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Introduction

The healthcare industry has seen a rise in mobile applications that target and encourage patients to take an active role in their health. Currently, there are no set regulatory or industry standards for developing these types of applications. The purpose of this study was to develop a list of criteria for creating an ideal diabetes mobile application that takes into consideration patient, provider, and government perspectives.

Methods

To get the different perspectives, we examined U.S. regulatory guidance, user reviews of select diabetes applications, and conducted a comprehensive review of literature related to mobile healthcare technology (listed below).

- Regulatory Guidances
 - FDA Mobile Medical Application Guidance issued on 09-25-2013
 - HIPAA Regulations¹
- Literature Search
 - Searched PubMed for: ((iPhone OR iOS) OR android OR mobile or smartphone) AND (app OR application)
 - Limits: Human, 2011 to 03-2013, English
 - Inclusion criteria: patient recorded data and diagnosis (only if resulting or enhancing from an interaction between a patient and provider); requirements for developing a good application
 - Exclusion criteria: provider focused EMR, patient data recording or fitness tracking with no provider interaction, reference materials, assessment tool made only for provider use, educational tools
- Application Comments
 - The top 4 most downloaded free applications on Google Play Store and Apple App Store when searching for Diabetes that met literature search criteria²⁻⁹
 - Considered 100 most recent mobile medical application user reviews as of 10-31-2013

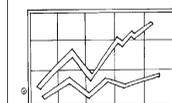
Recommendations

The most commonly requested and most important feature was **ease of use**. This refers to how simple it is for a **patient** to utilize the app, including how intuitive the interface is, how easy and flexible data entry and reporting is, and how straightforward data retrieval and display are. This will enable **patients** to more easily and accurately enter data on a consistent basis, allowing them and their **providers** to better track disease progress.



The next most commonly requested feature was **easy interactivity with providers**. This can be enabled through a variety of means, the easiest being sending logs and graphs directly from the application. This will supply the **provider** with more data and allow increased interaction between the **patient** and **provider** which could lead to better adherence and improved **patient** outcomes^{10,11,12}. Under current FDA **regulations**, apps that send information directly to physicians, such as blood glucose logs, are not subject to review as a medical device. However, if a physician is able to adjust medication doses or make treatment recommendations through the mobile app, the app will need to be reviewed by the FDA.

Many apps feature **interactive components**, including incentives such as the ability to earn new characters or unlock additional features. Interactivity and incentives encourage app use by **patients** and may potentially lead to improved adherence to regimens and thus, improved **patient** outcomes¹³. These features encourage the **patient** to continue using the application, creating a larger dataset for the **provider** to use in treatment decisions.



Graphing is a feature that allows both **patients** and **providers** to visualize the inputted data and track their overall progress. Additionally, **patients** find visualized data to be beneficial, increasing the likelihood of continued utilization¹³.

The ability to **sync** data allows **patients** to use the app on multiple devices, enabling them to use whichever device suits their preferences (e.g. easier data entry vs. increased portability). In addition, it provides the ability to backup data in case their mobile device is lost, stolen or broken. Availability of a web interface would make it easier for a **provider** to review the data with a **patient**. Hosting health information online, however will require adhering to HIPAA **regulations** concerning data transfer, privacy, and **patient** consent¹.



Patients commonly requested that apps **capture additional information** indirectly related to the given disease state. **Providers** would benefit from this feature because it would provide data from various aspects of the **patients** life, from blood pressure to physical activity. While important, this feature would be hard to implement without increasing the complexity of the application.

Creating an **interface with monitoring devices** would provide **patients** with an easier method of collection and more accurate data for **providers**. Depending on how this is implemented, however, federal **regulations** will need to be considered as it may qualify as extending the use of a medical device.



Limitations

- This study took into account current regulatory documents, articles from a comprehensive literature review, and reviews from app users. Trends were assessed to develop the study's conclusion. However, there is currently no standardized method to develop criteria considering the three data sources.
- This analysis assessed only diabetes logging apps, anticipating that their popularity would lead to a greater number of comments and a more diverse user base.
- Because the literature search and apps focused on diabetes and logging apps, the recommendations may not be applicable to other disease states.
- FDA guidance and regulations are subject to updates and changes based on the dynamic healthcare and technology environments and will thus necessitate an updated analysis

Conclusions

- This study highlights the importance of the patient-provider interaction. When used alone, mobile apps do not lead to better outcomes, however, the increased interaction and improved relationship does¹¹. Future studies could focus on the health outcomes knowledge gap associated with mobile apps.
- The increasing popularity of mobile health apps emphasizes the importance of the patient taking a more active role in their healthcare.
- While mostly physicians were cited in the literature, pharmacists have an opportunity to play a more substantial role in diabetes care for the patient, as they have easier access to the patient on a day-to-day basis.
- Several features, especially ones that rely on syncing, hosting information, maintaining a database, or collecting data from other sources, will incur costs for the developer. Covering these costs is a complicated issue. While many patients mentioned they would pay for a given feature, most complained that not enough was offered for free. Additionally, most applications are purchased with a one-time fee while costs are ongoing. HIPAA Regulations regarding patient privacy need to be considered if selling information is one of the methods to obtain revenue¹. Another option is having insurance companies provide reimbursement; however that will likely require data on effectiveness.
- More detailed information about the app reviews, literature search, and a summary of the current regulations is available through the QR code located at the top right corner of the poster.

References