THE NATIONAL QUALITY FORUM

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NATIONAL VOLUNTARY CONSENSUS STANDARDS

FOR PATIENT OUTCOMES

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CHILD HEALTH STEERING COMMITTEE

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THURSDAY

MAY 6, 2010

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The Steering Committee convened at

8:30 a.m. in Suite 600 North of the Homer

Building, located at 601 13th Street, N.W.,

Washington, D.C., Charles Homer and Marina L.

Weiss, Co-Chairs, presiding.

PRESENT:
CHARLES HOMER, MD, CO-CHAIR
MARINA L. WEISS, PhD, CO-CHAIR
DAVID R. CLARKE, MD, MEMBER
SHARRON DOCHERTY, PhD, CPNP (AC/PC), MEMBER
NANCY L. FISHER, MD, MPH, MEMBER
FAYE A. GARY, EdD, RN, FAAN, MEMBER
KATHY J. JENKINS, MD, MPH, MEMBER
PHILLIP KIBORT, MD, MBA, MEMBER
ALLAN LIEBERTHAL, MD, FAAP, MEMBER
THOMAS McINERNY, MD, MEMBER
LEE PARTRIDGE, MEMBER
DONNA PERSAUD, MD, MEMBER
GOUTHAM RAO, MD, MEMBER
ELLEN SCHWALENSTOCKER, PhD, MBA, MEMBER
BONNIE ZIMA, MD, MPH, MEMBER
MARK ANTMAN, DDS, MDA (via telephone)
LISA BERGERSEN, MD
JAY BERRY, MD, MPD
KERRI FEI, MSN (via telephone)
BARBARA FIVUSH, MD (via telephone)
KIMBERLEE GAUVREAU, ScD
CRAIG LILLEHEI, MD
ELLIOTT MAIN, MD (via telephone)
NINA RAUSCHER, MS, RN
SCOTT STUMBO (via telephone)

SONJA ZINIEL, MD

NQF STAFF MEMBERS PRESENT:

HEIDI BOSSLEY, MSN, MBA, NQF STAFF
HELEN BURSTIN, MD, MPH, NQF STAFF
NICOLE McELVEEN, MPH, NQF STAFF

ASHLEY MORSELL, NQF STAFF
NALINI PANDE, NQF STAFF
SUZANNE THEBERGE, NQF STAFF
REVA WINKLER, MD, MPH, NQF STAFF

NOT PRESENT:

JANE PERKINS, JD, MPH, MEMBER

C-O-N-T-E-N-T-S

C-O-N-T-E-N-T-S (Cont'd)

C-O-N-T-E-N-T-S (Cont'd)

C-O-N-T-E-N-T-S (Cont'd)

C-O-N-T-E-N-T-S (Cont'd)

1   P-R-O-C-E-E-D-I-N-G-S

2   8:31 a.m.

3   CO-CHAIR HOMER: It is 8:30. It

4   is a few minutes after, so I think we should

5   get started because we have a lot more to

6   cover today.

7   Good morning, everybody. Thank

8   you, members of the Committee, for coming back

9   after yesterday's experience. That's always

10   a vote of confidence.

11   (Laughter.)

12   We do have a number of new members

13   here, and we also have some new guests. So,

14   should we just go around the room and everyone

15   introduce themselves, first among the

16   Committee members and then our guests and

17   speakers and members of the public afterwards?

18   So, I will start. My name is

19   Charlie Homer. I am CEO of the National

20   Initiative for Children's Healthcare Quality,

21   and with Marina, always happy to co-chair the

22   Committee.

 1   DR. WINKLER: Hi, everybody. I'm

 2   Reva Winkler. I am NQF staff.

 3   MEMBER PERSUAD: Donna Persaud,

 4   Parkland Health and Hospital System,

 5   Pediatrics, in Dallas.

 6   MEMBER McINERNY: Tom McInerny,

 7   Golisano Children's Hospital, University of

 8   Rochester Medical Center.

 9   MEMBER KIBORT: Phil Kibort, Vice

10   President, Medical Affairs, Children's,

11   Minnesota.

12   MEMBER FISHER: Nancy Fisher. I

13   am the Chief Medical Officer at Washington

14   State Health Care Authority.

15   DR. WINKLER: I will remind

16   everybody to please use your microphones.

17   MEMBER CLARKE: David Clarke,

18   pediatric cardiac surgeon, Denver Children's

19   Hospital, retired.

20   MEMBER JENKINS: I am Kathy

21   Jenkins. I am a pediatric cardiologist at the

22   Children's Hospital in Boston and the Chief

1 Safety and Quality Officer.

2   And as I said yesterday, the

3 Program for Patient Safety and Quality is a

4 measure developer on the agenda for today.

5 So, I will be recusing myself from that part

6 of the discussion.

7   MEMBER PARTRIDGE: I am Lee

8 Partridge, the Senior Health Policy Advisor at

9 the National Partnership for Women and

10 Families.

11   MEMBER GARY: I am Faye Gary,

12 child psychiatric nurse, Case Western Reserve

13 University, Cleveland, Ohio.

14   MEMBER ZIMA: I am Bonnie Zima,

15 child psychiatry, UCLA.

16   MEMBER DOCHERTY: I am Sharron

17 Docherty, the Duke University School of

18 Nursing, and I am representing the National

19 Association of Pediatric Nurse Practitioners.

20   MEMBER RAO: Goutham Rao from the

21 University of Pittsburgh. I run the Pediatric

22 Obesity Center at Children's Hospital,

 1   Pittsburgh.

 2   MEMBER LIEBERTHAL: Allan

 3   Lieberthal, Kaiser Permanente, Panorama City,

 4   California.

 5   MS. MORSELL: I am Ashley Morsell.

 6   I am NQF staff.

 7   DR. BURSTIN: Hi. Helen Burstin,

 8   the Senior Vice President for Performance

 9   Measures at NQF.

10   Sorry I couldn't be with you

11   yesterday. We had our board meeting. Kind of

12   a hard thing to pass up.

13   MS. THEBERGE: Hi. I am Suzanne

14   Theberge, NQF staff.

15   MS. BOSSLEY: Heidi Bossley,

16   Senior Director, Performance Measures, NQF.

17   MS. McELVEEN: Good morning,

18   everyone.

19   Nicole McElveen, NQF staff.

20   We can now allow some of our

21   guests to introduce themselves briefly.

22   DR. BERRY: Hi. I am Jay Berry, a

 1   general pediatrician, Children's Hospital,

 2   Boston.

 3   MS. GAUVREAU: Kim Gauvreau, also

 4   from Children's Hospital, Boston, a

 5   biostatistician.

 6   DR. LILLEHEI: I am Craig

 7   Lillehei, a pediatric surgeon at Children's

 8   Hospital in Boston.

 9   DR. BERGERSEN: Lisa Bergersen, a

10   pediatric interventionalist at Children's

11   Hospital, Boston.

12   DR. ZINIEL: Hi. My name is Sonja

13   Ziniel. I am the Senior Survey Methodologist

14   of the Program for Patient Safety, Quality,

15   and Clinical Research Program at the

16   Children's Hospital, Boston.

17   MS. RAUSCHER: And I have the

18   privilege of serving as the steward for this

19   group for Children's Hospital, Boston. I am

20   Nina Rauscher, the Executive Director for the

21   Program for Patient Safety and Quality.

22   MS. GALLAGHER: I am Rita Munley

1   Gallagher, Senior Policy Fellow in the

2   National Center for Nursing Quality at the

3   American Nurses Association. I have the

4   privilege of supporting the work of the NQF

5   nursing organizational members.

6   MS. McELVEEN: Operator, you can

7   open up the conference line, and we can allow

8   some of the participants who called in to also

9   introduce themselves.

10   OPERATOR: All lines are open.

11   MS. McELVEEN: Do we have any

12   Steering Committee members or audience

13   members, measure developers, who have called

14   in to listen to our meeting today?

15   DR. ANTMAN: Yes. Mark Antman

16   from the AMA PCPI.

17   MS. McELVEEN: Anybody else?

18   (No response.)

19   Okay. I just wanted to quickly do

20   a recap of our deliberations yesterday. I was

21   looking through some of the measures to try to

22   really capture how many we passed, how many we

1   would probably review on a future conference

2   call, and how many the Committee just didn't

3   feel were appropriate for endorsement.

4   There were about three measures

5   which you did recommend for endorsement.

6   I am sorry, did someone call in?

7   (No response.)

8   There were actually three measures

9   that we did review and move forward with

10 endorsement on. That was the number of school

11 days missed due to illness for children;

12 children who have no problems obtaining

13 referrals when needed, and, also, children who

14 live in communities perceived as safe. Those

15 are the three I have on my list.

16   We also tabled a few measures.

17 Some were due to allow the measure developer

18 to provide some further clarifications on a

19 measure, and others were the larger-serving

20 measures submitted by the CAHMI developer, and

21 where NQF staff is going to work with CAHMI

22 to, hopefully --

1   CO-CHAIR HOMER: If we could ask

2   the person on the phone who is calling in to

3   put his phone on mute? We are hearing a good

4   deal of static which is broadcast over our

5   speaker system.

6   Thank you.

7   MS. McELVEEN: So, we will look

8   into those larger-serving measures and gather

9   the questions and some of the additional

10   materials that you will need to fully evaluate

11   those.

12   There were about three measures

13   that were out of scope or either considered to

14   be a process measure, which again we discussed

15   yesterday possibly taking some of those

16   measures and moving them on to the second

17   phase of the Child Health Project.

18   And it looks like there was one

19   measure that the Committee agreed was not

20   appropriate for endorsement. That was the

21   children living with illness and the effects

22   of that condition on their daily life.

 1   So, again, we will summarize all

 2   this information and get this out to the group

 3   in a meeting summary, but I just wanted to do

 4   a quick recap before we begin today.

 5   Helen, do you have any comments?

 6   DR. BURSTIN: No.

 7   MS. McELVEEN: Okay. So, we are

 8   going to start with some of our more clinical

 9   measures, which will be a little bit of a

10   change from yesterday.

11   We are in Work Group 1. So, if

12   you all have the materials, either on your

13   computer or printed, you can go ahead and pull

14   up the table that we have compiled of the

15   Committee reviewers, their initial comments on

16   this particular measure.

17   The first measure we are taking up

18   is No. 27. We do have our measure developers

19   and a lovely team of folks back there who have

20   worked on these measures.

21   Did you all want to take some

22   time?

 1   CO-CHAIR HOMER: Barry, would you

 2   like to present the measure?

 3   DR. BERRY: Sure.

 4   CO-CHAIR HOMER: That would be

 5   great.

 6   DR. BERRY: Thanks very much for

 7   having me today. It has been a great

 8   opportunity to develop this measure with our

 9   pediatric neurosurgeons at Children's.

10   This measure reflects sort of

11   bread-and-butter procedure by the pediatric

12   neurosurgeons there. It is also very

13   important to me. I have a clinic that is full

14   of children with special healthcare needs,

15   especially those who are technology-dependent.

16   We are seeing a lot of readmission rates

17   around these children, especially with

18   malfunctions. So, that is why I was brought

19   to the table to help these guys.

20   It has been fun developing the

21   measure. In terms of the neurosurgeons'

22   acceptance of it, it seems that most

 1   neurosurgeons across the country feel that

 2   shunt malfunction is on their radar and it is

 3   something that they consider an outcome

 4   already.

 5   So, the challenge for us was how

 6   to take that measure clinically and plug it

 7   into administrative data in order to pull out

 8   a valid measure. So, we spent most of our

 9   time searching through the codes and figuring

10   out the best way to do that, and then, also,

11   looking at populations that might be at risk

12   and the case-mix adjustment issues in trying

13   to figure out how to risk-adjust those things

14   or whether to exclude them in the end.

15   So, there were a number of parts

16   of the measure that we actually had built in

17   initially as risk-adjustment, and then we

18   ended up excluding them to try to homogenize

19   the measure a little bit. That is why we

20   excluded the population with spina bifida and

21   also with other types of shunts that could be

22   placed, that go not into the abdomen, but into

1   other places.

2   We have been using the measure for

3   a while at our hospital. It has been

4   accepted, and the neurosurgeons feel like it

5   has helped change their care and their

6   approach to the operation. So, we are proud

7   of it.

8   CO-CHAIR HOMER: I would like to

9   invite the other members of Work Group 1

10   initially to either make comments or ask the

11   developers in areas. I would suggest we go

12   through the sequence of the areas, the

13   criteria that we need to do in order to

14   approve, the first one being an indicator of

15   the importance.

16   MEMBER RAO: Dr. Berry, just a

17   couple of questions. I mean one of the

18   questions that came up for me is, not being

19   familiar with this area clinically, is, how

20   common is shunt malfunction?

21   The other more important question

22   from my standpoint is, how much of shunt

1   malfunction is actually due to procedural

2   issues as opposed to something that had just

3   happened spontaneously?

4   If you could address those two?

5   DR. BERRY: Right. So, in terms

6   of the commonality of it, we think that

7   probably you are looking at an overall average

8   of around 10 percent. So, 1 in 10 shunts are

9   malfunctioning within 30 days of being placed.

10   In terms of the variability of

11   that among hospitals, it seems that there is

12   around a four- to fivefold difference in the

13   variability. So, you can look at rates that

14   are going between like 3 to 25 percent. If

15   you expand out beyond 30 days, we see rates

16   that climb up much higher than that.

17   In terms of the quality of the

18   operation and how that can affect the

19   outcomes, the surgeons feel strongly that one

20   of the largest indicators of the shunt

21   survival is due to the actual placement. I

22   mean it actually is the angle and the

1 insertion of the shunt into the brain and also

2 into the abdomen, and the way that the shunt

3 is routed to make sure that it is not at risk

4 for being kinked or broken, or that somehow it

5 is being placed that would impede the flow of

6 cerebral spinal fluid.

7 They also believe that there are a

8 fair number of malfunctions that are due to

9 infection. So, in the operating room, trying

10 to increase the efficiency of the operation

11 being performed, double-gloving, antibiotics

12 at the procedure, et cetera, are all process

13 measures that they feel relate to the outcome.

14 So, they do feel that there is a

15 strong bit of clinical happenings that are

16 associated with the malfunction rates.

17 CO-CHAIR HOMER: Please, Faye.

18 Please use your microphone. Thank you.

19 MEMBER GARY: Would you just say a

20 bit more about infection? Could you just make

21 one or two additional statements about the

22 rates of infection and what kinds of

1 complications that might cause? And the other

2 issue is, what are the professional healthcare

3 providers that help take care of these

4 children, and did you get any feedback from

5 any of them?

6   DR. BERRY: Sure. So, in terms of

7 infection, the prevalence rates of infection

8 within the malfunction rates, you are probably

9 going to have around a third to a quarter of

10 these that will be associated with infection

11 in terms of the ones that are malfunctioning.

12   What infection means is that you

13 likely have bacteria that are getting into the

14 shunt. If the bacteria are inside of the

15 shunt, that is a direct route into the brain.

16 So, essentially, when you are talking about an

17 infected shunt, you are talking about treating

18 a child with suspected meningitis.

19   It is a problem. The shunt has to

20 be taken out. You are looking at maybe a 14-

21 to 21-day course of antibiotics, externalizing

22 the shunt. You still have got to deal with

1   the pressure when the shunt is removed to make

2   sure the kid is safe, and then you have got to

3   put another shunt back in. So, infection is

4   a big deal, and they take it very seriously.

5   In terms of the co-management, the

6   other operating staff, in addition to the

7   neurosurgeons, feel like they play a heavy

8   role into the process. Again, they try to

9   really streamline as much as they can in the

10   operating room the time of procedure and time

11   to completion. So, having the surgical

12   assistants there and everyone else onboard

13   with exactly what is going on and making sure

14   that they are comfortable with the procedure

15   makes a difference.

16   When a child is out of the

17   operating room, then at our hospital there is

18   a good bit of co-management that goes on

19   between some of the general and developmental

20   pediatricians and the surgeons to help manage

21   these children afterwards. Sometimes it is

22   harder than you would think to determine

1   whether a child actually has a shunt

2   malfunctioning or not. So, when a child has

3   symptoms that are suggestive of it, oftentimes

4   the surgeons will consult with us, if we know

5   the children very well, to determine if we are

6   highly suspicious of that happening or not.

7   CO-CHAIR HOMER: Dr. McInerny,

8   Tom?

9   MEMBER McINERNY: Yes, I think

10 this is a terrific idea. It reminds me a

11 little bit of what we have been able to do

12 with central line infections. You know, we

13 used to consider them, well, that is just part

14 of putting central lines in, and now we know

15 that if you do things correctly, you can avoid

16 that.

17   A couple of questions. I am

18 wondering, in Boston are they using checklists

19 when they are doing these?

20   DR. BERRY: Surgical checklists, I

21 am not sure if they are using the checklists

22 or not.

 1   DR. LILLEHEI: Yes, as one of the

 2   surgeons in the operating room in Boston, yes,

 3   checklists have become a part, a required

 4   part.

 5   MEMBER McINERNY: Okay. So, that

 6   should help.

 7   And two, essentially, you are sort

 8   of providing a 30-day guarantee. I am

 9   wondering why you pick 30 and not, say, 60,

10   90, or 365 days. Any evidence to suggest --

11   because my experience has been 30 days, you

12   know, you may get some, but another month or

13   two or three later you are going to get more.

14   So, where do you draw the line? Can you

15   perhaps extend it to more than just 30 days?

16   DR. BERRY: It is a great

17   question. We really argued about this for a

18   while.

19   So, it seems that the majority of

20   shunt malfunctions are occurring closer to the

21   operation than later out. Now, if you do

22   expand out to 60 or 90 days, you are going to

1   pick up more signal.

2   However, it was a little bit of a

3   dance with the neurosurgeons in terms of how

4   the quality of the operation was related to

5   the outcome. So, they sort of felt like, yes,

6   well, the further you are going out, the less

7   likely it was associated with a previous

8   operation. So, in that regard, we sort of

9   negotiated and ended up on 30 days.

10   However, I would say that I think

11   that we are minimally considering going out

12   further, if that is important to the group.

13   CO-CHAIR HOMER: Phil? If I could

14   also ask the questions right now, I would like

15   them focused on the importance question

16   particularly. We can deal with some of the

17   other issues as we go through, but go ahead.

18   MEMBER KIBORT: All right. So,

19   from my perspective, and I will concur that

20   there is importance there. I think most

21   active children's hospitals believe that this

22   is a major problem. I think there are data

 1   about anywhere from 3 to 20 percent or 25

 2   percent is true. So, for me, it is an

 3   important operation.

 4   And in some hospitals, the

 5   hospitalists also take care of the patients

 6   post-op, as do our neonatal or our pediatric

 7   nurse practitioner hospitalists. So, it

 8   crosses different aspects, different

 9   professionals.

10   CO-CHAIR HOMER: David?

11   MEMBER CLARKE: Just one issue

12   that I am not sure that the Committee is

13   really aware of related to the importance of

14   this measure is, what are the implications of

15   shunt failure, particularly acute shunt

16   failure, from the standpoint of

17   morbidity/mortality of the patient, and also

18   the cost? My impression is most of these are

19   emergencies, particularly when they occlude.

20   Would you comment?

21   DR. BERRY: Thank you.

22   So, they are considered

1   emergencies, and if not treated promptly,

2   there is a high risk of death. If death does

3   not occur, then you are looking at essentially

4   a lot of permanent neurologic sequelae from

5   pressure on the brain.

6   In terms of the economic impact,

7   we were able to go back and look at some of

8   the HCUP data from AHRQ that has been

9   published on this. And it is estimated that

10   there are probably around 10,000 admissions a

11   year associated with shunt malfunction in

12   children, and the mean cost of those

13   admissions is around $17,000 to $20,000. So,

14   you are looking, I think, at around $200

15   million annually just in shunt malfunction

16   admissions.

17   CO-CHAIR HOMER: That is very

18   helpful, David. That last point is the kind

19   of data that I was looking for in figuring out

20   the importance.

21   I understand the clinical

22   importance and the frequency of shunts that

1   are put in that fail. One thing in the

2   measure specifications, in your description,

3   though, that concerns me is if it requires

4   three-year averages, three-year running

5   averages, to come up with stable rates

6   sufficient for conducting analysis and

7   benchmarking, what are the implications of

8   that in terms of really the frequency and our

9   ability to use it to actually track changes?

10   DR. BERRY: So, I was thinking

11   more of the three-year running average less in

12   order to collect the numbers --

13   CO-CHAIR HOMER: Okay.

14   DR. BERRY: -- but more to

15   stabilize the confidence intervals of that,

16   and, also, so that you are not trying to

17   change or do not change the quality of care

18   that you are doing for these things just

19   because of a quarter where you may have looked

20   bad or maybe a year. So, we thought that it

21   stabilized the measure to median in terms of

22   more of the variance than it did the actual

 1   signal.

 2   CO-CHAIR HOMER: Okay.

 3   DR. BERRY: And that was sort of

 4   my approach to it.

 5   MEMBER LIEBERTHAL: I would like

 6   to ask members of the Group 1 why they chose

 7   partially rather than completely as far as

 8   impact. We went from yesterday these very

 9   broad measures that had value as far as

10   populations and government to now a very

11   operational small volume, but to this

12   specialty very important measure that is a

13   true outcome measure. I wanted to know why

14   people considered it only partially meeting

15   the impact, that one.

16   CO-CHAIR HOMER: For me, it was

17   basically we didn't have population prevalence

18   data. We didn't have the financial data. The

19   three-year average concerned me. I think this

20   was the measure with the lack of improvability

21   over time. Well, there was the variation --

22   I may be confusing with a different one where

1   it had been tracked, but there hadn't been

2   changes. If I am confusing it, please tell

3   me.

4   But those were why I put it only

5   in the partially rather than the completely

6   area. So, even if it was clinically -- again,

7   I am operating a little on the assumption that

8   NQF already has 600 measures, many of which

9   are -- 450 -- many of which are clinically-

10   accurate, but relatively low-prevalence

11   conditions and so aren't going to have broad

12   impact on changing.

13   So, that is why I wanted to make

14   sure this was something that was not only sort

15   of valid and clinically important for a very

16   small subset, but actually was worthy of

17   investing the resources in maintaining and

18   continued for a significant impact. That was

19   my personal reason for only putting it at

20   partially rather than completely.

21   DR. BURSTIN: Just one comment on

22   the criteria, and the way we read this

 1   specifically was that impact could either be

 2   in terms of broad impact, broad population,

 3   big numbers, or a small population with a

 4   significant impact on them. So, I think part

 5   of what you have heard is the significant

 6   impact on a small population is quite

 7   reasonable as well.

 8   MEMBER DOCHERTY: Yes, and I would

 9   say that that was really my learning curve

10   over the past two days, is that it had to do

11   with the broad population. I was thinking

12   more of the impact broadly and now realizing

13   that this is a very strong measure of a

14   specific group.

15   MEMBER RAO: My concern is, and I

16   think Dr. Berry has addressed this to some

17   degree, I was under the assumption that the

18   vast majority of shunts are placed in a

19   handful of hospitals, and therefore, it would

20   be harder to pick up variation. But it seems

21   like there's a lot of different places where

22   they are performing the procedure.

1   DR. BERRY: That is right.

2   So, going back into the HCUP data,

3   not in the nationally-weighted data, but in

4   their actual sample from 38 states in 2003,

5   there were over 300 pediatric hospitals that

6   were performing these across the country.

7   About 70 percent of those are considered by

8   NACHRI to be teaching hospitals in some way.

9   Thirty percent are community hospitals. So,

10   we think that there is a lot more bandwidth

11   out there for this than we initially thought.

12   CO-CHAIR HOMER: So, Tom?

13   MEMBER McINERNY: Yes, just a

14   quick question. Is this somewhat similar to

15   pediatric cardiac surgery in that, the more

16   you do, the better you are, the less you are

17   going to have some failures?

18   DR. BERRY: So, that is emerging.

19   You know, the volume/outcome relationship for

20   this over time is emerging as in cardiac

21   surgery, yes.

22   CO-CHAIR HOMER: So, just

1   following our procedure, the first thing we

2   need to do is vote. Because importance is a

3   threshold we have to vote on the importance

4   first, and then we can go on to discuss the

5   other elements of the measure.

6   So, I would like to have a vote

7   from the Committee on whether this measure

8   meets the threshold criteria for importance.

9   So, all in favor raise your hand.

10   DR. WINKLER: Marlene, are you on

11   the phone?

12   (No response.)

13   No.

14   CO-CHAIR HOMER: Terrific. So, it

15   meets that criteria. So, let's move on to

16   discussion of scientific acceptability.

17   Any members of the Committee, the

18   Work Group, want to make any comments?

19   MEMBER CLARKE: I have a couple of

20   points that I would like to ask about. Going

21   back just tangentially to the 30-day issue,

22   one of your data-gathering points was

 1   reoperation for ventriculoperitoneal shunt

 2   during the same hospital admission. I am

 3   wondering, does the 30-day rule still apply in

 4   that situation?

 5   And I would also like for you to

 6   comment on the exclusion of the children under

 7   one-month of age or children with spina

 8   bifida, which are known risks for shunt

 9   failure that are, I guess, at this time

10   considered non-preventable. But my concern

11   about that is that, if you don't measure those

12   kinds of things, they never become preventable

13   because they are not identified.

14   One of the things that has been

15   applied, for example, in the STS database is

16   that the data is harvested, but these things

17   are initially excluded from analysis until

18   they determine exactly what their relationship

19   is to the overall measure.

20   Could you comment on those points?

21   DR. BERRY: Sure. So, if a child

22   receives an initial shunt, remains in the

1   hospital past 30 days, and has a shunt

2   malfunction at 30 or greater days, then they

3   are not counted.

4   In terms of the age less than one

5   month, we are understanding now that there is

6   a lot of treatment variability going on across

7   the country in how to manage hydrocephalus in

8   those kids with modalities that lie in

9   addition to VP shunts, which makes it more

10   complicated to study.

11   There is an endoscopic third

12   ventriculostomy and a reservoir of things the

13   neurosurgeons know much more about than I do,

14   but they felt like it was better to pursue

15   what is actually going on among the treatment

16   modalities for those kids than to single out

17   shunts in those kids less than 30 days for the

18   measure. They thought that it made it more

19   homogenous across hospitals to exclude them.

20   In terms of the spina bifida, I

21   think you have a very valid point. So, when

22   we initially created the measure, we included

1   spina bifida within the cohort and we risk-

2   adjusted for it. Then, after some discussion,

3   we thought it was best, again, to draw a nice

4   circle around the measure and exclude the

5   children with spina bifida because they

6   weren't exactly sure what is going on and why

7   their malfunction rates are so high.

8   We did have discussion yesterday

9   about whether it would be appropriate to have

10   a subdomain measure for those kids. I feel

11   that that would be important for something for

12   us to do as we test the measure and move

13   forward. I agree with you, if there is a lot

14   of signal without that group, we should not

15   exclude it.

16   MEMBER PERSUAD: What percentage

17   do you know of children who have shunts placed

18   have shunts placed for spina bifida?

19   DR. BERRY: Total?

20   MEMBER PERSUAD: Yes.

21   DR. BERRY: I think you are

22   looking at around 10 percent, 10 to 15 percent

1   at the most.

2   CO-CHAIR HOMER: So, Jay, could

3   you talk a little about the validity

4   assessment? Have you compared, for example,

5   the chart review data with the PHIS data, et

6   cetera? So, just technical aspects of the

7   measure.

8   DR. BERRY: That was our first

9   step. The neurosurgeons at first did not

10   trust the administrative data whatsoever,

11   which was a great process.

12   (Laughter.)

13   Luckily, they were collecting

14   their own. They had their own registry, which

15   was nice. So, they had all of their shunt

16   patients lined up. Then, we went through and

17   correlated that with the administrative data

18   from our hospital first. That made them much

19   more comfortable when they saw that the same

20   patients were showing up.

21   I don't have specific specificity

22   or sensitivity data for you, but there was a

1   litmus test of this work and the neurosurgeons

2   bought it, which made me feel good.

3   It seems that the codes are okay.

4   I mean to have a code that is specifically for

5   ventriculoperitoneal shunt is very well-

6   circumscribed. There is not a lot of noise in

7   that code from other things that can be thrown

8   in. And they had specific codes for shunt

9   removal, shunt revision, et cetera. I think

10   they have done a nice job upfront of sort of

11   thinking about these codes. So, we like the

12   face validity of the codes as they are.

13   CO-CHAIR HOMER: Any other

14   questions about different aspects of that?

15   Ellen, please.

16   MEMBER SCHWALENSTOCKER: This may

17   actually be a feasibility question, but the

18   one question I had is about the 30-day and

19   whether they always come back to the same

20   hospital, or how can you capture a 30-day rate

21   if a child is admitted to a different

22   hospital?

1   DR. BERRY: That is a very, very

2   important question. So, the data that you see

3   before you captures only kids who come back to

4   the same hospital. We polled a number of

5   neurosurgeons and did a few key informant

6   interviews to just try to get a sense of could

7   these kids go elsewhere. Because you could

8   imagine if a kid lives in a more rural area,

9   say, they have shunt malfunction; they may not

10   have time to come back to the tertiary care

11   center where they were operated first.

12   However, the surgeons feel strongly that the

13   vast, vast majority of the time the kids are

14   coming back to the same hospital.

15   CO-CHAIR HOMER: Jay, did these

16   data come from the PHIS database?

17   DR. BERRY: That's right.

18   CO-CHAIR HOMER: Describe how you

19   have applied this or have you tested this with

20   other discharge data for non -- since you said

21   only 30, you said a very significant number of

22   children have these procedures that are not in

1 tertiary children's hospitals, so would not be

2 in the PHIS database.

3 DR. BERRY: That's right. That's

4 right. So, beyond PHIS, we know that using

5 the HCUP and AHRQ data, that the codes are

6 being used across the country nationally. Now

7 the problem with the AHRQ data is that we do

8 not have the ability to link patients across

9 hospitalizations at the moment.

10 However, there have been a few

11 states that have been released in the last few

12 months where they have their patient linker,

13 which is allowing that process to occur, with

14 Claudia Steiner from AHRQ, I think with the

15 ultimate hope that they will be expanding out

16 for longitudinal data as it grows over the

17 next few years.

18 So, our next, I think, is to look

19 into that small sample of AHRQ data, have some

20 of the community hospital cohort included, and

21 start to test the measure there to see if the

22 codes are lining up appropriately.

 1   CO-CHAIR HOMER: And somewhere in

 2   the specifications it says the measure hasn't

 3   been tested, but, in fact, you are using it.

 4   It sounds like maybe you are doing more than

 5   you gave yourself credit for.

 6   DR. BERRY: That is a good

 7   question, Charlie. I wasn't sure exactly what

 8   the testing meant. I mean, in terms of what

 9   we have done at our hospital, we have done the

10   chart review. It has been plugged into PHIS.

11   We have looked at the rates and benchmarked

12   and targeted against other hospitals, and we

13   have acted on the data.

14   So, to a certain extent, I mean we

15   are using it, but the gold standard to me, if

16   you are really going to test it, I think,

17   would be to go out and do a multi-

18   institutional chart review and validation

19   process to make sure that there is not a lot

20   of coding variability, et cetera. That hasn't

21   been performed.

22   CO-CHAIR HOMER: It really was

 1   just performed at your institute? When you

 2   said you compared to registry data, that was

 3   really only within your own institution?

 4   DR. BERRY: Exactly. Right.

 5   CO-CHAIR HOMER: Okay.

 6   MEMBER CLARKE: I have a question

 7   relative to your three-year rolling data plan.

 8   Does that apply only to single institutions

 9   or, if you are implementing it more broadly --

10   in other words, if the entire group of 70

11   institutions, academic institutions, are

12   participating in the measurement, does that

13   modify your need to do that?

14   DR. BERRY: This is a great

15   question. I think it depends on what you are

16   going to use the data for, what's the

17   actionability of the data. I think if you are

18   looking on a population level of are we

19   getting better with shunt care, are we

20   decreasing the malfunction rates, I don't

21   think you need the three-year rolling average.

22   I think you can do that on the population data

1   with a year of data and be fine.

2   I think, however, if you are

3   trying to look at yourself and say, within

4   this cohort of hospitals, are we doing better;

5   are we doing worse; are we in the middle; do

6   we need to think about changing or not

7   changing our care, then I do like to

8   incorporate the variance surrounding that

9   measure and making sure that, before I say

10   that my hospital has worse malfunction rates

11   than Hospital B, that I sort of look around

12   the noise of that signal and make sure that it

13   is not due to the noise, that it is the

14   signal. So, I would say go for the three-year

15   if you are doing that.

16   CO-CHAIR HOMER: Just one more

17   technical question on this, and then I think

18   we can probably on to vote on this. Have you

19   looked at disparities issues? Have you looked

20   at variation in rates across different

21   populations?

22   DR. BERRY: We did, and this is

1   what we found. So, in our bivariate analyses

2   we found that non-Hispanic Blacks have higher

3   rates of shunt malfunction compared to Whites.

4   Now when we threw that into a multivariate

5   model, controlling for other things, the

6   effect went away. So, I am not sure if there

7   is something there or not, and at this point

8   I felt that it was best not to cull it and put

9   it into the measure.

10   However, if people are thinking

11   that it is important to present within the

12   measure subdomains rates within different

13   race/ethnicity groups, we are certainly

14   amenable to doing that.

15   CO-CHAIR HOMER: I mean the NQF

16   process is to stratify results by different

17   populations rather than adjust. So, okay, the

18   point is, again, you looked at it and that it

19   is feasible to look at within the dataset.

20   DR. BERRY: Yes.

21   CO-CHAIR HOMER: I think that is

22   what is important from the NQF perspective.

 1   Members of the --

 2   MS. BOSSLEY: This is Heidi. Can

 3   I just jump in?

 4   Going back to the evaluation

 5   criteria, which all of you have been working

 6   off in rating all these measures, the key

 7   piece on testing, I want to make sure you all

 8   understand why staff rated this as not tested

 9   is it hasn't had reliability testing, the

10   test/retest or some type of look, and it

11   hasn't gone through any validity testing as

12   well, which is something that you all can

13   decide is okay for this measure, but we would

14   really feel that it needs to have a time-

15   limited endorsement, which means they have 12

16   months, or we will negotiate with them -- I

17   think sometimes it takes a little longer -- to

18   come back and provide that information.

19   I think the key piece that we

20   always want to make sure is any measure you

21   put out there for public reporting, anyone

22   else who goes and does the same thing with the

1   specifications that they provide can be

2   replicated to the greatest extent possible.

3   We don't know that yet, that you can with the

4   way this measure is specified. So, that is

5   really, I think, why we had it labeled as

6   needing time-limited endorsements.

7   Does that make sense to everyone?

8   CO-CHAIR HOMER: I think NQF,

9   quite appropriately, is tightening its

10   criteria. Certainly, this is more tested than

11   a number of measures I know when I was on the

12   Ambulatory Steering Committee -- (laughter) --

13   which was we sort of kind of think this is a

14   good idea, and we could actually pull the

15   data. That was viewed as testing.

16   This one has been validated in one

17   site, but not in multiple sites. And

18   test/retest in this seems like that, you know,

19   with administrative data, I am not sure that

20   concept is really quite applicability, but

21   that is probably getting too deep into the

22   weeds.

1   DR. BURSTIN: I'm sorry, we can

2   also take just a closer look at the testing

3   and get back to Children's as well, just to be

4   sure.

5   MEMBER DOCHERTY: Yes, I was just

6   going to say that I was less worried about the

7   validity than the reliability, and that there

8   should be some formal measure that across

9   sites people are --

10   CO-CHAIR HOMER: Well, I guess we

11   go through all the criteria and then we vote.

12   We will go through.

13   So, let's move on to -- and we may

14   have already addressed this -- the usability?

15   Do you want to vote on each

16   section? Okay. I forgot.

17   So, then, to vote on the

18   scientific acceptability, how many feel it is

19   completely meets criteria?

20   And how many feel it partially

21   meets criteria?

22   Okay. And does that get everybody

1   or are we down to minimally -- okay, good.

2   All right. So, moving on to

3   usability, that is, is it understandable? Is

4   it harmonized? Are there any other measures

5   out there? And does it provide added value?

6   Any comments from the Work Group

7   on that?

8   MEMBER PERSUAD: I think I would

9   like to ask, you said you are using it at your

10   institution. So, what I want to know is, what

11   has happened since you started the measure?

12   What has happened to your rates and what have

13   you done?

14   DR. BERRY: Since starting to

15   measure, I think the first thing that happened

16   there was a little of a Hawthorne effect going

17   on, which was fantastic. I think it just got

18   people thinking about malfunction.

19   And it also had non-neurosurgeons

20   thinking about malfunction as well. I mean

21   hospitalists, other people when they were

22   admitting to our services said, "Jay, we had

 1   another kid that was readmitted with a shunt

 2   malfunction," you know, blah, blah, blah. So,

 3   it created a lot of buzz.

 4   The second thing that happened is

 5   that the neurosurgeons really felt like they

 6   needed to streamline the amount of time it was

 7   taking to perform these operations initially

 8   in the OR, and that they really needed to have

 9   a core competency within a small group of

10   staff in the OR to make sure the operation was

11   right.

12   So, they have actually tried to

13   decrease the number of personnel that are

14   physically in the room during the operation

15   because they feel like the more people that

16   are there, strictly adding another person may

17   increase the risk of the child having an

18   infection. So, they really are trying to make

19   a difference.

20   We have seen some small decreases

21   in our rates. Now, if you look at the

22   confidence intervals around that, they haven't

1   changed significantly, but we have seen a

2   little decrease in our signal since the

3   measure was put onboard.

4   CO-CHAIR HOMER: Any further

5   questions about usability?

6   (No response.)

7   All right. So, why don't we call

8   a vote on how many feel this completely meets

9   usability criteria?

10   That's everybody, right? No?

11   DR. WINKLER: You're a partial?

12   Many people are looking at Ellen back there.

13   Partial?   Okay, good. Okay.

14   MEMBER PERSUAD: Ellen, are you a

15   complete or partial?

16   MEMBER SCHWALENSTOCKER: Partial.

17   CO-CHAIR HOMER: Okay. All right.

18   So, let's move on to the feasibility. I think

19   you have already addressed many of the

20   questions there, which is that it is feasible

21   within the PHIS database, may be feasible in

22   the other ones, but hasn't been, because of

1   the idea of whether you can actually track

2   individuals over time, hasn't yet been

3   applied. Is that correct?

4   DR. BERRY: That is correct. I

5   think that is the data that you are going to

6   need to really establish your targeting and

7   benchmarking.

8   I mean I would hope that most

9   hospitals across the country have enough admin

10   data in terms of for every admission they have

11   the procedures and the diagnoses that occur in

12   order to bill for them, that they have an

13   internal structure which from their admin data

14   they can pull their own rates.

15   So, I think you are looking at

16   more the national databases, then, to

17   determine, okay, how well are we doing

18   compared to other hospitals?

19   MEMBER LIEBERTHAL: What exactly

20   is the PHIS database?

21   DR. BERRY: So, the PHIS database

22   is a database of inpatient hospitalizations

1   for 42 freestanding children's hospitals

2   across the country. It is unique in that the

3   patients are linked across multiple

4   encounters. So, you can track a patient over

5   time to see the number of times they are

6   hospitalized, and for each admission you have

7   the diagnoses and procedures that occurred,

8   demographics, et cetera, to allow you to pull

9   data such as this.

10   MEMBER LIEBERTHAL: So, for

11   patients who do not receive the procedure at

12   one of these 42 hospitals, their own

13   administrative data would have to be used, is

14   that correct?

15   DR. BERRY: That is correct.

16   MEMBER LIEBERTHAL: And you are

17   basing this on assumptions that they have

18   accurate databases that they can pull data

19   from?

20   DR. BERRY: Yes, some type of

21   administrative billing database that the

22   hospital would use for their coding, which

 1   would be the same that PHIS is pulling from

 2   our hospital. It is the same sort of

 3   coordinated set. But the assumption would be

 4   that they have that same similar dataset.

 5   MEMBER CLARKE: I would like to

 6   ask if there exists a Neurosurgical Society-

 7   based database that would cover this issue,

 8   and would that be useful?

 9   DR. BERRY: Yes. So, one product

10   that has emerged from this work to start is

11   the creation of a multi-institutional

12   Hydrocephalus Collaborative, which is now

13   being started up by John Kestle in Utah, and

14   one of the collaborators in some of our work,

15   Tamara Simon.

16   It is really good stuff,

17   prospective data collection, looking at very,

18   very specific variables around quality of care

19   around the shunt procedure. Hopefully, we

20   will see data from them in the next year or

21   two.

22   CO-CHAIR HOMER: That's very

 1 exciting.

 2   Nancy?

 3   MEMBER FISHER: I would like to

 4 make a comment about this. In the State of

 5 Washington, we have been doing collaboratives

 6 like this. We have done it around

 7 cardiovascular surgery. We now are including

 8 some things in cardiology and PCI. We have

 9 done it around surgical procedures that we

10 thought, like for appendectomies you ought to

11 be able to do an appendectomy. And we were

12 quite surprised to see the variation.

13   One of the things is that we have

14 used the three-year rolling average. It does

15 eliminate problems when people think that they

16 are being unfairly targeted for something that

17 it was just it happened.

18   The core thing that we found that

19 was going on when you started looking at

20 administrative data was one is the people that

21 were extracting the data. And we even get

22 asked by the hospitals to send out people to

 1   make sure that we could look at this and do

 2   validation on it.

 3   The other thing is, when you first

 4   start out, whether people take it, if you are

 5   collecting the data, they say they will, if

 6   they take it seriously. They have been pinged

 7   and looked bad because they did sloppy data

 8   collection. But all you have to do is be

 9   pinged and you put yourself back together.

10   The other thing that I found good

11   about what he was saying is, if you want to go

12   into different hospitals, what we found out is

13   the key is to get a physician in that

14   specialty to be your champion. That is the

15   way to get in. This is one way -- I mean I am

16   very glad that you realize about the data and

17   stuff because the first thing we had to do was

18   get this data. People got sick of hearing

19   about it. So that we answered everybody's

20   questions about the data, so they could

21   believe, yes, maybe you do have a problem.

22   I am really happy to hear that you

 1   are going to do a collaborative about that.

 2   CO-CHAIR HOMER: Tom?

 3   MEMBER McINERNY: Just a quick

 4   question, sort of suggestion. As more and

 5   more hospitals migrate to electronic medical

 6   records for both their inpatients and their

 7   outpatients, would you foresee that maybe

 8   sometime in the future you would be able to

 9   use that data and get rid of the

10   administrative data?

11   DR. BERRY: Oh, boy, that would be

12   absolutely fantastic. I mean to move beyond

13   codes, to move into a lot of clinical detail,

14   the size of the shunt that is placed, the time

15   in the operating room, you know, very, very

16   specific clinical details going into it will

17   trump this stuff like no tomorrow. So, I

18   can't wait for that day.

19   CO-CHAIR HOMER: All right. So,

20   in terms of feasibility, I suggest that we

21   call a vote.

22   How many feel this completely

1   meets criteria for feasibility?

2   And partially?

3   Okay, good.

4   All right. So, now it is time to

5   call the vote on the overall measure. I think

6   the recommendation we are hearing from staff

7   would be that this should be recommended for

8   time-limited approval, pending additional

9   testing. I think particularly the idea of

10   looking at validity across multiple

11   institutions and potentially expansion beyond

12   the CHCA dataset seem to be the two areas we

13   would like to see additional testing on.

14   CO-CHAIR WEISS: With no

15   specificity about the time limit, right? They

16   would work that out?

17   CO-CHAIR HOMER: It's 12 months,

18   generally?

19   DR. BURSTIN: It's generally 12

20   months, but if there's a little wiggle room,

21   we can do it.

22   CO-CHAIR HOMER: Okay. So, all

1   those in favor of conditional approval -- I'm

2   sorry -- time-limited approval? Thank you.

3   There you have it. All right.

4   Thank you very much.

5   DR. BERRY: Thanks for your time.

6   Thanks for everything.

7   MEMBER PERSUAD: Charlie, I have

8   just two final comments about that measure

9   before we pass it.

10   CO-CHAIR HOMER: Yes, please,

11   Donna. We did pass it, but before we move on

12   it.

13   MEMBER PERSUAD: Well, before we

14   move on it.

15   CO-CHAIR HOMER: Okay.

16   MEMBER PERSUAD: One is I may have

17   just blanked out over the discussion regarding

18   when children get readmitted from different

19   institutions, and if it's possible to work

20   that out in the follow-up period through the

21   PHIS. I don't remember what he said. There

22   is a way to do it with the PHIS database, but

 1   getting it cleaner to where not only from the

 2   institution where you did the surgery, if you

 3   readmit to another hospital for shunt

 4   malfunction, if you can get that into the

 5   data? It may not be doable just yet, but --

 6   CO-CHAIR HOMER: If they do that

 7   collaborative, it would be.

 8   MEMBER PERSUAD: Yes, if they did

 9   a collaborative, I guess they could sort that

10   out there.

11   CO-CHAIR HOMER: That's a good

12   question. I guess that is the challenge of

13   not having a Medicare database, that you can't

14   track individuals across institutions. But,

15   okay, so something during the test period to

16   encourage them to look at. That is a great

17   suggestion.

18   MEMBER PERSUAD: And, then,

19   speaking for Marlene in her absence over the

20   toolkit issue, since this group has a

21   checklist already, where the measure is

22   published, the checklist could become

 1   available or I guess the collaborative would

 2   probably come up with tools for having better

 3   rates.

 4   CO-CHAIR HOMER: So, that is a

 5   question I think for Helen, which was

 6   Marlene --

 7   MS. RAUSCHER: Could I just ask

 8   the measure developer to come in?

 9   CO-CHAIR HOMER: Sure.

10   But just sort of more as a policy

11   or process, Marlene Miller suggested yesterday

12   that, when we approve or consider a measure,

13   the idea of linking that to a quality

14   improvement toolkit. I didn't know whether

15   NQF had considered as part of its process

16   making those available together with their

17   measures.

18   DR. BURSTIN: We haven't done that

19   to date, but we are moving towards trying to

20   create this relational database. We are

21   calling it MAPS, Measures and Practices. It

22   will try to package everything together saying

1   here's the measure; here's the practice;

2   here's related information. It is all sort of

3   developmental, but that is something we can

4   work on as well.

5   CO-CHAIR HOMER: So, Jay, there

6   were really two sets of questions that were

7   raised. One was the idea of linking across

8   institutions. So, a child gets operated on at

9   Boston Children's and shows up at some other

10   institution in town, for example. Is there

11   the capability or at least can you look during

12   the testing period at that potential to look

13   at? That was one of the questions.

14   DR. BERRY: I think we should

15   explore it. I am wondering, I think that AHRQ

16   may actually have more data that is just not

17   publicly available yet.

18   CO-CHAIR HOMER: Okay.

19   DR. BERRY: And I feel comfortable

20   talking with them and asking them if we could

21   do something like that through the state

22   inpatient databases and merging them together.

 1   CO-CHAIR HOMER: And the other

 2   question was, building on conversation we had

 3   yesterday, was the desirability of linking

 4   measures with quality improvement-related

 5   toolkits. NQF is in the process of putting

 6   together a database that you could just cue up

 7   your issue and you would link a variety of

 8   things. So, I think more expression of

 9   interest in that toolkit being made broadly

10   available as the collaborative moves forward.

11   DR. BERRY: Sounds great.

12   CO-CHAIR HOMER: Did I capture

13   that, Donna?

14   MEMBER PERSUAD: Yes. Thank you.

15   CO-CHAIR HOMER: Good. All right,

16   thank you very much. That is really great.

17   MS. McELVEEN: Okay. Moving on to

18   our next measure, Measure 28, is the

19   standardized mortality ratio for neonates

20   undergoing non-cardiac surgery. This is the

21   ratio of observed-to-expected rate, observed

22   to -- yes, ratio of observed-to-expected rate

1   of in-hospital mortality following non-cardiac

2   surgery among infants less than 30 days of age

3   and risk-adjusted.

4   So, this is, again, under the same

5   group. We will open it up for importance.

6   CO-CHAIR HOMER: Or should we ask

7   the presenters --

8   MS. McELVEEN: Oh, sure. Yes.

9   Absolutely.

10   CO-CHAIR HOMER: -- to briefly

11   describe the measure?

12   Maybe also, Dr. Lillehei, having

13   heard the conversation before, maybe sort of

14   focusing some of your comments on some sort of

15   sequentially thinking about the importance of

16   the measure and then its scientific

17   credibility, et cetera, that would be great.

18   DR. LILLEHEI: Certainly. I can

19   try to do that.

20   CO-CHAIR HOMER: Thanks.

21   DR. LILLEHEI: Together with Kim

22   Gauvreau, the statistician, I am a pediatric

1   surgeon, and together developed this model.

2   One of the problems that we face

3   in surgery is, obviously, an ability to risk-

4   adjust, and that is particularly a problem in

5   pediatrics and pediatric surgery, where we

6   have a wide variety of different sort of

7   problems that present in children.

8   What we have done especially is

9   for a variety of different diseases, we will

10   pick a disease and then study that either in

11   a particular institution or across

12   institutions. But, again, it is limited to

13   that. Whether it is gastroschisis or

14   omphalocele or diaphragmatic hernia,

15   necrotizing enterocolitis, a variety of those

16   studies have been done.

17   We were looking for a broader

18   measure, and specifically a broader measure to

19   look at neonatal surgery. So that, as you see

20   in our measure, we are focusing on operations

21   that occur within the first 30 days of life.

22   Those are primarily congenital lesions, but,

 1   again, they are infrequent. Surgery in

 2   children is, fortunately, rare. In order to

 3   develop a risk-adjustment method, we used a

 4   strategy where we could combine procedures of

 5   similar risk.

 6   Now, in order to do that reliably,

 7   first of all, we chose to use a large national

 8   database. So, this is based on the KIDS 2000,

 9   where we have developed the model. And within

10   that, we focused on procedures that had at

11   least 20 cases. In those circumstances where

12   there were just a handful of cases, we didn't

13   feel that that gave us a reliable tool for

14   assessing risk. So, they are limited to cases

15   that are greater than 20 cases.

16   Of those, there are 63 different

17   procedures that are included out of a total of

18   some 570, something like that. But, in fact,

19   those 63 cases account for almost 85 percent

20   of all the procedures done. So, we think it

21   is based on a large sample from that KIDS

22   database.

 1   With that, then, to take you

 2   through the rest of the model, we developed

 3   risk categories based on that. Then, as a

 4   measure, we thought the most reliable measure

 5   and, in fact, in many ways the most important

 6   measure for us was in-hospital mortality. So,

 7   that was something that we could measure that

 8   we felt was reliably reported, even within an

 9   administrative database, and would allow us to

10   make assessments from institution to

11   institution and risk-adjust appropriately.

12   CO-CHAIR HOMER: Kim?

13   MS. GAUVREAU: I don't have

14   anything more to add at this time.

15   CO-CHAIR HOMER: Members of the

16   Work Group, questions? Again, probably start

17   with maybe first your observations and then

18   questions, starting on the importance first.

19   MEMBER RAO: Sure. I think that

20   my concerns and observations were actually the

21   second lengthy comment up there. It is just,

22   essentially, I am not sure how many children

 1   actually undergo surgery in the neonatal

 2   period. The incredible variety of procedures,

 3   even 63 procedures, seems like it is too

 4   heterogeneous to mix together.

 5   And finally, just looking at the

 6   data that you had, only one hospital had a

 7   significantly different rate of neonatal

 8   mortality listed there.

 9   So, if you could address some of

10   those points?

11   DR. LILLEHEI: There's no question

12   that the heterogeneity of cases is a challenge

13   in making that assessment of neonatal surgery,

14   newborn surgery. But I think the most telling

15   thing about that is that, in fact, when we

16   made this analysis, we derived it in the KIDS

17   2000 base and then validated it in the 2003,

18   that our ROC curve, that it was actually quite

19   reliable, that 90, 92.92 was the -- they were

20   under the curve with the ROC curve. So, that

21   it showed that we really were able to reliably

22   risk-adjust in this population.

 1   So, to be sure, it is a challenge,

 2   and there is a considerable heterogeneity,

 3   but, in fact, the results seem to underscore

 4   that.

 5   CO-CHAIR HOMER: When it comes to

 6   the second question of the lack of variety,

 7   can you describe the variety across sites?

 8   DR. LILLEHEI: Yes. We presented

 9   the table where you saw 15 different

10   institutions. I think what you could see

11   within that table is there was a considerable

12   variability from institution to institution.

13   However, you are quite correct that it was

14   only one in which that achieved statistical

15   significance. So, it may be that, by virtue

16   of the fact that we are dealing with

17   relatively small numbers, that we would need

18   a larger time period to accrue greater numbers

19   and highlight some of those differences from

20   institution to institution.

21   MS. GAUVREAU: Right. We were

22   only looking at one year of data in that case.

 1   So, maybe something like we were talking about

 2   with the previous measure, maybe it needs to

 3   be a two-year measure or a three-year measure.

 4   We have started looking at this

 5   method a little bit in the PHIS database, and

 6   in that case we were using three years of data

 7   to look. The confidence intervals are

 8   narrower in that case.

 9   CO-CHAIR HOMER: Faye, please.

10   MEMBER GARY: I was wondering,

11   across the 15 different institutions and

12   collectively, do you have data about the

13   mortality for subgroups of populations,

14   African-Americans, American Indian, Hispanic,

15   et cetera? Do you have those data? And if

16   you do, could you share those with us

17   collectively? And if you see a variability

18   across the 15 different institutions?

19   DR. LILLEHEI: No, you've cut to

20   the core, but the exciting thing about this

21   method for us is the ability to look at that

22   administrative database, which will have

1   access to things like race, insurance, type of

2   hospital, those sorts of data. But I don't

3   have that data for you today, no.

4   MEMBER GARY: Those data are

5   forthcoming?

6   DR. LILLEHEI: Well, that is

7   something that we are working on right now.

8   We developed that model for just that reason,

9   to be able to look at those sorts of issues.

10   You bet.

11   CO-CHAIR HOMER: Tom?

12   MEMBER McINERNY: I think we all

13   know that morbidity, I mean mortality in

14   children, even in neonates, is so rare that it

15   makes it difficult sometimes to come up with

16   significant differences. I wondered if you

17   have looked at, if you could take a

18   combination of morbidity and mortality, such

19   as needing a second operation or getting an

20   infection, and if you might, then, be able to

21   get a bit more variability in the data by

22   adding in morbidity to mortality?

 1   DR. LILLEHEI: To be sure, the

 2   more we know and understand of how that

 3   surgery impacts on children, the more valuable

 4   that becomes. The problem for us or the

 5   challenge for us is that in administrative

 6   databases they have certain limitations, of

 7   which you are all quite aware. We really felt

 8   that what we wanted to be able to generate is

 9   a very reliable method for assessing that

10   risk. We thought that, as such, mortality is

11   the most reliable measure to do that.

12   CO-CHAIR HOMER: David?

13   MEMBER CLARKE: Yes, I certainly

14   agree with that. I have been there and tried

15   to do that, and it is tough.

16   The one thing on my first run-

17   through of the application that I came across

18   that I think is a fatal flaw, but it

19   apparently is not, potentially a fatal flaw,

20   is basing the total project on operative

21   cases. Cases don't die; patients do.

22   When you have patients who have

1   multiple procedures, particularly, this

2   becomes an extremely unreliable method of

3   measurement. But I was talking to Kim a

4   little earlier, and apparently this is not

5   exactly true.

6   DR. LILLEHEI: Yes, Dr. Clarke, we

7   perhaps didn't make that clear enough in our

8   application. But, in fact, no, it does refer

9   to specific patients. When a patient has more

10   than one procedure, which obviously is a not

11   uncommon occurrence, they are assigned to the

12   highest risk category associated with those

13   procedures.

14   MEMBER CLARKE: So, the mortality

15   is only attributed to one procedure? Because,

16   otherwise, you wouldn't know what you were

17   talking about.

18   DR. LILLEHEI: Correct.

19   MEMBER CLARKE: The other question

20   that I had was the ordinary criteria for

21   operative morality is either death during the

22   same hospital admission or death prior to 30

 1   days. I am wondering whether your limitation

 2   on data is the reason that that is not

 3   included or whether it would just be so rare

 4   in the neonatal population that a child would

 5   die within 30 days of operation but after

 6   hospital discharge, that it is probably

 7   unnecessary to look at that. Any comment?

 8   DR. LILLEHEI: Well, fortunately,

 9   it is rare, but to be sure, in-hospital

10   mortality was once again what we felt was the

11   most reliable piece of data that we could gain

12   from that administrative database. So, that

13   is why it was chosen.

14   MS. GAUVREAU: And also because

15   the database we were using didn't allow us to

16   link multiple admissions on the same patient.

17   So, if a patient was discharged, was

18   readmitted, and died subsequently, we wouldn't

19   know that.

20   MEMBER DOCHERTY: My concerns were

21   similar to David's in that I was trying to

22   make sure I understood that the mortality

 1   associated with these infants could be

 2   directly related to the surgery and not other

 3   things that happen, the other morbidity that

 4   is associated with this age group being

 5   hospitalized. But you are pretty certain that

 6   you will be able to, that the database will be

 7   able to link that mortality specifically to

 8   their surgical outcomes and not iatrogenic

 9   things for infants in hospitals?

10   DR. LILLEHEI: Yes, I think that

11   is a good question. A couple of different

12   things.

13   No. 1 was that we looked at a

14   variety of different clinical variables that

15   might impact on outcome, mortality in this

16   case, and there were only two that showed up

17   in that. That was serious respiratory

18   diseases and necrotizing enterocolitis. They

19   are included, those two clinical variables,

20   and only those two, are the ones that are

21   included in our model and are part of this

22   risk-adjustment method.

1   CO-CHAIR HOMER: So, just to focus

2   the conversation, this has been a fantastic

3   conversation, but, again, the first question

4   we want to ask is, is this important enough?

5   That is, either prevalent enough or for a

6   certain population important enough for us to

7   feel that it is worth proceeding with the

8   review of the other detailed attributes of the

9   measure.

10   MEMBER RAO: As the measure is

11   currently structured?

12   CO-CHAIR HOMER: As the measure is

13   currently structured, right.

14   MEMBER CLARKE: I have a question.

15   CO-CHAIR HOMER: David?

16   MEMBER CLARKE: Do we have to rely

17   on what's present in the application or do

18   their comments contribute? Because it changes

19   everything.

20   CO-CHAIR HOMER: The comments

21   count. I mean that is why they are here.

22   So, your main concern was this

 1   issue of if there were multiple surgical

 2   procedures done?

 3   MEMBER CLARKE: Right, and using

 4   procedures as your basis, and then you have

 5   multiple procedures per patient. Then, you

 6   try to attribute mortality to what procedure.

 7   It was not clear how that was going to be

 8   handled. But the way that it is being handled

 9   I think is perfectly appropriate.

10   CO-CHAIR HOMER: So, going back to

11   this question of in-hospital mortality versus

12   a 30-day kind of mortality figure, have either

13   you or anyone else looked at basically a

14   survival curve post-surgery of when, for

15   children who do die post-surgical, when that

16   actually happens and how many or what

17   proportion of deaths might be the child is

18   home and an untoward event happened, and they

19   ended up being rehospitalized? Do you have

20   any sense, either from this analysis or from

21   Medicaid claims or other cohort studies, or

22   anything like that?

 1   DR. LILLEHEI: No, Mr. Chairman, I

 2   don't think we have it beyond my own

 3   experience as a pediatric surgeon that, yes,

 4   when children die of neonatal surgery, that is

 5   typically they don't make it home, yes. Yes.

 6   CO-CHAIR HOMER: That makes sense.

 7   Nancy, please.

 8   MEMBER FISHER: I think I just

 9   need a little bit more clarification because

10   what I am trying to see is, first of all, my

11   understanding is that there is a small

12   percentage of kids that die from surgeries in

13   this age in pediatric hospitals, that we are

14   looking at a small number of people. Then,

15   you start talking about things like

16   gastroschisis, operating on neck, operating

17   on -- my question is, you have to operate on

18   those kids with gastroschisis or they will

19   die. So, my question is, what exactly are you

20   trying to get at to improve?

21   I am just sort of confused about

22   it because it is not like you have a choice.

1   I mean, have you run some data, and what you

2   are talking about is the kids that died from

3   the operation because it was the really the

4   infection; it wasn't the procedure? If you

5   don't have a choice about operating on

6   somebody, you have to operate.

7   DR. LILLEHEI: I think part of --

8   Kim, did you want to respond?

9   MS. GAUVREAU: I was just going to

10   add the piece of information that in the KID

11   database that we looked at to develop the

12   model, there were about more than 5,000

13   neonatal surgeries, and that does not

14   encompass all states. That is only an 80

15   percent sample of cases. So, we were able to

16   extrapolate that probably somewhere between 9

17   and 10 thousand surgeries happen in the United

18   States each year, just to put it into context.

19   CO-CHAIR HOMER: Nancy, if I could

20   answer just for a second?

21   MEMBER FISHER: Yes.

22   CO-CHAIR HOMER: I mean, if we

1   think of the last presentation on shunts, I

2   mean those children need their shunts, too.

3   So, the question is, is there variability?

4   Children will need surgery for their

5   gastroschisis or the other conditions. And

6   the question is, is there variability in

7   mortality rates across institutions that,

8   presumably, is attributable to some element of

9   the care that they are receiving in those

10 institutions? I think that fundamentally is,

11 is there improvability based on variability

12 across institutions for kids who need surgical

13 procedures?

14   MEMBER FISHER: I see this a

15 little bit different from the last one. I

16 just can't get my hands around -- you know, to

17 me, I don't know, I just can't seem to get my

18 hands around how you are going to improve it.

19 Maybe it is because the other ones had said

20 they had looked at it, and they said that,

21 when they did the procedure, it was the angle

22 at which they put the shunt in. I can see

1   that it is a device that you are putting in

2   someone, and the device could malfunction or

3   you could do something to the device. I am

4   not seeing that with these procedures. I

5   guess that is the difference.

6   CO-CHAIR HOMER: Okay. Dr.

7   Lillehei?

8   DR. LILLEHEI: Well, I think that

9   your point is well-taken that this is not a

10   specific surgical, telling an individual

11   surgeon or identifying even an individual

12   surgeon as to their specific outcomes, but we

13   are really looking at a broader level at an

14   institution, all of those things that impact

15   on successful surgery in neonates.

16   And what we anticipate is that, in

17   fact, we will see variability, whether it is

18   from institution to institution, whether it is

19   socioeconomic groups, whether it is regions.

20   To understand by identifying that variability,

21   then, hopefully, we can move to the next,

22   which is to say, how can we impact that; how

1   can we change that, whether it is access to

2   care, whatever that might be?

3   But you are right, what we are

4   looking at is for what that variability is and

5   then how we might use that to change practice.

6   CO-CHAIR HOMER: Thank you.

7   Faye?

8   MEMBER GARY: I just have a quick

9   question, please. That is, I know the study

10   involves 15 hospitals. Is that correct?

11   DR. LILLEHEI: No, no. Actually,

12   the study, we just gave you data, a table of

13   15 hospitals for the evaluation form. In

14   fact, we have applied it to the entire KIDS

15   database, which is surgery in -- what? -- 37

16   states that provide data to the KIDS. We have

17   actually applied it to the PHIS as well. So,

18   no, our intent, this is population-based.

19   MEMBER GARY: Well, then, I would

20   just amend my question just a little bit. I

21   was wondering if you also have any data, or

22   will have any data, about the basic

1   characteristics of the hospitals or the

2   populations that these hospitals serve.

3   Because I think that, based on the populations

4   that they serve, you will probably see some

5   influence with the outcome. How will you

6   address that issue?

7   DR. LILLEHEI: Absolutely. Those

8   are elements that are available in the KIDS

9   database. So, the nice thing about using this

10   database is it will allow us to interrogate

11   just those sorts of questions about what other

12   factors related to those patients.

13   CO-CHAIR HOMER: I have just one

14   more observation, and maybe the NQF staff can

15   help me on this. I see this as analogous to

16   the hospitalized standardized mortality rate

17   measure in adults. It is not precisely the

18   same because that is overall hospital.

19   I mean my understanding is you

20   probably do have on the adult side some

21   indicator of hospital-specific mortality rate

22   or standardized mortality rate that you use as

 1   an overall performance measure, or not?

 2   DR. WINKLER: Well, if you are

 3   talking about a multiple-surgery, across-the-

 4   board kind of measure -- is that what you are

 5   talking about for adults in a surgical

 6   measure?

 7   CO-CHAIR HOMER: Well, I know,

 8   again, at the IHI they certainly use as

 9   quality improvement --

10   DR. BURSTIN: We have not brought

11   on any of the HSMR measures. I'm sorry. None

12   of the HSMR measures have come to NQF yet.

13   All of our mortality measures tend to be

14   procedure- or condition-specific, although we

15   do have composites of selected mortality for

16   certain procedures.

17   DR. WINKLER: In another part of

18   the project, the main Steering Committee is

19   reviewing surgical complications, which

20   includes mortality, but also other serious

21   morbidities for all of the age 65 patients,

22   but it encompasses a wide variety of

 1   surgeries. So, we are getting there.

 2   MEMBER McINERNY: And, Charlie,

 3   there is the NSQIP, the National Surgery

 4   Quality Improvement Program.

 5   CO-CHAIR HOMER: Right.

 6   MEMBER McINERNY: Which is for

 7   adult surgeries. But there is now also a

 8   pediatric NSQIP that is up and running. I

 9   don't know if they reported any data yet. I

10   think they are still collecting it. So, this

11   would be similar.

12   CO-CHAIR HOMER: So, then, why

13   don't we vote on, if there are no questions

14   further, let's vote on the importance

15   question.

16   So, all those who feel -- again,

17   this is a dichotomous, yes, this is

18   sufficiently important based either on its

19   prevalence or within a narrower clinical area,

20   which this, presumably, isn't, but within a

21   narrow clinical area, whether it is an

22   important measure.

 1   So, all those who feel this meets

 2   the importance criteria raise your hand.

 3   Good. Okay.

 4   And all those who do not feel this

 5   meets the criteria?

 6   Good. Thanks.

 7   I think we have already had a good

 8   bit of discussion, but let's move on with any

 9   additional questions or observations related

10   to the scientific acceptability of the

11   measure.

12   Are there further either

13   observations from the Work Group or questions

14   from any members of the Committee around the

15   scientific acceptability?

16   MEMBER LIEBERTHAL: Yes, I am

17   still having trouble with the risk-adjustment

18   model. There is such a broad variety and

19   there are so many underlying conditions that

20   affect it, that I don't know that the risk

21   adjustment is adequate to give good

22   information.

1   CO-CHAIR HOMER: So, Kim, could

2   you tell us about, first of all, how the risk

3   adjustment, how the panel created the risk-

4   adjustment measure, and then perhaps, for some

5   of us whose statistics are a little rusty,

6   describe what an ROC curve and the area under

7   the ROC curve means, and things like that?

8   MS. GAUVREAU: So, the risk

9   categories were derived primarily empirically

10   in that we looked in the dataset, the KID 2000

11   dataset, and looked at, for our procedures

12   that occurred at least 20 times in that

13   dataset, we looked at the in-hospital

14   mortality rates.

15   Then, we grouped procedures by

16   those rates. We started out with more than

17   four categories, so looking at lots of

18   possible different splits in the data, but

19   knowing that we somehow wanted to group

20   procedures by mortality rates.

21   We, then, sort of worked backwards

22   and looked at adjacent categories. If there

 1   was not much overlap between them, we would

 2   collapse them. We did that both looking at

 3   actual mortality rates and by putting things

 4   into logistic regression models and looking at

 5   odds of in-hospital mortality relative to what

 6   we considered to be the baseline group.

 7   And for the baseline group, from

 8   the very beginning, we said that we were going

 9   to include procedures with a less than 2

10   percent mortality rate. There were a lot of

11   procedures that didn't have any mortality in

12   the database at all, but we would not be able

13   to fit our regression model if we had a

14   category with no deaths. So, we wanted to be

15   sure we would have at least some deaths, even

16   in our baseline risk category.

17   So, then, we looked at the various

18   cutpoints and found the one with the best

19   discrimination. That was measured by the C-

20   statistic or area under the ROC curve, which

21   basically is a measure of how well the model

22   is able to predict who dies and who doesn't

1   die.

2   Just with the four risk categories

3   that we ended up with alone, the area under

4   the ROC curve was, I believe, .87. In

5   general, anything over .8 is considered very

6   good. So, the model, the risk categories were

7   very highly discriminative about predicting

8   in-hospital mortality in this case.

9   CO-CHAIR HOMER: And then you

10   retest your validation?

11   MS. GAUVREAU: We validated that

12   in a second dataset, the KID 2003, and found

13   the area under the ROC curve to be, I believe

14   in that case it was .85 or .86. I mean just

15   only a little bit less.

16   I guess we haven't mentioned it.

17   On top of that, so in addition to the risk

18   categories, we did look at these other

19   clinical factors that might contribute and

20   help us to predict risk of in-hospital

21   mortality, even beyond the risk categories.

22   That was the necrotizing enterocolitis and

1   serious respiratory conditions. We considered

2   a list of about 10 or 15 other variables that

3   might help contribute to risk and found only

4   those two to be statistically-significant.

5   DR. BURSTIN: Just a quick

6   question, just because untested outcome

7   measures make people a little anxious. How

8   does this relate -- there's a reference you've

9   got at the bottom of 2a to an article that is

10   the Annals of Surgery in press. Is that the

11   risk model you are talking about with the

12   validation?

13   MS. GAUVREAU: Yes, it is.

14   DR. BURSTIN: Okay. Because I

15   think there is at least a comfort zone to know

16   the risk model used in this particular

17   measure --

18   MS. GAUVREAU: Yes.

19   DR. BURSTIN: -- has been

20   validated.

21   MS. GAUVREAU: Yes.

22   DR. LILLEHEI: Yes, it was just

1   published last month in the Annals of Surgery.

2   Yes. Sorry.

3   CO-CHAIR HOMER: Other questions

4   about the scientific acceptability of it or

5   comments from the Work Group members?

6   (No response.)

7   So, it sounds like some concern

8   about the risk-adjustment issue. Coding

9   issues, probably any sense of the validity of

10   coding? Any concerns? I mean death seems

11   like it is pretty reliably coded, and the

12   procedure itself seems like it is going to be

13   pretty reliably coded. That is basically all

14   you need or?

15   CO-CHAIR WEISS: I actually have a

16   question about that. I just wondered, aside

17   from factoring out the cardiac procedures, is

18   everything else in that bucket or did you make

19   some selections about what you included in the

20   non-cardiac surgery compendium or inventory?

21   DR. LILLEHEI: Yes, I don't know

22   that we have provided that table, but, yes,

1 there were procedures that we viewed as closed

2 procedures. So, I can list sort of a sample

3 of that for you here. But the excluded

4 procedures were any closed biopsies, closed

5 reductions, superficial lacerations,

6 catheterization, delutations, injections,

7 aspirations, radiologic procedures, dental

8 extractions, circumcision, and other

9 incidental procedures.

10   So, yes, you're right. Of those

11 procedures, there were certain ones that we

12 excluded because we didn't think that they

13 would really fit under the umbrella of

14 neonatal surgery as we were trying to

15 understand risk and mortality.

16   MS. RAUSCHER: We can provide a

17 copy of the article for the Committee, if you

18 would like that.

19   CO-CHAIR HOMER: That would be

20 great.

21   MS. RAUSCHER: Okay.

22   MEMBER LIEBERTHAL: I would like

1   to ask, since you excluded a number of very

2   minor procedures, why you included lingual

3   frenectomy as a significant condition.

4   DR. LILLEHEI: Fair enough. We

5   can talk through one of the others, but, in

6   fact, most of the time those procedures now

7   are actually done, unlike perhaps an earlier

8   era when they were done in the pediatrician's

9   office, kind of a clipping at the bedside, now

10   most often, in fact, they are done in the

11   hospital and usually in an ambulatory setting

12   with some element of anesthesia. Anesthesia

13   and a surgical team, we felt that was kind of

14   the bar that put us into this category, but

15   I am open to --

16   CO-CHAIR HOMER: I'm sorry, I

17   thought you said there actually did need to be

18   some deaths for it to be included in your

19   risk? No? I misheard that?

20   MS. GAUVREAU: So, we wanted our

21   lowest baseline risk category to at least have

22   some deaths, so that we could compare the

1   other categories to that one. In the end, the

2   mortality rate in that category 1 was .2

3   percent.

4   DR. LILLEHEI: No, but in answer

5   to your question --

6   CO-CHAIR HOMER: In individual

7   procedures --

8   DR. LILLEHEI: Yes, individual

9   procedures didn't need to have deaths, no.

10   MS. GAUVREAU: That's right, just

11   in the categories.

12   CO-CHAIR HOMER: Just in the

13   category?

14   DR. LILLEHEI: Yes.

15   CO-CHAIR HOMER: Okay. And again,

16   this issue of meaningful differences, so your

17   sense simply is, because you have only done it

18   one year and don't have multiple-year

19   averages, that your confidence intervals are

20   sufficiently --

21   MS. GAUVREAU: Are fairly wide.

22   CO-CHAIR HOMER: Are wide? So, if

1   this were trended over time, perhaps that

2   would result in significant narrowing.

3   All right. My next question will

4   be towards usability.

5   Any other questions on scientific

6   acceptability? Or we could move ahead and

7   vote on that. Or comments? Kathy, did you --

8   MEMBER JENKINS: Yes, may I make

9   one comment? Even in cardiac surgery where

10   there is twentyfold differences in the

11   country, it is extremely unusual in pediatric

12   sample sizes to find statistical differences.

13   I actually think it is extremely amazing that

14   in a single year of data we did find any

15   institution that was statistically different

16   with an area under the ROC curve of .9.

17   So, I think perhaps having looked

18   at rare pediatric procedures and outcomes more

19   than maybe people who do more work on more

20   common procedures, people may not be aware of

21   that.

22   MEMBER CLARKE: If I might

1   comment, I think that the kind of AUC numbers

2   that they are giving us are absolutely

3   incredible with the kind of broad

4   categorization that we see here. I am very,

5   very surprised at that, but that is really

6   excellent.

7   CO-CHAIR HOMER: All right. So,

8   why don't we go ahead and vote on the

9   scientific acceptability?

10   Those who would consider the

11   criteria completely met raise your hands.

12   DR. WINKLER: One.

13   CO-CHAIR HOMER: One. Okay.

14   Those who feel they are partially

15   met?

16   DR. WINKLER: Nine. Okay.

17   CO-CHAIR HOMER: And minimally?

18   Okay. That got everybody? Okay.

19   Usability. So, I think there one

20   question I would ask is, has there been

21   interest in the surgical community around this

22   measure? And how does it seem to be received?

1   And how understandable have there been --

2   again, comparing a little with the previous

3   conversation, as you have vetted this with

4   your colleagues at the hospital, as you

5   discussed it at CHCA meetings or NACHRI

6   meetings or Surgical Society meetings, what

7   kind of interest is there in this? What kind

8   of reactions are you getting? Just to get

9   some flavor for the usability of the measure.

10   DR. LILLEHEI: Well, in fairness

11 to you, we are pretty early on in that. In

12 fact, the surgical community, at least at

13 large, are only those who have read the last

14 month's Annals thus far perhaps.

15   (Laughter.)

16   But, in fact, within the surgical

17 community, and specifically the pediatric

18 surgical community, we are, as a group, very

19 interested in understanding reliable ways of

20 risk adjusting for what we do, and then making

21 things better accordingly.

22   Now, to date, we have done that

1   with specific diseases, like congenital

2   diaphragmatic hernia registries or necrotizing

3   enterocolitis working group, but there are

4   certainly limitations to that analysis and

5   questions that really don't lend themselves to

6   answering in that context.

7   There is the pediatric NSQIP that

8   was alluded to earlier that is being developed

9   in an effort to allow us to better understand

10   what we do and how we might change things

11   accordingly.

12   But, in fact, specifically, as

13   regards our measure, no, we are just in the

14   process of springing it on them, if you will,

15   yes.

16   CO-CHAIR HOMER: Ellen? Or you

17   weren't on the Work Group. Any other members

18   of the Work Group? No, go ahead, Lee.

19   MEMBER PARTRIDGE: If I am

20   understanding this correctly, and I am looking

21   at it from the consumer perspective primarily,

22   this has the potential to be a very powerful

 1   measure in the sense that I believe what you

 2   are trying to do is develop an overall measure

 3   of predictability of mortality of children

 4   prior to 30 days of age from non-cardiac

 5   surgery.

 6   It is perhaps one of the two or

 7   three most powerful kinds of measures that

 8   anybody wants to know about a hospital. I

 9   guess it would be helpful to me if you would

10   just take a minute and explain how you would

11   explain this to a patient or a purchaser as a

12   good predictor of whether I should hospitalize

13   my child or have that hospital in my network.

14   Is that too tall an order?

15   DR. LILLEHEI: We do think that

16   this has the potential for a considerable

17   impact. Obviously, results of neonatal

18   surgery, for those of us who look after

19   neonates or have neonates, or whatever, is

20   exceedingly important.

21   We do think that with this tool we

22   will be able to dissect out whether it is

1   institution-specific, whether it is types of

2   institution, whether freestanding pediatric

3   hospitals do better or not, or whether a

4   children's hospital within a large general

5   hospital, a children's unit within that

6   neonatal surgery is the same, whether

7   anesthesiologists that have the ability to

8   have access to pediatric anesthesiologists

9   makes a difference versus not. I don't know

10   the answer to those questions.

11   We may be surprised by some of the

12   results, to be sure, but, yes, I think that is

13   why we are excited about this particular

14   study.

15   MEMBER McINERNY: Well, of course,

16   you know, for adult cardiac surgery, this kind

17   of reporting has been going on for at least a

18   decade. But my impression -- and correct me

19   if I am wrong -- is that, as far as either

20   purchasers or consumers are concerned, whether

21   they even know the data, No. 1, and whether it

22   makes any difference where they decide to go,

1   No. 2, I haven't seen a lot of evidence that

2   it has influenced that. Maybe I am wrong.

3   CO-CHAIR HOMER: The data on these

4   kinds of things tends to influence providers

5   a great deal. Because even though the

6   expectation, of course, was that consumers

7   would use it to drive, what frequently happens

8   is we, hospitals and physicians, are very

9   driven by comparative data. We all didn't

10   want to be in the bottom of our classes, and

11   therefore, we look at these data and it tends

12   to drive improvement through that strategy

13   more than --

14   MEMBER PARTRIDGE: I think we all

15   know that. Of course, you are in the State

16   that has been the leader in cardiac surgery

17   reporting. But I think, in fact, it has

18   impacted some of the purchasing patterns in

19   your State.

20   So, in my understanding also, we

21   haven't actually done a lot of testing of this

22   yet. So, we would be, presumably, talking

1   about this as a time-limited, yes, because I

2   would want to get a little better sense of how

3   much variability we are really turning up. I

4   know you have been working at that.

5   CO-CHAIR HOMER: Allan, did you

6   have a question?

7   MEMBER LIEBERTHAL: Yes, I did. I

8   am looking for the exact wording. But you

9   said something about, to be included, you

10   would have to have more than 20 procedures, is

11   that correct?

12   MS. GAUVREAU: That's right.

13   MEMBER LIEBERTHAL: Is that out of

14   20 individual procedures or 20 in a risk

15   category?

16   MS. GAUVREAU: Twenty in an

17   individual surgical procedure.

18   MEMBER LIEBERTHAL: Okay. One of

19   my concerns about usability is that, if there

20   are institutions that are doing fewer than 20,

21   and they are excluded from the data --

22   DR. LILLEHEI: No, let me clarify

1   because I think we are leading you in the

2   wrong direction. When we developed the model,

3   in order to develop the model, what we used

4   were procedures in the KIDS database that were

5   20 or more. Okay? Procedures in the KIDS

6   database that did not have 20 procedures, we

7   did not include in our risk category. We

8   didn't put them into a specific risk category.

9   So, do we, by that, do we omit

10   certain rare procedures? Indeed, we do, but

11   the fact of the matter is our analysis

12   encompassed about 85 percent of the types of

13   procedures being done. So, that was just to

14   develop the model.

15   MEMBER LIEBERTHAL: So, hospitals

16   that are doing fewer than 20 procedures still

17   would be part of this?

18   DR. LILLEHEI: Oh, absolutely.

19   Absolutely. Yes.

20   MS. GAUVREAU: Yes.

21   MEMBER LIEBERTHAL: That answers

22   my question then.

 1   DR. LILLEHEI: Thank you.

 2   CO-CHAIR HOMER: Faye?

 3   MEMBER GARY: I just had a quick

 4   question, and it is related to Lee's question.

 5   Lee asked about how the data will impact

 6   decisions, administrative decisions, et

 7   cetera, et cetera.

 8   And my question is, have you all

 9   given any thought to how our outcome data can

10   be used or will be used when communicating

11   with consumers, i.e., parents and family

12   members? Could you just talk about the

13   usability of this data as it relates to I

14   think one of the most important groups, and

15   that is the parents of the child? I am trying

16   to get translation here to how it appears in

17   the clinical setting with the variety of

18   different kinds of parents and families who

19   might have this experience.

20   DR. LILLEHEI: Your point is well-

21   taken. Obviously, that is a decision that, as

22   a parent looking to a surgical procedure, that

1   is paramount in your mind.

2   This data is really, by virtue of

3   the fact that we are including a lot of

4   different types of procedures and combining

5   those risk categories, we are really not

6   looking at individual operations. So, I don't

7   think this is a tool for that individual

8   parent to decide whether I am going to have

9   Dr. Lillehei do my hernia repair or not, based

10   on that.

11   It is talking about institutions

12   as a whole, whether we think that institution

13   specifically or that type of institution or

14   that region of the country -- those are the

15   sorts of questions that we will be able to

16   answer about this, and not the specific one,

17   you know, where do I get my hernia fixed or

18   with whom?

19   So, I just wanted to underscore

20   that limitation of what we are going to be

21   able to answer.

22   MEMBER DOCHERTY: Yes, I think

1   what I like about it is that it reflects more

2   than just the procedure itself, but the post-

3   operative care that is given in a hospital.

4   So, it is nursing care. It is all the post-

5   surgical care, anesthesia, all of those

6   things.

7   DR. LILLEHEI: Absolutely.

8   CO-CHAIR HOMER: Nancy?

9   MEMBER FISHER: I just wanted to

10   make a comment in response to Tom's question.

11   Large purchasers are looking at things like

12   this. There is a large company that looks at

13   what you have done with Leapfrog, and they set

14   up their payment for you, so that if you are

15   at a hospital that they approve of, you get 90

16   percent reimbursement; if it is not, it is 80

17   percent reimbursement. There has been talk

18   about tiering hospitals, so putting them into

19   three different tiers and then shifting it

20   over.

21   So, there is all of this stuff

22   going on sort of coming out of value-based

1   purchasing that is looking at all of this.

2   So, yes, this is very important.

3   CO-CHAIR HOMER: So, I think we

4   are ready to vote on the usability criteria.

5   So, those who feel it fully meets

6   the usability, completely meets the usability

7   criteria?

8   All right. Those who feel it

9   partially meets the usability criteria?

10   DR. WINKLER: Ten.

11   CO-CHAIR HOMER: And those who

12   feel it minimally meets the usability

13   criteria?

14   All right, good.

15   And then, moving on to

16   feasibility, so that is how easy it is to

17   collect, report on issues, concerns about

18   exclusions, inaccuracies, and implementation

19   issues.

20   Seems like it is pretty

21   straightforward in that it comes from

22   administrative databases. That is where you

1   have validated it. It is not a narrow

2   dataset, that it is not PHIS, or it is

3   something that really can be used on any

4   standard set of discharge data. So, it seems

5   pretty straightforward.

6   Tom?

7   MEMBER McINERNY: Do you have any

8   idea, I mean, how much of the data-based

9   person time does it take to collect and sort

10 of analyze and report the data? Is this a 1.0

11 FTE for a full year or a .2, or do we know?

12   MS. GAUVREAU: Well, assuming the

13 data is coming from an electronic database or

14 an administrative dataset, it doesn't take

15 very long at all. So, it is not based on

16 primary data collection.

17   MEMBER McINERNY: So, you could

18 probably somehow program it once --

19   MS. GAUVREAU: Yes.

20   MEMBER McINERNY: -- and then it

21 becomes automatic?

22   MS. GAUVREAU: Yes. Right.

1   Exactly.

2   MEMBER McINERNY: Okay.

3   MS. GAUVREAU: And we have the

4   program and documentation to do all that.

5   MEMBER McINERNY: Okay. Thank

6   you.

7   CO-CHAIR HOMER: All right. So, I

8   think we could vote on the issue of

9   feasibility.

10   Those who feel it completely meets

11   the criteria for feasibility?

12   DR. WINKLER: I think it is

13   everybody.

14   CO-CHAIR HOMER: Very good.

15   All right. Then, we move on to

16   voting overall for the measure. Again, I

17   think because this measure has not been in

18   general use, this would be a time-limited

19   endorsement, presumably with the request for

20   specific testing about applicability and

21   usability, I think looking at the potential

22   for narrowing the confidence interval by

1   extending the data over periods of time, et

2   cetera.

3   So, those in favor of a time-

4   limited endorsement of the measure raise your

5   hand.

6   DR. WINKLER: I have got

7   everybody.

8   CO-CHAIR HOMER: Good. Okay.

9   We're done. Thank you very much.

10   All right. I think we will do one

11   more measure before our break on my 10:30

12   break time rule.

13   MS. McELVEEN: Okay. Our next

14   measure is Measure 29. This is the

15   standardized adverse event for children and

16   adults undergoing cardiac catheterization for

17   congenital heart disease. This is the ratio

18   of observed-to-expected clinically-important,

19   preventable, and possibly preventable adverse

20   events risk-adjusted.

21   DR. BERGERSEN: Hi. My name is

22   Lisa Bergersen again.

 1   I want to thank you for the

 2   opportunity to be at the table today from a

 3   smaller community of physicians who perform

 4   cardiac catheterization procedures on both

 5   children and adults for congenital heart

 6   disease.

 7   Over the past 15 years, cardiac

 8   catheterization has evolved from diagnostic

 9   studies to primarily interventional studies

10   with not an insignificant amount of morbidity

11   associated with those procedures. So, as a

12   field, it has become very important for us to

13   understand the outcomes for these children

14   that can eventually have bad outcomes in the

15   catheterization lab.

16   We look at a lot of different

17   measures: overall event rates, clinically-

18   important event rates. But I chose this

19   outcome to share with you because it has some

20   face validity in its importance to us as a

21   community as a measure to track.

22   That being clinically-important

1   events, those events that are life-threatening

2   or potentially life-threatening to the child

3   and with a potential opportunity for

4   improvement in care. So, those that are

5   either possibly preventable or preventable.

6   As a community, we think that this is an

7   important measure and outcome for the

8   children.

9   CO-CHAIR HOMER: Terrific. So,

10   why don't I ask members of the Work Group to

11   comment and specifically, again, initially on

12   the area of importance? A request to raise

13   questions. Any comments from the Work Group?

14   And then open to comments and questions from

15   anybody else on the Committee.

16   David?

17   MEMBER CLARKE: Well, I think she

18   has adequately addressed the importance of

19   this. This is becoming a very strong

20   interventional type of a specialty as opposed

21   to diagnostic, as it was historically. This

22   brings on whole new implications.

1   Basically, now they are doing a

2   lot of cardiac surgery with a little, tiny

3   tube. So, I think looking at adverse events

4   and the things that can go wrong with that,

5   which are not inconsequential, is extremely

6   important as this specialty evolves.

7   CO-CHAIR HOMER: Any other

8   questions from the Work Group members or the

9   members of the Committee about the importance

10   of this?

11   DR. WINKLER: I just want to

12   follow up on one of the Committee's comments

13   about why we are including adults as part of

14   the measure. Can you give us some numbers?

15   Because I am assuming you are defining the

16   adults are probably young adults as opposed to

17   I don't see a lot of 65-year-olds, but maybe.

18   DR. BERGERSEN: Well, it is

19   congenital heart disease.

20   DR. WINKLER: Exactly. That is my

21   point.

22   DR. BERGERSEN: So, the measure

1   was developed to capture our entire

2   population. Depending on the physician, their

3   case mix can have a varied amount of adults.

4   So, it was developed to capture the entire

5   case mix for institutions performing these

6   procedures.

7   We could limit this outcome

8   measure to children less than 21 years of age

9   without losing validity, we believe.

10   CO-CHAIR HOMER: So, for example,

11   an adult with an anomalous coronary -- now I

12   am showing my clinical ignorance -- but, you

13   know, anomalous coronary artery, or something

14   like that, which is presumably a congenital

15   problem, you are not talking about that?

16   DR. BERGERSEN: Right. So, among

17   our six physicians who primarily do neonates,

18   the percentage of adults that we do ranges

19   from zero to 15 percent. So, it is a small

20   percentage.

21   MEMBER RAO: My concern in raising

22   that question was that, is there a significant

1   proportion of adults who are going through

2   revision surgeries, second or third surgeries

3   for their congenital heart disease, as opposed

4   to their first surgery? Because I assume if

5   you are 25 years old, somebody has picked up

6   on this at this point.

7   DR. BERGERSEN: Right. Exactly.

8   CO-CHAIR HOMER: But you still

9   might be catheterized, presumably, in your

10   pre-operative revision --

11   DR. BERGERSEN: Some of the adults

12   that we catheterize will be -- and again, this

13   depends on the case mix of the particular

14   interventionalist -- it may include late-

15   presentation ASDs, late-presentation PDAs,

16   pulmonary hypertension, or redo operations,

17   conduit revisions requiring human NMX pre-

18   operatively.

19   But, like I said, we could limit

20   this measure to less than 21 years of age.

21   MEMBER RAO: Yes, I just thought

22   that maybe somebody going through

 1   catheterization as an adult probably had a

 2   different morbidity or risk than somebody who

 3   is younger.

 4   DR. BURSTIN: Having spent a

 5   decade practicing at the Brigham and taking

 6   care of a lot of these adult cardiac

 7   surgeries, I mean, literally, you have 30- and

 8   40-year-olds who had tetrology procedures a

 9   decade ago who still go to Children's for cath

10   because they know that better than anybody

11   else does. So, the question would be, are

12   they really the same group or should you

13   really segregate it?

14   CO-CHAIR HOMER: Have you looked

15   at --

16   DR. BERGERSEN: We haven't looked

17   at these outcomes -- well, the risk-adjustment

18   method for this outcome was developed using it

19   with the adult population in it. We haven't

20   excluded them and gone through the same steps

21   to look at how the model performs, but I would

22   expect that it would perform at least equally

1 as well.

2 　　　　　MS. GAUVREAU: But we also didn't

3 find age to be a statistically-significant

4 predictor of adverse events in our model.

5 　　　　　DR. BERGERSEN: That's correct.

6 　　　　　CO-CHAIR HOMER: Allan?

7 　　　　　MEMBER LIEBERTHAL: Your

8 specification for numerator specifies a

9 pediatric cardiac catheterization lab. The

10 majority of hospitals that are not children's

11 hospitals use one cardiac catheterization lab

12 for both children and adults. Using your

13 definition, you would confine it to only

14 specialized pediatric cardiac catheterization

15 labs, which excludes a significant number of

16 cardiac caths.

17 　　　　　Then, when you start including

18 stint placements in adults, you haven't really

19 specified congenital heart disease. So, I

20 think I understand what your intent is, but

21 your wording can lead to the measure being

22 applied differently than you intended.

1   DR. BERGERSEN: That is a good

2   point. I think, to be more precise, it would

3   be procedures done for congenital or acquired

4   heart disease, congenital heart disease in the

5   adult or child.

6   So, if you were doing, let's say

7   you were an institution that was not a

8   pediatric institution, but you were doing

9   procedures for congenital heart disease. You

10   could apply this measure.

11   Does that answer your question or

12   address it?

13   MEMBER LIEBERTHAL: Yes, it does.

14   I would just ask that, if we approve this,

15   that the conditions be a change in the

16   wording.

17   CO-CHAIR HOMER: Again, prevalence

18   is not an absolute requirement, but do you

19   have any sense of the number of procedures

20   done in a year that this would apply to?

21   DR. BERGERSEN: Yes. We estimate

22   that there's about 100 institutions across the

1   country that do regular cath procedures on

2   both adults and children with congenital heart

3   disease.

4   CO-CHAIR HOMER: And how many --

5   DR. BERGERSEN: And the volume

6   there, our institution probably performs more

7   than most at about 1200 a year.

8   CO-CHAIR HOMER: Yes.

9   DR. BERGERSEN: And then the other

10   institutions, about between 300 and 600, some

11   a little less. So, let's see --

12   CO-CHAIR HOMER: So, if you are

13   thinking about 500 per institution, then

14   you've got -- yes, okay, then you have about

15   1,000. So, 500; you said how many

16   institutions, 100?

17   DR. BERGERSEN: About 100, yes.

18   CO-CHAIR HOMER: So, 50,000.

19   Okay, good.

20   DR. BERGERSEN: Fifty thousand.

21   MEMBER McINERNY: I wonder if we

22   could change the numerator to catheterization

1   cases performed by a pediatric interventional

2   cardiologist instead in a pediatric cardiac

3   cath lab. Because I know our institution, we

4   have an interventional cardiologist, but he

5   is, as Al describes, he does his in a general

6   cardiac cath lab, but there is a specialized,

7   sort of a specialized room where he does it,

8   but it is still considered an adult cardiac

9   cath lab.

10   DR. BERGERSEN: That would be

11   clearer, specifying it by the physician.

12   MEMBER LIEBERTHAL: I actually

13   disagree with the wording. I would just say

14   cardiac cath procedures done on congenital

15   heart disease. Because what worries me is

16   adult cardiologists who are doing procedures

17   on adults with congenital, oh, yes, congenital

18   heart disease. I think that quality measures

19   may, hopefully, put an end to that.

20   (Laughter.)

21   CO-CHAIR HOMER: Okay. So, on our

22   first criteria of importance -- and this is a

1   threshold criteria, so it would be either yes

2   or no -- the question is, how many believe

3   this meets the threshold criteria for

4   importance? Show of hands.

5   Okay. So, now we can move on,

6   which we have already been delving into, but

7   we can move on to the issues of the scientific

8   acceptability of the measure. So, why don't

9   delve more deeply into that?

10   Can you talk a little bit more

11 about how adverse events are defined, how

12 reliable, adverse events, preventable adverse

13 events, how reliable the identification of

14 those are? You had some data in the report.

15   DR. BERGERSEN: Yes.

16   CO-CHAIR HOMER: But if you could

17 talk more about that?

18   DR. BERGERSEN: Well, in 2003,

19 2004, reviewing the previous literature on

20 cardiac catheterization and how people were

21 reporting outcomes, most institutions would

22 report them as minor or major. We thought

1   that that didn't lend itself to -- could have

2   greater clarity by separating them out into

3   five categories.

4   So, we started collecting adverse

5   events at our institution using these five

6   categories of severity, one being an event

7   that happened, but there was really no

8   clinical consequence; two being a minor event;

9   three being something that was potentially

10   life-threatening, like a supraventricular

11   tachycardia that you had to cardio vert; four

12   being something that was clearly life-

13   threatening. You had to do CPR on a patient

14   because of an arrhythmia. And five being

15   death.

16   So, we started collecting our

17   adverse events using these definitions. Our

18   hospital later adopted them in other areas

19   across the entire hospital.

20   As a field, recently, we have

21   gotten together as a group and started to talk

22   about nomenclature and how we are going to

1   define both the procedures that we do and

2   complications, because the nomenclature just

3   didn't exist previously.

4   So, in the next year, our

5   definitions for severity will be adopted by

6   the International Pediatric Cardiac Code and

7   will be available to the community to use.

8   So, we will be publishing a complications list

9   that has qualifiers for severity and

10   definitions, as we have been collecting events

11   over the past six years.

12   Currently, there are eight other

13   institutions who are collecting data in a

14   similar fashion and coding their events using

15   our severity classifications. And I referred

16   to them in the background material.

17   This is the Congenital Cardiac

18   Catheterization outcomes Project. This group

19   of institutions started collecting data in

20   2007, and we now have a dataset using uniform

21   definitions since 2007. It includes now

22   13,000 cases.

1   CO-CHAIR HOMER: So, as I hear

2   these, I guess the reason I was asking about

3   it, but I think you have started to answer it

4   beautifully, so we know that voluntary

5   reporting of adverse events in hospitals is

6   miserable, to put it bluntly. And we know

7   that when people do audits using something

8   like a trigger tool, they vastly increase by

9   factors of five or ten the number of adverse

10   events that are identified.

11   But this seems different. This

12   you have got specific events that are defined

13   and typically recorded in a procedure anyway,

14   and you are capturing more routinely. So,

15   again, it is different than routine hospital

16   collection of adverse event data and more

17   valid and reliable?

18   DR. BERGERSEN: When we audited

19   the dataset that was in the paper for the

20   measure development, for Level 3, 4, and 5

21   events at our institution, we captured all of

22   them. In this group of institutions that have

1   been collecting data over three years, they do

2   pretty good with the 3's, 4's, and 5's. As

3   you would imagine, the 1's and 2's, there is

4   some variation in what people would consider

5   important enough to record.

6   But among the 4's and 5's, at

7   least in a 10 percent audit, they reported all

8   of them. And among the 3's, 4's, and 5's, it

9   was as high as 92 percent. So, there were a

10   few what we consider Level 3 events which were

11   primarily respiratory events even before the

12   procedure had started related to anesthesia.

13   So, because they are clinically important,

14   they tend to be captured.

15   CO-CHAIR HOMER: Okay. Thank you.

16   David?

17   MEMBER CLARKE: Well, I have, I

18   guess, a real problem with allowing so-called

19   non-preventable events to be excluded because

20   I think that, first of all, what might be

21   preventable by one person is non-preventable

22   by another. Second of all, you know, maybe it

 1   is just because surgeons enjoy wearing hair

 2   shirts, but, traditionally, when you are doing

 3   surgery, if the patient dies within 30 days of

 4   the operation, even being run over by a bus,

 5   that is an operative mortality.

 6   (Laughter.)

 7   So, I really have a problem with

 8   excluding these sort of big -- what is an

 9   example of an unpreventable event?

10   DR. BERGERSEN: Yes, let me

11   explain to you why we did exclude it and why

12   it is important that we exclude preventable

13   events when looking at this outcome.

14   MEMBER CLARKE: You mean

15   unpreventable?

16   DR. BERGERSEN: Non-preventable.

17   And it actually goes towards the other

18   comment, which was the moderate events, as

19   defined -- let's see, how do you know that

20   they are not based on the patient's condition

21   rather than how the procedure was performed?

22   So, what we are trying to do here

 1   is exclude those events that, because of the

 2   patient's condition, that you could not have

 3   avoided. So, for example, you get called in

 4   the middle of the night to catheterize a

 5   patient who is having ventricular tachycardia,

 6   and there's a suspected anatomic problem. And

 7   they are trying to manage them medically.

 8   You bring them down to the

 9   catheterization lab and they go into

10   ventricular tachycardia, and you have to do

11   CPR on that patient. There was no way as an

12   operator that you could have avoided that

13   event.

14   Whereas, I bring a patient to the

15   catheterization lab for an elective aortic

16   valvotomy. I cross the aortic valve and I jam

17   the catheter down in the LV, and the patient

18   goes into ventricular tachycardia. In that

19   case, maybe there was something that I could

20   possibly have done to have avoided that event.

21   And I want to make sure that I capture that.

22   MEMBER CLARKE: Right, and I am

1   not talking about events that occur and result

2   in maybe a patient's death just on the way to

3   the cath lab before you do a procedure.

4   DR. BERGERSEN: No, I am talking

5   about, if I bring a patient to the cath lab

6   and they have ventricular tachycardia, and I

7   put catheters in them, and I am doing a

8   diagnostic catheterization, and they go into

9   their fatal arrhythmia, and I can't get them

10   out of it, and it was a pre-existing condition

11   where there was nothing I could have done in

12   the cath lab to avoid it, then those are the

13   events that we're --

14   MEMBER CLARKE: So, if a patient

15   dies when you are opening the chest, it

16   doesn't count, and that just isn't right.

17   DR. BERGERSEN: Well, it depends

18   on what the outcome of interest is, I think.

19   MEMBER CLARKE: You know, I guess

20   I look at it this way, from a broader

21   perspective, and I said this earlier. If you

22   exclude things that are not preventable from

 1   the collection of the data, they are never

 2   going to be preventable because you won't

 3   identify them. Okay?

 4   And what you can do, and I think

 5   it is very reasonable in some cases to do

 6   this, we do it at the STS database, congenital

 7   database in several instances, is you collect

 8   the data and you exclude them from the

 9   analysis, which means you exclude them from

10   both the numerator and the denominator.

11   CO-CHAIR HOMER: So, you would

12   have the data, but the measure, then, would

13   still not reflect those data?

14   MEMBER CLARKE: Right. You could

15   decide to exclude those from the analysis of

16   the data. Then, at some point, you might want

17   to change your mind and put them back in for

18   some various reason, some events or --

19   DR. BERGERSEN: Yes. So, we are

20   not proposing that people not collect data on

21   not preventable events. And we feel,

22   actually, quite strongly that any event should

1   be recorded in your database and looked at.

2   But for this particular metric, we wanted to

3   focus on events where there was a possibility

4   for improvement of care.

5   So, the problem with putting

6   preventable events in it, if you are going to

7   look at different institutions, is, well, it

8   wasn't the outcome that we were interested in.

9   CO-CHAIR HOMER: Can you remind me

10   how you are determining preventability? Is it

11   on the code or is it the judgment of the

12   person who is entering the data?

13   DR. BERGERSEN: Yes. At our

14   institution, we collect this data at a monthly

15   meeting or more often. We review all of the

16   events and, as a group, come to consensus on

17   both the severity and the preventability.

18   There are fairly precise

19   definitions. I think one thing that we would

20   need to do, if this metric went forward, is

21   look at within our dataset and the C3PO

22   dataset what were those events that were not

 1   preventable, so that we can have clear

 2   definitions for the community of what we would

 3   consider, like I did with the v tac example.

 4   CO-CHAIR HOMER: I love the name,

 5   with your C3PO data.

 6   (Laughter.)

 7   That is just great.

 8   Did the other sites do assessments

 9   of preventability, and did you assess

10   comparability of the preventability

11   assessments across multiple institutions?

12   DR. BERGERSEN: You know, it is

13   really interesting. When we started this

14   project, many people said -- and it was part

15   of one of the comments about I think

16   feasibility -- "Oh, you're not going to get

17   the community to tell you about their bad

18   outcomes."

19   But, in fact, the project was met

20   with a lot of enthusiasm. We actually had to

21   limit the number of sites that could

22   participate.

1   Like I mentioned, the audit, they

2   report both their minor as well as their high-

3   severity events. Two cardiologists review all

4   of the events, and they have reported, similar

5   to our earlier data, about a 30 percent rate

6   of not preventables. So, they have not been

7   liberal with the definition and rarely

8   misapply it. So, we rarely change it when we

9   review their preliminary classifications.

10   Did I confuse it? I'm sorry.

11   MEMBER PERSUAD: I just have one

12   final comment about the issue of excluding

13   non-preventable cases, and there's probably

14   nothing to do about it now, but going forward

15   I think, when we began this discussion about

16   the overall importance, this is a ballooning

17   area.

18   (Laughter.)

19   And your example, the example you

20   described says to me really that you are doing

21   more and more non-surgical corrective

22   procedures on an increasing risk population,

1   is what it is. And that doesn't mean to me

2   necessarily that, when they carry higher risk,

3   it is non-preventable. It may mean that more

4   sensitivity in the procedure has to be

5   addressed for their risk to be lower because

6   they are carrying higher risk. So, I just

7   throw that out there.

8   DR. BERGERSEN: So, there is

9   -- I'm sorry.

10   MEMBER McINERNY: No, no, finish.

11   DR. BERGERSEN: So, there is

12   variation in rates of these events among even

13   our practitioners at one institution. This

14   variation has to do with different populations

15   of patients being catheterized by different

16   interventionalists.

17   When we sat down to look at

18   procedures, we were able to identify 84

19   different types of procedures that we do with

20   varying frequency, from 1 percent of our cases

21   to maybe 20 percent of our cases. So, similar

22   to what Dr. Lillehei had explained, we

1   couldn't adjust just based on one procedure

2   type. So, what we did is we put all of those

3   different procedure types into different

4   procedure type risk groups, so then we could

5   adjust for the case-mix complexity of a

6   particular operator.

7   Then, this would apply an

8   institutional outcome. You could apply this

9   risk-adjustment model to an institution's

10   outcome.

11   We haven't compared adverse event

12   rates among institutions in cardiac

13   catheterization because for many years you

14   say, well, my case-mix complexity is more

15   complicated than yours. But what we have

16   shown by developing these models and looking

17   at this measure is that you can do it fairly.

18   You can do it fairly, and we should be looking

19   at these outcomes.

20   CO-CHAIR HOMER: Tom, did you have

21   a question?

22   MEMBER McINERNY: Yes. I, too, am

 1   very concerned about putting some things in

 2   the non-preventable category. I think 10

 3   years ago many people would have said that a

 4   central line infection was non-preventable.

 5   We know that, in fact, they are preventable.

 6   I just worry that, when you do

 7   that, then it sort of becomes an accepted

 8   complication, and, oh, well, you know, yeah,

 9   we put a central line in and they get

10   infected. Oh, well, we do this particular

11   cardiac catheterization procedure and

12   something happens, but it is non-preventable.

13   And that worries me because I

14   think you stop thinking about, yes, well,

15   maybe it is preventable if we did something

16   else.

17   CO-CHAIR HOMER: So, maybe to

18   delve a little further into this, could you

19   walk through, because I am a little fuzzy on

20   this, just kind of the algorithm for what

21   actually happens in terms of the data

22   collection and the categorization of adverse

1   events, and then adverse events as preventable

2   or not?

3   So, I just don't understand the

4   process right now by who it is going through

5   and who is making which decision and judgment,

6   and how it is being based. So, if you could

7   just walk that process through, I think it

8   would help the Committee. It certainly would

9   help me.

10   MEMBER JENKINS: Can I say one

11   background thing?

12   CO-CHAIR HOMER: Good.

13   MEMBER JENKINS: I just want to

14   say that, as Lisa mentioned, we imposed these

15   categories at the entire institution of the

16   Children's Hospital, Boston, for all of our

17   adverse event reporting. One of the things,

18   the discussion is very important, and I don't

19   want to minimize it.

20   I just want to make this point:

21   one of the things that is the most difficult

22   barrier to overcome for clinicians to feel

1   good about measurement is feel like they are

2   being unfairly measured against something that

3   happened on the day they were there, that

4   there is absolutely nothing they could have

5   done to prevent it, like the v tac example.

6   And it has been comforting and

7   helped with our adoption of this concept to

8   include a way out for that. How exactly to

9   measure it or where the slippery slopes are is

10   a real issue, and I don't want to minimize

11   that.

12   One of the things that we have

13   done at Children's is, if someone says

14   something, we ask them to articulate what they

15   could have done differently to prevent it.

16   Okay? Because if there's absolutely nothing

17   that anybody can think of that they could have

18   possibly done differently to prevent it, it is

19   different. Okay?

20   So, I don't know if that helps,

21   but this is a field that is getting their

22   hands around some of those issues, around

 1   infection and the rest of it.

 2   So, I just want to state that

 3   point, that in order to have clinicians adopt

 4   these measures, they do have to believe that

 5   it is fair.

 6   CO-CHAIR HOMER: I agree fully

 7   actually. I think it is totally on target.

 8   I think the challenge comes in when you are

 9   sort of doing this high-stakes, potentially

10   high-stakes measurement and wanting to be sure

11   that different institutions are using similar

12   criteria.

13   So, that is why really just I

14   think, at least for me, I am not completely

15   clear on the process that actually takes

16   place. So, just walk that through, how you

17   are proposing that it take place with the

18   measure that you are proposing.

19   Could she respond or --

20   MEMBER CLARKE: Oh, sure. I'm

21   sorry.

22   DR. BERGERSEN: I think I have

 1   articulated that this is evolving and that

 2   institutions, all institutions that perform

 3   these procedures are collecting adverse

 4   events. They are doing it in one way or

 5   another.

 6   So, to make the measure work, they

 7   would need to collect their adverse events and

 8   record them using the definitions that are

 9   available through the International Pediatric

10   Cardiac Code, which will be published this

11   year.

12   They will have the severity as a

13   qualifier for an event. They will have clear

14   definitions attached to them, and institutions

15   would have to adopt those definitions into

16   their collection of their adverse events to be

17   able to apply the measure to their

18   institution.

19   There is a national registry that

20   is starting for congenital cardiac cath

21   through the ACC called IMPACT. That could

22   potentially be a way to centralize data

1   collection if they adopted the same strategy.

2   CO-CHAIR HOMER: So, again, the

3   event happens. The institution records it.

4   The institution categorizes it reliably, using

5   the 1-to-5 scale.

6   And again, really, just a process

7   question then: after that happens or before

8   that happens, when does that preventability

9   assessment take place and who is making that

10   judgment? I believe it is really a process

11   question.

12   DR. BERGERSEN: Well, I think

13   there's two that I would like to answer. One,

14   within C3PO, the registry of these eight

15   institutions, when the event happens, they

16   assign preliminary categories, and then those

17   are independently reviewed by two physicians.

18   Now that is a research project. So, that is

19   how that registry works.

20   So, what the individual

21   institutions would need to do is do what they

22   are already doing, record their adverse event

 1   and assign a severity category and a

 2   preventability category at the time of the

 3   event, and all institutions also review events

 4   as a group, I think in some format, whether

 5   that is weekly or monthly or bimonthly. I

 6   think it is pretty common in most institutions

 7   to review their adverse outcomes.

 8   So, then, they would have the

 9   opportunity in that venue to come to consensus

10   and make sure that there is agreement and no

11   operator bias in the classification.

12   MEMBER CLARKE: I just want to

13   clarify that non-preventable adverse events

14   are all collected. There is not an option to

15   not report? Because, obviously, voluntary

16   adverse event reporting is a problem, and if

17   you give a provider a loophole, it is going to

18   take it. That is the thing I am most

19   concerned about.

20   But whether or not you determine

21   after careful analysis that this event should

22   not be included when we analyze the data and

 1   present and report results, that is a totally

 2   different matter and I fully understand that.

 3   But you have to identify these adverse events

 4   or nothing is ever going to be done about

 5   them.

 6   DR. BERGERSEN: I think in terms

 7   of this metric and the usability by

 8   institutions, I would like to just echo what

 9   Kathy said in terms of physician buy-in and

10   feeling that they are fairly evaluated.

11   Also, I think we underestimate

12   sometimes physicians' willingness to be

13   transparent, especially when it comes to the

14   opportunity to improve their care. So, if you

15   collected your events and you had the

16   opportunity to apply this model to your

17   outcome and calculate your standard adverse

18   event ratio, and you looked in the literature

19   and you saw that Hospital X's rate was this,

20   and you were outside of the bar for

21   performance, you might try to do a little bit

22   better. That is the purpose of putting this

1　forward and sharing it with the community.

2　　　　　　　CO-CHAIR HOMER: I think we have

3　had a great discussion. I would like to move

4　-- one more question about scientific

5　acceptability? Because then we want to be

6　able to vote on it.

7　　　　　　　MEMBER McINERNY: I think what

8　Charlie is trying to say is that, as long as

9　there is a standard criteria for what is

10　considered preventable that is applied across

11　the board uniformly to all institutions, then

12　that would go a long way to making us feel a

13　bit more comfortable. But what we would be

14　uncomfortable about is that Institution A

15　says, "Well, that was unpreventable," and

16　Institution B says, "Yes, it was preventable."

17　Then, you are not comparing equally.

18　　　　　　　CO-CHAIR HOMER: So, why don't we

19　vote on the scientific acceptability

20　criterion?

21　　　　　　　So, how many vote that it

22　completely meets the criteria for scientific

 1   acceptability?

 2   Okay. How many would vote that it

 3   partially meets the criteria for scientific

 4   acceptability?

 5   Okay.

 6   DR. WINKLER: Eight.

 7   CO-CHAIR HOMER: And feel that it

 8   minimally meets the criteria?

 9   DR. WINKLER: I probably need to

10   check. Did Marlene Miller join us at all?

11   (No response.)

12   Okay.

13   CO-CHAIR HOMER: Okay. Did we get

14   everyone then?

15   DR. WINKLER: Yes.

16   CO-CHAIR HOMER: Okay. Good.

17   Then, on the usability, because I

18   think we have discussed the usability a fair

19   amount in the context of discussing the

20   scientific. So, this relates to the issue of

21   whether it is understandable, harmonization,

22   and there is another element to it, which is

1   whether it provides added value.

2   How many feel it completely meets

3   the criteria for usability?

4   Feel that it partially meets the

5   criteria for usability?

6   DR. WINKLER: Nine.

7   CO-CHAIR HOMER: Okay. How many

8   feel it minimally meets the criteria for

9   usability?

10   DR. WINKLER: Five.

11   CO-CHAIR HOMER: Okay. All right.

12   We got everyone?

13   Then, for feasibility, I guess

14   that is actually -- so, again, data being a

15   byproduct of care, available through

16   electronic mechanisms, exclusions

17   appropriately specified, not susceptible to

18   inaccuracies, and ease of implementation.

19   So, how many feel it completely

20   meets the criteria for feasibility?

21   Partially meets the criteria for

22   feasibility?

1   DR. WINKLER: Twelve.

2   CO-CHAIR HOMER: And minimally?

3   Two?

4   And then I think an overall vote.

5   And again, this one, again, I think would be,

6   the vote would be for time-limited endorsement

7   subject to conditions.

8   MEMBER LIEBERTHAL: With the

9   conditions on the wording changes.

10   CO-CHAIR HOMER: Conditions for

11   wording changes around setting and provider

12   and even age, potentially age restriction to

13   under -- age to be determined.

14   Okay, David, question?

15   MEMBER CLARKE: I would like to

16   see some testing of non-preventable adverse

17   events.

18   CO-CHAIR HOMER: I think, again,

19   the question there is, is that something where

20   we would want conditional approval for testing

21   or more recommendation or suggestion to the

22   developer that they sort of do further

1   evaluation and testing and come back at a

2   future date?

3   CO-CHAIR WEISS: And could we add

4   to that the objective being to standardize the

5   definition?

6   MEMBER CLARKE: Yes, I agree. I

7   think that the measure ought to be introduced

8   and used, but I think a lot of attention ought

9   to be paid to this non-preventable event

10   issue. That should be monitored and reported

11   back at a specific time in the future.

12   CO-CHAIR HOMER: I could repeat

13   what you said, but Helen?

14   DR. BURSTIN: Well, we were just

15   talking a little bit about there's enough

16   changes that you guys are recommending that

17   the question be, do you actually want to see

18   some analyses back before you make this

19   decision? I mean I don't know how much you

20   could look at these analyses.

21   I think one of my only concerns at

22   looking at this is, at least the way it is

1   written in the submission form, the

2   definitions of how anybody beyond your

3   institutions would use this measure would be

4   very difficult. This is intended to be a

5   measure of a national, that any hospital could

6   pick up and use, and at least what is in the

7   submission form is really fairly imprecise.

8   You may just have more of it that

9   we haven't seen, but I think, given the number

10   of conditions, I just sort of wonder whether

11   you actually want to take just a quick look-

12   back.

13   DR. BERGERSEN: Also, what I have

14   presented to you was based on a single

15   institution. As I mentioned, we now have

16   three years of multi-center data that we could

17   insert your questions with.

18   CO-CHAIR HOMER: You know, one of

19   my concerns is, again, my suspicion is that

20   the institutions you test this in are all very

21   high-performing, highly-competitive, academic

22   institutions, and that if we were to apply

 1   this broadly to the many places that are doing

 2   cardiac catheterizations, they may not all

 3   share the values.

 4   I mean we can't assume some of the

 5   transparent orientation of some of those

 6   institutions. So, that is partly why at least

 7   I have questions about standardization and

 8   consistency that would not be as dependent on

 9   the goodwill of the participating

10   institutions, to put it bluntly.

11   So, that is why I am not sure some

12   of those questions would be fully addressed

13   within the context of the collaborative

14   among -- I just want to say C3PO again, since

15   I like that term -- institutions.

16   (Laughter.)

17   So, I don't know. My sense is

18   there's a lot of interest and excitement about

19   this measure and the desirability for further

20   testing of it before we are kind of on record

21   endorsing it even in a time-limited manner.

22   But we don't want to give the perception of

1   kind of going back to ground zero and come

2   back at some indefinite future date.

3   MEMBER CLARKE: It sounds like the

4   testing may have already been done, and we

5   could just table it and then consider it at a

6   phone conference call, or something.

7   CO-CHAIR HOMER: So, rather than

8   vote, a suggestion that we table this and that

9   you provide additional information on, first,

10   clarifying the definitions, looking at how

11   this would be affected if you limited the age

12   criteria, for example, and coming back with

13   some of that information.

14   MEMBER PARTRIDGE: And, Charlie, I

15   think there were several suggestions about

16   actually --

17   CO-CHAIR HOMER: Clarifying the

18   wording?

19   MEMBER PARTRIDGE: Specifications

20   for the numerator and denominator.

21   CO-CHAIR HOMER: Yes.

22   MEMBER PARTRIDGE: So, that should

1   be in here, too. I would kind of like to see

2   the actual text of what we are voting on.

3   CO-CHAIR HOMER: Okay. Good.

4   Was there a comment on the phone?

5   Did someone on the phone say anything?

6   DR. MAIN: No, this is Elliott

7   Main. I am waiting for the next measure.

8   CO-CHAIR HOMER: Oh, okay. Thank

9   you.

10   (Laughter.)

11   Thank you for your patience. We

12   are a little behind schedule, I am afraid.

13   DR. BURSTIN: And just one more

14   analysis, since it was brought up, since you

15   have the data, if there is any ability to look

16   at the number of events that weren't

17   classified as potentially preventable and

18   preventable? Just to kind of give a sum of

19   how many are actually being excluded might be

20   useful, given the number of comments.

21   DR. BERGERSEN: I would be happy

22   to provide additional analyses. It would be

 1   helpful for me if all of the comments and

 2   suggestions could be summarized in something.

 3   CO-CHAIR HOMER: Okay.

 4   DR. BERGERSEN: Great. Thank you

 5   very much.

 6   CO-CHAIR HOMER: So, I think, yes,

 7   rather than calling a vote, why don't we

 8   recommend that and revisit this on a phone

 9   call?

10   Thank you very much. I think this

11   was great.

12   So, what I would like to do is

13   call for a 15-minute, well, I will say 10

14   minutes, but it will be 15 minutes, but a 10-

15   minute break. We will try to reconvene at

16   11:10. Okay?

17   With Elliott. So, Elliott, you

18   have a 10-minute break.

19   Thank you.

20   (Whereupon, the foregoing matter

21   went off the record at 10:57 a.m. and resumed

22   at 11:10 p.m.)

1   MS. McELVEEN: Let's go ahead and

2   get started. We are going to reconvene, if we

3   could have everyone come back to their seats.

4   I promise you will get a lunch break, so you

5   can chat then.

6   So, Elliott, are you still on the

7   line with us?

8   DR. MAIN: Yes, I am.

9   MS. McELVEEN: Okay. Great.

10   Our next measure we are going to

11   be reviewing is No. 31. This is the healthy

12   term newborn, is the title of this measure.

13   This is the percent of term singleton live

14   births, excluding those with diagnoses

15   originating in the fetal period, who do not

16   have significant complications during birth or

17   the nursery care.

18   I just want to also mention to the

19   group one of the attachments I sent out last

20   night was a visual diagram of this measure,

21   which may help as we discuss it.

22   Elliott, just so you know, I also

1   have it here, projecting it, so the group can

2   view it.

3   Elliott, did you want to take a

4   few minutes just to make a few comments about

5   the measure or introduce it any way? Or we

6   can just open it up for discussion.

7   DR. MAIN: Well, I would like to

8   say a few comments.

9   Thank you very much for allowing

10 me to speak from San Francisco. It is a long

11 trip back to D.C.

12   I am going to take you back to the

13 beginning to pediatric care. Instead of

14 looking at complications of sort of operations

15 or procedures, this is really a reflection of

16 both maternity, the summation, if you would,

17 of maternity care and newborn care or regular

18 nursery care.

19   A normal newborn is the most

20 important outcome for us as obstetricians. I

21 am perinatologist in the California Maternal

22 Quality Care Collaborative, which is the

1   sister organization for the Perinatal

2   Collaborative, led by Gould.

3   It actually serves as a balancing

4   measure for most of the other measures that we

5   have in the maternity realm. Ideally, you

6   would like an institution that has an average

7   or even a below-average maternity infection

8   rate and a good, healthy newborn outcome rate,

9   as opposed to a hospital that has a very high

10   C-section rate and also a low rate of healthy

11   term newborns. So, you really don't want to

12   be in the position of pushing in one direction

13   and having adverse outcomes in the other.

14   This is applicable to all

15   hospitals that do maternity care. We have

16   been working on it for over 10 years, tweaking

17   the codes, looking at ways of capturing data

18   in settings where people don't choose to code

19   diagnoses for medical legal reasons.

20   For example, a number of hospitals

21   in California have given up coding for

22   perinatal asphyxia because that is a marker

1   for plaintiff's attorney.

2   What we have learned over that

3   decade, though, is that they do code for

4   procedures because you get paid for

5   procedures. So, being on a ventilator, having

6   CT scans, et cetera, all get coded quite

7   accurately.

8   So, this measure is a mix of

9   diagnostics, diagnoses codes, procedure codes.

10   What we have had more recently as a failsafe

11   is a length-of-stay indicator.

12   To start it off, though, instead

13   of doing extensive risk adjustments, we did

14   exclusions from the denominator. The

15   denominator is chosen to reflect healthy baby

16   as the mother arrives to the hospital for

17   maternity care. So, we have excluded the

18   general anomalies, intrauterine growth

19   retardation, babies who have hemolytic disease

20   due to Rh, for example, or hydrox, or infants

21   of mothers who have drug addiction, for

22   example.

1   So, that is our starting point.

2   That actually accounts for over 3 million

3   babies in the United States. This is a very

4   high-volume measure, which is important

5   because bad outcomes in babies are still an

6   uncommon event. So, the infants that we are

7   looking at here are somewhere between 1 and 3

8   percent, is the range we see in the hospitals,

9   which makes it still a reasonable number,

10   given the maternity ward denominator.

11   The only other measurement in this

12   domain that has been approved is the AHRQ

13   measure, ES-17, for birth injury/birth trauma,

14   and a version of that was previously picked by

15   NQF to be a measure.

16   Unfortunately, that measure has

17   significant limitations. It is very low

18   incidence, about 2 to 3 per 1,000 births. It

19   is highly dependent on coding.

20   An article came out this last

21   month looking at the HCUP's experience with

22   that measure nationwide and found that 75

1   percent of all the kids that meet this

2   criteria for birth injury/birth trauma are

3   identified with two ICD-9 codes that both

4   begin with "other", other specified birth

5   injuries and other non-specified birth

6   injuries, which are very variable diagnoses.

7   That is probably the reason that that measure

8   was not picked up by the Joint Commission or

9   Leapfrog for their measure set.

10   This is really trying to fill a

11   void of a neonatal measure that would go into

12   the basket of measures to support maternity

13   care, and maternity care that includes nursery

14   care.

15   I would be glad to take any

16   questions or I will be available. Thank you.

17   CO-CHAIR HOMER: So, first, if I

18   could ask members of the Work Group if they

19   have questions. So, any questions? David?

20   MEMBER CLARKE: I would just like

21   to comment that I felt that this was the best

22   worked-out, most complete, and probably

 1   easiest-to-evaluate measure that I reviewed.

 2   I really don't have any thing wrong with it.

 3   (Laughter.)

 4   MEMBER RAO: Just a question,

 5   Elliott. Could you comment on its use in

 6   other environments? I understand it is being

 7   used internationally in the UK and other

 8   countries.

 9   DR. MAIN: There is a normal birth

10   measure in the UK, but that actually is a

11   maternity measure rather than a newborn

12   measure. A normal birth there is one without

13   any interventions at all.

14   Everyone has been looking for this

15   kind of a measure for a long period of time.

16   This is the Holy Grail of what we are trying

17   to do. And it has taken a while to put

18   together the different pieces of the different

19   codes to do this.

20   One of the challenges is in past

21   measures the charts included codes from the

22   mother, codes from the baby, and that is very

 1   hard to do on any kind of large scale because

 2   those two charts don't intersect, don't relate

 3   to each other, and no data assessment. So, we

 4   had to take some extra time to focus only on

 5   the codes that we could get from the newborn

 6   codes.

 7   So, there are flavors or

 8   variations of this that have been tried

 9   elsewhere. There is not one in the United

10   States that has gotten to this point.

11   CO-CHAIR HOMER: So, again, if you

12   were explaining this in words, and I know you

13   could do it either on the healthy side or on

14   the non-healthy side, but, basically, you are

15   saying this is a term infant who doesn't have

16   -- so, I am just trying to think how you are

17   explaining this to a consumer.

18   DR. MAIN: We wanted to frame it

19   specifically so it would be understandable by

20   the public. But it is the proportion of term

21   live births without a diagnosis, without a

22   complication prior to birth, who do not have

 1   significant complications during the birth or

 2   nursery care. In other words, this is a good

 3   take-home baby.

 4   CO-CHAIR HOMER: Well, I know

 5   that, but I may be the only one on the

 6   Committee who is having just a little trouble

 7   understanding, but I am still unclear.

 8   Because, again, if you are coming to the

 9   hospital, actually, you don't know whether you

10   have a congenital anomaly or not.

11   DR. MAIN: In this day and age,

12   you often do with the advent of ultrasound,

13   but it is excluding diagnoses originating in

14   the fetal period, is the other way of

15   explaining it.

16   CO-CHAIR HOMER: Okay. So, you

17   are coming to the hospital. Presumably, you

18   have had an ultrasound or something like that.

19   So, you know if there is going to be a major

20   congenital anomaly. Then, you are saying you

21   know you have made it all the way to full

22   term. Then, you are saying, what's the

 1   likelihood that everything is going to go okay

 2   in the hospital and you will come home with a

 3   healthy baby, excluding bilirubin issues and

 4   excluding a few other --

 5   DR. MAIN: Yes, there's a few

 6   minor things like bilirubin, but things that

 7   are clearly -- we also have excluded if we go

 8   into details of social situations such as

 9   babies being put up for foster care that may

10   have a long length of stay in the hospital,

11   babies that have drug withdrawal. Conditions

12   that originated before you enter the labor and

13   birth process, these are the ones that would

14   be excluded. Conditions that arise during or

15   after the birth process are the ones that are

16   included.

17   CO-CHAIR HOMER: Okay. Good.

18   All right. Any other questions

19   specifically on the importance? Then, we can

20   move to the others. Kathy?

21   MEMBER JENKINS: I was just

22   curious about the variation that has been

1   observed in the measure.

2   DR. MAIN: We field tested in a

3   large health system in northern California

4   with 25 maternity hospitals. We have seen

5   variations there. Of the full measure, almost

6   150 to 200 percent, a fair amount of

7   variation.

8   We have more limited detail on

9   subsets of the measure that we published in

10   the past which show actually quite large

11   variation looking at the State of California,

12   and, again, subsets of the adults where

13   there's probably three- to fourfold variation.

14   CO-CHAIR HOMER: Faye?

15   MEMBER GARY: I just wanted to ask

16   a quick question. I am not clear how you

17   would deal with low-birth-weight babies.

18   DR. MAIN: Those are not included

19   in this measure. This is 37 weeks or beyond,

20   because those, obviously, have a large number

21   of complications. You know, the mother's

22   expectations are quite different if you are

 1   coming in in pre-term labor or premature.

 2   We also do exclude term low-birth-

 3   weight babies, which I mentioned before, those

 4   with small birth weights or intrauterine

 5   growth retardation. That, again, is a

 6   condition that arises before the labor and

 7   delivery process. So, that is a specific

 8   exclusion.

 9   MEMBER GARY: But you have here

10   that have not been -- these are morbidities

11   that may or may not be clearly related to

12   medical care. I was just thinking about all

13   of the conditions that might impact whether a

14   woman has a healthy baby or not, such as

15   nutrition, diet, where she lives, what kind of

16   support she has. There are just tons of data

17   that support that especially, let's say, with

18   African-American women that even healthy,

19   middle-class African-American women deliver

20   more low-birth-weight babies and have higher

21   mortality/morbidities than their Caucasian

22   counterparts.

 1   So, I am not clear how these

 2   measures will help us to get at disparities

 3   among different groups who have had poor

 4   outcomes for a very long time.

 5   I was just commenting, well, Dr.

 6   Zimmer just commented that, if you are poor,

 7   then what happens if you need a sonogram, for

 8   an example? Or what happens if you can't

 9   afford your calcium and your milk, or

10   whatever?

11   I like what you have written, but

12   it seems like to me there's so many other

13   issues that revolve around what you are trying

14   to do here, and I don't see any discussion

15   about it or any acknowledgment of it.

16   So, would you just help me with my

17   confusion?

18   DR. MAIN: Okay. Of course. It

19   is very well-known that African-American

20   populations and other disadvantaged

21   populations have higher rates of pre-term

22   births and small birth weight babies. That

1   would be covered by other measures that

2   address our nationwide racially-associated

3   rate of low birth weight.

4   This is really focused on, once

5   the mother gets to term, what are the

6   complications that arise during the labor and

7   birth process, rather than the prenatal care,

8   which is a subject of a different type of

9   measure. This is, whether or not you have

10   ultrasound, if you end up with a birth defect,

11   you would be excluded from this measure.

12   So, this is really trying to set

13   up an apples-to-apples type of comparison. It

14   has been looked at in actually rural

15   hospitals, urban hospitals, and big and small,

16   that would compare really what happens in

17   labor and delivery as to the outcomes then in

18   the nursery.

19   So, this looks, for example, at --

20   the numerator, then, is full of the codes for

21   birth trauma/birth injury, including the ones,

22   actually, that were excluded from the AHRQ

1   measure, such as brachial plexus injuries and

2   clavicle fracture, the diagnosis and procedure

3   codes around hypoxia and asphyxia and

4   respiratory complications.

5   We have seen a rise in newborn

6   respiratory complications from the use of

7   elective recent C-sections at 37 and 38 weeks.

8   This is the measure that would identify those.

9   There is the partner in quality

10   improvement arm. That is one, for example.

11   The other partner in quality improvement arm

12   is the IHI safety for oxytoxin, where this

13   would be the neonatal measure that would go

14   with that to identify babies that had

15   perinatal hypoxia or asphyxia related to

16   prolonged oxytoxin use.

17   In terms of disparities per se,

18   though, it does not address the low-birth-

19   weight issue or any really of the prenatal

20   issues that occur in those types of

21   populations, but it is focused on how you

22   manage labor and delivery, which should be the

1   same for everyone.

2   CO-CHAIR WEISS: Elliott, this is

3   Marina Weiss.

4   I may just be reading this wrong,

5   but as I understood the measure, it was the

6   absence of conditions or procedures reflecting

7   morbidity, but you are going to the other side

8   and identifying the morbidities or the

9   procedural problems that may occur, is that

10   right?

11   DR. MAIN: It is either you get

12   the absence by identifying the presence and

13   subtracting it. It is a nice way of terming,

14   I think, for families, and that is why we

15   chose to do it that way, which is to focus on

16   a healthy baby outcome rather than an ill baby

17   outcome. The two are mirrors of each other.

18   MEMBER GARY: And the use, the

19   utility of this measure is stated in the

20   positive from your perspective? Suppose you

21   were able to say that at your institution 97.2

22   percent of the children are born healthy and

 1   everything is fine, given the exclusions, and

 2   so on. What have we learned?

 3   DR. MAIN: Well, in comparison to

 4   other measures, and alone this should be as

 5   close to 100 percent as you can get. So, we

 6   have worked with some focus groups on whether

 7   it should be positively or negatively. People

 8   are attracted to the positive nature of it.

 9   When you get down to the exact

10   numbers of how it is presented, is 98

11   different than 97.5 percent? It gets a little

12   tricky.

13   As with a number of the measures

14   we've included, they end up with stars, based

15   on their quintile distribution and the

16   statistics that have been applied to them.

17   That is probably how it would be displayed in

18   a public release mode.

19   MEMBER GARY: So, would it be

20   fair --

21   DR. MAIN: It is better than

22   expected or worse than expected or average.

1   MEMBER GARY: So, would it be fair

2   to say, then, that what you are doing here is

3   attempting to think in terms of presentation

4   to the general public, but at the same time

5   you are capturing information that will be

6   relevant to clinicians who are providing care,

7   in that you are, in fact, keeping tabs on the

8   morbidities? Is that correct?

9   DR. MAIN: That is exactly

10   correct. We wanted to have something that

11   would be easy to use, and perhaps for

12   clinicians we might flip it and say, what is

13   the incidence of ill term infant outcomes,

14   which should give you, then, around 30 per

15   1,000 on average if it goes through the AHRQ

16   thing. As I said earlier, about 3 per 1,000,

17   and that allows you a lot more play in the

18   ability to statistically compare hospital to

19   hospital. It allows you to look at more

20   hospitals as well as bigger hospitals.

21   MEMBER GARY: And if you could

22   indulge me just one more minute here, and then

1   I will be quiet and let others interact with

2   you, you said in your opening description that

3   the purpose of this measure was to be a

4   neonatal measure to support maternity care.

5   Could you explain to me a little bit more --

6   maybe I am just not getting it here -- that

7   link?

8   I mean a healthy newborn is the

9   ultimate positive outcome. We all agree on

10   that. But how does that reflect on the care

11   that is given to the mom?

12   DR. MAIN: One of the major

13   concepts in maternity or elsewhere is that you

14   want to have balancing measures so that you

15   don't push too hard in one direction to the

16   detriment of another direction. And here, in

17   theory, you have two patients, the mother and

18   the baby. One of the concerns, for example,

19   with trying to reduce the various infection

20   rates is that you may end up with worse

21   babies. That is possible. Or any of the

22   other interventions that we do in obstetrics,

1   really we have our eye on what happens on the

2   fetus, and we haven't had an initiative to go

3   with that.

4   So, it is a balancing measure

5   where we do more or less things to the mother

6   that may advantage or disadvantage the baby.

7   CO-CHAIR HOMER: Nancy?

8   CO-CHAIR WEISS: I have a

9   question. Speaking about the caesarean rate,

10   we have a high incidence of caesarean. It

11   says in here that you see babies now at 38, 39

12   weeks that end up with respiratory problems

13   because of caesarean section. Okay, I

14   understand that. But according to this data,

15   if you come in and your baby gets a

16   respiratory problem, aren't they excluded?

17   DR. MAIN: No. That is one of the

18   numerators where there is both TTN and RDS and

19   all these procedures that go along with being

20   on a ventilator. A test tube, for example,

21   non-invasive ventilatory, those are also

22   included.

1   MEMBER FISHER: So, on 2a.3, all

2   of those are included?

3   DR. MAIN: Again, it is the

4   framing of whether it is healthy or, you know

5   -- so, those, if you go down to the measure

6   calculation, those are in the numerator, that

7   it excludes you from being healthy.

8   CO-CHAIR HOMER: So, basically,

9   what he is doing is he is identifying the

10   number of kids who have one of these

11   complications like TTN or respiratory disease,

12   and comes up with a number or a percent and

13   then subtracts that from 100 percent.

14   So, what is important is he comes

15   up with either half a percent or 2 percent or

16   3 percent of the population, but presents it

17   as 99.5 or 97 percent. But you still have the

18   challenges identifying that percentage, that

19   small percentage, and then it is a question of

20   marketing your presentation or what families

21   want to know as to whether you present it as

22   that 2 percent of kids have a problem or 98

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1   percent of kids come out just fine.

2   Kathy?

3   MEMBER JENKINS: I just want to be

4   sure that I understand then. Everything that

5   you have basically included in the definition

6   of not a healthy newborn you believe is

7   preventable or avoidable by changes in

8   maternal care? Is that correct?

9   DR. MAIN: That is one of the

10   topics that is debated. The neonatal births

11   that we work with, the procedures, that is

12   basically an offshoot of Vermont Oxford, in

13   our group we looked at these very, very

14   carefully. One example that I said before was

15   brachial plexus injuries. You know, AHRQ

16   excludes that, though that is a major

17   morbidity for babies. It can be prevented if

18   you do a C-section. It does not mean that

19   this is malpractice though. That is why it is

20   excluded, because people thought, well, you

21   can do perfectly normal or perfectly adequate

22   obstetric care and still get brachial plexus

1   injuries.

2   From the patient's perspective,

3   though, that was an unexpected outcome, and it

4   is a significant outcome, that you don't have

5   a healthy term newborn if you have a baby with

6   brachial plexus injury. And that was the

7   philosophy that we ended up choosing to use in

8   those borderline cases, balanced by trying to

9   exclude as many diagnoses that were present in

10   fetal life before we get into the measure

11   itself by screening those from the

12   denominator.

13   CO-CHAIR HOMER: Do you have a

14   follow-up question?

15   MEMBER JENKINS: I asked that

16   question when you mentioned TTN. So, I assume

17   that there is a way that TTN can be avoided.

18   CO-CHAIR HOMER: Through a

19   C-section.

20   DR. MAIN: TTN, the most frequent

21   cause by far is C-section without labor. We

22   don't have the squeeze on the lungs, and you

 1   have often a little bit of early gestation

 2   involved at 37, 38 weeks as opposed to 40.

 3   That has a three- to fourfold increase rate

 4   just from that case alone.

 5   Of course, our goal 100 percent.

 6   But, no, there's no center that will get 100

 7   percent from this measure. There will always

 8   be something that gets through. But there is

 9   big variation and big opportunities for

10   improvement here.

11   CO-CHAIR HOMER: If I could ask a

12   question, I had a question. I was a little

13   confused about your definition says that it is

14   identified term signals in infants, and yet

15   you said this would be sensitive to this issue

16   of, quote, "late pre-term" births, which is,

17   of course, the most important contribution to

18   the increase in pre-term.

19   DR. MAIN: The term is, the normal

20   is focused up the early problems at 37 to 39.

21   Actually, there is a big project we are doing

22   with the March of Dimes right now on

1   prevention of low-weight births, which we

2   think will sort of spill over into the late

3   pre-term population.

4   CO-CHAIR HOMER: So, I guess,

5   again, I agree that is a critical or the

6   critical thing to be addressing. It feels to

7   me there are more direct ways to address that,

8   like, you know, measuring the proportion of

9   infants that are born less than 38 weeks or

10   something like that. Do we have that measure

11   already? Okay.

12   Because I was going to say that

13   this seems like a rather broad brush to use to

14   attack that specific thing that should be

15   addressed. So, okay.

16   Allan?

17   MEMBER LIEBERTHAL: Yes, I have

18   two questions. One is how you deal with

19   intrapartum fever in the mother and whether

20   those are excluded or not. And the second is,

21   now that you have excluded so many of the

22   things that cause neonatal morbidity and

 1   mortality, even 150 percent difference among

 2   institutions, what is the effect size of that

 3   difference? In other words, does 150 percent

 4   really mean anything?

 5   DR. MAIN: Sure. Let me do the

 6   last one and then I will go back to

 7   intrapartum fever.

 8   We are talking the differences

 9   between basically 1 percent and 3 percent or

10   a little over 1 percent or a little less than

11   3 percent of the population. So, that is

12   still a significant effect size. Yet, when we

13   get into term babies, the biggest proportion

14   of morbidity -- this is a general anomaly --

15   but there is still a fair amount of morbidity

16   of babies admitted to NICUs, which in a sense

17   this is a surrogate for, babies that go into

18   the NICU and have other morbidities that don't

19   quite get you to the NICU, but it still

20   accounts for a real number of cases.

21   The trouble with anomalies is that

22   there isn't really much we can do at this

1 point to prevent them once they occur. We are

2 all giving everybody a lot of folic acid and

3 taking that route, but prenatal diagnosis

4 doesn't actually cure your anomalies unless

5 the family should terminate. So, that is a

6 very different population, a very different

7 issue than what we are dealing with in birth

8 issues and counting managed labor and delivery

9 and its consequences for the baby.

10 In terms of fever, that is one

11 that the expert panel worked on a fair amount.

12 There is very large variation in how infants

13 are handled in all the nurseries around the

14 country, and we have most of them in

15 California, in terms of what kind of workup

16 the baby gets after the mother has had a fever

17 in labor. It goes from observation to IV

18 antibiotics.

19 It is quite interesting that there

20 is not a lot of difference in outcomes when we

21 look at those. So, we are looking at

22 encouraging mothers in labor with fever to get

 1   aggressively treated in labor. That does

 2   appear to prevent a lot of the neonatal

 3   outcomes. So, there is the ability to affect

 4   that.

 5   Now what is included in our

 6   numerator or in the, quote, "exclusion" set is

 7   babies that actually have sepsis, not babies

 8   who got antibiotics. So, that gives the

 9   obstetrician the opportunity to have that

10   intervention. There will be some of the cases

11   where IV antibiotics with the mother actually

12   is significantly reducing sepsis rate in

13   infants.

14   CO-CHAIR HOMER: Tom?

15   MEMBER McINERNY: I think if this

16   really becomes widespread, that it may be one

17   of the first things, if not the only thing,

18   that would reverse the trend in increased

19   caesarean section rates.

20   I don't know, do you anticipate

21   that or have you actually seen any evidence of

22   that since you have been using it?

 1   DR. MAIN: Yes, that is one of my

 2   directions; I will have to put that out.

 3   Actually, what you would like to have is a

 4   good rate of good babies and a reasonable rate

 5   of C-sections. Right now, we have C-section

 6   rates that range from 15 percent to 50 percent

 7   in hospitals in California. There is not much

 8   variation in there, and everybody wants to

 9   have good babies. You don't get that much

10   additional benefit, if any, on the baby's side

11   for those kinds of variations in C-sections.

12   You may have been following in

13   Sutter Health, which is, again, 25 hospitals

14   in northern California, some variations of

15   this. That includes Apgar scores, for

16   example, 500 Apgar scores. That has elevated

17   our C-section rate quite significantly. So,

18   we are way below the State average and the

19   national average. It still has increased. I

20   can't say it is flat, and even though the

21   quality effort is there, but it is much below

22   the national and State rate.

1   I think you want to have data like

2   this to really show what your outcomes for

3   your babies are in your term babies. They

4   have focused a lot in outcomes on prematures

5   and survival rates for under 15000-gram kids,

6   and so forth, but we haven't really had much

7   attention looking at term babies, which this

8   will fill the gap for.

9   CO-CHAIR HOMER: Can I just ask

10   what the drivers are of these rates? I mean,

11   do you have -- no, not the C-section rates,

12   but this performance measure. You know,

13   again, you have got lots of different codes

14   that can get in there, but I am trying to see,

15   basically, is it the TTN for the 37- to 38-

16   weekers that is driving 80 percent of the

17   variance here or is it everything together?

18   DR. MAIN: When you look at

19   composite measures, you always have to look at

20   which component has the biggest frequency

21   within. I mean which drives the code.

22   Respiratory is the main one. Birth hypoxia

1   and asphyxia is probably second or third in

2   there. First would be respiratory. The

3   second would be infections. The third would

4   be hypoxia/asphyxia.

5   For more hospitals, it is

6   transferred for care, you know, where you

7   have to transfer the baby out to another

8   facility. That is Part B on this schema.

9   That is a major dissatisfier, a major negative

10   for families to be put in that position where

11   they are separated from their baby.

12   CO-CHAIR WEISS: Let me just

13   observe that that is very interesting in that

14   it correlates perfectly with the top

15   expenditure codes in the Medicaid program. I

16   mean there are four or five different

17   categories in which expenditures for these

18   kids fall that are pretty high, highest in the

19   respiratory distress arena.

20   CO-CHAIR HOMER: Nancy, I think

21   you had a question?

22   MEMBER FISHER: I had a comment.

1   I think you asked about -- I don't know about

2   since this measure has been out there, but

3   there are several studies across the United

4   States with people in hospitals reducing the

5   C-section rate. Especially I can think of

6   one; it was in Akron, Ohio, and they talk

7   about reducing the C-section rate by making

8   sure that you have a protocol for induction

9   and that the people buy into it and stuff like

10   that.

11   In Washington, we are also working

12   on that, but we are just taking that measure,

13   not something this big. I was wondering the

14   advantage over this because I believe Leapfrog

15   is now going to start collecting information,

16   too, on -- what do you call it? -- C-section

17   rates and in what we call late-term babies,

18   38, 39 weeks. I mean late C-section is what

19   they call it.

20   DR. MAIN: Yes, the risk adjuster

21   in the low-risk term C-section rate is

22   actually a measure from our institution. It

 1   is an NQF measure. It is now a Joint

 2   Commission measure.

 3   If we use that and implement it

 4   around both in systems and in states, the

 5   obstetric pushback is, what about the baby?

 6   You know, we may be high for C-sections, but

 7   we want to make sure we have good babies at

 8   the end. That is one of the drivers, to have

 9   this as a balancing issue.

10   I think the effective measure that

11   you mentioned helped the elective delivery

12   prior to 39 weeks measure, a little bit by

13   C-section induction. It is a very important

14   measure and it will change some of the

15   practice. That is just measuring the

16   frequency of births at that time period. That

17   is going to be a very important measure, as I

18   have said. This will allow us to say that

19   this is actually includes outcomes for the

20   babies at the same time.

21   MEMBER FISHER: I was saying, yes,

22   we have the measure. What I am saying is that

1   we are doing something about the number of

2   C-sections. So, it is the same thing. We

3   have got a couple of hospitals that have a 50

4   percent rate for C-section. They are small

5   hospitals. The average rate in Washington is

6   33 percent. We know that, and we know we need

7   to reduce it.

8   So, we have five pilot projects

9   going about looking at babies born at 38, 37

10   weeks, and we do things about induction. So,

11   we have the numbers. We are implementing

12   something.

13   I guess what I am saying is, why

14   is this measure better than what is being

15   measured out already?

16   MEMBER PARTRIDGE: I don't want to

17   respond for Elliott, but I served on the

18   Perinatal Steering Committee, and we debated

19   the C-section rate measure endlessly.

20   (Laughter.)

21   I think that we need both. The

22   C-section rate tells you you've got a rate

 1   that seems way out of line. As I understand

 2   it, what Elliott is trying to say is people

 3   advance in support of a high C-section the

 4   danger of an unfortunate outcome for the baby.

 5   This measure is designed to give you some

 6   sense of, I think as Elliott said earlier on,

 7   if you lower the C-section rate, your rate of

 8   bad babies is going to go up.

 9   Am I sort of right?

10   DR. MAIN: That is, well, there is

11   a legal risk, there's all kinds of risks out

12   there in terms of babies, but the reality is

13   that the C-section rate has gone up, but the

14   outcomes for babies has not changed. It has

15   not improved with the higher C-section rate.

16   But we don't have a measure to really show

17   that.

18   So, it is a complementary measure

19   that allows you to put it in the place of

20   projects on C-sections and have it be the

21   safety measure that shows that you are not

22   being harmed. In fact, you may be actually

1   improving neonatal care by having a more

2   moderate C-section rate.

3   CO-CHAIR HOMER: And this measure

4   doesn't weight different complications

5   differently, which is fine.

6   DR. MAIN: No, no, we decided not

7   to do that. That is inherently objective one

8   way or the other.

9   CO-CHAIR HOMER: Yes, I am not

10   arguing with that. I am just thinking of the

11   countervailing argument. When you reduce

12   C-section rates and reduce with them,

13   presumably, the respiratory complications,

14   there may or may not be, but probably there

15   won't be, there may or may not be some small

16   increase in some other kinds of complications,

17   which was the rationale for the C-section in

18   the first place.

19   I think we have actually had a

20   great conversation about this. I would

21   suggest we could probably move on to voting,

22   unless there are compelling questions. I

 1   don't see any.

 2   So, I would say the first

 3   threshold question is whether this is

 4   important enough for us to proceed.

 5   So, why don't we have all those

 6   who believe this is sufficiently important to

 7   proceed, show of hands?

 8   DR. WINKLER: Fourteen. That's

 9   all we've got now.

10   CO-CHAIR HOMER: Okay. Good.

11   Great.

12   So, then, let's move on to the

13   discussion of scientific acceptability. We

14   have had a fair amount of conversation about

15   this, but I don't know, Elliott, if you have

16   any comments or there are questions from any

17   of the members about validity, reliability of

18   this measure and the various other elements of

19   scientific acceptability. Or do we feel that

20   it has adequately been addressed?

21   Some people do need lunch. Okay,

22   but we are not quite there yet.

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 1                    Okay.  Any questions about

 2    scientific acceptability of the measure?

 3                    (No response.)

 4                    People feel good about it.

 5                    Okay.  So, those who feel it

 6    completely meets the criteria for scientific

 7    acceptability show of hands.

 8                    And partially meets?

 9                    Good.  Okay, that has got

10    everyone.

11                    Next is the area of usability.

12    And again, you have said you have done a fair

13    amount of focus group work with this and

14    efforts to communicate it.

15                    DR. MAIN:  And also, if it is

16    straightforward administrative data, that

17    would probably be nice.  So, that is the gun

18    I am under in California, is that it has to

19    be, new quality measures need to be using

20    administrative data as much as possible.

21                    CO-CHAIR HOMER:  And can you

22    describe any use in your Collaborative or at
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 1   Sutter or Kaiser or any of the other places in

 2   terms of how providers have experienced this

 3   measure and how it has contributed or not

 4   contributed to quality improvement activities,

 5   et cetera?

 6   DR. MAIN: We used earlier

 7   versions of this extensively in Sutter Health

 8   as the parallel to our C-section quality

 9   improvement effort and our oxytoxin quality

10   improvement effort. We are starting the

11   elective delivery for 39 weeks, and we will

12   probably go with that, but it has been both a

13   source of reassurance and, you know, it

14   changes the focus of this to say, okay, what

15   could we do to optimize the baby outcomes that

16   is appropriate? So, it has been the patient

17   measure that goes along with the other quality

18   improvement measure.

19   CO-CHAIR HOMER: And is there any

20   evidence of improvability? That is, I know

21   there is variability across sites. Have you

22   seen within single sites any trend data on

1   that?

2   DR. MAIN: We have seen trend data

3   both for the components of respiratory and

4   infection. We have been pretty good on

5   hypoxia and asphyxia, the biggest categories.

6   That is a third the big three categories. So,

7   we haven't seen as much there.

8   But there are places around that

9   have higher rates. We don't have quality

10   improvement efforts that are just for show.

11   We have improvements for the respiratory

12   complications, for infection. So, there is

13   opportunity.

14   CO-CHAIR HOMER: All right. So,

15   in terms of usability criteria, those who feel

16   it completely meets the usability criteria?

17   DR. WINKLER: Eight.

18   CO-CHAIR HOMER: And partially

19   meets?

20   DR. WINKLER: Six.

21   CO-CHAIR HOMER: All right. So,

22   that's got everyone. Good.

1   And then, feasibility, which is

2   the one that does specifically get at the

3   issue of availability of administrative data

4   and ability to collect and generate reports,

5   and all that sort of stuff.

6   So, how many feel it completely

7   meets the criteria for feasibility?

8   DR. WINKLER: That's everybody.

9   CO-CHAIR HOMER: Okay. Good.

10   All right. So, I will call for a

11   measure to recommend endorsement of the

12   measure. This one would not be conditional or

13   time-limited. This would be endorsement of

14   the measure to go forward as a regular measure

15   within the NQF.

16   So, all in favor of recommending

17   endorsement?

18   DR. WINKLER: Fourteen.

19   CO-CHAIR HOMER: All right.

20   Congratulations. This is good.

21   DR. MAIN: Thank you.

22   CO-CHAIR HOMER: We've got two

1   more measures, guys.

2   (Laughter.)

3   DR. WINKLER: Thank you, Elliott,

4   very much.

5   DR. MAIN: Thank you very much.

6   CO-CHAIR HOMER: Thank you.

7   MS. McELVEEN: Okay. We are going

8   to move on to our next measure. It is Measure

9   48. I hope we still have folks from AMA PCPI

10   on the phone, who have been waiting for this

11   measure.

12   MS. FEI: Hi. This is Kerri Fei,

13   staff from the AMA PCPI, and we also have Dr.

14   Barbara Fivush, who is our Co-Chair.

15   MS. McELVEEN: Okay. So, again,

16   this is Measure 48. The title is plan of care

17   for hemodialysis. This is the percentage of

18   calendar months during the 12-month reporting

19   period in which patients age 17 years and

20   younger with a diagnosis of ESRD receiving

21   hemodialysis have a single-pool Kt/V greater

22   than -- yes, okay -- or have a single-pool

 1   with a documented plan of care for inadequate

 2   hemodialysis.

 3   So, I will allow you guys to kind

 4   of explain that. Sorry, I butchered the

 5   description a little bit.

 6   (Laughter.)

 7   MS. FEI: Oh, no, you did fine.

 8   Did you want me to give a little, brief

 9   description or --

10   MS. McELVEEN: Sure, that would be

11   fine.

12   MS. FEI: Okay. So, we developed

13   this measure I think about two years ago,

14   after we had developed the same measure for

15   the adult population, which was actually

16   developed prior to this one, wanting to have

17   the same measure for the pediatric population

18   as well.

19   So, really, there's really not

20   much difference between this one, and the RB

21   panel did endorse the adult measure, which is

22   actually, we just gave testing results for.

 1 I think we will be going to the CPAC sometime

 2 next month for potential full endorsement.

 3   We did provide the testing results

 4 from the adult measure. We have not had the

 5 uptake for the pediatric measure as of yet.

 6   So, really, Dr. Fivush, was there

 7 anything else you would like to add?

 8   DR. FIVUSH: Yes, just because

 9 this is a highly-specialized field within a

10 field, so we are really talking about a small

11 population of patients. Probably in our

12 country maybe 800 pediatric patients maintain

13 on chronic hemodialysis, but it is a very

14 vulnerable population in that it has a fairly

15 high mortality rate, which we are trying to

16 address in other ways.

17   But there is a gap in care here,

18 in that we think about 12 percent of patients

19 in previous datasets have not met what we

20 think is adequate dialysis. That is measured

21 by a Kt/V which looks at the way urea moves,

22 to simplify it.

 1   So, we have good evidence that a

 2   Kt/V of 1.2 is a dialysis prescription that is

 3   adequate, and it is a really minimal

 4   prescription. We have linked a low Kt/V to

 5   poor outcomes. We have a high mortality rate,

 6   and we think this is an easy-to-capture

 7   measure.

 8   It is reported on a monthly basis,

 9   physicians have coverage. Doctors can easily

10   get to this number, and we will be able to

11   closely monitor how patients are getting

12   dialysis in the country that are pediatric.

13   Hopefully, we will be able to use this data

14   long-term to really link it to more long-term

15   outcomes. This is an intermediate outcome.

16   The measure is both a process and

17   an outcomes measure in that we are looking at

18   a standard of 1.2, but we are, additionally,

19   looking at a thought process that, if you do

20   not dialyze this patient well enough, what

21   would you do to change that? So, we think it

22   is a good combination measure that is going to

1   give us important information in a vulnerable

2   population that has a high mortality rate that

3   we think is easy to capture.

4   CO-CHAIR HOMER: This is Charlie

5   Homer.

6   Could you explain again why it is

7   an outcome measure rather than a process

8   measure?

9   DR. FIVUSH: Kerri may want to

10   help me.

11   It is an outcomes measure. It is

12   single-pool for a Kt/V of greater than 1.2.

13   So, we aren't looking at an outcome

14   specifically, but we are looking at this as

15   long-term.

16   Do you want to clarify that?

17   MS. FEI: Sure. The measure

18   actually is a combined process and outcome

19   measure. So, when the measure results get

20   reported out, you are going to know your

21   patients meet the outcome, and for the

22   patients who don't meet the outcome, that they

1   have a documented plan of care.

2   So, the users of the measure would

3   get all pieces of the measure reported back to

4   them. They would have patients with a single-

5   pool Kt/V greater than or equal to 1.2,

6   patients who have Kt/V less than 1.2 with a

7   documented plan of care, and have patients

8   with a single-pool Kt/V less than 1.2 who

9   don't have a documented plan of care, which

10   would be your measure failure.

11   CO-CHAIR HOMER: Could you explain

12   Kt? I mean it has been a long time since I

13   did dialysis or nephrology. Just in laymen's

14   terms, what Kt/V is?

15   MS. FEI: It is urea kinetic

16   modeling. As I briefly alluded to before, it

17   is really the movement of urea and how long

18   you are clearing it from the body over the

19   course of the dialysis procedure. We use that

20   as a measure of adequacy, with the idea that

21   if we are moving urea, we are moving any

22   pools, you know, through the process of

 1   dialysis, and then if we are dilating someone

 2   well, the movement of urea going through

 3   results in a higher urea kinetic modeling. It

 4   is going to result in a higher Kt/V than if we

 5   do not.

 6   So, higher would mean more

 7   dialysis, either longer dialysis, a different

 8   cartridge, higher blood flow, but it would

 9   indicate with the Kt/V, the higher the number,

10   the more dialysis a patient is receiving by

11   measuring the way urea moves.

12   CO-CHAIR HOMER: Kathy?

13   MEMBER JENKINS: So, can you help

14   us understand why a patient would not have an

15   adequate Kt/V and why the measure wouldn't

16   just be having an adequate Kt/V as opposed to

17   if you didn't have the plan?

18   DR. FIVUSH: I think I don't feel

19   that it would be simple to just dial up the

20   dialysis or to make everybody have a Kt/V

21   greater than 1.2. It is hard for me to speak

22   to specifically why people wouldn't try to do

1   that, and my assumption is they would.

2   But there are patient

3   characteristics and catheter characteristics

4   that lead to the inability to dilate the

5   patient adequately. For example, in a

6   pediatrics population, one of the things we do

7   think is a problem is that most of our

8   patients we chronically dilate have external

9   catheters as opposed to internal fistulas or

10   grafts, and so they have a higher risk of

11   infection, will try to move in that direction.

12   But if you have a catheter, they

13   may not get the best blood flow. There may be

14   recirculation of blood within that catheter,

15   and you may not be able to adequately dialyze

16   this patient. So, there are some factors, and

17   then there are some patient factors about

18   their ability to tolerate how we dialyze them.

19   If we are dialyzing them three times a week

20   and trying low fluid, we may be unsuccessful;

21   they may get hypotensive during the procedure.

22   We may not be able to do what we would like to

1   prescribe.

2   So, maybe that patient would have

3   a Kt/V on a single session of less than 1.2,

4   but the nephrologist would be bringing them in

5   for a fourth treatment a week. And another

6   plan of care might be to change the access in

7   the patient. Another care plan might be to

8   try to change blood flow by changing the way

9   you actually expose the patient to sodium.

10   So, although it sounds that it

11 would be easy, in this many patients we can't

12 always get the blood flow rates we want. We

13 have recirculation. We have patients'

14 vulnerability. They can't tolerate how long

15 we want to dialyze them for.

16   So, sometimes, to get to that 1.2,

17 we have to be creative. We have to put

18 thought into, and we may have to change an

19 access. We may have to work with the family

20 and our surgeons to move towards a better

21 access. We may have to do dialysis more often

22 or differently.

1   And it actually is allowed in our

2   care plan to say, well, you know, we are going

3   to change this. We are going to change the

4   rate of flow. We are going to consider more

5   frequent dialysis. We are going to change to

6   a different dialysis. We are going to change

7   our modality.

8   It just gives us the ability to

9   address the fact that, although it sounds very

10   easy -- I would just use the example of when

11   we talk about target hemoglobins, and we say

12   they should be 10 in our patients, that we can

13   give them a lot of erythropoietin-simulating

14   agents. And many times, we can't reach that

15   10 anyway.

16   So, there are just patient

17   variables that prevent that from always

18   getting to be adequate, to what we think is

19   needed. The care plan will let us look to

20   make sure that physicians are addressing the

21   adequate Kt/V.

22   MEMBER RAO: I just wanted to echo

1   what Kathy's concern is. I think with only

2   800 children going through hemodialysis, I am

3   concerned that the numerator, the number of

4   patients who don't have a documented plan, is

5   going to be very, very small.

6   What constitutes a documented

7   plan? It sounds like it would be complete

8   lack of recognition that the Kt/V was less

9   than 1.2. I mean, if somebody wrote down,

10   well, increase frequency of dialysis, would

11   that be adequate?

12   If the standard of 1.2 is so well

13   accepted, it is hard to imagine too many

14   physicians not documenting something to that

15   effect.

16   DR. FIVUSH: I think until we look

17   at this -- I mean we have looked at Kt/V

18   through the KTM dataset. We have been

19   fortunate that the government -- because

20   overall the pediatric part of the this is not

21   in Medicare; the adult part is. So, we have

22   had scrutiny for a long time in data

1 collection, for a long time, and we know there

2 is a gap in care, you know, in terms of Kt/V.

3 I am not sure we know why yet. This measure

4 will allow us to better understand practice

5 around it.

6   MEMBER RAO: Right, and I

7 understand there is a gap in Kt/V. It is the

8 documentation of plans that I am not sure

9 there would be such a big gap for.

10   MEMBER DOCHERTY: I was wondering

11 what the evidence was of the relationship

12 between documented plan of care and better

13 outcomes for these patients.

14   DR. FIVUSH: Well, you know, as I

15 said, in the United States we have a very,

16 very high mortality rate in the first six

17 months of patients placed on hemodialysis. It

18 is about 22 percent. It is very high, and it

19 is high in pediatrics as well, and going up,

20 but probably not that high.

21   We have never really been able to

22 capture the data looking at individual

 1   physician practice patterns. We have looked

 2   at it in the CPM. It has been looked at more

 3   as -- it is not being broken down regionally

 4   because the cells are too small. But I think

 5   it is important, you know, to really improve

 6   care, to start looking at this as a physician

 7   measure to see if there are practice patterns

 8   that can change, because, clearly, there seems

 9   to be in the literature the suggestion -- we

10   know we are looking at intermediate outcomes

11   in our patients. I mean a payment of a

12   dialysis prescription is an intermediate

13   outcome; it is not a true outcome.

14   But there is in the data evidence

15   to suggest that needing the intermediate

16   outcomes results in fatality and

17   hospitalization. So, it is a complex, it will

18   be a complex analysis because there are other

19   intermediate outcomes that we have to do as

20   well.

21   You know, I mentioned hemoglobin

22   before, but there are nutritional outcomes.

1   There are a lot of intermediate outcomes we

2   have to meet, but this is one that we thought

3   we could target, start educating physicians.

4   That will be important for this measure and

5   its linkage to mortality, and additionally, to

6   start having them submit their care plans

7   because I think that is critical to start

8   thinking about how people are addressing it.

9   MEMBER DOCHERTY: I think that is

10   just the piece that I am having a hard time

11   understanding, not the physiologic outcome,

12   but that a documented plan of care will lead

13   to that physiologic outcome.

14   DR. FIVUSH: Sometimes I guess I

15   think if a physician, because we get licensed

16   in the State of Maryland, certified for a

17   dialysis unit on a yearly basis here, we have

18   to write care plans. Most states do not have

19   yearly licensing of dialysis facilities as we

20   do. So, they may not be licensed or certified

21   for seven to ten years.

22   But we write down a care plan for

1   every patient that doesn't meet standard

2   targets here. And actually, I have found it

3   has -- and we have looked at our numbers over

4   time -- it has driven quality improvement.

5   Because if you continue to report that you

6   have 2 percent of your Kt/V's less than 1.2,

7   or 5 percent, you have to justify each six

8   months what you are doing. It has really

9   started to -- not just dialing it up in

10   dialysis; it is really pushing our unit toward

11   start using in-dwelling lines, to move away

12   from external catheters, which is critically

13   important.

14   So, I think, looking at your

15   numbers and reporting them, and looking at

16   your inadequacy in dialysis, and documenting

17   what you are doing about it, is going to be

18   very important for driving improvement.

19   CO-CHAIR HOMER: Kathy?

20   MEMBER JENKINS: I am sure that

21   that is correct. I guess the question I still

22   have is, first of all, there's general issues

 1   about composite outcomes, but this is even

 2   more complicated because it is a composite

 3   outcome and a process outcome at the same

 4   time.

 5   So, just to state it in the

 6   extreme, if there was one site that met the

 7   outcome by having all the patients meet the

 8   physiological outcome, and another center who

 9   met the outcome by having none of the patients

10   meet the physiological outcome, but have all

11   of them have a documented plan, I do not

12   consider those two to be equivalent.

13   So, it almost feels to me like you

14   are trying to have all the sites like look

15   fine or be able to achieve 100 percent, and I

16   think it is the variation, and then, to your

17   point, you know, the steps they take to

18   achieve the 100 percent on the physiological

19   outcome which is actually the relevant

20   outcome.

21   And if there are intractable

22   patient factors that make it much harder to do

1   that, then that becomes a need for risk

2   adjustment for the outcome variable, as

3   opposed to adding in the process, at least the

4   way I am hearing this.

5   DR. FIVUSH: I think one of the

6   things that we can do, and we are moving

7   towards, when we have those types of patients,

8   it is to move to more frequent dialysis, which

9   is a move across the country. And again, I

10   think we will, you're right, the way they

11   state it clearly suggests that those outcomes

12   would be equal, but I think those outcomes are

13   not equal, and I agree they are not equal.

14   But the way they will be reporting back to the

15   physicians will include which of their

16   patients had what adequacies and how many were

17   over 1.2, but how many weren't over 1.2 and

18   had a care plan.

19   I think, clearly, having a care

20   plan and not having an adequate dialysis means

21   that that is something that needs to change

22   over time. You have to figure out a way to

1   have adequate dialysis. You can't just report

2   that you are trying. So, I think it is going

3   to be very valuable because it is reported

4   back to people, because they are going to see

5   those numbers and that detail.

6   If we just left it at greater than

7   1.2, I think as just an outcomes measure, I

8   think we wouldn't be giving an opportunity for

9   the kind of improvement we are hoping to see.

10   Because in many patients it is going to be

11   difficult to get to 1.2 because of the factors

12   we have discussed.

13   I think, again, when we started

14   the conversation, if it were easy to achieve

15   a 1.2 in everybody, I don't think we would

16   have a gap of 12 percent. So, I would agree

17   with your point that it is very important, but

18   it clearly is not the same to have 10 patients

19   who have met your Kt/V of 1.2 and another unit

20   has 10 patients who have not met any adequacy

21   measures but have a plan. Those would be very

22   different outcomes.

 1   CO-CHAIR HOMER: Helen?

 2   DR. BURSTIN: This is Helen

 3   Burstin. I just want to weigh-in.

 4   Having lived through the first

 5   round of ESRD measures in 2007, this is

 6   essentially -- just correct me if I am wrong

 7   -- the same measure with a different level.

 8   It was 1.7 for adults; it is 1.2 here. Yes?

 9   MS. FEI: It is the past

10   hemodialysis measure that is 1.7. The adult

11   hemodialysis measure is also 1.2.

12   DR. FIVUSH: Right. So, we are

13   really aligned with that adult measure.

14   MS. FEI: And with this measure,

15   you can have a rate report out of patients

16   between 1.2 and 1.7. That is done through the

17   administrative coding for the adult measure as

18   well.

19   DR. BURSTIN: All right. I guess

20   my question was trying to understand, is there

21   any reason you couldn't potentially take the

22   initial measure that is already endorsed and

 1   just extend the age down to children?

 2   MS. FEI: Actually, we did talk

 3   about that. However, the plan-of-care

 4   definition for the pediatric measure is just

 5   a little bit different than --

 6   DR. BURSTIN: You could stratify

 7   the measure and have that information in

 8   there. It just doesn't necessarily seem like,

 9   you know, if it is really very, very similar,

10   do we really need another measure in this

11   case?

12   My second point was just that,

13   when we went through this the first time, we

14   had a lot of discussion about this exact issue

15   that you are grappling with today of adequacy

16   of dialysis and plan of care. One of the

17   requirements that came out of that process was

18   that the expectation was the measure would

19   reported with two rates, so that you would be

20   able to see the adequacy of dialysis and,

21   then, you would be able to see, if not

22   adequacy of dialysis, is there a plan of care?

1   I just want to be sure that that

2   -- I mean, certainly, we would hope to be

3   internally consistent as best as we can at

4   NQF. So, that would certainly be the

5   expectation for this one as well. I just want

6   to make sure that that's your understanding as

7   well.

8   MS. FEI: Yes, and that is how we

9   have it set up.

10   CO-CHAIR HOMER: Okay. So, it

11   really is, in essence, two measures under one,

12   or at least reported as two linked, paired

13   measures in some sense.

14   And again, is there an assessment

15   of the adequacy of the plan or it is simply

16   they have a plan? Now how does that work?

17   DR. FIVUSH: I think we put down

18   in our description there are various plans

19   that we would consider acceptable, and we

20   listed examples of plans that we would say

21   were acceptable plans.

22   I think the level at this point

 1   would reveal that there was a plan. This is

 2   a little different than the adult language in

 3   what is an acceptable plan.

 4   CO-CHAIR HOMER: I am trying to be

 5   a little consistent with some of our earlier

 6   conversations when we gave another group a

 7   very hard time about the categorization of

 8   preventability or not, and things like that.

 9   So, is the idea here that all the

10   plans would come to a single place? It would

11   make a judgment based on criteria as to

12   whether a plan is adequate or not? And again,

13   I may have missed it in the specifications.

14   So, how will you be judging the adequacy of

15   the plan?

16   MS. FEI: I don't think through

17   the use of the measure we would be able to

18   just have the adequacy of the plan.

19   CO-CHAIR HOMER: Okay.

20   MS. FEI: It would be that there

21   is a plan of care in place.

22   CO-CHAIR HOMER: Okay. So, any --

1   MS. FEI: In the definition, we

2   have a definition of what the documented plan

3   of care may include.

4   CO-CHAIR HOMER: It may include

5   any of those things, and if it doesn't include

6   any of those things, but says, you know, I

7   don't know, "I will see them back more

8   frequently" or "I will call the mother to make

9   sure he is doing okay," or something like

10   that, or less frequently? I mean, you know,

11   in asthma we talk about the importance of a

12   written care plan. So, maybe that is kind of

13   similar to what we are talking about here.

14   But, to be honest, there is also at least a

15   little bit of evidence in that case that --

16   MEMBER DOCHERTY: So, is it just a

17   dichotomous variable? Either it is there or

18   not?

19   Then, along with that, I was just

20   wondering about your Kappa statistic. Then,

21   it looked like it ranged from 42 percent all

22   the way to 93 percent. I guess it appears,

 1   then, that there might be some differences in

 2   definition of whether there is an adequate

 3   plan of care.

 4   MS. FEI: There is a lot of static

 5   on the line. So, I am not sure --

 6   CO-CHAIR HOMER: The question

 7   really was what the reliability of the

 8   assessment -- there was a Kappa statistic that

 9   was presented that has a pretty low bottom

10   number of .4, you said, a pretty wide range,

11   and didn't know --

12   MS. FEI: Right, and the Kappa is

13   from the testing of the adult measure.

14   CO-CHAIR HOMER: Okay.

15   MS. FEI: And really, through that

16   experience, what they found was that at

17   different sites the manner in which the plan

18   of care was documented was different, found at

19   different places or not present at all. Or it

20   was either in the physician's office or at the

21   dialysis facility, depending upon where the

22   physician was seeing the patient.

1   CO-CHAIR HOMER: So, Ellen, you

2   had a question?

3   MEMBER SCHWALENSTOCKER: Yes. It

4   just relates to the plan-of-care

5   specification. I am drawing a parallel, as

6   you did, Charlie, to the children's asthma

7   care measures, which actually has components

8   of what should be in the plan of care.

9   That has problems of its own, but

10   I am wondering if you have looked at that, and

11   if it would be possible to get a little bit

12   more specific around what must be in the plan

13   of care in order for it to be adequate.

14   DR. FIVUSH: There's a difference

15   between what a documented plan of care may

16   include and what a documented plan of care

17   should include.

18   I think, looking at our plan of

19   care, I mean our measure, I know that the

20   reason we didn't say "should" is because, for

21   example, one of the things that could be in a

22   documented plan of care would be increasing

1   the blood flow or increasing the dial at the

2   site. That is not possible for some patients.

3   They may not tolerate that. So, if we say

4   "should" -- we can't say "should" because the

5   same "should", if the patient is big enough,

6   it should, but we can't say that in a patient

7   who is hyposensitive because that would make

8   the patient sick.

9   That is one of the problems we had

10   in creating the measure. You know, certainly

11   we should say it should include documenting

12   revisional renal function because that is

13   easy. But many of the things we can't say

14   that is the way to fix it. We can't say, for

15   example, changing the access because it is

16   possible that that patient isn't a surgical

17   candidate for better access.

18   So, I think there are things that

19   should be in a plan of care, but I don't think

20   we could standardly say they must have this in

21   a plan of care because it wouldn't allow for

22   any patient variability. Do you know what I

1   mean? The patient per se couldn't have a

2   better access because they had sort of used

3   all their blood vessels. The patient couldn't

4   tolerate a higher blood flow. Those are

5   really very real scenarios.

6   MEMBER RAO: Once again, in the

7   interest of simplicity, and I know you have

8   addressed this, if you just switched to a

9   simple Kt/V measure up and down, is there any

10   reason to think that some of those other

11   factors, children with poor access, are

12   distributed any differently across the country

13   among those 800 patients? I mean you are

14   going to get those people everywhere. So, as

15   a quality measure, wouldn't it be simpler just

16   to switch to the 1.2?

17   MS. FEI: The other thing that we

18   don't know precisely is this is a pediatric

19   measure we talked about, but we are not sure

20   how many pediatric patients are dialyzed as

21   adult. We know that we can tell something

22   about provider types, but in a study that we

1   did several years ago trying to figure out how

2   pediatric patients were dialyzed and where, we

3   think that at least one-third of children

4   under the age of 17 were dialyzed chronically

5   or dialyzed by an internal medicine

6   nephrologist.

7   So, we are not sure, as we go

8   forward, if practices are different

9   regionally, if they are different, say, in

10   provider type, if they are different based on

11   care as in a pediatric unit versus an adult

12   unit. I think we will find out some of that

13   information when we start looking at a

14   physician-level measure that we don't have

15   right now.

16   CO-CHAIR HOMER: Kathy?

17   MEMBER JENKINS: Can I just ask if

18   most of the issues of essentially patient

19   factors that make it impossible to achieve the

20   goal, is that only in the little babies? I

21   mean, is there a way that you could perhaps

22   not go down all the way to zero here and get

1   rid of some of the challenges? Or else, I

2   guess alternatively, create an age

3   stratification or a risk adjustment by age or

4   size?

5   DR. FIVUSH: Well, you know, one

6   of the things about this, we just haven't got

7   the simplicity. It is not a large population.

8   When you try to take out or look at the small

9   children, you end up going into more and more

10 subgroups and losing your ability to look at

11 children, although, clearly, the babies, the

12 infants, they are different than the

13 adolescents.

14   But I think that even knowing that

15 it is harder in an infant, it is probably more

16 important for the younger children to have the

17 dialysis, if we were to say, where is it more

18 important, because of issues in growth and

19 development.

20   So, I really don't want to take

21 out the infants, even though there aren't

22 many, and say, okay, we're not going to look

 1 at how you dialyze babies. Because if people

 2 are doing dialysis in young children, they

 3 need to be very aware of their adequacy.

 4   I agree it is hard. As in all

 5 pediatrics, we are dealing with different

 6 patient issues as children grow. And

 7 certainly, there is an impact on growth in

 8 terms of if we can use blood flows. But I

 9 still think we need to look at the young

10 children because they probably are the most

11 vulnerable patients.

12   CO-CHAIR HOMER: The last comment

13 and then I think we could probably move

14 towards voting. Faye?

15   MEMBER GARY: I just wanted,

16 before I vote, to clarify that there will be

17 some determination about where the care takes

18 place, and thinking about university centers

19 and where they are all, let's say, intensive

20 research-oriented university center versus,

21 let's say, private facilities that might be in

22 rural areas, for an example.

 1   DR. FIVUSH: I think, certainly,

 2   because this is a physician measure, I will be

 3   able to find out who is providing care for

 4   these patients. I don't know that we will be

 5   able to tease it out at this level yet.

 6   Kerri, you can help be with that.

 7   This will probably also go in, we

 8   are hoping, as the facility-level measure, as

 9   part of the clinical performance measures, but

10   they don't have physician-level measures

11   throughout. So, hopefully, if we can get

12   these measures in place, we will be able to

13   address that very important question: who is

14   the primary provider? Is it an internal

15   medicine, a pediatrician? That may really

16   have no difference; we don't know.

17   And where is that care being

18   provided? In a hospital unit? In a

19   freestanding pediatric unit? In an adult unit

20   that takes care of children? In a private

21   practice facility? I think those are very

22   important questions.

1   CO-CHAIR HOMER: All right. So, I

2   would suggest -- this has been very helpful --

3   that we move towards voting on the measure.

4   MEMBER LIEBERTHAL: Have we

5   decided whether this is, indeed, an outcome

6   measure or a process measure?

7   CO-CHAIR HOMER: I think my sense

8   is it is a combination, that the Kt/V is an

9   outcome measure, but it is a paired measure,

10   both outcome and process.

11   MEMBER LIEBERTHAL: So, it meets

12   our scope?

13   CO-CHAIR HOMER: I think it would

14   fit within our outcomes scope.

15   DR. BURSTIN: We have basically

16   been saying any composite measure that

17   included outcomes was in. So, I assume a

18   paired measure that included an outcome would

19   be within scope, too.

20   CO-CHAIR HOMER: Okay. So, voting

21   on the importance of the measure. Remind me

22   the criteria for importance? Okay. So,

1   clearly, in terms of relation to outcome, it

2   seems strong. For the Kt/V, it is challenging

3   because we've got one where I think we have a

4   lot of confidence in the relationship between

5   the intermediate and long-term outcomes.

6   But, okay, without more

7   editorializing, let's vote.

8   All those who believe it meets the

9   importance criteria?

10   DR. WINKLER: Eleven, 12.

11   CO-CHAIR HOMER: Okay. Those who

12   believe it does not meet the importance

13   criteria?

14   Two? Okay, good.

15   The next one is the scientific

16   acceptability of the measure. How many would

17   believe that it completely meets the criteria

18   for scientific acceptability?

19   How many feel it partially meets

20   the criteria for scientific acceptability?

21   DR. WINKLER: One, two, three,

22   four, five.

 1   CO-CHAIR HOMER: How many believe

 2   it minimally meets the criteria?

 3   DR. WINKLER: One, two, three,

 4   four, five, six, seven, eight.

 5   CO-CHAIR HOMER: Has that got

 6   everybody?

 7   MEMBER PERSUAD: I'm a none.

 8   DR. WINKLER: No, I am missing

 9   one.

10   CO-CHAIR HOMER: Okay. Not at

11   all? All right.

12   The next one is the usability of

13   the measure. Does everyone remember the

14   criteria, the elements of usability?

15   So, again, understandable

16   harmonization and added value. From a

17   harmonization, just simply the point is there

18   is an adult measures that is almost precisely

19   the same. And understandable, I think we

20   should view this again as a paired measure.

21   That is, it is really reported as two

22   different components of the measure rather

1   than a single item.

2   So, how many believe that it

3   completely meets the criteria for usability?

4   None.

5   Believe it partially meets the

6   criteria for usability?

7   DR. WINKLER: Six.

8   CO-CHAIR HOMER: And minimally

9   meets the criteria for usability?

10   DR. WINKLER: One, two, three,

11   four, five.

12   CO-CHAIR HOMER: And then not at

13   all?

14   DR. WINKLER: One, two, three.

15   CO-CHAIR HOMER: Okay. All right.

16   And then, feasibility, which is, again, data

17   is a byproduct of care, electronic exclusions,

18   inaccuracies, and implementation.

19   How many believe it is completely

20   feasible?

21   One.

22   How many believe it is partially

 1   feasible?

 2   DR. WINKLER: One, two, three.

 3   CO-CHAIR HOMER: How many would

 4   say minimally feasible?

 5   DR. WINKLER: Nine.

 6   CO-CHAIR HOMER: Okay. And not at

 7   all?

 8   DR. WINKLER: One.

 9   CO-CHAIR HOMER: Okay. Good.

10   All right. Then, why don't we

11   move to an overall recommendation? I think

12   this would a time-limited, given that the

13   adult measure is time-limited, and with

14   conditions that would relate to -- what

15   conditions would we want to put on it? Do we

16   need to?

17   DR. WINKLER: I don't remember any

18   conditions.

19   CO-CHAIR HOMER: Well, do we want

20   conditions related to --

21   MEMBER JENKINS: The two

22   conditions I heard, one had to do with age

 1   stratification and one had to do with

 2   specification of the elements of the plan in

 3   more detail.

 4   CO-CHAIR HOMER: Again, this is

 5   where, just as a comment, it is not that we

 6   would be dictating what the plan is, but that

 7   it needed to address those elements.

 8   MEMBER RAO: And I thought age

 9   stratification wasn't possible because of the

10   small number. That is what she said.

11   CO-CHAIR HOMER: We want to see

12   the data reported, I would suggest we would

13   like to at least potentially look at that. It

14   may be impossible.

15   MEMBER JENKINS: What I heard her

16   say -- maybe she could say what she said

17   instead of what I heard -- is she did not want

18   to exclude the babies, but that is different

19   than reporting the results by age

20   stratification or risk adjustment by age of

21   baby.

22   DR. FIVUSH: Yes, and I'm the

1   "she".

2   (Laughter.)

3   I'm sorry, it is Barbara Fivush.

4   I think that is a very good

5   summary. Yes, I didn't want to exclude them

6   because I didn't want to lose the importance

7   of them, but was concerned about the numbers.

8   We could report it out that way and see how it

9   looks.

10   CO-CHAIR HOMER: Okay.

11   MEMBER FISHER: Can I ask --

12   CO-CHAIR HOMER: Yes, please.

13   MEMBER FISHER: There is no way

14   for us to do what was suggested, is extend the

15   age group under the adult endorsement?

16   DR. BURSTIN: It sounded like they

17   said the plan of care was different.

18   MEMBER FISHER: Oh.

19   DR. FIVUSH: The plan of care was

20   different, and the other thing is we really

21   have specified in our measure, our

22   numerator -- and please tell me -- I know I

1   have already had opportunity to speak, and I

2   know you all have been working hard.

3   I just will quickly say the other

4   difference is we want this to be a single-pool

5   Kt/V, which means it is precisely measured at

6   a certain time after the dialysis session, as

7   opposed to the adults who are less concerned

8   about when they measure that Kt/V. That has

9   to do with body size in pediatric patients and

10   the way things may rebound.

11   So, those were the two things that

12   came up about harmonization. I think the

13   measures are very close, though. It is

14   possible that over time, if we get time-

15   limited data on this, we could really think

16   about harmonization. So, I don't want to say

17   that is not close with the issue of

18   harmonization when it came up earlier, but

19   harmonization can be very valuable, if we can

20   do that.

21   CO-CHAIR HOMER: And my

22   understanding, so I am just thinking of

1   advantages or disadvantages to having this an

2   extension in age group. Dialysis is covered

3   through Medicare on the CMS side. So, one

4   reason we sometimes would like to be under the

5   common element would be because we want CMS to

6   use this. But in this case, we know CMS is

7   paying increasing attention to the Medicaid,

8   and this would be consistent with their

9   longstanding emphasis on Medicare quality.

10 So, by having it a separate measure does not

11 decrease the likelihood that CMS would use

12 this.

13   DR. FIVUSH: And I would just

14 point out that these patients are Medicare-

15 eligible, but one of our problems is that

16 often their parents may have other insurers.

17 So, they are not necessarily covered by

18 Medicare, even though they could be covered by

19 Medicare. That really ends up making it

20 difficult for us to just enter a Medicare

21 database and see claims and reporting. That

22 is why this is a great opportunity for an

1   additional reporting system that we can

2   perhaps see this information, with Medicare

3   supporting the concept.

4   CO-CHAIR HOMER: Okay. So, again,

5   I think the vote is for a time-limited

6   endorsement with the conditions that Kathy so

7   well articulated.

8   So, all those in favor of a time-

9   limited endorsement with the conditions that

10   were mentioned?

11   DR. WINKLER: Six.

12   CO-CHAIR HOMER: Okay. All those

13   opposed to a conditional endorsement?

14   DR. WINKLER: Eight.

15   CO-CHAIR HOMER: Okay. I think

16   the measure did not pass muster.

17   Anyone want to reconsider their

18   votes?

19   (Laughter.)

20   No, that's fine. No. So, okay,

21   the measure didn't go through as is.

22   I do want to thank the stewards

1   for presenting the measure, and I do look

2   forward to -- well, I would encourage you,

3   nonetheless, to continue to collect these

4   kinds of data and bring it back.

5   DR. BURSTIN: Great. I just want

6   to point out as well that we are planning a

7   ESRD/CKD project starting in the late summer

8   or early fall. So, if any of this input makes

9   you want to think about a new submission, that

10   would be a good time.

11   CO-CHAIR HOMER: Right.

12   DR. BURSTIN: With a committee

13   filled with nephrologists who understand all

14   this Kt/V stuff.

15   CO-CHAIR HOMER: I would love,

16   also, to see an ongoing learning collaborative

17   amongst these institutions that share these

18   patients. Then, we could actually see whether

19   you could refine further the issue of this

20   plan. But that would be outside the scope of

21   the current --

22   DR. FIVUSH: I want to thank you

1   for giving us the opportunity to present.

2   It is a moving target. I think we

3   are all trying to improve care, and we will

4   just keep these measures. Thank you.

5   CO-CHAIR HOMER: Thank you.

6   MS. McELVEEN: Okay. We are going

7   to go ahead and take a very brief break for

8   lunch. If you could take maybe 10 to 15

9   minutes and get your food and come back, and

10   we will have to reconvene.

11   We are adjourning around three

12   o'clock, and we have about six more measures

13   to go through.

14   (Whereupon, the foregoing matter

15   went off the record at 12:37 p.m. for lunch

16   and resumed at 1:02 p.m.)

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 1            A-F-T-E-R-N-O-O-N   S-E-S-S-I-O-N

 2     1:02 p.m.

 3                 CO-CHAIR HOMER:  While Marina is

 4     getting a little bit of food, I think we could

 5     probably get started.

 6                 I would like to ask, the measure

 7     that we are going to be addressing next is the

 8     validated family-centered survey questionnaire

 9     for parents' and patients' experiences during

10     inpatient hospital stay, if I got that

11     correct.

12                 Nancy, are you okay?

13                 She is still sitting upright,

14     seems to be breathing.  I just wanted to make

15     sure you are okay.

16                 MEMBER KIBORT:  That is what I was

17     asking about.

18                 MEMBER FISHER:  I got this

19     horrible virus.  I have had all my flu shots.

20     Okay?  Then, after it -- I hadn't had this

21     happen to me since I was in medical school --

22     I got bronchitis with an asthmatic component.
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1   Okay? Or some people say you have reactive

2   airway disease.

3   (Laughter.)

4   And then, I am getting better, and

5   something went down the wrong way, and then I

6   kept coughing.

7   CO-CHAIR HOMER: It triggered the

8   reactivity.

9   MEMBER FISHER: Yes.

10   CO-CHAIR HOMER: So, I wonder if I

11   could ask the stewards from Children's to tell

12   us about this measure, Boston Children's.

13   That would be wonderful, the developer. That

14   would be great. Not the steward, the

15   developer, yes.

16   DR. ZINIEL: Okay. Does that

17   work? I think so.

18   So, I am just going to give you a

19   brief overview over the measure. We have high

20   goals with this measure. We really hope that

21   this survey becomes, so to speak, the

22   pediatric H-CAHPS.

1   In the work I have done at

2 Children's Hospital, also in collaboration

3 with CHCA, I have seen the great heterogeneity

4 in patient experience or patient satisfaction

5 surveys, however you would like to call it.

6 And I have also seen the quality of these

7 surveys with regard to survey methodology

8 principle. I was quite appalled as the survey

9 methodology, what I have seen.

10   So, we basically did this project

11 to really get a set of survey items that could

12 be used like H-CAHPS as benchmarking across

13 institutions, across departments, within the

14 institution, for several dimensions of the

15 care of patients.

16   Due to the third-party involved in

17 pediatric settings, it is not really possible

18 to just rephrase the H-CAHPS questionnaire.

19 There are certain aspects that have to be

20 taken into account. So, we have several

21 dimensions that this instrument that we

22 propose addresses.

 1   There are experiences that parents

 2   report with regard to nurses, doctors,

 3   admissions, discharge, care coordination,

 4   medications, and there are, of course, a set

 5   of demographic items in order to be able to

 6   look at differences between ethnicity, et

 7   cetera.

 8   For all items, reliability and

 9   validity data are available. So, we have

10   test/retest reliability. We have predictive

11   validity. We have validity for items within

12   a certain domain. We have calculated Cronbach

13   alpha to make sure that there are no redundant

14   items in there to minimize the respondent

15   burden.

16   We have validated, and I should

17   say that these are items are a subset of a

18   120-item questionnaire that we selected due to

19   their good performance with regard to missing

20   data, validity, ceiling effects, and

21   reliability.

22   The survey is validated for mail

1   and phone. We have also mode effects

2   calculated. The reason why we were able to do

3   that was because we had a very strict protocol

4   when we started with this project. So,

5   patients that were recruited were randomly

6   assigned to either mail or phone mode. So, on

7   average, we would really expect that the

8   differences we observe are due to the mode and

9   not to any other aspects of their care.

10   We also have really rich frame

11   information. We have kept data, processed

12   data, in order to be able to look at non-

13   response bias. We have medical record data,

14   so that we can stratify for different

15   categories in complexity of care.

16   So, we can relate it to clinical

17   outcomes. And what we are doing right now is

18   that we are proposing within the framework of

19   CHCA to field the survey at other institutions

20   in order to use their data to get the survey

21   down to about 30 questions.

22   We wanted to do this with other

 1   institutions to make sure that the questions

 2   that we select are really the ones that allow

 3   good validity and reliability across national

 4   institutions, and not just one hospital. So,

 5   we basically used our hospital to get to the

 6   62 items that really perform good in terms of

 7   psychometric properties, and now going to go

 8   and use other hospitals as well to sort of get

 9   the survey shorter.

10   We also plan to have the survey in

11   other languages as well as an adolescent

12   version.

13   So, the sampling approach that we

14   proposed was a random sample of all patients

15   that were discharged within a certain time

16   period. It is, obviously, possible to

17   stratify for race and ethnicity.

18   We found, looking at the non-

19   response across the different modes, that it

20   is actually important to use a mixed-mode

21   approach for patient experience because

22   Hispanics and other minorities were

 1   significantly more likely to answer the phone

 2   survey than the mail survey.

 3   So, I think we have enough data to

 4   look at outcomes across race/ethnicity, if

 5   this was the first hospital stay for that

 6   child, if it was not the first hospital stay,

 7   if it was medical/surgical, how complex the

 8   procedure was.

 9   So, based on the data in the

10   survey as well as frame data, we can evaluate

11   how the experiences of parents and patients

12   differ across these dimensions.

13   CO-CHAIR HOMER: Can you describe

14   the domains it mentions and the measures that

15   derive from the survey?

16   DR. ZINIEL: So, we have not

17   derived composite measures per se for the

18   domains. Also, it is possible. So, the

19   domains are experiences with nurses,

20   experiences with doctors, experiences with

21   regard to how they work together, if the

22   parent felt that there was communication.

1   We asked about the admission

2   process, about the discharge process, the care

3   coordination after the discharge, medications

4   during the hospital stay, as well as

5   medications that were provided when the child

6   or prescribed when the child was going home.

7   Then, we have about 12 items that are

8   demographic of nature.

9   CO-CHAIR HOMER: Again, so there

10 are composites that are calculated? It is

11 done as an item-by-item reporting?

12   DR. ZINIEL: It is an item-by-

13 item, but it is completely possible to

14 calculate composite scores.

15   CO-CHAIR HOMER: Okay.

16   DR. ZINIEL: Because the scales

17 are fairly similar. And there is, of course,

18 I forgot to say, an overall rating. There is

19 a section with a few overall ratings.

20   So, composite scores would be

21 added, summative scores. The scales are

22 usually from 1 to 5.

1   CO-CHAIR HOMER: And could you

2   compare and contrast with the H-CAHPS, I mean

3   realizing that H-CAHPS you would have to

4   either alter the questions, so it would be

5   your child rather than you, and things like

6   that, but as you look at the structure of this

7   compared to the H-CAHPS survey?

8   DR. ZINIEL: There are domains

9   that are the same where questions are very

10   similar. There are also domains that we

11   realized are more significant for the care.

12   So, for example, parents, with regard to how

13   they rate their experiences at the hospital,

14   are really, really -- or they feel it is very

15   important with regard to the communication.

16   So, the items that we have are

17   more in number or higher in number than with

18   regard to H-CAHPS just by the fact how

19   predictive they were with regard to how the

20   parent rates their experience in the hospital.

21   CO-CHAIR HOMER: I'm sorry. So,

22   there are more items because there was a more

1   diverse number of issues?

2   DR. ZINIEL: Right. There are

3   aspects, I think, in a pediatric setting that

4   are important to consider with regard to the

5   overall satisfaction. They were highly

6   predictive of overall satisfaction, but the

7   correlation among them was fairly low. So

8   that we can assume that they measure different

9   dimensions.

10   CO-CHAIR HOMER: Lee?

11   MEMBER PARTRIDGE: Could you just

12   tell us a little bit more about the domain?

13   You talked about care coordination after

14   discharge. Is that care coordination between

15   whom?

16   DR. ZINIEL: So, we have items in

17   there that ask if they have seen their primary

18   care physician right after they went home. I

19   mean that's, I think, one of the -- we also

20   ask about if they felt comfortable to go home

21   with regard to the information they had,

22   things like that.

1   MEMBER PARTRIDGE: In some of the

2   work that we have done, focus groups with

3   families across the country, the care

4   coordination element turns out to be very,

5   very important to them and a lot of the areas

6   in which they feel it doesn't work very well.

7   DR. ZINIEL: That's correct.

8   MEMBER PARTRIDGE: So, you are

9   going a little bit beyond the hospital here.

10   DR. ZINIEL: Right. So, the other

11   thing that one of the comments mention sort of

12   as a point was that we do not collect the data

13   sort of during the hospital stay. The reason

14   why we do not collect the data during the

15   hospital stay is that we also want their

16   experiences with regard to discharge and sort

17   of right after discharge. That is the reason

18   why we can't. I mean either we would then

19   have two surveys, but then it is really hard

20   to link them together and to get responses

21   from the parent in both. So, that is why we

22   are doing it after the child has left the

 1 hospital.

 2   CO-CHAIR HOMER: So, are there

 3 questions from the Work Group. We had started

 4 already, but other questions from the Work

 5 Group that reviewed this?

 6   DR. WINKLER: I just have one

 7 question. Do we have a copy of the survey

 8 tool?

 9   DR. ZINIEL: Yes. I submitted it.

10   CO-CHAIR HOMER: It was filed in

11 the wrong -- no, maybe it was. Where was it?

12   DR. ZINIEL: Yes, we submitted the

13 current survey tool when we submitted the

14 measure.

15   MEMBER PARTRIDGE: Can I ask one

16 more question?

17   DR. ZINIEL: Yes.

18   MEMBER PARTRIDGE: You are talking

19 about developing an adolescent tool.

20   DR. ZINIEL: Yes.

21   MEMBER PARTRIDGE: And this is an

22 issue that came up frequently for those of us

 1   who were on the stakeholder group way back

 2   when H-CAHPS was being developed because we

 3   were concerned particularly about the teenager

 4   who was hospitalized, most often for maternity

 5   care, but also for other reasons, you know,

 6   like they skied downhill into a tree.

 7   And we really wanted the

 8   adolescent patient assessment of care rather

 9   than the parents' assessment of care.

10   DR. ZINIEL: Yes.

11   MEMBER PARTRIDGE: And you don't

12   have that subset yet. So, you are putting

13   adolescents in here?

14   DR. ZINIEL: No. So, this survey

15   will be for parents 18 years and older of

16   their child. The reason why we did this is

17   because we really wanted to develop an extra

18   tool just for adolescents.

19   MEMBER PARTRIDGE: Right, but for

20   the interim, if my teenaged child is

21   discharged, you are going to ask me my opinion

22   of the experience and not that teenager?

 1   DR. ZINIEL: Oh, sorry, I

 2   misunderstood you. Yes. I mean we

 3   definitely could go down to maybe 15, 16

 4   years. I wouldn't go down to like, not that

 5   I know how this happens, like 13 years,

 6   because from a scientific point of view we

 7   don't know enough about the response formation

 8   process in adolescence, and there is a lot of

 9   research to be done.

10   CO-CHAIR HOMER: So, just for the

11   members of the Committee who maybe hadn't seen

12   the survey, it was misfiled. It is under Work

13   Group 1, Measure 27, and it is a PDF document.

14   So, if you happen to have your flash drive,

15   that is where the item is.

16   I am still, I guess, a little

17   maybe -- your writeup, I guess more the

18   scientific characteristics, the writeup says

19   you describe things like Cronbach alpha and

20   dimensions and things like that, but I am

21   still asking the question of dimensions

22   because, typically, with the CAHPS survey that

1   is typically what people report out. At least

2   it used to be in the old days when I used to

3   work with surveys.

4   DR. ZINIEL: I mean the dimensions

5   are basically the headings in the survey. So,

6   we have a report about 300 pages long that

7   describes all of the results.

8   I was a little unclear how to sort

9   of attach that, or I mean not attach that, but

10   to describe that in the application. So, I am

11   definitely happy to submit that one.

12   So, we have done factor analysis,

13   et cetera, of the items that we had where we

14   selected these 62 from. It is nursing,

15   doctors, medications, admission, discharge.

16   CO-CHAIR HOMER: So, I think we

17   would want to see that, yes.

18   MS. RAUSCHER: Just from a

19   perspective of this tool, the possibility of

20   reporting out by composite score was able to

21   just --

22   DR. ZINIEL: Yes.

 1   CO-CHAIR HOMER: Okay. Good.

 2   So, Ellen?

 3   MEMBER SCHWALENSTOCKER: I'm

 4 sorry, I'm going to share the microphone with

 5 you, even though I am sitting right next to

 6 you.

 7   I guess two questions. One, you

 8 mention the importance of having both modes.

 9 Have you found a difference in response in

10 mode influencing the response, whether it is

11 phone or mail?

12   DR. ZINIEL: So, there are some

13 differences with regard to distribution. So,

14 at Children's Hospital, Boston, we have the

15 problem that I think no national survey has,

16 that like everyone is always super-satisfied.

17 So you have like this ceiling effect, and it

18 is really hard to track something over time if

19 everyone is always satisfied.

20   So, we try to extend the scale in

21 a way, based on focus groups, and during the

22 survey what people actually reported, in order

1   to get sort of the differences.

2   In the telephone survey, which is

3   known from a scientific point of view, people

4   are more likely on average to rate it higher.

5   However, the items that had significant

6   differences, and I think there is only one

7   item left in the set of 62. So, the reason

8   why we started out with 120 was really to

9   figure out what are the items that have high

10   percentages of missing data, that have a great

11   ceiling effect, where tracking change is hard,

12   that have low test/retest reliability. And

13   that is exactly why we excluded them.

14   So, another factor was, if the

15   mode effect was very strong, we also

16   considered the item to be excluded in order to

17   minimize that exact problem.

18   MEMBER SCHWALENSTOCKER: Then, the

19   only other question I had is it sounded like,

20   I think you mentioned earlier, that you are

21   hoping to reduce the number of items in the

22   survey?

1   DR. ZINIEL: Yes. Yes.

2   MEMBER SCHWALENSTOCKER: So, kind

3   of what is the plan going forward, the

4   timeline for doing that?

5   DR. ZINIEL: So, we are right now

6   talking with CHCA about how to set all of this

7   up. We had talked with CHCA about a year ago,

8   and there are a number of hospitals that are

9   interested in fielding this survey to compare

10   it to the current survey that they have. So,

11   there is interest there.

12   I think the steps forward that

13   have to be figured out is from a

14   methodological point of view what I would

15   really like is I would also get data that is

16   at the same time collected using the current

17   tool from the hospital as well as the scores.

18   It would have to be randomly selected, what

19   patient gets what tool, or what parent gets

20   what tool. So, that we really can assess if

21   there are differences across hospital with

22   regard to the validity of items, how these

 1   items fall within a dimension.

 2   So, just really we didn't do that

 3   for the current version. Because of the

 4   importance to really look at several

 5   institutions and see if we want to use this

 6   nationally, then we really should use items

 7   that are applicable to all institutions and

 8   not just to the Children's Hospital, Boston.

 9   MEMBER SCHWALENSTOCKER: Right.

10   DR. ZINIEL: So, that is why we

11   felt, okay, we start out with 120. We get the

12   items out that perform badly from a

13   psychometric point of view and from a survey

14   methods point of view. Then, we basically go

15   national and say, okay, let's collect data;

16   let's collect data to compare it at the same

17   time. So that we can really make sure that

18   the ultimate tool with about 30 items, that

19   the measures that are in there are really the

20   ones that are applicable and good for every

21   institution, if I can say it like that.

22   MEMBER DOCHERTY: That was sort of

1   my question, but your factor analysis, you

2   have done more limited factor analysis? And

3   you are going to do more later?

4   DR. ZINIEL: Correct.

5   MEMBER DOCHERTY: Okay. That

6   makes sense.

7   DR. ZINIEL: Yes. I want to get

8   the data and figure out, you know, is there an

9   item that is really important? Or, based on

10   the current analysis, seems to be really

11   important for our situation, but that might

12   not be that important if I take other data

13   into account.

14   CO-CHAIR HOMER: Allan?

15   MEMBER LIEBERTHAL: You mentioned

16   the H-CAHPS before. Who is the owner of

17   H-CAHPS, and have you talked with them about

18   an H-CAHPS version that would be for children

19   and one for adolescents, so that non-

20   children's hospitals would be dealing with one

21   organization or one set of questionnaires?

22   DR. ZINIEL: So, the measurement

 1   owner or developer is AHRQ. We have not been

 2   in contact with them yet. The last thing that

 3   I have heard, based on their statement on

 4   their website, is that they are not currently

 5   working at a pediatric version.

 6   I am not quite sure if behind the

 7   curtain, so to speak, there is something going

 8   on.

 9   (Laughter.)

10   This survey will, nevertheless, be

11   able to be used in hospitals that just have

12   sort of a pediatric department and are not

13   freestanding.

14   So, the way we phrased the

15   question was that we really wanted to make

16   sure that it would be applicable for all

17   situations.

18   MEMBER LIEBERTHAL: Maybe the "not

19   created here" wouldn't apply and AHRQ might

20   welcome working with you.

21   CO-CHAIR HOMER: Bonnie?

22   MEMBER ZIMA: I probably have a

1   less interesting question than Marina.

2   (Laughter.)

3   But I was wondering in sort of

4   your preliminary analyses whether you explored

5   the impact of variable length of stay.

6   DR. ZINIEL: Yes. So, length of

7   stay, we explored length of stay,

8   medical/surgical, if this is the first time

9   they are at the hospital or not.

10   So, generally, I mean it depends

11   on the item, but overall I can say that people

12   where this not the first hospital stay are

13   overall less satisfied. The people who have

14   like a longer length of stay are less

15   satisfied. Minorities overall seem to be less

16   satisfied, and surgical, no, medical are less

17   satisfied as well.

18   MEMBER ZIMA: How did you think

19   about the impact of the severity of the

20   illness and the child's prognosis?

21   DR. ZINIEL: This is a really good

22   question. The problem with surveys in general

1   is that they are measuring something that

2   usually cannot be measured otherwise. So,

3   from a provider perspective, we would hope

4   that -- I mean they should be satisfied, no

5   matter how they go through the hospital, no

6   matter how long they stay, no matter how often

7   they have to come back. The service that we

8   provide should be satisfactory.

9   The other thing is it is always

10   based on expectations. So, parents that, for

11   example, have been in the hospital previously

12   have other expectations than parents that have

13   been there the first time.

14   So, there will always be a

15   subjective, based on just the experience that

16   you had, there will always be sort of an

17   influence of expectations. That is what

18   surveys basically measure.

19   It is really hard to sort of get

20   people to set to an expectation. They come in

21   with an expectation, and these expectations

22   vary, but I think from a hospital point of

1   view, no matter what these expectations are,

2   our goal is that parents have a good

3   experience.

4   MEMBER ZIMA: I just have one more

5   question. That was, with a response rate of

6   25-35 percent -- I know this is kind of

7   generic question.

8   DR. ZINIEL: That is actually a

9   comment.

10   MEMBER ZIMA: Oh, okay.

11   DR. ZINIEL: Yes, go ahead.

12   Sorry.

13   MEMBER ZIMA: How are you thinking

14   about the selection bias? How do you avoid

15   overrepresenting happy campers?

16   DR. ZINIEL: So, this is a common

17   phenomenon in satisfaction surveys. The

18   concerns are that happy campers and really,

19   really unhappy campers do not answer.

20   So, what we found is that, on

21   average, in this survey it equals out. So, it

22   doesn't really affect the score. We can say

1   that because we have frame data. So, if you

2   have frame data, you can actually adjust for

3   it. So, you can use non-response weighting,

4   which that is another part of this project, to

5   calculate non-response rate to see how that

6   affects, actually, the differences of the

7   scores.

8   You need a really good protocol to

9   make them participate. The unfortunate thing

10   is that the survey climate nowadays, I mean

11   everyone is completely oversurveyed. You

12   really have to write a letter that convinces

13   the participant or the parent to participate.

14   CO-CHAIR HOMER: Marina?

15   MEMBER ZIMA: Just one more issue,

16   and that is you only have your English

17   speakers, as you had said. So, I was

18   wondering if you could speak a little bit

19   more. Particularly something like this could

20   not be used in California.

21   DR. ZINIEL: And that is where,

22   basically, the plan is so we started out with

     1   the English version. We plan to develop this

     2   into other languages. I mean that is one

     3   goal, to be able to use it as a sort, if I can

     4   frame it like that, pediatric H-CAHPS tools.

     5   CO-CHAIR WEISS: Okay. We may not

     6   have caught some of the questions that are

     7   intended to get to this, but going back to

     8   Lee's point about care coordination, and

     9   particularly the handoff from the inpatient to

    10   the outpatient setting, this is a really

    11   sensitive area, and an area that gets a lot of

    12   attention from the consumer community. But I

    13   don't see, as Reva and I have been scrolling

    14   through your questions here, the questions

    15   appear to be more oriented toward parent

    16   satisfaction that they understood --

    17   DR. ZINIEL: Right.

    18   CO-CHAIR WEISS: -- something

    19   about medication, and so on, but not

    20   specifically toward the issue of did they get

    21   adequate instruction about what to do with the

    22   child once they left the hospital. How do

1   they hand off from the main, as you call them,

2   the main physician in the hospital to the

3   office-based practice? Is there a different

4   instrument that does that or do you just

5   presume that every child who leaves your

6   institution has a care plan, so that is not

7   even a question that should be asked?

8   DR. ZINIEL: No. So, if you are

9   sort of really interested in that domain, I

10   refer you to Jay Berry, who is actually

11   working on that right now.

12   (Laughter.)

13   So, I have the honor to work with

14   him on that as well with regard to the survey.

15   So, this is really an experience

16   survey. While I completely agree with you

17   that that might not be the case for every

18   child, what we are really trying to measure is

19   the satisfaction. If parents see that the

20   care, that there is something that they are

21   missing or it is difficult, and the left hand

22   doesn't know what the right is doing, they

1   will express that in dissatisfaction.

2   So, it is really to measure the

3   subjective view of the process. So, patients

4   can be really, really satisfied or parents can

5   be really satisfied, even though the medical

6   care itself might not have been optimal. But

7   it is hard for a parent to judge that because

8   the parent doesn't know the standards. So,

9   this is really to get at the subjective

10   opinions of the parents.

11   CO-CHAIR WEISS: Okay. I would

12   just say that, particularly with parents who

13   have children with chronic conditions, and who

14   are in and out of the hospital on a regular

15   basis, a part of satisfaction is going to be

16   feeling confident that they know what to do

17   once they leave the institution, who to call,

18   where to go.

19   MS. RAUSCHER: That is a very

20   important piece of the. This is more general.

21   As Dr. Ziniel said, Dr. Berry is working on

22   one for complex care.

 1   I just wanted to add another bit

 2   of a detail about how we got into this

 3   process, which was that we always intended to

 4   do this, but about two years ago one of our

 5   payers came to the table and said, "You will

 6   do H-CAHPS for a p-for-p contract," a huge

 7   piece of it. We said to them, "There is no

 8   pediatric H-CAHPS."

 9   So, that has been the impetus for

10   this, of trying to develop something that

11   could be used across the country, and would

12   carefully reflect the domains specific, not

13   just changing from you to your child, a lot of

14   rigor into that measurement process. That is

15   what we have been doing.

16   CO-CHAIR HOMER: Tom, did you

17   first have a question? And then, Ellen and

18   Faye.

19   MEMBER McINERNY: Yes. You know,

20   our hospital has been doing the Press-Ganey

21   surveys for years. Obviously, it crosses over

22   to the children that get care in our hospital,

 1   and I suspect other hospitals do that. I

 2   don't know whether you have taken a look at

 3   your survey versus the Press-Ganey survey. I

 4   suspect there may be some overlaps, and there

 5   may be a way of sort of trying to help form

 6   which of your questions are the ones that are

 7   most important, based on Press-Ganey as well.

 8   DR. ZINIEL: Yes. I mean that is

 9   one reason why we planned the multi-center.

10   So, we are not using Press-Ganey. It is

11   really hard to get data from hospitals, you

12   know, to basically say we would love to have

13   your data to be able to analyze it with regard

14   to patient satisfaction. That is one of sort

15   of the conditions I would like to put on this

16   sort of more national project, to say I really

17   would like to see the data that you currently

18   collect during the same timespan with your

19   instrument, to be able to see how they

20   actually correlate.

21   CO-CHAIR HOMER: Ellen, and then

22   Faye.

 1   MEMBER SCHWALENSTOCKER: Oops,

 2   sorry, I hope I didn't just turn someone's

 3   computer off.

 4   So, I just wanted to make the

 5   point, first, I really want to applaud you for

 6   this work because I think it is a huge gap

 7   that we don't have a pediatric H-CAHPS. I

 8   think the survey, Marina, to your question, in

 9   my view, it goes beyond satisfaction. It

10   includes parent reports on how well-prepared

11   they were. So, it may be perceptions of care,

12   but, in my view, it is more than satisfaction.

13   What I am struggling with a bit is

14   it sounds like it is still being developed.

15   I guess I need to understand a little bit from

16   the NQF staff perspective, you know, what the

17   implications of endorsing this are, given that

18   you are looking to maybe reduce the number of

19   items.

20   Then, kind of knowing a little bit

21   about the history of H-CAHPS and the vendor

22   involvement in that, I am struggling a bit

1   with, well, you know, nobody has stepped to do

2   that, although there are instruments out

3   there. I guess I am struggling with kind of

4   what the path forward in terms of process

5   needs to be, but I also feel like this is the

6   first opportunity we have had to really look

7   at a great step in the direction of developing

8   a survey.

9   CO-CHAIR HOMER: Helen, do you

10   want to respond to that? Then, we have Faye.

11   DR. BURSTIN: Sure. I will just

12   respond briefly.

13   I mean, certainly, the group would

14   have to decide if they feel like it is ready

15   for primetime. That is sort of the issue.

16   We do routinely get measures that

17   get updated. We have a three-year maintenance

18   policy. So, that if you made a significant

19   change to the survey, you would have to bring

20   it back to us for our re-review.

21   DR. ZINIEL: Yes, we know that.

22   DR. BURSTIN: So, that is fine.

 1   DR. BURSTIN: I mean I don't see

 2   that as a problem. My major question was

 3   actually more about harmonization, and I know

 4   you can't harmonize completely with a CAHPS

 5   tool.

 6   DR. ZINIEL: Right.

 7   DR. BURSTIN: And I give my bias

 8   here as an adult-only doc, but a whole lot of

 9   these items look really similar to H-CAHPS.

10   DR. ZINIEL: Yes.

11   DR. BURSTIN: I am imagining

12   myself in my old days that I used to run

13   quality measure for a hospital. If I had to

14   look at the H-CAHPS responses on some of

15   these, and then look at these, the response

16   categories aren't aligned. You have five;

17   they have gone to three.

18   I am just trying to think about

19   what a hospital who is not a freestanding

20   children's hospital would have to sort of

21   think through to make it work, if you had an

22   adult survey. I mean we used to try to parse

 1   it by adult surgery and OB. We didn't have

 2   kids at the Brigham.

 3   But how do you imagine this kind

 4   of working in the real world, I guess?

 5   DR. ZINIEL: So, the problem with

 6   the response category, where from a scientific

 7   point of view sort of what you would really

 8   like to measure is with a three-category

 9   scale, based on the ceilings effect that we

10   just observed in our hospital, there is no way

11   you would be able to really measure a change.

12   I mean, if 85 percent are in the

13   top category, how would you measure change?

14   So, I mean, this tool is basically really to

15   be able to measure change. Not that I was in

16   the AHRQ group and want to criticize their

17   work, but when I looked at H-CAHPS, I didn't

18   understand why they have three. I mean three

19   is really limited.

20   So, the problem that we have seen

21   in the focus groups is it is really hard to

22   get someone who is almost always satisfied to

 1   completely satisfied.

 2   DR. BURSTIN: I think some of this

 3   actually truly is the nature of adult care

 4   versus kids care. I mean I have seen H-CAHPS

 5   scores, and it is remarkable how much of a

 6   splay there is between those categories. It

 7   may just be that maybe kids truly -- Lisa

 8   Simpson always told me, "They're not just

 9   little adults." Maybe they are really

10   different.

11   (Laughter.)

12   And maybe those parents have very

13   different perspectives on their care. Your

14   kid is sick; everything is great.

15   DR. ZINIEL: Right. I mean that

16   is why we, for example, selected the five-

17   point scale because with a three-point scale,

18   I mean there would be no chance --

19   DR. BURSTIN: That is very

20   helpful. Right. Maybe just some of those

21   responses back formally, if we put this out --

22   DR. ZINIEL: I mean the other

 1   thing is what I just don't know is on a

 2   national level, when we give this instrument

 3   to other hospitals, what the range is that is

 4   there.

 5   With regard to what you report, I

 6   mean boards usually like to see the percentage

 7   where everyone is super-satisfied. From an

 8   improvement point of view, I want to see the

 9   percentage that has really problems because

10   that is where you actually can do something

11   about it.

12   DR. BURSTIN: I'm with you. What

13   I will tell you, though, is H-CAHPS actually

14   shows that, only because you would be amazed

15   at how poor this is when patients report on

16   their care.

17   DR. ZINIEL: Right.

18   DR. BURSTIN: It is not

19   satisfaction. There is only one satisfaction

20   item on CAHPS. It is really the very similar

21   patient reports of care. "Did somebody

22   explain your medications to you in a way you

1   can understand?" "Did somebody explain your

2   discharge instructions?"

3   DR. ZINIEL: Yes.

4   DR. BURSTIN: That

5   always/sometimes, those categories remarkably

6   show lots of dissatisfaction.

7   CO-CHAIR HOMER: Because it is the

8   percent always that -- and it is hard to

9   get --

10   DR. ZINIEL: I mean, you know,

11   based on the data that we have, I can tell

12   you, I mean we have items that have like 85

13   percent always, very satisfied, extremely. I

14   mean that's where we started developing the

15   survey. So, how do you measure something if

16   you have 85 percent?

17   DR. BURSTIN: I think you just

18   justified it, but I think those are probably

19   some of the explanations we would need when

20   this would go forward.

21   DR. ZINIEL: Okay.

22   DR. BURSTIN: Otherwise, people

1   will look at this, particularly people who

2   know CAHPS well, and --

3   MS. RAUSCHER: We also wanted to

4   just share that we did do an assessment of the

5   freestanding hospitals. One-third used

6   Picker, one-third used Press-Ganey, and

7   actually one-third have a hybrid, which makes

8   it very interesting.

9   CO-CHAIR HOMER: So, there were

10 some other --

11   MS. RAUSCHER: Or some other --

12   CO-CHAIR HOMER: I think, Faye,

13 you were up next.

14   MEMBER GARY: I just have several

15 quick questions. No. 1, how do you explain to

16 the parent who the physician is or who the

17 nurse is, and how are they going to use that

18 as the base to make the decision about their

19 satisfaction, especially in a teaching

20 hospital?

21   DR. ZINIEL: So, we actually had

22 items, well -- sorry. Go ahead.

1   MS. RAUSCHER: So, originally,

2   what we did when we planned this out was hold

3   focus groups. When we asked the question

4   about satisfaction with your physician, the

5   very first thing they asked was, "Which one?"

6   because we are in an academic medical center.

7   So, the team put together a whole

8   battery of test questions specific to three --

9   DR. ZINIEL: If it is a resident

10   or if it is the attending.

11   MS. RAUSCHER: And now you can

12   tell what the results were.

13   DR. ZINIEL: So, the results were

14   interesting because, if it is the first

15   hospital stay, about 80 percent, or I think it

16   was 80 or 85 people could not tell the

17   difference. So, it was like I don't know what

18   the difference is. So, they said, like I

19   didn't have a resident or a fellow. I mean

20   this is a teaching hospital, like there is no

21   child that goes through there that doesn't see

22   someone who is in teaching. So, we knew that

 1   they didn't -- it's all doctors, all white

 2   coats. However, in the people that are

 3   frequent flyers and are there more often, they

 4   can make the difference.

 5   So, now, if I can sort of take a

 6   step back, that is why we didn't include it

 7   here, but we at Children's would like to go to

 8   a modular system to have this as a core and

 9   add on modular questions that like rotate

10   throughout the year that will allow us to get

11   to certain areas and have, for example, 10

12   questions. So, there will be surgery, ER,

13   ICU. And one of these modules will be the

14   question with regard to the difference of

15   attendings and fellows.

16   So, kind of the criteria would be

17   that it would not be a person who was staying

18   there the first time because they can't -- it

19   is really the people that have been there

20   before know the difference; the other people

21   don't.

22   MEMBER GARY: Well, yes, I think

1   that to determine the difference sometimes can

2   be quite a struggle for even seasoned

3   people --

4   DR. ZINIEL: Correct. Yes.

5   MEMBER GARY: -- in hospital

6   settings.

7   The same question could be also

8   related to nurses. What nurses are you

9   talking about? Because they have three shifts

10   or two shifts --

11   DR. ZINIEL: Yes.

12   MEMBER GARY: -- and many people

13   who provide many different services. How do

14   you differentiate them from the people who

15   come up to do the x-rays, to take the blood,

16   the respiratory therapists? Because in a care

17   mode, that is a lot to ask people to separate

18   and to understand conceptually what the

19   difference is.

20   DR. ZINIEL: That is correct. And

21   we had items like that in there, too, and they

22   have really high missing value rates because

1   people just cannot -- it is one of these

2   things that I think surveys have to deal with

3   because you can only ask questions where

4   people know something about it. If they don't

5   know the difference, there is no point in

6   asking a question. And people really have

7   difficulties. I think it is just sort of how

8   compressed everything is, too. You know, they

9   go from one department to the other. It is

10   like they can't remember who was what and who

11   had what title and what procedure they got.

12   MEMBER GARY: Absolutely.

13   MS. RAUSCHER: But we are not

14   saying that that is not important. It was an

15   "aha" moment for us.

16   DR. ZINIEL: It was an "aha"

17   because we had this in there, and we asked

18   them, how did these technicians do and those

19   technicians. And I mean people sometimes,

20   they had procedures and the parent would

21   indicate they didn't.

22   MEMBER GARY: The other follow-up

 1   question to that is this is about

 2   satisfaction. The way I am looking at it, it

 3   is about the child, big children, because they

 4   are over 13, so they are big children.

 5   CO-CHAIR HOMER: No.

 6   DR. ZINIEL: No. It is all

 7   children.

 8   MEMBER GARY: You said you are not

 9   asking anyone who is younger than --

10   CO-CHAIR HOMER: No.

11   DR. ZINIEL: No. So, the question

12   that came up here was if we should give these

13   surveys to parents that are teenaged parents.

14   MEMBER GARY: Okay.

15   DR. ZINIEL: So, this survey is

16   for parents of all ages of children that are

17   at the hospital.

18   MEMBER GARY: Okay.

19   DR. ZINIEL: We would like to

20   develop a version for adolescents for the

21   patient itself.

22   MEMBER GARY: Yes.

1   DR. ZINIEL: But I think that this

2   instrument is completely feasible for, for

3   example, 15 years, a parent of 15 years and

4   older.

5   MEMBER GARY: Yes. Okay. That

6   clarifies one part of the question. But the

7   other part of the question is that it seems to

8   me in many ways for the older children, at

9   least it is a proxy measure, and have you

10   thought through what happens when the parent

11   wants to participate and the child does not?

12   Or is that a problem, that you ask them, the

13   parent, about the child, and the child would

14   prefer not to have parents respond on his or

15   her behalf about the care?

16   DR. ZINIEL: So, I don't think

17   that we have like clearly thought through, and

18   I think this is a great opportunity for a

19   scientific study with regard to proxy

20   measures.

21   I have looked at other data from

22   -- let me phrase it like that. There are

 1   areas where the parent is much better as a

 2   reporter than the child. There are also areas

 3   where the child is a better reporter than the

 4   parent.

 5   So, if I construct this sort of

 6   adolescent survey, I am pretty sure that one

 7   of the items for the adolescents would be,

 8   "Was I able to sleep in?", has a clear impact

 9   on satisfaction for an adolescent in the

10   hospital, which we would consider as fairly

11   unimportant in the grand scheme of things.

12   Like I have never encountered that

13   an adolescent was not happy because the parent

14   rated on their part. I mean the survey was

15   never introduced that way. It was really,

16   what were your experiences in the hospital?

17   MEMBER GARY: What was the

18   parent's experiences in the hospital?

19   DR. ZINIEL: Correct.

20   MEMBER GARY: Not the child's

21   experiences?

22   DR. ZINIEL: Correct.

1   MEMBER GARY: Okay.

2   CO-CHAIR HOMER: So, we could talk

3   at great length about the survey.

4   (Laughter.)

5   Go ahead.

6   CO-CHAIR WEISS: Just a very quick

7   question. Are you planning to make available

8   to the public the results of the surveys on a

9   regular basis?

10   DR. ZINIEL: Yes.

11   CO-CHAIR WEISS: And how do you do

12   that? Do you do that in each of the question

13   categories or is it just selected questions?

14   Or how do you handle that?

15   DR. ZINIEL: I mean,

16   theoretically, it is possible to display every

17   question.

18   CO-CHAIR WEISS: But what have you

19   done with CAHPS, for example?

20   DR. ZINIEL: Well, we don't have

21   CAHPS.

22   CO-CHAIR WEISS: Well, you don't,

 1   but have you discussed how you intend to make

 2   the information available to the public?

 3   DR. ZINIEL: So, I definitely

 4   think that it would be on the web page. The

 5   other thing --

 6   MS. RAUSCHER: Excuse me. I think

 7   it is just a little bit of a different

 8   question. You are talking about, if I am

 9   understanding you correctly, the question is,

10   how would this be available to everybody?

11   CO-CHAIR WEISS: Right. If I am a

12   parent considering your institution, and I

13   went on your website, would I be able to find

14   the answers to these questions?

15   CO-CHAIR HOMER: Or could you go

16   to any website and find out comparative data

17   on, should I go to --

18   CO-CHAIR WEISS: Across

19   institutions?

20   CO-CHAIR HOMER: -- Boston

21   Children's compared to --

22   MS. RAUSCHER: Our goal is

 1   definitely to try to make this the pediatric

 2   H-CAHPS. At that point, it would be available

 3   in the public domain to whomever.

 4   DR. ZINIEL: Yes.

 5   MS. RAUSCHER: At that time, and

 6   your question about contacting AHRQ, it would

 7   also be about contacting the individual

 8   vendors who are going to basically be able to

 9   pick this up and move ahead with it.

10   DR. ZINIEL: Right.

11   MS. RAUSCHER: But from a

12   perspective of maybe you could just share the

13   experience that we have done with the

14   children's hospitals based on whole system

15   measures, which is our first step of taking a

16   high-level measure and agreeing that we are

17   going to look at it together.

18   DR. ZINIEL: Do you mean with

19   regard to the differences and --

20   MS. RAUSCHER: Well, just the

21   process of trying to get people to accept the

22   measure.

 1   DR. ZINIEL: Oh. So, CHCA has

 2   this initiative about whole system measures.

 3   I don't know if you know about it or not. So,

 4   there was a group formed about service

 5   excellence, and we had, I think, 15

 6   representatives of hospital in there. We were

 7   trying to figure out what question to use to

 8   be able to compare across these 15 hospitals.

 9   It was a rather difficult

10   discussion because people do not want to

11   change their measure because they always

12   measured it that way, and like how could you

13   compare it if you changed it? And just

14   administering the two-service profile at the

15   same time to be able -- how to sort of

16   recalculate one score or the other didn't seem

17   as a valid option for them, either.

18   The questions are sometimes very

19   different. There are sometimes, if I might

20   say from a scientific point of view, some are

21   horrible. I mean, how likely or unlikely

22   would you be to recommend this hospital to

1   families and friends? And the answer

2   categories are poor. Poor? Yes, I mean

3   hello.

4   (Laughter.)

5   Anyhow, so it was a real battle to

6   get 15 hospitals to agree to choose the

7   question, how satisfied or unsatisfied are you

8   with the quality of care at this hospital? We

9   discussed this for over a year.

10   MS. RAUSCHER: But it is being

11   trained.

12   DR. ZINIEL: It is being trained,

13   exactly.

14   MS. RAUSCHER: The thing rolls out

15   and it is finally accepted. So, that we

16   anticipate is going to be part of moving us

17   forward.

18   DR. ZINIEL: But we really hope, I

19   mean based on this experience, what we really

20   hope is that there will be a national measure

21   that everyone will use, and that really allows

22   us to compare across hospitals and states.

1   I mean right now it is really hard

2 because the questions are different, the modes

3 are different. There are not adjustments

4 recommended whatsoever.

5   CO-CHAIR HOMER: So, I am going to

6 take the Chair's prerogative here and first

7 tell a brief story, and then move this along.

8   So, the brief story is I was

9 involved, as you may know, and I guess it is

10 disclosure, in developing the previous

11 iteration of the Boston Children's Picker

12 hospital survey. My first presentation at

13 Children's Hospital in 1991 as a presenter

14 was, "Do you know who your child's doctor is?"

15 And the answer was, of course, no --

16 (laughter) -- very consistent with what you

17 were reporting. So, it is interesting how

18 some things change and some things don't,

19 because it is hard in a complex institution.

20   So, having said that, we do need

21 to sort of wrap this conversation and come to

22 a decision about where we are going to go with

1 this survey. We have the process we need to

2 go through. So, the first would be we need a

3 series of votes on these.

4   So, the first one is, is this

5 concept or construct or measure sufficiently

6 important for us to proceed? And I would like

7 to call the vote.

8   All those who believe this is

9 sufficiently important show your hands.

10   Good. Everybody.

11   So, everyone, they were all yeses?

12 Okay.

13   DR. WINKLER: They were all yeses

14 except Tom.

15   CO-CHAIR HOMER: Who is crawling

16 under the table.

17   (Laughter.)

18   MEMBER McINERNY: Sorry.

19   CO-CHAIR HOMER: So, the next

20 question is scientific acceptability of the

21 measure. To be honest, I would contend that

22 we haven't, because the developers didn't know

 1   how to send us the information, were concerned

 2   we would be overwhelmed by a 300-page

 3   document. I am a little concerned we don't

 4   have sufficient information to actually make

 5   that judgment.

 6   So, I guess I need to call for a

 7   vote as to whether it is -- I guess, really,

 8   where I am going on this is, rather than

 9   proceed with the next series of votes on this,

10   do we want to, again, request the developer to

11   provide us some of that additional

12   information?

13   MEMBER DOCHERTY: Charlie, I just

14   have a question. You know, in methods

15   measurement, with a new scale, we tend to

16   accept indices that are slightly less than our

17   older, well-established scale. Could that

18   also be true for our assessment here, that we

19   recognize that it is a very new scale, and it

20   is under development, and that the author or

21   the developer is willing to continue to

22   provide us with reliability and validity in

1   development --

2   CO-CHAIR HOMER: The caveat is, as

3   Helen pointed out earlier, if we endorse or

4   recommend endorsement, that would be basically

5   anybody else can pick this item up and use it,

6   and that we would have some assumption of

7   comparability across institutions.

8   DR. BURSTIN: Charlie, it might

9   just be that we would ask you to actually

10   submit that document, and perhaps just give a

11   brief summary of the reliability and validity

12   based on the statistics that are in there.

13   And you could vote on it today, conditional

14   upon approval of that plan, just so you don't

15   have to get into yet another spinning game.

16   CO-CHAIR HOMER: Okay. So, should

17   we proceed, then, with the different votes on

18   the different elements, and then come back?

19   Okay.

20   So, in terms of scientific

21   acceptability, then, how many would feel this

22   is completely meets the criteria for

 1 scientific acceptability?

 2   I see none.

 3   How many feel this partially meets

 4 the criteria for scientific acceptability?

 5   All right. So, then I will move

 6 to minimally meets the criteria. I guess we

 7 would say minimally. Okay.

 8   Okay. Good.

 9   So, then, the next one is

10 usability, which is how interpretable are the

11 results, as well as -- why can't I ever

12 remember the other elements? How

13 understandable they are, whether they are

14 harmonized.

15   And again, we have got this issue

16 of comparability with CAHPS and where it is

17 and isn't, and the added value again. And

18 there is no H-CAHPS for pediatric, but there

19 are different scales and things like that.

20   So, how many would vote that it

21 completely meets the criteria for usability?

22   Okay. How many would say it

1   partially meets the criteria for usability?

2   And how many believe it minimally

3   meets the criteria for usability?

4   Has that got everybody?

5   Or not at all? Because we don't

6   have any comparative data and things like

7   that, and English only.

8   Okay. Good.

9   And then, for feasibility, again,

10   data clearly are not a byproduct of care. This

11   needs to be just a survey. But it is

12   feasible, electronic, exclusions, potential

13   for inaccuracies, and experience with or

14   capability for widespread implementation.

15   MEMBER GARY: I wanted to ask one

16   point before --

17   CO-CHAIR HOMER: Related to

18   feasibility? Sure.

19   MEMBER GARY: I think it was

20   Marina who asked about how this data might be

21   used by consumers. But I wanted to also know,

22   have you all thought through in your focus

 1   groups, or whatever, how this data would be

 2   used at the hospitals among the providers to

 3   improve care? That is No. 1.

 4   And No. 2, do you have a standard

 5   definition that you share with people who

 6   participate about what quality of care means?

 7   Because that, even providers, don't have any

 8   clear idea about the qualities. How do you

 9   grapple with that? Do you give us a scenario?

10   Or how are you going to do that?

11   DR. ZINIEL: So, from a

12   standardized interview point, my answer to

13   your question would be whatever means to you.

14   It is really hard to give definitions for a

15   concept because, once you give a definition --

16   I mean, how complicated would that definition

17   be? Would people understand it?

18   And with regard to scenarios,

19   there is enough scientific evidence that

20   scenarios actually bias the way you answer

21   because people will only think about the

22   scenarios you provide.

1   So, it is really what the parent

2   encompasses in that quality of care for

3   themselves, as subjective as satisfaction.

4   Your first question, can you

5   repeat your first question? Or go ahead.

6   MEMBER GARY: I am just concerned

7   that people in general without literacy

8   issues, many, many people will not have an

9   understanding for quality-of-care use. So, I

10   am wondering if it is quality of care you are

11   measuring, that one's own experience in terms

12   of interactions with staff --

13   CO-CHAIR HOMER: I do think that

14   test, that question has been subject to very

15   extensive -- I mean there have been a lot of

16   focus groups, there have been a lot of

17   cognitive interviews across a variety of

18   socioeconomic -- even though the term is very

19   abstract, people are able to make judgments

20   with this poor-to-exceptional or 1-to-10 scale

21   around rating quality of care.

22   DR. ZINIEL: I mean, you know,

1   sort of my "rebuttal", quote/unquote, would

2   be, if the providers can't decide what's

3   quality of care, like how should we explain it

4   to a parent? I mean, if you, you know --

5   CO-CHAIR HOMER: I think it is the

6   first line, actually, of "Zen and the Art of

7   Motorcycle Maintenance".

8   (Laughter.)

9   It's exactly about that term

10   "quality".

11   MEMBER GARY: The other question

12   is, how you are getting the agreements among

13   the professionals --

14   DR. ZINIEL: Oh, right.

15   MEMBER GARY: -- to improve the

16   care?

17   DR. ZINIEL: So, I mean,

18   definitely, there is a long-term monitoring of

19   how rates change. The other thing that I

20   would personally like to see with this

21   instrument is that there is a clear linkage to

22   data with regard to department. So, that if

1 the percentage of people that say they really

2 had a problem, you know, sort of below the

3 standard, like poor to excellent, where people

4 say poor to average, that the department sort

5 of really has to address if that percentage,

6 for example, goes up.

7   I think that that tool is really

8 to monitor how it goes overall, and that if

9 this percentage increases or the percent of

10 satisfied/very satisfied drops, that that is

11 really the point where the department, or

12 whatever area it is that shows these changes,

13 has to start investigating what is going on.

14   CO-CHAIR HOMER: Thank you for the

15 question and the response.

16   I am going to go back to voting on

17 the feasibility question.

18   How many believe that this

19 completely meets the criteria for feasibility?

20   Again, the components of

21 feasibility are, they don't -- again, it is a

22 little challenging because the data is not big

1   because it is a survey. But, basically, how

2   feasible is this to implement? What is the

3   burden, the hassle? How well-specified is it?

4   How easily could this be picked up and done in

5   a consistent manner?

6   So, how many believe this

7   completely meets the criteria for feasibility?

8   We said that?

9   How many believe it partially

10   meets the criteria for feasibility?

11   How many believe this minimally

12   meets the criteria for feasibility?

13   Anyone in the not at all?

14   Okay. All right. Now I think

15   again comes the question whether we move to

16   endorse it or not. So, I think there are

17   several options that we have on the table.

18   One is, as we did I think in one

19   of the early ones, is not move that question,

20   but, rather, recommend or request that we have

21   additional data provided to the Committee.

22   Isn't that what you were basically suggesting?

 1   DR. BURSTIN: Oh, no, no, no. You

 2   could just move it with conditions, if you

 3   would like.

 4   CO-CHAIR HOMER: So, we could --

 5   DR. BURSTIN: Conditions on the

 6   satisfactory analysis of the tome.

 7   CO-CHAIR HOMER: Okay. So, we

 8   could do one of three things, but really one

 9   of two things, in my view.

10   One is not vote and request

11   further information. Second is vote

12   conditionally, and I would still say vote for

13   time-limited because, again, this is only in

14   English. This hasn't been applied across in

15   one institution. We haven't been presented

16   with domain scores or mechanisms really for

17   reporting out.

18   So, we could either make it

19   conditional -- we could either request more

20   information or we could vote a conditional,

21   time-limited endorsement. I think those are

22   really the options.

1   Lee?

2   MEMBER PARTRIDGE: I think

3   probably several of us are struggling with the

4   problem that the work has been largely done in

5   cooperation with children's hospitals.

6   I think I heard Allan say that --

7   CO-CHAIR HOMER: With just one

8   children's hospital.

9   MS. RAUSCHER: Just one children's

10   hospital.

11   MEMBER PARTRIDGE: But you also

12   had conversations with other children's

13   hospitals.

14   DR. ZINIEL: Correct.

15   CO-CHAIR HOMER: But that is, yes,

16   only one question really, that satisfaction

17   dimension.

18   MEMBER PARTRIDGE: Right. I think

19   my basic dilemma is I want an H-CAHPS for

20   pediatrics.

21   CO-CHAIR HOMER: Right.

22   MEMBER PARTRIDGE: What I don't

 1   feel comfortable with, as we have it in front

 2   of us today, how well it would also work in

 3   Kaiser's hospitals or in community hospitals

 4   in more rural areas. I don't know whether we

 5   can get that in a reasonable period of time.

 6   I think it is difficult to get it through the

 7   NQF process without having a little better

 8   sense of how it would work outside the

 9   children's hospital.

10   MEMBER LIEBERTHAL: I didn't speak

11   directly to Kaiser, but knowing how it works,

12   I think that they would respond better to a

13   pediatric questionnaire that was under the

14   H-CAHPS title, which they already use, than a

15   totally new questionnaire.

16   And also, the issue of similar

17   rollups, so they could have some comparison of

18   their pediatric services to their adult

19   services, recognizing the differences.

20   And I am usually not one who

21   advocates that children are small adults.

22   (Laughter.)

1   DR. BURSTIN: I did just email the

2   CAHPS team. It helps that I spent seven years

3   there. I can do that stuff.

4   So, they wrote me back. "The

5   CAHPS team acknowledges the importance of this

6   population, but they have limited resources to

7   do it at this time."

8   So, I think the reality is it is

9   not there now. There you go.

10   MEMBER PARTRIDGE: And we all are

11   very aware of that. Therefore, you don't want

12   to stifle progress.

13   DR. BURSTIN: And at some point,

14   if a pediatric H-CAHPS came in, those measures

15   could be harmonized or one would be determined

16   to be best in class. But, at this point,

17   there's not a competing measure on the table.

18   There is a theoretical one on the table, but

19   it doesn't exist.

20   CO-CHAIR HOMER: But I also know

21   what was required of the CAHPS team to get

22   through both NQCA approval and then NQF

 1   approval, which was vastly more data --

 2   DR. BURSTIN: The first time. It

 3   hasn't been that way since, and the first

 4   time -- I was at AHRQ at the time.

 5   CO-CHAIR HOMER: Yes.

 6   DR. BURSTIN: I mean H-CAHPS was

 7   more of a political battle than anything else.

 8   Getting it through NQF actually wasn't the

 9   problem.

10   CO-CHAIR HOMER: But I did sit, I

11   sat, as you know, on the Hospital Review

12   Committee, and there was a lot more data

13   presented. So, I am just a little worried

14   that we haven't yet seen comparative data. We

15   don't have domain scores. But that is my own

16   stick.

17   DR. BURSTIN: So, why don't you

18   just defer the vote until you have set a time?

19   That is fine.

20   CO-CHAIR HOMER: I am just

21   speaking --

22   MEMBER JENKINS: I would just like

1   to say, if anyone here has any suggestions or

2   advice for us, we would more than entertain

3   them. Because we started by having the adult

4   measure tried to be stuffed down on us, which

5   is how we got this far, and you guys are

6   seeing exactly how far we have gotten.

7   MEMBER LIEBERTHAL: Recognizing

8   that H-CAHPS doesn't have the resources to

9   start from scratch and write a pediatric

10   questionnaire, they might welcome working with

11   you and merge the two. It would require much

12   reduced resources on their part and

13   acknowledge the extensive work that you have

14   done. So, I think that might be a compromise

15   that would be more satisfactory to many

16   people.

17   CO-CHAIR HOMER: But I don't want

18   to put on the team -- they are not in control

19   of whether the H-CAHPS people will work with

20   them or not. So, that seems, it is a

21   wonderful suggestion, but, you know --

22   DR. BURSTIN: But, Charlie, to

1   your point, I think based on what you just

2   said that the discomfort is, I think we should

3   actually wait and get the methods piece back

4   to assess reliability and validity, and just

5   vote on another conference call. I think

6   doing it now would feel premature, it sounds

7   like, for too many folks here.

8   CO-CHAIR HOMER: Well, it would be

9   for me. I am just speaking more as an

10   individual than as the Chair.

11   So, my motion would be that we

12   request additional information specifically on

13   the domain score issue and really I think even

14   crisper specifications, then, tied to what the

15   reporting would look like, and then bring that

16   back for a vote for time-limited endorsement,

17   based on that.

18   Then, I think the conditions

19   probably at the time of the time-limited

20   endorsement would be application across

21   multiple institutions to look at the

22   feasibility of use.

1   DR. BURSTIN: Right. Which is in

2   the works. Yes.

3   CO-CHAIR HOMER: Then, that would

4   be the criteria for coming back within 12

5   months, more or less, after we do the time-

6   limited endorsement.

7   So, that is my motion, is that we

8   defer a vote, pending additional information.

9   Do I have general agreement? I am

10   seeing a lot of heads shaking that we do that.

11   Okay. Good.

12   All right. So, why don't we go

13   forward with that?

14   DR. BURSTIN: And I am also happy

15   to play the matchmaking role, if you would

16   like, with AHRQ.

17   CO-CHAIR HOMER: Well, I guess I

18   would be specifically interested in AHRQ, in

19   where there are disparities in scales, in

20   particular, like, again, you've got this

21   different five-point scale than the standard

22   CAHPS 10-point overall rating scale, which I

1   know was a very intensely-researched topic.

2   I would at least like to hear a little bit

3   more -- this is probably my old survey

4   researcher coming out -- on some of those

5   items.

6   DR. ZINIEL: Yes, I am happy to do

7   that.

8   CO-CHAIR HOMER: Good. Great.

9   Thank you very much. Wonderful

10   discussion. Wonderful work.

11   Also, I guess, on behalf of the

12   child health community, I express my

13   appreciation to Boston Children's for

14   investing in developing and moving this

15   measure forward.

16   DR. ZINIEL: Thank you.

17   CO-CHAIR HOMER: That is great, as

18   well as the other one.

19   MS. RAUSCHER: Thank you.

20   MS. McELVEEN: Okay. We have five

21   measures left and about 50 minutes.

22   CO-CHAIR HOMER: So, 10 minutes

1   each.

2   MS. McELVEEN: Yes, I think we all

3   know that that's probably not going to happen.

4   This is my suggestion: the five measures left

5   are the individual metrics that are, again,

6   part of this larger survey measure submitted

7   by CAHMI. My suggestion is, either out of the

8   five, if we could quickly look through them

9   just based on maybe title description and the

10   reviewers who looked at it and do a scope

11   call. Because I know a lot of the other

12   individual metrics we viewed them as out of

13   scope for various reasons.

14   And also, taking up the first

15   measure to look through more in-depth, if it

16   does get that far, is the one on measure of a

17   medical home for children and adolescents,

18   only because I think that one will probably

19   have a little more discussion than the others.

20   Is that okay with the group to do

21   that first and go from there? Any objections?

22   None. Okay.

1   So, the first out of the five is

2   41. And again, this is a brief, you know

3   -- I'm sorry. This is Work Group 4.

4   Sorry. I apologize. I am just

5   trying to get through these. I am probably

6   talking, working faster than I should.

7   So, this is Group 4.

8   Unfortunately, Tom had to leave early, but he

9   did provide his feedback. So, that is

10   probably what you see up on the screen, is

11   mainly his comments and ratings.

12   But, first, Measure 41 is children

13   who attend schools perceived as safe. This

14   measure ascertains the perceived safety of the

15   child's school. So, again, just looking at

16   that description, and based on the reviewers

17   who did look at the measure more in-depth, if

18   we could kind of give a call as far as

19   importance and scope, whether it fits within

20   scope of the project.

21   MEMBER PARTRIDGE: I was on Work

22   Group 4, and I was a negative on this one,

1   primarily because I had difficulty with

2   evidence of relationship to child health.

3   We had a long discussion about

4   this issue in the context of Measure 2 above,

5   which is children who live in communities

6   perceived as safe. So, I guess from my point

7   of view right now, I would still consider this

8   one out of the scope, but I am willing to be

9   convinced.

10   MEMBER PERSUAD: I was on the

11   subgroup that reviewed this. I would concur

12   with that. This is a single item on a larger

13   questionnaire. It is a single item. It is

14   very general.

15   The only thing I could think of

16   that would be of interest in this would be

17   bullying, and I don't think that the statement

18   on linked to outcomes was strong enough as is

19   written here. I am not sure that it is not,

20   actually, because it is a child's school.

21   But I would be fine if it is out

22   of scope. It is a single item, and it is very

1   general.

2   CO-CHAIR HOMER: Ellen?

3   MEMBER SCHWALENSTOCKER: I was not

4   part of that Work Group. So, I hope I am not

5   out of turn speaking.

6   CO-CHAIR HOMER: No, that is fine.

7   MEMBER SCHWALENSTOCKER: I agree

8   with what has been said, but, then, it seems

9   inconsistent to me that we would endorse the

10   safe community and not endorse the safe

11   school.

12   CO-CHAIR HOMER: The amenities was

13   out, but we did -- the safety was in.

14   MEMBER PERSUAD: Which is one

15   thing I was thinking about. I did want to ask

16   us to review maybe a little bit of the

17   discussion about the safety in neighborhoods.

18   Right? That was a safety in neighborhoods.

19   Communities, safety in communities.

20   CO-CHAIR HOMER: We felt that the

21   experience of being safe in your community was

22   an important stressor, health-related

1   stressor. So, the question is whether we feel

2   that the perception of safety in the school

3   is --

4   MEMBER JENKINS: There is the link

5   to physical functioning and obesity --

6   CO-CHAIR HOMER: Yes.

7   MEMBER JENKINS: -- because of

8   safety --

9   MEMBER PERSUAD: In this document,

10   the summary of evidence for linkage was that

11   children who attend schools that are usually

12   or always felt as safe are much more likely to

13   be in better overall health than those who

14   attend schools which are never safe, 85

15   percent to 59 percent. That is the only piece

16   of evidence that we have in this document that

17   they listed.

18   MEMBER KIBORT: Charlie, when you

19   made the comment that for the communities it

20   seemed to correlate, their sense of safety

21   correlated with their health, but since the

22   child spends so much time in school, wouldn't

1   it sort be the same logic?

2   CO-CHAIR HOMER: You could make

3   that argument.

4   MEMBER FISHER: Why isn't the

5   school part of your community?

6   MEMBER KIBORT: It is.

7   CO-CHAIR HOMER: So, Faye?

8   MEMBER GARY: One of the --

9   MR. STUMBO: This is Scott Stumbo

10 on the call.

11   CO-CHAIR HOMER: Oh, good.

12   Faye, I'm sorry. Please.

13   MEMBER GARY: That is okay.

14   One of the struggles I had is that

15 some schools are in very blighted

16 neighborhoods, and children feel very unsafe

17 when they are walking from home to the

18 schools. When they get to the schools, they

19 may feel relatively safe in the schools, but

20 when they walk out on the sidewalk and head

21 home, they don't feel safe. Lots of things

22 happen between school and home.

1   MEMBER KIBORT: Faye, it may be

2   the opposite, too, though, right?

3   MEMBER GARY: Yes, it might be the

4   opposite.

5   MEMBER KIBORT: That the community

6   is safe, but the school is not.

7   MEMBER GARY: Well, then, in some

8   of the schools they have police in the schools

9   and there are surveillance secret men in the

10   school to make the children feel safe.

11   And those neighborhoods, I would

12   suggest, are relatively unsafe. So, in my

13   mind, it is hard for me to separate out a safe

14   school and not a safe neighborhood, and no

15   information about how a child feels safe in

16   the neighborhood. Then, conflicts in the

17   school just spill over in the neighborhood.

18   So, I am having difficulty with

19   this.

20   CO-CHAIR HOMER: Scott, have they

21   looked, have you looked at the correlation

22   between these two items?

1   MR. STUMBO: They are highly

2   correlated, yes.

3   CO-CHAIR HOMER: Okay. Is there

4   additional information in one compared to the

5   other or they so highly correlated that they

6   are really no added value?

7   MR. STUMBO: That I don't know. I

8   am not sure.

9   CO-CHAIR HOMER: So, I guess for

10   consistency -- I mean I am not going to

11   revisit yesterday's vote -- for consistency's

12   sake, it is hard, I guess in light of this

13   conversation, for us to view this out of

14   scope. Is that an accurate -- so, it is

15   within scope. So, that means, how do you want

16   to deal with that? Do you want to go to the

17   other ones that we think maybe are out of

18   scope?

19   MS. McELVEEN: Yes.

20   CO-CHAIR HOMER: Then, we will

21   either come back to this one now or come back

22   to it in a conference call.

1   MS. McELVEEN: Yes. Okay.

2   Okay. The next one on the list is

3   42. It is children who receive the mental

4   health care they need, and this is the

5   percentage of children age 2 to 17 who have an

6   ongoing condition which requires mental

7   healthcare who actually have seen a mental

8   healthcare professional in the past 12 months.

9   CO-CHAIR HOMER: So, I guess the

10   question would be, is this a process measure

11   or an outcome measure?

12   MEMBER PERSUAD: I was two minds

13   about this. I think it is at face value is a

14   process measure, but, as a general

15   pediatrician, I know that that is such a

16   critical early make-or-break, and that is

17   really the thing that we are dealing with that

18   I was trying to figure out if it moves over to

19   being somewhat of a proxy measure.

20   CO-CHAIR HOMER: Bonnie?

21   MEMBER ZIMA: I had some concerns.

22   But my initial impression was that there was

1   too much diversity on what a mental health

2   professional was, and I could not link sort of

3   whether the condition that child had connected

4   with the right provider.

5   CO-CHAIR HOMER: Could we confine

6   the responses to this issue of whether we

7   consider it a process or -- because that is

8   really going to be a question of whether we

9   consider this in scope or out of scope, as

10   opposed to the validity of the measure.

11   MEMBER LIEBERTHAL: Seeing a

12   mental health professional may lead to better

13   outcome or may not. So, I see it as a process

14   measure. It is just one step on the path. It

15   may lead to better outcome.

16   CO-CHAIR HOMER: Lee?

17   MEMBER FISHER: I felt it was

18   partially important. I am perfectly happy

19   ruling it out as a process measure.

20   CO-CHAIR HOMER: Okay. So, all

21   that means is it just goes to our meeting in

22   July, you know.

1   (Laughter.)

2   So, I think this one is considered

3 a process.

4   MR. STUMBO: Can I ask a question?

5   CO-CHAIR HOMER: Yes.

6   MR. STUMBO: So, it is not purely

7 based on an item saying did you or did you not

8 see a mental health professional. There is an

9 identified need. So, this I would think it

10 would fall under the same category as any

11 other unmet need for access to healthcare, and

12 so in my mindset, makes it much more in the

13 realm of outcome. If it was just did you or

14 did you not see a mental health professional,

15 but it is clearly based on a two-item measure,

16 and based on the first item, the child has

17 been identified as having an ongoing need, not

18 just a crisis, but an ongoing need for mental

19 health care.

20   And then, completely unrelated to

21 a different part of the survey, it says, by

22 the way, did you happen to see a mental health

1   professional? It does define what could be

2   included as a mental health professional.

3   So, those who said no have somehow

4   indicated earlier that their child did,

5   indeed, have a need. That is the risk --

6   MEMBER ZIMA: Certainly in the

7   title we see that there is a need. In the

8   title it implies appropriateness.

9   CO-CHAIR HOMER: Certainly, that

10   was a good point, but I think I am still in

11   the category, I think, that it is a process.

12   So, the first question is, is

13   there a need? To some extent, that is a

14   health status indicator. That is an unmet

15   need, it is a combination of a process and an

16   outcome.

17   MEMBER PARTRIDGE: I assume if we

18   deal with this later on as a process measure,

19   we are not totally precluded from identifying

20   some element of it as also an outcome measure.

21   Just as we have talked to the payers here, I

22   think we all feel there needs to be something

1   that addresses the question of assessing the

2   unmet need.

3   MEMBER FISHER: Of mental health

4   problems.

5   MEMBER PARTRIDGE: Of mental

6   health, yes.

7   MEMBER ZIMA: It mirrors a little

8   bit of the discussion we had yesterday with

9   Dr. Murphy around the pediatric symptom

10   checklist.

11   CO-CHAIR HOMER: But at least the

12   pediatric symptom checklist was a direct

13   indicator, at least intended to be a direct

14   indicator of the health status, you know,

15   whether you had symptomology that you had

16   indicated you had --

17   MEMBER FISHER: But this says that

18   you have a diagnosis, you have a need, so you

19   have a diagnosis.

20   CO-CHAIR WEISS: It also says they

21   received the care.

22   MEMBER FISHER: And so, to me, if

1   you didn't receive the care, that is pretty

2   bad. I just think that we are so used to

3   taking mental health and taking it away from

4   physical health, that we forget you get bad

5   outcomes if you don't get to see -- if you

6   don't see the cardiologist about your

7   arrhythmia, you know, you get into problems.

8   So, I am thinking if you don't see

9   a mental health person about your, let's say,

10   bipolar disease, you can get into problems.

11   Of course, it might be fun to go out and spend

12   a lot of money, but you know what I am trying

13   to say. If there is a problem there --

14   CO-CHAIR HOMER: Yes, Donna?

15   MEMBER PERSUAD: I guess one thing

16   is, I notice in the measure specification it

17   is children who have a mental health condition

18   and saw a mental health professional in the

19   last 12 months. I guess I didn't see that as

20   meaning necessarily that they got the total

21   cure for their condition or the level of care

22   they needed. I saw it more as process on that

1 point. They just got there.

2   MEMBER RAO: And there is the

3 other issue that I think a significant

4 proportion of mental illness is treated by

5 primary care physicians, too, and it is

6 ongoing as well.

7   CO-CHAIR HOMER: So, are we,

8 again, are we deferring this, then, to our

9 process conversations in a couple of months?

10 Okay.

11   CO-CHAIR WEISS: On the basis that

12 one would expect that most mental health care

13 is going to be given over time, I think

14 process makes -- I mean I think there are

15 elements of both, but I would put it in the

16 60/40 process basket.

17   CO-CHAIR HOMER: So, let's defer

18 this until our next long meeting and

19 conversation. Good.

20   MS. McELVEEN: Okay. The next one

21 up is No. 44, and this is children who have an

22 adequate insurance coverage for optimal

1   health. The measure is designed to ascertain

2   whether or not current insurance program

3   coverage is adequate for the child's health

4   needs, whether the out-of-pocket expenses are

5   reasonable, whether the child is limited or

6   not in choice of doctors, and whether the

7   benefits meet the children's healthcare needs.

8   So, it is a lot of components.

9   CO-CHAIR WEISS: Let me just say

10   that I think this one needs to be thought

11   about in context of health reform, and health

12   reform is going to phase in over time. So, I

13   think we should be thinking about a broader

14   timeframe than just the year 2010.

15   But I do believe that this

16   particular set of questions needs to be

17   measured. It just really important,

18   particularly for people who will be getting

19   their health insurance coverage through the

20   exchanges and for adolescents and others who

21   will be getting the stripped-down, Spartan

22   healthcare plans. It is just very important

1   to monitor whether those plans have an

2   adequate scope of coverage. So, whether

3   outcome or process, this is super-important,

4   in my mind.

5   CO-CHAIR HOMER: Lee?

6   MEMBER PARTRIDGE: I think you can

7   tell by the scores up here that we had some

8   unanimity on the importance of this measure.

9   I would argue that it is not a process

10   measure. I would argue it is an outcome

11   measure because the flip side is you cannot

12   have access to your healthcare in many

13   instances if you don't have the capacity to

14   pay for it. So, I put it in the outcome

15   bucket comfortably. Probably on a slippery

16   slope, but --

17   MEMBER FISHER: Also, because you

18   have insurance doesn't mean you have access.

19   I am just adding that --

20   MEMBER PARTRIDGE: I am well aware

21   of that.

22   MEMBER FISHER: Okay. I am just

1 adding that to what you said. I am not

2 arguing this.

3   MEMBER PARTRIDGE: You are talking

4 about mental health?

5   MEMBER FISHER: Talking about any

6 kind of insurance, health insurance.

7   CO-CHAIR HOMER: So, we think this

8 is in scope. That seems to be -- I think this

9 is definitely in scope.

10   So, all of our efforts to expedite

11 this conversation are not really being very

12 productive, but that's all right.

13   (Laughter.)

14   So, that is in scope.

15   And then, the last one?

16   MS. McELVEEN: That one is in

17 scope.

18   CO-CHAIR HOMER: The measure --

19   MS. McELVEEN: Medical homes. So,

20 the next one -- and we probably could take

21 some time to discuss this one a little more

22 in-depth -- is around the medical home. This

1   is the measure of the medical home for

2   children and adolescents.

3   It is basically a composite

4   measure that assesses whether children and

5   adolescents receive healthcare within their

6   medical care. This is according to the survey

7   respondent. Then, it looks like there the

8   measure is based on six of seven components

9   that are proposed by the American Academy of

10   Pediatrics, I think, it looks like defining

11   what the medical home is.

12   CO-CHAIR HOMER: So, again, I

13   think the key question is, is this in scope,

14   first. Is that what you wanted?

15   MS. McELVEEN: Yes.

16   CO-CHAIR HOMER: And then we are

17   going to have to prioritize which of these

18   various ones we are going to cover during our

19   discussion.

20   So, the first question is, do

21   people feel this is an outcome measure within

22   the scope of our deliberations?

 1   DR. BURSTIN: I don't see it as

 2   out of scope, but I am not sure I see it as in

 3   scope. I mean, when we put it together at the

 4   start of the Outcomes Project, we explicitly

 5   put patient self-report on the list of

 6   outcomes. So, from that perspective, I think

 7   it is potentially in.

 8   CO-CHAIR HOMER: Yes.

 9   CO-CHAIR WEISS: Could I weigh-in

10   with maybe a different way of looking at it?

11   That is, it seems to me that currently it is

12   an outcome because not every child has a

13   medical home, and we are driving in that

14   direction.

15   There will come a point in time

16   where every child does have a medical home, at

17   which point it becomes a process.

18   MEMBER FISHER: I like that, yes.

19   And I think, also, it is that we have got to

20   think differently about medical care, and that

21   is the problem; this is different.

22   MEMBER JENKINS: Or maybe another

1   way of saying it is it is an intermediate

2   outcome.

3   CO-CHAIR HOMER: Yes, I am just

4   wondering about our consistency with our unmet

5   mental health need and whether that would also

6   fit the same criteria, but let's not go there.

7   So, this is also, clearly, within

8   scope.

9   MEMBER FISHER: Remember it when

10   it comes up again.

11   CO-CHAIR HOMER: And then the last

12   one for us to decide if it is in or out of

13   scope would be Measure 50. So, then, who

14   receives standardized developmental -- yes.

15   MEMBER LIEBERTHAL: Yes, that is

16   clearly a process.

17   CO-CHAIR HOMER: Okay. We took

18   care of two, one.

19   So, I think the question is, which

20   one do we want to pick up and which ones do we

21   think that we have a reasonable likelihood of

22   being able to complete within a half-hour

1   conversation? Do you think we can medical

2   home and insurance?

3   DR. BURSTIN: Go for it.

4   CO-CHAIR HOMER: Okay.

5   MS. McELVEEN: I won't object to

6   that, of course.

7   (Laughter.)

8   CO-CHAIR HOMER: So, let's do the

9   insurance one first. Since there was a lot of

10   enthusiasm that I saw around the room, maybe

11   that will be an expeditious measure.

12   CO-CHAIR WEISS: Shall we time it?

13   (Laughter.)

14   CO-CHAIR HOMER: So, the insurance

15   item is item 44.

16   Again, either does the steward,

17   the way we were doing it today, want to make

18   a brief, any brief introductory comments about

19   this item?

20   MR. STUMBO: Sure. Well, this is

21   one that we are particularly fond of.

22   This is a national survey, first

1   of all. This is being used by the Maternal

2   and Child Health Bureau for quite a while. It

3   is a relatively-new measure. It was

4   introduced into the 2007 survey, but we are

5   still getting publications out about it.

6   Like a commenter on your panel, we

7   believe very strongly that saying whether a

8   child has coverage or not is actually not the

9   whole picture. It is when you actually start

10   to dive a little deeper, we do find that, even

11   among children who are reporting or their

12   parents are reporting that they are in current

13   coverage, 15 or more percent, and it is

14   actually much worse among the private, are

15   stating that they do not have adequate

16   coverage, based on whether they have

17   unreasonable out-of-pocket expenses, not able

18   to see all the providers they need, and/or the

19   benefit does not talk to the child's needs.

20   So, we think that's a really

21   important story to tell.

22   CO-CHAIR HOMER: Great.

1   So, any other questions about

2   importance issues on this particular question?

3   (No response.)

4   Okay. So, let's vote.

5   How many believe this is an

6   important item sufficient to proceed?

7   DR. WINKLER: Eleven.

8   CO-CHAIR HOMER: Good. There were

9   none opposed. Good.

10   All right. So, then, the

11   scientific validity of the items, again, I

12   think we reviewed the characteristics of the

13   survey overall quite a bit.

14   Any comments on the testing, the

15   questions themselves, the cognitive interview,

16   the testings, and also, any assessment of

17   these items and how they fit together, how

18   well the algorithm works?

19   MEMBER LIEBERTHAL: The questions

20   are very subjective. This is parents'

21   perception of their insurance plan. As being

22   subjective, it can be all over the place as to

1   what is adequate coverage. Again, somebody

2   may perceive adequate coverage as no out-of-

3   pocket expense; whereas, somebody else may be

4   happy with some out-of-pocket expense. I

5   don't know how to draw conclusions on that as

6   to whether a child has adequate insurance.

7   It also depends so much on the

8   family's inherent finances and socioeconomic

9   status.

10   CO-CHAIR HOMER: Okay.

11   CO-CHAIR WEISS: Let me just say

12   that that is a point that is debated and has

13   been for many, many years. Five percent of

14   adjusted gross income is one measure that has

15   been used. Of course, you know, the Internal

16   Revenue Service has used different measures.

17   So, I don't know that we are going to be able

18   to even come close to settling that issue. It

19   is a subjective judgment.

20   MEMBER PERSUAD: I guess the

21   measure steward can comment on this. They do

22   recommend stratification based on

 1   vulnerability. So, that may be a way to get

 2   at the issue of whether there's comparative

 3   relationship between what they would think is

 4   unreasonable and what they really have.

 5   I would actually argue that what

 6   the parents' perception is of unreasonable is

 7   unreasonable. That is face validity to me.

 8   MR. STUMBO: Right. In fact, this

 9   measure has so much face validity. Basically,

10   it is an incredibly low bar. In fact, I think

11   you guys were discussing the previous measure

12   prior to our measure. There is an immense

13   positive bias on all these questions. So, all

14   they have to do is there are these three

15   components: whether or not the out-of-pocket

16   costs are unreasonable, whether the plan

17   provides for everything the child needs, you

18   know, that the benefits provide for the

19   child's need, and it never, sometimes,

20   usually, always -- this is a usually-and-

21   always measure on all of them. So, all you

22   have to do is fall into the sometimes or never

1   on one and you become adequate, which is

2   actually a relative low bar.

3   Of the three domains, it is the

4   out-of-pocket expenses which drive a bit of

5   it. To give a little flavor on the

6   stratification of the face validity, it is the

7   private insurance which is actually doing

8   much, much worse on the overall measure and on

9   that component. You know, public-insured kids

10   are actually doing better.

11   And when you stratify by income,

12   it is not related to income the way you might

13   think it is. In fact, the people doing the

14   worse are the folks in the 200 to 400 percent

15   poverty rate, which often fall outside of that

16   SCHIP. And the lowest under poverty and the

17   highest 400 percent above are equal on whether

18   or not the insurance is adequate. So, it is

19   not being driven entirely by the out-of-pocket

20   expenses, but can be for the privately-insured

21   kids.

22   CO-CHAIR HOMER: So, Kathy,

 1   please.

 2   MEMBER JENKINS: I thought what

 3   you just said was that any of those needed to

 4   be usually or always, but the way it is

 5   written, it is a series of "and" statements.

 6   You actually have to meet all the criteria.

 7   Isn't that true?

 8   MR. STUMBO: Yes, in order to have

 9   adequate coverage, you have to be usually or

10   always in all three of the components. And

11   nationally, without any stratification, 15

12   percent of kids are not usually or always

13   meeting those criteria.

14   When I have talked to both the

15   National Caucus of State Legislators, and we

16   have brought these numbers for a lot of other

17   folks, the preschool and regional, they can't

18   believe that it is not significantly higher

19   than that. Most people's personal experience

20   is that they can't believe everyone says they

21   don't have adequate coverage.

22   MEMBER ZIMA: This is probably a

1   fine point, but I am looking at the 2a.21

2   calculation algorithm, and it looks to me like

3   it is needed to see the healthcare provider.

4   How are you handling mental health?

5   MR. STUMBO: I'm sorry, I don't

6   actually have the form, submission form, in

7   front of me. Can you explain a little bit

8   further?

9   MEMBER ZIMA: Yes. It says,

10   "Current insurance offers benefits or covers

11   services that meet the child's needs. Current

12   insurance allows the child to see needed

13   healthcare providers."

14   Does healthcare provider include

15   mental health or not?

16   MR. STUMBO: Objective to parent

17   interpretation.

18   CO-CHAIR HOMER: I'm sorry, what

19   was the --

20   MR. STUMBO: If the coverage does

21   not cover mental health coverage and the

22   parent thinks it should, then maybe, like we

1   said, they were not happy with that.

2   CO-CHAIR HOMER: Okay. All right.

3   Do we have sufficient information to move on

4   the scientific validity, scientific

5   acceptability of the measure? I think so.

6   So, how many --

7   MEMBER JENKINS: Can I ask one

8   more question?

9   CO-CHAIR HOMER: Yes, of course,

10   Kathy.

11   MEMBER JENKINS: Could I ask you,

12   then, what I heard you say is that there is

13   this positive response bias, and that people

14   are shocked that the measure does as well as

15   it does. Is there a potential unintended

16   consequence that the problem with the positive

17   response bias could be misleading in the

18   opposite direction?

19   MR. STUMBO: I'm not sure I could

20   comment on that. We do find that, in general,

21   parents tend to be positive on everything.

22   How well are your kids doing? If anything --

1   I have three.

2   (Laughter.)

3   Yes, I was surprised on the

4   positive bias myself.

5   MEMBER JENKINS: So, you are

6   saying you are not worried about that, that

7   families are inaccurate and that could be an

8   unintended consequence? Because what you are

9   really saying is you are not sure they are

10   accurate.

11   MR. STUMBO: I cannot reach inside

12   a parent's brain and understand if they are

13   confused by the question or the world around

14   them.

15   CO-CHAIR HOMER: But you said 85

16   percent of parents report that their child has

17   adequate insurance, meaning they meet all five

18   of those criteria, that it covers their needs

19   and that they don't have too high out-of-

20   pocket expenses, et cetera?

21   MR. STUMBO: Right.

22   CO-CHAIR HOMER: Okay. And that

1   includes people who have no insurance at all?

2   MR. STUMBO: No, it does not.

3   This is all children who have current

4   insurance, regardless of the type of

5   insurance.

6   MEMBER JENKINS: That is actually

7   a question.   It is one of the five criteria.

8   CO-CHAIR HOMER: Yes.

9   MEMBER JENKINS: So, I assume that

10 if they said they don't have insurance, then

11 they are not excluded, I don't think.

12   MR. STUMBO: I'm not sure they

13 have that, but --

14   MEMBER JENKINS: You are just not

15 in the numerator.

16   MR. STUMBO: -- but it is just

17 children with insurance.

18   CO-CHAIR HOMER: Now I'm sorry,

19 are they in the -- I am still confused. I'm

20 sorry. Are they included or not included?

21   MR. STUMBO: They are not included

22 in the denominator. It is of children with

 1   insurance --

 2   CO-CHAIR HOMER: Okay.

 3   MR. STUMBO: -- how many have

 4   adequate or inadequate --

 5   MEMBER JENKINS: Well, for a child

 6   to be included in the numerator of having

 7   adequate insurance, criteria from the

 8   following five questions must be met. Child

 9   has current health insurance coverage.

10   CO-CHAIR HOMER: But, then, the

11   denominator excludes -- so, if you have 5

12   percent uninsured in your community and you

13   then have 15 percent who say they have

14   inadequate insurance, so the total would be 20

15   percent if you were speaking to the

16   legislature, how many children are, quote,

17   "underinsured" in your community, you would

18   say that would include the 15 plus 5. Right?

19   Okay, that would be the way to interpret it.

20   Okay.

21   Okay, scientific validity then or

22   scientific acceptability, how many feel this

1   completely meets the criteria for scientific

2   acceptability?

3   Pretty good, actually.

4   How many feel it partially meets

5   the criteria?

6   Good. Did that catch everybody?

7   DR. WINKLER: No.

8   CO-CHAIR HOMER: No?

9   How many believe this is minimal?

10   Okay. All right. I think from

11   the usability, which is how understandable

12   this is as well as issues of harmonization

13   with other measures, and whatever the third

14   one is which -- added value.

15   So, any questions about this?

16   (No response.)

17   If not, we will move on to voting.

18   To what extent does it completely

19   meet the criteria for usability? Yes?

20   How many believe it partially

21   meets?

22   Okay. That is a lot of other

1   people.

2   DR. WINKLER: Okay, that is

3   everybody.

4   CO-CHAIR HOMER: That's everybody.

5   Okay.

6   And then, feasibility as part of

7   the national survey.

8   So, how many feel it completely

9   meets?

10   DR. WINKLER: Nine.

11   CO-CHAIR HOMER: Okay. And how

12   many feel it partially meets?

13   Good.

14   All right. Then, to move the

15   question, recommend endorsement of this

16   measure?

17   DR. WINKLER: That's everybody.

18   CO-CHAIR HOMER: Good. So, we got

19   one.

20   Now we have 14 minutes to do

21   medical home, which I think is going to be

22   pretty hard because that is a very complicated

1   measure.

2   (Laughter.)

3   I don't think --

4   MEMBER PARTRIDGE: I wonder if I

5   could raise an issue.

6   CO-CHAIR HOMER: I would rather

7   not, actually.

8   MEMBER PARTRIDGE: Yes, I would

9   like to raise an issue here that might make

10   our discussions a little shorter. That is,

11   and these were my comments on the measure.

12   CO-CHAIR HOMER: The medical home

13   measure?

14   MEMBER PARTRIDGE: The medical

15   home measure. Since this survey was developed

16   and used in the field, the definition of

17   medical home has become multiple definitions.

18   I am not sure, therefore, that this question

19   in quite this form with these characteristics

20   is as timely today as it ought to be. I don't

21   quite know how to deal with that on a

22   procedural basis because CAHMI can't go back

1   and rewrite their survey.

2   But if you put this out as the

3   standalone survey and a practice was graded

4   very highly against this definition, it would

5   not be consistent probably with the Minnesota

6   definition of a medical home or health home.

7   It might not be consistent with the definition

8   that comes out of NCQA, PPC-PCMH, which the

9   revisions will go public next week.

10   CO-CHAIR HOMER: But isn't that a

11   harmonization question?

12   MEMBER PARTRIDGE: It is a

13   harmonization question, and I don't know

14   quite, from a procedural point of view, how to

15   deal with it. I guess maybe we discuss it and

16   deal with it in the harmonization context.

17   CO-CHAIR HOMER: I think we would

18   have to discuss it in the harmonization

19   context.

20   MEMBER PARTRIDGE: And maybe,

21   since we are not going to get to it today --

22   CO-CHAIR HOMER: I just don't

 1   think, in fairness --

 2   MEMBER PARTRIDGE: No.

 3   CO-CHAIR HOMER: -- to the

 4   complexity of this measure --

 5   MEMBER PARTRIDGE: Right. I

 6   wonder if our measure developer might want to

 7   look at that issue a little bit and give us

 8   any further guidance about how completely this

 9   really would be consistent. I don't know.

10   I just worry about conflicting

11   standards out there.

12   CO-CHAIR HOMER: There are really

13   different definitions of what a medical home

14   is.

15   MEMBER PARTRIDGE: There are quite

16   different definitions, yes.

17   CO-CHAIR HOMER: So, the question

18   might be how well this concept maps to the

19   joint principles --

20   MEMBER PARTRIDGE: Yes.

21   CO-CHAIR HOMER: -- that have been

22   adopted by the primary care associations.

1   MEMBER PARTRIDGE: Yes.

2   CO-CHAIR HOMER: As part of that

3   presentation.

4   MR. STUMBO: We are submitting the

5   measure because we would like to create a

6   national standard based on the American

7   Academy of Pediatrics. So, especially in

8   regard to the question of, does Minnesota or

9   Oregon or California, different communities'

10   definitions -- we would actually say that that

11   is the whole reason why the national survey

12   was revised, to measure it across states in a

13   systematic way.

14   CO-CHAIR HOMER: Well, I am quite

15   sympathetic to that, but I do think we need to

16   have a longer conversation. So, I don't think

17   it is fair to do that in 10 minutes.

18   I think I might actually suggest

19   we adjourn 10 minutes early rather than rush

20   through another one in the last --

21   DR. BURSTIN: Right, and it just

22   might be helpful, if you are going to do this

1   measure on a subsequent phone call, perhaps

2   for the measure developer to specifically look

3   towards the updated medical home survey and

4   come back with some responses around

5   harmonization, so we are that much closer.

6   CO-CHAIR WEISS: Right, and as

7   long as we have the measure developer

8   listening, are there any other things, aside

9   from the issue that Lee raised, that we want

10   to put on the table right now for the measure

11   developer to think about?

12   MR. STUMBO: I'm sorry, was that a

13   question?

14   CO-CHAIR WEISS: To this group.

15   CO-CHAIR HOMER: I, for example,

16   would be interested in knowing from the

17   members who sat on the SNAC CHIPRA Committee

18   why this measure basically, which was

19   recommended by me to the Committee to be

20   adopted, why it was turned down, and whether

21   there is anything that the steward could do

22   that would help address any of the concerns

1   that that Committee had. I realize that is a

2   different process and it was using different

3   criteria, but I don't know if there were any

4   specific issues raised that would inform our

5   further conversations.

6   CO-CHAIR WEISS: Well, I think one

7   of the issues that colored all of the

8   conversations had to do with how widely the

9   concept is used in the Medicaid and the CHIP

10   programs currently, and the ease with which

11   states could move to universal application in

12   those programs.

13   CO-CHAIR HOMER: So, the context

14   of the recommendation here, by the way, for

15   the medical home measure is not that these

16   items would be used in a different context,

17   but, really, again, this is more in the

18   context of using the national survey in the

19   way that we are using it on all the other.

20   So, as a measure of population health, okay.

21   MEMBER PARTRIDGE: Yes, it is a

22   population health measure.

1   CO-CHAIR HOMER: It is a

2   population health measure. Okay.

3   MS. McELVEEN: Okay. Well, thank

4   you all for plowing through as much as we

5   could to get the day completed.

6   I can say we certainly

7   accomplished a lot in the past few days. We

8   definitely got through a lot of these

9   measures. Many of them were different

10   measures than what NQF is traditionally

11   considered to be looking at. So, applause and

12   hats off to you all for getting through that

13   information.

14   And also, thank you to Charlie and

15   Marina for leading the discussion over the

16   past few days.

17   So, quickly, next steps: I did a

18   quick count on the tabled measures. There's

19   about seven of them, which in my mind and

20   experience I don't think we can do that on one

21   conference call, even if it is for two hours.

22   So, just thinking out loud right now, I

1 suspect we could possibly have two conference

2 calls coming up.

3 Again, we are going to work really

4 closely with the measure developers to try to

5 really narrow down and get down the exact

6 items and information that you all would need

7 to inform your decision and to expedite the

8 process, of course. But I just want to put

9 that on your radar.

10 Again, we will be following up

11 with a summary from this meeting and get your

12 feedback on that to make sure we have captured

13 your thoughts accurately.

14 Also, following up on your

15 involvement and participation with the CHIPER

16 project.

17 MEMBER JENKINS: What about scope,

18 the unmet needs part?

19 MS. McELVEEN: I'm sorry.

20 MEMBER JENKINS: That part about

21 the unmet, the gaps.

22 MS. McELVEEN: Oh, the gaps, yes,

1   that is a specific deliverable as part of this

2   project. So, we will set aside time to

3   identify gaps as well.

4   DR. WINKLER: We are having the

5   same issue in other parts of the project,

6   getting the measures done. So, a lot of what

7   you talked about, we are capturing and we will

8   probably start drafting some things for you to

9   review and add to, and all of that, as we go

10   along. But our first priority is getting

11   through the measures.

12   DR. BURSTIN: But, as long as it

13   is fresh in your mind, on your plane rides

14   home, or whatever, feel free to write them

15   down and send it to us.

16   DR. WINKLER: Yes, if you've got

17   anything, yes, send them in.

18   DR. BURSTIN: We will start

19   compiling them.

20   DR. WINKLER: Yes, compiling them.

21   MEMBER PARTRIDGE: Nicole, have

22   you got any sense of the timeframe for the

1   conference calls and when you want to get this

2   part completed before we start phase 2?

3   MS. McELVEEN: That is a good

4   question. I was looking at my calendar. I

5   think that, well, probably we will give the

6   measure developers at least two weeks to get

7   this information together and work with them.

8   So, looking at probably the last

9   week of May, first week of June -- this is

10   just, again, off the top of my head -- for a

11   call, factoring in vacation time and then

12   holidays and that sort of thing.

13   So, we will have to really talk

14   about it internally because, on our timeline,

15   we are trying to go out for comment in June.

16   So, we will have to figure out the best way to

17   adjust our timeline and, obviously, meet the

18   needs of the project.

19   CO-CHAIR HOMER: I just wanted to

20   express my appreciation to staff, to Nicole

21   and Reva and your teams, for all the hard work

22   that you did. The materials were excellently

1 presented. You did a superb job. On behalf

2 of the Committee, I want to thank you. We

3 couldn't have gotten as far as we have without

4 all of your hard work and the excellent

5 preparation. So, thank you.

6   (Applause.)

7   All right.

8   MEMBER PERSUAD: I have a

9 housekeeping question. Where do our receipts

10 go again?

11   (Laughter.)

12   MS. McELVEEN: The receipts are

13 sent to Leslie Reader-Thompson. I can forward

14 you her information, yes. The receipts, and

15 I believe there is a form that has to be

16 filled out for reimbursibles.

17   CO-CHAIR HOMER: Thank you very

18 much.

19   (Whereupon, at 2:54 p.m., the

20 proceedings in the above-entitled matter were

21 adjourned.)

22

A

abdomen 18:22
21:2
ability 29:9 41:8
65:3 70:21 100:7
151:15 170:18
180:3 193:4
201:18 203:8
222:10
able 24:11 28:7
55:11 57:8 68:21
71:9,20 72:8 75:6
75:7 79:15 88:12
88:22 99:22
105:15,21 133:18
139:17 143:6
168:21 197:10,13
201:15,22 205:21
209:15 213:20,21
215:17 224:3,5,12
240:5 241:2,12
251:20 257:11
262:3 266:13,19
270:11,15 281:8
283:13 284:8
285:8,15 294:19
327:22 329:17
331:17
above-entitled
352:20
absence 60:19
168:6,12
absolute 118:18
absolutely 57:12
64:9 83:7 96:2
103:18,19 106:7
137:4,16 278:12
abstract 294:19
academic 43:11
148:21 275:6
Academy 325:9
345:7
ACC 139:21
accept 284:21
289:16
acceptability 3:13
3:14 4:4,5,21,22

5:11,12 6:3,14
7:13 34:16 48:18
86:10,15 91:4
95:6 96:9 121:8
143:5,19 144:1,4
189:13,19 190:2,7
226:16,18,20
288:20 290:21
291:1,4 336:5
339:22 340:2
acceptable 214:19
214:21 215:3
acceptance 17:22
accepted 19:4
135:7 204:13
286:15
access 71:1 82:1
100:8 202:6,19,21
219:15,17 220:2
220:11 317:11
323:12,18
accomplished
348:7
account 66:19
239:20 256:13
accounts 157:2
178:20
accrue 69:18
accurate 31:10
53:18 314:14
337:10
accurately 156:7
349:13
achieve 209:15,18
211:14 221:19
achieved 69:14
acid 179:2
acknowledge
303:13
acknowledges
301:5
acknowledgment
165:15
acquired 118:3
across-the 84:3
acted 42:13
actionability 43:17

active 26:21
activities 191:4
actual 20:21 29:22
33:4 88:3 151:2
acute 27:15
AC/PC 2:4
add 67:14 79:10
147:3 196:7 265:1
276:9 350:9
added 49:5 145:1
227:16 244:21
291:17 314:6
340:14
addiction 156:21
adding 50:16 71:22
210:3 323:19
324:1
addition 23:6 36:9
89:17
additional 15:9
21:21 58:8,13
86:9 150:9 151:22
181:10 234:1
289:11 297:21
304:12 305:8
314:4
additionally 197:18
207:5
address 20:4 68:9
83:6 118:12 166:2
167:18 177:7
196:16 203:9
224:13 230:7
296:5 346:22
addressed 32:16
48:14 51:19
112:18 133:5
149:12 177:15
189:20 220:8
addresses 239:22
319:1
addressing 177:6
203:20 207:8
237:7
adequacies 210:16
adequacy 199:20
211:20 213:15,20

213:22 214:15
215:14,18 223:3
adequate 86:21
174:21 196:20
197:3 200:15,16
203:18,21 204:11
210:20 211:1
215:12 217:2
218:13 262:21
321:22 322:3
323:2 329:15
331:1,2,6 333:1
333:18 334:9,21
337:17 339:4,7
adequately 112:18
189:20 201:5,15
adjacent 87:22
adjourn 345:19
adjourned 352:21
adjourning 236:11
adjust 45:17 65:4
134:1,5 261:2
351:17
adjusted 37:2
331:14
adjuster 184:20
adjusting 97:20
adjustment 18:12
86:21 87:3,4
210:2 222:3
230:20
adjustments
156:13 287:3
admin 52:9,13
administering
285:14
administrative
18:7 38:10,17
47:19 53:13,21
55:20 57:10 67:9
70:22 72:5 74:12
104:6 107:22
108:14 190:16,20
193:3 212:17
admission 35:2
52:10 53:6 73:22
244:1 251:15

admissions 28:10
28:13,16 74:16
240:3
admitted 39:21
178:16
admitting 49:22
adolescence 250:8
adolescent 242:11
248:19 249:8
281:6,9,13
adolescents 7:5
222:13 249:13,18
256:19 279:20
281:7 307:17
322:20 325:2,5
adopt 138:3 139:15
adopted 122:18
123:5 140:1
344:22 346:20
adoption 137:7
adult 83:20 85:7
100:16 114:11
116:1,6,19 118:5
120:8,16 195:15
195:21 196:4
204:21 212:10,13
212:17 215:2
217:13 220:21
221:11 224:19
227:18 229:13
231:15 269:22
270:1 271:3
300:18 303:3
adults 4:14 83:17
84:5 110:16 111:5
113:13,16,16
114:3,18 115:1,11
117:12,18 119:2
120:17 163:12
212:8 232:7 271:9
300:21
adult-only 269:8
advance 187:3
advantage 172:6
184:14
advantages 233:1
advent 161:12

adverse 4:13
110:15,19 113:3
117:4 121:11,12
121:12 122:4,17
124:5,9,16 134:11
135:22 136:1,17
139:3,7,16 140:22
141:7,13,16 142:3
142:17 146:16
155:13
advice 303:2
Advisor 10:8
advocates 300:21
Affairs 9:10
affect 20:18 86:20
180:3 260:22
afford 165:9
afraid 151:12
African-American
164:18,19 165:19
African-America...
70:14
age 35:7 36:4 64:2
75:4 78:13 84:21
99:4 114:8 115:20
117:3 146:12,12
146:13 150:11
161:11 194:19
213:1 221:4 222:2
222:3 229:22
230:8,19,20
231:15 233:2
315:5
agenda 10:4
agents 203:14
ages 279:16
aggressively 180:1
ago 116:9 135:3
195:13 221:1
254:7 265:4
agree 37:13 72:14
138:6 147:6 171:9
177:5 210:13
211:16 223:4
263:16 286:6
310:7
agreed 15:19

agreeing 284:16
agreement 141:10
305:9
agreements 295:12
aha 278:15,16
ahead 16:13 26:17
95:6 96:8 98:18
153:1 236:7
260:11 274:22
282:5 284:9 294:5
AHRQ 28:8 41:5,7
41:14,19 62:15
157:12 166:22
170:15 174:15
257:1,19 270:16
284:6 302:4
305:16,18
airway 238:2
Akron 184:6
Al 120:5
algorithm 135:20
330:18 335:2
aligned 212:13
269:16
Allan 2:6 11:2
102:5 117:6
177:16 256:14
299:6
allow 11:20 13:7
14:17 53:8 67:9
74:15 83:10 98:9
185:18 195:3
205:4 219:21
242:2 276:10
allowed 203:1
allowing 41:13
125:18 154:9
allows 170:17,19
187:19 286:21
335:12
alluded 98:8
199:16
alpha 240:13
250:19
alter 245:4
alternatively 222:2
always/sometimes

273:5
AMA 13:16 194:9
194:13
amazed 272:14
amazing 95:13
ambulatory 47:12
93:11
amenable 45:14
amend 82:20
amenities 310:12
American 13:3
70:14 325:9 345:6
amount 50:6
111:10 114:3
144:19 163:6
178:15 179:11
189:14 190:13
analogous 83:15
analyses 45:1
147:18,20 151:22
258:4
analysis 29:6 35:17
68:16 77:20 98:4
103:11 129:9,15
141:21 151:14
206:18 251:12
256:1,2,10 298:6
analyze 108:10
141:22 266:13
anatomic 127:6
and/or 329:18
anesthesia 93:12
93:12 106:5
125:12
anesthesiologists
100:7,8
angle 20:22 80:21
Annals 90:10 91:1
97:14
annually 28:15
anomalies 156:18
178:21 179:4
anomalous 114:11
114:13
anomaly 161:10,20
178:14
answer 79:20 94:4

100:10 105:16,21
118:11 124:3
140:13 243:1
260:19 286:1
287:15 293:12,20
answered 56:19
answering 98:6
answers 103:21
283:14
antibiotics 21:11
22:21 179:18
180:8,11
anticipate 81:16
180:20 286:16
Antman 2:10 13:15
13:15
anxious 90:7
anybody 13:17
99:8 112:15
116:10 137:17
148:2 290:5
anyway 124:13
203:15
aortic 127:15,16
Apgar 181:15,16
apologize 308:4
appalled 239:8
apparently 72:19
73:4
appear 180:2
262:15
appears 104:16
216:22
appendectomies
55:10
appendectomy
55:11
applaud 267:5
applause 348:11
352:6
apples-to-apples
166:13
applicability 47:20
109:20
applicable 155:14
255:7,20 257:16
application 72:17

73:8 76:17 251:10
304:20 347:11
applied 35:15
40:19 52:3 82:14
82:17 117:22
143:10 169:16
298:14
apply 35:3 43:8
118:10,20 134:7,8
139:17 142:16
148:22 257:19
appreciation
306:13 351:20
approach 19:6 30:4
242:13,21
appropriate 14:3
15:20 37:9 77:9
191:16
appropriately
41:22 47:9 67:11
145:17
appropriateness
318:8
approval 58:8 59:1
59:2 146:20
290:14 301:22
302:1
approve 19:14
61:12 106:15
118:14
approved 157:12
area 19:19 31:6
40:8 85:19,21
87:6 88:20 89:3
89:13 95:16
112:12 132:17
190:11 262:11,11
296:12
areas 19:11,12
58:12 122:18
223:22 247:5
276:11 281:1,2
300:4
arena 183:19
argue 323:9,10
332:5
argued 25:17

beautifully 124:4
becoming 112:19
bedside 93:9
began 132:15
beginning 88:8
154:13
behalf 280:15
306:11 352:1
behavioral 7:8
believe 21:7 26:21
56:21 89:4,13
99:1 114:9 121:2
138:4 140:10
174:6 184:14
189:6 226:8,12,17
227:1 228:2,5,19
228:22 288:8
292:2 296:18
297:6,9,11 322:15
329:7 330:5
334:18,20 340:9
340:20 352:15
below-average
155:7
benchmarked
42:11
benchmarking
29:7 52:7 239:12
benefit 181:10
329:19
benefits 322:7
332:18 335:10
Bergersen 2:11
4:16 12:9,9
110:21,22 113:18
113:22 114:16
115:7,11 116:16
117:5 118:1,21
119:5,9,17,20
120:10 121:15,18
124:18 126:10,16
128:4,17 129:19
130:13 131:12
133:8,11 138:22
140:12 142:6
148:13 151:21
152:4

Berry 2:12 3:9
11:22,22 17:3,6
19:16 20:5 22:6
24:20 25:16 27:21
29:10,14 30:3
32:16 33:1,18
35:21 37:19,21
38:8 40:1,17 41:3
42:6 43:4,14
44:22 45:20 49:14
52:4,21 53:15,20
54:9 57:11 59:5
62:14,19 63:11
263:10 264:21
best 18:10 37:3
45:8 88:18 158:21
201:13 214:3
301:16 351:16
bet 71:10
better 33:16 36:14
43:19 44:4 61:2
97:21 98:9 100:3
102:2 116:10
142:22 169:21
186:14 202:20
205:4,12 219:17
220:2 238:4 281:1
281:3 300:7,12
311:13 316:12,15
333:10
beyond 20:15 41:4
57:12 58:11 78:2
89:21 148:2
163:19 247:9
267:9
bias 141:11 241:13
260:14 269:7
293:20 332:13
336:13,17 337:4
bifida 18:20 35:8
36:20 37:1,5,18
big 23:4 32:3 126:8
166:15 176:9,9,21
184:13 192:6
205:9 219:5 279:3
279:4 296:22
bigger 170:20

biggest 178:13
182:20 192:5
bilirubin 162:3,6
bill 52:12
billing 53:21
bimonthly 141:5
biopsies 92:4
biostatistician 12:5
bipolar 320:10
birth 153:16
157:13 158:2,4,5
159:9,12 160:22
161:1 162:13,15
164:4 165:22
166:3,7,10,21
179:7 182:22
births 153:14
157:18 160:21
165:22 174:10
176:16 177:1
185:16
bit 16:9 18:19
21:15,20 23:18
24:11 26:2 70:5
71:21 78:9 80:15
82:20 86:8 89:15
121:10 142:21
143:13 147:15
171:5 176:1
185:12 195:5
213:5 216:15
218:11 237:4
246:12 247:9
261:18 265:1
267:13,15,20,22
283:7 306:2
310:16 319:8
330:13 333:4
335:7 344:7
bivariate 45:1
Blacks 45:2
blah 50:2,2,2
blanked 59:17
blighted 312:15
blood 200:8 201:13
201:14 202:8,12
219:1 220:3,4

223:8 277:15
bluntly 124:6
149:10
board 11:11 84:4
143:11
boards 272:6
body 199:18 232:9
Bonnie 2:10 10:14
257:21 315:20
borderline 175:8
born 168:22 177:9
186:9
Bossley 2:18 11:15
11:15 46:2
Boston 9:22 12:2,4
12:8,11,16,19
24:18 25:2 62:9
136:16 238:12
252:14 255:8
283:20 287:11
306:13
bottom 90:9 101:10
217:9
bought 39:2
boy 57:11
brachial 167:1
174:15,22 175:6
brain 21:1 22:15
28:5 337:12
bread-and-butter
17:11
break 110:11,12
152:15,18 153:4
236:7
breathing 237:14
brief 195:8 236:7
238:19 287:7,8
290:11 308:2
328:18,18
briefly 11:21 64:10
199:16 268:12
Brigham 116:5
270:2
bring 127:8,14
128:5 235:4
268:19 304:15
bringing 202:4

brings 112:22
broad 30:9 31:11
32:2,2,11 86:18
96:3 177:13
broadcast 15:4
broader 65:17,18
81:13 128:20
322:13
broadly 32:12 43:9
63:9 149:1
broken 21:4 206:3
bronchitis 237:22
brought 17:18
84:10 151:14
334:16
brush 177:13
bucket 91:18
323:15
building 1:20 63:2
built 18:16
bullying 309:17
burden 240:15
297:3
Bureau 329:2
Burstin 2:19 11:7,7
16:6 31:21 48:1
58:19 61:18 84:10
90:5,14,19 116:4
147:14 151:13
212:2,3,19 213:6
225:15 231:16
235:5,12 268:11
268:22 269:1,7,11
271:2,19 272:12
272:18 273:4,17
273:22 290:8
298:1,5 301:1,13
302:2,6,17 303:22
305:1,14 326:1
328:3 345:21
350:12,18
bus 126:4
butchered 195:4
buy 184:9
buy-in 142:9
buzz 50:3
byproduct 145:15

228:17 292:10

C

C 88:19
caesarean 172:9,10
172:13 180:19
CAHMI 14:20,21
307:7 342:22
CAHPS 250:22
269:4 272:20
274:2 282:19,21
291:16 301:2,5,21
305:22
calcium 165:9
calculate 142:17
244:14 261:5
calculated 240:12
241:2 244:10
calculation 173:6
335:2
calendar 194:18
351:4
California 11:4
154:21 155:21
163:3,11 179:15
181:7,14 190:18
261:20 345:9
call 3:2 14:2,6 51:7
57:21 58:5 150:6
152:9,13 184:16
184:17,19 193:10
216:8 239:5 263:1
264:17 288:7
289:6 304:5
307:11 308:18
312:10 314:22
346:1 348:21
351:11
called 13:8,13
127:3 139:21
calling 15:2 61:21
152:7
calls 349:2 351:1
campers 260:15,18
260:19
candidate 219:17
capability 62:11

292:14
capacity 323:13
capture 13:22
39:20 63:12 114:1
114:4 127:21
198:3 205:22
captured 124:21
125:14 349:12
captures 40:3
capturing 124:14
155:17 170:5
350:7
cardiac 4:14 9:18
33:15,20 91:17
95:9 100:16
101:16 110:16
111:4,7 113:2
116:6 117:9,11,14
117:16 120:2,6,8
120:14 121:20
123:6,17 134:12
135:11 139:10,20
149:2
cardio 122:11
cardiologist 9:21
120:2,4 320:6
cardiologists
120:16 132:3
cardiology 55:8
cardiovascular
55:7
care 5:21 6:25 9:14
19:5 22:3 27:5
29:17 40:10 43:19
44:7 54:18 80:9
82:2 106:3,4,5
112:4 116:6 130:4
142:14 145:15
153:17 154:13,17
154:17,18,22
155:15 156:17
158:13,13,14
161:2 162:9
164:12 166:7
170:6 171:4,10
174:8,22 183:6
188:1 194:16

195:1 196:17
199:1,7,9 202:6,7
203:2,19 205:2,12
206:6 207:6,12,18
207:22 210:18,19
213:16,22 215:21
216:3,12 217:3,18
218:7,8,13,15,16
218:19,22 219:19
219:21 221:11
223:17 224:3,17
224:20 228:17
231:17,19 236:3
239:15 240:3
241:9,15 244:2
245:11 246:13,14
246:18 247:3
249:5,8,9 262:8
263:6,20 264:6,22
265:22 267:11
271:3,4,13 272:16
272:21 277:16
280:15 286:8
292:10 293:3,6
294:2,10,21 295:3
295:16 315:4
317:19 319:21
320:1,21 321:5,12
325:6 326:20
327:18 344:22
careful 141:21
carefully 174:14
265:12
carry 133:2
carrying 133:6
cartridge 200:8
case 10:12 69:22
70:6,8 75:16 89:8
89:14 114:3,5
115:13 127:19
176:4 213:11
216:15 233:6
263:17
cases 66:11,12,14
66:15,19 68:12
72:21,21 79:15
120:1 123:22

129:5 132:13
133:20,21 175:8
178:20 180:10
case-mix 18:12
134:5,14
catch 340:6
categories 67:3
87:9,17,22 89:2,6
89:18,21 94:1,11
105:5 122:3,6
136:15 140:16
183:17 192:5,6
241:15 269:16
271:6 273:5
282:13 286:2
categorization 96:4
135:22 215:7
categorizes 140:4
category 73:12
88:14,16 93:14,21
94:2,13 102:15
103:7,8 135:2
141:1,2 270:6,13
317:10 318:11
cath 116:9 119:1
120:3,6,9,14
128:3,5,12 139:20
catheter 127:17
201:3,12,14
catheterization
4:14 92:6 110:16
111:4,8,15 116:1
117:9,11,14
119:22 121:20
123:18 127:9,15
128:8 134:13
135:11
catheterizations
149:2
catheterize 115:12
127:4
catheterized 115:9
133:15
catheters 128:7
201:9 208:12
caths 117:16
Caucasian 164:21

Caucus 334:15
caught 262:6
cause 22:1 175:21
177:22
caveat 290:2
ceiling 240:20
252:17 253:11
ceilings 270:9
cells 206:4
center 9:8 10:22
13:2 40:11 176:6
209:8 223:20
275:6
centers 223:18
central 24:12,14
135:4,9
centralize 139:22
CEO 8:19
cerebral 21:6
certain 42:14 72:6
75:5 76:6 84:16
92:11 103:10
232:6 239:19
240:12 242:15
276:11
certainly 45:13
47:10 64:18 72:13
84:8 98:4 136:8
214:2,4 219:10
223:7 224:1
268:13 318:6,9
348:6
certified 207:16,20
cetera 21:12 38:6
39:9 42:20 53:8
64:17 70:15 104:7
104:7 110:2 156:6
191:5 240:7
251:13 337:20
Chair 304:10
Chairman 78:1
Chair's 287:6
challenge 18:5
60:12 68:12 69:1
72:5 138:8
challenges 159:20
173:18 222:1

challenging 226:2
296:22
champion 56:14
chance 271:18
change 16:10 19:5
29:17,17 82:1,5
98:10 118:15
119:22 129:17
132:8 185:14
197:21 202:6,8,18
203:3,3,5,6 206:8
210:21 253:11
268:19 270:11,13
270:15 285:11
287:18 295:19
changed 51:1
187:14 285:13
changes 29:9 31:2
76:18 146:9,11
147:16 174:7
191:14 296:12
changing 31:12
44:6,7 202:8
219:15 265:13
characteristics
83:1 201:3,3
250:18 330:12
342:19
Charles 1:21 2:2
3:3
Charlie 8:19 42:7
59:7 85:2 143:8
150:14 198:4
218:6 289:13
290:8 303:22
311:18 348:14
chart 38:5 42:10,18
charts 159:21
160:2
chat 153:5
CHCA 58:12 97:5
239:3 241:19
254:6,7 285:1
check 144:10
checklist 60:21,22
319:10,12
checklists 24:18,20

24:21 25:3
chest 128:15
Chief 9:13,22
child 1:7 10:12,15
15:17 22:18 23:16
24:1,2 35:21
39:21 50:17 62:8
74:4 77:17 99:13
104:15 112:2
118:5 243:6 244:5
244:6 245:5
247:22 249:16,20
262:22 263:5,18
265:13 275:21
279:3 280:11,13
280:13 281:2,3
306:12 309:2
311:22 313:15
316:3 317:16
318:4 322:5
326:12,16 329:2,8
331:6 332:17
335:12 337:16
339:5,8
children 3:8 4:14
6:22,25 7:2,5,7,9
14:11,12,13 15:21
17:14,17 22:4
23:21 24:5 28:12
35:6,7 37:5,17
40:22 59:18 65:7
66:2 67:22 71:14
72:3 77:15 78:4
80:2,4 99:3
110:15 111:5,13
112:8 114:8
117:12 119:2
168:22 204:2
213:1 220:11
221:3 222:9,11,16
223:2,6,10 224:20
256:18 264:13
265:22 279:3,4,7
279:16 280:8
300:21 307:17
308:12 309:5
311:11 312:16

313:10 315:3,5
320:17 321:21
325:2,4 329:11
338:3,17,22
339:16
children's 8:20 9:7
9:10,18,22 10:22
12:1,4,7,10,16,19
17:9 26:21 41:1
48:3 53:1 62:9
100:4,5 116:9
117:10 136:16
137:13 218:6
238:11,12 239:2
252:14 255:8
256:20 269:20
276:7 283:21
284:14 287:11,13
299:5,8,9,12
300:9 306:13
322:7
child's 258:20
281:20 287:14
308:15 309:20
322:3 329:19
332:19 335:11
CHIP 347:9
CHIPER 349:15
CHIPRA 346:17
choice 78:22 79:5
322:6
choose 155:18
286:6
choosing 175:7
chose 30:6 66:7
111:18 168:15
chosen 74:13
156:15
chronic 196:13
264:13
chronically 201:8
221:4
circle 37:4
circumcision 92:8
circumscribed 39:6
circumstances
66:11

City 11:3
claims 77:21
233:21
clarification 78:9
clarifications 14:18
clarifies 280:6
clarify 102:22
141:13 198:16
223:16
clarifying 150:10
150:17
clarity 122:2
Clarke 2:3 9:17,17
27:11 34:19 43:6
54:5 72:13 73:6
73:14,19 76:14,16
77:3 95:22 112:17
125:17 126:14
127:22 128:14,19
129:14 138:20
141:12 146:15
147:6 150:3
158:20
class 301:16
classes 101:10
classification
141:11
classifications
123:15 132:9
classified 151:17
Claudia 41:14
clavicle 167:2
cleaner 60:1
clear 73:7 77:7
131:1 138:15
139:13 163:16
165:1 281:8 293:8
295:21
clearer 120:11
clearing 199:18
clearly 122:12
162:7 164:11
206:8 210:11,19
211:18 222:11
226:1 280:17
292:10 317:15
327:7,16

City 11:3
Cleveland 10:13
climate 261:10
climb 20:16
clinic 17:13
clinical 12:15 16:8
21:15 28:21 57:13
57:16 75:14,19
85:19,21 89:19
104:17 114:12
122:8 224:9
241:16
clinically 18:6
19:19 31:6,9,15
111:17 125:13
clinically-import...
110:18 111:22
clinicians 136:22
138:3 170:6,12
clipping 93:9
close 169:5 232:13
232:17 331:18
closed 92:1,4,4
closely 197:11
349:4
closer 25:20 48:2
346:5
CMS 233:3,5,6,11
coats 276:2
code 39:4,7 123:6
130:11 139:10
155:18 156:3
182:21
coded 91:11,13
156:6
codes 18:9 39:3,8
39:11,12 41:5,22
57:13 155:17
156:9,9 158:3
159:19,21,22
160:5,6 166:20
167:3 182:13
183:15
coding 42:20 53:22
91:8,10 123:14
155:21 157:19
212:17
cognitive 294:17

330:15
cohort 37:1 41:20
44:4 77:21
collaboration
239:2
collaborative 54:12
57:1 60:7,9 61:1
63:10 149:13
154:22 155:2
190:22 235:16
collaboratives 55:5
collaborators
54:14
collapse 88:2
colleagues 97:4
collect 29:12
107:17 108:9
129:7,20 130:14
139:7 193:4 235:3
247:12,14 255:15
255:16 266:18
collected 141:14
142:15 254:16
collecting 38:13
56:5 85:10 122:4
122:16 123:10,13
123:19 125:1
139:3 184:15
collection 54:17
56:8 108:16
124:16 129:1
135:22 139:16
140:1 205:1
collectively 70:12
70:17
colored 347:7
combination 71:18
197:22 225:8
318:15
combine 66:4
combined 198:18
combining 105:4
come 29:5 39:19
40:3,10,16 46:18
61:2,8 71:15
84:12 130:16
141:9 147:1 150:1

153:3 162:2
172:15 174:1
215:10 236:9
259:7,20 277:15
287:21 290:18
314:21,21 326:15
331:18 346:4
comes 69:5 107:21
138:8 142:13
173:12,14 297:15
327:10 343:8
comfort 90:15
comfortable 23:14
38:19 62:19
143:13 246:20
300:1
comfortably
323:15
comforting 137:6
coming 8:8 40:14
106:22 108:13
150:12 161:8,17
164:1 305:4 306:4
349:2
comment 27:20
31:21 35:6,20
55:4 67:21 74:7
95:9 96:1 106:10
112:11 126:18
132:12 151:4
158:21 159:5
183:22 223:12
230:5 260:9
311:19 331:21
336:20 351:15
commented 165:6
commenter 329:6
commenting 165:5
comments 16:5,15
19:10 34:18 49:6
59:8 64:14 76:18
76:20 91:5 95:7
112:13,14 113:12
131:15 151:20
152:1 154:4,8
189:16 247:11
308:11 328:18

330:14 342:11
Commission 158:8
185:2
committee 1:7,17
8:8,16,22 13:12
14:2 15:19 16:15
27:12 34:7,17
47:12 84:18 86:14
92:17 112:15
113:9 136:8 161:6
186:18 235:12
250:11 297:21
302:12 346:17,19
347:1 352:2
Committee's
113:12
common 19:20
95:20 141:6 233:5
260:16
commonality 20:6
communicate
190:14
communicating
104:10
communication
243:22 245:15
communities 14:14
309:5 310:19,19
311:19 345:9
community 33:9
41:20 96:21 97:12
97:17,18 111:3,21
112:6 123:7 131:2
131:17 143:1
262:12 300:3
306:12 310:10,21
312:5 313:5
339:12,17
company 106:12
comparability
131:10 290:7
291:16
comparative 101:9
283:16 292:6
302:14 332:2
compare 93:22
166:16 170:18

245:2 254:9
255:16 285:8,13
286:22
compared 38:4
43:2 45:3 52:18
134:11 245:7
283:21 314:4
comparing 97:2
143:17
comparison 166:13
169:3 300:17
compelling 188:22
compendium 91:20
competency 50:9
competing 301:17
compiled 16:14
compiling 350:19
350:20
complementary
187:18
complete 51:15
158:22 204:7
327:22
completed 348:5
351:2
completely 30:7
31:5,20 48:19
51:8 57:22 96:11
107:6 109:10
138:14 143:22
145:2,19 190:6
192:16 193:6
226:17 228:3,19
244:13 261:11
263:16 269:4
271:1 280:2
290:22 291:21
296:19 297:7
317:20 340:1,18
341:8 344:8
completion 23:11
complex 206:17,18
243:7 264:22
287:19
complexity 134:5
134:14 241:15
344:4

complicated 36:10
134:15 209:2
293:16 341:22
complication 135:8
160:22
complications 22:1
84:19 123:2,8
153:16 154:14
161:1 163:21
166:6 167:4,6
173:11 188:4,13
188:16 192:12
component 182:20
237:22 333:9
components 192:3
218:7 227:22
296:20 322:8
325:8 332:15
334:10
composite 182:19
209:1,2 225:16
243:17 244:14,20
251:20 325:3
composites 84:15
244:10
compressed 278:8
compromise
303:14
computer 16:13
267:3
concept 47:20
137:7 234:3 288:5
293:15 344:18
347:9
concepts 171:13
conceptually
277:18
concern 32:15
35:10 76:22 91:7
114:21 204:1
concerned 30:19
100:20 135:1
141:19 204:3
231:7 232:7 249:3
289:1,3 294:6
concerns 29:3
67:20 74:20 91:10

102:19 107:17
147:21 148:19
171:18 260:18
315:21 346:22
conclusions 331:5
concur 26:19
309:11
condition 15:22
93:3 126:20 127:2
128:10 164:6
315:6 316:3
320:17,21
conditional 59:1
146:20 193:12
234:13 290:13
298:19,20
conditionally
298:12
conditions 31:11
80:5 86:19 90:1
118:15 146:7,9,10
148:10 162:11,14
164:13 168:6
229:14,15,18,20
229:22 234:6,9
264:13 266:15
298:2,5 304:18
condition-specific
84:14
conducting 29:6
conduit 115:17
conference 13:7
14:1 150:6 304:5
314:22 348:21
349:1 351:1
confidence 8:10
29:15 50:22 70:7
94:19 109:22
226:4
confident 264:16
confine 117:13
316:5
conflicting 344:10
conflicts 313:16
confuse 132:10
confused 78:21
176:13 337:13

338:19
confusing 30:22
31:2
confusion 165:17
congenital 4:14
65:22 98:1 110:17
111:5 113:19
114:14 115:3
117:19 118:3,4,9
119:2 120:14,17
120:17 123:17
129:6 139:20
161:10,20
Congratulations
193:20
connected 316:3
consensus 1:3
130:16 141:9
consequence 122:8
336:16 337:8
consequences
179:9
consider 18:3
24:13 61:12 96:10
125:4,10 131:3
150:5 203:4
209:12 214:19
246:4 281:10
309:7 316:7,9
considerable 69:2
69:11 99:16
considered 15:13
27:22 30:14 33:7
35:10 61:15 88:6
89:5 90:1 120:8
143:10 253:16
317:2 348:11
considering 26:11
283:12
consistency 149:8
314:10 327:4
consistency's
314:11
consistent 214:3
215:5 233:8
287:16 297:5
343:5,7 344:9

constitutes 204:6
construct 281:5
288:5
consult 24:4
consumer 98:21
160:17 262:12
consumers 100:20
101:6 104:11
292:21
contact 257:2
contacting 284:6,7
contend 288:21
context 79:18 98:6
144:19 149:13
309:4 322:11
343:16,19 347:13
347:16,18
continue 208:5
235:3 289:21
continued 4:17
5:14 31:18
contract 265:6
contrast 245:2
contribute 76:18
89:19 90:3
contributed 191:3
191:4
contribution
176:17
control 303:18
controlling 45:5
Cont'd 4:1 5:1 6:1
7:1
convened 1:17
conversation 63:2
64:13 76:2,3 97:3
188:20 189:14
211:14 287:21
314:13 321:19
324:11 328:1
345:16
conversations
215:6 299:12
321:9 347:5,8
convinced 309:9
convinces 261:12
cooperation 299:5

coordinated 54:3
coordination 240:3
244:3 246:13,14
247:4 262:8
copy 92:17 248:7
core 50:9 55:18
70:20 276:8
coronary 114:11
114:13
correct 52:3,4
53:14,15 69:13
73:18 82:10
100:18 102:11
117:5 170:8,10
174:8 208:21
212:6 237:11
247:7 256:4 277:4
277:20 281:19,22
299:14
corrective 132:21
correctly 24:15
98:20 283:9
correlate 266:20
311:20
correlated 38:17
311:21 314:2,5
correlates 183:14
correlation 246:7
313:21
cost 27:18 28:12
costs 332:16
coughing 238:6
count 76:21 128:16
348:18
counted 36:3
counterparts
164:22
countervailing
188:11
counting 179:8
countries 159:8
country 18:1 33:6
36:7 41:6 52:9
53:2 95:11 105:14
119:1 179:14
196:12 197:12
210:9 220:12

247:3 265:11
couple 19:17 24:17
34:19 75:11 186:3
321:9
course 22:21
100:15 101:6,15
165:18 176:5,17
199:19 240:4
244:17 287:15
320:11 328:6
331:15 336:9
349:8
cover 8:6 54:7
325:18 335:21
coverage 7:3,10
197:9 321:22
322:3,19 323:2
329:8,13,16 331:1
331:2 334:9,21
335:20,21 339:9
covered 166:1
233:2,17,18
covers 335:10
337:18
co-chair 2:2,2 3:3
8:3,21 15:1 17:1,4
19:8 21:17 24:7
26:13 27:10 28:17
29:13 30:2,16
33:12,22 34:14
38:2 39:13 40:15
40:18 42:1,22
43:5 44:16 45:15
45:21 47:8 48:10
51:4,17 54:22
57:2,19 58:14,17
58:22 59:10,15
60:6,11 61:4,9
62:5,18 63:1,12
63:15 64:6,10,20
67:12,15 69:5
70:9 71:11 72:12
76:1,12,15,20
77:10 78:6 79:19
79:22 81:6 82:6
83:13 84:7 85:5
85:12 87:1 89:9

91:3,15 92:19
93:16 94:6,12,15
94:22 96:7,13,17
98:16 101:3 102:5
104:2 106:8 107:3
107:11 109:7,14
110:8 112:9 113:7
114:10 115:8
116:14 117:6
118:17 119:4,8,12
119:18 120:21
121:16 124:1
125:15 129:11
130:9 131:4
134:20 135:17
136:12 138:6
140:2 143:2,18
144:7,13,16 145:7
145:11 146:2,10
146:18 147:3,12
148:18 150:7,17
150:21 151:3,8
152:3,6 158:17
160:11 161:4,16
162:17 163:14
168:2 172:7,8
173:8 175:13,18
176:11 177:4
180:14 182:9
183:12,20 188:3,9
189:10 190:21
191:19 192:14,18
192:21 193:9,19
193:22 194:6,14
198:4 199:11
200:12 208:19
212:1 214:10
215:4,19,22 216:4
217:6,14 218:1
221:16 223:12
225:1,7,13,20
226:11 227:1,5,10
228:8,12,15 229:3
229:6,9,19 230:4
230:11 231:10,12
232:21 234:4,12
234:15 235:11,15

236:5 237:3 238:7
238:10 243:13
244:9,15 245:1,21
246:10 248:2,10
250:10 251:16
252:1 256:14
257:21 261:14
262:5,18 264:11
265:16 266:21
268:9 273:7 274:9
274:12 279:5,10
282:2,6,11,18,22
283:11,15,18,20
287:5 288:15,19
290:2,16 292:17
294:13 295:5
296:14 298:4,7
299:7,15,21
301:20 302:5,10
302:20 303:17
304:8 305:3,17
306:8,17,22 310:2
310:6,12,20 311:6
312:2,7,11 313:20
314:3,9,20 315:9
315:20 316:5,16
316:20 317:5
318:9 319:11,20
320:14 321:7,11
321:17 322:9
323:5 324:7,18
325:12,16 326:8,9
327:3,11,17 328:4
328:8,12,14
329:22 330:8
331:10,11 333:22
335:18 336:2,9
337:15,22 338:8
338:18 339:2,10
340:8 341:4,11,18
342:6,12 343:10
343:17,22 344:3
344:12,17,21
345:2,14 346:6,14
346:15 347:6,13
348:1 351:19
352:17

Co-Chairs 1:22
co-management
23:5,18
CPAC 196:1
CPM 206:2
CPNP 2:4
CPR 122:13 127:11
Craig 2:14 3:23
12:6
crawling 288:15
create 61:20 222:2
345:5
created 36:22 50:3
87:3 257:19
creating 219:10
creation 54:11
creative 202:17
credibility 64:17
credit 42:5
crisis 317:18
crisper 304:14
criteria 19:13
31:22 34:8,15
46:5 47:10 48:11
48:19,21 51:9
58:1 73:20 86:2,5
96:11 107:4,7,9
107:13 109:11
120:22 121:1,3
138:12 143:9,22
144:3,8 145:3,5,8
145:20,21 150:12
158:2 190:6
192:15,16 193:7
215:11 225:22
226:9,13,17,20
227:2,14 228:3,6
228:9 276:16
290:22 291:4,6,21
292:1,3 296:19
297:7,10,12 305:4
327:6 334:6,13
337:18 338:7
339:7 340:1,5,19
347:3
criterion 143:20
critical 177:5,6

207:7 315:16
critically 208:12
criticize 270:16
Cronbach 240:12
250:19
cross 127:16
crosses 27:8 265:21
CT 156:6
cue 63:6
cull 45:8
cure 179:4 320:21
curious 162:22
current 235:21
248:13 254:10,16
255:3 256:10
322:2 329:12
335:10,11 338:3
339:9
currently 76:11,13
123:12 257:4
266:17 326:11
347:10
curtain 257:7
curve 32:9 68:18
68:20,20 77:14
87:6,7 88:20 89:4
89:13 95:16
cut 70:19
cutpoints 88:18
C-O-N-T-E-N-T-S
3:1 4:1 5:1 6:1
7:1
C-section 155:10
174:18 175:19,21
181:5,17 182:11
184:5,7,16,18,21
185:13 186:4,19
186:22 187:3,7,13
187:15 188:2,12
188:17 191:8
C-sections 167:7
181:5,11 185:6
186:2 187:20
C3PO 130:21
131:5 140:14
149:14

D

daily 15:22
Dallas 9:5
dance 26:3
danger 187:4
data 18:7 26:22
28:8,19 30:18,18
33:2,3 35:16 38:5
38:5,10,17,22
40:2,16,20 41:5,7
41:16,19 42:13
43:2,7,16,17,22
44:1 47:15,19
52:5,10,13 53:9
53:13,18 54:17,20
55:20,21 56:5,7
56:16,18,20 57:9
57:10 60:5 62:16
68:6 69:22 70:6
70:12,15 71:2,3,4
71:21 74:2,11
79:1 82:12,16,21
82:22 85:9 87:18
95:14 100:21
101:3,9,11 102:21
104:5,9,13 105:2
108:4,10,13,16
110:1 121:14
123:13,19 124:16
125:1 129:1,8,12
129:13,16,20
130:12,14 131:5
132:5 135:21
139:22 141:22
145:14 148:16
151:15 155:17
160:3 164:16
172:14 182:1
190:16,20 191:22
192:2 193:3
197:13 204:22
205:22 206:14
228:16 230:12
232:15 235:4
240:9,20 241:11
241:12,13,20
243:3,9,10 247:12

247:14 253:10
254:15 255:15,16
256:8,12 261:1,2
266:11,13,17
273:11 280:21
283:16 292:6,10
292:20 293:1
295:22 296:22
297:21 302:1,12
302:14
database 35:15
40:16 41:2 51:21
52:20,21,22 53:21
54:7 59:22 60:13
61:20 63:6 66:8
66:22 67:9 70:5
70:22 74:12,15
75:6 79:11 82:15
83:9,10 88:12
103:4,6 108:13
129:6,7 130:1
233:21
databases 52:16
53:18 62:22 72:6
107:22
dataset 45:19 54:4
58:12 87:10,11,13
89:12 108:2,14
123:20 124:19
130:21,22 204:18
datasets 196:19
data-based 108:8
data-gathering
34:22
date 61:19 97:22
147:2 150:2
David 2:3 9:17
27:10 28:18 72:12
76:15 112:16
125:16 146:14
158:19
David's 74:21
day 57:18 137:3
161:11 348:5
days 14:11 20:9,15
25:10,11,15,22
26:9 32:10 36:1,2

36:17 64:2 65:21
74:1,5 99:4 126:3
251:2 269:12
348:7,16
Day's 3:5
DDS 2:10
deal 15:4 22:22
23:4 26:16 101:5
163:17 177:18
278:2 314:16
318:18 342:21
343:15,16
dealing 69:16
179:7 223:5
256:20 315:17
death 28:2,2 73:21
73:22 91:10
122:15 128:2
deaths 77:17 88:14
88:15 93:18,22
94:9
debated 174:10
186:18 331:12
decade 100:18
116:5,9 156:3
decide 46:13
100:22 105:8
129:15 268:14
295:2 327:12
decided 188:6
225:5
decision 104:21
136:5 147:19
274:18 287:22
349:7
decisions 104:6,6
decrease 50:13
51:2 233:11
decreases 50:20
decreasing 43:20
deep 47:21
deeper 329:10
deeply 121:9
defect 166:10
defer 302:18 305:8
321:17
deferred 6:21

deferring 321:8
define 123:1 318:1
defined 121:11
124:12 126:19
defining 113:15
325:10
definitely 250:3
251:11 283:3
284:1 295:18
324:9 348:8
definition 117:13
132:7 147:5 174:5
176:13 213:4
216:1,2 217:2
293:5,15,16
342:16 343:4,6,7
definitions 122:17
123:5,10,21
130:19 131:2
139:8,14,15 148:2
150:10 293:14
342:17 344:13,16
345:10
degree 32:17
deliberations 3:5
13:20 325:22
deliver 164:19
deliverable 350:1
delivery 164:7
166:17 167:22
179:8 185:11
191:11
delutations 92:6
delve 121:9 135:18
delving 121:6
demographic 240:5
244:8
demographics 53:8
denominator
129:10 150:20
156:14,15 157:10
175:12 338:22
339:11
dental 92:7
Denver 9:18
department 257:12
278:9 295:22

296:4,11
departments
239:13
dependent 149:8
157:19
depending 114:2
217:21
depends 43:15
115:13 128:17
258:10 331:7
derive 243:15
derived 68:16 87:9
243:17
describe 40:18
64:11 69:7 87:6
190:22 243:13
250:19 251:10
described 132:20
describes 120:5
251:7
description 29:2
171:2 195:5,9
214:18 307:9
308:16
designed 187:5
322:1
desirability 63:3
149:19
detail 57:13 163:8
211:5 230:3 265:2
detailed 76:8
details 57:16 162:8
determination
223:17
determine 23:22
24:5 35:18 52:17
141:20 277:1
determined 146:13
301:15
determining
130:10
detriment 171:16
develop 17:8 66:3
79:11 99:2 103:3
103:14 249:17
262:1 265:10
279:20

developed 65:1
66:9 67:2 71:8
98:8 103:2 114:1
114:4 116:18
195:12,14,16
249:2 267:14
342:15
developer 10:4
14:17,20 61:8
146:22 238:13,15
257:1 289:10,21
344:6 346:2,7,11
developers 13:13
16:18 19:11
288:22 349:4
351:6
developing 17:20
134:16 248:19
268:7 273:14
287:10 306:14
development
124:20 222:19
289:20 290:1
developmental 7:8
23:19 62:3 327:14
device 81:1,2,3
diagnoses 52:11
53:7 153:14
155:19 156:9
158:6 161:13
175:9
diagnosis 160:21
167:2 179:3
194:20 319:18,19
diagnostic 111:8
112:21 128:8
diagnostics 156:9
diagram 153:20
dial 200:19 219:1
dialing 208:9
dialysis 196:20
197:2,12 199:13
199:19 200:1,7,7
200:10,20 202:21
203:5,6 204:10
206:12 207:17,19
208:10,16 210:8

210:20 211:1
213:16,20,22
217:21 222:17
223:2 232:6 233:2
dialyze 197:20
201:15,18 202:15
223:1
dialyzed 220:20
221:2,4,5
dialyzing 201:19
diaphragmatic
65:14 98:2
dichotomous 85:17
216:17
dictating 230:6
die 72:21 74:5
77:15 78:4,12,19
89:1
died 74:18 79:2
dies 88:22 126:3
128:15
diet 164:15
differ 243:12
difference 20:12
23:15 50:19 81:5
100:9,22 178:1,3
179:20 195:20
218:14 224:16
232:4 252:9
275:17,18 276:4
276:14,20 277:1
277:19 278:5
differences 69:19
71:16 94:16 95:10
95:12 178:8 217:1
240:6 241:8
252:13 253:1,6
254:21 261:6
284:19 300:19
different 27:8,8
30:22 32:21 39:14
39:21 44:20 45:12
45:16 56:12 59:18
65:6,9 66:16 68:7
69:9 70:11,18
75:11,14 80:15
87:18 95:15

104:18 105:4
106:19 111:16
116:2 124:11,15
130:7 133:14,15
133:19 134:3,3
137:19 138:11
142:2 159:18,18
163:22 165:3
166:8 169:11
179:6,6 182:13
183:16 188:4
200:7 203:6
211:22 212:7
213:5 215:2
217:17,18,19
221:8,9,10 222:12
223:5 227:22
230:18 231:17,20
241:14 242:19
246:8 263:3
271:10,13 277:13
283:7 285:19
287:2,3 290:17,18
291:19 305:21
317:21 326:10,21
331:16 344:13,16
345:9 347:2,2,16
348:9
differentiate
277:14
differently 117:22
137:15,18 188:5
202:22 220:12
326:20
difficult 71:15
136:21 148:4
211:11 233:20
263:21 285:9
300:6
difficulties 278:7
difficulty 309:1
313:18
dilate 201:4,8
dilating 200:1
dilemma 299:19
dimension 255:1
299:17

dimensions 239:14
239:21 243:12
246:9 250:20,21
251:4
Dimes 176:22
direct 22:15 177:7
319:12,13
direction 103:2
155:12 171:15,16
201:11 268:7
326:14 336:18
directions 181:2
directly 75:2
300:11
Director 11:16
12:20
disadvantage 172:6
disadvantaged
165:20
disadvantages
233:1
disagree 120:13
discharge 40:20
74:6 108:4 240:3
244:2,3 246:14
247:16,17 251:15
273:2
discharged 74:17
242:15 249:21
disclosure 287:10
discomfort 304:2
discrimination
88:19
discriminative 89:7
discuss 34:4 153:21
324:21 343:15,18
discussed 15:14
97:5 144:18
211:12 283:1
286:9
discussing 144:19
332:11
discussion 3:10,13
3:15,17 4:2,4,6,9
4:18,21,23 5:2,9
5:11,13,17,24
6:12,17,19 10:6

34:16 37:2,8
59:17 86:8 132:15
136:18 143:3
154:6 165:14
189:13 213:14
285:10 306:10
307:19 309:3
310:17 319:8
325:19 348:15
discussions 342:10
disease 4:15 65:10
110:17 111:6
113:19 115:3
117:19 118:4,4,9
119:3 120:15,18
156:19 173:11
238:2 320:10
diseases 65:9 75:18
98:1
disparities 44:19
165:2 167:17
305:19
display 282:16
displayed 169:17
dissatisfaction
264:1 273:6
dissatisfier 183:9
dissect 99:22
distress 183:19
distributed 220:12
distribution 169:15
252:13
dive 329:10
diverse 246:1
diversity 316:1
doable 60:5
doc 269:8
Docherty 2:4 10:16
10:17 32:8 48:5
74:20 105:22
205:10 207:9
216:16 255:22
256:5 289:13
doctor 287:14
doctors 197:9
240:2 243:20
251:15 276:1

322:6
document 250:13
289:3 290:10
311:9,16
documentation
109:4 205:8
documented 195:1
199:1,7,9 204:4,6
205:12 207:12
209:11 216:2
217:18 218:15,16
218:22
documenting
204:14 208:16
219:11
doing 24:19 29:18
42:4 44:4,5,15
45:14 52:17 55:5
102:20 103:16
113:1 118:6,8
120:16 126:2
128:7 132:20
138:9 139:4
140:22 149:1
156:13 170:2
173:9 176:21
186:1 208:8,17
216:9 223:2
241:17 247:22
254:4 263:22
265:15,20 304:6
328:17 333:7,10
333:13 336:22
domain 157:12
240:12 246:12
263:9 284:3
298:16 302:15
304:13
domains 243:14,18
243:19 245:8,10
265:12 333:3
Donna 2:8 9:3
59:11 63:13
320:14
double-gloving
21:11
downhill 249:6

encouraging 179:22

ended 18:18 26:9 77:19 89:3 175:7

endlessly 186:19

endorse 195:21 290:3 297:16 310:9,10

endorsed 212:22

endorsement 14:3 14:5,10 15:20 46:15 109:19 110:4 146:6 193:11,13,17 196:2 231:15 234:6,9,13 290:4 298:21 304:16,20 305:6 341:15

endorsements 47:6

endorsing 149:21 267:17

endoscopic 36:11

ends 233:19

English 261:16 262:1 292:7 298:14

enjoy 126:1

enter 162:12 233:20

entering 130:12

enterocolitis 65:15 75:18 89:22 98:3

entertain 303:2

enthusiasm 131:20 328:10

entire 43:10 82:14 114:1,4 122:19 136:15

entirely 333:19

environments 159:6

equal 199:5 210:12 210:13,13 333:17

equally 116:22 143:17

equals 260:21

equivalent 209:12

ER 276:12

era 93:8

erythropoietin-si... 203:13

especially 17:15,17 65:8 142:13 164:17 184:5 274:19 345:7

ESRD 194:20 212:5

ESRD/CKD 235:7

essence 214:11

essentially 22:16 25:7 28:3 67:22 212:6 221:18

establish 52:6

estimate 118:21

estimated 28:9

ES-17 157:13

et 21:12 38:5 39:9 42:20 53:8 64:17 70:15 104:6,7 110:1 156:6 191:5 240:6 251:13 337:20

ethnicity 240:6 242:17

evaluate 15:10 243:10

evaluated 142:10

evaluation 46:4 82:13 147:1

event 4:13 77:18 110:15 111:17,18 122:6,8 124:16 126:9 127:13,20 129:22 134:11 136:17 139:13 140:3,15,22 141:3 141:16,21 142:18 147:9 157:6

events 110:20 112:1,1 113:3 117:4 121:11,12 121:13 122:5,17 123:10,14 124:5 124:10,12,21

125:10,11,19 126:13,18 127:1 128:1,13 129:18 129:21 130:3,6,16 130:22 132:3,4 133:12 136:1,1 139:4,7,16 141:3 141:13 142:3,15 146:17 151:16

eventually 111:14

everybody 8:7 9:1 9:16 48:22 51:10 96:18 109:13 110:7 179:2 181:8 193:8 200:20 211:15 227:6 283:10 288:10 292:4 340:6 341:3 341:4,17

everybody's 56:19

evidence 25:10 101:1 180:21 191:20 197:1 205:11 206:14 216:15 293:19 309:2 311:10,16

evolved 111:8

evolves 113:6

evolving 139:1

exact 102:8 169:9 213:14 253:17 349:5

exactly 23:13 35:18 37:6 42:7 43:4 52:19 73:5 78:19 109:1 113:20 115:7 137:8 170:9 253:13 286:13 295:9 303:6

example 35:15 38:4 62:10 114:10 126:9 127:3 131:3 132:19,19 137:5 150:12 155:20 156:20,22 165:8 166:19 167:10 171:18 172:20

174:14 181:16 201:5 203:10 218:21 219:15 223:22 245:12 259:11 271:16 276:11 280:3 282:19 296:6 346:15

examples 214:20

exceedingly 99:20

excellence 285:5

excellent 96:6 296:3 352:4

excellently 351:22

exchanges 322:20

excited 100:13

excitement 149:18

exciting 55:1 70:20

exclude 18:14 36:19 37:4,15 126:11,12 127:1 128:22 129:8,9,15 164:2 175:9 230:18 231:5

excluded 18:20 35:17 92:3,12 93:1 102:21 116:20 125:19 151:19 156:17 162:7,14 166:11 166:22 172:16 174:20 177:20,21 253:13,16 338:11

excludes 117:15 173:7 174:16 339:11

excluding 18:18 126:8 132:12 153:14 161:13 162:3,4

exclusion 35:6 164:8 180:6

exclusions 107:18 145:16 156:14 169:1 228:17 292:12

Excuse 283:6

Executive 12:20

exist 123:3 301:19

exists 54:6

expand 20:15 25:22

expanding 41:15

expansion 58:11

expect 116:22 241:7 321:12

expectation 101:6 213:18 214:5 259:20,21

expectations 163:22 259:10,12 259:17,21 260:1

expected 169:22,22

expedite 324:10 349:7

expeditious 328:11

expenditure 183:15

expenditures 183:17

expense 331:3,4

expenses 322:4 329:17 333:4,20 337:20

experience 8:9 25:11 78:3 104:19 157:21 217:16 239:4 242:21 245:20 249:22 259:15 260:3 263:15 284:13 286:19 292:13 294:11 310:21 334:19 348:20

experienced 191:2

experiences 6:9 237:9 240:1 243:11,19,20,20 245:13 247:16 281:16,18,21

expert 179:11

explain 99:10,11 126:11 171:5 195:4 198:6 199:11 272:22

273:1 274:15
295:3 335:7
explained 133:22
explaining 160:12
160:17 161:15
explanations
273:19
explicitly 326:4
explore 62:15
explored 258:4,7
expose 202:9
express 264:1
306:12 351:20
expression 63:8
extend 25:15 213:1
231:14 252:20
extending 110:1
extension 233:2
extensive 156:13
294:15 303:13
extensively 191:7
extent 42:14 47:2
318:13 340:18
external 201:8
208:12
externalizing 22:21
extra 160:4 249:17
extracting 55:21
extractions 92:8
extrapolate 79:16
extreme 209:6
extremely 73:2
95:11,13 113:5
273:13
eye 172:1

___
F
___
FAAN 2:5
FAAP 2:6
face 39:12 65:2
111:20 315:13
332:7,9 333:6
facilities 207:19
223:21
facility 183:8
217:21 224:21
facility-level 224:8

fact 42:3 66:18
67:5 68:15 69:3
69:16 73:8 81:17
82:14 93:6,10
97:12,16 98:12
101:17 103:11
105:3 131:19
135:5 170:7
187:22 203:9
245:18 332:8,10
333:13
factor 251:12
253:14 256:1,2
factoring 91:17
351:11
factors 83:12 89:19
124:9 201:16,17
209:22 211:11
220:11 221:19
fail 29:1
failsafe 156:10
failure 27:15,16
35:9 199:10
failures 33:17
fair 21:8 93:4 138:5
144:18 163:6
169:20 170:1
178:15 179:11
189:14 190:12
345:17
fairly 94:21 130:18
134:17,18 142:10
148:7 196:14
244:17 246:7
281:10
fairness 97:10
344:1
fall 183:18 235:8
255:1 317:10
332:22 333:15
familiar 19:19
families 10:10
104:18 168:14
173:20 183:10
247:3 286:1 337:7
family 104:11
179:5 202:19

family's 331:8
family-centered
6:8 237:8
fantastic 49:17
57:12 76:2
far 30:7,9 97:14
100:19 175:21
303:5,6 307:16
308:18 352:3
fashion 123:14
faster 308:6
fatal 72:18,19
128:9
fatality 206:16
favor 34:9 59:1
110:3 193:16
234:8
Faye 2:5 10:11
21:17 70:9 82:7
104:2 163:14
223:14 265:18
266:22 268:10
274:12 312:7,12
313:1
feasibility 3:17,18
4:9,10 5:2,4,17,18
6:5,17,18 7:16
39:17 51:18 57:20
58:1 107:16 109:9
109:11 131:16
145:13,20,22
193:1,7 228:16
292:9,18 296:17
296:19,21 297:7
297:10,12 304:22
341:6
feasible 45:19
51:20,21 228:20
229:1,4 280:2
292:12 297:2
feedback 22:4
308:9 349:12
feel 14:3 18:1 19:4
20:19 21:13,14
23:7 37:10 39:2
40:12 46:14 48:18
48:20 50:15 51:8

57:22 62:19 66:13
76:7 85:16 86:1,4
96:14 107:5,8,12
109:10 129:21
136:22 137:1
143:12 144:7
145:2,4,8,19
189:19 190:4,5
192:15 193:6
200:18 226:19
245:14 247:6
268:5,14 290:21
291:3 300:1 304:6
311:1 312:16,19
312:21 313:10
318:22 325:21
339:22 340:4
341:8,12 350:14
feeling 142:10
264:16
feels 177:6 209:13
313:15
Fei 2:12 5:22
194:12,12 195:7
195:12 198:17
199:15 212:9,14
213:2 214:8
215:16,20 216:1
217:4,12,15
220:17
fellow 13:1 275:19
fellows 276:15
felt 26:5 36:14 45:8
50:5 67:8 72:7
74:10 93:13
158:21 243:22
246:20 255:11
310:20 311:12
316:17
fetal 153:15 161:14
175:10
fetus 172:2
fever 177:19 178:7
179:10,16,22
fewer 102:20
103:16
field 111:12 122:20

137:21 163:2
196:9,10 241:19
342:16
fielding 254:9
Fifty 119:20
figure 18:13 77:12
210:22 221:1
253:9 256:8 285:7
315:18 351:16
figured 254:13
figuring 18:9 28:19
filed 248:10
fill 158:10 182:8
filled 235:13
352:16
final 59:8 132:12
finally 68:5 286:15
finances 331:8
financial 30:18
find 95:12,14 117:3
221:12 224:3
283:13,16 329:10
336:20
fine 44:1 169:1
174:1 188:5 195:7
195:11 209:15
234:20 268:22
302:19 309:21
310:6 335:1
finish 133:10
first 8:15 16:17
19:14 34:1,4 38:8
38:9,18 40:11
49:15 56:3,17
65:21 66:7 67:17
67:18 72:16 76:3
78:10 87:2 115:4
120:22 125:20
150:9 158:17
180:17 183:2
188:18 189:2
205:16 208:22
212:4 213:13
243:5,6 258:8,12
259:13 265:17
267:5 268:6 275:5
275:14 276:18

284:15 287:6,12
288:2,4 294:4,5
295:6 302:2,3
307:14,21 308:1
308:12 317:16
318:12 325:14,20
328:9,22 350:10
351:9
Fisher 2:4 9:12,12
55:3 78:8 79:21
80:14 106:9 173:1
183:22 185:21
231:11,13,18
237:18 238:9
312:4 316:17
319:3,17,22
323:17,22 324:5
326:18 327:9
fistulas 201:9
fit 88:13 92:13
225:14 327:6
330:17
fits 308:19
five 122:3,5,14
124:9 145:10
183:16 186:8
226:22 227:4
228:11 269:16
271:16 306:20
307:4,8 308:1
331:13 337:17
338:7 339:8
fivefold 20:12
five-point 305:21
Fivush 2:13 5:23
194:14 196:6,8
198:9 200:18
204:16 205:14
207:14 210:5
212:12 214:17
218:14 222:5
224:1 230:22
231:3,19 233:13
235:22
fix 219:14
fixed 105:17
flash 250:14

flat 181:20
flavor 97:9 333:5
flavors 160:7
flaw 72:18,19
flip 170:12 323:11
flow 21:5 200:8
201:13 202:8,12
203:4 219:1 220:4
flows 223:8
flu 237:19
fluid 21:6 201:20
flyers 276:3
focus 76:1 130:3
160:4 168:15
169:6 190:13
191:14 247:2
252:21 270:21
275:3 292:22
294:16
focused 26:15
66:10 166:4
167:21 176:20
182:4
focusing 64:14
65:20
folic 179:2
folks 16:19 194:9
304:7 333:14
334:17
follow 113:12
following 34:1 64:1
181:12 339:8
349:10,14
follow-up 59:20
175:14 278:22
fond 328:21
food 236:9 237:4
foregoing 152:20
236:14
foresee 57:7
forget 320:4
forgot 48:16
244:18
form 82:13 148:1,7
266:5 335:6,6
342:19 352:15
formal 48:8

formally 271:21
format 141:4
formation 250:7
formed 285:4
forth 182:6
forthcoming 71:5
fortunate 204:19
fortunately 66:2
74:8
FORUM 1:1
forward 14:9 37:13
63:10 130:20
132:14 143:1
193:14 221:8
235:2 254:3,12
268:4 273:20
286:17 305:13
306:15 352:13
foster 162:9
found 45:1,2 55:18
56:10,12 88:18
89:12 90:3 157:22
208:2 217:16,18
242:18 252:9
260:20
four 20:12 87:17
89:2 122:11
183:16 226:22
227:4 228:11
fourfold 163:13
176:3
Fourteen 189:8
193:18
fourth 202:5
fracture 167:2
frame 160:18
241:10 243:10
261:1,2 262:4
framework 241:18
framing 173:4
Francisco 154:10
free 350:14
freestanding 53:1
100:2 224:19
257:13 269:19
274:5
frenectomy 93:3

frequency 28:22
29:8 133:20
182:20 185:16
204:10
frequent 175:20
203:5 210:8 276:3
frequently 101:7
216:8,10 248:22
fresh 350:13
friends 286:1
front 300:1 335:7
FTE 108:11
full 17:13 108:11
161:21 163:5
166:20 196:2
fully 15:10 107:5
138:6 142:2
149:12
fun 17:20 320:11
function 219:12
functioning 311:5
fundamentally
80:10
further 14:18 26:6
26:12 51:4 85:14
86:12 135:18
146:22 149:19
235:19 298:11
335:8 344:8 347:5
future 14:1 57:8
147:2,11 150:2
fuzzy 135:19

— **G** —

gain 74:11
Gallagher 12:22
13:1
game 290:15
gap 182:8 196:17
205:2,7,9 211:16
267:6
gaps 349:21,22
350:3
Gary 2:5 10:11,11
21:19 70:10 71:4
82:8,19 104:3
163:15 164:9

168:18 169:19
170:1,21 223:15
274:14 276:22
277:5,12 278:12
278:22 279:8,14
279:18,22 280:5
281:17,20 282:1
292:15,19 294:6
295:11,15 312:8
312:13 313:3,7
gastroschisis 65:13
78:16,18 80:5
gather 15:8
Gauvreau 2:13
3:25 12:3,3 64:22
67:13 69:21 74:14
79:9 87:8 89:11
90:13,18,21 93:20
94:10,21 102:12
102:16 103:20
108:12,19,22
109:3 117:2
general 12:1 23:19
89:5 100:4 109:18
120:5 156:18
170:4 178:14
208:22 258:22
264:20 294:7
305:9 309:14
310:1 315:14
336:20
generally 58:18,19
258:10
generate 72:8
193:4
generic 260:7
gestation 176:1
getting 22:13 43:19
47:21 60:1 71:19
85:1 97:8 137:21
171:6 197:11
203:18 237:4
238:4 295:12
302:8 322:18,21
329:5 348:12
350:6,10
give 86:21 113:14

141:17 149:22
151:18 170:14
187:5 195:8 198:1
203:13 238:18
269:7 272:2
279:12 290:10
293:9,14,15
308:18 333:5
344:7 351:5
given 104:9 106:3
148:9 151:20
155:21 157:10
169:1 171:11
229:12 267:17
321:13
gives 180:8 203:8
giving 96:2 179:2
211:8 236:1
glad 56:16 158:15
go 8:14 16:13 18:22
19:11 26:17,17
28:7 34:4 40:7
42:17 44:14 48:11
48:12 56:11 96:8
98:18 100:22
113:4 116:9 127:9
128:8 143:12
153:1 158:11
162:1,7 167:13
172:2,19 173:5
178:6,17 187:8
191:12 193:14
221:7,22 224:7
234:21 236:7,13
242:7 246:20
250:3,4 255:14
259:5 260:11
264:18 273:20
274:22 276:7
278:9 282:5
283:15,17 287:22
288:2 294:5
296:16 301:9
305:12 307:21
314:16 320:11
327:6 328:3
342:22 343:9

350:9 351:15
352:10
goal 176:5 221:20
260:2 262:3
283:22
goals 238:20
goes 23:18 46:22
126:17 127:18
170:15 179:17
191:17 267:9
275:21 296:6,8
316:21
going 14:21 16:8
20:14 22:9 23:13
25:13,22 26:6,11
31:11 33:2,17
34:20 36:6,15
37:6 42:16 43:16
46:4 48:6 49:16
52:5 55:19 57:1
57:16 77:7,10
79:9 80:18 88:8
91:12 100:17
105:8,20 106:22
115:1,22 122:22
129:2 130:6
131:16 132:14
136:4 141:17
142:4 150:1 153:2
153:10 154:12
161:19 162:1
168:7 177:12
184:15 185:17
186:9 187:8 194:7
196:1 197:22
198:20 200:2,4
203:2,3,4,5,6
204:2,5 205:19
208:17 211:2,4,10
220:14 222:9,22
236:6 237:7
238:18 242:7
244:6 247:9
249:21 252:4
254:3 256:3 257:7
262:7 264:15
274:17 284:8,17

286:16 287:5,22
289:8 293:10
296:13,16 307:3
314:10 316:8
321:13 322:12
325:17,18 331:17
341:21 343:21
345:22 349:3
gold 42:15
Golisano 9:7
good 8:7 11:17 15:3
23:18 39:2 42:6
47:14 49:1 51:13
54:16 56:10 58:3
60:11 63:15 75:11
86:3,6,7,21 89:6
99:12 107:14
109:14 110:8
118:1 119:19
125:2 136:12
137:1 144:16
151:3 155:8 161:2
162:17 181:4,4,9
185:7 189:10
190:4,9 192:4,22
193:9,20 197:1,22
226:14 229:9
231:4 235:10
240:19 242:3,6
252:1 255:20
258:21 260:2
261:8 288:10
291:8 292:8
305:11 306:8
312:11 318:10
321:19 330:8,9
340:3,6 341:13,18
351:3
goodwill 149:9
gotten 122:21
160:10 303:6
352:3
Gould 155:2
Goutham 2:9 10:20
government 30:10
204:19
graded 343:3

grafts 201:10
Grail 159:16
grand 281:11
grapple 293:9
grappling 213:15
great 17:5,7 25:16
38:11 43:14 60:16
63:11,16 64:17
92:20 101:5 131:7
143:3 152:4,11
153:9 188:20
189:11 233:22
235:5 238:14
239:3 253:10
268:7 271:14
280:18 282:3
306:8,17 329:22
greater 36:2 66:15
69:18 122:2
194:21 198:12
199:5 200:21
211:6
greatest 47:2
gross 331:14
ground 150:1
group 12:19 16:2
16:11 19:9 26:12
30:6 32:14 34:18
37:14 43:10 49:6
50:9 60:20 64:5
67:16 75:4 86:13
87:19 88:6,7 91:5
97:18 98:3,17,18
112:10,13 113:8
116:12 122:21
123:18 124:22
130:16 141:4
153:19 154:1
158:18 174:13
190:13 215:6
231:15 233:2
248:3,5 249:1
250:13 268:13
270:16 285:4
307:20 308:3,7,22
310:4 346:14
grouped 87:15

groups 45:13 81:19
104:14 134:4
165:3 169:6 247:2
252:21 270:21
275:3 293:1
294:16
grow 223:6
grows 41:16
growth 156:18
164:5 222:18
223:7
guarantee 25:8
guess 35:9 48:10
60:9,12 61:1 81:5
89:16 99:9 124:2
125:18 128:19
145:13 177:4
186:13 207:14
208:21 212:19
216:22 222:2
250:16,17 252:7
267:15 268:3
270:4 287:9 289:6
289:7 291:6
305:17 306:11
309:6 314:9,12
315:9 320:15,19
331:20 343:15
guests 8:13,16
11:21
guidance 344:8
gun 190:17
guys 17:19 147:16
194:1 195:3 303:5
332:11

H
---
hair 126:1
half 173:15
half-hour 327:22
hand 34:9 86:2
110:5 263:1,21
handful 32:19
66:12
handle 282:14
handled 77:8,8
179:13

handling 335:4
handoff 262:9
hands 80:16,18
96:11 121:4
137:22 189:7
190:7 288:9
happen 75:3 79:17
237:21 250:14
307:3 312:22
317:22
happened 20:3
49:11,12,15 50:4
55:17 77:18 122:7
137:3
happening 24:6
happenings 21:15
happens 77:16
101:7 135:12,21
140:3,7,8,15
165:7,8 166:16
172:1 250:5
280:10
happy 8:21 56:22
151:21 251:11
260:15,18 281:13
305:14 306:6
316:18 331:4
336:1
hard 11:12 160:1
171:15 200:21
204:13 207:10
215:7 223:4 232:2
247:19 252:18
253:11 259:19
264:7 266:11
270:21 273:8
287:1,19 293:14
313:13 314:12
341:22 351:21
352:4
harder 23:22 32:20
209:22 222:15
harmed 187:22
harmonization
144:21 227:16,17
232:12,16,18,19
269:3 340:12

343:11,13,16,18
346:5
harmonize 269:4
harmonized 49:4
291:14 301:15
harvested 35:16
hassle 297:3
hats 348:12
Hawthorne 49:16
HCUP 28:8 33:2
41:5
HCUP's 157:21
head 312:20 351:10
headings 251:5
heads 305:10
health 1:7 6:25 7:3
7:10 9:4,14 10:8
15:17 163:3
181:13 191:7
306:12 309:2
311:13,21 315:4
316:1,12 317:8,14
317:19,22 318:2
318:14 319:3,6,14
320:3,4,9,17,18
321:12 322:1,3,11
322:11,19 324:4,6
327:5 329:2 335:4
335:15,21 339:9
343:6 347:20,22
348:2
healthcare 8:20
17:14 22:2 315:7
315:8 317:11
322:7,22 323:12
325:5 335:3,13,14
healthy 5:6 153:11
155:8,10 156:15
160:13 162:3
164:14,18 168:16
168:22 171:8
173:4,7 174:6
175:5
health-related
310:22
hear 56:22 124:1
306:2

heard 32:5 64:13
229:22 230:15,17
257:3 299:6
336:12
hearing 15:3 56:18
58:6 210:4
heart 4:15 110:17
111:5 113:19
115:3 117:19
118:4,4,9 119:2
120:15,18
heavy 23:7
Heidi 2:18 11:15
46:2
Helen 2:19 11:7
16:5 61:5 147:13
212:1,2 268:9
290:3
hello 286:3
help 17:19 22:3
23:20 25:6 83:15
89:20 90:3 136:8
136:9 153:21
165:2,16 198:10
200:13 224:6
266:5 346:22
helped 19:5 137:7
185:11
helpful 28:18 99:9
152:1 225:2
271:20 345:22
helps 137:20 301:2
hemodialysis 5:21
194:17,21 195:2
196:13 204:2
205:17 212:10,11
hemoglobin 206:21
hemoglobins
203:11
hemolytic 156:19
hernia 65:14 98:2
105:9,17
heterogeneity
68:12 69:2 239:3
heterogeneous 68:4
Hi 9:1 11:7,13,22
12:12 110:21

194:12
high 28:2 37:7
125:9 132:2 155:9
172:10 183:18
185:6 187:3
196:15 197:5
198:2 205:16,18
205:19,20 238:19
253:9 277:22
337:19
higher 20:16 45:2
133:2,6 164:20
165:21 187:15
192:9 200:3,4,6,8
200:9 201:10
220:4 245:17
253:4 334:18
highest 73:12
183:18 333:17
highlight 69:19
highly 24:6 89:7
157:19 246:5
314:1,5 343:4
highly-competitive
148:21
highly-specialized
196:9
high-level 284:16
high-performing
148:21
high-stakes 138:9
138:10
high-volume 157:4
Hispanic 70:14
Hispanics 242:22
historically 112:21
history 267:21
hold 275:2
holidays 351:12
Holy 159:16
home 7:5 77:18
78:5 162:2 244:6
246:18,20 307:17
312:17,21,22
324:22 325:1,11
326:13,16 328:2
341:21 342:12,15

342:17 343:6,6
344:13 346:3
347:15 350:14
Homer 1:19,21 2:2
3:3 8:3,19 15:1
17:1,4 19:8 21:17
24:7 26:13 27:10
28:17 29:13 30:2
30:16 33:12,22
34:14 38:2 39:13
40:15,18 42:1,22
43:5 44:16 45:15
45:21 47:8 48:10
51:4,17 54:22
57:2,19 58:17,22
59:10,15 60:6,11
61:4,9 62:5,18
63:1,12,15 64:6
64:10,20 67:12,15
69:5 70:9 71:11
72:12 76:1,12,15
76:20 77:10 78:6
79:19,22 81:6
82:6 83:13 84:7
85:5,12 87:1 89:9
91:3 92:19 93:16
94:6,12,15,22
96:7,13,17 98:16
101:3 102:5 104:2
106:8 107:3,11
109:7,14 110:8
112:9 113:7
114:10 115:8
116:14 117:6
118:17 119:4,8,12
119:18 120:21
121:16 124:1
125:15 129:11
130:9 131:4
134:20 135:17
136:12 138:6
140:2 143:2,18
144:7,13,16 145:7
145:11 146:2,10
146:18 147:12
148:18 150:7,17
150:21 151:3,8

29:7 112:22 267:17

implies 318:8

importance 3:10 3:12 4:2,3,18,19 5:9,10,24 6:2,13 7:12 19:15 26:15 26:20 27:13 28:20 28:22 34:2,3,8 64:5,15 67:18 85:14 86:2 111:20 112:12,18 113:9 120:22 121:4 132:16 162:19 216:11 225:21,22 226:9,12 231:6 252:8 255:4 301:5 308:19 323:8 330:2

important 17:13 19:21 26:12 27:3 30:12 31:15 37:11 40:2 45:11,22 67:5 76:4,6 85:18 85:22 99:20 104:14 107:2 111:12,18 112:7 113:6 125:5,13 126:12 136:18 154:20 157:4 173:14 176:17 185:13,17 189:4,6 198:1 206:5 207:4 208:13,18 211:17 222:16,18 224:13 224:22 242:20 245:15 246:4 247:5 256:9,11,12 264:20 266:7 278:14 288:6,9 310:22 316:18 322:17,22 329:21 330:6

imposed 136:14

impossible 221:19 230:14

imprecise 148:7

impression 27:18 100:18 315:22

improvability 30:20 80:11 191:20

improve 78:20 80:18 142:14 206:5 236:3 293:3 295:15

improved 187:15

improvement 61:14 84:9 85:4 101:12 112:4 130:4 167:10,11 176:10 191:4,9,10 191:18 192:10 208:4,18 211:9 272:8

improvements 192:11

improvement-rel... 63:4

improving 188:1

inability 201:4

inaccuracies 107:18 145:18 228:18 292:13

inaccurate 337:7

inadequacy 208:16

inadequate 5:21 7:2,9 195:1 339:4 339:14

incidence 157:18 170:13 172:10

incidental 92:9

include 88:9 103:7 115:14 137:8 210:15 216:3,4,5 218:16,17 219:11 276:6 335:14 339:18

included 36:22 41:20 66:17 74:3 75:19,21 91:19 93:2,18 102:9 141:22 159:21 162:16 163:18

169:14 172:22 173:2 174:5 180:5 225:17,18 318:2 338:20,20,21 339:6

includes 84:20 123:21 158:13 181:15 185:19 267:10 338:1

including 55:7 105:3 113:13 117:17 166:21

income 331:14 333:11,12

inconsequential 113:5

inconsistent 310:9

incorporate 44:8

increase 21:10 50:17 124:8 176:3 176:18 188:16 204:10

increased 180:18 181:19

increases 296:9

increasing 132:22 218:22 219:1 233:7

incredible 68:2 96:3

incredibly 332:10

indefinite 150:2

independently 140:17

Indian 70:14

indicate 200:9 278:21

indicated 318:4 319:16

indicator 19:14 83:21 156:11 318:14 319:13,14

indicators 20:20

indices 289:16

individual 81:10,11 94:6,8 102:14,17 105:6,7 140:20

205:22 284:7 304:10 307:5,12

individuals 52:2 60:14

induction 184:8 185:13 186:10

indulge 170:22

infant 160:15 170:13 222:15

infants 64:2 75:1,9 156:20 157:6 176:14 177:9 179:12 180:13 222:12,21

infected 22:17 135:10

infection 21:9,20 21:22 22:7,7,10 22:12 23:3 50:18 71:20 79:4 135:4 138:1 155:7 171:19 192:4,12 201:11

infections 24:12 183:3

influence 83:5 101:4 259:17

influenced 101:2

influencing 252:10

inform 347:4 349:7

informant 40:5

information 16:2 46:18 62:2 79:10 86:22 150:9,13 170:5 184:15 198:1 213:7 221:13 234:2 241:11 246:21 283:2 289:1,4,12 298:11,20 304:12 305:8 313:15 314:4 336:3 348:13 349:6 351:7 352:14

infrequent 66:1

inherent 331:8

inherently 188:7

initial 16:15 35:22 212:22 315:22

initially 18:17 19:10 33:11 35:17 36:22 50:7 112:11

initiative 8:20 172:2 285:2

injections 92:6

injuries 158:5,6 167:1 174:15 175:1

injury 166:21 175:6

injury/birth 157:13 158:2

inpatient 6:9 52:22 62:22 237:10 262:9

inpatients 57:6

input 235:8

insert 148:17

insertion 21:1

inside 22:14 337:11

insignificant 111:10

instances 129:7 323:13

institute 43:1

institution 43:3 49:10 60:2 62:10 65:11 67:10,11 69:12,12,20,20 81:14,18,18 95:15 100:2 105:12,13 118:7,8 119:6,13 120:3 122:5 124:21 130:14 133:13 136:15 139:18 140:3,4 143:14,16 148:15 155:6 168:21 184:22 239:14 255:21 263:6 264:17 283:12 287:19 298:15

institutional 42:18 134:8

institutions 43:8,11
43:11 58:11 59:19
60:14 62:8 65:12
69:10 70:11,18
80:7,10,12 102:20
105:11 114:5
118:22 119:10,16
121:21 123:13,19
124:22 130:7
131:11 134:12
138:11 139:2,2,14
140:15,21 141:3,6
142:8 143:11
148:3,20,22 149:6
149:10,15 178:2
235:17 239:13
241:19 242:1,4
255:5,7 283:19
290:7 304:21
institution's 134:9
institution-specific
100:1
instruction 262:21
instructions 273:2
instrument 239:21
263:4 266:19
272:2 280:2
295:21
instruments 268:2
insurance 7:3,10
71:1 321:22 322:2
322:19 323:18
324:6,6 328:2,9
328:14 330:21
331:6 333:7,18
335:10,12 337:17
338:1,4,5,10,17
339:1,7,9,14
insurers 233:16
intend 283:1
intended 117:22
148:4 262:7 265:3
319:13
intensely-researc...
306:1
intensive 223:19
intent 82:18 117:20

interact 171:1
interactions 294:12
interest 63:9 96:21
97:7 128:18
149:18 220:7
254:11 309:16
interested 97:19
130:8 254:9 263:9
305:18 346:16
interesting 131:13
179:19 183:13
258:1 274:8
275:14 287:17
interim 249:20
intermediate
197:15 206:10,12
206:15,19 207:1
226:5 327:1
internal 52:13
201:9 221:5
224:14 331:15
internally 214:3
351:14
International
123:6 139:9
internationally
159:7
interpret 339:19
interpretable
291:10
interpretation
335:17
interrogate 83:10
intersect 160:2
interval 109:22
intervals 29:15
50:22 70:7 94:19
intervention
180:10
interventional
111:9 112:20
120:1,4
interventionalist
12:10 115:14
interventionalists
133:16
interventions

159:13 171:22
interview 293:12
330:15
interviews 40:6
294:17
intractable 209:21
intrapartum
177:19 178:7
intrauterine
156:18 164:4
introduce 8:15
11:21 13:9 154:5
introduced 147:7
281:15 329:4
Introductions 3:4
introductory
328:18
inventory 91:20
investigating
296:13
investing 31:17
306:14
invite 19:9
involved 176:2
239:16 287:9
involvement
267:22 349:15
involves 82:10
in-depth 307:15
308:17 324:22
in-dwelling 208:11
in-hospital 64:1
67:6 74:9 77:11
87:13 88:5 89:8
89:20
issue 22:2 27:11
34:21 54:7 60:20
63:7 77:1 83:6
91:8 94:16 109:8
132:12 137:10
144:20 147:10
167:19 176:15
179:7 185:9 193:3
213:14 232:17
235:19 248:22
261:15 262:20
268:15 291:15

300:16 304:13
309:4 316:6 321:3
331:18 332:2
342:5,9 344:7
346:9 350:5
issues 18:12 20:2
26:17 44:19 71:9
91:9 107:17,19
121:7 137:22
162:3 165:13
167:20 179:8
208:22 221:18
222:18 223:6
246:1 294:8 330:2
340:12 347:4,7
item 228:1 244:13
250:15 253:7,16
256:9 258:11
272:20 290:5
309:12,13,22
317:7,16 328:15
328:15,19 330:6
items 239:11 240:5
240:8,11,14,17
242:6 244:7
245:16,22 246:16
251:13 253:5,9,21
254:22 255:1,6,12
255:18 267:19
269:9 273:12
274:22 277:21
281:7 306:5
313:22 330:11,17
347:16 349:6
item-by 244:12
item-by-item
244:11
iteration 287:11
IV 179:17 180:11
i.e 104:11

J 2:5
jam 127:16
JANE 2:25
Jay 2:12 3:9 11:22
38:2 40:15 49:22

62:5 263:10
JD 2:25
Jenkins 2:5 9:20,21
95:8 136:10,13
162:21 174:3
175:15 200:13
208:20 221:17
229:21 230:15
302:22 311:4,7
326:22 334:2
336:7,11 337:5
338:6,9,14 339:5
349:17,20
job 39:10 352:1
John 54:13
join 144:10
joint 158:8 185:1
344:19
judge 264:7
judging 215:14
judgment 130:11
136:5 140:10
215:11 289:5
331:19
judgments 294:19
July 316:22
jump 46:3
June 351:9,15
justified 273:18
justify 208:7

Kaiser 11:3 191:1
300:11
Kaiser's 300:3
Kappa 216:20
217:8,12
Kathy 2:5 9:20
95:7 142:9 162:20
174:2 200:12
208:19 221:16
234:6 333:22
336:10
Kathy's 204:1
keep 236:4
keeping 170:7
kept 238:6 241:11

Kerri 2:12 5:22
194:12 198:9
224:6
Kestle 54:13
key 40:5 46:6,19
56:13 325:13
Kibort 2:6 9:9,9
26:18 237:16
311:18 312:6
313:1,5
kid 23:2 40:8 50:1
79:10 87:10 89:12
271:14
kids 36:8,16,17
37:10 40:3,7,13
66:8,21 68:16
78:12,18 79:2
80:12 82:14,16
83:8 103:4,5
158:1 173:10,22
174:1 182:5
183:18 270:2
271:4,7 333:9,21
334:12 336:22
Kim 12:3 64:21
67:12 73:3 79:8
87:1
Kimberlee 2:13
3:25
kind 11:11 28:18
47:13 77:12 84:4
93:9,13 96:1,3
97:7,7 100:16
135:20 149:20
150:1 151:1,18
159:15 160:1
164:15 179:15
195:3 211:9
216:12 254:2
260:6 267:20
268:3 270:3
276:16 308:18
324:6
kinds 21:22 35:12
99:7 101:4 104:18
181:11 187:11
188:16 235:4

kinetic 199:15
200:3
kinked 21:4
knew 275:22
know 24:4,12,14
25:12 30:13 33:19
36:13 37:17 41:4
47:3,11,18 49:10
50:2 57:15 61:14
71:13 72:2 73:16
74:19 80:16,17
82:9 84:7 85:9
86:20 90:15 91:21
99:8 100:9,16,21
101:15 102:4
105:17 108:11
114:13 116:10
120:3 124:4,6
125:22 126:19
128:19 131:12
135:5,8 137:20
147:19 148:18
149:17 153:22
160:12 161:4,9,19
161:21 163:21
173:4,21 174:15
177:8 180:20
182:12 183:6
184:1 185:6 186:6
186:6 189:15
191:13,20 198:20
199:22 203:2
205:1,2,3,14
206:5,10,21
209:17 213:9
216:6,7,10 217:11
218:19 219:10,22
220:7,18,21 222:5
224:4,16 231:22
232:2 233:6 249:5
250:5,7 256:8
260:6 263:22
264:8,16 265:19
266:2,12 267:16
268:1,21 269:3
272:1 273:10
274:2 275:17

276:20 278:4,5,8
285:3,3 287:9,14
288:22 289:14
292:21 294:22
295:4 296:2 300:4
301:20 302:11
303:21 306:1
307:3,11 308:2
314:7 315:15
316:22 319:14
320:7,12 331:5,15
331:17 332:18
333:9 342:21
343:13 344:9
347:3
knowing 87:19
222:14 267:20
300:11 346:16
known 35:8 253:3
Kt 199:12
KTM 204:18
Kt/V 194:21
196:21 197:2,4
198:12 199:5,6,8
199:14 200:4,9,15
200:16,20 202:3
203:21 204:8,17
205:2,7 211:19
220:9 225:8 226:2
232:5,8 235:14
Kt/V's 208:6

L

L 1:21 2:2,4
lab 111:15 117:9,11
120:3,6,9 127:9
127:15 128:3,5,12
labeled 47:5
labor 162:12 164:1
164:6 166:6,17
167:22 175:21
179:8,17,22 180:1
labs 117:15
lacerations 92:5
lack 30:20 69:6
204:8
language 215:2

languages 242:11
262:2
large 66:7,21 97:13
100:4 106:11,12
160:1 163:3,10,20
179:12 222:7
largely 299:4
larger 69:18 307:6
309:12
larger-serving
14:19 15:8
largest 20:20
late 115:14 176:16
177:2 184:18
235:7
late-presentation
115:15
late-term 184:17
laughter 8:11
38:12 47:12 97:15
120:20 126:6
131:6 132:18
149:16 151:10
159:3 186:20
194:2 195:6 231:2
234:19 238:3
257:9 258:2
263:12 271:11
282:4 286:4
287:16 288:17
295:8 300:22
317:1 324:13
328:7,13 337:2
342:2 352:11
laymen's 199:13
lead 117:21 201:4
207:12 316:12,15
leader 101:16
leading 103:1
348:15
Leapfrog 106:13
158:9 184:14
learned 156:2
169:2
learning 32:9
235:16
leave 264:17 308:8

leaves 263:5
led 155:2
Lee 2:8 10:7 98:18
104:5 246:10
299:1 316:16
323:5 346:9
Lee's 104:4 262:8
left 211:6 247:22
253:7 262:22
263:21 306:21
307:4
legal 155:19 187:11
Legislators 334:15
legislature 339:16
lend 98:5 122:1
length 162:10
258:5,6,7,14
282:3
lengthy 67:21
length-of-stay
156:11
lesions 65:22
Leslie 352:13
letter 261:12
let's 34:15 48:13
51:18 85:14 86:8
118:6 119:11
126:19 153:1
164:17 189:12
223:19,21 226:7
255:15,16 320:9
321:17 327:6
328:8 330:4
level 43:18 81:13
124:20 125:10
212:7 214:22
224:5 272:2
320:21
liberal 132:7
licensed 207:15,20
licensing 207:19
lie 36:8
Lieberthal 2:6 11:2
11:3 30:5 52:19
53:10,16 86:16
92:22 102:7,13,18
103:15,21 117:7

118:13 120:12
146:8 177:17
225:4,11 256:15
257:18 300:10
303:7 316:11
327:15 330:19
life 15:22 65:21
122:12 175:10
life-threatening
112:1,2 122:10
light 314:12
likelihood 162:1
233:11 327:21
Lillehei 2:14 3:23
12:6,7 25:1 64:12
64:18,21 68:11
69:8 70:19 71:6
72:1 73:6,18 74:8
75:10 78:1 79:7
81:7,8 82:11 83:7
90:22 91:21 93:4
94:4,8,14 97:10
99:15 102:22
103:18 104:1,20
105:9 106:7
133:22
limit 58:15 114:7
115:19 131:21
limitation 74:1
105:20
limitations 72:6
98:4 157:17
limited 46:15 65:12
66:14 110:4
150:11 163:8
232:15 234:9
256:2 270:19
301:6 305:6 322:5
line 13:7 24:12
25:14 135:4,9
153:7 187:1 217:5
295:6
lined 38:16
lines 13:10 24:14
208:11
lingual 93:2
lining 41:22

link 41:8 63:7
74:16 75:7 171:7
197:14 247:20
311:4 316:2
linkage 207:5
295:21 311:10
linked 53:3 197:4
214:12 309:18
linker 41:12
linking 61:13 62:7
63:3
Lisa 2:11 4:16 12:9
110:22 136:14
271:7
list 14:15 90:2 92:2
123:8 315:2 326:5
listed 68:8 214:20
311:17
listen 13:14
listening 346:8
literacy 294:7
literally 116:7
literature 121:19
142:18 206:9
litmus 39:1
little 16:9 18:19
24:11 26:2 31:7
38:3 46:17 49:16
51:2 58:20 70:5
73:4 78:9 80:15
82:20 87:5 89:15
90:7 97:2 102:2
113:2 119:11
121:10 135:18,19
142:21 147:15
151:12 161:6
169:11 171:5
176:1,12 178:10
178:10 185:12
195:5,8 213:5
215:2,5 216:15
218:11 221:20
237:4 246:12
247:9 250:16
251:8 261:18
267:15,20 271:9
283:7 289:3

296:22 300:7
302:13 306:2
307:19 310:16
319:7 324:21
329:10 333:5
335:7 342:10
344:7
live 14:14 153:13
160:21 309:5
lived 212:4
lives 40:8 164:15
living 15:21
located 1:20
logic 312:1
logistic 88:4
long 108:15 143:8
143:12 154:10
159:15 162:10
165:4 199:12,17
202:14 204:22
205:1 251:6 259:6
309:3 321:18
346:7 350:12
longer 46:17 200:7
258:14 345:16
longitudinal 41:16
longstanding 233:9
long-term 197:14
197:14 198:15
226:5 295:18
look 15:7 20:13
28:7 41:18 44:3
44:11 45:19 46:10
48:2 50:21 56:1
60:16 62:11,12
65:19 70:7,21
71:9 74:7 89:18
99:18 101:11
111:16 116:21
128:20 130:7,21
133:17 147:20
148:11 151:15
170:19 179:21
182:18,19 203:19
204:16 209:14
222:8,10,22 223:9
230:13 235:1

240:6 241:12
243:4 245:6 255:4
266:2 268:6 269:9
269:14,15 274:1
284:17 304:15,21
307:8,15 308:17
344:7 346:2
looked 29:19 42:11
44:19,19 45:18
56:7 71:17 75:13
77:13 79:11 80:20
87:10,11,13,22
88:17 95:17
116:14,16 130:1
142:18 166:14
174:13 204:17
206:1,2 208:3
216:21 218:10
270:17 280:21
307:10 313:21,21
looking 13:21
18:11 20:7 22:20
28:3,14,19 37:22
43:18 51:12 52:15
54:17 55:19 58:10
65:17 68:5 69:22
70:4 78:14 81:13
82:4 87:17 88:2,4
98:20 102:8
104:22 105:6
106:11 107:1
109:21 113:3
126:13 134:16,18
147:22 150:10
154:14 155:17
157:7,21 159:14
163:11 179:21
182:7 186:9
197:17,19 198:13
198:14 205:22
206:6,10 208:14
208:15 218:18
221:13 242:18
267:18 279:2
308:15 326:10
335:1 348:11
351:4,8

looks 15:18 106:12
166:19 196:21
231:9 325:7,10
335:2
loophole 141:17
lose 231:6
losing 114:9 222:10
lot 8:5 17:16 28:4
32:21 33:10 36:6
37:13 39:6 42:19
50:3 57:13 88:10
101:1,21 105:3
111:16 113:2,17
116:6 131:20
147:8 149:18
170:17 179:2,20
180:2 182:4
203:13 207:1
213:14 217:4
226:4 247:5 250:8
262:11 265:13
269:8 277:17
294:15,16 302:12
305:10 307:11
320:12 322:8
328:9 334:16
340:22 348:7,8
350:6
lots 87:17 182:13
273:6 312:21
loud 348:22
love 131:4 235:15
266:12
lovely 16:19
low 155:10 157:17
166:3 197:4
201:20 217:9
246:7 253:12
332:10 333:2
lower 133:5 187:7
lowest 93:21
333:16
low-birth 164:2
167:18
low-birth-weight
163:17 164:20
low-prevalence

219:10 220:9,15
220:19 221:14
224:2,8 225:3,6,6
225:9,9,16,18,21
226:16 227:13,20
227:22 229:13
231:21 232:8
233:10 234:16,21
235:1 237:6
238:12,19,20
246:8 248:14
250:13 259:18
263:18 264:2
269:13 270:8,11
270:13,15 273:15
280:9 284:16,22
285:11 286:20
288:5,21 301:17
303:4 306:15
307:6,15,16
308:12,14,17
309:4 315:10,11
315:14,19 316:10
316:14,19 317:15
318:18,20 320:16
322:1 323:8,10,11
324:18 325:1,4,8
325:21 327:13
328:11 329:3
331:14,21 332:9
332:11,12,21
333:8 336:5,14
341:16 342:1,11
342:13,15 344:4,6
345:5,12 346:1,2
346:7,10,18
347:15,20,22
348:2 349:4 351:6
measured 88:19
137:2 186:15
196:20 232:5
259:2 285:12
322:17
measurement
43:12 73:3 137:1
138:10 157:11
256:22 265:14

289:15
measures 11:9,16
13:21 14:4,8,16
14:20 15:8,12,16
16:9,20 21:13
30:9 31:8 46:6
47:11 49:4 61:17
61:21 63:4 84:11
84:12,13 90:7
99:7 111:17
120:18 138:4
155:4 158:12
159:21 165:2
166:1 169:4,13
171:14 182:19
190:19 194:1
211:21 212:5
214:11,13 218:7
224:9,10,12
227:18 232:13
236:4,12 243:14
243:17 255:19
268:16 280:20
284:15 285:2
301:14 306:21
307:4 331:16
340:13 348:9,10
348:18 350:6,11
measuring 177:8
185:15 200:11
259:1 294:11
mechanisms
145:16 298:16
median 29:21
Medicaid 77:21
183:15 233:7
347:9
medical 7:5 9:8,10
9:13 57:5 155:19
164:12 237:21
241:13 258:16
264:5 275:6
307:17 324:19,22
325:1,6,11 326:13
326:16,20 328:1
341:21 342:12,14
342:17 343:6

344:13 346:3
347:15
medically 127:7
medical/surgical
243:7 258:8
Medicare 60:13
204:21 233:3,9,14
233:18,19,20
234:2
medication 262:19
medications 240:4
244:3,5 251:15
272:22
medicine 221:5
224:15
meet 158:1 198:21
198:22 207:2
208:1 209:7,10
226:12 322:7
334:6 335:11
337:17 340:19
351:17
meeting 11:11
13:14 16:3 30:14
130:15 316:21
321:18 334:13
349:11
meetings 97:5,6,6
meets 34:8,15
48:19,21 51:8
58:1 86:1,5 107:5
107:6,9,12 109:10
121:3 143:22
144:3,8 145:2,4,8
145:20,21 190:6,8
192:16,19 193:7
225:11 226:8,17
226:19 227:2
228:3,5,9 290:22
291:3,6,21 292:1
292:3 296:19
297:7,10,12 340:1
340:4,21 341:9,12
MEMBER 2:3,4,4
2:5,5,6,6,7,8,8,9,9
2:10,25 9:3,6,9,12
9:17,20 10:7,11

10:14,16,20 11:2
19:16 21:19 24:9
25:5 26:18 27:11
30:5 32:8,15
33:13 34:19 37:16
37:20 39:16 43:6
48:5 49:8 51:14
51:16 52:19 53:10
53:16 54:5 55:3
57:3 59:7,13,16
60:8,18 63:14
67:19 70:10 71:4
71:12 72:13 73:14
73:19 74:20 76:10
76:14,16 77:3
78:8 79:21 80:14
82:8,19 85:2,6
86:16 92:22 95:8
95:22 98:19
100:15 101:14
102:7,13,18
103:15,21 104:3
105:22 106:9
108:7,17,20 109:2
109:5 112:17
114:21 115:21
117:7 118:13
119:21 120:12
125:17 126:14
127:22 128:14,19
129:14 132:11
133:10 134:22
136:10,13 138:20
141:12 143:7
146:8,15 147:6
150:3,14,19,22
158:20 159:4
162:21 163:15
164:9 168:18
169:19 170:1,21
173:1 174:3
175:15 177:17
180:15 183:22
185:21 186:16
200:13 203:22
205:6,10 207:9
208:20 216:16

218:3 220:6
221:17 223:15
225:4,11 227:7
229:21 230:8,15
231:11,13,18
237:16,18 238:9
246:11 247:1,8
248:15,18,21
249:11,19 252:3
253:18 254:2
255:9,22 256:5,15
257:18,22 258:18
260:4,10,13
261:15 265:19
267:1 274:14
276:22 277:5,12
278:12,22 279:8
279:14,18,22
280:5 281:17,20
282:1 288:18
289:13 292:15,19
294:6 295:11,15
299:2,11,18,22
300:10 301:10
302:22 303:7
308:21 309:10
310:3,7,14 311:4
311:7,9,18 312:4
312:6,8,13 313:1
313:3,5,7 315:12
315:21 316:11,17
318:6,17 319:3,5
319:7,17,22
320:15 321:2
323:6,17,20,22
324:3,5 326:18,22
327:9,15 330:19
331:20 334:2,22
335:9 336:7,11
337:5 338:6,9,14
339:5 342:4,8,14
343:12,20 344:2,5
344:15,20 345:1
347:21 349:17,20
350:21 352:8
members 2:17 8:8
8:12,16,17 13:5

13:12,13 19:9
30:6 34:17 46:1
67:15 86:14 91:5
98:17 104:12
112:10 113:8,9
158:18 189:17
250:11 346:17
men 313:9
meningitis 22:18
mental 6:25 315:3
315:6,7 316:1,12
317:8,14,18,22
318:2 319:3,5
320:3,9,17,18
321:4,12 324:4
327:5 335:4,15,21
mention 153:18
247:11 252:8
mentioned 89:16
132:1 136:14
148:15 164:3
175:16 185:11
206:21 234:10
253:20 256:15
mentions 243:14
merge 303:11
merging 62:22
met 96:11,15
131:19 196:19
209:6,9 211:19,20
339:8
method 66:3 70:5
70:21 72:9 73:2
75:22 116:18
methodological
254:14
Methodologist
12:13
methodology 239:7
239:9
methods 255:14
289:14 304:3
metric 130:2,20
142:7
metrics 307:5,12
microphone 21:18
252:4

microphones 9:16
middle 44:5 127:4
middle-class
164:19
migrate 57:5
milk 165:9
Miller 61:11
144:10
million 28:15 157:2
mind 105:1 129:17
313:13 323:4
348:19 350:13
minds 315:12
mindset 317:12
minimal 197:3
340:9
minimally 26:11
49:1 96:17 107:12
144:8 145:8 146:2
227:2 228:8 229:4
291:6,7 292:2
297:11
minimize 136:19
137:10 240:14
253:17
Minnesota 9:11
343:5 345:8
minor 93:2 121:22
122:8 132:2 162:6
minorities 242:22
258:15
minute 99:10
152:15 170:22
minutes 8:4 152:14
152:14 154:4
236:9 306:21,22
341:20 345:17,19
mirrors 168:17
319:7
misapply 132:8
miserable 124:6
misfiled 250:12
misheard 93:19
misleading 336:17
missed 14:11
215:13
missing 227:8

240:19 253:10
263:21 277:22
misunderstood
250:2
mix 68:4 114:3,5
115:13 156:8
mixed-mode
242:20
modalities 36:8,16
modality 203:7
mode 169:18 241:1
241:6,8 252:10
253:15 277:17
model 45:5 65:1
66:9 67:2 71:8
75:21 79:12 86:18
88:13,21 89:6
90:11,16 103:2,3
103:14 116:21
117:4 134:9
142:16
modeling 199:16
200:3
models 88:4 134:16
moderate 126:18
188:2
modes 242:19
252:8 287:2
modify 43:13
modular 276:8,9
modules 276:13
mom 171:11
moment 41:9
278:15
money 320:12
monitor 197:11
296:8 323:1
monitored 147:10
monitoring 295:18
month 25:12 36:5
91:1 157:21 196:2
monthly 130:14
141:5 197:8
months 41:12
46:16 58:17,20
194:18 205:17
208:8 305:5 315:8

320:19 321:9
month's 97:14
morality 73:21
morbidities 84:21
164:10 168:8
170:8 178:18
morbidity 71:13,18
71:22 75:3 111:10
116:2 168:7
174:17 177:22
178:14,15
morbidity/morta...
27:17
morning 8:7 11:17
Morsell 2:20 11:5,5
mortality 3:21
63:19 64:1 67:6
68:8 70:13 71:13
71:18,22 72:10
73:14 74:10,22
75:7,15 77:6,11
77:12 80:7 83:16
83:21,22 84:13,15
84:20 87:14,20
88:3,5,10,11 89:8
89:21 92:15 94:2
99:3 126:5 178:1
196:15 197:5
198:2 205:16
207:5
mortality/morbi...
164:21
mother 156:16
159:22 166:5
171:17 172:5
177:19 179:16
180:11 216:8
mothers 156:21
179:22
mother's 163:21
motion 304:11
305:7
Motorcycle 295:7
move 14:9 34:15
37:12 48:13 51:18
57:12,13 59:11,14
81:21 86:8 95:6

109:15 121:5,7
143:3 162:20
188:21 189:12
194:8 201:11
202:20 208:11
210:8,9 223:13
225:3 229:11
284:9 287:7 291:5
297:15,19 298:2
336:3 340:17
341:14 347:11
movement 199:17
200:2
moves 63:10
196:21 200:11
315:18
moving 15:16 49:2
61:19 63:17
107:15 199:21,21
210:6 236:2
286:16 306:14
MPD 2:12
MPH 2:4,5,10,19
2:19,22,25
MSN 2:12,18
multi 42:17
multiple 47:17 53:3
58:10 73:1 74:16
77:1,5 131:11
304:21 342:17
multiple-surgery
84:3
multiple-year
94:18
multivariate 45:4
multi-center
148:16 266:9
multi-institutional
54:11
Munley 12:22
Murphy 319:9
muster 234:16
mute 15:3

———————
N
———————
NACHRI 33:8 97:5
NALINI 2:21

name 8:18 12:12 110:21 131:4
Nancy 2:4 9:12 55:2 78:7 79:19 106:8 172:7 183:20 237:12
narrow 85:21 108:1 349:5
narrower 70:8 85:19
narrowing 95:2 109:22
national 1:1,3 8:19 10:9,18 13:2 52:16 66:7 85:3 139:19 148:5 181:19,22 242:3 252:15 255:15 266:16 272:2 286:20 328:22 334:15 341:7 345:6,11 347:18
nationally 41:6 255:6 334:11
nationally-weigh... 33:3
nationwide 157:22 166:2
nature 169:8 244:8 271:3
NCQA 343:8
necessarily 133:2 213:8 233:17 320:20
neck 78:16
necrotizing 65:15 75:18 89:22 98:2
need 6:25 15:10 19:13 34:2 43:13 43:21 44:6 52:6 69:17 78:9 80:2,4 80:12 91:14 93:17 94:9 130:20 139:7 140:21 144:9 165:7 186:6,21 189:21 190:19 210:1 213:10

223:3,9 229:16 261:8 267:15 273:19 287:20 288:1,2 289:6 315:4 317:9,11,17 317:18 318:5,7,13 318:15 319:2,18 327:5 329:18 332:19 345:15 349:6
needed 14:13 50:6 50:8 203:19 230:7 320:22 334:3 335:3,12
needing 47:6 71:19 206:15
needs 17:14 46:14 70:2 210:21 268:5 292:11 318:22 322:4,7,10,16 329:19 332:17 335:11 337:18 349:18 351:18
negative 183:9 308:22
negatively 169:7
negotiate 46:16
negotiated 26:9
neighborhood 313:14,16,17
neighborhoods 310:17,18 312:16 313:11
neonatal 27:6 65:19 68:1,7,13 74:4 78:4 79:13 92:14 99:17 100:6 158:11 167:13 171:4 174:10 177:22 180:2 188:1
neonates 3:22 63:19 71:14 81:15 99:19,19 114:17
nephrologist 202:4 221:6
nephrologists

235:13
nephrology 199:13
network 99:13
neurologic 28:4
neurosurgeons 17:9,12,21 18:1 19:4 23:7 26:3 36:13 38:9 39:1 40:5 50:5
Neurosurgical 54:6
never 35:12 129:1 205:21 281:12,15 311:14 332:19,22
nevertheless 257:10
new 8:12,13 112:22 190:19 235:9 289:15,19 300:15
newborn 5:6 68:14 153:12 154:17,19 155:8 159:11 160:5 167:5 171:8 174:6 175:5
newborns 155:11
nice 37:3 38:15 39:10 83:9 168:13 190:17
Nicole 2:19 3:6 11:19 350:21 351:20
NICU 178:18,19
NICUs 178:16
night 127:4 153:20
Nina 2:15 12:20
Nine 96:16 145:6 229:5 341:10
NMX 115:17
noise 39:6 44:12,13
nomenclature 122:22 123:2
non 40:20 241:12 242:18 256:19
non-cardiac 3:22 63:20 64:1 91:20 99:4
non-healthy 160:14
non-Hispanic 45:2

non-invasive 172:21
non-neurosurgeo... 49:19
non-preventable 35:10 125:19,21 126:16 132:13 133:3 135:2,4,12 141:13 146:16 147:9
non-response 261:3,5
non-specified 158:5
non-surgical 132:21
normal 154:19 159:9,12 174:21 176:19
North 1:19
northern 163:3 181:14
notice 320:16
nowadays 261:10
NQCA 301:22
NQF 2:17,18,19,19 2:20,21,21,22 9:2 11:6,9,14,16,19 13:4 14:21 31:8 45:15,22 47:8 61:15 63:5 83:14 84:12 157:15 185:1 193:15 214:4 267:16 300:7 301:22 302:8 348:10
NSQIP 85:3,8 98:7
number 8:12 14:10 18:15 21:8 40:4 40:21 47:11 50:13 53:5 78:14 93:1 117:15 118:19 124:9 131:21 148:9 151:16,20 155:20 157:9 163:20 169:13 173:10,12 178:20

186:1 197:10 200:9 204:3 217:10 230:10 245:17,17 246:1 253:21 254:8 267:18
numbers 29:12 32:3 69:17,18 96:1 113:14 169:10 186:11 208:3,15 211:5 231:7 334:16
numerator 117:8 119:22 129:10 150:20 166:20 173:6 180:6 204:3 231:22 338:15 339:6
numerators 172:18
nurse 10:12,19 27:7 274:17
nurseries 179:13
nursery 153:17 154:18 158:13 161:2 166:18
nurses 13:3 240:2 243:19 277:8,8
nursing 10:18 13:2 13:5 106:4 251:14
nutrition 164:15
nutritional 206:22
N.W 1:20

O

OB 270:1
obesity 10:22 311:5
object 328:5
objections 307:21
objective 147:4 188:7 335:16
observation 83:14 179:17
observations 67:17 67:20 86:9,13
observe 183:13 241:8
observed 63:21

163:1 270:10
observed-to-expe...
63:21,22 110:18
obstetric 174:22
185:5
obstetrician 180:9
obstetricians
154:20
obstetrics 171:22
obtaining 14:12
obviously 65:3
73:10 99:17
104:21 141:15
163:20 242:16
265:21 351:17
occlude 27:19
occur 28:3 41:13
52:11 65:21 128:1
167:20 168:9
179:1
occurred 53:7
87:12
occurrence 73:11
occurring 25:20
odds 88:5
offers 335:10
office 93:9 217:20
Officer 9:13 10:1
office-based 263:3
offshoot 174:12
oftentimes 24:3
oh 57:11 64:8
103:18 120:17
131:16 135:8,10
138:20 151:8
195:7 231:18
250:1 260:10
285:1 295:14
298:1 312:11
349:22
Ohio 10:13 184:6
okay 13:19 16:7
25:5 29:13 30:2
39:3 43:5 45:17
46:13 48:16,22
49:1 51:13,13,17
52:17 58:3,22

59:15 60:15 62:18
63:17 81:6 86:3
90:14 92:21 94:15
96:13,16,18,18
102:18 103:5
109:2,5 110:8,13
119:14,19 120:21
121:5 125:15
129:3 137:16,19
144:2,5,12,13,16
145:7,11 146:14
151:3,8 152:3,16
153:9 161:16
162:1,17 165:18
172:13 177:11,15
189:10,21 190:1,5
190:9 191:14
193:9 194:7,15,22
195:12 214:10
215:19,22 216:9
217:14 222:22
225:20,22 226:6
226:11,14 227:10
228:15 229:6,9
231:10 234:4,12
234:15,20 236:6
237:12,15,20
238:1,16 244:15
252:1 255:11,15
256:5 260:10
262:5 264:11
273:21 279:14,18
280:5 282:1
288:12 290:16,19
291:7,8,22 292:8
297:14 298:7
305:11 306:20
307:20,22 312:13
314:3 315:1,2
316:20 321:10,20
323:22 327:17
328:4 330:4
331:10 336:2
337:22 339:2,19
339:20,21 340:10
340:22 341:2,5,11
347:20 348:2,3

old 115:5 251:2
269:12 306:3
older 249:15 280:4
280:8 289:17
omit 103:9
omphalocele 65:14
onboard 23:12
51:3
once 74:10 108:18
166:4 179:1 220:6
262:22 264:17
293:15
ones 22:11 51:22
75:20 80:19 92:11
162:13,15 166:21
242:2 255:20
266:6 297:19
314:17 325:18
327:20
one's 294:11
one-month 35:7
one-third 221:3
274:5,6,7
ongoing 235:16
315:6 317:17,18
321:6
Oops 267:1
open 13:7,10 64:5
93:15 112:14
154:6
opening 128:15
171:2
operate 78:17 79:6
operated 40:11
62:8
operating 21:9
23:6,10,17 25:2
31:7 57:15 78:16
78:16 79:5
operation 19:6
20:18 21:10 25:21
26:4,8 27:3 50:10
50:14 71:19 74:5
79:3 126:4
operational 30:11
operations 50:7
65:20 105:6

115:16 154:14
operative 72:20
73:21 106:3 126:5
operatively 115:18
operator 13:6,10
127:12 134:6
141:11
opinion 249:21
opinions 264:10
opportunities
176:9
opportunity 17:8
111:2 112:3 141:9
142:14,16 180:9
192:13 211:8
232:1 233:22
236:1 268:6
280:18
opposed 20:2
112:20 113:16
115:3 155:9 176:2
200:16 201:9
210:3 232:7
234:13 316:10
330:9
opposite 313:2,4
336:18
optimal 7:3,10
264:6 321:22
optimize 191:15
option 141:14
285:17
options 297:17
298:22
order 3:2 18:7
19:13 29:12 52:12
66:2,6 99:14
103:3 138:3
218:13 240:5
241:12,20 252:22
253:16 334:8
ordinary 73:20
Oregon 345:9
organization 155:1
256:21
organizational
13:5

orientation 149:5
oriented 262:15
originally 275:1
originated 162:12
originating 153:15
161:13
OT3-029 4:13,17
OT3-031 5:6,14
OT3-041 6:22
OT3-042 6:24
OT3-044 7:2,9,19
OT3-045 7:4
OT3-050 7:6
OT3-27 3:7,19
OT3-28 3:21 4:11
6:20
OT3-29 5:19
OT3-46 6:8
OT3-48 5:20 6:6
ought 55:10 147:7
147:8 342:20
outcome 18:3
21:13 26:5 30:13
75:15 83:5 90:6
104:9 111:19
112:7 114:7
116:18 126:13
128:18 130:8
134:8,10 142:17
154:20 155:8
168:16,17 171:9
175:3,4 187:4
197:15 198:7,13
198:18,21,22
206:13,13 207:11
207:13 209:3,3,7
209:8,9,10,19,20
210:2 225:5,9,10
225:18 226:1
315:11 316:13,15
317:13 318:16,20
323:3,10,14
325:21 326:12
327:2
outcomes 1:4 20:19
75:8 81:12 95:18
111:13,14 116:17

121:21 123:18
131:18 134:19
141:7 155:13
157:5 165:4
166:17 170:13
179:20 180:3
182:2,4 185:19
187:14 191:15
197:5,15,17
198:11 205:13
206:10,16,19,22
207:1 209:1
210:11,12 211:7
211:22 225:14,17
226:5 241:17
243:4 309:18
320:5 326:4,6
outpatient 262:10
outpatients 57:7
outside 142:20
235:20 300:8
333:15
out-of 331:2 337:19
out-of-pocket
322:4 329:17
331:4 332:15
333:4,19
overall 3:19 4:11
5:19 6:6,20 7:19
20:7 35:19 58:5
83:18 84:1 99:2
109:16 111:17
132:16 146:4
204:20 229:11
244:18,19 246:5,6
258:11,13,15
296:8 305:22
311:13 330:13
333:8
overcome 136:22
overlap 88:1
overlaps 266:4
overrepresenting
260:15
oversurveyed
261:11
overview 238:19

overwhelmed
289:2
owner 256:16
257:1
Oxford 174:12
oxytoxin 167:12,16
191:9
o'clock 236:12

_____
P
_____

package 61:22
page 283:4
pages 251:6
paid 147:9 156:4
paired 214:12
225:9,18 227:20
PANDE 2:21
panel 87:3 179:11
195:21 329:6
Panorama 11:3
paper 124:19
parallel 191:8
218:5
paramount 105:1
parent 104:22
105:8 243:22
245:20 247:21
254:19 261:13
262:15 264:7,8
267:10 274:16
278:20 280:3,10
280:13 281:1,4,13
283:12 294:1
295:4 335:16,22
parents 6:9 104:11
104:15,18 233:16
237:9 240:1
243:11 245:12
249:9,15 259:10
259:12 260:2
263:19 264:4,10
264:12 271:12
279:13,13,16
280:14 329:12
330:20 332:6
336:21 337:16
parent's 281:18

337:12
Parkland 9:4
parse 269:22
part 10:5 24:13
25:3,4 32:4 61:15
75:21 79:7 84:17
103:17 113:13
131:14 183:8
204:20,21 224:9
261:4 264:15
280:6,7 281:14
286:16 303:12
307:6 310:4 312:5
317:21 341:6
345:2 349:18,20
350:1 351:2
partial 51:11,13,15
51:16
partially 30:7,14
31:5,20 48:20
58:2 96:14 107:9
144:3 145:4,21
190:8 192:18
226:19 228:5,22
291:3 292:1 297:9
316:18 340:4,20
341:12
participant 261:13
participants 13:8
participate 131:22
261:9,13 280:11
293:6
participating 43:12
149:9
participation
349:15
particular 16:16
65:11 90:16
100:13 115:13
130:2 134:6
135:10 305:20
322:16 330:2
particularly 26:16
27:15,19 58:9
65:4 73:1 249:3
261:19 262:9
264:12 274:1

322:18 328:21
partly 149:6
partner 167:9,11
Partnership 10:9
Partridge 2:8 10:7
10:8 98:19 101:14
150:14,19,22
186:16 246:11
247:1,8 248:15,18
248:21 249:11,19
299:2,11,18,22
301:10 308:21
318:17 319:5
323:6,20 324:3
342:4,8,14 343:12
343:20 344:2,5,15
344:20 345:1
347:21 350:21
parts 18:15 350:5
pass 11:12 59:9,11
234:16
passed 13:22
path 268:4 316:14
patience 151:11
patient 1:4 10:3
12:14,21 27:17
41:12 53:4 73:9
74:16,17 77:5
99:11 122:13
126:3 127:5,11,14
127:17 128:5,14
191:16 197:20
200:10,14 201:2,5
201:16,17 202:2,7
202:9 203:16
208:1 209:22
217:22 219:5,6,8
219:16,22 220:1,3
221:18 223:6
239:4,4 242:21
249:8 254:19
266:14 272:21
279:21 326:5
patients 6:9 27:5
38:16,20 41:8
53:3,11 72:21,22
73:9 83:12 84:21

133:15 171:17
194:19 196:11,12
196:18 197:11
198:21,22 199:4,6
199:7 201:8
202:11,13 203:12
204:4 205:13,17
206:11 209:7,9
210:7,16 211:10
211:18,20 212:15
219:2 220:13,20
221:2 223:11
224:4 232:9
233:14 235:18
237:9 239:15
241:5 242:14
243:11 264:3
272:15
patient's 126:20
127:2 128:2 175:2
patterns 101:18
206:1,7
pay 323:14
payers 265:5
318:21
paying 233:7
payment 106:14
206:11
PCI 55:8
PCPI 13:16 194:9
194:13
PDAs 115:15
PDF 250:13
pediatric 9:18,21
10:19,21 12:7,10
17:9,11 27:6 33:5
33:15 64:22 65:5
78:3,13 85:8
95:11,18 97:17
98:7 100:2,8
117:9,14 118:8
120:1,2 123:6
139:9 154:13
195:17 196:5,12
197:12 204:20
213:4 220:18,20
221:2,11 224:19

232:9 238:22
239:17 246:3
257:5,12 262:4
265:8 267:7 284:1
291:18 300:13,18
301:14 303:9
319:9,12
pediatrician 12:1
224:15 315:15
pediatricians 23:20
pediatrician's 93:8
pediatrics 9:5 65:5
201:6 205:19
223:5 299:20
325:10 345:7
pending 58:8 305:8
people 30:14 45:10
48:9 49:18,21
50:15 51:12 55:15
55:20,22 56:4,18
78:14 90:7 95:19
95:20 121:20
124:7 125:4
129:20 131:14
135:3 155:18
169:7 174:20
184:4,9 187:2
189:21 190:4
200:22 207:8
211:4 220:14
223:1 238:1 251:1
252:22 253:3
258:11,13 259:20
273:22 274:1
275:16 276:2,19
276:20 277:3,12
277:14,17 278:1,4
278:6,19 284:21
285:10 293:5,17
293:21 294:7,8,19
296:1,3 303:16,19
322:18 325:21
333:13 336:13
338:1 341:1
people's 334:19
perceive 331:2
perceived 6:23

14:14 308:13,14
309:6
percent 20:8,14
27:1,2 33:7,9
37:22,22 66:19
79:15 88:10 94:3
103:12 106:16,17
114:19 125:7,9
132:5 133:20,21
153:13 157:8
158:1 163:6
168:22 169:5,11
173:12,13,15,15
173:16,17,22
174:1 176:5,7
178:1,3,9,9,10,11
181:6,6 182:16
186:4,6 196:18
205:18 208:6,7
209:15,18 211:16
216:21,22 260:6
270:12 273:8,13
273:16 275:15
296:9 311:15,15
329:13 331:13
333:14,17 334:12
337:16 339:12,13
339:15
percentage 37:16
78:12 114:18,20
173:18,19 194:17
272:6,9 296:1,5,9
315:5
percentages 253:10
perception 149:22
311:2 330:21
332:6
perceptions 267:11
perfectly 77:9
174:21,21 183:14
316:18
perform 50:7 111:3
116:22 139:2
242:6 255:12
performance 11:8
11:16 84:1 142:21
182:12 224:9

240:19
performed 21:11
42:21 43:1 120:1
126:21
performing 32:22
33:6 114:5
performs 116:21
119:6
perinatal 155:1,22
167:15 186:18
perinatologist
154:21
period 59:20 60:15
62:12 68:2 69:18
153:15 159:15
161:14 185:16
194:19 242:16
300:5
periods 110:1
PERKINS 2:25
permanent 28:4
Permanente 11:3
Persaud 2:8 9:3
person 15:2 50:16
108:9 125:21
130:12 276:17
320:9
personal 31:19
334:19
personally 295:20
personnel 50:13
perspective 26:19
45:22 98:21
128:21 168:20
175:2 251:19
259:3 267:16
284:12 326:6
perspectives
271:13
PERSUAD 9:3
37:16,20 49:8
51:14 59:7,13,16
60:8,18 63:14
132:11 227:7
309:10 310:14
311:9 315:12
320:15 331:20

352:8
phase 15:17 322:12
351:2
PhD 2:2,4,9
phenomenon
260:17
Phil 9:9 26:13
PHILLIP 2:6
philosophy 175:7
PHIS 38:5 40:16
41:2,4 42:10
51:21 52:20,21
54:1 59:21,22
70:5 82:17 108:2
phone 15:2,3 34:11
150:6 151:4,5
152:8 194:10
241:1,6 243:1
252:11 346:1
phrase 280:22
phrased 257:14
physical 311:5
320:4
physically 50:14
physician 56:13
114:2 120:11
142:9 206:1,6
207:15 217:22
224:2 246:18
263:2 274:16
275:4
physicians 101:8
111:3 114:17
140:17 142:12
197:9 203:20
204:14 207:3
210:15 321:5
physician's 217:20
physician-level
221:14 224:10
physiologic 207:11
207:13
physiological 209:8
209:10,18
pick 25:9 26:1
32:20 65:10 148:6
284:9 290:5

327:20
picked 115:5
157:14 158:8
297:4
Picker 274:6
287:11
picture 329:9
piece 46:7,19 74:11
79:10 207:10
264:20 265:7
304:3 311:15
pieces 159:18 199:3
pilot 186:8
pinged 56:6,9
Pittsburgh 10:21
11:1
place 138:16,17
140:9 187:19
188:18 215:10,21
223:18 224:12
330:22
placed 18:22 20:9
21:5 32:18 37:17
37:18 57:14
205:17
placement 20:21
placements 117:18
places 19:1 32:21
149:1 191:1 192:8
217:19
plaintiff's 156:1
plan 5:21 43:7
194:16 195:1
199:1,7,9 200:17
202:6,7 203:2,19
204:4,7 205:12
207:12,22 209:11
210:18,20 211:21
213:16,22 214:15
214:16 215:1,3,12
215:15,18,21
216:2,12 217:3,17
218:8,12,15,16,18
218:22 219:19,21
230:2,6 231:17,19
235:20 242:10
254:3 261:22

165:21 176:16,18
177:3
primarily 65:22
87:9 98:21 111:9
114:17 125:11
309:1
primary 108:16
224:14 246:17
321:5 344:22
primetime 268:15
principle 239:8
principles 344:19
printed 16:13
prior 73:22 99:4
160:22 185:12
195:16 332:12
prioritize 325:17
priority 350:10
private 223:21
224:20 329:14
333:7
privately-insured
333:20
privilege 12:18
13:4
probably 14:1 20:7
22:8 28:10 44:18
47:21 61:2 67:16
74:6 79:16 83:4
83:20 91:9 108:18
113:16 116:1
119:6 132:13
144:9 158:7,22
163:13 169:17
183:1 188:14,21
190:17 191:12
196:11 205:20
222:15 223:10,13
224:7 237:5
257:22 273:18
299:3 304:19
306:3 307:3,18
308:5,10 323:15
324:20 334:22
343:5 350:8 351:5
351:8
problem 22:19

26:22 41:7 56:21
65:4 72:4 114:15
125:18 126:7
127:6 130:5
141:16 172:16
173:22 201:7
252:15 253:17
258:22 269:2
270:5,20 280:12
296:2 299:4 302:9
320:13 326:21
336:16
problems 14:12
55:15 65:2,7
168:9 172:12
176:20 218:9
219:9 233:15
272:9 319:4 320:7
320:10
procedural 20:1
168:9 342:22
343:14
procedure 17:11
21:12 23:10,14
32:22 34:1 53:11
54:19 73:10,15
77:6 79:4 80:21
84:14 91:12
102:17 104:22
106:2 124:13
125:12 126:21
128:3 133:4 134:1
134:3,4 135:11
156:9 167:2
199:19 201:21
243:8 278:11
procedures 40:22
52:11 53:7 55:9
66:4,10,17,20
68:2,3 73:1,13
77:2,4,5 80:13
81:4 84:16 87:11
87:15,20 88:9,11
91:17 92:1,2,4,7,9
92:11 93:2,6 94:7
94:9 95:18,20
102:10,14 103:4,5

103:6,10,13,16
105:4 111:4,11
114:6 116:8 118:3
118:9,19 119:1
120:14,16 123:1
132:22 133:18,19
139:3 154:15
156:4,5 168:6
172:19 174:11
278:20
proceed 189:4,7
288:6 289:9
290:17 330:6
proceeding 76:7
proceedings 352:20
process 15:14
21:12 23:8 38:11
41:13 42:19 45:16
61:11,15 63:5
98:14 136:4,7
138:15 140:6,10
162:13,15 164:7
166:7 197:16,19
198:7,18 199:22
209:3 210:3
213:17 225:6,10
244:2,2 250:8
264:3 265:3,14
268:4 284:21
288:1 300:7
315:10,14 316:7
316:13,19 317:3
318:11,15,18
320:22 321:9,14
321:16 323:3,9
326:17 327:16
347:2 349:8
processed 241:11
product 54:9
productive 324:12
professional 22:2
315:8 316:2,12
317:8,14 318:1,2
320:18
professionals 27:9
295:13
profile 285:14

prognosis 258:20
program 10:3
12:14,15,21 85:4
108:18 109:4
183:15 322:2
programs 347:10
347:12
progress 301:12
project 15:17 72:20
84:18 123:18
131:14,19 140:18
176:21 235:7
239:10 241:4
261:4 266:16
308:20 326:4
349:16 350:2,5
351:18
projecting 154:1
projects 186:8
187:20
prolonged 167:16
promise 153:4
promptly 28:1
properties 242:7
proportion 77:17
115:1 160:20
177:8 178:13
321:4
propose 239:22
proposed 242:14
325:9
proposing 129:20
138:17,18 241:18
prospective 54:17
protocol 184:8
241:3 261:8
proud 19:6
provide 14:18
46:18 47:1 49:5
82:16 92:16 150:9
151:22 196:3
259:8 277:13
289:11,22 293:22
308:9 332:18
provided 91:22
224:18 244:5
297:21

provider 141:17
146:11 220:22
221:10 224:14
259:3 316:4 335:3
335:14
providers 22:3
101:4 191:2 293:2
293:7 295:2
329:18 335:13
provides 145:1
332:17
providing 25:8
170:6 224:3
proxy 280:9,19
315:19
psychiatric 10:12
psychiatry 10:15
psychometric
242:7 255:13
public 8:17 46:21
160:20 169:18
170:4 282:8 283:2
284:3 343:9
publications 329:5
publicly 62:17
public-insured
333:9
published 28:9
60:22 91:1 139:10
163:9
publishing 123:8
pull 16:13 18:7
47:14 52:14 53:8
53:18
pulling 54:1
pulmonary 115:16
purchaser 99:11
purchasers 100:20
106:11
purchasing 101:18
107:1
purely 317:6
purpose 142:22
171:3
pursue 36:14
push 171:15
pushback 185:5

pushing 155:12
208:10
put 15:3 23:3 29:1
31:4 45:8 46:21
51:3 56:9 79:18
80:22 93:14 103:8
120:19 124:6
128:7 129:17
134:2 135:9
149:10 159:17
162:9 181:2
183:10 187:19
202:17 214:17
229:15 266:15
271:21 275:7
303:18 321:15
323:14 326:3,5
343:2 346:10
349:8
putting 24:14
31:19 63:5 81:1
88:3 106:18 130:5
135:1 142:22
249:12
p-for-p 265:6
P-R-O-C-E-E-D-...
8:1
p.m 152:22 236:15
236:16 237:2
352:19

Q
---

qualifier 139:13
qualifiers 123:9
qualities 293:8
quality 1:1 8:20
10:1,3 12:14,21
13:2 20:17 26:4
29:17 54:18 61:13
63:4 84:9 85:4
120:18 154:22
167:9,11 181:21
190:19 191:4,8,9
191:17 192:9
208:4 220:15
233:9 239:6
269:13 286:8

293:6 294:2,10,21
295:3,10
quality-of-care
294:9
quarter 22:9 29:19
question 19:21
25:17 26:15 33:14
39:17,18 40:2
42:7 43:6,15
44:17 57:4 60:12
61:5 63:2 68:11
69:6 73:19 75:11
76:3,14 77:11
78:17,19 80:3,6
82:9,20 85:15
90:6 91:16 94:5
95:3 96:20 102:6
103:22 104:4,4,8
106:10 114:22
116:11 118:11
121:2 134:21
140:7,11 143:4
146:14,19 147:17
159:4 163:16
172:9 173:19
175:14,16 176:12
176:12 183:21
189:3 208:21
212:20 217:6
218:2 224:13
248:7,16 250:21
253:19 256:1
257:15 258:1,22
260:5,7 263:7
265:17 267:8
269:2 275:3
276:14 277:7
278:6 279:1,11
280:6,7 282:7,12
282:17 283:8,9
284:6 285:7 286:7
288:20 289:14
293:13 294:4,5,14
295:11 296:15,17
297:15,19 299:16
311:1 315:10
316:8 317:4

318:12 319:1
325:13,20 327:19
330:2 336:8
337:13 338:7
341:15 342:18
343:11,13 344:17
345:8 346:13
351:4 352:9
questionnaire 6:9
237:8 239:18
240:18 300:13,15
303:10 309:13
questionnaires
256:21
questions 15:9
19:17,18 24:17
26:14 39:14 51:5
51:20 56:20 62:6
62:13 67:16,18
83:11 85:13 86:9
86:13 91:3 95:5
98:5 100:10
105:15 112:13,14
113:8 148:17
149:7,12 158:16
158:19,19 162:18
177:18 188:22
189:16 190:1
224:22 241:21
242:1 245:4,9
248:3,4 252:7
262:6,14,14 266:6
274:15 275:8
276:9,12 278:3
282:13 283:14
285:18 287:2
322:16 330:1,15
330:19 332:13
339:8 340:15
quick 16:4 33:14
57:3 82:8 90:5
104:3 148:11
163:16 274:15
282:6 348:18
quickly 13:19
232:3 307:8
348:17

quiet 171:1
quintile 169:15
quite 32:6 47:9,20
55:12 68:18 69:13
72:7 129:22 156:6
163:10,22 178:19
179:19 181:17
189:22 239:8
257:6 277:2 329:2
330:13 342:19,21
343:14 344:15
345:14
quote 176:16 180:6
339:16
quote/unquote
295:1

R

R 2:3
race 71:1 242:17
race/ethnicity
45:13 243:4
racially-associated
166:2
radar 18:2 349:9
radiologic 92:7
raise 34:9 86:2
96:11 110:4
112:12 342:5,9
raised 62:7 346:9
347:4
raising 114:21
random 242:14
randomly 241:5
254:18
range 157:8 181:6
217:10 272:3
ranged 216:21
ranges 114:18
Rao 2:9 10:20,20
19:16 32:15 67:19
76:10 114:21
115:21 159:4
203:22 205:6
220:6 230:8 321:2
rare 66:2 71:14
74:3,9 95:18

103:10
rarely 132:7,8
rate 3:8 39:20
63:21,22 68:7
83:16,21,22 88:10
94:2 132:5 142:19
155:8,8,10,10
166:3 172:9 176:3
180:12 181:4,4,17
181:22 184:5,7,21
186:4,5,19,22,22
187:7,7,13,15
188:2 196:15
197:5 198:2 203:4
205:16 212:15
245:13 253:4
260:5 261:5
333:15
rated 46:8 281:14
rates 17:16 20:13
20:15 21:16,22
22:7,8 29:5 37:7
42:11 43:20 44:10
44:20 45:3,12
49:12 50:21 52:14
61:3 80:7 87:14
87:16,20 88:3
111:17,18 133:12
134:12 165:21
171:20 180:19
181:6 182:5,10,11
184:17 188:12
192:9 202:12
213:19 245:20
277:22 295:19
rating 46:6 244:18
294:21 305:22
ratings 244:19
308:11
ratio 3:21 4:13
63:19,21,22
110:17 142:18
rationale 188:17
Rauscher 2:15
12:17,20 61:7
92:16,21 251:18
264:19 274:3,11

275:1,11 278:13
283:6,22 284:5,11
284:20 286:10,14
299:9 306:19
RB 195:20
RDS 172:18
reach 203:14
337:11
reactions 97:8
reactive 238:1
reactivity 238:8
read 31:22 97:13
Reader-Thompson
352:13
reading 168:4
readmission 17:16
readmit 60:3
readmitted 50:1
59:18 74:18
ready 107:4 268:14
real 125:18 137:10
178:20 220:5
270:4 286:5
reality 187:12
301:8
realize 56:16 347:1
realized 245:11
realizing 32:12
245:3
really 13:22 23:9
25:17 27:13 29:8
32:9 42:16,22
43:3 46:14 47:5
47:20 50:5,8,18
52:6 54:16 56:22
62:6 63:16 68:21
72:7 79:3 81:13
92:13 96:5 98:5
102:3 105:2,5
108:3 116:12,13
117:18 122:7
126:7 131:13
132:20 138:13
140:6,10 148:7
154:15 155:11
158:10 159:2
166:4,12,16

167:19 172:1
178:4,22 180:16
182:2,6 187:16
195:19,19 196:6
196:10 197:3,14
199:17 205:21
206:5 208:8,10
212:13 213:9,10
214:11 217:7,15
220:5 222:20
224:15 227:21
231:20 232:15
233:19 238:20
239:11,17 241:7
241:10 242:2,6
245:14,14 247:19
249:7,17 252:18
253:8 254:15,20
255:2,4,6,17,19
256:9,10 257:15
258:21 259:19
260:18,19,22
261:8,12 262:10
263:9,15,18 264:2
264:4,4,5,9
266:11,16 267:5
268:6 269:9 270:7
270:11,14,19,21
271:9 272:9,20
276:19 277:22
278:6 281:15
286:18,19,21
287:1 289:7
293:14 294:1
296:1,5,7,11
298:8,16,22
299:16 304:13
314:6 315:17
316:8 322:17
324:11 329:20
332:4 337:9 344:9
344:12 347:17
349:3,5 351:13
realm 155:5 317:13
reason 31:19 71:8
74:2 124:2 129:18
158:7 212:21

218:20 220:10
233:4 241:2
247:13,17 249:16
253:7 266:9
345:11
reasonable 32:7
129:5 157:9 181:4
300:5 322:5
327:21
reasons 155:19
249:5 307:13
reassurance 191:13
rebound 232:10
rebuttal 295:1
recalculate 285:16
recap 3:5 13:20
16:4
receipts 352:9,12
352:14
receive 6:25 7:7
53:11 315:3 320:1
325:5
received 96:22
319:21
receives 35:22
327:14
receiving 80:9
194:20 200:10
recirculation
201:14 202:13
recognition 204:8
recognize 289:19
recognizing 300:19
303:7
recommend 14:5
152:8 193:11
285:22 290:4
297:20 331:22
341:15
recommendation
58:6 146:21
229:11 347:14
recommended 58:7
287:4 346:19
recommending
147:16 193:16
reconsider 234:17

reconvene 152:15
153:2 236:10
record 125:5 139:8
140:22 149:20
152:21 236:15
241:13
recorded 124:13
130:1
records 57:6 140:3
recruited 241:5
recusing 10:5
redo 115:16
reduce 171:19
186:7 188:11,12
253:21 267:18
reduced 303:12
reducing 180:12
184:4,7
reductions 92:5
redundant 240:13
refer 73:8 263:10
reference 90:8
referrals 14:13
referred 123:15
refine 235:19
reflect 129:13
156:15 171:10
265:12
reflecting 168:6
reflection 154:15
reflects 17:10
106:1
reform 322:11,12
regard 26:8 239:7
240:2,19 243:21
245:12,15,18,19
246:4,21 247:16
252:13 254:22
263:14 266:13
272:5 276:14
280:19 284:19
293:18 295:22
345:8
regarding 59:17
regardless 338:4
regards 98:13
region 105:14

regional 334:17
regionally 206:3
221:9
regions 81:19
registries 98:2
registry 38:14 43:2
139:19 140:14,19
regression 88:4,13
regular 119:1
154:17 193:14
264:14 282:9
rehospitalized
77:19
reimbursement
106:16,17
reimbursibles
352:16
relate 21:13 90:8
160:2 229:14
241:16
related 26:4 27:13
62:2 75:2 83:12
86:9 104:4 125:12
164:11 167:15
229:20 277:8
292:17 333:12
relates 104:13
144:20 218:4
relation 226:1
relational 61:20
relationship 33:19
35:18 205:11
226:4 309:2 332:3
relative 43:7 88:5
333:2
relatively 31:10
69:17 312:19
313:12
relatively-new
329:3
release 169:18
released 41:11
relevant 170:6
209:19
reliability 46:9
48:7 189:17 217:7
240:8,10,21 242:3

253:12 289:22
290:11 304:4
reliable 66:13 67:4
68:19 72:9,11
74:11 97:19
121:12,13 124:17
reliably 66:6 67:8
68:21 91:11,13
140:4
rely 76:16
remains 35:22
remarkable 271:5
remarkably 273:5
remember 59:21
227:13 229:17
278:10 291:12
327:9
remind 9:15 130:9
225:21
reminds 24:10
removal 39:9
removed 23:1
renal 219:12
reoperation 35:1
repair 105:9
repeat 147:12
294:5
rephrase 239:18
replicated 47:2
report 107:17
108:10 121:14,22
132:2 141:15
142:1 208:5 211:1
212:15 231:8
240:2 251:1,6
272:5,15 337:16
reported 67:8 85:9
125:7 132:4
147:10 197:8
198:20 199:3
211:3 213:19
214:12 227:21
230:12 252:22
reporter 281:2,3
reporting 46:21
100:17 101:17
121:21 124:5

136:17 141:16
194:18 208:15
210:14 230:19
233:21 234:1
244:11 251:20
287:17 298:17
304:15 329:11,12
reports 193:4
267:10 272:21
representatives
285:6
representing 10:18
request 109:19
112:12 289:10
297:20 298:10,19
304:12
require 303:11
required 25:3
301:21
requirement
118:18
requirements
213:17
requires 29:3 315:6
requiring 115:17
research 12:15
140:18 250:9
researcher 306:4
research-oriented
223:20
Reserve 10:12
reservoir 36:12
resident 275:9,19
resources 31:17
301:6 303:8,12
respiratory 75:17
90:1 125:11 167:4
167:6 172:12,16
173:11 182:22
183:2,19 188:13
192:3,11 277:16
respond 79:8
138:19 186:17
268:10,12 280:14
300:12
respondent 240:14
325:7

response 13:18
14:7 34:12 51:6
91:6 106:10
144:11 190:3
241:13 242:19
250:7 252:9,10
260:5 269:15
270:6 296:15
330:3 336:13,17
340:16
responses 247:20
269:14 271:21
316:6 346:4
rest 67:2 138:1
restriction 146:12
result 95:2 128:1
200:4
results 45:16 69:3
99:17 100:12
142:1 195:22
196:3 198:19
200:3 206:16
230:19 251:7
275:12,13 282:8
291:11
resumed 152:21
236:16
retardation 156:19
164:5
retest 89:10
retired 9:19
Reva 2:22 9:2
262:13 351:21
reveal 215:1
Revenue 331:16
reverse 180:18
review 14:1,9 38:5
42:10,18 76:8
130:15 132:3,9
141:3,7 302:11
310:16 350:9
reviewed 140:17
159:1 248:5
309:11 330:12
reviewers 16:15
307:10 308:16
reviewing 84:19

121:19 153:11
revised 345:12
revision 39:9 115:2
115:10
revisional 219:12
revisions 115:17
343:9
revisit 152:8
314:11
revolve 165:13
rewrite 343:1
re-review 268:20
Rh 156:20
rich 241:10
rid 57:9 222:1
rides 350:13
right 20:5 26:14,18
33:1 40:17 41:3,4
43:4 49:2 50:11
51:7,10,17 57:19
58:4,15 59:3
63:15 69:21 71:7
76:13 77:3 82:3
85:5 92:10 94:10
95:3 96:7 102:12
107:8,14 108:22
109:7,15 110:10
114:16 115:7
127:22 128:16
129:14 136:4
145:11 162:18
168:10 176:22
181:5 187:9
192:14,21 193:10
193:19 205:6
210:10 212:12,19
217:12 221:15
225:1 227:11
228:15 229:10
235:11 241:17
246:2,18 247:10
247:17 249:19
252:5 254:5 255:9
262:17 263:11,22
269:6 271:15,20
272:17 283:11
284:10 287:1

291:5 295:14
297:14 299:18,21
305:1,12 309:7
310:18 313:2
316:4 324:12
330:10 332:8
336:2 337:21
339:18 340:10
341:14 344:5
345:21 346:6,10
348:22 352:7
rigor 265:14
rise 167:5
risk 18:11 21:3
28:2 37:1 50:17
65:3 66:5,14 67:3
72:10 73:12 86:20
87:2,3,8 88:16
89:2,6,17,20,21
90:3,11,16 92:15
93:19,21 97:20
102:14 103:7,8
105:5 116:2
132:22 133:2,5,6
134:4 156:13
184:20 187:11
201:10 210:1
222:3 230:20
318:5
risks 35:8 187:11
risk-adjust 18:13
67:11 68:22
risk-adjusted 64:3
110:20
risk-adjustment
18:17 66:3 75:22
86:17 91:8 116:17
134:9
Rita 12:22
RN 2:5,15
ROC 68:18,20 87:6
87:7 88:20 89:4
89:13 95:16
Rochester 9:8
role 23:8 305:15
rolling 43:7,21
55:14

rolls 286:14
rollups 300:17
room 8:14 21:9
    23:10,17 25:2
    50:14 57:15 58:20
    120:7 328:10
rotate 276:9
round 212:5
route 22:15 179:3
routed 21:3
routine 124:15
routinely 124:14
    268:16
rule 35:3 110:12
ruling 316:19
run 10:21 72:16
    79:1 126:4 269:12
running 29:4,11
    85:8
rural 40:8 166:14
    223:22 300:4
rush 345:19
rusty 87:5

———— S ————
safe 6:23 14:14
    23:2 308:13 309:6
    310:10,10,21
    311:12,14 312:19
    312:21 313:6,10
    313:13,14,15
safety 10:1,3 12:14
    12:21 167:12
    187:21 308:14
    310:13,17,18,19
    311:2,8,20
sake 314:12
sample 33:4 41:19
    66:21 79:15 92:2
    95:12 242:14
sampling 242:13
San 154:10
sat 133:17 302:11
    346:17
satisfaction 239:4
    246:5,6 260:17
    262:16 263:19

264:15 266:14
267:9,12 272:19
272:19 274:19
275:4 279:2 281:9
294:3 299:16
satisfactory 259:8
    298:6 303:15
satisfied 252:19
    258:13,15,16,17
    259:4 264:4,5
    270:22 271:1
    273:13 286:7
    296:10
satisfied/very
    296:10
saw 38:19 69:9
    142:19 320:18,22
    328:10
saying 56:11 61:22
    160:15 161:20,22
    185:21,22 186:13
    225:16 278:14
    317:7 327:1 329:7
    337:6,9
says 42:2 132:20
    137:13 143:15,16
    172:11 176:13
    216:6 250:18
    317:21 319:17,20
    334:20 335:9
scale 140:5 160:1
    252:20 270:9
    271:17,17 289:15
    289:17,19 294:20
    305:21,22
scales 244:16,21
    291:19 305:19
scans 156:6
ScD 2:13
scenario 293:9
scenarios 220:5
    293:18,20,22
schedule 151:12
schema 183:8
scheme 281:11
SCHIP 333:16
school 10:17 14:10

237:21 308:15
309:20 310:11
311:2,22 312:5,22
313:6,10,14,17
schools 6:22 308:13
    311:11,14 312:15
    312:18,18,19
    313:8,8
SCHWALENST...
    2:9 39:16 51:16
    218:3 252:3
    253:18 254:2
    255:9 267:1 310:3
    310:7
scientific 3:13,14
    4:4,5,21,22 5:11
    5:12 6:3,14 7:13
    34:16 48:18 64:16
    86:10,15 91:4
    95:5 96:9 121:7
    143:4,19,22 144:3
    144:20 189:13,19
    190:2,6 226:15,18
    226:20 250:6,18
    253:3 270:6
    280:19 285:20
    288:20 290:20
    291:1,4 293:19
    330:11 336:4,4
    339:21,22 340:1
scope 15:13 225:12
    225:14,19 235:20
    307:10,13 308:19
    308:20 309:8,22
    314:14,15,18
    316:9,9 323:2
    324:8,9,14,17
    325:13,22 326:2,3
    327:8,13 349:17
score 251:20
    260:22 285:16
    304:13
scores 181:15,16
    244:14,20,21
    254:17 261:7
    271:5 298:16
    302:15 323:7

Scott 2:15 7:11
    312:9 313:20
scratch 303:9
screen 308:10
screening 7:8
    175:11
scrolling 262:13
scrutiny 204:22
se 167:17 220:1
    243:17
searching 18:9
seasoned 277:2
seats 153:3
second 15:16 50:4
    67:21 69:6 71:19
    79:20 89:12 115:2
    125:22 177:20
    183:1,3 213:12
    298:11
secret 313:9
section 48:16
    172:13 180:19
    244:19
see 20:15 40:2
    41:21 53:5 54:20
    55:12 58:13 65:19
    69:10 70:17 78:10
    80:14,22 81:17
    83:4,15 96:4
    113:17 119:11
    126:19 146:16
    147:17 151:1
    157:8 165:14
    172:11 182:14
    189:1 206:7 211:4
    211:9 213:20,21
    216:7 230:11
    231:8 233:21
    234:2 235:16,18
    251:17 255:5
    261:5 262:13
    263:19 266:17,19
    269:1 272:6,8
    275:21 291:2
    295:20 308:10
    316:13 317:8,14
    317:22 318:7

320:5,6,8,19
326:1,2 329:18
335:3,12
seeing 17:16 81:4
    217:22 303:6
    305:10 316:11
seen 50:20 51:1
    101:1 148:9 163:4
    167:5 180:21
    191:22 192:2,7
    239:3,6,9 246:17
    250:11 270:20
    271:4 302:14
    315:7
segregate 116:13
select 242:2
selected 84:15
    240:18 251:14
    254:18 271:16
    282:13
selection 260:14
selections 91:19
self-report 326:5
send 55:22 289:1
    350:15,17
Senior 10:8 11:8,16
    12:13 13:1
sense 40:6 47:7
    77:20 78:6 91:9
    94:17 99:1 102:2
    118:19 149:17
    178:16 187:6
    214:13 225:7
    256:6 300:8
    311:20 350:22
sensitive 176:15
    262:11
sensitivity 38:22
    133:4
sent 153:19 352:13
separate 233:10
    277:17 313:13
separated 183:11
separating 122:2
sepsis 180:7,12
sequelae 28:4
sequence 19:12

sequentially 64:15
series 288:3 289:9
    334:5
serious 75:17 84:20
    90:1
seriously 23:4 56:6
serve 83:2,4
served 186:17
serves 155:3
service 259:7 285:4
    331:16
services 49:22
    277:13 300:18,19
    335:11
serving 12:18
session 202:3 232:6
set 54:3 106:13
    108:4 158:9
    166:12 180:6
    214:9 239:11
    240:4 253:7 254:6
    256:21 259:20
    302:18 322:16
    350:2
sets 62:6
setting 93:11
    104:17 146:11
    246:3 262:10
settings 155:18
    239:17 277:6
settling 331:18
seven 207:21 227:4
    301:2 325:8
    348:19
severity 122:6
    123:5,9,15 130:17
    132:3 139:12
    141:1 258:19
shaking 305:10
share 70:16 111:19
    149:3 235:17
    252:4 274:4
    284:12 293:5
sharing 143:1
Sharron 2:4 10:16
shifting 106:19
shifts 277:9,10

shirts 126:2
shocked 336:14
shorter 242:9
    342:10
shots 237:19
show 121:4 163:10
    182:2 187:16
    189:7 190:7
    192:10 273:6
    288:9
showed 68:21
    75:16
showing 38:20
    114:12
shown 134:16
shows 62:9 187:21
    272:14 296:12
shunt 3:8 18:2
    19:20,22 20:20
    21:1,2 22:14,15
    22:17,19,22 23:1
    23:3 24:1 25:20
    27:15,15 28:11,15
    35:1,8,22 36:1
    38:15 39:5,8,9
    40:9 43:19 45:3
    50:1 54:19 57:14
    60:3 80:22
shunts 18:21 20:8
    28:22 32:18 36:9
    36:17 37:17,18
    80:1,2
sick 56:18 219:8
    271:14
side 83:20 160:13
    160:14 168:7
    181:10 233:3
    323:11
sidewalk 312:20
signal 26:1 30:1
    37:14 44:12,14
    51:2
signals 176:14
significance 69:15
significant 31:18
    32:4,5 40:21
    71:16 93:3 95:2

114:22 117:15
    153:16 157:17
    161:1 175:4
    178:12 245:11
    253:5 268:18
    321:3
significantly 51:1
    68:7 180:12
    181:17 243:1
    334:18
similar 33:14 54:4
    66:5 74:21 85:11
    123:14 132:4
    133:21 138:11
    213:9 216:13
    244:17 245:10
    269:9 272:20
    300:16
Simon 54:15
simple 200:19
    220:9
simpler 220:15
simplicity 220:7
    222:7
simplify 196:22
simply 94:17
    214:15 227:17
Simpson 271:8
single 36:16 43:8
    95:14 148:14
    191:22 199:4
    202:3 215:10
    228:1 309:12,13
    309:22
singleton 153:13
single-pool 194:21
    194:22 198:12
    199:8 232:4
sister 155:1
sit 302:10
site 47:17 209:6
    219:2
sites 47:17 48:9
    69:7 131:8,21
    191:21,22 209:14
    217:17
sitting 237:13

252:5
situation 35:4
    256:11
situations 162:8
    257:17
six 114:17 123:11
    192:20 205:16
    208:7 227:4 228:7
    234:11 236:12
    325:8
size 57:14 178:2,12
    222:4 232:9
sizes 95:12
skied 249:6
sleep 281:8
slightly 289:16
slippery 137:9
    323:15
slope 323:16
slopes 137:9
sloppy 56:7
small 30:11 31:16
    32:3,6 41:19 50:9
    50:20 69:17 78:11
    78:14 114:19
    164:4 165:22
    166:15 173:19
    186:4 188:15
    196:10 204:5
    206:4 222:8
    230:10 300:21
smaller 111:3
SNAC 346:17
social 162:8
Society 54:6 97:6
socioeconomic
    81:19 294:18
    331:8
sodium 202:9
somebody 79:6
    115:5,22 116:2
    204:9 272:21
    273:1 331:1,3
someone's 267:2
somewhat 33:14
    315:19
Sonja 2:16 6:11

12:12
sonogram 165:7
sorry 11:10 14:6
    48:1 59:2 84:11
    91:2 93:16 132:10
    133:9 138:21
    195:4 231:3
    245:21 250:1
    252:4 260:12
    267:2 274:22
    288:18 308:3,4
    312:12 335:5,18
    338:18,20 346:12
    349:19
sort 17:10 25:7
    26:5,8 30:3 31:14
    39:10 44:11 47:13
    54:2 57:4 60:9
    61:10 62:2 64:13
    64:14 65:6 78:21
    87:21 92:2 106:22
    108:9 120:7 126:8
    135:7 138:9
    146:22 148:10
    154:14 177:2
    187:9 193:5 220:2
    242:8 247:11,13
    247:16 251:8
    253:1 255:22
    257:12 258:3
    259:16,19 262:3
    263:9 266:5,14,16
    268:15 269:20
    270:7 276:5 278:7
    281:5 285:15
    287:21 295:1
    296:2,4 312:1
    316:2 351:12
sorts 71:2,9 83:11
    105:15
sounded 231:16
    253:19
sounds 42:4 63:11
    91:7 150:3 202:10
    203:9 204:7
    267:14 304:6
source 191:13

so-called 125:18
Spartan 322:21
speak 154:10
200:21 232:1
238:21 257:7
261:18 300:10
speaker 15:5
speakers 8:17
261:17
speaking 60:19
172:9 302:21
304:9 310:5
339:15
special 17:14
specialized 117:14
120:6,7
specialty 30:12
56:14 112:20
113:6
specific 32:14
38:21 39:8 54:18
57:16 73:9 81:10
81:12 98:1 103:8
105:16 109:20
124:12 147:11
164:7 177:14
218:12 265:12
275:8 347:4 350:1
specifically 32:1
39:4 65:18 75:7
97:17 98:12
105:13 112:11
160:19 162:19
193:2 198:14
200:22 262:20
304:12 305:18
346:2
specification 117:8
218:5 230:2
320:16
specifications 29:2
42:2 47:1 150:19
215:13 304:14
specificity 38:21
58:15
specified 47:4
117:19 145:17

158:4 231:21
specifies 117:8
specifying 120:11
spend 320:11
spends 311:22
spent 18:8 116:4
301:2
spill 177:2 313:17
spina 18:20 35:7
36:20 37:1,5,18
spinal 21:6
spinning 290:15
splay 271:6
splits 87:18
spontaneously 20:3
springing 98:14
squeeze 175:22
stabilize 29:15
stabilized 29:21
stable 29:5
staff 2:17,18,19,19
2:20,21,21,22 9:2
11:6,14,19 14:21
23:6 46:8 50:10
58:6 83:14 194:13
267:16 294:12
351:20
stakeholder 249:1
standalone 343:3
standard 3:21
42:15 108:4
142:17 143:9
197:18 204:12
208:1 293:4 296:3
305:21 345:6
standardization
149:7
standardize 147:4
standardized 4:13
7:7 63:19 83:16
83:22 110:15
293:12 327:14
standardly 219:20
standards 1:3
264:8 344:11
standpoint 19:22
27:16

stars 169:14
start 8:18 16:8
41:21 54:10 56:4
67:16 78:15
117:17 156:12
184:15 206:6
207:3,6,7 208:11
221:13 255:11
296:13 303:9
326:4 329:9 350:8
350:18 351:2
started 8:5 49:11
54:13 55:19 70:4
87:16 122:4,16,21
123:19 124:3
125:12 131:13
153:2 208:9
211:13 237:5
241:4 248:3 253:8
261:22 273:14
303:3
starting 49:14
67:18 139:20
157:1 191:10
235:7
state 9:14 55:4
62:21 101:15,19
138:2 163:11
181:18,22 207:16
209:5 210:11
334:15
stated 168:19
statement 257:3
309:17
statements 21:21
334:5
states 33:4 41:11
79:14,18 82:16
157:3 160:10
184:4 185:4
205:15 207:18
286:22 345:12
347:11
static 15:4 217:4
stating 329:15
statistic 88:20
216:20 217:8

statistical 69:14
95:12
statistically 95:15
170:18
statistically-signi...
90:4 117:3
statistician 64:22
statistics 87:5
169:16 290:12
status 318:14
319:14 331:9
stay 6:10 162:10
237:10 243:5,6
244:4 247:13,15
258:5,7,7,12,14
259:6 275:15
staying 276:17
Steering 1:7,17
13:12 47:12 84:18
186:18
Steiner 41:14
step 38:9 268:7
276:6 284:15
316:14
stepped 268:1
steps 116:20
209:17 254:12
348:17
steward 12:18
238:14 328:16
331:21 346:21
stewards 234:22
238:11
stick 302:16
stifle 301:12
stint 117:18
stop 135:14
story 287:7,8
329:21
straightforward
107:21 108:5
190:16
strategy 66:4
101:12 140:1
stratification 222:3
230:1,9,20 331:22
333:6 334:11

stratify 45:16
213:6 241:14
242:17 333:11
streamline 23:9
50:6
Street 1:20
stressor 310:22
311:1
strict 241:3
strictly 50:16
stripped-down
322:21
strong 21:15 32:13
112:19 226:2
253:15 309:18
strongly 20:19
40:12 129:22
329:7
structure 52:13
245:6
structured 76:11
76:13
struggle 277:2
struggles 312:14
struggling 267:13
267:22 268:3
299:3
STS 35:15 129:6
studies 65:16 77:21
111:9,9 184:3
study 36:10 65:10
82:9,12 100:14
220:22 280:19
stuff 54:16 56:17
57:17 106:21
184:9 193:5
235:14 301:3
stuffed 303:4
Stumbo 2:15 7:11
312:9,9 314:1,7
317:4,6 328:20
332:8 334:8 335:5
335:16,20 336:19
337:11,21 338:2
338:12,16,21
339:3 345:4
346:12

subdomain 37:10
subdomains 45:12
subgroup 309:11
subgroups 70:13
222:10
subject 146:7 166:8
294:14
subjective 259:15
264:3,9 294:3
330:20,22 331:19
submission 148:1,7
235:9 335:6
submit 207:6
251:11 290:10
submitted 14:20
248:9,12,13 307:6
submitting 345:4
subsequent 346:1
subsequently 74:18
subset 31:16
240:17 249:12
subsets 163:9,12
subtracting 168:13
subtracts 173:13
successful 81:15
sufficient 29:6
289:4 330:6 336:3
sufficiently 85:18
94:20 189:6 288:5
288:9
suggest 19:11
25:10 57:20
188:21 206:15
225:2 230:12
313:12 345:18
suggested 61:11
231:14
suggesting 297:22
suggestion 57:4
60:17 146:21
150:8 206:9
303:21 307:4,7
suggestions 150:15
152:2 303:1
suggestive 24:3
suggests 210:11
Suite 1:19

sum 151:18
summarize 16:1
summarized 152:2
summary 16:3
231:5 290:11
311:10 349:11
summation 154:16
summative 244:21
summer 235:7
superb 352:1
superficial 92:5
super-important
323:3
super-satisfied
252:16 272:7
support 158:12
164:16,17 171:4
187:3
supporting 13:4
234:3
Suppose 168:20
supraventricular
122:10
sure 17:3 21:3 22:6
23:2,13 24:21
27:12 31:14 35:21
37:6 42:7,19 44:9
44:12 45:6 46:7
46:20 47:19 48:4
50:10 56:1 61:9
64:8 67:19,22
69:1 72:1 74:9,22
88:15 100:12
127:21 138:10,20
141:10 149:11
174:4 178:5 184:8
185:7 195:10
198:17 203:20
205:3,8 208:20
214:1,6 216:9
217:5 220:19
221:7 237:15
240:13 242:1
255:17 257:6,16
268:11 281:6
292:18 309:19
314:8 326:2

328:20 336:19
337:9 338:12
342:18 349:12
surgeon 9:18 12:7
65:1 78:3 81:11
81:12
surgeons 20:19
23:20 24:4 25:2
40:12 126:1
202:20
surgeries 78:12
79:13,17 85:1,7
115:2,2 116:7
surgery 3:22 33:15
33:21 55:7 60:2
63:20 64:2 65:3,5
65:19 66:1 68:1
68:13,14 72:3
75:2 78:4 80:4
81:15 82:15 85:3
90:10 91:1,20
92:14 95:9 99:5
99:18 100:6,16
101:16 113:2
115:4 126:3 270:1
276:12
surgical 23:11
24:20 55:9 75:8
77:1 80:12 81:10
84:5,19 93:13
96:21 97:6,12,16
97:18 102:17
104:22 106:5
219:16 258:16
surprised 55:12
96:5 100:11 337:3
surrogate 178:17
surrounding 44:8
surveillance 313:9
survey 6:8 12:13
237:8 238:21
239:7,8,11 240:22
241:19,20 242:9
242:10 243:2,2,10
243:15 245:7
248:7,13 249:14
250:12,22 251:5

252:15,22 253:2
253:22 254:9,10
255:13 257:10
260:21 261:10
263:14,16 266:3,3
267:8 268:8,19
269:22 273:15
279:15 281:6,14
282:3 287:12
288:1 292:11
297:1 306:3 307:6
317:21 325:6
328:22 329:4
330:13 341:7
342:15 343:1,3
345:11 346:3
347:18
surveys 239:5,7
247:19 251:3
258:22 259:18
260:17 265:21
278:2 279:13
282:8
survival 20:21
77:14 182:5
susceptible 145:17
suspect 266:1,4
349:1
suspected 22:18
127:6
suspicion 148:19
suspicious 24:6
Sutter 181:13
191:1,7
Suzanne 2:21 11:13
switch 220:16
switched 220:8
sympathetic
345:15
symptom 319:9,12
symptomology
319:15
symptoms 24:3
system 9:4 15:5
163:3 234:1 276:8
284:14 285:2
systematic 345:13

systems 185:4
S-E-S-S-I-O-N
237:1

T
table 16:14 17:19
69:9,11 82:12
91:22 111:2 150:5
150:8 265:5
288:16 297:17
301:17,18 346:10
tabled 5:5 14:16
348:18
tabs 170:7
tac 131:3 137:5
tachycardia 122:11
127:5,10,18 128:6
take 16:21 18:6
22:3 23:4 27:5
48:2 56:4,6 67:1
71:17 99:10 108:9
108:14 138:17
140:9 141:18
148:11 154:3,12
158:15 160:4
209:17 212:21
222:8,20 236:7,8
256:12 276:5
277:15 287:6
324:20
taken 22:20 104:21
159:17 239:20
266:2
takes 46:17 138:15
223:17 224:20
take-home 161:3
talk 38:3 93:5
104:12 106:17
121:10,17 122:21
184:6 203:11
213:2 216:11
282:2 329:19
351:13
talked 220:19
246:13 254:7
256:17 318:21
334:14 350:7

talking 22:16,17
62:20 70:1 73:3
73:17 78:15 79:2
84:3,5 90:11
101:22 105:11
114:15 128:1,4
147:15 178:8
196:10 216:13
248:18 254:6
277:9 283:8 308:6
324:3,5
tall 99:14
Tamara 54:15
tangentially 34:21
target 138:7 203:11
207:3 236:2
targeted 42:12
55:16
targeting 52:6
targets 208:2
teaching 33:8
274:19 275:20,22
team 16:19 93:13
275:7 301:2,5,21
303:18
teams 351:21
tease 224:5
technical 38:6
44:17
technicians 278:18
278:19
technology-depe...
17:15
teenaged 249:20
279:13
teenager 249:3,22
telephone 2:10,12
2:13,14,15 253:2
tell 31:2 87:2
131:17 220:21
231:22 238:11
246:12 272:13
273:11 275:12,16
287:7 323:7
329:21
telling 68:14 81:10
tells 186:22

ten 107:10 124:9
207:21
tend 84:13 125:14
289:15 336:21
tends 101:4,11
term 5:6 149:15
153:12,13 155:11
160:15,20 161:22
164:2 166:5
170:13 175:5
176:14,19 178:13
182:3,7 184:21
294:18 295:9
terminate 179:5
terming 168:13
terms 17:21 20:5
20:10,17 22:6,11
23:5 26:3 28:6
29:8,21 32:2 36:4
36:20 42:8 52:10
57:20 135:21
142:6,9 167:17
170:3 179:10,15
187:12 191:2
192:15 199:14
205:2 223:8 226:1
242:6 268:4
290:20 294:11
terrific 24:10 34:14
112:9
tertiary 40:10 41:1
test 37:12 39:1
41:21 42:16 60:15
148:20 172:20
275:8 294:14
tested 40:19 42:3
46:8 47:10 163:2
testing 42:8 46:7,9
46:11 47:15 48:2
58:9,13 62:12
101:21 109:20
146:16,20 147:1
149:20 150:4
195:22 196:3
217:13 330:14
testings 330:16
test/retest 46:10

47:18 240:10
253:12
tetrology 116:8
text 151:2
thank 8:7 15:6
21:18 27:21 59:2
59:4 63:14,16
82:6 104:1 109:5
110:9 111:1
125:15 151:8,11
152:4,10,19 154:9
158:16 193:21
194:3,5,6 234:22
235:22 236:4,5
296:14 306:9,16
306:19 348:3,14
352:2,5,17
Thanks 17:6 59:5,6
64:20 86:6
Theberge 2:21
11:13,14
theoretical 301:18
theoretically
282:16
theory 171:17
therapists 277:16
thing 11:12 29:1
34:1 46:22 49:15
50:4 55:18 56:3
56:10,17 68:15
70:20 72:16 83:9
130:19 136:11
141:18 159:2
170:16 177:6,14
180:17 186:2
220:17 231:20
247:11 257:2
259:9 261:9 272:1
275:5 283:5
286:14 295:19
309:15 310:15
315:17 320:15
351:12
things 18:13 24:15
29:18 35:12,14,16
36:12 39:7 45:5
55:8,13 63:8 71:1

75:3,9,12 78:15
81:14 87:7 88:3
97:21 98:10 101:4
106:6,11 113:4
128:22 135:1
136:17,21 137:12
162:6,6 172:5
177:22 180:17
186:10 201:6
210:6 215:8 216:5
216:6 218:21
219:13,18 222:6
232:10,11 245:5
246:22 250:19,20
278:2 281:11
287:18,18 291:19
292:6 298:8,9
312:21 346:8
350:8
think 8:4 20:6
23:22 24:9 26:10
26:20,22 28:14
30:19 32:4,16
33:10 36:21 37:21
39:9 41:14,18
42:16 43:15,17,21
43:22 44:2,6,17
45:21 46:17,19
47:5,8,13 49:8,15
49:17 51:18 52:5
52:15 55:15 58:5
58:9 61:5 62:14
62:15 63:8 66:20
67:19 68:14 69:10
71:12 72:18 75:10
77:9 78:2,8 79:7
80:1,10 81:8 83:3
85:10 86:7 90:15
92:12 95:13,17
96:1,19 99:15,21
100:12 101:14,17
103:1 104:14
105:7,12,22 107:3
109:8,12,17,21
110:10 112:6,17
113:3 117:20
118:2 120:18

124:3 125:20
128:18 129:4
130:19 131:15
132:15 135:2,14
136:7 137:17
138:7,8,14,22
140:12 141:4,6
142:6,11 143:2,7
144:18 146:4,5,18
147:7,8,21 148:9
150:15 152:6,10
160:16 168:14
170:3 177:2
180:15 182:1
183:20 184:1,5
185:10 186:21
187:6 188:19
195:13 196:1,18
196:20 197:6,21
198:3 200:18
201:7 203:18
204:1,16 206:4
207:7,9,15 208:14
209:16 210:5,10
210:12,19 211:2,7
211:8,13,15
214:17,22 215:16
218:18 219:18,19
220:10 221:3,12
222:14 223:9,13
224:1,21 225:7,13
226:3 227:19
229:11 231:4
232:12,15 234:5
234:15 235:9
236:2 237:4
238:17 243:3
246:3,19 251:16
252:15 253:6,20
254:12 258:18
259:22 267:6,8
269:18,21 271:2
273:17,18 274:12
275:15 276:22
278:2,7 280:1,16
280:18 283:4,6
285:5 292:19

293:21 294:13
295:5 296:7
297:14,16,18
298:21 299:2,6,18
300:6,12 301:8
303:14 304:1,2,5
304:13,18 307:2
307:18 309:15,17
314:17 315:13
317:2,9 318:10,11
318:22 320:2
321:3,13,14
322:10,13 323:6
324:7,8 325:10,13
326:6,19,20
327:19,21 328:1
329:20 330:12
332:3,10 333:13
336:5 338:11
340:10 341:21
342:3 343:17
344:1 345:15,16
345:18 346:11
347:6 348:20
351:5
thinking 29:10
32:11 39:11 45:10
49:18,20 64:15
119:13 135:14
164:12 188:10
207:8 223:18
232:22 260:13
310:15 320:8
322:13 348:22
thinks 335:22
third 22:9 36:11
115:2 183:1,3
192:6 340:13
third-party 239:16
Thirty 33:9
THOMAS 2:7
thought 29:20
33:11 36:18 37:3
55:10 67:4 72:10
93:17 104:9
115:21 121:22
174:20 197:19

202:18 207:2
230:8 280:10,17
292:22 322:10
334:2
thoughts 349:13
thousand 79:17
119:20
threatening 122:13
three 14:4,8,15
15:12 25:13 70:6
99:7 106:19 122:9
125:1 148:16
163:13 176:3
192:6 201:19
226:21 227:3
228:10,14 229:2
236:11 269:17
270:18,18 275:8
277:9 298:8
332:14 333:3
334:10 337:1
three-category
270:8
three-point 271:17
three-year 29:4,4
29:11 30:19 43:7
43:21 44:14 55:14
70:3 268:17
threshold 34:3,8
121:1,3 189:3
threw 45:4
throw 133:7
thrown 39:7
THURSDAY 1:12
tied 304:14
tiering 106:18
tiers 106:19
tightening 47:9
time 16:22 18:9
23:10,10 30:21
33:20 35:9 40:10
40:13 46:14 50:6
52:2 53:5 57:14
58:4,15 59:5
67:14 69:18 93:6
95:1 108:9 110:1
110:3,12 141:2

147:11 159:15
160:4 165:4 170:4
185:16,20 199:12
204:22 205:1
207:10 208:4
209:4 210:22
213:13 215:7
232:6,14,14 234:8
235:10 242:15
252:18 254:16
255:17 258:8
259:13 276:18
284:5 285:15
300:5 301:7 302:2
302:4,4,18 304:19
305:5 311:22
321:13 322:12
324:21 326:15
328:12 350:2
351:11
timeframe 322:14
350:22
timeline 254:4
351:14,17
timely 342:20
times 53:5 87:12
201:19 203:14
timespan 266:18
time-limited 47:6
58:8 59:2 102:1
109:18 146:6
149:21 193:13
229:12,13 234:5
298:13,21 304:16
304:19
tiny 113:2
title 153:12 194:16
278:11 300:14
307:9 318:7,8
today 8:6 10:4
13:14 16:4 17:7
71:3 111:2 213:15
290:13 300:2
328:17 342:20
343:21
told 271:8
tolerate 201:18

202:14 219:3
220:4
Tom 9:6 24:8 33:12
57:2 71:11 108:6
134:20 180:14
265:16 288:14
308:8
tome 298:6
tomorrow 57:17
Tom's 106:10
tons 164:16
tool 66:13 99:21
105:7 124:8 248:8
248:13,19 249:18
251:19 254:17,19
254:20 255:18
269:5 270:14
296:7
toolkit 60:20 61:14
63:9
toolkits 63:5
tools 61:2 262:4
top 89:17 183:14
270:13 351:10
topic 306:1
topics 174:10
total 37:19 66:17
72:20 320:20
339:14
totally 138:7 142:1
300:15 318:19
tough 72:15
town 62:10
track 29:9 52:1
53:4 60:14 111:21
252:18
tracked 31:1
tracking 253:11
traditionally 126:2
348:10
trained 286:11,12
transfer 183:7
transferred 183:6
translation 104:16
transparent 142:13
149:5
trauma 157:13

158:2
trauma/birth
166:21
treated 28:1 180:1
321:4
treating 22:17
treatment 36:6,15
202:5
tree 249:6
trend 180:18
191:22 192:2
trended 95:1
tricky 169:12
tried 50:12 72:14
160:8 303:4
trigger 124:8
triggered 238:7
trip 154:11
trouble 86:17
161:6 178:21
true 27:2 30:13
73:5 206:13
289:18 334:7
truly 271:3,7
trump 57:17
trust 38:10
try 13:21 18:18
23:8 40:6 61:22
64:19 77:6 142:21
152:15 200:22
201:11 202:8
222:8 252:20
269:22 284:1
349:4
trying 18:12 21:9
29:16 44:3 50:18
61:19 74:21 78:10
78:20 92:14 99:2
104:15 126:22
127:7 143:8
158:10 159:16
160:16 165:13
166:12 171:19
175:8 182:14
187:2 196:15
201:20 209:14
211:2 212:20

215:4 221:1 236:3
263:18 265:10
266:5 269:18
284:21 285:7
308:5 315:18
320:12 351:15
TTN 172:18 173:11
175:16,17,20
182:15
tube 113:3 172:20
turn 267:2 310:5
turned 346:20
turning 102:3
turns 247:4
tweaking 155:16
Twelve 146:1
Twenty 102:16
twentyfold 95:10
two 20:4 21:21 25:7
25:13 32:10 54:21
58:12 59:8 62:6
75:16,19,20 90:4
99:6 122:8 132:3
140:13,17 146:3
158:3 160:2
168:17 171:17
177:18 193:22
195:13 209:12
213:19 214:11,12
226:14,21 227:3
227:21 228:10,14
229:2,21 232:11
247:19 252:7
265:4 277:10
298:9 303:11
313:22 315:12
327:18 348:21
349:1 351:6
two-item 317:15
two-service 285:14
two-year 70:3
type 46:10 53:20
71:1 105:13
112:20 134:2,4
166:8,13 221:10
338:4
types 18:21 100:1

103:12 105:4
133:19 134:3
167:20 210:7
220:22
typically 78:5
124:13 250:22
251:1

U

UCLA 10:15
UK 159:7,10
ultimate 41:15
171:9 255:18
ultrasound 161:12
161:18 166:10
umbrella 92:13
unanimity 323:8
unclear 161:7
251:8
uncomfortable
143:14
uncommon 73:11
157:6
underestimate
142:11
undergo 68:1
undergoing 3:22
4:14 63:20 110:16
underinsured
339:17
underlying 86:19
underscore 69:3
105:19
understand 28:21
46:8 72:2 81:20
92:15 98:9 111:13
117:20 136:3
142:2 159:6
172:14 174:4
187:1 200:14
205:4,7 212:20
235:13 267:15
270:18 273:1
277:18 293:17
337:12
understandable
49:3 97:1 144:21

160:19 227:15,19
291:13 340:11
understanding
36:5 78:11 83:19
97:19 98:20
101:20 161:7
207:11 214:6
232:22 283:9
294:9
understood 74:22
168:5 262:16
unexpected 175:3
unfairly 55:16
137:2
unfortunate 187:4
261:9
Unfortunately
157:16 308:8
unhappy 260:19
uniform 123:20
uniformly 143:11
unimportant
281:11
uninsured 339:12
unintended 336:15
337:8
unique 53:2
unit 100:5 207:17
208:10 211:19
221:11,12 224:18
224:19,19
United 79:17 157:3
160:9 184:3
205:15
universal 347:11
university 9:7
10:13,17,21
223:18,20
unmet 317:11
318:14 319:2
327:4 349:18,21
unnecessary 74:7
unpreventable
126:9,15 143:15
unreasonable
329:17 332:4,6,7
332:16

unrelated 317:20
unreliable 73:2
unsafe 312:16
313:12
unsatisfied 286:7
unsuccessful
201:20
untested 90:6
untoward 77:18
unusual 95:11
updated 268:17
346:3
upfront 39:10
upright 237:13
uptake 196:5
urban 166:15
urea 196:21 199:15
199:17,21 200:2,3
200:11
usability 3:15,16
4:6,8,23,24 5:13
5:15 6:4,15 7:14
48:14 49:3 51:5,9
95:4 96:19 97:9
102:19 104:13
107:4,6,6,9,12
109:21 142:7
144:17,18 145:3,5
145:9 190:11
192:15,16 227:12
227:14 228:3,6,9
291:10,21 292:1,3
340:11,19
use 9:16 21:18 29:9
43:16 53:22 57:9
66:7 82:5 83:22
84:8 101:7 109:18
117:11 123:7
148:3,6 159:5
167:6,16 168:18
170:11 175:7
177:13 185:3
190:22 197:13
199:19 203:10
215:17 223:8
233:6,11 241:20
242:8,20 255:5,6

261:3 262:3
274:17 285:7
286:21 290:5
294:9 300:14
304:22
useful 54:8 151:20
users 199:2
usually 93:11
244:22 259:2
272:6 300:20
311:11 332:20
334:4,9,12
usually-and 332:20
Utah 54:13
utility 168:19

V

v 131:3 137:5
vacation 351:11
valid 18:8 31:15
36:21 124:17
285:17
validated 6:8 47:16
68:17 89:11 90:20
108:1 237:8
240:16,22
validation 42:18
56:2 89:10 90:12
validity 38:3 39:12
46:11 48:7 58:10
91:9 111:20 114:9
189:17 240:9,11
240:11,20 242:3
254:22 289:22
290:11 304:4
316:10 330:11
332:7,9 333:6
336:4 339:21
valuable 72:3
211:3 232:19
value 30:9 49:5
145:1 227:16
277:22 291:17
314:6 315:13
340:14
values 149:3
value-based 106:22