Technical Brief Disposition of Comments Report

Title: *Evaluation of Mental Health Mobile Applications*

Draft report available for public comment from October 20, 2021, to November 16, 2021.

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Comments to Draft Report

The Effective Health Care (EHC) Program encourages the public to participate in the development of its research projects. Each draft report is posted to the EHC Program website or AHRQ website for public comment for a 3- to 4-week period. Comments can be submitted via the website, mail, or email. At the conclusion of the public comment period, authors use the commentators' comments to revise the draft report.

Comments on draft reports and the authors' responses to the comments are posted for public viewing on the website approximately 3 months after the final report 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.

This document includes the responses by the authors of the report to comments that were submitted for this draft report. 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.

Summary of Peer Reviewer Comments and Author Response

This research review underwent peer review before the draft report was posted for public comment on the EHC website.

Themes and responses to themes from peer review of draft report

1. **Clarification is needed on the target audience of the framework and intended purpose.**
   This framework is not intended for direct use by clinicians or consumers; rather, we expect use by intermediary organizations, such as mental health agencies, to evaluate apps. The "results" of the application of the framework could then be used by clinicians and consumers.

2. **More detail is needed on specific gaps in existing frameworks and rationale for a new framework.**
   We have added a more comprehensive discussion of the specific gaps in the existing frameworks under "Findings: Gaps in the existing frameworks." Most existing frameworks are geared toward evaluating specific aspects of health apps (e.g., usability) and do not adequately reflect concerns around assessment of risks posed by the apps, as well as recent advancements in use of artificial intelligence (AI). This project was requested by nominators who desired a Government-developed framework, developed with a transparent and rigorous process with input from stakeholders (including Federal partners: National Institute of Mental Health [NIMH], Food and Drug Administration [FDA], Substance Abuse and Mental Health Services Administration [SAMHSA], and Health Resources and Services Administration [HRSA]).

3. **More discussion is needed on importance/benefits of digital mental health apps, access for BIPOC individuals, factors driving recent growth, and FDA status/classifications.**
   We have added detail to the background about the current state of the science, statistics about use of apps, and FDA regulations.

4. **The section on risk assessment is confusing and may inadvertently exclude the most needy from using apps that could help them.**
   We now cite documented safety/privacy and/or physical/mental "harms" of mental health apps outside of the theoretical harms previously noted. We agree that the risk of the app should stand separately, and it does in the framework. Those with serious mental illness or more severe mental conditions/impairment could be served best by using an app under the care of a health provider. An app should not be a replacement for mental health care for those with more chronic and severe mental health conditions. We agree that we do not want to prevent individuals from benefitting from app use, but we do want to provide an assessment of the risks. We tried to find the right balance in the revised framework so that the threshold for classifying the risk posed by an app is appropriately calibrated.

Source: https://effectivehealthcare.ahrq.gov/products/mental-health-apps/report
Published Online: May 20, 2022

5. **Pilot testing with 10 apps is inadequate (possible bias in app selection); more detail is needed on evaluation of apps (methods and results).**
The process of app selection is described in greater detail in the Methods section. The section on pilot testing has been revised based on results from further rounds of testing. The final report describes the pre-pilot test of 10 apps and six rounds of dual-review pilot testing of 35 additional apps.

6. **More detail is needed on marketing, training, maintenance, and dissemination of the framework. How will this framework be used in practice?**
We acknowledge in the Discussion that this is a rapidly developing area and that any framework developed for this purpose would require updating as the field evolves. We have added to the Discussion the range of possibilities for dissemination of the framework. The final paragraph of the report addresses issues of updating and sustainability. One possible solution is to have an electronic, accessible, and interactive version of the framework located on a web page to be leveraged by individuals and advocacy groups. We may be able to leverage the SAMHSA, NIMH, HRSA grantee pool and networks for dissemination and the SAMHSA technical assistance center for possible training and updating/maintenance. Given the rapid advancements in technology and regulations around the use of such apps, we expect revisions to be needed in the near term.

   One reviewer suggested "I would hope that in the future this skill set will become a digital health competency that is part of a clinician's educational path- that may be broader than you want to go with this review but the journey from publication/guideline to front line practice is long and these potential new treatment modalities need to be accelerated." The framework could be used as part of an online Continuing Medical Education course to provide this information to various types of healthcare providers.

   In terms of how this framework would be used in practice, this framework is not intended for direct use by clinicians or consumers; rather, we expect use by intermediary organizations, such as mental health agencies, to evaluate apps and the "results" of the framework to be used by clinicians and consumers.

7. **Cultural competence in framework does not fit into the existing guiding questions.**
Cultural competence was not identified in the initial scope of work provided by AHRQ (including the initial guiding questions) but identified during the stakeholder interviews as a priority and thus added to the framework.

8. **The framework includes too many mental health disorders as well as wellness.**
One reviewer expressed concern about whether a "one size fits all" framework will work only for certain mental disorders ("the framework focuses on too many mental health disorders, given that different disorders may be more or less amenable to treatment via digital therapeutics").

   The scope of work from AHRQ (the funding agency) specified inclusion of a broad range of mental health states and conditions (including wellness). The intention

of the framework is to assess safety and relevance of apps based on certain transdiagnostic symptoms. It does not provide a comprehensive assessment of apps for a specific condition. We attempted to go in that direction, only to recognize that the evidence to guide specifications for apps targeted at specific mental health conditions is still weak. We have added this to the Discussion: "The framework presents considerations that can be generalized for most mental health apps; as such, it does not facilitate a comprehensive assessment of apps for a specific mental health condition."

9. **Complexity of framework, average time of 75 minutes per app to complete assessment, and low interrater reliability suggest this framework is not feasible.** After multiple rounds of revisions to the framework and additions to the guidance, the framework now takes 45–60 minutes to complete per app. Because the framework will be applied by an intermediary body (and not individual consumers or clinicians), we consider this to be a feasible amount of time for a comprehensive assessment. We have reported the interrater reliability for the additional rounds of pilot testing, which is now at an acceptable level.

Public Comments and Author Response *for reports with sequential peer review and public comment*

Commentator & Affiliation	Section	Comment	Response
Public review #1 (APA)	Overall	1. The proposed framework has many strengths, is generally well-done and addresses important and critical gaps, such as assessing the risk posed by the app and assigning a safety and credibility rating to it.	Thank you
Public review #1 (APA)	Overall	2. The inclusion of utilization data in the framework is also an important addition, as previous research (https://pubmed.ncbi.nlm.nih.gov/32881542/) has found that the two most popular smartphone apps for depression and anxiety were responsible for 90% of monthly active users employing a user-adjusted analysis. This provides important data on the impact of mobile apps and may provide better information related to integrity than whether an employer has provided access to an app as a part of their employee benefits (Endorsement and Usage section).	We agree that utilization is critically important to app impact. In the framework, utilization is embedded in app ratings as the number of users who provided apple store ratings gets at impact by proving a ranking of the app by category and the number of users on which the summary rating is based.
Public review #1 (APA)	Overall	3. The introduction and background would improve from some clarity as it relates to FDA regulation in this space. What are the three classifications for FDA approval? What does it mean that the FDA has taken a “hands-off” approach towards regulation when apps do not fall into the realm of “device software functions”? Additional clarification on language about “prescribing” an app as an adjunct to treatment being “restricted” would also be helpful. Restricted by whom, for example?	We have revised this section based on your feedback, thank you.
Public review #1 (APA)	Overall	4. On page 7, MIND is incorrectly attributed to a framework based on the American Psychological Association; it should say American Psychiatric Association.	This correction has been made. Thank you.

Commentator & Affiliation	Section	Comment	Response
Public review #1 (APA)	Overall	5. We are concerned that the response to the following question - Is the app either being used or been endorsed by a government agency or trusted mental health professional association? - alone in the App Integrity Assessment would not provide sufficient evidence to meet the threshold for safety and credibility in this category.	We agree that this question not does not capture evidence. There is a separate section with questions on evidence, use of a theoretical framework, etc. that are aimed at assessment of risk/safety. Additionally, the framework has questions on privacy/security that all together get at various dimensions of "integrity" of the app.
Public review #1 (APA)	Overall	6. The Framework would benefit from additional guidance or scoring criteria on how to weigh and evaluate responses to the framework questions, similar to the App Integrity Assessment. Cut-offs would be especially helpful.	Currently, only Section 1 "Risk and Mitigation Strategies" is scored. We discussed this repeatedly over the course of the development of the framework, including during the interviews with the stakeholders, and arrived at the conclusion that scoring every aspect of apps didn't seem feasible, especially given the limitations in evidence to guide the "weights" of such scores. Additionally, the use of numerical scoring and cut-offs masks critical information which might be helpful for decision-makers.

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Public review #1 (APA)	Overall	7. Having only one question in the E. Evidence & Clinical Foundation does not seem sufficient nor does using the term “function” accurately describe “evidence and clinical foundation.”	Other questions on evidence are included in Section 1C (Risk and Mitigation Strategy). These are the most prioritized questions and therefore placed at the start of the assessment.
Public review #1 (APA)	Overall	8. The technical brief and associated framework acknowledge being built upon existing frameworks; however, it remains unclear how the field will move from framework to a curated and maintained library of apps. Where will the resources come from to support such an initiative?	Please note that this issue was raised in the future direction section and is the natural next step. This next step is beyond the scope of the existing project.
Public review #1 (APA)	Overall	9. We are also seeing an increased number of apps that use psychological intervention science to address behavioral health conditions such as fibromyalgia and IBS. Do the developers of this draft report see these types of apps also being appropriate to evaluate with the existing framework or will a new framework be necessary?	We focused on apps addressing mental health and mental wellness goals as that was the purpose of the AHRQ task order.
Public review #1 (APA)	Overall	10. When the framework is finalized and published, it would be helpful to provide some examples of the evaluations that were done on various apps, in addition to providing the inter-rater reliability, in order to assist the reader (or potential evaluator) with a template for operationalizing the questions. This would also encourage buy-in of the utility of the framework itself.	Great suggestion! We have included example applications of the framework for three apps in the Appendix of the report.

Commentator & Affiliation	Section	Comment	Response
Public review #1 (APA)	Overall	11. One of the continued challenges and limitations of this and other existing frameworks is that they do not fully address whether an app is of high quality but whether they are transparent and have followed certain processes. For example, the evidence section asks whether a randomized trial showing efficacy exists but not whether that randomized trial is of any quality. A publication that was funded by industry and then published in an open-access, non-peer reviewed journal may not demonstrate efficacy. The efficacy should be clinically relevant and clearly attributable to the app.	We agree with this observation and have added this issue to the limitations section of the discussion. Assessing the quality of a study and summarizing the strength of the evidence of an intervention would necessitate a systematic review and use of GRADE or equivalent evidence summary profiles. This would require specialized skills of those applying the framework and significant resources.
Public review #2	Overall	The framework overall seems really good. The one overarching comment I have is that the framework treats mental health apps as though they are static, fixed entities. However, apps are often continuously evolving through ongoing updates. While these updates are often minor, fixing bugs or minor issues related to usability, they are also occasionally substantive, with major changes in functionality. This has implications for an evidence or evaluation framework. For example, if the app being evaluated has a clinical trial, how close is the app being evaluated to the app that was evaluated during the clinical trial? Demanding that an app be identical to what was evaluated in a trial that may have taken place years before seems unreasonable. But it seems recognizing and alerting the evaluator to this possibility, and if possible providing some guidance on how an evaluator should consider this issue would be helpful.	Thank you. The framework currently has a question on when the app was last updated, and the assessment is linked to the last update. If an app undergoes updates, the framework could be reapplied and associated information about the app could be updated. We agree that if this framework is implemented (through a webpage), it would be important to update the reviewers when an app undergoes substantial updates.

Commentator & Affiliation	Section	Comment	Response
Public review #3 (Holon Inclusive Health System)	Introduction	Healthcare apps very much need to focus on a strong position for safety to consumers as many apps like medical devices can cause patient harm. Safety can be compromised through the app offering "treatments" or "solutions" which could be "practicing medicine without a license" by offering treatment advice to patients with health conditions. Businesses may have access to sensitive PHI and now target patients health data in a way that is exploitive when the clinician is not offering the interventions or approving the interventions at hand. A technology company offering healthcare data and advice based on healthcare data and PHI it has obtained from a health record is not different than practicing medicine and should be held to the same regulations such as anti-kick back, Stark Law, and other standards related to financial gain that many of these technology companies seek by accessing patient healthcare data. Especially as it relates to vulnerable populations such as children and adolescents, the mentally ill, the elderly, chronic pain patients, and patients with substance use disorders. As a CEO myself, and strong user for healthcare technology, I have already run into issues with apps, taking healthcare data, ciphoning that information in attempt to barrage the patients with marketing for other purchases that they may make based on the app, or offering "related reading material". There is no clinical oversight of the marketing that is being aimed at these patients. There is also no informed consent process to ensure that the client on the other end of the application is understanding the potential risks vs. benefits of the app. This isn't just in Remote patient monitoring apps. We have seen this same problem arise from EHR companies that are making "sub companies" and marketing to patients based on their data, telehealth platforms, collections and billing platforms, etc. Patients with other health conditions are also vulnerable. Other medical conditions may be impacted by the use of these applications. They are through marketing, statements, asking questions, and screening possibly guiding the choices and controlling the activity of a patient. This can ultimately lead to harm of the patient. A technology company is not ethically in a position from a liability standpoint preparing the way pharmaceutical companies must in order to prove safety from the use of their applications despite the fact that they may cause just as much patient harm by offering interventions based on PHI. Saba Akbar, Enrico Coiera,, Farah Magrabi, Safety concerns with consumer-facing mobile health applications and their consequences: a scoping review, Journal of the American Medical Informa	Thank you, we have now added more detail on safety to the introduction. We have also provided a future direction that licensed mental health professionals receive training on how to speak with patients about the safety and risks regarding mental health apps. We appreciate these reflections- it provides appropriate justification for why oversight of mental health apps and companies is needed, as well as the need for such a framework. Currently, the framework addresses all the issues raised by the reviewer: 1. Presence of evidence on the utility; 2. Whether the app requires consent; 3. Whether appropriate disclosures exists for how data are used; 4. Considerations for vulnerable populations and minor; 5. Whether the app actually does what it markets itself as.

Commentator & Affiliation	Section	Comment	Response
Public review #3 (Holon Inclusive Health System) (cont'd)	Introduction (cont'd)	(comment above)	We note that these areas have been addressed by the framework guided by the principles of developing this framework (i.e., can be undertaken by non-specialized evaluators with a reasonable amount of effort and resources).
Public review #3 (Holon Inclusive Health System)	Methods	While asking providers is a valuable start. Healthcare applications that are being applied based on PHI, should have much stronger criteria for evaluating effectiveness and safety for clinical use. Healthcare apps should be held to the same standard as medical devices, medications, etc. These apps are no different than any other healthcare intervention in addition to screening tools. Rigorous studies are conducted in order to offer the application of medical devices, medications etc. for the safety vs. harm to patients. I would say the methods of this study, while helpful, are not at all rigorous for determining the safety of application to the patient, the safety for phi privacy and safety away from hacking, there is nothing that evaluates the tech company itself for secondary financial gain, etc.	We have a section on Organizational Credibility meant to determine whether the app comes from a trusted source and whether any complaints have been filed against the developer. Other questions around whether the app has been endorsed by mental health agencies, the use of data, appropriate disclosures, availability of clinically relevant evidence address several other aspects of safety. A complete analyses of the financial gains of the company is beyond the scope of this framework.

Commentator & Affiliation	Section	Comment	Response
Public review #3 (Holon Inclusive Health System)	Findings	The findings are a great start to discussing the risks of medical apps, but doesn't go near in depth into the issues regarding platforms that are ciphoning PHI. How that information is to be disseminated. We have already seen from the documentary on the "Social Dilemma" that tech companies stand to profit exponentially with a large amount of secondary gain by creating these apps that will be managing protected health information. There needs to be ethics and oversight committees that are formed to ensure that these do not take more advantage. We have seen with pharmaceutical companies the power of suggestion as it relates with marketing, suggestive information. None of this is oversighted with these medical intervention apps which can cause severe safety concerns for vulnerable patients. Most tech companies are not showing how they are keeping IP addresses safe, ensuring security for patients, not standing to gain secondary kickbacks by getting patients onto their platforms. If they are selling the data or giving the other data to another company, this is no different than a physician getting money from forcing patients to get treatments or buy extra services in their practice which in the wrong circumstance could be a violation of anti-kickback statutes. These tech companies are also not showing how they are protecting financial data etc. By selling their data to pharmaceutical companies, they are also not selling it at "fair market value" and more than likely are selling to the highest bidder. Patients may find themselves with data being sent to employers, other people on the internet, hackers, identity theft is a possibility for these patients based on healthcare apps that are not forced through a standard safety process for evaluation and application for health related reasons. Many of these apps may offer interventions to food, medication, or vitamins. These could be harmful if they are not operating within the patient charts. Providers may be kept in the dark about the safety. I have already had this occur in my own practice with healthcare apps that are purchased for "medical reasons"...were targeting my patients with more sales based off their health information. They made it sound like I the clinician could also have financial gain for their services making it seem like it was being promoted by me, which was not at all the case nor in my BAA. It was false advertising and information being given to my patients. I was only able to find out because a patient snapped me pictures of the application forcing her to "sign away all HIPAA rights" in order to be able to access me on the telehealth platform (unbeknownst to me). This places patients and providers at risk by technology companies. Currently providers are forced to have malpractices and cover HIPAA and data breaches. These apps could lead to more lawsuits for practitioners in addition to the patient harm. Providers are already strapped because of the cost of malpractice in an already dysfunctional system. Yet the technology company for most of these apps are not holding any liability and forces in the BAA for the covered entity to hold them harmless for their less that secure products.	Thank you, as noted below, we have enhanced the section on risks of mental health mobile apps. We appreciate the reviewer's comments on the use of PHI. As pointed out by the reviewer, this is a very complex issue which requires systematic assessment and regulation. The framework focuses on aspects of transparency and whether the app discloses how data are used to the user, so that the user is appropriately informed before providing consent. The actual regulation of how PHI are used are beyond the scope of this framework.

Commentator & Affiliation	Section	Comment	Response
Public review #3 (Holon Inclusive Health System)	References	Please see references: https://www.businessofapps.com/insights/privacy-and-security-in-mhealth-applications-guide/ https://www.healthitanswers.net/healthcare-apps-data-privacy-and-security-risks/ https://aithority.com/ait-featured-posts/71-of-healthcare-medical-apps-have-a-serious-vulnerability-91-fail-crypto-tests/ https://www.fiercehealthcare.com/tech/report-shows-patient-data-vulnerable-to-hacks-third-party-aggregators https://healthcareglobal.com/technology-and-ai-3/most-healthcare-apps-have-weak-security-report-finds https://www.infosecurity-magazine.com/news/most-healthcare-apps-are-riddled/	Thank you, as noted below, we have enhanced the section on risks of mental health apps.
Public review #3 (Holon Inclusive Health System)	Overall	It does offer up the problem in a very understandable way. However, it is not near in depth to the problems that can arise with the use of healthcare apps.	We have elaborated on the risks related mental health apps, and the use of data in the background as well as in the identified gaps section and in the discussion section.

Commentator & Affiliation	Section	Comment	Response
Public review #4 Digital Therapeutics Alliance (DTA)	Scope of AHRQ's Evaluation Framework	The approach taken to develop the FASTER framework to evaluate mental health apps is well-planned and executed. In terms of the framework's scope of product applicability, the draft technical brief states, "Mental health apps are being used to support diagnosis, treatment, and management for mental health illness, as well as to provide wellness support through meditation and mindfulness. Some mental health apps can provide diagnostic support or assist in the diagnostic pathway by improving time to diagnosis, for example by offering automated standardized mental health assessments. Apps might also facilitate treatment for certain mental health conditions and provide therapeutic support." (emphases added) Since the draft brief defines mental health apps as those intended to support, diagnose, and facilitate medical care, digital therapeutics do not fit into this definition, as DTx products use software to directly treat diseases and disorders. It is important to note at the industry level that digital health apps are generally recognized as different from digital therapeutics. We therefore welcome further conversations with AHRQ should the above definition eventually be expanded to include DTx products under the umbrella of health apps. The distinction between DTx products and health apps is often made on the grounds that digital therapeutics use software to directly prevent/manage/treat diseases and disorders, are recognized by regulatory agencies as medical devices, are incorporated into formal treatment pathways alongside or in place of medications and in-person therapies, and must adhere to industry principles, including pre- and post-market clinical validation, privacy and security protection requirements, and regulatory oversight according to product claims and risk levels. In referencing the above definition and figure included below, it appears that certain products in the 'wellness & support' and 'diagnostic & monitoring' categories are currently subject to AHRQ's draft evaluation framework (i.e., software that supports or facilitates care), and that products in the 'therapeutic interventions' category are not subject to this framework (i.e., software that directly treat medical conditions).	The framework currently does provide for assessment of apps that aim to provide treatment and places a higher requirement of evidence for such apps. However, during the pilot testing phase, we were unable to test the framework on apps that could be classified as digital therapeutics (DTx) as we were unable to get the required approval to access these apps. We have added this issue to the limitations of the framework.

Commentator & Affiliation	Section	Comment	Response
Public review #4 Digital Therapeutics Alliance (DTA)	Importance of Distinguishing Between Product Types	Despite the significant differences between digital health products that are currently on the market, relatively few people are able to differentiate between digital health technologies that serve different purposes. Using traditional pharmaceutical products as an example, most people understand that even if two capsules or tablets look alike, that each medication type can serve a different purpose from the other (i.e., antihypertensive vs. allergy relief). It's common understanding that the active ingredient inside the medication is what dictates a medication's clinical impact, not the packaging or shell it is delivered in. Nevertheless, patients and clinicians rarely realize that even though software-based products ranging from wellness to therapeutic may be accessed through an online platform such as an app store and downloaded onto their smartphone or tablet – thus appearing externally to be the same – each product type has a very different purpose, indication, and level of clinical impact and risk. Significant education across the healthcare ecosystem is necessary, for example, to convey to end users the different mechanisms of action and clinical impacts that DTx products have from wellness, support, diagnostic, and monitoring products. Additional education and resources are also necessary for end users as they navigate various app stores. In the case of digital therapeutics, even though the product shell of a DTx product may be available on an app store – thus appearing to be the same as all other wellness and support apps – an authorization code provided by a clinician, insurer, employer, or DTx manufacturer is required to access the full product content. While end users may initially find this confusing, this important process helps ensure that the DTx therapy is being used by the right patient at the right time for the right indication, similar to the requirements established for traditional medications. While these definitional distinctions may be nuanced, they are important to helping patients, caregivers, policymakers, and payors understand what therapies are available to them and what expectations they should have in terms of the product's clinical impact. An analogy to summarize this section: digital health apps are the likely equivalent of over-the-counter medications, whereas digital therapeutics are the equivalent of behind-the-counter and prescription medications. Every one of these products serves an important role, but the impacts and safety guards vary significantly.	These are all great points. We have added information under next steps to highlight the need to educate both end users and clinicians on the use of mental health apps. This framework aims to address the concerns addressed by the reviewer by systematically classifying the purpose and functionalities provided by the various apps.

Commentator & Affiliation	Section	Comment	Response
Public review #4 Digital Therapeutics Alliance (DTA)	Applicability of the Framework	In the draft technical brief, free versions of apps that did not require permission from an employer, healthcare professional, or insurance agency were chosen for assessment. Since DTx product content is not available online at no charge, none of these products will have been included in the initial evaluation process. Assuming that DTx products are not included in the final 'mental health app' definition, this is not a problem. If, however digital therapeutics are eventually included in this framework, it will be necessary to include certain DTx products in the initial evaluation of this framework to ensure applicability.	As per the protocol, apps were excluded from the testing of the framework if they required an access code or a payment of greater than $100. As such, we were unable to test the framework on apps that might be classified as digital therapeutics (DTx) and have noted this as a limitation and next step for the framework.

Commentator & Affiliation	Section	Comment	Response
Public review #4 Digital Therapeutics Alliance (DTA)	Other Relevant Frameworks	And lastly, since the Appendices of the draft technical brief do not appear to be publicly available, we want to inform you of a highly relevant industry standard that was published earlier this year by International Organization for Standardization (ISO), an independent, non-governmental international organization with a membership of 165 national standards bodies. Through its members, ISO brings together experts to develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges. Following years of development, ISO published this framework to assess health and wellness apps earlier this year: • ISO/TS 82304-2:2021 Health software — Part 2: Health and wellness apps — Quality and reliability oProvides quality requirements for health apps and defines a health app quality label in order to visualize the quality and reliability of health apps. o Applicable to health apps, which are a special form of health software. It covers the entire life cycle of health apps. o Intended for use by app manufacturers as well as app assessment organizations in order to communicate the quality and reliability of a health app. Consumers, patients, carers, health care professionals and their organizations, health authorities, health insurers and the wider public can use the health app quality label and report when recommending or selecting a health app for use, or for adoption in care guidelines, care pathways and care contracts. In case this standard was not already included in AHRQ's initial research phase, we encourage your team to review this and consider areas of possible overlap and/or applicability.	Thank you for this resource. We have not referenced this for the development of the framework as it was published after we were well into this work, and behind a paywall.

Commentator & Affiliation	Section	Comment	Response
Public review #5 (Strathmore Health)	Introduction	We appreciate that the Introduction section acknowledged the value of technology in closing care gaps and reducing inequities in access to mental health services, as well as patient preference considerations (e.g., stigma, privacy, convenience) that may favor technology-driven services over face-to-face encounters for some patients. We urge AHRQ to ensure that its final Technical Brief evaluating mental health mobile apps clarifies that the evidence, review, and findings are limited to "apps" and that it define the term "apps" to align with its identification methodology. AHRQ utilized the "42matters" database of apps available in the U.S. through the Apple iTunes store or the Google Play marketplace. The Framework was created and refined to address concerns with safety, efficacy, data privacy and consumer protections associated with apps available to consumers for download on a mobile device and has not been evaluated for appropriateness in assessing digital therapeutics that are not mobile mental health apps available for consumer download.	This technical brief addresses only mobile health apps that can be downloaded on a smartphone and does not include pure text-based apps, wearable devices, or general telehealth and telemedicine apps. We have added text to description of objective to clarify this point.

Commentator & Affiliation	Section	Comment	Response
Public review #5 (Strathmore Health)	Methods	Although the Introduction provided a relatively lengthy discussion of the role that mental health apps might have in addressing the needs of patients in underserved communities, there did not appear to be stakeholder outreach that included patients and providers in racial minorities, low-income communities, and rural areas. AHRQ did conduct interviews with family members of those living with mental illness, clinicians with a background in mental health, primary health care, and emergency medicine, and payers to gain insights into perceptions and experience with mental health apps and the essential features and omissions in existing frameworks that they were familiar with. It would be helpful to understand whether and how consumers access and use "rating" information to guide their selection of apps, and the extent to which they review any agreements on use of an app, data privacy, and other important features. We also suggest that the Framework would be most valuable to consumers if it captures the experience and preferences of individuals in the underserved communities most likely to benefit from high-quality, safe and effective technology-based interventions. In addition, AHRQ did not consider the potential impact that the platform from which a particular app is downloaded might impact patient privacy and ensure consumer protection. For example, it is unclear whether and how iTunes and Google might utilize consumer information related to an individual's selection, download, and use of specific mental health apps.	Thank you for raising this important point. First, we did not conduct qualitative research and we are limited in the number and type of interviews or discussions we can conduct, both by our timeline and government restrictions. The stakeholders engaged were asked to provide input from their experience and expertise and were identified to represent different perspectives. Second, the framework has been designed to be used by a third-party individual or organization and not by patients or their caregivers. We did not consider the potential impact of the platform used to download the app (Google or iTunes). We did seek to include apps from both platforms in our pilot testing and note in framework the platform used. The specific policies of those platforms moves beyond intended scope of this framework.

Commentator & Affiliation	Section	Comment	Response
Public review #5 (Strathmore Health)	Findings	**Section 1: Risks and Mitigation Strategies** We agree that consumers should have information on the trustworthiness of apps, but are concerned that developers could earn a “High” score on “App Integrity” by making minimal “updates” each 6 months and providing boilerplate “disclaimers and warnings” on data use. The privacy provisions should be in plain language and clearly obtain consent for each potential use of each type of data, rather than a simple “click-through” to discharge the app manufacturer from data privacy considerations. Similarly, apps should be required to disclose how information available on the individual’s device might be accessed by the app, including location, search history, purchase history, contacts, and other information. We also support AHRQ’s approach with respect to risk and the requirement for evidence and, for high-risk apps, a connection to resources for care or integration of a clinician in app use. We urge AHRQ to provide greater granularity around how it defines low, moderate and high risk, and vulnerable patient populations.	Thank you for bringing your concern regarding app integrity to our attention. We limited the items to information that could be found publicly. Your concern about privacy provisions is covered under Informed Consent in Section 2. Greater transparency on how device information is accessed by the app is important. However, there is no mandate or regulation that require apps to share this information.

Commentator & Affiliation	Section	Comment	Response
Public review #5 (Strathmore Health)	Findings	**Section 2: Function** We suggest that: - App functionality information should include whether or not internet access is required to use the app as intended, and provide information on the amount of data the average user might "consume" on a monthly basis; - "Freemium" apps should disclose the costs for each element of functionality and how the cost is assessed (e.g., per click, usage time, per month, one-time fee) - AHRQ stated that "[t]he questions in the AI category are important because we want to gauge the potential for the apps to cause harm and also to determine whether apps are updating algorithms based on user input." Although there is a question on whether the app uses data from user interactions to improve precision on AI models, there is insufficient consideration on the level of appropriateness that the AI model is able to drive for user-specific content.	Most apps require internet access to use as intended, hence this question was not included in the framework. The information on the amount of data the user might consume on a monthly basis is not publicly available and hence not included as part of the assessment. The cost for each element of functionality is not publicly available and hence not included as part of the assessment. We agree that the framework does not consider the level of appropriateness that the AI model is able to drive for user-specific content. This is because the AI algorithms used by companies are usually proprietary and this information is not shared publicly.