Rachel: Hello, so this might be the first time I’m meeting many of you and so I’ll just introduce myself. As you found out, I like to be called Rachel. I’ve been here now for six months and I’ll tell you a little bit about how I ended up being in this position, starting out as a dentist and I also – I have my PhD in Epidemiology. And as you went through the facilitation talk, I found it kind of funny because I was a researcher. I had a career development award from the NIH and I was feeling lonely. And I think when you’re young, you think maybe there are like four jobs like, you know, firefighter, veterinarian, etc. And so I never knew there was a job called Executive Director of a project.

 So I described the job I wanted as being a high-level and well-paid facilitator of research. So I found out then that there were jobs called Executive Director of projects and that’s when I moved into my first job coordinating a very large research program. It was about interoperability, actually.

 And so this is kind of a dream job for me because I feel like I can be a high-level facilitator, though it must be said that I took a significant pay cut to come here. So I stepped back a little bit from the well-paid part.

 So I want to go through and maybe just leave five minutes at the end so that people in the audience – I’ll be milling around for a while at this meeting –but if you have any questions for me. You’ll notice that I’m not going to delve into the intricacies of the substance of the work here. I’m going to be talking about things at a kind of meta level about research. And I hope by having this format, people will learn a little bit more about what I consider to be important, and you can give me feedback on that.

 So some of my big things are about impact, efficiency, and cost-agency coordination. The other thing that’s important to me – I’ve made seven site visits – is finding out, you know, what barriers – how can I be a better facilitator of research? And so it would be great if you could describe very briefly the biggest pain in the butt you’ve faced in doing this research. Yeah, and please be brief. I mean, there’s only so much my ego can take here [laughter]. And I think we have two microphones going. Yeah, HR, Contracting, and IT, I’m already aware of those, yeah? [Laughter]

Elizabeth Gifford: The horses of the apocalypse. No, I think that is actually – to start a process in terms of hiring staff before extremely onerous for us because it was in the middle of various freezes at various points. And when that happened, we had to work creatively and it was very difficult.

 So really, the basic bureaucracies of the system that everyone struggles with, to me, were the greatest barrier just in terms of the amount of time it took to get things moving.

Karen Drummond: Well [laughter], big question. You know, in the evaluation work, I want to say that doing evaluation, one of the things that helped us was that it’s constructed as QI so we didn’t have the usual IRB barriers. IRB is often for qualitative work, something that can cause some delays, especially multisite central IRB. I think they’re really working hard, have been, on you know, diminishing the delays. So that we didn’t face that in this work.

 I do want to mention that in other projects, for more research projects, transcription delays, contracting with services that ended up not being so successful, having to have things re-transcribed, impacted multiple projects at our center. We now, as I understand it, have a really great transcription service within the system and that seems to be working well. And so I just want to put in a plug for supporting our internal transcription services because I think that’s really helping us to overcome that barrier.

Jeremy Sussman: Yeah, thanks. And then, I do really want to start positive, also. From the time that we learned of funding until the time that we were done with data collection was 15 months for this project. And it was a randomized trial and there were new staff who I’d never worked with before who got involved. We didn’t do a six-month development process. And to be able to do that without a massive delay is quite rare in NIH-funded projects, also. And so that was something where having good operational partners in place, being a QI project rather than research, made really quite substantial differences.

 In terms of the difficulties, you said no IT? You already – you said no IT? [Laughter] I mean, in this case, you know, the biggest IT limitation we had was a fairly hard-to-avoid structural one, which was that any change to the actual clinical side of IT – CPRS or whatnot – has to be done by clinical people. And so that’s a pretty big ask of our operational partners. This was a level of coding difficulty that as researchers we do all the time. But the people who put in the decision support tools obviously do not usually do complex ones. And that’s something where, you know, essentially, we’re going to ask them a very large favor that wasn’t fair at the time period and that’s why we did a paper-based HR.

Jean Yoon: I guess one of the limitations of our project was that it was also a randomized quality improvement trial and that we could collect very detailed information from the intervention patients because the sites knew who they were because they had these patient lists. So they were able to collect detailed patient assessments and use health factors, collect health outcomes on patients. But we didn’t have the comparable information for the controlled patients – sites where we didn’t know who the control patients were. And so it was a limit to sort of outcomes that we could measure in a QI type of trial but we were able to get all the cost utilization data.

Rachel: Great, alright. So the other thing I kind of am struggling with is that I know we can sometimes find a lot of projects that have a very promising startup, interesting early results, and when I go to meet with the Undersecretary for Health, it’s, you know, “Okay, then where did they go? You know, what are we doing to get…” And you know, it’s hard to describe the value of, let’s say – I’m just going to pick on you, I’m sorry – of doing this, you know, risk-based statin treatment intervention for a short period of time at one site in terms of a research investment.

 And so where do you or your operational partners plan to go from here? And in the area of facilitation, is this scalable? Is this something that we can extend to other sites? It seems like a fairly intensive intervention in terms of having numbers of facilitators.

 So that’s a question I have for all of you in terms of where do we go from here and who do you expect to help you scale up your – what seems all like promising work into something that impacts our healthcare system?

Elizabeth Gifford: I’m going to answer this first. In terms of scalability and what comes next, I think – well, I guess they’re two different questions. In terms of what comes next, one of the interesting things in facilitation is that there are probably – you know, we know from sort of research that Amy’s done that there is actually virtual facilitation that’s been effective in certain kinds of settings and the work that Joanne’s done that there’s been what some people have even called “extreme facilitation,” a much more intensive facilitation that’s been effective in other settings.

 So one interesting question is can we sort of titrate the amount of facilitation to whatever variables we think will apply? The complexity perhaps of the components of the intervention, the complexity of the setting. But to be completely honest, also the priority. So what are the priorities and where do we want to make that investment? And what level we need? Those, we don’t really have answers for. We’re getting information from this series of studies; however, I think that are important and that will enable us to make some educated guesses.

 In terms of scalability, so next steps, I think, are to really think that through systematically as a kind of facilitation collaborative. And Joanne has established a facilitation collaborative that’s kind of a think tank now looking at these kinds of questions.

 The question of scalability is interesting to me because I, with my other hat, run a national program that we’ve been taking to scale at the request of the Secretary when he was the Undersecretary. And it’s one that’s very focused on relationships and human connection and requires a lot of coaching. So we actually developed some really interesting methods to do that, and I think there are ways to do that and ensure quality. But again, it requires an investment and a commitment on the part of our operational partners in particular, as well as the knowledge.

Rachel: So I just want to clarify something. Is it – I heard you say you need to know the priorities. Is that something you need to know from, let’s say, the Undersecretary level to say, “What are our priorities as a healthcare system? Where are we going to put, you know, more widespread facilitation in place?” Okay, thank you.

Elizabeth Gifford: Well, I would say – so you know, our leaders, David and Amy, can respond more completely. But my experience working with the operations partners is there are the Secretary’s priorities and there’s the Undersecretary’s priorities, absolutely the top priorities.

 But then, there are priorities of like various partners that we are working with in VACO that, you know, they have to fulfill their own strategic plan objectives. And so they have priorities related to those strategic plans. So there are multiple layers of priorities as you work your way through the system.

Karen Drummond: So for us, you know, ours was a partnered evaluation. We’re doing final analyses and we’re going to be delivering a final report September 30 to the Office of Rural Health. And so we’ll hear back from them more about what they would like. We have ideas for continuing work that can be done either as a funded evaluation or if the budget doesn’t allow for that, we will turn these into research proposals.

 One area the qualitative team would really like to take the work in now is we heard a lot from the veterans, we heard about barriers – especially for CBOX. So we’d really, really like to be talking to the CBOX, talking to the providers and the staff at the CBOX and finding out what barriers are they encountering. We’ve heard what the veteran experience is. Now we want to know from our providers, the people who serve our veterans. And so we’ll definitely be proposing something along those lines.

Jeremy Sussman: Yeah, and ours was specifically designed so that as is, it is not scalable. But with a pretty approachable investment, it could be integrated into the electronic health record and not that bad, the fact that therefore, it would be scalable. And obviously, that could’ve happened directly through partners or we could write a research grant that would augment that a little bit.

Rachel: So you know, I often hear – I am sorry, I continue to pick on you, it’s terrible – I hear people that it could be scalable. What are you doing to [laugh] make sure that it is scalable?

Jeremy Sussman: Our plan with it right now is to make some changes that would include other components that didn’t show up in what we did, and probably write a grant for it the next year.

Rachel: So my question is – and you know, here – and this is something I’m not saying I have the answers to this – but at what point do we engage our clinical partners and how can we better engage our partners on the Operations side? Because if you’re writing a grant in order to essentially just fund something on the clinical side, you know, that you know will be useful and works. It seems like it’d be great if that could come out of Operations fund and that would represent, you know, that they also see value in this.

Jeremy Sussman: That would be great, yes. [Laughter] But yeah, obviously, we’re working with Operations partners as we move along. It is distinctly easier to work with local Operational partners than Federal ones. And so when it comes to, for example, planning intervention that would scale us up to five sites, it’s not very hard for me to find five friends. It’s kind of hard for me to find a friend in DC, right? It’s not as clear what that process would be and it’s not as clear [interruption]…

Rachel: I’ll be your friend, and it looks like [interruption]…

Jeremy Sussman: Appreciate that, that’s great [laughter].

Rachel: …David will be your friend, too. [Applause]

Jeremy Sussman: But in general, especially because we do work with the Operations partners on the clinical side locally all the time, that sort of change is certainly easier for us. And of course, there is a question of is this worth actually – are we at a stage where sticking this network computer system in the VA is something people would want? That’s not – you know, as much as I’d love to say it is, it’s not clear to me from what we’ve done anyway.

Rachel: Well, and yeah, I keep hearing this. You know, and again, I don’t have the answers that we need to make these connections at Central Office to the places where decisions are made about this. Oh, and David, David has something to say.

David Atkins: Well, I think this may get very interesting as with the modernization, the sense I get is that more decision-makings are going to be devolved to the local level. And someone in the audience may the more direct information but I thought I saw something that in the vision, they envision that something like 75% of decisions will be made locally and maybe 15% will be made at the network level and then, a small percentage will be centrally.

 So it’s going to create challenges for us in the sense of do we think that change in the VA is going to be the function – the old model, which we’re sort of there were directives that thou shalt do this and then, everybody was left to try to – and maybe it would be in a sale measure or – and everybody was expected to march to the tune. Or is it going to be, “You’re all responsible for figuring out where you need to improve,” and some of you may want to tackle, you know, smoking cessation and some of you may want to tackle lipid management. And then, our case is to figure out rather than partnering with the chief consultant for Cardiology or Pharmacy Benefits, to say, “What are your priorities in terms of improving medication management?” We have to say, “Who needs help in these areas,” and give you tools.

 So I think we’ve done – generally, it’s been easier for us to partner centrally with the Central Office leaders. That often doesn’t translate down into the network level. There’s been so much turnover at Network Director level and Medical Center Director level, a decreasing number of those people are clinicians and have research experience. That’s always been a challenge.

 So I think we need to sort of do partnering at both levels. Where the change – where the push for change is going to come in the future landscape, I think, is an interesting question for us. You know, we sort of joke that the – one of our query directors, Paul Heinreich, said, “Gee, I wish there’d been a GAO report about heart failure. You know, because then I could get somebody’s attention, you know, the way that they did when there was a report about a treatment of acute MI.” But it’s trying to figure out where the pull in the system is going to come from. Is it going to come from the pressure that meets sale criteria? In which case, the pull is going to be very different in Ann Arbor than it is in El Paso. Or is it going to be, you know, where’s the pull going to be because the Secretary says, “I need you to do this?”

Jeremy Sussman: Just one quick related thing. For the work that I’m doing with this, of course, the uncertainty and changes for IT are complicated. Because if I’m going to propose, for example, a decision support tool of some sort, I can’t even propose what program it’s going to be in. And there’s not a lot you can do about that, but it is a problem.

Rachel: So I know that we’re – time flies in this kind of a session, actually. So then, are there any questions from people out there for me? Yes, thank you. Or anybody else? [Laughter] Oh, goodness, I’m going to slink off the stage now. David, you are my Deputy. So you can answer all the questions.

David: [Inaudible]

Rachel: Alright.

Mary: Hi, I’m Mary Hooley from San Francisco. Thank you so much for taking the time to be here and speak with us. In terms of the big three – HR, IT, and Contracting – I don’t think there’s anyone here who wouldn’t agree that those are the three main obstacles to our work. And so what are we doing to engage partnerships in HR at the high levels, in IT at the high levels, and in Contracting and Purchasing to try to address some of these issues?

Rachel: So you know, what I’m trying to do as a new person is to not immediately give up on making changes, however. Because there is some culture in here of, you know, HR, Contracting, IT are the sort of plagues that will never go away.

David: Learned helplessness, I think.

Rachel: Yeah, exactly. And so I think we ought to do something, and we will do something. I think we’ll have to pick a very narrow band to engage at first. And I know that the Secretary himself wants to see changes in those areas because he’s heard also that those hold up everything. But you know, to be honest, I haven’t seen that much movement in making changes in those areas yet.

 The thing I also say when I’ve gone out to my field visits is that we’re – you know, when I go to meetings with the Undersecretary, there’s this big, big table and it looks, you know, kind of scary and you’re in seats and there are a lot of people. And we’re just one voice, “Me, me, me,” about research. And really, communications from the field. Look, there’s so many of you, getting communications from the field up the chain, I think is something that’s valuable. Because you know, the Undersecretary and the Secretary have so many questions and so many issues every day that something almost needs to be raised to the level of a crisis in order to make changes.

Mary Hooley: This is a crisis [laughter].

Rachel: I know. I know it’s a crisis but [interruption]…

Mary Hooley: And not just for Research, it’s [interruption] for clinical work and everything.

Rachel: Oh, I know, it’s widespread. And that’s why I’m saying I think as a group, not just as the Office of Research and Development but including the field, you have to think about how to raise this to the level of urgency that it is rather than just accept it.

 And so I think what we should do, David, is kind of coordinate through our Field Research Advisory Committee and say, “How can we help to mobilize the voices of the field to add to our own and raising issues, and coming up…” And I know the Secretary and Undersecretary don’t just want to hear about issues. They want to have proposed solutions.

 So I think we’d have to have very specific asks. So to the extent that we can formulate those, I think, at the level of the Field Research Advisory Committee, that would be good. Do you have anything to add to that, David? No? Okay.

Unidentified Male: I want to answer. I want to answer that first question you had about barriers. Quality improvement work is really helpful in getting our, you know, ideas into practice. The problem is there’s a lot of variation across IRBs. So the Department of Health and Human Services has really clear criteria about what is quality improvement and what is research. But when you talk to some IRBs, they say, “Well, that’s great, but we’re not the Department of Health and Human Services. We’re VA.”

 There isn’t any, to my knowledge, any national guidance for VA about what is quality improvement and [interruption]…

David: There actually is.

Unidentified Male: Oh, there is? Okay.

David: Yeah, yeah. And Amy had – so ORO put out some guidance about – and Amy, I think, is it on the website to help people, walk people through?

Amy: Yeah, no, but it’s – but you bring up a really good question. The short answer is yes, we have a QI and ethics toolkit developed by David Ganz and Lisa Rubinstein on our QUERI website that helps discern the difference. We have a policy in query we developed on discerning what’s research and non-research. And I think on the horizon – and Rachel, maybe correct me if I’m wrong – the common rule is also being changed across all agencies. They just need to push the button and say, “Yes, it is happening.”

 So that’s the third level that’s happening. But part of it is just it is a process locally. You know, the Federal-State thing going, the process – we also have to educate our local IRBs about this, so I’m really glad you brought that question up.

Unidentified Male: Thank you.

Rachel: And it has struck me, you know, when I myself was a researcher in that sometimes, you know, basically the same risks are present for QI and Research on a given topic, right? Like, you know, let’s say again the cardiovascular risk. You know, if you did this as a research project, there’d be the same risk associated. Yet we subject these studies to longer wait times, which in fact, can delay, you know, benefits reaching our population.

 And so it’s something I do want to engage in and I’ll educate myself about what guidance we have there. I want to engage our IRBs to say now, you know, “Would it be possible…” These are not promises, these are just me fantasizing here so allow me to do so. Would it be possible to have a sort of rapid review for things that, you know, if they weren’t saying, “I’m going to publish this,” you know, would not even need review. Like if this could just as easily exactly be construed as QI, is there any acceleration we can put into place? And the answer may be no but I’m interested in looking into it.

David Atkins: So just to amplify on that, I mean, so there is some guidance about QI versus Research that you can refer to in ORO. There’s still a lot of variation among IRBs and also, in terms of what they’ll qualify for expat or review.

 QUERI obviously has much more flexibility because they have program office dollars. The problem we run into is if we use research dollars, the IRB says, “This is not Research, it’s QI,” we run into a problem in our Finance Department saying we’re not supposed to use our Research appropriation for something that has been deemed not Research, even though we say, “Well, it’s all part of the process that this is sort of an artificial line.” So more to come.

Rachel: Well, and I would hope – that’s why I was saying I was hoping we could have like a rapid review process at the IRB for things that otherwise could be viewed as QI. Because I knew about this issue. We don’t suddenly want people saying, “Well, all of HS R&D is not actually Research.”

Amy Kilbourne: [Inaudible] They call it exceptions. The difference is if you’re paid – sorry, I’m shouting here. If it’s money from HS R&D, it has to be seen by an IRB regardless. The IRB can just say, “This is exempt for Research.” They don’t have to see it ever again.

 The difference with QUERI money is that it doesn’t need to be seen by an IRB. You get a memo from your program office official saying that this is considered non-Research because it’s not for generalizable knowledge. IRB doesn’t have to see it so that’s the difference.

 But it’s subtle but I think we’re trying to work out more efficient processes in HS R&D but we can certainly use your guidance on this, so thanks.

Rachel: Thank you.

David Atkins: When is this – are we over time?

Rachel: Oh, we are way over.

David Atkins: Yeah, so let’s take last two questions. Keep them succinct.

Mike: I’m Mike Weiner, I’m from Indianapolis. You asked a really key question about scaling up. And you know, I have mixed feelings about our current skill in doing that within our Research community. I think that there are probably a lot of people in this room who actually don’t have any training in implementing. You know, if you look at what a company does, the people who actually develop and test the product are usually not the ones who are putting the product into the field or selling it or marketing it. And I feel like some of us are really experts at doing that but a lot of us are terrible at it.

 So I feel like – and I’ve seen this in my own center, you know, where our scientists don’t necessarily have the ability to take their fantastic idea and actually implement it.

 So I think in some way, the VA needs a more efficient implementation engine – something that’s more organized and structured. Maybe it’s some QUERI does, I don’t know. Maybe it’s something that’s new. But I just raise that as a consideration.

Rachel: Thank you.

Matt: Matt Samore, Salt Lake City. This is a question for you, Rachel. So you directed a variety of different kinds of research networks involving different kinds of researchers across disciplines, pathological areas, etc. Can you talk about your strategies, your thoughts on promoting connectedness across different parts of the ORD, different kinds of researchers, not just HSR&D but other services?

Rachel: Surely. I mean, I can talk about a little bit of that but also, David can. Where I’ve mostly frankly been focused on is rather than this sort of high-level connectedness across the services, it will initially be in the form of focused projects. For instance, you know, opioids – big, big issue. For us, it crosses a number of services that opioids – HSR&D, CSR&D – you know, all of the services. Rehab is where pain – or pain subject matter expert is, obviously, basic sciences.

 And so in addition to not just coordinating within our own group but also, across agencies. So we just had meetings with the DOD and the NIH and it would be my intention, rather than saying – and I know people have heard, “Oh, we’re going to have cross-agency coordination.” But I think they try to do it, you know, try to boil the ocean in some way. All I’m trying to do is to get us to compare what projects we’re funding in opioids, see if we can up with a roadmap in certain areas, and then, fill in those gaps. And I’m hoping that that same structure will help to inform our services about which gaps they should fill in those areas and thereby, coordinate around a common goal.

 So that’s how I envision it occurring. And from those processes then, perhaps we can abstract a structure that would allow that to happen more broadly. But did you have particular ideas?

Matt Samore: I should’ve expected that you might throw that question back at me.

Rachel: Or we can talk afterwards and you can give me specific ideas.

Matt Samore: Okay, great.

Rachel: And then, the final point I want to make – and this is a question for David – is, you know, scalability issue. Would it be possible for us, you know, from this meeting to pick one or two things that we would go for where – and it’s not like they’re the best things or whatever. It could, you know, almost be a random selection, I think. That we could go forward and try to make the connections in Central Office to move them forward? To see, you know, is there a model for us to overcome this Research to Operations, the gulf between them?