**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**Moderator: Barbara Cebuhar**
**May 4, 2011**
**1:00 p.m. ET**

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

At this time I would like to welcome everyone to the ESRD Quality Measurement Listening session. All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a comments session. If you would like to make a comment at this time, simply press star then the number one on your telephone keypad. If you would like to withdraw your comment, please press the pound key.

Thank you

Miss Barbara Cebuhar, you may begin your conference.

Barbara Cebuhar: Thank you, (Alicia).

Good afternoon. My name is Barbara Cebuhar and I work in the Office of Public Engagement here at the Centers for Medicare and Medicaid Services. I just want folks to know that I'm not an expert on ESRD or quality measurements but have been asked by my colleagues in the Office of Clinical Standards and Quality to help moderate this session in order to get maximum input from the industry and advocates about the best way to measure quality in the end stage renal disease community.

Through this listening session, CMS is seeking to learn what metrics stakeholders in the ESRD community have used to drive meaningful

improvements in patient care. Areas for consideration include but are not limited to anemia, mineral metabolism, and patient experiences with care or satisfaction.

Your thoughts and insights about measures will be considered as part of our effort to further our public reporting program. Because CMS is in the process of rule making for the Quality Incentive Program, we will be unable to answer questions during this listening session.

And I really would appreciate it if folks could try and keep their comments to about two minutes when we – when we open the line for comments. Our operator will instruct you how to access the queue so you can get in line to provide some feedback after I read each question.

Know that a transcript and a recording of this call will be available in approximately two weeks at the following address:www.cms.hhs.gov/center/quality.asp so you can read and listen to the various thoughts offered during the call later.

I'm going to go ahead and start with the first question, of the quality measures that you are currently using in your setting, which measures have been effective in driving quality improvement?

(Alicia), could you please instruct our listeners how they can participate by answering this question again, please?

Operator: Absolutely.

In order to make your comment, you may press star then the number one on your telephone keypad.

We'll pause for just a moment.

And we have a comment from the line of Mahesh Krishnan from DaVita.

Your line is open.

Mahesh Krishnan: Hi. Dr. Mahesh Krishnan, I'm the Vice President for Clinical Research for DaVita. We actually have our – a composite quality metric that we use ourselves called the DaVita Quality Index, and we have been very successful in using that with a number of different measures. Some of the principles that we've used are focused – focusing in on a very small set of measures and specifically focusing in on high value measures.

For example, our current priorities are catheter reduction, and so measures such as vascular access measures, (bone and mineral measures), such as a phosphorous measure have all been very important to us in terms of efficacy in driving clinical improvements year after year.

Barbara Cebuhar: Thank you very much.

And we would really appreciate if folks could get their comments to us. We – I will give you at the end of the call – two email addresses where you can get your comments if you'd like to submit them in writing. That would be very helpful.

Our next question, please, (Alicia)?

Operator: Our next comment comes from the line of Raymond Hakim with Fresenius Medical.

Your line is open.

Raymond Hakim: Hi, Barbara:

We have also – this is Ray Hakim, the Chief Medical Officer for Fresenius Medical Care, and we had also, some time ago, analyzed the measures that we felt made the most significant impact on patient outcome. And by that I mean hospitalizations as well as mortality. And we have narrowed those to five measures that I wanted to share with you to – that you may want to consider. The most important of the two is catheter reduction, as Dr. Mahesh also mentioned.

What we find is that catheter reduction is – has a major impact on outcomes of patients and is also, as you may know, consistent with the drive by the CDC (NHHS) in terms of reducing blood stream also. So of all the ones that we focus on, that's the most important one.

But the other one that we focus on is also the level of nutrition in these patients as determined as reflected by albumin levels. We find that to be also a very important measure in determining outcomes of patients. And the higher the albumin and meeting the (kdoqi) guidelines really makes a significant impact or a significant improvement in the patient's hospitalization and reduction in mortality.

The other three that we focus on relate to phosphorus, relate to anemia measurements and so these are the ones that we focus on.

Barbara Cebuhar: Thank you very much, Dr. Hakim.

Our next comment, please.

Operator: Our next comment comes from the line of Kathy Lester with Kidney Care Partners.

Your line is open.

Kathy Lester: Thank you.

Hi. I'm Kathy Lester, council to Kidney Care Partners, and as you may know, we're an umbrella organization, a coalition of a variety of stakeholders, providers, patients, physicians, other health care professionals, including nurses and patient advocates and manufacturers. What we have been working on for several years is looking at quality measures. And so my comments are really an amalgamation of the members of KCP and their experiences.

We've found that measures that are actionable, meaning those measures that a dialysis facility or provider can actually impact and direct action leads to a change in outcome are the most helpful and the most meaningful. And in that bucket, we too have looked at having unlimited number of measures that

allow the facility folks to target on those specific measures and really make changes.

In that regard, I would echo the comments of Mahesh and Ray that vascular access measures (fistula first catheter last) measures are of overwhelming importance and you can see through the fistula first program as well hasn't resulted in important changes in outcomes. Phosphorus measures are also measures that our members think are very important as well as the NQF CDC related infection measure.

So various dialysis facilities have used these measures and, you know, we would hope that in terms of spelling them out and thinking about moving forward that there would be a dialogue with the community in terms of drilling down into the specifications for measures in these domains.

Barbara Cebuhar: Thank you, Miss Lester.

Our next comment, please.

Operator: We have no further comments at this time.

Barbara Cebuhar: OK. Great. We'll go on to our next question.

And I know a number of you have already indicated answers to this but, which measures do you feel are meaningful for public reporting? Which measures do you feel are meaningful for public reporting?

(Alicia), if you could instruct people how to get in the queue again, I appreciate it.

Operator: Absolutely.

Again, in order to make your comments, you may press star then the number one on your telephone keypad. We have a comment from the line of (Doug Johnson) with (Dialysis Incorporated).

Your line is open.

(Doug Johnson): Hi, this is (Doug Johnson). I actually was slow hitting star one for the first question, so I apologize for being late. I just wanted to comment in support of the use of albumin or nutritional status as a quality marker. I know one of the concerns that some providers have had is that that is a difficult – that is a difficult marker that is – it is a marker that's difficult to change.

We recently started a nutritional supplement program within our company giving nutritional supplement to our patients with an albumin less than 3.5, and we have been effective – from the preliminary data, it does look like we've been effective at being able to increase the albumin for those patients.

Barbara Cebuhar: Thank you, Mr. (Johnson).

Our next comment, please.

Operator: Our next comment comes from the line of Kathy Lester with Kidney Care Partners.

Your line is open.

Kathy Lester: Hello, again. KCP has long supported reporting measures before they are implemented into a QIP. And I think the current QIP measures have kind of followed that practice, and I think that as we've seen with (Crown Web), it's important to get that reporting period to align data specifications to make sure that the reporting mechanisms work et cetera.

And so of the three measures that I just referenced in 1A, I think it's important to start a reporting phase for the serum phosphorous measure, for example, serum phosphorous greater than six, would be a public reported measure and to look at obtaining the sufficient data as to how it actually affects outcomes before you would add that to a QIP.

Similarly, we would want a reporting period around the (NQF endorsed) in section measure before moving forward in a QIP. And I just say here too, we thought about, you know, on the claims form currently V8 and V9 modifiers – they're not well defined at this point, so we would actually say that those should not be part of a public reporting or a QIP program. Rather, use the

(NQF endorsed) measure at this point, public reporting to get it right and then eventually phase that into a QIP.

Barbara Cebuhar: Thank you, Miss Lester.

Our next comment, please.

Operator: Our next comment comes from the line of Raymond Hakim with Fresenius Medical.

Your line is open.

Raymond Hakim: Hi, Barbara.

I think the one that we think is the most important in some of the public reporting is the percent of patients who are (dialyzed) with a catheter because that is something that we feel is modifiable. And I just wanted to add one comment here that clearly, improvements in the catheter rates depends on many factors, but the one that, at the moment, is the focus of many of the networks and (inaudible) is at the dialysis units.

And we think it ought to be broadened to include not only the referring physician but also the surgeons who are doing some of these procedures because a reduction of catheters and improvements in the catheter rates requires the collaboration of all of these things – of all of these entities. So clearly, the catheter rate would be one measure. The other one that I mentioned earlier and you know, the anemia levels in these patients, how many of them are between the goals that CMS has set between 10 to 12 hemoglobin can (inaudible) and also on the phosphorous side.

As well as we feel that the goals of aiming to publish data on the percentage of patients with albumin of four or greater, which is defined by the (kdoqi) guidelines as a measure of adequate nutrition, should potentially be also part of public reporting.

But I do also want to support Kathy Lester's comment that between public reporting and QIP measures there should be a lot of thought and – before we

can make this a punitive or a performance that, you know, has financial implications, because these are things that will take time and are not easily achievable. So I'm in support of public reporting but I would reserve my comments for QIP measures for later on.

Barbara Cebuhar: Thank you, Dr. Hakim.

Our next comment, please.

Operator: Our next comment comes from the line of Klemens Meyer with (Forum or) ESRD Network.

Your line is open.

Klemens Meyer: Thank you. I think that the (forum) would agree with everything that has been said so far. I do want to make the point with respect to public reporting that the way CMS set out to report mortality on dialysis facility compare (originally) was the – was the correct way that is reporting it as significantly greater than or less than one and not reporting absolute values.

And I think that that (inaudible) – it's unfortunate that that decision has been changed and I hope that when further measures are considered that this issue will be opened again because otherwise people will find themselves chasing non-significant differences and that will just distract people's energy.

Thank you.

Barbara Cebuhar: Thank you for your comment.

Our next comment, please.

Operator: Our next comment comes from the line of Mahesh Krishnan with DaVita.

Your line is open.

Mahesh Krishnan: Thank you.

I think many of my (inaudible) (have actually been) addressed and the one I think that I'd just like to put emphasis on is the standardized hospitalization ratio, which was briefly commented on before. One of the biggest problems that we see with the standardized hospitalization ratio is the methodology used to calculate the expected hospitalization rate, same for mortality rate – has not necessarily been validated by an external group unlike standardized hospitalization ratio, which is used in your hospital program – I think was validated by (Krumholtz recently) in a published article.

We would – we would ask that if that were to be included that that maybe included potentially even just for reporting if included at all but the (methological) issues need to be addressed and need to be validated before that measure can be used as it's currently stated.

Barbara Cebuhar: Thank you.

Our next comment, please.

Operator: Our next comment comes from the line of (Roberta Mikles) with (Advocates for Quality).

Your line is open.

(Roberta Mikles): Yes, this is (Roberta Mikles) in San Diego. I represent Advocates for Quality Safe Care. We're a patient advocacy group made up of mostly patients and families who have experienced retaliation in facilities for speaking out to ensure safe care.

We fully support public reporting and support that which the others – participants have mentioned, and also we support public reporting in the fact that we believe CMS on the dialysis facility compares site, (inaudible) posts the surveys that are conducted by the state because these truly show the day to day care that is provided.

We also support reporting of infection data only when the data is truly valid data and has been obtained in a method which would be effective for patients so that they can make informed choices.

Thank you.

Barbara Cebuhar: Thank you, Miss (Mikles).

Our next comment, please.

Operator: Our next comment comes from the line of Rich Berkowitz with NxStage Users.

Your line is open.

Rich Berkowitz: Hi. The original intent of the dialysis program, when it was first enacted was for there to be as much home dialysis and especially rehabilitation, so people can go back to work. I think that this has been a complete failure on the part of the dialysis service providers community. And some of the things that I think that we need to be looking at, and this is reported by the networks in their consolidated annual report, is the number of people who are working, the number of people who are going to school, the number of people who have gone back to work due to rehabilitation, and a very important figure is the number of centers, which are open after 5:00 pm which allow the people to work.

The biological markers are fine but they don't necessarily answer the quality of life issues that patients need to live with. And so therefore I think we need to start emphasizing other things besides just biological markers.

Barbara Cebuhar: Thank you, Mr. Berkowitz.

Our next comment please.

Operator: Our next comment comes from the line of (Roberta Mikles) with (Advocates for Quality).

Your line is open.

(Roberta Mikles): Yes. I would like to just support what Rich Berkowitz just stated. I have worked with patients from all over the United States who have wanted to go

back to work to be rehabilitated and because their schedule – at the dialysis unit was unable to work with their schedule, they missed out not only on job interviews but actually many have lost their job because of the schedule. So I fully support what Mr. Berkowitz has said.

Thank you.

Barbara Cebuhar: Thank you.

Our next comment, please

Operator: We have no further comments at this time.

(Barbara Cebuhar): OK. Great.

Our next question is, which measures do you feel are meaningful for inclusion in the ESRD Quality Incentive program?

(Alicia), if you could instruct people how to get into the queue again, I appreciate it.

Operator: Absolutely.

In order to make your comment, you may press star then the number one on your telephone keypad.

We'll pause for just a moment to compile the roster.

And our first comment comes from the line of Jennifer Russell with American Kidney Fund.

Your line is open.

Jennifer Russell: Thank you.

I think one of the things to consider in terms of quality incentive program would be measures that would focus on patient satisfaction as well as patient education. I think there's a lot of issues that – in terms of outcome – that are based on proper education. And certainly when we see that there is benefits

being offered to patients via the (inaudible) kidney disease education benefit and some of the other self care benefits that are available, perhaps there should be some sort of quality measure that would be tied then to patient education so that they can take better care of themselves and improve self care and ultimately improve their outcomes..

Barbara Cebuhar: Thank you for your comment.

Our next one, please.

Operator: Our next comment comes from the line of Rich Berkowitz with NxStage Users.

Your line is open.

Rich Berkowitz: I'm here again. One more thing that I think needs to be in basically included in the ESRD Quality Incentive program are the number of patients which each dialysis center has doing home dialysis, meaning (peritoneal) and home (inaudible) dialysis especially after the frequent (inaudible) which just came out which showed that more frequent dialysis is definitely a better dialysis than the standard conventional (hemo) dialysis, which is three days a week four hours a day.

I think we need to get to longer and more frequent dialysis, and I think that people who are looking for these types of therapies need to know which dialysis centers are providing them.

Barbara Cebuhar: Thank you, Mr. Berkowitz.

Our next comment, please.

Operator: Our next comment comes from the line of Dolph Chianchiano with National Kidney Foundation.

Your line is open.

Dolph Chianchiano: Hi, Barbara. This is Dolph Chianchiano for the National Kidney Foundation. As the final rule for the quality incentive program specifies, there

are many reasons for the QIP but one of the reasons why the agency has developed this program is to overcome any potential unintended consequences that might arise from bundled payment for dialysis. And along that line, there probably should be some consideration for measures that have – that relate to an upper limit for phosphorous and also the question of iron overload in a bundled payment system.

Thank you.

Barbara Cebuhar: Thank you, Dolph.

Our next comment, please.

Operator: Our next comment comes from the line of Kathy Lester with Kidney Care Partners.

Your line is open.

Kathy Lester: Thank you.

I usually – we make a strong distinction between public reporting and QIP and so in terms of the specific measures that we think should be added on the QIP side at this point, would be a fistula catheter related measure or measures to address the issue of vascular access in the program. And you know, we also are very strong supporters of the phosphorous and infection measure that we discussed earlier, but again think they need to be tested through a reporting system first.

Just to comment on two other pieces that were mentioned, we have been supportive of anemia management measures that almost goes without saying, and through the Kidney Care Quality Alliance, the KCP members and broader members of the health community actually submitted (inaudible) patient satisfaction measures.

Again, we think that that type of a measure would need to go through reporting first, but it is obviously important and something that should be examined but probably not quite ready for inclusion in the QIP at this time.

Barbara Cebuhar: Thank you, Miss Lester.

Our next comment, please.

Operator: Our next comment comes from the line of Raymond Hakim with Fresenius Medical.

Your line is open.

Raymond Hakim: Thanks.

Barbara, I wanted to make a comment related to the concept of the QIP in itself. It's as you know, the QIP stands for Quality Incentive Program but effectively it is a withhold on the payments, so there is no incentives in that sense. It's only penalty. And what I'm hoping is that CMS, as it develops more QIP measures, considers the possibility of redistributing whatever they withhold from facilities that don't meet the criteria to ones that meet or exceed the criteria. That's the only fair way in which I believe the QIP measures can be effectively implemented.

Thank…

Barbara Cebuhar: Thank you, Dr. Hakim.

Our next comment, please.

Operator: Our next comment comes from the line of Donna Painter with American Nephrology.

Your line is open.

Donna Painter: Yes. Well, one thing that the nurses have noted is we do know that the burden of all this reporting many times does fall to the nursing staff, and so one of the things we would like to be considered is that the future QIP include some nurse sensitive measures. Because we know that there's several that are already out there that are for general nursing and can – and very much apply to nephrology, and we believe that there's an opportunity to use some of those.

Barbara Cebuhar: Thank you, Miss Painter.

Our next comment, please.

Operator: Our next comment comes from the line of (Roberta Mikles) with (Advocates for Quality).

Your line is open.

(Roberta Mikles: Yes. I'd like to add on to what Jennifer mentioned about the patient satisfaction surveys. It has been our organization's experience that we feel the patient surveys should be revised and the process that accompanies such also, so that the patients can feel free to address real concerns. Right now (process) as it is, we don't believe is effective, and we also support that which Miss Painter just stated fully.

Barbara Cebuhar: Thank you, Miss (Mikles).

Our next comment, please.

Operator: Our next comment comes from the line of (Hajim Goshin) with (Dialysis Clinic).

Your line is open.

(Hajim Goshin): Hi, this is (Hajim Goshin) with (Dialysis Patient Citizens) and I think as far as the QIP goes – I think from our perspective, one of the most things is to ensure that the data that's provided is timely. You know, using outdated data could reduce the impact, not only of patient outcomes but also minimize any improvements in patient quality of life.

And you know, as a result, we want to ensure that, you know, CMS prioritizes reducing any of the time lags and while we generally support (NQF) you know, proposals so far, we also do believe that for example, measure 1427 (adult) dialysis patients the phosphorous proposal should also be included as well.

Barbara Cebuhar: Thank you, very much.

Our next comment, please.

Operator: Our next comment comes from the line of Rich Berkowitz with NxStage Users.

Your line is open.

Rich Berkowitz: (Inaudible) there are two measures for anemia, both a lower measure and an upper limit measure. Previously there have been some issues with – because (epogen) had been a profit center and now with (bundling it) as a cost center, so we're experiencing people using less and less (epogen) rather than more. So I don't think there should be two measures for anemia. I think we should get rid of the upper limit and just keep the lower limit, if we're going to be keeping biological markers.

Barbara Cebuhar: Thank you very much for your comment.

Our next one, please.

Operator: Our next comment comes from the line of Dr. John Stivellman with Northwestern Kidney Center.

Your line is open.

John Stivellman: Thank you.

I just wanted to underscore a point that has been alluded to by several previous speakers, but in the construction of QIP accountability, that the issue needs to be actionable at the facility or through the provider. In some instances, that may become quite complicated because many of the potential measures – for example a catheter reduction, require accountability beyond the facility. That is not to say that that should not be a critical item. Perhaps the – perhaps the accountable party may need to be broadened as Dr. Hakim alluded to, but I think one of the most critical – one of the most critical issues is evolving intelligent QIP measures is that they are in fact actionable.

Thank you.

Barbara Cebuhar: Thank you for your comment.

Our next one, please.

Operator: Our next comment comes from the line of Mahesh Krishnan of DaVita.

Your line is open.

Mahesh Krishnan: Thank you.

Just to add to what everyone else is saying, one thing that hasn't (been) touched on yet and is the adequacy measure. Obviously (bars) are currently on the claim forms as are (Kt/Vs) now. (Kt/V) would be a preferred (inaudible) (once all the bugs and definitions are worked out).

I mean and secondly I think it's been stated before but I'll say it again, we – the CDC (BSI) measure as submitted and endorsed by the (NQF) – but a lot of us are sort of thinking about and doing in various states but has significant superiority over the current (loosely defined) V8, V9 infection measure that's currently on the claims form.

Barbara Cebuhar: Thank you very much, Dr. Krishnan.

Our next comment, please.

Operator: We have no further comments at this time.

Barbara Cebuhar: OK. Great.

I am going to revisit question number one and rephrase it slightly so that we can focus on what's working for you all. Which quality measure or metrics have been effective at driving quality improvement within your organization or do you think will drive quality improvements to help achieve better patient outcomes.

(Alicia), if you could instruct people how to get into the queue, I appreciate.

Operator: Absolutely.

Again, if you would like to make a comment, you may press star then the number one on your telephone keypad.

Our first comment comes from the line of Klemens Meyer with (Forum) ESRD Network.

Your line is open.

Klemens Meyer: Vaccination rates are one obvious measure that's already being cracked and I think should be – deserves more attention.

Thank you.

Barbara Cebuhar: Thank you.

Our next comment.

Operator: Again, if you would like to make a comment, you may press star then the number one on your telephone keypad.

Our next comment comes from the line of Kathy Lester from Kidney Care Partners.

Your line is open.

Kathy Lester: Hi, and I – I'm not sure that my answer changes but just to be clear I think that we think that the measures – in the experience of our members that have been effective in driving quality are vascular access related measures, catheter reduction, increase in fistulas, it's our first measure would be very important on a going forward basis to track quality as would the (inaudible) endorsed infection measure.

Barbara Cebuhar: Thank you.

Our next comment, please.

Operator: Our next comment comes from the line of Mahesh Krishnan with DaVita.

Your line is open.

Mahesh Krishnan: I think, specifically (mirroring) what Ray Hakim said on this response to this, earlier – vascular access definitely we've seen significant relationships between that metric and outcomes, immunization as I think Klemens mentioned, also the same. Our vaccination rates are really driven by that. And then anemia adequacy and the bone and mineral parameters, specifically phosphorous, I think are all good markers which reflect a merging of this sphere of influence and this sphere of responsibility of the dialysis provider as John Stivellman said earlier.

Barbara Cebuhar: Thank you very much, Dr. Krishnan.

Our next comment, please.

Operator: We have no further comments at this time.

Barbara Cebuhar: OK.

The next question is do your measures meet the National Quality Forum Endorsement criteria or have they been endorsed?

(Alicia), if you could instruct people how to get into the queue, I appreciate it.

Operator: Absolutely.

Again, in order to make your comment, you may press star then the number one on your telephone keypad.

We'll pause for just a moment to compile the queue.

Again, in order to make your comment, you may press star then the number one on your telephone keypad.

We have no questions – pardon me we have a question from the line of Kathy Lester from Kidney Care Partners.

Your line is open.

Kathy Lester: Hi. I mean I think that of the three measures our members have identified, obviously the infection measure that (NQF) endorsed has gone through that process. There are vascular access measures that (NQF) has endorsed as well. I think the measure that the (NQF) is working on (in) phosphorous now is something that we are looking at but obviously (NQF) endorsement, we believe is an important component of moving measures forward.

Barbara Cebuhar: Thank you.

Our next comment.

Operator: Our next comment comes from the line of Rich Berkowitz with NxStage Users.

Rich Berkowitz: Hi.

Operator: Your line is open.

(Rich Berkowitz): The fact that not many people responded to this question, I think possibly indicates that we're on the wrong road per say. And I think we need to be looking at other markers. The other thing is that we have to remember that currently we're only looking at two percent (withhold). The more quality measures there are, the less the penalty per quality measure and they become even more ineffective.

Barbara Cebuhar: Thank you, Mr. Berkowitz.

Do we have another comment?

Operator: We have no other comments at this time.

Barbara Cebuhar: OK. We're moving pretty quickly here, so I appreciate everybody's help

What is the quality of the evidence linking your measures to patient outcomes?

If you could instruct people how to get into the queue, that would be helpful, (Alicia).

Operator: Absolutely.

Again, in order to make your comment, you may press star then the number one on your telephone keypad.

We have a comment comes from the line of Raymond Hakim with Fresenius Medical.

Your line is open.

Raymond Hakim: Hey, Barbara, what we have done in the past is constantly analyze our data in terms of patient outcomes and lab outcomes and that's how we narrowed it down to about five measures that make – that we felt have the greatest relationship between the outcomes and – the lab outcomes and the patient outcomes. And as I mentioned earlier these were how we ended up with the five measures that I mentioned, anemia measure, catheter measures, phosphorous measures, albumin as a measure of nutrition and the dose of dialysis. And I wanted to add also that what Dr. Meyer has mentioned that vaccination is also one of those measures.

So what we have done is to look back at the data and analyze it and see what correlates with patient outcomes both in terms of hospitalization and mortality and then proposed these five measures. Subsequently we have then gone forward and said, OK if we make changes to these measures somehow, do we make a difference in the patient's outcome and consistently, we have been able to show again through (inaudible) journal publications that making improvements in those measures do make a difference in the patient outcomes.

So I think we have both prospective and retrospective measures, and that's how we arrived at – the retrospective ones allows us to come up with hypothesis and then the prospective ones allow us then to ascertain that the hypothesis is correct.

So, thank you.

Barbara Cebuhar: Thank you, Dr. Hakim.

Do we have another comment?

Operator: We do. We have a comment comes from the line of Cherilyn Cepriano with the Kidney Care Council.

Your line is open.

Cherilyn Cepriano: (Good) afternoon.

Excuse the voice. (Inaudible) our members have spoken about we can identify that they're recommended and supported by observational data and data that's aggregated and available to CMS for utilization and so (inaudible) vascular measures, there's data available from (inaudible) program as well as (DOPPS) data and (US RDS) data.

For phosphate measures, we have observational studies that show the relationship between mortality and morbidity in some of the providers (inaudible) their own in those regards as well as (inaudible) data. A for infection measures, we know there's observational data as well as (USRDS) data. So (we do) think that there's a lot of data for us that's available to substantiate the measures that we have discussed and have suggested here today.

Barbara Cebuhar: Thank you.

Our next comment, please.

Operator: Our next comment comes from the line of Kathy Lester with Kidney Care Partners.

Your line is open.

Kathy Lester: Thank you. I would echo what Cherilyn said of the three measures that we have proposed here. The vascular access measure has observational data

through (fistula first the catheter last) program. A lot of observational data around the phosphorous levels and there is a 2007 (Jason) article, which we'll include in our written comments to you that provides support for the measure that we're looking at.

And then in terms of the infection measure that (NQF) has endorsed, there is observational and (DOPPS) data around that, but it has also been validated through the testing process for measures. And I think that last point I would just want to emphasize that in addition looking at the evidence linking the measures to quality, it's important that as you think of measures to report and to incorporate into a QIP program, that you also look into measures that have been validated and are scientifically meaningful. So you are sure that what is being reported is comparable from measure to measure as well and is something that can be collected in the facilities.

Barbara Cebuhar: Thank you, Miss Lester.

Our next comment, please.

Operator: Our next comment comes from the line of Mahesh Krishnan with DaVita.

Your line is open.

Mahesh Krishnan: (Thank you).

I think the only point I want to make in addition to what's already been said is as you probably know or have seen, (inaudible) randomized control trial data within ESRD, the analysis that was done (probably) four or five years ago in JAMA and (Nephrology) (inaudible) have to do with the severity of disease in (inaudible) populations. People are hesitant to subject a fragile population to (people controlled trials).

That being said, we have excelled within the observational data to adjust for (confounding). I would argue that within (Hall's literature) there's been significant strides made in trying to as well (thoughtful) replicate randomized controlled trials and adjust for bias seen in observational data.

And so all the data that was previously cited there is good robust adjustment for confounding, and so we use that as the basis, just as Ray mentioned, in order to determine which of our measures are – have the highest patient impact.

Barbara Cebuhar: Thank you, Dr. Krishnan.

Our next comment, please.

Operator: Our next comment comes from the line of Dr. John Stivellman with Northwest Kidney Center.

Your line is open.

John Stivellman: Thank you

I think both Dr. Hakim and Dr. Krishnan have alluded to a very critical issue in design of guidelines, which relates to the overall quality of knowledge. As the overall sort of sweep of research in the country has increasingly moved toward prospective randomized controlled trials, which at least in the field of nephrology is a famous paper showed a while ago has landed behind many of the other specialties in the country, the concern I have related to his is that so much of our previous guidelines and the standard literature has looked both at anecdotal retrospective and opinion based material, which is problematical in the present climate and going forward.

However, I think that the lack of randomized controlled trials should not be stumbling blocks to trying to put together intelligent benchmarking. It does obligate, though those who are responsible for making guidelines to provide experimental or observational data going forward, which is of the very, very highest quality, and I think going forward, that's a critical concept to the guideline formation, particularly for QIP.

Thank you.

Barbara Cebuhar: Thank you, Dr. Stivellman.

Our next comment, please.

Operator: Our next comment comes from the line of Rich Berkowitz with NxStage Users.

Your line is open.

Rich Berkowitz: I agree that there's been a problem in terms of needing to have randomized studies to prove the validity of many of the things out there. I want to make a point that I think I'm the only actual dialysis patient who has made some comments. And one of the things which, obviously, is very important to a patient is survivability, and even though all of my biological numbers were good during my monthly tests, it didn't stop me from having a heart attack driving home from dialysis and the fact of what kind of issues come up when someone has a dialysis treatment.

So I think we need to look at survivability. And I think we have to look at the modalities which are – can provide the best outcomes. And so we need better comparisons per center on survivability, on mortality and the differences between the different modalities that they offer being in-center hemo-dialysis, peritoneal and home hemo-dialysis.

Thank you.

Barbara Cebuhar: Thank you, Mr. Berkowitz.

Our next comment, please.

Operator: Our next comment comes from the line of (Roberta Mikles) with (Advocates for Quality).

Your line is open.

(Roberta Mikles): Yes. Our organization fully supports that which Rich Berkowitz just stated and personally I support that as a family member of someone who is now deceased but who was on dialysis for six years. We fully support that which he said.

Thank you.

Barbara Cebuhar: Our next comment, please.

Thank you, Miss (Mikles).

Operator: We have no further comments at this time.

(Barbara Cebuhar): OK.

Our next question is, what lessons have you learned from your quality measurement and improvement efforts that maybe useful to CMS as we implement our programs?

Could you instruct people how to get into the queue again, please?

Operator: Absolutely.

In order to make your comment, again, you may press star then the number one on your telephone keypad.

We have a comment from the line of Kathy Lester with Kidney Care Partners.

Your line is open.

Kathy Lester: Thank you.

I wanted to focus on three things very quickly from the survey of our members who are running internal quality programs. The first is I think that it is very important that when you set the benchmarks for the performance standards as well as the performance period, that you do so in a way that is contemporary.

So we've talked about the need for actionable measures but the performance standards, in a same sense, need to be set in a way that people know about them before the performance period begins and that the performance period itself needs to be a time when individuals within the facilities can actually take action. So the performance measure drives behavior.

The current (QIP) is retroactive and so all of the activity has already taken place and the performance standards are based on information and practices that are not necessarily appropriate under today's standards and so that type of a system does not allow you as a provider to really move the curve for improving quality.

We also recognized that CMS has data challenges so I think part of it is working with community so you do have very contemporaneous data and you're judging current quality practices.

The second point is that we really do see that bonus payments or incentive payments or some other type of incentive really works to drive quality. A punishment only system has not worked in our experience. And so you know, along those lines, again, we recognize the challenges CMS faces under the statute but finding ways perhaps to take the dollars that are being removed under the penalty requirement and putting them back in, in some way in an incentive would align the QIP more with the experience of folks within the community and with the experience folks have had with private payers.

And then finally, to – just to touch on – and we've said it before, a limited number of measures really helps focus facility staff and drive quality in those areas. So you know, one of our concerns has been that CMS has submitted a large number of measures to be in (NQF) in this latest round, and we would hope that when you think about expanding the QIP that it is done so in a very limited way so you can keep a target focus by staff.

Barbara Cebuhar: Thank you, Miss Lester.

Our next comment, please.

Operator: Our next comment comes from the line of Raymond Hakim with Fresenius Medical.

Your line is open.

Raymond Hakim: Hi, Barbara.

What I wanted to emphasize to you is one of the major lessons we learned in our improvement process. Is that it really requires the collaboration, not just of the facility staff or the provider staff, but also requires physicians, both nephrologists and surgeons in some cases to impact on this improvement.

I'll give you an example, we have focused on reduction of catheters but in a sense because it makes such a huge impact on patient outcomes, both on survival as well as hospitalization. But to make that impact – to make that improvement, it takes much more than the facility staff to provide the resources for the patient to get to a surgeon and have a successful placement of the permanent access. It requires also that the nephrologists who refer the patients to the facility be conscious of that effort.

As you know from the USRDS data, unfortunately, eighty-two percent of patients starting dialysis in the United States start with a catheter. That is something that is much higher than other countries. And so we need to think of a QIP measure, potentially that not only involves the facility staff but potentially the physicians who are referring the patients to the facility so that they're also engaged in the process of improvement. And in the case of catheter reduction, we also need to have the involvement of the surgical staff who are putting these – who are putting these permanent accesses and make sure that they are successful and have a QIP process for them also.

So my plea to you is that as you develop these measures, think how many people can impact that measure and see how we can involve them into the same process of QIP. And in my estimation, it should be both reward as well as a penalty, not just penalty as it is right now. But get as many other people who can impact those outcomes to be involved in that process.

Thank you.

Barbara Cebuhar: Thank you, Dr. Hakim.

Our next comment, please.

Operator: Our next comment comes from the line of Dr. Mahesh Krishnan with DaVita.

Your line is open

Mahesh Krishnan: (Inaudible).

As I mentioned, we have a composite quality metric that we've been using for over 10 years now and been able to show significant improvements as well as a correlation with morbidity and mortality. I think what has been stated, I'll just restate. Our (inaudible) is one unlimited number of measures is really important and that (those) measures need to be clearly, clearly defined.

When there's ambiguities in the system, people tend to find that and that diminishes the effectiveness of the quality improvement program. Two is ensure that (the) data that's being used, both in terms of the business world, the actual lab test et cetera has been standardized in some way, shape or form or else you're making an oranges to apples comparison.

Three is be very clear in what the goals ought to be in terms of the improvement and communicate that in a timely and redundant fashion in order to allow changes for provider feedback. I think Kathy said that if you have a system which allows continuous input into the system in terms of how someone is doing, that person is more likely (to) change their behavior than if it's just a marathon at the end you – you're completely blind as to how you did until finish – finish line and then you just see if you made it or didn't make it. That we don't really find the process drives improvement as continuous feedback throughout the system.

Barbara Cebuhar: Thank you, Dr. Krishnan.

Our next comment, please.

Operator: Our next comment comes from the line of Dr. John Stivellman with Northwest Kidney Centers.

Your line is open.

John Stivelman: Thank you.

I would like to elaborate slightly on Dr. Krishnan's point – he made – a key issue relating to the standardization of laboratory tests, which I think is a critical issue if we are going to compare apples to apples, particularly on a national scale – particularly issues such as albumin and maybe perhaps to a lesser degree phosphorous.

But more importantly, I think it needs to be clear that if we are comparing, for example, adequacy of results, that the methodologies for obtaining the specimens are standardized in some fashion that – so that there is a sort of a transparent process of obtaining – taking (inaudible) distributions nationally. Because if these are – if this is going to be an issue from the standpoint of quality, the methodologies really need to be synchronized and the formulas for the derivation of the values need to be comparable, as do issues relating to inclusion and non-inclusion of residual function.

So that if these are going to be utilized as quality measures then there needs to be some way that everyone is on the same playing field both with the mechanism for determination in the lab, the methodology by which the lab is drawn and the quantitative basis for the calculation.

Thank you.

Barbara Cebuhar: Thank you, Dr. Stivellman.

Our next comment, please.

Operator: Our next comment comes from the line of Raymond Hakim with Fresenius Medical.

Your line is open.

Raymond Hakim: Yes, Barbara, I want to support what Dr. Stivellman just mentioned and I'll give you a perfect example. As far as I know, CMS does not require that the samples that they – that they – on which the measurement of anemia is done should be done pre-dialysis. So we have had, you know, some concerns that some may be doing it pre-dialysis, some may be doing it post-dialysis, which would make a big difference in the QIP measures.

So I would also encourage CMS to be as detailed as possible in the descriptions of measures and how it should be measured, when it should be measured and so on so that we can have a level playing field and go forward. But at the minimum what I would encourage CMS is to make sure that what ever bio-chemical measures are done, are done pre-dialysis rather than post-dialysis so that everybody is in the current measure even that we have, the anemia and the (URR) is on the same level playing field.

Thank you.

Barbara Cebuhar: Thank you, Dr. Hakim.

Our next comment, please.

Operator: Our next comment comes from the line of Dr. Mahesh Krishnan with DaVita.

Your line is open.

Mahesh Krishnan: Yes. One thing I just neglected to mention in supporting what everyone said is our system has been successful in utilizing a (not a) penalty system but rather the reverse. And so I would just advocate that.

I know that there's certain thoughts around how that should be, but if you ask for our experience, our experience has been that penalties are not as effective as reward.

Barbara Cebuhar: Thank you, Dr. Krishnan.

Our next comment, please.

Operator: Our next comment comes from the line of (Roberta Mikles) with (Advocates for Quality).

Your line is open.

(Roberta Mikles): Yes. I'd like to support the physicians that are speaking to standardization. As a member of a state level legislatively mandated committee here in

California that is focused on public reporting of (HAIs), I cannot stress enough, as a consumer advocate, the importance of having standardization in order for the data to be useful to the consumer. That absolutely has to happen.

Thank you.

Barbara Cebuhar: Thank you, (Roberta).

Our next comment, please.

Operator: Our next comment comes from the line of Dolph Chianchiano with National Kidney Foundation.

Your line is open.

Dolph Chianchiano: Hello again, Barbara.

I just wanted to mention the – although the National Kidney Foundation does not develop performance measures, the Medicare Clinical Performance Measures project was based upon the (kdoqi) guidelines that were promulgated by the National Kidney Foundation. And I think we can learn a lot of lessons from that precedent of the Critical Performance Measures program.

And in particular I probably would echo a lot of the comments we've already heard, that the most valuable performance measures are those that impact directly on patient care and those where the data elements and the measure specifications are clearly defined in advance, and also that the goals are known prior to the performance period so that behaviors can be modified. And finally the need and value of timely feedback is important because that permits opportunities for change.

Thank you.

Barbara Cebuhar: Thank you, Dolph.

Our next comment, please.

Operator: Our next comment comes from the line of Cherilyn Cepriano with the Kidney Care Council.

Your line is open.

Cherilyn Cepriano: Yes. I clearly support a lot of the comments that have been made and want to add that it'll be important for CMS to establish a coordinated process for evaluating the measures that would be included (inaudible) had a lot of discussion about (inaudible). There are also other quality issues (inaudible) about the (inaudible) network initiatives, corporate, (inaudible) initiative such as (inaudible).

And not all of the measures that are in play (inaudible) are harmonized and so when you talk about the ability of providers to actually move numbers to improve (patient qualities), if you have multiple benchmarks going on that are not in agreement with one another, it becomes difficult for providers to know which target to try and reach. (Inaudible).CMS is in an excellent position to try and bring some harmony amongst these (inaudible) players, many of which answer to or are included (inaudible), we think that's an important goal.

Barbara Cebuhar: Thank you, Cherilyn.

Our next comment, please.

Operator: Our next comment comes from the line of Klemens Meyer with (Forum) or ESRD Networks.

Your line is open.

Klemens Meyer: Thank you.

I want to comment about the expansion of measures to include those which will require data entry directly from dialysis facilities such as infection measures. These measures are obviously very important, but one thing that has to be taken into account is the burden on staff involved in setting up the mechanisms for reporting. It's not the data entry itself that's so burdensome,

but the current federal security requirements may require upwards of four hours for a Nurse Manager just to get the software working on a computer.

This is – this was for the CDC's (NHSM) program. There have also, in the past, been proposals for rather burdensome requirements for (Crown Web), although I think those have been modified. This must be taken into account because otherwise the – this valuable time will come out of patient care.

Thank you.

Barbara Cebuhar: Thank you.

Our next comment, please.

Operator: Our next comment comes from the line of Kathy Lester with Kidney Care Partners.

Your line is open.

Kathy Lester: Thank you.

Sorry one last thought here that I had. Our members are obviously a variety of sizes and some facilities care for a large number of patients and some facilities care for a small number of patients. And I think one of the things that all of our facilities have had the challenge of in their own programs is how do you address the problem of small numbers?

Meaning that if you have a few number of patients you're treating and one falls below the performance standard, what actually happens (inaudible) that facility. And there are a variety of answers to that question, but I think it is one thing that we have found to be very critical that you take into account the number of patients being cared for in a facility and adjust the performance evaluation appropriately so you are not inappropriately penalizing a facility that's caring for a small number of patients.

Barbara Cebuhar: Thank you, Miss Lester.

Our next comment, please.

Operator: Our next comment comes from the line of Dr. John Stivellman with Northwest Kidney Centers.

Your line is open.

John Stivellman: Thank you.

I'd just like to elaborate on something that Miss Cepriano says that is very important. In terms of attaining the kind of quality improvements all of us seek from the standpoint is the harmonization of benchmarking and expectation. At the present time, all facilities are obligated to address issues that are raised by their own internal quality indicators, by the networks, by the state in the analysis of the dialysis reports coming from (inaudible), and by the measures assessment tool.

And in fact, these are not the same in many instances. So that the levels of accountability on a variety of disparate standards are going to (militate) against the ability to come up with uniform quality expectations that will move the national agenda ahead, and I would ask that CMS contemplate this further to address either some of the redundancy or discord in the various elements of quality improvement because it will enable facilities to function more effectively.

Thank you.

Barbara Cebuhar: Thank you.

Our next comment, please.

Operator: We have no further comments at this time.

Barbara Cebuhar: I have a final question that I hope everybody can wrap their arms around, do you have any other comments or thoughts that we haven't spoken about that would be useful for the CMS team to consider as they put together their thinking about the – this issue?

Are – if people can indicate that they've got an answer to our question that would be really helpful, so star one.

Operator: We have a comment comes from the line of Rich Berkowitz with NxStage Users.

Your line is open.

Rich Berkowitz: Thank you.

We heard form many medical professionals today and I think CMS needs to get more involved with the patient community itself and try to develop something there in terms of getting input from more patients. It seems that – I would think that renal professionals and patients look at things differently in terms of what quality measures should be and in terms of what outcomes should be. So I think it's really important that CMS get a handle on what the patient community is thinking as well.

Barbara Cebuhar: Thank you, Mr. Berkowitz.

Our next comment, please.

Operator: Our next comment comes from the line of Leslie Wong with Satellite Health Care.

Your line is open.

Leslie Wong: Hi, I'm Leslie Wong, the Vice President for Clinical Affairs at Satellite, and I think what's been absent in our discussion so far from all the participants is talk about home dialysis but specifically about peritoneal dialysis.

We do have some outcome measures in peritoneal dialysis for example, (peritonitis) that we know has a very tangible effect on technique survival, and it really should be used as a quality measure. But I think by and large CMS hasn't really addressed peritoneal dialysis in most of this discussion, so I would just put that forth that, you know, we do have some measures that are not only widely agreed upon but also are substantiated by a broad variety of evidence and evidence based guidelines.

Thank you.

Barbara Cebuhar: Thank you, Dr. Wong.

Our next comment, please.

Operator: Our next comment comes from the line of Dr. Mahesh Krishnan with DaVita.

Your line is open.

Mahesh Krishnan: One other comment that I would raise that probably hasn't been raised here is the process by which future measures are developed and vetted. I think we saw through the (c-tep) and the (d-tep) process culminating into the (inaudible) process that there really needs to be a lot of discussion, at least with the community, around what is practical.

It seemed to me there were a number of measures that were submitted that would have been nice to have but in the end were not practical and probably could have been judged as being impractical earlier on in the process and that stuff created inefficiency. And so I would advocate that we think through for future measures how best to make that process the most efficient as possible, potentially vetting some of these earlier on before they (have) too far down the process and then consume bandwidth and resources to deal with them as we saw by the limited number of measures that NQF endorsed compared to the large number of measures that were submitted to it.

Barbara Cebuhar: Thank you, Dr. Krishnan.

Our next comment, please.

Operator: Our next comment comes from the line of Kathy Lester with Kidney Care Partners.

Your line is open.

Kathy Lester: Thank you.

I think one of the things that Kidney Care Partners has focused on historically and is particularly – would be useful as the QIP matures is using the secretary's existing authority to create an ESRD specific advisory committee. And the idea here is that you would have stakeholders as you do with other advisory committees from the variety of aspects of the kidney care community, so patients, a facility, physicians, nurses, technicians.

You know, it could be a broad swath of the community, and (we) could help address issues that arise such as the criteria used to develop measures to report versus incorporate into the quality program, domains that should be examined, structural questions that arise, data collection issues. And it would just be a resource that the agency could turn to and in terms of experts. Obviously we, you know, wouldn't shut out anyone from participating, but it would be a standing committee that you all could use and that the community could provide assistance to you with.

Barbara Cebuhar: Thank you, Miss Lester.

Our next comment, please.

Operator: Our next comment comes from the line of Raymond Hakim with Fresenius Medical.

Your line is open.

Raymond Hakim: Yes, Barbara, I wanted to second what Kathy Lester has mentioned that it would be very important for CMS to have a advisory board or a working group that they can consult on a regular basis.

But I also wanted to come back to one of the issues that I mentioned earlier, that I believe needs more emphasis, which is that we, for any measures, I hope CMS will keep in mind all the organizations or all the personnel that can impact that measure. So again focusing, for example, on a very important parameter like reduction of catheters should not be the exclusive target of the facility because the facility's ability to impact that measure is much more limited than what physicians, surgeons are able to impact.

So I do hope that CMS will keep those other organizations in mind as it develops these complex but very important measures that really focus on improvement of patient outcomes. So don't just focus on facilities, focus on everybody who can contribute to the improvement if at all possible.

Thank you.

Barbara Cebuhar: Thank you, Dr. Hakim.

Our next comment, please.

Operator: Our next comment comes from the line of Dolph Chianchiano with National Kidney Foundation.

Your line is open.

Dolph Chianchiano: Hi, I'd like to add a little bit to what Dr. Hakim just stated and that is that there are often measures that can be impacted by patient adherence and the role of the patient hasn't been discussed this afternoon, but I think that should be an important factor in looking at certain measures where patient compliance can make a difference.

On a completely different note, I noticed in the final rule for the Quality Incentive Program there was a discussion of the future of the QIP and one of the areas that was mentioned in that discussion was risk adjustment for performance measures and I – the National Kidney Foundation doesn't necessarily have a position on that but one of our concerns with the bundled payment system and with the Quality Incentive Program is that they could lead to cherry picking and therefore difficulties in access to care. And we're wondering whether risk adjusted performance measures might be a way of mitigating that concern.

Thank you.

Barbara Cebuhar: Thank you, Dolph.

Our next comment, please.

Operator: Our next comment comes from the line of (Roberta Mikles) with (Advocates for Quality).

Your line is open.

(Roberta Mikles): Yes, we'd like to support what Dr. Hakim just stated as well as make a comment about Dolph's statement about the role and the patient.

First we believe that CMS needs to be involve – to involve more patient advocacy organizations that have no ties to the dialysis industry, involve patients and their family members who have experienced negative aspects of care in order to fully understand that which happens in (the units).

Additionally in driving and improving quality care, we believe, after the review of surveys conducted by the state as well as dialysis facility reports, along with communicating with patients and families and staff throughout the United States that there needs to be more patient education as this is a major component of patient outcomes. This is stated, we further believe after the review of documents I mentioned, that the facility staff, who have a major impact on outcomes, need to have more education in regards to facility policies and procedures and support in understanding the importance of compliance.

Thank you.

Barbara Cebuhar: Thank you.

Our next comment, please.

Operator: Our next comment comes from the line of Cherilyn Cepriano with the Kidney Care Council.

Your line is open.

Cherilyn Cepriano: One (inaudible) positions about upcoming (inaudible) is we've had discussion here today about the importance of contemporaneous reporting and feedback and to have the benchmark here is – be as close in time to the evaluation period. And so for that CMS would have (within its authority and

upcoming rule making) to change the baseline year for the 2012 (inaudible) to 2009 meaning (inaudible) would be comparing 2010 data to 2009 data as opposed to comparing it to either 2007 or 2008 data, a period for which clinical standards have been evolving and so 2009 would be highly preferable.

Barbara Cebuhar: Thank you.

Our next comment, please.

Operator: We have no further comment at this time.

(Barbara Cebuhar): All right. Great.

We are very grateful for your insights and hope that this session has provided an opportunity to further illustrate what industry and advocates have done thus far to increase the quality of care received by ESRD patients.

Remember that you will be able to review the transcript of this call and listen to the MP3 file by going to www.cms.hhs.gov/center/quality.asp after about two weeks. If you know someone who wasn't able to make the call, they can go and listen to it until midnight on May the 6th. So it'll be available tonight starting at 7 o'clock by calling 800-642-1687 and asking for call #61730269.

You can also provide insights and ideas about measures and insights by forwarding them to Thomas dot Dudley D-U-D-L-E-Y at cms dot hhs dot gov or Renee, that's R-E-N-E-E dot Henry H-E-N-R-Y at cms dot hhs dot gov. And if you could get your comments into us by May the 27th, 2011 by close of business that would be very helpful.

Thank you again for everybody's insights and ideas. We do appreciate your time and your energy and we look forward to talking more soon.

If our speakers could just please hold on, we will move into the speaker's line. Thank you very much. The call is completed.

Operator: And this concludes today's conference call. Participants may disconnect their lines.

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