I. Introduction

“Smart” was added to smartphones in the early twenty first century and since then it has changed the way we live. Complex mobile applications, fondly known as apps, have altered the way we travel, bank, communicate and it is inexplicably going to change the way we manage our health. Smartphone technology provides promising ways for us to have more affordable and effective healthcare. The mobile health app (mHealth app) landscape is rich with apps eager to address healthcare needs for patients and providers. While most health and fitness apps function primarily to instruct or inform users and/or record their health information, they are projected to expand into more clinically focused functions (e.g., counseling, diagnosing). The Food and Drug Administration (FDA), which currently regulates a small group of mHealth apps considered more risky to the public, must correspondingly evolve new regulations to deal with the changing mHealth app functionalities. These functionalities may include apps that help a patient self-manage disease or conditions such as diabetes, high blood pressure and obesity. Current FDA regulations, which exempt certain mHealth apps from regulatory oversight, are not enough to deal with future projected growth of mHealth apps. As the volume and functionalities of mHealth apps on the market increase, they introduce technical, data privacy, efficacy, legality and scope of practice issues.

The aims of this paper are to:

- Describe the current climate of mHealth apps and its future trajectory;
- Discuss the gaps in mHealth app regulation;
- Explore the issues faced by various stakeholders;
- Provide basic recommendations for stakeholders to make mHealth apps safe and effective tools for patients and providers.

II. Background: Smartphone Technology Penetrating the Healthcare Field

Mobile phone and smartphone technology is widely adopted by the global community and will continue to grow. To date, there are seven billion people worldwide and six billion mobile phone subscriptions [1] showing that mobile technology is reaching saturation point in the market. While mobile phones have the limited capacity to purely communicate (e.g., phone calls and text messages), smartphones are a specialized mobile phone capable of being a miniature computer. The smartphone era began in 2002 with personal data assistants (PDAs) introduced by IBM Corporation but this technology did not take off until 2006 when Apple introduced its first iPhone. A 2013 Nielsen Report estimate 40% of the U.S. population has a smartphone. This figure, which began at 5%, rose to 40% in the span of four short years making it one of the quickest adopted technologies in human history [1].

The current smartphone capacity and complexity makes it useful beyond communication: Smartphones provide Internet access and geo-positioning and can serve as a high quality camera and recording device. Platforms like iOS and Android enables access to rich and complex mobile applications (apps) targeting varied user needs—finance, entertainment, news, health and fitness, and so forth [2]. Apps that address health and wellness are known as “mobile health apps (mHealth apps)” and they are poised to commercialize and monetize in the near future. Research2Guidance, a market research company focusing on the global app economy, found market revenue for mHealth apps was US$2.4B in 2013 and projected it would grow to US$26B by 2017 [3].
Because of the smartphone’s rapid penetration into the U.S. market, there is great “app-ertainment” for this technology to symbiotically collaborate with another giant industry: healthcare. Research2Guidance estimates that 500 million smartphone users worldwide will be using a healthcare app by 2015 and by 2018, more than 3.4 billion smartphone users will have downloaded a mHealth app [3]. Technology bears blame for increasing America’s rising healthcare costs but it can also mitigate that through promising approaches like electronic health records, telemedicine, telehealth and mHealth apps.

III. Current Landscape of mHealth Apps: From the perspective of healthcare providers

The IMS Institute for Healthcare Informatics’ 2013 report “Patient Apps for Improved Healthcare” provides a good backdrop to help us understand the mHealth app landscape from the perspective of healthcare providers. This report was published as recently as October 2013 and included an analysis of health apps by the IMS Health Team comprised of medical collaborators. They analyzed 43,689 apps in the “Health & Fitness” category of Apple’s App store and excluded 20,007 apps because these were considered gimmicks with no health benefits [4]. Only 23,682 mHealth apps were deemed beneficial and of these 7,407 were directed at healthcare professionals while 16,275 were directed at users/patients. These mHealth apps were categorized non-exclusively into seven functionality bins: 1) informs, 2) instructs, 3) records, 4) displays, 5) guides, 6) reminds/alerts, and 7) communicates. Figure 1 comes from the IMS Institute of Healthcare Informatics and shows the abundance of apps by functionality. Most apps are developed to inform, instruct or record with very few delving into the other functionalities.

"An analysis of 16, 275 consumer-focused mHealth apps showed most apps INFORM, INSTRUCT or RECORD. They have the potential to grow in other functionalities."

![Figure 1: Functionalities of Consumer-focused mHealth apps](image)

Given that mHealth apps revolve around these seven functionalities, the IMS Team believes that the best benefit to befall users would logically follow this scenario displayed by Figure 2:

![Figure 2: How users benefit from mHealth apps](image)
As Figure 2 logically points out, these providers want mHealth apps to collect health data that is then used to 1) supplement patient-provider interactions, and 2) help patients reach health goals. To understand how mHealth can achieve these, the IMS Health Team classified consumer-focused apps based on where they fit on the “patient journey” (see Figure 3). The patient journey is “how patients experience a disease or condition from their first awareness of symptoms through all stages of diagnosis and treatment; culmination in a cure, remission or worsening of the condition” [5]. Of the 16,275 mHealth apps, 14,428 apps were relevantly placed on the patient journey [4]. Clearly, the market is skewed towards apps focused on prevention/healthy lifestyle, which coincides with the scope of dietitians and is the main focus of this paper.

Dietitians and healthcare providers are eager for mHealth apps with improve functionalities that can fill in the gap of the patient journey, but the current landscape is mired with obstacles. Existing obstacles blocking mHealth apps from maximizing their usefulness include a lack of evidence proving mHealth app efficacy. Moreover, the use of smartphone technology is heavily skewed towards younger age groups but it is older adults that incur more healthcare costs. According to the Pew Research Center, in 2014, 97-98% of adults age 18-49 years old own smartphones compared to 88% in adults age 50-64 and 74% of adults age 65+ [6].

Certainly, mHealth apps will not be useful to populations that are technologically illiterate, and even for those who are technologically literate and have access to smartphones, navigating mHealth apps is a confusing affair. Current app stores are plagued with misclassified and gimmicky (e.g., they do not confer medical benefits) apps. App developers, public health leaders and healthcare professionals alike must address these obstacles if they want mHealth apps to be a powerful tool in the patient journey.

From the perspective of providers, the IMS Institute of Healthcare Informatics team points to six issues that all health professionals should consider when prescribing apps to patients [4]:

a) **LEGAL:** Does my institution endorse the app? Who is liable if the app is recommended?

b) **CHOICE/RATING:** Which app is most relevant to my patient and how good is the app?

c) **INFRASTRUCTURE:** How do I go about prescribing the app?

d) **REGULATIONS:** Who regulates this app? Is it safe for me to recommend the app to patients?

e) **DATA PRIVACY/SECURITY:** Can I be confident that my patient’s data is stored in a HIPAA complaint manner?

f) **REIMBURSEMENT:** If the app is paid then will my patients pay for it or can they be reimbursed by insurance?
As healthcare providers, dietitians must also consider the above six issues when prescribing or assigning mHealth apps to their clients.

Currently, the Academy of Nutrition and Dietetics, the largest organization for dietetic professionals, has not issued an official position paper for the use of mHealth apps to aid users/patients. Generally, the organization appears supportive towards dietitians using mHealth apps as supplemental tools for counseling patients. The Academy’s website features reviews for three nutrition-related app types including weight loss, diabetes and eating gluten-free [7]. Additionally, the Academy spotlights entrepreneurial dietitians that publish books reviewing apps available for purchase. Case in point: Catherine Frederico, MS, RD, LDN’s book “An App a Day” is available for purchase on her website and while it offers a good jumping point for finding “credible” apps, a book is not an ideal app delivery method since the mHealth app landscape is constantly changing. Still other dietitians like Elle Penner, MPH, RD (the MyFitnessPal dietitian) participate directly in the mHealth field by lending expertise to help developers create new app features.

In sum, the current landscape of mHealth app is relatively new and biodiverse making it difficult to traverse: there are so many different mHealth apps out there how do we, as patients/users and providers, know which ones to choose? This questions along with other concerns voiced in this section must be addressed by healthcare providers, policy makers and app developers alike before mHealth apps can be a powerful and effective tool for patients and providers. As the mHealth app field matures, regulation is necessary to oversee their scope and ensure this balance: that the public is not unduly harmed and that innovation is not stifled. It is this very balance, which makes FDA regulation of mHealth apps controversial.

IV. Food & Drug Administration (FDA) Policy: Regulation of Mobile Medical Apps

The Food and Drug Administration (FDA) asserts a public health responsibility to oversee the safety and effectiveness of medical devices, which includes mobile medical apps [8]. In September 2013, the FDA passed its final guidance for mHealth apps, which focuses regulation on mHealth apps that pose a greater risk to patients/users if they do not work as intended [8,9]. mHealth apps will be regulated by the FDA using a risk-based approach wherein apps that pose a greater risk to patients/users must bear more administrative burden. The three tiers of regulation are [9, 10]:

**CLASS I “LOW RISK”:** App is subjected to general controls but require no pre-market submission before releasing. To have general controls in place the app developer must assure the FDA they will prevent adulteration and misbranding, register the app, notify prior to market release and keep records/reports for these activities. The FDA has the right to ban devices it finds risky and force companies to repair replace or refund consumers if the device is found unduly risky [11].

**CLASS II “MODERATE RISK”:** App is subjected to special controls and requires submitting a notification document under section 501(k) of the Food Drug & Cosmetic Act (FD&CA). This document helps the app claim it is “substantially equivalent” to an existing app in class II and therefore does not need stringent regulation. Special controls means meeting general controls plus having: performance standards, post-market surveillance, patient registries, special labeling requirements, pre-market data requirements and guidelines for how app will be used [11].
**CLASS III “HIGH RISK”:** App is subjected to general controls and must get pre-market approval from the FDA. Premarket approval means the FDA will conduct scientific and regulatory review to evaluate safety and effectiveness before market release [12].

mHealth apps that are considered “mobile medical apps” will meet the definition for a “medical device” in section 201(h) of the FD&C Act [9, 13, 14]. An in-depth definition is provided in “Legal Lingo.” On the risk continuum, apps classified as class III are high risk because they’re meant to sustain or support human life while an app classified as class I may not be intended for this [12]. If a mHealth app is a medical device, it should and is regulated but what remains contentious are the many mHealth apps without FDA oversight.

In order to decrease regulation burden, the FDA created a category for apps that meet criteria for “enforcement discretion.” This category is separate from the class I-III risk categories described above so if a mHealth app meets this special category it will be exempt from regulation altogether. A number of mHealth apps falling into the FDA’s “enforcement discretion” category are intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases and conditions. These apps will not be reviewed by the FDA and include those that [9, 14]:

1. **Help patients self-manage disease or conditions without providing specific treatment or treatment suggestions.**
2. Provide patients with simple tools to organize and track health info.
3. Provide easy access to info related to patient’s health conditions or treatments.
4. Help patients document, show or communicate potential medical conditions to health care providers.
5. Automate simple tasks for health care providers (e.g. BMI calculator).
6. Enable patients or providers to interact with Personal Health Record or electronic health records (EHR) systems.

The first category for enforcement discretion is particularly pertinent to dietitians since these apps can “provide or facilitate supplemental clinical care, by coaching or promoting to help patients manage their health in their daily environment [10].” Patients can potentially receive coaching for cardiovascular disease, high blood pressure, diabetes, overweight/obesity, forming healthy eating habits and much more. This could breach on a dietitian’s scope of practice if non-registered dietitians are used as coaches [15]. While these mHealth apps are still treated a supplemental to professional clinical care advice, patients are prompted to wave their rights to litigate when they use these apps. Given the complexity of chronic diseases aforementioned, are these apps completely low risk? If not, what steps must be in place to protect patients/users? How will dietitians deal with the issue of mHealth apps that cross into their scope of practice? Will the relationship be supplementary, complementary or competitive? To answer these questions and many more we must explore gaps in the way that mHealth

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**Legal Lingo: “Medical Device”**

*An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

a) Recognized in the official National Formulary or the United States Pharmacopoeia, or any supplement to them,

b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

c) Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.*

*Source: FDA: “Is your product a medical device?”*
apps are currently created, distributed and used. These gaps will be classified into five areas: technical, data privacy, efficacy, legality and scope of practice.

V. Discussing the Gaps

Technical

As mHealth apps gain mass popularity, app developers must design features to reflect concerns for the user’s experience and data security. Users including patients and providers must demand that the following be addressed [16]:

1) **Connectivity**: how well connected is the app to the Internet and will disconnection disrupt service?
2) **Data integrity**: can electromagnetic interference with the phone corrupt data received and transmitted and what implications does it have?
3) **Data security**: is the information safe from cyber-attack, malware, viruses, etc. and can data be traced to the user?
4) **Updating protocol/procedures**: will the app require updates and security patches and how crucial are these things to make the app work safely for users?
5) **Display size/resolution**: could this distort information and lead to riskier outcomes?
6) **User-friendliness**: is the app designed for an intuitive user experience? Does the app have a clean and fun presentation? Does it quickly respond to users?

While most of the solution remains in the court of app developers, dietitians and other healthcare providers can step up by offering their expertise to mHealth app development companies. This way future app features will be better equipped to suit the needs of patients and providers.

Data Privacy

As for data privacy, HIPAA considers “protected health information (PHI)” as health information whether oral or recorded by a health care provider, health plan, public health authority, life insurer, school of university or health care clearinghouse that relates to the past, present, future physical or mental health of any individual [17]. Information kept by these mobile medical apps does not meet the criteria of PHI because they are not created by the aforementioned entity but the type of data that apps keep can be similar to those recorded by these entities (e.g., blood glucose, blood pressure, identifying health information like names, DOB, addresses). Therefore, mHealth apps targeting users with chronic conditions (e.g., diabetes, heart disease) should be subjected to similar levels of confidentiality that HIPAA imposes on other entities. Yang et al. suggests that mHealth app companies be considered an entity for whose records would count as PHI. He asserts that this threat of privacy liability will incentivize these companies to adopt policies minimizing data breach [18]. Not all information might require this level of protection, so in order to understand what data does need protection, new rules and regulations should be drafted involving all pertinent parties.

Efficacy

In a study by Buljink et al, researchers claimed that mHealth apps lack evidence, which undermines quality and safety for users [19]. The researchers stated two studies in dermatology and microbiology that less than 35% of medical apps had medical experts involved. 86% of 111 pain
management apps did not have medical professional involvement. A pharmaceutical app was recalled because it provided a different disease-severity score than those from calculated with an official formula (no harm to patients to date). Additionally, there is conflict of interest if pharmaceutical companies come up with apps for providers.

Buljink et al. suggests that we need to increase app safety by increasing transparency [19]. Given that the IMS Healthcare Informatics team found only 23,682 (54%) out of 43,689 “Health & Fitness” apps had useful benefits, there should be a system to help providers and users/patients navigate the app maze [4]. Buljink et al. suggests peer reviewed systems for mobile medical apps so that providers can have tried and true apps to recommend to patients. Additionally, Buljink et al. suggested that all mHealth app developers should register their app in an international app registry and submit premarket notifications to accrediting bodies and medical experts who can establish safety and effectiveness. While this is a prudent method the researchers conceded it would decelerate innovation in this industry.

Cortez et al. believes that FDA should regulate apps that incorporate clinical-decision support. They would like to see a post-market surveillance system since apps are likely to evolve in the direction of offering medical advice or suggestions [10]. Currently, there are apps in development and in the market that offers nutrition advice to users. Having a post-market surveillance system in the works will be a way to monitor if the FDA needs to up the ante with their regulation. Given the newness of the mHealth app industry, it is best to have a post-market surveillance so as not to dampen innovation.

Legality

As previously discussed, mHealth apps are beneficial to healthcare but not all apps meeting the “discretionary enforcement” category are necessarily low risk [10, 16]. For example, an app coaching users with diabetes may offer food suggestions based on the user’s entered blood glucose. Who is to blame if this suggestion adversely affects the user’s blood glucose (e.g., exacerbates hyperglycemia or induces hypoglycemia)? The FDA’s guidance for regulating mHealth apps is focused on the user’s risk but what about risk to the health care providers who recommend the app to their patients? Previously, the IMS Healthcare Informatics Team discussed legality as key provider concern and now it is time to address it.

In a Health Affairs policy brief, Yang et al. discusses the issue of licensure and how it can affect providers using mHealth apps to triage patients in other states [18]. He explains that using mHealth apps to communicate with other providers poses a cross-jurisdictional practice of medicine. Thus far, the health field’s regulation is left to state government with fifty US states having their own licensing requirements—this is true in medicine and in dietetics. For the purposes of delivering health diagnoses, medical advice, coaching or counseling would mHealth companies need to follow the model of telemedicine and telehealth services? Doing so would require they register providers (e.g., those interacting with users) in an interstate practice database and offer specialty licensing or certificates. Both these measures require more time and money for both mHealth app developers and the providers.

Additionally, Yang et al. suggests that mHealth apps are a new opportunity for litigation in the form of malpractice lawsuits. In the traditional sense, malpractice lawsuits occur when providers “owed a duty of care to a patient and deviated from it, with the patient being injured as a result” [18]. But, what happens if the provider’s breach in standard of care is the result of receiving faulty information from the mHealth app? While Yang et al. gave no good solutions to this issue it is precisely why providers may feel wary about using mHealth apps even as a supplement to their practice.
Scope of Practice

The *Academy of Nutrition and Dietetics* should also be more involved in regards to mHealth apps that infringe on the scope of dietitians. Not all users need the highly specialized health services of dietitians, so there should be a way to parse users at low-risk versus high-risk when it comes to receiving nutrition services. An example of such a system is the Women Infants and Children (WIC) program where mothers at “high-risk” for nutrition issues see a registered dietitian while nutritionists see mothers at “low-risk” for nutrition issues.

VI. Recommendations for Stakeholders

Given the gaps in current regulation and oversight of mHealth apps more must be done to ensure that mHealth apps will be safe tools for patients and providers alike. Recommendations for various stakeholders include:

**Researchers**
- Conduct studies that evaluate efficacy of mHealth apps relevant to their health claims.
- Identify the populations that would benefit most from the use of various types or functionalities of mHealth apps.

**Healthcare Industry (Health Insurance and Healthcare Organizations)**
- Come up with a system to rank mHealth apps in terms of efficacy.
- Create a dynamic database accessible and updated by practitioners who can play a contributory role in rating mHealth apps in their practice.
- Design a protocol (a standardized method) to prescribe mHealth apps to patients who may benefit from its use.
- Figure out how mHealth apps could be reimbursed by health insurance companies.
- Demand assurance from app developers that the products ensure security and privacy of patient data.

**Governmental Regulation**
- The FDA should re-evaluate their stance on “discretionary enforcement” particularly when it comes to mHealth apps that “help patients self-manage disease or conditions without providing specific treatment or treatment suggestions.”
- The Federal Trade Commission (FTC) should evaluate false claims and gimmicks that appear on the mHealth app store.
- mHealth app companies should be a stipulated entity under HIPAA and health information kept by these companies should be PHI. The Department of Health and Human Services (HHS) will then have a crucial role in monitoring HIPAA violations by mHealth apps.

**Health Organizations**
- Practitioner organizations like the *Academy of Nutrition and Dietetics*, the *American Medical Association*, the *American Nurses Association*, etc. should come up with their own position statement for the role of mHealth apps in their respective field.
• Practitioner organizations should collaborate with health industry (e.g. health insurance companies and healthcare organizations) to draft guidance for providers on how to use mHealth apps in their practice.

mHealth App Companies
• Have software developers address the five technical issues mentioned above (connectivity, data integrity, data security, updating protocol/procedures, display size/resolution).
• Consult pertinent healthcare providers such as physicians, dietitians, nurses, physicians assistants, etc. in the design and improvement of mHealth apps.
• Consult pertinent experts in the evaluation of app safety and efficacy.

Dietitian/Nutrition Professionals & Healthcare Providers
• Consult for mHealth app companies to guide design or improve features of mHealth apps.
• Contribute to mHealth app reviews to patients and providers surface the most safe and efficacious mHealth apps.
• Educate patients on which mHealth apps to purchase/use and how to use those apps effectively for their condition/goals.
• Demand assurance from app developers that the products ensure security and privacy of patient data.
• Demand that health insurance companies cover efficacious mHealth apps in their health insurance plans.

Users/Patients
• Contribute to mHealth app reviews to patients and providers surface the most safe and effective mHealth apps.
• Demand assurance from app developers that the products ensure security and privacy of patient data.
• Demand that health insurance companies cover efficacious mHealth apps in their health insurance plans.

VII. Conclusion

The expansion of mHealth apps into the healthcare field is a challenging thought exercise that is soon to become a reality. The best-case scenario for this reality is that mHealth apps will help patients achieve and providers provide cheaper, more optimal healthcare. The FDA, or any one entity alone, cannot be counted on the guarantee that this vision is realized. Rather, all stakeholders described above must work together to build the infrastructures and enact the policies necessary to guide mHealth app technology growth in a fruitful direction.
References


