Emerging Therapies Workgroup
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Valerie King: So, let's go to the first real slide here. What I'm going to attempt to do in the next few minutes is to kind of do some reviewing for you. This is stuff that many of you already know. There is a relationship between pharmaceuticals and Medicaid that is pretty unique and special. As advertised, we are going to talk about evidence and the hierarchy of evidence that is used to support the coverage decisions that you make in state Medicaid and other programs. Just to acknowledge here that we know that evidence isn't the only piece that goes into those decisions, but it's a key piece. Then, we're going to think about what states like Washington could do when there is little firm evidence to support a decision, particularly delving into the concept of coverage with evidence development and some aligned innovations. Then, you're all really going to be thinking about best pathways forward for Washington, as you make recommendations on this taskforce.

So, let's talk a little bit about pharmaceuticals and Medicaid. We really know that prescription drugs are a big part of healthcare spending and certainly of Medicaid budgets. They are the fastest growing component of healthcare spending in the U.S., and that's really due to two factors. One is that there are a lot more high cost specialty drugs coming onto the market, including genetic therapies, and the second is that those drugs can be extraordinarily expensive. So, when we're talking about these kinds of drugs, we're talking about some really important innovations. There are all kinds of new oncology drugs. There are new treatments, including genetic treatments for sickle cell anemia, hemophilias, Washington is well experienced with thinking in the hepatitis C space around direct acting antivirals, and then there are all kinds of genetic neurologic disorders that mostly come to be prominent in children and are life limiting or life ending, things like spinal muscular atrophy and Duchenne's muscular dystrophy.

So, this is a graphic from a recent January JAMA Darrow and colleagues. I don't expect you to read all that small print, but what I do want you to understand is that there's just been a lot of movement in the last few years, particularly since the year 2000, around changes in FDA programs,

rules, and regulations, and really since the Orphan Drug Act came in, in 1983, all the way up to 2016, the 21st Century Cures Act, that these have all increased the speed with which products move their way through the FDA approval process. And that is on one hand great for patients who are waiting for these drugs. On the other hand, this means that the evidence that we have to support the clinical decisions that you, and others, need to make about these drugs is weaker.

So, this is from the same article. All I want you to appreciate here is that there are many more drugs that go through these expedited processes. So, you can see that trendline going up. Then, on the right hand side of the graphic is just all the various programs under which those particular drugs are moving through.

As a clinician, while I am actually kind of excited about many of these things that are coming out, and I think that the pace of innovation can be just really inspiring, there are problems on the other side of that. So, about 80% of drugs that are newly approved by the FDA benefit from at least one expedited program. The proportion of these new approvals that are supported by what used to be the minimum of two pivotal trials, has really decreased from the vast majority of 80% in the 1995 to 1997 time period to just a little over half of them in 2015 to 2017. The average trial size, RCT size, did not change during that period. So, it just means that we have fewer patients overall contributing evidence on these new drugs. The other issue is that overall drug approvals are really being based on not only fewer trials but earlier stage trials. So, things that used to be supported by, for example, a phase 3 study, or two or three of them, are now being supported by studies that might not even be randomized, blinded, controlled, or based on outcomes that matter to me, as a physician, or to my patients. So, the FDA, when it faces this situation of approving a drug on limited evidence and these expedited processes, does require post-approval studies. Unfortunately, about a third of the time, those studies are never done, and when they are done, the vast majority of them, two-thirds to nearly all, are done using surrogate outcomes that were often used in the approval study, and only 5% of those drugs ultimately end up being able to demonstrate superiority over comparator drugs.

So, I want to give you an example of that, that's fairly near and dear to my heart. This is the issue of 17a hydroxyprogesterone caproate, abbreviated 17p. The brand name is Makena. So, between 2003 and 2011, 17p was available and used by perinatologists and my colleagues, and it was available as a compounded product. So, you had to order it at a compounding pharmacy. It would be turned into an IM injectable product, and the patient would get it, either at your clinic or administered at home. Preterm birth is an incredible issue in the U.S., as it is in many countries, and it's an area where there is a lot of disparity. So, it was an important thing that we felt that we were offering our patients. The FDA approved the brand name, Makena, via an accelerated approval pathway based on just one RCT that used a surrogate outcome, that being, um, gestational age, and there were some other methodologic limitations in that one RCT. In the approval, the FDA required a second confirmatory trial. That was actually not begun until 2009, and it was really difficult to mount that trial, because it essentially had become standard of care in America. So, the confirmatory trial was done in really different populations, a lot of them international. So, there were other kinds of issues with that. When the drug was initially approved, it got seven years of exclusivity under the Orphan Drug Act, and between the time that the pharmaceutical maker, AMAG, bought the company and purchased in 2014, and the entry of generics into that space in 2018, Makena made 1.2 billion dollars for the company. That's a lot of money. An awful lot of that was paid by Medicaid programs, since Medicaid is the single largest insurer of pregnant women in the U.S. That confirmatory trial did eventually publish a few months ago, and it did not find improvements in the surrogate outcomes of gestational age, preterm birth, and importantly, it didn't find any differences in the real patient important outcome of perinatal mortality. So, last fall, and FDA advisory committee recommended that the FDA withdraw support approval of Makena for preventing preterm birth. We are still awaiting a final FDA decision on that.

There are some other issues around Medicaid, in particular, and drug approvals, and the most sticky wicket of these, and I can't at all pretend that I understand the Medicaid drug rebate program, or the MDRP, as well as people like Donna Sullivan do, but the MDRP has been around for a while, since 1990. It's a voluntary rebate agreement between drug

manufacturers and Health and Human Services. Its manufacturers enter into the rebate agreement. They are assured coverage of their drugs by Medicaid and Medicare. Although the program is voluntary for Medicaid, all states participate and are bound by it at this point. That rebate agreement assures that states are supposed to get a rebate on the drug price and that they are paying the lowest possible price, or the best price, in the U.S. market.

Under the MDRP, as you are probably well aware, states have pretty limited management tools. They have to cover the drug in some way if the federal rebate agreement exists. They are allowed to negotiate supplemental state rebates, although the terms of these agreements are confidential. States cannot use closed formularies, although PDL's are allowed, and prescription limits are regulated under this agreement. States can use prior authorization criteria with the PDL and medical necessity criteria setting into those prior authorizations, but in the end, if it's FDA approved, under the MDRP, states are going to have to cover that drug in some way, even if the drug is incredibly expensive and crowds out other things the state might want to do, and even if that drug has limited or no evidence of its effectiveness or efficacy.

So, as you're well aware, newer and higher cost therapies are increasing, and while that's exciting, state budgets, particularly in the time of COVID are really finite and getting more so. Most states have balanced budget requirements. So, the tradeoffs are real. States don't have the option of printing money. So, states are looking for better tools to make sure that drugs get to the populations that need them, but at the same time, not going broke doing so.

So, let's talk a little bit about evidence hierarchy. You can go forward a couple of slides. This is a slide that probably looks a little bit complicated, but I'm going to talk you through the main pieces of it. This is a fairly traditional look at what we call an evidence hierarchy, as we move from the bottom, which is ideas, editorials, opinions to the top, our confidence in what we can say about the evidence increases, and that's because the quality of the research is also going up. So, let me give you an example here. Evidence really comes in two main flavors. The first are observations. The second are experiments. So, if, for example, you

wanted to know if smaller class sizes improves test scores, you might do an observational study. You could observe that class size correlates with test scores. The obvious problem with that is that there are all kinds of things that confound the relationship between class size and test scores. So, for example, maybe kids who are in the smaller classes are more likely to come from more privileged backgrounds. The difference in test scores that you are attributing to class size could really be due to that and other factors that go along with being in a smaller classroom. Randomized control trials are a type of experiment. They try to address the problem that we see with observational studies by randomly assigning, or allocating, people to receive the intervention, in this case, the class size. So, students could be randomly assigned a classroom with 35 students or to a classroom of 17 students, and when randomization is done properly, and the study is a big enough one, all of the other variables that could influence test scores, like the educational attainment of one's parents, could be evenly distributed between each group, bigger classes, smaller classes. That allows you to essentially isolate the effect of class size without the interference of all those other variables that can have a tremendous effect on educational performance, and that's why randomized control trials are thought of as bringing more reliable evidence than observational studies.

What I just want to say with this graphic that we also recognize that there are differences among these types of studies. So, you can have a randomized control trial that is small and, excuse my French, really crappy. In that case, a large and well done observational study can actually provide better evidence than a randomized control trial, but you have to look at both of them and see what they each bring to the table.

Unfortunately, why we bang on so much about randomized trials is that we have lots of examples of interventions where they come into being and into common use without sufficient evidence, and sometimes with almost no study at all. So, I've given you here examples that all come from the pharmaceutical world, but there are plenty of examples of surgeries and other interventions where somebody just thought it was a good idea. There wasn't even an FDA looking at one small crappy trial. So, in the pharmaceutical realm, we've talked about the 17p example. Most of you are probably aware during influenza season that Tamiflu was

stockpiled by many states and other governments in the event of pandemic influenza. As it turns out, there were a lot of suppressed studies about this drug that the manufacturer held back. When those studies finally came to light, a high quality Cochran review that pooled all of those studies together, the good, the bad, and the ugly, um, really found that the drug is remarkably ineffective. It maybe gets people over their worst of their flu symptoms by a few hours to maybe a day, but it doesn't really keep people from dying from influenza, which is the thing we care about, or being hospitalized for it. So, it ends up being a case of both wasted money and on the part of governments that stockpiled it, also a sense of false security that they had something to really offer in pandemic influenza. They would have been better off widely encouraging immunization. Another example is antiarrhythmic drugs like Flecainide used after myocardial infarction or a heart attack. They do suppress arrhythmias that you can see after a heart attack. Unfortunately, in suppressing those arrhythmias, it turns out they actually suppress the heart, too and were pro-arrhythmic in some cases. So, they actually ended up causing excess deaths and that wasted money. It wasted lives and also, on the part of my guild of clinicians, created a false sense of security that we had and also transmitted to our patients. Bad idea. You're probably aware of Vioxx used for osteoarthritis several years ago. Although it really is a pain, um, osteoarthritis is not a fatal condition, but the drug caused excess myocardial infarction deaths and other cardiovascular events like stroke. That's all for a condition that probably can be treated in other ways. Then, a couple of weeks ago, the FDA revoked the emergency approval for hydroxychloroquine and chloroquine for COVID-19, because although data, I think, are still accumulating, there were excess stats and a lot of wasted money in that space.

So, I feel for you. Here you are in a circumstance where there is a fair amount of poor evidence, and you are trying to make recommendations to the State of Washington, and oh my gosh. What are you gonna do? What can you say here? So, are states to simply throw up their hands and say we'll cover it for all the FDA indications? OK. We get the rebate, and we'll get the best one we can, and we'll negotiate for the best supplemental we can. States have a little bit of room to move about basing medical necessity criteria on characteristics of the populations

that were actually studied in the approval trial or trials to limit use to the population that was included in those studies. Strict adherence to that kind of medical necessity criteria, that which mirrors the approval trials, it's a little bit difficult because that doesn't work well at all if the FDA approves drugs with no evidence of efficacy. It doesn't work well for children where EPSDT rules apply. It doesn't work well when states have protected drug classes. States can move forward with conditional coverage, um, conditional continuation criteria based on progress. So, is the drug doing for that patient what it was advertised as doing? Or is the patient essentially getting no benefit from it? States can negotiate price based on volume or exclusivity, usually with waivers. That's kind of what Washington has done with Hep C treatment. States can enter into, with manufacturers, a price that is outcome based. They can pay on time. They can require data for coverage and use that data to subsequently cover the drug differently than they did initially. I don't know any state that is just printing money. Even if you could, it's probably not just about cost. It is about people's lives and trying to do the best thing for them that you can.

So, let's talk about one of those innovations, coverage with evidence development. Go to slide 17. So, coverage with evidence development is something that is allowed by CMS and done, I would say, with reasonable frequency, in the Medicare program. Although this guidance was issued in 2014, it's actually been done longer than this. It was just codified in that period of time. I have pulled on this slide a quote that I think is pretty telling. This is actually kind of a small document from CMS. So, feel free to read it yourself, but it acknowledges that CMS has been challenged in the Medicare program and that they get a lot of requests to cover things, and that interested parties have high expectations whether it's patients or manufacturers. Those expectations and hopes can very quickly outstrip the existing evidence base. So, CMS acknowledged that it had a role to help develop evidence, as well as cover things in the Medicare program and that when approval studies were not really providing a sufficiently robust evidence base that they would enter into these coverage with evidence development decisions. It's important to know that it doesn't apply to self-administered treatments. So, it's only Medicare parts A and B that in the CED agreements, that the routine costs of care are covered for both the experimental and control arms of

people entered into the study. So, just the routine care that goes around the drug, the device, the intervention, is covered for both groups. Typically, manufacturers will cover the cost of pharmaceuticals or other interventions that are in the trial itself, although that can be subject to negotiation. So, the study's sponsor is supposed to bear the costs that are exclusive to the intervention itself, whether that study sponsor is industry or the NIH.

So, there are currently 23 different treatments in the CED program with CMS. I've pulled out five examples here that are pharmacologic or are things that are treated as pharmacology. So, hematopoietic stem cell transplants for a whole bunch of different conditions, platelet rich plasma injections for nonhealing wounds, bedsores essentially, and diabetic leg ulcers. The off label use of a whole host of drugs for colorectal cancer. Again, near and dear to my heart, these last two are things that your Washington HTA has taken on in the last two and a half years. So, pharmacogenomic testing for warfarin dosing early on and vagus nerve stimulation for treatment resistant depression. In the case of both of those things, your HTA clinical committee decided that there actually was plenty of evidence to decide that neither of those things would be covered and made that decision, but there are CED's in the Medicare program. In the case of vagus nerve stimulation, the clinical committee actually spent a lot of time talking about whether people could appeal to be in the clinical trials. There is a way of doing that through the Washington Medicaid program and other insurance. So, CMS will stop a CED program if it gets to the point that there is more definitive evidence, either pro or con. So, for example, PET, or positron emission tomography, for particular types of solid tumors, mostly brain tumors but some others, as well, went into the CED program in 2004, and it was determined that it was effective as a way of helping to stage and manage those kinds of solid tumors. So, the CED was discontinued, and the intervention is just covered as of five years after that.

Private insurers have been less on board with CED. They kind of just said experimental, and we don't cover things that are experimental. One really prominent example is the WISDOM trial that is run out of UCSF. They enroll basically all the commercial insurers in California and also in Missouri, interestingly. It's a comparative effectiveness study that

compares age based screening at 40 years of age versus risk based screening for women for breast cancer. It's a big trial. It's trying to enroll 100,000 women. It really got started off because UCSF investigators and Blue Shield of California were on board and convinced other people to be on board. It was funded by PCORI. It's due to run its course and report out in the next three to five years.

So, I think you can explore coverage with evidence development is an option in the Medicaid program. As we noted before, states can allow participation in trials. In doing so, paying for the routine costs of care that they would be paying for anyway. Washington can do this. States could participate in evidence development while just covering the treatment. They could decide to cover it, but gather evidence that would help them to fill in gaps that the studies haven't answered. A lot of these conditions end up being fairly uncommon. That's not true with hepatitis C, but lots of other things are fairly uncommon and state data collaborations across states can help to gather data faster and accumulate numbers. These efforts do require a fair amount of coordination and effort. It puts a lot on the state program to essentially be running a study. To that end, academic partners can be super valuable and outside funding is something to consider, as well. So, again, it would be best if the FDA did all of this in the approval process, but that comes at the cost of time. There has been a lot of outcry on the part of the public and industry to get the FDA to approve things quicker, but there are tradeoffs there.

One example of data collaboration across states is the SMARTEN project, or the spinal muscular atrophy research effectiveness of nusinersen project. That is run out of the center that I work at and is jointly funded by the Drug Effectiveness Review Project and the Medicaid Evidence Based Decisions Project. There are seven participating states. Spoiler alert, Washington is not one of them, but Washington will get access to what is found in this particular data gathering exercise. It is looking at children who have SMA types one or two and are not already enrolled in a trial with the drug being covered by their state Medicaid program. It's looking at important outcomes, like death, need for permanent ventilation, and the child's motor function over time. It's gathering a very few other data points to help with the analysis, including age, sex, what

the diagnosis exactly was, and the date of diagnosis and the use of physical therapy or other care modalities. It's going for a 30-month data collection period and is due to complete later next year.

Just a super brief tour through other things that states can do. So, thinking about prescription drug alternative payment models, there are many things that I know you've talked about and explored on other calls.

These kind of break down into two flavors. One are the financial based models. The other are the health outcome based models. What we're really talking about so far today are the health outcome based models. You've spent a lot of time talking about the financial based one. So, I'm not really going to go there, but in the health outcome based ones, there are conditional coverage, that's coverage with evidence development or coverage for treatment continuation. That would be things like approving nusinersen for continuation in an infant or child who was improving or at least maintaining with their SMA with use of the treatment. Then, there are performance based arrangements that may be outcome guarantees so that the insurer is paying only for particular kinds of outcomes and another where the insurer may be paying for a particular constellation or process of care pattern around that condition that involves the use of that treatment or intervention.

In the center SMART-D work, which many of you on the call are aware of, we did some surveying of a bunch of states and their readiness to engage in APM development and talked to them about what kinds of drugs were ripe and ready, and were they ready to think about? The ones on this list were really the ones that rose to the surface in those conversations. So, I don't think that any of these pharmaceuticals are particularly surprising to see on the list, but I'll ask you to reflect in your conversation time about whether there's anything here that you think should be here and you're not seeing on the list.

Now, this is super similar to the graphic that Mike showed at the beginning in his introductory comments, but just to say that we know that the context and the environment in which you live and make decisions is really all important. So, you have some degree of research evidence that's available to help inform these decisions, but you also

have a population that has particular needs. You, as a state, have particular values or preferences, or needs, and there are also resources, not only financial resources but whether or not there's the expertise in your state to even do something. So, an example is CARTi therapies, and that just isn't done everywhere. So, decision making really is something that happens at the nexus of all three of these circles, but is always in the context of the bigger environment and bigger context. So, let's go to the final slide.

I think that's just questions and your discussion. So, just to sort of kick that off, some things for you to think about as you discuss are, what do you think is the role of evidence in Washington, as you make these decisions and programs and plans. How explicit should the State be about the tradeoff? Things that are potentially good for individuals aren't necessarily good for the population. There's always going to be tension there. Health is but one priority that the State has. So, how do you balance off what you're paying for pharmaceuticals and what you're covering in the Medicaid program and other health insurance versus schools and corrections and roads and other things? There are always tradeoffs. Do you think differently about this by condition, by drug, but population, by who manufactures the drug, by some magical price or quality life year threshold, or something else? Do you think about it differently by a particular evidence threshold? So, those are some things that you could reflect on in the discussion that you're going to be having here.

So, let me ask if you have any technical questions about what I've talked to, but I'll turn it back to Mike to moderate and facilitate this discussion.

Mike Bonetto: Thanks so much. That was really helpful. Leta, could you go up to the prior slide. People are looking at those and kind of reflecting on Val's comments. I didn't see anything in the chat box, but did anything kind of come to mind, as you guys are thinking through some of this. I think, Val, I like the way you've kind of outlined this. I know we're going to get into some deeper discussion after John's presentation, as well, but I'm kind of curious of any initial thoughts from folks.

Thomas May: I'd say versus the health versus other State priorities and needs, I think that we do need to be mindful of other State priorities and needs, but I think that as the Health Care Authority, our role here, in particular, is to be advocates for health. I think it is an important priority. If we aren't advocates, and we're trying to make those other tradeoffs within our own group, that it will . . . we will end up being an afterthought. We will lose the advocacy that other priorities will have on their behalf.

Mike Bonetto: Thanks, Thomas. Yeah. Great point.

Stephanie Simpson: I had a question on the list of diseases that I can kind of gather that states felt comfortable kind of looking at their options, and I just didn't have a chance to read it well. Was sickle cell on there?

Mike Bonetto: Stephanie, I do not believe it was.

Stephanie Simpson: Yeah. And so my question would be is why not, especially because that community is so underserved and often neglected?

Donna Sullivan: When the SMART-d project kicked off, that was probably almost five years ago now, the sickle cell products were so far deep into the pipeline that I don't think that they were really being bubbled up to the surface, because there weren't any good drugs on the market. So, that was before the newer product that was just approved for hemoglobin. The gene therapies were so much further away from being real life than some of the diseases that were listed here, but if it were today that we were developing the list, sickle cell would definitely be on that list.

Stephanie Simpson: OK. Great.

Valerie King: I think that's absolutely correct. This is not an all-inclusive list. This is what bubbled up to the top over the last five years.

Mike Bonetto: One thing that came to mind is, I really like your example on 17p. I think that has a lot of relevance to how we're looking at this. I'm just trying to think of it as you kind of look on your career, look back, I mean, what would you have done differently, had you been in a policy making decision, you know? A policy decision making position back then, and

you think about solidifying a different type of contract. How would you have approached that differently?

Valerie King: Mike, it's such a good question. I can tell you what I did as a clinician. So, based on observational studies only, I ordered the compounded version of 17p for patients. That's what I did, because, why? Because recurrent preterm birth is a horrible thing, bad enough the first time, worse the second. The drug, we did have, if we didn't know that it would definitively help, what we had was evidence that said that it didn't hurt. At the point that it was compounded, it was also dirt cheap. You could do it for between $200 and $300 during a pregnancy. So, low cost, low harm, maybe an upside.

Mike Bonetto: Got it.

Valerie King: So, that's what I did. That's what most people did.

Donna Sullivan: At that same time, there was a war on compounding pharmacies also where if a product was available commercially that pharmacies were not allowed to compound it for mass dispensing. They had to compound it on a patient by patient basis. So, that's another avenue where it really impacted states.

Leta Evaskus: Mike, I have a comment here from Vivienne Souter. She said another issue is walking back interventions when assessment of the evidence changes. Quite difficult to get clinicians to stop using non-evidence based drugs; 170HP is a good example of this.

Mike Bonetto: Vivienne, do you want to expand on that?

Vivienne Souter: I was at the Society for Maternal Fetal Medicine meeting in February this year. There were a number of different discussions and lectures about 17OHP. I didn't go to one, but a representative from the FDA attended, um, but what I did hear was that they said there was not gonna be another trial. So, I think it's highly unlikely the FDA will continue to approve this drug, but all the clinician meetings I went to, clinicians said they still believed it, and they were still going to use it. Although there is no evidence of harm, there really isn't any definite evidence that there

isn't harm, my only home, the United Kingdom, has never used 17 hydroxyprogesterone for preterm labor prevention. They just felt the evidence was insufficient, but I do think in America there is a sort of, in my specialty anyway, a more is better approach. I think maternal fetal medicine doctors, in particular right now, are having a really hard time letting go of 17 hydroxyprogesterone.

Valerie King: Yeah. I think that's very right, Vivienne. The other thing I would say is that we could have done a lot to decrease perinatal mortality disparity with that 1.2 billion that AMAG earned by selling the drug in this country. That is I think a real reflection of the cost that we could have put people in better housing. We could have given them better support and better nutrition and we could have made sure that they got into SUD treatment when they needed it. There was a lot we could have done with that money. While I think that people who take care of expecting moms are going to be resistant to not using this drug, a lot of that has to do with, we don't have other things to offer from our offices.

Mike Bonetto: Right.

Vivienne Souter: It might be easier to fund a drug than to fund better housing and social circumstance.

Valerie King: It's the way we've constructed our system. And it's fantastically easier. Yes.

Mike Bonetto: Donna and Judy, a question for you guys. As you guys think about coverage with evidence development, and knowing what you guys have done on the SMART-d specifically with hep C, I'm just kind of curious on how this plays out when you have one manufacturer with that innovative breakthrough drug, and there's no competition. How does that play out in terms of where's the leverage. I'm just kind of curious on your thoughts. What you guys have done on the Hep C front was very kind of ground-breaking, but at the same time, you had two manufacturers that you could kind of, or more, that you were able to use almost against each other and get the best deal. How are you guys looking at that coverage with evidence development if there isn't that?

Donna Sullivan: Great question, Mike. They say it's a negotiation when both parties can equally walk away from the table. We can't walk away. We're required by law to cover these drugs. So, we really have no leverage. A great example is Vertex Pharmaceuticals with the cystic fibrosis drugs. They've brought out three drugs over the past probably ten years that are all kind of ground-breaking, but they hold the monopoly on really the treatment for cystic fibrosis. They are not willing, at all, to give discounts to the State Medicaid program. Other than begging and pleading for price discounts, there's really not a lot of leverage that we can do or can insert, which is why we believe that having some sort of registry or a way to track the outcomes of the patients that are receiving these medications is extremely important, because as we can gather more evidence to show that it either does or doesn't improve clinically meaningful outcomes in patients, then we might have the ability to maybe get an outcomes based contract or put pressure on them from a regulatory standpoint where they might lose their FDA indication if they don't do additional studies.

Mike Bonetto: Thanks, Donna.

Judy Zerzan: Yeah. I think one of the parts that is hard, and I think why Washington decided not to take part in the SMARTEN is that it's hard and expensive on the State side to get those outcomes and track stuff. I think Hep C is a good example of that. We think, and we hope people are going to collect postviral loads and ensure that the Hep C infection has cleared, but there isn't a way that we can for sure guarantee that. So, that makes all of this a little harder. Not to say that we still shouldn't try to do it, but it makes it a little more challenging.

Mike Bonetto: Got it.

Carly Rodriguez: I wanted to drop in on some of the questions that were presented on this slide, as I was thinking about looking at pathways that vary by drugs or condition or manufacturer or price, I think that Donna really highlighted the challenge here is that in theory, you could think about doing any of these things, but at the end of the day, you have no, currently there is no leverage to actually . . . or there's no mechanism really to actually follow through on many of these things. It makes me think of Oregon where they are supposed to have a mechanism, right? With the prioritized list

where you can think about conditions or something like that. They actually do have a mechanism to try to prioritize their creative pathway to not cover things based on evidence, but it all comes back to the Medicaid drug rebate program, and if the manufacturer is participating even with that prioritized list you have in Oregon, you essentially have no leverage or no ability to say no.

Mike Bonetto: Right. Fair point. Other thoughts? Before I saw a list growing here, I just want to make sure Monica, Petra, and Foxy, I thought you guys may have joined just a few minutes late after we did intros. Are you guys all on right now?

Judy Zerzan: I think Monica had to step away. She sent me a chat. She'll be back short.

Mike Bonetto: OK.

Foxy: I'm still on.

Mike Bonetto: Great. Thanks, Foxy. Any other thoughts, questions, comments regarding Val's slides? Well, now, thank you. I mean, I think that was very helpful. And I think, you know, Donna, the way you just teed this up, you started talking about the need for data and outcomes, and potentially this next step even with a registry. So, I think the Segway could be very beneficial, as we kind of transition over to John, but I want to just do a little time check. We're 10 after 2:00. Would people like maybe a five minute quick standing break? Then, we can kind of . . . we'll come back. Does that sound fair? Looking at some nodding heads here.

Female: Thank you. That would be great.

Mike Bonetto: Let's take five minutes. We'll be back at 2:15 and, John, we'll go with you.

Leta Evaskus: Sounds good.

Mike Bonetto: Alright. Well, let's get going. John, Vivienne, Kristin, thank you guys so much for taking time. I think you got a flavor of kind of what this group has been dealing with over the last hour and kind of what lies ahead for them, but I think it Segways well into kind of your overview. So, we're looking forward to hearing from you. So, the floor is yours. Thanks.

John Vassall: Great. Thanks. I'm just going to tee this up and then get out of the way for my smarter colleagues to actually do the presentation. The Foundation for Health Care Quality has been around for about 32 years, I think, this year. Among the programs are the clinical outcomes assessment programs. These programs actually look at clinical data abstracted from patients' medical records and look at the clinical care that's being developed. We have clinicians, physicians, nurses, midwives, and others who look at the clinical care being developed and help improve the care at the bedside. So, that's what these programs do. Primarily, they are focused right now on procedural medicine. So, we have surgical program, cardiac program for cardiac interventions, spine surgery, and obstetrics. However, we're very much interested in getting into outcomes programs and look at medical outcomes, as well. We are looking . . . we have been actively engaged in trying to put together a program around biologicals in the rheumatology arena. In that regard, I want to really thank Valerie for that last presentation. I thought it was fantastic, and it's very helpful for us to see where this committee is going and what your needs might be going forward with this project. So, with that, I'll turn it over to Kristin. Thank you.

Kristin Sitcov: Great. Thanks, so much. Thank you for having us. Thank you, John. So, as John mentioned, we're going to talk today about the care outcomes assessment programs and sort of the basis for the model of these programs, and then specifically how we have used OB COAP to do some tracking of outcomes around emerging therapies. So, we'll get some specific examples from the OB side, but the basic model applies to all of the clinical areas where we have programs. Then also, I think, as you all know, the Bree Collaborative, the Washington Patient Safety Coalition, and Smooth Transitions were also part of the programs that fall under our umbrella.

So, the model of the COAP approach is really built on continuous quality improvement, really looking at making the knowledge to practice loop and looking at how that change can happen, identifying what you want to change, measuring, implementing, and then measuring again to see what's happening.

The programs are collaborative. We look at benchmarking and comparative reporting. We have meetings to look at the data and to share best practices. We're working on increasing transparency among both within the program, as well as externally and in the public arena.

They are clinician led, which I think is one of their strongest points that there is a management committee that really looks at the strategic direction and plan for each of the programs. They are multidisciplinary clinicians and stakeholders. So, in the spine area we have both neurologists and orthopedic surgeons. In OB, we've got the community midwives talk with fetal medicine specialists and everything in between. So, I think that multidisciplinary input is really a key part of how this works.

And then, the clinical data, it's, as John was mentioning, it's high quality chart abstracted data. It's timely reporting at the aggregate and the system level, as well as looking at individual provider, and it can also be drilled down to the patient level to give sites the ability to go down and look at where the fallouts are. They can look at a comparison of outcomes before and after the implementation of the quality improvement initiatives so that they can see the impact to those changes. We can also examine balancing measures. So, the things we are doing to lower the cesarean rate, are they having a positive or negative outcome on newborns. Are there more babies going to the NICU? Those are important things that we need to be looking at in order to evaluate whether quality initiatives are having the impact we want. We can also look at the evaluation of the site and practice culture. So, looking across sites really important with the ability to look not only within your own hospital or your own system, but to look across the entire cohort and see what are my . . . what's my competition doing across town or across the State, and how does that impact what direction we want to go in. There is also the ability to monitor resource

implications and costs. We can look at staffing things and cost of care and those kinds of things to connect that with the clinical data to see, again, what kind of impact we're having overall.

So, we think that that's really sort of the key of why this clinical data is so important and really the basis for the model that we use in the COAP programs.

So, specifically with our OB COAP data, the heart of the OB COAP database is the pregnancy and delivery care. So, everything that happens on consecutive deliveries from the time of admission through delivery, but added in with that to give us a full picture of what's going on are the demographics and risk factors, the provider information. So, we know not only the provider name and their NPI number, but we also know the provider type. So, we can do some analyses by looking at specific provider types and comparison and their role, which is really critical for looking at attribution, especially in OB where one practitioner may be admitting the patient and doing most of the labor management, but when a cesarean comes, if it's a CNM or a family practice physician that doesn't do cesareans, somebody else steps in and does that cesarean. So, in order to really look at an individual practitioner's performance, we have to be able to look at the attribution of care. We also know transfers of care. So, if patients have had a planned out of hospital birth, either in the home or in the birth center, we know if those come into the hospital or from a lower level hospital, a level one family transferring into a higher level of care. We know the outcomes for both maternal and newborn, and 30 day readmissions, specifically on the maternal side. With the newborns, we only know if they come back to the same facility for readmission. So, we know that we miss some of those in the database.

A few areas where we're looking at adding data, and we've got some current collaborations going on to examine adding patient experience data and looking at that in conjunction with the clinical outcomes, the financial data and long-term maternal and newborn outcomes. So, those are areas that we're investigating and currently work to expand the database.

Just a little bit here. This is a very busy slide. So, I've got some animation added here so it's not quite as overwhelming when it opens up, but the whole idea is just for you to be able to see the continuum of the fields and where in the point of care we collect these kinds of things.

So, as I mentioned, with practitioners, we're looking at the different practitioner types in the different practitioner roles. The same with nurses so we know what nurse is working with them upon admission, the primary person during labor management, and who was there at delivery. We have a lot of date and time fields. We're able to examine many different points in care throughout labor and delivery. We know cervical dilation at different points in time, the mode of delivery, and then as I mentioned, the postpartum 30 day readmission.

This is a little bit about who is currently in OB COAP. We're getting about 35,000 deliveries a year added to the database. We have over 200,000 records in there now. So, it's a really rich source to look, even now looking retrospectively at the data that we've collected. There's 20 hospitals in Washington and also we have a facility in Montana participating. They represent all levels of neonatal and maternal care, so levels one through four. We have the planned community births through the Midwives Association of Washington State. So, those are all the planned home and birth center deliveries. They represent urban, suburban, and rural areas. There are some tiny places. There are some very large places. As you can see, we don't have really anybody in north central Washington currently participating. There is not a lot of facilities there, but there certainly are some critical access hospitals. So, we're hoping to get more of those sites participating so that we can be sure that we're representing what's going on, especially in those critical access hospitals. Then, we have all obstetrical provider types represented, as I mentioned, OB, family practice with and without cesarean privileges, maternal fetal medicine, the OB hospitalists, nurse practitioners working within hospital, and then the community professional midwives working on the home and birth center studies. So, that's just a little overview of our current data and the platform from which we're operating. Then, I'm going to turn it over here to Vivienne to give some actual real world examples of how we have utilized this data to look at emerging therapies.

So, Viv, would you like me to advance the slides? Or do you want to turn it over to share your screen?

Vivienne Souter: You can advance it, Kristin.

Kristin Sitcov: Great.

Vivienne Souter: Can everyone hear me OK with my phone?

Kristin Sitcov: Yes.

Vivienne Souter: Yep? OK. Just let me know if it's not working. So, I did think about including 17 hydroxyprogesterone. Maybe that would have been a good one to do, but I have chosen two real world examples of how OB COAP has the data quality improvement program and data registry been able to track some new interventions. I have to tell you, innovation in obstetrics is actually quite unusual. We have very, very few new therapies. We tend to reinvent our own old therapies. Compared to other specialties, we're really not doing very well. I've got two, I think, pretty interesting examples. Kristin do you want to move on?

So, the first one is the use of what we call late preterm steroids. Now, I don't know how many of the audience really have a good handle on obstetrics, but as Val said earlier on, preterm birth is a big, big issue in the United States. It's associated with a lot of cost, a lot of short-term impact on babies, and a lot of long-term impact on babies and families. We have known for about 30 years that if the mother received antenatal corticosteroids, within a week roughly of the birth of a preterm baby, or less than 34 weeks, that there are real benefits to the baby, both in survival and also in reducing morbidity for these babies. However, it's been unclear if what we call late preterm babies, babies born between 34 weeks and 36+6 weeks, if giving them antenatal steroids is associated with any significant benefit in terms of newborn complications.

So, about five years ago, a study was started in the United States to answer that question. Does antenatal fetal medicine, which the most commonly used antenatal corticosteroid, reduce newborn complications for babies born at 34 to 36 weeks? Now, I should tell you that our

preterm birth rate is actually low in Washington State compared to a lot of states. It's usually in the 8 to 10% range. However, most of these babies are not born less than 34 weeks. Most preterm babies are actually born between 34 and 36 weeks. So, this study was designed with primary composite outcome as the primary outcome, and it was really a combination mostly of respiratory complications with some other complications for the baby. What this study found was that the risk of the newborn complication composite was about 11.6% in the betamethasone group and 14% in the placebo group. So, this is statistically significant and suggested that betamethasone reduced the risk of these complications by about 20%. Interestingly, and probably not surprisingly, we find that babies that were exposed antenatally to betamethasone had a higher rate of neonatal hypoglycemia with 24% in the betamethasone group versus 15% in the placebo group. Neonatal hypoglycemia can be treated if it's recognized, and it should be recognized in a late preterm baby. If it's very severe, there is concern that this may have long-term impacts on development of the baby. It's kind of controversial exactly how severe the hypoglycemia has to be, but there is a question about whether this really is a long-term issue for babies.

At the time this was published, we felt there were really a lot of issues with this paper. First of all, that 34 to 36 weeks period, there's a lot of maturation that goes on in the baby at that time. The rate of complications at 34 weeks is a lot higher compared to 36 weeks. In addition, when we looked at our own data in OB COAP, 50% of all late preterm babies were born at 36 weeks, the time that the risk of complications was the lowest. We find that the risk of complications at 36 weeks is relatively low in terms of respiratory complications, about 16%, and most of these were fairly minor complications, because they weren't associated with intubation or ventilation. In addition, the study was underpowered to evaluate the effect of steroids week by week. At this time, actually, we wrote and published a paper just highlighting the issues we felt potentially with implementing the policy of late preterm steroids across the board.

So, I think this speaks to really looking at evidence, and basing evidence on one trial. I said that there wasn't any data on . . . the study wasn't par

to look at icons week by week. In the appendix of the paper, which, you know, how many times do you look at the appendix? They did actually do a [inaudible] analysis and looked at the newborn complication rate by two groups. One was at 34 to 35 weeks, the earlier gestational age at birth, and then at 36 weeks. What they find that clearly at 34 to 35 weeks, there was a benefit of getting antenatal steroids, but at 36 weeks, although it was underpowered, there's absolutely no evidence whatsoever of any benefit.

In addition, in the appendix, they also look specifically at severe respiratory complications, and if you look down at the bottom, you will see that at 34 to 35 weeks, there is no statistically significant difference in severe respiratory complications. And in fact, although it wasn't statistically significant, at 36 weeks, the relative risk suggested there may be a trend towards more severe respiratory complications in the group that received the betamethasone. So, in fact, although this study was touted as showing benefit across this late preterm period, really, there were some issues with just where that benefit was.

So, after the study was published, ACOG produced a committee opinion that they've revised a couple of times, but it's largely the same, which is administration of betamethasone may be considered in pregnant women between 34 and 36 weeks who are at risk of preterm birth within seven days.

So, what happened in the OB COAP population? We were able to track this, and what you can see along the X-factor is each quarter from quarter 3, 2016, up to quarter 1, 2019. I have that data handy. On the Y-axis, you can see the percent is 0 exposure percent of all late preterm births. Excuse me, all preterm births who were exposed to antenatal steroids. At the top, you will see the early preterm births. So, about 80% of them across the whole time period were treated with antenatal steroids prior to birth. Then, if you look at the purple line, it shows the percent of late preterm births who received any antenatal steroids. You can see that it's gone from about 30% to about 38, 39%. So, we're definitely seeing more use of steroids in late preterm births.

When you look it over, you will see, again, on the Y-axis, this is the percent of over in purple that received antenatal steroids. It's gone up from 3.8% to 5.2%. So, what that means, it looks very small numbers, but actually, if you translate this into all births in the United States, it's almost 300,000 of the 3.9 million births in the United States received preterm steroids, or antenatal steroids. Then, along the blue line you'll see that this is the rate of babies that were actually born at term who received antenatal steroids at some point during the pregnancy, probably because there was some concern they might deliver early. That's gone up from about 0.8% to 1.3%. So, there's an increase in the use of steroids in babies that are born late preterm, but also more babies were born at term are also getting steroids. That's because we're not very good at predicting preterm births.

So, one of the great things about having OB COAP and a registry like this is that we can look at exactly where these new therapies are actually being implemented. So, I broke the [inaudible] down into two periods. The blue is a period at the end of 2016, which I'm going to call baseline, which is just around the time that this evidence is coming out before really the ACOG statement had time to make a big impact. Then, in purple, I've got a cohort from later on from 2018, early 2019. That's in purple. We can see how this is being implemented across our population. What you'll see, in fact, across all populations all racial and ethnic groups that we have information on, but the rate of preterm . . . the rate of antenatal steroid use went up. We can also see the sort of information, even by the patient's insurer so that we could see on the right that there was a statistically significant increase in antenatal steroid use in patients with commercial health insurance, and there was a smaller but not statistically significant increase in the use of antenatal steroids in Medicaid patients. This might actually be one time I think it might be of benefit that this wasn't perhaps implemented so vigorously in the Medicaid population.

We can also see what type of hospitals are actually using the therapy more commonly. So, along the X-axis, you will see level one hospitals, level two, and level three/four hospitals. You will see that most of the use, the increase in use of antenatal steroids has occurred at level three/four hospitals.

So, why is this so important? Well, more than 1 in 20 involves singleton babies in OB COAP. In fact, about 1 in 60 of all babies born in the OB COAP cohort is exposed to antenatal steroids. Because we're not very good at actually predicting preterm birth, also to receive antenatal steroids, about a third are born less than 34 weeks. So, that is quite a population that really, really needs steroids. About 45% are born at 34 to 36 weeks when the benefits are probably there at 34 weeks are not at all there at 36 I would say. About 21% of all the antenatal pregnancies associated with antenatal steroids are actually born at term. This would be fine if there was no risk/benefit ratio, but there really is a big question mark over antenatal steroid exposure and whether this is entirely benign for the baby, particularly babies that are born, receive antenatal steroids during pregnancy and then go on to be born at term. There's just been a big paper published in JAMA from Finland in May, which projected there was an increased risk in babies exposed to steroids antenatally and born at term, in terms of behavioral issues and neurodevelopment. There have also been some questions about an increased risk of metabolic disease later in life. Potential for babies who are exposed to steroids and delivered at term to be smaller for whatever reason. Also, we've got this question about the short-term and potentially long-term effects of neonatal hypoglycemia.

So, how to improve the outcomes in our late preterm births in Washington State, given that we're exposing a lot more of the patients to antenatal betamethasone. So, along the X-axis, again just the year and quarter and the percent of late preterm babies who had any of these issues. So, you'll see the orange line is incubation, and it's a very, very small percentage of these babies who are intubated. Ventilation, again, it's a minority of them, and you see that the line has really not changed over the last few years. Oxygen use is unchanged. Respiratory complications, which is kind of a broad bag of things, may be going up a little but certainly hasn't gone down. NICU, as mentioned, are pretty much exactly the same.

In addition, not surprisingly, based on the [inaudible] trial is that since 2016 to 2019, the percentage of late preterm babies are having issues with hypoglycemia shown in the blue line, has gone up quite a lot. It's

gone up from 15% to 23 almost 24%. Another thing that we have seen in our data that has not been reported before is that we're also seeing more of what we call temperature instability or issues with these late preterm babies maintaining their body temperature. If this happens, it means that the baby may have to go into a warmer or incubator again. They have to be separated from the mother. This was something that wasn't looked at in the trial.

We also had the ability to look at resource used over this same time period. This is, again, from late preterm babies only in our OB COAP data. This is the median length of stay in hours for late preterm babies from 2016 at baseline to quarter one 2019. You'll see that there certainly hasn't been a decrease in the length of the hospital stay for late preterm babies. If anything, it looks like it may have increased over that time period.

So, I'm going to just mention another trial and another new therapy that happened in the last few years. For many years, we told patients, if you have an induction of labor, your risk for cesarean birth increases. What we didn't really know was whether this was due to induction of labor itself or the indication for induction. So, in 2018, another big randomized control trial was performed reported in the United States to assess the effect on the baby of induction of labor at 39 weeks in first time mothers where there was no reason to induce the labor. It was totally elective for no medical indication. The primary outcome was how the babies did, whether they had any complications or died, and a secondary outcome with cesarean births. What they found was that the primary outcome, how the baby sits, whether you induce the mom at 39 weeks or whether you just expectantly manage them, there was no difference for the baby. However, the secondary outcome, cesarean birth, appeared to be lower in the induction of labor group with about a 16% lower risk of cesarean birth with induction of labor at 39 weeks performed. So, this was really embraced by a lot of people in the community. However, there were some issues with this study, notably, the average age of patients in this study was 23 years. Now, in our OB COAP data for this same population, the average age is 28 years. We know that as you get older, things get more complicated, and labor doesn't always work just quite the same way it does when you're young.

So, what happen in the OB COAP population? Well, I am going to try and show you something that I think is kind of a [inaudible] way to look at this. I wonder, yes, great. I'm going to try and share my screen.

Kristin Sitcov: I'll turn it over to you, Vivienne.

Vivienne Souter: Thank you. This is actually a presentation of our data using a Microsoft platform called Power BI. This just shows how we can use our very granular data to really quickly explore trends and changes in our calculations. So, this is actually a cohort of the NPXB population, [inaudible] first time pregnancy, term, singleton one baby, vertex head first presentation of the baby. This is the group that we use a lot in the United States to kind of compare metrics. Along the top bar, you'll see the number of deliveries, which is 34,000. There were about 8000 cesareans performed, which gives a cesarean rate of 26%. About 35% were induced, and so on and so forth. Over here under percent of cesareans, there is a box which has a number key metric. I have it actually on percent cesarean. I can click through it and make sure the number of patients, the percent of operative vaginal birth, third and fourth [inaudible]. There are a whole lot [inaudible] tabs. In the next box, I can click and see if labor was allowed, or a cesarean was performed with no intent of vaginal birth. The next box, which is this browny color, I can look at whether the labor was induced and filtered by inductions or continuous labor. I can look and see who the type of clinician was at the time the patient was admitted for labor and delivery, whether it was maternal fetal medicine, OB, midwife, family practice. Underneath that, I can look at the practitioner in a different way, looking at who actually did the delivery. If you move to your left at the box in purple, I can see the racial and ethnic distribution of patients, and I can also filter all the metrics by that. On the left, you have in the blue bars just the number of deliveries. You can see that on the left Y-axis. On the right Y-axis, you can see the percent of the population who have that intervention, and the red line shows you the trends of the time. So, I can look very quickly and show you that since January 2016 to 3/2019, [inaudible] patients, the rate of all of these patients who actually have an elective induction or no medically indicated induction of labor term went up from about 1% to over 4%. And if I again just look at all inductions, it should change on the

bottom. You can now see that almost 10% of all inductions of labor in our population are elected inductions of labor. The rest will be [inaudible] preeclampsia or a concern for the baby's well-being or whatever. So, how has that changed our infection rate? So, I can click on the percent of infections in the same time period, and I can look at it just for those for labor with [inaudible]. You can see that in the bottom left hand corner that red line is pretty much [inaudible]. So, what we can see is that we're seeing an increasing number of elective inductions of labor, and we're seeing really no change in this NTSD population in the cesarean delivery. So, can I hand it back to you, Kristin?

Kristin Sitcov: I'll switch back.

Vivienne Souter: Thank you.

Mike Bonetto: Vivienne, I want to, at some point, go back to that, because that is an amazing tool. I think the question is then, how do we have other emerging therapies have a tool like that. Right? I mean, that's impressive.

Vivienne Souter: I can go back to it in a minute or two. Kristin, do you want to just show them my last slide. That would be great. So, right now, randomized control trials are the gold standards for testing new therapies in medicine. This is my personal view, nearly always in my specialty suffer from being performed in relatively narrow populations and under very strict management conditions. Monitoring how these therapies are implemented in the real world and their consequences both intended and not intended, patient outcomes and their implications for healthcare resource use, I think is a really crucial and largely underappreciated issue, at least in obstetrics. Data registries and quality improvement programs, like OB COAP, can really fill this gap and see what happens to resource use and outcomes. Also, how these therapies are actually implemented in different hospitals and different providers and different racial and ethnic groups. I see the future for a lot of these trials not in fact being standard randomized control trials, but this is happening in Europe. I think it's probably beginning to happen in other specialties in the United States, but this potential for doing what's called stepped-wedge cluster randomized trials where therapies are actually implemented in hospitals

sequentially, and the before and after effects in terms of outcomes are measured using the hospitals at full control. I think this is another context where OB COAP, for example, could actually play a really big part in not just monitoring but also testing new therapies.

Mike Bonetto: Awesome. Thank you, guys, very much for that. I didn't see anything in the chat box, but welcome thoughts, comments. Maybe I'll just start with where I kind of left it, Vivienne. As you guys kind of look at what this group is reviewing in terms of emerging therapies, and just as I was even looking at that tool, how do you see you guys involving to kind of look at some of this newer emerging stuff that's coming out, certainly in the pharmaceutical space. I mean, is that a tool that you're looking at would be applicable in other settings?

Vivienne Souter: I think over the next few years, I know this is mostly about emerging therapies, but I actually think for some of our best and most important improvements in care might be will be using the therapies that we have more effectively. I think that data analytics are going to become really on board. I mean, right now in the commercial world, if you're Nordstrom, you're looking at your data day by day, moment by moment, and you're adjusting to your space, your position in the marketplace. In medicine, we're just not doing that in a lot of places. I think we're really missing opportunities, because we don't have data to actually even use the therapies we have to their maximum benefit, and we're losing opportunities to improve care and also [inaudible]. So, I think that this . . . acquiring data and feeding it into these data visualization tools and using data analysis, I mean, I think it's incredibly exciting. I really hope that we can embrace this more in OB COAP and in healthcare in general. I think it's applicable to all specialties.

John Vassall: If I could agree and add on that. I'll [inaudible] as an example. Docs, like everybody else, like the nice new shiny fancy stuff. Very often, that old stationwagon works just as good as that beautiful shiny new electric SUV, and it's probably cheaper. So, people are jumping to biologicals, we believe, too quickly and giving up less expensive therapies that have not been fully used, fully utilized, as Vivienne is saying, and going to very expensive new medications, because they seem to be the best and brightest thing. So, if we can really maximize the use of therapies that

have not been maximized before we start jumping to untried very expensive medications, I think we can save a lot of money.

Mike Bonetto: I'll throw in one. Donna kind of laid this out earlier in terms of just the need to be looking at registries. You guys have some data sets there that are very impressive. Talk about just data acquisition on your end of how that comes about.

Vivienne Souter: Can you answer that, Kristin?

Kristin Sitcov: Yeah. So, some of the data, and I can speak most thoroughly about the OB data, because that's the group that I work with most closely, but across all of our clinical programs, some of the data is uploaded directly from the electronic health record into the cloud based data portal that we maintain with our data partner. Then, there is actual human validation of that data and going through and adding. So, there are some fields that are not discreet, easily uploadable fields. So, somebody actually goes in and adds those and checks and validates the data that is uploaded, as well. Then, they go through a data quality reporting processing, and the data then is available to them on a real-time basis. Once that's finalized, they are able to view it through the reporting portal at the site level. So, that's connected . . . those reporting tools are connected directly to their data entry.

Mike Bonetto: Got it. Thanks.

Stephanie Simpson: I have a question for the folks that are presenting. I representing rare disease, specifically like hemophilia, some sickle cell, people who have babies, that is a lot of people. How does your data apply . . . a lot of these emerging therapies are specifically for rare diseases. They have very small groups of individuals. So, I would be . . . not that I disagree on registries, but, like, how would you use this to make sure that we don't . . . I imagine by the time you would get enough data, you would eventually probably served the amount of people that may potentially need the treatment. So, how would you apply this to rarer?

Vivienne Souter: So, thank you for that question, we don't have a field specifically for example hemophilia or even sickle cell. We do have a free text field that

we can put pregnancy complications into, or preexisting conditions. So, we do actually . . . I mean, I've gone through these free text fields. We do actually have quite a lot of information on some quite rare conditions. We also, because we are a collaborative, we've now got 20 hospitals participating. If there is something that we want to look at, as a group, we can function . . . obviously, even at the tertiary referral center of which we have I think 7, one hospital really wouldn't be enough to look at all these cases. So, we can actually work together with our other hospitals so that we can actually collect some meaningful data. So, this would be really helpful for us to note if there is something that's new on the market or some particular patient group that we need to look at for pregnancy, we can work with our 20 sites to actually collect and monitor that data.

Donna Sullivan: I think what we're thinking of, from a perspective of a registry, would be to set up a new registry for Duchenne's muscular dystrophy or spinal muscular atrophy where we're tracking the outcomes of those patients that are getting these extensive gene therapies and being able to look at differences in complications across the different facilities and the providers that are administering them, and then the long-term outcome of some of these patients, as well. So, it wouldn't necessarily be adding onto the OB COAP. It would be creating a whole new registry to follow other cohorts of patients.

Judy Zerzan: Though I think that might be something we could look into, because we just heard about OB COAP, but there is also cardiac COAP and SCOAP surgery COAP, and I think the foundation for medical quality has relationships with hospitals and some of these expensive new therapies are mostly given in a hospital setting. If not inpatient then in the outpatient hospital setting. So, it might be interesting, as a potential idea, to sort of think about is there a way that we could sort of utilize, and again, it'll be slightly different from what the foundation does right now, but it might be somewhat easier than setting up a brand new database, because some of the relationships are there, and some of the database guts are there.

Mike Bonetto: Yeah. Thanks, Judy. Other comments, questions?

Judy Zerzan: Although I totally [inaudible] for John and his staff. So, I'm not holding you to anything. I'm just brainstorming.

Vivienne Souter: I'm board certified in genetics, as well as obstetrics and gynecology. So, this is something that I'm really interested in, as well. I think we struggle also at getting long-term outcomes. I know if we were Sweden, we'd be able to track everybody from pregnancy right through birth long-term, but we really have very little long-term data on anything in the United States. I think looking at ways to link all the pieces of data and different registries is I think something that would be absolutely wonderful if we could do that in Washington State.

Valerie King: Let me just throw one other piece into that, which is to say that there are rare outcomes. There are rare diseases. That's a place where multiple insurers, multiple states, multiple entities contributing to a registry can really, really help. That does happen in the field of maternity care with CMQCC out of California. I know Oregon gets its data analyzed and contributes to that database. So, that may also be part of the pathway forward.

Mike Bonetto: Thanks. That's a good point. Other thoughts?

Stephanie Simpson: I just think that if 20 hospitals, they have not seen a lot of hemophilia patients. Gene therapy is likely to be provided, maybe none of those hospitals are going to be providing gene therapy the way they're looking at developing that for hemophilia. I just have to say since hemophilia, especially those that are getting gene therapy will be almost 95 to 99% of them will be male. So, they're not going to show up in any OB data. So, I just think that it's really important that if we use registries [inaudible] use is that . . . I think there could be some awesome things that are pulled from it for rare. I'm looking at different things, but just making sure that we really understand the questions that need to be answered for rare.

Mike Bonetto: Right. Vivienne, John, Kristin, do you have thoughts on that on how what you have done kind of taking it down another level to the rare diseases on those, and then specifically linking to the emerging therapies?

John Vassall: In terms of our model, it would be sort of cost prohibitive to stand up another program like that, but it is a very important point, because even with routine therapies for routine diseases, when they do these clinical trials, they're only doing them on a small number of people, a relatively small number of people, because that's all you can really do. So, 7,000, 10,000 people. Then, when you give this drug to half a million people, you've got side effects that didn't show up in those 10,000 people or odd things that happen to people when you give it to that many. So, you really have to look at large populations, and you have to follow it over a period of time. So, for these rarer diseases, it [inaudible] I think. Again, I'm just talking out loud, a national, a regional national registry so you can get . . . or maybe even an international registry, so you can get as much information in it as possible to tease out those little things that you won't be able to see in small populations. It's a very important question. It's one that we really do need to take under advisement.

Kristin Sitcov: I'll just add to that in that the platform that we use, it's relatively easy to set up a new registry in terms of defining what fields need to be collected. We're more acutely aware now than when our registries were initially developed that the more data that we can map to being easily uploadable makes it that much more simple to implement at the hospital level. So, actually getting that part of it set up is not a big mountain to climb. So, it's certainly something that we could look at for a number of different rare entities and implementing those simultaneously. So, it's certainly something worth exploring.

Donna Sullivan: I think to Stephanie's point, what would it take to add new facilities? Like, Blood Works Northwest would be seeing and administering potentially these medications to hemophilia patients. So, is there opportunity to add different provider types or facilities to the reporting cadre so that we could collect that kind of data? You'll have other FQHC or hemophilia treatment centers that are probably in connection with a hospital, like OHSU, but there are some that would not be connected to a hospital.

Kristin Sitcov: Yeah. We can certainly do that. For example, with the community burbs that we get, that's through a relationship we have with the Midwives Association of Washington State. So, that being a professional

organization where we get the data through them. So, it's not exclusively a hospital based model.

Vivienne Souter: Can I ask Stephanie, I was just going to ask, it seems to me that there is a lot of power from the consumer, from patients themselves. While it can sometimes be very difficult to get information from hospitals or physicians to monitor treatment, if patients themselves could actually provide the data for the database or the registry. There's a lot of that going on right now even in our space in obstetrics, and I wondered if you had considered that as a source of data.

Stephanie Simpson: Well [inaudible] most of the gene therapy companies are following their patients. Going into the conversation, there's not a lot of data to follow through on. The issue with gene therapy for something like hemophilia is the treatment is [inaudible]. It takes less than a day. Then, we don't have to do a lot of followup. So, finding those patients to follow up with and making sure they continue to show up is what they're expecting to be difficult. There are going to be so few, but it's also likely to be the first disease really to come to market that has quite a few patients. So, yes. We can ask them to self-report. They just anticipate it to be difficult, because they're going to be so excited that they're better. They don't want to go to the doctor. So, yeah. There's a lot of discussion in the community on how to require and encourage them to continue to self-report.

Mike Bonetto: Judy, one thought that I had as John was talking about kind of economy as a scale, something to think about, just another conversation with Pam on your other project. At some point down the line, I don't know, but I think this could tie into something like that. It's an interesting concept.

Judy Zerzan: yeah. I mean, I like part of why we asked Valerie to speak and talk a little bit about SMARTEN and how do you have multiple states work together to be able to get data from lots of places. A lot of these are more rare disease. So, that's harder to track outcomes and figure out effectiveness and figure out harms.

Valerie King: I'll tag onto that just one piece to say in any kind of registry activity, it's super important to get to good outcomes. The better the outcome, the

harder it is to gather usually. There's inverse relationship there, but many times industry wants to gather a data point that is most favorable to how they look. That isn't necessarily the outcome that matters to patients. So, you have to think about in the field of the SMARTEN study with nusinersen, which functional motor measure are you going to gather? What do parents really care about? It's incredibly important to get to good outcomes.

Mike Bonetto: Yeah. Thanks, Val. Well, guys, we've got . . . we're not holding everybody to 4:00. So, I want to make sure that we kind of cover our bases, but Leta, could you maybe throw up that slide . . . Val's slide based on the questions? I want to go back to that so we can maybe get people thinking about both presentations and thinking more about what counsel advise are we looking at giving HCA in terms of some of these next steps.

Leta Evaskus: So, what do we want to do for next steps? Is that what you're asking, Mike?

Mike Bonetto: No. I was looking, sorry. Val's slide that had the questions on it.

Leta Evaskus: Yeah. I'm getting there. It's slowly getting there.

Mike Bonetto: There we go. Thanks. I think those were framed, yeah. So, I mean, even starting with this first one, as you guys have kind of heard a number of things today when you think about how HCA should consider evidence. What is some initial feedback right now, knowing that it can be all over the map?

Yusuf Rashid: This is Yusuf with Community Health Plan of Washington. Sort of listening to the last presentation, I've been struggling to see a direct relevance to emerging therapies and the HCA, Mike, but something in place as a recommendation of this more immediate, a lot of the data that's for collection and gathering, it's all very important, and interesting findings longitudinally over time and a number of systems, but the problem here is, emerging therapies where the data is very limited, and I am not clear on the relevance to a more immediate applicability to Health Care Authority and Emerging Therapies.

Mike Bonetto: Thanks, Yusuf. Other opinions on that?

John Vassall: I'm going to get [inaudible], it's kind of a general question. So, I sort of have a general answer. As a practicing internist general, primary care doctor for many years, maybe too many. One of the things that always bugged me is new therapies that have just an incremental marginal difference improvement over what I'm already using, but not an incremental cost, much higher cost. It all of a sudden becomes the standard of care. That always irked me. So, I don't know how you determine what is an incremental benefit versus a real benefit when there are other therapies that are available. I think that's kind of what Vivienne was talking about earlier about looking at . . . getting the maximum out of what's already available rather than looking to something new. So, I think whenever I look at a new medication or a new therapy, I look at what's already in my tool chest, and is this really just a different spin on what I already have? Or is this actually something different? With regard to this tradeoff, that's kind of part of that same question. In order to answer that question, I think you have to be explicit about what is the benefit of what you're doing now and what is the true benefit of doing something new, something that's called emerging. So, that's my take on it.

Mike Bonetto: Thanks, John.

Vivienne Souter: I think there are two different issues here. There are obviously diseases where there really is no treatment or very limited treatment, specifically rare diseases, and we are really anything that looks like it might be of benefit is obviously very, very attractive. We just don't have many of these things in pregnancy. So, that's why really our example is on a much broader issue, which is benefits for a much broader part of the population, and risks are much broader for the populations. I think there are two different kinds of disease categories, therapies that we're kind of talking about here in one forum.

Mike Bonetto: Got it. I see some other folks that are still with us. I'd love to hear from some other workgroup members. Thomas, I still see you there. Petra, Kari, others. I'm interested in your thoughts.

Thomas May: I'm still sort of processing all of the presentations. It's difficult to know, or to set a final strategy for how to approach this evidence when there is mixed and not a single compelling sort of case to be made. So, I'm still kind of processing really.

Mike Bonetto: Got it. Thanks, Thomas. Donna and Judy, have you guys, when you're thinking about kind of where we've been, even over the last year and knowing you've got the pipeline coming, where are you with coverage with evidence development, thinking through this and how this plays out in the future?

Donna Sullivan: I don't think we've gotten very far other than we would have to be doing manual tracking of our own data when we've made that coverage determination for one of these new emerging therapies. It would just be trying to follow them based on our claims data over time, and as we're . . . for some of the medications that are ongoing, we'll get renewal criteria. We can request chart notes, because we'll have to continuously reevaluate the effectiveness of the treatment in order to determine whether or not we're going to continue it or continue to pay for it. I think what'll be really challenging, what everybody said, is some of these treatments that are one time only and we pay for it in the Medicaid population, but then they might migrate into a different health insurance company. So, then we no longer have visibility into their continued outcomes.

Mike Bonetto: Got it. Donna, are there things that would change with, like, MCO contracts, in terms of data? In terms of what you would be requiring of them, as well?

Donna Sullivan: Well, we get all of the data from the managed care plan. So, we would just be internally mining it ourselves. A lot of those treatments are also carved out of the managed care responsibilities. So, they are covered through the fee for service program, but it would be potentially asking them to help us get data, contacting providers. We tried, with the hepatitis B program, we sent out . . . tried to get outcomes, the followup SVR12 tests and test results and providers just were not cooperative in giving us that information so that we could have tried to track our outcomes within Medicaid.

Mike Bonetto: So, thinking of the next step, everything that we just heard from Vivienne for the most part, it sounds like, those 20 hospitals, this is all voluntary. From a state perspective, is the next step legislation that would kind of require providers to be producing that type of information to you?

Vivienne Souter: I think that this sort of information should be available for every hospital. Yes. I would like to see that. I think that we're seeing also a call for greater public transparency of data, as well. I think there's going to be a big push for both purchasers and patients themselves to be able to get information about quality at different hospitals. So, yes. I mean, I think if there was legislation, maybe to provide some subset or the whole of the OB COAP data set it would put our State in a really strong position to insure both equity and quality of maternity care for every pregnant person in the State.

Donna Sullivan: Mike, just kind of brainstorming, we talked about a regional or national registry. One of the . . . and to kind of Stephanie's point where manufacturers are following these patients, I think they'll probably have the most resources to try and follow these patients over time, even for those that are in a one-time gene therapy. It might be legislation that they have to make this data publically available or available to research. The concern is that sure, the manufacturers are going to be report . . . I think they have to cover or follow them for, like, 20 years, but they are not going to be sharing the data. So, is there a national registry that maybe it's run by PCORI or something where there's researchers within PCORI that can be following the data from these manufacturers or require the manufacturers to report their data to a centralized registry. Again, that requires national legislation, but it is a way to get there. The data is going to be collected, but we're just not going to be able to see it.

Stephanie Simpson: Donna, I think that because hemophilia is likely to be first up in that bigger registry, I think that [inaudible] would likely be supportive of that data being published due to the history of hemophilia and being fearful that something was happening underneath new treatments that they weren't knowing about, or knowing about them too late. Then, I think having physicians provide some questions that they wanted to know, as

well, or the states that they wanted to know, as well, and these would probably get some community support for that.

Mike Bonetto: So, just to piggyback on that. Val, when I think of DERP and MED, have there been any other discussions around registry type of activity?

Valerie King: Really, the SMARTEN project is kind of first out of the box for that kind of registry gathering, even though it's a 30-month window. Obviously, it could go longer if needed. The MED collaborative has done some joint data gathering work and has looked at coverage policies and prices and things like that across states. So, it's possible, but it's also a big lift. You're asking states to essentially self-fund something. So, the juice has to be worth the squeeze. There are economies of scale, but it has to be a big enough price tag, and I will say that by the time you get one project up and running, like in the SMA space, dang. They're going to have three more therapies out. So, you have to really pay attention to the pipeline, as well.

Mike Bonetto: Yeah. Yeah. Great point. I'm just going to, I hate to pick on folks. I would love to hear from other workgroup members. Petra, I know you were on for a while. I think you're still there. Kari, thoughts?

Petra Eichelsdoerfer: I've actually been on the whole time. I've just been kind of off and on, on the video. One of the things that strikes me about the data collection, there is a lot to be said for voluntary participation, but one thing you need to do if you're going to have that is, you have to make it easy for people to participate. Where are you going to upload the data? So, using the example of the electronic health records that are automatically uploading, they need to be . . . what they're uploading to has to be compatible with the systems that are out there, as opposed to expecting the providers to upgrade their systems so that they can then do this. I'm a little concerned about legislating it, although I like the idea. I like the idea, because you are going to get more data, but the concern that I have is that if you are having the data, you have to be pretty specific about the format in which the data is going to be coming. Or it may not be all that useable. The thing that comes to mind is if you require the chart notes come, but you don't specify the format in which they come, it may not be very searchable. You may wind up having to literally go through

everybody's charts to find the information. That's just not practical from a research standpoint. So, it is a little bit of a messy proposition, especially when you're thinking about cost. There is going to be a cost outlay from somebody. These are also very, very pricey drugs. So, it is probably with the investment, but we have to be cautious about how we do it to try and make sure that it is something that works well for everybody.

Mike Bonetto: Good points. Jonathan, are you still with us?

Jonathan Espenschied: Yeah. I'm still here.

Mike Bonetto: Thoughts from you?

Jonathan Espenschied: Lots of thoughts. Lots of questions. This is one thing that, as powerful as the United States is, it has missed the mark. Europe does this much better. Many countries in Europe do this much better, but there's a cost to that, too. There's the tradeoff of having government or legislation dictate a detail certain drugs or certain pathways or clinical trials compared to the open market we have here, and you're going to get pushback from pharma. So, I would love to have a huge data bank with just about every disease and every drug and every trial. I mean, the amount of just state of mind to be able to come up with certain approaches to different medications, as well as diseases would be phenomenal. Clinicaltrials.gov for those of you, I know, are very familiar with that. It does have data, but that's not until a year after the study closes. So, there really is, if we're looking at emerging therapies, how are we going to get that information? We could be one of the first states to get that on certain drugs or certain diseases, but like everyone has said, it does come at a cost, and whether the State needs to get behind something like that I think is the question. The first bullet is how should the State consider evidence? That's I think really the crux of the question. What type of evidence, what are we talking about? Are we talking antidotal? Are we talking very small cohorts? There's a lot of questions that I think can steer us in the right direction, but there's also a lot that can steer us away from really the answer we're trying. So, this is not an easy, and I know my answer is all over the place, but this is not an

easy question to answer by any means. So, this has been a great discussion.

Mike Bonetto: Thanks, John. No. I think your points are spot on. This whole concept of you hit it too, just the cost and the infrastructure of the data gathering. I'm not saying this is a legislative mandate or even this is a legislative ask, but there also, I think, is a conversation to be had about the value proposition, of if there is that infrastructure in place to collect the data that you put yourself in a position to actually lower costs over time. So, how do you have that conversation? Otherwise, you could be on the hook for spending Val's example of whatever it was, Val, 1-point something billion dollars over a period of time that turned out to be ineffective. So, how do we prevent that from happening by making this up-front investment?

John Vassall: I think the State, to that point, Mike, the State can probably look at specific diseases or something that they subsidize and require every single institution to report on that. That actually could be a pretty wide sweeping impact on specific diseases or specific therapies to be honest. If the State is subsidizing, it can certainly require institutions to report on it.

Mike Bonetto: Got it. Thanks, Jonathan.

Donna Sullivan: I have a comment from Vivienne. She said the NICE technology appraisal process is maybe an interesting template to look at.

Mike Bonetto: Vivienne, do you want to talk more about that?

Vivienne Souter: This is the National Health [inaudible] in the UK. Their kind of process for assessing whether new technologies or drugs should be introduced, I don't know a whole lot about this. I think they are much more focused on cost, but they look at all sorts of things, like the social implications of it and the effectiveness and the cost. I just think as a group it might be quite interesting to look at that. It's all available on the internet if you just go to NICE.org and look for this. I do think it'd be really thoughtful about the components that should be considered and the populations

where this drug should be used or whatever. It might be worth looking at that as just a template. I don't know. You might want to [inaudible].

Mike Bonetto: Vivienne, thank you for that. Val, you said something earlier, just, not of NICE but of ICER. Correct? They were doing some work in this space now?

Valerie King: So, yeah. I, thank you, Vivienne, for that suggestion. I think those of us who are methodologists really respect NICE's process and think of it as being fairly state of the art. They've really kept up. So, in the UK, they do consider cost of care less so than they used to I will say, as somebody who did a post hoc there 20 years ago. Their QALY threshold has really shifted over time, but they've got a good process, even if you don't think about the cost element, or the cost-effectiveness element about a way of organizing what you're going to look at for discreet technologies and drugs. As far as ICER goes, in the U.S., it's health economics group. They are the group that's behind, for example, the California Health Foundations work on particular drugs and technologies. They also work with a group of kind of upper northeastern states. There's a Midwest collaborative. They take on a few really high profile, usually drugs, sometimes other devices and treatments issues per year. They have changed and are changing their methodology just as NICE has. They typically project three cost-effectiveness thresholds, depending on whatever QALY threshold you want to use. I think those of us who were on the evidence side of the business, sometimes question whether they are critical enough about the inputs into their models, and in my group, we, and by my group I mean a whole international health technology assessment group of people, we often have maybe not so charitable thoughts around modelers. That desire to just find an input that fits into the model and not really being critical about how good an input that is. So, the modeling technique and the method really matters. How does the model vary across areas where it's not uncertain or not known? That's critically important. So, I would say on some of their reviews, ICER has done a better or worser job of that. More than you asked for, Mike. Sorry.

Mike Bonetto: No. Thanks, Val. I'm just going down . . . I want to make sure we kind of get a chance to hear from everybody. Kerrie, are you still there?

Kerrie Fowler: Yes. I'm here. I've really just been kind of thinking about the pipeline actually. Then, in terms of just thinking about COVID and the budget and how to best accommodate these new drugs that are coming to the market. I know working with Donna and the Health Care Authority, there are several that we have in our contracts that will be kind of carved out to the State, but are not even FDA approved yet, but they're in there just in case. My mind is really on the pipeline and how we're going to best accommodate our members knowing that we have a budget shortfall that will likely continue.

Mike Bonetto: Yeah. Thanks, Kari. Is anybody on the phone that I missed that has other thoughts, comments? Well, guys, this was I think a robust one for sure. I think we got into more detail than we were hoping to. This is not always black and white. Right? We kind of want to make it just really clean to say, oh, well we're going to do this. It's just not that way. We've got all of this messiness among us, but I think . . . I'm hopeful that this was robust enough to give HCA, I think, some framework really around how they could think about moving forward in this way. Judy, Donna, what are your thoughts on even kind of your own next steps after having this conversation today?

Donna Sullivan: Do you go first, Judy?

Judy Zerzan: You can go.

Donna Sullivan: It's gonna be really challenging to figure out the best path forward, whether it be request legislation, which wouldn't . . . just recommend . . . not really request legislation, but recommendations to the legislature on maybe where they could improve some of the current statues on coverage. If we were to go down the road of some sort of registry, I do believe it would require statutory action in order to do that, to get the compliance with the different entities. I just still scratch my head, because we are still required to cover them. I guess as the costs continue to increase over time and the federal government starts experiencing the impact of these medications, maybe they'll begin to take action, but again, it's, like, we are operating in an area where we really don't have

the authority to make the changes that are necessary to do anything with these medications with a lot of these topics that we've been discussing.

Mike Bonetto: Thanks, Donna.

Donna Sullivan: Yeah. I would love to be able to say, I'll pay you $100,000 until we figure out that your drug actually works in the long-term. Right now, it's just the Medicaid program is now funding all of the manufacturers post-marketing trials and other payers. For those with rare disease, the majority of them do fall into the Medicaid arena for coverage. So, that's a conversation that the federal government really needs to take into consideration.

Mike Bonetto: Right. Thanks, Donna. Judy, what are your thoughts?

Judy Zerzan: Yeah. I think this has been a really helpful process. There is this sort of push pull tension between what the State can do and what the federal government can do and how to sort that out. Yet, at the same time, there's also the State's obligation to deal with this. So, I think it's been really helpful to have these conversations. I'd like these questions that are still on there, I think there's going to be more to be talked about. I'm not sure if there will be any action this legislative session on this space, because there's going to be a lot of other things to talk about. Certainly, with COVID, I think that although you could perhaps say the COVID vaccine happens, you know, what's the evidence? What's the price? How do we all pay for it? Does it work? Does it not work? Those are all the same questions we're struggling with now. So, there aren't any easy answers, which is why we pulled together this group, but I think there's some good structure to the problem.

Mike Bonetto: Judy, one thing, as you were kind of summarizing that, I was also just thinking about Kari and Jonathan's point. I mean, I think this State budget situation that every state's in right now, is dire as we've seen it in a very, very long time. Right? And now you're compounding that with this pipeline. Right? Of emerging therapies. Just kind of thinking through, like, how can HCA and maybe with Robin or others, you really start to, as best you can, quantify that pipeline. Right? So, we really start to look, you know, what that is going to be in those 3, 5 years out. Does

that then potentially justify some initial investment to do this sort of infrastructure development work? Whether its registry work or anything else. Otherwise, you really are kind of dead in the water of not having anything to respond to. So, is there anything that you can kinda get ahead of the curve by even showing him, you know? If we do nothing, right, we know we've got this pipeline coming where we're going to be spending this much money. And if we make this smaller investment, we actually can give ourselves a chance. I don't know. I'm just trying to think about how we can be as proactive as possible.

Judy Zerzan: Yeah. I mean, I do think that that's sort of a, a helpful idea. I think figuring out what we're going to do is sort of necessary to do ahead of time with this sort of rock and a hard place that we're being asked to cut 15% of our budget across the board. That is getting rid of benefits, you know? There isn't an easy way to do that, because in times of economic downturn, that's when more people end up on the Medicaid rolls. So, there's not really another way to make such big cuts, except by changing benefits or changing payment to benefits, which in some ways ends up as a cut to benefits, because if you get too low, people won't provide the service. So, I think it is something that we should be thinking about, because if we find, or when we find the 15% to cut now, some of these things in the pipeline could require us to cut another 5%, because we have to cover them. So, how do we sort of weigh those tradeoffs? How do we make sure that people get the healthcare they need? I think it's a really hard question.

Donna Sullivan: Yeah, and Mike, I mean, this is where the drug and the pharmacy I guess side of healthcare is quite different, because we are price takers. We don't get a say when we have a budget crisis we're only going to pay you $50,000 a year for this particular drug. All of the other services we set a rate, and we'll say, OK. For a knee replacement, we're going to pay X amount of dollars regardless of which joint you use. So, I think that's kind of the difference between some of the tradeoffs and some of the evidence gathering ideas that were shared earlier today. That's, I think, the biggest challenge. Unless we can say, sure, we'll cover your drug, but this is what we're going to pay. Because we have to pay the pharmacy for dispensing the medication in most part, that's challenge for those drugs that are self-administered. Maybe for physician administered

drugs, it'll be different. Maybe we begin purchasing the drugs directly from the manufacturer rather than having the provider buy it. That way, we're controlling what we want to pay for it.

Mike Bonetto: Right. Right. Great points.

Yusuf Rashid: I can't underscore Donna's points strongly enough, but I just want to add to them even, because the irony I see is, even if a socialist system, for instance, has better ability to coordinate nationwide data gathering, etc. If you can't actually do anything with the data to negotiate pricing, it's quite ineffective. Other systems, the irony is, they have more open market ability on the government program side than we do. It's not just the, as a manufacturer participates in the drug rebate program that they can set the pricing, there's also the state programs and government programs subsidizing the free market commercial world like patient assistance programs where those are now being used to not just pay down the patient's assistance but also reduce the commercial plans exposure to drug costs. So, with commercial plans being able to use these free market mechanics or work arounds to bring down their pricing, we end up having to subsidize that is what I'm seeing on Medicaid's side, because we don't have the option to use those open market principles. So, I'm just saying that in summary, all the data once we got it in place, if the government programs can't actually effectively negotiate drugs with more free market principles, then our hands are tied on this one, and we end up subsidizing [inaudible] subsidizing the commercial program.

Mike Bonetto: Thank you. Absolutely. Leta, can we talk about with this group, we will get out meeting minutes, and meeting summaries like you had done last time?

Leta Evaskus: Yeah. So, I'll put the presentations on the website and I'll have the recording transcribed. So, that'll take a couple weeks.

Mike Bonetto: OK. And then, Judy, Donna, and Leta, as things evolve on the HCA front, if there is a maybe a list or anything on this front, we can kinda keep people informed of the future decisions and kind of go from there.

Donna Sullivan: Right.

Mike Bonetto: Alright, but I can't thank everyone enough for a year's worth of work. I think you guys have made tremendous progress. This has actually been interesting, in my work, 'cuz I work with other states. Other states are now looking at how they implement an emerging therapies type of workgroup and just getting ahead of this, like you guys are. So, I would say you guys are far . . . you guys are ahead of almost every state right now. So, kudos to you, even though I know this is difficult. I think you guys are at least having the right conversations at the right time. So, kudos.

Donna Sullivan: Thanks, Mike. It's hard to believe it's been a year already. It seems like just yesterday.

Mike Bonetto: Right.

Judy Zerzan: COVID time is so weird.

Mike Bonetto: So, Donna, Judy, anything else on your end?

Donna Sullivan: No. I just want to thank everybody for participating in the workgroup. It's really appreciated, all of your input, all of your ideas, and the support that you've given us. So, thank you, very much. Judy, what are our next steps? I know originally we were going to have a kind of wrap it all up meeting that was a public meeting. What are the next steps on closing out this work?

Judy Zerzan: Yeah. I mean I think that's going to be delayed a bit, because of COVID, and we're starting mandatory furloughs next week. So, that's going to impact all of our work and slow it down some. I think we still hope to have a pull it all together public meeting at some point in the future, but certainly we will add your names to a listserv and communication that we do about this topic. Again, thank you, so much, for your time over the last year and your participation and thoughts. We really appreciate it. So, thank you.

Mike Bonetto: Alright. Well, thanks, guys. I think we'll sign off from here. We'll give you seven minutes back.