


What do we know about mobile applications for diabetes self-management? A review of reviews

Megan Hood¹  · Rebecca Wilson¹ · Joyce Corsica¹ · Lauren Bradley¹ · Diana Chirinos¹ · Amanda Vivo¹

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Abstract Diabetes is a chronic illness with significant health consequences, especially for those who are unable to adhere to the complex treatment regimen. Self-management tasks such as regular medication and insulin use, frequent blood sugar checks, strict diet management, and consistent exercise can be quite challenging. Mobile technologies, specifically mobile applications (apps), present a unique opportunity to help patients improve adherence to these behaviors. The availability of commercial diabetes self-management apps is increasing rapidly, making it difficult for patients and providers to stay informed about app options. A number of reviews have described commercial app technology and use for patients with diabetes. The aims of this article are to summarize the results and themes of those reviews, to review outcomes of apps described in the research literature, and to identify areas for further consideration in the use of mobile apps for diabetes self-management.

Keywords Diabetes · Self-management · Behavior adherence · Mobile applications · Review · mHealth

Introduction

Over 9 % of the US population (i.e., over 29 million Americans) has some form of diabetes (CDC, 2014). The seventh leading cause of death in the US, diabetes is associated with greater rates of cardiovascular conditions,

kidney disease, vision problems, and non-traumatic amputations (CDC, 2014). Total costs of diabetes in the US totaled \$245 billion in 2012 (CDC, 2014). Diabetes, therefore, is a prevalent, harmful, and costly illness.

Successful management of diabetes relies heavily on patient adherence to behavioral treatment recommendations. This includes regular use of medication and/or insulin, consistently checking blood sugar, maintaining a healthy diet and exercise routine, and attending regular follow-up visits with providers. Many of these behaviors require daily maintenance, and a large percentage of patients do not adhere to their treatment regimens (Cramer, 2004). Poor adherence can lead to significant morbidity and mortality as well as poor quality of life (Asche et al., 2011).

Advances in technology have led to numerous innovative strategies to help patients with diabetes improve their self-management. Mobile health (mHealth), a component of eHealth, is the “medical and public health practice supported by mobile devices” (WHO, 2011), which enhances access to health information for patients/providers, facilitates remote patient monitoring, and delivers timely health-care recommendations and reminders to patients (Klonoff, 2013). Given the potential for cost savings and the dramatic increase in physiologic data that will be available to patients via continuous sensors of glucose, cardiovascular function, physical activity, and other health variables, many see mHealth as an emerging technology area that is transforming health care.

With an estimated 1.08 billion individuals having smartphones worldwide (GO-Gulf, 2012), and an estimated 500 million people using mobile device applications (apps) for sport, diet, and chronic disease management in 2015 (Rho et al., 2014), the potential for use of mobile applications to improve diabetes self-management is unprecedented. A major challenge to the effective use of apps for

✉ Megan Hood
megan_hood@rush.edu

¹ Department of Behavioral Sciences, Rush University Medical Center, 1645 W Jackson, Suite 400, Chicago, IL 60612, USA

chronic disease management is the overwhelming number of apps that are currently available. There are almost 100,000 health-related apps available in the Apple App Store and Google Play Store (Tamony et al., 2015). Of all the medical conditions, diabetes is the most common condition targeted by current commercial apps, followed by depression and asthma (Martínez-Pérez et al., 2013). Numerous reviews have attempted to assess the qualities and characteristics of current mobile applications, a challenge in the ever-changing world of app development. The rapid proliferation of app development is also significantly outpacing research on app use and related outcomes, meaning there are little data available about the efficacy of current commercially available apps. The aims of this paper are to (1) summarize the results and themes of the reviews of commercial diabetes self-management apps that have been conducted to date, (2) review outcomes from research on stand-alone self-management apps for diabetes reported on in the literature, and (3) make suggestions for ways in which mobile apps can be used to enhance treatment adherence for patients with diabetes.

Methods

Search strategy

PubMed was searched for published articles through January 2016 using combinations of the terms “mobile application”, “app”, or “smartphone”, with “diabetes”, along with references list searches. Article abstracts were reviewed for study eligibility, followed by reviews of full papers in cases in which eligibility was not clear from the abstract review alone. Eligibility criteria for each aim were reviewed by all authors and two authors (M.H. and D.C. for aim 1 and L.B. and D.C. for aim 2) independently performed the reviews.

For aim 1, articles were included if they consisted of reviews of commercial mobile applications (those available in app stores, such as the Apple App Store or Google Play Store) specifically. Articles were excluded if they were reviews of other telehealth technologies (such as text-messaging based programs), reviewed 5 or fewer apps, were in a non-English language, were primarily editorials, or solely described study protocols.

For aim 2, articles were included if they described the development and evaluation of a mobile app for the self-management of diabetes. Exclusion criteria included non-app telehealth technologies, apps that were not designed primarily for a patient’s independent self-management (e.g., apps used as a component of a broader intervention program), or non-English studies.

Study selection

The initial search resulted in 485 articles. After eliminating duplicates and studies that did not fit the inclusion criteria (e.g., reviewed other telehealth technologies, were primarily editorials), 11 articles were included in the review for aim 1 and 13 articles were included for aim two. Descriptions of the studies used in aim 1 and aim 2 are included in Tables 1 and 2, respectively.

Aim 1 results

While there was some variability amongst reviews regarding which app features were reported, review topics generally fell in the following categories: app description information (number of apps available, cost, user ratings, language, and app audience), usability analyses (comprehensibility, image and text presentation, understandability, and intuitiveness), app content (e.g., self-monitoring of blood glucose, diabetes education), and other app features (personalized feedback, data transfer and communication options, security, and social networking).

App availability

Given the dramatic rate of app development, the number of commercial apps that are available is a moving target. Martínez-Pérez et al. (2013) reported finding >1000 diabetes apps in the Google Play Store (for Android), 605 in the Apple App store (for iOS), 33 in Blackberry World, 81 in the Windows Store, and 40 in Nokia’s Ovi Store. One review noted that in their initial January 2013 search of iOS apps, they found 600 diabetes apps, and then in an updated search in July of 2014, this number had increased to 969 apps (Lee, 2014), highlighting the significant rate of growth in this field. Another review found that among iOS diabetes apps, 44 % were categorized in the “health and fitness” category, and another 44 % were in the “medical” category (Caburnay et al., 2015), suggesting that these apps are categorized under a variety of headings. Interestingly, most apps (87 %) were not targeted for a specific type of diabetes (or this was not specified). Finally, the majority (74 %) of apps addressed diabetes management or therapeutics, compared to 33 % that addressed diabetes prevention (Caburnay et al., 2015). In summary, the number of apps that are available for general diabetes management is massive and likely to expand even further given recent rates of app development. The growing number of available apps may be overwhelming for providers and patients who are searching for reliable and well-designed apps to support diabetes management. Therefore, better under-

Table 1 Reviews of commercial apps for diabetes self-management

Review	Search and inclusion criteria	Search date	No. apps reviewed	App Characteristics	Self-monitoring functions	Other features
Arnhold et al. (2014)	English or German diabetes apps	March 2013	276 iOS, 266 Android, 114 iOS/Android	96 % patient target user 54 % free Median price €1.90 3.6/5 stars 11 % of iOS and 71 % of Android apps had ratings	Blood glucose 53 %	Education 35 % Advisory/support function 9 % Glucometer connection 5 % Data forwarding 31 %
Breland et al. (2013)	English diabetes apps	March 2012	227 iOS	Median price \$0.99 3.1/5 stars 47 % had ratings	Medication 47 % Exercise 25 % Food intake 45 %	n/a
Caburnay et al. (2015)	English diabetes apps, random selection of 110 out of 460 results	April 2014	110 iOS	69 % free Mean price \$4.57 3.4/5 stars 59 % had ratings	n/a	n/a
Chomutare et al. (2011)	English diabetes apps for self-monitoring of blood glucose	Feb 2011	49 iOS, 33 Android, 13 Blackberry World, 6 Nokia's Ovi Store	40 % free Mean price €2.50	Insulin 65 % Exercise 40 % Food intake 52 % Weight 39 % Blood pressure 32 %	Education 27 % PHR or web portals link 29 % Social media 15 %
Demidowich et al. (2012)	Diabetes apps for self-monitoring of blood glucose, prandial insulin dose calculation, or diabetes medication/insulin data tracking	April 2011	42 Android	43 % free Mean price \$2.86 3.7/5 stars 83 % had ratings	Blood glucose 86 % Insulin/med use 45 % Exercise 74 % Food intake 31 % Weight 50 % Blood pressure 43 %	Data export 74 %
El-Gayar et al. (2013)	English diabetes apps for patients for self-monitoring of blood glucose with ≥ 1 self-management task	Aug 2012	71 iOS	46 % free 54 % had ratings	Blood glucose 100 % Med use 76 % Exercise 41 % Food intake 68 % Weight 25 % Blood pressure 23 %	Self-management education 18 % Decision support 17 % Communication 83 % PHR link 21 % Security 11 % Social media 7 %
Eng and Lee (2013)	English endocrine apps	Jan 2013	492 iOS, 260 Android	8 % provider target user	Health tracking 33 % Food intake 8 %	Teaching/training 22 % Social media 5 %
Huckvale et al. (2015)	English apps that contained a rapid-acting insulin dose calculator	Aug 2013	25 iOS, 21 Android	41 % free	Food intake 17 %	Glucometer connection- 1 app Data sharing 41 %
Martínez-Pérez et al. (2013)	English diabetes apps	April 2013	605 iOS, > 1000 Android, 33 Blackberry World, 81 Windows Store, 40 Nokia's Ovi Store	n/a	n/a	n/a

Table 1 continued

Review	Search and inclusion criteria	Search date	No. apps reviewed	App Characteristics	Self-monitoring functions	Other features
Rao et al. (2010)	Top 12 diabetes apps based on customer ratings	Oct 2009	12 iOS	n/a	Blood glucose 100 % Insulin/med use 75 % Exercise 58 % Food intake 58 % Weight 25 % Blood pressure 8 %	Email composer 83 % Autosync to website 33 %
Williams and Schroeder (2015)	Top 10 paid and unpaid apps for self-monitoring of blood glucose	Jan 2014	10 iOS, 10 Android	35 % available in Spanish Mean price \$5.03	Blood glucose 100 % Insulin 80 % Exercise 85 % Food/carb log 70 % Weight 75 % Blood pressure 55 %	Data export 80 % Online account link 30 % Glucometer connection 20 % Passcode required 25 % Social media 65 %

standing the utility and quality of commercially available apps is necessary.

App characteristics and features

App audience

Patients are overwhelmingly the primary audience for apps, with 96 % of apps directed at individuals with diabetes (Arnhold et al., 2014). Physicians or health professionals are targeted users in a smaller proportion of apps (7–8 %; Arnhold et al., 2014; Eng & Lee, 2013).

Language

Many reviews only assessed apps that were in English, so language availability data were limited. One review of the top 10 iOS and Android apps for blood glucose monitoring found that 35 % were available in both English and Spanish (20 % of iOS and 50 % of Android apps; Williams & Schroeder, 2015). In a review of English and German apps, only 96 of the 656 apps found were in German (Arnhold et al., 2014), suggesting that the majority of apps currently available on online platforms are in English.

Cost

Between 38 and 69 % of apps reviewed were free (Arnhold et al., 2014; Caburnay et al., 2015; Chomutare et al., 2011; Demidowich et al., 2012), with Android apps tending to be

free more often than iOS apps. Average prices of paid apps were \$4.57 to \$5.03 (Caburnay et al., 2015; Williams & Schroeder, 2015) or €1.90 to €2.50 (Arnhold et al., 2014; Chomutare et al., 2011), with lower average prices for Android (\$2.86–\$3.66, €1.30) than iOS apps (\$6.39, €2.30) apps (Arnhold et al., 2014; Demidowich et al., 2012; Williams & Schroeder, 2015). Apps available on both iOS and Android operating systems tended to be more expensive than those available for only one system and approximately 5 % of apps offered less expensive “lite” versions with limited functionalities (Arnhold et al., 2014). Interestingly, no differences in app features (type and stage of diabetes targeted, app focus) were found between paid and free apps (Caburnay et al., 2015; Demidowich et al., 2012). Apps developed by non-profit, education, or government institutions were significantly less expensive than those developed by other groups (Breland et al., 2013).

User ratings

The median number of total app store ratings per app across studies was 6–13 for iOS apps and 9–10 for Android apps (Arnhold et al., 2014; Breland et al., 2013; Demidowich et al., 2012), though only 11–47 % of iOS apps (versus 71 % of Android apps and 66 % of apps running on both systems) were rated by users at all (Arnhold et al., 2014; Breland et al., 2013). For those apps with ratings available, average user ratings ranged from 3.3 to 3.7 stars out of 5, with 50 % of apps earning moderate to good ratings of 3.5 or more (Arnhold et al., 2014; Breland et al.,

Table 2 Research-based app studies

Author	DM type	App features	Conditions	Duration (months)	n	Age (mean ± SD)	Gender (%male)	Clinical outcomes		
<i>Uncontrolled studies</i>								<i>Within group</i>		
Årsand et al. (2010)	DM2	Glucometer Pedometer Self-monitoring Feedback	App only	6	12	52.6 ± 5.6	33.3 %	BG (mg/dL)		
								Pre	Post	<i>p</i>
								142	140	–
Forjuoh et al. (2008)	DM2	Self-monitoring BG trend visualization	App only	6	18	57.6 ± 9.9	44.4 %	HbA1c (%)		
								Pre	Post	<i>p</i>
								9.7	8.0	–
Kollmann et al. (2007)	DM1	Self-monitoring Feedback Graphical visualization of data Reminders Web portal for patients and providers	App only	3	10	36.6 ± 11.0	60.0 %	BG (mg/dL)		
								Pre	Post	<i>p</i>
								141.8	141.2	.69
								HbA1c (%)		
								Pre	Post	<i>p</i>
								7.9	7.5	.02*
Rossi et al. (2009)	DM1	Self-monitoring CHO/insulin bolus calculator Food exchange Reminders Text messaging	App only	9 (mean)	41	31.6 ± 11.9	61.0 %	FBG (mg/dL)		
								Pre	Post	<i>p</i>
								147.9	138.2	.09
								PPG (mg/dL)		
								Pre	Post	<i>p</i>
								149.2	134.5	.13
								HbA1c (%)		
								Pre	Post	<i>p</i>
								7.6	7.3	.27
Cafazzo et al. (2012)	DM1	BG trend alerts Visualization of BG data Rewards Social networking Decision support	App only	3	12	15.1 ± 1.3	66.7 %	HbA1c (%)		
								Pre	Post	<i>p</i>
								8.8	9.2	.11
Padman et al. (2013)	DM1	Self-monitoring Visualization of data Social networking	App only	2	8	Range 10–18	–	NS reductions of variability in BG readings		

Table 2 continued

Author	DM type	App features	Conditions	Duration (months)	<i>n</i>	Age (mean ± SD)	Gender (%male)	Clinical outcomes			
<i>Controlled studies</i>								<i>Between groups</i>			
Quinn et al. (2008)	DM2	Feedback to patient Display of medication regimens Suggested treatment plans to HCPs Wireless transfer of BG data from glucometer	App versus control (regular BG monitoring sent to HCP)	3	30	51.0 ± 11.0	35 %	ΔHbA1c (%)	App	Control	<i>p</i>
								−2.0	−0.7	.04*	
Waki et al. (2014)	DM2	Data transmission Feedback Dietary evaluation Text messaging	App versus control (usual self-care regime)	3	54	57.3 ± 9.7	66 %	ΔHbA1c (%)	App	Control	<i>p</i>
								−0.4	−0.1	.02*	
								ΔFBG (mg/dL)	App	Control	<i>p</i>
								−5.5	+16.9	.02*	
Kim et al. (2014)	DM2	Self-monitoring Data transmission to HCP Feedback	App versus matched control	3	70	52.8 ± 9.7	57.1 %	ΔHbA1c (%)	App	Control	<i>p</i>
								−0.2	0	–	
Torbjørnsen et al. (2014); Holmen et al. (2014)	DM2	Wireless transfer of blood glucose data Self-monitoring Goal-setting Diabetes information	App versus app with counseling (AppC) versus TAU	4; 12	151	51.0 ± 12.0	58.9 %	ΔHbA1c (%)—4 months	App	AppC	Control <i>p</i>
								−0.23	−0.41	−0.39 NS	
								ΔHbA1c (%)—1 year	App	AppC	Control <i>p</i>
								−0.31	−0.15	−0.16 NS	
Rossi et al. (2010)	DM1	CHO/insulin bolus calculator Text messaging with HCP Self-monitoring	App versus standard education	6	119	35.7 ± 9.5	43.1 %	ΔHbA1c (%)	App	Control	<i>p</i>
								−0.4	−0.5	.68	
								ΔFBG (mg/dL)	App	Control	<i>p</i>
								−22	15.5	.13	
Kumar et al. (2004)	DM1 DM2	Self-monitoring Transfer of data	App versus app with game (AppG)	~4	40	13.6 ± 2.5	55 %	ΔHbA1c (%)	App	AppG	<i>p</i>
								0.1	−0.1	NS	

Table 2 continued

Author	DM type	App features	Conditions	Duration (months)	<i>n</i>	Age (mean ± SD)	Gender (%male)	Clinical outcomes		
Gibson et al. (2007)	DM1	Self-monitoring Transfer of data Visualization of data	App versus app with nurse support (AppS)	9	93	Range 18–30	–	ΔHbA1c (%)		
								App	AppS	<i>p</i>
								–0.4	–0.6	.30

DM diabetes mellitus, BG blood glucose, HbA1c glycated hemoglobin, CHO carbohydrate, HCP health care provider, FBG fasting blood glucose, PPG post-prandial glucose, TAU treatment as usual, NS non-significant

– Not included

* $p < .05$

2013; Caburnay et al., 2015; Demidowich et al., 2012). There were no clear differences in ratings between paid and free apps, but more expensive apps tended to have poorer ratings (Arnhold et al., 2014).

Usability

An important consideration of mobile applications is the ease with which the user and the product interact. Usability analyses assess comprehensibility, image and text presentation, understandability, and intuitiveness, among other features, in order to determine how easily users can interact with apps. Among diabetes apps, most appear to be comprehensible, but many did not have good fault tolerance (i.e., the ability of the app to respond well to unexpected hardware or software failures; Arnhold et al., 2014). Accessibility features (i.e. screen reader, large type, color contrast) were available in many apps, with 73 % of apps offering the ability to read the screen content aloud and 41 % of Android apps offering large font (versus 0 % of iOS apps). Paid apps tended to have more usability strategies for patients with low health literacy (e.g., plain language, clearly labeled links, organization features; Caburnay et al., 2015). Integration with other mobile applications (e.g., email, calendar, maps) was available in 44 % of apps (Caburnay et al., 2015). Interestingly, the number of functions available was negatively correlated with usability, with functions related to self-monitoring and visual presentation of data patterns (e.g., graphically displaying blood glucose ratings over time), in particular reducing usability scores for adults over age 50 (Arnhold et al., 2014).

Demidowich et al. (2012) created a usability composite score for the apps reviewed in their study, based on ease of use, user interface design, customizability, data entry and retrieval, integration of data into charts or graphs, and data sharing. Of a possible total score of 30, the mean composite usability score was 11.3 (SD = 5.9), with only 4 of the 42 apps reviewed achieving a composite score above 20.

Interestingly, the composite score was poorly correlated with user ratings and download frequency. The authors suggest that this discrepancy highlights the limitations of using user ratings, which are unregulated, and download frequency, which does not necessarily reflect actual use of the app, as measures of app quality.

In sum, apps appear to be primarily available in English, with limited available user rating data. On a broad level, there do not appear to be major advantages of paid over free apps, other than some improved features for those with low health literacy. And finally, user ratings and number of downloads do not appear to be reliable indicators of app quality.

App content

Mobile apps are available to support the ADA and AACE guidelines for care and self-management of diabetes and all seven of the American Association of Diabetes Educators self-management behaviors (AADE7), including healthy eating, being active, monitoring, taking medications, problem solving, reducing risks, and healthy coping (Breland et al., 2013; Sieverdes et al., 2013). Breland et al. (2013) found that apps in their search referenced a median of two (range 0–6) of the seven AADE7 self-management behaviors, with monitoring tasks being the most common features.

Monitoring tasks

Diabetes-specific self-management tasks Timely use of insulin and oral medication, blood glucose testing and recording, exercise, and food intake were the diabetes-specific health behaviors that were tracked most commonly by apps reviewed. Prevalence of these features in apps varied quite a bit by review, likely due to slight differences in search/eligibility criteria in different reviews (see Table 1 for details on each review). For example, one review (El-Gayar et al., 2013) found that 39 % of apps

supported one or more of these self-monitoring tasks. Another (Arnhold et al., 2014) found that 54 % of apps offered only one function and 28 % combined two functions, with iOS apps tending to offer a wider range of functions than Android apps. Across reviews, insulin/medication recording features were found frequently in apps (45–80 % of apps), as were carbohydrate logs (70–75 %), diet recording (8–68 %), and physical activity tracking (25–85 %) features (Chomutare et al., 2011; Demidowich et al., 2012; El-Gayar et al., 2013; Eng & Lee, 2013; Rao et al., 2010; Williams & Schroeder, 2015). Breland et al. (2013) found that 48 % of apps reviewed included tracking of blood glucose levels, weight, and/or blood pressure, and only 33 % of apps in Eng and Lee (2013) focused on health tracking (blood glucose, insulin, carbohydrates, weight, or physical activity). Eight percent of the apps were strictly food reference databases for carbohydrate counting (Eng & Lee, 2013).

Glucose recording/documenting was the most common app function (53 % of apps) in a review of diabetes apps with broad inclusion criteria (Arnhold et al., 2014), with 11 % of apps also including a reminder function. Given the importance of self-monitoring for health behavior change (Miltenberger, 2015) and the encouragement by medical providers of regular checking of blood sugar, it is unsurprising that this is a key feature of many apps. The ability to record blood glucose measurements is such an important feature that some articles (Chomutare et al., 2011; Demidowich et al., 2012; El-Gayar et al., 2013) made it an inclusion criterion for their review. Most apps required manual entry of blood glucose numbers, with only 4–20 % of apps (Arnhold et al., 2014; El-Gayar et al., 2013; Williams & Schroeder, 2015) offering the ability to obtain data directly from glucometers. This feature was offered equally in iOS and Android apps (Williams & Schroeder, 2015), and typically these uploads could be done through Bluetooth or Wi-Fi (Arnhold et al., 2014). While most data entry automation features were related to blood glucose tracking, one app also included the ability to upload physical activity information from a step counter (Årsand et al., 2012).

Weight and blood pressure tracking Weight and blood pressure were additional health variables that were tracked in many apps. Weight was the 3rd most common monitoring function in Williams and Schroeder's (2015) review, found in 75 % of their top apps; though it was found in only 25–50 % of apps in other reviews (Chomutare et al., 2011; Demidowich et al., 2012; El-Gayar et al., 2013; Rao et al., 2010). Blood pressure tracking was found in a relatively smaller number of apps, though there was significant variability across reviews (8–55 %; Chomutare et al.,

2011; Demidowich et al., 2012; El-Gayar et al., 2013; Rao et al., 2010; Williams & Schroeder, 2015). The lowest rates of weight and blood pressure monitoring capability were found in the oldest review (Rao et al., 2010), suggesting that these functions are becoming more common over time.

Education

Modules providing educational information on diabetes or diabetes-related treatment were available in 16–35 % of apps (Arnhold et al., 2014; Chomutare et al., 2011; El-Gayar et al., 2013). Multiple reviews commented that the low rates of educational features are concerning, given the importance of education noted in the clinical guidelines for diabetes. A small number of apps provided personalized education or tips for users.

In sum, the content of diabetes-related apps appears to vary significantly by app and the majority of apps seem to focus on one app function, suggesting a fairly specialized focus in target diabetes management tasks. This variability could be seen positively, as app options are available for users who want apps either targeting one function (e.g., only support with blood glucose monitoring) or more comprehensively targeting multiple aspects of diabetes management. Of concern is the lack of diabetes education information, particularly given that inclusion of this information would be fairly straightforward. This highlights an area of potential improvement in newly developed apps.

Other app features

In addition to app description information, usability ratings, and app content, features such as feedback and communication options, security, and social networking support have been discussed in multiple reviews, given the importance of these features in engaging the user and in improving contact with providers.

Support and feedback

Personalized feedback or advice based on patient data, typically insulin dosage suggestions, was available in 9–17 % of apps reviewed (Arnhold et al., 2014; El-Gayar et al., 2013). One study (Huckvale et al., 2015) reviewed only apps that contained a rapid-acting insulin dose calculator. Of the 46 apps (25 iOS, 21 Android) that met their criteria, 37 % were stand-alone calculators, while 59 % combined a calculator with a blood glucose tracking function. Of concern, of these apps only 59 % included a clinical disclaimer (i.e. text recommending discussion of app use with a healthcare professional), only 30 % documented the calculation formula, and 67 % were deemed to carry a risk of inappropriate output dose recommendations.

These concerning deficiencies also highlight the potential risk of using unregulated apps for medical purposes.

Other support features found in some apps include functions such as disease-related reminders for users (12 % of apps in Chomutare et al., 2011). These tailorable features are important areas of future development, which will help to further personalize the app user experience.

Data transfer and communication

One major strength of these apps is the possibility of sharing data with treatment providers or other supporters. Data export functions (typically sending data to the user's email) were available in 74–83 % of the apps in the four reviews of apps that included self-monitoring of blood glucose as an inclusion criteria (Demidowich et al., 2012; El-Gayar et al., 2013; Rao et al., 2010; Williams & Schroeder, 2015), while a broader review (Arnhold et al., 2014) found that only 31 % of apps included a data forwarding/communication function. The large difference in these findings is likely due to the differences in study inclusion criteria, as data exports are typically of blood glucose readings. Fewer than 1/3 of apps allowed upload of data to a patient health record or web portal (Chomutare et al., 2011; El-Gayar et al., 2013; Rao et al., 2010; Williams & Schroeder, 2015). Communication functions are one of the primary ways in which app use can benefit providers, and given the many benefits of accessibility of physiologic data on the medical management of diabetes (e.g., medication dosage, adherence information), maximizing the functionality of these features is likely to be a key preference of medical providers.

Security

Given the large amount of physiologic data that are available in apps with monitoring features, data security was a concern mentioned in numerous reviews. Only 7–18 % of apps offered password-protection services (Arnhold et al., 2014; El-Gayar et al., 2013). In terms of protection of patient health information, El-Gayar et al. (2013) found that only one of 71 commercial apps indicated HIPAA compliance. As tracking and communicating physiological data becomes increasingly prevalent and providers become accustomed to using apps to monitor such data with their patients, having security measures will likely become an important app feature.

Social networking

Social networking features (integration with social networks, forums, blogs, etc.) were fairly uncommon in broad

reviews (5 % of apps in Eng & Lee, 2013 and 15 % of apps in Chomutare et al., 2011), but quite common (65 %) in a review of top consumer-rated diabetes apps (Williams & Schroeder, 2015), indicating the desirability of this feature. Social networking features may be appealing for a variety of reasons, including providing connection with other diabetes patients and/or friends and family supporters, social support for challenges related to health goals, and reinforcement of progress toward self-management goals. This function may be particularly appealing for younger and more technologically-savvy users.

Aim 2 results

Researched-based applications: app outcomes and efficacy

There appears to be a lack of reviews that synthesize published studies on outcome data of apps specifically, rather than mHealth applications more globally. We therefore conducted a review of original research studies that tested the impact of the use of diabetes apps and included clinical outcome data. These results are summarized in Table 2. Much of the research consisted of small ($n = 8–18$), uncontrolled studies to establish feasibility, acceptability, and preliminary effectiveness of the apps (Årsand et al., 2010; Forjuoh et al., 2008; Kollmann et al., 2007; Rossi et al., 2009; Cafazzo et al., 2012; Padman et al., 2013). Overall, these studies demonstrated some clinical improvements, but changes tended to be small and were not statistically significant (possibly due to lack of statistical power). However, one larger pilot study ($n = 41$) demonstrated that at 9-month follow-up, participants displayed a statistically significant reduction in fasting blood glucose values (Rossi et al., 2009).

There are a limited number of studies that compared apps to control conditions. Several studies found greater clinical improvements in participants utilizing apps compared to control conditions (Quinn et al., 2008; Waki et al., 2014; Kim et al., 2014; Rossi et al., 2010); however, only one study reported statistically significant differences (Quinn et al., 2008). Several other studies compared the efficacy of different components of app interventions. For example, Kumar et al. (2004) demonstrated some benefit of adding a game-type component to an app for adolescents ($n = 40$), particularly for greater improvement in diabetes knowledge. Studies that evaluated the benefit of added counseling combined with app usage did not find significant differences compared to using the app alone (Gibson et al., 2007; Holmen et al., 2014; Torbjørnsen et al., 2014). For example, one study randomized 151 participants to one of three conditions: (1) app, (2) app with telephone coun-

selling from a diabetes nurse, or (3) treatment as usual. At four months ($n = 124$) and at one year ($n = 120$), improvements in HbA1c were demonstrated in all groups, with no statistically significant differences among groups.

Taken together, our review indicates that there are currently limited data available on the effectiveness of apps for the self-management of diabetes. Further, many studies are uncontrolled and have small sample sizes. Studies using comparison groups do not provide strong evidence for the use of apps compared to standard care. Although there appear to be promising results in some studies, more rigorous testing is necessary to draw conclusions on the clinical utility of such apps.

Discussion of the use of mobile apps for diabetes self-management

The proliferation of apps targeting diabetes self-management, with options such as blood glucose monitoring, medication reminders, and communication with physicians and social networks, is encouraging in light of the great need for improved methods to address poor rates of behavioral adherence in patients with diabetes (Bailey & Kodack, 2011). Yet, the vast number of apps that are commercially available is overwhelming, and the content and usability of these apps varies. In addition, only a very small percentage of apps have been studied using rigorous research methodology (e.g., randomized clinical trials), meaning little is known about the actual efficacy of these strategies. The few studies that have investigated the efficacy of specific apps in improving diabetes self-management and glycemic control, while preliminary, are encouraging and suggest that there is a need to further evaluate app effectiveness and compare effectiveness across studies, particularly in this medically high risk population.

It appears that tracking health variables, most commonly blood glucose, is the primary function available in commercial apps. This is encouraging, given that self-monitoring of blood glucose is considered a critical component of diabetes management. More frequent testing of blood sugar has been associated with lower HbA1c levels and numerous technologies are being developed to improve the ease and accuracy of blood glucose tracking for patients (Knapp et al., 2016). Self-monitoring, particularly with provision of feedback on the data being monitored, is a key component of health behavior change interventions (Miltnerberger, 2015) and has been found to be the most common behavior change technique in technology-based interventions for other chronic medical conditions (Winter et al., 2016). Yet, outside of self-monitoring, few evidence-based tools seemed to be used regularly in commercial apps to enhance diabetes self-management, and further-

more, few apps appear to be based on validated behavioral theories, such as Social Cognitive Theory, the Trans-theoretical Model, or the Theory of Planned Behavior/Reasoned Action. While some mobile apps are being designed based on behavior change theories for diabetes management and associated behaviors such as weight management, medication adherence, and physical activity, multiple reviews have found that current commercially available health management apps have very low rates of inclusion of behavior change techniques (Azar et al., 2013; Chen et al., 2015; Morrissey et al., 2016; Payne et al., 2015). The use of behavior change theories as well as patient-centered motivational strategies could serve to improve app features for diabetes self-management, such as the integration of features focused on goal-setting and problem-solving of barriers to adherence. In addition, further integration of personalized feedback and tailored reminder features would likely be beneficial for improving user engagement and adherence. Just in Time Adaptive Interventions (JITAI; Nahum-Shani et al., 2014) are mobile phone interventions designed to provide support tailored to the user in terms of what, when, and how the support is provided by using data collected from the user to inform real-time delivery of interventions. JITAI are one example of a promising design using personalized behavioral strategies to enhance self-management for patients. Potential self-management benefits of social networking features are also theoretically encouraging and have shown some promise in a few studies (Giménez-Pérez et al., 2016; Vaala et al., 2015), but the true effects of this feature remain unclear in this population, as few apps seem to have this function. However, those apps do appear to be the more popular diabetes apps among users and social networking has been shown to be beneficial for behavior change in other populations (Laranjo et al., 2014).

With little research support available, user ratings may be one of the first ways in which patients (and providers) research app options and quality. Yet, as multiple reviews noted, most apps do not have any user ratings available or have a very small number of ratings. Of those that did have ratings, only half had moderate to good ratings. In addition, search and filter functions in app stores tend to be difficult for users to navigate (e.g. limited ability for advanced searching), making finding helpful apps a challenge. A small number of independent organizations have embarked on developing formal app review processes (Eng & Lee, 2013), which could improve patients' ability to find appropriate apps for their needs. For example, online publication *iMedicalApps* independently reviews mobile medical technology applications using expert reviewers (mHealth analysts, physicians, and other health professionals) and has been identified as a trusted social media blog by the Cochrane Collaboration (Cochrane Collabora-

Table 3 FDA approved apps for diabetes

Device Name	Manufacturer	Approved or cleared	Year	Platform ^a	Capabilities
The Dexcom Share	Dexacom Inc	Approved	2015	iOS	Share data from a continuous glucose monitor (CGM) with other people in real-time
Accu-Chek Connect	Roche Diabetes Care	Approved	2013	iOS, Android	Give specific insulin bolus recommendations
WellDoc Diabetes Manager System	WellDoc	Cleared	2010	iOS, Android	Medication adherence program and secure capture, storage, and real-time transmission of blood glucose data
BlueStar	WellDoc	Cleared	2014	iOS, Android	Rx app, suggesting, in real time, when to test blood sugar and how to control it by varying medication, food, and exercise. May be reimbursed by insurance
Glooko Device System	Glooko Inc	Cleared	2012	iOS, Android	Monitoring and management via connection to FDA cleared meters
MiniMed Connect	Medtronic	Cleared	2015	iOS	Management. View insulin pump and continuous glucose monitor (CGM) data on a smartphone and provides remote monitoring and text message notifications. Gives healthcare teams more convenient access to more comprehensive patient data so they can adjust patients' care plans

The highest-risk devices (e.g. implantable infusion pumps) require FDA *approval* before marketing, indicating that the manufacturer has demonstrated reasonable assurance of safety and effectiveness. Moderate-risk medical devices (e.g. dialysis equipment) are FDA *cleared* provided they are equivalent to an already marketed device of the same type. (FDA, 2015)

^a Platform availability as of 1/8/16

tion, 2014). More broadly, mobile application testing processes exist to determine app quality based on functionality, speed, simplicity, and other related features (SmartBear Software, 2015), though use of these processes with the diabetes apps described in this review is unclear. Diabetes-focused and other medical apps are somewhat unique in that there may be higher risk involved in the use of low quality apps (such as miscalculating insulin dosages, or failure in reminder or other functions).

The FDA could have an important role in providing guidance to consumers and providers regarding the quality and safety of mobile apps. In a 2012 guidance publication, the FDA determined that it would limit regulatory oversight to those apps that qualify as medical devices (i.e., those that provide patient-specific diagnosis, treatment, or prevention of a disease) and could pose a safety risk if they were not to function as intended (FDA, 2015). As such, the FDA will not actively regulate many categories of apps, including those that facilitate self-management of diseases and medical conditions, health information organization and tracking, interaction with health records, health coaching, etc. (FDA, 2015). Examples of apps that the FDA is choosing to regulate include those that operate in conjunction with blood sugar monitors and provide insulin dose recommendations. Six apps to date have received FDA approval or clearance (see Table 3). Two apps are FDA-approved for the management of diabetes: DexCom Share, which transmits real-time continuous glucose monitoring (CGM) data to designated others, and Accu-

check Connect Diabetes Management system, which is the first FDA-approved app that can recommend bolus insulin dosing based on blood sugar readings and other factors. Once an app has been approved, substantively similar apps can qualify for FDA clearance. App development company Welldoc has received FDA clearance for two apps, Diabetes Manager and Bluestar; Bluestar is the first “prescription-only” diabetes app to receive FDA clearance for the medical management of type 2 diabetes in adults (Lee, 2014). Two apps that can directly upload and/or transmit glucose levels to a mobile phone have also received FDA clearance, the Glooko system and Minimed (Medtronic). MySugr, a diary and monitoring app that leverages gamification style to keep users engaged and motivated, is also FDA cleared (Lee, 2014). Although FDA regulation of apps that may pose a risk to patient safety is critical, there may be some confusion among consumers and providers as to the role of FDA approval and clearance. It is challenging to obtain information about which diabetes apps have FDA approval or clearance, and even among apps that appear to fall within the domain that FDA intends to regulate (e.g., insulin dose calculator apps), there appear to be a number on the market with no approval or clearance (Lee, 2014).

Given the massive amount of physiologic data that are becoming available via objective monitors of glucose, as well as other health variables such as heart rate and physical activity, apps that allow for the uploading and transmission of these data are likely to be most beneficial to patients and their providers. Only a small number of apps

currently allow this function, some of which have FDA approval/clearance (as noted above). The sharing of these physiologic data requires additional attention to security and patient health information privacy, which may be the reason that so few apps allow integration with patient health records. This limits the ease of communication and collaboration with providers on self-management goals.

As providers play an important role in introducing new health-related technologies to their patients, better understanding the provider experience is important as well. Maximizing utility and minimizing provider and patient burden should be key goals in app design. Interestingly, the number of functions provided by apps was negatively correlated with usability ratings (Arnhold et al., 2014), suggesting that current patients tend to prefer simpler designs. Providers, too, are likely to prefer apps with direct applicability to their role with patients. Providing education on diabetes, a key role of providers, is a feature that surprisingly has not seemed to be well-integrated in current apps (Arnhold et al., 2014; Chomutare et al., 2011; El-Gayar et al., 2013), despite this being stressed in clinical standards. This seems to be a relatively easy target for improvement in future app development.

Patient engagement in app use is still unclear. Some evidence suggests that a few highly active users are the most involved in app use, suggesting it will be important to better understand who actually uses the apps and what keeps them engaged. Patients with low health literacy are of particular concern, as they tend to have poorer glycemic control but are less likely to be computer literate or to use health information technology (Caburnay et al., 2015). In addition, most apps appear to target diabetes patients broadly, rather than focusing on features most relevant for patients based on factors like age or type of diabetes. Given that some differences in self-management demands exist for each type of diabetes, tailoring apps for the specific condition may be beneficial for app designers to consider. For example, patients with Type 1 diabetes may need to check their blood sugar more regularly, or social media features may be more popular with younger patients.

In summary, mobile applications for diabetes self-management are promising and proliferating at a very high rate, though limited efficacy data are currently available. App use, and mHealth in general, is likely to be a major area of continued development in the area of self-management for diabetes and should therefore be an important area of focus for patients and providers alike.

Compliance with ethical standards

Conflict of interest Megan Hood, Rebecca Wilson, Joyce Corsica, Lauren Bradley, Diana Chirinos, Amanda Vivo declare that they have no conflict of interest.

Human and animal rights and Informed consent All procedures followed were in accordance with ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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