eating disorders, disruptive, impulse-control or conduct disorders, substance use disorders, neurocognitive disorder (i.e., Parkinson disease, unspecified disorders), suicidal behaviour, self-injurious behaviour, stress, and sleep.[38] The scope of this bulletin does not allow for a detailed description of every application available in Canada, so general information is provided.

Youth Mental Health

A systematic review by Domhardt et al. (2021) analyzed mHealth apps for mental health disorders in youth.[15] The health apps included features such as:

- psychological treatments (e.g., eye movement desensitization and reprocessing, cognitive behavioural therapy, acceptance therapy)
- data collection and monitoring with feedback
- information, reminders, tips, goals, and strategies
- relaxation exercises, mindfulness, breathing exercises
- physical exercises.

Despite the number of apps that were identified, 1 application out of 15 scored higher than "very poor" with regard to the evidence-based score of the Enlight checklist — a validated rating scale for mobile and web-based apps. The authors of the systematic review noted a

lack of empirical and well-designed studies or evidence to support claims for efficacy of these apps. Notably, most of the identified apps also did not have information regarding conflicts of interest, password protection, or consent to data collection.

PTSD

Five reviews that were identified in the literature examined apps that could be used in symptoms management of PTSD.[16,49-52] One of these reviews looked at the content and published data on 5 apps' effectiveness,[50] and 2 reviews examined 30 apps and 69 apps using content analysis, respectively,.[49,51] and 16 apps included in these reviews were endorsed by the US Departments of Veteran Affairs' NCPTSD.[16] These apps are available in Canada through app stores. Some apps are designed for use alongside conventional treatment (i.e., alongside treatment from a clinical provider), and some apps are designed for self-management, either used independently or in conjunction with other treatments.[16]

The content of these apps includes relaxation exercises designed for PTSD, apps to deal with sleep disturbance, psychoeducation, logging or tracking of episodes (e.g., logging anger episodes or triggers), couples therapies, mindfulness therapies, and assessments.[16]

In addition to apps endorsed by the NCPTSD, there are many other PTSD-related health apps on the market. However, according to a systematic review of PTSD-related apps on Google Play and Apple iTunes, more than 20% of the apps did include evidence-based content in their app descriptions.[51]

PTSD-Related Insomnia and Night Terrors

People with PTSD may commonly experience insomnia and night terrors.[53] Several applications to support people with these sleep-related conditions, who may or may not have PTSD, were identified. Examples of apps to support treatment of these sleep conditions (with or without PTSD) and their features are described in Table 1. Some of these apps require an additional piece of hardware (i.e., NightWare requires an Apple Watch) and may require a prescription from a health care provider.

Substance Use

These apps can use a variety of smartphone features and application designs to deliver the intended product or interventions. This includes psychoeducation, self-tracking and diaries, personalized feedback through algorithms or a health care provider, counselling, social support (e.g., forums), rewards, geolocation features, just-in-time adaptive interventions (i.e., an intervention that delivers the appropriate amount and type of support at the right time for the user by using adaptive interventions)[55] and machine learning or artificial intelligence. As noted by Watkins et al. (2018), 1 common approach to online interventions for alcohol and substance use is to use a technique based on motivational interviewing — a client centred counselling approach for behaviour change or to use cognitive behavioural therapy approaches.[37]

Examples of apps for substance use are:

- DynamiCare — a digital care program administered through a mobile app. The app includes a personal "recovery coach," appointment reminders and calendars, reward-based motivation (e.g., financial rewards up to US$100 a month), and at-home substance testing (breath- and saliva-based tests provided by DynamiCare). The app is based on principles of cognitive behavioural therapy (CBT). There is also a feature that can block debit and credit

card purchases at high-risk places such as liquor stores or bars. This application requires a monthly fee and subscription, and it is unclear if it is available in Canada.[34]

- HARBOR — an app designed for peers of emerging adults (18 to 29 years of age) who are concerned about a friend's substance use.[56,57]

Alcohol Use

Reviews of alcohol use disorder-based commercial apps available in app stores revealed that the evidence is inconclusive or lacking for many apps, especially for youth.[17,58] In adults, the evidence is mixed, with the single available app in Canada, called Step Away, showing some measured success in reducing drinking.[17] However, the reviews reported that studies often have small sample sizes and are frequently designed as pilot studies, so it is unclear if the lack of measured differences is due to a lack of power to detect differences, or directly due to the intervention. Additionally, it was noted in 1 review that blood alcohol content measurements/estimations in 1 app reviewed led to an increase in alcohol use.[58] The authors noted that some apps can, either implicitly or explicitly, encourage substance use.[58] Another review found the majority of alcohol-related apps in the app store were "for entertainment purposes" with a small minority discouraging alcohol use.[59] Table 2 details some identified apps for alcohol use disorders.

A Canadian-based app developed by the Centre for Addiction and Mental Health (CAMH) called "Saying When" was also identified and is available for free download for individuals

Table 1: Examples of Emerging Apps to Support People with Insomnia

Application	Purpose and features
Nightware[54]	• For people with nightmare disorders and PTSD • Uses an Apple Watch and Apple iPhone • Senses movement and heart rate during regular sleep and creates a unique sleep profile for the user • During sleep, if a nightmare is detected, the watch sends a gentle vibration to interrupt the nightmare without waking up the user • For use in conjunction with therapy and available by prescription only[29]
COAST by NOCTEM Health	• For people with insomnia • Users self-report sleep data and a proprietary algorithm detects disordered sleep patterns • The app recommends personalized interventions to the clinician overseeing the person's care • Includes educational components, secure messaging, and a corresponding portal for clinicians
CBT-i Coach[30]	• For people with insomnia, based on the manual Cognitive Behavioral Therapy for Insomnia in Veterans • Provides educational content to guide sleeping habits and encourage better sleep • Structured program to improve sleep length and quality with assessments, reminders, and a sleep diary • For use in conjunction with a health care professional
Insomnia Coach[31]	• For people with insomnia • Includes training plan and tools to track and improve sleep habits • Provides a sleep diary for tracking changes • May provide option for a sleep coach • Either for use as a standalone app or with the support of a health care provider

CBT = cognitive behavioural therapy; COAST = Clinician-Operated Assistive Sleep Technology.

concerned about their drinking but who are not necessarily diagnosed with an alcohol use disorder (AUD).[60] The app provides ways to track alcohol use, goal setting, education, and linkages to community resources. There were no quantitative or qualitative clinical studies identified for this application, but the application is based on an evidence-based program offering from CAMH.

Apps identified to assist with AUD are described in Table 2.

Smoking Cessation

The majority of identified smoking cessation apps used psychoeducation and self-tracking as part of the active intervention for the application. It was noted however, that app features were often not well described in identified studies.[18] Similar to AUD apps, there were many apps were available to download, but limited evidence to assess the value-add or clinical effectiveness of the apps. There was a lack of late phase trials appropriately testing these apps in practice.[18]

Cannabis Use

Problematic cannabis use has also been addressed by mHealth apps. For example, "Stop-Cannabis," is a French language app that scored high in a survey for frequency of use of the app and for helping stop or reduce cannabis use by participants.[65] However, no study assessing the efficacy of the app to stop or reduce cannabis use was identified.[65] In Australia, the National Cannabis Prevention and Information Centre created the "Assess,

Table 2: Selection of Apps for Supporting Alcohol and Substance Use Recovery

Application	Purpose and features
Saying When[60]	• Canadian app from Centre for Addiction and Mental Health • Free download for individuals concerned about their drinking but who are not necessarily diagnosed with an AUD • track alcohol use, goal setting, education, and linkages to community resources • based on an evidence-based program offering from CAMH • No quantitative or qualitative clinical studies identified for this application
Daybreak[61]	• Provides online peer support community and activities to reduce drinking • One-on-one support from health coaches but is mostly self-directed • Original app developed for Australian market • Paid app (AU$119.88 annual or AU$12.99 monthly, free for Australia)
Step Away	• Includes assessment and feedback for drinking, identification of high-risk locations, and strategies for craving-coping • Communication skills training for client-identified "supportive persons" • Veteran version ("Stand Down: Think Before You Drink") includes for veteran centric content[62]
Connections (A-CHESS)[63]	• Uses location-based tracking to alert individuals if they are close to high-risk locations • Includes a panic button for users, connection to peer support groups, online resources for reducing drinking, and 24/7 support • Intended for patients leaving residential treatment facilities • Includes a clinician dashboard for tracking user progress • Based on self-determination theory[64]

Plan, Track, and Tips" (APTT) app for cannabis users who wish to cut back on use. It focuses on motivational enhancement therapy and CBT for reducing problematic cannabis use. It is unclear if this app is commercially available in Canada through app stores or through a prescription.[66]

With an increase in the use of cannabis and social acceptability in Canada post-legalization,[67] as well as a potential increase in cannabis use due to the COVID-19 pandemic, there may be an increase in cannabis use disorders and therefore an interest in mobile health treatment options.

Opioid Use Disorder

A review by Aggarwal and Borycki[68] found a number of apps available for opioid use disorder; however, 6 of 16 apps used evidence-based methods during development.

One application (reSET-O by Pear therapeutics) focuses on opioid use disorder and has received FDA authorization. CADTH published a newsletter detailing this application in 2019.[35] The company is based in the US and it is unclear if the application is available in Canada. Additionally, the studies that the FDA authorization was based on were for a computer-based intervention in a clinic environment, so the results may not translate directly to the mobile application for home use or in community settings. The results of the computer-based intervention were favourable, reporting that drop out in the groups that were assigned to 12 weeks of a standard treatment (buprenorphine, weekly urine testing and visits with a clinician) in combination with a therapeutic educational system was lower than for groups that received only the standard treatments.[69] The primary outcome of abstinence was not clinically significant. A cost-effectiveness evaluation of the mobile-based app was conducted in 2021 and reported that standard treatment combined with reSET-O was less costly and more cost-effective than standard treatment alone.[70] The study was funded and conducted by the app developer and therefore, despite the declaration of no conflicts of interest, independent third-party studies would be beneficial to confirm these findings.[70]

A review by Nuamah et al. (2020)[71] searched for apps that were intended for patients or clinicians of patients with opioid use disorder, finding 62 apps ranging in price from free to download to US$9.99. Most apps were for assisting clinicians with opioid conversion.[71] Most frequently identified were clinician facing apps, but only 2 apps for OUD were intentionally designed to support medication assisted therapy — FlexDek and MATx by the Substance Abuse and Mental Health Services Administration (SAMHSA).[71] FlexDek won first place in a National Opioid Recovery App Challenge sponsored by SAMHSA in 2016,[72] but neither FlexDek nor MATx appear to still be available at the time of the writing of this document.

In 2020, the Institute for Clinical and Economic Review (ICER) published a review of 3 mobile health apps, including reSET-O, DynamiCare, and Connections. The report panellists (i.e., New England Comparative Effectiveness Public Advisory Council) voted that the evidence was not sufficient for any of these apps to prove a net health benefit.[73]

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a chronic condition that affects lungs and airways. COPD affects individuals differently, but common symptoms include coughing, breathlessness and shortness of breath, limited airway flow, sputum production, wheezing, and chest tightness. COPD can severely affect people's quality of life and is associated with an increased risk of developing heart disease, lung cancer, and stroke.[74]

Self-supporting interventions (e.g., interventions to increase self-sufficiency with the condition such as carrying out disease regimes, changing health behaviours, and emotionally supporting patients) have the potential to reduce the impact of chronic disease, but these interventions have so far reached small portions of the population with COPD.[22] Digital interventions, including video conferencing, electronic medical records, remote patient monitoring and mobile health are potential avenues to increase the reach of these interventions.[22]

A 2021 Cochrane review[22] searched for digital interventions, including mobile and smartphone apps for patients with COPD. The Cochrane review reported no apps had been tested rigorously to assess their evidence for clinical effectiveness or other outcomes.[22]

Examples of emerging COPD apps include MyCOPD, Aeri COPD and Prevexair. MyCOPD was approved by the National Health service of the UK for self-management of COPD and is available in the UK and in New Zealand,[75] but not in Canada. Prevexair (by Virtual Ware) was identified in a number of studies but does not appear to be commercially available to patients yet. The app enables patients to track symptom changes and COPD exacerbations.[76] Aeri COPD was an application created by the Canadian Lung Association and Aeri Health, launched in 2015, but did not appear to exist anymore at the time of this writing. Other than Aeri COPD, there did not appear to be any Canadian-based apps for COPD management.[77]

The COPD Foundation in the US launched an application version of its "COPD Pocket Consultant Guide" in 2019,[78] an interactive version of the guide that could be updated as new therapies are approved for management of COPD. The is a new interactive component which allows for the filling out of a COPD Assessment test or a modified Medical Research Council. This app is available for use in Canada.

Mindfulness for People with Lung Disease

Owens et al. (2018)[79] searched for apps that could promote great mental wellness through mindfulness in individuals who have chronic lung disease, including survivors of lung cancer and COPD. Similar to the mental health apps, there was a lack of scientific support for identified apps and a lack of transparency in the application (e.g., reference to sources of information, confidentiality and privacy, advertising policies, and financial disclosures).[79]

Diabetes

A 2018 global review of diabetes apps found over 1,000 apps focused on the condition in varying languages and for varying countries.[23] A 2017 systematic review regarding mobile apps for the management of obesity and diabetes, found that a quarter of the identified apps used wearable trackers and 21% used mobile apps. These apps provided patient monitoring through information regarding weight management and diabetes management, reminders for medications or diet, feedback for diet and test results, and supportive and motivational remarks. There were positive results for many of the examined apps, but the authors cautioned that the studies included had many limitations such as small sample sizes and short-term follow-ups.[24] Another systematic review published in 2021 found that many mobile apps designed for diabetes were effective in reducing A1C, but this was not consistent between different apps.[25]

Examples of identified diabetes-centric apps include myDiabetes (fitness, education course, monitoring of A1C, connectivity with a clinical team and includes the option to sync external

hardware),[80] FDA approved BlueStar Rx System (Welldoc platform, diabetes management),[81] and Diabetes:M (diabetes management with an artificial intelligence [AI] assistant).[82]

Heart Rate and Blood Pressure

Hypertension is 1 of the most common disorders in the world. High blood pressure is a risk factor for a variety of conditions including cardiovascular disease. Stroke, renal failure, and vision loss.[83] The prevention and monitoring of hypertension is therefore a potentially large market for mHealth, and potentially new smartphone technology may allow for at-home blood pressure measurement and tracking.

Alessa et al. (2019)[12] examined smartphone apps for self-management of hypertension, finding a multitude of apps available to the public through the Apple store and Android store. However, like mental health and COPD apps, there was also a lack of evidence to support the use of these apps and a lack of information on what behaviour change theories the apps were based on. There were also few privacy and confidentiality measures to protect consumer data, leading to potential risk of exposure of health data.[12]

The most common functionalities for these apps were self-monitoring, automatic feedback (i.e., letting patients know if they have diverged from the normal readings), reminders regarding blood pressure measurements, appointments, and medications, communication with health providers and exporting of health data to be sent to health care providers.[12] A small proportion (3.2%) of the identified apps claimed to have included health care providers during the development of the app, and no apps included end users in the development. There was also no scientific evaluation of the apps in practice, and none were FDA or European Union Conformité Européenne (CE) approved.

Additionally, a small number of the identified apps claimed to be able to use the smartphone directly as a medical device to measure blood pressure, by using the camera of the phone. According to a hypertension app content analysis by Kumar et al. (2014), people may preferentially choose and rate these apps higher than other apps, despite there being a lack of evidence to prove accuracy of these methods.[84] In another systematic review examining blood pressure apps, Leong et al. (2019) found that the educational material in identified apps was not comprehensive, and many did not follow recent and updated hypertension guidelines.[85] Additionally, if there was a blood pressure monitor required for use, none were Hypertension Canada endorsed brands.[85]

Atrial Fibrillation

There are a few apps designed to detect and manage atrial fibrillation in patients. Some of these apps require additional devices, such as the KardiaMobile app which requires a finger pad sensor, while others may use the phone's built-in camera such as the CardiioRhythm app (Cardiio) and the FibriCheck app.[13] The Cardiio app includes a machine learning component (support vector machine) to detect atrial fibrillation. There is some evidence of the app accurately detecting atrial fibrillation by using the phone's camera to analyze the face of a patient and without contacting a person's skin.[13] Another method of fibrillation detection using the modern microelectromechanical sensors in a phone is a potentially promising avenue of exploration.[13] The patient lies supine and places the device on their chest. The movement of the phone coupled with the interval between movements is used to determine the presence of atrial fibrillation.

The FibriCheck app is certified by the FDA, CE and TGA[86] It was CE certified in 2017 and was the first heart rhythm disorder application certified by the FDA in 2018. The technology was given semi-continuous heart rhythm monitoring approval by SGS Belgium (Belgian inspection authority for medical devices) and the company plans to expand into wearable devices to continuously monitor atrial fibrillation, including smart earplugs, smart jewellery, and other wearables, and to potentially integrate the technology into existing devices.[86]

Rating Scales

Some identified systematic reviews that included content analyses of apps used validated rating scales to rate the content of apps within their reports.[3,15] The most commonly used rating scales were the Mobile App Rating Scale (MARS)[87] and Enlight.[88] These rating scales include usability, design, engagement from users, content of the app and therapeutic potential. They also include questions regarding the privacy and confidentiality of the app and a ranking of the evidence base for the application.

The authors of Domhardt et al. (2021) noted that the German site MHAD (Mobile Health App Database) is a resource for individuals and clinicians looking to compare the scores for health apps in varying subjects.[15] However, the website is in German with no official English translations. An English (US-based) equivalent for mental health apps, ONEMIND PsyberGuide, is also a non-profit organization that rates mobile health apps based on credibility, user experience, and transparency. Table 3 details additional resources to compare applications and make informed choices when using mHealth.

Table 3: Additional Resources For mHealth App Choices

Group	Type of app
Canadian groups	
The Mental Health Commission of Canada's Mental Health Apps: How to Make an Informed Choice Framework	Mental health apps
The Canadian Medical Association's Guiding Principles for Physicians Recommending Mobile Health Applications to Patients	General health apps
international groups	
American Psychiatric Association's App Evaluation Model	General health apps
Anxiety and Depression Association of America	Mental health apps
Beacon	Mental health and physical health apps
Head to Health	Mental health apps
Health Navigator	General health apps
MHAD	Mental health apps
MindApps	Mental health apps
ORCHA	General health apps
Reachout.com	General health apps
PsyberGuide	Mental health apps

MHAD = mobile health app database; ORCHA = The Organization for the Review of Care and Health Apps.

Operational Considerations

Limited Evidence Base About Safety and Effectiveness

A major operational concern with mobile apps is the lack of clinical evidence to support claims made by app developers about their efficacy.[21] The descriptions in apps routinely state medical expertise and backgrounds that are not supported by the application content or development process.[3] There are limited apps that have been tested in clinical studies, and of those that have been tested in studies, the results are not supportive of their efficacy or there are limitations in their study designs. For example, in a systematic review analyzing mental health apps in 2020, over 94% (1,230 of 1,299 identified) of apps available were not considered to be evidence based.[89] Furthermore, if apps purport to be evidence based and have underpinnings that follow proven principles of behavioural change, health care providers who do not have a specialized background in the subject matter (e.g., in trauma management) might recommend apps that may not have sufficient evidence to assess their effectiveness.[52]

ICER recommended that all manufacturers of digital health technologies should provide "robust evidence of the clinical effectiveness and broader impact… a minimum evidence requirement is high-quality observational or quasi-experimental studies with an appropriate comparator and relevant patient outcomes" (P. 3)[73] A review of studies that assessed safety of health apps found over 80 safety concerns within health apps — including health misinformation (e.g., bipolar disorder is contagious), incomplete information (e.g., missing key information areas for cardiovascular disease), variation in content (e.g., different information required for the same disease in different apps), incorrect outputs (e.g., incorrect diagnoses), and inappropriate responses (e.g., not responding appropriately to suicidal ideation).[90]

A concern for public health in the rapid creation of health apps is the potential for growth that does not meet demand for these apps. It was noted by Freudenberg (2017) that in other business sectors, such as the tobacco industry, alcohol industry, and food industry, a drop in demand has previously led to over production of goods and subsequent aggressive deceptive marketing campaigns. The concern lies in whether a desire for profitability of apps will jeopardize evidence-based claims of effectiveness and lead to greater numbers of misleading claims or unscrupulous marketing for these apps. Some apps may be evidence-based but not as marketable as others and therefore become obsolete over time or removed from the app stores, leaving users unable to access them. Combined with unclear definitions for health apps as medical devices and the lenient regulation of health apps that do not fall under medical devices of health apps, there may be a potential risk that app developers favour profitability over consumer health and safety.[91] Zawati and Lang (2019) stated that in situations where an app's classification as a medical device is debated, it is unclear if Health Canada is able to oversee the sheer number of medical apps that are available, or track future changes in app use and functionality.[2]

Another factor that relates to the efficacy of health apps is their considerations for equitable user experience, accessibility, and engagement. An app may provide useful content, but if it is poorly designed or difficult to use, not all users may be able to benefit.[65] This is especially true for people in different age groups. For example, younger users may need differently designed apps and features to appeal to them than older adults. Meanwhile, older adults may require larger fonts and options for visual and hearing aids, and individuals with disabilities may require additional features to accommodate their needs.[11] Health information and

educational components also need to be appropriately presented to ensure people with diverse backgrounds and varying levels of medical knowledge can reap the full benefits of the apps. These design choices must be made during the development of the application. Many of the identified apps struggled with retention rates for the evaluated apps.[20] This issue with user satisfaction and engagement means that regardless of how well an efficacy study is designed, if the intended users do not use the application, there will uncertainty about the app's effectiveness. A small qualitative realist evaluation that included patients using diabetes apps found that self-efficacy, competing life priorities, successful behavioural changes in the past, and personal beliefs about digital or web-based interventions had an impact on engagement with applications, and therefore clinical outcomes.[92]

Biases and Need for Equity in App Development

There is a potential for different biases to arise in app development if the diversity of users is not considered. For example, AI relies on large datasets to produce algorithms, but if the initial data used to develop these algorithms are biased, the AI will inherently carry on the bias.[93,94] If such technology is inserted into a health app, it will likely affect the outputs of the app. More explicit biases and disregard for diversity can arise during development of apps. For example, the Apple Watch and its companion tracking app were released in 2014, touted as the most comprehensive health tracker with many metrics that individuals were interested in, but distinctly lacked the ability to track menstruation. It took almost a year before menstruation tracking was added to the application.[95]

Lack of regulation of health apps can lead to the creation of apps based on outdated information or information rooted in systemic health disparities that disproportionately affect marginalized groups.[11] There also may be disparities with access to the technology for certain groups of people — without access to a phone, limited or unstable internet access, these individuals cannot take advantage of mHealth. This is especially problematic in certain population groups, such as people experiencing homelessness or people who live in rural or remote areas with limited internet access. For apps that require a fast and reliable connection with the internet (e.g., for video conferencing or sending of files), delivering therapies through mHealth apps may drive health inequity.

There is also a call for apps to be more culturally sensitive. For example, the manifestation and treatments for PTSD can differ widely between cultures,[96] and there can be an underrepresentation of non-Caucasian individuals in research studies for the condition. A review by Drissi et al. (2019) found that many apps for PTSD were only available in 1 language.[49]

The Center for Democracy and Technology[11] recommends that a series of questions be asking during various stages of app development to understand and mitigate biases. Questions should be asked during the initial design phase, during selection or design of health interventions, during identification of user populations, during assembly of the team to create the app, during development of the user interface, and during design of any models that the app will use. The list includes questions such as[11]:

- Does this app have accessible features for disabled people?
- Does your design team include individuals with medical expertise who can evaluate the medical portion of the app?
- Are the interventions included in the application evidence based?

- Have you taken users' needs and opinions into account during the design process?

Privacy and Confidentiality

One of the most commonly cited issues with mHealth apps across all disease fields was the lack of privacy and confidentiality. Many apps did not provide basic patient protections, such as an available privacy policy.[2] This disregard for a privacy policy creates a potential for privacy breaches and unauthorized data releases that would put people's health data at risk.[12] The Online Trust Alliance[97] states that best practices for mobile apps include providing a privacy policy — both within the app and without needing to download the app in plain language (multiple languages, if applicable) that details key data practices, collecting the minimum amount of data needed to make the application work, anonymizing personal data of users, allowing users to access ad preferences, encrypting sensitive information, and using secure code development, among other practices. The Privacy Commissioner of Canada also recommends a privacy policy should be available before downloading an app and that only the minimum amount of data needed for app functionality should be collected.[98]

There is a concern about the lack of regulations regarding sharing of health data to third parties by apps. For example, in 2021, Flo Health Inc., the creators of the Flo application for tracking menstruation, finalized a settlement with the Federal Trade Commission (US) due to sharing users' personal data with marketing firms.[99] There were also concerns regarding privacy with opioid treatment apps available for use, including DynamiCare and reSET-O.[100] The Federal Trade Commission suggests all consumers using health apps consider their options with regard to privacy – asking why the app requires this information, with who and how does the app share the information, if is it possible to control the amount of data that is collected or shared, and if the app is up to date.[101]

Final Remarks

Analyses of app stores and the literature reveal that there are hundreds of thousands of apps related to health conditions. However, many do not have efficacy trials or evidence assessing their effectiveness and many that do not outline the purpose or background to the app with complete transparency. Apps that may not require as much evidence base (such as logging data) will still require testing to ensure usability. Regulations on software as medical devices often outline criteria that is related to the intended use of an application, but in real world use, there may be discrepancies in how a certain app is used in practice. Individual app stores do not carry out strict filtering of health apps to ensure that only evidence-based apps are available. Increasingly, there is a concern for users about the potential privacy and confidentiality issues that apps may create, with many apps not including appropriate privacy policies or apps engaging in the selling of data to third parties. Zawati and Lang (2019) in a commentary paper emphasize the need for health care providers to be aware of these apps and how patients are using them and they suggest that medical faculties acknowledge and teach future physicians on how to navigate the medical field with these apps.[2] Additionally, it will be important to educate patients and the public on how to choose apps that are beneficial to their goals — it will be important to not solely use app store ratings and reviews to judge the trustworthiness and efficacy of an application as these reviews may be inauthentic or inaccurate.[52] The limited oversight of health apps may require an unbiased centralized body that can provide guidance on which apps to choose, and stricter regulations surrounding

proof of efficacy, building of apps on proven evidence-based frameworks, and early testing of apps before public release. Despite these concerns, health apps as a component of digital health will likely see continued growth and expansion. There are many potential benefits to mHealth as technologies improve (i.e., as access to internet becomes more equitable and phone technology improves). If shown to be clinically effective and safe, apps may help increase accessibility, provide cost-savings to people and health systems, and expand the reach of certain health care services, which could be invaluable to many people. Apps also provide a way of tracking symptoms or conditions in real time for health care providers between visits. With the number of apps and reliance on digital health showing no signs of slowing down, regulations and the medical field will need to keep pace with mHealth solutions for patients and consumers.

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