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Presenter(s): Melissa Bottrell and Tom Puglisi

Molly: And we now are at the top of the hour, so at this time, I would like to introduce Nina Smith, who will be introducing the rest of our speakers. Nina?

Nina Smith: Perfect, thank you very much, Molly, and thank you for all your help bringing this presentation about. I have the pleasure of co-presenting with the Melissa Bottrell and also Tom Puglisi. Dr. Bottrell is the Chief of Integrated Ethics at the VA National Center for Ethics and Healthcare. Dr. Puglisi is the Chief Officer of ORO, the office of Research Oversight. They also come in with experience as funded research investigators, an understanding of what it means from an ethical standpoint, from a policy standpoint and from the viewpoint of an investigator, and so I am really glad that we can bring that view point to the presentation. As for myself, I was previously the Communication and Dissemination Coordinator for Cypress and some of the content on this presentation represents the work that Cypress did. Now, I hope that at some point during this presentation, we will be able to be joined by Amy Kilbourne. I wanted to thank her just for the support that she has shown for not only this presentation but also for the work that has brought about this presentation. And so, Molly, if you can just let me know if Amy is able to join us. I can start with the slideshow.

Molly: Absolutely. I will go ahead and touch base with Amy now and get her online, but until then, yeah, I think it is a good idea to start the presentation, so you should have that pop up on your screen now, to share your slides.

Nina Smith: Absolutely. Do you see the slides? There we go, perfect. So here we are. So the objective for today, or just what we hope to accomplish is to discuss current thoughts regarding the common rule in learning healthcare system, just as a matter of background. There are considerations for changes to the common rule being considered right now, and so it is just information about the QI ethics and compliance toolkit, which was a Cypress developed resource in this area, and brought about by query support. We want to leave time in this session for a conversation with my co-presenters about resources and FAQs in this area, and also to take questions from you, the audience. So, just for the sake of background, and I am sure everyone in this audience could answer this question in their sleep, but if only for my sake, the common rule outlines the basic provisions for IRBs, informed consent and insurances and compliance. For the VA, the common rule is encoded through 38 CFR 16 and ORO has the authority and responsibility to enforce the common rule for VA research. I am sorry, Molly, just to check with you, do you see this control panel?

Molly: No, we do not see yours. We each see our own, but if you want to get yours out of the way, just click that orange arrow in the upper left hand corner of it and it will collapse.

Nina Smith: Thank you. Sorry for that. Well, the original intent and inspiration behind the common rule, which was the Belmont report, and it outlines ethical principle in research, although we all know it is noble, there has been recent conversations about the suboptimal operationalization of the common rule in current healthcare organizations. For example, in the 2006 Hastings Center Report on the ethics of using QI methods to improve healthcare quality and safety. The authors, which include Dr. Bottrell, one of our co-presenters wrote that and I really like this quote, so I am just going to say it verbatim, the mechanism developed to govern ethical conduct in one important area, human subjects research, could have the perverse, if unintended consequence of interfering directly with an equally important ethical imperative in other area, that is unceasing efforts by healthcare professionals to make clinical care safer and more effective. The current state of uncertainty about what is ethically and legally required to safeguard participants in QI activities has already become a disincentive to engage in QI, making it more difficult to bring about the system transformation urgently needed if healthcare is to be made better and safer for patients.

Dr. Puglisi also wrote on this topic in the 2013 Hasting Centers Report on ethical oversight of learning healthcare systems, he made the case for reform within the common rule. To quote verbatim, healthcare institutions have a moral obligation to become learning organizations that continually improve the quality, value and efficiency of care in support of a just healthcare system. However, the traditional distinction between research and clinical practice, distinctions that for almost forty years, have provided an ethical and regulatory framework for our current human research protection system have become blurred from a moral perspective and outmoded from a practical perspective.

So the charge is to think bigger than the common rule and IRB review when thinking about ethics and quality improvement, and what we have previously looked at, the 2016 Hasting Centers Report delineated ethical requirements for protection of human participants in QI activities, and I am going to turn it over to one of the co-authors of that report and co-presenters. Melissa, do you care to take us through some of the these slides?

Dr. Melissa Bottrell: Sure, I cannot take over the slides, you will have to move forward for me, because I am on a phone, but you can hear me, right?

Nina Smith: I can hear you.

Dr. Melissa Bottrell: I will be more than happy to go through the slides.

Nina Smith: Fabulous.

Dr. Melissa Bottrell: So starting on this first slide, slide seven, back in 2006 and talking about this experience here, a group of experts from quality improvement, research ethics, experts in ethics in general, we all got together at the Hasting Center with a grant that was actually funded by the federal government to really think about the scope and what does it mean to do the ethical quality improvement, and that is where we started, and we started out really because we were really wrestling with the issue of what the common rule said and how do we manage when we are trying to do these quality improvement projects that are thoughtful, well designed, but are really about organizing healthcare systems and doing the best quality of care, not about necessarily the newest drug or innovation of that type. But we kept bumping up against the common rule definition of what is research. So we started out spending a lot of time trying to distinguish between what is quality improvement and what is ethics. And what we found is that from a logical process, it actually was a fruitless approach and what we came back around to is what we really cared about and what was most important, was that irrespective of whether or not you define something as research or quality improvement, or quality improvement research or any other type of thing that involves making the healthcare system work better, what is really essential is that you make sure that the practice of that improvement process meets ethical standards.

So, what we did is we started by looking at, in order to understand what those ethical standards are, we started by looking at what are the standards for ethical research. We started looking at a number of categories, and importantly the basics where thinking about that came from, how do you think about what are the ethical standards for research, and so we looked at quality improvement from the same categories but really applied them to the concept of quality improvement, and the standards that we were looking at were things like social and scientific value, scientific validity, fair subject selection, favorable risk/benefit ratio, respect for subjects, informed consent and independent review, and those are kind of the standards for ethical research, but what does it mean when you apply those concepts to the area of quality improvement.

So, let us talk a little bit about that in these few slides here. So first of all, when we think about what does it mean to have social or scientific value in the area of quality improvement, we really want the gains from the quality improvement activity to justify the resources spent within your healthcare system and the risk that are proposed on those participants. It is really important when we think about this, particularly quality improvement, that the risk to the participants are both on the patients who might be receiving your quality improvement, but also the providers that are part of the reorganization, because so much of quality improvement, especially in healthcare is all about reorganizing care, redesigning care, what we do, and that makes the subject and also your providers. Everyone from your clinicians to the non-clinical providers who are part of that care system, and it would be wrong to expose our subjects, whether they be the clinicians or the providers, to risk, without benefit, particularly because we are in a resource limiting healthcare system. You have to really think about the cost and the value that you are going to get out of this work, the work that you are doing. Of course, there is always a chance that you try a quality improvement cycle and it in fact makes things worse. That is why we do analysis, that is why we do quality, and that is why we make sure we have good data systems, but at least you should be looking at it that you think the benefits of the work are going to outweigh the cost of burdens and the risks that are imposed. And that calculation is somewhat different in a research environment, because you are really caring very much about the knowledge basis, not necessarily about the benefit to the healthcare system in which you are actually imposing these changes.

So, let us think about the category of scientific validity. To justify resource use, again, it is really important in the healthcare system where we have limited resources, you have to have methodological sound quality improvement, and this means that the methods that are used to implement are actually an important part of the context. You know, often in research we use the gold standard of course of the randomized control trial, but we are trying to actually remove the context from what we are doing in the research project. Strip many of those factors out. Well, in fact, in quality improvement, you want that context. You care about the fact that this innovation that worked someplace else, is it going to work in this different kind of unit and this different type of environment. That changes your method. That changes how you think about what a good methodological design is for your project. It does not necessarily mean that randomization of a sort is not necessarily appropriate for quality improvement study does not automatically mean that if you are doing randomization that something should be considered research, but it does help you think about okay, doing randomization there may be higher risks that you need to be thinking about and that is where we are pushing. Are we really thinking about what is going to be a quality improvement project and that is going to be methodologically failing in this kind of environment.

Moving on to the category of fair subject selection, again, participants should be selected to achieve a fair distribution of the benefits and burdens of quality improvement, and that is particularly important of course in our VA setting because we care for, often, some of the most vulnerable patients. But no matter what, whether you are in VA or outside, your quality improvement project needs to assure that the most vulnerable patients and providers are protected, and that includes those with the least hierarchy of your providers in your system. That does not mean that everyone has to benefit directly from the quality improvement project, and does not also mean that people who are marginalized, stigmatized, powerless or poor should not participate in quality improvement projects in the healthcare system, but especially as you think about who your populations are and how you distribute the benefits and the burden of the quality improvement interventions that you are doing, it should be fairly distributed across population so that the high-risk, most expensive patients are not always the recipients necessarily of the burdens or the patients who might be unfairly stigmatized by a kind of project, but there is some thinking about that issue as you think about who you are selecting and also how you are attending in your project.

Next slide, so thinking about respect for participants, quality improvement activity should be designed to protect the privacy of participants through confidentiality of both the patients and the providers. This is importantly, the participants in the quality improvement activity should receive information about the findings from the activity that are clinically relevant for their care. This becomes, of course, complicated when you think about the different stages of participation. We are going to talk about informed consent in a minute, and these two pieces go hand in hand. There is a moral imperative, and we talk about this in the article separately, we are not going to get into this today, but there is a moral imperative in healthcare to do quality improvement, not to just sit on our behinds and not have our healthcare system continually evolving to do better. We have that moral imperative and so participants in the healthcare system are obligated to participate in activities that have low risks that do not increase the risk beyond what they would already be receiving in the healthcare system. But you also need to make sure that people have the access to know how your system is improving. So that means that you may have an obligation to inform your patients and your providers about the quality improvement activities you are doing in your healthcare system, broadly through information, through communications, through other pieces like that and when you specifically have activities that have higher risks, that is where we get into informed consent where you might need to have different kinds of information for two people as the risk ratios go up.

Let us talk a little bit about patients and workers in healthcare setting who should receive information about the program of quality improvement activities, and there are different ways you can think about how you do that, whether it be for your specific QI initiative or for it be the healthcare system as a whole. We talk a little bit about that in the article, but in general, there is this obligation to provide information about quality improvement that is being done. You also want to make sure you sure information about the quality improvement initiatives. You cannot just do your quality improvement imitative in your area and not let it be no more broadly than it would be within your facility if you are doing a small scale quality improvement cycle or a more broadly in a system like yay, across facilities so that others can benefit also. That is part of your risk/benefit analysis, which was one of our categories earlier.

So let us talk about informed consent. At minimum, you have to get basic consent for admission, everybody does this. But the part of that we should be thinking about are the moral standards. Now, whether or not VA has done this well, we can have a different discussion about, but as a moral standard, people should be getting information about how your healthcare system is regularly participating in and patients will be part of efforts to improve the quality of their care. That is part of what they get when they enter they healthcare system. That is where you want to be balancing those benefits and burdens to patients. But as you increase the risks of the burdens, you might want to be very careful of your quality improvement projects if you start to inform patients. That is important because in general, quality improvement is not about introducing novel treatments, it is about introducing what is known to be effective in one context and applying it to other contexts or comparing data on standard practices and tweaking it to make it better, not finding a novel, but talking to patients about what might be different about their care between what their buddy down the road might hear or what their friend might have experienced. Patients understand why they might have received a different kind of care or burden and making sure that you are thinking about things like whether or not those care differences might stigmatize certain patients is really important. Workers, talking specifically about workers, employees or non employees professionals providing care are expected to participate in minimal risk quality improvement activities as part of their job. But in the commission, we spend a lot of time thinking about some of the burdens that actually can be imposed on workers and that they should be informed about and good actually improvement efforts do in fact inform patients and inform providers about quality improvement efforts that are going on, and they can be asked for thought about their informed consent for minimal risk activities. But just because you ask them for informed consent, does not mean that workers can opt out of activities that might, in fact, identify practices that are doing bad things, practices that might harm patients. They do not get to opt out just because it might identify risks. They can opt out if it puts them at risk that would be not related to the regular burdens of their job.

Final category that I want to talk a little bit about is independent review. Again, accountability of ethical conduct of quality improvement should be integral into the system accountability for clinical care, just like we do for medical care, we should be overseeing quality of care in how we do quality improvement. And that means everything from the lowest level to doing tedious day cycles and one clinical unit. You should have some local review mechanism, whether it be a supervisor thinking about whether or not you are meeting ethical standards locally and also talk to your ethics consultation service in your facility if you are thinking, hey we want to make sure we are doing this in a way that is going to be meeting ethical standards, and as you move up in terms of more and more vigorous approaches. You know, in the VA we do a lot of multi-facility quality improvement projects with very robust data collection. Those systems are happy to say in VA actually have some good policies that Dr. Puglisi is going to talk about to manage assuring that we have thought about the ethical standards, and that is very different actually than many other healthcare systems. But there is this requirement that even if you are dealing with local quality improvement efforts, and this is from an ethics standpoint, to think about making sure you had the right kind of independent review to the right level of quality of project to assure that you are meeting ethical standards.

So I want this over at this point to Dr. Puglisi to talk a little bit about implementation of the common role in VA.

Dr. Tom Puglisi: Okay, thank you. As you know in VA, we do a huge amount of quality improvement projects, a huge number of quality improvement projects and we do a lot of evaluation activities that really do not qualify as research under the federal definition. Research is defined federally for regulatory purposes as a systematic investigation designed to contribute to generalizable knowledge. Now, there are a couple of problematic words in that definition. The word design and the word generalized. Both of these words have been since the common rule was implemented and even before that when the HHS Regulations governed NIH supported research. There have been arguments in the IRB and the research community about what the word designed meant and what the word generalizable knowledge meant. So the definition that is in the common rule has been inadequate for the purposes of distinguishing activities that really are not research and were intended to be covered by the common rule from other kinds of activities that use research-like methodologies but are not really designed to develop or contribute to generalizable knowledge, and when I came to VA ten or eleven years ago, it became obvious to me that the VA was a particularly context in which would be very, very important to provide some guidance to folks conducting activities like quality improvement activities and other kinds of evaluation activities.

To decided first of all whether or not their activities were covered by the common rule by the federal policy for the protection of human subjects, and secondly if they were not covered by the common rule, to give these projects some direction in terms of how they should be reviewed and overseen. So, we have a handbook, 1058.05 that tries to make a distinction between operational activities that are not research and activities that do, indeed, constitute research. If an activity is not designed to generalizable knowledge and in the handbook we define that as intended to contribute to scientific or scholarly discipline. It is not research under the common rule, and what we need to do to help investigators draw the line between when they are conducting research that is subject to the federal regulations for research and when they are not. What we tried to do in 1058.05 was to help investigators draw the line between research and non-research activities and to provide them with some, what is a good word, defense? If at some point down the road, somebody were to accuse investigators or VA of conducting research outside the federal regulatory requirement, so what we did is establish a system of accountability and documentation for activities that do not constitute research, and we also provided a mechanism for publishing the results of non-research activities. This is particularly important because a common misunderstanding within the IRB community, and even among researchers and journal editors, is that if something is published, disseminated for other professionals or the public, then it is by definition generalizable and therefore was research. That is actually not the case. The definition of research has nothing to do with whether or not the results of an activity are published. It has nothing to do with whether or not they are presented at a professional meeting. It has nothing to do with whether or not they are of interest to a body of scientist or to an academic discipline. What matters is what the project was intended to do and whether the intent of the project was to contribute to generalizable knowledge, in other words, to expand the knowledge base of a professional discipline or scholarly area of expertise.

Let us go to the next slide.

Dr. Melissa Bottrell: Perfect, thank you so much Dr. Puglisi. I am going to go through these slides really, really quickly because I want to make sure that we have time to have that Q and A segment.

Molly: I am so sorry to interrupt. This is Molly. I just wanted to let you know, whenever you are ready, we do have Dr. Kilbourne on the call.

Dr. Melissa Bottrell: This is a great time actually. So Dr. Kilbourne, Amy, please go ahead if you can provide some type of opening remarks.

Dr. Amy Kilbourne: Thank you, and can everyone hear me? I am on a cell phone in a building, so…

Dr. Melissa Bottrell: Nope, you are good.

Dr. Amy Kilbourne: Okay, wonderful. I really appreciate the opportunity and my apologies for not being there at the beginning. There are a lot of meetings going on here in Vigo, but I just wanted to thank everyone for participating and also thank Tom and Nina and others who are presenting because this is such an important topic to really make sure that we provide as much insight and input in to the field with all the investigators to really understand the delineation of research and QI. It really helps ultimately what we should do to better serve our veterans in terms of doing work that is considered TY or operations, because that can definitely help with the more rapid translation of best practices into the hands of the frontline providers and veterans, and so I just wanted to thank everyone again for participating and just know that really this has been, I think, a sort of labor of love particularly from office of research oversight who is really, in Tom’s leadership, in terms of coming up with these guidelines to help us do the right thing at the right time, so I will just stop there and really Nina and others, please take it and carry on. This is just a wonderful presentation so far.

Molly: Thank you, Dr. Kilbourne. I also wanted to thank you and the QUERI program for supporting this work as well, helping moving it forward. And along those lines, I actually wanted to provide a quick demonstration of this Cypress product created with support from the QUERI program and the HSR&D COIN in Los Angeles, that was inspired by QUERI and local experience with ethical and regulatory issues, and QI projects. The content reflects conversations with Dr. Puglisi at the Office of Research Oversight, Dr. Bottrell at the National Center for Ethics in Healthcare, and VIReC and NDS. So, just as we have discussed so far, we want to keep in mind the basic ethical principles in whatever we do regardless of whether it is research activities or non-research QI activities. This is the framework by which we put together this tool kit. So, we keep in mind the basic ethical principles as delineated in the Belmont report mainly, respect for person, beneficence and justice.

We also want to acknowledge that QI and research is held accountable to the same organizations that govern the behavior of healthcare operations, namely entities such as the Office of the Medical Inspector, the Office of the General Council. So it behooves all of us to think about minimizing the potential for controversy as Dr. Puglisi had said before, or allegations of noncompliance with VA requirements. We encourage the following practices to protect against potential harm or unintended consequences as well as to minimize the potential for controversy and that is to continuously keep ethical principles in mind and maintain a compliance oriented mind sight, as Dr. Bottrell said earlier, seek consultation and accountability early and often and develop systems accountability.

So, let me go through portions of the toolkit. So it is made up of several web pages that are available on the intranet, so behind the VA firewall, and if you download the slides afterwards, the URLs above are hyperlinked and you can go ahead and click on those. So one of the pages is a principles page that operationalizes the ethical principles into day to day issues and considerations, so to the left is the principle and to the right is the day to day consideration. We also have a scenarios page, which provides case studies of how ethical regulatory issues may present in QI or research activities. Each scenario has hyperlinks to the principles webpage and vice versa. We have an FAQ space the provides guidance for questions that we thought investigators may ask, for example, who can give me a determination of non-research and a resources page, which provides hyperlinks to VA policy, a list of local and national resources, a bibliography, samples of documents that can be downloaded and edited for the needs of your project, as Dr. Puglisi had mentioned before. These are some of the sample forms for documentation for non-research activities in case you want to publish or if you are going to present the material from your projects.

And we also have, on the resources page, there is a variety of tools that you might find useful. Some of them are the ORO Decision Chart for determining whether or not a QI activity constitutes research, the 18 HIPAA identifiers. One tool in particular that I wanted to pull out and highlight is the Ethics and Compliance Planning worksheet. The worksheet is a series of questions about a project and under the questions, the worksheet lists issues to consider when planning and conducting QI. For example, the worksheet asks will providers and staff be involved. Will patients be involved? Do you plan to interview or survey patients? Do you plan to interview or survey providers? It does not list issues such as information on the OMB process for collection of information from more than nine patients.

Another tool is the Level of Review recommendation based on project activities. It contains a list of different study designs and groups them into risk categories depending on burdens of participants and proximity to research activities. It also suggests the level of oversight for the projects that employed, so this is a screen shot of the level of review recommendations. It is a list of study designs on the right that could be considered of minimal burden or risks and are usually considered to be non-research operations activities. Now to the meat of the matter, we have prepared a couple of frequently asked questions and we are going to have a conversation about them. So to begin with, how can I tell if my project is research or QI, and I know we had covered some of this before in the presentation, but to take it further, I am going to pass the mic onto Dr. Puglisi.

Dr. Tom Puglisi: Okay, first of all you should become familiar with the handbook, 1058.05, which draws the distinction between research and non-research activities. The investigator should be clear in her mind or his mind from the very beginning what the purpose of the activity is. If your purpose is in part, to contribute to generalizable knowledge, you are conducting research. If your project is intended to be applied solely within VA and to be generalizable only within VA, and the purpose is to improve the quality of VA processes or care, then you are not engaged in research. So, the quick and easy way is to answer two questions. Is the project intended to improve VA processes or care? And is the project not intended to contribute to generalizable knowledge in a scientific field or discipline. If both of those answers is yes, then you are not conducting research. You need to think about how to validate your determination as the investigator that the activity is not research.

The next thing to do is to look at the level of your project. It is a project that is just conducted at the local level. Is it conducted at the business levels. It is conducted at a national level and sponsored by one of the VA program offices? There are different mechanisms for validating your activity depending upon the level of involvement of the activity. If it is a facility based study, then the medical center director is the person who ultimately determines or can validate that your project is quality improvement. Now in practice, most medical center directors have delegated somebody at the institution to make that determination, and usually it is the IRB chair. So, you would go to your IRB chair, discuss the project with your IRB chairperson and receive that persons confirmation or validation that the activity is indeed a non-research operations quality improvement activity. If it is at the business level, it should be a business official who can make that determination. If your project is supported be a VHA program office or it uses the data from a VHA program office, or it some other way involves a VHA program office, then there is an official within that program office that can validate your project as a non-research operations activity.

If you go to OROs website, you will find a list of folks in each program office who are capable of making that validation. Now, the handbook only requires you to obtain validation if you intend either prospectively or later to publish the results of your project in a peer review journal. However the handbook very strongly recommends that for any activity in which there may be some disagreement or controversy or lack of understanding, wither within VA or in the part of the public about the nature of this activity, it is to your advantage as the investigator or project director to get that validation very, very early on. As early as possible in the life of your project. That is for your protection and for VA’s protection. We, as a matter of fact, have a very dicey situation right now at one medical center where a valid quality assurance, non-research project activity was undertaken where the local union vehemently objects to the process, believes that workers, providers in this case, were unfairly subjected to research, had the involvement of higher level union officials and members of congress. And even though ORO has made the determination that that research was not involved on this situation, it continues to be extremely controversial and problematic for VA. Had there been a clear determination ahead of time that this was not a research activity, I think the investigators would be in a better situation right at the moment. So it is very, very important for your own protection to get validation outside of your own research team or your own quality improvement team or your operations team about the real nature of the activity. It is also important to note that, you know, having been a person, who in another life, both conducted funded research and who did program evaluation work out in the community, I was kind of schizophrenic in my academic life. I did hard cognitive science, very, very detailed memory reaction time research and I also did quality improvement out in the community. But you know, the nature of what you do sometimes evolves. Sometimes you are doing an activity that you think is going to start out as quality improvement or program evaluation, and you find something interesting that you would like to design in such a way as to contribute to generalizable knowledge and you make little changes along the way and suddenly you find yourself conducting a research project that kind of crept on you without, so it is important to be careful that any changes you make in a project, as it evolved, does not change your ultimate purpose, which is either on the quality improvement non-research side, which is to focus on applications within the VA and not contributing to the knowledge base of a scientific discipline or a scholar area. If that evolves and your purpose changes, and you have moved into research, and then you have a whole series of other considerations that have to be addressed.

Let us go to the next slide.

Dr. Amy Kilbourne: I am actually going to ask Molly, given the time that we have left, how does it look in the audience questions? Should we transition to the audience questions or?

Molly: We can go on for a few more minutes, we just have a couple pending ones.

Dr. Amy Kilbourne: Okay perfect.

Molly: If it gets above a dozen or so, I will break in.

Dr. Amy Kilbourne: Absolutely. So, I wanted to turn this particular questions over to Melissa, do I need to document informed consent in a QI project?

Dr. Melissa Bottrell: So I want to feed a little bit off of what Dr. Puglisi was talking about with respect to quality improvement projects. Just because you have something that has been defined as a quality improvement project, and so you are “all good” with the regulations aspect and you have dotted your Is and got your documentation, you have all of the pieces that are required for change management as part of that project. In some ways you can call that informed consent, you can call that community building, you can call that community engagement but there are a lot of pieces that are involved in that and I want people to think more broadly than just what we typically think about as informed consent, which is a five second conversation. This is not the best case, this is the worst case, but a five minute conversation with somebody where we throw some information at them, we do not necessarily fully inform them and we get them to sign a piece of paper, or we do not even because maybe it is a pretty low risk thing.

We need to be thinking especially in quality improvement, because of the nature of quality improvement, and I think the risk situation that Dr. Puglisi talked about with the union is a good example of as you are thinking about your quality improvement project. You need to be thinking about how you are informing everybody who might be touched by this project, and you need to create a transparent process for obtaining their information, for informing them, for creating their buy in and for obtaining their consent to participate. Now that does not necessarily mean that you have to have written consent in a quality improvement project from every participant, everybody who might be effected. There are different categories and there are different levels, for something that might involve risks to a patient or provider, you probably do want to have a written documentation of the conversation of some sort, at minimum you want to have a protocol where you describe the process where you have your clear information sheet and information documentation about your process, and you document in some way that you have had this kind of conversation. It does not necessarily mean you have to have to forms of signatures and all those pieces, but you need to have clear protocols and clear processes for assuring that information flows and that you have that documentation. So when you come back around at the end of your project, whether the project was so amazing that it was worthy of talking about more broadly and public forums of various types, you have that kind of history but you also have the buy in from people because they know that you really care and respected them as people for engaging with them.

You need to make sure that they understand in terms of quality and the content of that information. They understand what their involvement in the project entails, that they understand what circumstances the data they provide or information about them will be used, and you also have to be very aware of the power relationships in your quality improvement setting. You know, be aware that in VA we do have coercive settings where a patient may feel very much that if they say no they do not want to participate in this project, even if it is little risk, but have some more risks than medical care, they may fear that their healthcare may be taking away, all of these other things. I mean we have populations in VA who have had many times been treated poorly by the healthcare system. We want to make sure that you really think about what the impact on them could be as you talk with them, inform them and share information, and really make them participants in your quality improvement project.

Nina Smith: Thank you so much, Melissa. Our next FAQ is how should I contact patients for my QI project and first we will take it from the regulatory standpoint with Tom.

Dr. Tom Puglisi: Okay, so I think there are really two issues that you need to think through very carefully in terms of contacting individuals about a QI project. I mean the first has to do with very much reflective of what Melissa just said. You need to be as transparent as possible about what is going to be taking place. If that involves—depending upon the kind of project, it may involve talking to people one on one or it may involve simply having lots of information available at the site about what is taking place. One of the dicier areas has to do with questionnaires involving patients. There is this animal called the Paperwork Reduction Act that is enforced by the Office of Management and Budget that has very strict requirements regarding the kinds of surveys that can be presented to folks, and generally, most of the projects that we have seen that involve surveys can fit under one of the exemptions that is listed there on the slide. The problem is that in fact, it is very, very difficult to get confirmation either from OMB or from the VA Liaison to OMB regarding the Paperwork Act that an individual project really does fit the exceptions. This is something that over the years that I have been in VA, we have many times tried to facilitate. All ways to no avail, I have to report sadly. So, the best advice I can give you is to look at the exemptions that are referenced there with the hyperlinks and at least in your own mind justify why what you are doing fits one of the exemption categories. My office, the Office of Research Oversight, actually does not have the authority to enforce this particular regulatory requirement and we do not. If we see something that is potentially a problem, we will inform the investigator and tell them that they need to validate what they are doing as best they can and at least attempt to get OMB or the liaison to validate what they are doing, but I have to tell you honestly, it does not fit any you think it does.

Nina Smith: So it has been a work in progress, would you say, Tom?

Dr. Tom Puglisi: A work in progress but to mix metaphors, there is not light at the end of the tunnel as far as I can see.

Nina Smith: I would also like to hand it over to Melissa, just to talk about a big picture perspective on contacting patients.

Dr. Melissa Bottrell: Yeah, I mean I think the overall way that you should approach your quality improvement project is you need to respect our patients and our providers. You need to protect their privacy. You need to demonstrate patient tenderness and have working protocols that you really think about in your quality improvement project. Everything from the same things you would do in a research project assuring that the research data is in locked file cabinets, that you have followed all the HIPAA privacy rules. All the various things that you need to make sure that you protect their information, that you think about the way that your project is constructed to assure that people are not going to feel stigmatized or that their care in VA might not have changes that they feel is burdensome or that you call them out. Particularly important when you think about the fact that many of our employees are also our patients and so we certainly have projects that are quality improvement projects that target special levels of services to our high need or high risk patients, but perhaps projects like that, especially when our patients are also our employees, can call people out and stigmatize them and have burdens for them in the workplace, so you really need to think about what is the impact of your project on your patients and on your providers and have robust mechanisms, sometimes more or less than your local clinical systems, for your protection.

The other thing that I just want to repeat the fact that even once you have your approval from the IRB that your project is not research, you know, you do have resources whether it be both in the IRB and in your work ethic consultation services to get help when you are working through the sticky system, situations of how do I assure that I am meeting the ethical standards? Okay, so it is not research, but I still want to do right by my patients and providers. If you need someone to talk through these kinds of issues, you can call your local Ethics Consultation Service or you can call the National Center and that information is on the slide.

Nina Smith: So Molly, I am just checking with the time. How are we looking? Do we have time to address one more FAQ?

Molly: Yeah, I will go ahead and prompt our attendees to write in any questions or comments they have now while you go over that last one and then we should have a good pending list when you are done.

Nina: Perfect. So this last FAQ is how should I contact providers from my QI project? And I’ll start first with Melissa.

Dr. Melissa Bottrell: Sure, I think this really fits in with what we talked about earlier. It is so important that you inform and engage everyone from your leaders to your employee participants at all levels of the organization. In thinking about knowing about your quality improvement project, and that is whatever is the appropriate scale. If you are doing a PDSA cycle in the local unit on a single wing, that might require one kind of information. If you are doing something that is hospital wide or it is particularly intense or covers multiple subjects, it is going to require a different level of informing and engaging providers. This is not just an ethics standard. This is actually a changed management practice. Right? We know that change quality principles show that if you do not engage the people who are going to be impacted by your change, they are not going to buy in and they will put up barriers to whatever your change is. So you really need to think about how do you get them on board and engage them at various points. If you are reorganizing your systems and patients might be taken away from their regular primary care physician, how do you inform that primary care physician about patients who might be leaving their service for part time or for all time. How do you engage them and make them part of the solution as opposed to a piece that is outside? Tom what did you want to add?

Dr. Tom Puglisi: I just wanted to reemphasize how important it is to be aware of the need to touch base with unions if any providers or other VA employees are involved. If you are doing a project that is a multi-facility project, make sure that you touch base with the unions in all of those facilities because they are not all necessarily going to react the same way. In the particular case that I just alluded to, the union officials at one participating facility were absolutely fine with the project. They had done consultation beforehand and had given their blessing to the project beforehand and the investigators thought they were good to go because they had contacted the union beforehand, but when they took it to another facility, they did not do enough ground work with the union at the second facility and the union at the second facility had a very different perspective than the union at the first facility and that is one of the things that kind of led to the problem. So, the involvement with all stakeholders is incredibly important as Melissa said. Being transparent and trying to engage all the stakeholders is a really important step in the process that unfortunately a lot of folks tend to forget about.

Nina Smith: And with that in mind, I want to go ahead and show this slide which provides resources in case the audience has any questions that are not addressed during this presentation or that they have post presentation. That is the link for the toolkit, links for ORO’s website as well as two emails, one for ORO’s Research Compliance and Education Program and for the VA National Center for Ethics in Healthcare. Molly, we can turn it over the questions.

Molly: Excellent, thank you. We do have some great pending questions, and for anybody that joined us after the top of the hour, just use the question of your GoToWebinar dashboard to submit any questions or comments you have. The first came in towards the beginning: With each service performing their own QI projects, there are different standards, different levels of maturity of the projects and different levels or resources. Do other VAs centralize QI tasks for accountability, consistent standards and to share resources?

Dr. Tom Puglisi: I do not know of facilities that have partnered for that kind of resource sharing. Some of the program offices that are heavily involved in either supporting or providing data for operations projects do have very detailed standards. But I do not know of any individual facilities or groups of facilities that have developed shared resources for this purpose. Melissa you may have more experience with this than I do.

Dr. Melissa Bottrell: Yeah, I also do not have any experience of any specific VA facilities that have thoughtfully organized that. We spent a lot of time when we were doing the Hasting Center work talking about how that would be really valuable and many of our outside VA industry representatives from other healthcare systems talked a lot about how that was their goal. I know that some healthcare systems have really thought about really consolidating and coordinating including coordination of their thinking about application of ethical standards, so some healthcare systems outside of VA have thought about that, but I do not know of any in VA that have gotten to that point.

Molly: Thank you both for those replies. In a QI project examining the role of peer support specialists, for example, peers delivering an intervention for veterans, how would you suggest classifying the peers, as staff or as veterans when they straddle the line between the two categories. I would suppose it would depend on the role they are taking in the project. Are they an interventionist or a patient recipient in some capacity? Thoughts?

Dr. Melissa Bottrell: I can say that our office has actually had this question come up a couple of times in projects in terms of thinking through what their role is, and there is I believe, in fact, a policy that is pretty clear that says that staffing these kinds of peer roles are patients first, and so they have the rights and the roles and they need to be treated like and protected like patients and not necessarily treated like staff whom you might have a very different role or relationship. For more specific feedback on that, you could definitely send an email to our office and we can provide support and the specific legal and backgrounds on that, but this is a really important area. Those patients who are in the peer support roles are at highly risky situations because of their roles when you start to think about and unpack these QI situations, so you have to be very careful though..

Molly: Thank you. We just have one pending question left and then I will let you all make some concluding comments. Would preliminary data collection regarding an intervention which could or could not be of general interest to the scientific community, be appropriately considered QI or research?

Dr. Tom Puglisi: Well the problem there is with use of the word interest. On one level, just about any finding from any QI activity could be of interest to a scientific discipline. The question you want to ask yourself is not will this data be of interest but what is the purpose of the data collection? Is the purpose to develop a project that is internal with the VA and not designed to such a way as to be contributing to generalized knowledge, or is the purpose to do a project that has the potential and is designed with the right methodological strategies to be able to produce the contribution to generalizable knowledge as a goal. So the answer to your question really depends on what that initial purpose is. If there is a clear intent on the part of the person collecting the data to contribute to generalized knowledge, collecting that private data is a research activity from the very start.

Dr. Melissa Bottrell: I was going to say the other thing to add to that is sometimes there is this tendency to have a project that is really well designed and carefully QI and for intention purposes great and then somebody decides to add five more questions to the design, just to get that extra little bit, and that is really not to the benefit of the project or the patient, that is the piece that might be the research piece. People really need to think about those kinds of little add ones, which can really put your whole project in jeopardy. You really need to think about your intent and what the point of those little add ones are.

Dr. Tom Puglisi: That is very, very important, and you know, there are ways to get that intent for people who interested in gaming the system. If you have a project that is described as a quality assurance program and you have a methodology that goes way beyond the goals of that project, it can be pretty clear that you have used a methodology that is really designed to produce generalizable knowledge rather than to answer the specific quality improvement or operations questions that you posed. If you are not sure what you are doing, get advice and document the advice that you have gotten. You know, if none of the resources that we have already talked about can help you make that decision, you can always come to either ORO or ORD. We have a working group that looks at these projects whenever they are referred to us. They are usually projects where a program office cannot decide or where the areas are gray enough that the decision maker wants to have an objective look at it from ORO or ORD. We have a working group that is very efficient. We can get back to you with an answer in a week and usually more quickly than that. It is a group of about five people who are used to working together, and if you send us the entire project description, we can get you an answer in writing very quickly.

Molly: Thank you. That is an excellent resource. I know we are a few minutes past the top of the hour, but we do have a last minute question that came in, are you all able to stay on and answer that for the recording?

Dr. Tom Puglisi: Sure.

Molly: Okay, thank you. If any attendees need to drop off, when you do exit the session, please wait just a second while our feedback survey pops up as we do look closely at your responses to these few questions and it helps us to decide which future topics to facilitate. So the final question is if a facility participates in an IHI initiative to improve care and the results will be used by IHI to future the understanding in healthcare, that would then be considered research?

Dr. Tom Puglisi: We would have to look at the specific project to make a cut on that.

Molly: Okay, thank you. Well it looks like we are at the end of our Q and A so I just want to ask if any of you have any concluding comments you would like to make? Nina we can start with you

Nina Smith: Sure, first of all I want to say it is an honor to work with the co-presenters on this seminar. Melissa and Tom are not only the go-to people in the VA when it comes to ethics and compliance, but also thought leaders in this topic and healthcare in general. Once you download the slides, you will be able to obtain the references for those publications that we cited during the presentation. And then second I want to credit the leadership of Cypress just for supporting the work that brought about this presentation. I will pass the mic on to anyone else who has closing comments.

Dr. Melissa Bottrell: I just want to say thank you to you, Nina, for your excellent work preparing this and to the whole structure that put this call on. This is such an important issue and something that I really care about, and so I was happy to be able to provide a chair with my thinking about the VA.

Dr. Tom Puglisi: I would like to echo that as well and just as one parting thought, if in doubt, consult and document that consultation. If you are not absolutely sure about what you are doing, get an objective person to validate your approach.

Molly: Thank you, Tom. Not to overstep my bounds but I think that is good advice for any situation. So I want to thank you all for joining us today. I especially want to thank our presenters for lending their expertise to the field. The cyber seminar series each session takes place the first Thursday of the month at twelve noon eastern so please do join us for future sessions and at this point I am going to close the meeting, so again, please do take just a moment to fill out our feedback survey. Thank you once again, everyone. Have a great rest of the day.