THE NATIONAL QUALITY FORUM

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PEDIATRIC CARDIAC SURGERY STEERING COMMITTEE

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR

PEDIATRIC CARDIAC SURGERY

EXECUTIVE SESSION

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WEDNESDAY OCTOBER 21, 2009

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The Pediatric Cardiac Surgery Steering Committee met in Congressional A in the Hyatt Regency Washington Hotel, 400 New Jersey Avenue, N.W., Washington, D.C., at 9:30 a.m., Howard Jeffries and Lisa Kohr, Co-Chairs, presiding.

STEERING COMMITTEE MEMBERS PRESENT:

HOWARD JEFFRIES, MD, MPH, MBA, Co-Chair LISA M. KOHR, MS, MPH, RN, CPNP, Co-Chair SCHONAY BARNETT-JONES, MBA PATRICIA A. GALVIN, RN, BSN, CNOR NANCY GHANAYEM, MD

DARRYL GRAY, MD, ScD ALLEN J. HINKLE, MD MARK HOYER, MD SYLVIA LOPEZ, MD CONSTANTINE MAVROUDIS, MD JOHN E. MAYER, MD LISA NUGENT, MFA

NQF STAFF PRESENT:

HELEN BURSTIN

SARAH FANTA

TINA GRANNIS

LISA HINES

CHRISTINA TSIATIS

ASHLIE WILBON

ALSO PRESENT:

DR. KATHY JENKINS

DR. KIMBERLEE GAUVREAU

DR. MARSHALL JACOBS

DR. JEFFREY JACOBS

1 P-R-O-C-E-E-D-I-N-G-S 2 9:34 a.m. 3 MS. GRANNIS: Good morning, 4 everybody. I'd like to welcome you to the 5 National Voluntary Consensus Standards for Pediatric Cardiac Surgery, the Steering 6 7 Committee Meeting. I am Tina Grannis, and this is 8 9 another Project Manager, Ashlie Wilbon. We 10 wanted to let you know the purpose of the Steering Committee is to evaluate and 11 recommend measures for pediatric cardiac 12 13 surgery for public reporting and quality improvement related to pediatric cardiac 14 15 surgery process, structure and patient 16 outcomes. This is our executive session. 17 It's a closed session right now. And just 18 kind of wanted to go through the flow of the 19 20 day and just kind of what to expect out of this meeting. And I'll be referencing the 21 22 revised agenda that Sarah Fanta handed out to

1 us. 2 Around ten o'clock we're going to open the session up. So, it will be - the 3 public can come and join us in the audience. 4 5 There may be people who will be participating, dialing in and calling in. 6 7 At that time, Dr. Jeffries, Howard Jeffries, and Lisa Kohr, who are co-chairs, 8 9 will be going around the room. We'll welcome, we'll do introductions, we will also have 10 disclosures of interest. 11 12 And since this is such a 13 specialized topic, we have a lot of experts here at our table. And these are experts in 14 the field of pediatric cardiac surgery, so we 15 may need - if you happen to work for a 16 particular organization that submitted a 17 measure - and for example, I spoke with Patty 18 this morning. 19 She works for Children's Hospital 20 21 They submitted a measure, but she of Boston. 22 had no part of developing the measure. So,

she is going to disclose that she works for 1 Children's Hospital of Boston and has not 2 developed any measures. 3 4 So, we just want to make sure that 5 we go on record disclosing any potential conflicts of interest. 6 7 After that, Ashlie Wilbon will be giving a project overview. And we also have 8 9 Helen Burstin who is our Senior Vice-President 10 of the Performance Measures Department at the National Quality Forum, and she'll be giving 11 just a brief overview as well. 12 13 Around 10:40 we're going to have measure developers give general comments. 14 And this is a chance for measure developers just 15 to kind of give the Steering Committee any 16 special instructions or any type of general 17 comments at that time. 18 If you have questions for the 19 20 measure developers, we just ask that you just hold off until we reconvene as the Steering 21 22 Committee and actually go into the measure

1 review.

2	We're going to break up into
3	workgroups after that. By now, everyone knows
4	that we're broken up into Workgroup A and
5	Workgroup B. And Workgroup A will be looking
6	at the process and structural measures, and
7	Workgroup B will be looking at the outcome
8	measures.
9	You have also been assigned as
10	primary and secondary reviewers. And when we
11	break up into the workgroups, Lisa Kohr will
12	be with Group A, and Howard Jeffries will be
13	with Group B. They'll be facilitating the
14	discussion.
15	You'll be kind of going over as
16	a primary/secondary reviewer, you'll be going
17	over the measure that you were assigned with
18	your group just kind of opening dialog and
19	discussion within your workgroup. We will
20	also have you fill out the evaluation form at
21	that time.
22	Also when we break into workgroup,

we're going to ask that there is somebody who 1 actually takes notes during this time. 2 And, Sarah, do you have the slide 3 for the -4 5 (Off the record comments.) 6 MS. GRANNIS: And we're just going 7 to bring this up on screen. And in the past in other steering committees, how we've done 8 9 this is sometimes it may be one person who 10 decides that they would like to take notes, other times it was the secondary reviewer who 11 would be taking notes while the primary 12 13 reviewer is just presenting it in their 14 workgroup. And then when we reconvene as a 15 steering committee, we are going to be able to 16 look at the notes from your workgroup 17 discussion and to just kind of serve as like 18 just kind of jogging our memory in everything. 19 20 Okay. And Sarah is just going to bring this 21 up so we can just go over it. 22 Everything is recorded. We have

1 someone who transcribes to our right behind 2 us, and the transcription is actually used for 3 our records, for NQF records. And sometimes 4 it's just when we're kind of trying to 5 remember how a discussion goes, we'll use the 6 transcripts.

7 It is recorded as well overhead 8 via the phone, and that will be posted online 9 on the NQF website. So, if you needed to go 10 back and listen to any discussion, you'll be 11 able to listen over the two days through the 12 website.

13 So, this is where you're going to 14 be taking notes. And during the workgroup 15 discussion, you're going to be evaluating 16 scientific acceptability, importance,

17 usability, feasibility.

18And under each - I believe - hold19on a second.

20 So, you're able to see all the 21 categories underneath there and you'll be able 22 to just take your notes accordingly.

		Pa
1	And again, it's up to the	
2	workgroup to decide whether they want to	
3	assign somebody to take the notes or whether	
4	you just wanted to assign the secondary	
5	reviewer to take the notes, and we can go over	
6	this more in depth when we break into the	
7	workgroups.	
8	And Ashlie and I will be available	
9	during the workgroup breakout sessions, to	
10	help guide you in any questions that you may	
11	have.	
12	After the workgroup discussions,	
13	we're going to reconvene. And I believe that	
14	is around three o'clock. We're going to	
15	reconvene and we will discuss - we'll start	
16	with the outcome measures.	
17	We have one outcome measure from	
18	the Children's Hospital in Boston. And we're	
19	going to review that first. And then we'll go	
20	into the STS measures after that.	
21	And then after the outcome	
22	measures, we will review the process and	

structure measures, and we have that slated 1 2 for Day 2. 3 And everyone also received the thumb drives, and it has all the meeting 4 5 materials that was either e-mailed to you and some of the meeting materials we revised. 6 And 7 that would just be the agenda. We also have a PowerPoint 8 9 presentation that Ashlie will be giving a 10 general overview, and that is on the thumb drive as well. 11 12 Anything else? 13 So, when the Steering Committee reconvenes and they're going to review, we'll 14 start the discussion and we'll have the 15 primary reviewer from the workgroup and from 16 the groups that you were assigned, to present 17 to the Steering Committee. 18 And after that, we'll have a 19 secondary reviewer add any additional input 20 21 that they may have. 22 Lisa and Howard will open it up

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Page 10

1	for Steering Committee discussion at that
2	time, and that is also the time to have any
3	type of clarification that you may need from
4	the measure developers.
5	The measure developers will come
6	and they'll stand by the microphone, and
7	you'll be able to ask them for any type of
8	clarification that you may need.
9	We will be voting after that, and
10	the co-chairs are responsible for kind of
11	facilitating and monitoring discussion. So
12	once they feel that the discussion has ended
13	that there's really no more issues, they can
14	call for a vote at that time.
15	There's also another way that -
16	they can call for a straw vote if for some
17	reason the discussion seems to be going
18	towards one way and they can't really get a
19	feel. Maybe half of the group seems to be
20	leaning towards yes, half the group seems to
21	be leaning towards no. They can call for a
22	straw vote at that time just to see, really,

how the group is leaning and if we need any
 more discussion.

The voting options that we have today are we could recommend the measures for endorsement, and that's if they meet the majority of the criteria, or you could not recommend them. And it's consensus that it goes on either for recommendation or not to recommend.

10 So, we will be asking when you 11 vote, to raise your hand. When one of the co-12 chairs says how are we going to vote, are we 13 going to recommend for endorsement, we would 14 need you to raise the hand because we need to 15 count how many people for and how many people 16 against.

Any questions at this time? DR. GRAY: I just had a question about the straw vote so that the purpose of that is to - when you sort of said get a sense that there is a divergence of opinion, to then have more discussion to clarify whatever the

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Page 12

issues are such that at the point we actually 1 have the more official vote that there is 2 going to be more of a preponderance in one 3 direction or the other, is that the point of 4 5 the straw vote? 6 MS. GRANNIS: Correct. Yes. And 7 it will - sometimes what ends up happening is there might be somebody in the crowd who wants 8 9 to play devil's advocate, get all the issues 10 out, but they may want to actually vote "Yes" for the actual measure. 11 12 So, really what the straw vote 13 would be showing was if really we do need more discussion on this issue or whether the issue 14 has been resolved and we can move to a final 15 16 vote. DR. GRAY: Okay. And the other 17 thing is that the recommendation of I guess it 18 was presumably yes, as is or a yes, with 19 20 conditions as an option. 21 So, it's not really just yes or 22 no, right?

1 MS. GRANNIS: Right. During your 2 discussion, you'll be clarifying with the measure developer if there's any type - and, 3 for example, I'll just bring up the example of 4 5 what we discussed on the orientation call which was - I think it was seven and eight, 6 7 Measure 7 and 8 where they had two similar titled -8 9 DR. GRAY: Right, right. 10 MS. GRANNIS: So, that might be the 11 time where you would say we would want one of them, the title changed to reflect more of the 12 13 measure depending on which one you want 14 changed. And then the measure developer 15 16 would say yes, we can agree to that condition. And then that's how we would go ahead and 17 vote. 18 DR. GRAY: So once the "with 19 20 conditions" is actually presumably addressed, 21 the measure developer is given the opportunity 22 during this meeting to - or the

1	representatives of the measure developers to
2	decide whether or not they accept the
3	conditions. And so that ends up getting
4	codified in terms of thethe recommendation
5	yes, but with the following conditions which
6	the measure developer has agreed to?
7	MS. GRANNIS: Correct. Yes. And
8	that will also be captured in the note taking
9	that you'll be doing in your groups, too. If
10	you find that there's something that you want
11	to clarify with the measure developer, you can
12	add that under the "comment" section that you
13	want this condition met.
14	And then when we reconvene as a
15	steering committee and the measure is actually
16	presented by the primary or secondary
17	reviewer, at that time you can ask the measure
18	developer if they're able to meet that
19	condition.
20	Does that answer your question?
21	DR. GRAY: Yes.
22	MS. GRANNIS: Okay.

1 DR. GRAY: And all these are being 2 accepted with a time - I guess it's -3 MS. GRANNIS: Time-limited 4 endorsement, yes. 5 DR. GRAY: Okay. 6 MS. GRANNIS: Exactly. Okay. 7 Great. MS. WILBON: Any other questions 8 9 before - I guess we can keep it moving. We left 30 minutes for the executive session. 10 But if there aren't any more questions or 11 anything else to discuss, we can just go ahead 12 13 and move forward to the open part of the meeting and keep the day rolling. We'll let 14 Dr. Jeffries and Lisa share any comments they 15 might have before we - or how they, you know, 16 the goal of the day or any goals you might 17 have for the meeting or what have you. 18 19 CO-CHAIR JEFFRIES: Okay. I wasn't 20 prepared for this. 21 MS. GRANNIS: Sorry to put you on 22 the spot.

CO-CHAIR JEFFRIES: That's okay.
 I'll figure it out.

Well, first I just want to thank the NQF for getting this together and asking me to be a part of it. And I won't speak for Lisa. I'll let her speak for herself, but I look forward to the work today.

8 I think these measures are very 9 interesting and are a great thing for us to 10 look through.

11 So, my background is in critical 12 care, and we have worked on some measures in 13 critical care in the past, and have found 14 those to be very helpful as we try to improve 15 our practice in ICU. And I think these 16 measures will allow for the same thing within 17 pediatric cardiac surgery.

So, I look forward to the work today and in working with all of you to work on this.

21 CO-CHAIR KOHR: I also want to22 thank you for being invited to participate in

		Page	18
1	this. I think it's extremely important for us		
2	to push this forward and I look forward to the		
3	dialog that we're going to have about these		
4	measures.		
5	MS. GRANNIS: Okay. So, any more		
6	questions from anybody?		
7	DR. HOYER: No, but I can make a		
8	comment. I can fill time if you want to.		
9	MS. GRANNIS: Sure.		
10	DR. HOYER: Just as I'm thinking		
11	about this, and, again, this is a new thing		
12	for me as a pediatric cardiologist to be		
13	sitting on this committee, but I see a lot of		
14	applicability of what will happen today to		
15	subsequent submissions.		
16	I'm part of something called the		
17	Congenital Cardiac Interventional Study		
18	Consortium, CCISC, if I can get that right,		
19	and we're 50 plus centers that are trying to		
20	kind of answer some questions at least so far.		
21	There's also the ACC's PCI data		
22	registry which has been pretty well		

established, and there's our attempts to try 1 to make something similar happen in the 2 pediatric cardiology or pediatric 3 interventional world coming up. 4 5 And it's been kind of coming on several fronts. And where that's ultimately 6 7 going to kind of, you know, basically ferret out and whether it will be ACC sponsored, 8 9 whether it will be something else is not 10 certain yet, but I can see this as being something that will be the next submission or 11 one of the next submissions in the next few 12 13 years, possibly. So, I am very interested and 14 excited about what we're going to be studying 15 and talking about because I think we'll all 16 learn something about how we will deal with 17 these things in the future. 18 MS. NUGENT: Could you talk a 19 20 little bit about what happens after the endorsement, where these things go, any 21 22 examples that you could provide?

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1	DR. BURSTIN: Yes, let me give you
2	a little bit of background. So, one of the
3	main goals of NQF is endorsing consensus
4	standards. And the logic for doing that is
5	actually something called the National
б	Technology Transfer and Advancement Act. That
7	specifically designates NQF as the standard
8	setting organization.
9	Some of you know the IT world,
10	know HITSP or any other standard setting
11	organizations. We are that organization for
12	healthcare quality.
13	So, the key and important piece of
14	this is that it obligates the federal
15	government to use NQF-endorsed standards
16	whenever available whenever they're seeking
17	standards.
18	So, for example, if you go to
19	hospital compare, if you go to nursing home
20	compare, all of those measures are NQF-
21	endorsed and are required to be. So, that's
22	part of the reason that there's a significant

emphasis on getting these measures NQF
 endorsed.

3 The pediatric side is a little 4 different because traditionally much of this 5 work to date as most pediatricians know, and 6 other folks know very well, has been heavily 7 emphasized on the Medicare side. And Sylvia 8 certainly know this at the federal level at 9 least, less so Medicaid.

But I think there is increasingly a push to start thinking about how some of these pediatric measures, especially in the age of the new CHIPRA legislation that went through and the requirement to have pediatric guality measures available will follow.

I also think we've also seen I significant uptake of these kinds of measures at the state level, the health plan level as well. So, having the imprimatur of being NQF endorsed is a powerful incentive to having the measures be used.

22

That being said, we don't control

1 the implementation of those measures, and it's 2 really important to remember that. Although we say this is a really good measure and this 3 goes forward, it's still up to the ultimate 4 5 implementer to say this is a measure we want to use as part of whatever the program, maybe 6 7 publicly reporting or pay for performance or however they choose to play it. 8

9 As long as we're still in 10 executive session, I just want to also mention some of you may have heard of a lot of 11 discussions recently around the STS adult 12 13 measures and the fact that we had some competing measures submitted that didn't have 14 perhaps that same rigor or risk adjustment, 15 clinical risk adjustment, that our board is 16 actually still grappling with. 17

18 We have deferred the decision on 19 those other measures for now, but part of the 20 issue here really was about the fact that to 21 date at least, the STS measures are not 22 publically reported. And really, one of the

ideas of NQF endorsement is that those measures are appropriate for both public reporting and quality improvement, but really the public reporting piece is pretty paramount.

6 So, the board just reaffirmed the 7 fact that yes, we really do expect that perhaps not at submission, you couldn't expect 8 9 measures at submission to NQF to be publically 10 reported, but by the time of the three-year maintenance review which we do for all of our 11 measures, there should at least be 12 13 demonstration of how far along the path towards public reporting, meaning reporting to 14 the public at large, is available. 15 So, as you think about this set of 16 measures, how soon can it be before a parent 17

18 is able to go online and find out some of the 19 outcomes of pediatric cardiac surgery before 20 they begin picking a site of care.

21 That's our ultimate goal and our22 expectation should be. And in discussions

1		
1	with STS and ACC and others, that's clearly	
2	a move, the direction in which they're going,	
3	but I think that that will be something we're	
4	really hoping to see, some of these registry-	
5	based measures increasingly see the light of	
6	day beyond - I mean they've been powerful	
7	forces for benchmarking and quality	
8	improvement, seen dramatic improvements on the	
9	adult side with outcomes related to cardiac	
10	surgery, but I think there's also as we'll go	
11	over with the NQF criteria, one of them	
12	specifically is usability.	
13	And the idea there is that that	
14	information can be used by consumers or those	
15	who purchase care on their behalf to make	
16	better decisions.	
17	And so, I think that's ultimately	
18	where we want to see these measures go.	
19	Questions?	
20	DR. HOYER: I do have a question	
21	about that. It's Helen, right?	
22	DR. BURSTIN: Yes.	

1 Thank you. DR. HOYER: Yes. Manv 2 different societies and organizations have also been endorsing -3 4 DR. BURSTIN: Yes. 5 DR. HOYER: - quality measures. 6 And I guess the question I had was with NQF 7 being somewhat of a federal charge to some degree, who else competes with NQF maybe in 8 9 the private sector for creating those kind of endorsement standards? 10 DR. BURSTIN: It's been an 11 interesting time, actually. And over the last 12 13 couple of years there was partly driven by the need to have rapid approval of a set of 14 measures for the Physician Quality Reporting 15 Initiative, PQRI, the AQA, formerly known as 16 the Ambulatory Care Quality Alliance, did 17 approval of measures. 18 That is now defunct and at this 19 20 point there is no other group that's actually 21 endorsing measures besides NQF. And part of 22 that has been our, you know, we've rapidly -

Page 25

we have tried to make the process move as
 quickly as it could.

There was issues in the past that NQF was too slow, not responsive. So as much as possible, we've been trying to move things quickly.

7 The other piece of this that's 8 important to know is part of the reason we can 9 make this happen and hire almost, you know, 10 half the staff up here are brand new in the 11 last year or so, is that we've also gotten a 12 significant federal appropriation through the 13 Medicare law last year.

14 So, we have up to \$10 million a 15 year over the next four years to focus on 16 setting national priorities and goals,

17 endorsing consensus standards.

And actually the big piece we're doing right now is trying to think about how these measures migrate to an electronic platform.

22

So these measures are great, but

how many of them could actually - how much could these clinical registries become interoperable with electronic health records, pull the key data elements you need out of EHRs, add in the data elements you could only get through a clinical registry and piece that together.

8 So, we now have the resources. 9 We're significantly expanding to be able to do 10 that so we can work faster, we can pick up 11 more projects, which is both a blessing and a 12 curse.

Which means I think I'm at a
steering committee almost every day through
the end of the month because we've got so many
projects now revving up including some very
exciting work.

18 The Outcomes Across 20 Conditions 19 has just started. That actually includes a 20 pediatric outcomes component as well that is 21 going to kick up shortly.

22 And so, this project will feed

into part of that, but it's an exciting time 1 to actually have, I think, a real impact of 2 picking the measures and putting forward 3 measures that we think people will use and 4 5 want to use for both QI and public reporting. 6 DR. GHANAYEM: Hi. I'm Nancy 7 Ghanayem from Wisconsin, Children's Hospital of Wisconsin. 8 9 To be a little bit of a devil's 10 advocate, the adult STS measures are largely based on outcome data because there's been far 11 more - I suspect far more contribution to the 12 13 adult database, adult STS database, which is somewhat different with the pediatric measures 14 that are proposed. For many of them there are 15 no outcome data linked to them. 16 How does that play into our 17 ability to vote on these measures when there's 18 lots of outcome data that's actually not 19 available? 20 21 DR. BURSTIN: That's a good 22 question. You've got to start somewhere.

1	And, in fact, I just did this analysis last
2	night looking at all the specialty
3	designations for all of our 500 measures. It
4	wasn't fun, but somebody had to do it.
5	We actually if you look through
6	the cardiac surgery database, the cardiac
7	surgery measures we've endorsed, there
8	actually are a blend of process and outcomes.
9	They're not all outcomes.
10	And I think the outcomes have
11	somewhat come in the latter part of bringing
12	those measure through, so there are a whole
13	set of measures about appropriate use of beta
14	blockade, anti-platelet agents, things like
15	that in addition to over time and the risk-
16	adjusted mortality, risk-adjusted
17	complications.
18	And actually, they've just
19	submitted to us as part of our large
20	cardiovascular outcomes project, their
21	composite measure on the adult cardiac surgery
22	side which we're very excited to review

1 shortly.

2	So, I think we're making progress.
3	But I think as we think about the vision of
4	where we think we need to go as you
5	ultimately, I think, want a package of
б	measures, that you want to have outcome
7	measures, you want to have some process
8	measures that clearly have some link to
9	outcome measures so that they're useful for
10	quality improvement.
11	And I think you also want to be
12	able to pull in some of the other key kinds of
13	measures like cost and resource use, patient
14	experience of care, really, to get a broad
15	view of where I think we want to get a full
16	view of what's happening in a given area.
17	DR. MAYER: Maybe, Nancy, I can
18	just respond a little bit to - I've sort of
19	been involved in this whole database thing for
20	a number of years because of my roles in the
21	STS.
22	DR. GHANAYEM: Sure.

1 DR. MAYER: The congenital database 2 at least is at an earlier point in its evolution than the adult cardiac database. 3 The adult cardiac database has been around 4 5 since 1989. It's got 3.6 million patients, 6 you know. It's got a huge denominator, as 7 they say. And I think what we are now is 8

9 we're on the sort of rapid uptake of adoption 10 by congenital heart surgery centers in the 11 United States. I think the last count is 12 we're at almost 70 congenital heart surgery 13 centers out of what we guess is 120 some odd 14 in the country.

The adult database now has just 15 enrolled its one-thousandth participating 16 institution, and we think that that represents 17 90 percent of the, as best you can guess, 18 adult cardiac centers in the country. So, I 19 20 think we're just at a different phase. 21 When we, STS, put the adult 22 cardiac surgery measures through the NQF

1	process, even at that point we had two-and-a-
2	half million or two million patients. So, the
3	database was much more mature, if you will,
4	than where we are.
5	But I think, and Jeff and Marshall
6	will tell you, I mean I think that this has
7	gotten support all up and down the STS
8	organizational structure. That even though we
9	know we're not as far along as the adult
10	database is, that this is something we clearly
11	think is important.
12	We think it's much better that we
13	figure out what the measures ought to be, we
14	the STS, rather than having them imposed from
15	outside.
16	And I think we're getting close to
17	the point now where we can get the expert
18	opinion part out of the database and
19	understanding outcomes, and get it entirely
20	data driven.
21	So, we don't have a denominator
22	nearly so large as three-and-a-half million,

but I think we're getting close. 1 MS. GRANNIS: Thank you. It is now 2 ten o'clock, so we're going to start the 3 meeting. We're going to open it up to our 4 5 open session, and we're out of our executive session now. 6 7 DR. GRAY: Sorry. Just had one other question. We had talked about trying to 8 9 get the books that Jeff Jacobs sent. 10 Do we know where they are? MS. GRANNIS: I think we're still 11 trying to look into that. 12 13 MS. WILBON: So, the measure developers are here. I think Lisa is just 14 15 making sure everyone gets in the room who was signed up to attend the meeting in the 16 audience. 17 18 So, we'll let them get settled briefly, and then we'll go ahead and get 19 20 started. 21 (Whereupon, the meeting went into 22 Open Session.)

Page 33

Page	3	4
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			1	
A	26:12	breakout 9:9	clearly 24:1 30:8	count 12:15 31:11
ability 28:18	approval 25:14,18	brief 5:12	32:10	country 31:14,19
able 7:16 8:11,20	AQA 25:16	briefly 33:19	clinical 22:16 27:2	couple 25:13
8:21 11:7 15:18	area 30:16	bring 7:7,20 14:4	27:6	Co-Chair 1:17,18
23:18 27:9 30:12	Ashlie 2:13 3:9 5:7	bringing 29:11	close 32:16 33:1	16:19 17:1,21
ACC 19:8 24:1	9:8 10:9	broad 30:14	closed 3:18	co-chairs 4:8 11:10
accept 15:2	asking 12:10 17:4	broken 6:4	CNOR 1:19	CPNP 1:18
acceptability 8:16	assign 9:3,4	BSN 1:19	codified 15:4	creating 25:9
accepted 16:2	assigned 6:9,17	Burstin 2:7 5:9	come 4:4 11:5	criteria 12:6 24:11
ACC's 18:21	10:17	20:1 24:22 25:4	29:11	critical 17:11,13
Act 20:6	attempts 19:1	25:11 28:21	coming 19:4,5	crowd 13:8
actual 13:11	attend 33:16		comment 15:12	curse 27:12
add 10:20 15:12	audience 4:4 33:17	<u> </u>	18:8	
27:5	available 9:8 20:16	call 11:14,16,21	comments 5:14,18	D
addition 29:15	21:15 23:15 28:20	14:5	7:5 16:15	DARRYL 1:20
additional 10:20	Avenue 1:13	called 18:16 20:5	committee 1:3,12	data 18:21 27:4,5
addressed 14:20	a.m 1:14 3:2	calling 4:6	1:16 3:7,11 5:16	28:11,16,19 32:20
adjusted 29:16		captured 15:8	5:22 7:16 10:13	database 28:13,13
adjustment 22:15	B	cardiac 1:3,5,12	10:18 11:1 15:15	29:6 30:19 31:1,3
22:16	B 6:5,7,13	3:6,12,14 4:15	18:13 27:14	31:4,15 32:3,10
adoption 31:9	back 8:10	17:17 18:17 23:19	committees 7:8	32:18
adult 22:12 24:9	background 17:11	24:9 29:6,6,21	compare 20:19,20	date 21:5 22:21
28:10,13,13 29:21	20:2	31:3,4,19,22	competes 25:8	day 3:20 10:2 16:14
31:3,4,15,19,21	BARNETT-JON	cardiologist 18:12	competing 22:14	16:17 24:6 27:14
32:9	1:18	cardiology 19:3	complications	days 8:11
Advancement 20:6	based 24:5 28:11	cardiovascular	29:17	deal 19:17
advocate 13:9	basically 19:7	29:20	component 27:20	decide 9:2 15:2
28:10	behalf 24:15	care 17:12,13 23:20	composite 29:21	decides 7:10
age 21:13	believe 8:18 9:13	24:15 25:17 30:14	condition 14:16	decision 22:18
agenda 3:22 10:7	benchmarking	categories 8:21	15:13,19	decisions 24:16
agents 29:14	24:7	CCISC 18:18	conditions 13:20	deferred 22:18
agree 14:16	best 31:18	centers 18:19 31:10	14:20 15:3,5	defunct 25:19
agreed 15:6	beta 29:13	31:13,19	27:18	degree 25:8
ahead 14:17 16:12	better 24:16 32:12	certain 19:10	conflicts 5:6	demonstration
33:19	beyond 24:6	certainly 21:8	congenital 18:17	23:13
ALLEN 1:21	big 26:18	chairs 1:14 12:12	31:1,10,12	denominator 31:6
Alliance 25:17	bit 19:20 20:2 28:9	chance 5:15	Congressional 1:12	32:21
allow 17:16	30:18	changed 14:12,14	consensus 1:4 3:5	Department 5:10
Ambulatory 25:17	blend 29:8	charge 25:7	12:7 20:3 26:17	depending 14:13
analysis 29:1	blessing 27:11	Children's 4:20 5:2	Consortium 18:18	depth 9:6
answer 15:20 18:20	blockade 29:14	9:18 28:7	CONSTANTINE	designates 20:7
anti-platelet 29:14	board 22:16 23:6	CHIPRA 21:13	1:22	designations 29:3
anybody 18:6	books 33:9	choose 22:8	consumers 24:14	developed 5:3
applicability 18:14	Boston 4:21 5:2	CHRISTINA 2:12	contribution 28:12	developer 14:3,15
appropriate 23:2	9:18	clarification 11:3,8	control 21:22	14:21 15:6,11,18
29:13	brand 26:10	clarify 12:22 15:11	Correct 13:6 15:7	developers 5:14,15
appropriation	break 6:2,11,22 9:6	clarifying 14:2	cost 30:13	5:20 11:4,5 15:1

	1	1		
33:14	emphasized 21:7	25:7 26:12	goals 16:17 20:3	help 9:10
developing 4:22	ended 11:12	feed 27:22	26:16	helpful 17:14
devil's 13:9 28:9	endorsed 20:21	feel 11:12,19	goes 8:5 12:8 22:4	Hi 28:6
dialing 4:6	21:2,20 29:7	ferret 19:7	going 4:2,9 5:1,13	HINES 2:11
dialog 6:18 18:3	endorsement 12:5	field 4:15	6:2,15,16 7:1,6,16	HINKLE 1:21
different 21:4 25:2	12:13 16:4 19:21	figure 17:2 32:13	7:20 8:13,15 9:13	hire 26:9
28:14 31:20	23:1 25:10	fill 6:20 18:8	9:14,19 10:14	HITSP 20:10
direction 13:4 24:2	endorsing 20:3	final 13:15	11:17 12:12,13	hold 5:21 8:18
disclose 5:1	25:3,21 26:17	find 15:10 23:18	13:3 18:3 19:7,15	home 20:19
disclosing 5:5	ends 13:7 15:3	first 9:19 17:3	24:2 27:21 33:3,4	hoping 24:4
disclosures 4:11	enrolled 31:16	flow 3:19	good 3:3 22:3 28:21	hospital 4:20 5:2
discuss 9:15 16:12	entirely 32:19	focus 26:15	gotten 26:11 32:7	9:18 20:19 28:7
discussed 14:5	especially 21:12	folks 21:6	government 20:15	Hotel 1:13
discussion 6:14,19	established 19:1	follow 21:15	Grannis 2:9 3:3,8	Howard 1:14,17
7:18 8:5,10,15	evaluate 3:11	following 15:5	7:6 13:6 14:1,10	4:7 6:12 10:22
10:15 11:1,11,12	evaluating 8:15	forces 24:7	15:7,22 16:3,6,21	HOYER 1:21 18:7
11:17 12:2,22	evaluation 6:20	form 6:20	18:5,9 33:2,11	18:10 24:20 25:1
13:14 14:2	everybody 3:4	formerly 25:16	grappling 22:17	25:5
discussions 9:12	evolution 31:3	Forum 1:1 5:11	GRAY 1:20 12:18	huge 31:6
22:12 23:22	Exactly 16:6	forward 16:13 17:7	13:17 14:9,19	Hyatt 1:13
divergence 12:21	example 4:18 14:4	17:18 18:2,2 22:4	15:21 16:1,5 33:7	
doing 15:9 20:4	14:4 20:18	28:3	great 16:7 17:9	
26:19	examples 19:22	found 17:13	26:22	ICU 17:15
Dr 2:19,20,21,22	excited 19:15 29:22	four 26:15	group 6:12,13,18	idea 24:13
4:7 12:18 13:17	exciting 27:17 28:1	fronts 19:6	11:19,20 12:1	ideas 23:1
14:9,19 15:21	executive 1:6 3:17	full 30:15	25:20	impact 28:2
16:1,5,15 18:7,10	16:10 22:10 33:5	fun 29:4	groups 10:17 15:9	implementation
20:1 24:20,22	expanding 27:9	future 19:18	guess 13:18 16:2,9	22:1
25:1,4,5,11 28:6	expect 3:20 23:7,8		25:6 31:13,18	implementer 22:5
28:21 30:17,22	expectation 23:22	G	guide 9:10	importance 8:16
31:1 33:7	experience 30:14	GALVIN 1:19		important 18:1
dramatic 24:8	expert 32:17	GAUVREAU 2:20	H	20:13 22:2 26:8
drive 10:11	experts 4:13,14	general 5:14,17	half 11:19,20 26:10	32:11
driven 25:13 32:20	extremely 18:1	10:10	32:2	imposed 32:14
drives 10:4	e-mailed 10:5	getting 15:3 17:4	hand 12:11,14	imprimatur 21:19
D.C 1:13		21:1 32:16 33:1	handed 3:22	improve 17:14
	$\frac{\mathbf{F}}{\mathbf{F}}$	Ghanayem 1:19	happen 4:16 18:14	improvement 3:14
$\frac{\mathbf{E}}{\mathbf{E}}$	facilitating 6:13	28:6,7 30:22	19:2 26:9	23:3 24:8 30:10
E 1:23	11:11	give 5:14,16 20:1	happening 13:7	improvements 24:8
earlier 31:2	fact 22:13,20 23:7	given 14:21 30:16	30:16	incentive 21:20
EHRs 27:5	29:1	giving 5:8,11 10:9	happens 19:20	includes 27:19
eight 14:6	Fanta 2:8 3:22	go 3:19 5:5,22 7:21	health 21:18 27:3	including 27:16
either 10:5 12:8	far 18:20 23:13	8:9 9:5,19 14:17	healthcare 20:12	increasingly 21:10
electronic 26:20	28:11,12 32:9	16:12 19:21 20:18	heard 22:11	24:5
27:3	faster 27:10	20:19 23:18 24:10	heart 31:10,12	information 24:14
elements 27:4,5	feasibility 8:17	24:18 30:4 33:19	heavily 21:6	Initiative 25:16
emphasis 21:1	federal 20:14 21:8	goal 16:17 23:21	Helen 2:7 5:9 24:21	input 10:20
	I	l	l	l

institution 31:17	26:9 31:6 32:9	materials 10:5,6	microphone 11:6	okay 7:20 13:17
instructions 5:17	33:10	mature 32:3	migrate 26:20	15:22 16:5,6,19
interest 4:11 5:6	known 25:16	MAVROUDIS	million 26:14 31:5	17:1 18:5
interested 19:14	known 23.10 knows 6:3	1:22	32:2,2,22	once 11:12 14:19
interesting 17:9	Kohr 1:14,18 4:8	MAYER 1:23	minutes 16:10	one-thousandth
25:12	6:11 17:21	30:17 31:1	monitoring 11:11	31:16
interoperable 27:3	0.11 17.21	MBA 1:17,18	month 27:15	online 8:8 23:18
interventional	L	MD 1:17,19,20,21	morning 3:3 4:19	open 4:3 10:22
18:17 19:4	large 23:15 29:19	1:21,22,22,23	mortality 29:16	16:13 33:4,5,22
introductions 4:10	32:22	mean 24:6 32:6	more 13:15 16:13	opening 6:18
invited 17:22	largely 28:10	meaning 23:14	24:2 26:1,5	opinion 12:21
involved 30:19	law 26:13	means 27:13	moving 16:9	32:18
issue 13:14,14	leaning 11:20,21	measure 4:18,21,22	MPH 1:17,18	opportunity 14:21
22:20	12:1	5:14,15,20,22	WII II 1.17,10	option 13:20
issues 11:13 13:1,9	learn 19:17	6:17 9:17 11:4,5	N	option 15.20 options 12:3
26:3	left 16:10	13:11 14:3,7,13	Nancy 1:19 28:6	organization 4:17
20:5	legislation 21:13		30:17	0
J	level 21:8,18,18	14:15,21 15:1,6	national 1:1,4 3:5	20:8,11 organizational
$\overline{\mathbf{J}}$ 1:21	light 24:5	15:11,15,17 22:3	5:11 20:5 26:16	32:8
Jacobs 2:21,22	link 30:8	22:5 29:12,21 33:13	nearly 32:22	
33:9	linked 28:16	· · -	need 4:16 11:3,8	organizations 20:11 25:2
Jeff 32:5 33:9	Lisa 1:14,18,23	measures 3:12 5:3	12:1,14,14 13:13	
JEFFREY 2:22	2:11 4:8 6:11	5:10 6:6,8 9:16,20	25:14 27:4 30:4	orientation 14:5
Jeffries 1:14,17 4:7	10:22 16:15 17:6	9:22 10:1 12:4	needed 8:9	ought 32:13
4:8 6:12 16:15,19	33:14	17:8,12,16 18:4	new 1:13 18:11	outcome 6:7 9:16
17:1	listen 8:10,11	20:20 21:1,12,15	21:13 26:10	9:17,21 28:11,16
JENKINS 2:19	little 19:20 20:2	21:17,21 22:1,13	night 29:2	28:19 30:6,9
Jersey 1:13	21:3 28:9 30:18	22:14,19,21 23:2	note 15:8	outcomes 3:16
jogging 7:19	logic 20:4	23:9,12,17 24:5	notes 7:2,10,12,17	23:19 24:9 27:18
JOHN 1:23	long 22:9	24:18 25:5,15,18	8:14,22 9:3,5	27:20 29:8,9,10
join 4:4	look 7:17 17:7,10	25:21 26:20,22	NOF 2:5 8:3,9 17:4	29:20 32:19
JOIII 4.4	17:18 18:2 29:5	28:3,4,10,14,18	20:3,7,20 21:1,19	outside 32:15
K	33:12	29:3,7,13 30:6,7,8	23:1,9 24:11 25:6	overhead 8:7
KATHY 2:19		30:9,13 31:22	25:8,21 26:4	overview 5:8,12
keep 16:9,14	looking 6:5,7 29:2 LOPEZ 1:22	32:13	31:22	10:10
key 20:13 27:4	lot 4:13 18:13	Medicaid 21:9	NQF-endorsed	o'clock 4:2 9:14
30:12	22:11	Medicare 21:7	20:15	33:3
kick 27:21	lots 28:19	26:13	NUGENT 1:23	P
KIMBERLEE	1015 20.19	meet 12:5 15:18	19:19	
2:20	M	meeting 3:7,21	number 30:20	package 30:5
kind 3:19,20 5:16	M 1:18	10:4,6 14:22		paramount 23:5
6:15,18 7:18,19	main 20:3	16:14,18 33:4,16	nursing 20:19	parent 23:17 part 4:22 16:13
8:4 11:10 18:20	maintenance 23:11	33:21	N.W 1:13	1
19:5,7 25:9	majority 12:6	MEMBERS 1:16	0	17:5 18:16 20:22
kinds 21:17 30:12	making 30:2 33:15	memory 7:19	obligates 20:14	22:6,19 25:21
know 3:10 16:16	Manager 3:9	mention 22:10	OCTOBER 1:9	26:8 28:1 29:11
19:7 20:9,10 21:5	MARK 1:21	met 1:12 15:13	odd 31:13	29:19 32:18
21:6,8 25:22 26:8	Marshall 2:21 32:5	MFA 1:23	official 13:2	participate 17:22
21.0,0 23.22 20.0	17101 SHall 2.21 J2.J			l

participating 4:5	preponderance	question 12:18	represents 31:17	seen 21:16 24:8
31:16	13:3	15:20 24:20 25:6	required 20:21	Senior 5:9
particular 4:17	present 1:16 2:5,16	28:22 33:8	requirement 21:14	sense 12:20
partly 25:13	10:17	questions 5:19 9:10	resolved 13:15	sent 33:9
path 23:13	presentation 10:9	12:17 16:8,11	resource 30:13	serve 7:18
patient 3:15 30:13	presented 15:16	18:6,20 24:19	resources 27:8	session 1:6 3:17,18
patients 31:5 32:2	presenting 7:13	quickly 26:2,6	respond 30:18	4:3 16:10 22:10
PATRICIA 1:19	presiding 1:14		responsible 11:10	33:5,6,22
Patty 4:18	presumably 13:19	R	responsive 26:4	sessions 9:9
pay 22:7	14:20	raise 12:11,14	review 6:1 9:19,22	set 23:16 25:14
PCI 18:21	pretty 18:22 23:4	rapid 25:14 31:9	10:14 23:11 29:22	29:13
pediatric 1:3,5,12	primary 6:10 7:12	rapidly 25:22	reviewer 6:16 7:11	setting 20:8,10
3:6,12,14 4:15	10:16 15:16	reaffirmed 23:6	7:13 9:5 10:16,20	26:16
17:17 18:12 19:3	primary/seconda	real 28:2	15:17	settled 33:18
19:3 21:3,12,14	6:16	really 11:13,18,22	reviewers 6:10	seven 14:6
23:19 27:20 28:14	priorities 26:16	13:12,13,21 22:2	revised 3:22 10:6	share 16:15
pediatricians 21:5	private 25:9	22:3,20,22 23:3,7	revving 27:16	she'll 5:11
people 4:5 12:15,15	process 3:15 6:6	24:4 30:14	right 3:18 8:1	shortly 27:21 30:1
28:4	9:22 26:1 29:8	reason 11:17 20:22	13:22 14:1,9,9	showing 13:13
percent 31:18	30:7 32:1	26:8	18:18 24:21 26:19	side 21:3,7 24:9
performance 5:10	program 22:6	received 10:3	rigor 22:15	29:22
22:7	progress 30:2	recommend 3:12	risk 22:15,16 29:15	signed 33:16
person 7:9	project 3:9 5:8	12:4,7,9,13	risk-adjusted	significant 20:22
phase 31:20	27:22 29:20	recommendation	29:16	21:17 26:12
phone 8:8	projects 27:11,16	12:8 13:18 15:4	RN 1:18,19	significantly 27:9
Physician 25:15	proposed 28:15	reconvene 5:21	roles 30:20	similar 14:7 19:2
pick 27:10	provide 19:22	7:15 9:13,15	rolling 16:14	site 23:20
picking 23:20 28:3	public 3:13 4:4	15:14	room 4:9 33:15	sitting 18:13
piece 20:13 23:4	23:2,4,14,15 28:5	reconvenes 10:14		slated 10:1
26:7,18 27:6	publically 22:22	record 5:5 7:5	<u> </u>	slide 7:3
plan 21:18	23:9	recorded 7:22 8:7	Sarah 2:8 3:22 7:3	slow 26:4
platform 26:21	publicly 22:7	records 8:3,3 27:3	7:20	societies 25:2
play 13:9 22:8	pull 27:4 30:12	referencing 3:21	says 12:12	somebody 7:1 9:3
28:17	purchase 24:15	reflect 14:12	ScD 1:20	13:8 29:4
plus 18:19	purpose 3:10 12:19	Regency 1:13	SCHONAY 1:18	somewhat 25:7
point 13:1,4 25:20	push 18:2 21:11	registries 27:2	scientific 8:16	28:14 29:11
31:2 32:1,17	put 16:21 31:21	registry 18:22 24:4	screen 7:7	soon 23:17
possible 26:5	putting 28:3	27:6	second 8:19	Sorry 16:21 33:7
possibly 19:13	P-R-O-C-E-E-D	related 3:14 24:9	secondary 6:10	sort 12:20 30:18
posted 8:8	3:1	remember 8:5 22:2	7:11 9:4 10:20	31:9
potential 5:5		reported 22:22	15:16	speak 17:5,6
powerful 21:20	Q	23:10	section 15:12	special 5:17
24:6	QI 28:5	reporting 3:13 22:7	sector 25:9	specialized 4:13
PowerPoint 10:8	quality 1:1 3:13	23:3,4,14,14	see 8:20 11:22	specialty 29:2
PQRI 25:16	5:11 20:12 21:15	25:15 28:5	18:13 19:10 24:4	specifically 20:7
practice 17:15	23:3 24:7 25:5,15	representatives	24:5,18	24:12
prepared 16:20	25:17 30:10	15:1	seeking 20:16	spoke 4:18
L.,		•		•

sponsored 19:8	table 4:14	traditionally 21:4	wanted 3:10,19 9:4	\$10 26:14
spot 16:22	take 7:10 8:22 9:3	transcribes 8:1	wants 13:8	1
staff 2:5 26:10	9:5	transcription 8:2	Washington 1:13	$\frac{1}{10,405,10}$
stand 11:6	takes 7:2	transcripts 8:6	1:13	10:40 5:13
standard 20:7,10	talk 19:19	Transfer 20:6	wasn't 16:19 29:4	120 31:13
standards 1:4 3:5	talked 33:8	tried 26:1	way 11:15,18	1989 31:5
20:4,15,17 25:10	talking 19:16	try 17:14 19:1	website 8:9,12	2
26:17	Technology 20:6	trying 8:4 18:19	WEDNESDAY 1:9	$\frac{2}{210:2}$
start 9:15 10:15	tell 32:6	26:5,19 33:8,12	welcome 3:4 4:9	2 10.2 20 27:18
21:11 28:22 33:3	ten 4:2 33:3	TSIATIS 2:12	went 21:13 33:21	2009 1:9
started 27:19 33:20	terms 15:4	two 8:11 14:7 32:2	we'll 4:9,10 8:5	2009 1.9 21 1:9
state 21:18	thank 17:3,22 25:1	two-and-a 32:1	9:15,19 10:14,15	41 1.7
States 31:11	33:2	type 5:17 11:3,7	10:19 16:14 19:16	3
steering 1:3,12,16	thing 13:18 17:9,16	14:3	24:10 33:18,19	3.6 31:5
3:6,11 5:16,21 7:8	18:11 30:19	U	we're 4:2 5:13 6:2	30 16:10
7:16 10:13,18	things 19:18,21	ultimate 22:4 23:21	6:4 7:1,6 8:4 9:13	
11:1 15:15 27:14	26:5 29:14	ultimate 22:4 23:21 ultimately 19:6	9:14,18 18:3,19	4
straw 11:16,22	think 14:6 17:8,15	24:17 30:5	19:15 22:9 24:3	400 1:13
12:19 13:5,12	18:1 19:16 21:10	underneath 8:21	26:18 27:9 29:22	
structural 6:6	21:16 23:16 24:3	understanding	30:2 31:9,12,20	5
structure 3:15 10:1	24:10,17 26:19	32:19	32:9,16 33:1,3,4,5	50 18:19
32:8	27:13 28:2,4	United 31:11	33:11	500 29:3
STS 9:20 22:12,21	29:10 30:2,3,3,4,5	uptake 21:17 31:9	we've 7:8 21:16	7
24:1 28:10,13	30:11,15 31:8,11	usability 8:17	25:22 26:5,11	
30:21 31:21 32:7 32:14	31:17,20 32:5,6	24:12	27:15 29:7	7 14:7
Study 18:17	32:11,12,16 33:1 33:11,14	use 8:5 20:15 22:6	Wilbon 2:13 3:9 5:7 16:8 33:13	70 31:12
studying 19:15	thinking 18:10	28:4,5 29:13	Wisconsin 28:7,8	8
submission 19:11	21:11	30:13	work 4:16 17:7,18	8 14:7
23:8,9	three 9:14	useful 30:9	17:19 21:5 27:10	
submissions 18:15	three-and-a-half		27:17	9
19:12	32:22	V	worked 17:12	9:30 1:13
submitted 4:17,21	three-year 23:10	Vice-President 5:9	workgroup 6:4,5,5	9:34 3:2
22:14 29:19	thumb 10:4,10	view 30:15,16	6:7,19,22 7:14,17	90 31:18
subsequent 18:15	time 4:7 5:18 6:21	vision 30:3	8:14 9:2,9,12	
support 32:7	7:2 11:2,2,14,22	Voluntary 1:4 3:5	10:16	
sure 5:4 18:9 30:22	12:17 14:11 15:17	vote 11:14,16,22	workgroups 6:3,11	
33:15	16:2 18:8 23:10	12:11,12,19 13:2	9:7	
surgery 1:3,5,12	25:12 28:1 29:15	13:5,10,12,16	working 17:19	
3:6,13,15 4:15	times 7:11	14:18 28:18	works 4:20 5:1	
17:17 23:19 24:10	Time-limited 16:3	voting 11:9 12:3	world 19:4 20:9	
29:6,7,21 31:10	Tina 2:9 3:8	W		
31:12,22	title 14:12	want 5:4 9:2 13:10	<u> </u>	
suspect 28:12	titled 14:8		year 26:11,13,15	
Sylvia 1:22 21:7	today 12:4 17:7,19	14:11,13 15:10,13	years 19:13 25:13	
	18:14	17:3,21 18:8 22:5 22:10 24:18 28:5	26:15 30:20	
T	topic 4:13	30:5,6,7,11,15	\$	
		50.5,0,7,11,15	φ	