Bleeding Disorder Collaborative
December 16, 2015

Donna Sullivan: It said that there are four people on the phone. Could the others please introduce themselves?

Heidi Forrester: Hi. I'm with the BDFW.

Donna Sullivan: Welcome, Heidi.

Rebecca Kruse-Jarres: Hi, Heidi. This is Rebecca.

Donna Sullivan: We're just gathering and will start real soon. Is there anybody else on the phone? Is it time?

Dan Lessler: Welcome everybody. I'm the Chief Medical Officer at the Health Care Authority. This is the first meeting of the bleeding disorder collaborative, which is great after a number of planning meetings to finally convene. It's great to have everybody. I think what I'm going to do is just ask folks who are members of the collaborative to introduce themselves, maybe, starting down at the end and we can go around and introduce the ACA and then I think I'll formally introduce Ray and hand it off just to facilitate us here. That would be great.

Dana Matthews: I'm the Director of Hematology at Children's and have led the Hemophilia Treatment Center there although I'm about to hand that off and back up.

Amanda Blair: I'm going to be starting at Children's next month taking over the Hemophilia [inaudible] program.

Rebecca Kruse-Jarres: I'm the Director of the Washington Center for Bleeding Disorders at Blood Works Northwest.

Judy Felgenhauer: I am the Director at Providence Sacred Heart and Children's Hospital in Spokane.

Lisa Humphrey: I'm in the Clinical Policy section with Dr. Lessler at Health Care Authority.

Donna Sullivan: I'm the Chief Pharmacy Officer at the Health Care Authority.

Leta Evaskus: I'm with the Health Care Authority and the Prescription Drug Program.

Ryan Pistoresi: I'm the Assistant Chief Pharmacy Officer with the Health Care Authority.

Ray Hanley: I'm the Director of the Prescription Drug Program. Thanks, Dan. So I guess I'd like to thank everybody for coming out on this holiday afternoon for the Bleeding Disorder Collaborative. Everybody has an agenda in front of them.

I'd like to start off with just going over the budget proviso, which creates the Bleeding Disorder Collaborative. So, Donna.

Donna Sullivan: In the last legislative session there was a bill that was actually introduced to establish a bleeding disorder collaborative. However, that piece of legislation didn't pass and our legislature then opted to stick the collaborative, the creation of the collaborative in a budget proviso. So I don't have the actual language up here. It's summarized in the draft charter that we have. But essentially the collaborative appointed… stated that there needed to be committee members from the Bleeding Disorder Foundation, the Puget Sound… the Northwest… am I killing it?

[inaudible]

Donna Sullivan: Blood Works Northwest, yes, as well as the stakeholder groups and the Centers of Excellence from which the Health Care Authority contracts with, which is OHSU and Northwest Blood Center. And then there was also three committee members from the HCA that were appointed to the committee. There was a certain amount of money that the HCA was given to fund this collaborative and this is our first inaugural meeting that we're having today. I think other than that I think that's all we are going to do about the budget.

Dan Lessler: Okay. Thanks, Donna. I think that that… let's just move directly then into the charter, the Bleeding… the Bleeding Cooperative… the Bleeding

Collaborative Charter rather. You have a copy of the charter. It looks like this in front of you. Donna, do you want to pick that up?

Donna Sullivan: I will. So… also just a rule of order, we are recording the meeting. We are required to have open public meetings and keep minutes. So we are recording the meetings, which will then be transcribed as our official meeting minutes. So when you are speaking, it's awkward at first, but you'll get used to it, please introduce yourself every time before you speak so that the transcriber can keep track of who is saying what.

So with that we have in front of you a draft charter for the bleeding disorder collaborative for care. And, again, its members from the Health Care Authority are listed. The Bleeding Disorder's Foundation of Washington, the Bleeding Disorder Centers of Excellence are listed there. And then the Hemophilia Treatment Centers, which are the Centers of Excellence that I mentioned that I apologized to Seattle Children's that I did not mention that you were one of the Centers for Excellence.

Other members as the collaborative decides if we need additional expertise to come and provide technical advice to the collaborative members that we can invite whoever we want to speak and assist us as we conduct our work.

Again, the authority of the collaborative was established under the Engrossed Substitute Senate Bill 6052, which is our operating budget. The funding authority for the Charter is the Health Care Authority and the project oversight for the bleeding disorder will be the responsibility of Dr. Lessler as our Health Care Authority sponsor and he will report all of our work and findings up to the Health Care Authority leadership as we need to.

We've had some major milestones that were originally worked upon by some of the members prior to the formal establishment of the collaborative looking at purpose and scope of what the collaborative was, was going to entail, potential research that we will conducting, and that will be moving forward as we agree upon potential research and draft, research protocol as well as budgets, and then the intent will be to do some review of current evidence policy guidelines and then also identify

gaps in the literature based on the reviews that we feel like we want to conduct.

On page 4 we're also… part of the collaborative initiative was to provide some sort of cost benefit analysis, or cost effectiveness analysis around the treatment of hemophilia and bleeding disorders based on published guidelines or based on the best practices that this collaboration agrees upon moving forward with a report due to the legislature in August 2016.

So, moving down then to the organization roles and responsibilities. It just pretty much, you know, the Health Care Authority will provide three collaborative practice members. We will help select research projects for funding, oversee funding [inaudible], budgets and contracts, develop a cost-benefit analysis. We will be drafting a report to legislature and commit necessary resources to the project as needed. We ask that the Bleeding Disorder's Foundation provide three collaborative members, as well as help select research projects for funding, provide oversight to guarantee the mission of the project. And it's really the intent of HCH to enter into a contract with the Bleeding Disorder Foundation… I think it's Blood Works Northwest that we will be working with to do the research or the project management. Right? Northwest Blood?

Rebecca Kruse-Jarres: Exactly. So that's the next panel down.

Donna Sullivan: Okay. Perfect.

Rebecca Kruse-Jarres: There's the Foundation with Stephanie and that's the… we need to make the distinction between the Foundation, which is represented here by Stephanie and Heidi on the phone. That is the patient representation and then there are the Centers of Excellence and the Hemophilia Treatment Centers that are going to actually do the research, I think is the idea.

Donna Sullivan: So we'll flush that out better in the charter about roles and responsibilities. If we have a particular organization or representative tasked to function we'll make sure that we clarify that role and responsibility specific to that organization.

Rebecca Kruse-Jarres: I think the way it is written here is actually appropriate.

Donna Sullivan: I'm sorry. So it starts… so Bleeding Disorder Centers of Excellence on page 4 and then the Hemophilia Treatment Center is on page 5. So you are the Hemophilia Treatment Centers?

Rebecca Kruse-Jarres: So there are four hemophilia treatment centers involved here. One of them is OHSU, one of them is Blood Works Northwest, one of them is Sacred Heart and one of them is Children's Hospital. Two of these centers, for whatever reason, are centers of excellence and that's OHSU and Blood Works Northwest. But we are all really for in this the same way, excellence or not, we are all excellent. We are… it's just here for some reason separated out.

Stephanie Simpson: It was separated as a maneuver to make sure we can include OHSU without highlighting Oregon in the state bill.

Donna Sullivan: Okay. Thank you for that clarification.

Dana Matthews: One more clarification. I think not everybody has completely gotten used to the abbreviation, the WCBD, which is Washington Center for Bleeding Disorders, which basically is the piece of Blood Works Northwest that Rebecca is in charge of and that will do that part.

Donna Sullivan: Later today we will selecting a chair of the meeting and that chair will lead the meetings, commit resources for the project, ensure leaders of associated function commit resources, basically we will ensure that we are meeting the needs of the collaborative and working with fellow staff members to make sure that happens.

We will be working… obtaining a project manager to help facilitate and guide us through this process. I've invited Ray Hanley here today to really try to help us facilitate the meeting and he might be working with us in future meetings to facilitate the meeting so that whoever is the chair of the project manager if we need them to be more of a participant versus a facilitator that we are able to get people to participate freely within the meetings. HCA will also provide administrative support. And

then we will look towards some of the centers of excellence and other vendors or contractors that we have to conduct research.

One of them will be the Washington Center for Bleeding Disorder and then below that you'll see research [inaudible] too and it's MED question mark. MED stands for the Medicaid Evidence-Based Decision-Making Group. That is… it is housed in the Center for Evidence-Based Policy with Oregon's Health and Science University in Portland and Washington State has a contract with the MED program to do evaluations of literature and evidence that are out there. We are one of 12 to 13 member states and organizations across the country and we have engaged them to do our literature search and evaluation for the collaborative going forward based on the key questions and guiding principles that we'll be asking them to do and we'll work on that later today as well.

And then collaborative members we have an expectation that you'll attend the meetings as needed. All in-person meetings, as well as the phone meetings that we have and that we'll work together as a team, demonstrate respect for different viewpoints, support the process, ask questions, be engaged, volunteer for tasks, to do the work to help the collaborative be successful, and then also assist in developing the cost benefit analysis. So there's other things that we have discussed about our operating procedures or… interaction with collaborative members and some of our vendors has been contractual requirements, delegation of roles and responsibilities. We do have to adhere to open public meeting rules and we will make sure that we do that. We have a short timeline to get information… our report ready for the legislature and to conduct any research, if research is warranted and we decide we want to walk down that road. And we do have some limited resources as far as budget goes. The budget is displayed on page 6 in the center.

Item 5 on page 6 are recommendations for state finance programs. There's… implementation funding was not provided so that really means is that there was funding provided to do the research, the literature evaluation, the cost effectiveness reviews, but nothing… there was no funding to implement any policies that we might create. So there's no additional funding to assist providers or organizations in making changes to their practice at this point in time. Implementation was not required

in the law so we can develop the policies, but the budget proviso was a little vague on whether or not this would be a mandated policy that would be spread across the state. So I really believe that that's our decision, as well as the organizations that might adopt whatever policies we develop.

Again, it's obvious best practice implementation requires provider participation and then implementations may be guidelines, you know, recommendations, as opposed to policy.

At this point in time our assumption is that our funding will run out in June 2017 and the participating organizations are listed and that is all. So questions, comments, edits? We can approve the charter as it is or if you feel that you need time to study it further and make comments on it we can table that decision for next time. That's really up to the collaborative to decide.

Dana Matthews: I have a question. Just on the budget, not getting into the weeds, so personal service contract – does that include cost of things like labs that would be needed for research? It looked like a lot of salaries here and I was trying to figure out how much flexibility there was.

Donna Sullivan: The budget itself is very flexible. The dollars and the line items you see here were what we put into the fiscal note in response to the legislation that was introduced last year. So really we have a pot of money and we can spend it however we want. Does that answer your question?

Dana Matthews: Yes.

Donna Sullivan: Okay. Thank you.

Rebecca Kruse-Jarres: So if we approve this we don't really approve those exact numbers? That is still flexible?

Donna Sullivan: That is correct. And if the collaborative decides that it wants to encumber money towards research versus administrative projects and things like that it is our responsibility… that's up to our discretion if we

want to formally do that or if we just want to keep track of a running tally of the funds as we spend it.

Ray Hanley: Just one clarification and it goes with the financing. The way that the collaborative is set up now the… it sounds like a lot of it hinges on cost-benefit analysis. Is that something that could be done inside or outside?

Donna Sullivan: That is correct.

Ray Hanley: Okay.

Rebecca Kruse-Jarres: I have a question on the research role because I think that's either question words there and (b) it seems like we are the only one listed there and I'm not really sure…

Donna Sullivan: I think that… I haven't looked at this in a couple of weeks. I think that the question mark about that was from prior conversations we were walking down the road of the Health Care Authority contracting with the Washington Center for Bleeding Disorders and that you would manage and facilitate the research projects and subcontract with the other hemophilia treatment centers or participating organizations to perform the research as a project management research management function.

Rebecca Kruse-Jarres: So I just wanted to make sure that everybody is okay with that and that is really from an administrative, but certainly design and the research that would be all of us.

Donna Sullivan: So this is…

Mike Recht: I'm okay with that.

Rebecca Kruse-Jarres: Okay. Judy, you are okay with that?

Mike Recht: I think that's the appropriate structure.

Donna Sullivan: Thank you. I was just going to try to make sure that we have the people on the phone an opportunity to chime in. Any further discussion? Would you feel more comfortable, just going back to the budget, just kind of

taking out that line item budget and just talk about the funds that we have in each fiscal year to spend? Would that make it more clear?

Rebecca Kruse-Jarres: Either way or if we just have a little star and say that, you know, this might be flexible or can be reassigned.

Dan Lessler: I actually thing… I mean if we have that degree of flexibility I would just…

Donna Sullivan: Remove it?

Dan Lessler: Because then there's no confusion in terms of some assumed budget items at this point. And as we go along we can…

Donna Sullivan: Right. I will do that. So the only budgetary constraints are that the fiscal dollars were appropriated for… the dollars were appropriated for the specific fiscal year. So we have to spend the $308,000 before the end of June 2016 and then we only have $292,000 to spend the following year. That's the only constraint.

Dana Matthews: That's hard and soon. So there's no flex… that's six months from now.

Dan Lessler: That's correct. So in terms of… and what this could look like from the Health Care Authority standpoint I might ask Donna, but from, you know, this has to be spent, but spent, you know, the question is going to be whether or not for example, you know, if we have a contract with you can we get the money to you and then you're doing the work and how that might work. So it's got to be out the door from the Health Care Authority, the state door, and that's the main point. There are probably some devils in the details then after that, but that's the main point. I would underscore though that time is short even if you're looking at the end of fiscal year 2017. It's a good thing we're here today and we've got our work cut out for us in terms of really moving things along.

Mike Recht: Am I correct fiscal year in the state of Washington runs…

Dan Lessler: July 1st to June 30th. So we're just coming up on the closeout of the first six months of fiscal year 2016.

Mike Recht: Got it. Thanks.

Dan Lessler: Another question, Donna, just to clarify. In terms of dollars that might have been appropriated to support sort of the administrative efforts at HCA, are those in…

Donna Sullivan: That hasn't been addressed, but I think it's a good idea for us to pull that out and then we'll have a better idea of what's available research dollars.

Rebecca Kruse-Jarres: I think that would be really important so we know how much money do we actually have to do the actual research? And I think, if I remember right, in the budget there was some salary support for a project management and a data coordinator even though it's not quite clear to me how much of a position that would be of each and how much… what the dollar amount is. And that is something that has been discussed before and I would like to bring up again, is that the person who will be sitting at the Washington Center for Bleeding Disorder to make sure that this whole… that the projects go?

Donna Sullivan: Yes, that is the intent and I apologize for not getting the contract out sooner. But those dollars do come from these amounts of money that are here. So we will need to decide, once we get the research… if we agree that we are moving forward with the contract with the Washington Center for Bleeding Disorders then next time we can come back with a draft contract statement of work and how much we are going to spend, what that time commitment looks like for that staff member, and then have a better idea of the budget. So maybe that's a work item we can work on for next time.

Rebecca Kruse-Jarres: We have a very limited time here. So this is certainly something that I think we need to do fast because if the budget is already done by June 30th, you know, we need to hire… we need to do the contract, contracts take a little while, we need to hire a person just to assure that we're going to be successful with this.

Donna Sullivan: Okay. I agree with that. So with that I want to… I think that is a good segway into kind of our operation policy. So one of the challenges that we have had trying to get the collaborative up and off the ground is

getting a time where all of the collaborative members could meet together either in person or even on the phone has been a challenge with many of the members being practicing clinicians and all of our other busy schedules. So what I am proposing moving forward starting the first week of January 2016 is having a weekly meeting with the collaborative as long as we have a quorum attending the meeting we can make decisions. So we will have open public meetings. Most of them will be conference calls and we will send out call-in information for any stakeholders that want to participate and probably have a webinar or a web-x forum for the discussion as we move forward. With that being a weekly meeting and taking into consideration schedules of clinicians that might be, you know, seeing patients between 8:00 and 5:00; my recommendation is for us to pick a day of the week that we will meet and a time either in the morning before clinic or at 5:00, you know, in the evening after clinic like 5:30 to 6:00 or 7:30 to 9:00 and I would just like to get the feedback from the collaborative members and then really encourage them to adjust their schedules and make this a priority to attend.

Rebecca Kruse-Jarres: I completely agree and I love early meetings and late meetings, but it depends on everybody else too. And I… does it have to be a two-hour meeting?

Donna Sullivan: It doesn't have to be. I was just trying to figure out enough time. We can always shorten the meetings and we can cancel them if there's nothing to be discussed on the agenda. This is just to block time on our calendars so that we can move forward quickly with getting our work done.

Mike Recht: I agree with that.

Donna Sullivan: Do we want to try and pick a day of the week today and a time or do we want to… does everybody have a sense of what's available and what's not available?

Mike Recht: I'm willing to give it a shot.

Dana Matthews: I think early is probably the easiest way and I would throw out like 7:30 to 8:30 and I don't know… I mean, Amanda hardly even knows her schedule

yet, but I kind of know her schedule. I don't know if you guys want to try to do Tuesday since you're going to be collaborating anyway.

Rebecca Kruse-Jarres: Tuesdays, unfortunately, do not work because I already have a meeting at 7:30.

Dana Matthews: Wednesday? Thursday?

Rebecca Kruse-Jarres: Wednesdays and Thursdays are fine. Monday, Friday.

Dana Matthews: We have a competing meeting on Fridays. Wednesday or Thursday would probably work best for us. I don't know about Judy or Mike.

Mike Recht: Wednesday or Thursday 7:00 until 8:00, 7:30 to 8:30 is fine. Yeah. 7:00 to 8:00 is better on Wednesday for me. I have an 8:00 business meeting for my division, but they don't listen to me anyway.

Judy Felgenhauer: I will have some Wednesday/Thursday that I couldn't be there, but for the most part I could do early. I would probably agree that 7:00 to 8:00 would work better.

Donna Sullivan: Okay. This is what I'm hearing is that the majority, if not all of the members, can be available on Wednesday or Thursday 7:00 to 8:00 or 7:30 to 8:00. I'm going to suggest we do 7:00 to 8:00 since our business work day starts at 8:00 a.m.

Mike Recht: Yeah, I like that idea.

Donna Sullivan: We have our P&T Committee meetings every two months on Wednesday. So I might throw out there maybe a Thursday morning 7:00 a.m. call or I'll just be here early before our meetings and call-in from here. So we will set out a meeting invite and get that onto the calendars moving forward and based on potential conflicts we will make adjustments as needed.

Are we at a point where we would like to appoint a chair, Dan?

Dan Lessler: I think that that would be helpful. Our thinking is that it would be important and valuable to have one of the… one of you folks who are representing the facilities that treat people and will be participating in the research to serve as chair. As Donna said we will, the HCA will provide administrative support and so forth, but especially as we move forward envision these conversations really probably increasingly centering around any clinical research that might be going on and protocols that might be underway and so on and so forth that that would make the most sense. Maybe I could ask… how does that sound to folks here and on the phone for starters, as an idea?

Rebecca Kruse-Jarres: Quick question. There's a chair and there's a project manager. What was the vision for the project manager? I want to make sure I understand the difference.

Dan Lessler: Typically the way we think of project managers is, for all intents and purposes, they make sure the trains run on time. They assure that the meetings are scheduled, they help take note of what needs follow-up. They sort of ping people when somebody needs to get something done. They track the budget and so forth. Really they are the right hand person of the collaborative and certainly with support. I would envision, Donna, support the chair in that way.

Donna Sullivan: Yes. With the project manager working with HCA administrative staff, you know, making sure that the agendas are developed, that they are distributed, meeting materials are distributed to the collaborative members. The chair, and maybe this is… the chair typically would facil… like in our P&T Committee meetings the chair facilitates the meeting going through the agenda. However, we might have the option, you know, since you are also a collaborative member and want to participate in the discussion taking that function away from you and having an individual, either the project manager can do that or have another facilitator at the meeting so that the chair can participate fully in the discussion. And we can flush out details of more like what we envision project manager roles to be versus the chairperson roles and bring that back at another meeting.

Rebecca Kruse-Jarres: I just wanted to verbalize.

Donna Sullivan: Thank you.

Rebecca Kruse-Jarres: And I agree with your previous comments.

Dan Lessler: Are there other comments from folks from other sites or Mike on the phone and whether you all have… in terms of somebody here potentially serving as chair or if there are any thoughts people want to put on the table.

Dana Matthews: I would personally like it to be Rebecca and I'm not worried about conflict because I feel like this is a really open discussion. We all work really collaboratively. Mike could be the other consideration, but I feel like we're on such a tight timeline, really efficiency of being able to kind of be central to all of these systems would be a real advantage in terms of being as productive as possible. So that would be my vote.

Mike Recht: I completely agree with Dana. For all the reasons that Dana said and then for reasons of what my personal plate looks like right now and the fact that I'm not in Washington I think Rebecca is the right choice for chair, as long as Rebecca is interested.

Dana Matthews: Rebecca is interested.

Donna Sullivan: I guess as the acting facilitator, Ray, can you call for… we have a nomination.

Ray Hanley: Sure. We have a nomination for chair of the Bleeding Disorder Collaborative. Is there a second?

Lisa Humphrey: I second.

Ray Hanley: Okay. All those in favor say, aye.

Group: Aye.

Ray Hanley: Opposed? And it passes.

Donna Sullivan: Thank you.

Mike Recht: Congratulations.

Rebecca Kruse-Jarres: Thank you. Thank you.

Donna Sullivan: Rebecca, going back to that now I want to go back to the charter now that we have a chair to go ahead and review or readdress the charter. Do we want to table it for next time to get a final version or do we want to go ahead and adopt it as discussed with changes as discussed.

Rebecca Kruse-Jarres: I vote to go ahead and accept it.

Donna Sullivan: Okay.

Ray Hanley: Okay. So we have a motion.

Donna Sullivan: Everybody in agreement with that?

Ray Hanley: To accept the charter as-is, all those in favor say, aye.

Rebecca Kruse-Jarres: Sorry. Can we accept it with changes to exclude the chart with the budget on it?

Donna Sullivan: Correct.

Ray Hanley: Yes, that's correct. All those in favor say, aye.

Group: Aye.

Ray Hanley: Opposed?

Mike Recht: Aye.

Ray Hanley: The motion passes.

Donna Sullivan: Michael, did you say aye to the agree or aye to the opposed? You might have been delayed.

Mike Recht: I said aye to the agreed.

Donna Sullivan: Okay. Great.

Mike Recht: And I want to nominate Rebecca for chairman.

Donna Sullivan: Thank you.

Ray Hanley: Okay. So we can move on to the idea of key questions to guide the literature evaluation. We also have a description of OHSU as well.

Donna Sullivan: Yes. Again, I want to go back to the draft key questions is the one-pager. If you don't have a copy of it I have additional copies up here. Again, the Medicaid evidence-based decision-making group is a collaborative of 12 to 13 Medicaid states and their medical directors and they address evidence-based policies and reviewing literature for a myriad of policy decisions for our Medicaid programs and hemophilia is one of the ones that the group is interested in. We did approach them to conduct the evidence-based review for us. It is with Oregon Health Sciences University and I believe… I might misspeak that the conduction of this research will come out of our MED budget and contract with OHSU. So this work would not necessarily be commissioned out of the dollars that are budgeted for the collaborative. That is one of the reasons why we opted to go with the MED program in order to do this research evaluation on our behalf.

Mike Recht: Could you re-state that, please? I want to make sure I understood what you just said.

Donna Sullivan: I'm going to caveat this that it may change, but it is my understanding… Washington State currently has a contract with the Oregon Health Sciences University and we are a participant in the Medicaid evidence-based decision-making group. And part of that membership in that group allows the state to have what we call state member requests for research. And so Washington State will be opting to elect to perform or to use one of its state participant requests as this hemophilia research or evidence-based literature evaluation. So the dollars that we pay to OHSU

to perform this literature evaluation will come from Washington's contract with the MED program not the Bleeding Disorder Collaborative funds that we were appropriated.

Mike Recht: That's at a level way higher than I am allowed or even understand to comment on. So I'm not sure exactly what to say. I don't think that I was under the understanding that OHSU participate… the hemophilia centers at OHSU participation in this project would at all adversely affect OHSU's reimbursement with other projects.

Donna Sullivan: It won't. This is a completely… we have two contracts. We have the contract with the MED program, which is completely separate. I guess it's a gift of the Health Care Authority to the Bleeding Disorder Collaborative to pay for this work in our existing contract that we have through the Evidence-Based Practice Center at OHSU and the membership that we have in MED to perform the work. There isn't any disadvantage to OHSU in any way.

Stephanie Simpson: So can we do a little… can I maybe translate a little bit of what I'm hearing and then a question?

Mike Recht: That would be great.

Stephanie Simpson: Okay. Thanks. So my understanding to the HTC's is that there is a body at OHSU that is known that does evidence-based kind of evaluations of different diseases and questions. This actually was brought up when the BDFW, which is the Bleeding Disorder Foundation was looking to do this and electeds asked why isn't it being sent to, it's called something?

Donna Sullivan: Is it either MED or the Evidence-Based Practice Center?

Stephanie Simpson: Something like that.

Donna Sullivan: The Evidence-Based Practice Center facilitates the Medicaid evidence-based review.

Stephanie Simpson: Yeah. This is a gift that they are looking at giving it this way, to send it in that direction. I think my concern would be, and it's different from this is

that we advocated not to go this route originally. One, because it would have been an easy route because Medicaid could have done it one their own. But also, two, are the right people going to be looking at the evidence? Do they know enough about bleeding disorders because it such a niche market to be able to make an evaluation of the evidence that's available? And that is something that we discussed with legislators when we were looking at this process. And just more information to be looked at or to answer for the group.

Mike Recht: So this is all new to me. I'm speaking very much off the cuff. The expert in evidence-based medicine program at OHSU certainly has the expertise to look at this type of information with the bleeding disorders community as long as they have appropriate bleeding disorder experts to work with them, which this group would be. Again, I want to make sure that I'm not representing that OHSU's Evidence-Based Medicine Program will do this, has promised to do this. I can't be speaking for that program.

Donna Sullivan: I don't expect you to. I work very closely with the MED program staff within HCA as well as the staff at OHSU with Nichole King, as well as some of the other professional and scientists that are within that group. So I have already had offline discussions with them about using our resources internally to get this work done in parallel with the collaborative. And that was the purpose of this group actually meeting to develop the key questions and the… OHSU will be doing the work, but we will be guiding the research and the evaluation in what we want them to look at.

Mike Recht: Okay. I will reach out to Nichole King just to make sure that I understand what she has agreed and that I am not representing anything different than that.

Donna Sullivan: Perfect. I haven't talked to her in quite a while about this so it might take some dusting off.

Mike Recht: Okay. Okay.

Donna Sullivan: Moving on to the key questions. What I did… Washington also participates in the Drug Effectiveness Review Project. What I did is I took our core key questions from the evidence-based reviews that they do for

that project and tried to tailor them towards hemophilia and then got feedback from Dr. Lessler, as well as Dr. Pistoresi and we… so what is in front of you is just a draft key question for us to work from so that we didn't have to start from scratch. Their expectation really is that there will be a great dialogue and conversation back and forth and that we refine the questions that we want to use for… or provide to the MED program to initiate the literature evaluation.

Rebecca Kruse-Jarres: I keep hearing this guided literature evaluation. That's not the primary objective of us here.

Mike Recht: Right. That was going to be my next discussion.

Donna Sullivan: The state has to give a report to the legislature in September 2016. The literature evaluation is to help identify gaps in care. And so why I'm making it a priority is we need to allow them to get started on it because it will take them several months to complete the evaluation. So it's not the primary focus I think of the collaborative, but it is something that we need them to start now so we can get that evaluation back in time to incorporate anything into the report in September.

Dan Lessler: It is specifically called out in legislation. So we are legislatively required and expected to do this. Having said that, you know, we also have the expectation, the requirement, by the end of this fiscal year, if I'm correct, or is it August in the… it's early in the next fiscal year that the report is due. Right?

Donna Sullivan: Right.

Dan Lessler: Well before likely there would be anything clinically together in terms of a report we are… we have an expectation from the legislature that we will report back to them. So really this is, in some sense, serving two purposes. One is the… it addresses the legislative expectation that there will be a review and identification of gaps and so forth. And also it provides us with sort of the opportunity to package a report and deliver it on time.

Rebecca Kruse-Jarres: The whole collaborative, really, I mean doing the review and getting that data and still doing some clinical trial of some sort is within the realm of this collaborative, right?

Dan Lessler: Yes, absolutely. And I think to Donna's point in terms of having adequate resources to do the clinical piece of work we have the opportunity to leverage our contract with MED so that the dollars aren't coming out of this pool that we currently have appropriated. We are able to use other dollars to pay for this literature [inaudible].

Mike Recht: I understand.

Dana Matthews: I have the same questions about the literature review, but when I look at key question number 1 the first thing I think of is that there have been a lot of studies trying to look at efficacy and effectiveness and most of them require vast numbers of patients and most of them are beyond where we would be able to do in one state. But I guess I could imagine that the literature review would help to frame what is known, what's not known, what questions require vast pharma resources, thousands of patients that are way beyond our score versus what our… I think we probably feel like we know a lot of this, but it helps to frame and focus. Is that a reasonable way to look at this?

Rebecca Kruse-Jarres: It identifies the gap that we're trying to fill with our clinical research.

Dan Lessler: And so one of the things we can do here today, as you look at these questions, is actually, are there additional questions that you would want to… do you want to include to help with that framing? So for example I'm far from an expert in hemophilia and so forth, but I understand from some of the conversations we've had with Rebecca and Mike along the way that, you know, issues around dosing and weight-based dosing, and so forth that there are… so we might want to include a question along those lines, for example. I might think that… because then they could sort of do… provide that background. You could think of it as the background to an NHA/NIH grant. So that's leading up to these questions.

Donna Sullivan: Typically, the process is when we engage with MED is that we will develop a set of draft key questions that the collaborative is interested in and then we will bring, potentially to the next meeting, bring MED program staff, as well as their researchers to that meeting and have an open discussion with them and let them kind of tell us the ins and outs, the ease, the difficulty in doing the literature reviews. Once we get those a lot of times what they'll do is they will kind of do a scan of the literature and then bring back to us… this brought back like 6,000 studies. Are you sure you want to include all of these? Do you want to refine the questions and pair this down? It will be an iterative process and so when I say this is how we guide the research and the evaluation that's what I mean. I apologize if I didn't make that more explicit.

Dan Lessler: This would be a good time to think about additional questions. Donna, let me ask you a question. In terms of… obviously we could have some conversation here right now about questions that you might want to add or further develop here. When… I would think that we would have a little bit of time for people, you know, maybe we do some work today and then send it back out and refine it and so forth. What is the time line on actually getting these to MED?

Donna Sullivan: I think we could get them to them by the end of next week if we can get feedback from the provider… or from the collaborative before then. I guess the question… we could give them the draft so that they could make any additional comments. I believe we will either have to make a decision here today or at the next meeting. All decisions have to be made in an open public meeting. So that would also allow for stakeholder input and comment on the questions, as well, if we don't get that today. So it would be January, I guess.

Rebecca Kruse-Jarres: I think I asked that question before. Sometimes really defining a question and thinking about, you know, what do we see as the biggest gaps might be something that is really fostered well by the center heads coming together and just kind of thinking, you know, what is it we can feasibly do and answer it and what are the big questions? Is that kind of brainstorming session that's not really coming up with any… or in the end is going to come up with a list of let's say 10 things that then can be discussed. But this brainstorming session does that have to happen in

public as well? This is kind of throwing everything out and then coming up with a list and saying these are the potentials that we're entertaining that would fit this whole thing and this is what we're proposing and then vote on it.

Donna Sullivan: Yes. That would be considered a subcommittee of the collaborative. So any subcommittees that get formed they have to be in the open public process. So we can facilitate those. We could set up weekly meetings, you know, sooner than… starting next year, we could start next week if people will be available on Tuesday or Wednesday at that time. We can start the brainstorming process if that's what you'd like to do.

Rebecca Kruse-Jarres: Looking at Amanda and Judy and Mike, I mean do we want to define these questions today or do the five of us want to get together in say, you know, kind of really do some brainstorming and that can happen on the phone just to say, well, what do we think we want to answer here and what are the most appropriate questions?

Woman: Can I ask one more general question. We have like six key questions or sub points. You said these are using the more general format for the evidence-based approach. These are huge. This is like vast, all of hemophilia here on the half page. Are we going to try and narrow that down and then put a couple of key questions to the literature searching people? We're not really expecting the literature searching people to get every piece that addresses 1 through 6 are we?

Donna Sullivan: That's the purpose of our discussion of our now is to kind of put frames around the research. We're not going to go back to 1990 or the 1900s and start looking for research on hemophilia. We can frame to say, okay, in the past 10 years, however many years, go back and look and then we can also willow down what the research parameters are to help guide our moving forward and target what we want them to look at. Also, I mean if it's common knowledge with us that we really know that there's no evidence out there we don't want to focus that as a key question.

Dana Mathews: Except for that it might be a great place to get evidence.

Donna Sullivan: Or the lack… yes. And so Mike and Heidi on the phone, I believe that Leta just emailed you the questions to make sure that you actually have them in front of you. So if you're at a computer those should be in your in boxes.

Mike Recht: Okay. Great.

Heidi Forrester: Thank you.

Mike Birmingham: This is a second Mike on the phone. I appreciate that too.

Dan Lessler: I'm wondering if we want to just take these and go through and consider them 1 through 6 here and discuss them, get feedback and think about them.

Ray Hanley: The Evidence-Based Practice Center, we've been working with them for the Prescription Drug Program for about 10 years and these questions are very consistent with all of the drug classes we've been through. So as we're working towards scope, if you think this is too broad, it's not too broad for them. They can go through the literature and pull this stuff out.

Dana Matthews: I believe they can, but we have basically a year and a half to plan for. Some of these questions are really big and we know that there have been some big studies that try to address these questions that have come up with the answers and some that haven't. I mean I believe they can do it, it's just kind of a question of how much effort.

Ray Hanley: Narrowing scope, yes. Resources and schedule. That's what you guys are up against.

Donna Sullivan: Part of what the center will do is if there is already good summaries of evidence out there, where there's been meta-analyses done or a large summary of review they will start from there and work with that. They are not going to go back and recreate the wheel on some of those pooled analyses, meta-analyses, or summary reviews that have been done by another qualified evidence-based organization like the Cochrane or AHRQ. Even some of the ones that are done overseas. So they do… that

is something that we can say, you know, look for summary reviews, start from there, we don't want you to go back and do pulled comparative effectiveness analyses on head-to-head trials or on placebo-controlled trials.

Rebecca Kruse-Jarres: I'm looking, for example, at the first question comparing the efficacy and long-term effectiveness of all of these different drugs that are used for hemophilia. We would love to know that data, but I think that's almost impossible to get, and certainly impossible, you know, prospectively for us to collect in this collaborative that's impossible because it takes way too many patients for way too long to see what long-term effectiveness is and every clinical trial didn't look at, you know, if you're trying to do a meta-analyses wouldn't even have the same long-term effectiveness and I think this would be an impossible question, in my opinion, question 1 is not possible to really address in this collaborative.

Dan Lessler: I'm wondering if we're thinking about this work in different ways. Let me see if I can help and Donna, maybe you can help as well. So really this is… we're talking about a literature review here and we're talking about if there are gaps, for example, [inaudible] acknowledge related to question 1 then this would identify… this might identify those gaps. That doesn't mean that in terms of any clinical research that you would undertake that you have to address those particular gaps. This is really to… as the legislation says, to identify best practices, which frankly would be helpful to us as a purchaser, and to identify gaps. I think concurrent with that, now concurrent with that is presumably the work that you will also… or would undertake with respect to identifying, you know, a research question or research questions I would say in a very applied sense that, you know, can be addressed, we would think, in a relatively short time period that would yield… that would potentially yield very useful information in terms of improving the care of people with these disorders. So there's that piece. There's what you will do or might choose to do from a clinical research standpoint and then there's this which is really a review of the literature. The potential connection I see here goes back to the conversation we had, you know, just a little bit earlier and that has to do with, are there certain questions that we want to be sure to ask here that will, you know, throw into deep relief some of the gaps that are, you know, that you are already aware of that we can in

some sense codify in a report and it might be… and that's why I say I know the conversations around dosing seem to be of great interest. What would be the question and then they will go back and summarize, you know, review and summarize the literature and say, "This is what's known. This is what's not known," kind of thing.

Rebecca Kruse-Jarres: In thinking about what we're trying to achieve here, I'm kind of starting at the end point and saying… for example, and this is what would be [inaudible] for the state [inaudible] and this is the example, but we still don't really, really know how to dose factor on ideal body weight, on actual body weight and there is conceivably it's really that you can probably dose at an ideal body weight and there's a little bit of body literature out there, but really nothing conclusive. So I think looking at that would be… this is… what is the right thing for our patients? If it's really true that ideal body weight is the way to go we're going to save a lot of money and we've done a cost analysis kind of projecting that. And that would be something where we can do literature review. We can even do a basic science review why that would or would not be and then we can actually do the clinical trial within that year and a half and answer that question. And then we actually have a gap, we have answered, we have evidence, and you can take it from there and then we can make recommendations based on that. Some of these questions on here are definitely gaps, big gaps. Some of them are being answered as we speak. There are big collaboratives that are already working on that and I think what we are also throwing in here is there are some products, but there are all these new products that are coming out in hemophilia right now that are really going to muddy the way and if we are answering this with these products, are we really going to get something meaningful that's going to change practices and save costs in the long-term with all these new products coming out anyway. I think answering something with these newer products like the longer acting ones we can do… that can be wrapped into the weight-base dosing and we can look at it and that's going to answer some questions for tomorrow, as well as today, and is going to result hopefully in cost savings.

Donna Sullivan: This is actually great discussion because I am no… I have no agenda here. I am in no way married to these questions or these products. What I did is I just went through our clinch processing system and looked up what

was available. I am not a hemophilia expert and I have no clue what is in the pipeline. Hearing that there are new products in the pipeline or that are coming out, it might be better to really target our reviews to is there published literature that's available now and where is the place in therapy for these new products compared to existing products on the market? And possibly looking at, you know, starting with question number 4, instead of going back to more basic science review looking at, you know, what are clinical strategies being developed with respect to appropriate use of care? If you can identify what kinds of products that are the new products, you know, targeting… looking at what their place in therapy is compared to existing treatment, and then, you know, factoring in your weight-based dosing as well. So again I think that's some really good feedback on how to revise these questions and really target it to what we know and relying on your expertise of knowing… kind of having a rough idea of where the gaps already are because you're familiar with the literature base.

Dana Matthews: I would agree and I've always thought that was an interesting question with a potential big payout in terms of cost savings – the ideal versus actual body weight and I think it's interesting to compare in pediatric versus adults and pre-pubertal kind of biologic children versus the pubertal teens that are kind of more biologically adults. I think we have enough patients where we could get some meaningful answers there. And then the other question I'll just throw out there, not that it's necessarily the next thing to do, but we've been having bi-regional meetings for years and we all sit around and ask each other what we do for a portacath placement or, you know, what do you do for a head bump? And there is so little evidence out there upon which to base our dose, you know, how many days after a portacath placement do we treat? We can't easily come to a consensus but I also think perhaps… farther down the line and what I hope will be an ongoing collaborative that there are some opportunities there and that's probably, I think, under number 4, kind of clinical strategies. You might, I guess, try to put, you know, overweight versus not overweight into comorbidities, but it doesn't really matter. I think the concepts are similar.

Dan Lessler: What that specific question grew out of actually I think it was, I can't remember, it might have been Mike and this is Stephanie when we first

met, you know, a long time ago. But there was discussion about, you know, I think it was using ultrasound and maybe hand-held ultrasound to assess joints for bleeds and so forth and I know nothing more about the detail except that, you know, the issue of pain, which, you know, is it chronic arthritis or is it a recurrent bleed? And so… and so just coming back to the question and to your point, you know, maybe what we could do here is really axe questions 1 through 3 in some sense, I'm just putting this on the table. Look at 4 and develop a set of sub questions along the lines and you might think, you know, clinical strategy weight-base versus… or ideal weight versus true weight dosing might be, you know, that could be considered a clinical strategy, use of hand-held ultrasound, other things that you're much more familiar with whether it's worth… and one could pose a question around, you know, portacaths or as you say what do you do for head bumps and so forth. Things that it would help identify some very practical gaps in knowledge and among those would be one, you know, at least one such as the weight-based dosing that you could, you know, then address in some directed targeted clinical research.

Rebecca Kruse-Jarres: So I think for your questions, and that is definitely a gap, but that could maybe be retrospective review. We'll just do, between all our centers, rather than a press-based… so it's something that can be done in the timeline and put that together with a literature review, which I don't think there is a lot out there, but I think then that would be very…

Dan Lessler: So I think, and actually, you know, retrospective reviews likely I would imagine are very important in your field. Just a couple things here, one is that they do take… I would put on the table how much resource and time is available to actually accomplish, because a retrospective review across multiple sites could in fact be your entire… what you do here as opposed to a dosing study. I would imagine… I find it hard to think that you would… that you could actually accomplish both in the timeline that we're looking at here.

Having said that the other is just a very practical piece, if I may, and again you know, just going back to the legislation and what sort of got us thinking about doing this… some kind of targeted literature review to identify gaps and best practice is we do need to have a report to the

legislature in August and it has to have some substance to it. Ideally it would also help inform any work that you might do or help you in [inaudible] future work that you might do or help inform us as a purchaser. But I think part of what is driving is, you know, we do have that set timeframe for a deliverable.

Rebecca Kruse-Jarres: I'm painfully aware of that and I think that is most important for me that you have data or is something that you can present by August. I think we really need to think about what can be… we're going to set ourselves up for failure if we plan some big clinical trial. I keep going back to the weight-based dosing. I think literature review would be very doable before so you already identified the gap and then saying [inaudible] and these four sites are set up and they already have… this is the preliminary data on the first so many patients. Would that be something that is useful for you to present in September?

Dan Lessler: I would say, yes. Our thinking about this just again from a practical standpoint is, you know, we launch a literature review based on input from collaborative members in terms of the key questions. We get MED working on that and then we have you all, you know, coming together around what question or questions you want to address in a clinical research context and to the extent that, you know, for example the review identifies some gaps around weight-based dosing and we've got a report that's going to the legislature and we can also say, "And in addition to this these four sites have embarked upon clinical research to answer this important question." That's all to the good.

Donna Sullivan: I guess my question is… it sounds like are you already doing some weight-based dosing within your clinics at all? Okay. So I wasn't sure if that was already a practice that you were working towards.

Dana Matthews: I mean we dose… in pediatrics we dose per weight all the time, but we dose for actual body weight.

Donna Sullivan: For actual body weight and I meant the ideal body weight.

Dana Matthews: No, we have not done that in any way. No.

Donna Sullivan: I just wanted to make sure that that was part of what you were considering as a retrospective review of… if you were already doing that in practice and we were just going back and looking at those cases. That would be a different story than…

Woman: This would be prospective.

Dana Matthews: I could imagine some power in a retrospective review of portacath placement, for example, as preliminary data for a study down the line. I hear what you're saying about resources and timing. It's just that each one of us centers may put three or four ports in a year and so you can't do it prospectively very quickly. I guess I'm partly throwing that out there because I think it's nice to have more than one idea for us to be thinking about.

Donna Sullivan: Absolutely.

Dan Lessler: Sure.

Rebecca Kruse-Jarres: Just to get back to the ultrasound is… fits this bill completely, but unfortunately that's… it's not prime time for that yet. Most of us don't have ultrasound machines yet. It takes a long time. Should this ever go forward in the future then this is going to be very appropriate cost-saving measure potentially, but we're not quite there yet.

Donna Sullivan: That's good to know. I might be completely off base. I know just enough about it to be dangerous. I guess my question was, is there the concern of using factor prophylactically as opposed in reaction to an actual bleed? Is there any evaluation or literature that we want to look at or a question that we want to look at regarding that or am I completely unfounded and off base?

Mike Recht: The… in pediatrics at least the question of whether prophylactic administration of factor is beneficial has been answered and is the positive. There are multiple trials supporting the use of prophylaxis.

Ryan Pistoresi: So what type of measures and outcomes were they looking at? Because I had a question, which came in as number 5. I'm curious about patient

reported outcomes, quality of life measures. And so are those questions that have been answered in those trials? Or were they specifically looking at clinical outcomes?

Mike Recht: Two big trials. The American trial and the European trial were both looking at clinical outcomes.

Rebecca Kruse-Jarres: And radiologic outcomes.

Mike Recht: Right.

Rebecca Kruse-Jarres: But Mike, correct me if I'm wrong, was there not a quality of life attached to that?

Mike Recht: There was no patient-reported outcome in the joint outcome study. I'd have to re-read the study to see if there was any in there.

Dana Matthews: I guess it's interesting… I'm sitting here quietly bristling. It's like if you ask me to take my prophylaxis patients off prophylaxis there would be a huge outcry from everyone, especially the community. So it's just interesting for me to reflect on that. So you're asking great questions and there are limits to the studies, but I completely agree with Mike's statement that the studies have shown definite benefits to prophylaxis.

Mike Recht: Yeah. That's an asked and answered question.

Man: Thank you.

Stephanie Simpson: I'm from the patient's side of it and I just want to kind of note what we're doing here. From all that we know this is the first time that payers, patients and providers are sitting down at one time to talk about this. So it's a little uncomfortable, it's a little odd. I'm like, "Oh my gosh, I'm going to get a lot of calls tomorrow." But I think it's really exciting and it's something we can all sit here and do and really reflect and honor that the state legislators saw this is a state that we can all respect each other to ask these questions and all be a little uncomfortable in our seats. But you guys, this is the first group doing that, so I think that is something for us all to be aware of.

Heidi Forrester: Thank you, Stephanie.

Donna Sullivan: Do we have any more discussion or any other like specific topics that we feel the questions are missing? Is there… I guess based on the… we've discussed prophylaxis in children. Is it still beneficial to look at patient reported outcomes and quality of life in adults? Or other populations? Or is that a question that we feel has been asked and answered?

Ryan Pistoresi: I'd just like to add that if we are developing a cost benefit… cost effectiveness or a cost utility analysis with this project, which is one of the deliverables for the legislature we should have some form of outcomes that we're looking at and I think understanding if there have been non-clinical trials that are looking at patient-reported outcomes, especially observational trials, or looking at quality of life, and actually I forgot to add one thing to that. I'd like to propose that we add it now, but to look at indirect medical costs with this. Because I'm sure as we all are aware that we're not just looking at the cost of the pharmaceuticals or the biologics. We're also looking at administrative fees, time loss to go into the hospitals, time loss to events and things like that. So an oversight on my part, but I think that would be a good thing to look at. I know that I've looked at a few cost utility analyses yesterday getting prepared for this and I did see that there are a few interesting ones out in Italy looking at different prophylactic schedules versus treating on demand and I think that they would have some robust information that we could use. But I'm also curious from an American perspective, because I know utility values in Europe, cost values in Europe, do not translate well to the US. And so if we are going to be developing a model to understand the impact of what this collaborative hopes to accomplish I think we should continue and see what research is available even if it is a question that has been answered, to what degree has it been answered? How significant are these patient-reported outcomes? How significant is this change in quality of life? And that would be incorporated into the cost benefit analysis or cost effectiveness analysis.

Rebecca Kruse-Jarres: I'm going back to, you know, doing any kind of comparison between on demand versus prophylaxis that… horse is out of the barn, you know, the standard of care is to put people on prophylaxis. Even if you would show

that their quality of life is the same you wouldn't go to on demand… back to on demand dosing. So I don't think, you know, even if we show a big difference I don't think that it's going to have any impact on how we're practicing or on cost or anything. So I really think that whatever we decide to do let's really think about is this then, in the end, does it have the potential to effect and reduce cost?

Ryan Pistoresi: Correct. I was just saying that the on demand versus prophylaxis was one of the papers that I read and it was an older paper, but it was just an example that I wanted to bring up because it helped provoke these questions that I then brought today. I'm glad to hear that the current practice is the prophylaxis because that was the one that was most appropriate from the trial. So I'm glad to hear that, but I'm still curious what other data is out there and what… and to what quantities these data show. So that's more in line, not so much the on demand versus prophylaxis, which was… between the prophylaxes for other schedules. I'm still not as familiar with the hemophilia's, obviously, you all are.

Rebecca Kruse-Jarres: We've been doing this for a couple years.

Donna Sullivan: Kind of what I'm hearing from the discussion is that there seems to be general consensus within the collaborative members here, as well as the practicing community of when to use factor. The question really is how much factor do we need to use and is there a better way for us to predict who really, you know, is there an active bleeder or not an active bleed?

Rebecca Kruse-Jarres: The active bleeder or not, that I think would be answered maybe more with the ultrasound that we're not quite ready for, for many reasons. If you have an hour I'll give it to you now, but you don't.

Dan Lessler: In terms of a review we might do. That would be useful just to define that gap and see what, you know, what's there.

Rebecca Kruse-Jarres: There's actually a paper that was published on that relatively recently that looked at. If people are coming in with pain 50% of the time they are really wrong in saying this is a bleed or not. So that gap is already identified and that gap is trying to be filled with ultrasound. So that's actively being worked on.

Mike Recht: I agree with what both Dan and Rebecca are saying in that a gap at a single center has been identified. If this is something that we want to move… this would be like the perfect second stage project, for example, in that maybe the next year or the year after that, if funding continues, as our little northwest corner of the country we roll out… we tech people and roll out how to use ultrasound effectively and demonstrate the cost effectiveness, cost utility of such a project.

Dan Lessler: Thanks for that, Mike. So, again, I think the purpose of the literature review is to summarize and just make explicit to the legislature what the gaps are. We know that you know that there are gaps.

Rebecca Kruse-Jarres: I think with that in mind, you know, summarizing for example what is known about dose… treating bleeds or not bleeds and how that can be identified and what are all the gaps and what are potential solutions, that would be an interesting review.

Ryan Pistoresi: I'm also looking ahead towards one of our deliverables, which is the June 2016 cost benefit analysis and I think this literature review would identify a lot of these variables that would be, you know, the input to this cost benefit analysis or cost effectiveness analysis. So I do think in that regard, even if these questions have been answered, we can use the data from these trials to build this cost benefit analysis for Washington State patients and I think in that regard, you know, it may not be as appropriate to some of these other deliverables, but I do think for that deliverable it would be useful.

Rebecca Kruse-Jarres: Are there any other ideas and thoughts about gaps that could be identified or…

Stephanie Simpson: So from the patient perspective, some things that they have kind of mentioned is being able to give pain management, and this may be off grounds, because I am not a physician to any extent, so you can smile and nod, is that pain management being done… like if they have arthritis they get arthritis meds versus narcotics, because right now they can't get as access to arthritis meds off of Medicaid, so therefore we're creating

really expensive patients to be potentially addicted to narcotics. So that would be a cost reduction.

Also looking at whether or not a patient who receives services from Medicaid can get in-home nursing services or home care during specific time periods. Is there a way to do like a panel of three physicians? We say, hey, this patient is… they are living in utmost poverty. The dad was deported, they cannot keep this child safe by doing self-infusion at home. Then we initiate using an in-home care? Obviously right now we can't do it because it's written into state law, but that would definitely be a cost-saving measure as well. I think always, and this is a big one, how do we avoid inhibitors? Any practices on that? Any practice to avoid inhibitors?

Mike Recht: We learned about this at ASH.

Stephanie Simpson: I can't help it if I set you up, Mike.

Rebecca Kruse-Jarres: Especially the period home care I think is a really important issue. That is something that we can do a literature review on and see what the gaps are and see whether having this periodic home care, for example, after a surgery does that then result in less complications, re-admissions, days lost from work, school.

Dana Matthews: Can I not put Amanda on the spot too much, but Amanda has been in Texas and you're just coming here to Washington State. Is there anything, and we're all talking a lot, is there anything from your outside perspective that comes to mind that you wanted to mention?

Amanda Blair: It's all very similar to conversations we had as far as cost reduction, having limitations with our patients on Medicaid, plans and access to care at home, nursing services. I don't feel like there is anything really that hasn't been addressed already.

Rebecca Kruse-Jarres: I just thought of something else. Another literature review would be the use of antifibrinolytics because that's a lot cheaper than clotting factor and just do a literature review what's been done with that and this would be a potential cost saving to use those together with clotting factor and see whether overall there's less use.

Mike Recht: That's interesting, Rebecca. Yeah, that's good.

Donna Sullivan: I just want to kind of get some clarification so when I try to incorporate maybe into a question. So would it be the use in antifibrinolytics versus clotting factors? So would it be replacing clotting factor or in addition to clotting factor?

Rebecca Kruse-Jarres: No. It would be in addition to and by that maybe a reduce… and I don't know what's in the literature. My thought is there is probably not going to be an overwhelming amount. But this is something that I've been thinking of for a long time, you know, can we reduce prophylaxis, for example, and maybe not give as high of a dose or not as often if we also give something like [inaudible] or tranexamic acid.

Donna Sullivan: Okay. Thank you.

Rebecca Kruse-Jarres: And that would result in huge cost savings.

Donna Sullivan: Michael, did you have some comments?

Mike Recht: No. I just think that was genius.

Donna Sullivan: I think this has been great discussion.

Dan Lessler: Yeah, it has. That's what I was going to say. I think this has been very helpful and what I'm… I might be jumping ahead a little bit, Ray. I apologize. Donna, I'm thinking we can kind of put these together and create another version of questions and then send them out to the group and maybe that could be the… one of the discussion items for the next… to finalize at the next convening.

Donna Sullivan: I think that was great. I was just about to ask if we think we're kind of… hit all the topics for today. We can table this discussion. Ryan and I will work together with revising the questions and get them out to the group and get a meeting scheduled potentially for next week or potentially the week between Christmas and New Year's based on people's schedules. And then I think now would be a good time to segway to the next agenda

item and see if there is any feedback from the stakeholders that have come to the meeting. Leta, do we have a sign-up sheet or no?

I guess I'll just turn around and ask if any of you in the audience if you would like to speak or have comments, please feel free to proceed up to the podium and introduce yourself and let us know what you feel about the collaborative and the discussion that you heard and the reason I ask you to come up to the… you can actually go over there and sit at one of those microphones, but I just ask that if you do want to make some comments that you speak into the microphone so we can capture your comments for our public record.

Shirene Boss: Hi, Shirene Boss(?), clinical pharmacist with Premera. I want to echo the comment that was made around longer acting newer agents and maybe one of the questions would be in what clinical situation would a longer acting agent be preferred or better… whatever terminology, compared to one of the traditional practices.

Rebecca Kruse-Jarres: We know that there, you know, factor 8 not being that much longer and factor 9 being somewhat longer. So there are some patients where I think this is very appropriate to use, but when we are talking about this collaborative I think these are just gaps that we're going to be talking about in maybe five years, but you can't… there's no literature in comparing them yet really. I don't… I think it's way too early and not really the… good for this collaborative to do any research around that. I think that's way too complicated and takes too long.

Shirene Boss: And I understand the short timeframe. I just wanted to put that as one of the questions.

Dana Matthews: It's a great question. We all want to know the answer and we're all, you know, we're having these discussions with patients. Most of us haven't really taken a deep dive into… in terms of [inaudible] for payers yet. So it's a great question, but I agree with Rebecca that it's a big question and very ambitious and there's gonna probably have to be some pretty big studies going forward including quality of life and cost, you know, pokes, bleeds, costs, all of those things that are going to be some of the next big questions in our field.

Mike Recht: I concur.

Joan Zurzan: I'm Joan Zurzan(?) with the Children with Special Healthcare Needs Program at the Department of Health and I was just curious about the whole discussion about weight-based dosing for pediatric and your use of ideal body weight. Is that because your population in general has a different composition or you're concerned about over fat? And are you… what are you using for ideal body weight calculations?

Rebecca Kruse-Jarres: This is just an observation I made maybe… before I was in Louisiana for 10 years and there is certainly a lot of obesity there and we traditionally always face factor on actual body weight. So sometimes you have a kid that may be 200 pounds and you're thinking do they really need that much? And very, very, very limited and anecdotal experience is that I just did some pharmacokinetic studies and I said, well… and they got much more factor or their factor went up much higher than I would have predicted by their body weight. So that made me think about ideal body weight and is that the right or is it the ideal weight, is it something in between? We just don't know. We're just giving it based on the actual body weight and I'm just wondering whether we're wasting a lot of factor and what does that do as people are… then get older do these very high factor levels that maybe are not desirable in an older population that now might be at a cardiovascular risk if they are getting older.

Joan Zurzan: My follow-up question was how do you… how are you defining or is that something you would be working out how you are defining your calculation by ideal body weight?

Dana Matthews: As a pediatrician we would have to agree upon a method. It's somewhat controversial. The factoring in particular has a very… it's a big molecule so it has not got as big of volume in distribution. So there might be pharmacokinetic reasons why you wouldn't… it wouldn't go out into the several kilograms of lipid in a patient. But it's a great question and I'm sure need to pull in some experts to make sure we were using a method everybody could agree on.

Joan Zurzan: Thank you.

Donna Sullivan: Any other comments from the stakeholders? I don't think we have any stakeholders on the phone, but I just want to reach out to that. Okay.

Ray Hanley: So with that I guess we can, unless there's any further discussion, we can bring this meeting to a close and…

Donna Sullivan: I do want to summarize the next steps of what we… kind of what we agreed upon. We will bring back the revised and edited charter for… just for the final… this is what we discussed today and this is the charter that was approved earlier today, as well as bringing back some revised key questions and getting calendars booked for meetings weekly either or Tuesdays or… Wednesdays or Thursdays at 7:00 a.m. So we will get that out to you and start working on that later.

Rebecca Kruse-Jarres: Before we close the whole thing around the project manager, because I think that's going to be very important to get this… this about who this person is going to be and… because that takes some time to hire and I don't want us to have… wait for the next meeting and the next meeting and the next meeting and then it's March and then we start hiring. We're not going to set ourselves up for success. So I think deciding on that sooner rather than later and with that coming the whole contract will be very important to make sure that we can deliver on time.

Donna Sullivan: Sure. I think you and I can work offline on contract language without having to be open public negotiations of the contract language and bring it back to the meeting. So we'll do that.

Rebecca Kruse-Jarres: Okay.

Mike Recht: Before the close I do want to say I apologize for not being there. My intention is to be at the face-to-face meetings as often as possible, but while I was sitting here I actually re-booked for the 8:00 flight to Seattle tonight.

Woman: Hey, we can go out for dinner.

Mike Recht: Right. And I got 5,000 miles on my frequent flyer program. So there you go.

Ray Hanley: Thanks, Mike. With that I just want to thank everybody for coming out today. A productive meeting, first meeting of Bleeding Disorder Collaborative and until we meet again. Thank you.

Dana Matthews: Thank you.

Dan Lessler: Thank you.