

Centers for Medicare & Medicaid Services  
Special Open Door Forum  
Survey and Certification – Transplant Program  
Introduction to Quality Assessment and Performance Improvement Survey Tool and  
General Questions and Answers  
For Transplant Program Providers, State Transplant Surveyors and CMS Regional Office  
Transplant Staff  
Wednesday, November 10, 2010  
2:00PM - 3:30PM ET  
Conference Call Only

The transplant Conditions of Participation require every transplant program to have a comprehensive, data-driven quality assessment and performance improvement (QAPI) program – 42CFR§482.96. The Centers for Medicare & Medicaid Services (CMS) will hold an Open Door Forum (ODF) to introduce and review a new surveyor tool for QAPI programs. This call will also offer participants an opportunity to discuss any concerns or questions they may have about the transplant survey and certification process.

The purpose of the call is to increase provider awareness and understanding of the QAPI regulation and the tools surveyors maybe using to review the QAPI program while onsite. This Forum also provides CMS with the opportunity to engage and listen to the needs and concerns of the transplant providers. During the ODF, CMS will provide an overview of the QAPI Worksheet and Resource Guide (a tool that may be used by transplant surveyors) which will define CMS' expectations of transplant QAPI programs. After CMS' presentation, participants will have an opportunity to ask question specific to QAPI. The estimated time for this part of the ODF is approximately 60 minutes.

Following the QAPI discussion there will also be time for other questions and concerns that the transplant community may want to raise with CMS. Since the initial transplant surveys have been completed, CMS felt this was an opportune time to hear from the providers and State surveyors as the transplant survey and certification process goes forward.

QAPI materials for this ODF are attached.

We look forward to your participation and comments.

Open Door Forum Participation Instructions:  
Dial: 1-800-837-1935 Reference Conference ID#: 21452777.

Note: TTY Communications Relay Services are available for the Hearing Impaired. For TTY services dial 7-1-1 or 1-800-855-2880. A Relay Communications Assistant will help.

An audio recording and transcript of this Open Door Forum will be posted to the Open Door Forum website: [http://www.cms.gov/OpenDoorForums/05\\_ODF\\_SpecialODF.asp](http://www.cms.gov/OpenDoorForums/05_ODF_SpecialODF.asp) and will be accessible for downloading beginning on or around December 10, 2010 and will be available for 30 days.

For automatic emails of Open Door Forum schedule updates (E-Mailing list subscriptions) and to view Frequently Asked Questions please visit our website at <http://www.cms.gov/opendoorforums> .

Thank you for your interest in CMS Open Door Forums.

Audio file for this transcript  
<http://media.cms.hhs.gov/audio/Survey&CertificationtransplantProgramODF111010pdf.mp3>

**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**Moderator: Barbara Cebuhar  
November 10, 2010  
1:00 p.m. CT**

Operator: Good afternoon. My name is (Sarah), and I will be your conference operator today.

At this time, I would like to welcome everyone to the Special Open-Door Forum on Survey and Certification with a Focus on Transplant Quality Assurance Program.

All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer session. If you would like to ask a question during this time, simply press star then the number one on your telephone keypad. And if you would like to withdraw your question, press the pound key. Thank you. Ms. Barbara Cebuhar, you may begin your conference.

Barbara Cebuhar: Good afternoon, everyone. We're thrilled that you could join us today.

My name is Barbara Cebuhar, and I work in the office of External Affairs here at CMS. I will be assisting my colleagues in the CMS survey and certification group by moderating this call.

The purpose of the call is to increase provider awareness and understanding of the quality assessment and performance improvement program regulations and the tools that the surveyors may be using to review the quality of transplant programs while onsite.

This program – this forum also provides CMS with the opportunity to engage and listen to the needs and concerns of the transplant providers. Our hope

today is to provide an overview of the quality assessment and performance improvement worksheet and resource guide which will be used by transplant surveyors that defines CMS' expectations of transplant quality assessment and improvement program and to give you an opportunity to ask questions specific to the program.

We anticipate spending about 60 minutes going over the survey tools which were included as part of the agenda. And just in case you need them, I will go ahead and give you the website address where they're located. So, it's [www.cms.hhs.gov/opendoorforum/o5\\_odf\\_specialodf.afp](http://www.cms.hhs.gov/opendoorforum/o5_odf_specialodf.afp). Let me repeat that again so that if you're online and want to have it in front of you while we're talking about them, that would be great. It's [www.cms.hhs.gov/opendoorforum/o5\\_odf\\_specialodf.afp](http://www.cms.hhs.gov/opendoorforum/o5_odf_specialodf.afp).

We will have about 30 minutes for your questions and concerns that you'd like to raise with CMS. I know that many of you may have questions or other issues that we won't be able to get to today. Please know that you can write us at [transplant@cms.hhs.gov](mailto:transplant@cms.hhs.gov) to let us know how these issues stand to affect you and your organization.

It's time to get started on our program. I'd like to introduce (Karen Tritz) who's the technical director of the Division of Continuing Care Providers of the CMS' Survey and Certification Group who will introduce the other speakers who are online ready to provide insights into this process and the importance of this new tool. (Karen), you want to go ahead?

(Karen Tritz): Yes. Thank you very much, Barbara. Thank you very much, everyone, for taking the time today out of your busy schedules to talk with us today about the quality assessment performance improvement process at – within transplant programs and the new surveyor tools that we drafted to help in that process.

Just to give you a little bit of background on the call today, we're going to – Thomas Hamilton has joined us. He's the director of the Survey and Certification Group. And he's going to provide a few opening remarks.

And then we'll talk a bit about the rationale for the tool and the process that we went through to develop it. And then we're going to walk through the tool itself and provide examples and a description of what would be looked at in the tool and then talk a little bit about the surveyor decision-making process as it relates to anything they might gather through the tool. And then we'll open it up for questions and comments that you may have.

So, with that, let me just say that Dianne Smith, my colleague here at the Survey and Certification Group has been working with us closely or with me closely on developing this and researching it. And she's also going to be sharing in the presentation for this afternoon. But let me turn it over to Thomas for opening remarks.

Thomas Hamilton: Good afternoon, everyone. (Karen), I'm just delighted that we're having this open-door forum because it not only gives us the opportunity to share our thinking so far with people, but more importantly an opportunity for us to hear back and to gain the insights from people who are engaged in the transplant programs every single day so that we can improve the tool.

As everyone knows, CMS spells out in the regulations a variety of conditions of participation that basically identify public expectations for quality and safety in the transplant arena as well as acceptable ranges of outcomes.

One of the most important of these requirements, I think, is the quality assurance and performance improvement requirement that our colleagues in the Office of Clinical Standards and Quality have had the foresight and have put a tremendous amount of work over the years to craft and ensure that, increasingly, this particular provision shows up not just with hospitals, not just with transplant centers, but as a standard operating principle that would apply to every major provider so that in some of the more recent regulations that the office of Clinical Standards and Quality has developed for hospices, for home health agencies, for dialysis facilities, for ambulatory surgical centers, for example.

You will see an identical or slightly modified version of the QAPI requirement. And it's an important requirement because it's an expectation

that we have that every organization has the infrastructure and the capability within the organization to regularly monitor program performance and to stream performance information back to the administrators, to management and everyone who is in a position to act on the feedback that they receive so as to engage in continuous quality improvement and to the extent that there are problems that are surfacing to act on that information in a timely and effective way to make systemic improvements.

If you look at our regulations, there are a number of aspects that stand out. For example, we expect that every organization have the capability to inventory, to track and to monitor any adverse events and to analyze those adverse events and then to use that analysis to make program improvements.

So, when the surveyors are onsite, for example, you could expect that the surveyors would ask to see your system for making sure the adverse events are reported in an effective and timely way, that they are analyzed and that that information is used.

Secondly, the regulations oblige programs to have a regular system of quality indicators that are tracked over time that are used for quality improvement, particularly measures that address high-risk areas or problem-prone areas.

Thirdly, the regulations require that the organizations have a performance improvement project system in which the organization has identified areas that would benefit from improvement and have structured processes and projects to effect that improvement over time.

Fourthly, that the organization use all of these activities, the adverse events investigations or quality indicator tracking the performance of improvement projects for the purpose of making systemic improvements that will prevent recurrence of problems and that will improve overall outcomes in the long term.

And lastly, the requirements oblige the governing body to set safety expectations to ensure that the QAPI analysis results are used and the QAPI program is resourced.

Now, you may notice in the regulations themselves pertaining to the QAPI requirement at 42 CFR 482.96 that you may not see the governing body expectations expressed in that section of the regulations. The reason for that is that they are expressed in the overall hospital expectations.

There's a larger set of expectations for QAPI in the overall hospital. You can find that at 42 CFR 482.21. And the hospital regulations overall require that the hospital itself have a QAPI program that is manifest in every department, that is agency-wide, that is data-driven and that the governing body ensure that the QAPI system is resourced and in effect.

This is an important observation, I think, because it does mean that if a transplant program does not have an effectively functioning QAPI program or is not resourced and we found numerous instances in which there was no QAPI program that can redound to the hospital at large.

So, the absence of QAPI program, for example, places the transplant center in a risk position for potential Medicare termination of participation. But then they also put the overall hospital at risk as well because it is a responsibility of the governing body of the hospital to ensure that the system is in place for QAPI and is working effectively.

So, we know that transplant programs operate within a larger context of the overall hospital. And I think it's important to make that observation because there is a connection directly to the governing body of the hospital.

(Karen) and Dianne and others here have worked very hard on developing together with the consultant group, Catapult, the materials to get us started in doing a better job of providing direction to the surveyors.

And the first purpose, of course, is to make sure that we're asking the right questions. But the second purpose is to ensure that we have as much consistency between survey teams as possible. Equally important is the third purpose, and that is to ensure that we have full transparency in terms of how we were thinking about things. We make all of our information available on our website, both in the state operations manual, which is the manual that we use to provide direction to the state survey agencies with whom we have

contractual relationships, or for our own consultants that are doing the surveys directly.

And, lastly, I'll mention another purpose is that while this could be a tool for surveyors, it could also, we hope, be an effective risk management tool for administrators and others. I would make a distinction between this surveyor tool that we're trying to develop which is designed for the purpose of someone coming in and analyzing how well the QAPI program is established and functioning. That's one purpose that is quite different than the function of developing a QAPI program from the ground up.

So this is not and cannot be a technical assistance tool to describe how one would go about developing a QAPI program that does not exist. That's a much more involved endeavor. This is a tool designed to go in and look at a program that's established and say, "All right, let's – let's give it a once over and try to see if the essential components are in place and if it's functioning well." Both are important, but at this point we're concentrating just on the surveyor tool.

We hope at a later time that we can organize some forums in which we can promote sharing of information among transplant centers with regard to the lessons that they've learned in developing QAPI programs and to offer that kind of technical assistance in a more organized way. But that's further down the road.

So, those are few opening remarks. And I would just conclude the opening remarks by saying that I hope you all appreciate this as a draft. We're putting it out there for people to get some experience with right now, but it is not a set of final directions to surveyors. It's not a final tool because we really want your feedback and we know that there's more work that we need to do on the tool itself.

So, with that, I'll turn it over to the folks who are doing the heavy lifting here.

(Karen Tritz): Great. Thank you very much, Thomas. Let me spend a few minutes talking about the background in developing the tool just to give everyone a context for how we sort of came up with the tool and a little bit about the development

and the input that we've had in it thus far. The rationale, the need for the tool and the resource guide came from – as you know, we've been doing surveys for the last three years, give or take, and it is – it has been one of the more commonly cited deficiencies in terms of having it – not having a QAPI program at all or not having a fully functional or well-developed QAPI program.

Upon review of the deficiencies that we were finding and in talking to surveyors, it was clear to the team that we needed to increase overall understanding of QAPI. We needed to more formally capture some of the information that's outlined in the regulation in terms of the core functions of the QAPI, to provide some definitions for what we mean by a comprehensive QAPI and what we mean by thorough analysis of adverse events, all within the context of the regulatory requirements.

So we started with the development – we started with the regulatory language and identified the core functions that are outlined in that regulatory language and then went from there to further flush out those areas and try and identify questions and tables that would help surveyors and assist them in gathering information. We understand that the tool is directed at surveyors, as Thomas had mentioned. It was developed for somebody coming in, but we also recognized that this is something that programs also may find useful, which is why we're having the call today.

We developed an initial draft of the tool and had some wonderful volunteer transplant programs that were willing to let us come and test out the tool in their program. There were three hospitals that were willing to host us for a day. And the transplant team went there, and, with each visit, were able to refine the information that we collected. It started with a much – first initial round with a much more expansive, extensive kind of a tool. And the visits to the hospitals helped us sort of focus it down to the core elements that we thought would be particularly important when assessing for this Condition. So we sincerely appreciate the work that the three hospitals went to host us for this endeavor.

And we then sent it out to a technical panel at transplant programs, many of whom are running their QAPI programs, to ask for their feedback and what, you know – what their thoughts were, what their comments were, what areas would you have questions about, that sort of thing. And that also greatly contributed to our overall understanding of the different issues that are coming up in these various areas.

We do want this to be a fully transparent process, that's why we're having the call, that's why all the materials are available and that's why we went through the process that we did in trying to ensure that, as much as possible, we can ground this in the reality of the day to day work that you all are doing.

As (Thomas) mentioned, it is set in the overall context of the hospital's QAPI. And there are a couple of areas of the tool that are focused on that. It also is organ-specific. So, as you know, the Conditions of Participation apply to all organ types that are being reviewed for Medicare approval and have Medicare approval now. This doesn't mean that there has to be an individual (QAPI) coordinator for each organ, but it does mean that the surveyors would be reviewing the tool in the context of how it addresses each organ that the transplant program does that is under Medicare's approval and have to meet the minimum Medicare quality requirements.

Let me say that it's not our intention with this Condition or with any other Condition really to be prescriptive about the specific measures, the specific policies, the specific process. And the intention is to create a tool that measures the minimum core requirements. But it is not intended to be a road map or to be all-inclusive of the areas that you might want to look at in your QAPI program as it relates to quality issues that come up in your program.

So I'll stop there as a background and turn it over to my colleague, (Dianne Smith), who's going to start talking with us about the nuts and bolts of the tool itself.

(Dianne Smith): Thanks, (Karen). You folks have two documents hopefully available to you. We're not going to go through and read it to you, either one of them, and we're not going to do a training. What we'd rather do is walk through the worksheet

and tell you what it's about and where it came from and why it's there, remembering that this is a surveyor tool rather than a provider tool, and just mention the resource guide once we get into the worksheet. So, if I say a page number – I've noticed in looking around the table that all the page numbers are different, which probably is accounted for by 508 compliance changing the format for us.

So, if I mention a page number and it's not exactly your page number, you just have to hunt a little bit to find the right place. But let's start with the worksheet. Of course, you have the general program information, that's a given. We start with policies and procedures on the worksheet. And you need to understand that just because of that policies and procedures are first on the worksheet, it does not mean that we're telling the surveyors that the first thing they have to do is run into a QAPI transplant program and read the policies and procedures.

They may in fact want to do that, but they don't have to. This worksheet does not dictate the format or the way a transplant surveyor will act. Rather, it gives them the content they need to be aware of, look for, ask for and read about. Policies and procedures are detailed here. And they're detailed according to what the regulations require, which makes pretty much common sense. However, don't fall into the trap as the provider in thinking that this is the only thing.

If you go by what's here on the worksheet, you check it off and say, "Oh, good, we have all our policies and procedures." That's not necessarily true because we expect policies and procedures – and you need policies and procedures for yourself – that are unique to your program, unique to your needs. They need to be dynamic in that they need to describe how your QAPI program works, who does it, when you do it, how you do it, and why you do it.

Policies and procedures provide all of us with a foundation to assure that your transplant program can be sustainable and consistent and operate with best practices. So, these are to just check off items that you'll see for the surveyor to ask about, look for and to read. Part two of your worksheet is the part that

forces us as surveyors and you as providers to not just have a paper process. It's saying that we want to know as surveyors how you communicate with other people about QAPI, not other people just in the transplant arena and your close colleagues and neighbors, but also the people in the hospital, other people in general.

The transplant QAPI program communicates with the hospitals' QAPI program and how did that happen. So we have the evaluation and monitoring section in part two. It's two questions, two points for the surveyor to use, but it's extremely important to know that your QAPI transplant program includes decision-makers and people with programmatic expertise that can guide the QAPI program to reflect the kinds of services that will end up providing quality for your beneficiaries, for your patient.

Part three starts the meat of the program and what drives I think a lot of people a little bit around the bend when we start talking about objective measures. Again, as (Karen) mentioned, we're not prescriptive. We're not going to tell you what those objective measures should be, but rather we're going to give you some guidelines by virtue of this worksheet. We're also going to provide a little more definition to some words that you'll find in the regulations.

To go back a minute, you'll note on your worksheet that we have instructions that are boxed in and we have regulations that are boxed, and the regulations are in italics. The two regulations that are – we're going to define and further discuss are the regulation (X099) found on page one of your picture book. And the words are “comprehensive” and “data driven.” Those are two words that we want to talk about when we're discussing objective measures.

The other regulation is (X100), which is on page two. And it says that the transplant QAPIs program's objective measures have to deal with transplant activities as well as transplant outcomes. So, if you look at the chart, which I suppose appear to be somewhat overwhelming at first glance but broken down aren't that scary, you'll see that we have pre-transplant, transplant, and post transplant listed there under the transplant activities for process. In fact, the definition for comprehensive as we are defining it means that you need

objective – you need objective measures in the area of pre-transplant services, transplant services, and post-transplant services. That's a piece of the definition for comprehensive.

The other piece of it is on the next page which talks about living donors. In order to have a comprehensive QAPI transplant program, you must have objective measures in the area for each organ in the area of pre-transplant, transplant, and post transplant for both recipient and living donors. Living donors, historically, using our previous information that we got from the surveys that (Karen) mentioned seemed to be left out in the cold so to speak.

So we understand that some of this information is going to be new information for you, but we encourage you not to run out. And just because you now know that you have to have objective measures and living donors, don't just jot down something just in order to meet the compliance of the survey process. But rather take time with your QAPI committee and QAPI – and your transplant staff to think about what's important to measure, where are the places that you get hung up or that get in the way of providing the quality that you want to living donors and for living donors and develop your objective measures around that kind of thought process rather than just trying to make up one that will get you through the survey process.

So, you see the chart that the surveyors have to fill out. You'll also see process and outcomes, the activity's process and outcomes. And that are – those we're expecting each of you in your QAPI program to have objectives that reflect process and objectives that reflect outcomes. And this is where the resource guide jumps in and maybe helpful to you because the resource guide has examples and has explanations of some of the points that you'll see in the worksheet. And even though I'm saying to go there and to look at that after this open-door forum, I'm not saying to you to use the resource guide as a way to develop and implement transplant QAPI program.

The resource guide is written for surveyors. It's written to complement the worksheet, to expand horizons and to give people a foundation about what they might see or hear or read about when they're out doing a survey. I think it would be useful for transplant programs to go through the resource guide. It

will give you some of the phrases, some information that you can then further research. But understand that it really is a surveyor tool to help them use the worksheet that we're going over more consistently between different hospitals.

So, you have on page three, a chart and you have on page four, a chart. And those charts will – we're asking the surveyors to fill out per organ. And if you've read the instructions, which are not necessarily saying you should have before this, but if you read the instructions for surveyors that you'll find on this worksheet, it says that they're supposed to report one example in, let's say, their looking at a QAPI program for livers, they'll need to have one process objective measure for pre-transplant that had to do with livers, one that has to do with transplant, and one that has to do for post transplant.

That does not mean – and listen very carefully to this – that does not mean that we're saying providers only have to have one objective measure per organ per area. We are expecting you to have at least one, but what we're expecting is that you will have the number that you need to effectively measure whether you're doing a good job in providing services around liver transplant. So remember that. Even you old folks that have memory lapses, remember it's not saying that we're telling you, you only have to have one. We're telling you that we're telling the surveyors we just want one example.

Below each one of the charts, under your recipient chart as well as your living donor chart, you will see some questions under a topic called summary. If you remember in the regulation (WO100), it talked about data driven. Data driven means that you have benchmarks – you know, what's your goal, where you are going, what do you want to do? And we don't give you benchmarks. Now, your (SRTR) data may in fact have some interesting benchmarks you might want to use, but where the CMS is depending upon you folks and your expertise and your knowledge of your own program to determine your own benchmarks through whatever sources appropriate.

It might be research. It could be best practices. It could be past experiences and the good old (SRTR) data that's out there. It could be the people in the field that have the expertise in that area. And it could be something that right now you pull, sounds reasonable to the group, everybody agrees with it and

you work towards it and you figure out not to swell and you change it. But we're not dictating benchmarks, but we certainly expect that your objective measures will have benchmarks.

We're expecting that you maintain data on your objective measures and that you track and trend that data. We're not expecting that you just put little marks on a piece of paper and say, "Yay, we've done it. We're collecting that data." We want you to use the data, and it's expected that you will use the data, to make projections, make changes and to guide the continuation of your services.

You'll see that we direct the surveyors to check to make sure there are benchmarks. Are there – is there a missing data? When we give questions to surveyors that they need to check out, we expect them to check it out through one of three methods – observations, interviews, record reviews. And we expect that they use information from more than one source or typically use information from more than one source so that if they see a blank spot, let's say, on a dashboard and a data is missing, we expect them to go out and find out why is there data missing. The point in fact is it may be a very justifiable reason and, therefore, would not lead the surveyor to be thinking about citing a deficient practice.

We're expecting to see there is a consistency with the QAPI program written, whether it's in the dashboard, whether it's in policies and procedures, regardless of where it is from what they see. For example, we did see a dashboard that recorded that there had been two deaths and we've heard that there had been three and we – and the surveyor, any surveyor that would want to cross that situation, would be required to figure out what's going on, which one is right and where the breakdown was.

So that's probably the fastest you'll ever hear me go through anything. But we wanted to make sure that we allow for questions. So, (Karen) is going to start of page five with performance improvement activities.

(Karen Tritz): Great. Thanks very much, (Dianne).

The performance improvement activities are grounded in the regulation that says that the transplant center must take actions that result in performance improvement and track performance to ensure that improvements are sustained. And we've essentially broken it down into two charts that are for the surveyors to look at. The first of which would be the transplant program's activities, actions that are initiated.

So it may – it would include those areas that the program identified they've decided they wanted to – they were looking at the data in a particular area for example and decided that a different patient selection process was needed and so they were going to be making those kinds of changes and, you know, look at the issue, what was needed and would be implementing those sorts of changes. Those kinds of activities would fall along the first chart.

And let me just walk through. This is intended to help the surveyors and others analyze a particular issue in a consistent way using certain kinds of questions that I'll talk through – you know, what was the issue that was identified, what was the change that was identified, was that tracked, how was it brought to light, was it – was the issue analyzed? Was there a corrective action that was implemented? And then, because we know that not all of these changes happen over night, where there any negative outcomes from delays?

And this is essentially going to be a judgment call. I mean we're – we know that some of these activities take time, but if there is an identified quality problem that has not been addressed for two or three years, then surveyors may look at that and say the program really isn't taking action on this. We want to have the surveyors confirm that the corrective action is fully implemented. So that means not only that it was decided at a particular meeting that now we're going to do it this way, but that the full implementation happens, that the policies and procedures were changed to reflect that, that there was staff training on the new process.

And this is not intended to be a – an all encompassing list of the potential corrective actions that may occur. It could be, for example, that a piece of equipment was taken out and will now be – you'll be using a different piece of

equipment. So, that may be the corrective action. This is just intended to identify those that are more commonly used in terms of corrective actions.

And then, subsequently, is that improvement being tracked? Is there, you know, nine months after or six months after a policy has been changed? Does the program have any – does the program know whether or not that improvement is sustained over time? And then is there any evidence that the improvement was not sustained? So if it is a particular piece of equipment for example, is there any evidence that – that's back in – that old piece is in circulation and that it never got fully implemented throughout. So that's the thought process that the surveyors would go through and the kinds of questions that they would be asking for the kinds of evidence that they would be asking for in looking through the performance improvement actions.

And we realize that not all of this may be documented in one place. It may not be in a nice, neat little chart. And we understand that. And surveyors understand that. And in all areas, we – the training is – and most surveyors know this and do this, and we would encourage you to provide this – that there will need to be some sort of evidence, but that evidence can take many forms. And so we would encourage you to think about that in terms of how, you know – how can we show that a particular improvement action overtime and these – at these areas were met.

The second area, the second chart, this looks very similar, except that it looks at surveyor identified problems or resolution of known problems or recommendations that came from adverse events. So that's where part five, which we're going to talk about in the second related to adverse event, rolls back into part four. So, it would be expected that in looking at an adverse event that as I've said that we needed to re-do our evaluation process up front or we needed to change our post-transplant process or our (inaudible) process in relationship to a specific adverse event, but that the surveyor could use that as an example to walk through the analysis of is the program taking action that results in performance improvement based on known issues that have identified and unidentified quality problem.

And that may come from the (SRTR) data, any kinds of adverse events substantiated complaints so that, for example, if the program is out of compliance with Medicare related to the outcome threshold, if there are outcome performance issues, that is a known problem – performance issue that we would expect there would be an analysis of, that there would be actions to identify what may be going on there and that there would be activities taken to address whatever is the core issue may be there.

So, that is essentially the process that surveyors would be looking at through the performance improvement action section of the worksheet. So let's turn, finally, to the adverse events section. I'm going to talk about that a bit. The first is the policies and procedures. It is expected that there are written policies that address and document adverse event that occur during organ transplantation cases. The hospitals adverse event policy may be complementary to that, but it is expected that there is a specific adverse event policy for transplant, and particularly because there are specific reporting requirements and other things that are specific to transplant that would not be in a hospital adverse event policy, such as reporting a certain disease transmission activities to or disease transmission to the (OPO) for example.

So there needs to be a specific written policy that would address and document adverse events that occur during any phase of organ transplantation. And the questions under part five address what would be expected or what kinds of issues would be – or topics would generally be covered in an adverse event policy. The second part of that is the transplant center must conduct a thorough analysis and document any adverse events and then must utilize that analysis to affect changes. And so the last part of that, utilizing the analysis to affect changes, is the portion we already talked on a bit. And that's that linkage between the analysis that occurs and the performance improvement actions.

So let's talk a little bit about what we mean by a thorough analysis. We would expect that there would be primary root causes, any contributing factor in potential areas to prevent repeat incidences. That would – that's sort of the broad brush look at what the adverse event analysis showed. And, specifically, we want – we outlined, you know, if there's not a chronology of

the event or if there's not an interview, its key staff were left out, or not discussed interviews with the patient if that's applicable, relevant – any relevant policies and procedures and any variation that occurred from that, any contextual factors related to the environment.

For those of you who have - and any – and then, finally, any common factors for the same or similar events. Is this the first time this even occurred? Are there any other incidences that are linked to this? Many – there are many different models of identifying all of the analysis of adverse events. I can tell you that this is an area I think that's of critical importance. And as you know, the transplant process, what happens at the front end in terms of the evaluation and the screening and the wait list management and all those sorts of things can – are critical for identifying issues and factors that can lead to adverse events in the backend.

And so, as you know, it's a continuum and with many interrelated phases and areas in a long period of time with a particular transplant patient. And so that's the kind of – looking at that in a broad systems based way – is critical for doing a thorough analysis of adverse events. And that's something that we're trying to emphasize with the surveyors that any variation of the process or – is just critical.

We'd want to ensure that the – that somebody that has the authority to make decisions about the transplant program participate if this analysis is intended to affect changes in the program, then folks with the decision authority need to be involved in that process, and that's what the surveyors will be looking for. And then are there recommendations or action steps that resulted from the analysis? And, if not, is there a sound rationale for making changes?

And that's – those are the kinds of questions that surveyors would be looking at. It may not be that every adverse event leads to, you know, complete systems overhaul. And we understand that, but I think there needs to be – that that would need to be something that would need to be walked through with the surveyor. So, I wanted to – so that is essentially it in terms of the worksheet.

I want to spend a couple of minutes talking about the decision-making guidelines that we included also with the worksheet. The decision-making guidelines talk through sort of threshold for surveyors to consider when there are certain – when the information tool revealed certain kinds of missing information or certain incomplete information. We want to emphasize that these are general guidelines for surveyors. Ultimately, all decisions by surveyors are made by, you know, at the team level based on the findings that they have when they are on site.

We do not want to – this is not intended to be the last word on the level of deficiency, and there are other conditions that are being reviewed and other factors that may go in to surveyor decision-making related to the level of deficiencies. So, it is intended to be a guide, but it is not intended to be the final word on this.

(Dianne), is there anything else that you wanted to add? Anyone else before we open it up for questions? OK. So that – this – that concludes sort of the walk through of the tool and our thinking around that. And additional information about how we're looking at certain sections of the regulation, I'm going to – let me just say a little bit about the questions and answers section. What we'd like to do is primarily use this time to address any questions that you may have about the tool and about the information that we prevented and get your comments on it as well. As Thomas mentioned, this is, you know – that will be particularly valuable for us.

If there are other questions related to any part of the survey certification process, we're happy to take those as well. We also have some resources from our other components at CMS to address any other areas that may come up. But as I mentioned we like to try and focus our time – our limited time on the material that we just covered. And as Barbara mentioned, feel free to send us – if we don't get your questions, feel free to send us an email to the mail box that Barbara mentioned, which is [transplant@cms.hhs.gov](mailto:transplant@cms.hhs.gov).

So, with that, I'll turn in over to Barbara to start the Q&A portion.

Barbara Cebuhar: Thank you. (Sarah), do you want to help everybody get into the queue please?

Operator: At this time, I would like to remind everyone, in order to ask a question, please press star then the number one on your telephone keypad. And we'll pause for just a moment to compile the Q&A roster.

And your first question comes from the line of (May Knott) from the University of Illinois Medical Center.

Your line is open.

(May Nocht): I have a quick question on the processes on the tools – surgical protocols. What would the surveyor be looking for surgical protocols?

(Karen Tritz): That – I mean that would be certainly up to the program to decide what they wanted in terms of what – or what they felt was important in terms of surgical protocols. What we've seen for example is programs that decide to administer a certain drug immediately pre-operatively for because they found it's related to the post transplant outcome. And so those would be the kinds of things that could fall under that surgical protocol category.

(May Nocht): I see. The other one, I had – the last question is just related to pretty much the same tool. Is health maintenance on the wait list for the living donors? Are we – are you looking for whether or not the living donors have a primary care physician seen regular, receive primary care services or?

(Karen Tritz): Again, it would be whatever (inaudible).

(May Nocht): Is there anything in particular that the surveyors would be looking for?

(Karen Tritz): Right. Again, it would be whatever the program believed is the most important related to the issues that they've identified with living donors. It may be things related to, you know, checkups, or how – you know, how many living donors are meeting the recommendations that are followed or that there are prescribed prior to their final acceptance as a living donor. So, we'd really – it's an area that – a general category from a pre-donation phase that we're looking at. But we really are not prescript – and those are just examples, and you may actually have better examples than we do, but really is intended to be

quite broad for the programs to be able to determine what is going to be most useful for them.

(May Nocht): Will you be looking at the correlation between whatever that we pick for that particular indicator and its relation to the patient outcome? Or it's just the data that you're looking at us gathering? In other words, do we need to show the link between what we choose as our indicator in the patient outcome?

(Karen Tritz): It would be good for the program to have a – to be able to describe why it picked a certain measure that it did, or what, why they – what the rationale was or why they felt it was an important measure. We are not going to be asking for every measure and any kind of a formal analysis of how that relates to patient outcomes. Certainly, if the analysis of the patient outcomes show particular quality problem, the tracking of the correction of those quality problems would be part of the overall process. But we're not looking for a kind of laundry list of the objective measures.

But for your own purposes, it would be helpful to know why you're picking certain measures that you're picking.

(May Nocht): OK. Thank you.

Operator: And your next question comes from the line of David Hill from Hartford Hospital. Your line is open.

David Hill: All right. Thank you very much. I have a question about adverse events. Many adverse events are looked at through peer review in the hospital or root cause analysis from the peer review. Is this – this information could be harmful in a way if negligence was found or something of that sort, how are the hospitals and the physicians and staff protected against CMS audits under the peer review system?

(Karen Tritz): Let me take a stab – and Thomas may want to weigh as well on this – the peer – the surveyors do have access to information that is collected under an adverse event analysis process, including peer review that we do – we have instructed surveyors that this information is sensitive and that there – care should be taken. We do not essentially want surveyors to go out and make

copies and take copies with them of all of the analyses that are done under that system.

It is however open to surveyors to be able to assess whether or not there is an effectively functioning system to be able to thoroughly analyze those adverse events. And so if there's a problem found, as you know, as you may be aware, surveyors generally copy the source information that are used for deficiencies so that there is a firm evidence that they have the evidence that they used to make a particular finding. So there may be issues that come up there, but surveyors do have access to it. We do guide them that this is sensitive information. But the core function for the surveyor is to access whether or not there's an effectively functioning system in place to address these issues.

Thomas, did you want to say anything else about that?

Thomas Hamilton: Yes. And, (David), this is a very important question and I'm glad you asked it. We do need to do some more work in this arena, including work in which we self-circumscribe ourselves because in a very good, as you all know I'm sure, a good process, you want to have a very frank discussion internally in your organization about all the problems and you don't want to have the chilling effect that – that, you know, having all of that information publicly available would convey.

So we need to make sure that in the survey process, we are safeguarding the QAPI process in the hospitals and making sure that things aren't going into the public domain at the same time that we're able to get enough information to judge the adequacy of, say, a root cause analysis. And we've generated over the past three years quite a bit of experience in which we found hospitals that have done an excellent job (inaudible) root cause analysis.

In other instances in which the hospitals said, "Yes, we did it," we did peer review, for example, and as we delved more deeply, it turns out that peer review process itself was inadequate. So a hospital may have looked in the case of surgical competence, for example, they may have looked at the outcomes by surgeons, but what they may not have done is compare the observed against the expected by surgeon and discovered that there were great

differences and cause for concern when the latter analysis was done but not the former.

So, that's a concrete example of the differences that you might see in a root cause analysis. Somehow, we need to make sure that if you think about the feedback, the survey process as a form of feedback, we need to make sure that that feedback system is, indeed, operative while safeguarding the hospital's process.

So, we would invite your thoughts on this. And we will definitely be doing quite a bit more work to try to strike the appropriate balance between these two objectives.

David Hill: Well, I am very supportive of the QAPI process. I think it's a great idea and I think it makes us all better. But if the CMS review is able to be subpoenaed in a court of law, I think very quickly this information will get through the transplant community and it will circumvent what we are trying to do. People are going to be willing to open themselves up and really get to the nitty-gritty of it. And so I would ask if there is ability for CMS legally to be as tight at the peer review processes in the hospital?

Thomas Hamilton: I appreciate those thoughts. And we will, of course, be engaged with the professional societies such as the American Society of Transplant Surgeons in further developments of this. But I think you well expressed the concern.

David Hill: OK. Thank you.

Operator: And your next question comes from the line of Gwen Menott from Memorial Hospital in Illinois.

And your line is open.

Gwen Menott: Hello. Thanks. I really appreciate having this opportunity to have this call. And I really think that this QA process will – and the survey will really help and improve transplant care. I do have a question though about the provision that there has to be a process of the outcome measure for donors, pre-donations events and post, and the same with – in particular – well, that whole

provision. I think that it – in some cases, particularly, pre-donation or even pre-donation with kidneys, you're asking for an outcome when really the care of that patient or the – who's going to control the outcome, you know, the health-related outcome is really not in the transplant center's domain.

For example, the example that was given is a donor losing weight, that's not the transplant center's purview to be supervising weight loss for donors. That's really the donor and their physician. Now, I mean, really what your goal is or the outcome you're looking for in donation is that if the donor comes out as healthy as they went in, that you did good screening and you had informed consent. Those seem like – those are all kind of more events in post donation. So, I am just throwing it out there. I'm not sure that all three of those phases having outcome measurements necessarily fit.

(Karen Tritz): OK. I think that's the – you raised an important issue. And I think it's one of the areas in our discussions with some of the transplant programs that we're looking at, that were helping us in the development of this. It's an area that has also come up. And so I think we'll take that comment back and do some more discussion about it. We want to make sure that there's a balance in that the living donors are getting the – that they're not getting short-tripped in the process because they do play such an important role. But I hear what you are saying and I think it's something we'll have to take back and do some more discussion about.

Gwen Menott: Well, I think that may apply – I mean, applies to – well, even like even (depth) on the wait list. That isn't really necessarily your function. It's a function of your OPO and what organs are available to you. I mean, I think – I think what we could all do and what we should probably do is we can have a patient-related outcome. And maybe that's what we want to push for as more evaluation of the patient understanding the informed consent or patient satisfaction. But these biochemical, biophysical outcomes for patients that you're not taking care of don't necessarily fit, I don't think.

(Karen Tritz): Well, I think on the mortality on the wait list I think that's been a – we've seen that as an indicator of potentially the updating of the clinical information process and the review of whether a person continue to be a good transplant

candidate. And so I think that's the one where we have seen program quality as measure as that's an important flag for programs to take a look at what is the pre-transplant process with wait list candidates.

Gwen Menott: Sure. Sure.

(Karen Tritz): I think – but – and in terms of, you know, sort of quality literature overall – and I don't want to get too theoretical here – but, you know, the process is something that's very concrete with the program. Did we provide informed consent? Is the form filled out? Was the dialysis facility notified? In the quality sort of arena, outcomes can get at those areas that are a bit more complex, a bit more – a bit harder to understand in terms of the overall system, what might be going on, and may lead to processes that you didn't necessarily have on the radar before.

Gwen Menott: Sure.

(Karen Tritz): And so that's why we felt that it was important to have both of those kinds of indicators measured in this process.

Thomas Hamilton: And I think it's important to stress that we're not saying which measures or exactly which processes to look at and to have measures. I think it's the challenge for transplant programs to look at their outcomes and try to identify where there are significant issues, maybe not problems that are caused by the transplant center's own actions, but ones that might be solvable or addressable by other actors if there was a better arrangement between, say, the community physicians or the community hospitals and the transplant hospitals.

You know, for example, we encountered one situation in which a number of people died from fungal infections post transplant and the transplant program was very concerned because they had written instructions, "Don't go near construction sites," and a variety of things of that nature. And as they looked at it more closely, they discovered that maybe there were things that they could do by way of better educating the transplant recipients and their families about the importance of adhering to those instructions. But people had gotten those instructions in a paper form buried with a lot of other forms, but they didn't really appreciate the importance of the guidance.

So, again, that's an example of something that's outside the immediate control of the transplant program, but maybe influenced by the transplant program's own actions.

Barbara Cebuhar: Sure. It's a great example. Is there a next question?

Operator: Your next question comes from the line of (Maria Ness) from the Children's Hospital in Pennsylvania.

Your line is open.

(Maria Ness): Hello. My question is pertaining to new programs seeking initial certification. Specifically, how far into the implementation phase of the QAPI would be sufficient for CMS? In other words, if we've – we're just at the phase of collecting baseline information and we have a comprehensive data-driven QAPI program and yet we haven't gotten to the step of analyzing data, would that still be sufficient?

(Karen Tritz): If you have a QAPI program in place, if you've got meeting minutes for as long as the program has been in operation that you can show, if you've got the policies and procedures, both on the QAPI side of things as well as the – any potential adverse events that you kind of thought through that process, you've got the measures identified that are potentially important – perhaps, you contacted other transplant programs to help identify what areas have been coming up, there maybe from your experience, you know, if you weren't previously Medicare-certified before but you've been in operation – all of those would be the surveyors would look at.

I don't – I don't want to say that surveyors are going to require a year's worth of tracking data and, you know, full-on analysis and graphs. I think that's not realistic. But it is expected that you can show the surveyors that you've got the infrastructure in place so that if something happens tomorrow, everything would be a go and there wouldn't be delays and – because you don't have the system in place.

(Maria Ness): Thank you very much. And this tool – if you're looking for comments of the tool, we still have the tools. Actually, it's very helpful for us in sort of enhancing the plans that we already have in place.

(Karen Tritz): Good.

(Maria Ness): I actually have one follow-up question pertaining to live donors and the live donor QAPI. Coming from a pediatric center where our live donor transplants are actually predominately done at the – an affiliated adult center, would we be responsible as the pediatric program for the live donor QAPI measures or would that be the responsibility of the center that actually performs the live donor surgery and (inaudible)?

(Karen Tritz): The way that we're looking at that is that it is essentially a – you're essentially getting it via arrangement or via contract with the adult program. The live donor organ is being used at your hospital. And so just as in the other – in the hospital QAPI, it's expected that your QAPI program would incorporate any services that are under contractor arrangements. So that would be – you would need to have a process in place to review the quality of the living donor services and organs that you're getting for the children in your hospital.

(Maria Ness): OK. Thank you very much.

Operator: And your next question comes from the line of (Katie Everest) from Cincinnati Children's Hospital.

Your line is open.

(Katie Everest): Hi. Thanks for the opportunity. I have one question for (Karen) and one for Thomas.

(Karen), it was mentioned several times at the beginning, I mean, throughout the call that these documents that we're reviewing today are draft documents. I was wondering if you could help us understand what the process will be to vet the documents again after feedback and what the process will be as far timeline goes to post those?

And then, Thomas, my question for you is will transplant programs be surveyed on the quantity performance metrics as a separate site survey or will that be obviously included in our first site survey? But since they'll be released separately, what's the certification process or survey process for this portion of the regulation?

(Karen Tritz): So, the process is that this tool is – it is a draft tool. This is a tool that follows the regulations and helps surveyors to gather information and organize the information in a way that we hope they have been doing and to help formalize that process. So, surveyors are using this tool now. We do want feedback on that and on the tool. And you can certainly send that to the mailbox if you don't get a chance to provide it today.

We are – it will probably be a couple of month's process at least until we get any other revisions out on this because of the process to review and that sort of thing as well. So, it's a – it is under revision, but it is also something that surveyors are using and maybe using, you know, tomorrow to gather and organize the information related to QAPI.

Thomas Hamilton: And right now, of course, the QAPI requirement is in regulation for the past three years. Surveyors have been surveying on that regulation. And if the surveyors make a citation, it is always on the basis of the regulation not on the guidance. So, you won't see a citation that says, "Well, on the worksheet, question 3B was a no." It was – it's really harkening back right to the regulation itself. That's the authoritative basis for any citation.

What's been happening so far in the surveys is, of course, that we've had training in our training with the surveyors. And what hasn't happened is for this more elaborative process with the greater transparency that we're trying to effect right now and the greater involvement that we'd like from the entire transplant community. So, we will be sending out formal letters to some of the major organizations to formally invite their inputs to this document. We wanted a lead off with this off open-door forum to just get the word out to a lot of people at once and then we'll be taking that information back.

We will be communicating to folks subsequently when we're coming out with the final document. The final document, they're always published online in two forms – one, we issue a survey and certification letter to the surveyors and you can go to the CMS websites and look at all of the survey and certification letters that we issue that contain clarifications or guidance for surveyors, and then that material is incorporated into the state operations manual which is always online as well.

There is sometimes a little bit of a time lag between when we issue the survey and cert letter with the guidance and when it gets incorporated in the online state operations manual. But that's the public process. In terms of the surveys themselves where we have been training the individual surveyors in about a half of the states, our contract with the state public health department are the vehicles by which the transplant programs have been surveyed. In the other half of the states, typically, the smaller states, we have a contract with HMS and they've been doing the contracts directly at our direction.

And so they'll continue to do that. You know, in the future, we have looked at the possibility of more specialization particularly for the QAPI requirement. It is a little bit more of a systems orientation, a little bit more complex, but, presently, we haven't made that decision.

(Karen Tritz): I would also just add in terms of a public release of any survey and cert letter or the operations manual that, as we've been doing since the beginning of its process, when we have a transplant survey and cert letter, we routinely send it out to all of the transplant administrators so that you don't feel like – I mean you can go obviously and check the website if you want regularly, so that you feel like you have to add it to your weekly to-dos as well because we ensured that we have your up-to-date contact information for the transplant administrator. And as we got some new ones for this process as well, we will send that out via email as well.

Thomas Hamilton: Weekly trolling of the CMS website (inaudible).

(Karen Tritz): Right, because there is nothing else to do.

(Katie Everest): We tend to that anyway, Thomas. We enjoy seeing your postings and information. So, thanks for the opportunity to participate.

Thomas Hamilton: Yes. You're very diplomatic.

Barbara Cebuhar: We have time for one more question, Sarah.

Operator: And your last question comes from the line of (Helen De Jardin) from the University Hospital in Newark, New Jersey.

And your line is open.

(Helen De Jardin): Thank you. Hi. We have a question on whether the surveyor would look at the psychosocial evaluation on transplant care.

(Karen Tritz): Just to clarify, the question is what they would be looking at...

(Helen De Jardin): Yes.

(Karen Tritz): ...in the psychosocial evaluation?

(Helen De Jardin): Yes.

(Karen Tritz): Well, first, they would they would take a look at who did the psychosocial evaluation and is that consistent with the policies that the program has or who's they're determining as qualified to do that psychosocial evaluations? They would want to ensure that it was done prior to placement on the waiting list. And then they would look at it to review for any issues that were identified and that's needing additional follow up or referral and then would review the other components of the medical record to ensure that any of those additional – additional follow up actually did occur and that it was consistent with the program's selection criteria prior to placement for placement on the waiting list if that person was ultimately listed.

(Helen De Jardin): All right. Thank you. I just have one more question. Very quick question, in terms of collecting the data, are there any mandates with regard to whether the documentation is paper or electronic?

(Karen Tritz): No. We don't have any requirements in that regard.

(Helen De Jardin): And just a related item, we keep our data on an ongoing basis from the very beginning. We just add each month. Would that be acceptable or do we need to show evidence that – of a report during a particular month? I mean, can we just...

(Karen Tritz): We don't specify a time period. I would – I am not sure I understand exactly how you're tracking it, but I think it would be important to be able to look at any trends over time so that if, for example, there is an infection rate, you would be able to easily identify changes to infection rates over time – spikes, those kinds of things – to be able to follow up on any issues that were identified through that.

Barbara Cebuhar: Many thanks to all of you for joining us for the call. I just want to make sure that people do know that in case we didn't get to your question today, you can feel free to send them to [transplant@cms.hhs.gov](mailto:transplant@cms.hhs.gov). And we do welcome your feedback and do appreciate your time today. Thank you again. And if our other callers couldn't wait to go offline, I'd appreciate it.

Thank you.

Operator: And that concludes today's conference call. You may now disconnect.

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