Dr. Teresa Hudson: …this morning. Their presentation is titled “Managed Suicide Risk in Veteran Research Participants”. We have four presenters. Dr. Alan Teo is a Physician Investigator from the HSR&D Center to Improve Veteran Involvement in Care located in Portland. Dr. Mark Ilgen, a Research Career Scientist in VA located at the Center for Clinical Management and Research in Ann Arbor. Cortney Bagge, PhD, Research Investigator also located at the Center for Clinical Management in Ann Arbor. And Emily Yeagley, also located at the Ann Arbor center. So I look forward to your presentation this morning. And I think Dr. Teo, we’re ready for you.

Dr. Alan Teo: Perfect, alright. Well, thanks for the introduction, Dr. Hudson. Great—I’m looking forward to our discussion today. I’m going to begin things with talking about a framework that can be used for assessing suicide outcomes in research, and I actually want to begin….

Dr. Teresa Hudson: Alan, you’re muted.

Dr. Alan Teo: Thank you. That somehow went back to mute. So I wanted to begin briefly with a personal anecdote which takes me back to a number of years ago when I was doing my VA career development award. And at the time, I was recruiting veterans with active symptoms of depression, and I really faced a decision. Would I be using the PHQ-8, or would I be using the PHQ-9 as a screener, as a way to determine eligibility for a participant in this study. And as you can see here, really the only difference between the PHQ-8 and 9 is the exclusion of item 9, the exclusion of the question on suicidal ideation in the shorter form. And so ultimately, I ended up—I was earlier in my VA career. I was maybe confused and unclear about how to proceed. I ended up using the PHQ-8 that you see here on the screen. And ultimately, I feel like that was a missed opportunity or a point of failure. I think I could have done better. And part of our goal here today is to show how you, how all of us together, I think, can do better by incorporating, by safety and appropriately incorporating suicide measures and things of that sort in our research. So let me move onto the slide.

Alright, so what do I mean by “we can do better”? We can do better in our research related to suicide. Well, the first point to make is that similar to the anecdote I shared, many studies, VA studies, non-VA studies, have historically excluded patients with suicide risk, even when that risk is relatively minimal. And that was certainly the case in my VA CDA, relatively minimal risk. We’ve also tended in research to not include suicide measures or avoid including them when there have been opportunities to do so, and this becomes a research because many of us on the call are researchers. You need data. You need measures in order to study phenomena, and that’s certainly the case with suicide where suicide has what we call a low base rate.

So you need to collect data in order to study a phenomenon, and we’ve been short on data for many years. At the same, we recognize that there is a challenge here. There is perceived burden for investigators and researchers to include suicide measures. And I think part of our vantage point, at least personally, is that there is a way to balance the ethical obligation. There is a critical ethical obligation to protect our research participants. But at the same time, I think we can balance that with maintaining the integrity and the spirit of our research to not necessarily take suicide risk assessment—it doesn’t have to go overboard in the research process. And so we’re hoping that we can demonstrate that, the ability to achieve a balance.

So what we’re going to go through today or the piece that I’m going to introduce before other distinguished speakers talk about their work is to really present a potential framework for managing participant risk. And as you can see here is there are seven different components or seven different steps that we’ve included in this framework, and so let me touch on them just briefly one by one. But this is a process that we think that researchers can use when developing and conducting their research studies.

So the first step is to really actually step back and actually think about your study design. Think about also the informed consent process, what kind of process you’d like to include in your study. And what I mean by this is that the degree of safety monitoring. Here safety monitoring is referring to safety monitoring related to suicide risk. What degree of safety monitoring is indicated is really going to be indicated on your safety design. Is your study an intervention study? Is it an observation study, as in the anecdote I shared? What is the baseline risk of suicide in this study population? Is it a high-risk or a low-risk population?

And really at the core here is, again, from an ethical standpoint, what IRBs are worried about what others are worried about is could the study potentially cause increase in risk in suicide? Research doesn’t exist to monitor and measure all suicide that exists—suicidal ideation or suicide risk that exists in the world. The key again from a safety standpoint is making sure that the research isn’t account for increased risk. At the same time, you may want to communicate some of these processes to your participants in the study, and that’s often done through the informed consent process. And there are specific requirement, for instance, related to disclosures on limits of confidentiality that can be included in informed consent forms. So that is Step 1.

Step 2 in this framework is then to think about collection of data related to suicide. What kind of data, what kind of measures would you like to include or propose to include in your study? And oftentimes this is a structure measure, an instrument, or a scale. The PHQ-9 that I shared in my anecdote, the Columbia-Suicide Severity Rating Scale that is widely used at the VA. There are many, many examples, of course, of different measures that relate to suicide risk. But you can log these or catalog these potential measures. That would be Step 2.

And then in Step 3 of the framework is to begin to think through really making a determination of when a more detailed suicide risk assessment is indicated. So you have certain measures that you might be including or collecting data on in your study, but when would you need to go beyond that? When would you need to interact with participants to do a more detailed assessment? And I think there are two basic scenarios, broadly speaking, two scenarios where this comes up.

The first scenario is for those measures that you are including, researcher including in the study, think about a pre-specified threshold, some level that would then trigger a more detailed risk assessment. So that can be a score threshold. It can also be a change, a change in someone’s suicide risk, a change in their level of suicidal ideation or some demonstrated increase in suicidal behavior. So that’s the first scenario.

The second scenario is when a study staff member would incidentally detect a concern. What do I mean my incidentally detect a concern? Well, this could be a participant who completes a survey and scribbles something in the margin indicating suicidal thoughts. This was not part of the study design, so it’s incidentally detected. Another common scenario would be comments made during an interview with a participant. So these are potential indicators of when you might want to do a more detail risk assessment.

And then the fourth step in the framework, naturally, is to actually conduct a suicide risk assessment. Now the conduct of a suicide risk assessment is one or more lectures onto itself, so we’re going to be very brief for today’s purposes. But I think a few key takeaways are to have a standardized operating procedure or template of some sort for research staff members to follow, and this is going to vary, again, depending on the research project. But a decision guide there will be helpful. Another tip is to gather information on a participant’s location, their current contact information, contact information of the day, before going into a detailed risk assessment. It can often be difficult to obtain, or a participant, a veteran, may be reluctant to share this once you’ve gone down the road of a detailed risk assessment.

But fundamentally, there are two determinations a person is trying to make during this risk assessment. And the first is how acute is that risk related to suicide? Is it an imminent risk? And the second basic determination you’re trying to make is the level, the degree of risk. And again, things like intentions or preparatory behaviors, et cetera, these things can help in making that determination.

I want to give, also, a brief shoutout to the Rocky Mountain MIRECC Suicide Risk Table. This is one example of what a risk assessment approach, what a framework for conducting risk assessment might look like. And this designed, I believe, more for clinical scenarios than research. One might argue in a research context you could simplify this potentially, but I think it’s a very useful way of thinking about this. Again, they divide risk assessment into high risk, intermediate risk, low risk, and then also whether the risk is acute or more chronic.

Alright, so moving along in the framework, Step 5 is to then decide, think about how you would respond to suicide risk if and when it’s detected. And again similar to the last step, we suggest having some sort of template or guide for research staff to follow step by step. And in developing this, and you’ll want to consider whether the research staff member is interacting with the person in person or more and more these days whether your interaction is in this format, remotely over the phone or on Teams. I think it’s also helpful to think about developing a potential menu of action steps, meaning that there are many possible responses to suicide risk. You may want to include multiple options. And it doesn’t mean that all options are taken, but there are several possibilities.

And you may also—and this is where I’m actually going to remind individuals or make a plug here for things like the Veterans Crisis Line. There are processes, for example, for conducting a warm handoff to the Veterans Crisis Line. That’s often used as one of these potential action steps. The VA also has safety planning worksheets. This something that can be done with participants, too. But suffice it, again, to say that there are many potential action steps. And you can finally also think about when you would hand this off, you being a research team member, when you would want to hand this off to a VA clinician for ongoing or for followup care.

Alright, we’re wrapping up the last couple of pieces here of the framework. After researcher has gone through all of these steps, then there is a final key step here of thinking about how this will be reported. So there are specific reporting procedures, and the general guidance or general recommendation is to use some sort of log in which you will be documenting these events. And events, when I say events there, we’re referring to adverse events, as well as serious adverse events. Now of course in our research study, a suicide attempt, for instance, is one type of event, but there’s all sorts of—it’s not limited here for suicide risk. We’re just focusing on that aspect there today.

And as you log these things or as you develop a log, you would want to think about what constitutes an adverse event versus a serious adverse event. There are guidelines on this. Things like a hospitalization, for instance, is typically considered a serious adverse event. Another consideration is how expected—what is the expectedness related to an event? Meaning that suicidal ideation may or may not—may be actually quite expected depending on if you’re studying a high-risk population. At baseline, you expect these things to happen in the population. That’s part of the nature of why you’re studying it at some level. And all of these factors will then determine your reporting to the Institutional Review Board, and if there’s a Data Safety Monitoring Board, them also.

And so I’ve just flashed that here on the right side of the screen. A general conceptual distinction here between the IRB and reporting is that IRBs generally like to have individual events, events as they come one by one. They tend to want to have that reporting done in a more quickly or timely fashion. It may be a day. It may be five days but more quickly. Whereas the Data Safety Monitoring Board tends to look at data in aggregate. They tend to meet, if it is HSR&D, once a year for instance, but they can. So even though the reporting is less frequent, they can definitely impact where your study needs modification for instance.

Alright, and the last piece of the framework, and then I’m going to hand things off, is to think about your research staff on a project and thinking about training. The PI on a study may be a clinician or may not be a clinician. What kind of professional background is necessary to conduct the suicide risk assessments, as well as not only of course for the PI but the day-to-day work of research staff. So these are the considerations to keep in mind when determining training. And so with that, let’s see if we can smoothly segue here to Dr. Ilgen who will be taking it over.

Dr. Mark Ilgen: Thank you, Dr. Teo. I think you just have to drag that little red square….

Dr. Alan Teo: Yeah, there it goes.

Dr. Mark Ilgen: Yep, and thank you for the opportunity to talk today. I’m Mark Ilgen. I’m at the Ann Arbor VA. And what I’ll be discussing is how we might apply the framework that Dr. Teo presented to a specific VA study, and in this case, it’s randomized trial of an intervention to reduce suicide risk in VA psychiatric inpatients. Just very briefly on the study method—let’s see here. Oops, when the wrong direction. There we go. This was an HSR&D-funded study of 300 veterans recruited from an inpatient psychiatric unit, and we didn’t just take all-comers in that setting but focused on those who were hospitalized for an acute suicidal crisis. So this was a very high-risk group of veterans.

They were then randomized to a single session intervention, what we call Crisis Line Facilitation or an Enhanced Usual Care condition. And our goals with this randomized trial was to overlay the research onto standard care, trying to interfere as little as possible with how that care might look in the real world. So whenever possible, we wanted to not put things in the chart. We wanted to not engage with clinicians, unless it was absolutely necessary to ensure the safety of participants. The final phase of the study involved follow-up assessments conducted in the community or at follow-up appointments or remotely over the phone.

So just to use the framework that Alan described, we had a group of patients that were very high baseline risk. And if you did nothing and were just observing from afar, there would likely be risk-related events occurring in this population. On top of that, there was the research study methods that have their own associated potential for risk. And from an ethical perspective, once we’re inquiring about risk and trying to learn more about this patient population, we essentially own both of those types of risk, but the two categories matter when we talk about reporting.

And for our procedures in this research, they varied depending on where we were doing the work. So the screening, baseline intervention delivery, and first assessment all occurred in the inpatient setting. And from the standpoint of a researcher, this was great because there was a lot of support, and we were confident that participants in that setting were going to be safe. It gave us a little more time to plan our next steps, and we knew that we could easily reach someone to help out if we were really concerned about a participant.

But then we pivoted and had the follow-up assessment window where we were conducting work in the community and still had to manage risk. We spend a lot of time thinking about informed consent on this study, and we made it really a priority to disclose to our veteran participants the limits of confidentially, talked to them about our duty to warn if we were concerned. And in practice, we did this not just during the initial completion of a consent form but throughout the study, and really we began most interactions with participants with a brief review of the limits of confidentiality, reminding them that if they told us something that was concerning, we would need to potentially involve members of their clinical team.

When it comes to collection of data, we gathered data in our assessments that might lead to the need for a more thorough assessment of risk. We also encountered situations in this incidental category that Alan mentioned that related to things we didn’t necessarily plan on but where we became concerned about risk with participants. So the assessment side is pretty straightforward. This included having pre-specified decision rules around self-reported assessments, asking more detailed questions when concerns came up during clinical interviews.

The incidental situations were a little harder to predict, and certainly in practice, they involved a wider array of potential scenarios. But this ranged from participants saying things in texts that made us concerned, mentioning things to their therapist, or fleshing out a story of something that happened more recently that made us concerned, even if that followed a standard assessment where we previously had come to the determination that the veteran was not at higher acute risk. And we needed to be prepared and have plans in place to adjust to all of these sources of information.

So in terms of planning for the self-reported assessments, this was just having pre-specified thresholds where we could classify someone as needing a more thorough follow-up assessment. For interviews, it was relatively straightforward to pivot into gathering more information about risk with an assessment like the Columbia, for example, you’re already asking about thoughts and plans. And for a risk assessment, you just gather similar questions or similar data, but you’re really just trying to hone in on the recent period of time and what someone’s acute risk might be.

For the incidental situation, we thought it was really helpful and ended drafting structured questions that could help us pivot from being slightly concerned that someone might be at risk, to asking detailed questions about risk. And as I mentioned before when talking about limits of confidentiality, in each of these interactions, we always felt better if we begun our most recent contact with a veteran by explaining how we approached risk and the fact that we may need to break confidentiality if were really concerned.

So this is an example of how we created decision rules for our research staff to ask follow-up questions and explore when they became concerned about risk. We actually came up with this decision tree before at least I was aware of the VISN 19 Rocky Mountain MIRECC guidelines. I think those two different approaches, complementing each other well. And what we’re trying to do here is understand not only global risk but pretty quickly pivot into understanding what are the levels of risk in an acute sense, and then what are the actions steps, which are on the right-hand side of your screen, that we might need to manage that risk?

One key question that comes up when you’re talking about how to respond to suicide risk is when to involve a supervisor, when to pull in others to classify someone as a high acute risk or low or medium. And ideally, these would be clearly discrete categories. So with a decision tree we just looked at, map out exactly how to know when you pull someone in. In practice, there are factors that made it more challenging, more nuanced than that, specifically related to the timing and immediacy of risk. So we always want to put the safety of the veteran first, so even though it might be ideal to pull in a supervisor to get a second opinion, if someone was not on the inpatient unit, was in the community, they were on the phone, and you were concerned about immediate safety, you could bypass some of those steps. Or maybe even have a little less information that would be ideal, in order to take that next step and come up with a plan to keep a veteran safe.

Even under the best circumstances and asking the best questions, there was still a lot of ambiguity. In our case, a lot of that around substance use and whether the substance use was motivated by a desire or self-injury or not. And we tried to do our best to understand what someone’s level of ideation and their planning was, but sometimes it was just really not possible to know for sure. And of course, participants themselves can choose to disclose more or less information. And so that was a limiting factor, and we encouraged our research team to make their best possible determination based on the information available to them. As I mentioned before, all of this was easier in a more structured setting.

And in all of our interactions with participants, our goal was always to have them self-disclose. So instead of us going outside of the study to someone on the clinical team, we always talked to the participant and gave them the opportunity to disclose themselves. So in their own words, they could describe what their concerns were, and hopefully we could match them up with the right clinician but then back out of that interaction so that it wasn’t filtered through our understanding of events but instead really reflected the existing relationship between the veteran and their clinical team.

Two last slides here in terms of reporting, Dr. Teo went through a lot of details about the importance of expected versus unexpected as well as study related versus non-study related. The important part of us with reporting was to be very explicit on the frontend about what was or wasn’t expected. And then when it came time for reporting, we relied on the approval we had from our local sites for guidance on what needed to be reported when. Irrespective of all that that, we kept very detailed documentation of all our risk assessments and why we made the determinations we made and then what the outcomes were of those determinations. And so even if nothing got reported for any specific event to, let’s say, the DSMB at the time—or the IRB at the time or DSMB later, we knew what went into our decision-making process. And we had a record of our rationale and our actions.

And finally, just to talk through training, we had a team with a wide variety of backgrounds, and we wanted our risk procedures to work across different levels of comfort and exposure with talking about suicide. I think from the investigator level, it’s tempting to say that you want all the decision to pass through a doctoral level licensed clinician. Well, that’s not really realistic, and so it requires thinking about what your risk tolerance might be, and how can you support the frontline staff members on a research study to make as good as decisions as they can on their own and also to feel comfortable when reaching out whenever they had concerns.

We did a lot of trainings. One of the things I really like about being a part of a research group is we often try to train one another and train ourselves as new studies start up, just on suicide risk and risk assessment, how to make determinations of acuity and to try and standardize that across studies and really feeling like it’s the sort of thing you need as an ongoing process. The last point is that culturally we want to strike an appropriate balance between autonomy where RAs feel supported to make decisions on the frontlines but also knowing that they have that support and are making the hardest decisions, ideally, with consultation from other team members. I think it’s, again, tempting when you’re running a study to really drill home the importance of the accuracy of the data you collect, that we shouldn’t have missing data.

But we also need to balance that with an acknowledgment there are times you may just need to abandon an assessment and move right into risk management. So we need to put the safety of the veteran first. And also, ask questions about suicide that don’t feel formulaic or feel like they’re only being asked to populate a decision tree or a chart but instead reflect compassion, are expressed in ways that are clinically appropriate, and encourage veterans to answer questions honestly and openly with the research team. And that is my last slide, so I’m going to hand it off here to Dr. Bagge.

Dr. Courtney Bagge: Okay. Hello, everyone. So I’m going to—thank you very much, Dr. Ilgen, and thank you for the opportunity to present today. I’m going to be discussing a practical application of risk assessment. Okay, there we go. Okay, so I’m going to be discussing the University of Washington Risk Assessment Protocol, the UWRAP. This was developed by Marsha Linehan, and there’s the key citation below. One of the authors on that manuscript, Kate Comtois, was a consultant on a study where we used the UWRAP protocol. So I want to acknowledge that. And the manuscript, since we will have limited time today, I really want to refer you to that because it’s lots of details and different scenarios about when you might want to use this protocol. Also, all of the forms that I’ll reference are actually on the Behavioral Research & Therapy Clinic website as well. I’ll give a citation to that at that end.

So that being said, I wanted to present today on, provide an overview on the UWRAP because what I realize is that a lot of seasoned suicidologists, including myself for some time, didn’t realize it existed or hadn’t used it. And this is despite that it’s recommended by NIMH as something that we should be considered for high-risk populations. So what is it? It is an assessment protocol for managing risk in high-risk samples for suicide. That’s why it was originally developed. And it is something that you can use in a variety of different ways. You can use it for observational or assessment-only studies or clinical trials. I’m going to be discussing, a little bit, my experience with an assessment-only study. It can also be delivered by phone, in person, by video, so it is really quite flexible.

So it is named the UWRAP because it’s a protocol that wraps around your study interview in my case. So there’s things that you do before your actual study assessment and after that has nothing to do specifically with the questions that you’re asking while you’re doing the study. So that’s why it’s called the UWRAP. We have a pre-assessment where we’ll ask some questions and actually prepare to cope. Why this is really different is that instead of waiting for distress to occur, before you do anything, the assessor works with your participant to see what strategies would be helpful if the participant gets distressed during the interview or afterwards. And then I’ll talk about the other components in a minute. Looks like there’s a little bit of a delay. Okay.

So what you do is you start out with a Face Sheet, and this is something, there’s like a number of different questions. These are just two examples that we really focused on in our study about their current state. So this is before you do anything, and you use this—the assessor uses it to pace the interview, to determine the structure, whether it’s likely you’re going to need breaks. These kinds of things. If it’s by phone, it’s very important to record the location of the participant and then also some more contact information.

And after this is where you begin a mood improvement protocol. Again, this is you want to prepare to cope, so you just let the participant know that these interviews could be stressful. And so we want to pretend that the interview will be stressful for them, and what are some strategies that would be helpful? So you ask two major questions. Anything you could do, or I could do, to make it easier during the interview? And you ask the same question then for another time reference, and that would be for after the interview is over. So you do that before you do anything. We have found that it’s lot of time participants didn’t really know what would be helpful, so providing examples can be really helpful to the research team.

So example, deep breathing, walking them through a breathing exercise. Most people pick chit-chat on noncontroversial topics. Listening to music, you want to ask what kind. Walking outside. You can walk with the participant. And we actually had a library of all different kind of vetted funny YouTube clips. Sometimes people really liked animals, so we would have a category for that. Or soothing pictures of beaches and things like that. And the pro tip is that if you can easily send things links to individuals if you’re not in person, and it’s also helpful to encourage the participant to describe what they’re seeing or hearing around them, like you’re talking about going on a walk, if you’re using these strategies. But again, we’re just preparing right now.

Okay, so then we do our study assessment, whatever that is, your interview. So now we’re going to the wrap, the post-interview phase, and this is the debrief protocol. And this is where you ask those same questions again. Again, there’s more than this in the protocol, and you ask about what their state is. So what you’re really interested in is if there’s been any considerable changes; however you define that, as far as their level of stress and their intent to kill themselves. And I’ll go into risk management in a minute. After you ask that, you can ask questions about, so how will you cope with any negative feelings or suicidal impulses after we get off the phone or after you leave here? Or do you have any fun activities that are planned for the rest of the day, and this is going to then be the end of the question component.

When you finish the mood improvement protocol, you offer the mood induction activity that the participant chose themselves, and so here’s the examples again. And after the participant leaves or they hang up, you can document whether any activity was used, what the effect was on someone’s mood. What I love about his protocol is that—if you print out the forms, is that’s very easy. There’s checkboxes. It walks you through, so it makes sure you don’t miss any steps.

Okay, evaluating and managing risk. So here I’m going to be very broad because the major components are listed in terms of the UWRAP. But there might be variations—there likely will be variations for your specific study, so I don’t want to call it the UWRAP. It would be more inspired versions at this point. But what I can tell you is that the UWRAP protocol says you have to do a suicide risk assessment, it’s at the bare minimum is if it’s higher than a 3 at any point on intent to kill yourself. Or the participant is uncertain that they can control their suicide impulses or based on the assessors’ judgment. So again, for my study that was by phone, we had any presence of suicide intent, so there is some flexibility with that if you’re using inspired versions.

Then there’s an assessment of suicide risk and determination of risk level. That within the protocol is the Suicide Risk/Protective Factors Assessment that you could also use if you’re using an inspired version, an SRA of your choice.

And then the responding to suicide risk, so the management. Well, it depends on your level of risk. But what is important to be consistent with the protocols, that you want to have the assessor use the lowest-level intervention that is appropriate. And then if that doesn’t work, then move onto the next higher level. So this can be a lowest level as reminding them, having them talk about some positive things that they mentioned during the assessment. To the highest level is a warm hand-off to the crisis line, which could involve some emergency services.

What I want to stress here is that these can vary across studies depending on your resources, depending on your facility, the IRB, and what I mean by that is as far as what the threshold is, who conducts an SRA, a suicide risk assessment. If you have less resources, you might partner with another agency to compensate for that. And how risk is managed. There’s also differences in that, depending on the level of your study.

The one thing I do want to put a shoutout to is something that Marsha Linehan also made called the L-RAMP, and it’s fabulous. I’ve used this as a clinician. It was actually a protocol for study clinicians. She did a lot of randomized trials, as everyone knows, but this is a very thorough risk assessment. And it talks about specific things that you considering doing but did not, and it’s documenting that, lots of checkboxes and different options for managing it.

So I just wanted to acknowledge Kate Comtois, who’s our desk consultant on the work that I’ve done using the UWRAP. And then here is also the website where you can get the associated materials. So now I will pass it on to Ms. Emily Yeagley to finish us off, and I’m trying to move it.

Dr. Emily Yeagley: Thank you, Dr. Bagge. So before we get to answering some questions, some good questions that were sent in, we wanted to just share where we have some resources for folks to access. Based on the conversation we had today, a couple did ask questions about [audio dropout] made available. So they’re located on the SPRINT website, and there’s a section on the side or within the SPRINT Core. This is risk management resources, and then you see them available in different sections. And you can click on the different documents based on your needs.

There are a couple of things that we wanted to point out related to these resources, that these are really examples collected from various research teams who have involved suicide risk and risk assessment in their studies, but they really need to be tailored for your particular population and study and to make sure that your study protocols are being approved by the IRB. And that you’re putting some thought into those. And with that, that means that study teams can choose their best approach based on what they think is best. We also high encourage that you coordinate with your suicide prevention coordinator at your site, whether that means working with them to develop the resources or running the resources by them before you implement them. It’s really good to be on the same page with them. And then just to shout out, again, to say that you obviously need RD and IRB approval for the resources that you use, to make sure that they’re being reviewed for participant safety.

The different categories of resources that we have, we have both guides that a little bit longer and walk you through step-by-step, and then also templates for contacting the clinician, how is the decision documented. Dr. Ilgen mentioned documenting the decisions that we make carefully, and then also those flowcharts of making decisions [audio dropout]. And then the different topics covered within these documents, like I said, risk management and assessment protocols and flow charts, documenting the risk. There’s also participant-facing resources, so handouts that you might give participants to so I can tell them about informed consent or what the study procedures are going to be. And the regulatory resources to submit your IRB or DSMB. There’s some guided language that might be useful.

Alright, so the ideas that will be updating these resources as new ideas or new protocols come in, and so we suggest that you go to the website to check [audio dropout]. And then we can move to our question and answer section. So we got some great questions here. First one, so talking about the PHQ-9 versus the PHQ-8. Some study teams are saying that they encounter some false-positives with the PHQ-9, and do you have any recommendations for alternatives that seem to have better sensitivity [audio dropout]?

Dr. Alan Teo: I can start off with that. Thanks, Emily. I would agree with the comment there that item nine in the PHQ-9 tends to identify passive suicidal ideation, so that definitely can be an issue for researchers. I think the number of different possibilities, one approach that I’m currently using in one of the studies I’m actually going through the IRB right now for is to use a combination of questions, multiple questions. And so we’re using several items from the Columbia-Suicide Severity Rating Scale that is actually used across the VA. And that combination of questions touches on whether there is intent related to intent to harm yourself, whether there is preparation, whether there is planning.

You can also think then also about these are not binary responses, so another approach is to think about whether it’s appropriate in your particular study to use a score of—if you were using the item nine on the PHQ-9, whether you want to use a response of more than half the days or some—what your cutoff might be within a particular item. So a general approach again I think is possibly combining multiple questions using other scales such as the Columbia scale, and then thinking about the response choices. Let me see if other would like to add to that, though.

Dr. Mark Ilgen: I agree with what you said, Alan. I would add that just because something is not very specific doesn’t mean that you want to ignore it, so I think there are different ways of using these tools. And if you’re giving a survey and you include the PHQ-9, we know from some of Greg Simons’ work in group health that the higher scores on PHQ-9 of predictive of subsequent suicidal behaviors. And by some definitions, they’re reasonable predictors depending on the patient population. So I think many IRBs—and I probably agree with this mentality—would say that you don’t want to just become aware of that information and sit on it and not take action. And so that’s where it’s great to have those additional follow-up questions that Alan was talking about, and ways to make it a little more specific before you need to act on responding to everyone. And those are things that you really—it’s good to map out before you begin your research, so you don’t end up either responding too much or too little to these potential indicators of risk.

Dr. Emily Yeagley: Thank you. Another question, is there truly a non-zero chance of increasing risk in veteran participants simply by engaging them in a conversation about suicide through the research? And if so, that would seem to contradict the standardized suicide prevention, gate keeper training content, the VA S.A.V.E., as issued by the Office of Mental Health and Suicide Prevention.

Dr. Mark Ilgen: That’s a great—I’ll take a first crack at that. It’s a great question because I think that I could see where it could feel like it’s contradictory. A lot of the messages around suicide assessment, as this question is pointing out, encourage asking about suicide and highlight the fact that there’s not research supporting that asking about suicide can “make someone suicidal”. So the goal would be to ask questions and engage a veteran in discussion of their suicide risk. I believe all that’s true. The guidance we’re giving relates to a couple of factors. One is that from an IRB perspective, you need to be prepared for the fact that your research protocol could be stressful to a participant and could cause an adverse event. That’s part of what you do when you propose a research design, is try to think through all the scenarios where it might be destressing for someone to participate in your study, and you could have an unintended consequence.

So a lot of studies, our included, specify risk related to assessments because we want to make sure we cover the whole range of potential events. And even though there’s data on average about the fact that it’s safe to ask about suicide, you never know in any individual instance how a veteran will respond. I think in our studies what we find is that it’s not the assessment, per se, but it could be the prolonged focus on distressing content that could be hard on participants or could make it hard for them to cope. And I think that’s part of what I really liked about what Courtney presented, is just acknowledging that people may feel distressed after talking about a prior crisis. Maybe it just reminds them of the situation they were in at the time or the reasons they were upset in the first place, and having a plan in place to respond to that is helpful. I think it’s the ethical thing to do, and it’s just strategic and useful to the research, too. I don’t know if you guys have other thoughts.

Dr. Alan Teo: Yeah, I’ll add and agree with you and accentuate that. I will just say point blank asking about suicidal ideation does not cause suicidal ideation. I think that’s been pretty clearly demonstrated, and so I think again, that’s separate from again a potentially longer conversation or discussion prior \_\_\_\_\_ [00:52:12], et cetera. But I think, again, Tyson’s question is fantastic. It’s a common question, and I do want to say pretty clearly that asking about SI is not a risk-inducing thing. We often include this also in the background of our IRB protocols as sort of the citations in literature on this. And to me, that actually brings up a really important point that we haven’t directly addressed which is really dialoging with your IRB. Some might say educating the IRB about your study.

Certainly, you as a researcher are going to know the most about your study, and the IRB panel members may or not have background in—they’re covering a wide range of studies. Cardiovascular studies, mental health studies, et cetera, so they may not have a particular background. I, in my experience, found it really rewarding to actually talk about your study, educate IRB members, again, about what suicide risk looks like, what suicidal ideation is, what it is not. And again, that tends to have a beneficial effect in terms of going through the review. So that includes educating on things like this about, asking about suicidal ideation. And the last point I’ll make again, in this school of less is more, sometimes is thinking about the interventions that you might do in terms of interventions on behalf of research participants.

There is an argument to be made that in some cases sending out an example here is a welfare check, being cautious about that determination. A welfare check, for instance, having a police officer do a welfare check on a person, I think some would argue, that could be extremely distressing and counterproductive, lead to veterans being less likely to engage in care. So again, there is an argument to be made sometimes where less is more. And again, these are complex questions. I’m not trying to say that these are easy choices but just to point out that throwing everything at a research participant isn’t necessarily the best course either.

Dr. Courtney Bagge: Just to add one thing to that, I agree with everything that has been said, I think if you go to the article that I mentioned, there is a lot of different examples of how stress cannot increase. That’s probably the vast majority. A small subgroup of individuals it can increase or decrease. That’s not saying asking about suicide causes distress but asking about trauma or asking what led up to it, yes, these can be things that are distressing. But if you think of chain analysis in some of the interventions that we do, it can be very distressing, about what led up to a self-harm incident. The research does show that your distress can increase, but it will decrease, and it’s not longstanding. So that’s actually having different levels, like Alan was saying, can be incredibly helpful because it also shows that—inadvertently, I think it can show that the distress can be managed in a safe place. So there might be a little bit of exposure of that just because you’re asking about those kinds of sensitive questions.

Dr. Emily Yeagley: Thank you. I think that might be all that we have time for. We’re right up onto the hour. Just a reminder that if you do have additional questions, here’s a link on the slide to ask additional questions or send comments. And then we’re always open to hearing about more resources that would be helpful to list on the website, so please reach out to us if you have any ideas or holes that you see in the resources. So think you, everybody, for attending. And I think that’s it.

Dr. Teresa Hudson: Thank you, Emily. To the presenters, I really want to thank all of you for your time today. We really do appreciate it. For the audience, when I close the meeting out, you will be promoted with a feedback form. We would appreciate if you took a few moments to fill that out. Thank you, everyone, for joining us today, and we look forward to seeing you at a future HSR&D Cyberseminar. Have a great day, everyone.