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 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 selected diabetes applications, and conducted a comprehensive search of literature related to mobile healthcare technology (listed below).

- **Regulatory Guidance**: FDA, Mobile Medical Application Guidance issued on 09-25-2013
- **HIPAA Regulations**
- **Literature Search**
  - Searched PubMed for: (iPhone OR IOS) OR android OR mobile OR smartphone AND (apps 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 downloadable free applications on Google Play and Apple App Store were chosen for diabetes that met literature search criteria 8
    - Considered 100 recent mobile medical application user reviews as of 10-31-2013

### Criteria for Developing the Ideal Diabetes Mobile Application – Examining Patient, Provider and Regulatory Perspectives


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#### Introduction

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 patients and providers to better track disease progression.

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 data directly from the application. The supply will be provided with more data and allow increased interaction between the patient and provider who could lead to better adherence and improved patient outcomes. 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 the ability to earn badges 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 outcomes. These features encourage the patient to continue using the application, creating a larger dataset for the provider to use in treatment decisions.

#### Recommendations

- **This study took into account current regulatory documents, applications from a comprehensive search, and reviews and feedback from app users. Trends were assessed to develop the study’s conclusion. However, there is currently no standardized method or organization 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.**

#### Limitations

- **This study highlights the importance of the patient provider interaction. While used alone, mobile apps do not lead to better outcomes, however, the increased interaction and improved relationships does**. 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 to 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 to third parties, as the methods used to recover another’s medical information is not currently regulated.**

#### Conclusions

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.

### References

8. Searched PubMed for: (iPhone OR IOS) OR android OR mobile OR smartphone AND (apps OR application)
9. Limits: Human, 2011 to 03-2013, English
10. 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
11. 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
12. Application Comments
13. The top 4 most downloadable free applications on Google Play and Apple App Store were chosen for diabetes that met literature search criteria
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**Graphing is a feature that allows both patients and providers to visualize the inputted data and track their overall trend.**

**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 and cost of the application.