Technical Brief Disposition of Comments Report

Research Review Title:
Mobile Applications for Self-Management of Diabetes

Draft review available for public comment from November 17, 2017 to December 7, 2017.

Research Review Citation: Veazie S, Winchell K, Gilbert J, Paynter R, Ivlev I, Eden K, Nussbaum K, Weiskopf N, Guise J-M, Helfand M. Mobile Applications for Self-Management of Diabetes. Technical Brief No. 31. (Prepared by the Scientific Resource Center under Contract Nos. 290- 2012-0004-C and 290-2017-00003-C.) AHRQ Publication No. 18-EHC010-EF. Rockville, MD: Agency for Healthcare Research and Quality; May 2018. Posted final reports are located on the Effective Healthcare Program search page. DOI: https://doi.org/10.23970/AHRQEPCTB31.

Comments to Research Review

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Comments on draft reviews and the authors' responses to the comments are posted for public viewing on the EHC Program Web site approximately 3 months after the final research review is published. Comments are not edited for spelling, grammar, or other content errors. Each comment is listed with the name and affiliation of the commentator, if this information is provided. Commentators are not required to provide their names or affiliations in order to submit suggestions or comments.

The tables below include the responses by the authors of the review to each comment submitted for this draft review. The responses to comments in this disposition report are those of the authors, who are responsible for its contents, and do not necessarily represent the views of the Agency for Healthcare Research and Quality.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	General	A journalism story may make the point that hundreds of apps are available, but researchers found few are backed by scientific studies, and none of the studies were high quality.	This is a better way to express our key message #1, so we have revised accordingly.
Peer Reviewer #1	General	A journalism story may make the point that of the eleven where they found published studies, less than half showed improvements in an important lab test for monitoring diabetes	This is a better way to express our key message #2, so we have revised accordingly.
Peer Reviewer #1	General	A journalism story may make the point that they say even where studies have been done, it is hard to tell whether patients are helped, because of problems/weaknesses in the studies.	We communicate this message in different ways throughout the report (methodological quality "hinders interpretation of results" or "made it difficult to interpret and apply findings").
Peer Reviewer #1	General	A journalism story may make the point that the apps can be hard to use, only two of seven apps tested for usability were considered acceptable	We added a sentence on p. 26 under "Variation in usability scores" to make the point more direct that consumers may have a difficult time using some apps.
Peer Reviewer #3	General	This is an excellent review. It's thorough, clearly written and touches all the relevant methodological bases.	Thank you.
Key Informant #1	General	This Technical Brief is both well done and well written. Given the broad nature of mHealth and diabetes, the authors clearly define the focus of the brief and the focus was well chosen.	Thank you.
Key Informant #1	General	Although the findings point out more limitations and issues than positive findings in this area, this brief can really serve as a focal point for encouraging further attention to improving the quality of studies and subsequent evidence for this important topic.	Agreed.
Key Informant #1	General	The conclusions can be used to inform future research and reference to tools that have been developed for quality mHealth studies is particularly helpful. Importantly this brief can and should be used to galvanize the diabetes community around promoting the tools for better studies in this area so higher quality and more complete evidence is available.	Thank you, we agree.
Key Informant #2	General	Many of the same statements occurred multiple times in various sections of the document. There are some apps for shared decision making that were not addressed such as the Mayo clinic app.	We have eliminated unnecessary repetition. We believe you are referring to this app - https://diabetesdecisionaid.mayoclinic.org/. While shared decision-making during clinic visits is an important aspect of diabetes care, we did not consider these types of apps as supporting diabetes self-management, so they were excluded based on our eligibility criteria.

Commentator & Affiliation	Section	Comment	Response
Key Informant #3	General	Overall, this is a well-written report. I appreciate the limitations in both the results and the methodology, and these were well-documented and explained. I think the key concept for all reviews is transparency and realistic description of the results as demonstrated by this review.	Thank you.
Key Informant #3	General	My one major suggestion is to consider including some information on the most-widely used apps. I understand that there are no studies examining outcomes, but I wonder from a patient/consumer perspective if it would be helpful to at least document what is known about usability, features, etc with the acknowledgement that there is no evidence to support their use. It may provide additional incentive for the makers to conduct studies and may also help consumers and physicians understand their limitations.	We provided examples of other studies that evaluated the usability of all available apps or a selection of popular apps under "Variation in usability scores." We also provided a sentence naming a few apps we did not find evidence for under "Limited statistical efficacy of commercially available apps.
Key Informant #4	General	Page 10 of 43, the 2nd sentence repeatedly uses word telehealth (redundant) and is somewhat confusing.	We rephrased this sentence and removed the telehealth repetitions.
Key Informant #4	General	Sentences should not begin with lower case 'm' as in mHealth.	Tradenames with a lower cased initial letter should retain the lower case even at the beginning of a sentence. In the case of "mHealth," we used a WHO document on mHealth as precedent for using lower-case mHealth at the beginning of a sentence- http://www.who.int/goe/publications/goe_mhealth_web.pdf.
Key Informant #4	General	Page 10, description of mHealth evaluation, this section is much too brief to do justice to the field. Either suggest it be expanded to cover mHealth evaluation methods more generally (e.g., there is a lot of evidence and rigorous studies in fields of smoking cessation, HIV/STIs, and maternal/child health) or deleted. The section as written doesn't really add much and understates work done in broader field of mHealth evaluation.	We deleted this section.
Public Reviewer #1 Debbie Salamanca	General	Comment 1: This is simple answers. Comment 2: I am not sure to say.	This does not appear to be a comment about the report.

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2 Malinda Peeples, WellDoc	General	This is a timely review. This technology space is rapidly evolving and expanding beyond mobile apps to digital therapeutics and other categories. It would be helpful for your readers to include a high level review of where apps fit into the overall regulatory picture with the FDA guidance and categorization of enforcement discretion and mobile medical applications.	The FDA is currently revisiting their guidance on mobile medical apps based on the 21st Century Cures Act- https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf Because the FDA may update its guidance in the near future, we chose not to include any information on regulatory guidance to avoid misleading the reader.
Public Reviewer #2 Malinda Peeples, WellDoc	General	[Ms. Peeples attached a summary of eight completed studies and one ongoing study, titled "Evaluate the Value of Telehomecare for Diabetes" that WellDoc sponsored on diabetes self-management. See reference list for a complete list of these studies.[1-8] This list was previously submitted through AHRQ's supplemental evidence and data request on September 14, 2017. Ms. Peeples also attached a copy of the first page of the Quinn 2008 study.]	When we initially evaluated the Quinn 2008 study, we excluded it because the app was called "WellDoc System" and we could not find an app by this name that patients could access. After reviewing a 2010 letter from the FDA to WellDoc, we determined that WellDoc System and BlueStar are indeed the same app, and therefore we included the Quinn 2008 study. None of the other studies that were provided by WellDoc met inclusion criteria for this review.
Peer reviewer #1	Abstract	Does "statistically significant improvements in multiple outcomes" mean that they showed improvements in all of the outcomes listed… or that these particular devices showed improvements in some of the outcomes listed?	We acknowledge that this sentence was unclear, so we have removed it.
Peer reviewer #1	Abstract	Glad the abstract included the issue about difficulty distinguishing effect of apps from other things done in the studies.	Thank you.
Peer reviewer #2	Background	Please review references. Where is ref 5 and 7? May have numbered incorrectly in the body of background.	We addressed this.
Peer reviewer #2	Background	p. 1 line 29/30 A reasonable HbA1c goal for non-pregnant adult is less than 7 percent. (only UKPDS data in type 2 to support this for new patients w/dm early in the disease). Not all dm! I would take this statement out.	We deleted that sentence.
Peer reviewer #3	Background	Might be worth mentioning briefly the scope of the world of health care apps....to put the diabetes apps in context. I think that data is readily available. How many health apps are now available and number of downloads. Would be good to add that data specifically for diabetes apps.	Agreed. We added statistics about the number of available mHealth apps as well as the proportion of which are designed for people with diabetes.
Key Informant #1	Background	Page 1. Correction needed. The Diabetes Control and Complications Trial was funded by NIH.	We changed CDC to NIH.

Commentator & Affiliation	Section	Comment	Response
Key Informant #1	Background	Page 2. Last sentence of mHealth section and several other places in the document. The term glucometer is used. The word glucometer is associated with a specific brand of blood glucose meter. While for some it has become a term similar to kleenex, for this review I strongly suggest that glucometer be replaced with blood glucose meter. No reason to use a term that is associated with a brand (which is referenced in the brief) and could raise a concern when one without issue is available	We changed “glucometer” to “blood glucose meter” here and everywhere it appears in the report.
Key Informant #2	Background	Well done.	Thank you.
Key Informant #4	Background	Well done other than previous comments	Thank you.
Public Reviewer #1 Debbie Salamanca	Background	1: My background is about depression. I am improvement for physical therapy. Comment 2: Sensitive. Temper.	This does not appear to be a comment about the report.
Peer Reviewer #2	Guiding Questions	p. 6 line 24/35 missing a period.	We added a period.
Peer Reviewer #3	Guiding Questions	Well framed.	Thank you.
Key Informant #2	Guiding Questions	Well done.	Thank you.
Key Informant #4	Guiding Questions	Well done.	Thank you.
Peer Reviewer #3	Methods	Clearly explained. I have no suggestions	Thank you.
Key Informant #1	Methods	It is understandable that the SUS had to be conducted by the available research staff for the project. It is unfortunate that none of the people assessing the usability had diabetes and that all had advanced education levels. Since none of these people are the target audience for the apps, it calls into question the usability review. However, this is stated (although not as a limitation) in the brief and those results can be viewed accordingly.	We added a more detailed description of the limitations of how we administered the SUS in the “limitations” section.
Key Informant #2	Methods	I was a little unclear about how usability was determined.	We changed the language in the “app features and usability testing” section to make it clearer how we used the SUS.
Key Informant #4	Methods	Well done.	Thank you.
Public Reviewer #1 Debbie Salamanca	Methods	Comment 1: Not accpeted. Comment 2: N/A	This does not appear to be a comment about the report.

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2 Malinda Peeples, WellDoc	Methods	Page 5. States that app developers were contacted. WellDoc was not contacted and we would have been happy to provide access to the app.	Per our protocol, we contacted study authors or app developers to gain access to apps. For WellDoc, we contacted Dr. Charlene Quinn, but did not receive a response. We subsequently contacted Ms. Peeples for an access code and additional information on BlueStar.
Peer Reviewer #1	Findings	The Description of Apps section is useful. This section is likely to attract attention, much like the reviews on app stores.	Thank you.
Peer Reviewer #2	Findings	p. 12 line 38 needs a period	We added a period.
Peer Reviewer #2	Findings	p. 14 line 49 & 51 dietitian spelled wrong?	We changed “dietician” to “dietitian.”
Peer Reviewer #2	Findings	p. 15 line 18 "poorly" controlled dm if HbA1c is > or = to 8 %. this is misleading.... I would suggest instead "Of note this population had more difficult to control....8% may be good in a type 1 w/severe hypoglycemia and no access to continuous glucose monitoring technology	We changed “poorly controlled diabetes” to “diabetes that was difficult to control.”
Peer Reviewer #3	Findings	Also clearly presented and with sufficient detail in context of the scope of this review.	Thank you.
Key Informant #1	Findings	Page 14 under findings for DID. Minor editorial comment. Preferred spelling is dietitian and not dietician.	We changed the spelling from “dietician” to “dietitian.”
Key Informant #1	Findings	Page 15 under Diabeo it is unclear what is meant by chronic diabetes. All diabetes, except gestational diabetes, is chronic. Please clarify why this is different from just saying diabetes. If it is not, the word chronic should be deleted.	We removed the term “chronic.”
Key Informant #2	Findings	The tables should indicate for each study what the primary outcome was and what the results were for that.	We added a paragraph under “Rapid review limitations” section to explain why we did not report author’s primary and secondary outcomes: “Also of note, although we took steps to critically assess the potential for bias in these studies, we did not consider every potential area for bias. Specifically, we did not evaluate primary and secondary outcomes as specified by study authors. Therefore, we could not tell if these outcomes were selectively reported.”

Commentator & Affiliation	Section	Comment	Response
Key Informant #2	Findings	Secondary outcomes and effects on secondary outcomes should be clearly identified as such	We added a paragraph under "Rapid review limitations" section to explain why we did not report author's primary and secondary outcomes: "Also of note, although we took steps to critically assess the potential for bias in these studies, we did not consider every potential area for bias. Specifically, we did not evaluate primary and secondary outcomes as specified by study authors. Therefore, we could not tell if these outcomes were selectively reported."
Key Informant #2	Findings	There are no p values provided.	We provide p-values for each study outcome (when available) in Appendix C.
Key Informant #2	Findings	It would be more helpful to have a table with the information provided in text on number of people studied, diabetes duration, age etc.	We provide number of people studied, diabetes duration, age, and other study details in Appendix C.
Key Informant #3	Findings	Type on p.23 line 6	We clarified that Diabeo Telesage is not available to download in the United States.
Key Informant #3	Findings	If possible, add names of apps to studies in RoB summary.	Unfortunately, the app names did not fit into this graph, but we put the citation by each (Author, Year) so readers could trace the citation across different sections of the report.
Key Informant #4	Findings	Supported by methods.	Agreed.
Public Reviewer #1 Debbie Salamanca	Findings	Comment 2: Un exactly	This does not appear to be a comment about the report.
Public Reviewer #2 Malinda Peeples, WellDoc	Findings	Page 16. Paragraph 3 states that each app was evaluated in only 1 study. The foundation app for BlueStar was evaluated in 2 studies (Quinn 2008, Quinn 2011). I have attached the 2008 study.	When we initially evaluated the Quinn 2008 study, we excluded it because the app was called "WellDoc System" and we could not find an app by this name that patients could access. After reviewing a 2010 letter from the FDA to WellDoc, we determined that WellDoc System and BlueStar are indeed the same app, and therefore we included the Quinn 2008 study. We revised the statement from "findings" to indicate that the BlueStar app was evaluated in 2 studies.

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2 Malinda Peeples, WellDoc	Findings	[Ms. Peeples attached a PDF document which had additional track changes to the BlueStar Diabetes app section in "Findings." Track changes are described below. • Changed "BlueStar (free)" to "BlueStar (free to download but requires an access code from a member of the care team.)" • Removed "This app requires a "prescription" from a doctor to create an account." • Removed "It was announced in January 2017 that the FDA has cleared BlueStar for 510(k) Class II clearance for a nonprescription version, though it is not clear when this version of the app will be released" and replaced with "The app received a 510 (k) clearance as a class II medical device in 2010 as a prescription product. In 2017, the FDA cleared BlueStar as non-prescription with a prescription required for the in-app insulin calculation feature." • Removed "This app is not available in all 50 states yet, but the BlueStar Web site says that it will be available in more states soon." • Removed "prescription required app" from "We were unable to log into and use the 50.9 MB, prescription-required app." • Added "sleep" to the list of health data tracked by BlueStar. • Changed "insulin dose suggestions" to "insulin dose calculations." • Changed "though this feature will not be available in the forthcoming nonprescription version" to "through an in-app prescription upgrade" • Changed "dietary advice" to "dietary coaching." • Added "real-time feedback" to the list of features provided by BlueStar. • Changed "a connection to the user's EMR or patient portal" to "the ability to send a report into the EMR."]	We made the following revisions: • After WellDoc provided an access code, we were able to confirm that the app is "free to download but requires an access code from a member of the care team to use the app." • We removed "This app requires a "prescription" from a doctor to create an account." When the app was recently updated, it became accessible through an access code. • We reviewed FDA's 2010 letter to WellDoc in addition to the 2017 letter that was previously reviewed. We revised the FDA language to say: "In 2010, an earlier version of BlueStar (then called DiabetesManager) received 510(k) clearance as a Class II medical device, with a prescription required for the use of coaching messages. In 2017, the FDA cleared BlueStar, including coaching messages, as a non-prescription device due to its low risk. A prescription was required for its in-app insulin calculation feature." • We removed discussion of where the app is available, as this is no longer accurate. • The scope of this review was focused on diabetes-related app features. Therefore, we did not include sleep. Under "Methods, App features and usability testing" we clarified that we only collected "diabetes-related health information tracked." • We left "dietary advice" as is. This is the terminology we chose to describe the feature for this app and others. • We did not evaluate whether apps gave real-time or delayed feedback; however, we do describe the type of feedback provided. • We updated information on EMR connection based on accessing the app. The app provides "a connection to the user's EMR or patient portal using Human API integration software."

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #2	Summary & Implications	p. 28 line22 under limitations typo...consideration for decisionmaking that "we" were unfortunately…	We addressed this.
Peer Reviewer #3	Summary & Implications	Although perhaps beyond the bounds of this kind of AHRQ review, I would suggest perhaps just a paragraph or two about the implications for both physicians and people with diabetes -- by way of a caveat emptor regarding m-health tools and apps. Such tools have proliferated rapidly in the new world of smart phones, mobile devices -- and it is not a trivial thing at all that there is a lack of evidence of efficacy as millions of people experiment with these tools.	We added a section “Implications for clinicians and patients” under “Next steps” to address this comment.
Key Informant #1	Summary & Implications	Statement about findings being generalizable to most people with diabetes should state adults with diabetes. It says so later in the paragraph, but should say in the first sentence for clarity	We changed “patients” to “adults” in the first sentence of that section for clarification.
Key Informant #2	Summary & Implications	Results could be more clearly presented as histograms indicating statistical significance of primary and secondary outcomes for each app.	We decided to provide written rather than visual descriptions of study findings in this report. Because we evaluated evidence for specific apps, and most studies had multiple outcomes, we decided it was not feasible to include a table for each outcome. We do however provide detailed information on findings for primary and secondary outcomes in Appendix C.
Key Informant #4	Summary & Implications	Well done.	Thank you.
Peer Reviewer #3	Next Steps	In addition to calling for more research, the authors might consider clarifying in a paragraph or two where the responsibility lies in government for addressing this issue. FDA, etc.	The FDA is currently revisiting their guidance on mobile medical apps based on the 21st Century Cures Act- https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf Because the FDA may update its guidance in the near future, we chose not to include any information on regulatory guidance to avoid misleading the reader.

Commentator & Affiliation	Section	Comment	Response
Key Informant #1	Next Steps	Page 29, Future Research Needs section. The statement is made that future studies are needed to determine long term impact of apps and whether other self-management interventions are needed for improving outcomes. There is little question that other interventions are needed so this statement is not really accurate. As was noted in the summary of the KI comments, these apps are viewed by some as a magic bullet and that is not the case. People with diabetes need diabetes self-management education and support (DSMES) which has standards. Apps and other tools may provide support and enhancement to DSMES. Some of the apps, provided access to "diabetes education" or to diabetes educators but is was not clear what exactly was provided. Future studies need to more clearly describe and define what diabetes education the study participants are receiving (it may not meet the standards of DSMES) or have received and when.so that the apps can be more clearly examined in light of this cornerstone of diabetes care. It is in this context that further interventions should be identified.	We removed the statement "and other interventions for self-management are needed to maintain goals." In "methodological issues with available evidence", we added that studies provided "limited information on the content of diabetes education provided by the app or provider."
Key Informant #4	Next Steps	More specifics on exact types of studies that need to be conducted would enhance this section. Brief descriptions of some specific studies should be added.	We added more detail to make it clear where there are research gaps and how they should be filled, with some examples of the exact type of studies that would be helpful.
Peer Reviewer #2	Clarity & Usability	Yes well done.	Thank you.
Peer Reviewer #3	Clarity & Usability	Yes, to all these questions. This is a very useful and well structured report on a critical topic.	Thank you.
Key Informant #1	Clarity & Usability	As noted in my general comments above, this is very well written and clear.	Thank you.
Key Informant #3	Clarity & Usability	Report was well-structured and provided as much information as possible. Unfortunately, due to the lack of information and availability of apps I am unsure of how it will be used to inform guidance..	We hope that the report highlights the most important limitations of the literature so there are better, more rigorous studies in the future that can inform guidance.
Key Informant #3	Clarity & Usability	The report may be helpful if clinicians would like to discuss pros/cons of the different apps in terms of outcomes. But again this will be limited in nature (see comment above).	Agreed.
Key Informant #3	Clarity & Usability	I am hopeful that the report will encourage better reporting by the app makers themselves and encourage future research in this area.	Agreed.
Key Informant #4	Clarity & Usability	Yes to all of these questions. More specifics on the nature of the future research that is needed should be added.	We added more detail to make it clear where there are research gaps and how they should be filled, with some examples of the exact type of studies that would be helpful.

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #1 Debbie Salamanca	Discussion	Comment 1: I like to have an debate in the general. Comment 2: Counselor	This does not appear to be a comment about the report.
Public Reviewer #1 Debbie Salamanca	References	Comment 1. [Ms. Salamanca provided names and phone numbers.] Comment 2. N/A.	This does not appear to be a comment about the report.
Public Reviewer #1 Debbie Salamanca	Tables	Comment 1. I have an RX for it. Comment 2. N/A	This does not appear to be a comment about the report.
Public Reviewer #2 Malinda Peeples, WellDoc	Tables	Table 2. Features: BlueStar Diabetes. • In the Cost Column, please change free to "free to download, requires access code from care team" • In the What Feedback Column, please change insulin dose suggestion to insulin dose calculation, add to BG real-time contextual feedback & trending messages. Also please change A1C "calculation" to "tracking". The same changes should be applied to both the Apple and Android rows • In the Can I Trust the Results column the 2008 Quinn study should also be included.	We made the following revisions: • We changed the "cost" column from "free to download" to "free to download but requires an access code." • We removed "insulin dose suggestion" because the app described in this table (BlueStar Diabetes) does not have that feature. • We removed "HbA1c calculation" from the "what feedback" column. HbA1c is listed under "what does the app track" so we left that as is. • We added the Quinn 2008 study reference to "can I trust the results" column.
Public Reviewer #1 Debbie Salamanca	Figures	Comment 1. I am figures about goals. Comment 2. Positive	This does not appear to be a comment about the report.
Public Reviewer #1 Debbie Salamanca	Appendices	Comment 1: N/A. Comment 2: Unknown	This does not appear to be a comment about the report.

References

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