



CME Review

Mobile health applications in clinical practice: pearls, pitfalls, and key considerations



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Overall Purpose

Participants will be able to demonstrate increased knowledge of the clinical treatment of allergy/asthma/immunology and how new information can be applied to their own practices.

Learning Objectives

At the conclusion of this activity, participants should be able to:

- Describe mobile health applications and the potential benefits associated with use
- Evaluate a mobile health application in regards to accessibility, content, and privacy

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Target Audience

Physicians involved in providing patient care in the field of allergy/asthma/immunology

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Introduction

Mobile technology is rapidly transforming the delivery of health care. More than 100,000 health applications (apps) are available for download¹ by the more than 7 billion users with mobile subscriptions.² Advancement in technology often precedes the implementation of government regulation, and clinical practice recommendations lag even further behind when technology is incorporated into patient care. This article aims to inform physicians on the background of mobile health applications, including key definitions, how mobile health applications are currently used by patients and health care professionals, and the potential benefits of this technology in improving patient outcomes. This article also reviews important pitfalls and their implications, including privacy of patient information, content development, and data ownership. Lastly, a simple checklist tool is offered to enable physicians to assess mobile health applications before discussing their use with patients.

Background

A mobile app is software intended for use on a mobile device.³ Within the context of health care, terms such as *health app* and *mobile medical app* are common. The World Health Organization (WHO) has defined the term *mHealth* as medical and public health practices supported by mobile devices.⁴ Apps are created in 1 of 2 ways: a native app is downloaded to the device and can run on a mobile platform irrespective of wireless connectivity but is limited to the operating system for which it was developed (ie, iOS, Android).⁵ In contrast, a web-based app is a software application that can be used across mobile device operating systems but is executed on a server and requires Internet connectivity to run.⁵ Once created, native apps are available to consumers through an online marketplace specific to the operating system of the mobile device, such as iTunes and Google marketplace. Web apps are not available through these stores and require independent marketing.

Health apps are a growing market, projected to be worth 26 billion dollars by 2017.¹ Between 2011 and 2013, a review of apps for asthma found a doubling in numbers.⁶ A recent review of health apps found that most were available from either the Apple store or Google Play, although Google Play has a significantly greater

number of apps available. This difference may reflect the stricter development criteria put in place by Apple to maintain the quality of apps made available through iTunes.⁷

More than a third of physicians recommend mobile health apps to patients,⁸ and services such as iPrescribe and Appscript are used to facilitate the prescription of apps.^{9,10} Forty percent of physicians agreed that apps could improve patient outcomes⁸; however, many indicated they would not prescribe apps because of perceived lack of regulatory oversight.¹¹ Although physicians may not be prescribing mHealth apps, it is estimated that 1.5 billion mobile device users worldwide will use mobile health apps by 2018.¹² App use is increasing among children, even those in lower socioeconomic households with lower rates of smartphone and tablet device ownership.¹³ A 2015 survey found that nearly all (91%) teens used mobile devices and nearly one-quarter reported downloading mHealth apps.¹⁴

Most apps interact well with social media platforms, such as Twitter and Facebook, and several apps are specifically designed for easy sharing of a patient's weekly statistics. In addition, many mHealth apps promote themselves through advertising on social media channels, thus increasing their use. Unique to social media is the use of a hashtag before the search term, allowing for ease of search to locate topics, which is used by many for frequent searches (eg, #asthmapatients). Not-for-profit organizations, such as Allergy & Asthma Network, have developed mHealth apps for asthma monitoring. Patient advocacy groups, such as The Lung Association and the American Thoracic Society, have created accounts on social media platforms to promote information about apps for asthma on their websites. Social media is a natural extension of mHealth, and more than 40% of consumers say that information found via social media affects the way they deal with their health.¹⁵

Benefits of mHealth Apps

Mobile devices and mHealth apps provide an accessible and convenient means for the user to interact with the health care system, facilitating patient control of health information while simultaneously reducing the burden and cost associated with health care delivery. Most mHealth apps focus on disease

prevention and promotion of healthy lifestyles by tracking health behaviors, such as diet and exercise.¹⁶ The current literature suggests that mHealth apps promoting behavioral changes have led to improvement in health outcomes, including body mass index and hemoglobin A_{1c} levels.¹⁶ The use of mHealth apps can reduce the number of patient visits, maximizing convenience to the patient while minimizing cost to the health care system.^{16,17} mHealth apps may further support physicians caring for children and adolescents with chronic diseases, such as asthma. A systematic review to determine whether mHealth apps may support the transition to self-care is currently under way.¹⁸ These results will be of interest to allergy and immunology specialists, as many allergic and immunologic conditions with onset in childhood persist in adult patients. The ultimate goal of mHealth app technology is to share information between the mobile device and a patient's electronic medical record (EMR). Although the technology is available for this information sharing to occur, barriers include a lack of EMR standardization and the inability to process such large volumes of information.¹⁹

mHealth Apps for Allergic Diseases

Currently, there are no published appraisals of mHealth apps targeting allergic disease, although apps for asthma are numerous and have been reviewed in detail.^{6,20} Table 1 summarizes a search of popular app marketplaces using terms relevant to allergic disease. These numbers reflect all apps returned using the search words described and that are available for download in Canada. Many apps returned in the search were in fact unrelated to the disease searched. For example, the Yoga for Fertility app was included among Google Play results for eczema, and of the 1646 results listed under food allergy in the BlackBerry App world store, nearly all were recipe- and restaurant-related apps. Advanced search options were not available. These findings reflect the challenges faced by patients when searching for apps relevant to their allergic conditions.

Navigating the mHealth App Industry: Key Considerations

The potential for mHealth apps is exciting; however, caution is required because development and technology outpace our ability to evaluate privacy, safety, and efficacy of interventions. Assessment of mHealth app quality is analogous to critical appraisal of scientific literature as part of evidence-based medicine. To properly assess safety and appropriateness of mHealth apps for patients, physicians must consider the authors, conflicts of interests, accessibility (literacy, platform, cost, and maintenance), health information handling, privacy, content accuracy, and evidence for outcomes. Below, we have outlined key considerations for mHealth

app appraisal covering the major themes of accessibility, privacy, and content.

Accessibility

- Language, health, and computer literacy may pose barriers to patient mHealth app use.
- mHealth app use may be limited by access to a mobile device or a particular platform.
- Cost is less likely to be a barrier to access.

To promote widespread change in health care delivery and patient outcomes, mHealth apps must be universally accessible. Low health literacy is associated with reduced preventive care and earlier mortality,²¹ and those with low health literacy are more likely to have poor computer literacy.²² Suggestions for developers outlining features that can facilitate mHealth app use by those with low computer literacy are available.²³ Language may pose an additional barrier for use in non-native English speakers. Literacy and language are important in review of the mHealth app's privacy policy: many privacy policies are difficult to find and use complex language, placing patients with lower literacy levels at increased risk of privacy and health information breaches. Effective mHealth apps should be available across all platforms to ensure accessibility to all patients. Currently, the smartphone market is led by Android phones, followed by iOS (Apple).²⁴ Lower income households are less likely to have a smartphone or tablet device, although this disparity appears to be improving among certain demographics, particularly teenagers and young adults.^{13,14} Most mHealth apps are free, and most that charge per download are low cost.^{6,25} Among asthma mHealth apps, the number of free apps featuring advertising within the app is increasing,⁶ suggesting accessibility is traded for consumer-directed marketing and industry bias. Cost does not appear to be a reliable indicator of content but may affect clarity of language and organization, which are important for those with poor health literacy.^{20,26} mHealth app maintenance and longitudinal accessibility are imperative if they are to be recommended as part of a treatment plan. An updated review of asthma apps revealed that more than 25% of apps reviewed in their initial study had been withdrawn only 2 years later.⁶ Language, health literacy, platform-specific availability, cost, and upkeep should be considered when determining accessibility to a patient population.

Privacy

- Digital information legislation does not cover all mHealth apps.
- Apps often share poorly secured information with third-party consumers (including insurance companies and advertisers).
- Even nonidentifiable information can be identifying through data triangulation techniques.

Many physicians are unaware of information privacy concerns relating to use of mHealth apps and mobile devices in general.²⁷ In the United States, digitized health information is covered by legislation, including the Health Insurance Portability and Accountability Act (HIPAA),²⁸ the Computer Fraud and Abuse Act (CFAA),²⁹ and the Children's Online Privacy and Protection Act (COPPA).³⁰ HIPAA was created to protect privacy of digital health information²⁷ and applies to electronic health records, health care plans, health care clearinghouses, and any health care professional who transmits health care information electronically.²⁸ HIPAA applies to mHealth apps functioning within a medical institution³¹ and may apply to information transmitted between an app and health care professional,²⁸ such as an asthma app that monitors inhaler use and relays this information back to the patient medical record. The CFAA functions to prevent unauthorized

Table 1
mHealth Apps Searchable Through Popular App Stores Accessed From Canada, September 2015^a

App	No. of apps							
	Anaphylaxis	Allergic rhinitis	Food allergy	FPIES	EoE	HAE	Allergy	Eczema
Google Play	67	49	138	0	7	12	250	148
iTunes	16	6	100	0	1	2	100	56
Windows Marketplace	1	1	4	0	0	0	20	1
BlackBerry World	1	2	1646	0	0	0	16	1
Nokia app (Softonic/Ovi)	0	0	0	0	0	0	0	1

Abbreviations: EoE, eosinophilic esophagitis; FPIES, food protein-induced enterocolitis; HAE, hereditary angioedema.

^aSearched using the terms identified above, across all categories, limited to the Canadian market.

access of a computer to retrieve patient information. Although the CFAA applies to the access of hospital databases, its extension to private use of health apps remains unclear.³¹ COPPA was enacted in 1998 to protect the personal information of children younger than 13 years and requires that any information shared requires express consent from a parent or legal tutor/guardian.²⁹ In Canada, personal information is governed by the Personal Information Protection and Electronic Documents Act (PIPEDA), except in provinces where similar provincial legislation exists (Quebec, British Columbia, and Alberta).³² According to the Federal Court of Canada, identifiable information includes anything that could potentially be used to recognize an individual, either alone or in combination with other available information.³³ PIPEDA applies to commercial activities. It does not extend to the use or disclosure of identifiable information by an individual for personal use, such as user collection of information within a lifestyle app that is then shared via social media.^{32,33} mHealth app privacy policies, where they exist, are based on this legislation. The key features of privacy policies are summarized in Table 2. For more comprehensive information, see previously published reviews.^{27,34}

Despite government legislation and guidelines for app developers,³⁵ poor handling of health information is prevalent among mHealth apps. A review of mobile health and fitness apps found that 26% of free apps and 40% of paid apps had no privacy policy in place.³⁶ Even when a privacy policy exists, most fail to provide nontechnical information regarding precisely what data are shared and with whom,³⁶ and placement of the privacy policy agreement as a barrier to app access discourages careful review by users.³⁷ The office of the Privacy Commissioner of Canada has recommended that app developers make privacy policies available for review before app download.³⁸ Although apps may claim to meet privacy requirements, in the absence of enforcement, many do not actually comply.³⁹ A review by the US Federal Trade Commission (FTC) found that developers of 12 mobile health and fitness apps shared user information with 76 different third parties, including advertisers.³⁶ Of concern, analysis has revealed that release of consumer information that is not specifically

identifiable, such as exercise routines, dietary habits, and symptom searches, could be aggregated and subsequently used to identify individuals.⁴⁰ The FTC review also revealed that most apps studied posed a significant privacy risk through insecure handling of patient data. Most apps stored data locally in an unencrypted format and sent these data through a nonsecure format to both developers and third parties.³⁶ The FTC has recently taken action against an app in breach of COPPA regulations. The operators of Path, a social networking app, paid an \$800,000 settlement after charges of breach of personal information after failing to provide parents with consent for collection and use of their children's personal information.⁴¹

In addition to security concerns with data storage, transmission, and third-party distribution, physicians must consider the relative safety of health information on portable devices themselves. Smartphones, tablets, and wearable devices that contain health care information are targets for thieves.^{42,43} Before the release of the Apple watch, the US Attorney General summarized privacy-related concerns.⁴⁴ In response, Apple revised their privacy policy for new app developments seeking to sell apps on the iTunes store,³⁵ barred developers from sharing health data collected via Apple devices with advertisers, and stipulated that health information may no longer be stored on shared cloud servers.³⁵ Even with these changes in place, reasons for concern remain: previous research found that a third of apps evaluated known to share information with third parties did not disclose the release of information,³⁶ and Apple's new guidelines do not require app sellers to account for third-party disclosures they make.⁴⁵ It remains unclear whether Apple intends to apply this new privacy policy to the existing apps in its store. mHealth apps sold through the Google Play store do not have to meet even these seemingly basic privacy requirements.

Content

- mHealth app authors may have conflicts of interest that influence content.
- Most mHealth apps are created without medical expert involvement.
- Inaccurate medical content within mHealth apps may place patients at risk of harm.
- Monetization practices, including in-app advertising, should be considered.

Content within mHealth apps includes the material within the mHealth app accessed by the consumer and the data entered into the mHealth app by the consumer. mHealth app content is influenced by a number of factors, including the identity of the development team, inclusion or consultation of expert advisers, monetization strategies, and presence of associated parties, including businesses, interest groups, and institutions. In addition to considering these factors, physicians should be aware that most health apps reviewed to date do not adhere to medical evidence, and content sources are poorly described.

Medical Content Within an mHealth App

Understanding app authorship may facilitate the recognition of personal or financial interests that may influence content. Medical expert consultation is currently poorly represented in app development, with a systematic review reporting involvement in only 33% of apps reviewed.⁴⁶ Other reviews have noted similarly poor representation of medical centers or academic institutions in app development.^{25,47} A systematic review of asthma apps found that more than half contained content copied from freely available online resources without reference to original content and 35% provided this low-quality information in an advertisement-supported

Table 2
Privacy Requirements for mHealth Apps Based on Existing US and Canadian Legislation^a

Data covered	• Identifying information (identification numbers and physical, physiologic, mental, economic, genetic, social, medical, or cultural factors relating to the past, present, or future of the patient)
App users ^b must be informed about	• Identity of those who can access or use personal health information • Reason for collection of health information • Privacy practices of those collecting the information • User right to access and modify data • Contact method for questions or complaints
Data storage	• Health information should be kept for the minimum necessary period • Health information must be deleted when use is finished • A clear information storage policy including security should be described
Security	• Health information must be protected from unauthorized loss, access, or disclosure
Notification in case of breach	• Users and relevant authorities must be notified in the event that personal health information is breached • In the event of a massive breach, media should be notified
Data transfer	• User consent is required before transfer of personal health information to a third party

^aTable adapted from Martínez-Pérez et al.²⁷

^bInformation must be provided to the patient or to parent/legal tutor if younger than 13 years.

Table 3
Physician Tool and Checklist for Assessment of mHealth Apps

Criteria for evaluation	Benchmarks of a high-quality mHealth app
Is authorship easily identifiable and are the stated affiliations and endorsements evident?	• Creator and developer are identifiable • Affiliations and endorsements are evident • Medical expert involved in development
Is the app accessible with respect to language, health literacy, and technology literacy?	• Plain language • Clear content display • Engaging and interactive content • Source of medical information content is clearly visible in app and referenced
Is the content consistent with evidence-based medical literature or current best practice/standard of care?	
Is the app free or does it cost? Does advertising within the app contribute to bias or conflict of interest?	• No advertising within the app • No commercial sponsorship • No perceived conflicts of interest or bias
Is the mHealth app licensed by the Food and Drug Administration or Health Canada; is it endorsed by an academic institution or medical professional organization?	• Licensing obtained through a government agency • Endorsed by an academic institution or professional medical organization • Health apps that have undergone peer review
Is there a privacy policy stating information will be encrypted and not shared with third parties?	• A privacy policy exists and is easy to read and understand • Data encryption should be standard • No data sharing with any third parties • Unnecessary data collection is minimized; collects only what is needed for core function of the app • Clear data destruction policies are described • Parental/guardian permission is described in privacy policy
Is there a clear requirement for parental/guardian permission for apps directed at children and adolescents?	
Is the app functional over time with recent updates?	• Recent version or update within the last year
Are consumers notified in the event of a breach of privacy and health information?	• Consumers notification described in privacy policy • Contact method for further questions or complaints is listed
Is there a way for consumers to contact the app?	• Consumers receive replies when questions put forward to app contact listed

format.⁴⁶ Huckvale et al⁶ noted that a few apps emphasized evidence-based management tools, such as asthma action plans, but many included recommendations without clear scientific basis. Some contained information that could cause direct patient harm, such as incorrect use of inhaler devices.^{6,20} A systematic review of adherence to medical evidence in mHealth apps evaluated 6520 apps in 52 studies, spanning a variety of medical specialties.⁴⁶ Less than half of included studies documented the variable (10%–87%) adherence to evidence, whereas most studies found that none of the apps adhered fully to evidence.⁴⁶ Furthermore, of asthma apps reviewed, 23% had some combination of alternative and conventional medical information, whereas 28% provided isolated alternative health information.⁶ Alternative content was prevalent in our search for food allergy apps, including one advertising “pressure point massage” for treatment of allergies.⁴⁸ The poor quality of medical content within mHealth apps perpetuates misinformation, clouds the ability to study the effect of apps on health outcomes, and, most seriously, places patients at potential risk for harm. Standards do not exist to ensure clear labeling of app authorship and associated sponsors. Physicians should be aware of branding and advertising within any recommended apps and counsel patients about the possible effect this may have on content.⁴⁹

Government Regulation of mHealth Apps

In the United States, claims about mHealth app function and content are regulated by the Food and Drug Administration (FDA),³¹ which can enforce its mandate through civil and criminal penalties, along with forced removal from the app store.³⁴ The FDA updated formal guidelines in 2015.³ mHealth apps are considered to be software devices and are classified according to claims about their use and associated risk. The FDA intends to regulate apps that could threaten patient safety in the event the app fails to function as intended and includes apps that engage in diagnostic assessment and treatment recommendations.³ Similarly, Health Canada requires licensing of health apps as medical devices under the Canadian Food and Drugs Act, which applies to any apps sold, imported to, or distributed in Canada.⁵⁰ At present, the FDA and

Health Canada do not regulate mHealth apps without diagnostic and therapeutic function. The FTC functions to protect consumers from unfair practices and has demonstrated its willingness to act on false claims made by mHealth apps. The FTC reprimanded 2 health apps on the basis of unsubstantiated claims, including curing acne⁵¹ and assessing melanoma risk.⁵²

Empowering Physician Specialists in Reviewing mHealth Apps

Given the overwhelming volume of apps and the relatively limited regulations currently in place, physicians need effective strategies to assist with mHealth app evaluation. Strategies should be accessible and sustainable and follow industry and professional standards for safety, accuracy, and security.

Government and Professional Association Involvement

The UK's National Health Service maintains its own library of health apps⁵³ and features programs considered to be medically trustworthy after review by medical professionals.⁵⁴ The Kitemark quality certification designation, owned by the British Standards Institution Group, is now being applied to health apps to provide the consumer with an additional means of identifying high-quality products.⁵⁵ Presently, there are no consistent means of labeling health app quality for consumers within North America, although physicians have been encouraged to contribute to a repository of “health-e-apps.”⁵⁶ The Canadian Medical Association has released general recommendations for using health apps in clinical practice.⁴⁹

Patient Advocacy Groups

Patient advocacy groups have also played a role in screening and selecting apps. The 2012–2013 European directory of health apps was compiled and recommended by patient groups,⁵⁷ and in 2013 a company representing patient groups launched the online resource myhealthapps,⁵⁸ which featured searchable apps recommended by patient and consumer groups.

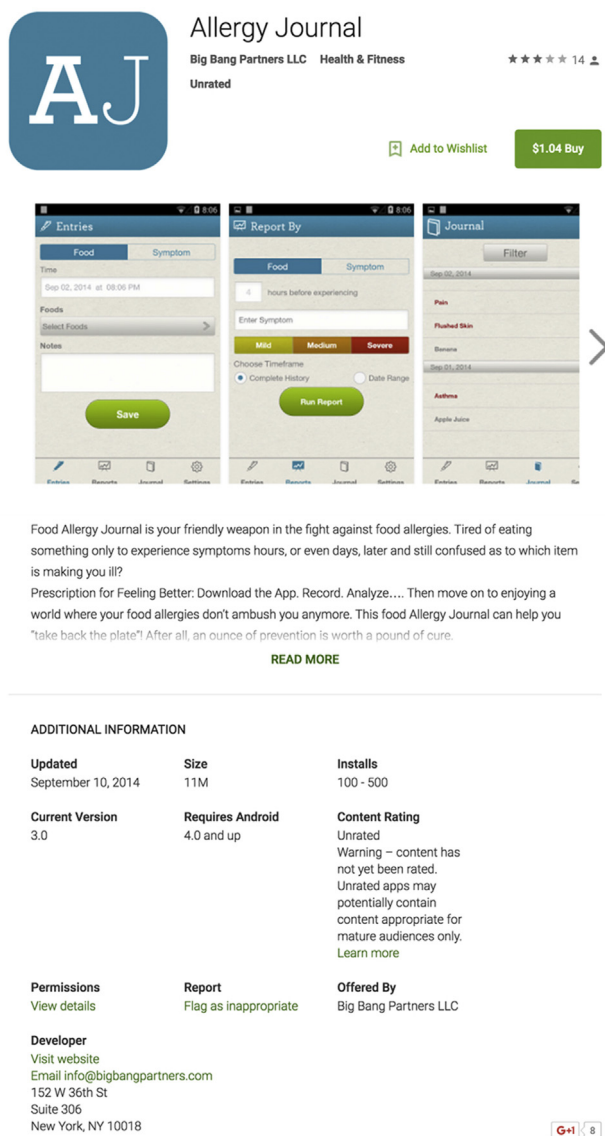


Figure 1. A visual guide to mHealth app assessment. Example of Android app description accessed through the Google Play store via web browser. The app seller identity is listed beneath the product name, and the price is displayed on the main screen. The Android app store displays additional information, including date of last update, number of installs, developer contact information, and links to the developer web site lower on the same page. Android and Google Play are trademarks of Google Inc.

Commercial Services

Several commercial services are available to assist physicians in selecting and electronically prescribing apps that may benefit their patients. iPrescribe apps⁹ allows physicians to search according to disease and have the selected apps electronically delivered to patients along with instructional videos to facilitate use. iPrescribe apps does not require payment from developers for apps to be listed and is the only service run exclusively by physicians.⁵⁹ A similar product called Appscript was created by IMS Health, a global information and technology service company and also the largest vendor of physician-prescribing data.^{10,60} This program lists apps based on a proprietary system that incorporates customer ratings, number of downloads, and prescribing patterns. Enrolled physicians can search apps and electronically prescribe them to patients.⁶¹ This website provides app developers the option of

submitting apps for priority review,¹⁰ which raises concern about commercial influence on app recommendations.

A Tool for Physicians in Reviewing mHealth Apps

Health care professionals have a responsibility to critically evaluate mHealth apps before recommending their use by patients. The following checklist summarizes the key considerations described in this article may be used as a tool to assist physicians in reviewing mHealth applications (Table 3). Benchmarks of a high-quality mHealth app are also included. On review of an mHealth app, any noted deficiencies, including privacy concerns or inaccurate content, should be carefully reviewed with patients to minimize possible harm and to allow patients to make an informed decision regarding mHealth app use. For a visual guide in evaluating mHealth apps, refer to Figure 1.

Conclusions

mHealth apps are changing how health care is delivered, and the influence of mobile health will continue to increase exponentially in response to patient needs, overburdened health care systems, and the commercial interests of this multibillion dollar mHealth app industry. Although the possibilities for the use of mHealth apps within patient care are exciting, concerns surrounding accessibility, privacy, and content require rigorous oversight and regulation if mHealth apps are to be widely adopted by physicians and applied to clinical care. The checklist offered here provides a starting point for mHealth app appraisal by physicians. The intent of the checklist is to guide dialogue between physicians and patients to ensure consumers are aware of the benefits, risks, and limitations of health app use. As with all interventions, use of health apps requires longitudinal monitoring to ensure safe and appropriate use and thereby minimize potential harm.

Despite the many current pitfalls of mHealth apps, it is clear that within the physician competencies of health advocate and medical expert, physicians have a key role in the development of mHealth apps and effecting change in policy to ensure patient safety and accountability toward privacy of health data collection. Moving forward, physicians should aim to develop minimum standards for health app literacy, lobby for safe and appropriate data handling of patient information, research and develop mHealth apps using evidence-based medical content, and advocate for funding devoted to rigorous evaluation of health app effect on patient outcomes.

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