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LCD Open Meeting: J6 and JK
Moderator: Carolyn Cunningham, M.D.
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Operator: This is Conference #: 9183058.

Operator: Ladies and gentlemen, thank you for standing by and welcome to the NGS J6 and JK Open Meeting Conference Call.

At this time, all participants are in a listening only mode. After the speakers' presentation, there will be a question and answer session. To ask a question during the session, you will need to press star one on your telephone. Please be advised that today's conference is being recorded. If you require any further assistance, please press star zero.

I would now like to hand the conference over to your speaker today, Dr. Carolyn Cunningham, thank you. Please go ahead, madam.

Carolyn Cunningham: Thank you, (Frederica). Welcome everyone. I'm going to turn the meeting over to Dr. (McKinney), and then we'll go on with things later.

Greg McKinney: Good afternoon. Greg McKinney, Chief Medical Officer for NGS. Welcome everyone to our open meeting today, along with our medical directors who most of you probably know. Dr. Ola Awodele, Dr. Carolyn Cunningham, Dr. Mark Duerden, and Dr. Lara Burrows) is our newest CMD, who joined us a few months ago. She is an OB-GYN, and we're just thrilled to have her on board. I think she's a great complement to our already esteemed group of CMDs. And we have the CMDs who join us on the phone, who are not physically present.

I did want to open up with just a few comments, couple of housekeeping items. Phone on mute please. If you are a speaker today, we ask that you use this microphone and stand at this podium. We will drive your slides because it's all one

big slab of slides, and so we will forward your slides, so just say next. We have someone behind the scenes forwarding the slides.

So this allows the greatest autobility, if that's a word, over the phone. And so, hopefully this will work well.

The core of what I want to say is not to belabor the meeting. As you know, last year, we engaged in the new LCD process, development process that was outlined in Chapter 3 of the PIM based on the 21st Century Cures Act.

And for those who aren't aware, that's a very broad sweeping act. So if you have not read that legislation, it's probably affected much of healthcare last year and going forward, in a lot of ways outside of LCD. So there are a lot of things coming out of that act for healthcare purposes.

But it did revise how we conduct our LCDs, that format, very subtle nuances, so subtle I think it confused a lot of people, so we tried to unconfuse that, and hopefully last year was a learning year for us. This will be another year of transparency and openness to the provider, stakeholder community about how we do LCDs, the process we go through to develop an LCD, and invite those comments.

One thing we've done for this year that's a subtle change, we found that our meetings are normally two hours, and depending on the number of draft LCDs, we could have anywhere from none to 30 speakers. And so while we try to maintain that list in a manageable way, it kind of got difficult to kind of gauge. If one policy has 30 speakers, one policy had two, how do we allocate speakers and get fairness and equity to all draft policies.

So what we've started to do this February is what we're going to do for the rest of the year. Again, we're nimble to change, it's not written in stone but this is sort of what we're thinking. Kind of what I think the best model is of now like the government is of today, so it works.

When we have an open meeting, we will send out a notice, it will be on our website, and the policy will be posted there. We will call for request for speakers. So the policies will be posted, so that stakeholders, providers, whoever have an issue with the LCD draft and want to speak, they will have to give us their names so that we

can tally up. For example, we have eight speakers for this policy, five speakers for this policy, so that we can allocate appropriate time.

That's the way CMS does it. We are allowed to limit you. I know that's surprising. I know a lot of you want to talk an hour about something, but we will ration the time based on the number of speakers that we get back.

So we're going to be proactive in getting back to all of the speakers who will speak on a specific policy. There will be a cutoff date for registration to speak, and then we will send back out an e-mail saying, OK, based on the number of speakers, based on our time allotted, you will have five-minute, two-minutes. And we need your presentation before the meeting, OK?

And we can't have surprise speakers that messes everything up. We try to be fair. And come one come all, but we got to know ahead of time so we can be paced and fair to all policies, not partial to one. So there will be a cut off for speakers, and that date will be published on our website, so make sure you follow that. And then we will simulate the presentations into one fluid slide that we're going to have today.

So just ask your cooperation on that, for those on the phone. Again, you start seeing that modeling when the July meeting comes out, when we post that on our website. So we feel like last year was, really, a great success in trying to implement sort of a new way of doing things. I think sometimes if you do policy or a method of policy development that's totally 180 degrees from what you were doing, it's a lot easier to implement. Because it's totally new, you start fresh.

So with the revision of the LCD in that, they use a lot of words, in the same way that this words before, and we had to translate that in open meeting. It doesn't really mean open meeting like it is last time, (CACs) evolve in how it's functioning, and where its place is in the LCD developed process, and that (CACs) are optional. So a lot of – some of things that happen and so that was really a difficult messaging, but that was our job and our task to do that. So I think last year went fairly well.

So having said that, I don't want to belabor the meeting, but just one of few housekeeping rules, updates on what we're doing with the policies. Again, it's more transparent, we are – we did transition, all of our ICD-10 codes into articles. That was a mandate last CMS, about end of last year.

So if you look at our LCDs now, it will have no ICD-10 codes in them. The essence of the body of coverage is in the LCD. There will be an accompanying article that will have the ICD-10 codes to which we can change without too much trouble on the front end. There's a lot of trouble in the backend for our staff who do an amazing job of maintaining all those ICD-10 codes.

So every LCD should have an accompanying article that has all the ICD-10 codes in them. And so that's how we're going to move forward. So I don't foresee a lot of huge changes in the LCD process this year. There might be some subtle change as we kind of workout last year, what best practices some MACs did, what kind of is on the radar for CMS. So if something makes a subtle change and we'll try to communicate those and keep everyone abreast on our website.

Again, we do have a Medical Policy tab on our website, NGSMedicare.com. Under that medical policy tab, you can link to the policy on the Medicare coverage database.

That's a subtle change, we no longer house the policies in there totality on our website. We click and we link you to the Medicare coverage database. That is sort of the origin truth, if you will, for all policy. So that's where we like you to go for the latest version of the policy, any updates there, and that's where to find the article attached to LCDs.

So without further ado, welcome, appreciate you coming. And I think we have a couple policies today. So we extended the hours today so that, you know, always the rule. If you extend the hours to four hours, then it's only going to be 30 minutes.

So when we have two-hour meeting, it ends up being four hours. So we'll wiggle with that, adjust with that. So we appreciate your patience in all of the changes that have taken place.

So I'll turn it back to Carolyn and let her move this forward. Thank you.

Carolyn Cunningham: Should we ask if there's anyone on the phone or in the room has questions or comments?

Greg McKinney: No. We don't want any questions. Since we have two policies, we may have a little wiggle room in our four hours, not that we will be here for four hours, but we'll start in the room. Anyone in the room have a question that I might want to answer? OK.

Female: So you mentioned moving the code over to the articles, right?

Greg McKinney: Correct.

Female: So, does that change how you would update, add or subtract the codes versus when they were in the LCD?

Greg McKinney: So that question for those, if it didn't transmit, since you moved the ICD codes into the article, does that change how we update it? And that process is the same, the revisions will be to the article. And that we do those every October when the new codes come out, actually they come out a little bit earlier. October is just kind of the ballpark, where we start implementing those new codes for the New Year.

Female: What if it's a new diagnosis or a new indication? That has to change in the LCD first?

Greg McKinney: Correct. So the question is, if it's just an ICD-10 update that comes out every year that will be done in the article as usual. If a new indication comes out or you want to change coverage, whether we liberalize it, narrow it or change the policy, then that LCD has to go back through the whole LCD process, OK?

Before we could liberalize a policy and just make it more liberal add those diagnoses, and just go with the flow and do it, and it would be done in a matter of days, actually. But under the new regulations, we have to take that policy back to do the process and open up the entire policy. So it's a whole new policy again, and that can be a little bit arduous considering, we have to go back and review things for literature, for just that one change, OK.

Female: All right. Just for the (notification), if there is an article for a product and you have an expanded indication, the LCD has to go through the reconsideration process or you just need to add it to the article without going through that process?

Greg McKinney: So the question was, if there's a new indication, do we have to do the change of diagnosis and article or do we have to update the LCD. The process now is, we can't

change the LCD–basically the only change to ICD-10 codes is for the update. Like if (blank) code expands or one code shrinks, we can do that in an article.

But if we change any indication that's outlined in the LCD, restricted, liberalized, whether it's – whatever reason, we have to open up the LCD and go through the whole LCD process. So that's the new rule that makes it a little burdensome.

Dr. Awodele: If it's an FDA label indication change, then that's an FDA label indication change. And so, I think we would be able to, you know, if the FDA label that change, and then we would be able to change the FDA label accordingly, either something gets pulled, or something gets added.

Greg McKinney: Yes.

Female: Without going through reconsideration.

Greg McKinney: If it's a narrow coverage, the manual states specifically that all of the drugs are covered for an FDA indication. And so that's the policy – that's a manual citation. So I think we'd have some leeway in just updating that. But in general, most of our drug policies tend to address off label indications. But that's generally where we get LCD coming from.

It's not the usual, OK, FDA approved it for the fifth indication. We're going to liberalize the policy. It's usually when we're considering off label, we have to look at the compendium for approval. We look at other resources for approval for an off label indication from that drug.

But just a routine FDA indication, I think we would have some leeway in not following that process, because it's already covered. We just want to make sure the edits don't stop. I'm sure you want that too, OK.

Female: The same thing goes, if CMS would change an NCD, put an NCD into place, and then update) our policy. And so, we have to change that.

Greg McKinney: Yes. There's always exception NCD rule. And so if we happen to have a policy that complements with NCD, and the NCD changes so our LCD isn't in conflict with that. Then we would have, if you will change our LCD.

We are trying not to do that, I'm not saying we don't. But as you know, NCDs are the big, big dinosaur around and move very slowly. There are very few of them. And so they rarely ever change.

But as soon as I said that one will change tomorrow, that normally we try not to be too controversial. . But it can happen, and certainly when it happens we have to comply with the NCD, OK.

Let's see if there's any questions on the phone.

Operator: And star one to ask a question.

And we have no audio questions at this time.

Greg McKinney: OK. (Lara Burrows), it should be in the – if you got a copy of the presentation.

Carolyn Cunningham: Could you repeat the question for the people on the line?

Greg McKinney: OK. The question was, they didn't hear Dr. (Burrows') name, it's (Lara Burrows). Any final questions?

Appreciate all the questions. Again, some of this is fluid, we'll try to be here, communicate and be, transparent, it's very open process. So that's our goal is to make it transparent and collaborative. All right.

Carolyn Cunningham: Thank you, Greg.

Greg McKinney: All right. (Inaudible) Carolyn.

Carolyn Cunningham: Thank you. (Frederica)? I'm sorry. Operator, were you going to say something?

Operator: No, Ms. Cunningham.

Carolyn Cunningham: Thank you. OK, let's go to slide four. OK.

These were the two draft policies that we have – each of these is a revision of what we have in place now. And they're up for discussion and revision because of a request to reconsider the policy.

Dr. Haug is going to discuss prostate rectal spacers first.

(Dr. Haug): Good afternoon. Yes, and just as a little background, these rectal spacers are various materials or devices that are placed between the prostate and the anterior wall in the rectum in men receiving radiation for prostate cancer. The idea is that because the anterior wall of the rectum is the major dose limiting factor in radiation therapy, that this provides physical separation that allows less toxicity and possible treatment intensification, so that's the background.

As Dr. Cunningham mentioned the change, this isolated change that you see in the slide was the results instigated by a reconsideration request specifically to cover rectal spacer in the context of not just dose-escalated EBRT, but also – that's external beam radiation, but also moderate hypofraction – in the context of hypofractionation.

We found in researching the issue that moderate hypo fractionation has become an accepted alternative to conventionally fractionated EBRT. Despite that, it doesn't have standardized dose constraints and it doesn't have follow-up of five years.

However, as opposed to moderate, in the case of ultra-high hypofractionation, guidelines support were mixed. NCCN does include some treatment options for ultra, ASTRO, ASCO, AUA guidelines raid ultra-hypofractionation recommendation conditional, meaning remaining uncertainty in the balance between benefit and risk. And the EAU, European Association of Urology, recommends restricting ultra-hypofractionation to prospective clinical trials.

So that's why we opted to add coverage just for the moderate but not the ultra-hypofractionation in some of the references here in the slide.

That's all I had on this, Dr. Cunningham.

Carolyn Cunningham: Thank you, OK. Questions or comments for Dr. (Haug) in the room? On the line? OK, thank you.

Dr. (Bill Hartsell), who's one of our (CAC) members for radiation oncology is here with us. And he has some slides that are in your packet, he'd like to present.

(Bill Hartsell): Thanks very much. So I'm (Bill Hartsell). I'm the Chief (CAC) adviser for the IL Radiologic Society. I also serve as the Chair of Health Policy Council for radiation oncology, so I'm very familiar with ASTRO guidelines as well.

Carolyn Cunningham: They can't hear you on the phones.

(Bill Hartsell): OK. How about now? Is it better?

Carolyn Cunningham: Oh better, yes.

(Bill Hartsell): OK. I just have to eat the microphone.

Carolyn Cunningham: You might have to.

(Bill Hartsell): I guess so. All right, next slide please.

(Bill Hartsell): I have no disclosure, this should be on the next slide. And the next slide, please.

So as you just heard, there have been changes in the way that radiation therapy is given for treatment of prostate cancer. And there's a concept of biological equivalent doses. Typically, we have given long courses of treatment with small treatments over time in order to spare the normal tissues. This goes back for almost 100 years.

We have found lately that by increasing the dose per treatment, we can achieve equivalent results in certain areas in the body. And in some cases, we can give a lot more for treatment in a very short course, which achieves even better control, for example, the lung cancer.

In prostate cancer, because of the slow growth pattern of prostate cancers, it seems that these shorter courses with higher doses for treatment are much more effective while giving similar side effects. The problem is that you have to increase the accuracy with those treatments. And so that's what's happened over the past 10 to 15 years.

There is cost savings, because the treatment costs the same– each treatment cost the same whether it's given in 44 times or 20 times. So giving it a 20 times is half as expensive. But when you're giving more each time, it becomes very important to make sure that the treatment is accurate.

And so I think the change in this LCD is an important step in that direction. And I want to make some comments about this change and about some other things to consider. Next slide.

So, one of the issues, and I know that we're supposed to talk about the moderate hypofractionation. One of the issues though, is this becomes very important Item .1D on the LCD requires knowledge of what the rectal constraints would be in advance of the placement of the hydrogel. So these constraints are basically parameters that we use to look at how much of an organ is being treated and how much dose that's receiving.

So for example, in the guideline, there's a (V70) less than 10 percent. That means in the rectum, the dose that's getting less than 70 gray is 10 percent or less of that rectal volume. The problem is, that's not something you can do by looking at a patient. You have to do a procedure to figure that out, which would mean doing a CT scan.

So to do that, we would have to give unnecessary exposure to the patient to figure that out in advance. And what this means is that we would have to do extra procedures for each patient, including some that include risk. If the patient has additional markers, and then we do the simulation and find out that we need to do the spacer, then that means that we have to go back and put the spacer in which is again another procedure. And so, we've given them an extra scan because they'll have to come back and do another scan after they have to space to place.

And both the randomized trial and the other perspective studies which Dr. Haug mentioned in the LCD, have shown that the spacers reduce these doses at all the constraint levels irrespective of the patient's initial anatomy. Next slide, please.

Another exclusion has been patients with unfavorable intermediate risk or high risk prostate cancer. But in the guidelines, those patients aren't excluded. The restriction is for T3 or with posterior extension to tumor. And the rationale for this is, you know, you have fascia between the prostate and the rectum and basically, the spacer goes between the prostate and the rectum along the fascia.

That's a very effective barrier to posterior growth of the tumor, so very few prostate cancers grow posteriorly through that fascia. And so, even patients who have unfavorable intermediate risk or high risk disease typically don't have posterior growth. And so, you're taking these patients where we get dose-escalation most typically and saying they're not eligible for this spacer.

And then point number three is, I know on the randomized trial, they excluded patients with an active bleeding disorder or coagulopathy. But those patients are part of the group that are most likely to benefit. Those patients, plus the ones who have, for example, ulcerative colitis, the ones who are most likely to benefit from the procedure, because one of the complications of radiation therapy is that it cause fibrosis on the interior like a wall, and you could get bleeding. And a patient who has an active bleeding disorder has a much higher risk for the bleeding. So that's a group of patients who would really benefit from this procedure. Next slide, please.

One other thing that's not included is brachytherapy. And the problem is that another way of doing the dose-escalation was to combined external beam radiation therapy, plus brachytherapy, implanted seeds are done with a temporary implant of high-dose rate brachytherapy.

There is a randomized prospective trial which has shown improved outcomes in terms of prostate cancer control in patients with intermediate risk, unfavorable intermediate risk or favorable high risk, by adding the brachytherapy compared to external beam treatment alone.

The downside to that was a 17 percent risk of significant rectal complications. And that's something that the spacer, I'm sorry, the spacer would reduce, so that's an area where you are getting dose-escalation, but it's not just with the external beam treatment.

And if we go by the guidelines of modern hypofractionation over, we're only giving 45 or 50 gray with the external beam, and then we do the brachytherapy to a high-dose.

So that's a concern. One other thing while we're on brachytherapy, it's a high dose treatment. Rectal complications are one of the risk factors. You're already doing a procedure that's somewhat invasive, and it's a simple thing to include this at the time of that procedure, which reduces the risk of rectal complications.

And by the way, brachytherapy is the single least expensive kind of treatment that we can give for prostate cancer. So doing something that would increase the use of brachytherapy for the patients with favorable disease would probably, actually bring cost down.

And finally, the last slide, this goes to that notion of ultra-fractionation. Ultra-fractionation is giving a very short course of treatment. That means in five to seven treatments instead of the 20 or 44 treatments we've talked about. And in the US, that's primarily been done using stereotactic body radiation with five treatments.

But in Scandinavia, Denmark and Sweden, there was a study that looked at seven treatments versus 39 treatments. And the seven treatments was as effective as the longer course of treatment in prostate cancer control. That again, one of the side effects is rectal complications, which was the same in both groups. But that's a group of patients for whom doing the rectal spacer would make a lot of sense. You're going to reduce the risk of those rectal side effects and you finish the treatment at a very short course, which is going to be more convenient for the patient or less expensive for all the taxpayers as well.

So, I think those are the primary concerns I have. I know – I think this is a great step to include this modern hypofractionation. But I think we could go further because as we are getting shorter and shorter courses of treatment, this sounds more and more important to spare the rectum to keep that area from getting the high-dose radiation therapy. Thank you.

Carolyn Cunningham: Thank you, (Bill). Questions or comments for Dr. (Hartsell)?

Male: I have a question. This is outside.

Female: OK, hold on. Hold on. Hold on.

Male: Sorry.

Male: So the question is, this proposal (was maybe) outside of the addition to adding modern hypofractionation, so that needs to be within the confines and the bounds as you suggested versus something with the review at a future date?

Dr. Haug: Dr. Cunningham, I can address that if you want.

Carolyn Cunningham: Please.

Dr. Haug?: Yes, most of these comments would be are outside of the bounds that's open for comment. But I mean, I appreciate it nonetheless. And they would be certainly the subject of the reconsideration request.

And I also had some questions for Dr. (Hartsell), when – if nobody else has any questions.

Carolyn Cunningham: Why don't you go ahead, Craig, and then we'll go to the people on the on the phone.

Dr. Haug: OK, right. Yes. I wanted to thank Dr. (Hartsell) for his interesting comments, and also for being a (CAC) rep. And if I could I just wanted to pick your brain on a few of your points again, even though it's outside the official, you know, comment domain type of thing.

If you could go to slide 9, OK. You took issue with the requirement that limits use to patients in whom anatomic geometry precludes idea of rectal constraints. Your objection was that this requires a CT simulation, an initial one to determine if ideal dosimeter dose are indeed precluded and if they are second – the second one after the spacer placement.

If I have characterized it correctly, how do you select which patients need the spacer verses which don't. It sounded like almost like you're just saying, you know, because it decreases the dose in general, it should be applied in everyone. I mean, excluding some obvious contraindication like rectal expansion.

(Bill Hartsell): Well, I think the patients who are post-prostatectomy are not good candidates for this because there's been alteration to the anatomy. Patients who are receiving lower dose and some of the low-risk patients don't receive the dose escalation, that's mostly the patients who have intermediate or high-risk disease who receive the dose escalation. Those are the ones who would not likely benefit.

But I think– the higher the dose we give per treatments or more of the accuracy of the treatment is important. And the more small changes in anatomy can make a huge difference. So I think those especially the patients, I guess, I would characterize it the other way that the patients who are getting a longer course of treatment.

We have experienced where we know exactly what those side effects are when we're getting higher dose per fraction, I think we have more of a concern that there can be issues if you're off on the treatment in this space or allows a significant reduction in the rectal dose for those patients. So I think those are the patients where it would make the most sense to do is the patients where there's going to be dose escalation or especially those are getting a hypofractionated treatment course.

And whether that's moderate or ultra-fractionated, even more important with the ultra-fractionation, I think.

Dr. Haug: OK. So it sounds like basically anybody with those escalation or higher hypofractionation, basically you're working assumption is that a spacer should be placed.

(Bill Hartsell): Yes. If you look at the randomized study, the reduction in rectal toxicity, which was significant required treatment, was about a two-thirds reduction. It was from just under 8 percent, 7.5 percent, down to 2 percent, 2.5 percent with the use of the rectal spacer. And those were unselected patients that those weren't ones where they determined before and that they could meet the constraints or could not meet the constraints.

: Dr. Haug Where the – where this requirement comes from, straight out of the NCCN guidelines, which indicate that it should be selectively one of the criteria being when anatomic geometry precludes ideal rectal constraints. So the NCCN definitely indicates that when that type of thing is precluded based on, you know, modern localization techniques, that – that's when it should be used and not otherwise. How do you – what's your interpretation of how to implement the NCCN guidance?

(Bill Hartsell): You know, the issue with the guidance is oftentimes that follows along after the data is presented. For example, in the ASTRO AUA guidelines, those words I don't process it takes a long time. And those were done prior to the HYPO-RT study coming out. And that's why it doesn't have ultra-fractionation as a recommended treatment, because the study came out shortly after the guidelines were completed. I think that's the same thing for the NCCN guidelines.

Now there is – there are some considerations in terms of you can't do one of these a year. And so, this should be done by someone who has done multiple of these

procedures. And I think that actually the company has been very good about that as this was being rolled out and making sure that everyone had appropriate training.

: Dr. Haug Yes. As far as the guidelines are often here while the guidelines are out of date, and that may be true and a lot of them, especially ones that come out every few years or even decades. But as, you know, I'm sure NCCN updates their guidelines several times a year. So, at least right now, the way our policy is written, I think you'd agree it's consistent with the NCCN guidelines.

(Bill Hartsell): Yes, not necessarily with the ASTRO AUA guidelines and I know this is Canada, but Canadian guidelines also say, you know, basically, it did reduces the risk.

Dr. Haug: Right, OK. If we go to the next slide, we include low risk and favorable intermediate risk in the policy right now. You advocate for inclusion of select unfavorable and higher risk.

The way the policy is written, including or just below unfavorable and intermediate, was because these were the inclusion criteria in the main studies. So in other words, these were the patients that were studied and we're always loved to extrapolate outcomes beyond those patients that were studied. You alluded to the idea that, you know, the risk – this was probably because it was trying to minimize the risk of the microscopic T3 disease with the risk of the spacer actually displacing malignant cells toward the rectum, and away from the radiation field. Obviously, something that would be quite counterproductive.

I understand your point that, that there can be intermediate – unfavorable intermediate or even high risk disease that isn't grossly locally advanced, especially posterior toward the rectum. But how do you rule out extra capsular and micro extension toward the rectum or you just feel that this is negligible if there's no growth, visible tumor invasion.

(Bill Hartsell): There are three or four ways. One is that, many patients now are getting MRIs prior to biopsy, and that demonstrates they're confident that their significant capsular extension. And that's literally ...

~~Greg McKinney~~: Dr. Haug Microscopic? Microscopic?

Bill Hartsell:

The second is the criteria for high risk are much more associated with the Gleason score. So patients become stage 3, stage 3C high risk virtue of the Gleason score, so at least a 9 or 10, and not by what the disease is palpable or not. So you can have a T1c nonpalpable disease in a patient with high risk disease. And the likelihood of cluster extension there is going to be much less than a patient who has a palpable module but it's a Gleason 6 or 7.

So that's the issue, I think that's why the guidelines say T3 disease where there's either radiographic or clinical evidence and extension outside of the (project).

: Dr. Haug Right, gross T3, but I think the concern was microscopic. And that's why they erred on the somewhat conservative side leading it to low and favorable intermediate. And again, so that's one rationale, and the other rationale is that those were the main type of patients that were studied in the idea of extrapolating gets a little, you know, dicey because, you know, you can't necessary assume the outcomes will be the same when you apply it to patients that weren't studied. OK.

And then the last question I had was that, relative to the active bleeding disorder, which was in the exclusion, we also have an indication. And this is going back to the NCCN guidelines that in one indication decide the anatomic geometry might be medication use, and we have in there anticoagulants.

So the policy, you know, tries to tread that line between what would be an indication because it avoids post-RT bleeding, and what would be a contraindication because of the risk of bleeding from the procedure itself, would perhaps change in the contraindication to uncorrected active bleeding disorder or clinically significant coagulopathy, be something you would agree with? Or do you feel that the risk of bleeding from the procedure is minimal corrected or not?

(Bill Hartsell): I don't know enough about coagulopathies to know if we would see it uncorrected coagulopathy and not try to get it corrected before we treat the patient. So I'm not sure if that change would be sufficient. But I

– that makes sense to me. But it's like any other procedure that needs to be done. If you have a patient with a disorder, there are ways to bridge them through that to get a procedure done.

So I guess that's the confusion I have. You have in the criteria, excluding patients who have active bleeding disorder or coagulopathy, so.

: Dr. Haug Yes. I guess, the difference would be something that's kind of a chronic-sustained situation versus one that could be temporarily bridge like as you say, then perhaps was a more severe situation that could be temporarily bridged for the – have you done these procedures?

(Bill Hartsell): Yes, I have.

: Dr. Haug Would you, I mean, do you think that it presents any significant risk of bleeding, except in the case of the most severe coagulopathy or it's not that – there's not that much to it, I think, right?

(Bill Hartsell): Correct. And all these patients have already had a prostate biopsy. So I think if there were a significant issue that would – it would show up with the biopsy much more than this procedure, which is much, much less than basic. We're not pulling chunks of tissue out or just pulling the needle out of it, inserting this gel. And the gel has been used in the past to plug holes. So I think that the risk of bleeding in that way is small to begin with.

: Dr. Haug Yes. But you generally do something to ameliorate the actively disorder during the procedure itself.

(Bill Hartsell): That's correct.

: Dr. Haug So limiting the contraindication qualifying it with that uncorrected, it sounds like that would satisfy your concerns.

(Bill Hartsell): I said I'm not sure if – I don't know if that's about the uncorrected coagulopathy to know. But I – if you say so, I'll take your word.

: Dr. Haug OK. Dr. Cunningham, that's all I had. Thanks, doc. Thank you again, Dr. (Hartsell), for letting me pick your brain a little bit here.

(Bill Hartsell): Absolutely. Feel free to keep picking until the end of this comment period for the next few weeks.

Carolyn Cunningham: Operator, do we have any questions from those on the phone?

Operator: And again, that is star one to ask a question. And we have no questions. Thank you.

Carolyn Cunningham: Thank you. OK, let's see. Let's go to the next slide.

Our second policy which we have a draft, again, is a revision of the current policy. And if, again, we had requested cover transcranial magnetic stimulation for obsessive compulsive disorder. And the request really was for deep TMS, rather than what's called repetitive TMS although frankly all repetitive. So we decided to address the use of TMS for both repetitive and deep.

OCD is really a syndrome that you probably are familiar with. It's a repetitive action and for some people, they have severe enough that it's very time consuming and interferes with their live activity. The incidence – the prevalence in the USA is thought to be about 1.2 percent annually.

It's treated with a drug if that's needed but there are a few people who don't respond to (pharmacotherapy). So, the trials have been done to try to use TMS.

We have an addition to the LCD of noncoverage for OCD because we found that the people vary from study to study, the frequency varies by the site of stimulation. There's mixed results and there's short follow ups.

So, our conclusion was that the investigations for the TMS are even fewer, and that they're in the one randomized double-blind controlled trial. It had 99 patients, had 12 percent dropout rate, that's where we follow up. And that follows a pilot study by the same investigators.

So our conclusion is that it fails to improve outcomes in people with this disorder, and that there's not enough evidence to show the use of either repetitive or deep TMS for OCD is reasonable and necessary.

Questions or comments? Operator, do we have anyone on the phone with a question or comment?

Operator: And that's star one to ask a question. And we have no questions at this time.

Carolyn Cunningham: Thank you, (Frederica).

Operator: You're welcome.

Carolyn Cunningham: Considers that we've got more time than usual. So any other comments that you have or questions?

Operator: And again, that is star one on your telephone to ask a question. Star one.

Carolyn Cunningham: Thank you everyone.

Operator: And you have a question – and you have a question from (Sandra Egan).

(Sandra Egan): My question is regarding the request of consideration submitted on behalf of Exeter Hospital in regards to one of the points in LCD, where we must have a patient who falls within certain measurement or constraints that could only be calculated after the (calc) measurement would occur, pretreatment. And we wouldn't do that (calc) measurement pretreatment without the insertion of the hydrogel.

So we aren't able to meet that specific criteria set every – for every single patient because we won't know until after we've placed the gel, and then done the calculation. It seems to be a backward request, and something we wouldn't know till after the hydrogel is in place and the calc is done. I'm wondering if there's any intention to look at that criteria further.

Carolyn Cunningham: I think Dr. (Hartsell) brought that point up and it was discussed with – Dr. (Haug), do you have any additional comment?

(Dr. Haug): Yes. I think we just – I think we discussed that that's consistent with the NCCN guidelines that envision a selective use based on first assessment of the anatomic geometry before decision is made about the gel.

Carolyn Cunningham: OK, anything else?

Operator: Again, that is star one on your telephone to ask a question or make a comment.

Male: I think that's the (inaudible).

Carolyn Cunningham: And thanks everyone on the phone. See you in June.

Female: Disconnect the phone.

Carolyn Cunningham: Operator, I think we're finished, shall we just hang up?

Operator: OK, thank you. And ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect. To the presenters, please hold.

END