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## The Participant-Reported Implementation Update and Score (PRIUS): A Novel Method for Capturing Implementation-Related Data Over Time --Manuscript Draft--

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**TITLE:**

The Participant-Reported Implementation Update and Score (PRIUS): A Novel Method for Capturing Implementation-Related Data Over Time

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**KEYWORDS:**

mixed methods, longitudinal analysis, implementation, health services research, formative evaluation, rapid-cycle evaluation, quality improvement

**SUMMARY:**

This protocol describes a novel method for collecting and analyzing data related to ongoing implementation called the Participant-Reported Implementation Update and Score (PRIUS). The PRIUS method allows for the efficient and systematic capture of data over time and from multiple viewpoints in healthcare settings.

**ABSTRACT:**

“Implementation” of new initiatives in healthcare settings typically encompasses two distinct components: a “clinical intervention” plus accompanying “implementation strategies” that support putting the clinical intervention into day-to-day practice. A novel clinical intervention,

for example, might consist of a new medication, a new protocol, a new device, or a new program. As clinical interventions are not self-implementing, however, they nearly always require effective implementation strategies in order to succeed. Implementation strategies set out to engage healthcare providers, staff and patients in ways that increase the likelihood of the new initiative being successfully adopted, a process that often involves behavior change and new ways of thinking by participants. One of the challenges in studying implementation is that it can be difficult to collect data about the status and progress of implementation, including participants' own perspectives and experiences concerning implementation to date. This protocol describes a novel method for collecting and analyzing data related to ongoing implementation called the Participant-Reported Implementation Update and Score, or PRIUS. The PRIUS method allows for the efficient and systematic capture of qualitative and quantitative data that can provide a detailed and nuanced account of implementation over time and from multiple viewpoints. This longitudinal method can enable researchers, as well as implementation leaders and organizational stakeholders, to monitor implementation progress more closely, conduct formative evaluation, identify improvement opportunities, and gauge the effect of any implementation changes on a rolling basis.

## **INTRODUCTION:**

"Implementation" of new initiatives in healthcare settings typically encompasses two distinct components: a "clinical intervention" plus accompanying "implementation strategies" that support putting the clinical intervention into day-to-day practice. A simple analogy to explain the difference is that a clinical intervention represents "the new **thing**" to be put into practice, whereas an implementation strategy encourages people to "**do** the new thing<sup>1</sup>." A novel clinical intervention, for example, might consist of a new medication, a new protocol, a new device, or a new program. As clinical interventions are not self-implementing, however, they nearly always require effective implementation strategies in order to succeed. Implementation strategies set out to engage healthcare providers, staff and patients in ways that increase the likelihood of participants adopting the new initiative, a process that often involves behavior change and new ways of thinking<sup>2</sup>. One of the long-standing challenges in studying implementation is that it can be extremely difficult to collect data about the current status of implementation related to either of these two components, including participants' own perspectives on implementation progress. This protocol describes a novel method for collecting and analyzing data related to ongoing implementation called the Participant-Reported Implementation Update and Score, or PRIUS. The PRIUS method allows healthcare researchers to capture qualitative and quantitative data efficiently and systematically related to how implementation unfolds over time and how it appears from the vantage points of multiple participants.

The PRIUS occupies a unique niche within the larger family of methods used to study healthcare implementation. Other approaches that predate the PRIUS include Rapid Evaluation and Assessment Methods (REAM), which provides a way for researchers to collect and analyze data on an accelerated timetable yet maintain rigor<sup>3-5</sup>, as well as matrix displays, where researchers integrate large amounts of data into rows and columns that they can then sort and sift to support ongoing analyses<sup>6,7</sup>. A limitation of these methods, though, is that they can place

substantial time and resource demands on researchers, and hence have been primarily used retrospectively to analyze prior implementation.

The use of prospective and longitudinal approaches for collecting implementation-related information can help retain accuracy in data collection, minimizing the possibility of hindsight bias (i.e., when the ultimate success or failure of an initiative influences reporting of earlier events) and recall bias (i.e., when participants do not remember prior events accurately)<sup>8</sup>. Other prospective and longitudinal approaches exist in implementation but with different aims than the PRIUS. For example, a systemic method has been developed to describe and track local adaptations to implementation as they occur over time using a 10-item spreadsheet<sup>9</sup>. Another approach known as “Periodic Reflections” provides a structured way for implementation core members to conduct monthly or bimonthly 30-60 minute telephone discussions with implementation team members in to document ongoing implementation phenomena<sup>10</sup>.

The PRIUS, by contrast, is distinct from these other prospective methods in that it has been designed explicitly to address the need for (a) a brief and systematic method to collect data on the status and progress of implementation interventions as it happens (b) from the perspectives of front-line participants themselves. In the span of a 5-10 minute verbal check-in, the PRIUS both captures implementation developments deemed noteworthy by individual participants as well as their subjective input (in the form of scores assigned on a +2 to -2 scale) about the perceived implications of those developments for ongoing implementation. The PRIUS approach, moreover, integrates qualitative and numerical information from participants for each implementation-related update, generating linked data that can be easily categorized, sorted and sifted to identify major themes as well as trends and patterns over time. The PRIUS method is succinct and organized around three simple verbal prompts: (1) “What are some things that happened over the past two weeks (or since the last time we spoke) that seem relevant from your perspective to the implementation of this project?”; (2) “What impact do you think each of these developments has had on implementation progress?”; and (3) “Why?”

The conceptual framework for the PRIUS is the Consolidated Framework for Implementation Research (CFIR), which provides an overall typology for understanding implementation in health services settings. The CFIR framework is both theory-based and evidence-based, and represents the accumulated result of over 50 years of research on implementation and diffusion. The CFIR framework encompasses five interrelated domains: intervention characteristics, outer setting, inner setting, individuals involved, and implementation process. The PRIUS method focuses especially on the intersection of the last three domains, asking individuals about their own perspectives related to the implementation process actively underway in the inner setting.

The PRIUS method is in the public domain and freely available for anyone to use. The protocol presented here further develops the PRIUS approach presented in an earlier publication<sup>11</sup> and focuses exclusively on how to conduct the PRIUS with a single participant.

**PROTOCOL:**

This study was approved by the Indiana University Institutional Review Board (Protocol #1602800879). With this approval, the reviewing body included a waiver for the need for informed consent, as it was deemed that participation was entirely voluntary, there was minimal risk of harm, and the study involved no procedures for which written consent was normally required outside of the research context.

**1. Participant Reported Implementation Update and Score (PRIUS)**

**1.1. Ask participant PRIUS prompt #1.**

1.1.1. At a mutually agreed-upon time, meet the participant over a videoconferencing application like Zoom.

1.1.2. Pose the first verbal prompt to the participant: "What are some things that happened over the past two weeks (or since the last time we spoke) that seem relevant from your perspective to the implementation of this project"?

**1.2. Capture qualitative responses to prompt #1.**

1.2.1. Using a spreadsheet template like the one pictured below in **Table 1**, capture the first implementation-related development that the participant reports in the first row under the first column labeled "Update." It is not necessary to capture each development verbatim; a bullet-style summary is sufficient.

1.2.2. Repeat as needed for each additional development reported by the participant during the same session.

[insert Table 1 here]

**1.3. Ask participant PRIUS prompt #2.**

1.3.1. For each reported development, pose the second verbal prompt: "From your perspective, what would you say the impact of that development has had on the implementation of the project? Do you think it has has a strong, moderate or weak impact, and is the direction of that impact positive or negative?"

**1.4. Capture scored responses to prompt #2.**

1.4.1. Based on the response from the participant, score each development on the template on a 7-point scale ranging from +3 to -3, with zero as the middle value. Next to each development entered into the spreadsheet in Step 1.2, enter the score in the column labeled "Score." Positive scores indicate positive influence on the implementation process; negative

scores indicate negative influence; and zero indicates no discernible influence one way or the other. In terms of magnitude, 3 indicates a strong influence, 2 a moderate influence and 1 a weak influence. For example, a PRIUS update with a “-2” score would indicated that that the development was perceived to have a moderate negative impact on implementation of the project.

#### 1.5. Ask participant PRIUS prompt #3.

1.5.1. For each development reported and scored, ask the participant to provide a brief rationale for each score with the third verbal prompt: “Why do you think it has had that impact?” (i.e., strong/moderate/weak as well as positive/negative). For example, ask a participant to explain why they thought a particular development had a “weak negative” impact (i.e., a “-1”) on implementation progress.

#### 1.6. Capture qualitative responses to prompt #3.

1.6.1. Capture each rationale that the participant reports. Enter it in the third column of the spreadsheet entitled “Rationale” for each score captured in Step 1.4. As before, a short text summary is sufficient.

#### 1.7. Note any additional information.

1.7.1. Capture any additional information in the optional fourth column of the spreadsheet labeled “Comments” as desired. This might include observed nonverbal cues like facial expressions, body language, and tone of voice and/or additional relevant details.

#### 1.8. Check in with participant on a recurring basis.

1.8.1. Meet again with participant every two weeks and repeat steps 1.1 through 1.7.

### **REPRESENTATIVE RESULTS:**

As reported in an earlier publication<sup>11</sup>, twelve staff members at a single VA medical center in the midwestern United States participated in PRIUS sessions related to a quality improvement (QI) project over a 6-month period in 2016. This project resulted in a total of over 190 different PRIUS items. The typical PRIUS session yielded three or four items (or “rows” in the PRIUS template). New PRIUS updates were discussed during regular implementation support team meetings, with PRIUS-based findings and insights shared with the leaders of the QI project.

[INSERT TABLE 2 HERE]

**Table 2** above shows a summary of 190 PRIUS entries from the QI project by score and major descriptive themes. The most frequent score applied by participants to PRIUS entries in this project was +3, the highest possible score on the 7-point scale of +3 to -3. Entries scored with a +3 included initial professional development and training events, interactions with the outside

221 vendor and the implementation of new electronic tools. The next most frequent score was -2,  
222 the second-lowest possible score. Entries scored with a -2 included interactions between  
223 individuals from different clinical areas, slow initial patient enrollment, and the need for follow-  
224 up training for staff in order to meet the PAP needs of patients.

225  
226 Longitudinal analysis of this same PRIUS dataset demonstrated major changes in program-  
227 related components over time: for example, PRIUS items related to professional development  
228 changed from a strong positive score (i.e., +3) in February to a moderate negative score (-2) by  
229 April.

230  
231 Analysis of PRIUS data led directly to changes in the implementation intervention. During a  
232 formally scheduled meeting to review the PRIUS data, the implementation core support team  
233 shared with the clinical intervention leader that participants from different clinical areas had  
234 disparate and conflicting perspectives on project implementation. Subsequent discussion about  
235 this finding led to the realization that key frontline staff from two areas implementing the QI  
236 project had not been able to attend project meetings because of conflicting clinical duties,  
237 while managers and service chiefs in those same two clinical areas had been regular attendees.  
238 Key frontline staff across these two areas, furthermore, neither knew each other nor  
239 understood what happened when patients enrolled in the QI program transferred from one  
240 service to the other.

241  
242 The following month, patient enrollment in the QI project nearly came to a halt, with only 5  
243 patients enrolled when the original target had been 30. As a direct result of the earlier PRIUS  
244 discussion, the QI intervention leader and the implementation core support team decided to  
245 provide an “appreciation” lunch for all interested frontline staff in the two clinical areas. As part  
246 of this voluntary event, the clinical intervention leader thanked front-line staff personally for  
247 their participation in the program and shared data demonstrating the efficacy of the QI project  
248 to date in terms of improving patient outcomes. The appreciation lunch was well-attended and  
249 positively received, with frontline staff from the two services engaging in personal  
250 conversations for the first time.

251  
252 Program recruitment improved dramatically after this lunch; within a month enrollment had to  
253 be temporarily suspended so staff could catch up with the influx of new patients. PRIUS  
254 updates collected after the event clearly singled out this lunch as an inflection point for  
255 implementation. Independent of one another, several individuals reported in their PRIUS  
256 updates that it was only after this event that they understood the overall project, knew about  
257 the positive impact they were having on patients through the program, and appreciated the  
258 perspectives of other frontline staff from different clinical areas<sup>12</sup>. As intended, the PRIUS made  
259 the leader of the clinical intervention aware of an implementation issue that otherwise would  
260 have remained undetected, helped inform the development of a course correction, and  
261 provided a way to evaluate the effect of that change on ongoing implementation.

## 262 **FIGURE AND TABLE LEGENDS:**

263 **Table 1. A blank 4-column PRIUS template.**  
264

**Table 2. Summary of PRIUS entries from a QI project by score and major descriptive themes. (adapted from Miech et al., 2019).<sup>9</sup>**

**DISCUSSION:**

No special software is required to use the PRIUS method. PRIUS sessions can be administered by researchers, research assistants, and/or other research team members who have been appropriately trained.

Alternative settings for conducting PRIUS sessions include in-person check-ins or over the telephone. The recommended timeframe for checking in with participants is every two weeks; this frequency can be modified if necessary to more closely align with needs of specific projects.

The first PRIUS prompt ("What are some things that happened over the past two weeks (or since the last time we spoke that seem relevant from your perspective to the implementation of this project?") bounds participant responses in three specific ways: it provides a specific reporting timeframe; it engages others by explicitly valuing their individual perspectives on implementation; and it focuses attention on only the most notable (i.e., relevant) implementation developments. In practice, participants typically report two or three developments during a check-in session.

The rationale behind the second prompt (i.e., "From your perspective, what would you say the impact of that development has had on the implementation of the project?") is to draw upon the experience and perspectives of individual participants at the same time that they report each development to sort those developments into discrete categories of perceived impact. These numerical scores provide an additional factor with seven different possible values that link directly to the qualitative data reported in the developments and provide another source of data for the implementation support team to use when sorting, analyzing, and reporting on implementation progress in Data Analysis (i.e., step 4).

The third prompt (i.e., "Why do you think it has had that impact?") explicitly invites participants to explain the reason behind their score. In many cases, this may be the first time that individual participants working extremely busy schedules have had an opportunity to step back and reflect on the meaning and influence of specific implementation-related developments.

The fourth column in the PRIUS template (i.e., "Comments") affords researchers the option to capture any important contextual details related to the reporting of specific implementation developments.

As with any research method, project teams planning to use the PRIUS method in a formal research setting should obtain Institutional Review Board approval or exemption as required by the responsible institution.

It is highly recommended that team planning to use the PRIUS method schedule a dedicated



training session for team members. Suggested length is 1-2 hours. During the training, describe and explain each step of the PRIUS method (covered in Part 2 below) and watch the video accompanying this article. Pair up team members and have them practice administering PRIUS check-ins with one another in a simulated session, where each member of the pair takes turns being the person administering the PRIUS.

As individual PRIUS sessions are completed, project teams should integrate the PRIUS data on a rolling basis into a unified database in a secure online location that team members can access. A six-column spreadsheet is sufficient for this purpose, where the two additional columns capture the date and respondent for each entry. It is also a recommended practice to make a backup copy of the master PRIUS spreadsheet at regular intervals in case the original is damaged or corrupted.

The project team should conduct reviews of the ever-expanding PRIUS dataset on a periodic basis (e.g., once a month) to examine how recent entries compare with earlier entries, assess implementation-related trends and patterns, identify perceived strengths and weaknesses of the implementation intervention, and develop specific recommendations for implementation leaders about emergent opportunities to support and sustain implementation progress.

When preparing to conduct the PRIUS, the research team should determine the timeframe over which the PRIUS check-in sessions will occur, including start and end dates. A sample timeframe, for example, might involve administering the PRIUS method for a 3-month period, with individual PRIUS check-in sessions taking place roughly once every two weeks; in this example, the average participant would complete a total of five or six PRIUS check-in sessions.

It is also recommended that the research team send a general announcement to potential participants in advance to notify them that they may receive an invitation to participate in brief 5-minute check-ins to learn more about their perspectives on how implementation is faring. This message ideally would be sent through regular and established communication channels, such as email messages and/or announcements at regular staff meetings. The research team may wish to highlight the following points in the message:

1. participation is voluntary;
2. no preparation is necessary in advance of a PRIUS check-in;
3. the 5-minute check-ins will occur in a spoken conversation over the phone (or in person or over a videoconferencing application like Zoom) at a time convenient for the participant;
4. comments can be anonymous if desired;
5. the purpose of the check-ins is to develop an overall picture of how implementation is going throughout the organization – including the identification of problems and challenges - in order to improve the implementation process.

An important decision for the research team to consider at this juncture is **whom** to invite to participate in the PRIUS check-in sessions. This group of participants should represent a diverse sample of individuals affected by implementation; it is neither necessary nor advisable to invite **all** participants. The research team may wish to invite both individuals who are thought to be

supportive of the program as well as those who are thought to be critical or skeptical. The overall number of participants to invite should be dictated by the number of implementation core support team members available to administer the PRIUS check-ins, with each implementation core member assigned 1-3 individual participants. Keep in mind that anyone not extended an initial invitation can be added at a later point in time if desired.

After a group of participants has been identified, it is time for the implementation core team to pair particular members of the implementation core team with specific participants. It is suggested that the same implementation core members conduct the PRIUS check-in session with the same participants over the longer timeframe in order to allow rapport and trust to develop within the dyads.

Before the first PRIUS session, implementation core members may find it helpful to conduct individual outreach to the participants with whom they have been paired for the PRIUS check-in sessions. Ideally, this outreach would take place informally and in person to allow for a two-way conversation about the purpose and structure of the PRIUS check-ins. This individual outreach could emphasize in particular that the PRIUS is voluntary, that no preparation is necessary in advance of a session, and that the 5-minute check-ins occur at a time convenient for the participant. If the participant agrees, and if the IRB requirements (if any) for administering the PRIUS method have been satisfied, the first PRIUS check-in session should be conducted with that individual as soon as feasible.

It is highly recommended that any implementation core team using the PRIUS method also develop communication channels that link the implementation core with the intervention team responsible for implementing the new clinical program, especially if (as is often the case) these constitute two separate groups. These communication channels could consist of recurring meetings, shared online folders and/or email distribution lists. Regular exchange of information can facilitate a close working relationship across the evaluation and intervention teams, essential in order for PRIUS-related analysis and insights to inform mid-course adjustments to ongoing implementation.

The format of the PRIUS is easily sortable to facilitate data analysis. Researchers can review, sift and search the growing body of PRIUS entries at any time on an ongoing, iterative basis, and can conduct longitudinal analyses in at least two ways: comparing PRIUS updates scored with similar values at two different timepoints (e.g., comparing all updates scored with “-2” or “-3” in March 2020 with “-2” or “-3” entries in June 2020); and comparing how scores change over time for the same kind of entry (e.g., perspectives on the quality and adequacy of the professional development provided for the program).

When discrepancies in scores are observed across respondents for similar items, implementation core members can flag those implementation-related developments for further scrutiny and discussion in order to assess if the underlying source of the differences is due to a relatively minor semantic issue or if it reflects a deeper polarization of perspectives. If the latter, the research team may opt to bring these discrepancies to the attention of the team

responsible for implementing the new clinical intervention for further discussion and possible corrective action.

In terms of limitations, a business case analysis has not yet been conducted on the PRIUS, as cost and time data have not yet been formally collected. PRIUS methods may be better suited for small- and modest-sized interventions, where they could prove more feasible for capturing prospective data from participants on an ongoing basis.

Overall, the PRIUS method addresses an outstanding need in healthcare research for an efficient and structured method to capture data on the status and progress of implementation interventions. If the successful implementation of a novel clinical initiative (i.e., “the new thing”) hinges on an effective implementation intervention (i.e., the set of parallel activities encouraging staff to “do the new thing”), then the PRIUS method offers a novel and straightforward way to capture valuable implementation-related data that might otherwise prove evanescent.

#### **ACKNOWLEDGMENTS:**

This project was sponsored through internal funding provided by the PRIS-M QUERI at the Richard L. Roudebush VA Medical Center in Indianapolis, Indiana Veterans Health Administration (QUE 15-280). The funding body had no role in the design of the study, the collection, analysis, and interpretation of data, or the writing of the manuscript. The authors retain sole responsibility for the content of this study. The PRIUS method is in the public domain and freely available for anyone to use.

#### **DISCLOSURES:**

The authors have nothing to disclose.

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Participant:  
Notetaker:  
Date:

THE 4-COLUMN PRIUS TEMPLATE

Update	Score	Rationale	Comments

[1 additional rows as needed]

**Participant  
Notetake  
Date**

**Update**

**Score**

**Rationale**

**Comments**

PRIUS Updates (n=190)		
Score	Frequency (%)	Major Descriptive Themes
3	49 (26)	Positive experiences during general professional development and training events at beginning of TeleSleep project; positive interactions with vendor (ResMED); implementation of new electronic tools (e.g., TeleSleep template and tracking spreadsheet) very helpful
2	28 (15)	Positive interactions between individuals from different clinical areas
1	15 (8)	Small, incremental changes (e.g., enrolling an additional patient)
0	26 (14)	Potential opportunities representing a change from status quo (e.g., Telehealth not reviewing TeleSleep data during Telehealth meetings; possibility for additional funds to become available in future to TeleSleep)
-1	16 (8)	Perceived lack of interest by frontline clinical staff in starting TeleSleep program
-2	33 (17)	Negative interactions between individuals from different clinical areas; slow patient enrollment in TeleSleep between February-April 2016; perceived need for additional training to meet PAP needs of patients
-3	23 (12)	TeleSleep workload heavier than originally anticipated; distrust and hostility among individuals from different clinical areas

Name of Material/Equipment	Company	Catalog Number	Comments/Description
None			



January 25, 2021

To the Editorial Staff of *JoVE*:

We are pleased to submit our second revision of the protocol entitled “The Participant-Reported Implementation Update and Score (PRIUS): A Novel Method for Capturing Implementation-Related Developments Over Time” for consideration as a Behavior article in *JoVE*. Our original submission was in response to an invitation from the journal to submit a manuscript.

In response to editorial and reviewer comments, we have extensively edited the protocol using Track Changes and further detail our changes below. We have dramatically pared down the protocol, taking special care to ensure the bolded section that can be filmed as mechanical actions with the context of a behavior protocol.

Specifically, we now have in mind a simulated demonstration of the method where one implementation core member conducts a PRIUS check-in via Zoom (or other videoconferencing app) with one frontline participant, accompanied by screenshots where the newly-elicited information is entered directly into the PRIUS template. This will facilitate videotaping of the protocol and responds directly to the editorial comments to narrow the protocol’s scope. We have accordingly shortened the protocol so that it deals only with a single PRIUS session, moving other text not directly involved with the check-in process into the discussion section. Furthermore, we have modified the protocol title to “Participant-Reported Implementation Update and Score” to emphasize and reflect this change as well as to more clearly differentiate it from our earlier published article on the PRIUS.

Thank you for your consideration.

Sincerely,



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Please find our specific responses to editorial reviewer comments below:

Editorial comments:

Changes to be made by the Author(s):

1. Please take this opportunity to thoroughly proofread the manuscript to ensure that there are no spelling and grammar.

We have copyedited the manuscript and corrected spelling and grammar errors.

2. JoVE cannot publish manuscripts containing commercial language. This includes trademark symbols (™), registered symbols (®), and company names before an instrument or reagent. Please remove all commercial

language from your manuscript and use generic terms instead. All commercial products should be sufficiently referenced in the Table of Materials and Reagents.

For example: Microsoft Excel spreadsheet, etc

We have removed the reference to Microsoft Excel in the protocol and now use the generic term “spreadsheet.”

3. Unfortunately, there are sections of the manuscript that show overlap with previously published work. Please revise the following lines: 65-68 (in the end of the abstract), 187-189, 194-250.

We have revised this text to further differentiate them from our prior publication on the PRIUS.

4. To facilitate filming and to better link the protocol with the representative results, please consider writing the protocol as if using the PRIUS method to collect information from one (or two) staff member(s) in a quality improvement project. That way, the protocol can be executed for a very specific example and the results shown (along with the six-column Microsoft Excel spreadsheet to record data in 3.1) and filmed to demonstrate this, which will be helpful for readers and viewers.

As mentioned earlier in the body of this letter, we have edited and narrowed the protocol substantially. It is now a simulated demonstration of the method where one implementation core member conducts a PRIUS check-in via Zoom (or other videoconferencing app) with one frontline participant, accompanied by screenshots where the newly-elicited information is entered directly into the PRIUS template.

5. Please note that your protocol will be used to generate the script for the video and must contain everything and every action that you would like shown in the video. Please add more details to your protocol steps. Please ensure you answer the “how” question, i.e., how is the step performed? Alternatively, add references to published material specifying how to perform the protocol action. Please add more specific details (e.g. button clicks for software actions, numerical values for settings, etc) to your protocol steps. There should be enough detail in each step to supplement the actions seen in the video so that viewers can easily replicate the protocol.

We have modified the protocol to add specific details regarding particular rows and columns in the spreadsheet where data should be entered.

6. Please ensure that all text in the protocol section is written in the imperative tense as if telling someone how to do the technique (e.g., “Do this,” “Ensure that,” etc.). The actions should be described in the imperative tense in complete sentences wherever possible. Avoid usage of phrases such as “could be,” “should be,” and “would be” throughout the Protocol. Any text that cannot be written in the imperative tense may be added as a “Note.”

All text in the protocol section is now written using the imperative tense.

7. The Protocol should contain only action items that direct the reader to do something in the form of numbered action steps. There shouldnt be any large paragraph of text.

The protocol has been edited to now include only brief action items.

8. 2.5: what is the recommended frequency of meeting participants on a recurring basis?

The revised protocol now specifies every two weeks as the recommended frequency in step 1.8.

9. Please cite a minimum of 10 references.

The revised manuscript cites 12 references.

Reviewers' comments:

Reviewer #1:

Manuscript Summary:

This protocol on use of the Prospectively-Reported Implementation Update and Scoring (PRIUS) system summarizes and provides step by step instructions for collecting data on implementation strategies (called implementation interventions).

The paper provides detailed instructions for a pragmatic assessment process allowing for capture of and reflection on steps taken to enhance outcomes of a clinical intervention. In general the process is relatively well described, but does not at present provide context for, discuss strengths and limitations, other related approaches or directions for further research and application.

Strengths of the approach include that it is relatively straightforward; should be able to be completed by persons without high levels of expertise; and being fairly brief, it should be able to be done repeatedly during a project.

Major Concerns:

The three major concerns I have are:

- 1) In the field of implementation science the 'implementation intervention' described is more commonly referred to as adaptations of implementation strategies (and/or clinical interventions). The large and rapidly expanding literature on assessment of adaptations is not addressed, nor are leading methods and frameworks such as FRAME (Stirman et al) or the Adaptome (Chambers and Norton) cited....see references below

We realize we were not as clear as we could have been in our earlier version of the manuscript concerning our definitions. In our revised manuscript, we now use the term “implementation” to refer to both the clinical intervention and implementation strategies. The PRIUS captures information about both components of implementation. This squares with our own experiences using the PRIUS with frontline participants, who commonly interpret the term “implementation” to encompass both dimensions of implementation.

We did not intend to convey in our earlier version that the PRIUS is a method specifically focused on capturing implementation adaptations (as other methods already exist for doing so) and apologize for any lack of clarity on our part that led to that impression. Rather, the PRIUS seeks to collect input on notable implementation developments from the perspectives of participants themselves. To put it another way, informally speaking a PRIUS update reflects “blips” on individual participant’s “radar screens” relative to implementation.

We now explicitly name the CFIR as our conceptual framework (also in response to this comment).

- 2) The discussion and conclusions read more like an IRB application that a discussion and there is little or no mention of limitations, challenges that users will likely have, limitations or directions for future research on the method.

We have edited and expanded the discussion and conclusions sections in response to this reviewer comment.

- 3) While the data collection protocol is well described it is not clear what should be done with the results- are they for publication, to study relationships with clinical outcomes, to guide adaptations, etc.?

In the revised manuscript, we have clarified that the PRIUS method is used for formative evaluation to help support, inform and guide implementation as it unfolds, including designing any needed modifications to ongoing implementation. We have also edited the “Representative Results” section to demonstrate more clearly how the PRIUS was used in a prior project to make a needed course correction, and then to evaluate the impact of that change.

Minor Concerns:

More minor and specific concerns are listed below:

-on pg. 9 it would help to have more description of the 'implementation support team', its constitution and how PRIUS would work if sites do not have an implementation or research support team

We have changed this wording throughout the manuscript to “implementation core support team” to make it more consistent with descriptions in other publications (cf. Finley et al, 2018).

-there is not much direction about what types of stakeholders or implementation team members need to or should be involved

The revised discussion section includes detailed descriptions of preparing implementation core members to use the PRIUS.

-this process itself- especially when results are discussed with implementers (more information on how this should be done, especially when there are disagreements is needed) is itself an implementation strategy that may impact results

We agree and see this as consistent with the use of PRIUS as a method of formative evaluation.

-it is very likely that respondents will confuse the clinical intervention with the implementation strategies and no directions are provided as to how this should be handled.

As mentioned earlier in response to a related major concern, we now use the term “implementation” to refer to both the clinical intervention and implementation strategies. The PRIUS captures information about both components of implementation.

-there is no discussion of what will be done with the scores produced, or their interrater reliability or validity (e.g. comparison to observations or comparison to other assessment methods)

The revised manuscript describes the PRIUS scores – where participants provide subjective input on the perceived impact of specific developments on implementation – as a major difference between the PRIUS and other methods, including the analytic ability it provides to quickly sort and categorize discrete PRIUS items by perceived impact. The second and third PRIUS prompts explicitly invite “mini-reflections” on the part of participants to generate these scores, capturing subjective data in numerical format. The scores indicate individual’s own perspectives on implementation developments, which we view as inherently valid.

We view the PRIUS scores – where participants provide subjective input on the perceived impact of specific developments on implementation – as a major difference between the PRIUS and other methods. It adds the analytic ability to quickly sort and categorize discrete PRIUS items by perceived impact. The second and third PRIUS prompts explicitly invite “mini-reflections” on the part of participants to generate these scores, capturing subjective data in numerical format.

In the Discussion section we now describe how the scores can be used to review, sift and search the growing body of PRIUS entries at any time on an ongoing, iterative basis, and to conduct longitudinal analyses in at least two ways: comparing PRIUS updates scored with similar values at two different timepoints and comparing how scores change over time for the same kind of entry (e.g., items related to professional development).

Reviewer #2:

Manuscript Summary:

Very cool description of a straightforward process for documenting implementation intervention features as they are rolled out and their influence on implementation. This paper is informative, concise, and makes a substantial contribution to the literature. I'm eager to see it widely used in practice

Major Concerns:

None

Minor Concerns:

Consider adding to the PRIUS tool in the header a description of the intervention, any pre-planned, a priori implementation strategies, etc.

Add to recommendations that PRIUS data could be analyzed across interventions and institutions - great data for configurational comparative methods to identify combinations of features of interventions, implementation interventions, and contexts that influence implementation and/or effectiveness.

Thank you for these excellent suggestions! In response to editorial suggestions, we have opted to narrow (rather than expand) the revised PRIUS protocol and manuscript (though in principle we agree with both of these recommendations).

Reviewer #3:

Manuscript Summary:

This paper clearly and succinctly describes PRIUS methodology, which is likely to be useful for implementation and research teams attempting to observe and understand the implementation process, and potentially to make changes as needed in real time. Clarification of a few additional issues would strengthen the contribution of this manuscript.

Major Concerns:

- There is a growing variety of methods proposed to aid in longitudinal documentation of implementation phenomena, including periodic reflections (Finley et al., 2018) and phone check-ins (Grub et al., 2020), as well as a broader array of ethnographic and other approaches intended to capture longitudinal change in implementation efforts. It would be helpful for the manuscript to situate the PRIUS method in relation to these other methods in the introduction, and to provide the reader some guidance as to the relative pros and cons of the PRIUS method for specific purposes in the conclusion.

Thank you for this recommendation. We have added an entirely new section in the Introduction describing other existing prospective and longitudinal methods in implementation science (including the Finley et al. 2018 article on periodic reflections) and explain how the PRIUS offers something different relative to these other approaches .

- It was not clear to me whether the primary purpose of the PRIUS was research or formative evaluation during implementation or both? Please clarify the function of the PRIUS and provide some discussion of the relative caveats associated with each intended use.

In the revised manuscript we now explicitly clarify that the PRIUS method is used as part of formative evaluation.

- The description in general of how to conduct the PRIUS is admirably direct and clear. I appreciate the discussion of who to include in the PRIUS check-ins, but still wasn't sure whether this method was intended primarily for the implementation team, the frontline providers involved in implementation, staff and providers not specifically involved but potentially affected by implementation, etc. Who is best to include, and what should potential users of the method take into account when making those determinations? Were biweekly check-ins conducted with everyone participating? Who led the check-ins?

In response to editorial comments, we have revised and narrowed the protocol so that it now is a simulated demonstration of the method where one implementation core member conducts a PRIUS check-in via Zoom (or other videoconferencing app) with one frontline participant, accompanied by screenshots where the newly-elicited information is entered directly into the PRIUS template.

- The scoring is an interesting addition to prior methods, but raised a few concerns for me. Often in longitudinal work, it's very difficult to assess how impactful a given barrier or facilitator is likely to be until things play out for a while. The scores are given on a short-term basis, however. How would you recommend using these scores to aid in longitudinal analysis, or are they only intended for use in gauging some assessment of big issues right now? How much does the scoring add?

We view the PRIUS scores – where participants provide subjective input on the perceived impact of specific developments on implementation – as a major difference between the PRIUS and other methods. It adds the analytic ability to quickly sort and categorize discrete PRIUS items by perceived impact. The second and third PRIUS prompts explicitly invite “mini-reflections” on the part of participants to generate these scores, capturing subjective data in numerical format.

In the Discussion section we describe how the scores can be used to review, sift and search the growing body of PRIUS entries at any time on an ongoing, iterative basis, and to conduct longitudinal analyses in at least two ways: comparing PRIUS updates scored with similar values at two different timepoints and comparing how scores change over time for the same kind of entry (e.g., items related to professional development).

- Finally, what is the vision for longer term analysis of these data? How do you plan to make use of these check-ins, and/or integrate them with other data?

All in all an interesting paper and method. Look forward to learning more.