

NATIONAL QUALITY FORUM

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PERSON- AND FAMILY-CENTERED CARE PHASE 2  
STANDING COMMITTEE MEETING

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WEDNESDAY  
JANUARY 21, 2015

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., Lee Partridge, Co-Chair, and Chris Stille, Acting Co-Chair, presiding.

PRESENT:

LEE PARTRIDGE, Co-Chair, National Partnership  
for Women & Families

CHRIS STILLE, Acting Co-Chair, MD, MPH, FAAP,  
University of Colorado School of  
Medicine/Pediatrics University of Colorado  
School of Medicine & Children's Hospital  
Colorado

KATHERINE BEVANS, PhD, University of  
Pennsylvania School of Medicine and  
Children's Hospital of Philadelphia

SAMUEL BIERNER, MD, UT Southwestern Medical  
Center

REBECCA BRADLEY, LCSW, National Director of  
Quality Standards and Case Management  
HealthSouth Corporation

DAVID CELLA, PhD, Northwestern University

SHARON CROSS, LISW, The Ohio State University  
Wexner Medical Center

DAWN DOWDING, PhD, RN, Visiting Nurse Service of  
New York and Columbia University School of  
Nursing

SHERRIE KAPLAN, PhD, MPH, UC Irvine School of  
Medicine  
CAROL LEVINE, MA, United Hospital Fund  
BRIAN LINDBERG, BSW, MMHS, Consumer Coalition  
for Quality Health Care  
SHERRI LOEB, RN, BSN, EMMI Solutions  
ANN MONROE, Health Foundation for Western &  
Central New York  
LISA MORRISE, MA, Patient & Family Engagement  
Affinity Group, National Partnership for  
Patients  
ELIZABETH MORT, MD, MPH, Massachusetts General  
Hospital/Massachusetts General Physician  
Organization  
ESTEE NEUWIRTH, PhD, Center for Evaluation and  
Analytics and Care Management Institute  
Kaiser Permanente  
LENARD PARISI, RN, MA, CPHQ, FNAHQ, Metropolitan  
Jewish Health System  
DEBRA SALIBA, MD, MPH, UCLA/JH Borun Center, VA  
GRECC and Rand Health  
PETER THOMAS, JD, Powers, Pyles, Sutter &  
Verville, PC  
CARIN van ZYL, MD, FACEP, Palliative Care,  
Supportive Medicine City of Hope National  
Medical Center

NQF STAFF:

HELEN BURSTIN, Chief Scientific Officer  
ANN HAMMERSMITH  
MARCIA WILSON  
NADINE ALLEN  
MITRA GHAZINOUR

ALSO PRESENT:

SOPHIA AUTREY \*  
JEROME CONNOLLY  
ANNE DEUTSCH  
DANIEL DEUTSCHER  
CHRISTINE GOERTZ \*  
BEN JOHNSTON  
MARJORIE KING \*  
TRACY KLINE \*  
STEVE LICHTMAN \*  
JASMINE LARSON \*  
JANE LUCAS \*  
TARA McMULLEN  
POONAM PARDASANEY

COLLETTE PITZEN \*

LINDA RESNIK \*

GARY REZEK \*

JEANNETTE SHRIFT \*

LAURA SMITH

ANITA SOMPLASKY \*

MARK WERNEKE

TRACY ZHENG

\* Present via telephone

# C O N T E N T S

Opening Remarks and Introduction of New Members. . . . .	6
Conflict of Interest . . . . .	11
Introductions and Disclosures. . . . .	14
Introduction to NQF Staff. . . . .	28
Project Introduction and Overview of Evaluation Process. . . . .	28
Consideration of Candidate Measures	
0422: Functional Status Change for Patients with Knee Impairments. . . . .	64
0423: Functional Status Change for Patients with Hip Impairments. . . . .	64
0424: Functional Status Change for Patients with Foot and Ankle Impairments . . . . .	64
0425: Functional Status Change for Patients with Lumbar Impairments. . . . .	64
0426: Functional Status Change for Patients with Shoulder Impairments. . . . .	64
0427: Functional Status Change for Patients with Elbow, Wrist, and Hand Impairments. . . . .	64
0428: Functional Status Change for Patients with General Orthopaedic Impairments . . . . .	64
2624: Functional Outcome Assessment. . . . .	136
Member and Public Comment. . . . .	183
2653: Average Change in Functional Status Following Total Knee Replacement Surgery . . . . .	190

## Related and Competing Measures Discussion

Competing: 2653 and 0422

Related: 2624 and the FOTO measures

2643: Average Change in Functional Status  
Following Lumbar Spine Fusion Surgery. . . . . 241

2631: Percent of Long-Term Care Hospital  
Patients with an Admission and discharge  
Functional Assessment and a Care Plan that  
Addresses Function . . . . . 264

0688: Percent of Residents whose Need for  
Help with Activities of Daily Living has  
Increased (long stay). . . . . 265

0701: Functional Capacity in COPD Patients  
Before and After Pulmonary Rehabilitation. . . . . 355

0167: Improvement in Ambulation/Locomotion . . . . . 355

0174: Improvement in Bathing . . . . . 355

0175: Improvement in Bed Transferring. . . . . 355

0176: Improvement in Management of Oral  
Medications. . . . . 355

0177: Improvement in Pain Interfering with  
Activity . . . . . 355

2287: Functional Change: Change in Motor  
Score. . . . . 355

NQF Member and Public Comment. . . . . 388

Adjourn

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

2 8:38 a.m.

3 CO-CHAIRPERSON PARTRIDGE: Good

4 morning everyone. Welcome. I'm delighted to see  
5 you here early in the morning. And I'm  
6 particularly delighted that so many of us could  
7 be here in person. I want to begin our day with  
8 a couple of thank-yous. And then I'm going to  
9 move on to introduce a couple of new faces around  
10 the table. And we'll talk a little bit about the  
11 shape of this day and these next two days. Then  
12 Ann's going to take us through conflict of  
13 interest.

14 So let me begin first of all by saying  
15 thank you to our staff. For those of us, which  
16 includes everybody but David, who were here as  
17 part of -- participated in phase one. We  
18 experimented this time with a different way of  
19 presenting the rather large volume of material in  
20 a more digestible way for all of us. And I for  
21 one think it's a great improvement. So, thank  
22 you. I know it represented a tremendous amount

1 of work on your part because not only did you  
2 have to read it all, but you then had to write it  
3 up and put it together for all of us. And  
4 Sarah's sort of going uh.

5 And I also want to thank the man to my  
6 left, Dr. Chris Stille, who is substituting for  
7 Jim Merlino. Jim is back home. His father-in-  
8 law is having surgery this week, and not  
9 surprisingly, they decided they really needed the  
10 family doc in town. So he is not with us. And  
11 Chris very graciously has stepped in to co-chair  
12 with me these next two days. I want to welcome  
13 Charles -- where is, where's -- I'm sorry, not  
14 Charles, David, down at the end. David is our  
15 new member. And David would you just take a  
16 minute and tell us a little bit about yourself?

17 MEMBER CELLA: Sure, thank you. Good  
18 morning everyone. I'm Dave Cella. I'm a  
19 Professor of -- in a department called Medical  
20 Social Sciences at Northwestern University  
21 Medical School.

22 I, for many years, have developed and

1 validated outcome questionnaires. Mostly self-  
2 report patient-reported outcomes for use in  
3 clinical trials and clinical research. And my  
4 involvement in performance -- the performance  
5 measure arena is a little more recent. Mostly  
6 because for about a decade or so I was working  
7 with the NIH on some large scale crosscutting  
8 measure development work that has you know,  
9 possible future application in performance  
10 measures. It's sort of under the heading of  
11 PROMIS, Patient-Reported Outcome Measurement  
12 Information System. So that got me involved into  
13 this performance measurement area. But most of  
14 my work has been longitudinal clinical research,  
15 including clinical trials.

16 CO-CHAIRPERSON PARTRIDGE: Wonderful.  
17 Thank you. And it's going to be a valuable  
18 addition.

19 DR. BURSTIN: And if I can supplement,  
20 David also wrote our Commission paper for all our  
21 -- for our PRO work. So quite steeped in this  
22 phase. So thank you for that contribution. It



1 was really quite significant to this work.

2 CO-CHAIRPERSON PARTRIDGE: And Ann  
3 Monroe is joining us in person for the first  
4 time. Ann and I served on CSAC together. And  
5 I'm delighted that she's on this Committee. And  
6 I'm especially delighted that she's able to be  
7 with us in person. So Ann, why don't you also  
8 tell us a little bit about you?

9 MEMBER MONROE: Thank you. I'm Ann  
10 Monroe and I'm the President of the Health  
11 Foundation for Western and Central New York. And  
12 I wasn't here for the first session because I was  
13 a patient. I've had three surgeries on my leg.  
14 It's been eight weeks in rehab. And trust me,  
15 this is very relevant, although a little  
16 overwhelming to what I'm doing. So I'm very glad  
17 to be back and to be participating fully.

18 CO-CHAIRPERSON PARTRIDGE: We're  
19 certainly glad to have you here. And another  
20 face who's unfamiliar is Suzanne Theberge. Who  
21 is a veteran NQF staffer but is now with this  
22 Committee. Which just delights me.

1           Suzanne and I worked together on an  
2       earlier standing committee. And as I told you  
3       when I learned she was joining us, I think you  
4       will all enjoy working with her a lot. Suzanne  
5       also tells me she's a new mom. And if you get a  
6       chance to see that picture of that little girl,  
7       you'll just know it must be very hard for her to  
8       be here with your daughter back home.

9           All right. We are going to -- Chris  
10      and I are going to alternate sitting in the chair  
11      today. He's going to lead our first session this  
12      morning so that I can participate a little more  
13      fully in the discussion of that block of measures  
14      which were ones that I personally was assigned to  
15      review.

16           We slotted it somewhere between 15 and  
17      20 minutes a measure. But I think, probably, we  
18      will not adhere rigidly to that time frame.  
19      Particularly, since as we know, some of these  
20      measures overlap there. The first block is very  
21      similar in structure at different body parts, but  
22      a lot of the same issues come up.

1           So I think we will try to stay within  
2     the broad parameters of our time frame. But not  
3     necessarily strictly to 15 to 20 minutes. Chris  
4     and I are going to keep tabs on the time and  
5     we'll try very hard to keep us on track. We also  
6     want to leave ample time for some of the  
7     discussion items that are at the end of the  
8     agenda tomorrow. A few of us, I know Chris for  
9     one has to leave in time to catch a plane. So we  
10    may move that -- one of those discussions up into  
11    today if the scheduling works out to allow that.

12           We will, I promise you end on time  
13    both days. And I always believe in trying not to  
14    work through lunch. It's a time for us to get a  
15    chance to get acquainted a little better. To  
16    check our emails, et cetera. And I -- we may not  
17    be able to stick to that, but I'm going to try.  
18    So with that, I am going to turn it over to Ann  
19    who's going to take us through conflict of  
20    interest.

21           MS. HAMMERSMITH: Thank you Lee. Good  
22    morning everyone, I'm Ann Hammersmith. I'm NQF's

1 General Counsel. And as Lee said, I'm going to  
2 take you through the conflict of interest  
3 disclosure. We'll combine that with  
4 introductions because we find that that saves a  
5 little time. I'm going to go through a few  
6 points regarding the disclosures and then we'll  
7 go ahead and go around the table.

8 If you recall, you received a rather  
9 lengthy form from us where we asked you for  
10 information about your professional activities,  
11 such as research grants that you may have  
12 received, consulting that you do and so on. What  
13 we're looking for you to do here today is to go  
14 around the table and disclose things that you  
15 believe are relevant to your participation on  
16 this Committee.

17 So in other words, please don't  
18 summarize your resume. I know that you have a  
19 very full agenda, so we don't want any resume  
20 summarizing. But disclose things that are  
21 relevant to the subject matter of the Committee  
22 and the work that the Committee is doing. For

1 example, we are particularly interested in your  
2 disclosure of research activity, grants, and  
3 consulting is relevant to the work of the  
4 Committee. Anything else that you think is  
5 appropriate to disclose, such as you may have  
6 served on a committee that has something to do  
7 with the subject matter.

8 And one of the things that's a little  
9 bit different about NQF's disclosure of interest  
10 and conflict of interest process is we don't only  
11 look at financial conflicts of interest. So, in  
12 other words, you may have done something as a  
13 volunteer that may be relevant to your work on  
14 the Committee and that may be something that we  
15 would expect you to disclose.

16 A few reminders, you sit on the  
17 Committee as an individual. Sometimes people get  
18 tripped up by that a little bit and they'll say  
19 I'm Susie Jones, and I'm here representing the  
20 American Academy of fill in the blank with  
21 whatever the subject matter is. Actually you  
22 don't represent any organization. You don't

1 represent your employer. You don't represent any  
2 organization you may be associated with. You  
3 don't represent any group that may have nominated  
4 you for service on this Committee.

5           You're sitting as an individual.  
6 You're on the Committee because you are an  
7 expert. And we're looking for your expert  
8 assessments and opinions. So with that, let's go  
9 around the table, tell us who you are, who you're  
10 with. If you have anything you would like to  
11 disclose. Another reminder, just because you  
12 disclosed does not mean you have a conflict.  
13 Part of the idea of this is to be open and  
14 transparent, know where everyone is coming from.  
15 So, let's start with the Co-Chairs. I always  
16 start with the Co-Chairs.

17           CO-CHAIRMAN STILLE: There we are.  
18 Hi, I'm Chris Stille. I'm a general pediatrician  
19 and head of the Division of General Pediatrics at  
20 the University of Colorado School of Medicine and  
21 Children's Hospital, Colorado.

22           My work has a lot to do with the

1 patient-centered medical home and development of  
2 measures for coordination of care within the  
3 patient-centered medical home. I'm also at the  
4 American Academy of Pediatrics. I sit on the  
5 Committee of Children with Disabilities. Having  
6 said that, I don't believe I have anything to  
7 disclose related to these measures. Really  
8 nothing at all. I'm happy to discuss them.

9 CO-CHAIRPERSON PARTRIDGE: And I'm Lee  
10 Partridge. I'm Senior Health Policy Advisor at  
11 the National Partnership for Women and Families.  
12 I am also a current member of CSAC here at the  
13 National Quality Forum. I have -- I am a  
14 colleague of Chris' on the American Academy of  
15 Pediatrics' Patient-Centered Medical Home  
16 Committee. So in that role we work actively to  
17 encourage pediatricians to become qualified  
18 medical homes. But I don't think it has any  
19 conflict issue.

20 I also serve on the Clinical Programs  
21 Committee of the National Committee for Quality  
22 Assurance, which does not develop measures.

1 That's the standing committee of NCQA that  
2 approves the recognition tools for among other  
3 things, being recognized as a medical home. And  
4 I have nothing to disclose.

5 MEMBER VAN ZYL: Hi everyone, I'm  
6 Carin Van Zyl. I'm a Palliative Medicine  
7 Physician at City of Hope National Medical  
8 Center. Sadly I do not have any grants, research  
9 or consulting fees that would put me in conflict  
10 with any of these measures.

11 MEMBER BEVANS: Good morning everyone.  
12 I'm Katherine Bevans from the Children's Hospital  
13 Philadelphia. I'm an Assistant Research  
14 Professor there. I'm a health outcomes  
15 researcher. I have received funding from both  
16 the National Institutes of Health as well as  
17 Patient-Reported Outcome -- I'm sorry, the PCORI,  
18 Patient-Centered Outcomes Research Institute, to  
19 develop PROMIS measures, the Patient-Reported  
20 Outcome Measurement Information System. Measures  
21 are sort of generic patient-reported outcome  
22 measures. However, content-wise, I don't think



1       that poses a conflict. Thank you.

2               MEMBER DOWDING: Hi, I'm Dawn Dowding  
3       from the Visiting Nurse Services of New York and  
4       Columbia University School of Nursing. And I am  
5       not involved in any research that relates to the  
6       content measures we're discussing today.

7               MEMBER MONROE: Ann Monroe again. I'm  
8       not involved in any research on measures.  
9       Although I do sit on CSAC here at National  
10      Quality Forum. I also am on the Governor's  
11      Medicaid Redesign Team in New York, which means  
12      that we'll be using measures. So I don't know if  
13      that counts. But --

14              MS. HAMMERSMITH: It's not a conflict.  
15      But thanks for disclosing it.

16              MEMBER MONROE: Oh, okay. All right.

17              MEMBER NEUWIRTH: Hi, I'm Estee  
18      Neuwirth with Kaiser Permanente. And I'm the  
19      Director of Evaluation and the Care Management  
20      Institute at Kaiser Permanente in its national  
21      offices. And I mostly do very applied studies  
22      and research to understand opportunities to

1 improve care and spread leading practices. I  
2 don't have any research or consulting related to  
3 these measures. Thank you.

4 MEMBER THOMAS: Hi, I'm Peter Thomas.  
5 I'm with Powers, Pyles, Sutter & Verville, it's a  
6 law firm here in town. And I do healthcare law  
7 and represent a lot of clients on rehabilitation  
8 and disability issues. I have never participated  
9 in the development, I've never assisted in the  
10 development of a measurement tool. But I do  
11 represent a number of clients, and my firm  
12 represents a number of clients that are engaged  
13 in this work.

14 I don't advocate on behalf of  
15 particular tools. There is one that I disclosed  
16 involving a measure that's not on the table today  
17 that I've had some involvement in. But  
18 ultimately all of this is very familiar to me and  
19 some of the organizations are very familiar to  
20 me, and in fact I represent some of them. I'm  
21 happy to name names if you'd like me to. But  
22 I've never done any development or advocacy on

1       behalf of any given measure.

2                   MEMBER LINDBERG:   Good morning.   My  
3       name is Brian Lindberg and I'm the Executive  
4       Director of the Consumer Coalition for Quality  
5       Healthcare.   I also work with a number of  
6       nonprofits generally who don't have Washington  
7       offices, on policy development.   And I have no  
8       conflicts related to the measures.   Thank you.

9                   MEMBER CELLA:   Hi again.   Dave Cella,  
10      Professor of Medical Social Sciences at  
11      Northwestern.   Helen mentioned the white paper  
12      that I led the writing of on patient-reported  
13      outcome performance measures that I submitted to  
14      NQF now a year and a half ago or so.

15                   And I am involve -- and I mentioned  
16      PROMIS in my earlier introduction, which I've  
17      been involved in for 10 or 11 years.   More  
18      closely related but not, I don't think related  
19      enough to be a conflict, but I'll let you know,  
20      I'm involved with two current projects, both  
21      funded by PCORI to develop performance measures.  
22      One of them is to develop extensions of PROMIS

1 generic item banks into knee replacement  
2 candidates and heart failure candidates. That's  
3 led by Dartmouth and I'm a co-investigator.

4 The other one is led by Allen  
5 Heinemann at the Rehab Institute of Chicago to  
6 develop performance measures for acute care  
7 rehabilitation facilities. But I don't see  
8 anything on this list today that poses a conflict  
9 that I sense.

10 MEMBER SALIBA: I'm Debra Saliba. I  
11 am a Professor of Medicine at UCLA and the  
12 Veterans Administration in Los Angeles. I also  
13 work at the Rand Corporation. I'm a  
14 geriatrician. I do health services research and  
15 I've been funded by multiple organizations  
16 including NIH, CMS, ASPE, AHRQ. And I currently  
17 am going to recuse myself from one of the  
18 measures, 0688, because I was a member of an  
19 expert panel that gave feedback to the measure  
20 developers on that particular measure.

21 I'm on the Board of Directors for the  
22 American Geriatrics Society, a nonprofit

1 organization that advocates for patients and  
2 providers of older adults. And I'm also on the  
3 NQF's post-acute care and long term care expert  
4 panel. And I sit on the five-star TEP for CMS to  
5 advise them on their quality of metrics that are  
6 part of their Compare.

7 MEMBER MORT: Good morning. My name  
8 is Liz Mort and I'm an Internist at Mass General  
9 in Boston at Partners Healthcare. And I'm the  
10 Senior Vice President for Quality and Safety.

11 I have no conflicts, but I have had  
12 long-standing interest in patient-reported  
13 outcomes, having done research in my fellowship  
14 in 1990. But I'm not sure that's relevant in  
15 2015. It does take a long time for these things  
16 to translate, I was telling Estee in the  
17 elevator. I'm very interested in the use and I  
18 promote the use of PROMs in our hospital in the  
19 system. But I do not have any conflicts. I also  
20 participated in the NQF program on PROs about a  
21 year and a half ago.

22 MEMBER PARISI: Good morning. My name

1 is Len Parisi. I'm the Vice President of Quality  
2 Management for Metropolitan Jewish Health System  
3 in New York. We are a post-acute care provider  
4 and two managed care plans, Medicaid and  
5 Medicare.

6 I don't perceive any conflicts of  
7 interest. I am fortunate enough to have -- to  
8 use many of these measures in our post-acute care  
9 work both from a long term care and home health.  
10 I also had the opportunity to be a beta test site  
11 for the OASIS outcomes in the late '90s. So I'm  
12 looking forward to the discussion today. I am  
13 the immediate past President of the National  
14 Association for Healthcare Quality. And recently  
15 appointed to the Joint Commission on Standard and  
16 Survey Procedures Committee.

17 MEMBER BRADLEY: Good morning. I'm  
18 Becky Bradley. I'm a social worker, so I'm not a  
19 statistician. So I look at these measures that  
20 we'll be discussing today more from how they can  
21 be used for quality. I am the National Director  
22 for Quality for HealthSouth Corporation, which is

1 an inpatient rehabilitation company. We also  
2 have some home health agencies. So I'm very  
3 interested in these measures.

4 I've been in this field since 1980 and  
5 watched many of these measures be developed from  
6 the sidelines, not because I've been involved in  
7 the research. But we do use these measures and  
8 I'm very familiar with many of them. I did  
9 disclose that I sit on a product advisory  
10 committee for UDS which is one of the measurement  
11 developers that will be presenting today.

12 MEMBER KAPLAN: I'm Sherrie Kaplan.  
13 I'm a psychometrician by training. Which I  
14 always joke that my mother has no idea what I do  
15 for a living, and she still does not. So I am a  
16 Professor of Medicine. I'm Assistant Vice  
17 Chancellor for Healthcare Measurement and  
18 Evaluation at UC Irvine. I currently co-chair  
19 the Admissions-Readmissions Committee at NQF.  
20 I'm also just about to sign a consultant  
21 agreement with NQF for helping out I guess in  
22 general about measurement.

1 I have a grant from PCORI to enhance  
2 and develop a measure -- a self-reported measure  
3 for children ages four to 12, animated  
4 touchscreen-based measure of children's general  
5 function status, enhanced to do a module on  
6 perioperative anxiety and pain management.  
7 That's ongoing.

8 And I also have been involved since my  
9 Rand and UCLA days with the Total Illness Burden  
10 Index, a patient-reported review of systems that  
11 can be scored to summarize severity and  
12 complexity of illness. And we're currently have  
13 a contract with Eli Lilly to develop that for a  
14 priori stratification of randomized trials. I  
15 don't think I have any conflicts around either of  
16 those issues in these measures.

17 MEMBER CROSS: My name is Sharon  
18 Cross. I am part of the Patient Experience  
19 Department at the Ohio State University Wexner  
20 Medical Center. My background is in oncology  
21 social work. So like Rebecca, I am not a  
22 specialist in statistician work. So look forward



1 to hearing the discussions from everyone else.

2 But I do feel like I do a great job of  
3 representing the patient and family needs. I've  
4 been a chronic patient myself for many, many  
5 years. So I come from that background.

6 I do have a consulting job on the side  
7 with PCORI, but it is specifically in helping  
8 train reviewers who are looking at grants. So I  
9 have no impact on where the money goes or who  
10 gets selected for a grant or not. So I don't  
11 believe I have any disclosures that -- or any  
12 interest that I -- or conflict of interest that I  
13 need to disclose. Thank you.

14 MEMBER LOEB: hi, I'm Sherri Loeb. I  
15 am a nurse, have been for a long time. As of  
16 next week I will be working for Advocate  
17 Healthcare in the Chicago suburb taking care of  
18 Alzheimer's and dementia patients. So nothing  
19 really that fits with these measures per se of  
20 the -- but what brought me here was personal  
21 experience and advocacy that we need representing  
22 all patients. So I don't feel I have any

1 conflicts. But you know, really feel that this  
2 is critically important.

3 MEMBER MORRISE: My name is Lisa  
4 Morrise and I am a broadcaster. I have a  
5 background in media management and teach media  
6 management for Brigham Young University. I'm  
7 also a mom. Probably my most important thing.  
8 And my daughter was born unable to breathe or  
9 swallow and we've had -- just had surgery number  
10 44. She's almost 22.

11 So I got involved in patient advocacy  
12 and became a specialist in patient and family  
13 centered care in patient and family advisory  
14 councils. I'm doing a webinar next month for the  
15 Institute for Patient- and Family-Centered Care.  
16 It will be my fourth time doing this particular  
17 webinar in how to train patient advisors.

18 And I work with Consumers Advancing  
19 Patient Safety and Marty Hatlie and Natasha  
20 Washington. And I'm developing webinars for them  
21 around patient- and family-centered care and  
22 patient advocacy. I don't think that there is a

1 conflict there. I don't work with measures  
2 anywhere or research. I'm an advocate.

3 MEMBER BIERNER: I'm Sam Bierner from  
4 Dallas, Texas. I'm a physiatrist, a specialist  
5 in physical medicine and rehabilitation. I work  
6 in an academic institution where I'm involved in  
7 developing clinical guidelines for treatment of  
8 back pain. And also involved in inpatient  
9 rehabilitation and quality assurance. I don't  
10 have any grants currently. And I have no  
11 conflicts of interest otherwise.

12 MS. HAMMERSMITH: Okay. Thank you for  
13 those disclosures. Based on the disclosures this  
14 morning, do any of you have anything that you  
15 want to discuss with each other? Any questions  
16 of each other? Okay. Before I leave you, just  
17 one more reminder. In order for a conflict of  
18 interest process to really work well, we rely on  
19 each of you to participate actively. What that  
20 means is, if you think you have a conflict of  
21 interest during the meeting, please speak up  
22 right away.

1           If you think somebody else has a  
2    conflict of interest, or if they are acting in a  
3    biased manner, we'd also like you to speak up in  
4    real time. You're always welcome to do that  
5    during the meeting itself. If you'd rather not  
6    handle it that way, you can approach your co-  
7    chairs who will go to NQF staff, or you can  
8    approach NQF staff directly. What we don't want  
9    you to do is to sit there in silence and then six  
10   months later say you know, not quite sure if that  
11   was okay. So, that's my final reminder. And  
12   have a good meeting.

13           CO-CHAIRPERSON PARTRIDGE: Thank you  
14   Ann. And I'm now going to turn to Helen.

15           DR. BURSTIN: Good morning everybody.  
16   Again, thank you for those introductions. I am  
17   so struck by the breadth and depth of this  
18   Committee. It's really quite staggering. I  
19   can't imagine a better group to evaluate the  
20   measures before us today. And your work won't be  
21   done, because there's many more in the queue to  
22   follow in this particular space as it grows and

1 grows.

2 So I'm delighted. I mainly just  
3 wanted to take a chance to say good morning, but  
4 actually mainly to introduce Marsha Wilson, who  
5 has just joined NQF a week ago as the new Senior  
6 Vice President for Quality Measurement here. As  
7 some of you know, that was the job I had had, and  
8 I am now the Chief Scientific Officer. So we'll  
9 be working really closely together.

10 But Marsha joins us from years of  
11 helping to lead Aligning Forces for Quality, a  
12 community-based initiative with the Robert Wood  
13 Johnson Foundation. So brings a wealth of  
14 community based and implementation experience  
15 that I know we sorely lack. So we're just  
16 delighted to have her. You'll see lots of her at  
17 these meetings. I'll still be here to help with  
18 any of the science issues. But you know, really  
19 she will be leading this department. So I just  
20 wanted to add a welcome to her.

21 CO-CHAIRPERSON PARTRIDGE: Welcome to  
22 Marcia also. And welcome to the rest of the NQF

1 staff, Mitra, Nadine, for keeping us in line and  
2 keeping us informed. And always being so nice  
3 about it. Sarah?

4 MS. SAMPSEL: Yes. So, good morning  
5 everybody. And I do want to take just a real  
6 quick opportunity to have Mitra, Nadine and  
7 Suzanne introduce themselves as well. I started  
8 with this group at your last meeting in phase  
9 one, and kind of shadowing Karen Pace and Lorelei  
10 so I could pick up the work since they've  
11 subsequently left the organization.

12 I'm a consultant to NQF with years of  
13 measure development and implementation history.  
14 But you know, just want to reflect that it really  
15 is the staff team that has prepared these  
16 documents, as well as prepared and the logistics  
17 for today as well. And you know, as Lee  
18 mentioned earlier, we have changed the process a  
19 little bit. And we warned you of that at the end  
20 of the last phase, regarding removal of the  
21 workgroup meetings and starting to do a staff  
22 review.

1                   And so it will be really interesting  
2                   to us if you have any feedback on what, you know,  
3                   what different things we could do for that staff  
4                   review. We were really challenged by this  
5                   measurement set due to 28 measures and you know,  
6                   some complicated statistical issues with these  
7                   measures as well. So I'm very much looking  
8                   forward to hearing your expertise and feedback on  
9                   the measures. But with that I do want to make  
10                  sure everybody introduces themselves. And then I  
11                  know Mitra actually has a few slides she'll go  
12                  through.

13                 MS. THEBERGE: Good morning everyone.  
14                 I'm Suzanne Theberge. I'm a Senior Project  
15                 Manager here at NQF. And I'm happy to meet to  
16                 you all.

17                 MS. ALLEN: Hi everyone. I'm Nadine  
18                 Allen, Project Analyst. We worked on our  
19                 previous work for phase one. And now I'm glad to  
20                 be a part of phase two as well. I'm also working  
21                 on the home and community based services project  
22                 and the child Medicaid project.

1 MS. GHAZINOUR: Good morning everyone.  
2 This is Mitra Ghazinour. And I've been with NQF  
3 almost four years and supporting different  
4 committees, including the Measure Applications  
5 Partnership, MAP, Post-Acute Care/Long-Term Care  
6 Workgroup, and also supporting the new work on  
7 rural health. And I'm so happy that I'm also  
8 involved in this work, Person- and Family-  
9 Centered Care.

10 So I guess I'm just going to start  
11 with some introductory slides. We just wanted to  
12 go over quickly talking about Person- and Family-  
13 Centered Care Portfolio. And also discuss why  
14 functional status measures are under review for  
15 the person in this project. So, I currently --  
16 the Person- and Family-Centered Care Portfolio  
17 includes 56 endorsed measures and measure sets.  
18 And during phase one the Committee reviewed 11  
19 measures. 12 measures were submitted. One was  
20 withdrawn.

21 And the Committee reviewed 11 measures  
22 and 10 of which were recommended for endorsement.



1 And my understanding is that the measures have  
2 been reviewed by the Board and they are going to  
3 meet after this process. And so for this phase  
4 we have functional status measures to review. We  
5 have 21 endorsed functional status measures. And  
6 we have 7 additional new measures that were  
7 submitted during phase two. And we also have  
8 other measurement domains such as symptoms,  
9 symptom burden and other miscellaneous  
10 measurement domains.

11 So, why functional status is  
12 considered a measurement domain under person- and  
13 family-centered care? As you might be familiar  
14 with the work of Measure Applications  
15 Partnership, this is a multi-stakeholder group  
16 that is convened by NQF to provide  
17 recommendations on selection of measures for  
18 federal programs. And also to provide  
19 crosscutting recommendations, such as alignment,  
20 across federal programs, public programs and  
21 private programs.

22 So last year MAP convened three task

1 forces to identify families of measures for three  
2 NQF priorities of affordability, population  
3 health and person- and family-centered care. A  
4 family of measures are a set of related and  
5 available measures that address either high  
6 impact conditions or NQF priorities.

7 So the Person- and Family-Centered  
8 Care Task Force identified high priority areas --  
9 five high priority areas. Did we lose -- okay,  
10 so I'm just to keep talking without the slides.  
11 So the Person- and Family-Centered Care Task  
12 Force identified five high priority areas for  
13 measuring person- and family-centered care. And  
14 quality of life was one of them.

15 So the task force emphasized that the  
16 importance of measures under the quality of life,  
17 including measures of behavioral, physical,  
18 social, emotional and spiritual well being. And  
19 also the importance of interventions designed to  
20 improve or maintain physical and cognitive  
21 functioning. And other sub-domains under quality  
22 of life included alleviation of symptoms and

1 symptom burden. And minimization of treatment  
2 burden on patients' families and caregivers.

3 So also another committee convened by  
4 NQF, which they defined patient-reported outcomes  
5 and also identified domains addressing patient-  
6 reported outcomes. So the committee defined  
7 patient-reported outcomes as any report of the  
8 status of a patient's health condition that comes  
9 directly from the patient without interpretation  
10 of the patient's provider or anyone else.

11 And the four domains included health  
12 related quality of life, including functional  
13 status, symptoms and symptom burden, experience  
14 with health care and their behaviors. So the  
15 next slide demonstrates the distinctions in  
16 terminology used to describe patients before the  
17 measurement.

18 The first one, as I referred to  
19 earlier, the concept of any report of a status of  
20 a patient health outcomes or health status that  
21 comes directly from the patient without  
22 interpretation of the providers. And the symptom

1 a patient might report that they have -- they  
2 suffer from depression.

3 And then PROM, which refers to  
4 instrument, scale or single-item measure used to  
5 assess the pro-concepts as perceived by the  
6 patient and directly reported by the patient.  
7 And an example is PHQ-9, a standardized tool to  
8 assess depression.

9 And then we have PRO-PM, which means  
10 pro-based performance measure that is based on  
11 PROM data and aggregated for an accountable  
12 healthcare entity. And an example includes  
13 percentage of patients in an accountable care  
14 organization whose depression score, as measured  
15 by the tool PHQ-9, has improved.

16 So the next few slides include all the  
17 28 measures that the Committee is going to review  
18 today. I'm not going to list all the measures,  
19 name all the measures. However, these slides  
20 they show the display -- they display the  
21 breakdown of the functional status measures by  
22 setting. So the current slide demonstrates that

1 we have seven measures that address  
2 ambulatory/multiple setting rehabilitation. Such  
3 as a skilled nursing facility, outpatient  
4 rehabilitation.

5 And the next slide, it shows five  
6 measures that are applicable to home health and  
7 three measures that are specified for nursing  
8 homes and skilled nursing facilities. The next  
9 slide shows that we have seven measures that are  
10 specified for use inpatient -- we have inpatient  
11 facilities.

12 And lastly, we have two measures that  
13 address long-term care hospitals. And four  
14 measures that address outpatient settings. And  
15 also, I would like to go over some key points  
16 regarding functional status performance measures.  
17 So, surveys, instruments and tools are a method  
18 to collect data and not a measure by itself. And  
19 NQF endorses performance measures for accountable  
20 healthcare entities, not a survey tool or  
21 instrument alone. And a performance measure  
22 aggregates the data for the patient served by

1 each healthcare entity.

2 NQF endorsed performance measures are  
3 intended for use in both performance improvement  
4 and accountability applications, such as public  
5 reporting and pay for performance. And  
6 functional status, as I mentioned earlier, is  
7 considered a domain of person- and family-  
8 centered care. And we have a mixture of process  
9 outcome measures and patient-reported outcome  
10 measures for review in this phase.

11 There are some additional and key  
12 points including that measures can be based on  
13 single or multiple items, questions from surveys  
14 or instruments. And for outcome measures there's  
15 an exception to providing a summary of systematic  
16 review and grading of a body of evidence. And  
17 developers are asked to provide a rationale that  
18 at least one healthcare structure, process,  
19 intervention or service affects the patient  
20 experience being measured.

21 There are some key points specific to  
22 patient-reported outcome performance measures.

1 They are required to be tested at both levels of  
2 patient level data and score and the performance  
3 score for the healthcare entity. And lastly,  
4 PRO-PM developers are asked to provide evidence  
5 that the target population values the measure and  
6 finds it meaningful. And the last slide we just  
7 have included the list of patient-reported  
8 outcomes, performance measures that are under  
9 review in phase two. So before handing it over  
10 to Suzanne, I would like to know if there are any  
11 questions?

12 MEMBER MONROE: Are we -- when we look  
13 at these measures, we look at them as individual  
14 measures, not as groups of measures. I'll just  
15 use what's on the screen as an example for me.  
16 Should I be wondering is there enough difference  
17 between each of these to justify an individual  
18 measure? Or am I only looking at the measure and  
19 its properties and its value, et cetera? So  
20 that's just a question that I have.

21 MS. SAMPSEL: So, we will have that  
22 issue. And I think the important thing to

1 remember is we are considering these measures as  
2 individual measures. And then once we make a  
3 recommendation to move them forward or to endorse  
4 them or not, we would move into discussions about  
5 related and competing. So you do evaluate on the  
6 merits of the measure first.

7 MEMBER MONROE: Let's say we take 0422  
8 and move it forward. And then we talk about  
9 related and competing measures.

10 MS. SAMPSEL: Yes.

11 MEMBER MONROE: Do we have the option  
12 at that point of then reconsidering whether we  
13 want to move 0422 forward because of the related  
14 and competing discussion?

15 MS. SAMPSEL: Yes.

16 MEMBER MONROE: So we do have a two-  
17 phase opportunity to look at these measures?

18 MS. SAMPSEL: Exactly. And in the  
19 related and competing discussions what will  
20 happen is we'll have a discussion, you know, is  
21 there an opportunity for harmonization? Or is it  
22 a discussion regarding depending on where the



1 measures match up, if they are related and  
2 competing to one another, where we might choose a  
3 superior measure, or a best fit measure. And it  
4 would be one over the other. And the other would  
5 not be endorsed. Correct.

6 DR. BURSTIN: And just one comment to  
7 add to that. That's great, Sarah. The other  
8 thing to consider is when we think about related  
9 measures, meaning they need to be harmonized.,  
10 they're similar enough.

11 But if the patient population is  
12 different, as for example these would be, across  
13 different groups, they would not be considered  
14 competing because the patient populations are  
15 different. And that's where you'd want to make  
16 sure they are at least harmonized and make sense  
17 that the same sort of structure and method  
18 applies to each.

19 MEMBER KAPLAN: Can I ask a question?  
20 If some other group, like say there's a surgical  
21 group who's reviewing some measures of you know,  
22 performance measures for the surgery. And this

1       measure would actually enhance or in combination  
2       with some of those other surgical type measures  
3       create a -- is it NQF's job to go back and see if  
4       there's a mutuality there that can be enhanced?  
5       Or are you project specific? Are you bound by  
6       project?

7                   DR. BURSTIN: Yes, it's a great  
8       question Sherrie. It's complex certainly. What  
9       we try to do is just put what we think is the  
10      right set of measures in front of the right set  
11      of groups and experts and multi-stakeholder  
12      groups. But at the same time we will oftentimes  
13      ask other committees to take a look.

14                   And when we present the portfolio of  
15      measures for example to the surgery committee, we  
16      would add measures from this Committee so they  
17      could see the full view. But we probably need to  
18      do a better job of the sort of matchmaking of  
19      really thinking about how measures from disparate  
20      groups come together as composites or set of  
21      measures.

22                   CO-CHAIRPERSON PARTRIDGE: And

1 Sherrie, actually you're anticipating what we  
2 hope will be a little discussion of this issue  
3 tomorrow afternoon, and which I spent some time  
4 discussing with my colleagues at the partnership  
5 yesterday afternoon. It's, I think we all feel  
6 that there's an expertise building in this  
7 Committee, particularly around the PRO-PM  
8 measures. Yet there are obviously technical --  
9 clinical aspects that aren't necessarily  
10 reflected on the membership of this Committee.  
11 So how we put those together sensibly is an  
12 interesting question.

13 MEMBER THOMAS: In preparing for this  
14 meeting I read a letter that MEDPAC had submitted  
15 to the Department of Health and Human Services on  
16 the deluge of quality measures that are building  
17 and are coming into CMS every year. And it just  
18 got me thinking that we've got you know, take  
19 mobility. Mobility measures in home health.  
20 Mobility measures in SNF. Mobility measures in  
21 IRF.

22 I'm wondering you know, it's mobility.

1       There ought to be some ability to have a common  
2       set of instruments so -- or an instrument that  
3       cuts across settings, so that you can maybe  
4       eliminate some of the duplication of that.  
5       That's probably a naive comment but because I  
6       know a lot of this goes into each setting and  
7       accommodating the particular patient population  
8       that's served by those settings. But it just  
9       strikes me that therein lies I think a lot of the  
10      duplication.

11               DR. BURSTIN: This is a huge issue for  
12      the MAP, the measures of patient partnership as  
13      we're reviewing the measures that come forward.  
14      At the same time though again, you know, was much  
15      as we can harmonize the approaches, unfortunately  
16      we still live in a space where the data sets  
17      available in some of those settings tend to be  
18      quite different still.

19               Some of that is evolving, as you'll  
20      see today for some of the measures coming  
21      forward. But the key thing is to at least make  
22      sure that, however, its mobility is measured in

1 one setting should not be different then some of  
2 those key concepts. That's what we really think  
3 about in terms of harmonization. So I think  
4 that's going to be really important role for this  
5 Committee.

6 MEMBER PARISI: Actually Peter  
7 stimulated a thought in my head. Frequently in  
8 my experience and my observation, some measures  
9 are evaluated based on the perspective of the  
10 practitioner. For example, the way a physical  
11 therapist may evaluate or do an assessment of a  
12 patient's mobility, versus an RN.

13 So at what point does that figure into  
14 the discussion? Because some of these measures  
15 may be appropriate for a therapist, but not  
16 appropriate for a nurse or a physician. And that  
17 hasn't come up. So I was just wondering that  
18 question?

19 DR. BURSTIN: I think it's something  
20 you'll deal with. I mean in some instances there  
21 are going to be examples where there are measures  
22 directly from the voice of the patient, true

1 PROs. There are some where it's reflected  
2 through a nurse or a physical therapist. I think  
3 those are important questions to ask of the  
4 developers. Is this appropriate, it would be  
5 part of the measure specifications, that this is  
6 a measure done by X type of provider. Or maybe  
7 not.

8 I mean it could be pretty open. I  
9 think for example, I mean a set of committee  
10 measurements, PHQ-9 measures that we've endorsed,  
11 that look at the change in depression scores, are  
12 administered in a clinical setting to patients.  
13 But it doesn't prescribe who that person is.

14 There may be some instances for  
15 example, a physical therapist doing this work and  
16 doing the assessment, or a home health nurse  
17 doing that assessment, where they're the logical  
18 operator. But I think it's a question -- it's a  
19 fair question to be talking about through the  
20 day.

21 CO-CHAIRMAN STILLE: And I just want  
22 to thank all of you that have expertise in this

1 contents base. Because unlike our last set of  
2 discussions where we all kind of knew what  
3 patient- and family-centered care you know, was,  
4 some of these aren't as intuitive to many of us  
5 as they would be otherwise. So we'll probably be  
6 calling on more of you that have content  
7 expertise in this particular -- one or more  
8 particular areas depending on which measure we're  
9 talking about, to give us some perspective on  
10 that.

11 MEMBER BRADLEY: Could you help  
12 distinguish the -- because this was mentioned in  
13 several of the measure information that was  
14 presented. The difference between looking at the  
15 measure from a quality standpoint and an  
16 accountability standpoint? Because many of these  
17 measures are being proposed for payment. And so  
18 I'm just curious if you could define the  
19 difference. Is it pay for performance or are  
20 there other considerations under the  
21 accountability and payment issue?

22 DR. BURSTIN: I'm smiling just because

1       this is such a major issue for us at the moment  
2       at NQF. It's good I'm smiling. So, at this  
3       point in time, endorsement implies the measures  
4       are appropriate for a wide range of potential  
5       applications. Ranging all the way from quality  
6       improvement through all the way towards payment  
7       or penalties. We don't make that distinction.  
8       And that's how you should operate today.

9               That being said, the MAP process does  
10       in fact then take these measures and look  
11       specifically about whether they are applicable  
12       for a given program through CMS. Which will  
13       largely -- this is about a penalty, this is about  
14       public affording, et cetera.

15               So there is a second lens that offers  
16       that. The question we've really been grappling  
17       with, and I'd love your thoughts about this as we  
18       talk about this through the next couple of days,  
19       is whether we should also be moving the whole  
20       sort of evaluation process to being more about  
21       endorsement for intended use.

22               Or offering some gradation in the



1 endorsement that says this is a measure that  
2 meets the highest grades of testing, evidence, et  
3 cetera. And should be used for a variety of  
4 applications. These may not be quite ready for  
5 prime time for those, but could be appropriate  
6 for others.

7 That's still something worth talking  
8 about. And we're actually going to be convening  
9 an extra panel on that shortly. But for the  
10 meantime, assume it's the broad set of  
11 accountability applications. But know full well  
12 that actually next week the MAP will actually be  
13 talking about some of these very measures and  
14 their applicability to specific programs and  
15 whether they are reasonable for those programs.

16 MS. SAMPSEL: First of all, I wanted  
17 to kind of provide a little bit of context for  
18 some of the slides that Mitra presented. And  
19 there's a difference in this phase of work, which  
20 was the purpose of that slide, in that in the  
21 first phase of work, if you remember, we did a  
22 lot of patient-reported outcome process measures.

1 So we were looking for the item level of  
2 reliability and validity testing as well as the  
3 measure level reliability testing.

4 In this phase, it's only a few of the  
5 measures that are the PRO-PM. So we are looking  
6 at different levels of testing. So Suzanne is  
7 going to start talking and go through the measure  
8 evaluation guidance so we can start jumping into  
9 the measures.

10 But I do want to bring out, and we'll  
11 be bringing your attention back, when we are  
12 looking at PRO-PM and the level of testing that  
13 you're looking for based on the guidance that NQF  
14 issued last year. And there are some differences  
15 based on if it's a process, an outcome or a PRO-  
16 PM. And we have a mix of all measures.

17 So, you know, I wanted to make sure  
18 that folks understood that distinction because  
19 we're not looking all the time for the same  
20 things based on the different kinds of measures.  
21 So we'll bring that to your attention as we go  
22 through.

1 MS. THEBERGE: Okay. So I'll just  
2 talk real quickly about some process issues. We  
3 do have a quorum requirement of 75 percent of the  
4 Committee. We have 19 Committee members here, so  
5 that means we need 15 of you voting on any one  
6 measure to achieve quorum. So we do ask that, if  
7 at all possible, you not leave while we're in the  
8 middle of voting on a measure. If you need to  
9 step out, just try to do that during the  
10 discussion piece, because if our quorum numbers  
11 change during the votes it just causes some  
12 complications.

13 And also just to move something  
14 forward it needs a greater than 60 percent  
15 approval on any of the items. So that's at least  
16 12 of you need to vote. And I think our new  
17 voting software will actually give us the  
18 percentages so we don't need to be doing the math  
19 as we go.

20 Next slide.

21 CO-CHAIRPERSON PARTRIDGE: Suzanne, I  
22 think we need to discuss a tiny bit about these

1 two other dots.

2 MS. THEBERGE: Oh yes, sorry. Sure.  
3 We have changed the process a bit, for those of  
4 you who have served on committees in the past.  
5 We now have something called "consensus not  
6 reached" because we had a lot of measures that  
7 were falling into the, like, 52 percent, 55  
8 percent. And, you know, it's sort of like is  
9 that really consensus?

10 And so the three buckets that we have  
11 are pass/recommended, which is greater than 60  
12 percent. Consensus not reached, which is 40 to  
13 60 percent. And that includes both 40 and 60.  
14 And then does not pass/not recommended is less  
15 than 40 percent.

16 And so anything that's in that  
17 consensus not reached, "the gray zone" we call  
18 it, does continue to move forward. And we'll  
19 take it to comment and you will be asked for  
20 specific comments about that measure related to  
21 the consensus not reached status. And then the  
22 Committee will revote.

1           Of course, you have the opportunity to  
2       revote on any measure following comment. But you  
3       will definitely revote on those measures  
4       following the comment period. And just so you  
5       know, those consensus not reached, pass, does not  
6       pass, follows through at the NQF member voting  
7       and the CSAC as well.

8           So just process in terms of how we're  
9       going to move through everything today. The  
10      developers will briefly, two to three minutes,  
11      introduce their measures. And then our Chairs  
12      and Sarah will guide the discussion. We will  
13      have you comment on whether the measures do or do  
14      not meet the criteria. We ask that the lead  
15      discussant for each measure kind of run that  
16      piece of it.

17           If there are pre-meeting comments from  
18      the surveys that you all filled out, please refer  
19      to those during your introduction to the measure.  
20      And then we'll have you all vote on each of the  
21      criteria.

22           I think we already went over the

1 related competing thing. And then we can, of  
2 course, go over it again as it comes up.

3 Just some housekeeping things. Please  
4 make sure you turn your mic on when you would  
5 like to talk and then turn your mic off when  
6 you're done talking. I think we can only have  
7 two mics on at any one time. So that's why we  
8 need you to turn it off. And if you wish to make  
9 a comment, just turn your table tent up so that  
10 we know and our Co-Chairs will reach out to you.

11 And I'm going to turn it over to Sarah  
12 to talk about our criteria.

13 MS. SAMPSEL: Okay. So this is really  
14 meant to be a refresher course on the criteria.  
15 You know, as you'll recall, when we go through  
16 the votes and the discussions we'll ask you to,  
17 as the lead discussant, to introduce evidence and  
18 importance first and we'll vote.

19 We'll discuss scientific  
20 acceptability, which is the reliability, the  
21 validity, exclusions, et cetera. And we'll vote.  
22 And then we'll do feasibility and usability.

1           When Suzanne was mentioning the  
2           scoring thresholds, just as a reminder, if a  
3           measure does not pass importance or either of the  
4           scientific acceptability criteria for reliability  
5           and validity, that measure stops.

6           But then again, there may be a  
7           situation, and what we'll be doing is then asking  
8           you for some direct feedback to the developers  
9           regarding what it is it that stopped us so that  
10          we can give them direct and clear feedback on  
11          what they might do differently. Because there  
12          would be an opportunity for them to resubmit  
13          information prior to the end of public comment,  
14          which we had happen last time as well.

15          So, why are we concerned about  
16          evidence? Obviously it's the foundation for  
17          using as a quality indicator. And you know, it's  
18          a whole part of the validity testing and part of  
19          the validity requirements for is this a good  
20          measure and is this something we should be  
21          measuring in the first place?

22          For process and structure -- and,

1 again, we don't have any structure measure here,  
2 but we do want to make sure that each of these  
3 measures is something that healthcare units  
4 should be implementing. And I think we had a  
5 couple of questions earlier that were about that.  
6 I mean, are these measures important enough, is  
7 there enough evidence behind them that these are  
8 something that we should be recommending for use  
9 in the industry, whichever level of the industry  
10 they might be recommended?

11 And then when we're looking at the  
12 outcome measure, including those PR-PMs, which is  
13 the vast majority; I think that's 26 out of 28 of  
14 the measures that are either outcome or patient-  
15 recorded reported outcome. We want to make sure  
16 that whatever is being measured is something that  
17 the healthcare unit that's being measured,  
18 whether it's SNF, an inpatient rehab, long-term  
19 care, is something that they can influence and  
20 that there's evidence behind it. We want to see  
21 a tie between what is being measured to what can  
22 be done so that there could be improvement based



1 on what's being measured.

2 And we did, you know, focus a lot of  
3 our staff efforts in making sure that at least  
4 some information was provided on that. Was it  
5 the right information? That's up for us to  
6 discuss here.

7 Nadine, next slide. Why concerned  
8 about reliability and validity? Again, I think  
9 some of this has been discussed. That these  
10 measures are used in accountability applications  
11 such as public reporting and pay-for-performance.

12 We are going to have some examples.  
13 As Mitra mentioned earlier, some of these  
14 measures have already been considered by the  
15 Measures Application Partnership. And they're  
16 actually holding decisions on their measures on  
17 if they want to move them to final rulemaking  
18 based on the work of this Committee and  
19 recommendations for endorsement.

20 So, you know, these are important.  
21 And important discussions. And do want to make  
22 sure that we're moving forward reliable and valid

1 measures.

2           And then, you know, I think the rest  
3 of this slide is really just kind of issues that  
4 we'll talk about when we go through scientific  
5 soundness and scientific acceptability. But if  
6 we're moving a measure forward, we want to make  
7 sure the performance scores, you know, can be  
8 used to make conclusions. Because either the  
9 industry is using these measures to make quality  
10 improvement programs or to produce and move  
11 forward on quality improvement efforts. Or they  
12 are being used for pay-for-performance. Many of  
13 these measures are in some of the CMS Compare  
14 programs.

15           You know, I don't want to go through  
16 all of these notes on reliability and validity  
17 because of time at this point. We have created a  
18 cheat sheet on reliability and validity that  
19 we'll make copies of during lunchtime just to  
20 make sure you have reference. Because I know  
21 last time we had some questions, what is this  
22 Chronbach's analysis thing that you guys are

1 talking about? We have a new introduction this  
2 time of Rasch analysis, which is the first time  
3 folks have probably seen that. And so we do want  
4 to make sure everybody has the tools at their  
5 hand.

6 But we'll be asking the developers to  
7 comment exactly why they used a certain kind of  
8 testing as well so that we have that out. We'll  
9 be able to pull it up on the screen. It's  
10 actually on your SharePoint site if you want to  
11 pull it up. But at the same time, we've kind of  
12 spelled out and used some of the RAND tools  
13 because they do a really nice job of explaining  
14 this type of testing as well.

15 So I think we want to go into the  
16 measures at this point.

17 MEMBER KAPLAN: Sarah, sorry, I don't  
18 want to slow us down either because I know we're  
19 behind. But can I ask for some clarification  
20 about when a measure, for example, has been out  
21 there and it's up for reconsideration and it's  
22 now being moved into a performance category,

1 performance measure, is the guidance about --  
2 because the guidance for an outcome measure may  
3 not be that you have to have empirical support of  
4 a link between process and outcome, or at least  
5 for the units being compared, but you can do a  
6 conceptual model or something.

7 If the measure is up for  
8 reconsideration and it's now moving towards a  
9 performance assessment, is there a requirement  
10 that now you must show, that for the unit being  
11 compared, you have to have some empirical support  
12 for that?

13 DR. BURSTIN: No, we actually don't.  
14 And it's been an interesting issue over time. So  
15 we have actually allowed outcome measures to move  
16 forward with simply a rationale for how they  
17 relate to the process measures, fully knowing  
18 that, in some instances, central line-associated  
19 blood stream infection probably being the best  
20 example, the outcome measure went out before a  
21 lot of the interventions that showed how you  
22 could reduce this.

1 I think there was a hesitancy to  
2 require that you have process improvements in  
3 hand before an outcome could move forward,  
4 recognizing the outcome at times can be the  
5 forcing function for its ensuring that some of  
6 those process improvements are discovered.

7 But it's been a contentious issue.  
8 And one we'll probably revisit many times over  
9 the coming years.

10 CO-CHAIRMAN STILLE: Okay. Sounds  
11 good. Let's dive in. We'll start with Measure  
12 0423, Functional Status Change for Patients with  
13 Hip Impairments. And the FOTO folks will give a  
14 brief talk. And then, I believe, Sherrie, are  
15 you going to be the primary discussant, or  
16 Katherine? Sherrie, okay.

17 MR. JOHNSTON: Okay, great. Good  
18 morning, Madam and Mr. Co-Chairman, and members  
19 of the Committee. We thank you for the  
20 opportunity to present to you these seven  
21 measures that we are submitting today, Numbers  
22 0422 through 0428.

1 I want to provide a little bit of  
2 history of how these measures were developed and  
3 how they're being used. And I'll first identify  
4 that FOTO started collecting data in 1995 by a  
5 consortium of large multi-state, publically-held  
6 healthcare providers of rehab. And they  
7 presented the data to the industry. And the  
8 industry said, that's great, but we don't like  
9 the data being held by a provider. So, resulting  
10 of that reaction, the data depository was put  
11 into the control of an independent entity of  
12 providers, which it has been since 1998.

13 Currently a number of patients  
14 starting an episode using these measures in the  
15 last 12 months was 1.23 million surveys or intake  
16 surveys. That's the volume of our survey  
17 process. This data is coming from over 15,000  
18 clinicians, PT/OT and some speech, practicing in  
19 over 3,000 outpatient facilities in each of the  
20 states in the United States.

21 The survey platform is also being used  
22 by providers in the second largest HMO in the

1 State of Israel. And beginning this month, the  
2 Canadian Physiotherapy Association will begin to  
3 subsidize their member providers in the use of  
4 these measures to collect a standard data set.

5 The patient-report surveys are  
6 presented in seven languages. Of course,  
7 English, Spanish and French; Hebrew, Arabic and  
8 Russian.

9 The measures have evolved over the  
10 years. In 1995 we started with four legacy  
11 measures. The Oswestry for the lumbar spine, one  
12 for the knee, the Neck Disability Index for the  
13 neck, and the SF-36 for general health  
14 management.

15 In the last 20 years, to gain testing  
16 procession and efficiency in the clinic, we've  
17 added other anatomic-related patient-report  
18 measures. And to reduce the testing burden,  
19 we've gone to item response testing and processes  
20 and computer-assisted test technology to be able  
21 to successfully integrate the patient survey  
22 process in the clinical process.

1           The science of these measures was  
2   developed under the guidance of the late Dr.  
3   Dennis Hart, who served as the Director of  
4   Research and Development at FOTO since we  
5   started. FOTO's adherence to rigorous scientific  
6   methodology and psychometrics has led to the FOTO  
7   data being used at 89 refereed scientific  
8   publications.

9           FOTO may be the largest outcome  
10   database, measured externally, of outpatient  
11   rehabilitation. We currently have data on over  
12   9.3 million patient surveys dating back to 1998.

13          We'd like to introduce the measures as  
14   a group, or at least the introduction as a group.  
15   The measures you're reviewing today are patient-  
16   reported outcome performance measures which use  
17   as their basis one of FOTO's patient-reported  
18   outcome measures.

19          The back history and research are very  
20   similar of reach of these seven patient-reported  
21   outcome performance measures. Beginning with  
22   0422 for the knee and numerically advancing to



1 0428 general orthopaedic impairments.

2 Our performance measures are risk-  
3 adjusted and used at the patient and the  
4 clinician and the clinic level to assess  
5 functional level of a patient and the change in  
6 that functional level during patient care.

7 FOTO measures first received NQF  
8 approval in 2008 as a time-limited approval. And  
9 we received full endorsement in 2011. The PQRS  
10 has accepted FOTO's seven patient-reported  
11 outcome measures. And FOTO is qualified as a  
12 PQRS data registry.

13 Our application today includes some  
14 revisions, primarily moving it from what we think  
15 is a process measure to an outcome measure. And  
16 lowering the age from 18 to 14. And there's a  
17 few other small changes outlined in there.

18 Because I am also a physical therapist  
19 but have no expertise in research or the science  
20 of this, I have brought with me a presentation  
21 panel. Jerry Connolly back here, our consultant  
22 for public policy. Dr. Mark Werneke, who is a

1 clinician at Central State Medical Center in New  
2 Jersey and also a researcher. And Dr. Daniel  
3 Deutscher, Director of Research from Maccabi  
4 Health System in Israel. And hopefully on the  
5 phone is Dr. Linda Resnik, who has been the  
6 leader of this distinguished team and this  
7 challenging effort.

8 And, finally, FOTO thanks the NQF  
9 support staff, Mitra and Nadine, for their  
10 wonderful patience and their guidance and  
11 cooperation during this application process. In  
12 addition, they have helped us add additional  
13 measures to make our application more complete  
14 and to improve our measure analysis. Thank you  
15 very much.

16 CO-CHAIRMAN STILLE: Okay. Sherrie?

17 MS. KAPLAN: Hi, thank you for that  
18 introduction. I had some confusion starting off  
19 in trying to describe the measure. The term  
20 residuals to somebody like me -- and I'm  
21 statistically trained -- so a residual to me  
22 means unexplained variance. And what I think you

1 mean is that it's a changed score adjusted for  
2 certain characteristics of the patient. Is that  
3 correct? It's not a residual, right?

4 MR. JOHNSTON: Could I confirm that  
5 Linda is on the phone, Dr. Resnik?

6 DR. RESNIK: Yes, I'm on the phone.  
7 Do you want me to take that? Or, Dr. Deutscher,  
8 would you like to answer? Can you hear me?

9 MR. JOHNSTON: No, you couldn't hear  
10 me because I turned my button off. I'd like for  
11 you to determine whether you should answer or  
12 whether Dan or Mark should answer.

13 DR. RESNIK: Okay. Well, I'll take  
14 that question. After the risk adjustment  
15 process, what's remaining in the model is  
16 variation from the predicted value. So that is  
17 the residual score after modeling. That includes  
18 error and what we believe is the variance due to  
19 clinician and clinic characteristics. So that's  
20 what the residual is. So it's the risk-adjusted  
21 value after the modeling. Does that answer your  
22 question?

1                   MEMBER KAPLAN: No. Now I'm more  
2 confused. Because you say that it's the change  
3 between the intake and the discharge value, so in  
4 -- help me out with the model here. What's the  
5 dependent variable? A dependent variable -- let  
6 me just sort of frame my confusion.

7                   If the dependent variable is  
8 discharge, functional status at discharge, in the  
9 model do you include the baseline measure, the  
10 intake value, along with the other adjusters?  
11 How do you compute the -- or are you looking at  
12 the -- are you really looking at residuals,  
13 unexplained variation after adjustment? And  
14 what's in the model?

15                  DR. RESNIK: Okay. The risk  
16 adjustment model is specified. It includes  
17 intake functional status as well as key  
18 characteristics that are specified in the model:  
19 gender, age, comorbidities and so on, acuity or  
20 onset. And the dependent variable is change.  
21 Change from intake to discharge. So that's what  
22 the model looks like.

1                   MEMBER KAPLAN:   Okay.   So in the  
2   model, on the right-hand side of the model, is  
3   intake value?   And on the left-hand side is the  
4   change score?

5                   DR. RESNIK:   Yes.

6                   MEMBER KAPLAN:   So why isn't that an  
7   over-specification of the model?   Because you  
8   would not -- I'm sorry, I don't want to get into  
9   the details here, but it's important, I think,  
10   for the Committee to understand exactly what's  
11   being evaluated.

12                   If you put the -- the thing is  
13   predicting itself if you've got the intake value  
14   on the right-hand side and you use the intake  
15   value to compute a change score on the left-hand  
16   side.

17                   DR. RESNIK:   No, the intake value is  
18   not on the right-hand side.   The right-hand side,  
19   the dependent variable, is change.   So it's the  
20   difference between discharge and intake.

21                   MEMBER KAPLAN:   But you then don't  
22   have the intake value on the other side of the

1 equation.

2 DR. RESNIK: Yes, we do. Because  
3 change is dependent on the baseline status of the  
4 patient. So patients who come in with a great  
5 deal of impairment may change a different amount  
6 than patients who come in with minimal  
7 impairment.

8 MEMBER KAPLAN: Okay. I think that  
9 could be a problem. But we're going to probably  
10 need some more discussion on that.

11 MEMBER BIERNER: Can I ask a question  
12 there? So are you saying that the same delta,  
13 the same change, or the same measured change, in  
14 a given person will vary depending on what their  
15 disability is or what their level of impairment  
16 was when they started?

17 DR. RESNIK: Yes.

18 MEMBER BIERNER: Okay. So can I  
19 compare, if I were looking at a physical therapy  
20 clinic, can I take the scores that are generated  
21 from this measure and compare it to another  
22 clinic without knowing much about their patient

1 population? Would I have to know something a  
2 priori about the kinds of patients they see? Say  
3 they're severely disabled versus an outpatient  
4 sports medicine clinic. Would that delta, that  
5 change, be the same in those two settings or not?  
6 Or would there be some modification based on  
7 where the patient was when they came in?

8 DR. RESNIK: Right. Because the  
9 intake score is in the model, that accounts for  
10 the functional status of the patients within the  
11 clinic at intake. So that's why we have the risk  
12 adjustment model because we know that different  
13 clinics serve different populations.

14 MEMBER BIERNER: Okay. But it is  
15 possible to compare -- I just want to understand  
16 that I can compare apples to apples that you're -  
17 -

18 DR. RESNIK: Yes. That's why we have  
19 --

20 MEMBER BIERNER: I understand what  
21 Rasch analysis is and what you're trying to do,  
22 as I understand it, is to make sure that we are

1 comparing apples to apples, that we're comparing  
2 severely disabled to severely disabled and not  
3 sports medicine clinics to hospital-based PT, for  
4 example.

5 DR. RESNIK: Right. For each  
6 individual patient, each individual patient has a  
7 risk-adjusted score. So, in other words, for  
8 each individual patient we can, based on their  
9 intake status, age, gender, symptom acuity,  
10 surgical history, comorbid conditions, fear  
11 avoidance beliefs, payer, we predict their  
12 outcome. And then we understand the difference  
13 between their actual outcome and what's  
14 predicted.

15 MEMBER BIERNER: Okay, but --

16 DR. RESNIK: And that's for each  
17 individual patient. And then by clinic, we  
18 aggregate the risk-adjusted or residual scores by  
19 clinic so that we are comparing the predictions  
20 for individual patients within clinics. And so  
21 we're taking into account the patient  
22 characteristics within each clinic.



1                   MEMBER BIERNER: Okay. So that means,  
2                   though, that, in addition to the actual  
3                   questionnaire or instrument that we're being  
4                   shown, there's a lot of other demographic or  
5                   other information you're collecting that's not  
6                   shown in this instrument.

7                   DR. RESNIK: That's right. The  
8                   patient inquiry tool that's used by FOTO has a  
9                   key component of the survey where we assess  
10                  information on age, gender, onset of the  
11                  condition, number of surgeries for the condition.  
12                  We have a list of comorbid conditions known to be  
13                  associated with physical function. We have the  
14                  type of payer, we have other surveys, like fear  
15                  avoidance beliefs.

16                  Those are all accounted for in the  
17                  risk adjustment process. So, yes, there are a  
18                  suite of other survey items that are added into  
19                  the model. Those are not shown.

20                  MEMBER BIERNER: Okay. So I think  
21                  that's important for this Committee to  
22                  understand. Because I'm understanding it now,

1 but it wasn't immediately obvious from reading  
2 the material submitted. I mean, that's why --  
3 this is something that -- they're buying into  
4 your product because in order to collect all that  
5 other information and use your large database to  
6 analyze against prior history, that's what you're  
7 doing. It's not just this one instrument.

8 DR. RESNIK: Yes.

9 MEMBER KAPLAN: So, let me just kind  
10 of review the risk adjustment while we're on  
11 that. And then I want to kind of move us to a  
12 couple of other concerns I had about this measure  
13 that I need some clarification on.

14 One is that the risk adjustment scores  
15 -- I understand that the risk adjustment modeling  
16 you did was for age, gender, symptom acuity,  
17 surgical history, number of functional comorbid  
18 conditions, payer and level of fear avoidance  
19 beliefs of physical activities. And that's it,  
20 right? There are no other things that you're  
21 measuring in that risk adjustment that we need to  
22 understand?

1 DR. RESNIK: I think that's it, yes.

2 MEMBER KAPLAN: Okay. So, but does  
3 the etiology of hip impairment, is that included?  
4 For example, you say surgical history. Is the  
5 etiology of the hip impairment, is it a hip  
6 fracture, or is it just osteo-whatever,  
7 arthritis? Or is the hip impairment etiology  
8 included or is it just surgical history? So,  
9 does it matter? And I'm thinking about things  
10 like, well, if all the care prior to the time  
11 they hit your intake observation point could be  
12 the lion's share of the predictor of what the  
13 recovery trajectory looks like, then we're  
14 missing key information.

15 DR. RESNIK: Right. There is no  
16 diagnostic information taken into account in this  
17 risk adjustment model. And I think that the work  
18 that's been done in this area demonstrates that -  
19 - and I do believe etiology may be important.  
20 However, etiology is reflected in the intake  
21 functional to a great extent. And so we're able  
22 to predict a fair amount of the variation in

1 patient outcomes just with these characteristics,  
2 without diagnosis or etiology.

3 MEMBER KAPLAN: Thank you. The R-  
4 squared values are, if I recall, .37, .35,  
5 something like that. But --

6 (Simultaneous speaking.)

7 MEMBER KAPLAN: But if the intake  
8 measure is in there, then we would like to see  
9 the additional information accounted for by all  
10 the other variables taken as a group. Because if  
11 the thing is mostly predicting -- I mean, the  
12 best predictor for most functional status  
13 measures of future function is prior function. If  
14 that's accounting for most of the variability,  
15 the residual variance may largely be attributable  
16 to error.

17 DR. RESNIK: We could speculate that.  
18 And we don't present here, but we have looked at  
19 hierarchical models where we do see that a  
20 certain proportion is attributable to the clinic  
21 and the clinician level. And I have done that in  
22 my own research, yes.

1                   MEMBER KAPLAN: Okay. That is  
2 something that I also wanted to get some thoughts  
3 from the measures' developer on. Because only  
4 patient-level data and references are provided  
5 linking the performance measure to interpretable  
6 variability.

7                   And there's an assertion on page 22,  
8 and again on page 23, paragraph four, that the  
9 use of the measure for performance improvement at  
10 the provider level sort of "makes sense." And  
11 although you give some lines and stuff at the end  
12 at the clinic level, I have a lot of issues about  
13 whether that's enough justification given some of  
14 the analyses you've done.

15                  So let me just kind of walk you  
16 through what I found. And then other Committee  
17 members can chime in behind.

18                  With respect to things like missing  
19 data, you've got a 50 percent attrition rate  
20 between intake and discharge. And absent links  
21 between treatment intensity, because you do have  
22 the number of visits, the patient --

1 DR. RESNIK: We don't have the number  
2 of visits necessarily.

3 MEMBER KAPLAN: Okay, but you --

4 DR. RESNIK: Not in the model.

5 MEMBER KAPLAN: So help me out with  
6 who is in the sample. Because you make some  
7 statements about physicians have to have at least  
8 ten patients per -- right -- per physician.

9 DR. RESNIK: Yes. For clinician,  
10 yeah.

11 MEMBER KAPLAN: Okay. For clinician,  
12 sorry. And then at the clinic level you have to  
13 have at least -- for clinics smaller than five  
14 clinicians, they have to have ten patients per  
15 visit. But then for clinics larger than five  
16 clinicians, there was another sample size  
17 estimate. Forty completed episodes --

18 DR. RESNIK: Yes. Let me clarify. In  
19 the risk adjustment modeling that specifies the  
20 entire model and what the coefficients of the  
21 model will be, we use all patients who have  
22 complete discharge, intake and discharge scores.

1                   But then to calculate the performance  
2                   measures, we have thresholds for participation.  
3                   But then we have the rules about clinicians and  
4                   the number of patients they have to have each,  
5                   and clinics and the number of patients, so that  
6                   we have a more stable estimate for the  
7                   performance measure. But our entire risk model  
8                   uses all patients.

9                   MEMBER KAPLAN: Okay. The  
10                  specification on that, and the sample to whom it  
11                  applies, I think we need more information about.  
12                  At least I would feel more sanguine about it if  
13                  we had more information, because instability of  
14                  measurement, the fewer observations you have to  
15                  sample from, obviously, the more measurement  
16                  error you're going to make.

17                  So people who come more often are more  
18                  likely to get sampled and so on. And they're  
19                  more likely to get care, which would help  
20                  interpret the link between -- at least intensity  
21                  -- between the process and outcome issues.

22                  So I got real confused about what we

1 were kind of -- how we were sampling things. And  
2 then whether or not you did hierarchical models,  
3 how are the splines in Figure 2B, 52A, on page 17  
4 of the attachment? What statistical approach --  
5 did you use generalized estimation equations?  
6 Hierarchical linear -- how did you generate those  
7 lines?

8 DR. RESNIK: I'm sorry that I'm unable  
9 to see the slides that you're referring to.  
10 Daniel, if you're there, I believe these are your  
11 figures that you generated. And I'm fairly  
12 certain that these are models that are not from  
13 hierarchical models. These are the results of  
14 another analysis. Daniel, can you take that?

15 DR. DEUTSCHER: Yes. You were asking  
16 about hierarchical models. But we're not  
17 presenting any here. So we did not use  
18 hierarchical models for these applications.

19 MEMBER KAPLAN: But you have a nested  
20 design. You've got patients with -- the way I  
21 understand it, you've got patients within  
22 clinician and clinicians within clinic. So why



1 would you not use a hierarchical approach?

2 DR. DEUTSCHER: Well, since the risk  
3 adjustment model is used to calculate the  
4 prediction -- the predicted score -- I think  
5 you're absolutely correct on a research basis.  
6 But for applications on a day-to-day basis, if  
7 you want to provide a risk-adjusted change score,  
8 a risk-adjusted discharge score, that would be  
9 difficult for the clinicians using the software  
10 to take into account the nested models.

11 So that's something we thought of  
12 looking into. But we haven't done that yet in  
13 order to move that to a practical application in  
14 a routine clinical environment.

15 MEMBER KAPLAN: Yeah. My concern is  
16 the misinterpretation possibilities of  
17 interpreting small, very, very, very small  
18 numbers at the individual level certainly is  
19 going to get very noisy very quickly and be a  
20 real problem, if that's the intended use.

21 And my understanding was you had to  
22 have a year space between intake and discharge,

1 right? Does that vary?

2 DR. DEUTSCHER: Well, yes. First of  
3 all, I think it needs to be clarified that when  
4 we run the model, in order to achieve, to get  
5 those coefficients used for the prediction, we  
6 use all patients in the database that have scores  
7 at intake and discharge. So that's based on a  
8 very large sample size.

9 But then only for reporting purposes,  
10 because of what you've just said, we do not  
11 provide reports at the clinician or clinic level  
12 if they do not pass a certain threshold, because  
13 of this worry. We worried about very small  
14 sample sizes giving very unstable estimates.

15 MEMBER KAPLAN: And that's exactly  
16 what hierarchical linear modeling is designed to  
17 do, is to take into account the differences and  
18 standard error measurement that you would get  
19 when you have floating sample sizes. So I'm kind  
20 of surprised that you didn't use that technique.

21 Let me just follow up. The standard  
22 error of measurement at the clinician level may

1 not allow you -- the splines you projected look  
2 like you can't really discriminate except for the  
3 very, very ends of the distribution. And so you  
4 would mostly say that most things don't differ.  
5 They're not -- and the use for a performance  
6 measure means the thing really has to tell who's  
7 what. And certainly not at the individual level.  
8 So how do you envision the quartiles, deciles,  
9 five percent high and low?

10 DR. RESNIK: I guess I would disagree  
11 with your comment and say that we do demonstrate  
12 that we can differentiate three groups who do not  
13 have confidence intervals that overlap. And  
14 those we would say are people with average, or as  
15 predicted, outcomes of their patients. And then  
16 clinics with better than predicted and then those  
17 with below.

18 So I think we see three groups whose  
19 confidence intervals around this estimate of  
20 their patient outcomes do not overlap.

21 MEMBER KAPLAN: But what -- first of  
22 all, I'm not sure I can see that from what you've

1 generated. And second, how would you use that  
2 information? I mean, if those confidence  
3 intervals are great, but if they give you -- you  
4 would chop it into three groups and how? What  
5 distributional properties would be true over  
6 different observation points? Would they float?

7 Would you have -- you know, I'm now  
8 getting more confused than I was at the start  
9 about exactly what it is you're asking us to  
10 approve.

11 CO-CHAIRMAN STILLE: I'm going to need  
12 to pull us back a little bit. This is great  
13 discussion about validity. And actually let's  
14 bookmark that, because when we talk about  
15 validity all of this is going to be relevant,  
16 plus some of the other measures.

17 We need to kind of talk about  
18 importance in priority and stuff, because we need  
19 to vote on that, I believe.

20 CO-CHAIRPERSON PARTRIDGE: We have  
21 other discussants and we all have looked at -- I  
22 would -- since I'm one of the reviewers of other

1 of these measures, I'm very glad Sherrie went  
2 first. And I am because I think -- I don't know  
3 if I speak for others -- but I have question  
4 marks all over my particular review. And I'm  
5 getting nods around the table from some of the  
6 rest of us.

7 I think, for the perspective of our  
8 developers, we're really struggling with this  
9 one, I think, to understand pretty clearly what  
10 the numerator is, what the denominator is and how  
11 you calculate each one of them. And, Len?

12 MEMBER PARISI: It would also be  
13 helpful to understand the overlap on the  
14 methodologies across all the measures that are  
15 related so that we don't have to repeat the  
16 discussion.

17 CO-CHAIRMAN STILLE: Right. I'm  
18 guessing there's a lot.

19 CO-CHAIRPERSON PARTRIDGE: Yes. And  
20 for example, I think I've picked up what ODQ was  
21 in your discussion. I think you mean the  
22 Oswestry Disability Index. Am I right? That you

1       talked of using different intake tools depending  
2       upon what we're looking at. You use a different  
3       intake tool perhaps for the lumbar from what you  
4       use for knee. Am I right?

5               DR. DEUTSCHER: Well, the tools are  
6       basically different.

7               CO-CHAIRPERSON PARTRIDGE: They're  
8       standard tools. I understand that.

9               DR. DEUTSCHER: They're a combination  
10      -- sometimes combinations of standard tools.

11              CO-CHAIRPERSON PARTRIDGE: Okay.

12              DR. DEUTSCHER: For instance, for the  
13      lumbar, the lumbar computerized adaptive testing  
14      measure was created from the lower back pain  
15      functional scale, included also some items from  
16      the SF-36. They were all combined using an item  
17      response theory methodology, a Rasch analysis, to  
18      see unidimensionality and things of that sort.

19              CO-CHAIRPERSON PARTRIDGE: The reason,  
20      I think ,in some of the other measures we're  
21      reviewing, we some of these standard tools coming  
22      up again. Not used necessarily in the same way

1       you have used them. So it's going to be useful  
2       for us to sort it out.

3               DR. RESNIK I think we need to make it  
4       clear that the FOTO measures, while they might  
5       have had items that originated in some of the  
6       other tools, and in the lumbar application, we  
7       did present a comparison between the FOTO PROM  
8       and the Oswestry.

9               The FOTO measures are unique in that  
10       now they have gone beyond the original items to  
11       be computer adaptive tests or short forms based  
12       on the items test, the computer adaptive tests.  
13       And there's been, for most of the measures,  
14       extensive publications on the psychometrics of  
15       the development of the FOTO patient-reported  
16       outcome measures. So they're not the same as the  
17       Oswestry.

18              DR. DEUTSCHER: Could I add just a  
19       clarification regarding this point?

20              CO-CHAIRMAN STILLE: Go ahead. Yes.

21              DR. DEUTSCHER: It's important to  
22       understand that, as Linda Resnik has just

1 described, the measure itself is combined from  
2 several measures. Not all of the items were  
3 combined. But all of the data that's presented  
4 here that's been collected are data that were  
5 collected using the FOTO combined measure. Not  
6 separate measures. Not the Oswestry and then  
7 some other measures.

8 CO-CHAIRPERSON PARTRIDGE: Yes. Yes,  
9 I understand.

10 CO-CHAIRMAN STILLE: Yeah, let's have  
11 a brief discussion of the importance stuff and  
12 then we can vote on that. And then we can go  
13 back to the validity things.

14 MEMBER SALIBA: Thank you. I have a  
15 question. Can you clarify whether or not is this  
16 in the public domain? Is this quality measure in  
17 the public domain or is it copyrighted? I wasn't  
18 clear.

19 DR. RESNIK: Yes. As the application  
20 shows, each of the measures has short forms that  
21 are in the public domain. We have links to the  
22 FOTO website where the measures are available in



1 the public domain. And the risk models that FOTO  
2 uses are also available to anyone in the public  
3 domain.

4 MEMBER BIERNER: I wanted to ask a  
5 question about the small number of workers'  
6 compensation patients, it looks like five percent  
7 was approximately what you had. Is that correct?

8 DR. RESNIK: I think it varies by the  
9 PROM.

10 MEMBER BIERNER: And the one under  
11 discussion is the hip one is the one I was  
12 looking at. So I think it's five percent. But  
13 I'm not trying to talk about all of them at the  
14 same time. But the one under discussion is the  
15 hip one.

16 DR. RESNIK: Yes. In Table 1.6D,  
17 there's been so many analysis with the FOTO data  
18 that we have different samples for different of  
19 the analyses that has taken place over the last  
20 few years. So, in the first table, we study  
21 three percent with workers' comp.

22 MEMBER BIERNER: My point is that the

1 use of this measure in the future, in a setting  
2 involving workers' compensation, might not be  
3 accurate because of the small number of workers'  
4 compensation patients that you have in our data  
5 set.

6 DR. RESNIK: I think we should  
7 probably look to a different table for -- because  
8 that particular table, the first table, was a  
9 test/retest reliability sample, which was very  
10 small. And I'll try to find another table to  
11 confirm whether that is the case or whether it is  
12 still the same small --

13 CO-CHAIRPERSON PARTRIDGE: I think  
14 before we move off importance entirely, I would  
15 like to understand myself -- and my fellow  
16 reviewers, if you all get it, stop me. What's  
17 the gap? Let's start with the first measure,  
18 0423. The three elements under importance  
19 include link to procedure, performance and  
20 prevalence.

21 DR. RESNIK: Right. We understood  
22 that we did not present this clearly in the

1 application. And we have submitted some  
2 supplemental materials to address the gaps and  
3 disparities. So you'll see there is handouts.  
4 There's a table called Disparities, data tables,  
5 and I don't know what their handouts look like.  
6 But this shows differences in outcome between age  
7 group, gender and payer type for each of the  
8 measures. So if we're talking about the hip --

9 CO-CHAIRPERSON PARTRIDGE: So if I am  
10 trying to decide whether I want to use this  
11 clinic or another clinic post-surgery, and I go  
12 to your website, what went into saying that this  
13 clinic is an A-1 performer as opposed to others?  
14 I'm sorry, I'm getting into the data again. I  
15 take it back.

16 Sherrie, are you comfortable with  
17 their -- with the state -- she's shaking her  
18 head, around GAP?

19 MEMBER KAPLAN: No. And it's because  
20 I couldn't understand how the scores were  
21 constructed. And I still am confused about how -  
22 - I'm not sure what we're trying to -- what we're

1       being asked to endorse.

2                   And I didn't hear what the mode of  
3       administration did to the scores either. Because  
4       there's paper and pencil in here. There's IRT  
5       and CAT generated. Are we endorsing hip CAT?  
6       Are we endorsing the paper and pencil version?  
7       How are those related? What's mode of  
8       administration doing to all of this?

9                   I don't have enough information to  
10      know what I'm being asked to vote on.

11                   MEMBER NEUWIRTH: Can I ask a question  
12      as well? I was trying to find the actual  
13      instruments that were used. The hip CAT. And I  
14      couldn't find the link in here. I found it for  
15      the knee.

16                   MEMBER BIERNER: I found it on the  
17      FOTO website.

18                   MEMBER NEUWIRTH: So you had to go to  
19      the FOTO website. Okay, so --

20                   MEMBER BIERNER: Yes. I did find the  
21      instrument though.

22                   MEMBER NEUWIRTH: Okay.

1 MEMBER BIERNER: The paper one.

2 MEMBER NEUWIRTH: The paper one. And

3 is it --

4 DR. RESNIK: The paper form -- I'm  
5 sorry, the paper forms are short form versions of  
6 the CAT measures. They predict about 96 to 97  
7 percent of the variance of the full measures.

8 So we believe that they are equivalent  
9 or roughly, very close to equivalent. So in  
10 terms of the mode of administration, there's not  
11 a lot of any bias introduced or minimal bias.

12 MR. JOHNSTON: Well, and also on the  
13 website is a link to the actual survey, the CAT  
14 survey. And we believe that we've placed it in  
15 the public domain as well.

16 CO-CHAIRMAN STILLE: Yes, I found it  
17 on the FOTO website while we were talking. Is  
18 there a sense of the Committee that we're ready  
19 to vote on any of the initial measures such as  
20 Importance?

21 MEMBER BEVANS: Can I make one comment  
22 as a discussant? This is an issue that I think

1 does fall under importance. Probably though not  
2 just related to this version of the FOTO because  
3 just to bring up the more general point of  
4 whether functional status measures should include  
5 attributions to specific body parts.

6 So you know, not just this measure but  
7 the suite of them. The advantage of course being  
8 that it has a likelihood of greatly enhancing  
9 measures for, you know, the treatment specificity  
10 perhaps.

11 But of course that assumes that the  
12 body part approach -- assumes that a change in an  
13 individual's functional status can be attributed  
14 to that specific -- the function of that body  
15 part and that that is well understood by the  
16 patient. It also limits the degree to which  
17 comparisons can be made across clinics that are  
18 treating, you know, people for different sort of  
19 body part injuries.

20 I wanted to bring that up here. I  
21 realize it's something that applies to you know,  
22 the entire suite of instruments, not just that.

1 But I think it has some pretty important  
2 implications for the Importance of the measure.

3 DR. RESNIK: In my case I would argue  
4 that functional status may be a recent construct  
5 and we all can be comparable. However,  
6 conditions, say of the wrist and hand, affect  
7 functional status quite differently than  
8 conditions of the foot and ankle.

9 And because we want to be brief and be  
10 able to measure things in an efficient manner, we  
11 choose different items to get at that construct  
12 for people with hand impairments as compared to  
13 foot impairments. And for people with back  
14 impairments as compared to foot impairments.

15 So I think it's the selection of items  
16 to get the most efficient and accurate assessment  
17 of the aspects of function that are affected by  
18 impairments in those body regions. And that's  
19 why we have the different body part specific  
20 CATs.

21 MEMBER BEVANS: I get that rationale  
22 I think though that, you know, a lower extremity

1 mobility type construct or an upper extremity  
2 could also work.

3 CO-CHAIRMAN STILLE: And it's  
4 interesting because when you look at the --

5 MEMBER BIERNER: Well, there are  
6 already measures. There's a lower extremity  
7 functional scale, there's a DASH. There are  
8 other measures that cover like the upper  
9 extremity.

10 There's the Womack for the hip that I  
11 was going to ask about on this one. But so there  
12 are already other measures. But I'm supportive  
13 of the fact that you have to have different  
14 specific questions and different aspects of  
15 functional impairment that are specific to body  
16 parts because there are a lot of differences in a  
17 hip patient versus a foot and ankle injury  
18 patient or a hand or shoulder.

19 These all have significant differences  
20 and the kinds of impairments they -- or problems  
21 of daily living that they have. But there are  
22 some.



1                   So I'd like to know how does this  
2                   compare to the Womack, which has been around a  
3                   long time for the hip. Did you all -- has there  
4                   been any head to head testing? Or are you all  
5                   just started with when you first started this?

6                   DR. RESNIK: I don't think that we  
7                   have ever directly compared to the Womack. And  
8                   the Womack is not also -- it's not an NQF  
9                   endorsed measure.

10                  I mean there are many, many functional  
11                  scales. And we haven't compared to all of them.  
12                  That would involve some time collection of data  
13                  and different aspects.

14                  MEMBER BIERNER: Well, yes. But the  
15                  Womack has been around 30 years. And it's one of  
16                  the most well known for arthritis of the hip and  
17                  knee. The hip and their knee measures have been  
18                  around for you know, decades, and are very well  
19                  published.

20                  CO-CHAIRMAN STILLE: Ann, did you have  
21                  a question or did you just put your thing down?  
22                  No. There's three more up, Len, Liz, Sherrie?

1                   MEMBER KAPLAN: I just have a  
2                   feasibility question and it's a quick one.  
3                   Because that's why I asked the question about how  
4                   much these other risk adjuster variables are  
5                   important in explaining differences in these  
6                   measures? Because you've got a 15-point  
7                   improvement on a zero to 100 scale over a year's  
8                   period.

9                   Because nobody that I know collects  
10                  routinely level of fear, avoidance beliefs of  
11                  physical activities. So does that tie this to  
12                  this -- to FOTO in a way that makes it unusable  
13                  by a larger group of folks because of your risk  
14                  adjustment model?

15                 DR. RESNIK: The reason that fear  
16                  avoidance is in there is because we have found  
17                  that it is predictive of outcome. And that  
18                  patients who have higher levels of fear avoidance  
19                  do not do as well in therapy.

20                 And so to equalize clinics that may  
21                  see that type of patient, we do feel that it's  
22                  important to adjust for that. The measure that's

1       used for that is not lengthy and is available.

2               MEMBER SALIBA:   So fear avoidance is  
3       being used as an independent variable?

4               DR. RESNIK:   Yes.

5               MEMBER SALIBA:   Okay.

6               DR. WERNEKE:   The amount of time -- go  
7       ahead Linda.

8               DR. RESNIK:   Sorry.

9               DR. WERNEKE:   The amount of time it  
10       takes to collect this information using the CAT  
11       is about one to two minutes.   And as a clinician  
12       I used to collect information with the Oswestry,  
13       et cetera, and that took six to eight minutes for  
14       the patient to complete it, for the clinician to  
15       record it and then to try to interpret it.

16               And we did head to head comparisons  
17       between the FOTO CAT and the Oswestry.   They  
18       behaved similarly psychometrically, but the  
19       burden of using a similar tool was so reduced.  
20       It makes it so much more efficient.

21               And a matter of fact, the tool is so  
22       efficient I also collect biopsychosocial surveys

1 for all of my patients. And having that CAT  
2 efficiency is what allows me to do that.

3 So my specialty is in low back  
4 patients. And I collect multiple psychosocial  
5 factors along with the physical functioning  
6 scale. And I can do it very efficiently and the  
7 patients have not objected.

8 I had one other comment too about  
9 specific -- body part specific. This was really  
10 driven by customers and clinician input. Where  
11 they wanted to stop irrelevant items being asked  
12 to their patients. And the CAT enables us to do  
13 that.

14 And the clinicians were demanding a  
15 more efficient tool. And that led to the push to  
16 the development of the CAT.

17 MEMBER BEVANS: I'm glad you mentioned  
18 that. One of my questions was related to content  
19 validity. Unless I missed it, I didn't see any  
20 information about patient input or clinician  
21 input into the development of the actual items.  
22 And you know, verification that those are

1 important, meaningful constructs for people, so.

2 DR. WERNEKE: Yes, the clinician was  
3 involved. We canvassed not only patient managers  
4 as well the clinician input. And again, about  
5 relevancy and burden was very important.

6 In fact, when we asked patients what  
7 they thought of using the CAT, they were very  
8 happy first, oh wow, I get one question at a  
9 time. I don't have to see the whole ten  
10 questions on one form. And they liked the large  
11 font size.

12 The other positives were from the  
13 clinician. And again the manager was the  
14 efficiency. The only drawback that we heard from  
15 the managers was the cost. And then a fear of  
16 interfacing with the older population with the  
17 computer.

18 And that was resolved in about 2005  
19 when we started recommended the penlight and  
20 touchscreen. And I've been using that for a long  
21 time now. I have no problems having my older  
22 patients connect with use of computer

1 administered surveys.

2 CO-CHAIRMAN STILLE: Liz and then Len  
3 and then we should probably vote. Start to vote.

4 MEMBER MORT: On the issue of body  
5 part specific measures, I'm all in favor of body  
6 part specific measures taking care of patients.  
7 They really care about the function related to  
8 that body part.

9 So I actually have a question in the  
10 more disaggregated area of why the body part is  
11 affected. And this relates to what Dr. Kaplan  
12 was saying. When I look at -- I was the  
13 shoulder. I had the shoulder one.

14 And when I saw the variability in the  
15 injury and disease types of shoulder problems  
16 that were included in the denominator. And being  
17 a clinician, I just can't believe that you can  
18 actually risk adjust that difference away.

19 And therefore, when you are looking at  
20 an individual patient I would say fine. But if  
21 you're trying to aggregate anything that's that  
22 heterogeneous into a measure about a clinician's

1 performance or clinic's performance, I think  
2 you're just getting much too much variability  
3 that cannot be controlled adequately from the  
4 risk adjustment model as specified.

5 So I had trouble from the evidence  
6 perspective with that issue. I wondered if the  
7 developers had anything to say about it. But I  
8 must say, I do love your items.

9 Yesterday about 30 percent of my  
10 patients had shoulder injuries. They all went to  
11 physical therapists. And these are the things  
12 that they can't do. Lift, comb their hair, hair  
13 dryers and that sort of thing.

14 So I think you're really onto a very  
15 important area of people's function. But I have  
16 questions about the measure.

17 DR. DEUTSCHER: Okay. The actual  
18 truth is that the biomedical model has  
19 difficulties explaining exactly when somebody  
20 comes in and says I have a shoulder pain, what  
21 exactly is the source of that pain. And we know  
22 that the validity of many of ICD-9 codes and we

1 saw a lot of those codes in the applications is  
2 questionable.

3 What we do know is that the selection  
4 is the selection of the patient. They come and  
5 they say my shoulder is my main problem. And we  
6 also do know from the IRT analysis and the Rasch  
7 analysis that those measures function as  
8 unidimensional as possible.

9 It's never a fully unidimensional  
10 measure. But the unidimensionality is maintained  
11 as far as we can assess it. So I don't know if  
12 it's even possible because there's always a  
13 variability that we won't be able to explain.

14 I don't know if it's even possible  
15 today with the knowledge we have today to say  
16 exactly for a specific patient in a reliable and  
17 valid way, is it your labrum that's affected. Is  
18 it you know, the tendon or not.

19 Many studies have shown that that's  
20 not really possible. But as you said, when the  
21 functions themselves that are assessed, they  
22 relate to actual problems the patient have, the



1 measure becomes unidimensional.

2 MEMBER MORT: Well, but just imagine  
3 a 21-year-old man who skis and breaks his  
4 clavicle. And versus an 84-year-old man or woman  
5 who has adhesive capsulitis that's related to  
6 degenerative joint disease and not you know,  
7 inactivity.

8 Two entirely different -- both have  
9 pain. And maybe both can't do hair dryer and  
10 things. But they're very, very different. So I  
11 guess the clinician in me and the measurement  
12 person in me just finds difficulty in combining  
13 all of them around the symptom.

14 DR. DEUTSCHER: I agree that they're  
15 very different and we do risk adjust for age.  
16 But there are other differences that we might not  
17 be able to risk adjust for. But the question is  
18 which functions are they trying to achieve?

19 And many of the times even if the  
20 source of the injury is different, the functional  
21 tasks that they're trying to achieve are similar.  
22 And this is what we're actually measuring. How

1 do they perceive? What's the difficulty level  
2 that they perceive regarding specific tasks?

3 CO-CHAIRPERSON STILLE: Len?

4 DR. RESNIK: And I guess I would also  
5 add that because we adjust for onset of the  
6 condition, we would know that the patient who had  
7 the clavicle fracture was you know, had an acute  
8 injury. And we would also adjust for comorbid  
9 conditions. So we would know that the older  
10 person had a, you know, had a condition of  
11 arthritis.

12 So there is more than just the intake  
13 function into account in the models. Although  
14 certainly it's not perfect. But diagnosis codes  
15 are fraught with error.

16 MEMBER MORT: I guess I was thinking  
17 more of a stratification or having, you know,  
18 separating the populations. If I were the 21-  
19 year-old with the ski injury, I would want to  
20 know does that physical therapy rehab facility  
21 take care of people like me who are otherwise  
22 athletic and just had an injury.

1           If I was the 85-year-old, I'd want to  
2 know does that group really care about the  
3 elderly and our function as we get into our  
4 senior years. So stratification might be another  
5 approach.

6           CO-CHAIRMAN STILLE: Len, thanks.

7           MEMBER PARISI: I'm actually on a  
8 related question. As it relates to the GAP. I  
9 know we touched on it. But from a quality  
10 perspective it's not clear to me the connection  
11 between collecting this information and how it  
12 drives improvement apart from individual  
13 clinicians driving that improvement with  
14 individual patients.

15           So I'm not seeing the connection under  
16 the GAP. So if you could help me with that that  
17 would be good. And not only from the measure  
18 that I reviewed, which is 0424, but also for all  
19 of them.

20           DR. RESNIK: We did present another  
21 supplement on clinician performance over time.  
22 There is a supplemental handout where we looked

1 at clinician performance for clinicians who had  
2 been stable subscribers in the FOTO database over  
3 time to see if participating in the system and  
4 getting the feedback on their performance  
5 actually changed their performance.

6 And what we can see in that slide is  
7 for clinicians who again had a minimum of ten  
8 patients a year and participated for all three  
9 years, we see that -- an improvement in  
10 performance over time. A greater proportion of  
11 those clinicians moved from a lower and average  
12 performance to high performance. And you can see  
13 that in the handout.

14 So we think that just having the  
15 information and feedback on your performance as  
16 it relates to what's expected and what your peers  
17 are doing, does drive performance of the  
18 clinician and clinic level.

19 CO-CHAIRMAN STILLE: Sherrie?

20 MEMBER KAPLAN: I was trying to say  
21 nothing more this whole rest of this discussion.  
22 But that particular question bothered me.

1 Because where -- what was the -- what were the  
2 interclass correlation coefficients for measure  
3 0423 at the clinician level?

4 I know they're very high at the  
5 patient level. And at the patient level I real -  
6 - this doesn't bother me at all. When you start  
7 using it at the clinician and the clinic level,  
8 that's when I have concerns about using this as a  
9 performance measure.

10 I don't think we've got enough  
11 information about that issue. What were the ICCs  
12 at the clinician level?

13 DR. RESNIK: We have not calculated  
14 that yet. And we will do so and submit to you.

15 MEMBER KAPLAN: And the clinic level?

16 DR. RESNIK: Yes, we will present it  
17 at the clinician and the clinic level. We will  
18 calculate those. But we have not done so to  
19 date.

20 CO-CHAIRMAN STILLE: Okay. So this is  
21 actually a perfect segue. Because I was going to  
22 ask Sherrie and Katherine, what recommendations

1 they'd have for the measure developers to come  
2 back to us with things. If you had a checklist  
3 you'd like to maybe give them?

4 MEMBER KAPLAN: Well, that was number  
5 one. I would like to see what the ICCs are.  
6 Because with the interclass correlation  
7 coefficient is the different -- the between unit  
8 variation divided by the between minus within  
9 unit variation.

10 So if there's a strong clinician  
11 thumbprint and there's a lot they -- they tell  
12 the same story across all patients, then they're  
13 small within clinician variation. And if the  
14 measure then distinguishes lots between my  
15 colleague down the hall who does the same thing  
16 but way differently than I do who does the same  
17 thing, then that number will be fairly large.

18 And what you'd like to see for  
19 performance measures that are now being used at a  
20 different level, are the interclass correlation  
21 coefficients to make sure that there is enough  
22 evidence that these are distinguishing clinicians

1 from each other.

2 The second thing I'd like to see is  
3 some evidence of validity. But well, maybe  
4 that's not possible. Maybe my first checklist  
5 would be the interclass correlation coefficients.  
6 And then some link with either -- if you have  
7 intensity.

8 If you have some kind of visit  
9 information at all, the idea that clinician --  
10 patients who get seen more frequently are doing  
11 better. And that physicians who see patients on  
12 a more frequent basis have higher scores or some  
13 -- some evidence of validity outside of -- at the  
14 clinician and the clinic level, not the patient  
15 level.

16 DR. RESNIK: At one point we did also  
17 submit another piece of supplementary information  
18 that showed some additional validity of the  
19 provider classification method. And it's called  
20 -- the handout was called the link to the  
21 provider classification.

22 And I apologize if you may not have

1       seen it. But we did it. We looked at our  
2       classification of low performers, average  
3       performers and high performers.

4               And then we looked at those clinics  
5       what percentage of patients had made improvement  
6       in their functional status that was greater the  
7       minimally important -- minimally clinically  
8       important difference. And we found as we  
9       expected that clinics that were high performers,  
10      a greater proportion of patients improved greater  
11      than a minimally clinically important difference.

12             So we presented that type of validity  
13      evidence at the clinic level by year.

14             MEMBER BEVANS: In addition to the  
15      reliability information at the aggregated level,  
16      I have two other requests. One a justification  
17      for the risk adjustment variables. I'm concerned  
18      about a couple of those. Specifically gender and  
19      payer.

20             Because I don't know truly what the  
21      evidence is with regard to potential gender  
22      differences. For example, in the speed or



1 magnitude of improvement. And I'm concerned that  
2 both gender and payer risk adjustment may  
3 actually mask some of the important disparities  
4 in the quality of care provided.

5 The other point I wanted to make is  
6 the instrument has been modified for use  
7 originally with 18 years of age plus, down to use  
8 with youth I think as young as 14. But there's  
9 no evidence provided and perhaps you have it.  
10 But it's not provided that the measures have been  
11 tested for understandability and appropriateness  
12 with adolescents. That's on my list.

13 MEMBER MONROE: Just quickly, I'd like  
14 to pick up on Deb's earlier question. I just  
15 want to understand, when she asked if it was in  
16 the public domain, I think the response was that  
17 there's a short form that's in the public domain.

18 How different is that from the full  
19 measure? And why the distinction?

20 MR. JOHNSTON: Well, the short form,  
21 it's composed of a portion of the items that were  
22 considered to be the most important items in the

1 full item bank for that particular measure.

2 MEMBER MONROE: Has that been tested  
3 similarly to the full set?

4 DR. DEUTSCHER: Yes, the scores from  
5 the short form are -- were calibrated using a  
6 cross -- kind of a crossover table to the  
7 original CAT.

8 MEMBER MONROE: I'll have to rely on  
9 my statistician colleagues to tell me if that's  
10 an appropriate answer.

11 MEMBER BIERNER: What it is really,  
12 there's like a data bank of questions. And when  
13 you take the computerized test they can choose  
14 multiple questions. The short form on paper has  
15 ten questions. I was able to pull it up.

16 And those -- as he's saying, those ten  
17 will give you an equivalent score statistically  
18 compared with their computerized test.

19 DR. RESNIK: That's right.

20 MEMBER BIERNER: It's -- the pen and  
21 paper form is a document that they make available  
22 so we could use it ourselves without paying for

1 the full calibrated testing with all the  
2 background information.

3 So if you took the ten item instrument  
4 and used it in your own clinic, you wouldn't have  
5 the advantage of calibrating your scores against  
6 all of the independent variables that they have  
7 in their database. So that -- so you could still  
8 use it, but they do make it available. And  
9 that's what's true for all these different body  
10 part measures that I was able to find on their  
11 website.

12 CO-CHAIRMAN STILLE: But also --

13 MEMBER MONROE: Before you stop does  
14 that mean that all the demographic data and other  
15 data that's in the database isn't available for  
16 use in the short form? I think that's what they  
17 said.

18 MEMBER BIERNER: Well, as I understand  
19 it, yes. I would probably have to pay to be a --  
20 to subscribe to their service I assume. I mean  
21 I'm not speaking to that. I think that's what  
22 the website indicts then.

1                   MEMBER MONROE: Okay. So, well, I  
2 think you -- thank you.

3                   CO-CHAIRMAN STILLE: David, you had a  
4 question?

5                   DR. RESNIK: However, the risk models  
6 and all of the variables that are in the risk  
7 models, are available on the website. So people  
8 who don't subscribe can collect that data. And  
9 we provide the coefficients from the risk models  
10 so that they can use them.

11                   And then they can compare themselves  
12 to basically the average or the predicted values.

13                   MEMBER BIERNER: Yes, that's true.  
14 There's a spreadsheet. I pulled those off of the  
15 coefficients.

16                   MR. JOHNSTON: And also, the CAT is  
17 available to anyone who -- on our website as you  
18 know, as requested by the application process.  
19 The full CAT survey for each of the body parts is  
20 available on the website for anybody to log onto  
21 and take the survey and get a risk adjusted  
22 measure of the function at that time and the

1 predicted measure value.

2 CO-CHAIRMAN STILLE: Okay. David, one  
3 last question and then we've got to wrap this up.

4 MEMBER CELLA: Well, it's not a  
5 question I think. But my clarification was just  
6 answered. That the bottom line really is whether  
7 the short form, and now we just heard the CAT as  
8 well, that a provider can use the tool, including  
9 the risk adjustment, derive a score and report it  
10 without having to be a subscriber. And I hear  
11 the answer is yes.

12 So I think that to me makes it not  
13 public domain, but publically available without  
14 needing to subscribe. And I think that's what we  
15 heard. Is that correct? Is that right?

16 MR. JOHNSTON: Yes.

17 CO-CHAIRMAN STILL: Okay. Great,  
18 let's go. So, we're going to start to vote on  
19 Importance domains for measure 0423.

20 MS. ALLEN: So we're looking at  
21 measure 0423, Functional Status Change for  
22 Patients with Hip Impairments. To begin the vote

1 you will need to point your clicker towards me in  
2 my direction.

3 Please do not start voting until I say  
4 start. And I'll go over each slide before you  
5 start voting what your options are. The computer  
6 will record your last vote. So you can change  
7 vote as you desire. But it will only take the  
8 last one. Thank you.

9 CO-CHAIRMAN STILLE: We need a quick  
10 clicker tutorial with these new clickers.

11 MS. ALLEN: So we we're voting on  
12 Evidence. You press one or two. I'm going to go  
13 through the options.

14 CO-CHAIRMAN STILLE: Oh, okay.

15 MS. ALLEN: So, we're voting on  
16 Importance, 1A Evidence, rational support of the  
17 relationship of the health outcome or PRO to at  
18 least one healthcare structure, process,  
19 intervention or service. Press one for yes or  
20 two for no. Voting starts now.

21 We have a missing vote. Please --  
22 okay. Results are in.

1                   75 percent yes. 28 percent no.

2       Sorry, 72 percent yes. 28 percent no.

3                   We're voting on Performance GAP.

4       Performance GAP data demonstrate considerable  
5       variation or overall less than optimal  
6       performance across providers in all population  
7       groups, this aspires the use in care. One high,  
8       two moderate, three low, four insufficient.

9       Voting starts now.

10                   Zero high, 37 percent moderate, 26  
11       percent low, 37 percent insufficient.

12                   CO-CHAIRMAN STILLE: Okay. So we'll  
13       stop now.

14                   MEMBER THOMAS: Insufficient means  
15       insufficient information, correct?

16                   MS. ALLEN: Correct.

17                   MEMBER THOMAS: Just can't render a  
18       decision?

19                   CO-CHAIRMAN STILLE: Correct.

20                   MEMBER THOMAS: Okay.

21                   CO-CHAIRMAN STILLE: So, are we done?

22                   MS. SAMPSEL: Right. And so the

1 interpretation here, this is a must pass element.  
2 And what this means is we have greater than 60  
3 percent in the low to insufficient category. And  
4 you're correct, the insufficient means the  
5 Committee doesn't have enough information to  
6 further their vote.

7 I would just ask one last time, you  
8 know, the developers do have an opportunity prior  
9 to public comment to bring additional information  
10 back. And we have the list that Katherine and  
11 Sherrie have already provided.

12 Is there anything else the Committee,  
13 you know, kind of direction the Committee would  
14 like to give to the developers?

15 CO-CHAIRMAN STILLE: So do the  
16 developers understand sort of the checklist of  
17 things that I think came from Committee members?

18 DR. DEUTSCHER: Can I ask a question?  
19 Regarding the insufficient data on GAP. I think  
20 it would be good if you could specify, because we  
21 did show some information. But apparently it's  
22 not sufficient.



1           If you could specify the specific kind  
2 of analysis that you all are actually requesting.  
3 So one analysis was mentioned before, showing  
4 licensees at the different levels. Are there  
5 additional issues? Or types of analysis that you  
6 would like us to do?

7           CO-CHAIRPERSON PARTRIDGE: As one of  
8 the reviewers of two of these measures, I would  
9 also tell you -- the data that you submitted at  
10 perhaps the end of last week didn't reach me in  
11 time for me to understand it and digest it. And  
12 I suspect that may be true of several of the  
13 others.

14           So I think the staff will work with  
15 you on this issue. And we'll be happy to work  
16 back and forth with you on the issue through  
17 them. It may be some of what you've sent us  
18 recently is adequate to answer some of our  
19 questions. We'll just see.

20           MEMBER KAPLAN: Chris, can I just add  
21 one quick thing to the developers. It would also  
22 help, because we've seen this in other outcome

1 measures as well. If the components of variation  
2 attributable to the patient and then units up to  
3 the clinician and then units up to the clinic,  
4 can get -- we can get components of variation  
5 analysis because that gives us some confidence  
6 that.

7 CO-CHAIRMAN STILLE: Yes.

8 MEMBER KAPLAN: Yes, it's not all at  
9 the patient level. It's not who you see, it's  
10 actually what you do. And then maybe at the  
11 clinic level who you hire to do that.

12 So it gives us a little more of the  
13 components of variation analysis will help.

14 CO-CHAIRMAN STILLE: I think it's  
15 critically important to translate into policy as  
16 well. You know, if I'm a clinician or I'm the  
17 boss of a whole lot of clinicians, I want to know  
18 okay, where's this variation in care happening  
19 and what kind of data do you have to show us  
20 where that might be?

21 DR. DEUTSCHER: So you are referring  
22 to hierarchical models that you would like to see

1 in those -- using those different levels in  
2 showing the variance in each level?

3 MEMBER KAPLAN: There are different  
4 ways to do it. But you know, some confidence  
5 that some of you know, that the variation of the  
6 clinician and the clinic level is actually --  
7 represents a chunk that we would call meaningful.

8 CO-CHAIRMAN STILLE: And then for the  
9 rest of the group, there are a lot of measures in  
10 this group. But we want to give all the measures  
11 their due if there are differences.

12 For which measures or for if any, will  
13 we have substantially different discussions?

14 CO-CHAIRPERSON PARTRIDGE: I think  
15 what we would like to do is rather than formally  
16 vote each one of the other measures, if there's a  
17 general sense of the Committee that the issues  
18 raised around this measure are going to be raised  
19 with respect to the others.

20 MEMBER SALIBA: It would be helpful  
21 just to see the list to answer the question.  
22 Thank you.

1 CO-CHAIRMAN STILLE: Peter had a  
2 question.

3 MEMBER THOMAS: Because these measures  
4 are quite similar, it strikes me that I don't --  
5 my guess is that there's not a compelling  
6 difference in GAP between some of these other  
7 ones. So my question I guess goes to what about  
8 the other votes? I mean, I know normally we  
9 would stop now and move onto the next.

10 But because this is so many in one  
11 package, would it benefit the developers to go  
12 through the process of identifying other  
13 strengths or weaknesses in the questions we ask?  
14 So that they could prepare all that for the next  
15 iteration of this. Or is that just a break in  
16 the process? Do you see what I'm getting at?

17 DR. BURSTIN: I know what you're  
18 getting at. I think if there are condition  
19 specific issues that are going to come up that  
20 might be useful to them as they're preparing the  
21 materials back, I think it's useful to them.

22 MEMBER BIERNER: Yes, I have a

1 question on the measure 0428, which is what's  
2 labeled General Orthopedic Impairment. I wanted  
3 -- since we've talked a lot already about  
4 specifics that there's different body parts, what  
5 is the rationale or who is the audience that  
6 you're seeing will use this measure? And when  
7 are your clinicians, your therapists, choosing  
8 this measure instead of a more specific body part  
9 measure?

10 DR. WERNEKE: This measure would  
11 include impairments around cervical, TMJ,  
12 thoracic, ribs. Major ones.

13 MEMBER VAN ZYL: I was actually one of  
14 the developer -- reviewers. I'm sorry, not  
15 developer. I'm hopped up on Dayquil.

16 So it seemed to me that the General  
17 Orthopedic label was a little bit misleading.  
18 Because all of the data that you talked about was  
19 really cervical.

20 And at least when I looked at this, I  
21 wondered if this was a measure that would be  
22 applicable really to things not mentioned in the

1 others. Would it make more sense to call this  
2 cervical rather than general?

3 CO-CHAIRMAN STILLE: Can we call up  
4 that measure and maybe we can look at that?  
5 0428. Sure, why don't you answer while we're  
6 looking for it. That's great, thanks.

7 MR. JOHNSTON: Yes. The reason we  
8 presented the cervical data was because it was  
9 the predominant data in that -- or the  
10 predominant impairment group in that database.

11 MEMBER VAN ZYL: Right.

12 MR. JOHNSTON: I think it was 70  
13 percent of the data that was the cervical. But  
14 we still had the other 30 or 40 percent that were  
15 other body parts. So we elected to keep it.

16 You know, I think that the progression  
17 of this would be to separate out a cervical  
18 measure from this. Because we do have those  
19 other generalized orthopaedic impairments that  
20 need to be measured by something. And we have  
21 people participating in it for that.

22 But because of the large number of

1 cervical patients, I think we need to have a  
2 cervical measure. And we're actually working on  
3 approving one for our future submission.

4 MEMBER VAN ZYL: So you're already  
5 thinking about separating the cervical out  
6 explicitly. Okay.

7 CO-CHAIRMAN STILLE: So then to go  
8 back to Peter's question. What else can we do to  
9 be helpful in terms of either voting, giving the  
10 developer some more data that they can take back?

11 MEMBER NEUWIRTH: I guess this is a  
12 question maybe more for us. But maybe for the  
13 developers as well. I guess I'm thinking about  
14 you know, sort of feasibility and usability,  
15 especially coming from an integrated system.  
16 Where the body part specific surveys to some  
17 extent make sense, but then also, when I look  
18 across these different instruments, they look  
19 very similar at least in terms of the tenth item  
20 one.

21 And so I'm thinking about -- and  
22 maybe, I haven't looked comprehensively across

1 all of them. But I guess I'm just wondering you  
2 know, when we're thinking about cost and we're  
3 thinking about also you know, ease of application  
4 and desire for spread, are all these different  
5 instruments really going to make sense in  
6 practice?

7 And also the time that it's going to  
8 take you know, regularly to review these and so  
9 on. And then the cost associated. And I also  
10 feel like there's a question in my mind about you  
11 know, as patients, I think we hear over and over  
12 again that they're not a body part, that they're  
13 a whole person.

14 And so all of that to me questions  
15 sort of the distinctions between these different  
16 instruments and how useful and valuable it is to  
17 spend this much time and all these you know,  
18 developing these individual ones. When if we had  
19 a sort of holistic approach that might actually  
20 even better serve our patients.

21 So and that might be you know, moving  
22 forward, I think you mentioned Helen, that



1       there's a desire to collapse some of these. So I  
2       would look to the developers to maybe speak about  
3       that as well. But also for us as a Committee.

4               DR. DEUTSCHER: I think one of the  
5       answers are given by the different analysis we've  
6       done. And I'd like to give a simple example just  
7       to illustrate that.

8               Some of the measures that are very  
9       similar, actually they use the same items are  
10      hip, knee, foot and ankle. Coming from the lower  
11      extremity function skill.

12              But when we analyze the data for  
13      differential item functioning, which means that  
14      the patients might perceive different items  
15      having different difficulty levels. If we do not  
16      take and we found differential item functioning  
17      for example, for these measures.

18              So what that means is that a specific  
19      function might be perceived having -- or  
20      representing a different difficulty level whether  
21      I have a hip problem or a knee problem. And when  
22      those differences are found and they're

1 significant, so the measure works better if we  
2 recalibrate the difficulty level of the items for  
3 each of these body parts.

4 So it just makes these measures being  
5 more precise, more responsive. And that's the  
6 reason why they were separated.

7 DR. WERNEKE: And as a clinician,  
8 although they're coming up let's say with the  
9 back problem, you really have to address the  
10 patient's functioning in their ADLs and at work,  
11 et cetera. So if you focus on back, then you  
12 have to incorporate it into the total body for  
13 the purpose of improving their function and their  
14 perception of their function.

15 So I see us treating the whole body.  
16 We're just not treating the knee. But we want to  
17 know how that integrates or plays with their role  
18 in ADLs, work, et cetera. And that's important.

19 And if you do not do that and all you  
20 do is focus on their low back, you will not  
21 improve their quality of life or improvement in  
22 their self-report outcome. You won't see that.

1           So unless you address their -- the  
2           total package during that episode of care, you're  
3           not going to get higher patient self-report  
4           outcomes. So you can't just focus on one  
5           impairment during the treatment episode. Yes,  
6           but the survey captures that.

7           DR. RESNIK: Well I think one of the  
8           important points that I'd like to just reiterate  
9           is if there is differential items functioning and  
10          difficult -- differential difficulty for people  
11          with different impairments answering the same  
12          questions that if we don't separate the measures,  
13          the scores will not be accurate.

14          And then we'll have people basically  
15          answering on different metrics. And then we  
16          won't be able to compare them. So as much as it  
17          would be nice to have the universal measure to  
18          compare across all impairment types, it really  
19          wouldn't be valid.

20          CO-CHAIRPERSON PARTRIDGE: Peter,  
21          could we go back to your question. Is -- are you  
22          suggesting that we vote 1A and 1B individually

1 for each measure as a process?

2 MEMBER THOMAS: Sorry, thank you. I'm  
3 suggesting I guess for this measure that we go  
4 down the line of validity, reliability, use, and  
5 feasibility.

6 CO-CHAIRPERSON PARTRIDGE: Through 2A  
7 and B and 3 and 4?

8 MEMBER THOMAS: Just to give them a  
9 sense of whether there might be --

10 CO-CHAIRPERSON PARTRIDGE: Okay.  
11 Thank you very much.

12 MEMBER THOMAS: One real other  
13 weakness they could work on in the meantime so  
14 that they have to keep --

15 CO-CHAIRMAN STILLE: Yes. That's what  
16 we're talking about back here.

17 CO-CHAIRPERSON PARTRIDGE: All right.  
18 Okay. So the question before us is assuming that  
19 the measure had passed 1B, let us go on and vote  
20 for this measure, but thinking it's the others?

21 CO-CHAIRMAN STILLE: Yes. We're  
22 thinking probably between the group.

1 CO-CHAIRPERSON PARTRIDGE: To 1C?

2 Maybe?

3 CO-CHAIRMAN STILLE: Liz, did you have  
4 something to say before we -- you had your thing  
5 up.

6 MEMBER MORT: I did. And if I were  
7 the developer, I would be wondering after having  
8 been approved by NQF a couple of times, and then  
9 getting this response, did something change? Or  
10 did our criteria change?

11 CO-CHAIRPERSON PARTRIDGE: The answer  
12 is, yes. The developer has indicated, this is  
13 first of all modified from the approver's -- I'm  
14 right, yes?

15 MS. SAMPSEL: Correct. And I think if  
16 Ben -- well what Ben had summarized is this was  
17 originally a process measure. They've moved it  
18 to an outcome measure. So that was a significant  
19 change. And also the age range from 18 to 14.

20 MEMBER MORT: Well the PM part I get.  
21 I mean the PRO-PM. But some of these basic  
22 things like evidence would have been before the

1 NQF group approving it in the past. Anyway, it  
2 just seems, I might be confused if I were them.  
3 Okay.

4 MS. ALLEN: Voting is open now for 1C,  
5 High Priority. One high, two moderate, three  
6 low, four insufficient information. Voting  
7 starts now.

8 We're still waiting on a vote. 37  
9 percent high, 58 percent moderate, five percent  
10 low, zero percent insufficient information.

11 Voting on Reliability. One high, two  
12 moderate, three low, four insufficient. Voting  
13 starts now.

14 11 percent high, 21 percent moderate,  
15 37 percent low, 32 percent insufficient.

16 Voting on Validity. One high, two  
17 moderate, three low, four insufficient. Voting  
18 starts now.

19 11 percent high, 11 percent moderate,  
20 47 percent low, 32 percent insufficient.

21 Now we're voting on Feasibility. One  
22 high, two moderate, three low, four insufficient.

1 Voting starts now.

2 37 percent high, 42 percent moderate,  
3 16 percent low, five percent insufficient.

4 Voting on Usability. One high, two  
5 moderate, three low, four insufficient  
6 information. Voting starts now.

7 We're still waiting on a vote. 21  
8 percent high, 26 percent moderate, 37 percent  
9 low, 16 percent insufficient information.

10 CO-CHAIRMAN STILLE: So, just  
11 observing as the data have gone in. I think if a  
12 lot of the insufficients could be converted to  
13 highs or moderates, you know, the numbers would  
14 be there.

15 So I think this is much more a plea  
16 for more information than anything else.

17 DR. RESNIK: We haven't addressed  
18 usability. As far as a recommendation that I am  
19 aware of.

20 CO-CHAIRPERSON PARTRIDGE: Linda, we  
21 did. When we were voting on 3 and 4 we did.

22 CO-CHAIRMAN STILLE: Yes.

1 CO-CHAIRPERSON PARTRIDGE: And they  
2 passed.

3 CO-CHAIRMAN STILLE: Yes.

4 DR. RESNIK: I see.

5 CO-CHAIRPERSON PARTRIDGE: Okay.  
6 Thank you all. And let's be back in ten and then  
7 we'll take up 26 -- no, yes, it's 02624.

8 (Whereupon, the above-entitled matter  
9 went off the record at 11:01 a.m. and  
10 resumed at 11:23 a.m.)

11 CO-CHAIR STILLE: Welcome back. One of  
12 my career mentors ten years ago acquainted me  
13 with the phenomenon of the miracle of the agenda,  
14 which basically says that no matter how crazy  
15 agendas get during the meeting, by the end of the  
16 meeting everything else ends up being discussed  
17 on time, most of the time. So, we have  
18 accomplished a miracle.

19 Just real quickly just in case there  
20 was any confusion, the FOTO measures have been  
21 discussed. We feel like everything is adequate  
22 to inform everything we need to move forward on



1       that.

2                   Do you want to do logistics and  
3       housekeeping then, and then dive into the next  
4       measure?   Okay.

5                   MS. THEBERGE: Sure.   So, we have had  
6       a bunch of questions about whether there is going  
7       to be future meetings.   At this time, we don't  
8       have a Phase 3 for this project funded, but it's  
9       possible it's going to happen.

10                   So, we do not at this time have  
11       another in-person meeting scheduled.   We will  
12       keep you posted if and when that changes.

13                   We do have a call scheduled for next  
14       week, and then we will have a call after  
15       comments.   And we will probably be having an  
16       additional call at some point to deal with some  
17       related and competing issues, but, you know,  
18       we'll keep you all posted by email.

19                   There will be some surveying on  
20       availability and all that, but -- and there may  
21       be no need for the call next week.   We'll have to  
22       kind of see how today goes and how much we get

1 through, but we'll keep you all well-informed on  
2 scheduling.

3 CO-CHAIR STILLE: Okay. So, we're  
4 going to proceed then to discussion of Measure  
5 2624, the functional outcome assessment from CMS.  
6 The measure developers are here and the  
7 discussant, Katherine, will probably take the  
8 lead on the discussion, I assume.

9 Okay. Go ahead.

10 MS. SAMPSEL: And before I turn it over  
11 to Sven, I think there are a number of folks on  
12 the phone from CMS, correct, and perhaps Quality  
13 Insights as well.

14 So, if you could just announce  
15 yourselves real quick so we know who's on the  
16 phone?

17 MS. AUTREY: Good morning. This is  
18 Sophia Autrey calling from CMS.

19 MS. SOMPLASKY: Good morning. Anita  
20 Somplasky from Quality Insights.

21 MS. LUCAS: Jane Lucas and Jeannette  
22 Shrift from Quality Insights.

1 MS. GOERTZ: Christine Goertz with  
2 Quality Insights.

3 MR. REZEK: This is Gary Rezek with  
4 Quality Insights.

5 MR. BERG: Good morning, everyone. And  
6 although Sarah after this morning's earlier  
7 session gave me the opportunity to just run away  
8 --

9 (Laughter.)

10 MR. BERG: -- we're really, really  
11 happy to be here. And on behalf of the Centers  
12 for Medicare and Medicaid Services and the  
13 measure's developer, the Quality Insights of  
14 Pennsylvania, it's my pleasure to introduce to  
15 you NQF 2624 Functional Outcome Assessment for  
16 consideration of NQF endorsement.

17 This measure was actually initially  
18 developed in 2008 and was implemented as part of  
19 the Physician Quality Reporting System in 2009.  
20 An effort to fill a gap in reported measures that  
21 addressed clinical strategies that were relevant  
22 to the chiropractic community.

1                   Since its initial implementation, the  
2                   measure's use has been expanded to include  
3                   physical therapists and occupational therapists  
4                   as well.

5                   NQF 2624 measures the use of a  
6                   standardized functional outcome assessment tool  
7                   by eligible providers to identify deficiencies  
8                   and provision of a care plan that addresses the  
9                   deficiencies identified.

10                  Performance is assessed for all visits  
11                  for patients aged 18 years and older, and  
12                  reporting is required for each visit for patients  
13                  seen during the 12-month reporting period by way  
14                  of administration -- administrative claims or a  
15                  registry.

16                  As you all know, standardized outcome  
17                  assessments, questionnaires or tools are a vital  
18                  part of evidence-based practice, and outcomes  
19                  measures along with other standardized tests and  
20                  measures used throughout an episode of care are  
21                  being -- as part of a periodic reexamination  
22                  provide information about whether predicted

1 outcomes are being realized.

2 Despite the recognition of the  
3 importance of outcome assessments, questionnaires  
4 and tools, evidence still suggests that their use  
5 in clinical practices is still limited.

6 In addition, frameworks, guidelines by  
7 associated specialty societies support the  
8 documentation of the use of assessment tools, as  
9 well as documentation of a plan of care on each  
10 visit.

11 A need for improvement in care  
12 provided using this measure is evidenced by an  
13 average provider performance rate of 80.9 percent  
14 in 2012.

15 Differences in performance rates based  
16 on various demographic traits, for example,  
17 statistically significant performance gaps  
18 between urban/rural, male/female, non-  
19 white/white, ethnicity and age groups.

20 And so, we believe this measure  
21 addresses the importance of utilizing validated  
22 functional assessment tools to monitor the

1 patient's status and initiating adjusting care  
2 plans as appropriate.

3 So, we thank you for the opportunity  
4 to present today. Thank you for your  
5 consideration of endorsement, and we look forward  
6 to the Committee's questions.

7 CO-CHAIR STILLE: Great. Thank you.

8 Katherine, all yours.

9 MEMBER BEVANS: Yes, I just have a few  
10 comments and questions before we ask other people  
11 to add.

12 As this is one of, I think, the first,  
13 if not one of the first process measures that the  
14 Committee has evaluated, I'm wondering if you  
15 could provide a rationale for why and what  
16 evidence is there around the use of standardized  
17 functional assessments and care planning and  
18 outcomes, and what the evidence around that  
19 actual documentation, how that changes, whether  
20 or not it is associated with better outcomes for  
21 patients.

22 MR. BERG: Sure. And we -- I think we

1 have a member of our technical expert panel  
2 online who probably would be best able to answer  
3 that question, Dr. Goertz. So, if she could  
4 answer that question?

5 MS. GOERTZ: Yes. Thank you.

6 Could you please repeat the question?

7 MEMBER BEVANS: Yes, the question is --

8 MS. GOERTZ: I just want to make sure  
9 I understand.

10 MEMBER BEVANS: Yes. Sure. I'm  
11 wondering what prior evidence not necessarily for  
12 application of this measure, but prior evidence  
13 and research suggests that documentation of a  
14 standardized -- use of a standardized functional  
15 assessment and care planning, what that means for  
16 patient outcomes.

17 Is there an established link between  
18 the activity that the process measure is  
19 assessing and improved patient outcomes?

20 MS. GOERTZ: Right. There is  
21 definitely an established link between the care  
22 itself and the outcome measure.

1           The type of standardized tool is  
2 commonly used to assess the outcome of  
3 chiropractic care both in clinical practice and  
4 in research situations.

5           It's less clear to what extent  
6 actually the measure --- what component the  
7 measurement itself is contributing versus what  
8 component the care is contributing.

9           MEMBER BEVANS: Okay. So, if I'm  
10 understanding that correctly, there's not  
11 necessarily very strong documentation of the  
12 linkage between the actual recording of the use  
13 of this tool and patient outcomes; is that  
14 correct, or am I missing something?

15          MS. GOERTZ: In the chiropractic  
16 population, not that I'm aware of.

17          MEMBER BEVANS: Okay.

18          MR. BERG: So, if I understand your  
19 question, it's the link between reporting of the  
20 tool, not the link between the use of the tool.

21          MEMBER BEVANS: If that is what the  
22 process measure is, in fact, getting at, right?



1 MR. BERG: And I don't believe that  
2 we've assessed the effect that reporting has on  
3 performance.

4 MEMBER BEVANS: Okay. And I assume,  
5 you know, really a question to our leaders then,  
6 this is an issue in evaluating a process measure  
7 around the importance of that measure.

8 I notice also that with regard to  
9 reliability, the inter-rater reliability was fair  
10 only and I am wondering if there has been any  
11 attempt to kind of mitigate how the data are  
12 actually collected to improve inter-rater  
13 reliability.

14 MR. BERG: Sure. And I'll have Hiral  
15 talk to that issue.

16 MS. DUDHWALA: Yes, that's something  
17 that we observed as well. There was fair  
18 reliability when we compared our independent  
19 reviewer and our claims, what had been reported.

20 And what we found after we looked at  
21 that information, was what was lacking was a  
22 clear documentation of the outcome assessment

1 tool in the claims.

2 So, you know, as a response to that,  
3 we did take this back to our technical expert  
4 panel team and we did identify this and clarified  
5 the specification so that this is very clear, you  
6 know, for the providers that, you know, the name  
7 of the tool does need to be documented, because  
8 that was --- that was what --- really what was a  
9 big gap in that area. So, we did update that  
10 specification to note that.

11 MEMBER BEVANS: Okay. And the  
12 documentation, I may have missed it, but did that  
13 activity actually significantly improve the  
14 inter-rater reliability?

15 MS. DUDHWALA: So, that update just  
16 happened in the 2014 specification. So, further  
17 testing to see how that improved would happen  
18 this year.

19 MEMBER BEVANS: Okay. So, we're not  
20 quite sure there about that.

21 MS. DUDHWALA: Yes, we're not quite  
22 sure, but we did notice that was the issue that

1 had been showing up.

2 MS. SAMPSEL: So, Katherine, can we do  
3 importance first this time and --

4 MEMBER BEVANS: Yes.

5 MS. SAMPSEL: -- kind of focus so we  
6 can --

7 MEMBER BEVANS: Absolutely.

8 MS. SAMPSEL: -- so we can focus the  
9 conversation and vote? Thank you.

10 CO-CHAIR STILLE: I had a question  
11 about performance gap, which is actually pretty  
12 much right what's on your screen right now is  
13 that the median for providers although there is  
14 not very many providers that were reporting, was  
15 a hundred percent. And how do we kind of figure  
16 that out to maximize the value of this measure?

17 MR. BERG: Is Gary online? Does he  
18 want to answer that question? Gary is our  
19 statistician.

20 MR. REZEK: Well, yes. I would -- I  
21 can address that mainly by a point I try to  
22 emphasize. We're looking at the providers who

1 chose to report this on claims. So, it is --  
2 it's a small proportion of the total eligible  
3 population of providers who could have reported  
4 the measure. So, do have to take performance  
5 data with a grain of salt.

6 I think, you know, the median could  
7 be, you know, since it's a sort of self-selected  
8 group of providers who are reporting this, that  
9 the performance is -- maybe it's the high  
10 performers who are reporting, but we don't know  
11 that for sure.

12 So, although the median rate is a  
13 hundred percent, we do see, you know, I believe -  
14 - and I'm not looking at the webinar. I'm sorry.  
15 I'm remote here, but I believe our average  
16 performance was something in the range of 80  
17 percent. And we do see a lot of variation sort  
18 of in the bottom 50 percent of reporting  
19 providers.

20 CO-CHAIR STILLE: Right. And I think  
21 only like four percent of providers reported,  
22 too. So, yeah, I think your idea of some

1 selection bias in that initial sample is right.

2 MR. BERG: We do have an update in  
3 terms of -- and it's not part of the package  
4 here, but in terms of the number of providers or  
5 percentage of providers who are now using the  
6 tool as well. In preparation for this meeting,  
7 we went back and looked for the most recent data.

8 So, in 2013 there has been an  
9 appreciable increase in the number. And of  
10 providers that made application to attest to  
11 meaningful use, the utilization now is about 25,  
12 26 percent.

13 CO-CHAIR PARTRIDGE: And following up  
14 on Chris' question, in your 2013 data did your  
15 median and your percentiles change?

16 I mean, that 50th percentile, a  
17 hundred percent is kind of a big flag.

18 MR. BERG: Right. And, again, we just  
19 started to pull -- we just started to pull that  
20 data. And that's -- so, we haven't looked  
21 specifically at that in the 2013 data, because  
22 the data is just preliminary and not mature yet.

1 CO-CHAIR STILLE: Yes, David.

2 MEMBER CELLA: I'm sorry if I missed  
3 this, but to Katherine's point we're talking  
4 about importance, right?

5 So, there's an "and" in this numerator  
6 which is not just the documented functional  
7 outcome assessment, but a care plan that's based  
8 on the identified functional outcome  
9 deficiencies.

10 Is there a way, I mean, is that a true  
11 and, meaning -- because it seems to me that if  
12 there's a care plan that's tied to the functional  
13 assessment, in my mind that would become more  
14 important than if they just did the assessment.

15 So, in the way that this is collected  
16 and reported, is the link between the assessment  
17 being done and the care plan being provided,  
18 clear?

19 MR. BERG: That's the intent of the  
20 measure is for that to happen. And, again, the  
21 potential weakness, I think, has already been  
22 shown in terms of the difference between the

1 collected data, you know, the reliability data  
2 itself.

3 And so, the one thing that I can say  
4 is that when we compare the abstractors  
5 information to our own abstractors to determine  
6 an inter-rater reliability between the  
7 abstractors and then ourselves, that reliability  
8 went up into the 80 percent range itself. And  
9 so, an understanding amongst the abstractors and  
10 ourselves as to what was required for this  
11 measure was found.

12 However, we recognize the need to go  
13 back and to reevaluate following the changes that  
14 we have made to see if the increase in  
15 reliability has been accomplished as well.

16 CO-CHAIR STILLE: Sherrie.

17 MEMBER KAPLAN: I probably am going to  
18 win the prize for the most confused in the room,  
19 because I'm kind of confused about what -- when I  
20 first read this measure, I didn't know what we  
21 were actually being asked to endorse, because it  
22 says that a suite of, quote, standardized

1 functional status measures can be administered.

2 And then it says, unless I missed  
3 something, Kevin, because you can help me --- I  
4 read this over four times. I really did try to  
5 get this right.

6 And then -- and so, if you do it, it's  
7 zero/one at the patient level. So, it either was  
8 done or it was not done, but there's a whole host  
9 of different things that could be administered.

10 And then you have to interpret it ---  
11 you have to score it, interpret it correctly and  
12 formulate an appropriate functional impairment  
13 reduction plan. And that's what counts as you  
14 get a one. Then if that was done, you get  
15 scored.

16 Just to stop there, is that what you  
17 ---

18 MEMBER BEVANS: That was my  
19 understanding. Please, correct us. It's all or  
20 nothing kind of scoring system, right? Is that  
21 correct?

22 MR. BERG: Yes, that's correct.



1 MS. DUDHWALA: Yes, you have to -- you  
2 have to pass both parts to meet the measure, to  
3 pass the measure.

4 MEMBER KAPLAN: So, then my question  
5 is, who said somebody administered the right one?  
6 Was it sensitive and specific to the problem  
7 under consideration for improvement, A? B, how  
8 are you evaluating the functional improvement  
9 plan? Has that got some levels or tiers of it,  
10 or it was just done or not?

11 Is this a documentation measure, or is  
12 this a quality of care measure?

13 MR. BERG: Yes, it's a documentation  
14 measure.

15 MEMBER KAPLAN: Okay. So, now, NQF,  
16 you have to help me understand does that fall  
17 under the rubric here of a --- it's a  
18 documentation measure. So, you're documenting --

19 CO-CHAIR STILLE: So, it's a process  
20 measure, you know.

21 MEMBER KAPLAN: Okay. You're just  
22 documenting that it was done. But then if it was

1 done right, what happened?

2 I mean, how do you know if it was done  
3 correctly? The appropriate measure was applied,  
4 the appropriate care plan was applied. It's in  
5 the record and you can conceive of some EMR  
6 results that are just going to not let you go any  
7 further until you say yes or no and get a score  
8 right away as opposed to people who are EMR, some  
9 EMR and don't.

10 MR. BERG: This is a process measure.  
11 And so, that's not the purpose of the measure to  
12 evaluate whether it was done correctly or not.

13 And we recognize that process measures  
14 are beginning to fall out of favor at this point,  
15 and we really are looking for more on the  
16 outcomes-based type of measures.

17 This measure was developed, again,  
18 back in 2008 and implemented in 2009 by CMS as  
19 part of the PQRS program.

20 And so, this actually was supposed to  
21 come to this committee three years ago. And so,  
22 that's been -- that's been a bit of a delay. And

1       so, we understand the limitations of process  
2       measures, but it wasn't really built at the time  
3       it was built to evaluate the correctness of what  
4       was done.

5               MEMBER KAPLAN: Can I ask one follow-up  
6       question before we leave that?

7               MR. BERG: Sure.

8               MEMBER KAPLAN: So, if it's zero, you  
9       don't know if it wasn't done, or if it's just  
10      missing. That's what the nature of documentation  
11      is, right?

12              MR. BERG: That's correct.

13              MEMBER KAPLAN: Okay.

14              MR. BERG: That's correct. Yes.

15              MEMBER KAPLAN: So, then if you have a  
16      bunch of these things being done and now the  
17      median score --- this is a follow-up on Lee's  
18      point.

19              If the median score is a hundred  
20      percent, at what point do you retire this,  
21      because it's no longer varying or getting ceiling  
22      effect problems.

1 MR. BERG: We probably don't have  
2 enough data to know that because utilization was  
3 so small at the time.

4 CO-CHAIR STILLE: Right. Right. Yes.  
5 Once you have more complete data, you'll know is  
6 it still useful or not.

7 MR. BERG: That's correct.

8 CO-CHAIR STILLE: Sherrie, I might add  
9 that you know what you don't know, the rest of us  
10 don't know what we don't know. So, that's why  
11 you're making comments. So, thank you.

12 MR. BERG: And one thing you might  
13 argue is because the utilization up to this point  
14 or at least until recently has been so low, that  
15 in and of itself is perhaps evidence of a gap  
16 itself that needs to be filled.

17 CO-CHAIR STILLE: Peter.

18 MEMBER THOMAS: I'm having trouble  
19 understanding the 25 percent figure that you  
20 quoted of 2013 data.

21 Are you saying that providers in ---  
22 25 percent of providers did this?

1 MR. BERG: So, there are actually two  
2 numbers. There are actually the number of  
3 eligible providers which we calculated at that  
4 time to be somewhere over --- it was over 90,000  
5 providers.

6 However, of those providers, not all  
7 of them at that time had signed up to participate  
8 in the meaningful use program.

9 And so, of a smaller percentage of  
10 those that had signed up for meaningful use, of  
11 that population we found that 25 percent were  
12 using this measure.

13 MEMBER THOMAS: Okay. Using the  
14 measure, but not necessarily --- it doesn't  
15 necessarily correlate with whether or not they're  
16 doing this.

17 MR. BERG: That's correct.

18 MEMBER THOMAS: I mean, frankly I find  
19 it astounding that you would go to a PT or an OT  
20 or a chiropractor and they wouldn't assess your  
21 functional level and develop a plan of care.

22 I mean, what else would you be doing

1 if you weren't doing that to serve a patient's  
2 needs?

3 MR. BERG: This measure is designed for  
4 that to occur at each visit as well. So, that  
5 was part of the measure so that there would be an  
6 ongoing assessment of the functional status of  
7 the patient.

8 MEMBER THOMAS: Okay.

9 MR. BERG: And adjustments as necessary  
10 to the care plan.

11 MEMBER THOMAS: Thanks.

12 CO-CHAIR STILLE: Ann.

13 MEMBER MONROE: I'm struck by the  
14 disparity discussion that's here. In terms of  
15 the difference, I assume now it's in  
16 documentation or completion of this assessment,  
17 right?

18 Is that what the disparities refer to?  
19 I mean, they're very high, I think. You talk  
20 about statistically significant for gender and  
21 age and even larger differences between urban,  
22 rural providers and patient race, ethnic group.

1                   So, how do you look at those  
2                   disparities? Are they of sufficient significance  
3                   to you that you think this measure just isn't  
4                   being adapted, or what do you think that's  
5                   saying?

6                   MR. BERG: Dr. Goertz, do you have an  
7                   opinion on that? Obviously, you know, to me when  
8                   I look at the amount of disparity that's there,  
9                   it certainly means that there is a need for the  
10                  information to be there. There is a need for the  
11                  information to be considered.

12                  The thing that I thought was  
13                  interesting, though, is the disparity went in the  
14                  opposite direction in terms of the race  
15                  population --

16                  MEMBER MONROE: Right.

17                  MR. BERG: -- as I thought it would.  
18                  And I was very surprised by that. And I don't  
19                  really have an explanation for that, because it  
20                  appears that the performance was better in the  
21                  minority groups than in the white Caucasian  
22                  group.

1 MS. GOERTZ: Yes, and I'm not actually  
2 able to answer that question. The population  
3 that goes to a doctor of chiropractic is not as  
4 diverse as populations that may go to some other  
5 providers.

6 They tend to --- chiropractic patients  
7 tend to be Caucasian. They tend to be in a  
8 little bit higher socioeconomic status. And that  
9 tends to be the people that we attract in our  
10 randomized clinical trials as well.

11 To date, there hasn't been a study  
12 that has been sufficiently powered to look at  
13 differences in outcomes based on some of those  
14 criteria, though.

15 We're currently conducting a large-  
16 scale trial in the Department of Defense that  
17 should give us that data for the first time.

18 CO-CHAIR PARTRIDGE: Ann, I think also  
19 it's possible --- Mr. Berg, you said this is a  
20 meaningful use measure.

21 Part of the question could obviously  
22 be whether or not you have access to funding for



1 an EMR, a medical record system could turn on  
2 where your practice is located whether you're  
3 affiliated with the hospital and so on. So, that  
4 may account for some of your disparities, too.

5 MEMBER MONROE: I'm struggling with how  
6 to assess that. I mean, it feels very  
7 significant to me and what does that say about  
8 the measure? How do I interpret that thought in  
9 the face of what our task is?

10 I mean, does that make the measure  
11 less effective, score it more, I mean ---

12 CO-CHAIR STILLE: I think you need to  
13 take it in the context of these are the data that  
14 are available at this point.

15 MEMBER THOMAS: Doesn't it suggest that  
16 there is a need for the measure so that those  
17 that are not doing this and they are patients  
18 that are not experiencing this process are,  
19 therefore, higher likelihood that they would be  
20 exposed to that as a result of having this  
21 measured and tracked and isn't that what that  
22 means?

1 CO-CHAIR STILLE: On the end.

2 MEMBER LINDBERG: Thank you. I'm  
3 actually a fan of process measures. I think  
4 that, you know, the most maybe overused example  
5 of the process measure is the preoperative  
6 antibiotic, you know.

7 And the fact that once we started  
8 measuring that, doctors, hospitals, everybody,  
9 they're checking the box. Yes, somebody got the  
10 antibiotic.

11 I think this, unless I'm off here, it  
12 seems to me like this makes good sense to make  
13 sure that people check this box and that they've  
14 done this for each of their patients and they do  
15 it regularly as opposed to maybe once.

16 CO-CHAIR STILLE: Sort of a mantra in  
17 the quality field is not documented, not done.  
18 So, okay.

19 One more comment, and then I think we  
20 need to vote on importance. Sherrie.

21 MEMBER KAPLAN: I just had a quick  
22 question for clarification. Do the measures in

1 the suite of standardized measures have to be  
2 NQF-approved, or is -- they don't.

3 So, this is an NQF-approved measure of  
4 things that NQF has --

5 MR. BERG: I would say these are not  
6 necessarily measures that we're using. They're  
7 just the use of a functional tool, functional  
8 assessment tool.

9 So, yes, it would be correct they're  
10 not necessarily NQF-approved functional  
11 assessment tools.

12 MS. SAMPSEL: Well, and we want to  
13 clarify NQF doesn't review or endorse tools.  
14 Those don't come under the purview, just the  
15 measures that might be the result or the outcome  
16 of the tool.

17 MEMBER KAPLAN: I understood that part.  
18 I was just confused about the link. And then,  
19 still, the suite of acceptable measures is  
20 listed. Somewhere there's a long list for the  
21 coders to say it is or it isn't.

22 Nobody can just make up their own

1 little whatever or use something in children  
2 that's been used in adults and by the way, is  
3 pediatrics part of this, or is this an adult  
4 measure?

5 MR. BERG: No, this is AJT and older.

6 MEMBER THOMAS: Is there any setting  
7 other than outpatient that this would apply or  
8 that this is used or could be used?

9 MS. DUDHWALA: It's just currently  
10 outpatient setting at this point.

11 MEMBER THOMAS: Okay.

12 CO-CHAIR STILLE: Okay. Can we vote on  
13 importance?

14 MS. SOMPLASKY: This is Anita  
15 Somplasky. Can I just clarify something? This  
16 is not a meaningful use measure. It's a PQRS  
17 measure, which has made it a little bit more  
18 difficult to ascertain, you know, the actual  
19 documentation because you have to wait to see who  
20 has reported through the PQRS program and then be  
21 able to ask for a sampling of those to see if the  
22 documentation is present.

1 CO-CHAIR PARTRIDGE: And if this is not  
2 a meaningful use measure, then I take back what I  
3 said about whether or not you had access to an  
4 EMR.

5 MS. ALLEN: So, now we are voting on  
6 evidence. One, high. Two, moderate. Three,  
7 low. Four, insufficient evidence. Five,  
8 insufficient evidence with exception.

9 Voting starts now.

10 CO-CHAIR STILLE: And what does  
11 exception mean?

12 MS. SAMPSEL: Exception would mean that  
13 --- all right. So, and we had a big talk about  
14 this yesterday on if we should even have this  
15 category anymore, but basically what it means is  
16 not enough information was provided, but this is  
17 an important enough concept and you think the  
18 evidence is there based on feedback from other  
19 members of the Committee that you would give it  
20 an exception.

21 So, that Five category would actually,  
22 you know, so, let's say that, you know, you had

1 54 percent in one and two, and seven percent in  
2 Number 5. That takes it over the 60 percent.  
3 So, it would be above the gray zone and it would  
4 pass, if that makes sense. It counts as a pass.

5 MS. ALLEN: Voting starts now.

6 (Voting.)

7 MS. ALLEN: 11 percent high. 47  
8 percent moderate. 16 percent low. 16  
9 insufficient evidence. 11 percent insufficient  
10 evidence with exception.

11 MS. SAMPSEL: So, we do move -- we  
12 continue to move forward with this one.

13 MS. ALLEN: Voting on performance gap.  
14 One, high. Two, moderate. Three, low. Four,  
15 insufficient information.

16 Voting starts now.

17 (Voting.)

18 MS. ALLEN: 21 percent high. 63  
19 percent moderate. 16 percent low. Zero percent  
20 insufficient.

21 Voting on high priority. One, high.  
22 Two, moderate. Three, low. Four, insufficient.

1 Voting starts now.

2 (Voting.)

3 MS. ALLEN: 21 percent high. 63  
4 percent moderate. 16 percent low. Zero percent  
5 insufficient.

6 CO-CHAIR STILLE: Okay.  
7 Psychometricians, have at it.

8 MEMBER BEVANS: A quick question about  
9 reliability or the specification, I guess. And  
10 this kind of gets back to Dave's comment as well.

11 I think that in terms of  
12 operationalizing this measure, choosing from a  
13 list of potential outcome measures or  
14 standardized tools makes sense as part of the  
15 first element of the process measure, but could  
16 you help us to understand a little bit more about  
17 how the second element is operationalized?

18 How do we know that a documented care  
19 plan is based on the identified functional  
20 outcome deficiencies?

21 It is one thing to be able to document  
22 a care plan was generated, but the qualitative

1 element of that definition is based on the  
2 functional deficiency. It's trickier.

3 And so, I'm hoping you could help us  
4 to understand how that's operationalized for the  
5 purposes of coding.

6 MR. BERG: Dr. Goertz, do you want to  
7 answer that question?

8 MS. GOERTZ: I can talk a little bit  
9 about how it's operationalized or what our  
10 thought was when we were putting that together.  
11 I would not be able to answer how it's actually  
12 operationalized for coding purposes.

13 I can talk about our intent and the  
14 training, but I --- so, we added the care  
15 component, I think, in the second or third year  
16 after the measure was developed because we wanted  
17 to make sure that there was a direct link between  
18 quality of care and -- we have trained the  
19 doctors of chiropractic most familiar with the  
20 training that's gone to them about the importance  
21 of the measure itself and that it be linked to a  
22 care plan.



1                   And I believe that they are instructed  
2                   to record the date in which the care plan is  
3                   developed and the dates on which it is modified,  
4                   but I wasn't involved in any sort of an audit  
5                   that showed the extent to which that's actually  
6                   occurring.

7                   CO-CHAIR STILLE: I'm a little bit  
8                   concerned just as this continues to roll out,  
9                   about the reliability in as reported in a much  
10                  bigger sample.

11                  Sometimes it's hard to tell if there's  
12                  a care plan in a medical record, for example.  
13                  And so, I think it's going to be really important  
14                  to get follow-up data about how accurately can we  
15                  tell whether this stuff is there or not.

16                  It's hard to tell with the sample that  
17                  we have right now, but it's hard enough to get  
18                  anything out of an EMR. And sometimes care plans  
19                  can be a little bit of a weird part of that.

20                  MEMBER KAPLAN: Can I -- the  
21                  reliability issue is just reproducible. And  
22                  that's the agreement, you know, somebody looking

1 in this case at the same documentation or lack  
2 thereof and reproduce it, but just being -- what  
3 I understand is just if somebody said it was  
4 there, a care plan was there at all, it doesn't  
5 matter. Those two things could have been  
6 completely independent of each other.

7           Somebody did the functional status  
8 assessment. Somebody else wrote a care plan.  
9 Bingo. Both of them are there and the measure is  
10 satisfied. That's correct, right?

11           It doesn't matter if they were linked.  
12 They were just there. Somebody went through the  
13 record. Bingo, I found one. Bingo, I found two.  
14 Bob's your uncle.

15           MR. BERG: That's how the measure is  
16 designed.

17           MEMBER KAPLAN: So, then the question  
18 for reproducibility is did somebody else looking  
19 at that same information get the same answer?  
20 And what I understood from you is, not so much.

21           If you look at the medical record, if  
22 you go back and abstract the medical record and

1 try and compare it with the claims data results,  
2 you don't necessarily get too much agreement  
3 between those two sources and the same  
4 information; is that right, or no?

5 MR. BERG: The initial data would  
6 suggest that, again, we want to go back and re-  
7 look at that following the clarification that we  
8 gave after that initial data was obtained.

9 MEMBER KAPLAN: So, then the issue of  
10 who's right, you know, which is a validity issue,  
11 because then is it accurate, you know, that  
12 becomes then the validity question that we don't  
13 know the answer to yet.

14 MEMBER BIERNER: Well, it would be  
15 rather easy to have collected data that would  
16 say, this is the measure I used.

17 I understand you have a suite of  
18 previously validated measures like Oswestry or  
19 whatever, but it could have been a checkoff box.  
20 I used for this patient Oswestry or I used neck  
21 disability index, whichever, and identified  
22 functional outcomes or functional goals for the

1 treatment and that could have been specified.

2 I mean, it would be pretty easy to  
3 specify that in a general way. You could say  
4 we're, you know, these are the deficiencies in  
5 function.

6 So, I just have a lot of problems with  
7 this that we're -- that this measure which hasn't  
8 yet been widely used among the community of  
9 providers of chiropractors, it could be so much  
10 better and collect actually more useful  
11 information.

12 Otherwise, you're just saying there's  
13 a piece of paper in the record and nothing about  
14 whether it really relates to the functional  
15 deficits outlined in the tool they use, which  
16 just seems like a waste of time.

17 MEMBER BEVANS: I think this point  
18 about the connection between use of the  
19 standardized tool and the actual care plan  
20 whether the care plan is informed by results of  
21 the tool is really a key issue.

22 And I think that for me, I could

1 really better understand and make a judgment  
2 about this if we could know specifically how the  
3 observation was operationalized, you know, what  
4 exactly are the coders looking for. So, that  
5 information could be key.

6 If Sherrie is correct in saying what  
7 we're looking -- what the coders are looking for  
8 are did you use a measure and do you have a care  
9 plan, then if that's correct, then I think that  
10 the description of this measure in the document  
11 is a bit misleading because what it says is a  
12 documented care plan based on the identified  
13 functional outcome deficiencies.

14 That may or may not be true, you know,  
15 if all you're looking for is use of a tool and  
16 have a care plan, but it's hard to say maybe  
17 that's not actual, you know, how the measure is  
18 operationalized. So, more information would be  
19 helpful.

20 MR. BERG: And there are two sources of  
21 data for the calculation of the measure. One  
22 being claims data where there really is no way to

1 code that connection between the two, and then in  
2 a registry.

3 And the number of -- the percentage  
4 that is in registry as opposed to claim data is  
5 much smaller than that. But as a claims-based  
6 measure, I don't see a way to make that linkage  
7 based on the way claims are coded at this point.

8 MEMBER BEVANS: So, it would be  
9 important to respecify the definition?

10 CO-CHAIR PARTRIDGE: It's been a long  
11 time since I had to read claims. But as I  
12 remember, G codes are not payment-based. They're  
13 kind of additional information stuff.

14 MR. BERG: That's correct.

15 CO-CHAIR PARTRIDGE: And they won't be  
16 in any way detailed. What we determined was this  
17 person needs work on exercising his shoulder,  
18 right?

19 CO-CHAIR STILLE: Other questions?

20 Dave.

21 MEMBER CELLA: So, I just wanted to  
22 follow up on that point that Katherine was

1 bringing back which is exactly why I asked the  
2 question when we were voting on importance, was  
3 it based on part of the numerator. And you said  
4 that's the intent.

5 And so, I voted in favor of it being  
6 important because of that word "based on." I  
7 mean, that literally, to me, made the difference.

8 And then Sherrie, I think, illustrated  
9 that, and I think you've confirmed, that  
10 basically the way it would be done today, there  
11 would be no way to confirm based on.

12 So, I think at least from my  
13 perspective, what we have is a case where this is  
14 an effort to move a process measure into more of  
15 an outcome-like measure and more of a care --- a  
16 real care-based measure a little bit analogous to  
17 antibiotics.

18 I mean, people will do the right thing  
19 and the right thing should be tied to that tool  
20 and not just I've got to write a care plan  
21 because, you know, I have to.

22 So, it's important to make that based

1 on link, but I think what we're hearing is we're  
2 not sure how that's going to happen unless the  
3 system changes.

4 So, the reason I'm maybe belaboring  
5 this point is that I don't know how that means we  
6 should vote going forward. Because on the one  
7 hand, I personally as a member believe that it's  
8 important to have that based on link and that  
9 this should be encouraged and promoted in some  
10 way, but I don't know how when it leaves this  
11 meeting and then goes into use would we be  
12 favorably, you know, stamping something that will  
13 continue to be rolled out as Sherrie illustrated,  
14 you know, you do A, you do B, you get the one,  
15 you're in the numerator.

16 That would trouble me unless there was  
17 some way to get some teeth into that based on  
18 link that really to me is the core.

19 CO-CHAIR STILLE: Liz.

20 MEMBER MORT: I think another way of  
21 saying that is that this is very game-able. And  
22 game-able is a risky methodology, because that's



1 when you run into the unintended consequences  
2 associated with putting in non-linked plans or  
3 other such things.

4 And I know that some organizations are  
5 really taking a pretty active stance against  
6 promoting measures that are game-able.

7 I mean, perioperative antibiotics  
8 there's fraud. You can lie and you can check the  
9 box that said you did it.

10 But if you do it, there is a very --  
11 and it gets into the patient, that's not game-  
12 able. You've given the antibiotics as you  
13 should, but you could put a care plan down that  
14 clearly would be meeting the metric, but not  
15 necessarily delivering the care that would be  
16 right for the patient.

17 CO-CHAIR STILLE: So, it might be  
18 helpful for the developers to talk about kind of  
19 how this is measured, because there's some  
20 questions about that.

21 MR. BERG: Gary, do you think you can  
22 answer that question? Are you still there, Gary?

1 MR. REZEK: Ye, and I'm not exactly  
2 sure how our testing addressed that issue, the  
3 issue how this is essentially being implemented  
4 at the provider level and how they would define a  
5 care plan and if that explicit connection has  
6 been made between the outcome deficiencies.

7 We don't really have that answer in  
8 our data.

9 CO-CHAIR STILLE: Okay. Great. Let's  
10 vote.

11 MS. GOERTZ: Could I just say one  
12 thing? This is Christine Goertz.

13 CO-CHAIR STILLE: Yes.

14 MS. GOERTZ: Before you vote.

15 CO-CHAIR STILLE: Yes, please.

16 MS. GOERTZ: Oh, thank you.

17 I'm both a clinician and a scientist.  
18 And as a scientist who does randomized clinical  
19 trials for a living I completely understand this  
20 discussion and the need for data and that clearly  
21 links the care plan with the collection of the  
22 outcomes data.

1           As a clinician, I can tell you that  
2   when you have that data, you link it to the care  
3   plan. It's not something that you would  
4   necessarily gain as --- if you have that data  
5   collected, you would just naturally link that to  
6   your care. It would be data that you wouldn't  
7   just ignore. So, I would just ask that you keep  
8   that in mind as you're voting.

9           While I understand the need for data  
10   and I'm thinking of ways right now that we might  
11   be able to educate our providers to make sure  
12   that we are, in fact, able to make that link and  
13   that we do it in a way that's auditable, I would  
14   -- I just would like you to think about it just a  
15   little bit from a clinical perspective and all  
16   where that link would just naturally be made.

17           MEMBER KAPLAN: Can I respond to that,  
18   because the one thing patients complain about  
19   almost uniformly is they complete these forms in  
20   the office at intake of review of systems and  
21   they carefully complete them and often are  
22   frustrated because they may not have them

1 finished before they go to see the doctor. Do  
2 you have any diabetes? Blah, blah, blah. And  
3 the doctor systematically ignores all those data.

4 So, I don't know that just because  
5 somebody filled out the form, that it actually  
6 got integrated into -- effectively into care  
7 plans without some extra steps.

8 CO-CHAIR STILLE: Yes. A quality  
9 metric for quality of a care plan is so badly  
10 needed, I think.

11 Anyway, let's vote.

12 MS. ALLEN: Voting on reliability,  
13 which includes precise specifications in testing.  
14 One, high. Two, moderate. Three, low. Four,  
15 insufficient.

16 Voting starts now.

17 (Voting.)

18 MS. ALLEN: Zero percent high. 53  
19 percent moderate. 21 percent low. 26 percent  
20 insufficient.

21 MS. SAMPSEL: So, this is considered in  
22 the gray zone, but we still move forward to the

1 next vote.

2 MS. ALLEN: Voting on validity  
3 including specification consistent with evidence,  
4 testing, exclusion, meaningful differences. One,  
5 high. Two, moderate. Three, low. Four,  
6 insufficient.

7 Voting starts now.

8 (Voting.)

9 MS. ALLEN: Zero percent high. 42  
10 percent moderate. 32 percent low. 26 percent  
11 insufficient.

12 CO-CHAIR STILLE: Brief comments on  
13 feasibility.

14 (No comments.)

15 CO-CHAIR STILLE: Anyone? Should we  
16 vote?

17 (No comments.)

18 CO-CHAIR STILLE: Let's vote.

19 MS. ALLEN: Voting on feasibility.  
20 One, high. Two, moderate. Three, low. Four,  
21 insufficient.

22 Voting starts now.

1 (Voting.)

2 MS. ALLEN: 16 percent high. 58  
3 percent moderate. 26 percent low. Zero percent  
4 insufficient.

5 CO-CHAIR STILLE: Comments on  
6 usability. There were a few from before.

7 (No comments.)

8 CO-CHAIR STILLE: Anything? Okay.  
9 Should we vote? Let's vote.

10 MS. ALLEN: Voting on usability. One,  
11 high. Two, moderate. Three, low. Four,  
12 insufficient information.

13 Voting starts now.

14 (Voting.)

15 MS. ALLEN: 21 percent high. 47  
16 percent moderate. 32 percent low. Zero percent  
17 insufficient information.

18 CO-CHAIR STILLE: And finally overall  
19 suitability. Any last comments?

20 (No comments.)

21 CO-CHAIR STILLE: Okay. Let's vote.

22 MS. ALLEN: Overall suitability for

1 endorsement for Measure Number 2624, Functional  
2 Outcome Assessment. One, yes. Two, no.

3 Voting starts now.

4 (Voting.)

5 MS. ALLEN: 53 percent yes. 47 percent  
6 no.

7 CO-CHAIR STILLE: Okay. So, lots of  
8 gray zone things. Anything, Sarah, before we go  
9 to member comment?

10 Okay. Right before we break for  
11 lunch, member and public comment is open  
12 including the folks behind us.

13 MS. GHAZINOUR: Operator, would you  
14 please open the lines for public comment?

15 THE OPERATOR: At this time if you  
16 would like to make a public comment, please press  
17 \*1 on your telephone keypad. Again, that's \*1 to  
18 make a public comment.

19 (Pause.)

20 MS. AUTREY: Hello. This is Sophia  
21 Autrey with CMS. Can you hear me?

22 CO-CHAIR STILLE: Go ahead.

1 MS. AUTREY: Okay. So, I just want to  
2 be clear on some of the reasons that were  
3 identified that were issues for the reliability  
4 and validity.

5 So, are we -- am I to understand that  
6 most of the issues are surrounding the  
7 possibility or probability of gaming the measure  
8 and that's why there was hesitation, or on the  
9 reliability and validity?

10 CO-CHAIR STILLE: I think gaming was a  
11 relatively minor issue. I think a lot of people  
12 were wondering about sample size. There were  
13 some inter-rater reliability things, if I  
14 remember correctly, that were kind of borderline.  
15 Different things.

16 I think that having some new data from  
17 2013 will be helpful. And what does everybody  
18 else think generally?

19 MEMBER BEVANS: I think that greater  
20 clarity on how each element of the process  
21 definition is actually measured in the field  
22 would go a really long way to help us understand



1       what this measure is actually getting at.

2                   And by extension, whether it is an  
3       important outcome or important process.

4                   MS. AUTREY: Okay.

5                   MEMBER KAPLAN: Yeah, I echo that.  
6       This is Sherrie Kaplan. I echo what Katherine  
7       just said.

8                   I think the link between reporting a  
9       functional status measure in one place and a care  
10      plan in another place, and they could be for  
11      completely different problems as long as they  
12      were done, and done is all we're being measured,  
13      would help us interpret what the measure is  
14      actually getting at, what it means.

15                  So, I think that link was the thing  
16      that was most disturbing at least for me.

17                  MS. AUTREY: So, what I'm hearing is  
18      the fact that you would want additional  
19      information on how the measure is actually  
20      operated at the level within -- for the  
21      physician, and you want to know specifically the  
22      link between the functional status outcome and

1 the care plan.

2 Wanting to know that established link  
3 documented, or we just have to figure out  
4 something that -- I'm just trying to figure out  
5 how that would be identified in the measure if  
6 you are not trusting that the physician that is  
7 putting the information in is clearly putting  
8 what has been done.

9 MEMBER BEVANS: For me, that's less the  
10 concern, in part, because it will be very  
11 difficult to mitigate that.

12 It's more understanding what are your  
13 coders looking for. What exactly are the  
14 criteria that are used to check the box, yes, a  
15 measure was used, yes, there is a care plan?

16 That is linked to outcomes from the  
17 functional status assessment.

18 MEMBER KAPLAN: Yes, I agree. If it  
19 was a shoulder pain functional status assessment,  
20 one would like to see a shoulder pain care plan  
21 or something that --- and if that's not doable,  
22 then some clarification about exactly what

1 documentation we actually are making and then  
2 give some feedback on how to improve that  
3 performance because, you know, if you're going to  
4 use it in quality improvement and public  
5 reporting, how do you get a better score if those  
6 two things really can't be linked?

7 MS. AUTREY: Okay. All right. That's  
8 clarified. Thank you.

9 MEMBER CELLA: So, just one more  
10 comment. I might put a different spin on it, the  
11 same basic idea, because I agree with what's  
12 being said.

13 But what about imaging a case where  
14 the numerator isn't just populated by a one or a  
15 zero, but that there was some way to, you know,  
16 because I keep keying in on the capital AND and  
17 the based on bridge in the numerator statement of  
18 the indicator.

19 And in order to achieve that, there  
20 has to be some way for somebody to document that  
21 they're linked and that it actually did flow that  
22 way, but maybe that could be a bonus.

1           Maybe the current reporting of, yes,  
2           there was an assessment done and, yes, there's a  
3           care plan gets you one point, but maybe showing  
4           the link gets you two points.

5           So, I don't know if you want to think  
6           about it that way, but that would make a little  
7           more sense to me because then somebody could be  
8           getting a bonus for doing more than reporting on  
9           the two components of this linked measure.

10           MS. AUTREY: Yeah, this is something to  
11           think about. I think that one of the issues  
12           identified as far as specifically quantifying the  
13           operationalization of the measure is really a key  
14           point.

15           So, I appreciate your feedback. Thank  
16           you.

17           CO-CHAIR STILLE: Okay. Any other  
18           member or public comments?

19           THE OPERATOR: And there are no public  
20           comments at this time.

21           CO-CHAIR STILLE: Thank you.

22           CO-CHAIR PARTRIDGE: We are proceeding

1 to lunch. If we look at the agenda, the next  
2 item up is discussion of 2653 with -- is  
3 Minnesota going to be on the line, or are they  
4 here?

5 MS. PITZEN: Hi. This is Collette and  
6 Jasmine from Minnesota Community Measurement.  
7 And we are on the line ready whenever you guys  
8 are.

9 CO-CHAIR PARTRIDGE: Good. Well, we  
10 are just about to decide when that is.

11 MS. PITZEN: Okay.

12 CO-CHAIR PARTRIDGE: Quarter to 1:00?  
13 All right. 12:45 our time. 11:45 yours in  
14 Minnesota. And it's snowing here. I just want  
15 you to feel that we feel your misery.

16 MS. PITZEN: Is that okay if we just  
17 stay on the line until you return and we'll just  
18 mute ourselves?

19 CO-CHAIR PARTRIDGE: All right. We  
20 will skip the item scheduled at 1:10. And  
21 depending on time, we may move one of the -- some  
22 of the discussions scheduled for tomorrow

1 afternoon into that slot around one o'clock.

2 MEMBER MONROE: Excuse me, Lee. Did we  
3 move 422 off the agenda as well?

4 CO-CHAIR PARTRIDGE: 422 is off. It's  
5 in the group. I'm not sure we took a formal vote  
6 on 422.

7 (Whereupon, the above-entitled matter  
8 went off the record at 12:23 p.m. and resumed at  
9 12:57 p.m.)

10 CO-CHAIR PARTRIDGE: I think we are  
11 about ready to come back if most everybody is  
12 here.

13 CO-CHAIR STILLE: Pretty much. Mitra  
14 asked me to let everyone know that dinner, for  
15 those who are interested, tonight is at 6:00 p.m.  
16 at Mio, which is right across the street from the  
17 Residence Inn, for those of you who are staying  
18 there. And Mitra has the address if you need it.

19 CO-CHAIR PARTRIDGE: Okay. Our next  
20 measure is 2653, and our developer is the  
21 Minnesota -- I always get this mixed up --  
22 Minnesota Community Measurement.

1                   And, Minnesota, are you back on the  
2 line?

3                   MS. PITZEN: Yes, we are.

4                   CO-CHAIR PARTRIDGE: Well, welcome.

5                   MS. PITZEN: Thank you.

6                   CO-CHAIR PARTRIDGE: And would you  
7 like to proceed and give us a little description  
8 of the background for this measure and what it is  
9 you intend that it do?

10                  MS. PITZEN: Great.

11                  Good afternoon, everyone. I'm  
12 Collette Pitzen, a measure developer with  
13 Minnesota Community Measurement. And with me is  
14 Jasmine Larson, our Manager of Measure  
15 Development.

16                  We are pleased to be presenting the  
17 results of several years of development work for  
18 some new patient-reported outcome measures  
19 related to postoperative functional status.

20                  The first measure that we are talking  
21 about today is number 2653, Average Change in  
22 Functional Status Following Total Knee

1 Replacement Surgery.

2           This is a measure that is evaluating  
3 the change between a patient's preoperative  
4 functional status and their knee function one  
5 year postoperatively. It is an outcome measure,  
6 but its construction is a little bit different  
7 from a traditional measure with a numerator or  
8 target. Rather, it is assessing the average  
9 change in the functional status and has no  
10 numerator. I would like to spend a little bit of  
11 time walking through some of the measure  
12 construct details.

13           The initial patient population is  
14 adult patients age 18 and older, with no upper  
15 age limit, who undergo either a primary total  
16 knee replacement or revision total knee  
17 replacement with dates of procedure during the  
18 calendar year.

19           The measure focus is the orthopedic  
20 practice, and procedures are identified using the  
21 CPT codes that the surgeons use to bill their  
22 professional fees. There are no upfront



1 exclusions for the initial patient population,  
2 and outcomes are stratified by primary or  
3 revision procedure type.

4           The measure is a patient-reported  
5 outcome or PRO-based measure. The PRO tool that  
6 is used is the Oxford Knee Score tool, or OKS, a  
7 12 question tool selected by the Measure  
8 Development Work Group for its strong  
9 psychometric properties, easy for patients to  
10 complete, and simplicity in administration and  
11 scoring.

12           The patient completes the OKS anytime  
13 within three months prior to the date of the  
14 procedure. The patient then completes a full  
15 postoperative assessment at one year, with a  
16 fairly wide window to capture as many  
17 postoperative assessments as possible. One year  
18 is defined as nine to fifteen months  
19 postoperatively.

20           Change is first calculated for each  
21 patient, and then the changed scores are summed  
22 and the average is determined. The measure

1 calculation takes into account both patients that  
2 have an improvement and those patients whose  
3 function decreases postoperatively. In order to  
4 calculate the change in each patient's functional  
5 status, the measure denominator is comprised of  
6 patients who have a completed preoperative and  
7 postoperative assessment.

8 It is important to understand the rate  
9 of tool administration in the population prior to  
10 any use or reporting of outcome measures, and we  
11 accomplish this through paired process measures  
12 and the submission of all patients for rate  
13 calculation, even those patients who may be  
14 missing a PRO assessment. Paired process  
15 measures and the inclusion of all patients is one  
16 way to address potential gaming of this measure.

17 The first-year results for the measure  
18 demonstrate a 17-point increase on a 0-48 point  
19 scale, where a higher score indicates improved  
20 knee function. Variation is noticed based on the  
21 annual volume of TKR procedures performed, with  
22 groups performing 100 or more procedures per year

1 having a higher average functional status change.

2 Thank you for the opportunity to  
3 present this measure for your consideration, and  
4 we welcome your discussion and questions.

5 CO-CHAIR STILLE: Collette, I think it  
6 would be helpful to the Committee if you would  
7 also give us a little background as to why  
8 Minnesota Community Measurement undertook to  
9 develop this measure. What it was that --- I  
10 know it comes up again in the other measure we  
11 have before us today, but I think most of the  
12 Committee is probably not familiar with the  
13 process in Minnesota of how you develop measures,  
14 why you develop measures, and how they are now  
15 used across the State.

16 MS. PITZEN: Sure, I would be happy  
17 to.

18 This measure -- we are a subcontractor  
19 to the Minnesota Department of Health. As part  
20 of that subcontractor relationship, we also work  
21 on developing new measures in addition to  
22 publicly reporting and using our measures in a

1 statewide quality reporting and measurement  
2 system.

3 And we are frequently presented with  
4 a concept for measurement development for  
5 exploration of determining can excellent measures  
6 be built around a particular topic. This topic  
7 of total knee replacement was presented to us in  
8 2010.

9 So, when I talk about a couple of  
10 years of development, we have been working on  
11 this for a while. Part of the rationale for the  
12 selection of total knee patients is the  
13 anticipated large boom in volume of procedures  
14 over the next, I want to say, 10 years or so,  
15 with the Baby Boom population.

16 Part of the reason about the length of  
17 development time, because we are looking at a  
18 postoperative assessment period of 15 months, it  
19 did take us quite a bit of time to complete  
20 testing of this measure. Thank you.

21 CO-CHAIR PARTRIDGE: As I understood  
22 the narrative, one, the Department of Health in

1 Minnesota is concerned in part about the  
2 potential for overuse here. Is that correct?  
3 You see a boom. You want to be sure, given the  
4 dollar volume and the number of procedures, that  
5 your money is being properly spent. Am I putting  
6 words in your mouth?

7 MS. PITZEN: Just a tiny bit. Perhaps  
8 not a concern with overuse yet, but I think there  
9 is some underlying currents of that. But,  
10 rather, it was having really a lack of  
11 information for consumers to know what they could  
12 expect after undergoing this procedure.

13 And frequently, our work with the  
14 orthopedic and neurosurgeon groups and other  
15 specialties, oftentimes it's anecdotal. And so,  
16 this is a new effort to try to quantify and put  
17 some information together about what the outcomes  
18 are for this patient population and the spine  
19 measure that we will be presenting next.

20 CO-CHAIR PARTRIDGE: Good. Thank you.  
21 Dawn?

22 MEMBER DOWDING: Okay, thank you. In

1 terms of --- do you want me to just talk about  
2 importance first? Because I, then, have some  
3 issues about reliability and validity, but that  
4 comes later.

5 I think in terms of the description of  
6 importance, you have made a very good case for  
7 why at a national level we might be concerned  
8 about total knee replacements in terms of  
9 variation.

10 But I just wondered if you had any  
11 data from your pilot study in Minnesota, apart  
12 from size of practice, to illustrate variations  
13 in performance gaps for other factors such as  
14 age, ethnicity, and how different stratifications  
15 of patients, how the average difference may  
16 appear.

17 And one of the other things -- it is  
18 just a very general comment -- with a lot of  
19 these scores is that what we are actually asking  
20 --- being asked to endorse is the difference  
21 between preoperatively and postoperatively and  
22 how big that difference is, and whether that is

1 meaningful.

2 And I am not entirely sure the  
3 difference of 14 points to 17 points is actually  
4 meaningful, useful, different for the patients in  
5 terms of function on the scale. I just don't  
6 have any feel for what it actually means in terms  
7 of quality of care.

8 So, I just wondered if you could just  
9 talk us through some of those issues to do with  
10 this. Is there actually a gap in quality of care  
11 associated with these knee replacements, and how  
12 would we know that from this different score?

13 MS. PITZEN: This is Collette. Thank  
14 you very much for the discussion and questions.  
15 I am not entirely sure that I have all of the  
16 answers. I know that we --- and we struggled  
17 with performing some of the reliability  
18 statistics. In many of our other measures we can  
19 demonstrate meaningful differences between the  
20 practices and opportunities for improvement.

21 This is a newer-type measure. We  
22 believe that, as we keep going forward, that we

1 will be able to, like several other measures,  
2 have discernible differences between the  
3 practices.

4 Just to share a little bit about the  
5 Measure Development Work Group's thoughts around  
6 this patient population, though we are not  
7 specifically measuring, they felt that there  
8 could be some differences. We also have a three-  
9 month assessment measure that we did not put  
10 forward for endorsement, but the thought and  
11 feeling at the time was a three-month assessment  
12 of the patient, while not reflecting their full  
13 function, could discern differences in  
14 postoperative rehabilitation and perhaps surgical  
15 techniques used and the selection of patients.

16 So, there was that consideration as we  
17 went forward. And the Work Group felt that, with  
18 this brand-new measure, that differences would be  
19 demonstrated among the practices.

20 CO-CHAIR PARTRIDGE: Questions from  
21 other members of the Committee about importance?

22 Sherrie?



1                   MEMBER KAPLAN: Thank you. I guess I  
2 have a followup question on that. What is the  
3 effect size of that difference? What proportion  
4 of standard deviation is it?

5                   MS. PITZEN: This is Collette. I  
6 missed the initial, the first question, but we  
7 don't have that information in terms of the  
8 standard deviation.

9                   MS. LARSON: We don't have it in front  
10 of us right this moment.

11                  MEMBER KAPLAN: If you could give us  
12 a sense, that would help us interpret those  
13 differences you are observing as meaningful.

14                  MS. PITZEN: I don't know how much  
15 that we can pull together on the fly here. We  
16 will give it a try as the discussion keeps going.

17                  CO-CHAIR PARTRIDGE: Collette, I am  
18 looking at my notes from this measure, and I  
19 notice on page 16 of your attachment you did note  
20 that was a variation in the performance among the  
21 four regions of Minnesota on this measure, and  
22 that the range was from 10.8 to 12.9.

1                   And I think the question Dawn asked is  
2 similar to the one that I have. We would be  
3 curious to know that if you think that -- and I  
4 should say some of my colleagues on this  
5 Committee could probably answer this question for  
6 me, too. Is the two-point difference a  
7 significant one?

8                   CO-CHAIR STILLE: It all depends on  
9 the distribution and the number of patients and  
10 stuff. It depends a lot on the number of  
11 patients and the distribution of the scores and  
12 that kind of thing.

13                  CO-CHAIR PARTRIDGE: Go ahead,  
14 Sherrie.

15                  MEMBER KAPLAN: Yes, if we don't have  
16 the standard deviation, we can't interpret the  
17 effect size --

18                  CO-CHAIR STILLE: Right, right.

19                  MEMBER KAPLAN: -- and the magnitude  
20 of how much that difference is.

21                  CO-CHAIR STILLE: Right.

22                  CO-CHAIR PARTRIDGE: Okay. And part

1 of this is we are dealing with a pilot. So, we  
2 have a small sample.

3 MS. PITZEN: That's correct.

4 MEMBER BRADLEY: In the study, did you  
5 also collect data on interventions  
6 postoperatively that might have affected outcome?  
7 Say, patients that had rehab versus patients that  
8 did not have rehab?

9 MS. PITZEN: This is Collette. No,  
10 that we did not collect that information.

11 I just wanted to step back a second  
12 and describe our standard processes for the  
13 measures that we collect and report in Minnesota.  
14 And these are statewide measures.

15 We have a philosophy of collecting  
16 minimal datasets for what is necessary for risk  
17 adjustment and calculation of the measure. So,  
18 as we are working through our development  
19 process, we really caution our work groups, in  
20 our measure design and construction and the  
21 actual data fields that we are requiring groups  
22 to submit to us, to really be mindful towards

1       burden and not be asking for every possible  
2       element that they can think of.

3               MEMBER DOWDING:   Yes, and just a  
4       followup question as well.   I was also wondering  
5       why you decided to follow up a year post-surgery,  
6       with that sort of time scale, because it just  
7       seems to be quite a long time after the surgical  
8       intervention, and what effect that has on the  
9       state's rates.

10              MEMBER BIERNER:   Well, let me just  
11       comment that that is actually, I think, a good  
12       thing.   Joint replacement operations, patients  
13       often may have symptoms and don't really -- I  
14       think six months would be the minimum I would  
15       want to see anything after a joint replacement  
16       because there is a significant recovery time,  
17       depending on the age of the patient.   So, I think  
18       longer is actually better, and six months to a  
19       year is probably appropriate for a joint  
20       replacement.

21              MS. PITZEN:   Great.   This is Collette.  
22       Can I just add an additional comment?

1                   We did have a really thorough  
2           discussion at our work group level about the  
3           timeframes that they wanted to assess. I  
4           initially was suggesting a six-month timeframe,  
5           and the orthopedic surgeons very quickly shared  
6           those exact same feelings, that the one-year  
7           postoperative assessment was really hitting the  
8           patients at their true level of functional status  
9           improvement, and that to measure much sooner  
10          would not do justice to the measure. So, we do  
11          have that very long followup time.

12                   MEMBER KAPLAN: Can I just follow that  
13          up real quickly? This light test/retest  
14          reliability, where if you don't choose the right  
15          interval, true scores can vary because you  
16          measure somebody at one point, and then, they  
17          walk in front of a bus. And you measure them  
18          three weeks later, and their health looks really  
19          different.

20                   But this is the exact same problem  
21          with attribution. If you let the interval go too  
22          long -- and this is a content thing, so I am

1 talking way out of my depth here -- but if you  
2 let it go too long, there are lots of things that  
3 happen around the quality of care in between or  
4 that can happen to really move that score, rather  
5 than the attribution.

6 So, what is the attribution? What is  
7 the source of the attribution on this measure?  
8 Is it the baseline surgical procedure or?

9 MS. PITZEN: This is Collette. Is it  
10 okay if I jump in when I think the question is  
11 being directed to me?

12 CO-CHAIR PARTRIDGE: Yes.

13 MS. PITZEN: The attribution is to the  
14 surgeon who performed the procedure and thereby  
15 his practice.

16 MEMBER LOEB: Back to when someone had  
17 asked, you know, are you basing this on whether  
18 there was therapy or something, and what Lee had  
19 said is, are we using this ultimately to look at  
20 overuse?

21 As someone who took care of post-op  
22 total knee replacements, I think if this

1 ultimately is going to be used for someone  
2 looking to see, is there improvement by having  
3 this done, should I have this done, I think it is  
4 really important to know whether or not someone  
5 had therapy, because there is a huge difference.  
6 I mean, if you don't go for therapy after your  
7 knee replacement, you are probably worse off than  
8 before your knee replacement. So, I think that  
9 is one thing that is really missing.

10 So, this is definitely just a really  
11 broad, generalized -- and I am not sure how much  
12 17 points on a scale of 48, if that shows much  
13 improvement. You know, going through a major  
14 surgery like that, I would want a lot more  
15 improvement. That's not even 50 percent. Just a  
16 thought.

17 MEMBER BIERNER: May I say something?  
18 I am just looking online. There is a large study  
19 of over 3,000 patients using the same Oxford Knee  
20 Score, and the standard deviation for the mean  
21 score was 8. So, you are talking about a two-  
22 standard-deviation difference. And so, that is

1 potentially very significant, a 16-point  
2 difference. And they were looking at the  
3 difference among surgeons and how many operations  
4 per year each surgeon performed who does this  
5 operation.

6 So, I think this is measure is useful  
7 because the standard of care is knee arthroplasty  
8 for persons with end-stage degenerative arthritis  
9 of the knee. And so, there are not a lot of  
10 other treatment options one is going to be  
11 looking at. One really looks at is how well done  
12 was your knee surgery versus someone else and how  
13 good your functional outcome is at one year. In  
14 this study of 3,000 patients they used six months  
15 and two years. So, it is not unreasonable to use  
16 a one-year point.

17 CO-CHAIR PARTRIDGE: Becky? Peter?

18 MEMBER THOMAS: I am not a clinical  
19 person, but I do know a fair amount about joint  
20 replacements and policy around them and rehab  
21 potential. And so, Sherrie's comment about rehab  
22 certainly struck a chord with me.



1                   But the question I have is under  
2                   threats to validity in terms of the risk  
3                   adjustment. I am also aware that many joint  
4                   replacement patients have no comorbid conditions  
5                   and some have major multiple complications and  
6                   comorbidities. I am just wondering, there are no  
7                   exclusions in the denominator and I am just  
8                   trying to search for how you might have  
9                   accommodated that in the risk-adjustment  
10                  methodology.

11                  MS. PITZEN: This is Collette from  
12                  Community Measurement.

13                  I can appreciate that. There is a  
14                  couple of different things for consideration.

15                  Originally, the Work Group talked  
16                  about upfront exclusions, keeping in mind the  
17                  overall incidence of all those, particularly like  
18                  a typical exclusion is death, a very small  
19                  percentage in this population. And the actually  
20                  denominator for the measure are those patients  
21                  that had a pre- and post-operative assessment.  
22                  So, patients who died during the assessment

1 period are not included in the measure. So, that  
2 was part of their thinking about initially no  
3 upfront exclusions.

4 But we have several data elements  
5 that, when we have more data, when we have more  
6 patients, we plan to run these data through our  
7 risk-adjustment models, and those elements are  
8 included in the documentation. I will share them  
9 with you now. Age, gender, zip, race/ethnicity,  
10 country of origin, primary language, insurance  
11 product as a proxy for socioeconomic status.

12 In addition, part of our Development  
13 Work Group discussion is other clinical variables  
14 that are felt to be important. For this  
15 population, we also plan to include the pre-  
16 operative functional status Oxford Knee Score.  
17 We are actually collecting some quality-of-life  
18 data that is not part of this particular measure  
19 construct, but can be used in quality of life.  
20 So, we have those pre-operative scores.

21 We are also looking at the patients'  
22 BMI, the diagnosis of diabetes, and tobacco use

1 of the patient. So, our plan is to put all of  
2 those variables through our risk-adjustment model  
3 to determine which are relevant variables to use  
4 going forward.

5 Oh, and I just wanted to mention, too,  
6 the denominator does include primary knee  
7 replacement and revision knee replacement. We  
8 are collecting and reporting data on both of  
9 those procedure types, but they are not reported  
10 together. They are reported separately.

11 MEMBER THOMAS: So, a quick followup.  
12 For the physicians or clinical people in the  
13 room, is that sufficient to risk-adjust those  
14 with major multiple comorbidities or  
15 complications or not?

16 MEMBER BIERNER: Yes, I think so.  
17 Because Body Mass Index is a known negative  
18 predictor. The surgical deaths after total knee  
19 arthroplasty are going to be related a lot to  
20 those comorbidities. And so, they are not  
21 captured --- you know, those who die during the  
22 period would not be included in this study. But

1 I think those are useful ones.

2 CO-CHAIR PARTRIDGE: I don't want to  
3 cut off discussion if it on importance. If it is  
4 related to reliability and validity, I would like  
5 to hold.

6 So, Carin, Dawn, and Ann. Yes? Go  
7 ahead.

8 MEMBER MONROE: If I am understanding  
9 you, this is a measure of a surgeon about how  
10 well his folks are doing a year later. Is that  
11 correct?

12 MS. PITZEN: That is correct.

13 MEMBER MONROE: But you are not  
14 looking at anything that happened between the  
15 surgery and the measure a year later. Is that  
16 correct?

17 MS. PITZEN: This is Collette. Let me  
18 clarify.

19 So, you are asking me if we are  
20 collecting process measures associated with  
21 particular things that were done to the patient.  
22 And my answer to that is no. But I also wanted

1 to qualify it with a philosophy that we have in  
2 Minnesota. As we go forward with our  
3 transparency and public reporting, we start  
4 getting into identifying best practices among the  
5 different participants in the measure.

6 I frequently get calls on our  
7 depression measure; you know, what is Mayo Clinic  
8 doing? Their rates are fabulous. We would like  
9 to connect with someone there to understand how  
10 they are achieving excellence. So, we do have  
11 that philosophy.

12 MEMBER MONROE: Well, I would  
13 appreciate that, but I would think you are losing  
14 some opportunity here with this measure to really  
15 identify what might have made a difference.  
16 Because to hold a surgeon accountable -- I have  
17 had two knee replacements in the last year -- and  
18 if I hold my surgeon accountable for what I am  
19 doing a year from then, that's a pretty long  
20 period of time, whether I had rehab or not,  
21 whether I followed instructions, whether I even  
22 had rehab at home or went to a facility.

1           To me, there is so much that could  
2   happen in that year, that to hold a surgeon  
3   accountable for that seems both a missed  
4   opportunity and perhaps a misassignment of  
5   responsibility. That's just my comment.

6           CO-CHAIR PARTRIDGE: Any other  
7   questions on importance before we vote? Deb?

8           MEMBER SALIBA: So, I do want to speak  
9   to the idea, however, that surgeons should be  
10   held accountable for outcomes beyond hospital  
11   discharge. I mean, my husband had a knee  
12   replacement this year, too. And I would be  
13   telling the surgeon, "Well, aren't you going to  
14   send him for rehab?" when he was sending him  
15   home.

16           And I think there is a patient  
17   activation model that really involves the  
18   physician being part of that activity. So, one  
19   year may be too long, but I think there is  
20   something to be said for starting to think less  
21   about just the surgical episode and more about  
22   that surgeon is responsible for interacting with

1 the healthcare team. If rehab is not going well,  
2 figuring out why rehab is not going well, and  
3 sort of more than just being the procedural list.

4 If they are sort of the leader of that  
5 team of persons taking care of that knee  
6 replacement, which the way the system is set up  
7 right now, they are the lead of that team to a  
8 large extent. I mean, they are the ones that are  
9 interacting with rehab and with the physical  
10 therapists and are not in most cases.

11 But, anyway, I just want to put in a  
12 plug, as you think about how to modify this  
13 measure, that we really do want to start to  
14 encourage more long-term outcomes. Maybe a year  
15 is too long, but, yes.

16 MEMBER LOEB: I am just going to jump  
17 in really quick. I think you said the perfect  
18 word in "team." I mean, this is not just a  
19 surgeon. This is not just the patient. This is  
20 a team. And a surgeon can't have dynamic  
21 outcomes without the patient working with him,  
22 and the patient can't have dynamic outcomes

1 without a good surgeon. So, it needs to be a  
2 team with every single one of these measures that  
3 are measuring the outcome of the procedure. So,  
4 I mean, that word's vital.

5 MEMBER MONROE: I have just one other  
6 point.

7 CO-CHAIR PARTRIDGE: Ann, go ahead.

8 MEMBER MONROE: Were patients involved  
9 in looking at whether or not this was a useful  
10 measure for them?

11 MS. PITZEN: Yes, they were. They are  
12 part of our Measure Development Work Group.

13 CO-CHAIR PARTRIDGE: Thank you.

14 All right. Are we ready? Nadine?

15 MS. ALLEN: We are voting on evidence.  
16 The rationale supports the relationship of the  
17 health outcome to at least one of healthcare  
18 structure, process, intervention, or service.

19 One, yes; two, no. The voting starts  
20 now.

21 (Voting.)

22 All votes are in. Eighty-four



1 percent, yes; 16 percent no.

2 Voting on performance gap. One, high;  
3 two, moderate; three, low; four, insufficient.

4 (Voting.)

5 All votes are in. Sixteen percent,  
6 high; 63 percent, moderate; 16 percent, low; 5  
7 percent, insufficient.

8 Voting on high priority. One, high;  
9 two, moderate; three, low; four, insufficient.

10 Voting starts now.

11 (Voting.)

12 All votes are in. Forty-two percent,  
13 high; 47 percent, moderate; 11 percent, low; zero  
14 percent, insufficient.

15 CO-CHAIR PARTRIDGE: On to reliability  
16 and validity.

17 MEMBER DOWDING: Okay. Correct me if  
18 I am wrong, but the data that you have provided  
19 for the reliability and validity of this measure  
20 is actually taken from the original study that  
21 developed the Oxford Knee Scale in 1998 that  
22 looked at the reliability and validity of the

1 scale.

2 And we don't actually have any data  
3 from your pilot study to show that the measure,  
4 which is the difference between pre-op and post-  
5 op one year is reliable and valid in its use in  
6 Minnesota. Is that correct or have I read it  
7 wrong?

8 I have been through this form about  
9 four times trying to find some description of the  
10 patients that it was used on, some response  
11 rates, how many people actually filled in the  
12 form pre- or post-op one year, what their makeup  
13 is in terms of population, what age they are,  
14 gender, ethnicity.

15 And I can't find any data at all on  
16 that, and I can't find any data related to the  
17 pilot study to do with reliability and validity,  
18 just the original scale development data from  
19 1998. And being British, I can guarantee it was  
20 probably British patients in Oxford that filled  
21 it out. And I am not necessarily sure they are  
22 the same as people in Minnesota.

1 MS. LARSON: And so, this is Jasmine  
2 at Minnesota Community Measurement.

3 When it comes to reliability testing  
4 of the performance score measure itself, the  
5 nature of the problem is that it is a new type of  
6 measure, and there isn't a traditional  
7 numerator/denominator. And it is a continuous  
8 measure based on an eligible patient population.

9 And we worked with NQF staff to try to  
10 identify the appropriate testing for reliability  
11 at the performance score level. To our  
12 knowledge, the appropriate methodology to be  
13 applied in this type of scenario has not been  
14 established or performed by NQF or other measure  
15 developers of measures of this nature. So we  
16 don't know that the measurement science has  
17 evolved to the point of determining the  
18 appropriate methodology for testing reliability  
19 at the performance score level.

20 MS. SAMPSEL: And so, this is Sarah,  
21 and I just want to kind of talk through exactly  
22 how we have been working with Minnesota Community

1 Measurement as well as other developers that will  
2 be presenting over these two days.

3 We had identified, with Jasmine and  
4 Collette a couple of weeks ago that, while we  
5 were doing the measure reviews, that the measure  
6 level reliability scores were not there. They  
7 identified that as well.

8 And we were looking at kind of other  
9 potential examples within the NQF portfolio, and  
10 we found one, but we didn't share that back with  
11 the developers because we wanted to have this  
12 conversation with you all first, and kind of how  
13 we did with the last time, once we have some  
14 clear direction to the developers, give them the  
15 opportunity to provide that data.

16 And I don't know, Sherrie, if you have  
17 other examples. But the one that we found was  
18 actually some testing that Yale had done. I  
19 don't think it was an admission measure. I think  
20 it was a mortality measure. But they had done  
21 some testing on interclass correlations. We  
22 thought that might be a good fit, but we weren't

1       sure, which is why we wanted to make sure this  
2       Committee had the discussion that we can give  
3       them clear direction on what to do.

4               CO-CHAIR PARTRIDGE:   Sherrie?

5               MEMBER KAPLAN:   Yes.   First of all,  
6       there are ways.   And usually, what we do is the  
7       interclass correlations will tell you how much  
8       between subject reliability versus within subject  
9       reliability there is.   If you are going up to the  
10      physician level, you are dragging along the  
11      patient-level errors of measurement and you are  
12      creating a composite, then, at the physician  
13      level.

14              What you would then do is look at  
15      interclass correlation coefficients for between  
16      versus within physician-level variability.   And  
17      there are ways to accommodate both errors, and  
18      there is a thing called the Spearman-Brown  
19      prophecy formula.   It sounds really spooky, but  
20      it is not.   It is how many measures at the  
21      patient level do you need to aggregate and create  
22      a composite at the physician level that will give

1       you a certain level of precision.

2               So, there are certainly ways to do  
3       this. And interclass correlation coefficients  
4       would be the most reasonable in this  
5       circumstance. That is what we asked of the  
6       earlier measures developers as well, to give us a  
7       sense of the interclass correlation coefficients  
8       and the magnitudes.

9               So, can you discriminate and, if not,  
10       you certainly can't, almost never, discriminate  
11       one physician from another. But are you trying  
12       to discriminate the tails of the distribution  
13       from each other? Are you trying to discriminate  
14       a benchmark? It kind of depends on what the  
15       measure is ultimately going to be used for.

16               MEMBER DOWDING: And I also think just  
17       in general just some idea of the patient  
18       population that this was piloted on would be  
19       helpful and some indication of what the response  
20       rate was in terms of pre- and post-operatively.  
21       Is it 50 percent? Is it 70 percent? How  
22       representative of the patients? If they are

1       filling it in themselves, is it in other  
2       languages? Disparity information? Just some  
3       idea of the sample on which it was tested on.

4               We have some idea about the practices  
5       and how many operations they did, but no insight  
6       into the patients who were in the piloting. And  
7       that would be very helpful information.

8               MS. PITZEN: Great. This is Collette  
9       at Community Measurement.

10              We actually had two phases of pilots,  
11       so my apology. I have some demographics on the  
12       first phase of our primary knee replacement  
13       patients, and I would be happy to share that with  
14       you.

15              The first phase of the pilot had 1100  
16       patients in them. The majority of those were  
17       primary knee replacements, 92 percent. Our  
18       population was a little bit higher on the female  
19       side, with 59 percent female, 41 percent male.  
20       The average age was 64.7 years, with an age range  
21       between 36 and 93 years.

22              We also are collecting the location

1 where the procedure is happening. We have some  
2 movement to total knee replacement in the  
3 ambulatory care setting as well, and that  
4 reflected about 18 percent of our patient  
5 population.

6 In terms of race/ethnicity, we had  
7 fairly good capture of that data element from our  
8 pilot participants. About 91 percent were able  
9 to report race/ethnicity, and 95 percent of the  
10 patients were White.

11 Not as great capture in country of  
12 origin. However, primary language was captured  
13 almost 100 percent. And again, we have a very  
14 high English-speaking population.

15 I have some additional statistics  
16 around the risk-adjustment variables. Tobacco-  
17 free was about 87 percent. So, that would be  
18 about 23 percent smokers -- or, I'm sorry, 10  
19 percent smokers.

20 We have a 14-percent incidence of  
21 diabetes mellitus in the pilot participants.

22 And for this particular measure -- and



1 I want to qualify difference than our lumbar  
2 spine measure experience -- we did have some  
3 difficulty with the PRO tool administration  
4 rates. And we are choosing a phased approach to  
5 try to get those PRO tool administration rates  
6 up, so that we are able to report the outcomes.

7 CO-CHAIR PARTRIDGE: Are we ready to  
8 vote?

9 MEMBER KAPLAN: Can I ask one more  
10 question from the NQF staff? And this is not  
11 necessarily for this measure, but for all  
12 measures. Is it not reasonable to at least ask  
13 at the patient level what the standard error of  
14 measurement is? Standard error of measurement is  
15 the standard deviation times 1, minus the  
16 reliability.

17 So, with a very reliable measure, you  
18 get almost the standard deviation. With a less  
19 reliable measure, you get it amplified. So,  
20 distinguishing scores is going to be helped if  
21 the measures developers can provide that  
22 information. And certainly, even better, the

1 unit of inference that we are trying to draw,  
2 like the surgeon versus the patient versus the  
3 clinic.

4 MS. SAMPSEL: Yes, I mean, that is  
5 definitely reasonable, and I think there are  
6 times when -- I don't know if we err where we go  
7 on the side of caution to some degree, where we  
8 throw out some possible things and datapoints  
9 that could be provided to us.

10 And I think some of the measures that  
11 we have encountered in this project are helping  
12 us learn, too. So that I think that we could be  
13 more prescriptive in the future from this went  
14 forward with the measure developers for these  
15 types of measures, yes.

16 MS. LARSON: This is Jasmine at  
17 Minnesota Community Measurement, if I could just  
18 comment that I don't know that this is  
19 necessarily what was asked previously regarding  
20 the standard deviation and the effect size, but I  
21 was able to calculate the standard deviation at  
22 the reported entity level of 4.22 for this

1 measure. But it is not at the patient level, but  
2 4.22 for average change at the medical group  
3 level.

4 CO-CHAIR PARTRIDGE: Okay. Ready to  
5 vote?

6 MS. ALLEN: Voting on reliability.

7 One, high; two, moderate; three, low;  
8 four, insufficient. The voting starts now.

9 (Voting.)

10 All votes are in. Zero percent, high;  
11 47 percent, moderate; 16 percent, low; 37  
12 percent, insufficient.

13 Voting on validity.

14 One, high; two, moderate; three, low;  
15 four, insufficient information. The voting  
16 starts now.

17 (Voting.)

18 All votes are in. Five percent, high;  
19 37 percent, moderate; 26 percent, low; 32  
20 percent, insufficient information.

21 CO-CHAIR PARTRIDGE: Discussion on  
22 feasibility.

1                   MEMBER DOWDING: I wonder if you could  
2 just clarify for us. I think you have alluded to  
3 it a couple of times, that you have actually had  
4 difficulty with this measure, getting patients to  
5 fill it in and send it back. Am I right? I  
6 think you have mentioned that a couple of times.

7                   So, could you just talk us through how  
8 it is administered and how you would treat the  
9 data, so we can get some idea of how feasible it  
10 would be to collect routinely.

11                  MS. PITZEN: Sure. This is Collette  
12 again.

13                  As part of our pilot-testing process,  
14 we are doing full measure specifications and,  
15 also, field data element specifications for the  
16 information that is needed to calculate the  
17 measures.

18                  For this particular measure, we are  
19 asking for a pre-operative OKS summary score.  
20 The tool is simple to sum and score. There is  
21 not a complicated algorithm or formula that needs  
22 to be applied.

1           We have a process in Minnesota called  
2       direct data submission where the practices submit  
3       through a HIPAA-secured data portal, patient-  
4       level information that is needed to calculate  
5       these measures. And the data dictionary, which  
6       was quite extensive, was provided.

7           During our pilot process testing, we  
8       also are constantly working with the group in  
9       terms of questions and answers, but when we are  
10      completing the pilot, we are serving them for  
11      burden. And actually, measurement is new to the  
12      orthopedic practices. Unlike primary care, which  
13      has been accustomed to measuring and collecting  
14      data for quite some time, it is new in the  
15      orthopedic world.

16          There are a couple of different EMR  
17      systems that these practices use. And groups  
18      were successful in building retrievable or  
19      discrete fields within their EMR to capture this  
20      information and extract it back out.

21          And in fact, the groups, when they  
22      were rating things that were challenging for

1       them, rated the actual EMR build and store of  
2       this information as less challenging than getting  
3       the patient-report tools into their workflows.

4               So, if I could just briefly jump ahead  
5       a little bit to the lumbar spine measure, the  
6       Oxford Knee Score tool was used by a couple of  
7       groups in our State. Nobody was routinely using  
8       anything. So, it was a newer tool to be  
9       implemented into clinical workflows. And we did  
10      see that with lower than we would like pre-  
11      operative administrative rates of the Oxford  
12      Knee.

13              You have a captive population. You  
14      would hope that you would be building that into  
15      your pre-operative paperwork and workflow process  
16      to administer that tool as you are assessing the  
17      patient and planning for their surgery.

18              So, our pre-operative rates on average  
19      were less than 40 percent right. Some of them,  
20      some groups were performing at a very high rate,  
21      but on average it was about 40 percent.

22              And then, as they gained acceptance

1 and ease and familiarity with this process, we  
2 actually saw many groups that had a lower  
3 preoperative Oxford Knee Score rate, actually,  
4 their postoperative rate was higher than their  
5 preop. So, we are seeing this gradual  
6 implementation of these tools into the clinical  
7 workflow process.

8 So, our Measurement and Reporting  
9 Committee, which is our approval body for  
10 everything that we are publicly reporting,  
11 approved a plan to publicly report the process  
12 measures that go along with this for tool  
13 administration. And we have actually published  
14 that on Minnesota Health Scores. So, we are  
15 hoping to be in a place where we can publish the  
16 outcome scores in the next submission year.

17 Does that help answer your questions?

18 MEMBER DOWDING: Yes, for the pre-op,  
19 but post-operatively how were they filled out and  
20 what is the completion rate in terms of the  
21 percentage of patients who have both measures?

22 MS. PITZEN: Sure, sure. And in part

1 of our Work Group development process was the  
2 surgeons on the Work Group were seeing about 70  
3 percent of their patients routinely at one year.  
4 So, we are were kind of shooting or hoping. We  
5 would never expect 100 percent post-operative  
6 capture of patients.

7 So, that the data can be collected in  
8 a variety of different ways. We had several  
9 groups that would, if they weren't seeing the  
10 patient in clinic in that timeframe, they would  
11 mail out the questionnaire to the patient and  
12 have that returned or pushed out by their patient  
13 portal or EMR, and have that returned.

14 So, again, on average, for this --  
15 again, we are pilot testing -- for this measure,  
16 on average, we had a post-op rate of around 31  
17 percent, but some variability, with some groups  
18 achieving close to that 70 percent mark post-  
19 operatively.

20 So, because our pre-op rates were so  
21 low, the rate of having the denominator of pre-  
22 and post-operative gave us information that we



1       couldn't work with right away.

2                   CO-CHAIR PARTRIDGE:   Any further  
3       comments, questions?

4                   Are you ready to vote on feasibility?

5                   MS. ALLEN:   Voting on feasibility.

6                   One, high; two, moderate; three, low;  
7       four, insufficient.

8                   Voting starts now.

9                   (Voting.)

10                   Please point your clicker towards me.  
11       Please try again.

12                   It is probably frozen.   One second.  
13       Experiencing some technical difficulty.

14                   CO-CHAIR PARTRIDGE:   Collette and  
15       Jasmine, our vote register isn't working at the  
16       moment.   That is the silence.

17                   MS. LARSON:   Okay.   Well, Collette,  
18       you know, is a member of the Surgery Committee  
19       Standing Committee.   So, I think she is familiar  
20       with the technical hiccups that can happen during  
21       these meetings.

22                   CO-CHAIR PARTRIDGE:   Yes.   Go ahead.

1           MEMBER BRADLEY: I guess it just kind  
2 of occurred to me that, if we are really  
3 measuring the physicians -- and there was some  
4 reference to the physician does some screening  
5 prior to surgery to assess for appropriateness of  
6 the patient for surgery. So, there is some kind  
7 of risk adjustment that the surgeon does on the  
8 front-end that is not reflected here.

9           But was there ever any discussion  
10 that, because this is physician-reported  
11 outcomes, that they may, again, game the system  
12 by selecting patients that have the highest  
13 potential for outcomes, and then, patients who  
14 need this surgery, but perhaps have comorbidities  
15 or have other issues may not be eligible for  
16 surgeries from some physicians because they are  
17 trying to get their scores up?

18           MS. PITZEN: This is Collette. I  
19 would be happy to answer that question.

20           Actually, our Measure Development Work  
21 Group did also explore developing appropriateness  
22 criteria. And currently, there are no national

1 society guidelines for appropriateness criteria  
2 for knee replacement. The guidelines actually  
3 intentionally stop at that point. We had that  
4 discussion and we could not come to consensus or  
5 a resolution about appropriateness as a measure.

6 But I just wanted to share that we are  
7 collecting that preoperative functional status  
8 score, and that there is a plan to evaluate that  
9 for risk adjustment. So, we are not setting --  
10 you have to at least an OKS score of such to be  
11 in the measure. We are taking all patients.

12 In terms of gaming, again, I want to  
13 explain our process here as well. We are -- and  
14 it is state mandated by law -- we are collecting  
15 the data on all patients. Regardless of if they  
16 had an assessment or both assessments completed,  
17 we are collecting the information on all  
18 patients.

19 And if there is a low percentage of  
20 tool administration, one, we can't reliably  
21 report outcome measures, but that was one way to  
22 address potential gaming.

1 CO-CHAIR PARTRIDGE: Thank you.

2 I think we are going to switch to low-  
3 tech, so we can complete this measure.

4 So, let's use a hand vote, beginning  
5 on feasibility.

6 And in favor of high?

7 (Show of hands)

8 Okay. Moderate?

9 (Show of hands)

10 MS. THEBERGE: All right. Keep them  
11 up for a minute longer.

12 MS. ALLEN: Okay. Low?

13 (Show of hands)

14 And insufficient?

15 (Show of hands)

16 MS. THEBERGE: One high; 15 moderate;  
17 two low, and one insufficient.

18 CO-CHAIR PARTRIDGE: Any other  
19 questions?

20 CO-CHAIR STILLE: I guess just going  
21 back to the spread in differences between groups,  
22 which we were wondering what the effect size was

1 and whether that was clinically meaningful. And  
2 then, I think the measure developer said that the  
3 standard deviation was about four.

4 So, if that is the case, you know, we  
5 have got the difference between 14 point  
6 something and 17 point something, and the  
7 standard deviation of four. I wonder how usable  
8 it will be to discriminate between groups, if I  
9 have my numbers right and if that is my  
10 interpretation of what their numbers were.

11 CO-CHAIR PARTRIDGE: Collette, do you  
12 want to respond to whether or not -- whether  
13 Chris has understood you correctly?

14 MS. LARSON: This is Jasmine actually.  
15 And yes, it was -- the standard deviation was  
16 around four. And his point regarding the  
17 difference between 14 and change and 17 and  
18 change is well-taken.

19 However, there is more spread in the  
20 actual medical group that fall outside of the  
21 standard deviation range that would allow for  
22 classification. I am trying to pull that up

1 right now. So, just bear with me.

2 MEMBER KAPLAN: Can I ask a question?

3 I understood that there was no estimation of  
4 reliability at the physician level. Is that  
5 correct? Right now, they don't have anything for  
6 us to put in, so we can't understand what the  
7 magnitude of the standard error of measurement  
8 is. So, even if we knew the standard deviation  
9 is 4.22, for example, you would multiply that  
10 times the square root of the difference between  
11 one minus the reliability.

12 So, if we have low reliability, then  
13 we get a bigger spread, and it is less  
14 interpretative. Then you are pushing the  
15 extremes before you get meaningful differences.  
16 If we have high reliability at the physician  
17 level then we get four. So, the smallest  
18 difference we are looking for here is four for  
19 the standard error of measurement. So, two-point  
20 differences are probably within the standard  
21 error of measurement, which would be a little bit  
22 disconcerting.

1 MS. LARSON: Are you looking for me to  
2 respond? This is Community Measurement.

3 CO-CHAIR PARTRIDGE: Jasmine, yes, if  
4 you would like.

5 MS. LARSON: Yes. So, I again take  
6 that point well. And I hope, with the additional  
7 information that has been shared in this call,  
8 that we will be provided the opportunity to run  
9 the methods that were described here, because I  
10 am confident that we have the information to be  
11 able to do that and provide that additional  
12 detail for consideration.

13 CO-CHAIR PARTRIDGE: Jasmine, I think  
14 that would be very helpful to all of us, and  
15 there is a little time. I think NQF staff will  
16 get back and talk with you about that in more  
17 detail.

18 So, vote on usability.

19 MS. ALLEN: Voting on usability.

20 One, high; two, moderate; three, low;  
21 four, insufficient information. The voting  
22 starts now.

1 (Voting)

2 All votes are in. Zero percent high;  
3 63 percent, moderate; 26 percent, low; 11  
4 percent, insufficient information.

5 Voting on overall suitability for  
6 endorsement of Measure 2653, average change in  
7 functional status following total knee  
8 replacement surgery.

9 The voting starts now. One, yes; two,  
10 no.

11 (Voting)

12 All votes are in. Fifty-eight  
13 percent, yes; 42 percent, no.

14 MEMBER KAPLAN: I have a question for  
15 the NQF staff. If this isn't provisional, there  
16 should be a third category, which is no pending  
17 results or something like that, or, yes, pending  
18 results. Is there no opportunity -- this  
19 dichotomy is making me feel real uncomfortable.

20 MS. SAMPSEL: So, what will happen is  
21 -- there are a number of criteria here that fell  
22 in the gray zone. So, we would work with



1 Minnesota Community Measurement staff to have the  
2 opportunity to bring back information before the  
3 end of public comment. And so, you will  
4 reconsider the measure at your post-public-  
5 comment call and also be able to consider any  
6 public comment that comes in, and you will  
7 revote.

8 CO-CHAIR PARTRIDGE: Okay. Thank you  
9 very much, Minnesota team.

10 MS. LARSON: Thank you.

11 CO-CHAIR PARTRIDGE: I am just looking  
12 ahead, and I see it is the next item on the  
13 agenda because the intermediate item dropped out.

14 So, should we proceed to 2643 while  
15 you are on the line? And let's see who has the  
16 lead. It is Dawn and Sherrie. Okay, whichever  
17 one of you wants to lead off.

18 MEMBER DOWDING: Okay, it looks like  
19 it is me again.

20 And basically, I have exactly the same  
21 comments as for the last measure for this  
22 measure. Do you want the developer to talk

1 first?

2 CO-CHAIR PARTRIDGE: I apologize, I  
3 mixed up.

4 Liz is the other on this one.

5 MEMBER MORT: I will be happy to give  
6 it a whirl to start. Oh, was Minnesota going to  
7 say something first about this measure?

8 MS. SAMPSEL: Collette and Jasmine,  
9 did you have anything you wanted to say to  
10 introduce this one?

11 MS. PITZEN: Yes, please. This is  
12 Collette and Jasmine again.

13 Our second measure is 2643, the  
14 Average Change in Functional Status Following  
15 Lumbar Spine Fusion Surgery.

16 In terms of measure construct, there  
17 are many similarities to the total knee measure.  
18 In fact, both of these Work Groups started their  
19 development work at the same time and actually  
20 came to some of the same measurement decisions.

21 This is a PRO-based outcome measure  
22 evaluating the change between a patient's

1 preoperative functional status and their  
2 postoperational functional status at one year.  
3 The initial patient population is adult patients  
4 age 18 and older with no upper age limit who  
5 undergo a lumbar fusion procedure at any level or  
6 number of levels, including the lumbar  
7 vertebrae, during the calendar year.

8           The measure focuses orthopedic and  
9 neurosurgery practices, and the procedures are  
10 identified using CPT codes. Exclusions for this  
11 measure are cancer, fracture, and infection  
12 related to the spine and idiopathic or congenital  
13 scoliosis.

14           The PRO tool that is used is the  
15 Oswestry Disability Index, Version 2.1a, a 10-  
16 question tool that quantifies functional ability  
17 related to low back pain. The Oswestry  
18 Disability Index, otherwise known as the ODI, is  
19 used widely in clinical practice and research,  
20 has strong psychometric properties, and is  
21 considered the gold standard for assessing low  
22 back pain. The tool is scored to reflect a

1 percent disability where a higher percent  
2 indicates more impairment in function.

3 We like to remain aligned across  
4 measures where it makes sense clinically to do  
5 so. And this measure construct aligns with the  
6 total knee measure presented previously.

7 Assessments are completely  
8 preoperatively any time within three months prior  
9 to the procedure and, again, postoperatively at  
10 one year, defined as nine to 15 months.

11 Because the measure is one of change  
12 between pre- and postop functions, the measure  
13 denominator is comprised of patients who have  
14 completed a pre- and postoperative ODI tool.

15 Again, in an effort to reduce gaming,  
16 the initial population that is submitted for  
17 calculation of outcomes and paired process  
18 measure includes all patients, regardless of if  
19 assessment tools are completed. Again, there is  
20 no numerator or target ODI score, and change is  
21 calculated as in the previous measure.

22 Interesting discussions during the

1 Measure Development Work Group: design and  
2 specification of this measure. Lumbar surgery is  
3 an effective procedure for many spine conditions,  
4 but may be controversial and less successful for  
5 some patients, particularly those with  
6 degenerative disk disease whose pain may not be  
7 originating from the disk.

8 Originally, the Work Group wanted to  
9 focus on one-level fusion for spondylolisthesis  
10 only where fusion is an appropriate procedure and  
11 patients do well. But, as there is a very narrow  
12 percentage of patients who have lumbar fusion  
13 procedures, the Work Group evolved to expanding  
14 the denominator to be more inclusive and are also  
15 collecting the condition for which the procedure  
16 is being performed in one of four categories:  
17 degenerative disk disease, disk herniation,  
18 spinal stenosis, and spondylolisthesis. These  
19 categories may be used for further analysis  
20 and/or included in variables in the risk-  
21 adjustment model.

22 Pilot results for the measure

1 demonstrate an average improvement in function of  
2 17.2 points on a 100-point scale and variability  
3 in results among the practices.

4 And thank you very much.

5 CO-CHAIR PARTRIDGE: Yes.

6 MEMBER MORT: Thank you very much for  
7 the summary.

8 I want to applaud you for tackling  
9 this controversial area in utilization of  
10 surgical procedures. In the writeup you pointed  
11 out, although you didn't put this in your  
12 comments just now, that there is a 15-fold  
13 increase in the number of complex fusion  
14 procedures performed for Medicare beneficiaries.

15 So, this is a highly variable  
16 procedure. It is on the rise. As you pointed  
17 out, as you politely implied, there is a lot of  
18 criticism currently of this procedure being done.  
19 I can understand why your Work Group wanted to  
20 focus it on the narrow indication of  
21 spondylolisthesis because the fusion makes a lot  
22 of sense mechanically. For those who don't know,

1 it just means that there is a lateral translation  
2 of one vertebra over the other and potentially  
3 it is unstable or could cause damage. So, I  
4 understand exactly what you are trying to do and  
5 I applaud it in terms of the importance.

6 Let me stop there and see if there are  
7 other comments from other folks.

8 (No response)

9 So, the question about gap coming  
10 under importance, what I would say is that there  
11 is a gap in something here. I am not sure it is  
12 a gap in performance as much as it is a gap in  
13 the quality of care being delivered. And this  
14 might be a tool and a process whereby we could  
15 have a better understanding of what patients and  
16 what indications actually benefit from this  
17 surgery, which is a big procedure. This is not a  
18 little thing. This is a big procedure.

19 So, in terms of the gap, I think there  
20 is obviously variation. So, you could imply that  
21 there is a gap in quality of care based on that.  
22 I am less clear about the gap in terms of

1 variability in performance based on the pilot  
2 data.

3 Can you say a little bit more about  
4 the variability in performance and your  
5 understanding about that element of importance?

6 MS. PITZEN: Sure. This is Collette.

7 This may sounds like an apology, but  
8 this measure has gone through one phase of pilot  
9 testing. We had the opportunity to bring it  
10 forward to NQF during this project.

11 We had four practices that were  
12 participating in the pilot. Again, this is in  
13 the Statewide Quality Reporting and Measurement  
14 System for Minnesota, required of practitioners.

15 We are expecting full implementation  
16 data to be coming in this spring. So, we will  
17 fairly quickly have much more data than we have  
18 available to us today.

19 I am just going to share one more  
20 thing. Unlike the total knee measure pilots that  
21 we did, there was a much higher rate of tool  
22 administration in the pilot participants. As



1 indicated earlier, these patients have been under  
2 intense scrutiny from health plans for prior  
3 authorization. The Oswestry Disability Index  
4 tool is oftentimes required to be administered  
5 and submitted to health plan preoperatively to  
6 confirm a need for the procedure.

7 So, we have administration rates that  
8 are approaching our desired standard in terms of  
9 having pre- and postoperative assessments. So,  
10 we do only have four practices that we were  
11 comparing the variability between.

12 MEMBER MORT: So, you expect more  
13 information along these lines as the pilots  
14 mature?

15 MS. PITZEN: Actually, full  
16 implementation of all practices in Minnesota.  
17 The data will be coming in in May.

18 MEMBER MORT: I would say that, in  
19 terms of importance and priority, getting a  
20 better handle on whether or not we are subjecting  
21 -- I don't mean to say it that way -- whether or  
22 not we are offering procedures to patients, a big

1 procedure for patients who may not do well at  
2 all, I think it is obviously a high priority.  
3 And this is more than just an outcome measure, as  
4 I see it. I think it is a tool to actually  
5 change practice, which is beyond the scope of  
6 what we are looking at here, but, nonetheless,  
7 raises in my mind the importance of the work.

8 Those are my only comments on  
9 importance really.

10 Dawn, did you have others?

11 MEMBER DOWDING: I didn't. I actually  
12 though this was a really important issue. I  
13 guess, given the response of the developers,  
14 there is a bit of me going, wouldn't it be better  
15 to review this measure when we had all the pilot,  
16 all the data, rather than trying to make  
17 decisions on the basis of all practices?

18 I would be much more comfortable and  
19 more excited about looking at data variation and  
20 things if it has gone to full implementation and  
21 they are going to have a lot of data that we  
22 could look at, which would be able to provide us

1 with good insights into variability in practice,  
2 reliability and validity of the measure, and  
3 really understand how it could be used to measure  
4 quality of care. I think that would be much  
5 better than this effectively saying it is really  
6 interesting and important, but we need more data,  
7 when we know they are going to get more data.

8 MEMBER MORT: I couldn't agree more  
9 because I think, if we get to the next piece, the  
10 issues around reliability and risk adjustment,  
11 great ideas, the fact they are capturing  
12 indication and collecting a number of very  
13 important comorbid issues, but it is too soon to  
14 say. The jury is out. So, some of these things  
15 are still, I think, just as Dawn said, too early  
16 in development to really weigh-in with a  
17 definitive vote.

18 MEMBER BIERNER: I have a couple of  
19 comments, and I fully recognize the importance of  
20 this particular set of diagnoses that undergo  
21 surgery.

22 My concern is that the Oswestry may

1 not be the best tool. It is primarily aimed at  
2 pain, but it doesn't capture other neurological  
3 dysfunction. And you mentioned the four groups,  
4 which includes spinal stenosis.

5 And some patients have impairment in  
6 bowel and bladder function or weakness that may  
7 relate to either postoperative complications that  
8 occur as a result of the procedure itself or due  
9 to the disease for which they were receiving the  
10 surgery.

11 What is your concern about that? I  
12 don't see -- I have used the Oswestry before, and  
13 it doesn't capture some of those areas very well.  
14 What are your thoughts about that?

15 MS. PITZEN: This is Collette.

16 Although we are not putting forth  
17 these measures, additionally, we are capturing  
18 quality-of-life scores. We have been working the  
19 EQ-5D and now are transitioning to PROMIS 10.  
20 So, those kinds of measures are being captured  
21 for this patient population as well as pain scale  
22 measures or leg and back pain pre- and

1 postoperatively. But those aren't part of the  
2 measure that we are presenting today.

3 MEMBER BIERNER: Yes, I realize it is  
4 not directly, but what I am saying is, this tool,  
5 what you want to do is use it to assess the rate  
6 of -- or one of the things it will be used for is  
7 the rate of surgery varies greatly across the  
8 country and in your region as well. And I don't  
9 feel like the tool captures adequately the  
10 potential side effects of the surgery itself.

11 MEMBER MORT: I would think that is a  
12 very important point for the developers to  
13 consider. In fact, neurologic complications may  
14 be what push a surgeon to offer the procedure.  
15 It may also be sort of an indication, something  
16 you want to hopefully address through the  
17 surgery, but you may not, in fact, fix the  
18 neurologic complications. Or it could be a  
19 complication related to the surgery.

20 So, I just looked at the ODI here, and  
21 it doesn't have numbness. It doesn't have  
22 weakness. So, those would be aspects of

1 functional status that, to do a more complete  
2 assessment, would be good to consider including.

3 MEMBER THOMAS: I just have one more  
4 question, kind of a clinical question. This  
5 measure does address spinal fusion, right, spinal  
6 fusion for those with --

7 MS. PITZEN: That is correct.

8 MEMBER THOMAS: So, the real question  
9 in terms of the potential harm and the real  
10 controversial nature of this, is that with  
11 respect to individuals with disk disease or is it  
12 just in general?

13 MS. PITZEN: This is Collette. Let me  
14 clarify.

15 Patients come into the denominator of  
16 the measure by virtue of having a fusion  
17 procedure, by very specific CPT codes, and are  
18 not associated with diagnoses or other reasons.  
19 So, we are taking kind of a wide swathe of  
20 patients that are having fusions. Then, we are  
21 delineating the reason why they are having the  
22 procedure.

1                   But the intent really was to, again,  
2                   not go so narrow as the Work Group originally  
3                   wanted, but to really start addressing all the  
4                   patients that are undergoing this procedure.

5                   MEMBER BIERNER: But I think that the  
6                   measure that you bring forward should include, as  
7                   we have said, some of these other measurements  
8                   from the patient that may impact the actual  
9                   success of the operation itself. And the  
10                  Oswestry is somewhat limited in that way. And so  
11                  it would be behoove your group, I think, to  
12                  revisit that issue because I think that that is a  
13                  flaw, as this is rolled out to a larger and  
14                  larger group.

15                  You had, I think, 16 orthopedic  
16                  surgeons in your sample, and I think half as many  
17                  neurosurgeons. But it is going to be rolled out  
18                  to a much larger group of people, and you have a  
19                  wider variety of skill sets or there can be  
20                  greater variability in the outcomes, as you roll  
21                  it out to a wider audience.

22                  MS. PITZEN: This is Collette.

1                   Can I respectfully disagree about the  
2                   Oswestry tool in terms of some of the  
3                   neurological conditions that were talked about?  
4                   I mean, those kinds of conditions would prevent a  
5                   patient from having full function.

6                   If you are suggesting other tools, we  
7                   would take those under consideration and share  
8                   that with the Measure Development Work Group.  
9                   But I guess I am not seeing the point where the  
10                  Oswestry doesn't deal with function.

11                  MEMBER BIERNER: The Oswestry is a  
12                  pain questionnaire. It was geared toward  
13                  assessing chronic back pain and doesn't always  
14                  capture functional deficits that are more  
15                  neurological in nature that could occur after  
16                  this particular surgery, which has been  
17                  associated in the literature with things like  
18                  loss of function in bowel or bladder or -- it  
19                  does have a question about sexual function.

20                  But I am just saying that I think it  
21                  could be, the measure that you are bringing  
22                  forward could be improved a little by adding in



1 -- and I haven't looked at the PROMIS 10 -- but  
2 some other questions that might speak to those  
3 more than just the 10 or 15 questions in the  
4 Oswestry.

5 MS. PITZEN: Thank you. I can  
6 appreciate that. So, your concern is around the  
7 neurological symptoms that would be presenting  
8 themselves without pain?

9 MEMBER BIERNER: That's right.

10 MS. PITZEN: Okay.

11 CO-CHAIR PARTRIDGE: Ready to vote?

12 MS. ALLEN: Voting on evidence, health  
13 outcome, or PRO.

14 One, yes; two, no. The voting starts  
15 now.

16 (Voting)

17 All votes are in. Ninety-five  
18 percent, yes; five percent, no.

19 Voting on performance gap.

20 One, high; two, moderate; three, low;  
21 four, insufficient. The voting starts now.

22 (Voting)

1 All votes are in. Thirty-two percent,  
2 high; 42 percent, moderate; zero percent, low; 26  
3 percent, insufficient.

4 Voting on high priority.

5 One, high; two, moderate; three, low;  
6 four insufficient. The voting starts now.

7 (Voting)

8 All votes are in. Sixty-eight  
9 percent, high; 32 percent, moderate; zero  
10 percent, low; zero percent, insufficient.

11 CO-CHAIR PARTRIDGE: Moving on to  
12 reliability, are there further comments? We have  
13 talked about this a little bit along the way.

14 MEMBER MORT: I will just make a few  
15 more comments.

16 I think the specifications look very  
17 clear and some of the additional comments about  
18 adding in the specific indication I think is  
19 right on target. The risk-adjustment  
20 specifications are listed, but it hasn't yet been  
21 modeled or done. So, I think there you have,  
22 along the same lines, it is a little bit too soon

1 to say.

2 And in terms of the reliability  
3 testing, the ODI has been around for a while. As  
4 a measure, apparently, it is -- I'm just looking  
5 for the comments here; it is in the notes very  
6 nicely stated. It behaves well from the  
7 perspective of reliability testing. However, the  
8 score level, that is the change in the score pre-  
9 and post-surgery, again, has not yet been subject  
10 to scrutiny. So, again, the same theme there.

11 There was a problem raised in the  
12 writeup about being able to get the proper  
13 denominator as well. So, that was something else  
14 that I thought was important. In other words,  
15 knowing patients who didn't necessarily complete  
16 all of the questionnaires, this is probably more  
17 on the feasibility side, but you have patients  
18 who underwent the surgery, but weren't  
19 necessarily involved in actually completing all  
20 the questionnaires.

21 Those were my comments.

22 CO-CHAIR PARTRIDGE: Sherrie Kaplan?

1                   MEMBER DOWDING: I mean, I guess my  
2 concern is the same as the last measure, in that  
3 we don't actually have any score-level  
4 reliability testing data. We might be better  
5 waiting until they have the full dataset.

6                   MEMBER KAPLAN: Yes, the reliability  
7 that I am looking at is that the ICCs are patient  
8 level, not practice level, because there are only  
9 four practices, correct?

10                   And the developer hasn't done  
11 practice-level reliability testing yet, right?

12                   MS. LARSON: This is Jasmine.

13                   That is correct. You know, similar to  
14 the knee measure we just reviewed, we are happy  
15 to submit testing based on the information  
16 learned today.

17                   CO-CHAIR PARTRIDGE: Okay. Are we  
18 ready to vote?

19                   MS. ALLEN: Voting on reliability.

20                   One, high; two, moderate; three, low;  
21 four, insufficient information. The voting  
22 starts now.

1 (Voting)

2 All votes are in. Zero percent, high;  
3 32 percent, moderate; 21 percent, low; 47  
4 percent, insufficient information.

5 MS. SAMPSEL: Okay. So, this is where  
6 we would stop. But I think, as we did similar  
7 with the measures earlier this morning, if there  
8 were any additional comments or feedback for the  
9 developers regarding what can be done  
10 differently, I think we have already had some  
11 discussion about that.

12 But, you know, talking further through  
13 validity, feasibility, and usability, if there is  
14 any additional guidance to the developers, they  
15 will have the opportunity to bring data back to  
16 us.

17 MS. LARSON: I'm sorry, this is  
18 Jasmine at Community Measurement.

19 May I ask just a process question?

20 CO-CHAIR PARTRIDGE: Yes.

21 MS. LARSON: It seemed to me that the  
22 group continued through voting on all of the

1 other criteria for the knee measure, even after  
2 failing the reliability criteria, understanding  
3 that additional information would be forthcoming.

4 So, I guess I was wondering why that  
5 conversation was not going to continue for this  
6 spine measure.

7 MS. SAMPSEL: Actually, the votes were  
8 different. With reliability, for the knee  
9 measure, the votes fell into the gray zone, which  
10 means we do continue moving forward. In this  
11 case, you have 68 percent in low or insufficient,  
12 which means the measure fails at reliability.

13 MS. LARSON: Okay. I understand. So,  
14 then, does that mean we will still be able to  
15 provide additional information after --

16 MS. SAMPSEL: Yes. Yes, we will be on  
17 the same timeline.

18 MS. LARSON: Okay, and everything will  
19 be evaluated at that time, assuming we progress  
20 through the criteria?

21 MS. SAMPSEL: Correct. If you are  
22 able to, you know, if there is additional

1 information for the Committee to consider,  
2 correct.

3 MS. LARSON: Okay. All right. Pardon  
4 my interruption. Thank you.

5 MEMBER MORT: I have one suggestion  
6 for the developers. If you are collecting more  
7 information about the indication for the spinal  
8 fusion, you might want to also ask whether or not  
9 non-invasive treatments were tried, such as  
10 either physical therapy or pain consults, steroid  
11 injections, just to try to get a sense for onset  
12 of symptoms, other treatments that were tried,  
13 indication for the procedure, and then you get  
14 your functional status pre and post. You will  
15 have such a wealth of important information that  
16 could add to the literature.

17 CO-CHAIR PARTRIDGE: Okay. Any  
18 further comments?

19 (No response)

20 If not, Collette and Jasmine, we thank  
21 you.

22 And I think, am I correct, that on

1       this measure, of all the measures we have  
2       considered so far today, this would have the  
3       highest Importance score? So, I think you have  
4       got a pretty good feeling for the sentiment on  
5       this committee that we look forward to seeing  
6       your further data.

7                   MS. PITZEN: All right. That's  
8       wonderful. Thank you very much for your  
9       consideration and your time today.

10                   CO-CHAIR PARTRIDGE: We are going to  
11       do one more measure on this list, which is 0631  
12       -- oh, I'm sorry -- 2631.

13                   MEMBER MONROE: Madam Chair?

14                   CO-CHAIR PARTRIDGE: My vision is  
15       blurring.

16                   MEMBER MONROE: Madam Chair, may I ask  
17       that we reverse 0688 and 2631? I have my own  
18       Board meeting at 3:30 and I have to step out, and  
19       I am a commenter --

20                   CO-CHAIR PARTRIDGE: Oh, of course.

21                   MEMBER MONROE: -- on 0688. So, I  
22       would ask the permission of the group to move to



1       that, and then come back to 2631. Is that  
2       allowed?

3               MS. SMITH: That is acceptable to me,  
4       if the developer is available.

5               MEMBER MONROE: Thank you.

6               I think Tracy Kline, are you on the  
7       line? I think you were --

8               MEMBER SALIBA: And just a reminder,  
9       I not voting on this one. So, you are one short.

10              MS. KLINE: Tracy Kline is here.

11              MS. SMITH: Great. Karen Reilly and  
12       Xing-hua Lee, are you guys there as well?

13              MS. REILLY: This is Karen Reilly.  
14       I'm on the phone.

15              MS. SMITH: Great. I want to thank  
16       you for the opportunity to present today. My  
17       name is Laura Smith. I am here with my colleague  
18       Tracy Zheng. We are from RTI International. We  
19       are here presenting as developers for this  
20       measure with our colleagues from CMS.

21              NQF Measure 0688 estimates the  
22       percentage of long-stay residents in a nursing

1 facility whose need for assistance with the late  
2 loss ADLs has increased. Increase in need for  
3 assistance is identified by comparing ratings for  
4 resident self-performance on the four late-loss  
5 ADLs, bed mobility, transfer, eating, and toilet  
6 use. We compare residents' target assessment  
7 relative to their prior assessment. This is an  
8 important measure that addresses a CMS quality  
9 strategy priority, and it is included in the CMS  
10 Five-Star Rating System.

11 Greater functional dependency is a  
12 risk factor for complications, such as pressure  
13 ulcer, hospitalization, reduced quality of life.  
14 Although some ADL decline may be an unavoidable  
15 consequence of an individual's clinical  
16 conditions, many risk factors may be mitigated by  
17 nursing care, multidisciplinary communication,  
18 referral for rehabilitation and nutrition  
19 services, and modification of resident's physical  
20 environment.

21 By monitoring and publicly reporting  
22 nursing facility performance with regard to

1 prevention of ADL decline, nursing facilities  
2 have the tool and incentive to focus on  
3 maintaining and improving residents' functional  
4 status.

5 The data for this measure is based on  
6 the minimum dataset. And for testing, we used  
7 data on all eligible long-stay residents in all  
8 Medicare-certified nursing homes nationwide, as  
9 well as previously-published studies from the  
10 development of that MBS 3.0, which was based on a  
11 sample.

12 Median facility-level scores for this  
13 measure were 15.4 percent and 14.3 percent in  
14 quarter two of 2014. And this measure has shown  
15 a general improving trend since quarter one of  
16 2011.

17 Critical data elements for this  
18 measure show high item-level reliability and  
19 validity, with kappas above 0.95. Rasch analysis  
20 indicates that the ADL items have construct  
21 validity with items showing expected ordering  
22 with regard to the level of the difficulty to

1 perform each task. Items also show high internal  
2 consistency suggested by a Cronbach's alpha of  
3 0.87.

4 With regard to measure-level  
5 reliability, when we look at a single quarter of  
6 data, the signal-to-noise results are low.  
7 Looking at the proportion of facilities that had  
8 scores that are significantly different from the  
9 national mean, when you look at a single quarter,  
10 we see about a third of facilities with a  
11 significantly different score. But when you look  
12 at three-quarters of data, which is consistent  
13 with how the Nursing Home Compare scores are  
14 publicly reported, we see about half of  
15 facilities have scores that are significantly  
16 different from the national mean. We also find  
17 that scores are stable from quarter to quarter  
18 when you look at that combined mean of three  
19 quarters.

20 We saw a low but significant  
21 correlation, suggesting convergence validity  
22 between this measure and the NQF Measure 0674,

1       which is falls with major injury for nursing  
2       home, and missing data do not present a threat to  
3       the validity of this measure.

4               Although the testing results suggest  
5       that this measure is general valid and reliable,  
6       the measure may not differentiate decline  
7       resulting from inadequate care from unavoidable  
8       decline. The measure does apply under the life  
9       exclusions, with the purpose of trying to  
10      differentiate. But there are approximately three  
11      percent of residents who died in a given quarter  
12      that were not excluded based on whether they had  
13      a prognosis of less than six months to live or  
14      were on hospice.

15              With regard to risk adjustment,  
16      C-statistics for the model tested were low. So,  
17      there is no risk adjustment currently applied to  
18      this measure.

19              There are several related measures,  
20      but none have the same focus and none target the  
21      same population. This measure's focus on  
22      functional decline is the most appropriate for

1 long-stay nursing home residents. And as I said  
2 before, public reporting of this measure via  
3 Nursing Home Compare provides valuable  
4 information for residents and their families.

5 And we thank you again for this  
6 opportunity and look forward to the discussion.

7 CO-CHAIR PARTRIDGE: Thank you.

8 David?

9 MEMBER CELLA: Ann asked me to lead  
10 off.

11 So, thank you. That was a great  
12 summary. You have touched on all the things that  
13 are relevant, and I think given it in a very  
14 nice, coherent way.

15 In terms of important, I mean, this is  
16 a population that is going to as a group decline.  
17 And so, the therapeutic goal makes sense, to  
18 delay decline, to avoid it where possible, and  
19 therefore have some other benefits that are  
20 likely to occur in terms of fall risk and other  
21 things that co-vary with these four late-loss  
22 ADLs.

1                   So, I think the selection of an area  
2                   and, in particular, ADLs selected are very  
3                   sensible in the goal. I at first had to struggle  
4                   a little bit with this goal of maintenance, but  
5                   it actually makes sense, I think, with this  
6                   population.

7                   And if I understand it right -- and  
8                   this may be oversimplifying -- maybe you could  
9                   confirm that, basically, your sort of base rate  
10                  is at about one in seven people will lose one or  
11                  more functions in a three-month period. Is  
12                  that --

13                 MS. SMITH: Yes, it is at a different  
14                 threshold of going up sort of two levels on at  
15                 least one ADL or --

16                 MEMBER CELLA: Okay, as defined?

17                 MS. SMITH: Yes, as defined, yes.

18                 MEMBER CELLA: So, the rate of decline  
19                 that a facility is starting from as an average or  
20                 median is one in seven, and the period of time is  
21                 three months. Am I --

22                 MS. SMITH: That's right, because the

1 time between the target assessment and looking  
2 back in time to the prior assessment is, on  
3 average, a quarter to three months.

4 MEMBER CELLA: So, if the system were  
5 a closed system, and I was trying to get maximum  
6 differentiation, I would probably want more like  
7 one out of three than one out of seven, and that  
8 would maybe make me go to six months as opposed  
9 to 90 days. I think the choice of 90 days is on  
10 the short end because you are going to have fewer  
11 events.

12 And maybe that decision was made  
13 because of loss in both the denominator and,  
14 then, unfortunately, the numerator if somebody  
15 dies or whatever. So, I guess would just pause  
16 for a quick answer to that. Did you consider  
17 something longer, like six months or not?

18 MS. SMITH: So, this measure is  
19 actually -- well, I think we noted that this was  
20 maintenance now, but it actually is based on the  
21 original MBS 2.0 version of this measure. I  
22 don't think we did consider that in this current



1 round because certainly we consider whether there  
2 might be provisions in this area.

3 MEMBER CELLA: Okay.

4 MS. SMITH: So, I am not sure what  
5 sort of the history of it was.

6 MEMBER CELLA: Thank you.

7 And related to that, and maybe what I  
8 projected, you know, just trying to get into your  
9 heads when you are putting something like this  
10 together, there are a lot of exclusions for this  
11 denominator, people that come in totally  
12 dependent. That, of course, makes sense. People  
13 that are near totally dependent. I guess that  
14 also makes sense. Coma also makes sense.

15 But, then, I start to struggle because  
16 six months' expected survival is the next reason  
17 for exclusion. And I don't know how people do  
18 that, but I know the literature on doing it is  
19 pretty bad.

20 So, are you just asking the person's  
21 primary MD if they think they are going to live  
22 six months, and based upon their yes-or-no

1 answer, they go in the denominator?

2 MS. SMITH: So, it does need to be  
3 based on the primary, what is in the medical  
4 record, yes.

5 MEMBER CELLA: But that is usually not  
6 charted, right? I mean, maybe I am wrong about  
7 that because I don't look at nursing home charts.  
8 But I don't think people usually -- I mean, they  
9 will chart if they are going to hospice. So, you  
10 will know that, and that is the next -- I can  
11 understand doing hospice and saying, okay, that  
12 is a subgroup. But, short of hospice, I guess I  
13 would remove that less than six because that  
14 could be gamed. I mean, somebody could say,  
15 "Let's put them on the less-than-six-months  
16 list," and then, they don't count. Or, if they  
17 have got 32 residents eligible, they could put  
18 three on that list, and they wouldn't have to  
19 play, because 30 is the minimum. Anyway, that is  
20 just a quibble.

21 MS. McMULLEN: Hi. Tara McMullen from  
22 CMS.

1 MEMBER CELLA: Yes.

2 MS. McMULLEN: It is on the medical  
3 chart, and, actually, it should follow at  
4 admission from prior assessment or prior  
5 location. We should have that type of  
6 information.

7 MEMBER CELLA: Okay. So nursing home  
8 admissions require charting life expectancy?

9 MS. McMULLEN: We take from some  
10 charts, depending on the measure. Yes.

11 MEMBER CELLA: That's interesting  
12 because doctors can't do that.

13 MS. McMULLEN: Yes.

14 MEMBER CELLA: I guess they're not  
15 good at it.

16 MS. McMULLEN: No, right. It is an  
17 exclusion that I think at CMS we have also looked  
18 at and said how reliable it is. But, for this  
19 measure and purposes --

20 MEMBER CELLA: Okay. All right.

21 And then, there was a missing value  
22 basis for exclusion which troubled me because, if

1       you are not good at it, then you are able to  
2       exclude people from your denominator because you  
3       are not getting the data, which seems like I  
4       wouldn't do.

5                   What is the question?

6                   MS. McMULLEN:  It's in the  
7       administrative section, Section A.  Let me pull  
8       that up.

9                   MEMBER PARISI:  It is a question on  
10      the MDS there.

11                  MS. SMITH:  It is, but the instruction  
12      is to base it on the medical record, though.  So,  
13      whoever is filling it out should be basing it on  
14      the medical record as opposed to sort of it is  
15      not the MDS nurse that is making that assessment.

16                  MEMBER CELLA:  Well, it has been a  
17      while since I have published in this area, but I  
18      actually did some studies on predicting survival.  
19      Unless people have gotten better at it, going out  
20      more than a month is not good at all.  I mean,  
21      the reliability, it seems like it is not worth  
22      asking.

1           MEMBER MORT: If I could just add to  
2 that, you said three people died in your  
3 population within 90 days?

4           MS. SMITH: It was 3 percent of the  
5 population.

6           MEMBER MORT: Three percent?

7           MS. SMITH: Yes.

8           MEMBER MORT: Even so, that is  
9 relatively low for a nursing home population.  
10 So, I think you would have some wiggle room to  
11 exclude that highly subjective determination. It  
12 may be in the chart, but, believe me, I  
13 completely agree with Dr. Cella's concerns. I  
14 don't think you are losing much by excluding  
15 that.

16           MEMBER CELLA: That is all I am going  
17 to say about importance/relevance. So, let's  
18 open it up for maybe Ann.

19           MEMBER MONROE: I just want to clarify  
20 because it looks like it says that the patients  
21 who died in that quarter were counted in the  
22 numerator. It was 31 percent. Is that a

1 different -- it is substantially higher than the  
2 overall incidence rate.

3 MS. SMITH: So, the 3 percent is the  
4 proportion of the long-stay sample that died in  
5 that quarter, but you are correct. So, that 31  
6 percent that you are talking about is the rate,  
7 the proportion of the folks who died, the  
8 proportion of them ended in the numerator. So,  
9 there is a higher numerator-triggering rate  
10 amongst the people who died, which is not too  
11 surprising compared to the rest of the sample.

12 If it is all right, I just would like  
13 to address the missing data portion, which is --  
14 while I do recognize your concern with that, what  
15 we have found is that we actually have a very low  
16 missing data rate. For this particular measure,  
17 it is only about .9 percent. So, I just wanted  
18 to put that out.

19 MS. McMULLEN: Yes, and I do want to  
20 address, it is in Section A of the MDS, the  
21 current MDS.

22 MEMBER CELLA: Thank you.

1                   MEMBER MONROE: My only comment on  
2 importance relates also to the denominator  
3 exclusions because, at least as I see it where I  
4 observe, the line between long-term care,  
5 palliative care, and even hospice within a  
6 nursing home is getting more and more blurried.  
7 So, I wonder about those exclusions, whether they  
8 are perhaps more arbitrary. They assume more of  
9 an arbitrary nature than they really are. So, I  
10 don't know why you would exclude them in this  
11 measure.

12                   MS. SMITH: Well, I think the  
13 intention is -- there are multiple intentions,  
14 but one is to recognize that, if people truly are  
15 at end of life, that they are going to be at much  
16 higher risk for ADL decline. And at the same  
17 time, if you do include them in the measure, are  
18 you going, especially for folks who have opted  
19 for hospice, are you going to be sort of setting  
20 up warring kind of incentives where people, the  
21 facility may not be as willing to sort of set  
22 aside some of the things that they need to do in

1 order to maintain function, when that may not be  
2 the person's preference.

3 So, I think there is just this concern  
4 about, if they are included in the measure, there  
5 may be an unintended consequence where you may  
6 not be respecting preferences at end of life.

7 MEMBER PARISI: So, I just wanted to  
8 clarify. You said this was not a risk-adjusted  
9 measure, but the exclusions do account for some  
10 of that, particularly in patients that have no  
11 ability to progress. Is that correct?

12 MS. SMITH: That's correct.

13 MEMBER PARISI: Okay. One more  
14 question is related to the sampling, because not  
15 every resident gets included in the sample each  
16 time there is submission, correct? Is that  
17 addressed somehow?

18 MS. SMITH: Actually, that is not  
19 correct, that actually there is a requirement --  
20 well, every three months there should be a  
21 quarterly assessment done for all residents. And  
22 so, there isn't a sampling being done. And so,



1 we basically look at assessments that have been  
2 submitted for a particular quarter and basically  
3 identify everybody who has had -- so, there is  
4 like a slight possibility that you might not fall  
5 into it. No, you should actually end up in every  
6 -- everybody should have an assessment.

7 MEMBER PARISI: After a given period  
8 of time, but not every quarter? Agree?

9 MS. SMITH: No, it is actually every  
10 quarter, actually. Oh, but are you talking about  
11 the long-stay?

12 MEMBER PARISI: The MDS admission.

13 MS. SMITH: You're talking about the  
14 long-stay definition?

15 MEMBER PARISI: Yes, yes.

16 MS. SMITH: Okay. You're correct  
17 about it. Excuse me. This is a long-stay  
18 measure. So, you have to have accumulated 100  
19 days in order to be included in the measure. But  
20 part of that, it really ends up being sort of a  
21 form of stratification because you want to look  
22 at a population where ADL decline is more

1 appropriate to be monitoring, as a particular  
2 concern for the nursing home to monitor and  
3 prevent.

4 MEMBER PARISI: So, one more  
5 clarification. Is there also a reflection of  
6 other outcome measures that are being collected  
7 as well, correct? Is that what I heard? Right,  
8 right.

9 MS. SMITH: Oh, oh, are you talking  
10 about the correlation analysis that I reference  
11 in the summary? So, what we did with that  
12 analysis, we were interested in looking at  
13 validity at the measure level. And so, one  
14 strategy is to look at whether you see  
15 correlations amongst quality measures that may  
16 have some similar underlying processes or focus  
17 for a facility. And so, we looked at how well  
18 correlated this measure was with falls with major  
19 injury.

20 MEMBER THOMAS: So, I will repeat  
21 that. So, I had trouble with this measure  
22 because all the other measures, pretty much, that

1 we looked at measured functional improvement, or  
2 many of them did. And this measure looks at the  
3 percentage of residents whose need for help or  
4 greater assistance with activities of daily  
5 living is increasing. So, it is kind of looking  
6 at patient decline in function.

7 And I guess there is a 20-year history  
8 of some interest groups in the disability  
9 community, in particular, who are predominantly  
10 younger disability as opposed to over age 65, who  
11 are very upset with the Medicaid program and  
12 Congress and everyone for unnecessarily  
13 warehousing people with disabilities in nursing  
14 homes, and not providing enough home/community-  
15 based services.

16 And they might look at this and say,  
17 well, this is a measure of poor quality. This is  
18 a measure of how, if you are a 45-year-old with  
19 MS in a nursing home, and you are declining in  
20 function, and this is measuring your decline in  
21 function, that is just proving the point that you  
22 shouldn't be there, and you need greater

1 engagement and services and the like. Again, I  
2 am not sure where I am going with this, if it is  
3 even a question, but how do you respond to that?

4 MS. McMULLEN: So, I can respond from  
5 the CMS perspective. I will try to help here.  
6 Measures like these are important to CMS because  
7 not only do we publicly report and we benchmark,  
8 and we use this type of data for care  
9 coordination and goals of care, and things like  
10 that. But we also take this data to build on  
11 different types of measures, efficiency measures,  
12 utilization measures, things of that nature.

13 So, in understanding an individual's  
14 complexity while they are in a specific setting,  
15 it allows us to kind of build measures that allow  
16 us to look at quality, how we can improve quality  
17 in those settings, what is going on with the  
18 individuals, look at a facility, look at their  
19 practices, improve upon those practices.

20 And then, now in the way of  
21 standardization, allow us to look, if they leave  
22 that nursing facility setting and they go into

1       some home care or they go into the  
2       home/community-based setting, what does that look  
3       like? What do those transitions look like? And  
4       as they moved, what was the change? Did they  
5       become more dependent? Did they become more  
6       independent? And how does the data paint that  
7       picture for us?

8               So, this could be viewed in a negative  
9       light, well, we are looking at poor quality, but,  
10       actually, all this data is used for many  
11       different reasons, from anything from payment to  
12       care plans and goals of care. So, it is not just  
13       reporting on a facility that people are -- oh,  
14       and surveyors use this as well in the QIOs. That  
15       is my boss, Mary Pratt, the Director of the  
16       Division of Chronic and Post-Acute Care.

17              So, it is not just used for just  
18       reporting a negative outlook. It is used for  
19       many reasons. The data is kind of recycled. And  
20       you can look at it through many different lenses,  
21       depending on what part you are at CMS, what role  
22       you play.

1                   MEMBER THOMAS: Thank you.

2                   MS. ZHENG: And a full-up comment on  
3                   that. I think you mentioned that nowadays, given  
4                   like there are more options in the community- and  
5                   the home-based setting, actually, now we see this  
6                   trend in terms of case mix in the population in  
7                   nursing homes. Now it seems like, because of  
8                   those increased options in communities, people  
9                   actually entering a nursing home, and in the  
10                  nursing home after 101 days will become long-  
11                  stay. They are very frail, and their goal there  
12                  is really to maintain function and not to have  
13                  further decline, as opposed to restore function  
14                  to a higher level and improve their function  
15                  level.

16                  So, as Laura said, given this  
17                  population and given their risk and their goal,  
18                  we think a functional decline measure is a  
19                  negative measure, like higher value is that  
20                  quality, but we think this is more appropriate  
21                  for this population.

22                  MEMBER LINDBERG: Thank you. Well, I

1 had another comment. But, first, to add to  
2 Peter's point, it seems to me that this meshes  
3 nicely with the recent ruling, basically, that  
4 Medicare beneficiaries do not have to prove  
5 improvement in function to continue certain  
6 therapies. So that, even as they may stay flat  
7 on their level of function or decline, that they  
8 should still be able to receive the therapies.  
9 So, I think in that sense this is another  
10 positive thing that meshes well with that ruling.

11 The question I had, though, related to  
12 the other issue around the movement, if you will,  
13 toward potentially providing curative care along  
14 with hospice and the administration's current  
15 demonstration on that. And I would just want to  
16 make sure, or I would be interested in knowing  
17 how you would look at those individuals, not  
18 excluding them, because they could have a longer  
19 period of being on hospice than the six months  
20 that is required for being prescribed hospice  
21 care. Thank you.

22 MEMBER BIERNER: I have one question

1       that I am not clear on. There are now units that  
2       are labeled as cognitive care or Alzheimer-type  
3       dementia units. Are those included in your group  
4       that you are sampling from?

5               MS. SMITH: Yes. Potentially, yes.  
6       There's no reason why they would not be there.

7               MEMBER LINDBERG: Yes. I think mine,  
8       I didn't say it maybe in the right tone, but it  
9       was a question to you. Okay.

10              MS. SMITH: Sorry. I think part of it  
11       was also because it is a difficult question to  
12       answer. I mean, I think it will be that case  
13       that you are talking about will be very difficult  
14       to identify when you were already sort of talking  
15       about difficulties in identifying prognosis of  
16       six months.

17              I think it is something that this is  
18       something that is, maybe, going to be end up  
19       being an unsatisfying answer, but I think it is  
20       something that we will just have to do some  
21       thinking about and continue to monitor. Because  
22       I think figuring out how to identify those



1 individuals that we are talking about, it is  
2 going to be something that is complex.

3 MEMBER MONROE: Another aspect of that  
4 complexity that I looked at was you kind of had a  
5 throwaway line that some people are just going to  
6 decline, but there are a lot of things that could  
7 be done. How are you distinguishing between the  
8 two, between what is kind of just natural or  
9 expected decline, and decline that results from a  
10 lack of attention to tasks that could improve the  
11 functionality?

12 MS. SMITH: So, the way this measure  
13 is currently operationalized, the main way that  
14 we are distinguishing is with those exclusions  
15 that we were talking about. Otherwise, the  
16 decline is being counted in the numerator.

17 MEMBER MONROE: Plus, you are in an  
18 exclusion. It is assumed to be fixable or  
19 improvable.

20 MS. SMITH: Well, I am not sure that  
21 actually that is quite how one should interpret  
22 these measures because I don't think there is

1       ever an expectation that the measure is going to  
2       go to zero. But higher rates are equivalent  
3       with -- tend to interpreted as worse quality.  
4       But I don't think there is any expectation.  
5       Because I think what you are talking about is  
6       basically that there would be an expectation that  
7       it should be possible to go to zero. And there  
8       is no expectation of that.

9                   CO-CHAIR PARTRIDGE: Becky?

10                  MEMBER BRADLEY: And if this is not  
11       the right forum to ask to respond to this, let me  
12       know. But I guess, because we had so many  
13       measures that we reviewed and so many of them  
14       were similar and somewhat overlapping, and I kind  
15       of got them all confused in my head, but there  
16       was in many of the measures that CMS is  
17       presenting the implication that they are trying  
18       to standardize the tools across settings in the  
19       post-acute setting.

20                  But this one seems so different from  
21       some of the others, but you are continuing to  
22       want to use it and endorse it. But, I am just

1       curious, how does that fit into the philosophy of  
2       standardizing the measures and will this one  
3       continue to be used going forward? Because this  
4       is one of the post-acute settings that is  
5       mentioned.

6               MS. SMITH: So, you're right. I mean,  
7       I think that in nursing home, though, we have  
8       both the post-acute and long-term services and  
9       support populations. So, this measure is  
10      designed more with the long-term services and  
11      support population in mind. That is not entirely  
12      answering your question, and -- I don't know if  
13      Tara wants to respond to the rest of your  
14      question.

15             MS. McMULLEN: Yes. So, and this kind  
16      of gets into the next measure with RTI and CMS.  
17      But, yes, CMS has been, for a while, moving in  
18      the way of standardization. You saw that through  
19      the PAC PRD and the CARE tool, not the advent of  
20      the IMPACT Act. In the IMPACT Act, skilled  
21      nursing facilities are delineated among LTCHs and  
22      IRFs and home health agencies for

1 standardization.

2           This measure touches, like Laura said,  
3 upon the long-stay residents. This measure is  
4 used for the nursing home Five-Star Program. So,  
5 it is publicly reported and benchmarked. It is a  
6 Five-Star measure. So, basically, it is used to  
7 kind of report about the quality of a facility  
8 and add some sort of weight to that, to this  
9 measure, so that, basically, providers and  
10 consumers are able to make better choices about  
11 loved ones and things like that.

12           I digress. So, the measure was used  
13 in a different way than the actual intent of the  
14 IMPACT Act. It will continue to be used because  
15 CMS has found that it is a good measure. It is  
16 basically saying, what is going on with that  
17 person and when. At that target assessment where  
18 were they, in terms of late-loss ADLs? How did  
19 they score? And that is useful when you are  
20 comparing this measure with other types of Five-  
21 Star measures like restraint use and falls and  
22 things like that.

1 MS. SAMPSEL: I am mindful of Ann's  
2 obligation at 3:30, is that correct? 3:30?  
3 3:30. And I would like to get us through this  
4 measure, if we can, before we lose her. There  
5 has been considerable mention around this table  
6 -- and I think it is a feeling that is shared by  
7 a number of us -- that the one exclusion  
8 regarding expectation of six months is  
9 disturbing. And I am going to task our technical  
10 staff, if we were comfortable supporting this  
11 measure if that exclusion were eliminated, is  
12 there any way we deal with that in our voting or  
13 do we just have to work on making it a  
14 recommendation from the Committee for the next  
15 time the measure comes to us?

16 MS. THEBERGE: You can conditionally  
17 recommend, and then, the developer has the option  
18 to agree to make the change, in which case they  
19 would do that and bring it back. Or the option  
20 to disagree, in which case the measure does not  
21 move forward.

22 CO-CHAIR PARTRIDGE: We wouldn't have

1 an opportunity to revote? If they came back and  
2 said, "We can't"?

3 MS. THEBERGE: I think you could  
4 revote if they came back and said they can't.

5 CO-CHAIR PARTRIDGE: Okay.

6 MS. THEBERGE: You would have the  
7 opportunity to revote.

8 CO-CHAIR PARTRIDGE: Importance.

9 MS. ALLEN: Voting on evidence. One,  
10 yes; two, no. The voting starts now. Ninety-  
11 four percent, yes; 6 percent, no.

12 Voting on performance gap. One, high;  
13 two, moderate; three, low; four, insufficient.  
14 Voting starts now. 44 percent, high; 44 percent,  
15 moderate; zero percent, low; 11 percent,  
16 insufficient.

17 Voting on high priority. One, high;  
18 two, moderate; three, low; four, insufficient.  
19 Voting starts now. All votes are in. 61  
20 percent, high; 33 percent, moderate; 6 percent,  
21 low; zero percent, insufficient.

22 CO-CHAIR PARTRIDGE: Okay, moving onto

1 reliability. Ann or David, any comments?

2 MEMBER MONROE: I thought reliability  
3 was pretty standard. I had some comments on  
4 validity, but not on reliability. I don't know  
5 about you, David.

6 MEMBER CELLA: No, the same.  
7 Reliability was actually very good. The only  
8 thing I would say that there is one thing I  
9 looked at which is the stability of the facility  
10 ranks, which requires an assumption that  
11 facilities shouldn't change very much, which is  
12 probably a fair assumption. You know, looking at  
13 seeing it from time to time facilities change a  
14 lot relative to others, and they don't. Of  
15 course, if they really did, but you are assuming  
16 that they don't. And that is probably a good  
17 assuming. So, that is good. All the other  
18 reliability statistics were actually quite good.  
19 Sherrie?

20 MEMBER KAPLAN: Yes, I had some  
21 concerns about reliability because at the patient  
22 level it is pretty well. At the facility level,

1       however, the signal-to-noise analysis that was  
2       done indicates that there is a fair amount of  
3       noise in this measure at the facility level, and  
4       you can't distinguish the measurement error in  
5       the population from little perturbations at the  
6       facility.

7               So, while at the patient level it is  
8       good, I am troubled about the reliability at the  
9       facility level. And then, my trouble is  
10      exacerbated by the validity testing, which you  
11      found that there was a substantial stability,  
12      which is good news at one level and bad news at  
13      another. If it is not detecting fluctuations in  
14      quality of care, it is not useful for  
15      discriminating facilities one from another.

16              And the correlation with the other  
17      variables that were used for percentile ranks was  
18      pretty small. It is 1 percent. The R was .09.  
19      So, R-squared is 1 percent of the variation. So,  
20      that is not great news when you are using these  
21      to discriminate the care provided by different  
22      facilities.



1                   MEMBER CELLA:   Should we talk about  
2   validity now?   Do you want to talk about validity  
3   or --

4                   MEMBER THOMAS:   Just a quick followup  
5   to that statement.   Could you just clarify what  
6   it means that the facility characteristics --  
7   that the measure was not particularly reliable in  
8   separating facility characteristics from noise,  
9   the population variance, what does noise mean?  
10   What are we talking about?

11                  MS. SMITH:   So, one thing, I  
12   definitely recognize your point about the signal-  
13   to-noise analysis.   One thing I just wanted to  
14   point out, that I don't know whether it would  
15   actually mitigate your concern.   We only had  
16   reliability signal-to-noise analysis for a single  
17   quarter of data.   Recognizing that there is noise  
18   in the estimate, what is publicly reported is  
19   actually an average of three quarters.

20                  We weren't able to do the signal-to-  
21   noise analysis for that.   So, we did some  
22   analysis just looking -- we calculated confidence

1 intervals around the estimate for every facility.  
2 What is in the testing form is still one quarter.  
3 It is using 30 percent of the facilities are  
4 significantly different.

5 When we looked at that average of  
6 three-quarters, it was about 50 percent of the  
7 facilities that had 95-percent confidence  
8 intervals that were significantly different from  
9 the national mean. I know that doesn't kind of  
10 fix above .08 for the signal-to-noise.

11 MEMBER KAPLAN: Earlier measures  
12 developers did a nice line. You know, if it was  
13 generated from a generalized estimation  
14 disclosure of hierarchical modeling, wouldn't  
15 that be nice in this case, so that you could  
16 actually look at how good, how useful this kind  
17 of measure is, and over quarters that would make  
18 you happy in terms of there should not be random  
19 fluctuations one quarter over a whole year's  
20 worth of data, for example?

21 And certainly, CMS, if nobody else,  
22 has those kind of data. CMS has those kind of

1 data. So, that would actually give you a bit  
2 more confidence that you can use this to  
3 discriminate high functioning from low  
4 functioning. But one of the other things I  
5 noticed in your data was that 77 percent of the  
6 facilities were smack in the middle. The  
7 variation was, then, on the extremes, and that is  
8 when you plot those lines, often what you see is  
9 that these things are only merely useful to  
10 identify outliers.

11 So, how you are going to use this  
12 makes kind of a huge difference. You are  
13 certainly not going to use it, I don't think, at  
14 the individual facility level, but where you  
15 slice those benchmarks to do anything else, that  
16 gets at the issue of, gee, are you going to put  
17 confidence intervals around those little  
18 thresholds? How is this going to be used?

19 Because your signal-to-noise analyses  
20 are a little bit worrisome unless they straighten  
21 out with additional data, and your validity  
22 evidence doesn't suggest that what you are seeing

1 now is associated with other things you would  
2 expect to see. One percent of the variation  
3 shared in your rankings with other measures of  
4 quality around the same topic aren't really  
5 confidence-inspired.

6 MS. SMITH: Again, I am not sure. So,  
7 one thing about the validity data is that this is  
8 not atypical for the MDS-based measures, that  
9 they have historically not been well-correlated.

10 MS. McMULLEN: It should be stated  
11 that on Nursing Home Compare, like Laura said,  
12 that we are looking at multiple averages of  
13 weighted data across multiple quarters. So, it  
14 is not just assessing on one quarter for one  
15 targeted period and reporting at the patient  
16 level. It is a facility-level rate that is  
17 reported, I think, over three quarters and it is  
18 averaged.

19 So, you have the average for the  
20 entire country per state. So, it is a rate. You  
21 are not looking at the -- it is not a patient-  
22 level statistic. But there are some weights

1 applied to it, absolutely.

2 MEMBER KAPLAN: Okay. And the only  
3 way out of that, because you get into these  
4 tautologic loops when you are trying to figure  
5 out validity, so the only other thing you could  
6 do is maybe look at efforts to improve quality at  
7 the nursing home level. Did they do them or not?  
8 Or was there some kind of ongoing program among  
9 some or not? And then, did they move in  
10 conjunction with your expectation that this  
11 measure would reflect efforts to improve quality?

12 MS. McMULLEN: Yes, I think that is a  
13 point well-taken. That is absolutely what we  
14 think as well. I mean, the measure just reports  
15 on basic outcome. So, it could be used and  
16 revised and created or paired with so many other  
17 measures, so that you can look at so many  
18 outcomes. But, for what it is, it is just  
19 assessing the person at that time at that target  
20 assessment for what was going on with them. But  
21 you're absolutely right. And in the future we  
22 will expand upon this measurement set because it

1 is interesting to look at. I mean, it is gross  
2 indicator of so many things.

3 CO-CHAIR PARTRIDGE: Are we ready to  
4 vote on reliability? Or do we still have more  
5 conversation? Excuse me.

6 MEMBER MONROE: Did you say  
7 reliability and validity or just reliability?  
8 Because I have a comment on validity if we are --

9 CO-CHAIR PARTRIDGE: Reliability  
10 first. Well, reliability, let's do reliability  
11 first because I think validity may raise  
12 additional issues. Okay? Reliability.

13 MS. ALLEN: Voting on reliability.  
14 One, high; two, moderate; three, low; four,  
15 insufficient. Voting starts now. We are still  
16 missing a vote. Eighteen percent, high; 65  
17 percent, moderate; 12 percent, low; six percent,  
18 insufficient.

19 CO-CHAIR PARTRIDGE: Moving on to  
20 validity now.

21 MEMBER MONROE: On to validity, one of  
22 the points that was made in the summary was about

1 the variation by state. And I think the Five-  
2 Star reporting is related to a national standard.  
3 And I do think state policy has significant  
4 influence on staffing, on dollars, on a number of  
5 things. And I am not sure how valid the  
6 measurement across states might be, if you have  
7 very different state policies that give these  
8 nursing homes very different tools with which to  
9 work. So, I don't know how you manage that, and maybe  
10 that is not a validity question. But it  
11 certainly was an important one to me.

12 And the other one is related to kind  
13 of the unintended consequences of beginning to  
14 see nursing homes do adverse selection in order  
15 to only have patients where they can see an  
16 opportunity for them to improve. And I wondered  
17 how that would fit with this as well.

18 MS. SMITH: So, let's see, is it all  
19 right if I take the second one? I will take the  
20 second one. I will take the second first because  
21 I think it does seem like your first question is  
22 more of an implementation-type issue, yes.

1                   And then, in terms of -- I am trying  
2   to think about whether or not this measure is  
3   useful in terms of any kind of balancing-out  
4   concerns about what you were asking. I mean, I  
5   think this measure is trying to focus on a  
6   different objective in terms of reducing,  
7   preventing ADL loss. And I am not sure that this  
8   measure is going to help with that particular  
9   concern about cream-skimming that you are talking  
10   about and adverse selection. It is still an  
11   important focus because there is going to be a  
12   segment of the population that is their goals of  
13   care aren't improvement. I mean, it does point  
14   to risk adjustments.

15                  MS. McMULLEN: Yes, it points to risk  
16   adjustment, which we are working on those models  
17   now. In fact, we have finally found a model that  
18   actually works. At some point, we will take this  
19   back to NQF. But, I mean, from a broader sense,  
20   I think you could probably make this same  
21   argument, if you wanted to, about all the quality  
22   measures in the nursing homes set. How they



1       affect process, how they affect practice, and how  
2       people interpret them.

3               And I think that when individuals are  
4       using the Five-Stars as a means for information  
5       and knowledge, however that is, there is  
6       variation across states, and you can make the  
7       argument that states do affect that variation.  
8       But, on the Nursing Home Compare, how this  
9       measure and how other measures are portrayed are  
10      weighted-out so that there is not as much error;  
11      there is not as much sway, based on state-based  
12      policies.

13             So, the Five-Star itself is weighted  
14      in three different buckets. And I don't know if  
15      this is off-topic, just kind of melded together.  
16      Okay, well, it answers the first question. So,  
17      the measures aren't the only thing that weights-  
18      out those Five-Stars. You have citations, which  
19      goes back to the citation process for the  
20      surveyors as well as you have staffing, which is  
21      collected once a year and beyond that.

22             So, there is a complete threshold and

1 balancing of that. So, this measure could affect  
2 policy. It could affect practice. But, in the  
3 way that it is represented, so that we have an  
4 adequate amount of data, and the fact that it is  
5 weighted, we are hoping that it doesn't sway that  
6 so it doesn't create adverse events. But you can  
7 make that argument about every QM, I guess, that  
8 its intended purpose could be something different  
9 than what the outcome actually is truly meant to  
10 represent.

11 MEMBER KAPLAN: Can I ask a question  
12 procedure-wise? I just was going to ask a  
13 procedural question. So, there is all kinds of  
14 validity. There is face validity, which it is  
15 pretty clear that this has been given a lot of  
16 thought and it looks right on the surface. There  
17 is construct validity and there is discriminate  
18 validity.

19 For the purpose this is being put to,  
20 it strikes me that discriminate validity is where  
21 we are. You want to be able to discriminate  
22 facilities who do a good job from facilities who

1 don't. And I am still not hearing a lot of  
2 evidence that would support discriminate validity  
3 at this point, unless the next round of data  
4 comes in with some additional information that  
5 gives us more confidence that you are able to  
6 discriminate high-performers from low-performers  
7 with accuracy.

8 CO-CHAIR PARTRIDGE: David, do you  
9 have any comments on validity?

10 MEMBER CELLA: The best things about  
11 the validity of this, or the best thing was the  
12 correlation with falls, which was encouraging.  
13 It would have been nice to see more correlations  
14 with things like pressure ulcers or  
15 hospitalization or other things that the writeup  
16 suggests that these basic ADLs helped prevent,  
17 all of which is clinically sensible, but there  
18 really wasn't much data, although the fall data  
19 were there.

20 Using the Rasch Model to claim  
21 validity is kind of sketchy. It really just  
22 helps to show that people tend to lose the

1 ability to toilet before they lose the ability to  
2 eat. And in between, you have transfer and  
3 moving around in bed. And that they line up that  
4 way. But that is not really construct validity,  
5 at least by the way I would think of construct  
6 validity, although it was presented that way.

7 So, it is nice that these things are  
8 related to one another sufficiently that you can  
9 scale them in that way and consider that to be  
10 one thing, you know, like self-care. But I don't  
11 think it really gets at the kind of validity we  
12 are talking about.

13 The only other thing I will say -- and  
14 this gets to Len's point earlier -- is that if  
15 and when you open up the gate for more people  
16 that might die during the followup period,  
17 because you remove that requirement of not having  
18 that box checked, which I support, I was one of  
19 the ones that is supporting not having that, it  
20 does bring back the question of risk adjustment,  
21 I think, because now you are going to have a  
22 wider net of people.

1                   You are going to have more noise. So,  
2                   you don't want this unintended consequence of  
3                   nursing homes killing patients that take them out  
4                   of the denominator because they weren't doing  
5                   well, and then, they end up looking better than  
6                   they should because more people die. So, somehow  
7                   death needs to be included in this metric in some  
8                   way. If not, then you could have a false  
9                   denominator. But other than that, nothing to  
10                  add.

11                 CO-CHAIR PARTRIDGE: My colleagues to  
12                 my right tell me that, if we are concerned about  
13                 the question or the issue of whether or not the  
14                 exclusion should include people who are likely  
15                 not to survive more than six months, this is the  
16                 point in our voting where that would come up. I  
17                 don't know how many of us share that. I think we  
18                 may be getting a further consult.

19                 Helen, you came in in the middle of  
20                 this discussion. Is there anything you would  
21                 like to add? The concern -- you missed the  
22                 discussion earlier -- the concern is if we would

1 be very comfortable with this measure or more  
2 comfortable with this measure if that six-month  
3 exclusion were not part of the specifications.  
4 Could we, in essence, say we would vote for it,  
5 "but for" --

6 DR. BURSTIN: You have to vote on the  
7 measure as it is. You can certainly have the  
8 discussion and negotiation with the developers  
9 post hoc. I was just pointing out to Sarah -- my  
10 apologies, I had to give a speech in the middle  
11 of this -- but, you know, as much as all those  
12 higher levels of validity are great, it isn't  
13 actually required. You know, this would probably  
14 get a moderate, in and of itself, in terms of  
15 validity. And so, as much as we would love to  
16 get to those higher bars, I don't want to create  
17 a higher bar than actually exists for these  
18 measures.

19 CO-CHAIR PARTRIDGE: Are we ready to  
20 vote?

21 MS. ALLEN: Voting on validity. One,  
22 high; two, moderate; three, low; four,

1 insufficient information. Voting starts now.

2 All votes are in. Zero percent, high; 67

3 percent, moderate; 28 percent, low; six percent,

4 insufficient.

5 CO-CHAIR PARTRIDGE: Feasibility.

6 Discussion? Ann? David?

7 MEMBER MONROE: Can you hear me? Oh,

8 now it is red. My only thinking about

9 feasibility was, you know -- you used the term

10 "self-performance". I assume that means the

11 person performs, and somebody else rates their

12 performance. So, it is really not a patient

13 survey. Someone else is interpreting their

14 performance, correct?

15 MS. McMULLEN: Yes, that is correct.

16 MEMBER MONROE: And what I don't know

17 is the standardization of that interpretation and

18 how clear that is, so that there is the

19 feasibility that my review of you would be --

20 which is not the tool, which is not the measure,

21 but my review that creates the measure would be

22 the same as her review of you.

1                   And I don't know how you standardize  
2                   that or how you satisfy the feasibility of people  
3                   being the same, when they are all over the place  
4                   in terms of training and development and  
5                   expertise, when they do that evaluation. Does  
6                   that make any sense?

7                   MEMBER CELLA: I would put that with  
8                   reliability and say that this is higher moderate  
9                   in feasibility. I mean, it is already collected  
10                  in CARE. I sure hope it is.

11                  MEMBER MONROE: Okay. Well, sorry  
12                  then.

13                  MEMBER CELLA: But it is just whether  
14                  it is collected well, is your point. I am just  
15                  saying, Ann, that you could raise about all of  
16                  these, and I think that is a reliability -- it is  
17                  a concern and it is a reliability concern, and  
18                  not a feasibility.

19                  MEMBER PARISI: I kind of feel like I  
20                  have a little of an inside scoop here, and I  
21                  think everybody should be on the same page. So,  
22                  the MDS and the OASIS, it is really the same



1 issue. The rigor that goes behind that data  
2 collection is really, it is a lot of effort that  
3 goes into educating the nursing staff, both in  
4 home health as well as in long-term care. So, I  
5 think that is an important factor.

6 And these data are taken from the MDS,  
7 and when we get to home care, the OASIS as well.  
8 And a lot of education and a lot of rigor goes  
9 into developing those instruments as well as  
10 implementing them. So, I think that is an  
11 important point in terms of these outcome  
12 measures. Whether or not you can take that data  
13 and are they important for improvement, some are;  
14 some aren't. And that is reflected in the  
15 discussion. But I think that is an important  
16 point that everybody needs to be comfortable  
17 with.

18 CO-CHAIR PARTRIDGE: Are we ready to  
19 vote? Feasibility.

20 MS. ALLEN: Voting on feasibility.  
21 One, high; two, moderate; three, low; four,  
22 insufficient. Voting starts now. We are missing

1 a vote. Sixty-seven percent, high; 33 percent,  
2 moderate; zero percent, low; zero percent,  
3 insufficient.

4 Voting on usability in use. One,  
5 high; two, moderate; three, low; four,  
6 insufficient information. Voting starts now.  
7 Fifty-six percent, high; 39 percent, moderate;  
8 zero percent, low; six percent, insufficient  
9 information.

10 Overall suitability for endorsement of  
11 Measure 0688, Percentage of Residents Who Need  
12 for Help with Activities of Daily Living Has  
13 Increased Long-Stay. One, yes; two, no. Voting  
14 starts now. Eighty-three percent, yes; 17  
15 percent, no.

16 CO-CHAIR PARTRIDGE: Is it 3:25? We  
17 did it, Ann. I suggest we take a 10-minute  
18 break, if that's okay, come back at 3:35. We  
19 will pick up. We have got a block of similar  
20 measures and, then, one dissimilar measure, 2287.  
21 And it is our goal to be out of here by five  
22 o'clock.

1 (Whereupon, the above-entitled matter  
2 went off the record at 3:23 p.m. and resumed at  
3 3:38 p.m.)

4 CO-CHAIR PARTRIDGE: So we're going to  
5 reconvene and we will start with -- let's see,  
6 what did we skip? We skipped 2631 did we?

7 MALE PARTICIPANT: 2631.

8 CO-CHAIR PARTRIDGE: Yeah, okay, which  
9 looks so much like one we've already dealt with.

10 MALE PARTICIPANT: Both of us thought  
11 we did it already. So anyway, editorial kind of  
12 thing.

13 CO-CHAIR PARTRIDGE: All right, 2631,  
14 CMS you're up.

15 MS. DEUTSCH: Great. So thank you for  
16 the opportunity to allow us to present on this  
17 quality measure 2631, percent of long term care  
18 hospital patients with an admission and discharge  
19 functional assessment and care plan that  
20 addresses function.

21 So we have a large team who have been  
22 working on this measure as well as five other

1 measures that you'll hear about in the next day  
2 and a half. I'll introduce just a couple of  
3 people who are going to be speaking today. But  
4 again, there is a big team behind us. So from  
5 CMS.

6 MS. MCMULLEN: Hi, this is Tara  
7 McMullen. I'm the cross setting lead measure  
8 developer for the Division of Chronic and Post-  
9 Acute Care.

10 MS. PARDASANEY: I'm Poonam  
11 Pardasaney. I'm a research public health analyst  
12 and RTI International and also physical therapist  
13 at National Hospital.

14 MS. DEUTSCH: And I think on the  
15 phone, Tracy Kline, are you there?

16 MS. KLIEN: Hi, I'm Tracy Kline. I am  
17 a psychometrician at RTI.

18 MS. DEUTSCH: All right, great. And  
19 Laura Smith who you previously just heard talk  
20 did a lot of the reliability testing. So my name  
21 is Ann Deutsch. I did this work as part of a  
22 contract for CMS. I'm a registered nurse by

1 training. I'm also certified as a rehabilitation  
2 registered nurse.

3 In addition to working at RTI as a  
4 senior research public health analyst, I also  
5 work at the Rehab Institute of Chicago as a  
6 clinical research scientist, and I have a faculty  
7 appointment at Northwestern University.

8 So first, I would like to talk --  
9 again we've got six measures that are being  
10 proposed. And this kind of goes back to a  
11 comment that Peter made earlier today, and Becky  
12 also brought up this idea of the standardization.

13 So the measures that we are presenting  
14 are all built on some standardized items that are  
15 -- we call them the care function items. One of  
16 the other measure developers also has some  
17 measures related to care items.

18 The other thing I wanted to be sure  
19 that people were clear about is long term care  
20 hospitals. So this is a type of facility that  
21 takes care of very, very sick patients. They're  
22 referred to as chronically critically ill.

1                   There is about 400 or so LTCHs, Long  
2                   Term Care Hospitals across the country. So these  
3                   are not nursing homes. They are patients, again,  
4                   who have usually organ failure, a couple of  
5                   organs actually failing. So they're patients on  
6                   ventilators, they are very, very sick people.  
7                   People who maybe 20 years ago would not have  
8                   survived.

9                   The patients then who are admitted are  
10                  having conditions such as --- they have  
11                  respiratory failure, cardiac failure, often have  
12                  kidney failure.

13                  So they often have functional  
14                  limitations and they're at risk for having  
15                  additional functional limitations that develop as  
16                  part of their treatment because they are mainly  
17                  immobilized, oftentimes being on ventilators or  
18                  it's just very difficult for them to get out of  
19                  bed.

20                  So that's why functional assessment is  
21                  really, really important in this population. In  
22                  the past there was an interest in trying to help

1 patients recover medically. And so patients were  
2 kept in bed and on bed rest a lot, and there's  
3 been a lot of great research recently that's  
4 focused on getting people mobilized early so that  
5 their outcomes are better.

6 And so part of our evidence included a  
7 literature review that Poonam spent a lot of time  
8 just kind of reviewing kind of the overall  
9 outcomes that are affected by early mobilization.

10 So it's things like improved  
11 cognition, less delirium, improved functional  
12 status both as observed or perceived by patients,  
13 better employment, lower readmission rates, lower  
14 mortality rates, more people being able to get  
15 off ventilators, increased discharge to community  
16 homes. So that brings back something Peter  
17 mentioned earlier.

18 So that's kind of an overview of the  
19 long term care hospitals. So the actual quality  
20 measure in this case, it is a process measure so  
21 it's similar to what you heard about before.

22 We do have assessment and care plan

1 linked up. We -- as part of the development  
2 process, we have been actually working on this in  
3 several phases. The actual items were developed  
4 between about 2006 and 2012 they were tested.

5 We've had three expert panels that  
6 have focused on these measures across -- I guess  
7 it was two different CMS contracts as well as a  
8 contract funded by the Assistant Secretary for  
9 Planning and Evaluation. So we've had a lot of  
10 TEP input.

11 And when we first proposed looking at  
12 functional status among long term care hospital  
13 patients, our TEP who were specialists in the  
14 long term care hospital area felt that we really  
15 couldn't create an outcome measure across all the  
16 population of long term care hospital patients  
17 because the patients were so diverse.

18 Sometimes patients, again, are on  
19 ventilator, other patients get admitted with  
20 severe wounds. And so those patients are put  
21 onto specialized beds in order to help their  
22 wounds be healed.



1           And so their mobility is limited as  
2 part of their treatment and putting them on these  
3 specialized beds. So the expert panel feedback  
4 was really we're not at a stage yet in this area  
5 that we could develop an outcome measure.

6           You'll hear about outcome measures in  
7 our other settings. But for the long term care  
8 hospital, across all patient populations, they  
9 didn't feel that we were at that stage. That's  
10 why we felt that a process measure was the right  
11 measure to propose at this stage in time.

12           So the actual quality measure is that  
13 clinicians are needing to collect and then submit  
14 data on several functional items. And we include  
15 four self care items, so that's in the area of  
16 motor function, up to 11 mobility items in the  
17 motor area depending on if they use a wheelchair  
18 or walk.

19           We also include the confusion  
20 assessment method because delirium is a big  
21 concern among patients who are in ICU and in long  
22 term care hospitals. We have two communication

1 items, comprehension and expression, and also  
2 bladder function.

3 So the measure basically is that the  
4 assessment is conducted for these patients by  
5 clinicians on admission and discharge. And at  
6 the time of admission, we feel it's important  
7 obviously to consider whether a care plan has  
8 been put into place based on the function data.

9 And so how we operationalize that in  
10 this quality measure is that we're asking the  
11 clinicians to establish a discharge goal for the  
12 patient for at least one of these self care or  
13 mobility items.

14 We would of course hope for more, but  
15 we thought it was reasonable to expect a goal set  
16 at admission that would be the expected outcome  
17 by discharge for at least one item.

18 So again, the numerator is the  
19 admission data is completed, discharge data is  
20 completed, and that there's a goal. The  
21 denominator is all patients in the long term care  
22 hospital. We do not have any exclusion criteria.

1           The only thing that I need to qualify  
2   is that we know from our experiences in data  
3   collection in other settings that sometimes  
4   patients -- again these are very sick patients --  
5   sometimes they basically crash.

6           And so if somebody is having a medical  
7   event and need to be removed from the facility,  
8   go back to acute care or go into ICU, it may not  
9   be feasible to expect the clinicians to be able  
10   to worry about whether the person's eating or  
11   not.

12           And so we do say that it's okay not to  
13   have discharge data if the person has an  
14   unexpected discharge. And we have very specific  
15   criteria about discharge to acute meets that  
16   criteria.

17           So in terms of the gap, we've done a  
18   lot of site visits as part of the Post-Acute  
19   Payment Reform Demonstration. And we found that  
20   clinicians were collecting function data here and  
21   there, but they were not necessarily always  
22   collecting the same type of information, and they

1 certainly weren't collecting the same  
2 information.

3 So it was not standardized. And as  
4 many of you know, part of the challenge with our  
5 current healthcare system is that care is very  
6 fragmented.

7 So you can imagine, these patients  
8 were very sick, they're going into acute care,  
9 they're going into a long term care hospital,  
10 they're also often going on to another post-acute  
11 care setting, maybe a skilled nursing facility, a  
12 rehab hospital, or going to home care.

13 So the idea of having standardized  
14 items that -- or function items that would be  
15 tracked across those settings is a really  
16 appealing issue.

17 So let's see. Tara, do you want to  
18 add anything or are you, you're good. Okay, so  
19 again, you know, we've had a lot of input. We've  
20 been working on these measures quite intensively  
21 since 2011.

22 And we, as part of the development

1 process, put these specifications out for public  
2 comment, and we got I think 22 comments from the  
3 public in the past spring.

4 We also put this out formally through  
5 rulemaking in the Federal Register last year.

6 And so in April that was put out, and then we got  
7 several comments related to these measures. And  
8 this measure was finalized for the Long Term Care  
9 Hospital Quality Reporting Program in August of  
10 last year.

11 So I think I will stop there and open  
12 it up to questions or comments.

13 CO-CHAIR PARTRIDGE: And our lead  
14 discussions on this one are David, again, and  
15 Karen.

16 MEMBER BIERNER: Can I just ask a  
17 simple question about -- you mentioned bladder  
18 function, was bowel function or incontinence of  
19 the bowel also included?

20 MS. DEUTSCH: So bowel function is  
21 actually already collected as there is -- under  
22 the Quality Reporting Program there is a long-

1 term care data set. And that is already  
2 collected because it's a risk factor for another  
3 quality measure. So it's already actually  
4 required on admission.

5 CO-CHAIR PARTRIDGE: Okay.

6 MEMBER CELLA: Okay, well thanks Ann,  
7 for again a very clear and accurate rendering of  
8 the submission and the history. It's useful to  
9 know this is, you know, it's a really, really  
10 tough population to think about performance  
11 measures and quality indicators and including  
12 something like functional capacity.

13 So I, you know, I cheer the effort and  
14 I think that in that sense it makes it important.  
15 The thing that I worry about is -- kind of  
16 related to some previous discussions -- is even  
17 though no one's taken out of the denominator,  
18 with this population how many people end up  
19 incomplete, you know, because they go to the ICU  
20 or they die or, you know, they otherwise -- if  
21 you can't get that discharge functional  
22 assessment, you're excused from, right, from the

1 report card, from the reporting.

2 And I just don't know what that number  
3 is. Maybe I missed it.

4 MS. DEUTSCH: Okay. So let me  
5 clarify, sorry if I wasn't clear. So if somebody  
6 has an unexpected discharge, the admission data  
7 is still required and the goal is still required  
8 because obviously you don't know if somebody is  
9 going to have this unexpected discharge.

10 So they're only excused from reporting  
11 the discharge information. So they're included,  
12 but they just don't have to include the discharge  
13 data.

14 MEMBER CELLA: Oh, that's helpful.  
15 Yeah, I was going by the introductory paragraph  
16 that talked about incomplete cases, and it  
17 appeared as though they were being excluded  
18 completely. So I appreciate that clarification.

19 MS. DEUTSCH: And Poonam is just  
20 looking up the percent discharge unexpectedly we  
21 did, I think, report that. So we'll get back to  
22 you.

1                   MEMBER CELLA: I guess, and I don't  
2 know what category this is in, but about the risk  
3 adjustment. They're all high risk people, right?  
4 So I guess, you know, it seems okay not to have a  
5 risk adjustment because everyone in this group of  
6 patients is a risk.

7                   MS. DEUTSCH: Right.

8                   MEMBER CELLA: I mean, there's like  
9 real high risk and high risk, but --

10                  MS. DEUTSCH: Right.

11                  (Off microphone comment)

12                  MS. DEUTSCH: Yeah, and we do have a  
13 code that says the activity did not occur. So if  
14 somebody, yeah, so it's -- they just have to  
15 report something.

16                  MEMBER CELLA: Anyway, we're still at  
17 the level of importance and I, you know, I'll  
18 stop talking because I think it's good that  
19 there's something in this area because it's such  
20 a tough area. So I'm high on importance.

21                  MEMBER BIERNER: I just want to point  
22 out that more and more patients are getting



1 discharged to this type of facility with  
2 pressures on the acute care side to move people  
3 into other alternatives.

4 And so we're seeing -- this is  
5 becoming a bigger and bigger discharge  
6 disposition for a lot of acute care patients with  
7 wounds, with ventilators, and other medically  
8 complex problems.

9 MEMBER VAN ZYL: I had some questions  
10 about the difficulties you had looking at  
11 disparities data. I know that you mentioned  
12 specifically that you weren't able to find  
13 anything.

14 But the literature about disparities  
15 in long term care is pretty large. Can you tell  
16 me a little bit more about that?

17 MS. DEUTSCH: So you're asking, I'm  
18 sorry, about disparities?

19 MEMBER VAN ZYL: Yeah. I think in  
20 importance, one of the things we're looking for  
21 is evidence of disparities among different  
22 populations, and I think that there was a

1 specific comment that you couldn't identify any  
2 disparities among populations.

3 MS. DEUTSCH: So in the long term care  
4 hospitals, there's not a lot of literature about  
5 functional outcomes in particular. And so  
6 there's really no data in the literature about  
7 disparities.

8 And again, this is -- we're not  
9 looking at outcomes. We're just saying was a  
10 functional assessment conducted on admission and  
11 discharge, and was a care plan put together as  
12 part of the admission process.

13 So we actually don't have data to know  
14 whether there are disparities in terms of just  
15 doing the assessment. So we would love to know,  
16 but at this point, there's no data out there.

17 MEMBER VAN ZYL: Just for  
18 clarification, because this is a process measure  
19 or non-outcomes measure, is disparities data  
20 required? Sorry, my voice is a little off.  
21 Because this is a process measure and not an  
22 outcomes measure, does the NQF require

1 disparities data the way they do for outcomes?

2 They don't, right?

3 MS. SAMPSEL: I mean, what happens  
4 with the disparities data is -- I mean, obviously  
5 we want to see it across the board as often as we  
6 can. But there are times when the data's not  
7 there. And so it pretty -- you know, there are a  
8 lot of process measures that don't have that  
9 data.

10 CO-CHAIR PARTRIDGE: Dawn?

11 MEMBER DOWDING: Yeah, can I -- I'm  
12 just a bit confused about this measure. So am I  
13 right in thinking that you've piloted it?

14 MS. DEUTSCH: Yes.

15 MEMBER DOWDING: So do you have any  
16 data to show us on the variants in the actual  
17 score across different units in long term care  
18 hospitals because I read through all of the  
19 information you've submitted and there doesn't  
20 seem to be any indication of what the score  
21 actually is, the variation in it.

22 So what is the percentage of patients

1       who have this completed? What's the range that  
2       you found in long term care hospitals? Is there  
3       -- I mean, reliability and validity is another  
4       issue, we'll maybe get to that.

5               But I just couldn't see anything in  
6       your documentation to actually indicate this  
7       particular measure. I saw a lot about how the  
8       CARE measures function, but I didn't see anything  
9       about whether or not a patient actually has an  
10      assessment completed and it was linked to a care  
11      plan. So where is that data?

12              MS. DEUTSCH: Okay, great question.  
13      So we did as part of the material report the  
14      percent of missing data for the admission and  
15      discharge. So that's in the missing data  
16      section.

17              And so we had 4,186 records as part of  
18      our pilot. And there were three items on  
19      admission that had missing data, that was 6.14  
20      percent. And then at discharge, the same three  
21      items, it was slightly higher, 6.67 percent.

22              So I should clarify. We didn't test

1 the care plan part of this, that is done in other  
2 settings. So we were not able to test that part  
3 of it. But we did report the missing data.

4 And I should clarify that this was  
5 done as part of the Post-Acute Payment Reform  
6 Demonstration, and so the facilities were  
7 volunteers. And, you know, we would generally  
8 expect when people volunteer to be in projects  
9 that they are probably among the higher quality  
10 facilities. So I'm not sure we could generalize  
11 that that would apply to all, anyway.

12 MEMBER DOWDING: But the measure  
13 you're asking us to endorse includes the care  
14 plan bit.

15 MS. DEUTSCH: That is correct.

16 MEMBER DOWDING: But it's not in any  
17 of this.

18 MS. DEUTSCH: We don't have data on  
19 that. That is correct at this point.

20 CO-CHAIR STILLE: I just had a comment  
21 about -- we had a fairly extensive discussion  
22 about care plan this morning and how reliable

1 data were in detecting a care plan.

2 One thing that's actually sort of nice  
3 about this is that there's a measure that links  
4 having something in the care plan that's related  
5 to the assessment, which wasn't in this morning.

6 But I think, you know, data about how  
7 possible is it to measure both of those is going  
8 to be really important to look at value.

9 MEMBER MORT: I apologize if you  
10 already mentioned this, but what are the actual  
11 data elements or tools you'll use to assess  
12 function, self care, mobility, cognition,  
13 communication, and bladder. But is there a  
14 standardized CMS tool kit that you're implying,  
15 or is there a choice? I apologize if you  
16 mentioned that.

17 MS. MCMULLEN: Yes, so the items  
18 themselves are derived from the CARE tool, which  
19 came from testing that occurred in the PAC PRD,  
20 the Post-Acute Care Payment Reform Demonstration.

21 So the Post-Acute Care Payment Reform  
22 Demonstration derived out of the Deficit

1 Reduction Act of 2005. So basically the Deficit  
2 Reduction Act mandated that this demonstration  
3 occur to see if anything like standardization in  
4 post-acute care settings and acute care settings  
5 was possible to be able to assess patient  
6 complexities and, you know, to look at payment  
7 and things like that.

8 So from that payment reform  
9 demonstration came the CARE tool. And from that  
10 CARE tool we have many sections, domains. But  
11 one domain or one section is the function  
12 section.

13 So we used items from the function  
14 subset of the CARE tool, and that's how we  
15 developed these measures.

16 MEMBER MORT: And the items are  
17 listed, I think, in Table 1. But is the  
18 assumption that all of those will be assessed? I  
19 just don't know how the CARE tool works.

20 MS. MCMULLEN: Yeah. So there's four  
21 self care items: eating, oral hygiene, toileting  
22 hygiene and wash up your body. So we did not

1 include dressing items.

2 And that was based on our testing that  
3 in long term care hospitals, those items -- you  
4 know, patients were very sick, they were wearing  
5 gowns and so it's really not fair to assess  
6 whether somebody can put on shoes or not. It's  
7 just too hard for them.

8 So we only included the items that we  
9 thought made sense for that population. In the  
10 area of mobility, we have quite a few bed  
11 mobility items.

12 So we have roll left to right, sit to  
13 lying, lying to sitting on side of bed, sit to  
14 stand, chair to bed transfer, toilet transfer.  
15 There is different walking distances. If  
16 somebody's walking, they can otherwise skip,  
17 there's a couple of wheelchair distances,  
18 otherwise they can skip if they don't use a  
19 wheelchair.

20 We have the confusion assessment  
21 method which is a published instrument. We have  
22 a comprehension or understanding item, an



1 expression item, and then the bladder continence  
2 item.

3 I do want to highlight that there's a  
4 six level scale for the CARE tool, six being that  
5 the person is independent, level one being the  
6 person is dependent. If an activity does not  
7 occur, for example somebody does not walk at this  
8 point in time, they just record the reason that  
9 the person wasn't able to do it.

10 Maybe the person's too sick, there's a  
11 medical reason, or maybe the person refused. So  
12 there's special codes for somebody -- the  
13 clinician to document that the activity was not  
14 attempted, and again the rationale.

15 So if they put the code to say, you  
16 know, this wasn't attempted because it wasn't  
17 safe for the person to get out of bed, they get  
18 credit for that. All we're asking is that  
19 there's a response for each so we know that they  
20 considered doing that assessment item.

21 MEMBER MORT: Thank you.

22 CO-CHAIR PARTRIDGE: Peter?

1           MEMBER THOMAS: Again, what comes to  
2 mind just from a layperson's perspective I guess  
3 is, you know, what LTCH wouldn't be doing this?  
4 And I guess that gets to patients who come to  
5 them for treatment. And so I guess it goes to  
6 the issue of whether there's enough variants to  
7 make this measure really worthwhile, you know,  
8 conducting.

9           Are there really LTCHs out there that  
10 take patients and then don't have any assessment  
11 and any plan of care that they've got to treat  
12 the patient?

13           MS. DEUTSCH: So, great question.  
14 When we did the Post-Acute Payment Reform  
15 Demonstration, we saw variability in the types of  
16 items that were assessed. But certainly, you're  
17 right, a lot of patients were seen by therapists.

18           I think, you know, we don't know  
19 enough to know that that's happening. And so  
20 this measure could help document that. But  
21 whether it taps out, you know, soon and we should  
22 really move to outcomes more, that's I think a

1 great question.

2 CO-CHAIR PARTRIDGE: In order, David,  
3 Liz, Becky, Sherrie. Oh, Liz went down.

4 MEMBER CELLA: There we go. So it's  
5 really just to now clarify a couple of things  
6 because you actually mentioned it, Ann and then  
7 Chris, I think you restated this and it was not  
8 my impression that the assessment -- that the  
9 actual functional care had to be linked to the  
10 assessment, that the goal could be just any goal  
11 and it did not have to be linked.

12 I didn't see that anywhere in the  
13 document. Is it true that there needs to be a  
14 link as we had in the discussion this morning?

15 MS. DEUTSCH: Yeah, so basically let's  
16 say, I don't know, roll left to right, somebody  
17 might be admitted at a score of level one and the  
18 goal is that they would improve. So you would  
19 link up, you know, that the goal is this item and  
20 the goal is for them to get, I don't know, level  
21 two, they would improve in independence.

22 So I think that's what you're

1 referring to, that the function item is here and  
2 then there's a goal tied exactly to that item.  
3 So that's true.

4 MEMBER CELLA: Okay, that sounds  
5 great. But the performance measure's not written  
6 that way. I mean, it's written that you have to  
7 have both, but not that they have to be linked.  
8 Whereas this morning we saw a performance measure  
9 that was actually written that way.

10 MS. DEUTSCH: Well, so maybe it wasn't  
11 clearly worded, sorry. But what we intended was  
12 that you score each of the items that I listed  
13 out. So for example, you would score roll left  
14 to right, and then you have one or more goals for  
15 each of the self care or mobility items. At  
16 least one of those items that you score.

17 MEMBER CELLA: Okay. Well, in my mind  
18 that actually elevates the importance as opposed  
19 to be --

20 MS. DEUTSCH: Oh, okay, well good.

21 MEMBER CELLA: But maybe I want to  
22 encourage you to rewrite the measure so that it

1 actually shows the link in the terminology of the  
2 measure, and the way it's described because it's  
3 actually when you read into, like, actually how  
4 you get the number, there's nothing in there that  
5 says there has to be a demonstration that there's  
6 a connection.

7 CO-CHAIR STILLE: I was assuming just  
8 in the first sentence it says brief description,  
9 you know, a care plan that addresses function.

10 MEMBER CELLA: Yeah, but then -- well  
11 okay, anyway.

12 CO-CHAIR STILLE: I don't know. I  
13 don't know.

14 MEMBER CELLA: I'm glad to hear that  
15 there is a link because that strengthens it. The  
16 other thing is you mentioned the six percent  
17 missing data. But what's the percentage of  
18 documented non-adherence -- documented non-  
19 assessment because if somebody documents that it  
20 wasn't assessed, that actually counts, they get  
21 credit for that. So how often does that happen?

22 MS. DEUTSCH: You're asking what

1 percent of time the activity did not occur?

2 MEMBER CELLA: So if I'm reading it  
3 right, if the provider says, you know, I couldn't  
4 assess it, patient refused, patient was sleeping,  
5 whatever, it didn't work out, they get credit for  
6 it because they documented that they didn't get  
7 it.

8 MS. DEUTSCH: Right. So sleeping is  
9 actually not a reasonable rationale. But you  
10 know, somebody refusing is reasonable and they  
11 would get credit that they tried to assess the  
12 patient.

13 MEMBER CELLA: How often does that  
14 happen?

15 MS. DEUTSCH: So it really varies by  
16 item. I can certainly send that after this  
17 meeting. I actually have a report I can send you  
18 graphics by setting, how often the activity did  
19 not occur.

20 But I can tell you, like, things like  
21 stairs, which is not on this measure, and  
22 dressing, were very commonly not assessed, and

1 that's why we didn't include them as items.

2 MEMBER BIERNER: Because, as  
3 clarification, what is the length of time and the  
4 look back that this is being -- is this assessed  
5 the last 24 hours, in this week, like, the best  
6 performance in the last 72 hours? I have the  
7 same issue with the FIM that I have this issue  
8 too.

9 MS. DEUTSCH: Great question. So the  
10 instructions were if the patient was admitted  
11 before 12:00 noon, there was a two day assessment  
12 period. If the person was admitted after 12:00  
13 noon, they had a three day assessment period on  
14 admission.

15 Most people were admitted after 12:00  
16 noon, so it's generally a three day assessment  
17 period. And it's mutual performance. At discharge  
18 it's any time during the last three days. Mostly  
19 it's during the last day or so. But we did give  
20 people the option of three days given weekends,  
21 therapists aren't necessarily working every day.

22 CO-CHAIR PARTRIDGE: Becky?

1                   MEMBER BRADLEY: Thank you. I guess  
2 I'm having a little trouble figuring out how this  
3 would be a quality measure. I know it's a process  
4 measure. But it's -- the way I understand it  
5 it's did they do an assessment, did they do a  
6 plan.

7                   But they could pick -- a clinician  
8 could have two patients that are pretty much the  
9 same and pick different items to focus on as the  
10 goal. And so I'm confused as to how that rolls up  
11 to some type of benchmarking or comparison to  
12 make it a quality measure.

13                  MS. DEUTSCH: So our technical --- so  
14 just to kind of recap Becky's question, so it's  
15 basically how is this a quality measure just  
16 doing the assessment and the care plan.

17                  So our technical expert panel, which  
18 is our LTCH experts basically said that given the  
19 heterogeneity of the types of patients, it was  
20 really hard to think about trying to do an  
21 outcome measure or hold people accountable to  
22 goals.



1 I mean, that was something that I  
2 think we would love to be able to do potentially  
3 in the future. And actually tomorrow I will be  
4 presenting an outcome measure that's focused on  
5 patients who are on ventilators.

6 So it's a very specific sub-group, but  
7 in terms of having a measure -- a quality measure  
8 that would work across the entire LTCH  
9 population, I think we just don't know about the  
10 diversity of patients.

11 Also, there's major payment reforms  
12 that are happening in the long term care  
13 hospitals. They are going to be paid differently  
14 in the future. And so probably the types of  
15 patients admitted will really change a lot.

16 And so I would worry that if we did  
17 create an outcome measure, at this point in time,  
18 that applied to all patients now, it wouldn't  
19 necessarily work well in, I don't know, five, ten  
20 years whenever that shift happens. Does that  
21 help?

22 MEMBER BRADLEY: It helps.

1           MEMBER KAPLAN: I want to follow on  
2 Dawn's point about you've done a pilot study at  
3 the facility level but we don't know what the  
4 answer to that is in terms of means and  
5 variability, in terms of a performance gap.

6           Help us understand why that wasn't  
7 done because things like -- my concerns would be  
8 the same as the earlier one. You know, you guys  
9 have -- if nobody else has data on this, you have  
10 data on this to help us understand what the  
11 facility level on reliability is in terms of  
12 intraclass correlation coefficients, what the  
13 other kind of measures do you have available to  
14 help us understand why we don't see any of that.

15           MS. DEUTSCH: Okay, great question.  
16 So first of all, unlike the other post-acute care  
17 settings, long term care hospitals only recently  
18 implemented a clinical assessment data set.

19           That was as part of the Long Term Care  
20 Hospital Quality Reporting Program that started  
21 in October of 2012. So it's only recently that  
22 actually, pressure ulcer data and some function

1 data were available other than claims.

2 And so obviously this is a very  
3 clinical issue. And so there really aren't a lot  
4 of data out there at this point. So our pilot  
5 study, we did collect the CARE data on  
6 admission/discharge. We did not collect the CARE  
7 plan data. That was something that was made a  
8 decision after that got started.

9 MEMBER KAPLAN: So there are data on  
10 the front end of this measure at the facility  
11 level. So how are we to evaluate a performance  
12 gap with no data at the facility level?

13 Are we -- because all of the  
14 information is at the patient level. So I'm a  
15 little bit nervous about something that's going  
16 to be used. The attribution is to the facility  
17 with no evidence that there's a performance gap  
18 at this facility level.

19 MS. DEUTSCH: Right. So we did  
20 actually submit some supplemental information  
21 that talked about our experiences as part of the  
22 Post-Acute Payment Reform Demonstration in that

1       there was variability in terms of the items that  
2       were being collected.

3               And part of what we also feel is  
4       important is that there would be this  
5       standardized assessment data collected across  
6       settings potentially. And that would be helpful  
7       in terms of care coordination.

8               So there would be a common language of  
9       function just like if I told you somebody's blood  
10      pressure, you would automatically know, you know,  
11      whether somebody was in an IRF or a SNF or long  
12      term care hospital.

13              So standardization of assessment items  
14      is kind of part of what we're interested in also  
15      as part of this. So that should improve care.  
16      I'm sorry, I should --

17              CO-CHAIR PARTRIDGE: Dawn?

18              MEMBER DOWDING: Okay, I'm still going  
19      back to my same point. I'm really concerned that  
20      you're asking us to endorse a measure where you  
21      actually don't have data at all on part of it.

22              Like, you've said twice you haven't

1 collected the data on the care plan bit of this  
2 measure. So we can't -- I mean, I'm sort of  
3 sitting here thinking it's quarter past four.  
4 We're discussing a measure that we actually can't  
5 endorse because you haven't collected the data on  
6 part of it.

7 And I'm really, I don't know, maybe  
8 I'm just -- it's quarter past four and we've had  
9 to look at a lot of them. But it's like how can  
10 we evaluate reliability, validity, do anything  
11 with this measure when a key part of it, the key  
12 that makes it important is the link between  
13 assessment data and the care plan and you haven't  
14 got the data on the care plan.

15 I just -- I'm really sorry but I just  
16 think we have to say is it worth continuing with  
17 this discussion because we can't endorse it. We  
18 haven't got the data to endorse it because it  
19 hasn't been collected yet. Or am I missing  
20 something? Am I just totally on the wrong page?

21 MS. MCMULLEN: So from the CMS  
22 perspective, I think it's a point well taken. As

1 a researcher and academic, my other hat, I  
2 understand.

3 But in the development of process  
4 measures, we use these measures to be able to  
5 collect the data to make outcome measures, to  
6 make these measures where we are able to  
7 publically report and benchmark to a degree.

8 So the items would be nested within  
9 the LTCH long term CARE data set. That's the  
10 data set that Ann was just talking about. And we  
11 use these simply to collect data at this point  
12 because the data is not available. I get your  
13 point, but --

14 MEMBER DOWDING: But that's fine, but  
15 the NQF is not -- you're going to collect the  
16 data anyway. We're being asked to endorse a  
17 performance measure.

18 MS. MCMULLEN: Right, so --

19 MEMBER DOWDING: And we don't have the  
20 data in which to do that. So yes, collect the  
21 data and come back with the data so we can  
22 endorse it. But we can't -- I mean, unless I'm

1       misunderstanding the role of the committee.

2                   CO-CHAIR PARTRIDGE: I think it's very  
3       close to getting ready to vote on importance.  
4       But I want to see if Peter or Brian were  
5       addressing importance -- issues related to  
6       importance before we take that vote. And Karen,  
7       I'm sorry.

8                   MEMBER LINDBERG: Okay. Yeah, I just  
9       wanted to clarify. Have you had discussions  
10      about how the measure could be used for cost  
11      containment or fraud detection?

12                  MS. MCMULLEN: Yeah, so in the Post-  
13      Acute Care Payment Reform Demonstration, data was  
14      collected for more than just looking at quality,  
15      but really looking at efficiency and utilization  
16      being prediction type models and things like  
17      that.

18                  At this point with this data, we have  
19      not had that type of conversation. Of course,  
20      you have the IMPACT Act which mandates that we  
21      develop a resource and measures like Medicare  
22      spending per bene.

1                   And you will have a function measure.  
2           So at some point those worlds will collide where  
3           you're looking at attributable episodes and  
4           what's going on with that individual within that  
5           episode.

6                   But at that point, we have not  
7           discussed that. But that's definitely the  
8           direction we're moving in.

9                   MEMBER BEVANS: I want to support  
10          Dawn's statement and clarify, I think for myself  
11          and maybe some other members of the committee  
12          that we are not being asked to endorse the care  
13          measure.

14                   We are being asked to endorse a  
15          process measure that is about the administration  
16          of the care measure as well as the development of  
17          a care plan process, not the psychometric  
18          properties and importance of all of that of the  
19          care measure itself.

20                   Not to say that that isn't obviously  
21          an essential component of this. It is not a  
22          sufficient component of this measure. Being a



1 process measure, we don't have sufficient  
2 information to be able to, you know, make an  
3 informed decision about this measure at this  
4 time. We're missing half of the information.

5 CO-CHAIR PARTRIDGE: Okay, on to vote.  
6 I'm sorry.

7 MS. MCMULLEN: -- about time limited  
8 endorsements and if those things were feasible  
9 based on data collection and coming back to the  
10 table with further data collection for care  
11 plans.

12 MS. THEBERGE: We're not doing time  
13 limited anymore.

14 MS. MCMULLEN: Okay. Thank you.

15 CO-CHAIR PARTRIDGE: Okay. Nadine?

16 MS. ALLEN: Voting on evidence, one  
17 high, two moderate, three low, four insufficient  
18 evidence, five insufficient evidence with  
19 exception. Voting starts now. All votes are in,  
20 six percent high, 28 percent moderate, zero  
21 percent low, 50 percent insufficient evidence, 17  
22 percent insufficient evidence with exception.

1 (Off microphone comment)

2 CO-CHAIR PARTRIDGE: Okay. B.

3 MS. ALLEN: Performance gap, one high,  
4 two moderate, three low, four insufficient.  
5 Voting starts now. Six percent high, 11 percent  
6 moderate, 17 percent low, 67 percent  
7 insufficient.

8 MS. SAMPSEL: So at this point, I  
9 mean, the measure fails, we don't move forward.  
10 But as we did with the earlier developers -- you  
11 know, and I know we've had some discussion.

12 But I think what I've heard from the  
13 committee is, you know, what you want to see  
14 moving forward for additional data which could be  
15 submitted before the end of public comment for  
16 reconsideration and re-vote would be those -- you  
17 know, the additional data that you have as well  
18 as more information regarding the care part of  
19 the process measure because we want to tie those  
20 together.

21 Were there any other comments,  
22 considerations that the committee would like to

1 ask CMS and RTI to provide?

2 CO-CHAIR PARTRIDGE: If not, we're  
3 going to thank you very much. And let's see  
4 where we are. We are on -- aside from the fact  
5 that we're brain dead.

6 (Off microphone comment)

7 (Laughter)

8 CO-CHAIR PARTRIDGE: 0701 is the one  
9 remaining. You're up.

10 MS. SAMPSEL: Kate, are you still on  
11 the phone?

12 MR. LICHTMAN: Steve Lichtman still on  
13 the phone. I'm one of the developers.

14 MS. SAMPSEL: Okay. So we are ready  
15 to move on to 0701 and the developer is the  
16 American Association of Cardiovascular and  
17 Pulmonary Rehabilitation. So if you could do as  
18 brief as possible measure introduction.

19 MR. LICHTMAN: Yes.

20 MS. SAMPSEL: You know, at the same  
21 time make sure you hit your key points.

22 MR. LICHTMAN: Yeah. I fully

1 understand. We've been on the phone listening to  
2 you guys since about noon.

3 MS. SAMPSEL: Sorry.

4 MR. LICHTMAN: So it's been a  
5 fascinating listen, let me tell you. Hi, I'm  
6 Steve Lichtman, I'm a past president of AACVPR,  
7 that's the American Association of Cardiovascular  
8 and Pulmonary Rehab.

9 And I'm the current lead on the  
10 pulmonary rehab performance measure task force.  
11 And we're presenting to you today the functional  
12 capacity in COPD patients before and after  
13 pulmonary rehabilitation.

14 And I want to thank NQF and the  
15 Committee for considering our submission and  
16 letting us onto this conference call to speak  
17 about it.

18 Kate Murphy is also on the call, she's  
19 our staff person in charge of our task force from  
20 AACVPR. Dr. Marjorie King is also on the call,  
21 she's also a past president of AACVPR and she's  
22 the current chair of the quality care committee

1 under which the performance measure task force  
2 falls.

3 And Dr. King and I both work at Helen  
4 Hayes Hospital in New York, and we've been  
5 running the pulmonary rehab program for over 20  
6 years now. She's the medical director and I'm  
7 the program director.

8 And finally on the call is Gerene  
9 Bauldoff who's a professor of clinical nursing at  
10 Ohio State University College of Nursing. And  
11 she's been working in pulmonary rehab for over 18  
12 years. And she's also on our task force.

13 A little bit about pulmonary rehab.  
14 And I'll try to make this as brief as possible.  
15 Pulmonary rehab is a low cost, highly efficient,  
16 evidence based program that's been shown to  
17 improve function, quality of life, decreased  
18 dyspnea, decreased COPD exacerbation, and  
19 decreased rehospitalizations.

20 It's typically run in a group setting,  
21 the cornerstone is physical conditioning with  
22 many, many different devices used. Supplemental

1 oxygen is used, oximetry is used to make sure  
2 patients don't desaturate.

3 There's also a strong educational  
4 component to the program, and many programs also  
5 use breathing retraining methodology. It's  
6 recommended by the Gold guidelines for moderate  
7 and severe COPD patients as standard practice for  
8 treatment.

9 And a cornerstone of pulmonary rehab  
10 that's really related to all the changes is the  
11 improvement in functional capacity. This really  
12 relates to all the other outcomes that I've  
13 talked about in pulmonary rehab.

14 This measure that you guys are hearing  
15 today was endorsed by NQF in 2011. And it  
16 represents a clinically important measurable  
17 outcome that's vital for pulmonary rehab programs  
18 to utilize.

19 And the measure is defined as the  
20 percentage of patients with COPD who increase by  
21 at least 25 meters as measured by the six minute  
22 walk test.

1           And the six minute walk test is a  
2       valid and reliable standard test that's used in  
3       pulmonary rehab to assess the functional capacity  
4       and the functional changes of our patients. And  
5       we chose 25 meters because that is the minimal  
6       important difference that's been identified in  
7       the literature over and over.

8           The measure was tested utilizing two  
9       different methodologies. One we used a group of  
10      pulmonary experts, 32 experts from around the  
11      country and internationally replied to a  
12      questionnaire that looked at the reliability, the  
13      ability to differentiate quality programs, face  
14      validity, how we defined our numerator and  
15      denominator, are there any negative consequences  
16      to the measure and looking at our exceptions.

17           Overall, they used a Likert-like  
18      scale. And overall on all the questions, they  
19      were well above four out of five on all the  
20      categories, demonstrating an excellent response  
21      from our experts.

22           Then we also tested the measure using

1 the only nationally available database looking at  
2 outcomes in pulmonary rehab, and that's the  
3 AACVPR National Data Registry.

4 We used a one year period from August  
5 of 2013 to August of 2014. And in the definition  
6 of the measure, you look at change in the six  
7 minute walk test, pre and post pulmonary rehab  
8 participation, which is generally over a three  
9 month period with a minimum of ten sessions  
10 attended by the patients.

11 And when we examined this data, we  
12 found -- and we also looked at the raw data and  
13 we also looked at the data used in the Charleston  
14 Comorbidity Index to restratify the models also.

15 And there was no significant  
16 difference in the outcomes whether we used these  
17 Comorbidity Index as a covariant or whether we  
18 looked at the raw data. So there seems to be no  
19 impact of other comorbidities on our outcomes.

20 And we utilized over 2,668 patient  
21 records, pre and post pulmonary rehab. This  
22 represented 121 programs geographically



1 distributed across the country. To make it  
2 short, you have the demographic data, you have  
3 the distribution data in your report so you can  
4 look at that.

5 And to make a long story short, what  
6 we found is there were very few exceptions where  
7 patients didn't have pre or post data. And we  
8 did find a gap, and the gap was that 21 percent  
9 of the patients don't meet the minimal important  
10 difference in the programs across the country.

11 So there's a lot more analysis in the  
12 data, and I'm sure you'll question us about that,  
13 so I'll keep this short.

14 And in conclusion, what we really are  
15 looking at, what we really think this performance  
16 measure will allow programs to do, A is to guide  
17 them in what is important to measure in a  
18 pulmonary rehab program.

19 AACVPR also runs a program  
20 certification process. And we have found in that  
21 program certification process that there are many  
22 programs across the country that are fairly

1 ignorant in the use of outcomes, how to use them,  
2 and what to measure.

3 So this will initially serve as a  
4 guide for one of the most important outcomes to  
5 measure in pulmonary rehab. It will allow  
6 programs to establish or allow us to establish  
7 program quality by looking at the change in  
8 scores of a valid and reliable, clinically  
9 meaningful assessment of functional capacity.

10 AACVPR in the near future will be  
11 releasing benchmark data on six minute walks in  
12 pulmonary rehab, it will allow programs to  
13 compare themselves to benchmark, and most  
14 importantly will allow programs to develop  
15 quality improvement plans if they're not meeting  
16 the 25 meter change in a large number of their  
17 patients as compared to national benchmarks.

18 To make a long story short, that's  
19 what we've done with this measure.

20 CO-CHAIR PARTRIDGE: Thank you.  
21 Sherry, do you want to lead off our discussion on  
22 importance?

1                   MEMBER KAPLAN: Yeah. Help me  
2 understand who the target of inference is, whose  
3 quality of care are we measuring? The data you  
4 provided are, some of the data to support the  
5 quotes validity are all patient levels.

6                   There's no quality programs or  
7 physician or facility level information in at  
8 least what I could find. So help me, who is this  
9 supposed to be used to evaluate, what's the  
10 performance assessment?

11                  MR. LICHTMAN: The evaluation of each  
12 individual patient is on a patient level.  
13 However, what we intend this performance measure  
14 to be utilized for is for programs to be able to  
15 evaluate their own quality once they understand  
16 the process and the importance of measuring the  
17 six minute walk data performance.

18                  MEMBER KAPLAN: Okay. So now my  
19 question is what's a program?

20                  MR. LICHTMAN: Okay, pulmonary rehab  
21 programs are outpatient programs, they're run  
22 across the country. We estimate there's

1       probably, oh, 900 to 1,000 pulmonary rehab  
2       programs across the country.

3               They're delineated by a process of who  
4       can participate in the program. Medicare  
5       currently allows moderate to severe COPD patients  
6       to participate in their programs, private  
7       insurances have a little more open guidelines,  
8       and some states allow other types of patients to  
9       participate.

10              But across the country it's standard  
11       that patients with COPD are reimbursed for  
12       participating in pulmonary rehab. It's generally  
13       a 12 week program run two or three times a week  
14       anywhere from an hour to two hours of  
15       rehabilitation.

16              There's exercise training just like  
17       you would see in cardiac rehab or a gym. The  
18       only difference is we are monitoring SBL2 and a  
19       lot of the patients are on supplemental oxygen.

20              There is a breathing retraining class,  
21       and then there's an education component. And  
22       those are all required by Medicare to be standard

1 components of the pulmonary rehab programs.

2 MEMBER KAPLAN: Okay, so --

3 MR. LICHTMAN: Typically run, oh go  
4 ahead. I'm sorry.

5 MEMBER KAPLAN: Oh, that's all right.  
6 Sorry, finish.

7 MR. LICHTMAN: It's typically run by  
8 some combination of respiratory therapy, exercise  
9 physiology, nursing, physical therapy, and  
10 sometimes occupational therapy. Multi-  
11 disciplinary in nature, and it's designed to  
12 improve the function and the quality of life of  
13 the patients enrolled.

14 MEMBER KAPLAN: Okay, so right now  
15 though we don't have any evidence of between  
16 program differences or between program  
17 reliability, variations that would be  
18 attributable to, for example, how precise, how  
19 reliable or reproducible these scores are at the  
20 facility or program level.

21 MR. LICHTMAN: That is correct. The  
22 only national database, the AACVPR database when

1 we submitted this, even though it had over 2,000  
2 patient records, when you spread them across the  
3 programs, we really didn't yield enough data with  
4 each program to look at that.

5           However, the six minute walk test and  
6 functional capacity -- and Gerene can speak to  
7 this a little more -- has been shown to be  
8 extremely valid, reliable, and important in the  
9 established literature. And we submitted that in  
10 the evidence.

11           MEMBER KAPLAN: Okay. So reliable and  
12 reproducible scores, what you've actually  
13 provided us in terms of the agreement of expert  
14 panel is what we call content validity. That is  
15 did you sample correctly from the domain of  
16 observables.

17           And that really is more or less face  
18 validity, are they right -- it's not a  
19 reproducible score at the facility level. So  
20 right now, we don't have any information at the  
21 facility level on which to endorse this.

22           But that's the intent for us because

1 we can't -- without that information, I'm  
2 concerned about what actually we're being asked  
3 to endorse. Furthermore, without some evidence  
4 that this is hooked up at the facility or program  
5 level with something else, for example, for  
6 construct validity that you would think would  
7 actually distinguish facilities or programs in  
8 terms of variation quality, you don't have that  
9 either.

10 So I'm a little bit lost about exactly  
11 what it is we're being asked to endorse.

12 MR. LICHTMAN: Well, we did ask the  
13 expert panel if this would differentiate between  
14 quality programs, and they strongly agreed to  
15 that.

16 As far as what we're being asked to  
17 endorse is the program is to have a performance  
18 measure to follow so that they can begin testing  
19 and measuring this in the appropriate fashion.

20 MEMBER KAPLAN: So this is a question,  
21 I guess, for the NQF staff.

22 CO-CHAIR PARTRIDGE: Yes. I think, do

1 we want to have a two minute pause and let you  
2 confer?

3 MS. SAMPSEL: No, I mean, so your  
4 points are valid. However, the way that the  
5 criteria are written, this is not a patient  
6 reported outcome measure.

7 So on an outcome measure, all that is  
8 required is either the item or the kind of  
9 patient level result, or the measure level  
10 results.

11 MR. LICHTMAN: That's what we were --  
12 (Simultaneous speaking)

13 MS. SAMPSEL: Or, you know, that type  
14 of testing. So frankly, they did provide the  
15 amount of testing information required for an  
16 outcome measure. But if the patient --

17 MEMBER KAPLAN: So no, because --

18 MS. SAMPSEL: At the item level, so it  
19 could be at the scale level of what they were --  
20 or the tool level of what they've done, they can  
21 provide that for this measure. And that meets  
22 NQF criteria.



1                   MEMBER KAPLAN: Okay, so this sounds  
2                   like one, if we had a tiered system where this  
3                   would be like the Phase 1 and the FDA approval  
4                   level, this is to go out and start collecting  
5                   data rather than use it to discriminate programs  
6                   because right now it doesn't sound like we have  
7                   enough evidence that it's valid or reliable for  
8                   that purpose.

9                   And there is no such thing as a valid  
10                  measure. They're valid for populations and  
11                  purposes only. So if we use that as a criteria,  
12                  I'm still a little bit flummoxed about how much  
13                  evidence we have to support the reliability and  
14                  validity for the purpose that it's intended to be  
15                  used for unless it's just at the patient level.

16                 MR. LICHTMAN: Well, the measurement  
17                  is at the patient level and it's for programs to  
18                  measure their changes in functional capacity.  
19                  And then in the NQF application it said what is  
20                  your plan for reporting this in the future.

21                  And part of the plan would be to, in  
22                  the future, have programs compare to benchmarks

1       that will be available.

2               MEMBER KAPLAN:   See for me, Sarah,  
3       this is one of those tiered approval problems  
4       that we don't have in place yet.

5               MS. SAMPSEL:   Well, and I think the  
6       best mechanism, you know, kind of as a committee  
7       to work through some of this is going to the  
8       algorithm and going through the step by step  
9       process which you know kind of takes you through  
10      the concept of in the first question when  
11      thinking about validity is are the measure's  
12      specifications consistent.

13              And then it goes down to was empirical  
14      validity testing conducted using the measure as  
15      specified for the applicable tests, and then you  
16      do the yes or the no.   And if no, you go to face  
17      validity, et cetera.

18              But I think what you're getting to,  
19      Sherrie, is then you go down to the fact that was  
20      validity testing conducted with computed measure  
21      -- performance measure scores for each measured  
22      entity, the answer's no.

1                   So with the NQF criteria, the next  
2 question is was validity to that testing  
3 conducted with patient level data elements. And  
4 if yes, you have options to rate as moderate to  
5 low.

6                   So, I mean, it does kind of go through  
7 that step process. I think this is an area where  
8 in some cases with these types of measures we're  
9 in a little bit of untested grounds. And we'll  
10 look for your feedback on it, but we still need  
11 to kind of go through the process.

12                  CO-CHAIR PARTRIDGE: Further  
13 discussion?

14                  (Off microphone comment)

15                  CO-CHAIR PARTRIDGE: On importance,  
16 yes. I have to say one thing. I did like the  
17 fact that various threshold as opposed to, we  
18 aren't quite sure what the right level is. Here  
19 we've got a threshold. Peter?

20                  MEMBER LINDBERG: Again, I'm not a  
21 clinical person. But it strikes me as odd that  
22 the best way to measure pulmonary function is

1 through a distance, a walking test based on time  
2 that it takes to cross a certain distance. I'm  
3 just surprised by that. Is that --

4 MEMBER BIERNER: It's actually not  
5 surprising. It's a measure of function. You can  
6 improve someone's function and their  
7 physiological parameters may not improve that  
8 much. But their function can improve because  
9 they're debilitated from their disease.

10 And so this is true in cardiac as well  
11 as pulmonary rehab. You may improve functional  
12 measures like walking ability and endurance, it  
13 may not change other physiological parameters on  
14 it.

15 MEMBER LINDBERG: I don't know the  
16 percentage here, but what about persons that  
17 don't walk well, can't walk, have other  
18 ambulatory issues that they're dealing with?

19 MR. LICHTMAN: The six minute walk  
20 test is valid for patients who use assisted  
21 devices. So we can include them. And there are  
22 exclusions where patients who can't ambulate or

1 would be a risk would be excluded.

2           However, quite honestly, when patients  
3 come to outpatient pulmonary rehab, they are  
4 almost always ambulatory. Outpatient pulmonary  
5 rehab, because it's an outpatient program, the  
6 patients really need to have a minimum level of  
7 function in order to benefit from what we do.

8           And virtually all the patients can do  
9 a six minute walk test. They might not do the  
10 six minutes. They may have a very low value.  
11 You don't have to complete the six minutes for it  
12 to be a valid test.

13           And it could be for various reasons.  
14 But as long as they can attempt the walk test,  
15 it's considered a valid outcome.

16           MS. KING: This is Dr. Marjorie King.  
17 The six minute walk test is used in research to  
18 assess differences in outcomes, including in  
19 patients with pulmonary rehabilitation.

20           It was used in the National Emphysema  
21 Treatment trial which basically showed that  
22 pulmonary rehabilitation is better than some of

1 the surgical techniques used to treat patients  
2 with moderate to severe COPD.

3 So it is a tool that is used within  
4 pulmonary rehabilitation and has been valid and  
5 reliable in this population. It's also used  
6 individually clinically to assess improvements in  
7 patients in both inpatient and outpatient  
8 settings for heart failure or for COPD rehab.

9 MR. LICHTMAN: And the literature has  
10 been using the six minute walk test to assess  
11 function in COPD patients probably since the mid  
12 '80s. And there was a huge Medicare sponsored  
13 trial called the National Emphysema Treatment  
14 Trial that was done right around 2000.

15 And that was the only randomized,  
16 large scale examination of different treatments  
17 for COPD. Six minute walk test was a primary  
18 outcome to that study.

19 CO-CHAIR PARTRIDGE: Okay, importance  
20 to measure and report. Nadine?

21 MS. ALLEN: We're voting on evidence,  
22 one yes, two no, voting starts now. We're

1 missing one vote.

2 CO-CHAIR PARTRIDGE: Yes, Brian left.

3 MEMBER MONROE: I heard none of the  
4 discussion. So I won't vote.

5 CO-CHAIR PARTRIDGE: Oh, you didn't  
6 vote.

7 MS. ALLEN: Oh, you didn't vote. So  
8 we are just --

9 (Off microphone comment)

10 MS. ALLEN: Eighty-eight percent yes,  
11 twelve percent no. Voting on performance gap.  
12 One high, two moderate, three low, four  
13 insufficient. Voting starts now. Twenty-four  
14 percent high, forty-seven percent moderate, zero  
15 percent low, twenty-nine percent insufficient.

16 Voting on high priority. One high,  
17 two moderate, three low, four insufficient.  
18 Voting starts now. Forty-one percent high,  
19 fifty-nine percent moderate, zero percent low,  
20 zero percent insufficient.

21 CO-CHAIR PARTRIDGE: Okay, reliability  
22 next. And Sharon?

1                   MEMBER CROSS: Just a quick question  
2 in looking at the measure worksheet before we go  
3 any further. I just want a clarification for  
4 myself.

5                   This is an endorsement maintenance,  
6 meaning that this had already been moved forward  
7 in the past, correct? So is there something that  
8 we normally would see or that we would know as to  
9 what's changed or if there has been any changes  
10 since it was last endorsed, or is that not  
11 something that's important for our committee?

12                  MR. LICHTMAN: I can tell you that, if  
13 it's okay.

14                  CO-CHAIR PARTRIDGE: Go ahead.

15                  MR. LICHTMAN: Okay. Basically, the  
16 entire testing form is new. The survey of the  
17 experts is new, the statistical evaluation from  
18 the pulmonary rehab database from AACVPR is brand  
19 new, and the literature has been updated.

20                  CO-CHAIR PARTRIDGE: Further  
21 discussions on reliability? Sherry? And then  
22 David.



1                   MEMBER KAPLAN: I'm beginning to sound  
2                   like an old wheeze on this issue. But you know,  
3                   again, without some further guidance about  
4                   exactly what it is we're approving here, I get it  
5                   that this is a very important test for,  
6                   especially for people with cognitive deficit who  
7                   can't answer questionnaires, you know, can they  
8                   function, can they walk, and usefulness at the  
9                   clinical level for improving, you know, for  
10                  taking care of an individual is very supported by  
11                  the evidence provided.

12                 Its use for a quality measure,  
13                 however, at any level other than the patient  
14                 level which I can't imagine how you would use it  
15                 at the patient level, is problematic for me  
16                 because again, I'm not seeing evidence.

17                 And if this has been around for a  
18                 while, is there any evidence that, does the  
19                 change alone mean that now we're approving a  
20                 change for continuation for the prior uses or we  
21                 being asked to endorse something that as the  
22                 developer said, going to use it to kind of

1 compare facilities and gather data for  
2 reliability and validity tests?

3 MS. SAMPSEL: So I think this still  
4 goes back to the same issue. I mean, it's a  
5 valid question especially over time when this has  
6 been a measure in use for some time.

7 But when you go back to the NQF  
8 criteria of this being an outcome measure, we are  
9 just looking, you know, when you go through the  
10 criteria your choices are going to be moderate or  
11 low based on the fact that they didn't provide  
12 the measure level, reliability, more validity  
13 testing.

14 So that gives you the option below of  
15 then deciding from what they did provide at the  
16 item or patient level, is that sufficient for you  
17 to make a low or moderate decision.

18 MEMBER KAPLAN: For the purpose of?

19 MS. SAMPSEL: For the purpose of  
20 moving it forward for endorsement.

21 DR. BURSTIN: Again, ideally we'd love  
22 to see it at both levels, it's not required. But

1       it is a measure that, it's one of the few  
2       measures in use in the rehabs, in the sort of  
3       cardiac/pulmonary rehab space.

4               MR. LICHTMAN:  It's almost the only  
5       measure in use in pulmonary rehab, correct.  
6       Cardiac has others.

7               MS. KING:  This is Marjorie King.  Oh,  
8       I'm sorry.  I just wanted to mention that a six  
9       minute walk test is similar to checking a blood  
10      pressure for someone who does it.

11              There are specific, standardized ways  
12      that you do it, that you follow, criteria that  
13      you follow in order to perform the six minute  
14      walk.  It's a very standardized tool, measurement  
15      tool.

16              MR. LICHTMAN:  Yes, there's an entire  
17      American Thoracic Society guideline that outlines  
18      precisely how to do this.  And I think that's one  
19      of the reasons why in the evidence form with all  
20      the previous literature showed to be extremely  
21      valid and reliable because it's standardized.

22              It's not just go walk down the hall.

1       There are specific areas, there are specific  
2       measurements and there's even a script that the  
3       clinician should follow.

4               Additionally, AACVPR has a toolkit up  
5       on their website that clinicians can access that  
6       goes through where to find the instructions, how  
7       to do the test, what's the minimal important  
8       difference, et cetera.

9               So that's all available. We put that  
10      in the appendix. That's all available to the  
11      clinician.

12              CO-CHAIR PARTRIDGE: All right.  
13      David, did you have any further questions? No?  
14      Okay. Then I think we're ready to, we are going  
15      to vote ready or not on reliability and validity.

16              MS. ALLEN: Voting on reliability, one  
17      high, two moderate, three low, four insufficient.  
18      Voting starts now. We're still missing some  
19      votes.

20              (Off microphone comments)

21              MS. ALLEN: Nineteen percent high,  
22      thirty-eight percent moderate, nineteen percent

1 low, twenty-five percent insufficient.

2 CO-CHAIR PARTRIDGE: Okay, moving on  
3 to validity. Any discussion? David.

4 MEMBER CELLA: This might seem like in  
5 the weeds a little bit, but it kind of gets to  
6 the NQF position on not endorsing measures, I  
7 mean, not endorsing instruments but endorsing  
8 measures.

9 And so my questions really are about  
10 A, the choice of a specific distance as opposed  
11 to a percent improvement. Have they looked at  
12 that because, you know, I've done some stuff in  
13 this area and this is a, if you can make a good  
14 case for somebody who might start at 250 meters,  
15 25 meters may be a meaningful improvement.

16 But if they start at 500, that's  
17 proportionally only half the improvement and it's  
18 probably not all that meaningful. And they're  
19 going with a straight 25, and I realize that's  
20 been what's been used and you can maybe deal with  
21 the error.

22 But it seems to me, you know, thinking

1 about this, and I admit I've used this more in  
2 clinical trials and not in the real world, but a  
3 percent improvement would make more sense.

4 And this figure of 25 meters is low.  
5 It's the lowest figure of the debate in the area  
6 which ranges from 25 to 80. And I would have  
7 thought with individual classification which is  
8 what this is that you would go with a higher  
9 number, something more like 50, particularly in  
10 pulmonary rehab where people do pretty well  
11 generally.

12 So I guess those are my main  
13 questions, and then I have one other.

14 MR. LICHTMAN: Okay, those are good  
15 questions. Number one, you know, we went  
16 strictly by evidence based here. We didn't want  
17 to speculate, we didn't want to diverge from the  
18 evidence and the evidence basically says we look  
19 at the minimal important difference not a  
20 percentage.

21 One of the problems with a percentage  
22 is the patients who do better initially tend to

1 improve less than the patients who do poorly.

2 Twenty-five meters was selected because this is a  
3 very disabled population.

4 When you do work with this population  
5 clinically, these are really very low level  
6 patients. And setting the bar too high would do  
7 an injustice because a 25 meter increase, we see  
8 that, and this is a little bit anecdotal, we do  
9 see that in our patients that when they improve  
10 by more than that, they really are feeling a lot  
11 better.

12 We had this discussion on our  
13 committee level and this was years ago when we  
14 first developed this, and it was decided to go  
15 with the 25 meters rather than coming up with a  
16 percentage improvement that we haven't verified  
17 in peer reviewed literature or going with a  
18 higher level.

19 Twenty five meters does appear in more  
20 of the studies than the higher level. And in the  
21 research literature that we looked at,  
22 particularly Holland et al., that's where we

1 derived it from.

2 You had to arrive at a cut point  
3 somewhere, and that was our rationale behind it.

4 CO-CHAIR PARTRIDGE: But to clarify,  
5 as I understand this measure, you start with  
6 where I was coming in. So I might be, say, at 40  
7 percent functionality, David. But did I go up an  
8 additional X is the way I interpreted the specs.  
9 Am I right?

10 MR. LICHTMAN: Correct. Yes, that's  
11 correct.

12 CO-CHAIR PARTRIDGE: Yes, so it's not  
13 just across the board did everybody achieve 25  
14 meters. You start with where I am and evaluate.  
15 Okay.

16 MEMBER CELLA: And the other, just a  
17 follow up, could I, just a quick -- so related to  
18 this and I'm sort of pushing the percent again  
19 with this. But more to the NQF than, you know,  
20 if this is a reasonable thing for this particular  
21 measure in this particular area, this situation.

22 But six minutes is arbitrary. It's



1       used because it's historical. There's nothing  
2       magical about it. The NIH toolbox is now a two  
3       minute walk test. There's good reason to think  
4       that you could do this in two minutes and not six  
5       minutes.

6               And so when you think about the  
7       migrating of a measure like this to other areas  
8       where there may not be as much willingness to  
9       take six minutes, you know, in this particular  
10      pulmonary rehab setting, if you had a percent  
11      benefit which does seem, I think, clinically  
12      reasonable, you have easier migration to say a  
13      two minute walk test or other performance tests  
14      that are even shorter to do because the goal here  
15      is to demonstrate a benefit in performance and  
16      not more meters specifically.

17              So I just make that as a  
18      recommendation that there be some way over time  
19      to move this toward percent benefit as opposed to  
20      a specific number.

21              CO-CHAIR PARTRIDGE: Thank you. And  
22      actually, things that we make as recommendations

1 can indeed be part of our formal report. So it's  
2 not just recommending to NQF. We can say it.

3 MR. LICHTMAN: And not as part of this  
4 report, we can take those recommendations and  
5 explore them without putting them officially into  
6 the report because I think that's a very  
7 provocative suggestion.

8 And we would have to do careful data  
9 analysis from our pulmonary rehab database to  
10 establish those cut points, and that's going to  
11 require more work in the future, which is fine.

12 And I think it's a great suggestion,  
13 but I wouldn't -- and to respectfully disagree at  
14 this moment, I wouldn't change from the evidence  
15 base at this moment. But we would certainly  
16 consider that in the future.

17 As far as the two minute test goes,  
18 running a clinical program for 20 years, the six  
19 minute walk test, it's not onerous on the staff.  
20 It was rated very highly as to the feasibility  
21 and the usability by the expert panel.

22 In looking at program certification

1 process, that's really not an issue in our  
2 programs. So most programs, all programs right  
3 now utilize a six minute walk.

4 CO-CHAIR PARTRIDGE: Okay.

5 MR. LICHTMAN: Again, if that morphs  
6 in the future, we'd be open to changing that.

7 CO-CHAIR PARTRIDGE: Okay. Validity  
8 voting. Nadine?

9 MS. ALLEN: Voting on validity, one  
10 high, two moderate, three low, four insufficient.  
11 Voting starts now. Eighteen percent high, fifty-  
12 nine percent moderate, eighteen percent low, six  
13 percent insufficient.

14 CO-CHAIR PARTRIDGE: Okay. Moving  
15 now, feasibility. Comments on feasibility?  
16 David, Karen, anybody? Ready to vote? Okay.

17 MS. ALLEN: Voting on feasibility, one  
18 high, two moderate, three low, four insufficient.  
19 Voting starts now. Thirty-five percent high,  
20 sixty-five percent moderate, zero percent low,  
21 zero percent insufficient.

22 Voting on usability in use, one high,

1 two moderate, three low, four insufficient  
2 information. Voting starts now. Forty-one  
3 percent high, fifty-three percent moderate, six  
4 percent low, zero percent insufficient.

5 Voting on overall suitability for  
6 endorsement of measure 0701 functional capacity  
7 in COPD patients before and after pulmonary  
8 rehabilitation, one yes, two no. Voting starts  
9 now. Ninety four percent yes, six percent no.

10 CO-CHAIR PARTRIDGE: Okay. It's now  
11 time for public comment from anybody in the room  
12 or on the phone.

13 OPERATOR: Okay, at this time if you  
14 would like to make a public comment, please press  
15 star then the number one. There are no public  
16 comments from the phone line.

17 CO-CHAIR PARTRIDGE: All right. Then  
18 it's time to move on and take stock of where we  
19 are. It's 5 o'clock. Our adjournment is  
20 scheduled for 5:15. I don't have the feeling  
21 that anybody wants to go further.

22 I think we've all had a pretty

1       difficult time today working through a lot of  
2       difficult measures and more to come. I am  
3       concerned we had one, two, three, four, five, six  
4       measures scheduled for 3:00 to 5:00 this  
5       afternoon, and we didn't reach any of them.

6               I do think that because of the  
7       similarity of five of them, probably we can  
8       shorten the time allowed from two hours. I have  
9       no idea since we haven't dealt yet at all with  
10      the measures that are generated through the  
11      Uniform Data System for Medical Rehab what the  
12      issues are going to be there.

13              So I'm going to turn to my colleagues  
14      on the right and ask them if they think that we  
15      are likely to achieve finishing this measure set  
16      tomorrow by 3:00 or whether --

17              MS. SAMPSEL: So our hope was that we  
18      could huddle with you and Chris. And I think we  
19      still want to do that. But we do have some  
20      similar groupings of measures for tomorrow that  
21      we might be able to have discussions with the  
22      developers about kind of re-working the agenda a

1 little bit.

2 But I know we also have a couple folks  
3 that need to leave early, and I believe, David,  
4 you need to leave by 10:30 at the latest? Okay,  
5 so we want to kind of figure those out a little  
6 bit.

7 I mean, I don't know if anybody has,  
8 you know, kind of aptitude or interest in  
9 spending the next 15 minutes or so talking about  
10 either of the ending questions which would help  
11 with tomorrow.

12 But we do also have the time set up.  
13 We have two hours on everybody's calendar next  
14 week to discuss anything we don't get to. So I  
15 think it's more of a is everybody done for the  
16 day? Do you want to have a 15 minute discussion?

17 I don't think we'll make it through  
18 another measure today.

19 CO-CHAIR PARTRIDGE: David?

20 MEMBER CELLA: I don't know. I mean,  
21 most of us are here. We could take the list of  
22 five. They may go very, very quickly. The five

1 improvement ones? The five CMS ones? They have  
2 a lot of similarity. You know, with the photo  
3 this morning, we did one and that really covered,  
4 you know, six or seven.

5 CO-CHAIR PARTRIDGE: Right. And  
6 they're at --

7 MEMBER CELLA: Then we wouldn't feel  
8 so far behind. But you know, that's --

9 MEMBER MONROE: You know, especially  
10 if we're going to lose people like David --

11 CO-CHAIR PARTRIDGE: We are.

12 MEMBER MONROE: -- I would much rather  
13 hear --

14 CO-CHAIR PARTRIDGE: My only caution  
15 is this is at a provider level we haven't talked  
16 about. It's home health.

17 MEMBER MONROE: Right, I was going to  
18 say because we're going to lose some people, I  
19 would rather hear about what they have to say on  
20 the two discussion points for the next few  
21 minutes, PRO-PMs for specific disease states and  
22 how we handle multiple conditions because we

1 won't, like, David won't be here tomorrow when we  
2 talk about that and I guess --

3 CO-CHAIR PARTRIDGE: I agree.

4 MEMBER MONROE: -- if other people  
5 have to leave early.

6 CO-CHAIR PARTRIDGE: And we're going  
7 to lose Chris as well because --

8 MEMBER MONROE: Yes.

9 CO-CHAIR PARTRIDGE: So, oh dear, all  
10 right. Okay. Then of the two, which one would  
11 you like to hear about, Helen, Sarah, Suzanne,  
12 which would you rather hear us talk about briefly  
13 first?

14 MS. SAMPSEL: I actually think we  
15 should talk about the second one because I think  
16 we're going to have some issues with that  
17 tomorrow.

18 CO-CHAIR PARTRIDGE: Okay. Discussion  
19 of parsimony and need for multiple experience of  
20 care in functional status measures for different  
21 settings? Who would like to open? Anybody given  
22 any thought to this from the agenda item? Chris?



1 CO-CHAIR STILLE: Well, I'll start.  
2 This is not by any means sophisticated or based  
3 on a whole lot of experience. But you know, I  
4 think to the extent possible where measurement  
5 techniques or specific measure sets can be used  
6 in multiple settings, they should be.

7 And to that extent, you know,  
8 approving different things for small variations  
9 in care settings, unless there's a good reason  
10 not to, maybe we should think about that being a  
11 default.

12 It would make things a lot easier  
13 administratively for, you know, groups that are  
14 administering the measures and figuring out what  
15 to do with them. And I imagine a lot of other  
16 people sort of share my feeling.

17 MEMBER THOMAS: Sorry, could someone  
18 just frame the discussion a little better? I  
19 don't really know where we're going.

20 CO-CHAIR STILLE: Right. So I mean,  
21 my interpretation of it is that if you have a  
22 bunch of measures of care that are relatively

1 similar to one another, that using them to  
2 measure small things like, you know, like  
3 differences in joints or differences in care  
4 settings between long term acute care and long  
5 term rehab care, to the extent that those  
6 settings and those organ systems or whatever are  
7 similar enough that they can use the same  
8 metrics, we should probably push for that.

9 MEMBER CELLA: You framed it earlier  
10 in your own words, and then I asked you to send  
11 me that document. There are a lot of measures,  
12 there are a lot of ways to get numbers, and  
13 sometimes they don't maybe need to be so diverse.  
14 And that's what you may want to talk about,  
15 right.

16 CO-CHAIR STILLE: I guess the critical  
17 question that should be asked of anything, you  
18 know, new is could you use what's already there  
19 and if not, why not?

20 CO-CHAIR PARTRIDGE: And from a  
21 historical perspective, NQF was founded in part  
22 to try to reduce the proliferation of measures

1 that looked somewhat alike and maybe were in most  
2 dimensions and to move toward, and we heard this  
3 theme from CMS all through today, move toward  
4 having a more standardized set of tools or of  
5 measures that everybody will understand and  
6 frankly, from the consumer perspective, that can  
7 be explained pretty readily.

8 And once you get used to how this is  
9 measured, you're trying to make a choice,  
10 provider or treatment, it's very helpful that oh  
11 yes, I've got that framework.

12 MEMBER LOEB: What you are saying is  
13 kind of limited. And I agree because you get to  
14 a point where your choices are so overwhelming.

15 I know this is just a really dumbed  
16 down comparison but when you go to the grocery  
17 store and there's 50 different tubes of  
18 toothpaste and you're just like I don't know what  
19 I need because there's just so many choices.

20 And that's what's happening because  
21 there's just so many different measures to choose  
22 from and there's going to be less people on each

1 measure to really measure because there's so  
2 many.

3 MEMBER NEUWIRTH: Can I just ask a  
4 point of clarification? Is part of the framing  
5 here that it's not just across settings but it's  
6 also across, you know, conditions or bodily parts  
7 and stuff like that?

8 CO-CHAIR STILLE: Just when I was  
9 looking at the body part things, it would have  
10 been nice to say, for the developers to say and  
11 this is needed because this is different and this  
12 is why. And that wasn't a requirement so they  
13 didn't do it.

14 MEMBER THOMAS: The one thing that  
15 comes out to me is I did say earlier and I still  
16 believe that there is this proliferation of  
17 measures and there's little gradations and  
18 differences between measures that we're looking  
19 at in different settings.

20 And it does seem as though a more  
21 standardized approach would be beneficial. The  
22 flip side of that is that there are certain

1 measures in certain settings that are well  
2 ingrained, that providers have completely  
3 invested in and follow and track.

4 And, you know, CMS has bought into and  
5 payment systems are designed around them. And  
6 basically care is delivered in a sense around  
7 meeting certain measures, almost like working  
8 toward the test.

9 So that's a pretty big, you know,  
10 disruptive thing to choose one over the other  
11 without even considering that I think. So I'm  
12 not sure that's part of our purview or whether  
13 we're supposed to be specific --

14 CO-CHAIR PARTRIDGE: No, it is part of  
15 our purview. We've had this discussion at the  
16 CSAC level, and Ann will remember some of it.  
17 One of the things, particularly with measures  
18 that have been around a long time and are good  
19 and are well ingrained but we've close to topped  
20 out, most everybody's performing it pretty well,  
21 we call and sort of reserve status or parking  
22 lot.

1                   This is a good measure. It's out  
2                   there, it's still a valid measure. We don't  
3                   think that it's a cutting edge measure anymore.  
4                   But for all kinds of reasons, your internal QI or  
5                   something else, go ahead and use it, it's  
6                   validated and useful.

7                   MEMBER BRADLEY: I was just going to  
8                   say, kind of working in a provider environment,  
9                   this is an important discussion because it costs  
10                  a lot of money to collect these measures on our  
11                  end.

12                  And not just in terms of human  
13                  resources, but now we're in electronic medical  
14                  records, and to retool an electronic medical  
15                  record so that we can collect a similar measure  
16                  but not exactly the same measure, it's very  
17                  expensive and it just drives up the cost of care.

18                  So I do think it's important to look  
19                  at this as to why is it needed and what are the  
20                  resources going to be required to collect these  
21                  measures.

22                  MEMBER BIERNER: One thing I would

1       like to add specifically coming from a  
2       rehabilitation background is we're moving more  
3       toward helping, working with the patient to  
4       establish what is important to him or her.

5               And I haven't seen a lot of that in  
6       any of the measures really that have come through  
7       today. But there are some things that we know  
8       won't change much.

9               I mean, in the area of rehabilitation  
10      some people may not make changes in certain  
11      areas. But there's not a lot here where we're  
12      soliciting input from either the family, the  
13      spouse, the caregiver in some cases, or the  
14      patient about what are your goals and choosing  
15      measures that are specific to them.

16              And so I think if there's any movement  
17      in that direction, rather than just having long  
18      laundry list of, you know, body part specific, we  
19      need to move more toward the patient when they're  
20      able, when they're cognitively able or the proxy  
21      for the patient, the caregiver, spouse, whoever,  
22      moving towards establishing goals at the onset

1       that could be measured with the help of the rehab  
2       team or others.

3               MEMBER KAPLAN: I'll be really brief,  
4       but I think the standardization versus the  
5       interpretation issue and the all purpose measure,  
6       if you think about math, and my husband hates it  
7       when I do this but it's intuitive for people.

8               It's like, if you think of a uniform  
9       math test that was going to do the whole  
10       population's math ability, right, and now I'm  
11       going to try and discriminate students in MIT one  
12       from another versus I'm going to use it in  
13       seniors on high school and I'm going to  
14       discriminate their performance one from another.

15              It's going to get trashed because it's  
16       going to have absolutely, no matter what you put  
17       out there, it's going to have absolutely no use  
18       at one of those extremes at all.

19              It's not going to vary. Everybody's  
20       going to flunk in high school and if you use the  
21       high school one, everybody's going to pass at  
22       MIT. So the tensions between standardization and



1 the unique applications for specific purposes  
2 often lead you to well, I've got this core set of  
3 things that kind of work generally, and then I  
4 have to modularize around specific applications.

5 So maybe instead of these either/or  
6 tradeoffs, we could think about. But then I'm  
7 now thinking oh my God, we're going to get into  
8 vendor wars about instead of different developers  
9 we're going to end up with the vendors being able  
10 to I can name that tune and further, you know,  
11 and faster and faster.

12 But if you look at the application  
13 under what am I trying to do, what's the purpose  
14 of measurement and is this appropriate for that  
15 purpose for that population, you're going to get  
16 safer than if I tried to do a completely  
17 standardized approach, I'm going to use SF-36  
18 period, and I'm going to use it in every setting  
19 for all populations for functional status  
20 assessment.

21 MEMBER MORT: On the issue of specific  
22 versus general PRO-PMs, I think you can't have

1 your cake and eat it too. You just need some  
2 condition specific or disease specific measures,  
3 otherwise you'd be looking at something too  
4 generalized.

5 I think that's along the lines of what  
6 Sherrie was saying. And as far as parsimony or  
7 convergence or alignment, I would feel better  
8 about striving for that if there was a gold  
9 standard.

10 So rather than sort of be black and  
11 white about it, my point of view might be if  
12 there were questions that we could ask developers  
13 about, you know, have you tried to do it in a  
14 shorter form, have you piloted whether this  
15 format works better than that format, is there  
16 something similar.

17 So use it as considerations and  
18 actually tee up answers to the questions as  
19 developers bring forward their applications  
20 rather than say, you know, if there was a gold  
21 standard way of doing this that was simple,  
22 aligned, short, yes. But otherwise, I'm

1 struggling with it.

2 CO-CHAIR STILLE: Sherrie, did you  
3 have -- oh, okay. Dave, and then I'll talk.

4 MEMBER CELLA: I think I would like to  
5 offer a different perspective than what Sherrie  
6 and Liz just articulated which is that, you know,  
7 in that math example that you gave, Sherrie, if  
8 you have an item bank of math questions that runs  
9 the full gambit from very easy questions to very  
10 difficult questions, you can have your cake and  
11 eat it too.

12 That's what, I don't know if we're  
13 supposed to talk about previous applications, but  
14 that's what photo does. They have item banks and  
15 PROMIS does that.

16 And so it is possible. It's been  
17 demonstrated to have that cake. Now there may be  
18 differential item function by, you know, whether  
19 it's a knee or a shoulder or something like that  
20 in physical function and that's empirical  
21 question and can be tested.

22 So that is case by case, but that

1 vision is a realistic and reasonable vision to  
2 put forward that there can be one metric, one  
3 standard.

4 If you take, you know, let's take  
5 something that in some ways is a little simpler  
6 than physical function because physical function  
7 can be upper lower extremity, joint specific.

8 Depression, we've linked to one  
9 metric, the promise metric, you know, three other  
10 depression instruments including the PHQ-9. And  
11 I've talked here, actually part of the white  
12 paper that we put together about the concept and  
13 illustration, and now published illustration  
14 since that presentation last year of lining these  
15 measures up to the point where, and I think this  
16 is where NQF sits, you can have a performance  
17 measure that says you need to move a certain  
18 number of people up above this bar.

19 That bar may be set today by the PHQ-  
20 9, but because of this linking that works really  
21 well, you can replace PHQ-9 with PROMIS or with  
22 the Beck Depression Inventory or the CESD so that

1       you could come even more indifferent to whether  
2       somebody uses any one of those four things  
3       because you're concerned about the bar the same  
4       way you don't care which blood pressure cuff  
5       somebody used.

6                You want to know their blood pressure,  
7       you don't care which scale, who made the scale  
8       they're weighing somebody on, you want to know  
9       their weight.

10               So it is a vision that can be done for  
11       things like depression, certainly, I'm pretty  
12       certain at least, others may not be. Physical  
13       function is going to be a little trickier. There  
14       are the links that exist right now, and those are  
15       also published.

16               And all of this is pretty new. So you  
17       know, NQF and CMS find themselves now with this  
18       300 page document that has all these different  
19       performance measures and people have to go out  
20       and load their EMRs with different things.

21               But the future could be on some of  
22       these things that are fairly generic in their

1 human relevance, depression, physical function,  
2 pain, there could be a common metric because  
3 underlying all this there is a common metric.  
4 And that I think is a realistic striving.

5 Oh, the other thing, I just to say,  
6 that's part of why in a related way I push on the  
7 edge a little bit on distance of meters walked  
8 versus percent change because if you start  
9 thinking in terms of a percent improvement, then  
10 it might not matter whether you're doing six  
11 minutes or two minutes and it might not matter  
12 whether you're doing a get up and go test or a  
13 six minute walk in various clinical applications  
14 because what you're caring about at the quality  
15 level is are you demonstrating a percent benefit  
16 to an individual patient, whatever that percent  
17 might be.

18 CO-CHAIR PARTRIDGE: Anne?

19 MEMBER MONROE: There is an appeal to  
20 me to, I hesitate to use the word common core,  
21 but that idea with extra questions put on given  
22 the circumstances or whatever.

1                   And I'm wondering if the staff or  
2                   anyone has looked across these similar measures  
3                   to see if that common set already exists because  
4                   it's in every one of these measures because when  
5                   we think about having to develop one, it seems  
6                   so, you know, so huge and full of argument.

7                   But I would bet that if we looked  
8                   across all these measures that we looked at today  
9                   and probably tomorrow, there is a common core set  
10                  that could get adopted.

11                  And then extra two questions if it's  
12                  your knee or an extra three questions if it's,  
13                  you know, a nursing home setting. I don't know.  
14                  But it seems to me there's got to be a way to get  
15                  away from all of these things which should be a  
16                  more common approach with the details being  
17                  special to the circumstance.

18                  CO-CHAIR STILLE: I would like to,  
19                  just for a second, knit what Liz and Sam were  
20                  saying into sort of a question for NQF folks is  
21                  where the person and family centered care  
22                  steering committee?

1                   How much of a role do we have in  
2                   advocating for stuff we'd like to see in measures  
3                   that's person and family centered? So it may be,  
4                   you know, up to us to in getting a common list  
5                   we'd like to see these common things in the  
6                   measures that we see.

7                   You know, my experience as a  
8                   researcher is that we're developing measures of  
9                   coordination of care. And if there's not a  
10                  parent input place, it's not as useful of a  
11                  measure, for example. So how do we do that?

12                  DR. BURSTIN: That's a great question.  
13                  We've actually started part of the reason to move  
14                  to standing committees was to have a body  
15                  available to do exactly that.

16                  But it shouldn't just be about looking  
17                  at the measures that come before you. We  
18                  actually just drafted a charter just yesterday  
19                  actually to move towards what standing committees  
20                  we hope will do beyond the measure endorsement  
21                  piece which may include, for example, quarterly  
22                  touch bases or specific projects, or also



1 providing the subject matter expertise for other  
2 initiatives like the MAP process for example.

3 We often have the chairs of the  
4 committee provide input to that process, as well.  
5 So I think that is very fair game. We would love  
6 to see help not only evaluate the measures before  
7 us but kind of move the whole field forward. So  
8 most definitely.

9 MEMBER THOMAS: What I don't  
10 understand about that, I totally get the  
11 approach, the value of doing something where, all  
12 right, now we've got all these measures before  
13 us, we understand them, we understand the  
14 evidence base.

15 But maybe we come up with this uber  
16 super measure that you can use in all these  
17 areas. But there's so much work and investment  
18 and time that went into preparing these things  
19 and these very separate measures, and  
20 demonstrating them and validating them and  
21 testing them.

22 How do you do that in a way that a

1 committee like ours wouldn't completely pick  
2 apart that work product? See what I'm getting  
3 at? I mean, maybe CMS does it because they're in  
4 a position to mandate it for payment purposes and  
5 then collects data and comes back.

6 I don't know. It just strikes me as  
7 being a pretty daunting proposition.

8 DR. BURSTIN: I think that was part of  
9 the basis behind the work CMS did around the CARE  
10 tool was to try to get closer to that vision of  
11 something that cuts across settings.

12 MEMBER BRADLEY: Well, I think there  
13 may be common measures that cut across a lot of  
14 settings. But I think they don't necessarily  
15 speak to quality in each of those settings.

16 Things like, for instance, right now  
17 we're reporting wounds. But that doesn't really  
18 speak to the quality of an inpatient  
19 rehabilitation hospital.

20 It might speak to quality of an acute  
21 care nurse, nursing unit, or a different type of  
22 setting. But I mean, it's something that we can

1 certainly measure, but it's not necessarily an  
2 indication of the quality and the mission of the  
3 setting.

4 So I think as you try to identify  
5 common measures across all settings, you have to  
6 be very careful that those measures are also  
7 measuring quality, not just that you can collect  
8 the data.

9 MEMBER MORT: I was thinking about  
10 David's comment about PROMIS and how it's a  
11 measure bank. And when you start talking about  
12 measure banks, you're really in my mind talking  
13 more about vehicles for dissemination and  
14 implementation almost.

15 So to me I'm thinking maybe this isn't  
16 a measure question as more as an implementation,  
17 a measure question as much as it's an  
18 implementation question.

19 So as we think about more and more  
20 patients in integrated delivery systems, patients  
21 at our medical homes, they're connected to their  
22 providers through portals or through electronics.

1                   And do we want to think about  
2                   harmonization and alignment more from the  
3                   delivery of the measure and the measure  
4                   collection rather than the actual specific  
5                   indicator or metric because you'd go a long way I  
6                   think towards improving health if you made it  
7                   easier for the measures to be collected.

8                   So rather than shoot for the perfect  
9                   measure, shoot for more harmony around  
10                  implementation. I'm sort of, I've moved to that  
11                  way of thinking about it.

12                 MEMBER LOEB: Chris, I want to just  
13                 applaud you on what you said. What brought me to  
14                 this committee was my experience and what Jared,  
15                 my husband who passed away said. And you know,  
16                 he was one of the measurement gurus.

17                 And he said, you know, for 18 years I  
18                 worked on measures. And he said once I became a  
19                 patient, I realized that none of those measures  
20                 had any impact on my absolute care and my  
21                 patient-centered companionate care.

22                 And I actually gave a talk to American

1 College of Physician Executives, and I was paired  
2 with a measurement expert. I'm like that's a  
3 really weird paring.

4 But it turned out it was a dynamic  
5 talk because he spoke of all the measures they  
6 had developed, and my presentation was loving and  
7 losing, is current measurement really the answer.

8 And so what you've suggested and what  
9 I think as a committee in addition to your  
10 endorsing the measures is to really sit down and  
11 see how we could bring person and, you know,  
12 family centered care away from just the hard  
13 measures.

14 CO-CHAIR STILLE: Right. But at the  
15 same time, we have the fire power, as it were, to  
16 be methodologically really, really good.

17 MEMBER LOEB: Right.

18 CO-CHAIR STILLE: And that's going to  
19 be the hard part, I think.

20 MEMBER KAPLAN: I think what Sherrie  
21 was getting at was the expanding the domain of  
22 observables, if you will, to include things that

1 could be sampled, a collective of which actually  
2 represents patient's perspective, the clinician's  
3 perspective, you know, the system's perspective.

4 That if we figure out a semi-permeable  
5 membrane that actually puts things in and takes  
6 them out depending on the purpose of measurement,  
7 et cetera, et cetera, then we've got something  
8 that's really more meaningful to all levels of --

9 MEMBER LOEB: Because it's like, I  
10 mean, oh, I'm sorry. I mean, I know HCAHPS is a  
11 big thing. And you know, we can't do away with  
12 it. But truly, HCAHPS doesn't measure whether it  
13 was really a good experience for the patient.

14 You know, yes was your patient  
15 experience good and how you rate it. But when  
16 you really drill down to it, when you're in a  
17 hospital and getting prolonged care, it's not  
18 picked up by that. So we really need to get to  
19 the patient or the person as it's now called.

20 MEMBER NEUWIRTH: Yes, I would echo,  
21 Sherrie, exactly what you're saying. I think  
22 that one of the things it feels like it's missing

1 in both our process but also with some of the  
2 developers is really what's the patient  
3 experience of all these measures?

4 I am pretty confident that the  
5 majority of patients have nothing to do with the  
6 outcome of these measures. They don't know where  
7 they go, they don't track them, they don't see  
8 them.

9 And maybe it does impact their care,  
10 but I think there's, you know, I think that  
11 there's lots of variability in how actionable a  
12 lot of these measures are.

13 My mom was in a skilled nursing  
14 facility, had a five star rating. And I got to  
15 see five star rating care close up. And it was  
16 so, so horrible.

17 They did not detect C. diff, I had to,  
18 like, you know, really go all out and really plea  
19 to have the doctor come. And she ended up  
20 getting rushed to the emergency room and dying of  
21 complications from C. diff that they didn't  
22 really detect early enough. And there were many

1 signs and symptoms of it.

2 So you know, what do these measures  
3 mean? And I think that of course we need  
4 measures. But with the overwhelming number of  
5 them, it's dizzying both for us as providers and  
6 health plans and advocates, and it's ending up to  
7 be, you know, somewhat not that meaningful for  
8 patients.

9 So I guess I would really appreciate  
10 more feedback from patients. And maybe there  
11 needs to be, like, a deeper kind of study of the  
12 sort of comprehensiveness of the measures really  
13 starting with patients and families and doing  
14 some deeper inquiry into what would matter to  
15 them.

16 You know, I hate to bring up the Yelp!  
17 app, but every one of us, when we need to go out  
18 to a restaurant, how many of us go to Yelp!? You  
19 know, and it's simple, it's easy, it's there.  
20 And it's a simple rating. It's, like, totally  
21 simple.

22 And you know, I'd love to go Yelp! and



1 see a skilled nursing facility and be able to  
2 trust it. Now how much do we trust Yelp!, I  
3 don't know. But you know, it's not that far off,  
4 and it's continuing to get better.

5 But I do think that there's, you know,  
6 something in between this sort of overwhelming,  
7 what feels like overwhelming number of measures  
8 we have right now, and instruments. And it's  
9 really hard to implement.

10 I mean, we have had challenges  
11 implementing the PHQ-9. And One Group Health,  
12 one of our affiliate partners has done a terrific  
13 job. They're, like, leading and they're  
14 implementing what 30, 40 percent of the time.

15 They're leading in the country for  
16 PHQ-9 use. And that's, like, a measure that's  
17 been around a really long time. And that is a  
18 powerful measure.

19 So you know, I'm sorry I'm ranting  
20 here but I just feel like I think that it's been  
21 a little, I think, frustrating to see the number,  
22 the proliferation of these measures and not

1 really know how they're being implemented and  
2 used.

3 And I guess I would, I think the  
4 parsimony sounds like a great idea. I also think  
5 that to get to parsimony we need to have input  
6 from patients and families about the sort of  
7 comprehensive.

8 Let's have them look holistically at  
9 this because, you know, I'm sure that some of  
10 them, some of us because we're all going to be  
11 patients too and we all are at various times  
12 patients.

13 But you know, if we've had knee  
14 surgery, we do want a question about our knee,  
15 right? Or something related to our knee. But  
16 does it have to be completely, radically  
17 different instrument and set of questions?

18 So I'll stop there. Sorry for the  
19 rant. But I have a feeling many of us feel the  
20 same way about this, that we could be doing much  
21 better.

22 MEMBER MORRISE: You know, one way we

1 can involve patients and families in an area  
2 where patients and families consistently have  
3 expressed all the patients and families I talked  
4 to across the country concern is that they give  
5 input in a measure or they're asked in HCAPS  
6 whatever.

7 And sometimes somebody will even say  
8 would you like me to get back to you about your  
9 concern? No one ever does. And so I think  
10 particularly one thing we could do on measures,  
11 particularly if there's a patient reported  
12 outcome, when we get down to use, we could look  
13 to see if it's being used to counsel in any way  
14 with the patient or share information and data  
15 with the patient.

16 Let's get back to them. They took the  
17 time to say this is what's going on. In use, do  
18 we see that the patient then is engaged in the  
19 end process? That would be one thing.

20 MEMBER DOWDING: Yes, I guess I've  
21 been struck by today and also by reading the  
22 stuff for tomorrow how absent patients are from

1 anything in the documentation that we're looking  
2 at.

3 With a patient, person centered  
4 outcomes measurement committee, there's not even  
5 a question on the NQF assessment about whether or  
6 not patients have been involved in --

7 (Off microphone comment)

8 MEMBER DOWDING: There is, but it's  
9 not filled in. It's not something --

10 (Off microphone comment)

11 MEMBER DOWDING: Yes, and it might be  
12 there. But it's not something that's highlighted  
13 as it being important enough. It's not one of  
14 the criteria that we vote on, for instance.

15 It's not something to do with, in the  
16 importance is it a specific thing that we say has  
17 this been identified by patients as important,  
18 have they specifically said it's important, have  
19 patients been involved in developing this?

20 Where's the effort and the space for  
21 it? So it's sort of there, but it's something  
22 that's skirted over, it's not something that's

1 part of the procedures that we use.

2 And I just wonder if we might need to  
3 have slightly more discussion about, especially  
4 when you've got so many measures that are looking  
5 at the same thing.

6 I'm sure function is important, but  
7 I'm not entirely sure I've picked up from any of  
8 the measures today that the patients have been  
9 asked if it's important.

10 CO-CHAIR PARTRIDGE: I hope this has  
11 been helpful to you all. I think it's been very  
12 helpful to me anyway. And I encourage all of us  
13 to copy Karen -- who's the cake here -- who tends  
14 to ask the developer the extent to which patients  
15 were involved in some of the testing.

16 It's a good -- pardon?

17 (Off microphone comment)

18 CO-CHAIR PARTRIDGE: I'm sorry,  
19 Katherine, yes. It's a good thing to put the  
20 developers on notice that we're going to ask.  
21 Okay. I'm in favor of saying we've had it for  
22 the day.

1                   And Chris and I will huddle briefly  
2                   with the staff. And we hope to see those of you  
3                   who can still stay, we promise not to talk about  
4                   performance measures over dinner. But please do  
5                   come and join us.

6                   (Whereupon, the above-entitled matter  
7                   was concluded at 5:30 p.m.)  
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22

A			
<p><b>A-1</b> 91:13</p> <p><b>a.m</b> 1:9 6:2 136:9,10</p> <p><b>AACVPR</b> 356:6,20,21 360:3 361:19 362:10 365:22 376:18 380:4</p> <p><b>ability</b> 44:1 243:16 280:11 308:1,1 359:13 372:12 400:10</p> <p><b>able</b> 9:6 11:17 59:9 63:20 75:21 95:10 104:13 105:17 114:15 115:10 131:16 143:2 160:2 164:21 167:21 168:11 177:12 179:11 179:12 200:1 224:8 225:6 226:21 239:11 241:5 250:22 259:12 262:14,22 276:1 287:8 292:10 297:20 306:21 307:5 319:14 323:9 329:12 333:2 335:5 337:9 345:2 350:4,6 353:2 363:14 389:21 399:20,20 401:9 417:1</p> <p><b>above-entitled</b> 136:8 190:7 315:1 422:6</p> <p><b>absent</b> 77:20 419:22</p> <p><b>absolute</b> 412:20</p> <p><b>absolutely</b> 81:5 147:7 301:1,13,21 400:16 400:17</p> <p><b>abstract</b> 170:22</p> <p><b>abstractors</b> 151:4,5,7,9</p> <p><b>academic</b> 27:6 350:1</p> <p><b>Academy</b> 13:20 15:4,14</p> <p><b>acceptability</b> 54:20 55:4 58:5</p> <p><b>acceptable</b> 163:19 265:3</p> <p><b>acceptance</b> 230:22</p> <p><b>accepted</b> 65:10</p> <p><b>access</b> 160:22 165:3 380:5</p> <p><b>accommodate</b> 221:17</p> <p><b>accommodated</b> 209:9</p> <p><b>accommodating</b> 44:7</p> <p><b>accomplish</b> 194:11</p> <p><b>accomplished</b> 136:18 151:15</p> <p><b>account</b> 72:21 75:16 81:10 82:17 106:13 161:4 194:1 280:9</p> <p><b>accountability</b> 38:4 47:16,21 49:11 57:10</p> <p><b>accountable</b> 36:11,13 37:19 213:16,18</p>	<p>214:3,10 344:21</p> <p><b>accounted</b> 73:16 76:9</p> <p><b>accounting</b> 76:14</p> <p><b>accounts</b> 71:9</p> <p><b>accumulated</b> 281:18</p> <p><b>accuracy</b> 307:7</p> <p><b>accurate</b> 90:3 95:16 131:13 171:11 326:7</p> <p><b>accurately</b> 169:14</p> <p><b>accustomed</b> 229:13</p> <p><b>achieve</b> 51:6 82:4 105:18,21 187:19 384:13 389:15</p> <p><b>achieving</b> 213:10 232:18</p> <p><b>acquainted</b> 11:15 136:12</p> <p><b>Act</b> 291:20,20 292:14 335:1,2 351:20</p> <p><b>acting</b> 1:9,13 28:2</p> <p><b>actionable</b> 415:11</p> <p><b>activation</b> 214:17</p> <p><b>active</b> 177:5</p> <p><b>actively</b> 15:16 27:19</p> <p><b>activities</b> 5:7 12:10 74:19 98:11 283:4 314:12</p> <p><b>activity</b> 5:15 13:2 143:18 146:13 214:18 328:13 337:6,13 342:1,18</p> <p><b>actual</b> 72:13 73:2 92:12 93:13 100:21 103:17 104:22 142:19 144:12 164:18 172:19 173:17 203:21 230:1 237:20 255:8 292:13 319:19 320:3 321:12 331:16 334:10 339:9 412:4</p> <p><b>acuity</b> 68:19 72:9 74:16</p> <p><b>acute</b> 20:6 106:7 316:9 323:8,15 324:8 329:2 329:6 335:4 351:13 394:4 410:20</p> <p><b>adapted</b> 159:4</p> <p><b>adaptive</b> 86:13 87:11 87:12</p> <p><b>add</b> 29:20 41:7 42:16 66:12 87:18 106:5 121:20 142:11 156:8 204:22 263:16 277:1 287:1 292:8 309:10 309:21 324:18 399:1</p> <p><b>added</b> 63:17 73:18 168:14</p> <p><b>adding</b> 256:22 258:18</p> <p><b>addition</b> 8:18 66:12 73:2 112:14 141:6</p>	<p>195:21 210:12 317:3 413:9</p> <p><b>additional</b> 33:6 38:11 66:12 76:9 111:18 120:9 121:5 137:16 174:13 185:18 204:22 224:15 239:6,11 258:17 261:8,14 262:3,15,22 299:21 302:12 307:4 318:15 354:14,17 384:8</p> <p><b>additionally</b> 252:17 380:4</p> <p><b>address</b> 34:5 37:1,13 37:14 91:2 130:9 131:1 147:21 190:18 194:16 235:22 253:16 254:5 278:13,20</p> <p><b>addressed</b> 135:17 139:21 178:2 280:17</p> <p><b>addresses</b> 5:6 140:8 141:21 266:8 315:20 341:9</p> <p><b>addressing</b> 35:5 255:3 351:5</p> <p><b>adequate</b> 121:18 136:21 306:4</p> <p><b>adequately</b> 103:3 253:9</p> <p><b>adhere</b> 10:18</p> <p><b>adherence</b> 64:5</p> <p><b>adhesive</b> 105:5</p> <p><b>Adjourn</b> 5:21</p> <p><b>adjournment</b> 388:19</p> <p><b>adjust</b> 98:22 102:18 105:15,17 106:5,8</p> <p><b>adjusted</b> 65:3 67:1 116:21</p> <p><b>adjuster</b> 98:4</p> <p><b>adjusters</b> 68:10</p> <p><b>adjusting</b> 142:1</p> <p><b>adjustment</b> 67:14 68:13 68:16 71:12 73:17 74:10,14,15,21 75:17 78:19 81:3 98:14 103:4 112:17 113:2 117:9 203:17 209:3 234:7 235:9 245:21 251:10 269:15,17 304:16 308:20 328:3 328:5</p> <p><b>adjustments</b> 158:9 304:14</p> <p><b>ADL</b> 266:14 267:1,20 271:15 279:16 281:22 304:7</p> <p><b>ADLs</b> 130:10,18 266:2 266:5 270:22 271:2 292:18 307:16</p>	<p><b>administer</b> 230:16</p> <p><b>administered</b> 46:12 102:1 152:1,9 153:5 228:8 249:4</p> <p><b>administering</b> 393:14</p> <p><b>administration</b> 20:12 92:3,8 93:10 140:14 193:10 194:9 225:3,5 231:13 235:20 248:22 249:7 352:15</p> <p><b>administration's</b> 287:14</p> <p><b>administrative</b> 140:14 230:11 276:7</p> <p><b>administratively</b> 393:13</p> <p><b>admission</b> 5:5 220:19 275:4 281:12 315:18 322:5,6,16,19 326:4 327:6 330:10,12 332:14,19 343:14</p> <p><b>admission/discharge</b> 347:6</p> <p><b>admissions</b> 275:8</p> <p><b>Admissions-Readmi...</b> 23:19</p> <p><b>admit</b> 382:1</p> <p><b>admitted</b> 318:9 320:19 339:17 343:10,12,15 345:15</p> <p><b>adolescents</b> 113:12</p> <p><b>adopted</b> 407:10</p> <p><b>adult</b> 164:3 192:14 243:3</p> <p><b>adults</b> 21:2 164:2</p> <p><b>advancing</b> 26:18 64:22</p> <p><b>advantage</b> 94:7 115:5</p> <p><b>advent</b> 291:19</p> <p><b>adverse</b> 303:14 304:10 306:6</p> <p><b>advise</b> 21:5</p> <p><b>Advisor</b> 15:10</p> <p><b>advisors</b> 26:17</p> <p><b>advisory</b> 23:9 26:13</p> <p><b>advocacy</b> 18:22 25:21 26:11,22</p> <p><b>advocate</b> 18:14 25:16 27:2</p> <p><b>advocates</b> 21:1 416:6</p> <p><b>advocating</b> 408:2</p> <p><b>affect</b> 95:6 305:1,1,7 306:1,2</p> <p><b>affiliate</b> 417:12</p> <p><b>affiliated</b> 161:3</p> <p><b>Affinity</b> 2:5</p> <p><b>affordability</b> 34:2</p> <p><b>affording</b> 48:14</p> <p><b>afternoon</b> 43:3,5 190:1</p>

191:11 389:5	354:3 374:21 375:7	11:18,22 17:7 28:14	<b>applaud</b> 246:8 247:5
<b>age</b> 65:16 68:19 72:9	375:10 380:16,21	97:20 158:12 160:18	412:13
73:10 74:16 91:6	387:9,17	212:6 216:7 270:9	<b>apples</b> 71:16,16 72:1,1
105:15 113:7 133:19	<b>alleviation</b> 34:22	277:18 295:1 311:6	<b>applicability</b> 49:14
141:19 158:21 192:14	<b>allow</b> 11:11 83:1 237:21	312:15 314:17 316:21	<b>applicable</b> 37:6 48:11
192:15 198:14 204:17	284:15,21 315:16	326:6 339:6 350:10	125:22 370:15
210:9 218:13 223:20	361:16 362:5,6,12,14	397:16	<b>application</b> 8:9 57:15
223:20 243:4,4	364:8	<b>Ann's</b> 6:12 293:1	65:13 66:11,13 81:13
283:10	<b>allowed</b> 60:15 265:2	<b>Anne</b> 3:3 406:18	87:6 88:19 91:1
<b>aged</b> 140:11	389:8	<b>announce</b> 138:14	116:18 128:3 143:12
<b>agencies</b> 23:2 291:22	<b>allows</b> 100:2 284:15	<b>annual</b> 194:21	149:10 369:19 401:12
<b>agenda</b> 11:8 12:19	364:5	<b>answer</b> 67:8,11,12,21	<b>applications</b> 32:4 33:14
136:13 189:1 190:3	<b>alluded</b> 228:2	114:10 117:11 121:18	38:4 48:5 49:4,11
241:13 389:22 392:22	<b>alpha</b> 268:2	123:21 126:5 133:11	57:10 80:18 81:6
<b>agendas</b> 136:15	<b>alternate</b> 10:10	143:2,4 147:18 160:2	104:1 401:1,4 402:19
<b>ages</b> 24:3	<b>alternatives</b> 329:3	168:7,11 170:19	403:13 406:13
<b>aggregate</b> 72:18 102:21	<b>Alzheimer's</b> 25:18	171:13 177:22 178:7	<b>applied</b> 17:21 154:3,4
221:21	<b>Alzheimer-type</b> 288:2	202:5 212:22 231:17	219:13 228:22 269:17
<b>aggregated</b> 36:11	<b>ambulate</b> 372:22	234:19 272:16 274:1	301:1 345:18
112:15	<b>Ambulation/Locomot...</b>	288:12,19 346:4	<b>applies</b> 41:18 79:11
<b>aggregates</b> 37:22	5:10	377:7 413:7	94:21
<b>ago</b> 19:14 21:21 29:5	<b>ambulatory</b> 224:3	<b>answer's</b> 370:22	<b>apply</b> 164:7 269:8
136:12 154:21 220:4	372:18 373:4	<b>answered</b> 117:6	333:11
318:7 383:13	<b>ambulatory/multiple</b>	<b>answering</b> 131:11,15	<b>appointed</b> 22:15
<b>agree</b> 105:14 186:18	37:2	291:12	<b>appointment</b> 317:7
187:11 251:8 277:13	<b>American</b> 13:20 15:4	<b>answers</b> 129:5 199:16	<b>appreciable</b> 149:9
281:8 293:18 392:3	15:14 20:22 355:16	229:9 305:16 402:18	<b>appreciate</b> 188:15
395:13	356:7 379:17 412:22	<b>antibiotic</b> 162:6,10	209:13 213:13 257:6
<b>agreed</b> 367:14	<b>amount</b> 6:22 70:5 75:22	<b>antibiotics</b> 175:17	327:18 416:9
<b>agreement</b> 23:21	99:6,9 159:8 208:19	177:7,12	<b>approach</b> 28:6,8 80:4
169:22 171:2 366:13	296:2 306:4 368:15	<b>anticipated</b> 196:13	81:1 94:12 107:5
<b>ahead</b> 12:7 87:20 99:7	<b>ample</b> 11:6	<b>anticipating</b> 43:1	128:19 225:4 396:21
138:9 183:22 202:13	<b>amplified</b> 225:19	<b>anxiety</b> 24:6	401:17 407:16 409:11
212:7 216:7 230:4	<b>analogous</b> 175:16	<b>anybody</b> 116:20 387:16	<b>approaches</b> 44:15
233:22 241:12 365:4	<b>analyses</b> 77:14 89:19	388:11,21 390:7	<b>approaching</b> 249:8
376:14 398:5	299:19	392:21	<b>appropriate</b> 13:5 45:15
<b>AHRQ</b> 20:16	<b>analysis</b> 58:22 59:2	<b>anymore</b> 165:15 353:13	45:16 46:4 48:4 49:5
<b>aimed</b> 252:1	66:14 71:21 80:14	398:3	114:10 142:2 152:12
<b>AJT</b> 164:5	86:17 89:17 104:6,7	<b>anytime</b> 193:12	154:3,4 204:19
<b>al</b> 383:22	121:2,3,5 122:5,13	<b>anyway</b> 134:1 180:11	219:10,12,18 245:10
<b>algorithm</b> 228:21 370:8	129:5 245:19 267:19	215:11 274:19 315:11	269:22 282:1 286:20
<b>aligned</b> 244:3 402:22	282:10,12 296:1	328:16 333:11 341:11	367:19 401:14
<b>Aligning</b> 29:11	297:13,16,21,22	350:16 421:12	<b>appropriateness</b>
<b>alignment</b> 33:19 402:7	361:11 386:9	<b>apart</b> 107:12 198:11	113:11 234:5,21
412:2	<b>analyst</b> 31:18 316:11	410:2	235:1,5
<b>aligns</b> 244:5	317:4	<b>apologies</b> 310:10	<b>approval</b> 51:15 65:8,8
<b>alike</b> 395:1	<b>Analytics</b> 2:8	<b>apologize</b> 111:22 242:2	231:9 369:3 370:3
<b>Allen</b> 2:17 20:4 31:17	<b>analyze</b> 74:6 129:12	334:9,15	<b>approve</b> 84:10
31:18 117:20 118:11	<b>anatomic-related</b> 63:17	<b>apology</b> 223:11 248:7	<b>approved</b> 133:8 231:11
118:15 119:16 134:4	<b>and/or</b> 245:20	<b>app</b> 416:17	<b>approver's</b> 133:13
165:5 166:5,7,13,18	<b>anecdotal</b> 197:15 383:8	<b>apparently</b> 120:21	<b>approves</b> 16:2
167:3 180:12,18	<b>Angeles</b> 20:12	259:4	<b>approving</b> 127:3 134:1
181:2,9,19 182:2,10	<b>animated</b> 24:3	<b>appeal</b> 406:19	377:4,19 393:8
182:15,22 183:5	<b>Anita</b> 3:14 138:19	<b>appealing</b> 324:16	<b>approximately</b> 89:7
216:15 227:6 233:5	164:14	<b>appear</b> 198:16 383:19	269:10
236:12 239:19 257:12	<b>ankle</b> 4:12 95:8 96:17	<b>appeared</b> 327:17	<b>April</b> 325:6
260:19 294:9 302:13	129:10	<b>appears</b> 159:20	<b>aptitude</b> 390:8
310:21 313:20 353:16	<b>Ann</b> 2:4,16 9:2,4,7,9	<b>appendix</b> 380:10	<b>Arabic</b> 63:7



**arbitrary** 279:8,9  
384:22  
**area** 8:13 75:18 102:10  
103:15 146:9 246:9  
271:1 273:2 276:17  
320:14 321:4,15,17  
328:19,20 336:10  
371:7 381:13 382:5  
384:21 399:9 419:1  
**areas** 34:8,9,12 47:8  
252:13 380:1 385:7  
399:11 409:17  
**arena** 8:5  
**argue** 95:3 156:13  
**argument** 304:21 305:7  
306:7 407:6  
**arrive** 384:2  
**arthritis** 75:7 97:16  
106:11 208:8  
**arthroplasty** 208:7  
211:19  
**articulated** 403:6  
**ascertain** 164:18  
**aside** 279:22 355:4  
**asked** 12:9 38:17 39:4  
52:19 92:1,10 98:3  
100:11 101:6 113:15  
151:21 175:1 190:14  
198:20 202:1 206:17  
222:5 226:19 270:9  
350:16 352:12,14  
367:2,11,16 377:21  
394:10,17 419:5  
421:9  
**asking** 55:7 59:6 80:15  
84:9 198:19 204:1  
212:19 228:19 273:20  
276:22 304:4 322:10  
329:17 333:13 337:18  
341:22 348:20  
**ASPE** 20:16  
**aspect** 289:3  
**aspects** 43:9 95:17  
96:14 97:13 253:22  
**aspires** 119:7  
**assertion** 77:7  
**assess** 36:5,8 65:4 73:9  
104:11 144:2 157:20  
161:6 205:3 234:5  
253:5 334:11 335:5  
336:5 342:4,11 359:3  
373:18 374:6,10  
**assessed** 104:21  
140:10 145:2 335:18  
338:16 341:20 342:22  
343:4  
**assessing** 143:19  
192:8 230:16 243:21

256:13 300:14 301:19  
**assessment** 4:19 5:5  
45:11 46:16,17 60:9  
95:16 138:5 139:15  
140:6 141:8,22  
143:15 145:22 150:7  
150:13,14,16 158:6  
158:16 163:8,11  
170:8 183:2 186:17  
186:19 188:2 193:15  
194:7,14 196:18  
200:9,11 205:7  
209:21,22 235:16  
244:19 254:2 266:6,7  
272:1,2 275:4 276:15  
280:21 281:6 292:17  
301:20 315:19 318:20  
319:22 321:20 322:4  
326:22 330:10,15  
332:10 334:5 336:20  
337:20 338:10 339:8  
339:10 341:19 343:11  
343:13,16 344:5,16  
346:18 348:5,13  
349:13 362:9 363:10  
401:20 420:5  
**assessments** 14:8  
140:17 141:3 142:17  
193:17 235:16 244:7  
249:9 281:1  
**assigned** 10:14  
**assistance** 266:1,3  
283:4  
**Assistant** 16:13 23:16  
320:8  
**assisted** 18:9 372:20  
**associated** 14:2 73:13  
128:9 141:7 142:20  
177:2 199:11 212:20  
254:18 256:17 300:1  
**Association** 22:14 63:2  
355:16 356:7  
**assume** 49:10 115:20  
138:8 145:4 158:15  
279:8 311:10  
**assumed** 289:18  
**assumes** 94:11,12  
**assuming** 132:18  
262:19 295:15,17  
341:7  
**assumption** 295:10,12  
335:18  
**assurance** 15:22 27:9  
**astounding** 157:19  
**athletic** 106:22  
**attachment** 80:4 201:19  
**attempt** 145:11 373:14  
**attempted** 337:14,16

**attended** 360:10  
**attention** 50:11,21  
289:10  
**attest** 149:10  
**attract** 160:9  
**attributable** 76:15,20  
122:2 352:3 365:18  
**attributed** 94:13  
**attribution** 205:21  
206:5,6,7,13 347:16  
**attributions** 94:5  
**attrition** 77:19  
**atypical** 300:8  
**audience** 125:5 255:21  
**audit** 169:4  
**auditable** 179:13  
**August** 325:9 360:4,5  
**authorization** 249:3  
**automatically** 348:10  
**Autrey** 3:2 138:17,18  
183:20,21 184:1  
185:4,17 187:7  
188:10  
**availability** 137:20  
**available** 34:5 44:17  
88:22 89:2 99:1  
114:21 115:8,15  
116:7,17,20 117:13  
161:14 248:18 265:4  
346:13 347:1 350:12  
360:1 370:1 380:9,10  
408:15  
**average** 4:21 5:3 83:14  
108:11 112:2 116:12  
141:13 148:15 191:21  
192:8 193:22 195:1  
198:15 223:20 227:2  
230:18,21 232:14,16  
240:6 242:14 246:1  
271:19 272:3 297:19  
298:5 300:19  
**averaged** 300:18  
**averages** 300:12  
**avoid** 270:18  
**avoidance** 72:11 73:15  
74:18 98:10,16,18  
99:2  
**aware** 135:19 144:16  
209:3

---

## B

---

**B** 132:7 153:7 176:14  
354:2  
**Baby** 196:15  
**back** 7:7 9:17 10:8 27:8  
42:3 50:11 64:12,19  
65:21 84:12 86:14  
88:13 91:15 95:13

100:3 110:2 120:10  
121:16 124:21 127:8  
127:10 130:9,11,20  
131:21 132:16 136:6  
136:11 146:3 149:7  
151:13 154:18 165:2  
167:10 170:22 171:6  
175:1 190:11 191:1  
203:11 206:16 220:10  
228:5 229:20 236:21  
239:16 241:2 243:17  
243:22 252:22 256:13  
261:15 265:1 272:2  
293:19 294:1,4  
304:19 305:19 308:20  
314:18 317:10 319:16  
323:8 327:21 343:4  
348:19 350:21 353:9  
378:4,7 410:5 419:8  
419:16  
**background** 24:20 25:5  
26:5 115:2 191:8  
195:7 399:2  
**bad** 273:19 296:12  
**badly** 180:9  
**balancing** 306:1  
**balancing-out** 304:3  
**bank** 114:1,12 403:8  
411:11  
**banks** 20:1 403:14  
411:12  
**bar** 310:17 383:6  
404:18,19 405:3  
**bars** 310:16  
**base** 47:1 271:9 276:12  
386:15 409:14  
**based** 27:13 29:14  
31:21 36:10 38:12  
45:9 50:13,15,20  
56:22 57:18 71:6 72:8  
82:7 87:11 141:15  
150:7 160:13 165:18  
167:19 168:1 173:12  
174:7 175:3,6,11,22  
176:8,17 187:17  
194:20 219:8 247:21  
248:1 260:15 267:5  
267:10 269:12 272:20  
273:22 274:3 283:15  
305:11 322:8 336:2  
353:9 357:16 372:1  
378:11 382:16 393:2  
**baseline** 68:9 70:3  
206:8  
**bases** 408:22  
**basic** 133:21 187:11  
301:15 307:16  
**basically** 86:6 116:12

131:14 136:14 165:15  
175:10 241:20 271:9  
281:1,2 287:3 290:6  
292:6,9,16 322:3  
323:5 335:1 339:15  
344:15,18 373:21  
376:15 382:18 397:6  
**basing** 206:17 276:13  
**basis** 64:17 81:5,6  
111:12 250:17 275:22  
410:9  
**Bathing** 5:11  
**Bauldoff** 357:9  
**bear** 238:1  
**Beck** 404:22  
**Becky** 22:18 208:17  
290:9 317:11 339:3  
343:22  
**Becky's** 344:14  
**becoming** 329:5  
**bed** 5:12 266:5 308:3  
318:19 319:2,2  
336:10,13,14 337:17  
**beds** 320:21 321:3  
**beginning** 63:1 64:21  
154:14 236:4 303:13  
377:1  
**behalf** 18:14 19:1  
139:11  
**behaved** 99:18  
**behaves** 259:6  
**behavioral** 34:17  
**behaviors** 35:14  
**behoove** 255:11  
**belaboring** 176:4  
**beliefs** 72:11 73:15  
74:19 98:10  
**believe** 11:13 12:15  
15:6 25:11 61:14  
67:18 75:19 80:10  
84:19 93:8,14 102:17  
141:20 145:1 148:13  
148:15 169:1 176:7  
199:22 277:12 390:3  
396:16  
**Ben** 3:4 133:16,16  
**benchmark** 222:14  
284:7 350:7 362:11  
362:13  
**benchmarked** 292:5  
**benchmarking** 344:11  
**benchmarks** 299:15  
362:17 369:22  
**bene** 351:22  
**beneficial** 396:21  
**beneficiaries** 246:14  
287:4  
**benefit** 124:11 247:16

373:7 385:11,15,19  
406:15  
**benefits** 270:19  
**Berg** 139:5,10 142:22  
144:18 145:1,14  
147:17 149:2,18  
150:19 152:22 153:13  
154:10 155:7,12,14  
156:1,7,12 157:1,17  
158:3,9 159:6,17  
160:19 163:5 164:5  
168:6 170:15 171:5  
173:20 174:14 177:21  
**best** 41:3 60:19 76:12  
143:2 213:4 252:1  
307:10,11 343:5  
370:6 371:22  
**bet** 407:7  
**beta** 22:10  
**better** 11:15 28:19  
42:18 83:16 111:11  
128:20 130:1 142:20  
159:20 172:10 173:1  
187:5 204:18 225:22  
247:15 249:20 250:14  
251:5 260:4 276:19  
292:10 309:5 319:5  
319:13 373:22 382:22  
383:11 393:18 402:7  
402:15 417:4 418:21  
**Bevans** 1:15 16:11,12  
93:21 95:21 100:17  
112:14 142:9 143:7  
143:10 144:9,17,21  
145:4 146:11,19  
147:4,7 152:18 167:8  
172:17 174:8 184:19  
186:9 352:9  
**beyond** 87:10 214:10  
250:5 305:21 408:20  
**bias** 93:11,11 149:1  
**biased** 28:3  
**Bierner** 1:17 27:3,3  
70:11,18 71:14,20  
72:15 73:1,20 89:4,10  
89:22 92:16,20 93:1  
96:5 97:14 114:11,20  
115:18 116:13 124:22  
171:14 204:10 207:17  
211:16 251:18 253:3  
255:5 256:11 257:9  
287:22 325:16 328:21  
343:2 372:4 398:22  
**big** 146:9 149:17  
165:13 198:22 247:17  
247:18 249:22 316:4  
321:20 397:9 414:11  
**bigger** 169:10 238:13

329:5,5  
**bill** 192:21  
**Bingo** 170:9,13,13  
**biomedical** 103:18  
**biopsychosocial** 99:22  
**bit** 6:10 7:16 9:8 13:9  
13:18 30:19 49:17  
51:22 52:3 62:1 84:12  
125:17 154:22 160:8  
164:17 167:16 168:8  
169:7,19 173:11  
175:16 179:15 192:6  
192:10 196:19 197:7  
200:4 223:18 230:5  
238:21 248:3 250:14  
258:13,22 271:4  
299:1,20 329:16  
331:12 333:14 347:15  
349:1 357:13 367:10  
369:12 371:9 381:5  
383:8 390:1,6 406:7  
**black** 402:10  
**bladder** 252:6 256:18  
322:2 325:17 334:13  
337:1  
**blah** 180:2,2,2  
**blank** 13:20  
**block** 10:13,20 314:19  
**blood** 60:19 348:9  
379:9 405:4,6  
**blurried** 279:6  
**blurring** 264:15  
**BMI** 210:22  
**board** 20:21 33:2  
264:18 331:5 384:13  
**Bob's** 170:14  
**bodily** 396:6  
**body** 10:21 38:16 94:5  
94:12,14,19 95:18,19  
96:15 100:9 102:4,5,8  
102:10 115:9 116:19  
125:4,8 126:15  
127:16 128:12 130:3  
130:12,15 211:17  
231:9 335:22 396:9  
399:18 408:14  
**bonus** 187:22 188:8  
**bookmark** 84:14  
**boom** 196:13,15 197:3  
**borderline** 184:14  
**born** 26:8  
**Borun** 2:10  
**boss** 122:17 285:15  
**Boston** 21:9  
**bother** 109:6  
**bothered** 108:22  
**bottom** 117:6 148:18  
**bought** 397:4

**bound** 42:5  
**bowel** 252:6 256:18  
325:18,19,20  
**box** 162:9,13 171:19  
177:9 186:14 308:18  
**Bradley** 1:18 22:17,18  
47:11 203:4 234:1  
290:10 344:1 345:22  
398:7 410:12  
**brain** 355:5  
**brand** 376:18  
**brand-new** 200:18  
**breadth** 28:17  
**break** 124:15 183:10  
314:18  
**breakdown** 36:21  
**breaks** 105:3  
**breathe** 26:8  
**breathing** 358:5 364:20  
**Brian** 2:2 19:3 351:4  
375:2  
**bridge** 187:17  
**brief** 61:14 88:11 95:9  
181:12 341:8 355:18  
357:14 400:3  
**briefly** 53:10 230:4  
392:12 422:1  
**Brigham** 26:6  
**bring** 50:10,21 94:3,20  
120:9 241:2 248:9  
255:6 261:15 293:19  
308:20 402:19 413:11  
416:16  
**bringing** 50:11 175:1  
256:21  
**brings** 29:13 319:16  
**British** 218:19,20  
**broad** 11:2 49:10  
207:11  
**broadcaster** 26:4  
**broader** 304:19  
**brought** 25:20 65:20  
317:12 412:13  
**BSN** 2:3  
**BSW** 2:2  
**buckets** 52:10 305:14  
**build** 230:1 284:10,15  
**building** 43:6,16 229:18  
230:14  
**built** 155:2,3 196:6  
317:14  
**bunch** 137:6 155:16  
393:22  
**burden** 24:9 33:9 35:1,2  
35:13 63:18 99:19  
101:5 204:1 229:11  
**BURSTIN** 2:15 8:19  
28:15 41:6 42:7 44:11

45:19 47:22 60:13  
124:17 310:6 378:21  
408:12 410:8  
**bus** 205:17  
**button** 67:10  
**buying** 74:3

### C

**C** 4:1 415:17,21  
**C-statistics** 269:16  
**cake** 402:1 403:10,17  
421:13  
**calculate** 79:1 81:3  
85:11 109:18 194:4  
226:21 228:16 229:4  
**calculated** 109:13  
157:3 193:20 244:21  
297:22  
**calculation** 173:21  
194:1,13 203:17  
244:17  
**calendar** 192:18 243:7  
390:13  
**calibrated** 114:5 115:1  
**calibrating** 115:5  
**call** 52:17 123:7 126:1,3  
137:13,14,16,21  
239:7 241:5 317:15  
356:16,18,20 357:8  
366:14 397:21  
**called** 7:19 52:5 91:4  
111:19,20 221:18  
229:1 374:13 414:19  
**calling** 47:6 138:18  
**calls** 213:6  
**Canadian** 63:2  
**cancer** 243:11  
**Candidate** 4:8  
**candidates** 20:2,2  
**canvassed** 101:3  
**capacity** 5:9 326:12  
356:12 358:11 359:3  
362:9 366:6 369:18  
388:6  
**capital** 187:16  
**capsulitis** 105:5  
**captive** 230:13  
**capture** 193:16 224:7  
224:11 229:19 232:6  
252:2,13 256:14  
**captured** 211:21 224:12  
252:20  
**captures** 131:6 253:9  
**capturing** 251:11  
252:17  
**card** 327:1  
**cardiac** 318:11 364:17  
372:10 379:6

**cardiac/pulmonary**  
379:3  
**Cardiovascular** 355:16  
356:7  
**care** 1:3 2:3,8,12 5:4,5  
15:2 17:19 18:1 20:6  
21:3,3 22:3,4,8,9  
25:17 26:13,15,21  
32:5,9,13,16 33:13  
34:3,8,11,13 35:14  
36:13 37:13 38:8 47:3  
56:19 65:6 75:10  
79:19 102:6,7 106:21  
107:2 113:4 119:7  
122:18 131:2 140:8  
140:20 141:9,11  
142:1,17 143:15,21  
144:3,8 150:7,12,17  
153:12 154:4 157:21  
158:10 167:18,22  
168:14,18,22 169:2  
169:12,18 170:4,8  
172:19,20 173:8,12  
173:16 175:15,20  
177:13,15 178:5,21  
179:2,6 180:6,9 185:9  
186:1,15,20 188:3  
199:7,10 206:3,21  
208:7 215:5 224:3  
229:12 247:13,21  
251:4 266:17 269:7  
279:4,5 284:8,9 285:1  
285:12,12,16 287:13  
287:21 288:2 291:19  
296:14,21 304:13  
312:10 313:4,7  
315:17,19 316:9  
317:15,17,19,21  
318:2 319:19,22  
320:12,14,16 321:7  
321:15,22 322:7,12  
322:21 323:8 324:5,8  
324:9,11,12 325:8  
326:1 329:2,6,15  
330:3,11 331:17  
332:2,8,10 333:1,13  
333:22 334:1,4,12,18  
334:20,21 335:4,4,9  
335:10,14,19,21  
336:3 337:4 338:11  
339:9 340:15 341:9  
344:16 345:12 346:16  
346:17,19 347:5,6  
348:7,12,15 349:1,13  
349:14 350:9 351:13  
352:12,16,17,19  
353:10 354:18 356:22  
363:3 377:10 392:20

393:9,22 394:3,4,5  
397:6 398:17 405:4,7  
407:21 408:9 410:9  
410:21 412:20,21  
413:12 414:17 415:9  
415:15  
**care-based** 175:16  
**Care/Long-Term** 32:5  
**career** 136:12  
**careful** 386:8 411:6  
**carefully** 179:21  
**caregiver** 399:13,21  
**caregivers** 35:2  
**Carin** 2:12 16:6 212:6  
**caring** 406:14  
**CAROL** 2:2  
**case** 1:18 90:11 95:3  
136:19 170:1 175:13  
187:13 198:6 237:4  
262:11 286:6 288:12  
293:18,20 298:15  
319:20 381:14 403:22  
403:22  
**cases** 215:10 327:16  
371:8 399:13  
**CAT** 92:5,5,13 93:6,13  
99:10,17 100:1,12,16  
101:7 114:7 116:16  
116:19 117:7  
**catch** 11:9  
**categories** 245:16,19  
359:20  
**category** 59:22 120:3  
165:15,21 240:16  
328:2  
**CATs** 95:20  
**Caucasian** 159:21  
160:7  
**cause** 247:3  
**causes** 51:11  
**caution** 203:19 226:7  
391:14  
**ceiling** 155:21  
**Cella** 1:19 7:17,18 19:9  
19:9 117:4 150:2  
174:21 187:9 270:9  
271:16,18 272:4  
273:3,6 274:5 275:1,7  
275:11,14,20 276:16  
277:16 278:22 295:6  
297:1 307:10 312:7  
312:13 326:6 327:14  
328:1,8,16 339:4  
340:4,17,21 341:10  
341:14 342:2,13  
381:4 384:16 390:20  
391:7 394:9 403:4  
**Cella's** 277:13

**Center** 1:17,20 2:8,10  
2:13 16:8 24:20 66:1  
**centered** 26:13 32:9,13  
38:8 407:21 408:3  
413:12 420:3  
**Centers** 139:11  
**central** 2:4 9:11 60:18  
66:1  
**certain** 59:7 67:2 76:20  
80:12 82:12 222:1  
287:5 372:2 396:22  
397:1,7 399:10  
404:17 405:12  
**certainly** 9:19 42:8  
81:18 83:7 106:14  
159:9 208:22 222:2  
222:10 225:22 273:1  
298:21 299:13 303:11  
310:7 324:1 338:16  
342:16 386:15 405:11  
411:1  
**certification** 361:20,21  
386:22  
**certified** 317:1  
**cervical** 125:11,19  
126:2,8,13,17 127:1,2  
127:5  
**CESD** 404:22  
**cetera** 11:16 39:19  
48:14 49:3 54:21  
99:13 130:11,18  
370:17 380:8 414:7,7  
**chair** 1:10 10:10 264:13  
264:16 336:14 356:22  
**chairs** 28:7 53:11 409:3  
**challenge** 324:4  
**challenged** 31:4  
**challenges** 417:10  
**challenging** 66:7  
229:22 230:2  
**chance** 10:6 11:15 29:3  
**Chancellor** 23:17  
**change** 4:9,10,12,13,15  
4:16,18,21 5:3,16,16  
46:11 51:11 61:12  
65:5 68:2,20,21 69:4  
69:15,19 70:3,5,13,13  
71:5 81:7 94:12  
117:21 118:6 133:9  
133:10,19 149:15  
191:21 192:3,9  
193:20 194:4 195:1  
227:2 237:17,18  
240:6 242:14,22  
244:11,20 250:5  
259:8 285:4 293:18  
295:11,13 345:15  
360:6 362:7,16

372:13 377:19,20  
 386:14 399:8 406:8  
**changed** 30:18 52:3  
 67:1 108:5 193:21  
 376:9  
**changes** 65:17 137:12  
 142:19 151:13 176:3  
 358:10 359:4 369:18  
 376:9 399:10  
**changing** 387:6  
**characteristics** 67:2,19  
 68:18 72:22 76:1  
 297:6,8  
**charge** 356:19  
**Charles** 7:13,14  
**Charleston** 360:13  
**chart** 274:9 275:3  
 277:12  
**charted** 274:6  
**charter** 408:18  
**charting** 275:8  
**charts** 274:7 275:10  
**cheat** 58:18  
**check** 11:16 162:13  
 177:8 186:14  
**checked** 308:18  
**checking** 162:9 379:9  
**checklist** 110:2 111:4  
 120:16  
**checkoff** 171:19  
**cheer** 326:13  
**Chicago** 20:5 25:17  
 317:5  
**Chief** 2:15 29:8  
**child** 31:22  
**children** 15:5 24:3  
 164:1  
**children's** 1:14,16  
 14:21 16:12 24:4  
**chime** 77:17  
**chiropractic** 139:22  
 144:3,15 160:3,6  
 168:19  
**chiropractor** 157:20  
**chiropractors** 172:9  
**choice** 272:9 334:15  
 381:10 395:9  
**choices** 292:10 378:10  
 395:14,19  
**choose** 41:2 95:11  
 114:13 205:14 395:21  
 397:10  
**choosing** 125:7 167:12  
 225:4 399:14  
**chop** 84:4  
**chord** 208:22  
**chose** 148:1 359:5  
**Chris** 1:9,13 7:6,11 10:9

11:3,8 14:18 15:14  
 121:20 149:14 237:13  
 339:7 389:18 392:7  
 392:22 412:12 422:1  
**Christine** 3:4 139:1  
 178:12  
**Chronbach's** 58:22  
**chronic** 25:4 256:13  
 285:16 316:8  
**chronically** 317:22  
**chunk** 123:7  
**circumstance** 222:5  
 407:17  
**circumstances** 406:22  
**citation** 305:19  
**citations** 305:18  
**City** 2:13 16:7  
**claim** 174:4 307:20  
**claims** 140:14 145:19  
 146:1 148:1 171:1  
 173:22 174:7,11  
 347:1  
**claims-based** 174:5  
**clarification** 59:19  
 74:13 87:19 117:5  
 162:22 171:7 186:22  
 282:5 327:18 330:18  
 343:3 376:3 396:4  
**clarified** 82:3 146:4  
 187:8  
**clarify** 78:18 88:15  
 163:13 164:15 212:18  
 228:2 254:14 277:19  
 280:8 297:5 327:5  
 332:22 333:4 339:5  
 351:9 352:10 384:4  
**clarity** 184:20  
**class** 364:20  
**classification** 111:19  
 111:21 112:2 237:22  
 382:7  
**clavicle** 105:4 106:7  
**clear** 55:10 87:4 88:18  
 107:10 144:5 145:22  
 146:5 150:18 184:2  
 220:14 221:3 247:22  
 258:17 288:1 306:15  
 311:18 317:19 326:7  
 327:5  
**clearly** 85:9 90:22  
 177:14 178:20 186:7  
 340:11  
**clicker** 118:1,10 233:10  
**clickers** 118:10  
**clients** 18:7,11,12  
**clinic** 63:16 65:4 67:19  
 70:20,22 71:4,11  
 72:17,19,22 76:20

77:12 78:12 80:22  
 82:11 91:11,11,13  
 108:18 109:7,15,17  
 111:14 112:13 115:4  
 122:3,11 123:6 213:7  
 226:3 232:10  
**clinic's** 103:1  
**clinical** 8:3,3,14,15  
 15:20 27:7 43:9 46:12  
 63:22 81:14 139:21  
 141:5 144:3 160:10  
 178:18 179:15 208:18  
 210:13 211:12 230:9  
 231:6 243:19 254:4  
 266:15 317:6 346:18  
 347:3 357:9 371:21  
 377:9 382:2 386:18  
 406:13  
**clinically** 112:7,11  
 237:1 244:4 307:17  
 358:16 362:8 374:6  
 383:5 385:11  
**clinician** 65:4 66:1  
 67:19 76:21 78:9,11  
 80:22 82:11,22 99:11  
 99:14 100:10,20  
 101:2,4,13 102:17  
 105:11 107:21 108:1  
 108:18 109:3,7,12,17  
 110:10,13 111:9,14  
 122:3,16 123:6 130:7  
 178:17 179:1 337:13  
 344:7 380:3,11  
**clinician's** 102:22 414:2  
**clinicians** 62:18 78:14  
 78:16 79:3 80:22 81:9  
 100:14 107:13 108:1  
 108:7,11 110:22  
 122:17 125:7 321:13  
 322:5,11 323:9,20  
 380:5  
**clinics** 71:13 72:3,20  
 78:13,15 79:5 83:16  
 94:17 98:20 112:4,9  
**close** 93:9 232:18 351:3  
 397:19 415:15  
**closed** 272:5  
**closely** 19:18 29:9  
**closer** 410:10  
**CMS** 20:16 21:4 43:17  
 48:12 58:13 138:5,12  
 138:18 154:18 183:21  
 265:20 266:8,9  
 274:22 275:17 284:5  
 284:6 285:21 290:16  
 291:16,17 292:15  
 298:21,22 315:14  
 316:5,22 320:7

334:14 349:21 355:1  
 391:1 395:3 397:4  
 405:17 410:3,9  
**co-chair** 1:9,12,13 7:11  
 23:18 136:11 138:3  
 142:7 147:10 148:20  
 149:13 150:1 151:16  
 153:19 156:4,8,17  
 158:12 160:18 161:12  
 162:1,16 164:12  
 165:1,10 167:6 169:7  
 174:10,15,19 176:19  
 177:17 178:9,13,15  
 180:8 181:12,15,18  
 182:5,8,18,21 183:7  
 183:22 184:10 188:17  
 188:21,22 189:9,12  
 189:19 190:4,10,13  
 190:19 191:4,6 195:5  
 196:21 197:20 200:20  
 201:17 202:8,13,18  
 202:21,22 206:12  
 208:17 212:2 214:6  
 216:7,13 217:15  
 221:4 225:7 227:4,21  
 233:2,14,22 236:1,18  
 236:20 237:11 239:3  
 239:13 241:8,11  
 242:2 246:5 257:11  
 258:11 259:22 260:17  
 261:20 263:17 264:10  
 264:14,20 270:7  
 290:9 293:22 294:5,8  
 294:22 302:3,9,19  
 307:8 309:11 310:19  
 311:5 313:18 314:16  
 315:4,8,13 325:13  
 326:5 331:10 333:20  
 337:22 339:2 341:7  
 341:12 343:22 348:17  
 351:2 353:5,15 354:2  
 355:2,8 362:20  
 367:22 371:12,15  
 374:19 375:2,5,21  
 376:14,20 380:12  
 381:2 384:4,12  
 385:21 387:4,7,14  
 388:10,17 390:19  
 391:5,11,14 392:3,6,9  
 392:18 393:1,20  
 394:16,20 396:8  
 397:14 403:2 406:18  
 407:18 413:14,18  
 421:10,18  
**Co-Chairman** 14:17  
 46:21 61:10,18 66:16  
 84:11 85:17 87:20  
 88:10 93:16 96:3

97:20 102:2 107:6  
 108:19 109:20 115:12  
 116:3 117:2,17 118:9  
 118:14 119:12,19,21  
 120:15 122:7,14  
 123:8 124:1 126:3  
 127:7 132:15,21  
 133:3 135:10,22  
 136:3  
**CO-CHAIRPERSON** 6:3  
 8:16 9:2,18 15:9  
 28:13 29:21 42:22  
 51:21 84:20 85:19  
 86:7,11,19 88:8 90:13  
 91:9 106:3 121:7  
 123:14 131:20 132:6  
 132:10,17 133:1,11  
 135:20 136:1,5  
**Co-Chairs** 14:15,16  
 54:10  
**co-investigator** 20:3  
**co-vary** 270:21  
**Coalition** 2:2 19:4  
**code** 174:1 328:13  
 337:15  
**coded** 174:7  
**coders** 163:21 173:4,7  
 186:13  
**codes** 103:22 104:1  
 106:14 174:12 192:21  
 243:10 254:17 337:12  
**coding** 168:5,12  
**coefficient** 110:7  
**coefficients** 78:20 82:5  
 109:2 110:21 111:5  
 116:9,15 221:15  
 222:3,7 346:12  
**cognition** 319:11  
 334:12  
**cognitive** 34:20 288:2  
 377:6  
**cognitively** 399:20  
**coherent** 270:14  
**collapse** 129:1  
**colleague** 15:14 110:15  
 265:17  
**colleagues** 43:4 114:9  
 202:4 265:20 309:11  
 389:13  
**collect** 37:18 63:4 74:4  
 99:10,12,22 100:4  
 116:8 172:10 203:5  
 203:10,13 228:10  
 321:13 347:5,6 350:5  
 350:11,15,20 398:10  
 398:15,20 411:7  
**collected** 88:4,5 145:12  
 150:15 151:1 171:15

179:5 232:7 282:6  
 305:21 312:9,14  
 325:21 326:2 348:2,5  
 349:1,5,19 351:14  
 412:7  
**collecting** 62:4 73:5  
 107:11 210:17 211:8  
 212:20 223:22 229:13  
 235:7,14,17 245:15  
 251:12 263:6 323:20  
 323:22 324:1 369:4  
**collection** 97:12 178:21  
 313:2 323:3 353:9,10  
 412:4  
**collective** 414:1  
**collects** 98:9 410:5  
**College** 357:10 413:1  
**colleting** 203:15  
**Collette** 3:9 189:5  
 191:12 195:5 199:13  
 201:5,17 203:9  
 204:21 206:9 209:11  
 212:17 220:4 223:8  
 228:11 233:14,17  
 234:18 237:11 242:8  
 242:12 248:6 252:15  
 254:13 255:22 263:20  
**collide** 352:2  
**Colorado** 1:13,14,15  
 14:20,21  
**Columbia** 1:21 17:4  
**Coma** 273:14  
**comb** 103:12  
**combination** 42:1 86:9  
 365:8  
**combinations** 86:10  
**combine** 12:3  
**combined** 86:16 88:1,3  
 88:5 268:18  
**combining** 105:12  
**come** 10:22 25:5 42:20  
 44:13 45:17 70:4,6  
 79:17 104:4 110:1  
 124:19 154:21 163:14  
 190:11 235:4 254:15  
 265:1 273:11 309:16  
 314:18 338:4 350:21  
 373:3 389:2 399:6  
 405:1 408:17 409:15  
 415:19 422:5  
**comes** 35:8,21 54:2  
 103:20 195:10 198:4  
 219:3 241:6 293:15  
 307:4 338:1 396:15  
 410:5  
**comfortable** 91:16  
 250:18 293:10 310:1  
 310:2 313:16

**coming** 14:14 43:17  
 44:20 61:9 62:17  
 86:21 127:15 129:10  
 130:8 247:9 248:16  
 249:17 353:9 383:15  
 384:6 399:1  
**comment** 4:20 5:19  
 41:6 44:5 52:19 53:2  
 53:4,13 54:9 55:13  
 59:7 83:11 93:21  
 100:8 120:9 162:19  
 167:10 183:9,11,14  
 183:16,18 187:10  
 198:18 204:11,22  
 208:21 214:5 226:18  
 241:3,5,6 279:1 286:2  
 287:1 302:8 317:11  
 325:2 328:11 330:1  
 333:20 354:1,15  
 355:6 371:14 375:9  
 388:11,14 411:10  
 420:7,10 421:17  
**commenter** 264:19  
**comments** 52:20 53:17  
 137:15 142:10 156:11  
 181:12,14,17 182:5,7  
 182:19,20 188:18,20  
 233:3 241:21 246:12  
 247:7 250:8 251:19  
 258:12,15,17 259:5  
 259:21 261:8 263:18  
 295:1,3 307:9 325:2,7  
 325:12 354:21 380:20  
 387:15 388:16  
**Commission** 8:20  
 22:15  
**committee** 1:3,8 9:5,22  
 10:2 12:16,21,22 13:4  
 13:6,14,17 14:4,6  
 15:5,16,21,21 16:1  
 22:16 23:10,19 28:18  
 32:18,21 35:3,6 36:17  
 42:15,16 43:7,10 45:5  
 46:9 51:4,4 52:22  
 57:18 61:19 69:10  
 73:21 77:16 93:18  
 120:5,12,13,17  
 123:17 129:3 142:14  
 154:21 165:19 195:6  
 195:12 200:21 202:5  
 221:2 231:9 233:18  
 233:19 263:1 264:5  
 293:14 351:1 352:11  
 354:13,22 356:15,22  
 370:6 376:11 383:13  
 407:22 409:4 410:1  
 412:14 413:9 420:4  
**Committee's** 142:6

**committees** 32:4 42:13  
 52:4 408:14,19  
**common** 44:1 348:8  
 406:2,3,20 407:3,9,16  
 408:4,5 410:13 411:5  
**commonly** 144:2  
 342:22  
**communication** 266:17  
 321:22 334:13  
**communities** 286:8  
**community** 29:14 31:21  
 139:22 172:8 189:6  
 190:22 191:13 195:8  
 209:12 219:2,22  
 223:9 226:17 239:2  
 241:1 261:18 283:9  
 286:4 319:15  
**community-based**  
 29:12  
**comorbid** 72:10 73:12  
 74:17 106:8 209:4  
 251:13  
**comorbidities** 68:19  
 209:6 211:14,20  
 234:14 360:19  
**Comorbidity** 360:14,17  
**comp** 89:21  
**companionate** 412:21  
**company** 23:1  
**comparable** 95:5  
**compare** 21:6 58:13  
 70:19,21 71:15,16  
 97:2 116:11 131:16  
 131:18 151:4 171:1  
 266:6 268:13 270:3  
 300:11 305:8 362:13  
 369:22 378:1  
**compared** 60:5,11  
 95:12,14 97:7,11  
 114:18 145:18 278:11  
 362:17  
**comparing** 72:1,1,19  
 249:11 266:3 292:20  
**comparison** 87:7  
 344:11 395:16  
**comparisons** 94:17  
 99:16  
**compelling** 124:5  
**compensation** 89:6  
 90:2,4  
**competing** 5:1,1 40:5,9  
 40:14,19 41:2,14 54:1  
 137:17  
**complain** 179:18  
**complete** 66:13 78:22  
 99:14 156:5 179:19  
 179:21 193:10 196:19  
 236:3 254:1 259:15

305:22 373:11  
**completed** 78:17 194:6  
 235:16 244:14,19  
 322:19,20 332:1,10  
**completely** 170:6  
 178:19 185:11 244:7  
 277:13 327:18 397:2  
 401:16 410:1 418:16  
**completes** 193:12,14  
**completing** 229:10  
 259:19  
**completion** 158:16  
 231:20  
**complex** 42:8 246:13  
 289:2 329:8  
**complexities** 335:6  
**complexity** 24:12  
 284:14 289:4  
**complicated** 31:6  
 228:21  
**complication** 253:19  
**complications** 51:12  
 209:5 211:15 252:7  
 253:13,18 266:12  
 415:21  
**component** 73:9 144:6  
 144:8 168:15 352:21  
 352:22 358:4 364:21  
**components** 122:1,4  
 122:13 188:9 365:1  
**composed** 113:21  
**composite** 221:12,22  
**composites** 42:20  
**comprehension** 322:1  
 336:22  
**comprehensive** 418:7  
**comprehensively**  
 127:22  
**comprehensiveness**  
 416:12  
**comprised** 194:5  
 244:13  
**compute** 68:11 69:15  
**computed** 370:20  
**computer** 87:11,12  
 101:17,22 118:5  
**computer-assisted**  
 63:20  
**computerized** 86:13  
 114:13,18  
**conceive** 154:5  
**concept** 35:19 165:17  
 196:4 370:10 404:12  
**concepts** 45:2  
**conceptual** 60:6  
**concern** 81:15 186:10  
 197:8 251:22 252:11  
 257:6 260:2 278:14

280:3 282:2 297:15  
 304:9 309:21,22  
 312:17,17 321:21  
 419:4,9  
**concerned** 55:15 57:7  
 112:17 113:1 169:8  
 197:1 198:7 309:12  
 348:19 367:2 389:3  
 405:3  
**concerns** 74:12 109:8  
 277:13 295:21 304:4  
 346:7  
**concluded** 422:7  
**conclusion** 361:14  
**conclusions** 58:8  
**condition** 35:8 73:11,11  
 106:6,10 124:18  
 245:15 402:2  
**conditionally** 293:16  
**conditioning** 357:21  
**conditions** 34:6 72:10  
 73:12 74:18 95:6,8  
 106:9 209:4 245:3  
 256:3,4 266:16  
 318:10 391:22 396:6  
**conducted** 322:4  
 330:10 370:14,20  
 371:3  
**conducting** 160:15  
 338:8  
**confer** 368:2  
**conference** 1:8 356:16  
**confidence** 83:13,19  
 84:2 122:5 123:4  
 297:22 298:7 299:2  
 299:17 307:5  
**confidence-inspired**  
 300:5  
**confident** 239:10 415:4  
**confirm** 67:4 90:11  
 175:11 249:6 271:9  
**confirmed** 175:9  
**conflict** 4:3 6:12 11:19  
 12:2 13:10 14:12  
 15:19 16:9 17:1,14  
 19:19 20:8 25:12 27:1  
 27:17,20 28:2  
**conflicts** 13:11 19:8  
 21:11,19 22:6 24:15  
 26:1 27:11  
**confused** 68:2 79:22  
 84:8 91:21 134:2  
 151:18,19 163:18  
 290:15 331:12 344:10  
**confusion** 66:18 68:6  
 136:20 321:19 336:20  
**congenital** 243:12  
**Congress** 283:12

**conjunction** 301:10  
**connect** 101:22 213:9  
**connected** 411:21  
**connection** 107:10,15  
 172:18 174:1 178:5  
 341:6  
**Connolly** 3:2 65:21  
**consensus** 52:5,9,12  
 52:17,21 53:5 235:4  
**consequence** 266:15  
 280:5 309:2  
**consequences** 177:1  
 303:13 359:15  
**consider** 41:8 241:5  
 253:13 254:2 263:1  
 272:16,22 273:1  
 308:9 322:7 386:16  
**considerable** 119:4  
 293:5  
**consideration** 4:8  
 139:16 142:5 153:7  
 195:3 200:16 209:14  
 239:12 256:7 264:9  
**considerations** 47:20  
 354:22 402:17  
**considered** 33:12 38:7  
 41:13 57:14 113:22  
 159:11 180:21 243:21  
 264:2 337:20 373:15  
**considering** 40:1  
 356:15 397:11  
**consistency** 268:2  
**consistent** 181:3  
 268:12 370:12  
**consistently** 419:2  
**consortium** 62:5  
**constantly** 229:8  
**construct** 95:4,11 96:1  
 192:12 210:19 242:16  
 244:5 267:20 306:17  
 308:4,5 367:6  
**constructed** 91:21  
**construction** 192:6  
 203:20  
**constructs** 101:1  
**consult** 309:18  
**consultant** 23:20 30:12  
 65:21  
**consulting** 12:12 13:3  
 16:9 18:2 25:6  
**consults** 263:10  
**consumer** 2:2 19:4  
 395:6  
**consumers** 26:18  
 197:11 292:10  
**containment** 351:11  
**content** 17:6 47:6  
 100:18 205:22 366:14

**content-wise** 16:22  
**contentious** 61:7  
**contents** 47:1  
**context** 49:17 161:13  
**continence** 337:1  
**continuation** 377:20  
**continue** 52:18 166:12  
 176:13 262:5,10  
 287:5 288:21 291:3  
 292:14  
**continued** 261:22  
**continues** 169:8  
**continuing** 290:21  
 349:16 417:4  
**continuous** 219:7  
**contract** 24:13 316:22  
 320:8  
**contracts** 320:7  
**contributing** 144:7,8  
**contribution** 8:22  
**control** 62:11  
**controlled** 103:3  
**controversial** 245:4  
 246:9 254:10  
**convened** 33:16,22  
 35:3  
**convening** 49:8  
**convergence** 268:21  
 402:7  
**conversation** 147:9  
 220:12 262:5 302:5  
 351:19  
**converted** 135:12  
**cooperation** 66:11  
**coordination** 15:2  
 284:9 348:7 408:9  
**COPD** 5:9 356:12  
 357:18 358:7,20  
 364:5,11 374:2,8,11  
 374:17 388:7  
**copies** 58:19  
**copy** 421:13  
**copyrighted** 88:17  
**core** 176:18 401:2  
 406:20 407:9  
**cornerstone** 357:21  
 358:9  
**Corporation** 1:19 20:13  
 22:22  
**correct** 41:5 67:3 81:5  
 89:7 117:15 119:15  
 119:16,19 120:4  
 133:15 138:12 144:14  
 152:19,21,22 155:12  
 155:14 156:7 157:17  
 163:9 170:10 173:6,9  
 174:14 197:2 203:3  
 212:11,12,16 217:17

218:6 238:5 254:7  
 260:9,13 262:21  
 263:2,22 278:5  
 280:11,12,16,19  
 281:16 282:7 293:2  
 311:14,15 333:15,19  
 365:21 376:7 379:5  
 384:10,11  
**correctly** 144:10 152:11  
 154:3,12 184:14  
 237:13 366:15  
**correctness** 155:3  
**correlate** 157:15  
**correlated** 282:18  
**correlation** 109:2 110:6  
 110:20 111:5 221:15  
 222:3,7 268:21  
 282:10 296:16 307:12  
 346:12  
**correlations** 220:21  
 221:7 282:15 307:13  
**cost** 101:15 128:2,9  
 351:10 357:15 398:17  
**costs** 398:9  
**councils** 26:14  
**counsel** 12:1 419:13  
**count** 274:16  
**counted** 277:21 289:16  
**country** 210:10 224:11  
 253:8 300:20 318:2  
 359:11 361:1,10,22  
 363:22 364:2,10  
 417:15 419:4  
**counts** 17:13 152:13  
 166:4 341:20  
**couple** 6:8,9 48:18 56:5  
 74:12 112:18 133:8  
 196:9 209:14 220:4  
 228:3,6 229:16 230:6  
 251:18 316:2 318:4  
 336:17 339:5 390:2  
**course** 53:1 54:2,14  
 63:6 94:7,11 264:20  
 273:12 295:15 322:14  
 351:19 416:3  
**covariant** 360:17  
**cover** 96:8  
**covered** 391:3  
**CPHQ** 2:9  
**CPT** 192:21 243:10  
 254:17  
**crash** 323:5  
**crazy** 136:14  
**cream-skimming** 304:9  
**create** 42:3 221:21  
 306:6 310:16 320:15  
 345:17  
**created** 58:17 86:14

301:16  
**creates** 311:21  
**creating** 221:12  
**credit** 337:18 341:21  
 342:5,11  
**criteria** 53:14,21 54:12  
 54:14 55:4 133:10  
 160:14 186:14 234:22  
 235:1 240:21 262:1,2  
 262:20 322:22 323:15  
 323:16 368:5,22  
 369:11 371:1 378:8  
 378:10 379:12 420:14  
**critical** 267:17 394:16  
**critically** 26:2 122:15  
 317:22  
**criticism** 246:18  
**Cronbach's** 268:2  
**cross** 1:20 24:17,18  
 114:6 316:7 372:2  
 376:1  
**crosscutting** 8:7 33:19  
**crossover** 114:6  
**CSAC** 9:4 15:12 17:9  
 53:7 397:16  
**cuff** 405:4  
**curative** 287:13  
**curious** 47:18 202:3  
 291:1  
**current** 15:12 19:20  
 36:22 188:1 272:22  
 278:21 287:14 324:5  
 356:9,22 413:7  
**currently** 20:16 23:18  
 24:12 27:10 32:15  
 62:13 64:11 160:15  
 164:9 234:22 246:18  
 269:17 289:13 364:5  
**currents** 197:9  
**customers** 100:10  
**cut** 212:3 384:2 386:10  
 410:13  
**cuts** 44:3 410:11  
**cutting** 398:3

---

**D**

---

**D.C** 1:9  
**daily** 5:7 96:21 283:4  
 314:12  
**Dallas** 27:4  
**damage** 247:3  
**Dan** 67:12  
**Daniel** 3:3 66:2 80:10  
 80:14  
**Dartmouth** 20:3  
**DASH** 96:7  
**data** 36:11 37:18,22  
 39:2 44:16 62:4,7,9

62:10,17 63:4 64:7,11  
 65:12 77:4,19 88:3,4  
 89:17 90:4 91:4,14  
 97:12 114:12 115:14  
 115:15 116:8 119:4  
 120:19 121:9 122:19  
 125:18 126:8,9,13  
 127:10 129:12 135:11  
 145:11 148:5 149:7  
 149:14,20,21,22  
 151:1,1 156:2,5,20  
 160:17 161:13 169:14  
 171:1,5,8,15 173:21  
 173:22 174:4 178:8  
 178:20,22 179:2,4,6,9  
 180:3 184:16 198:11  
 203:5,21 210:4,5,6,18  
 211:8 217:18 218:2  
 218:15,16,18 220:15  
 224:7 228:9,15 229:2  
 229:3,5,14 232:7  
 235:15 248:2,16,17  
 249:17 250:16,19,21  
 251:6,7 260:4 261:15  
 264:6 267:5,7,17  
 268:6,12 269:2 276:3  
 278:13,16 284:8,10  
 285:6,10,19 297:17  
 298:20,22 299:1,5,21  
 300:7,13 306:4 307:3  
 307:18,18 313:1,6,12  
 321:14 322:8,19,19  
 323:2,13,20 326:1  
 327:6,13 329:11  
 330:6,13,16,19 331:1  
 331:4,9,16 332:11,14  
 332:15,19 333:3,18  
 334:1,6,11 341:17  
 346:9,10,18,22 347:1  
 347:4,5,7,9,12 348:5  
 348:21 349:1,5,13,14  
 349:18 350:5,9,10,11  
 350:12,16,20,21,21  
 351:13,18 353:9,10  
 354:14,17 360:3,11  
 360:12,13,18 361:2,3  
 361:7,12 362:11  
 363:3,4,17 366:3  
 369:5 371:3 378:1  
 386:8 389:11 410:5  
 411:8 419:14  
**data's** 331:6  
**database** 64:10 74:5  
 82:6 108:2 115:7,15  
 126:10 360:1 365:22  
 365:22 376:18 386:9  
**datapoints** 226:8  
**dataset** 260:5 267:6

**datasets** 203:16  
**date** 109:19 160:11  
 169:2 193:13  
**dates** 169:3 192:17  
**dating** 64:12  
**daughter** 10:8 26:8  
**daunting** 410:7  
**Dave** 7:18 19:9 174:20  
 403:3  
**Dave's** 167:10  
**David** 1:19 6:16 7:14,14  
 7:15 8:20 116:3 117:2  
 150:1 270:8 295:1,5  
 307:8 311:6 325:14  
 339:2 376:22 380:13  
 381:3 384:7 387:16  
 390:3,19 391:10  
 392:1  
**David's** 411:10  
**Dawn** 1:21 17:2 197:21  
 202:1 212:6 241:16  
 250:10 251:15 331:10  
 348:17  
**Dawn's** 346:2 352:10  
**day** 6:7,11 46:20 316:1  
 343:11,13,16,19,21  
 390:16 421:22  
**day-to-day** 81:6  
**Dayquil** 125:15  
**days** 6:11 7:12 11:13  
 24:9 48:18 220:2  
 272:9,9 277:3 281:19  
 286:10 343:18,20  
**dead** 355:5  
**deal** 45:20 70:5 137:16  
 256:10 293:12 381:20  
**dealing** 203:1 372:18  
**dealt** 315:9 389:9  
**dear** 392:9  
**death** 209:18 309:7  
**deaths** 211:18  
**Deb** 214:7  
**Deb's** 113:14  
**debate** 382:5  
**debilitated** 372:9  
**Debra** 2:10 20:10  
**decade** 8:6  
**decades** 97:18  
**decide** 91:10 189:10  
**decided** 7:9 204:5  
 383:14  
**deciding** 378:15  
**deciles** 83:8  
**decision** 119:18 272:12  
 347:8 353:3 378:17  
**decisions** 57:16 242:20  
 250:17  
**decline** 266:14 267:1

269:6,8,22 270:16,18 271:18 279:16 281:22 283:6,20 286:13,18 287:7 289:6,9,16 <b>declining</b> 283:19 <b>decreased</b> 357:17,18 357:19 <b>decreases</b> 194:3 <b>deeper</b> 416:11,14 <b>default</b> 393:11 <b>Defense</b> 160:16 <b>deficiencies</b> 140:7,9 150:9 167:20 172:4 173:13 178:6 <b>deficiency</b> 168:2 <b>deficit</b> 334:22 335:1 377:6 <b>deficits</b> 172:15 256:14 <b>define</b> 47:18 178:4 <b>defined</b> 35:4,6 193:18 244:10 271:16,17 358:19 359:14 <b>definitely</b> 53:3 143:21 207:10 226:5 297:12 352:7 409:8 <b>definition</b> 168:1 174:9 184:21 281:14 360:5 <b>definitive</b> 251:17 <b>degenerative</b> 105:6 208:8 245:6,17 <b>degree</b> 94:16 226:7 350:7 <b>delay</b> 154:22 270:18 <b>delighted</b> 6:4,6 9:5,6 29:2,16 <b>delights</b> 9:22 <b>delineated</b> 291:21 364:3 <b>delineating</b> 254:21 <b>delirium</b> 319:11 321:20 <b>delivered</b> 247:13 397:6 <b>delivering</b> 177:15 <b>delivery</b> 411:20 412:3 <b>delta</b> 70:12 71:4 <b>deluge</b> 43:16 <b>demanding</b> 100:14 <b>dementia</b> 25:18 288:3 <b>demographic</b> 73:4 115:14 141:16 361:2 <b>demographics</b> 223:11 <b>demonstrate</b> 83:11 119:4 194:18 199:19 246:1 385:15 <b>demonstrated</b> 200:19 403:17 <b>demonstrates</b> 35:15 36:22 75:18 <b>demonstrating</b> 359:20	406:15 409:20 <b>demonstration</b> 287:15 323:19 333:6 334:20 334:22 335:2,9 338:15 341:5 347:22 351:13 <b>Dennis</b> 64:3 <b>denominator</b> 85:10 102:16 194:5 209:7 209:20 211:6 232:21 244:13 245:14 254:15 259:13 272:13 273:11 274:1 276:2 279:2 309:4,9 322:21 326:17 359:15 <b>department</b> 7:19 24:19 29:19 43:15 160:16 195:19 196:22 <b>dependency</b> 266:11 <b>dependent</b> 68:5,5,7,20 69:19 70:3 273:12,13 285:5 337:6 <b>depending</b> 40:22 47:8 70:14 86:1 189:21 204:17 275:10 285:21 321:17 414:6 <b>depends</b> 202:8,10 222:14 <b>depository</b> 62:10 <b>depression</b> 36:2,8,14 46:11 213:7 404:8,10 404:22 405:11 406:1 <b>depth</b> 28:17 206:1 <b>derive</b> 117:9 <b>derived</b> 334:18,22 384:1 <b>desaturate</b> 358:2 <b>describe</b> 35:16 66:19 203:12 <b>described</b> 88:1 239:9 341:2 <b>description</b> 173:10 191:7 198:5 218:9 341:8 <b>design</b> 80:20 203:20 245:1 <b>designed</b> 34:19 82:16 158:3 170:16 291:10 365:11 397:5 <b>desire</b> 118:7 128:4 129:1 <b>desired</b> 249:8 <b>Despite</b> 141:2 <b>detail</b> 239:12,17 <b>detailed</b> 174:16 <b>details</b> 69:9 192:12 407:16 <b>detect</b> 415:17,22	<b>detecting</b> 296:13 334:1 <b>detection</b> 351:11 <b>determination</b> 277:11 <b>determine</b> 67:11 151:5 211:3 <b>determined</b> 174:16 193:22 <b>determining</b> 196:5 219:17 <b>Deutsch</b> 3:3 315:15 316:14,18,21 325:20 327:4,19 328:7,10,12 329:17 330:3 331:14 332:12 333:15,18 338:13 339:15 340:10 340:20 341:22 342:8 342:15 343:9 344:13 346:15 347:19 <b>Deutscher</b> 3:3 66:3 67:7 80:15 81:2 82:2 86:5,9,12 87:18,21 103:17 105:14 114:4 120:18 122:21 129:4 <b>develop</b> 15:22 16:19 19:21,22 20:6 24:2,13 157:21 195:9,13,14 318:15 321:5 351:21 362:14 407:5 <b>developed</b> 7:22 23:5 62:2 64:2 139:18 154:17 168:16 169:3 217:21 320:3 335:15 383:14 413:6 <b>developer</b> 77:3 125:14 125:15 127:10 133:7 133:12 139:13 190:20 191:12 237:2 241:22 260:10 265:4 293:17 316:8 355:15 377:22 421:14 <b>developers</b> 20:20 23:11 38:17 39:4 46:4 53:10 55:8 59:6 85:8 103:7 110:1 120:8,14,16 121:21 124:11 127:13 129:2 138:6 177:18 219:15 220:1,11,14 222:6 225:21 226:14 250:13 253:12 261:9 261:14 263:6 265:19 298:12 310:8 317:16 354:10 355:13 389:22 396:10 401:8 402:12 402:19 415:2 421:20 <b>developing</b> 26:20 27:7 128:18 195:21 234:21 313:9 408:8 420:19 <b>development</b> 8:8 15:1	18:9,10,22 19:7 30:13 64:4 87:15 100:16,21 191:15,17 193:8 196:4,10,17 200:5 203:18 210:12 216:12 218:18 232:1 234:20 242:19 245:1 251:16 256:8 267:10 312:4 320:1 324:22 350:3 352:16 <b>deviation</b> 201:4,8 202:16 207:20 225:15 225:18 226:20,21 237:3,7,15,21 238:8 <b>devices</b> 357:22 372:21 <b>diabetes</b> 180:2 210:22 224:21 <b>diagnoses</b> 251:20 254:18 <b>diagnosis</b> 76:2 106:14 210:22 <b>diagnostic</b> 75:16 <b>dichotomy</b> 240:19 <b>dictionary</b> 229:5 <b>die</b> 211:21 308:16 309:6 326:20 <b>died</b> 209:22 269:11 277:2,21 278:4,7,10 <b>dies</b> 272:15 <b>diff</b> 415:17,21 <b>differ</b> 83:4 <b>difference</b> 39:16 47:14 47:19 49:19 69:20 72:12 102:18 112:8 112:11 124:6 150:22 158:15 175:7 198:15 198:20,22 199:3 201:3 202:6,20 207:5 207:22 208:2,3 213:15 218:4 225:1 237:5,17 238:10,18 299:12 359:6 360:16 361:10 364:18 380:8 382:19 <b>differences</b> 50:14 82:17 91:6 96:16,19 98:5 105:16 112:22 123:11 129:22 141:15 158:21 160:13 181:4 199:19 200:2,8,13,18 201:13 236:21 238:15,20 365:16 373:18 394:3 394:3 396:18 <b>different</b> 6:18 10:21 13:9 31:3 32:3 41:12 41:13,15 44:18 45:1 50:6,20 70:5 71:12,13 84:6 86:1,2,6 89:18
--	---	---	--



89:18 90:7 94:18 95:11,19 96:13,14 97:13 105:8,10,15,20 110:7,20 113:18 115:9 121:4 123:1,3 123:13 125:4 127:18 128:4,15 129:5,14,15 129:20 131:11,15 152:9 184:15 185:11 187:10 192:6 198:14 199:4,12 205:19 209:14 213:5 229:16 232:8 262:8 268:8,11 268:16 271:13 278:1 284:11 285:11,20 290:20 292:13 296:21 298:4,8 303:7,8 304:6 305:14 306:8 320:7 329:21 331:17 336:15 344:9 357:22 359:9 374:16 392:20 393:8 395:17,21 396:11,19 401:8 403:5 405:18 405:20 410:21 418:17 <b>differential</b> 129:13,16 131:9,10 403:18 <b>differentiate</b> 83:12 269:6,10 359:13 367:13 <b>differentiation</b> 272:6 <b>differently</b> 55:11 95:7 110:16 261:10 345:13 <b>difficult</b> 81:9 131:10 164:18 186:11 288:11 288:13 318:18 389:1 389:2 403:10 <b>difficulties</b> 103:19 288:15 329:10 <b>difficulty</b> 105:12 106:1 129:15,20 130:2 131:10 225:3 228:4 233:13 267:22 <b>digest</b> 121:11 <b>digestible</b> 6:20 <b>digress</b> 292:12 <b>dimensions</b> 395:2 <b>dinner</b> 190:14 422:4 <b>direct</b> 55:8,10 168:17 229:2 <b>directed</b> 206:11 <b>direction</b> 118:2 120:13 159:14 220:14 221:3 352:8 399:17 <b>directly</b> 28:8 35:9,21 36:6 45:22 97:7 253:4 <b>director</b> 1:18 17:19 19:4 22:21 64:3 66:3 285:15 357:6,7	<b>Directors</b> 20:21 <b>disabilities</b> 15:5 283:13 <b>disability</b> 18:8 63:12 70:15 85:22 171:21 243:15,18 244:1 249:3 283:8,10 <b>disabled</b> 71:3 72:2,2 383:3 <b>disaggregated</b> 102:10 <b>disagree</b> 83:10 256:1 293:20 386:13 <b>discern</b> 200:13 <b>discernible</b> 200:2 <b>discharge</b> 5:5 68:3,8,8 68:21 69:20 77:20 78:22,22 81:8,22 82:7 214:11 315:18 319:15 322:5,11,17,19 323:13,14,15 326:21 327:6,9,11,12,20 329:5 330:11 332:15 332:20 343:17 <b>discharged</b> 329:1 <b>disciplinary</b> 365:11 <b>disclose</b> 12:14,20 13:5 13:15 14:11 15:7 16:4 23:9 25:13 <b>disclosed</b> 14:12 18:15 <b>disclosing</b> 17:15 <b>disclosure</b> 12:3 13:2,9 298:14 <b>disclosures</b> 4:4 12:6 25:11 27:13,13 <b>disconcerting</b> 238:22 <b>discovered</b> 61:6 <b>discrete</b> 229:19 <b>discriminate</b> 83:2 222:9 222:10,12,13 237:8 296:21 299:3 306:17 306:20,21 307:2,6 369:5 400:11,14 <b>discriminating</b> 296:15 <b>discuss</b> 15:8 27:15 32:13 51:22 54:19 57:6 390:14 <b>discussant</b> 53:15 54:17 61:15 93:22 138:7 <b>discussants</b> 84:21 <b>discussed</b> 57:9 136:16 136:21 352:7 <b>discussing</b> 17:6 22:20 43:4 349:4 <b>discussion</b> 5:1 10:13 11:7 22:12 40:14,20 40:22 43:2 45:14 51:10 53:12 70:10 84:13 85:16,21 88:11 89:11,14 108:21	138:4,8 158:14 178:20 189:2 195:4 199:14 201:16 205:2 210:13 212:3 221:2 227:21 234:9 235:4 261:11 270:6 309:20 309:22 310:8 311:6 313:15 333:21 339:14 349:17 354:11 362:21 371:13 375:4 381:3 383:12 390:16 391:20 392:18 393:18 397:15 398:9 421:3 <b>discussions</b> 11:10 25:1 40:4,19 47:2 54:16 57:21 123:13 189:22 244:22 325:14 326:16 351:9 376:21 389:21 <b>disease</b> 102:15 105:6 245:6,17 252:9 254:11 372:9 391:21 402:2 <b>disk</b> 245:6,7,17,17 254:11 <b>disparate</b> 42:19 <b>disparities</b> 91:3,4 113:3 158:18 159:2 161:4 329:11,14,18,21 330:2,7,14,19 331:1,4 <b>disparity</b> 158:14 159:8 159:13 223:2 <b>display</b> 36:20,20 <b>disposition</b> 329:6 <b>disruptive</b> 397:10 <b>dissemination</b> 411:13 <b>dissimilar</b> 314:20 <b>distance</b> 372:1,2 381:10 406:7 <b>distances</b> 336:15,17 <b>distinction</b> 48:7 50:18 113:19 <b>distinctions</b> 35:15 128:15 <b>distinguish</b> 47:12 296:4 367:7 <b>distinguished</b> 66:6 <b>distinguishes</b> 110:14 <b>distinguishing</b> 110:22 225:20 289:7,14 <b>distributed</b> 361:1 <b>distribution</b> 83:3 202:9 202:11 222:12 361:3 <b>distributional</b> 84:5 <b>disturbing</b> 185:16 293:9 <b>dive</b> 61:11 137:3 <b>diverge</b> 382:17 <b>diverse</b> 160:4 320:17	394:13 <b>diversity</b> 345:10 <b>divided</b> 110:8 <b>Division</b> 14:19 285:16 316:8 <b>dizzying</b> 416:5 <b>doable</b> 186:21 <b>doc</b> 7:10 <b>doctor</b> 160:3 180:1,3 415:19 <b>doctors</b> 162:8 168:19 275:12 <b>document</b> 114:21 167:21 173:10 187:20 337:13 338:20 339:13 394:11 405:18 <b>documentation</b> 141:8,9 142:19 143:13 144:11 145:22 146:12 153:11 153:13,18 155:10 158:16 164:19,22 170:1 187:1 210:8 332:6 420:1 <b>documented</b> 146:7 150:6 162:17 167:18 173:12 186:3 341:18 341:18 342:6 <b>documenting</b> 153:18 153:22 <b>documents</b> 30:16 341:19 <b>doing</b> 9:16 12:22 26:14 26:16 46:15,16,17 51:18 55:7 74:7 92:8 108:17 111:10 157:16 157:22 158:1 161:17 188:8 212:10 213:8 213:19 220:5 228:14 273:18 274:11 309:4 330:15 337:20 338:3 344:16 353:12 402:21 406:10,12 409:11 416:13 418:20 <b>dollar</b> 197:4 <b>dollars</b> 303:4 <b>domain</b> 33:12 38:7 88:16,17,21 89:1,3 93:15 113:16,17 117:13 335:11 366:15 413:21 <b>domains</b> 33:8,10 35:5 35:11 117:19 335:10 <b>dots</b> 52:1 <b>Dowding</b> 1:21 17:2,2 197:22 204:3 217:17 222:16 228:1 231:18 241:18 250:11 260:1 331:11,15 333:12,16
--	---	--	--

348:18 350:14,19  
 419:20 420:8,11  
**Dr** 7:6 8:19 28:15 41:6  
 42:7 44:11 45:19  
 47:22 60:13 64:2  
 65:22 66:2,5 67:5,6,7  
 67:13 68:15 69:5,17  
 70:2,17 71:8,18 72:5  
 72:16 73:7 74:8 75:1  
 75:15 76:17 78:1,4,9  
 78:18 80:8,15 81:2  
 82:2 83:10 86:5,9,12  
 87:3,18,21 88:19 89:8  
 89:16 90:6,21 93:4  
 95:3 97:6 98:15 99:4  
 99:6,8,9 101:2 102:11  
 103:17 105:14 106:4  
 107:20 109:13,16  
 111:16 114:4,19  
 116:5 120:18 122:21  
 124:17 125:10 129:4  
 130:7 131:7 135:17  
 136:4 143:3 159:6  
 168:6 277:13 310:6  
 356:20 357:3 373:16  
 378:21 408:12 410:8  
**drafted** 408:18  
**dragging** 221:10  
**draw** 226:1  
**drawback** 101:14  
**dressings** 336:1 342:22  
**drill** 414:16  
**drive** 108:17  
**driven** 100:10  
**drives** 107:12 398:17  
**driving** 107:13  
**dropped** 241:13  
**dryer** 105:9  
**dryers** 103:13  
**DUDHWALA** 145:16  
 146:15,21 153:1  
 164:9  
**due** 31:5 67:18 123:11  
 252:8  
**dumbed** 395:15  
**duplication** 44:4,10  
**dying** 415:20  
**dynamic** 215:20,22  
 413:4  
**dysfunction** 252:3  
**dyspnea** 357:18

## E

**E** 4:1  
**earlier** 10:2 19:16 30:18  
 35:19 38:6 56:5 57:13  
 113:14 139:6 222:6  
 249:1 261:7 298:11

308:14 309:22 317:11  
 319:17 346:8 354:10  
 394:9 396:15  
**early** 6:5 251:15 319:4  
 319:9 390:3 392:5  
 415:22  
**ease** 128:3 231:1  
**easier** 385:12 393:12  
 412:7  
**easy** 171:15 172:2  
 193:9 403:9 416:19  
**eat** 308:2 402:1 403:11  
**eating** 266:5 323:10  
 335:21  
**echo** 185:5,6 414:20  
**edge** 398:3 406:7  
**editorial** 315:11  
**educate** 179:11  
**educating** 313:3  
**education** 313:8 364:21  
**educational** 358:3  
**effect** 145:2 155:22  
 201:3 202:17 204:8  
 226:20 236:22  
**effective** 161:11 245:3  
**effectively** 180:6 251:5  
**effects** 253:10  
**efficiency** 63:16 100:2  
 101:14 284:11 351:15  
**efficient** 95:10,16 99:20  
 99:22 100:15 357:15  
**efficiently** 100:6  
**effort** 66:7 139:20  
 175:14 197:16 244:15  
 313:2 326:13 420:20  
**efforts** 57:3 58:11 301:6  
 301:11  
**eight** 9:14 99:13  
**eighteen** 302:16 387:11  
 387:12  
**Eighty-eight** 375:10  
**Eighty-four** 216:22  
**Eighty-three** 314:14  
**either** 24:15 34:5 55:3  
 56:14 58:8 59:18 92:3  
 111:6 127:9 152:7  
 192:15 252:7 263:10  
 367:9 368:8 390:10  
 399:12  
**either/or** 401:5  
**Elbow** 4:17  
**elderly** 107:3  
**elected** 126:15  
**electronic** 398:13,14  
**electronics** 411:22  
**element** 120:1 167:15  
 167:17 168:1 184:20  
 204:2 224:7 228:15

248:5  
**elements** 90:18 210:4,7  
 267:17 334:11 371:3  
**elevates** 340:18  
**elevator** 21:17  
**Eli** 24:13  
**eligible** 140:7 148:2  
 157:3 219:8 234:15  
 267:7 274:17  
**eliminate** 44:4  
**eliminated** 293:11  
**ELIZABETH** 2:6  
**email** 137:18  
**emails** 11:16  
**emergency** 415:20  
**EMMI** 2:3  
**emotional** 34:18  
**emphasize** 147:22  
**emphasized** 34:15  
**Emphysema** 373:20  
 374:13  
**empirical** 60:3,11  
 370:13 403:20  
**employer** 14:1  
**employment** 319:13  
**EMR** 154:5,8,9 161:1  
 165:4 169:18 229:16  
 229:19 230:1 232:13  
**EMRs** 405:20  
**enables** 100:12  
**encountered** 226:11  
**encourage** 15:17  
 215:14 340:22 421:12  
**encouraged** 176:9  
**encouraging** 307:12  
**end-stage** 208:8  
**ended** 278:8 415:19  
**endorse** 40:3 92:1  
 151:21 163:13 198:20  
 290:22 333:13 348:20  
 349:5,17,18 350:16  
 350:22 352:12,14  
 366:21 367:3,11,17  
 377:21  
**endorsed** 32:17 33:5  
 38:2 41:5 46:10 97:9  
 358:15 376:10  
**endorsement** 32:22  
 48:3,21 49:1 57:19  
 65:9 139:16 142:5  
 183:1 200:10 240:6  
 314:10 376:5 378:20  
 388:6 408:20  
**endorsements** 353:8  
**endorses** 37:19  
**endorsing** 92:5,6 381:6  
 381:7,7 413:10  
**ends** 83:3 136:16

281:20  
**endurance** 372:12  
**engaged** 18:12 419:18  
**engagement** 2:5 284:1  
**English** 63:7  
**English-speaking**  
 224:14  
**enhance** 24:1 42:1  
**enhanced** 24:5 42:4  
**enhancing** 94:8  
**enjoy** 10:4  
**enrolled** 365:13  
**ensuring** 61:5  
**entering** 286:9  
**entire** 78:20 79:7 94:22  
 300:20 345:8 376:16  
 379:16  
**entirely** 90:14 105:8  
 199:2,15 291:11  
 421:7  
**entities** 37:20  
**entity** 36:12 38:1 39:3  
 62:11 226:22 370:22  
**environment** 81:14  
 266:20 398:8  
**envision** 83:8  
**episode** 62:14 131:2,5  
 140:20 214:21 352:5  
**episodes** 78:17 352:3  
**EQ-5D** 252:19  
**equalize** 98:20  
**equation** 70:1  
**equations** 80:5  
**equivalent** 93:8,9  
 114:17 290:2  
**err** 226:6  
**error** 67:18 76:16 79:16  
 82:18,22 106:15  
 225:13,14 238:7,19  
 238:21 296:4 305:10  
 381:21  
**errors** 221:11,17  
**especially** 9:6 127:15  
 279:18 377:6 378:5  
 391:9 421:3  
**essence** 310:4  
**essential** 352:21  
**essentially** 178:3  
**establish** 322:11 362:6  
 362:6 386:10 399:4  
**established** 143:17,21  
 186:2 219:14 366:9  
**establishing** 399:22  
**Estee** 2:8 17:17 21:16  
**estimate** 78:17 79:6  
 83:19 297:18 298:1  
 363:22  
**estimates** 82:14 265:21

**estimation** 80:5 238:3  
298:13  
**et** 11:16 39:19 48:14  
49:2 54:21 99:13  
130:11,18 370:17  
380:8 383:22 414:7,7  
**ethnic** 158:22  
**ethnicity** 141:19 198:14  
218:14  
**etiology** 75:3,5,7,19,20  
76:2  
**evaluate** 28:19 40:5  
45:11 154:12 155:3  
235:8 347:11 349:10  
363:9,15 384:14  
409:6  
**evaluated** 45:9 69:11  
142:14 262:19  
**evaluating** 145:6 153:8  
192:2 242:22  
**evaluation** 2:8 4:6  
17:19 23:18 48:20  
50:8 312:5 320:9  
363:11 376:17  
**event** 323:7  
**events** 272:11 306:6  
**everybody** 6:16 28:15  
30:5 31:10 59:4 162:8  
184:17 190:11 281:3  
281:6 312:21 313:16  
384:13 390:15 395:5  
**everybody's** 390:13  
397:20 400:19,21  
**evidence** 38:16 39:4  
49:2 54:17 55:16 56:7  
56:20 103:5 110:22  
111:3,13 112:13,21  
113:9 118:12,16  
133:22 141:4 142:16  
142:18 143:11,12  
156:15 165:6,7,8,18  
166:9,10 181:3  
216:15 257:12 294:9  
299:22 307:2 319:6  
329:21 347:17 353:16  
353:18,18,21,22  
357:16 365:15 366:10  
367:3 369:7,13  
374:21 377:11,16,18  
379:19 382:16,18,18  
386:14 409:14  
**evidence-based** 140:18  
**evidenced** 141:12  
**evolved** 63:9 219:17  
245:13  
**evolving** 44:19  
**exacerbated** 296:10  
**exacerbation** 357:18

**exact** 205:6,20  
**exactly** 40:18 59:7  
69:10 82:15 84:9  
103:19,21 104:16  
173:4 175:1 178:1  
186:13,22 219:21  
241:20 247:4 340:2  
367:10 377:4 398:16  
408:15 414:21  
**examination** 374:16  
**examined** 360:11  
**example** 13:1 36:7,12  
39:15 41:12 42:15  
45:10 46:9,15 59:20  
60:20 72:4 75:4 85:20  
112:22 129:6,17  
141:16 162:4 169:12  
238:9 298:20 337:7  
340:13 365:18 367:5  
403:7 408:11,21  
409:2  
**examples** 45:21 57:12  
220:9,17  
**excellence** 213:10  
**excellent** 196:5 359:20  
**exception** 38:15 165:8  
165:11,12,20 166:10  
353:19,22  
**exceptions** 359:16  
361:6  
**excited** 250:19  
**exclude** 276:2 277:11  
279:10  
**excluded** 269:12  
327:17 373:1  
**excluding** 277:14  
287:18  
**exclusion** 181:4 209:18  
273:17 275:17,22  
289:18 293:7,11  
309:14 310:3 322:22  
**exclusions** 54:21 193:1  
209:7,16 210:3  
243:10 269:9 273:10  
279:3,7 280:9 289:14  
372:22  
**Excuse** 190:2 281:17  
302:5  
**excused** 326:22 327:10  
**Executive** 19:3  
**Executives** 413:1  
**exercise** 364:16 365:8  
**exercising** 174:17  
**exist** 405:14  
**exists** 310:17 407:3  
**expand** 301:22  
**expanded** 140:2  
**expanding** 245:13

413:21  
**expect** 13:15 197:12  
232:5 249:12 300:2  
322:15 323:9 333:8  
**expectancy** 275:8  
**expectation** 290:1,4,6,8  
293:8 301:10  
**expected** 108:16 112:9  
267:21 273:16 289:9  
322:16  
**expecting** 248:15  
**expensive** 398:17  
**experience** 24:18 25:21  
29:14 35:13 38:20  
45:8 225:2 392:19  
393:3 408:7 412:14  
414:13,15 415:3  
**experiences** 323:2  
347:21  
**experiencing** 161:18  
233:13  
**experimented** 6:18  
**expert** 14:7,7 20:19  
21:3 143:1 146:3  
320:5 321:3 344:17  
366:13 367:13 386:21  
413:2  
**expertise** 31:8 43:6  
46:22 47:7 65:19  
312:5 409:1  
**experts** 42:11 344:18  
359:10,10,21 376:17  
**explain** 104:13 235:13  
**explained** 395:7  
**explaining** 59:13 98:5  
103:19  
**explanation** 159:19  
**explicit** 178:5  
**explicitly** 127:6  
**exploration** 196:5  
**explore** 234:21 386:5  
**exposed** 161:20  
**expressed** 419:3  
**expression** 322:1 337:1  
**extension** 185:2  
**extensions** 19:22  
**extensive** 87:14 229:6  
333:21  
**extent** 75:21 127:17  
144:5 169:5 215:8  
393:4,7 394:5 421:14  
**externally** 64:10  
**extra** 49:9 180:7 406:21  
407:11,12  
**extract** 229:20  
**extremely** 366:8 379:20  
**extremes** 238:15 299:7  
400:18

**extremity** 95:22 96:1,6  
96:9 129:11 404:7

---

**F**


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**FAAP** 1:13  
**fabulous** 213:8  
**face** 9:20 161:9 306:14  
359:13 366:17 370:16  
**FACEP** 2:12  
**faces** 6:9  
**facilities** 20:7 37:8,11  
62:19 267:1 268:7,10  
268:15 291:21 295:11  
295:13 296:15,22  
298:3,7 299:6 306:22  
306:22 333:6,10  
367:7 378:1  
**facility** 37:3 106:20  
213:22 266:1,22  
271:19 279:21 282:17  
284:18,22 285:13  
292:7 295:9,22 296:3  
296:6,9 297:6,8 298:1  
299:14 317:20 323:7  
324:11 329:1 346:3  
346:11 347:10,12,16  
347:18 363:7 365:20  
366:19,21 367:4  
415:14 417:1  
**facility-level** 267:12  
300:16  
**fact** 18:20 48:10 96:13  
99:21 101:6 144:22  
162:7 179:12 185:18  
229:21 242:18 251:11  
253:13,17 304:17  
306:4 355:4 370:19  
371:17 378:11  
**factor** 266:12 313:5  
326:2  
**factors** 100:5 198:13  
266:16  
**faculty** 317:6  
**failing** 262:2 318:5  
**fails** 262:12 354:9  
**failure** 20:2 318:4,11,11  
318:12 374:8  
**fair** 46:19 75:22 145:9  
145:17 208:19 295:12  
296:2 336:5 409:5  
**fairly** 80:11 110:17  
193:16 224:7 248:17  
333:21 361:22 405:22  
**fall** 94:1 153:16 154:14  
237:20 270:20 281:4  
307:18  
**falling** 52:7  
**falls** 269:1 282:18

292:21 307:12 357:2  
**false** 309:8  
**familiar** 18:18,19 23:8  
 33:13 168:19 195:12  
 233:19  
**familiarity** 231:1  
**families** 1:12 15:11  
 34:1 35:2 270:4  
 416:13 418:6 419:1,2  
 419:3  
**family** 2:5 7:10 25:3  
 26:12,13 32:8,12 34:4  
 38:7 399:12 407:21  
 408:3 413:12  
**family-centered** 1:3  
 26:15,21 32:16 33:13  
 34:3,7,11,13 47:3  
**fan** 162:3  
**far** 104:11 135:18  
 188:12 264:2 367:16  
 386:17 391:8 402:6  
 417:3  
**fascinating** 356:5  
**fashion** 367:19  
**faster** 401:11,11  
**father-in** 7:7  
**favor** 102:5 154:14  
 175:5 236:6 421:21  
**favorably** 176:12  
**FDA** 369:3  
**fear** 72:10 73:14 74:18  
 98:10,15,18 99:2  
 101:15  
**feasibility** 54:22 98:2  
 127:14 132:5 134:21  
 181:13,19 227:22  
 233:4,5 236:5 259:17  
 261:13 311:5,9,19  
 312:2,9,18 313:19,20  
 386:20 387:15,15,17  
**feasible** 228:9 323:9  
 353:8  
**federal** 33:18,20 325:5  
**feedback** 20:19 31:2,8  
 55:8,10 108:4,15  
 165:18 187:2 188:15  
 261:8 321:3 371:10  
 416:10  
**feel** 25:2,22 26:1 43:5  
 79:12 98:21 128:10  
 136:21 189:15,15  
 199:6 240:19 253:9  
 312:19 321:9 322:6  
 348:3 391:7 402:7  
 417:20 418:19  
**feeling** 200:11 264:4  
 293:6 383:10 388:20  
 393:16 418:19

**feelings** 205:6  
**feels** 161:6 414:22  
 417:7  
**fees** 16:9 192:22  
**fell** 240:21 262:9  
**fellow** 90:15  
**fellowship** 21:13  
**felt** 200:7,17 210:14  
 320:14 321:10  
**female** 223:18,19  
**fewer** 79:14 272:10  
**field** 23:4 162:17  
 184:21 228:15 409:7  
**fields** 203:21 229:19  
**fifteen** 193:18  
**fifty** 387:11  
**Fifty-eight** 240:12  
**fifty-nine** 375:19  
**Fifty-six** 314:7  
**fifty-three** 388:3  
**figure** 45:13 80:3  
 147:15 156:19 186:3  
 186:4 301:4 382:4,5  
 390:5 414:4  
**figures** 80:11  
**figuring** 215:2 288:22  
 344:2 393:14  
**fill** 13:20 139:20 228:5  
**filled** 53:18 156:16  
 180:5 218:11,20  
 231:19 420:9  
**filling** 223:1 276:13  
**FIM** 343:7  
**final** 28:11 57:17  
**finalized** 325:8  
**finally** 66:8 182:18  
 304:17 357:8  
**financial** 13:11  
**find** 12:4 90:10 92:12  
 92:14,20 115:10  
 157:18 218:9,15,16  
 268:16 329:12 361:8  
 363:8 380:6 405:17  
**finds** 39:6 105:12  
**fine** 102:20 350:14  
 386:11  
**finish** 365:6  
**finished** 180:1  
**finishing** 389:15  
**fire** 413:15  
**firm** 18:6,11  
**first** 6:14 9:3,12 10:11  
 10:20 35:18 40:6  
 49:16,21 54:18 55:21  
 59:2 62:3 65:7 82:2  
 83:21 85:2 89:20 90:8  
 90:17 97:5 101:8  
 111:4 133:13 142:12

142:13 147:3 151:20  
 160:17 167:15 191:20  
 193:20 198:2 201:6  
 220:12 221:5 223:12  
 223:15 242:1,7 271:3  
 287:1 302:10,11  
 303:20,21 305:16  
 317:8 320:11 341:8  
 346:16 370:10 383:14  
 392:13  
**first-year** 194:17  
**fit** 41:3 220:22 291:1  
 303:17  
**fits** 25:19  
**five** 34:9,12 37:5 78:13  
 78:15 83:9 89:6,12  
 134:9 135:3 165:7,21  
 227:18 257:18 292:20  
 303:1 314:21 315:22  
 345:19 353:18 359:19  
 383:19 389:3,7  
 390:22,22 391:1  
 415:14,15  
**five-star** 21:4 266:10  
 292:4,6 305:13  
**Five-Stars** 305:4,18  
**fix** 253:17 298:10  
**fixable** 289:18  
**flag** 149:17  
**flat** 287:6  
**flaw** 255:13  
**flip** 396:22  
**float** 84:6  
**floating** 82:19  
**Floor** 1:8  
**flow** 187:21  
**fluctuations** 296:13  
 298:19  
**flummoxed** 369:12  
**flunk** 400:20  
**fly** 201:15  
**FNAHQ** 2:9  
**focus** 57:2 130:11,20  
 131:4 147:5,8 192:19  
 245:9 246:20 267:2  
 269:20,21 282:16  
 304:5,11 344:9  
**focused** 319:4 320:6  
 345:4  
**focuses** 243:8  
**folks** 50:18 59:3 61:13  
 98:13 138:11 183:12  
 212:10 247:7 278:7  
 279:18 390:2 407:20  
**follow** 28:22 82:21  
 174:22 204:5 205:12  
 275:3 346:1 367:18  
 379:12,13 380:3

384:17 397:3  
**follow-up** 155:5,17  
 169:14  
**followed** 213:21  
**following** 4:22 5:3 53:2  
 53:4 149:13 151:13  
 171:7 191:22 240:7  
 242:14  
**follows** 53:6  
**followup** 201:2 204:4  
 205:11 211:11 297:4  
 308:16  
**font** 101:11  
**foot** 4:12 95:8,13,14  
 96:17 129:10  
**force** 34:8,12,15 356:10  
 356:19 357:1,12  
**forces** 29:11 34:1  
**forcing** 61:5  
**form** 12:9 93:4,5 101:10  
 113:17,20 114:5,14  
 114:21 115:16 117:7  
 180:5 218:8,12  
 281:21 298:2 376:16  
 379:19 402:14  
**formal** 190:5 386:1  
**formally** 123:15 325:4  
**format** 402:15,15  
**forms** 87:11 88:20 93:5  
 179:19  
**formula** 221:19 228:21  
**formulate** 152:12  
**forth** 121:16 252:16  
**forthcoming** 262:3  
**fortunate** 22:7  
**Forty** 78:17  
**Forty-one** 375:18 388:2  
**forty-seven** 375:14  
**Forty-two** 217:12  
**forum** 1:1,8 15:13 17:10  
 290:11  
**forward** 22:12 24:22  
 31:8 40:3,8,13 44:13  
 44:21 51:14 52:18  
 57:22 58:6,11 60:16  
 61:3 128:22 136:22  
 142:5 166:12 176:6  
 180:22 199:22 200:10  
 200:17 211:4 213:2  
 226:14 248:10 255:6  
 256:22 262:10 264:5  
 270:6 291:3 293:21  
 354:9,14 376:6  
 378:20 402:19 404:2  
 409:7  
**FOTO** 5:2 61:13 62:4  
 64:4,6,9 65:7,11 66:8  
 73:8 87:4,7,9,15 88:5

88:22 89:1,17 92:17  
 92:19 93:17 94:2  
 98:12 99:17 108:2  
 136:20  
**FOTO's** 64:5,17 65:10  
**found** 77:16 92:14,16  
 93:16 98:16 112:8  
 129:16,22 145:20  
 151:11 157:11 170:13  
 170:13 220:10,17  
 278:15 292:15 296:11  
 304:17 323:19 332:2  
 360:12 361:6,20  
**foundation** 2:4 9:11  
 29:13 55:16  
**founded** 394:21  
**four** 24:3 32:3 35:11  
 37:13 63:10 77:8  
 119:8 134:6,12,17,22  
 135:5 148:21 152:4  
 165:7 166:14,22  
 180:14 181:5,20  
 182:11 201:21 217:3  
 217:9 218:9 227:8,15  
 233:7 237:3,7,16  
 238:17,18 239:21  
 245:16 248:11 249:10  
 252:3 257:21 258:6  
 260:9,21 266:4  
 270:21 294:11,13,18  
 302:14 310:22 313:21  
 314:5 321:15 335:20  
 349:3,8 353:17 354:4  
 359:19 375:12,17  
 380:17 387:10,18  
 388:1,9 389:3 405:2  
**fourth** 26:16  
**fracture** 75:6 106:7  
 243:11  
**fragmented** 324:6  
**frail** 286:11  
**frame** 10:18 11:2 68:6  
 393:18  
**framed** 394:9  
**framework** 395:11  
**frameworks** 141:6  
**framing** 396:4  
**frankly** 157:18 368:14  
 395:6  
**fraud** 177:8 351:11  
**fraught** 106:15  
**free** 224:17  
**French** 63:7  
**frequent** 111:12  
**frequently** 45:7 111:10  
 196:3 197:13 213:6  
**front** 42:10 201:9  
 205:17 347:10

**front-end** 234:8  
**frozen** 233:12  
**frustrated** 179:22  
**frustrating** 417:21  
**full** 12:19 42:17 49:11  
 65:9 93:7 113:18  
 114:1,3 115:1 116:19  
 193:14 200:12 228:14  
 248:15 249:15 250:20  
 256:5 260:5 403:9  
 407:6  
**full-up** 286:2  
**fully** 9:17 10:13 60:17  
 104:9 251:19 355:22  
**function** 5:6 24:5 61:5  
 73:13 76:13,13 94:14  
 95:17 102:7 103:15  
 104:7 106:13 107:3  
 116:22 129:11,19  
 130:13,14 172:5  
 192:4 194:3,20 199:5  
 200:13 244:2 246:1  
 252:6 256:5,10,18,19  
 280:1 283:6,20,21  
 286:12,13,14 287:5,7  
 315:20 317:15 321:16  
 322:2,8 323:20  
 324:14 325:18,18,20  
 332:8 334:12 335:11  
 335:13 340:1 341:9  
 346:22 348:9 352:1  
 357:17 365:12 371:22  
 372:5,6,8 373:7  
 374:11 377:8 403:18  
 403:20 404:6,6  
 405:13 406:1 421:6  
**functional** 4:9,10,12,13  
 4:15,16,18,19,21 5:3  
 5:5,9,16 32:14 33:4,5  
 33:11 35:12 36:21  
 37:16 38:6 61:12 65:5  
 65:6 68:8,17 71:10  
 74:17 75:21 76:12  
 86:15 94:4,13 95:4,7  
 96:7,15 97:10 105:20  
 112:6 117:21 138:5  
 139:15 140:6 141:22  
 142:17 143:14 150:6  
 150:8,12 152:1,12  
 153:8 157:21 158:6  
 163:7,7,10 167:19  
 168:2 170:7 171:22  
 171:22 172:14 173:13  
 183:1 185:9,22  
 186:17,19 191:19,22  
 192:4,9 194:4 195:1  
 205:8 208:13 210:16  
 235:7 240:7 242:14

243:1,2,16 254:1  
 256:14 263:14 266:11  
 267:3 269:22 283:1  
 286:18 315:19 318:13  
 318:15,20 319:11  
 320:12 321:14 326:12  
 326:21 330:5,10  
 339:9 356:11 358:11  
 359:3,4 362:9 366:6  
 369:18 372:11 388:6  
 392:20 401:19  
**functionality** 289:11  
 384:7  
**functioning** 34:21  
 100:5 129:13,16  
 130:10 131:9 299:3,4  
**functions** 104:21  
 105:18 244:12 271:11  
**Fund** 2:2  
**funded** 19:21 20:15  
 137:8 320:8  
**funding** 16:15 160:22  
**further** 120:6 146:16  
 154:7 233:2 245:19  
 258:12 261:12 263:18  
 264:6 286:13 309:18  
 353:10 371:12 376:3  
 376:20 377:3 380:13  
 388:21 401:10  
**Furthermore** 367:3  
**fusion** 5:3 242:15 243:5  
 245:9,10,12 246:13  
 246:21 254:5,6,16  
 263:8  
**fusions** 254:20  
**future** 8:9 76:13 90:1  
 127:3 137:7 226:13  
 301:21 345:3,14  
 362:10 369:20,22  
 386:11,16 387:6  
 405:21

## G

**G** 174:12  
**gain** 63:15 179:4  
**gained** 230:22  
**gambit** 403:9  
**game** 177:11 234:11  
 409:5  
**game-able** 176:21,22  
 177:6  
**gamed** 274:14  
**gaming** 184:7,10  
 194:16 235:12,22  
 244:15  
**gap** 90:17 91:18 107:8  
 107:16 119:3,4  
 120:19 124:6 139:20

146:9 147:11 156:15  
 166:13 199:10 217:2  
 247:9,11,12,12,19,21  
 247:22 257:19 294:12  
 323:17 346:5 347:12  
 347:17 354:3 361:8,8  
 375:11  
**gaps** 91:2 141:17  
 198:13  
**Gary** 3:11 139:3 147:17  
 147:18 177:21,22  
**gate** 308:15  
**gather** 378:1  
**geared** 256:12  
**gee** 299:16  
**gender** 68:19 72:9  
 73:10 74:16 91:7  
 112:18,21 113:2  
 158:20 210:9 218:14  
**general** 2:6,7 4:18 12:1  
 14:18,19 21:8 23:22  
 24:4 63:13 65:1 94:3  
 123:17 125:2,16  
 126:2 172:3 198:18  
 222:17 254:12 267:15  
 269:5 401:22  
**generalize** 333:10  
**generalized** 80:5  
 126:19 207:11 298:13  
 402:4  
**generally** 19:6 184:18  
 333:7 343:16 360:8  
 364:12 382:11 401:3  
**generate** 80:6  
**generated** 70:20 80:11  
 84:1 92:5 167:22  
 298:13 389:10  
**generic** 16:21 20:1  
 405:22  
**geographically** 360:22  
**Gerene** 357:8 366:6  
**geriatrician** 20:14  
**Geriatrics** 20:22  
**getting** 84:8 85:5 91:14  
 103:2 108:4 124:16  
 124:18 133:9 144:22  
 155:21 185:1,14  
 188:8 213:4 228:4  
 230:2 249:19 276:3  
 279:6 309:18 319:4  
 328:22 351:3 370:18  
 408:4 410:2 413:21  
 414:17 415:20  
**Ghazinour** 2:17 32:1,2  
 183:13  
**girl** 10:6  
**give** 47:9 51:17 55:10  
 61:13 77:11 84:3

110:3 114:17 120:14  
 123:10 129:6 132:8  
 160:17 165:19 187:2  
 191:7 195:7 201:11  
 201:16 220:14 221:2  
 221:22 222:6 242:5  
 299:1 303:7 310:10  
 343:19 419:4  
**given** 19:1 48:12 70:14  
 77:13 129:5 177:12  
 197:3 250:13 269:11  
 270:13 281:7 286:3  
 286:16,17 306:15  
 343:20 344:18 392:21  
 406:21  
**gives** 122:5,12 307:5  
 378:14  
**giving** 82:14 127:9  
**glad** 9:16,19 31:19 85:1  
 100:17 341:14  
**go** 12:5,7,13 14:8  
 28:7 31:11 32:12  
 37:15 42:3 50:7,21  
 51:19 54:2,15 58:4,15  
 59:15 87:20 88:12  
 91:11 92:18 99:6  
 117:18 118:4,12  
 124:11 127:7 131:21  
 132:3,19 138:9  
 151:12 154:6 157:19  
 160:4 170:22 171:6  
 180:1 183:8,22  
 184:22 202:13 205:21  
 206:2 207:6 212:6  
 213:2 216:7 226:6  
 231:12 233:22 255:2  
 272:8 274:1 284:22  
 285:1 290:2,7 323:8,8  
 326:19 339:4 365:3  
 369:4 370:16,19  
 371:6,11 376:2,14  
 378:7,9 379:22 382:8  
 383:14 384:7 388:21  
 390:22 395:16 398:5  
 405:19 406:12 412:5  
 415:7,18 416:17,18  
 416:22  
**goal** 270:17 271:3,4  
 286:11,17 314:21  
 322:11,15,20 327:7  
 339:10,10,18,19,20  
 340:2 344:10 385:14  
**goals** 171:22 284:9  
 285:12 304:12 340:14  
 344:22 399:14,22  
**God** 401:7  
**Goertz** 3:4 139:1,1  
 143:3,5,8,20 144:15

159:6 160:1 168:6,8  
 178:11,12,14,16  
**goes** 25:9 44:6 124:7  
 137:22 160:3 176:11  
 305:19 313:1,3,8  
 317:10 338:5 370:13  
 378:4 380:6 386:17  
**going** 6:8,12 7:4 8:17  
 10:9,10,11 11:4,17,18  
 11:19 12:1,5 20:17  
 28:14 32:10 33:2  
 36:17,18 45:4,21 49:8  
 50:7 53:9 54:11 57:12  
 61:15 70:9 79:16  
 81:19 84:11,15 87:1  
 96:11 109:21 117:18  
 118:12 123:18 124:19  
 128:5,7 131:3 137:6,9  
 138:4 151:17 154:6  
 169:13 176:2,6 187:3  
 189:3 199:22 201:16  
 207:1,13 208:10  
 211:4,19 214:13  
 215:1,2,16 221:9  
 222:15 225:20 236:2  
 236:20 242:6 248:19  
 250:14,21 251:7  
 255:17 262:5 264:10  
 270:16 271:14 272:10  
 273:21 274:9 276:19  
 277:16 279:15,18,19  
 284:2,17 288:18  
 289:2,5 290:1 291:3  
 292:16 293:9 299:11  
 299:13,16,18 301:20  
 304:8,11 306:12  
 308:21 309:1 315:4  
 316:3 324:8,9,10,12  
 327:9,15 334:7  
 345:13 347:15 348:18  
 350:15 352:4 355:3  
 370:7,8 377:22  
 378:10 380:14 381:19  
 383:17 386:10 389:12  
 389:13 391:10,17,18  
 392:6,16 393:19  
 395:22 398:7,20  
 400:9,11,12,13,15,16  
 400:17,19,20,21  
 401:7,9,15,17,18  
 405:13 413:18 418:10  
 419:17 421:20  
**gold** 243:21 358:6  
 402:8,20  
**good** 6:3 7:17 11:21  
 16:11 19:2 21:7,22  
 22:17 28:12,15 29:3  
 30:4 31:13 32:1 48:2

55:19 61:11,17  
 107:17 120:20 138:17  
 138:19 139:5 162:12  
 189:9 191:11 197:20  
 198:6 204:11 208:13  
 216:1 220:22 224:7  
 251:1 254:2 264:4  
 275:15 276:1,20  
 292:15 295:7,16,17  
 295:18 296:8,12  
 298:16 306:22 324:18  
 328:18 340:20 381:13  
 382:14 385:3 393:9  
 397:18 398:1 413:16  
 414:13,15 421:16,19  
**gotten** 276:19  
**Governor's** 17:10  
**gowns** 336:5  
**graciously** 7:11  
**gradation** 48:22  
**gradations** 396:17  
**grades** 49:2  
**grading** 38:16  
**gradual** 231:5  
**grain** 148:5  
**grant** 24:1 25:10  
**grants** 12:11 13:2 16:8  
 25:8 27:10  
**graphics** 342:18  
**grappling** 48:16  
**gray** 52:17 166:3  
 180:22 183:8 240:22  
 262:9  
**great** 6:21 25:2 41:7  
 42:7 61:17 62:8 70:4  
 75:21 84:3,12 117:17  
 126:6 142:7 178:9  
 191:10 204:21 223:8  
 224:11 251:11 265:11  
 265:15 270:11 296:20  
 310:12 315:15 316:18  
 319:3 332:12 338:13  
 339:1 340:5 343:9  
 346:15 386:12 408:12  
 418:4  
**greater** 51:14 52:11  
 108:10 112:6,10,10  
 120:2 184:19 255:20  
 266:11 283:4,22  
**greatly** 94:8 253:7  
**GRECC** 2:11  
**grocery** 395:16  
**gross** 302:1  
**grounds** 371:9  
**group** 2:5 14:3 28:19  
 30:8 33:15 41:20,21  
 64:14,14 76:10 91:7  
 98:13 107:2 123:9,10

126:10 132:22 134:1  
 148:8 158:22 159:22  
 190:5 193:8 200:17  
 205:2 209:15 210:13  
 216:12 227:2 229:8  
 232:1,2 234:21  
 237:20 245:1,8,13  
 246:19 255:2,11,14  
 255:18 256:8 261:22  
 264:22 270:16 288:3  
 328:5 357:20 359:9  
 417:11  
**Group's** 200:5  
**groupings** 389:20  
**groups** 39:14 41:13  
 42:11,12,20 83:12,18  
 84:4 119:7 141:19  
 159:21 194:22 197:14  
 203:19,21 229:17,21  
 230:7,20 231:2 232:9  
 232:17 236:21 237:8  
 242:18 252:3 283:8  
 393:13  
**grows** 28:22 29:1  
**guarantee** 218:19  
**guess** 23:21 32:10  
 83:10 105:11 106:4  
 106:16 124:5,7  
 127:11,13 128:1  
 132:3 167:9 201:1  
 234:1 236:20 250:13  
 256:9 260:1 262:4  
 272:15 273:13 274:12  
 275:14 283:7 290:12  
 306:7 320:6 328:1,4  
 338:2,4,5 344:1  
 367:21 382:12 392:2  
 394:16 416:9 418:3  
 419:20  
**guessing** 85:18  
**guidance** 50:8,13 60:1  
 60:2 64:2 66:10  
 261:14 377:3  
**guide** 53:12 361:16  
 362:4  
**guideline** 379:17  
**guidelines** 27:7 141:6  
 235:1,2 358:6 364:7  
**gurus** 412:16  
**guys** 58:22 189:7  
 265:12 346:8 356:2  
 358:14  
**gym** 364:17

---

**H**

---

**hair** 103:12,12 105:9  
**half** 19:14 21:21 255:16  
 268:14 316:2 353:4

381:17  
**hall** 110:15 379:22  
**Hammersmith** 2:16  
 11:21,22 17:14 27:12  
**hand** 4:17 59:5 61:3  
 95:6,12 96:18 176:7  
 236:4  
**handing** 39:9  
**handle** 28:6 249:20  
 391:22  
**handout** 107:22 108:13  
 111:20  
**handouts** 91:3,5  
**hands** 236:7,9,13,15  
**happen** 40:20 55:14  
 137:9 146:17 150:20  
 176:2 206:3,4 214:2  
 233:20 240:20 341:21  
 342:14  
**happened** 146:16 154:1  
 212:14  
**happening** 122:18  
 224:1 338:19 345:12  
 395:20  
**happens** 331:3 345:20  
**happy** 15:8 18:21 31:15  
 32:7 101:8 121:15  
 139:11 195:16 223:13  
 234:19 242:5 260:14  
 298:18  
**hard** 10:7 11:5 169:11  
 169:16,17 173:16  
 336:7 344:20 413:12  
 413:19 417:9  
**harm** 254:9  
**harmonization** 40:21  
 45:3 412:2  
**harmonize** 44:15  
**harmonized** 41:9,16  
**harmony** 412:9  
**Hart** 64:3  
**hat** 350:1  
**hate** 416:16  
**hates** 400:6  
**Hatlie** 26:19  
**Hayes** 357:4  
**HCAHPS** 414:10,12  
**HCAPS** 419:5  
**head** 14:19 45:7 91:18  
 97:4,4 99:16,16  
 290:15  
**heading** 8:10  
**heads** 273:9  
**healed** 320:22  
**health** 2:3,4,10,11 9:10  
 15:10 16:14,16 20:14  
 22:2,9 23:2 32:7 34:3  
 35:8,11,14,20,20 37:6

43:15,19 46:16 63:13  
 66:4 118:17 195:19  
 196:22 205:18 216:17  
 231:14 249:2,5  
 257:12 291:22 313:4  
 316:11 317:4 391:16  
 412:6 416:6 417:11  
**healthcare** 18:6 19:5  
 21:9 22:14 23:17  
 25:17 36:12 37:20  
 38:1,18 39:3 56:3,17  
 62:6 118:18 215:1  
 216:17 324:5  
**HealthSouth** 1:19 22:22  
**hear** 67:8,9 92:2 117:10  
 128:11 183:21 311:7  
 316:1 321:6 341:14  
 391:13,19 392:11,12  
**heard** 101:14 117:7,15  
 282:7 316:19 319:21  
 354:12 375:3 395:2  
**hearing** 25:1 31:8 176:1  
 185:17 307:1 358:14  
**heart** 20:2 374:8  
**Hebrew** 63:7  
**Heinemann** 20:5  
**held** 62:9 214:10  
**Helen** 2:15 19:11 28:14  
 128:22 309:19 357:3  
 392:11  
**Hello** 183:20  
**help** 5:7 29:17 47:11  
 68:4 78:5 79:19  
 107:16 121:22 122:13  
 152:3 153:16 167:16  
 168:3 184:22 185:13  
 201:12 231:17 283:3  
 284:5 304:8 314:12  
 318:22 320:21 338:20  
 345:21 346:6,10,14  
 363:1,8 390:10 400:1  
 409:6  
**helped** 66:12 225:20  
 307:16  
**helpful** 85:13 123:20  
 127:9 173:19 177:18  
 184:17 195:6 222:19  
 223:7 239:14 327:14  
 348:6 395:10 421:11  
 421:12  
**helping** 23:21 25:7  
 29:11 226:11 399:3  
**helps** 307:22 345:22  
**herniation** 245:17  
**hesitancy** 61:1  
**hesitate** 406:20  
**hesitation** 184:8  
**heterogeneity** 344:19

**heterogeneous** 102:22  
**hi** 14:18 16:5 17:2,17  
 18:4 19:9 25:14 31:17  
 66:17 189:5 274:21  
 316:6,16 356:5  
**hiccups** 233:20  
**hierarchical** 76:19 80:2  
 80:6,13,16,18 81:1  
 82:16 122:22 298:14  
**high** 34:5,8,9,12 83:9  
 108:12 109:4 112:3,9  
 119:7,10 134:5,5,9,11  
 134:14,16,19,22  
 135:2,4,8 148:9  
 158:19 165:6 166:7  
 166:14,18,21,21  
 167:3 180:14,18  
 181:5,9,20 182:2,11  
 182:15 217:2,6,8,8,13  
 224:14 227:7,10,14  
 227:18 230:20 233:6  
 236:6,16 238:16  
 239:20 240:2 250:2  
 257:20 258:2,4,5,9  
 260:20 261:2 267:18  
 268:1 294:12,14,17  
 294:17,20 299:3  
 302:14,16 310:22  
 311:2 313:21 314:1,5  
 314:7 328:3,9,9,20  
 353:17,20 354:3,5  
 375:12,14,16,16,18  
 380:17,21 383:6  
 387:10,11,18,19,22  
 388:3 400:13,20,21  
**high-performers** 307:6  
**higher** 98:18 111:12  
 131:3 160:8 161:19  
 194:19 195:1 223:18  
 231:4 244:1 248:21  
 278:1,9 279:16  
 286:14,19 290:2  
 310:12,16,17 312:8  
 332:21 333:9 382:8  
 383:18,20  
**highest** 49:2 234:12  
 264:3  
**highlight** 337:3  
**highlighted** 420:12  
**highly** 246:15 277:11  
 357:15 386:20  
**highs** 135:13  
**hip** 4:11 61:13 75:3,5,5  
 75:7 89:11,15 91:8  
 92:5,13 96:10,17 97:3  
 97:16,17 117:22  
 129:10,21  
**HIPAA-secured** 229:3

**Hiral** 145:14  
**hire** 122:11  
**historical** 385:1 394:21  
**historically** 300:9  
**history** 30:13 62:2  
 64:19 72:10 74:6,17  
 75:4,8 273:5 283:7  
 326:8  
**hit** 75:11 355:21  
**hitting** 205:7  
**HMO** 62:22  
**hoc** 310:9  
**hold** 212:5 213:16,18  
 214:2 344:21  
**holding** 57:16  
**holistic** 128:19  
**holistically** 418:8  
**Holland** 383:22  
**home** 7:7 10:8 15:1,3  
 15:15 16:3,7 22:9  
 23:2 31:21 37:6 43:19  
 46:16 213:22 214:15  
 268:13 269:2 270:1,3  
 274:7 275:7 277:9  
 279:6 282:2 283:19  
 285:1 286:9,10 291:7  
 291:22 292:4 300:11  
 301:7 305:8 313:4,7  
 324:12 391:16 407:13  
**home-based** 286:5  
**home/community**  
 283:14  
**home/community-ba...**  
 285:2  
**homes** 15:18 37:8  
 267:8 283:14 286:7  
 303:8,14 304:22  
 309:3 318:3 319:16  
 411:21  
**honestly** 373:2  
**hooked** 367:4  
**hope** 2:13 43:2 230:14  
 239:6 312:10 322:14  
 389:17 408:20 421:10  
 422:2  
**hopefully** 66:4 253:16  
**hoping** 168:3 231:15  
 232:4 306:5  
**hopped** 125:15  
**horrible** 415:16  
**hospice** 269:14 274:9  
 274:11,12 279:5,19  
 287:14,19,20  
**hospital** 1:14,16 2:2 5:4  
 14:21 16:12 21:18  
 161:3 214:10 315:18  
 316:13 320:12,14,16  
 321:8 322:22 324:9

324:12 325:9 346:20  
348:12 357:4 410:19  
414:17  
**hospital-based** 72:3  
**Hospital/Massachus...**  
2:7  
**hospitalization** 266:13  
307:15  
**hospitals** 37:13 162:8  
317:20 318:2 319:19  
321:22 330:4 331:18  
332:2 336:3 345:13  
346:17  
**host** 152:8  
**hour** 364:14  
**hours** 343:5,6 364:14  
389:8 390:13  
**housekeeping** 54:3  
137:3  
**huddle** 389:18 422:1  
**huge** 44:11 207:5  
299:12 374:12 407:6  
**human** 43:15 398:12  
406:1  
**hundred** 147:15 148:13  
149:17 155:19  
**husband** 214:11 400:6  
412:15  
**hygiene** 335:21,22

## I

**ICCs** 109:11 110:5  
260:7  
**ICD-9** 103:22  
**ICU** 321:21 323:8  
326:19  
**idea** 14:13 23:14 111:9  
148:22 187:11 214:9  
222:17 223:3,4 228:9  
317:12 324:13 389:9  
406:21 418:4  
**ideally** 378:21  
**ideas** 251:11  
**identified** 34:8,12 35:5  
140:9 150:8 167:19  
171:21 173:12 184:3  
186:5 188:12 192:20  
220:3,7 243:10 266:3  
359:6 420:17  
**identify** 34:1 62:3 140:7  
146:4 213:15 219:10  
281:3 288:14,22  
299:10 330:1 411:4  
**identifying** 124:12  
213:4 288:15  
**idiopathic** 243:12  
**ignorant** 362:1  
**ignore** 179:7

**ignores** 180:3  
**ill** 317:22  
**illness** 24:9,12  
**illustrate** 129:7 198:12  
**illustrated** 175:8 176:13  
**illustration** 404:13,13  
**imagine** 28:19 105:2  
324:7 377:14 393:15  
**imaging** 187:13  
**immediate** 22:13  
**immediately** 74:1  
**immobilized** 318:17  
**impact** 25:9 34:6 255:8  
291:20,20 292:14  
351:20 360:19 412:20  
415:9  
**impairment** 70:5,7,15  
75:3,5,7 96:15 125:2  
126:10 131:5,18  
152:12 244:2 252:5  
**impairments** 4:9,11,12  
4:14,15,17,18 61:13  
65:1 95:12,13,14,14  
95:18 96:20 117:22  
125:11 126:19 131:11  
**implement** 417:9  
**implementation** 29:14  
30:13 140:1 231:6  
248:15 249:16 250:20  
411:14,16,18 412:10  
**implementation-type**  
303:22  
**implemented** 139:18  
154:18 178:3 230:9  
346:18 418:1  
**implementing** 56:4  
313:10 417:11,14  
**implication** 290:17  
**implications** 95:2  
**implied** 246:17  
**implies** 48:3  
**imply** 247:20  
**implying** 334:14  
**importance** 34:16,19  
54:18 55:3 84:18  
88:11 90:14,18 93:20  
94:1 95:2 117:19  
118:16 141:3,21  
145:7 147:3 150:4  
162:20 164:13 168:20  
175:2 198:2,6 200:21  
212:3 214:7 247:5,10  
248:5 249:19 250:7,9  
251:19 264:3 279:2  
294:8 328:17,20  
329:20 340:18 351:3  
351:5,6 352:18  
362:22 363:16 371:15

374:19 420:16  
**importance/relevance**  
277:17  
**important** 26:2,7 39:22  
45:4 46:3 56:6 57:20  
57:21 69:9 73:21  
75:19 87:21 95:1 98:5  
98:22 101:1,5 103:15  
112:7,8,11 113:3,22  
122:15 130:18 131:8  
150:14 165:17 169:13  
174:9 175:6,22 176:8  
185:3,3 194:8 207:4  
210:14 250:12 251:6  
251:13 253:12 259:14  
263:15 266:8 270:15  
284:6 303:11 304:11  
313:5,11,13,15  
318:21 322:6 326:14  
334:8 348:4 349:12  
358:16 359:6 361:9  
361:17 362:4 366:8  
376:11 377:5 380:7  
382:19 398:9,18  
399:4 420:13,17,18  
421:6,9  
**importantly** 362:14  
**impression** 339:8  
**improvable** 289:19  
**improve** 18:1 34:20  
66:14 130:21 145:12  
146:13 187:2 284:16  
284:19 286:14 289:10  
301:6,11 303:16  
339:18,21 348:15  
357:17 365:12 372:6  
372:7,8,11 383:1,9  
**improved** 36:15 112:10  
143:19 146:17 194:19  
256:22 319:10,11  
**improvement** 5:10,11  
5:12,13,15 6:21 38:3  
48:6 56:22 58:10,11  
77:9 98:7 107:12,13  
108:9 112:5 113:1  
130:21 141:11 153:7  
153:8 187:4 194:2  
199:20 205:9 207:2  
207:13,15 246:1  
283:1 287:5 304:13  
313:13 358:11 362:15  
381:11,15,17 382:3  
383:16 391:1 406:9  
**improvements** 61:2,6  
374:6  
**improving** 130:13  
267:3,15 377:9 412:6  
**in-person** 137:11

**inactivity** 105:7  
**inadequate** 269:7  
**incentive** 267:2  
**incentives** 279:20  
**incidence** 209:17  
224:20 278:2  
**include** 36:16 68:9  
90:19 94:4 125:11  
140:2 210:15 211:6  
255:6 279:17 309:14  
321:14,19 327:12  
336:1 343:1 372:21  
408:21 413:22  
**included** 34:22 35:11  
39:7 75:3,8 86:15  
102:16 210:1,8  
211:22 245:20 266:9  
280:4,15 281:19  
288:3 309:7 319:6  
325:19 327:11 336:8  
**includes** 6:16 32:17  
36:12 52:13 65:13  
67:17 68:16 180:13  
244:18 252:4 333:13  
**including** 8:15 20:16  
32:4 34:17 35:12  
38:12 56:12 117:8  
181:3 183:12 243:6  
254:2 326:11 373:18  
404:10  
**inclusion** 194:15  
**inclusive** 245:14  
**incomplete** 326:19  
327:16  
**incontinence** 325:18  
**incorporate** 130:12  
**increase** 149:9 151:14  
194:18 246:13 266:2  
358:20 383:7  
**increased** 5:8 266:2  
286:8 314:13 319:15  
**increasing** 283:5  
**independence** 339:21  
**independent** 62:11  
99:3 115:6 145:18  
170:6 285:6 337:5  
**index** 24:10 63:12  
85:22 171:21 211:17  
243:15,18 249:3  
360:14,17  
**indicate** 332:6  
**indicated** 133:12 249:1  
**indicates** 194:19 244:2  
267:20 296:2  
**indication** 222:19  
246:20 251:12 253:15  
258:18 263:7,13  
331:20 411:2



<b>indications</b> 247:16	<b>informed</b> 30:2 172:20 353:3	165:7,8 166:9,9,15,20 166:22 167:5 180:15 180:20 181:6,11,21 182:4,12,17 217:3,7,9 217:14 227:8,12,15 227:20 233:7 236:14 236:17 239:21 240:4 257:21 258:3,6,10 260:21 261:4 262:11 294:13,16,18,21 302:15,18 311:1,4 313:22 314:3,6,8 353:17,18,21,22 354:4,7 375:13,15,17 375:20 380:17 381:1 387:10,13,18,21 388:1,4	287:16 348:14
<b>indicator</b> 55:17 187:18 302:2 412:5	<b>ingrained</b> 397:2,19		<b>interesting</b> 31:1 43:12 60:14 96:4 159:13 244:22 251:6 275:11 302:1
<b>indicators</b> 326:11	<b>initial</b> 93:19 140:1 149:1 171:5,8 192:13 193:1 201:6 243:3 244:16		<b>interfacing</b> 101:16
<b>indicts</b> 115:22			<b>Interfering</b> 5:15
<b>indifferent</b> 405:1	<b>initially</b> 139:17 205:4 210:2 362:3 382:22		<b>intermediate</b> 241:13
<b>individual</b> 13:17 14:5 39:13,17 40:2 72:6,6 72:8,17,20 81:18 83:7 102:20 107:12,14 128:18 299:14 352:4 363:12 377:10 382:7 406:16	<b>initiating</b> 142:1		<b>internal</b> 268:1 398:4
<b>individual's</b> 94:13	<b>initiative</b> 29:12		<b>International</b> 265:18 316:12
266:15 284:13	<b>initiatives</b> 409:2		<b>internationally</b> 359:11
<b>individually</b> 131:22 374:6	<b>injections</b> 263:11		<b>Internist</b> 21:8
<b>individuals</b> 254:11 284:18 287:17 289:1 305:3	<b>injuries</b> 94:19 103:10		<b>interpret</b> 79:20 99:15 152:10,11 161:8 185:13 201:12 202:16 289:21 305:2
<b>industry</b> 56:9,9 58:9 62:7,8	<b>injury</b> 96:17 102:15 105:20 106:8,19,22 269:1 282:19		<b>interpretable</b> 77:5
<b>infection</b> 60:19 243:11	<b>injustice</b> 383:7	<b>insufficients</b> 135:12	<b>interpretation</b> 35:9,22 120:1 237:10 311:17 393:21 400:5
<b>inference</b> 226:1 363:2	<b>Inn</b> 190:17	<b>insurance</b> 210:10	<b>interpretative</b> 238:14
<b>influence</b> 56:19 303:4	<b>inpatient</b> 23:1 27:8 37:10,10 56:18 374:7 410:18	<b>insurances</b> 364:7	<b>interpreted</b> 290:3 384:8
<b>inform</b> 136:22	<b>input</b> 100:10,20,21 101:4 320:10 324:19 399:12 408:10 409:4 418:5 419:5	<b>intake</b> 62:15 68:3,10,17 68:21 69:3,13,14,17 69:20,22 71:9,11 72:9 75:11,20 76:7 77:20 78:22 81:22 82:7 86:1 86:3 106:12 179:20	<b>interpreting</b> 81:17 311:13
<b>information</b> 8:12 12:10 16:20 47:13 55:13 57:4,5 73:5,10 74:5 75:14,16 76:9 79:11 79:13 84:2 92:9 99:10 99:12 100:20 107:11 108:15 109:11 111:9 111:17 112:15 115:2 119:15 120:5,9,21 134:6,10 135:6,9,16 140:22 145:21 151:5 159:10,11 165:16 166:15 170:19 171:4 172:11 173:5,18 174:13 182:12,17 185:19 186:7 197:11 197:17 201:7 203:10 223:2,7 225:22 227:15,20 228:16 229:4,20 230:2 232:22 235:17 239:7 239:10,21 240:4 241:2 249:13 260:15 260:21 261:4 262:3 262:15 263:1,7,15 270:4 275:6 305:4 307:4 311:1 314:6,9 323:22 324:2 327:11 331:19 347:14,20 353:2,4 354:18 363:7 366:20 367:1 368:15 388:2 419:14	<b>inquiry</b> 73:8 416:14	<b>integrate</b> 63:21	<b>interruption</b> 263:4
	<b>inside</b> 312:20	<b>integrated</b> 127:15 180:6 411:20	<b>interval</b> 205:15,21
	<b>insight</b> 223:5	<b>integrates</b> 130:17	<b>intervals</b> 83:13,19 84:3 298:1,8 299:17
	<b>insights</b> 138:13,20,22 139:2,4,13 251:1	<b>intend</b> 191:9 363:13	<b>intervention</b> 38:19 118:19 204:8 216:18
	<b>instability</b> 79:13	<b>intended</b> 38:3 48:21 81:20 306:8 340:11 369:14	<b>interventions</b> 34:19 60:21 203:5
	<b>instance</b> 86:12 410:16 420:14	<b>intense</b> 249:2	<b>intraclass</b> 346:12
	<b>instances</b> 45:20 46:14 60:18	<b>intensity</b> 77:21 79:20 111:7	<b>introduce</b> 6:9 29:4 30:7 53:11 54:17 64:13 139:14 242:10 316:2
	<b>Institute</b> 2:8 16:18 17:20 20:5 26:15 317:5	<b>intensively</b> 324:20	<b>introduced</b> 93:11
	<b>Institutes</b> 16:16	<b>intent</b> 150:19 168:13 175:4 255:1 292:13 366:22	<b>introduces</b> 31:10
	<b>institution</b> 27:6	<b>intention</b> 279:13	<b>introduction</b> 4:2,5,6 19:16 53:19 59:1 64:14 66:18 355:18
	<b>instructed</b> 169:1	<b>intentionally</b> 235:3	<b>introductions</b> 4:4 12:4 28:16
	<b>instruction</b> 276:11	<b>intentions</b> 279:13	<b>introductory</b> 32:11 327:15
	<b>instructions</b> 213:21 343:10 380:6	<b>inter-rater</b> 145:9,12 146:14 151:6 184:13	<b>intuitive</b> 47:4 400:7
	<b>instrument</b> 36:4 37:21 44:2 73:3,6 74:7 92:21 113:6 115:3 336:21 418:17	<b>interacting</b> 214:22 215:9	<b>Inventory</b> 404:22
	<b>instruments</b> 37:17 38:14 44:2 92:13 94:22 127:18 128:5 128:16 313:9 381:7 404:10 417:8	<b>interclass</b> 109:2 110:6 110:20 111:5 220:21 221:7,15 222:3,7	<b>invested</b> 397:3
	<b>insufficient</b> 119:8,11,14 119:15 120:3,4,19 134:6,10,12,15,17,20 134:22 135:3,5,9	<b>interest</b> 4:3 6:13 11:20 12:2 13:9,10,11 21:12 22:7 25:12,12 27:11 27:18,21 28:2 283:8 318:22 390:8	<b>investment</b> 409:17
		<b>interested</b> 13:1 21:17 23:3 190:15 282:12	<b>involve</b> 19:15 97:12 419:1
			<b>involved</b> 8:12 17:5,8 19:17,20 23:6 24:8 26:11 27:6,8 32:8 101:3 169:4 216:8 259:19 420:6,19 421:15

**involvement** 8:4 18:17  
**involves** 214:17  
**involving** 18:16 90:2  
**IRF** 43:21 348:11  
**IRFs** 291:22  
**irrelevant** 100:11  
**IRT** 92:4 104:6  
**Irvine** 2:1 23:18  
**Israel** 63:1 66:4  
**issue** 15:19 39:22 43:2  
 44:11 47:21 48:1  
 60:14 61:7 93:22  
 102:4 103:6 109:11  
 121:15,16 145:6,15  
 146:22 169:21 171:9  
 171:10 172:21 178:2  
 178:3 184:11 250:12  
 255:12 287:12 299:16  
 303:22 309:13 313:1  
 324:16 332:4 338:6  
 343:7,7 347:3 377:2  
 378:4 387:1 400:5  
 401:21  
**issued** 50:14  
**issues** 10:22 18:8 24:16  
 29:18 31:6 51:2 58:3  
 77:12 79:21 121:5  
 123:17 124:19 137:17  
 184:3,6 188:11 198:3  
 199:9 234:15 251:10  
 251:13 302:12 351:5  
 372:18 389:12 392:16  
**item** 20:1 50:1 63:19  
 86:16 114:1 115:3  
 127:19 129:13,16  
 189:2,20 241:12,13  
 322:17 336:22 337:1  
 337:2,20 339:19  
 340:1,2 342:16 368:8  
 368:18 378:16 392:22  
 403:8,14,18  
**item-level** 267:18  
**items** 11:7 38:13 51:15  
 73:18 86:15 87:5,10  
 87:12 88:2 95:11,15  
 100:11,21 103:8  
 113:21,22 129:9,14  
 130:2 131:9 267:20  
 267:21 268:1 317:14  
 317:15,17 320:3  
 321:14,15,16 322:1  
 322:13 324:14,14  
 332:18,21 334:17  
 335:13,16,21 336:1,3  
 336:8,11 338:16  
 340:12,15,16 343:1  
 344:9 348:1,13 350:8  
**iteration** 124:15

## J

**Jane** 3:7 138:21  
**JANUARY** 1:6  
**Jared** 412:14  
**Jasmine** 3:6 189:6  
 191:14 219:1 220:3  
 226:16 233:15 237:14  
 239:3,13 242:8,12  
 260:12 261:18 263:20  
**JD** 2:11  
**Jeannette** 3:12 138:21  
**JEROME** 3:2  
**Jerry** 65:21  
**Jersey** 66:2  
**Jewish** 2:10 22:2  
**Jim** 7:7,7  
**job** 25:2,6 29:7 42:3,18  
 59:13 306:22 417:13  
**Johnson** 29:13  
**JOHNSTON** 3:4 61:17  
 67:4,9 93:12 113:20  
 116:16 117:16 126:7  
 126:12  
**join** 422:5  
**joined** 29:5  
**joining** 9:3 10:3  
**joins** 29:10  
**joint** 22:15 105:6  
 204:12,15,19 208:19  
 209:3 404:7  
**joints** 394:3  
**joke** 23:14  
**Jones** 13:19  
**judgment** 173:1  
**jump** 206:10 215:16  
 230:4  
**jumping** 50:8  
**jury** 251:14  
**justice** 205:10  
**justification** 77:13  
 112:16  
**justify** 39:17

## K

**Kaiser** 2:9 17:18,20  
**Kaplan** 2:1 23:12,12  
 41:19 59:17 66:17  
 68:1 69:1,6,21 70:8  
 74:9 75:2 76:3,7 77:1  
 78:3,5,11 79:9 80:19  
 81:15 82:15 83:21  
 91:19 98:1 102:11  
 108:20 109:15 110:4  
 121:20 122:8 123:3  
 151:17 153:4,15,21  
 155:5,8,13,15 162:21  
 163:17 169:20 170:17  
 171:9 179:17 185:5,6

186:18 201:1,11  
 202:15,19 205:12  
 221:5 225:9 238:2  
 240:14 259:22 260:6  
 295:20 298:11 301:2  
 306:11 346:1 347:9  
 363:1,18 365:2,5,14  
 366:11 367:20 368:17  
 369:1 370:2 377:1  
 378:18 400:3 413:20  
**kappas** 267:19  
**Karen** 30:9 265:11,13  
 325:15 351:6 387:16  
 421:13  
**Kate** 355:10 356:18  
**Katherine** 1:15 16:12  
 61:16 109:22 120:10  
 138:7 142:8 147:2  
 174:22 185:6 421:19  
**Katherine's** 150:3  
**keep** 11:4,5 34:10  
 126:15 132:14 137:12  
 137:18 138:1 179:7  
 187:16 199:22 236:10  
 361:13  
**keeping** 30:1,2 209:16  
**keeps** 201:16  
**kept** 319:2  
**Kevin** 152:3  
**key** 37:15 38:11,21  
 44:21 45:2 68:17 73:9  
 75:14 172:21 173:5  
 188:13 349:11,11  
 355:21  
**keying** 187:16  
**keypad** 183:17  
**kidney** 318:12  
**killing** 309:3  
**kind** 30:9 47:2 49:17  
 53:15 58:3 59:7,11  
 74:9,11 77:15 80:1  
 82:19 84:17 111:8  
 114:6 120:13 121:1  
 122:19 137:22 145:11  
 147:5,15 149:17  
 151:19 152:20 167:10  
 174:13 177:18 184:14  
 202:12 219:21 220:8  
 220:12 222:14 232:4  
 234:1,6 254:4,19  
 279:20 283:5 284:15  
 285:19 289:4,8  
 290:14 291:15 292:7  
 298:9,16,22,22  
 299:12 301:8 303:12  
 304:3 305:15 307:21  
 308:11 312:19 315:11  
 317:10 319:8,8,18

326:15 344:14 346:13  
 348:14 368:8 370:6,9  
 371:6,11 377:22  
 381:5 389:22 390:5,8  
 395:13 398:8 401:3  
 409:7 416:11  
**kinds** 50:20 71:2 96:20  
 252:20 256:4 306:13  
 398:4  
**King** 3:5 356:20 357:3  
 373:16,16 379:7,7  
**kit** 334:14  
**KLIEN** 316:16  
**Kline** 3:5 265:6,10,10  
 316:15,16  
**knee** 4:9,22 20:1 63:12  
 64:22 86:4 92:15  
 97:17,17 129:10,21  
 130:16 191:22 192:4  
 192:16,16 193:6  
 194:20 196:7,12  
 198:8 199:11 206:22  
 207:7,8,19 208:7,9,12  
 210:16 211:6,7,18  
 213:17 214:11 215:5  
 217:21 223:12,17  
 224:2 230:6,12 231:3  
 235:2 240:7 242:17  
 244:6 248:20 260:14  
 262:1,8 403:19  
 407:12 418:13,14,15  
**knew** 47:2 238:8  
**knit** 407:19  
**know** 6:22 8:8 10:7,19  
 11:8 12:18 14:14  
 17:12 19:19 26:1  
 28:10 29:7,15,18  
 30:14,17 31:2,5,11  
 39:10 40:20 41:21  
 43:18,22 44:6,14 47:3  
 49:11 50:17 52:8 53:5  
 54:10,15 55:17 57:2  
 57:20 58:2,7,15,20  
 59:18 71:1,12 84:7  
 85:2 91:5 92:10 94:6  
 94:9,18,21 95:22 97:1  
 97:18 98:9 100:22  
 103:21 104:3,6,11,14  
 104:18 105:6 106:6,7  
 106:9,10,17,20 107:2  
 107:9 109:4 112:20  
 116:18 120:8,13  
 122:16,17 123:4,5  
 124:8,17 126:16  
 127:14 128:2,3,8,11  
 128:17,21 130:17  
 135:13 137:17 138:15  
 140:16 145:5 146:2,6

146:6 148:6,7,10,13  
 151:1,20 153:20  
 154:2 155:9 156:2,5,9  
 156:9,10,10 159:7  
 162:4,6 164:18  
 165:22,22 167:18  
 169:22 171:10,11,13  
 172:4 173:2,3,14,17  
 175:21 176:5,10,12  
 176:14 177:4 180:4  
 185:21 186:2 187:3  
 187:15 188:5 190:14  
 195:10 197:11 199:12  
 199:16 201:14 202:3  
 206:17 207:4,13  
 208:19 211:21 213:7  
 219:16 220:16 226:6  
 226:18 233:18 237:4  
 246:22 251:7 260:13  
 261:12 262:22 273:8  
 273:17,18 274:10  
 279:10 290:12 291:12  
 295:4,12 297:14  
 298:9,12 305:14  
 308:10 309:17 310:11  
 310:13 311:9,16  
 312:1 323:2 324:4,19  
 326:9,9,13,19,20  
 327:2,8 328:2,4,17  
 329:11 330:13,15  
 331:7 333:7 334:6  
 335:6,19 336:4  
 337:16,19 338:3,7,18  
 338:18,19,21 339:16  
 339:19,20 341:9,12  
 341:13 342:3,10  
 344:3 345:9,19 346:3  
 346:8 348:10,10  
 349:7 353:2 354:11  
 354:11,13,17 355:20  
 368:13 370:6,9  
 372:15 376:8 377:2,7  
 377:9 378:9 381:12  
 381:22 382:15 384:19  
 385:9 390:2,7,8,20  
 391:2,4,8,9 393:3,7  
 393:13,19 394:2,18  
 395:15,18 396:6  
 397:4,9 399:7,18  
 401:10 402:13,20  
 403:6,12,18 404:4,9  
 405:6,8,17 407:6,13  
 407:13 408:4,7 410:6  
 412:15,17 413:11  
 414:3,10,11,14 415:6  
 415:10,18 416:2,7,16  
 416:19,22 417:3,3,5  
 417:19 418:1,9,13,22

**knowing** 60:17 70:22  
 259:15 287:16  
**knowledge** 104:15  
 219:12 305:5  
**known** 73:12 97:16  
 211:17 243:18

# L

**label** 125:17  
**labeled** 125:2 288:2  
**labrum** 104:17  
**lack** 29:15 170:1 197:10  
 289:10  
**lacking** 145:21  
**language** 210:10  
 224:12 348:8  
**languages** 63:6 223:2  
**large** 6:19 8:7 62:5 74:5  
 82:8 101:10 110:17  
 126:22 160:15 196:13  
 207:18 215:8 315:21  
 329:15 362:16 374:16  
**largely** 48:13 76:15  
**larger** 78:15 98:13  
 158:21 255:13,14,18  
**largest** 62:22 64:9  
**Larson** 3:6 191:14  
 201:9 219:1 226:16  
 233:17 237:14 239:1  
 239:5 241:10 260:12  
 261:17,21 262:13,18  
 263:3  
**lastly** 37:12 39:3  
**late** 22:11 64:2 266:1  
**late-loss** 266:4 270:21  
 292:18  
**lateral** 247:1  
**latest** 390:4  
**Laughter** 139:9 355:7  
**laundry** 399:18  
**Laura** 3:13 265:17  
 286:16 292:2 300:11  
 316:19  
**law** 7:8 18:6,6 235:14  
**layperson's** 338:2  
**LCSW** 1:18  
**lead** 10:11 29:11 53:14  
 54:17 138:8 215:7  
 241:16,17 270:9  
 316:7 325:13 356:9  
 362:21 401:2  
**leader** 66:6 215:4  
**leaders** 145:5  
**leading** 18:1 29:19  
 417:13,15  
**learn** 226:12  
**learned** 10:3 260:16  
**leave** 11:6,9 27:16 51:7

155:6 284:21 390:3,4  
 392:5  
**leaves** 176:10  
**led** 19:12 20:3,4 64:6  
 100:15  
**Lee** 1:9,12 11:21 12:1  
 15:9 30:17 190:2  
 206:18 265:12  
**Lee's** 155:17  
**left** 7:6 30:11 336:12  
 339:16 340:13 375:2  
**left-hand** 69:3,15  
**leg** 9:13 252:22  
**legacy** 63:10  
**Len** 22:1 85:11 97:22  
 102:2 106:3 107:6  
**Len's** 308:14  
**LENARD** 2:9  
**length** 196:16 343:3  
**lengthy** 12:9 99:1  
**lens** 48:15  
**lenses** 285:20  
**less-than-six-months**  
 274:15  
**let's** 14:8,15 40:7 61:11  
 84:13 88:10 90:17  
 117:18 130:8 136:6  
 165:22 178:9 180:11  
 181:18 182:9,21  
 236:4 241:15 274:15  
 277:17 302:10 303:18  
 315:5 324:17 339:15  
 355:3 404:4 418:8  
 419:16  
**letter** 43:14  
**letting** 356:16  
**level** 39:2 50:1,3,12  
 56:9 65:4,5,6 70:15  
 74:18 76:21 77:10,12  
 78:12 81:18 82:11,22  
 83:7 98:10 106:1  
 108:18 109:3,5,5,7,12  
 109:15,17 110:20  
 111:14,15 112:13,15  
 122:9,11 123:2,6  
 129:20 130:2 152:7  
 157:21 178:4 185:20  
 198:7 205:2,8 219:11  
 219:19 220:6 221:10  
 221:13,21,22 222:1  
 225:13 226:22 227:1  
 227:3 229:4 238:4,17  
 243:5 259:8 260:8,8  
 267:22 282:13 286:14  
 286:15 287:7 295:22  
 295:22 296:3,7,9,12  
 299:14 300:16,22  
 301:7 328:17 337:4,5

339:17,20 346:3,11  
 347:11,12,14,18  
 363:7,12 365:20  
 366:19,21 367:5  
 368:9,9,18,19,20  
 369:4,15,17 371:3,18  
 373:6 377:9,13,14,15  
 378:12,16 383:5,13  
 383:18,20 391:15  
 397:16 406:15  
**levels** 39:1 50:6 98:18  
 121:4 123:1 129:15  
 153:9 243:6 271:14  
 310:12 363:5 378:22  
 414:8  
**LEVINE** 2:2  
**licensees** 121:4  
**Lichtman** 3:6 355:12,12  
 355:19,22 356:4,6  
 363:11,20 365:3,7,21  
 367:12 368:11 369:16  
 372:19 374:9 376:12  
 376:15 379:4,16  
 382:14 384:10 386:3  
 387:5  
**lie** 177:8  
**lies** 44:9  
**life** 34:14,16,22 35:12  
 130:21 210:19 266:13  
 269:8 275:8 279:15  
 280:6 357:17 365:12  
**Lift** 103:12  
**light** 205:13 285:9  
**liked** 101:10  
**likelihood** 94:8 161:19  
**Likert-like** 359:17  
**Lilly** 24:13  
**limit** 192:15 243:4  
**limitations** 155:1  
 318:14,15  
**limited** 141:5 255:10  
 321:1 353:7,13  
 395:13  
**limits** 94:16  
**Linda** 3:10 66:5 67:5  
 87:22 99:7 135:20  
**Lindberg** 2:2 19:2,3  
 162:2 286:22 288:7  
 351:8 371:20 372:15  
**line** 30:1 117:6 132:4  
 189:3,7,17 191:2  
 241:15 265:7 279:4  
 289:5 298:12 308:3  
 388:16  
**line-associated** 60:18  
**linear** 80:6 82:16  
**lines** 77:11 80:7 183:14  
 249:13 258:22 299:8

402:5  
**lining** 404:14  
**link** 60:4 79:20 90:19  
 92:14 93:13 111:6,20  
 143:17,21 144:19,20  
 150:16 163:18 168:17  
 176:1,8,18 179:2,5,12  
 179:16 185:8,15,22  
 186:2 188:4 339:14  
 339:19 341:1,15  
 349:12  
**linkage** 144:12 174:6  
**linked** 168:21 170:11  
 186:16 187:6,21  
 188:9 320:1 332:10  
 339:9,11 340:7 404:8  
**linking** 77:5 404:20  
**links** 77:20 88:21  
 178:21 334:3 405:14  
**lion's** 75:12  
**Lisa** 2:5 26:3  
**list** 20:8 36:18 39:7  
 73:12 113:12 120:10  
 123:21 163:20 167:13  
 215:3 264:11 274:16  
 274:18 390:21 399:18  
 408:4  
**listed** 163:20 258:20  
 335:17 340:12  
**listen** 356:5  
**listening** 356:1  
**LISW** 1:20  
**literally** 175:7  
**literature** 256:17  
 263:16 273:18 319:7  
 329:14 330:4,6 359:7  
 366:9 374:9 376:19  
 379:20 383:17,21  
**little** 6:10 7:16 8:5 9:8  
 9:15 10:6,12 11:15  
 12:5 13:8,18 30:19  
 43:2 49:17 62:1 84:12  
 122:12 125:17 160:8  
 164:1,17 167:16  
 168:8 169:7,19  
 175:16 179:15 188:6  
 191:7 192:6,10 195:7  
 200:4 223:18 230:5  
 238:21 239:15 247:18  
 248:3 256:22 258:13  
 258:22 271:4 296:5  
 299:17,20 312:20  
 329:16 330:20 344:2  
 347:15 357:13 364:7  
 366:7 367:10 369:12  
 371:9 381:5 383:8  
 390:1,5 393:18  
 396:17 404:5 405:13

406:7 417:21  
**live** 44:16 89:6 269:13  
 273:21  
**living** 5:7 23:15 96:21  
 178:19 283:5 314:12  
**Liz** 21:8 97:22 102:2  
 133:3 176:19 242:4  
 339:3,3 403:6 407:19  
**load** 405:20  
**located** 161:2  
**location** 223:22 275:5  
**Loeb** 2:3 25:14,14  
 206:16 215:16 395:12  
 412:12 413:17 414:9  
**log** 116:20  
**logical** 46:17  
**logistics** 30:16 137:2  
**long** 5:8 21:3,15 22:9  
 25:15 97:3 101:20  
 163:20 174:10 184:22  
 185:11 204:7 205:11  
 205:22 206:2 213:19  
 214:19 215:15 286:10  
 315:17 317:19 318:1  
 319:19 320:12,14,16  
 321:7,21 322:21  
 324:9 325:8,22  
 329:15 330:3 331:17  
 332:2 336:3 345:12  
 346:17,19 348:11  
 350:9 361:5 362:18  
 373:14 394:4,4  
 397:18 399:17 412:5  
 417:17  
**long-standing** 21:12  
**long-stay** 265:22 267:7  
 270:1 278:4 281:11  
 281:14,17 292:3  
 314:13  
**long-term** 5:4 37:13  
 56:18 215:14 279:4  
 291:8,10 313:4  
**longer** 155:21 204:18  
 236:11 272:17 287:18  
**longitudinal** 8:14  
**look** 13:11 22:19 24:22  
 39:12,13 40:17 42:13  
 46:11 48:10 83:1 90:7  
 91:5 96:4 102:12  
 126:4 127:17,18  
 129:2 142:5 159:1,8  
 160:12 170:21 171:7  
 189:1 206:19 221:14  
 250:22 258:16 264:5  
 268:5,9,11,18 270:6  
 274:7 281:1,21  
 282:14 283:16 284:16  
 284:18,18,21 285:2,3

285:20 287:17 298:16  
 301:6,17 302:1 334:8  
 335:6 343:4 349:9  
 360:6 361:4 366:4  
 371:10 382:18 398:18  
 401:12 418:8 419:12  
**looked** 76:18 84:21  
 107:22 112:1,4  
 125:20 127:22 145:20  
 149:7,20 217:22  
 253:20 257:1 275:17  
 282:17 283:1 289:4  
 295:9 298:5 359:12  
 360:12,13,18 381:11  
 383:21 395:1 407:2,7  
 407:8  
**looking** 12:13 14:7  
 22:12 25:8 31:7 39:18  
 47:14 50:1,5,12,13,19  
 56:11 68:11,12 70:19  
 81:12 86:2 89:12  
 102:19 117:20 126:6  
 147:22 148:14 154:15  
 169:22 170:18 173:4  
 173:7,7,15 186:13  
 196:17 201:18 207:2  
 207:18 208:2,11  
 210:21 212:14 216:9  
 220:8 238:18 239:1  
 241:11 250:6,19  
 259:4 260:7 268:7  
 272:1 282:12 283:5  
 285:9 295:12 297:22  
 300:12,21 309:5  
 320:11 327:20 329:10  
 329:20 330:9 351:14  
 351:15 352:3 359:16  
 360:1 361:15 362:7  
 376:2 378:9 386:22  
 396:9,18 402:3  
 408:16 420:1 421:4  
**looks** 68:22 75:13 89:6  
 205:18 208:11 241:18  
 277:20 283:2 306:16  
 315:9  
**loops** 301:4  
**Lorelei** 30:9  
**Los** 20:12  
**lose** 34:9 271:10 293:4  
 307:22 308:1 391:10  
 391:18 392:7  
**losing** 213:13 277:14  
 413:7  
**loss** 256:18 266:2  
 272:13 304:7  
**lost** 367:10  
**lot** 10:4,22 14:22 18:7  
 44:6,9 49:22 52:6

57:2 60:21 73:4 77:12  
 85:18 93:11 96:16  
 104:1 110:11 122:17  
 123:9 125:3 135:12  
 148:17 172:6 184:11  
 198:18 202:10 207:14  
 208:9 211:19 246:17  
 246:21 250:21 273:10  
 289:6 295:14 306:15  
 307:1 313:2,8,8  
 316:20 319:2,3,7  
 320:9 323:18 324:19  
 329:6 330:4 331:8  
 332:7 338:17 345:15  
 347:3 349:9 361:11  
 364:19 383:10 389:1  
 391:2 393:3,12,15  
 394:11,12 397:22  
 398:10 399:5,11  
 410:13 415:12  
**lots** 29:16 110:14 183:7  
 206:2 415:11  
**love** 48:17 103:8 310:15  
 330:15 345:2 378:21  
 409:5 416:22  
**loved** 292:11  
**loving** 413:6  
**low** 83:9 100:3 112:2  
 119:8,11 120:3  
 130:20 134:6,10,12  
 134:15,17,20,22  
 135:3,5,9 156:14  
 165:7 166:8,14,19,22  
 167:4 180:14,19  
 181:5,10,20 182:3,11  
 182:16 217:3,6,9,13  
 227:7,11,14,19  
 232:21 233:6 235:19  
 236:2,12,17 238:12  
 239:20 240:3 243:17  
 243:21 257:20 258:2  
 258:5,10 260:20  
 261:3 262:11 268:6  
 268:20 269:16 277:9  
 278:15 294:13,15,18  
 294:21 299:3 302:14  
 302:17 310:22 311:3  
 313:21 314:2,5,8  
 353:17,21 354:4,6  
 357:15 371:5 373:10  
 375:12,15,17,19  
 378:11,17 380:17  
 381:1 382:4 383:5  
 387:10,12,18,20  
 388:1,4  
**low-performers** 307:6  
**lower** 86:14 95:22 96:6  
 108:11 129:10 230:10

231:2 319:13,13  
404:7  
**lowering** 65:16  
**lowest** 382:5  
**LTCH** 338:3 344:18  
345:8 350:9  
**LTCHs** 291:21 318:1  
338:9  
**Lucas** 3:7 138:21,21  
**lumbar** 4:14 5:3 63:11  
86:3,13,13 87:6 225:1  
230:5 242:15 243:5,6  
245:2,12  
**lunch** 11:14 183:11  
189:1  
**lunchtime** 58:19  
**lying** 336:13,13

### M

**MA** 2:2,5,9  
**Maccabi** 66:3  
**Madam** 61:18 264:13  
264:16  
**magical** 385:2  
**magnitude** 113:1  
202:19 238:7  
**magnitudes** 222:8  
**mail** 232:11  
**main** 104:5 289:13  
382:12  
**maintain** 34:20 280:1  
286:12  
**maintained** 104:10  
**maintaining** 267:3  
**maintenance** 271:4  
272:20 376:5  
**major** 48:1 125:12  
207:13 209:5 211:14  
269:1 282:18 345:11  
**majority** 56:13 223:16  
415:5  
**makeup** 218:12  
**making** 57:3 156:11  
187:1 240:19 276:15  
293:13  
**male** 223:19 315:7,10  
**male/female** 141:18  
**man** 7:5 105:3,4  
**manage** 303:9  
**managed** 22:4  
**management** 1:18 2:8  
5:13 17:19 22:2 24:6  
26:5,6 63:14  
**manager** 31:15 101:13  
191:14  
**managers** 101:3,15  
**mandate** 410:4  
**mandated** 235:14 335:2

**mandates** 351:20  
**manner** 28:3 95:10  
**mantra** 162:16  
**MAP** 32:5 33:22 44:12  
48:9 49:12 409:2  
**Marcia** 2:16 29:22  
**Marjorie** 3:5 356:20  
373:16 379:7  
**mark** 3:15 65:22 67:12  
232:18  
**marks** 85:4  
**Marsha** 29:4,10  
**Marty** 26:19  
**Mary** 285:15  
**mask** 113:3  
**Mass** 21:8 211:17  
**Massachusetts** 2:6  
**match** 41:1  
**matchmaking** 42:18  
**material** 6:19 74:2  
332:13  
**materials** 91:2 124:21  
**math** 51:18 400:6,9,10  
403:7,8  
**matter** 12:21 13:7,21  
75:9 99:21 136:8,14  
170:5,11 190:7 315:1  
400:16 406:10,11  
409:1 416:14 422:6  
**mature** 149:22 249:14  
**maximize** 147:16  
**maximum** 272:5  
**Mayo** 213:7  
**MBS** 267:10 272:21  
**McMULLEN** 3:7 274:21  
274:21 275:2,9,13,16  
276:6 278:19 284:4  
291:15 300:10 301:12  
304:15 311:15 316:6  
316:7 334:17 335:20  
349:21 350:18 351:12  
353:7,14  
**MD** 1:13,17 2:6,10,12  
273:21  
**MDS** 276:10,15 278:20  
278:21 281:12 312:22  
313:6  
**MDS-based** 300:8  
**mean** 14:12 45:20 46:8  
46:9 56:6 67:1 74:2  
76:11 84:2 85:21  
97:10 115:14,20  
124:8 133:21 149:16  
150:10 154:2 157:18  
157:22 158:19 161:6  
161:10,11 165:11,12  
172:2 175:7,18 177:7  
207:6,20 214:11

215:8,18 216:4 226:4  
249:21 256:4 260:1  
262:14 268:9,16,18  
270:15 274:6,8,14  
276:20 288:12 291:6  
297:9 298:9 301:14  
302:1 304:4,13,19  
312:9 328:8 331:3,4  
332:3 340:6 345:1  
349:2 350:22 354:9  
368:3 371:6 377:19  
378:4 381:7 390:7,20  
393:20 399:9 410:3  
410:22 414:10,10  
416:3 417:10  
**meaning** 41:9 150:11  
376:6  
**meaningful** 39:6 101:1  
123:7 149:11 157:8  
157:10 160:20 164:16  
165:2 181:4 199:1,4  
199:19 201:13 237:1  
238:15 362:9 381:15  
381:18 414:8 416:7  
**means** 17:11 27:20  
36:9 51:5 66:22 73:1  
83:6 119:14 120:2,4  
129:13,18 143:15  
159:9 161:22 165:15  
176:5 185:14 199:6  
247:1 262:10,12  
297:6 305:4 311:10  
346:4 393:2  
**meant** 54:14 306:9  
**measurable** 358:16  
**measure** 8:5,8 10:17  
18:16 19:1 20:19,20  
24:2,2,4 30:13 32:4  
32:17 33:14 36:4,10  
37:18,21 39:5,18,18  
40:6 41:3,3 42:1 46:5  
46:6 47:8,13,15 49:1  
50:3,7 51:6,8 52:20  
53:2,15,19 55:3,5,20  
56:1,12 58:6 59:20  
60:1,2,7,20 61:11  
65:15,15 66:14,19  
68:9 70:21 74:12 76:8  
77:5,9 79:7 83:6  
86:14 88:1,5,16 90:1  
90:17 94:6 95:2,10  
97:9 98:22 102:22  
103:16 104:10 105:1  
107:17 109:2,9 110:1  
110:14 113:19 114:1  
116:22 117:1,19,21  
123:18 125:1,6,8,9,10  
125:21 126:4,18

127:2 130:1 131:17  
132:1,3,19,20 133:17  
133:18 137:4 138:4,6  
139:17 141:12,20  
143:12,18,22 144:6  
144:22 145:6,7  
147:16 148:4 150:20  
151:11,20 153:2,3,11  
153:12,14,18,20  
154:3,10,11,17  
157:12,14 158:3,5  
159:3 160:20 161:8  
161:10,16 162:5  
163:3 164:4,16,17  
165:2 167:12,15  
168:16,21 170:9,15  
171:16 172:7 173:8  
173:10,17,21 174:6  
175:14,15,16 183:1  
184:7 185:1,9,13,19  
186:5,15 188:9,13  
190:20 191:8,12,14  
191:20 192:2,5,7,11  
192:19 193:4,5,7,22  
194:5,16,17 195:3,9  
195:10,18 196:20  
197:19 199:21 200:5  
200:9,18 201:18,21  
203:17,20 205:9,10  
205:16,17 206:7  
208:6 209:20 210:1  
210:18 212:9,15  
213:5,7,14 215:13  
216:10,12 217:19  
218:3 219:4,6,8,14  
220:5,5,19,20 222:15  
224:22 225:2,11,17  
225:19 226:14 227:1  
228:4,14,18 230:5  
232:15 234:20 235:5  
235:11 236:3 237:2  
240:6 241:4,21,22  
242:7,13,16,17,21  
243:8,11 244:5,6,11  
244:12,18,21 245:1,2  
245:22 248:8,20  
250:3,15 251:2,3  
253:2 254:5,16 255:6  
256:8,21 259:4 260:2  
260:14 262:1,6,9,12  
264:1,11 265:20,21  
266:8 267:5,13,14,18  
268:22,22 269:3,5,6,8  
269:18 270:2 272:18  
272:21 275:10,19  
278:16 279:11,17  
280:4,9 281:18,19  
282:13,18,21 283:2

283:17,18 286:18,19	79:15 82:18,22	194:10,11,15 195:13	<b>medically</b> 319:1 329:7
289:12 290:1 291:9	105:11 144:7 189:6	195:14,21,22 196:5	<b>Medicare</b> 22:5 139:12
291:16 292:2,3,6,9,12	190:22 191:13 195:8	199:18 200:1 203:13	246:14 287:4 351:21
292:15,20 293:4,11	196:1,4 209:12 219:2	203:14 212:20 216:2	364:4,22 374:12
293:15,20 296:3	219:16 220:1 221:11	219:15 221:20 222:6	<b>Medicare-certified</b>
297:7 298:17 301:11	223:9 225:14,14	225:12,21 226:10,15	267:8
301:14 304:2,5,8	226:17 229:11 231:8	228:17 229:5 231:12	<b>Medications</b> 5:14
305:9 306:1 310:1,2,7	238:7,19,21 239:2	231:21 235:21 244:4	<b>medicine</b> 1:14,16 2:1
311:20,21 314:11,20	241:1 242:20 248:13	252:17,20,22 261:7	2:13 14:20 16:6 20:11
315:17,22 316:7	261:18 296:4 301:22	264:1 269:19 282:6	23:16 27:5 71:4 72:3
317:16 319:20,20	303:6 369:16 379:14	282:15,22 284:6,11	<b>Medicine/Pediatrics</b>
320:15 321:5,10,11	393:4 401:14 412:16	284:11,12,15 289:22	1:14
321:12 322:3,10	413:2,7 414:6 420:4	290:13,16 291:2	<b>MEDPAC</b> 43:14
325:8 326:3 330:18	<b>measurements</b> 46:10	292:21 298:11 300:3	<b>meet</b> 31:15 33:3 53:14
330:19,21,22 331:12	255:7 380:2	300:8 301:17 304:22	153:2 361:9
332:7 333:12 334:3,7	<b>measures</b> 4:8 5:1,2	305:9,17 310:18	<b>meeting</b> 1:3 27:21 28:5
338:7,20 340:8,22	8:10 10:13,20 15:2,7	313:12 314:20 316:1	28:12 30:8 43:14
341:2 342:21 344:3,4	15:22 16:10,19,20,22	317:9,13,17 320:6	136:15,16 137:11
344:12,15,21 345:4,7	17:6,8,12 18:3 19:8	321:6 324:20 325:7	149:6 176:11 177:14
345:7,17 347:10	19:13,21 20:6,18 22:8	326:11 331:8 332:8	264:18 342:17 362:15
348:20 349:2,4,11	22:19 23:3,5,7 24:16	335:15 346:13 350:4	397:7
350:17 351:10 352:1	25:19 27:1 28:20 31:5	350:4,5,6 351:21	<b>meetings</b> 29:17 30:21
352:13,15,16,19,22	31:7,9 32:14,17,19,19	371:8 372:12 379:2	137:7 233:21
353:1,3 354:9,19	32:21 33:1,4,5,6,17	381:6,8 389:2,4,10,20	<b>meets</b> 49:2 323:15
355:18 356:10 357:1	34:1,4,5,16,17 36:17	392:20 393:14,22	368:21
358:14,19 359:8,16	36:18,19,21 37:1,6,7	394:11,22 395:5,21	<b>melled</b> 305:15
359:22 360:6 361:16	37:9,12,14,16,19 38:2	396:17,18 397:1,7,17	<b>mellitus</b> 224:21
361:17 362:2,5,19	38:9,10,12,14,22 39:8	398:10,21 399:6,15	<b>member</b> 4:20 5:19 7:15
363:13 367:18 368:6	39:13,14,14 40:1,2,9	402:2 404:15 405:19	7:17 9:9 15:12 16:5
368:7,9,16,21 369:10	40:17 41:1,9,21,22	407:2,4,8 408:2,6,8	16:11 17:2,7,16,17
369:18 370:14,20,21	42:2,10,15,16,19,21	408:17 409:6,12,19	18:4 19:2,9 20:10,18
371:22 372:5 374:20	43:8,16,19,20,20	410:13 411:5,6 412:7	21:7,22 22:17 23:12
376:2 377:12 378:6,8	44:12,13,20 45:8,14	412:18,19 413:5,10	24:17 25:14 26:3 27:3
378:12 379:1,5 384:5	45:21 46:10 47:17	413:13 415:3,6,12	39:12 40:7,11,16
384:21 385:7 388:6	48:3,10 49:13,22 50:5	416:2,4,12 417:7,22	41:19 43:13 45:6
389:15 390:18 393:5	50:9,16,20 52:6 53:3	419:10 421:4,8 422:4	47:11 53:6 59:17 63:3
394:2 396:1,1 398:1,2	53:11,13 56:3,6,14	<b>measuring</b> 34:13 55:21	68:1 69:1,6,21 70:8
398:3,15,16 400:5	57:10,14,15,16 58:1,9	74:21 105:22 162:8	70:11,18 71:14,20
404:17 408:11,20	58:13 59:16 60:15,17	200:7 216:3 229:13	72:15 73:1,20 74:9
409:16 411:1,11,12	61:21 62:2,14 63:4,9	234:3 283:20 363:3	75:2 76:3,7 77:1 78:3
411:16,17 412:3,3,9	63:11,18 64:1,13,15	363:16 367:19 411:7	78:5,11 79:9 80:19
414:12 417:16,18	64:16,18,21 65:2,7,11	<b>mechanically</b> 246:22	81:15 82:15 83:21
419:5	66:13 76:13 77:3 79:2	<b>mechanism</b> 370:6	85:12 88:14 89:4,10
<b>measure's</b> 139:13	84:16 85:1,14 86:20	<b>media</b> 26:5,5	89:22 91:19 92:11,16
140:2 269:21 340:5	87:4,9,13,16 88:2,6,7	<b>median</b> 147:13 148:6	92:18,20,22 93:1,2,21
370:11	88:20,22 91:8 93:6,7	148:12 149:15 155:17	95:21 96:5 97:14 98:1
<b>measure-level</b> 268:4	93:19 94:4,9 96:6,8	155:19 267:12 271:20	99:2,5 100:17 102:4
<b>measured</b> 36:14 38:20	96:12 97:17 98:6	<b>Medicaid</b> 17:11 22:4	105:2 106:16 107:7
44:22 56:16,17,21	102:5,6 104:7 110:19	31:22 139:12 283:11	108:20 109:15 110:4
57:1 64:10 70:13	113:10 115:10 121:8	<b>medical</b> 1:17,20 2:13	112:14 113:13 114:2
126:20 161:21 177:19	122:1 123:9,10,12,16	7:19,21 15:1,3,15,18	114:8,11,20 115:13
184:21 185:12 283:1	124:3 129:8,17 130:4	16:3,7 19:10 24:20	115:18 116:1,13
358:21 370:21 395:9	131:12 136:20 139:20	66:1 161:1 169:12	117:4 119:14,17,20
400:1	140:5,19,20 142:13	170:21,22 227:2	121:20 122:8 123:3
<b>measurement</b> 8:11,13	152:1 154:13,16	237:20 274:3 275:2	123:20 124:3,22
16:20 18:10 23:10,17	155:2 162:3,22 163:1	276:12,14 323:6	125:13 126:11 127:4
23:22 29:6 31:5 33:8	163:6,15,19 167:13	337:11 357:6 389:11	127:11 132:2,8,12
33:10,12 35:17 79:14	171:18 177:6 191:18	398:13,14 411:21	133:6,20 142:9 143:1

143:7,10 144:9,17,21  
 145:4 146:11,19  
 147:4,7 150:2 151:17  
 152:18 153:4,15,21  
 155:5,8,13,15 156:18  
 157:13,18 158:8,11  
 158:13 159:16 161:5  
 161:15 162:2,21  
 163:17 164:6,11  
 167:8 169:20 170:17  
 171:9,14 172:17  
 174:8,21 176:7,20  
 179:17 183:9,11  
 184:19 185:5 186:9  
 186:18 187:9 188:18  
 190:2 197:22 201:1  
 201:11 202:15,19  
 203:4 204:3,10  
 205:12 206:16 207:17  
 208:18 211:11,16  
 212:8,13 213:12  
 214:8 215:16 216:5,8  
 217:17 221:5 222:16  
 225:9 228:1 231:18  
 233:18 234:1 238:2  
 240:14 241:18 242:5  
 246:6 249:12,18  
 250:11 251:8,18  
 253:3,11 254:3,8  
 255:5 256:11 257:9  
 258:14 260:1,6 263:5  
 264:13,16,21 265:5,8  
 270:9 271:16,18  
 272:4 273:3,6 274:5  
 275:1,7,11,14,20  
 276:9,16 277:1,6,8,16  
 277:19 278:22 279:1  
 280:7,13 281:7,12,15  
 282:4,20 286:1,22  
 287:22 288:7 289:3  
 289:17 290:10 295:2  
 295:6,20 297:1,4  
 298:11 301:2 302:6  
 302:21 306:11 307:10  
 311:7,16 312:7,11,13  
 312:19 325:16 326:6  
 327:14 328:1,8,16,21  
 329:9,19 330:17  
 331:11,15 333:12,16  
 334:9 335:16 337:21  
 338:1 339:4 340:4,17  
 340:21 341:10,14  
 342:2,13 343:2 344:1  
 345:22 346:1 347:9  
 348:18 350:14,19  
 351:8 352:9 363:1,18  
 365:2,5,14 366:11  
 367:20 368:17 369:1

370:2 371:20 372:4  
 372:15 375:3 376:1  
 377:1 378:18 381:4  
 384:16 390:20 391:7  
 391:9,12,17 392:4,8  
 393:17 394:9 395:12  
 396:3,14 398:7,22  
 400:3 401:21 403:4  
 406:19 409:9 410:12  
 411:9 412:12 413:17  
 413:20 414:9,20  
 418:22 419:20 420:8  
 420:11  
**members** 4:2 51:4  
 61:18 77:17 120:17  
 165:19 200:21 352:11  
**membership** 43:10  
**membrane** 414:5  
**mention** 211:5 293:5  
 379:8  
**mentioned** 19:11,15  
 30:18 38:6 47:12  
 57:13 100:17 121:3  
 125:22 128:22 228:6  
 252:3 286:3 291:5  
 319:17 325:17 329:11  
 334:10,16 339:6  
 341:16  
**mentioning** 55:1  
**mentors** 136:12  
**merely** 299:9  
**merits** 40:6  
**Merlino** 7:7  
**meshes** 287:2,10  
**met** 1:8  
**meter** 362:16 383:7  
**meters** 358:21 359:5  
 381:14,15 382:4  
 383:2,15,19 384:14  
 385:16 406:7  
**method** 37:17 41:17  
 111:19 321:20 336:21  
**methodologically**  
 413:16  
**methodologies** 85:14  
 359:9  
**methodology** 64:6  
 86:17 176:22 209:10  
 219:12,18 358:5  
**methods** 239:9  
**metric** 177:14 180:9  
 309:7 404:2,9,9 406:2  
 406:3 412:5  
**metrics** 21:5 131:15  
 394:8  
**Metropolitan** 2:9 22:2  
**mic** 54:4,5  
**microphone** 328:11

354:1 355:6 371:14  
 375:9 380:20 420:7  
 420:10 421:17  
**mics** 54:7  
**mid** 374:11  
**middle** 51:8 299:6  
 309:19 310:10  
**migrating** 385:7  
**migration** 385:12  
**million** 62:15 64:12  
**mind** 128:10 150:13  
 179:8 209:16 250:7  
 291:11 338:2 340:17  
 411:12  
**mindful** 203:22 293:1  
**mine** 288:7  
**minimal** 70:6 93:11  
 203:16 359:5 361:9  
 380:7 382:19  
**minimally** 112:7,7,11  
**minimization** 35:1  
**minimum** 108:7 204:14  
 267:6 274:19 360:9  
 373:6  
**Minnesota** 189:3,6,14  
 190:21,22 191:1,13  
 195:8,13,19 197:1  
 198:11 201:21 203:13  
 213:2 218:6,22 219:2  
 219:22 226:17 229:1  
 231:14 241:1,9 242:6  
 248:14 249:16  
**minor** 184:11  
**minority** 159:21  
**minus** 110:8 225:15  
 238:11  
**minute** 7:16 236:11  
 358:21 359:1 360:7  
 362:11 363:17 366:5  
 368:1 372:19 373:9  
 373:17 374:10,17  
 379:9,13 385:3,13  
 386:17,19 387:3  
 390:16 406:13  
**minutes** 10:17 11:3  
 53:10 99:11,13  
 373:10,11 384:22  
 385:4,5,9 390:9  
 391:21 406:11,11  
**Mio** 190:16  
**miracle** 136:13,18  
**misassignment** 214:4  
**miscellaneous** 33:9  
**misery** 189:15  
**misinterpretation**  
 81:16  
**misleading** 125:17  
 173:11

**missed** 100:19 146:12  
 150:2 152:2 201:6  
 214:3 309:21 327:3  
**missing** 75:14 77:18  
 118:21 144:14 155:10  
 194:14 207:9 269:2  
 275:21 278:13,16  
 302:16 313:22 332:14  
 332:15,19 333:3  
 341:17 349:19 353:4  
 375:1 380:18 414:22  
**mission** 411:2  
**misunderstanding**  
 351:1  
**MIT** 400:11,22  
**mitigate** 145:11 186:11  
 297:15  
**mitigated** 266:16  
**Mitra** 2:17 30:1,6 31:11  
 32:2 49:18 57:13 66:9  
 190:13,18  
**mix** 50:16 286:6  
**mixed** 190:21 242:3  
**mixture** 38:8  
**MMHS** 2:2  
**mobility** 43:19,19,20,20  
 43:22 44:22 45:12  
 96:1 266:5 321:1,16  
 322:13 334:12 336:10  
 336:11 340:15  
**mobilization** 319:9  
**mobilized** 319:4  
**mode** 92:2,7 93:10  
**model** 60:6 67:15 68:4  
 68:9,14,16,18,22 69:2  
 69:2,7 71:9,12 73:19  
 75:17 78:4,20,21 79:7  
 81:3 82:4 98:14 103:4  
 103:18 211:2 214:17  
 245:21 269:16 304:17  
 307:20  
**modeled** 258:21  
**modeling** 67:17,21  
 74:15 78:19 82:16  
 298:14  
**models** 76:19 80:2,12  
 80:13,16,18 81:10  
 89:1 106:13 116:5,7,9  
 122:22 210:7 304:16  
 351:16 360:14  
**moderate** 119:8,10  
 134:5,9,12,14,17,19  
 134:22 135:2,5,8  
 165:6 166:8,14,19,22  
 167:4 180:14,19  
 181:5,10,20 182:3,11  
 182:16 217:3,6,9,13  
 227:7,11,14,19 233:6

236:8,16 239:20  
 240:3 257:20 258:2,5  
 258:9 260:20 261:3  
 294:13,15,18,20  
 302:14,17 310:14,22  
 311:3 312:8 313:21  
 314:2,5,7 353:17,20  
 354:4,6 358:6 364:5  
 371:4 374:2 375:12  
 375:14,17,19 378:10  
 378:17 380:17,22  
 387:10,12,18,20  
 388:1,3  
**moderates** 135:13  
**modification** 71:6  
 266:19  
**modified** 113:6 133:13  
 169:3  
**modify** 215:12  
**modularize** 401:4  
**module** 24:5  
**mom** 10:5 26:7 415:13  
**moment** 48:1 201:10  
 233:16 386:14,15  
**money** 25:9 197:5  
 398:10  
**monitor** 141:22 282:2  
 288:21  
**monitoring** 266:21  
 282:1 364:18  
**Monroe** 2:4 9:3,9,10  
 17:7,7,16 39:12 40:7  
 40:11,16 113:13  
 114:2,8 115:13 116:1  
 158:13 159:16 161:5  
 190:2 212:8,13  
 213:12 216:5,8  
 264:13,16,21 265:5  
 277:19 279:1 289:3  
 289:17 295:2 302:6  
 302:21 311:7,16  
 312:11 375:3 391:9  
 391:12,17 392:4,8  
 406:19  
**month** 26:14 63:1 200:9  
 276:20 360:9  
**months** 28:10 62:15  
 193:13,18 196:18  
 204:14,18 208:14  
 244:8,10 269:13  
 271:21 272:3,8,17  
 273:16,22 280:20  
 287:19 288:16 293:8  
 309:15  
**morning** 6:4,5 7:18  
 10:12 11:22 16:11  
 19:2 21:7,22 22:17  
 27:14 28:15 29:3 30:4

31:13 32:1 61:18  
 138:17,19 139:5  
 261:7 333:22 334:5  
 339:14 340:8 391:3  
**morning's** 139:6  
**morphs** 387:5  
**Morrise** 2:5 26:3,4  
 418:22  
**Mort** 2:6 21:7,8 102:4  
 105:2 106:16 133:6  
 133:20 176:20 242:5  
 246:6 249:12,18  
 251:8 253:11 258:14  
 263:5 277:1,6,8 334:9  
 335:16 337:21 401:21  
 411:9  
**mortality** 220:20 319:14  
**mother** 23:14  
**motor** 5:16 321:16,17  
**mouth** 197:6  
**move** 6:9 11:10 40:3,4  
 40:8,13 51:13 52:18  
 53:9 57:17 58:10  
 60:15 61:3 74:11  
 81:13 90:14 124:9  
 136:22 166:11,12  
 175:14 180:22 189:21  
 190:3 206:4 264:22  
 293:21 301:9 329:2  
 338:22 354:9 355:15  
 385:19 388:18 395:2  
 395:3 399:19 404:17  
 408:13,19 409:7  
**moved** 59:22 108:11  
 133:17 285:4 376:6  
 412:10  
**movement** 224:2  
 287:12 399:16  
**moving** 48:19 57:22  
 58:6 60:8 65:14  
 128:21 258:11 262:10  
 291:17 294:22 302:19  
 308:3 352:8 354:14  
 378:20 381:2 387:14  
 399:2,22  
**MPH** 1:13 2:1,6,10  
**Multi** 365:10  
**multi-stakeholder**  
 33:15 42:11  
**multi-state** 62:5  
**multidisciplinary**  
 266:17  
**multiple** 20:15 38:13  
 100:4 114:14 209:5  
 211:14 279:13 300:12  
 300:13 391:22 392:19  
 393:6  
**multiply** 238:9

**Murphy** 356:18  
**mute** 189:18  
**mutual** 343:17  
**mutuality** 42:4

---

**N**

---

**N** 4:1,1  
**N.W** 1:9  
**Nadine** 2:17 30:1,6  
 31:17 57:7 66:9  
 216:14 353:15 374:20  
 387:8  
**naive** 44:5  
**name** 18:21 19:3 21:7  
 21:22 24:17 26:3  
 36:19 146:6 265:17  
 316:20 401:10  
**names** 18:21  
**narrative** 196:22  
**narrow** 245:11 246:20  
 255:2  
**Natasha** 26:19  
**national** 1:1,8,12,18 2:5  
 2:13 15:11,13,21 16:7  
 16:16 17:9,20 22:13  
 22:21 198:7 234:22  
 268:9,16 298:9 303:2  
 316:13 360:3 362:17  
 365:22 373:20 374:13  
**nationally** 360:1  
**nationwide** 267:8  
**natural** 289:8  
**naturally** 179:5,16  
**nature** 155:10 219:5,15  
 254:10 256:15 279:9  
 284:12 365:11  
**NCQA** 16:1  
**near** 273:13 362:10  
**necessarily** 11:3 43:9  
 78:2 86:22 143:11  
 144:11 157:14,15  
 163:6,10 171:2  
 177:15 179:4 218:21  
 225:11 226:19 259:15  
 259:19 323:21 343:21  
 345:19 410:14 411:1  
**necessary** 158:9  
 203:16  
**neck** 63:12,13 171:20  
**need** 5:7 25:13,21 41:9  
 42:17 51:5,8,16,18,22  
 54:8 70:10 74:13,21  
 79:11 84:11,17,18  
 87:3 118:1,9 126:20  
 127:1 136:22 137:21  
 141:11 146:7 151:12  
 159:9,10 161:12,16  
 162:20 178:20 179:9

190:18 221:21 234:14  
 249:6 251:6 266:1,2  
 274:2 279:22 283:3  
 283:22 314:11 323:1  
 323:7 371:10 373:6  
 390:3,4 392:19  
 394:13 395:19 399:19  
 402:1 404:17 414:18  
 416:3,17 418:5 421:2  
**needed** 7:9 180:10  
 228:16 229:4 396:11  
 398:19  
**needing** 117:14 321:13  
**needs** 25:3 51:14 82:3  
 156:16 158:2 174:17  
 216:1 228:21 309:7  
 313:16 339:13 416:11  
**negative** 211:17 285:8  
 285:18 286:19 359:15  
**negotiation** 310:8  
**nervous** 347:15  
**nested** 80:19 81:10  
 350:8  
**net** 308:22  
**neurologic** 253:13,18  
**neurological** 252:2  
 256:3,15 257:7  
**neurosurgeon** 197:14  
**neurosurgeons** 255:17  
**neurosurgery** 243:9  
**Neuwirth** 2:8 17:17,18  
 92:11,18,22 93:2  
 127:11 396:3 414:20  
**never** 18:8,9,22 104:9  
 222:10 232:5  
**new** 1:21 2:4 4:2 6:9  
 7:15 9:11 10:5 17:3  
 17:11 22:3 29:5 32:6  
 33:6 51:16 59:1 66:1  
 118:10 184:16 191:18  
 195:21 197:16 219:5  
 229:11,14 357:4  
 376:16,17,19 394:18  
 405:16  
**newer** 230:8  
**newer-type** 199:21  
**news** 296:12,12,20  
**nice** 30:2 59:13 131:17  
 270:14 298:12,15  
 307:13 308:7 334:2  
 396:10  
**nicely** 259:6 287:3  
**NIH** 8:7 20:16 385:2  
**nine** 193:18 244:10  
 387:12  
**nineteen** 380:21,22  
**Ninety** 294:10 388:9  
**Ninety-five** 257:17



<b>nods</b> 85:5	382:9,15 385:20	<b>obviously</b> 43:8 55:16	189:16 190:19 197:22
<b>noise</b> 296:3 297:8,9,17	388:15 404:18 416:4	79:15 159:7 160:21	202:22 206:10 217:17
297:21 309:1	417:7,21	247:20 250:2 322:7	227:4 233:17 236:8
<b>noisy</b> 81:19	<b>numbers</b> 51:10 61:21	327:8 331:4 347:2	236:12 241:8,16,18
<b>nominated</b> 14:3	81:18 135:13 157:2	352:20	257:10 260:17 261:5
<b>non</b> 141:18 341:18	237:9,10 394:12	<b>occupational</b> 140:3	262:13,18 263:3,17
<b>non-adherence</b> 341:18	<b>numbness</b> 253:21	365:10	271:16 273:3 274:11
<b>non-invasive</b> 263:9	<b>numerator</b> 85:10 150:5	<b>occur</b> 158:4 252:8	275:7,20 280:13
<b>non-linked</b> 177:2	175:3 176:15 187:14	256:15 270:20 328:13	281:16 288:9 294:5
<b>non-outcomes</b> 330:19	187:17 192:7,10	335:3 337:7 342:1,19	294:22 301:2 302:12
<b>nonprofit</b> 20:22	244:20 272:14 277:22	<b>occurred</b> 234:2 334:19	305:16 312:11 314:18
<b>nonprofits</b> 19:6	278:8 289:16 322:18	<b>occurring</b> 169:6	315:8 323:12 324:18
<b>noon</b> 343:11,13,16	359:14	<b>October</b> 346:21	326:5,6 327:4 328:4
356:2	<b>numerator-triggering</b>	<b>odd</b> 371:21	332:12 340:4,17,20
<b>normally</b> 124:8 376:8	278:9	<b>ODI</b> 243:18 244:14,20	341:11 346:15 348:18
<b>Northwestern</b> 1:19 7:20	<b>numerator/denomina...</b>	253:20 259:3	351:8 353:5,14,15
19:11 317:7	219:7	<b>ODQ</b> 85:20	354:2 355:14 363:18
<b>note</b> 146:10 201:19	<b>numerically</b> 64:22	<b>off-topic</b> 305:15	363:20 365:2,14
<b>noted</b> 272:19	<b>nurse</b> 1:21 17:3 25:15	<b>offer</b> 253:14 403:5	366:11 369:1 374:19
<b>notes</b> 58:16 201:18	45:16 46:2,16 276:15	<b>offering</b> 48:22 249:22	375:21 376:13,15
259:5	316:22 317:2 410:21	<b>offers</b> 48:15	380:14 381:2 382:14
<b>notice</b> 145:8 146:22	<b>nursing</b> 1:22 17:4 37:3	<b>office</b> 179:20	384:15 387:4,7,14,16
201:19 421:20	37:7,8 265:22 266:17	<b>Officer</b> 2:15 29:8	388:10,13 390:4
<b>noticed</b> 194:20 299:5	266:22 267:1,8	<b>offices</b> 17:21 19:7	392:10,18 403:3
<b>nowadays</b> 286:3	268:13 269:1 270:1,3	<b>officially</b> 386:5	421:21
<b>NQF</b> 2:14 4:5 5:19 9:21	274:7 275:7 277:9	<b>oftentimes</b> 42:12	<b>OKS</b> 193:6,12 228:19
19:14 21:20 23:19,21	279:6 282:2 283:13	197:15 249:4 318:17	235:10
28:7,8 29:5,22 30:12	283:19 284:22 286:7	<b>oh</b> 17:16 52:2 101:8	<b>old</b> 377:2
31:15 32:2 33:16 34:2	286:9,10 291:7,21	118:14 178:16 211:5	<b>older</b> 21:2 101:16,21
34:6 35:4 37:19 38:2	292:4 300:11 301:7	242:6 264:12,20	106:9 140:11 164:5
48:2 50:13 53:6 65:7	303:8,14 304:22	281:10 282:9,9	192:14 243:4
66:8 97:8 133:8 134:1	305:8 309:3 313:3	285:13 311:7 327:14	<b>once</b> 40:2 156:5 162:7
139:15,16 140:5	318:3 324:11 357:9	339:3 340:20 364:1	162:15 220:13 305:21
153:15 163:4,13	357:10 365:9 407:13	365:3,5 375:5,7 379:7	363:15 395:8 412:18
219:9,14 220:9	410:21 415:13 417:1	392:9 395:10 401:7	<b>oncology</b> 24:20
225:10 239:15 240:15	<b>nutrition</b> 266:18	403:3 406:5 414:10	<b>one's</b> 326:17
248:10 265:21 268:22		<b>Ohio</b> 1:20 24:19 357:10	<b>one-level</b> 245:9
304:19 330:22 350:15	<b>O</b>	<b>okay</b> 17:16 27:12,16	<b>one-year</b> 205:6 208:16
356:14 358:15 367:21	<b>O</b> 4:1	28:11 34:9 51:1 54:13	<b>onerous</b> 386:19
368:22 369:19 371:1	<b>o'clock</b> 190:1 314:22	61:10,16,17 66:16	<b>ones</b> 10:14 124:7
378:7 381:6 384:19	388:19	67:13 68:15 69:1 70:8	125:12 128:18 212:1
386:2 394:21 404:16	<b>OASIS</b> 22:11 312:22	70:18 71:14 72:15	215:8 292:11 308:19
405:17 407:20 420:5	313:7	73:1,20 75:2 77:1	391:1,1
<b>NQF's</b> 11:22 13:9 21:3	<b>objected</b> 100:7	78:3,11 79:9 86:11	<b>ongoing</b> 24:7 158:6
42:3	<b>objective</b> 304:6	92:19,22 99:5 103:17	301:8
<b>NQF-approved</b> 163:2,3	<b>obligation</b> 293:2	109:20 116:1 117:2	<b>online</b> 143:2 147:17
163:10	<b>observables</b> 366:16	117:17 118:14,22	207:18
<b>number</b> 18:11,12 19:5	413:22	119:12,20 122:18	<b>onset</b> 68:20 73:10
26:9 62:13 73:11	<b>observation</b> 45:8 75:11	127:6 132:10,18	106:5 263:11 399:22
74:17 77:22 78:1 79:4	84:6 173:3	134:3 136:5 137:4	<b>op</b> 218:5
79:5 89:5 90:3 110:4	<b>observations</b> 79:14	138:3,9 144:9,17	<b>open</b> 14:13 46:8 134:4
110:17 126:22 138:11	<b>observe</b> 279:4	145:4 146:11,19	183:11,14 277:18
149:4,9 157:2 166:2	<b>observed</b> 145:17	153:15,21 155:13	308:15 325:11 364:7
174:3 183:1 191:21	319:12	157:13 158:8 162:18	387:6 392:21
197:4 202:9,10	<b>observing</b> 135:11	164:11,12 167:6	<b>Opening</b> 4:2
240:21 243:6 246:13	201:13	178:9 182:8,21 183:7	<b>operate</b> 48:8
251:12 293:7 303:4	<b>obtained</b> 171:8	183:10 184:1 185:4	<b>operated</b> 185:20
327:2 341:4 362:16	<b>obvious</b> 74:1	187:7 188:17 189:11	<b>operation</b> 208:5 255:9

**operationalization** 188:13  
**operationalize** 322:9  
**operationalized** 167:17  
 168:4,9,12 173:3,18  
 289:13  
**operationalizing**  
 167:12  
**operations** 204:12  
 208:3 223:5  
**operative** 210:16  
 230:11  
**operatively** 232:19  
**operator** 46:18 183:13  
 183:15 188:19 388:13  
**opinion** 159:7  
**opinions** 14:8  
**opportunities** 17:22  
 199:20  
**opportunity** 22:10 30:6  
 40:17,21 53:1 55:12  
 61:20 120:8 139:7  
 142:3 195:2 213:14  
 214:4 220:15 239:8  
 240:18 241:2 248:9  
 261:15 265:16 270:6  
 294:1,7 303:16  
 315:16  
**opposed** 91:13 154:8  
 162:15 174:4 272:8  
 276:14 283:10 286:13  
 340:18 371:17 381:10  
 385:19  
**opposite** 159:14  
**opted** 279:18  
**optimal** 119:5  
**option** 40:11 293:17,19  
 343:20 378:14  
**options** 118:5,13  
 208:10 286:4,8 371:4  
**oral** 5:13 335:21  
**order** 27:17 74:4 81:13  
 82:4 187:19 194:3  
 280:1 281:19 303:14  
 320:21 339:2 373:7  
 379:13  
**ordering** 267:21  
**organ** 318:4 394:6  
**organization** 2:7 13:22  
 14:2 21:1 30:11 36:14  
**organizations** 18:19  
 20:15 177:4  
**organs** 318:5  
**origin** 210:10 224:12  
**original** 87:10 114:7  
 217:20 218:18 272:21  
**originally** 113:7 133:17  
 209:15 245:8 255:2

**originated** 87:5  
**originating** 245:7  
**orthopaedic** 4:18 65:1  
 126:19  
**orthopedic** 125:2,17  
 192:19 197:14 205:5  
 229:12,15 243:8  
 255:15  
**osteo-whatever** 75:6  
**Oswestry** 63:11 85:22  
 87:8,17 88:6 99:12,17  
 171:18,20 243:15,17  
 249:3 251:22 252:12  
 255:10 256:2,10,11  
 257:4  
**OT** 157:19  
**ought** 44:1  
**outcome** 4:19 8:1,11  
 16:17,20,21 19:13  
 38:9,9,14,22 49:22  
 50:15 56:12,14,15  
 60:2,4,15,20 61:3,4  
 64:9,16,18,21 65:11  
 65:15 72:12,13 79:21  
 87:16 91:6 98:17  
 118:17 121:22 130:22  
 133:18 138:5 139:15  
 140:6,16 141:3  
 143:22 144:2 145:22  
 150:7,8 163:15  
 167:13,20 173:13  
 178:6 183:2 185:3,22  
 191:18 192:5 193:5  
 194:10 203:6 208:13  
 216:3,17 231:16  
 235:21 242:21 250:3  
 257:13 282:6 301:15  
 306:9 313:11 320:15  
 321:5,6 322:16  
 344:21 345:4,17  
 350:5 358:17 368:6,7  
 368:16 373:15 374:18  
 378:8 415:6 419:12  
**outcome-like** 175:15  
**outcomes** 8:2 16:14,18  
 21:13 22:11 35:4,6,7  
 35:20 39:8 76:1 83:15  
 83:20 131:4 140:18  
 141:1 142:18,20  
 143:16,19 144:13  
 160:13 171:22 178:22  
 186:16 193:2 197:17  
 214:10 215:14,21,22  
 225:6 234:11,13  
 244:17 255:20 301:18  
 319:5,9 330:5,9,22  
 331:1 338:22 358:12  
 360:2,16,19 362:1,4

373:18 420:4  
**outcomes-based**  
 154:16  
**outliers** 299:10  
**outlined** 65:17 172:15  
**outlines** 379:17  
**outlook** 285:18  
**outpatient** 37:3,14  
 62:19 64:10 71:3  
 164:7,10 363:21  
 373:3,4,5 374:7  
**outside** 111:13 237:20  
**over-specification** 69:7  
**overall** 119:5 182:18,22  
 209:17 240:5 278:2  
 314:10 319:8 359:17  
 359:18 388:5  
**overlap** 10:20 83:13,20  
 85:13  
**overlapping** 290:14  
**oversimplifying** 271:8  
**overuse** 197:2,8 206:20  
**overused** 162:4  
**overview** 4:6 319:18  
**overwhelming** 9:16  
 395:14 416:4 417:6,7  
**Oxford** 193:6 207:19  
 210:16 217:21 218:20  
 230:6,11 231:3  
**oximetry** 358:1  
**oxygen** 358:1 364:19

## P

**P-R-O-C-E-E-D-I-N-G-S**  
 6:1  
**p.m** 190:8,9,15 315:2,3  
 422:7  
**PAC** 291:19 334:19  
**Pace** 30:9  
**package** 124:11 131:2  
 149:3  
**page** 77:7,8 80:3  
 201:19 312:21 349:20  
 405:18  
**paid** 345:13  
**pain** 5:15 24:6 27:8  
 86:14 103:20,21  
 105:9 186:19,20  
 243:17,22 245:6  
 252:2,21,22 256:12  
 256:13 257:8 263:10  
 406:2  
**paint** 285:6  
**paired** 194:11,14  
 244:17 301:16 413:1  
**palliative** 2:12 16:6  
 279:5  
**panel** 20:19 21:4 49:9

65:21 143:1 146:4  
 321:3 344:17 366:14  
 367:13 386:21  
**panels** 320:5  
**paper** 8:20 19:11 92:4,6  
 93:1,2,4,5 114:14,21  
 172:13 404:12  
**paperwork** 230:15  
**paragraph** 77:8 327:15  
**parameters** 11:2 372:7  
 372:13  
**Pardasaney** 3:8 316:10  
 316:11  
**pardon** 263:3 421:16  
**parent** 408:10  
**paring** 413:3  
**Parisi** 2:9 21:22 22:1  
 45:6 85:12 107:7  
 276:9 280:7,13 281:7  
 281:12,15 282:4  
 312:19  
**parking** 397:21  
**parsimony** 392:19  
 402:6 418:4,5  
**part** 6:17 7:1 14:13 21:6  
 24:18 31:20 46:5  
 55:18,18 94:12,15,19  
 95:19 100:9 102:5,6,8  
 102:10 115:10 125:8  
 127:16 128:12 133:20  
 139:18 140:18,21  
 149:3 154:19 158:5  
 160:21 163:17 164:3  
 167:14 169:19 175:3  
 186:10 195:19 196:11  
 196:16 197:1 202:22  
 210:2,12,18 214:18  
 216:12 228:13 231:22  
 253:1 281:20 285:21  
 288:10 310:3 316:21  
 318:16 319:6 320:1  
 321:2 323:18 324:4  
 324:22 330:12 332:13  
 332:17 333:1,2,5  
 346:19 347:21 348:3  
 348:14,15,21 349:6  
 349:11 354:18 369:21  
 386:1,3 394:21 396:4  
 396:9 397:12,14  
 399:18 404:11 406:6  
 408:13 410:8 413:19  
 421:1  
**PARTICIPANT** 315:7,10  
**participants** 213:5  
 224:8,21 248:22  
**participate** 10:12 27:19  
 157:7 364:4,6,9  
**participated** 6:17 18:8

21:20 108:8  
**participating** 9:17  
 108:3 126:21 248:12  
 364:12  
**participation** 12:15  
 79:2 360:8  
**particular** 18:15 20:20  
 26:16 28:22 44:7 47:7  
 47:8 85:4 90:8 108:22  
 114:1 196:6 210:18  
 212:21 224:22 228:18  
 251:20 256:16 271:2  
 278:16 281:2 282:1  
 283:9 304:8 330:5  
 332:7 384:20,21  
 385:9  
**particularly** 6:6 10:19  
 13:1 43:7 209:17  
 245:5 280:10 297:7  
 382:9 383:22 397:17  
 419:10,11  
**partners** 21:9 417:12  
**partnership** 1:12 2:5  
 15:11 32:5 33:15 43:4  
 44:12 57:15  
**Partridge** 1:9,12 6:3  
 8:16 9:2,18 15:9,10  
 28:13 29:21 42:22  
 51:21 84:20 85:19  
 86:7,11,19 88:8 90:13  
 91:9 121:7 123:14  
 131:20 132:6,10,17  
 133:1,11 135:20  
 136:1,5 149:13  
 160:18 165:1 174:10  
 174:15 188:22 189:9  
 189:12,19 190:4,10  
 190:19 191:4,6  
 196:21 197:20 200:20  
 201:17 202:13,22  
 206:12 208:17 212:2  
 214:6 216:7,13  
 217:15 221:4 225:7  
 227:4,21 233:2,14,22  
 236:1,18 237:11  
 239:3,13 241:8,11  
 242:2 246:5 257:11  
 258:11 259:22 260:17  
 261:20 263:17 264:10  
 264:14,20 270:7  
 290:9 293:22 294:5,8  
 294:22 302:3,9,19  
 307:8 309:11 310:19  
 311:5 313:18 314:16  
 315:4,8,13 325:13  
 326:5 331:10 337:22  
 339:2 343:22 348:17  
 351:2 353:5,15 354:2

355:2,8 362:20  
 367:22 371:12,15  
 374:19 375:2,5,21  
 376:14,20 380:12  
 381:2 384:4,12  
 385:21 387:4,7,14  
 388:10,17 390:19  
 391:5,11,14 392:3,6,9  
 392:18 394:20 397:14  
 406:18 421:10,18  
**parts** 10:21 94:5 96:16  
 116:19 125:4 126:15  
 130:3 153:2 396:6  
**pass** 53:5,6 55:3 82:12  
 120:1 153:2,3 166:4,4  
 400:21  
**pass/not** 52:14  
**pass/recommended**  
 52:11  
**passed** 132:19 136:2  
 412:15  
**patience** 66:10  
**patient** 2:5 9:13 24:18  
 25:3,4 26:11,12,13,15  
 26:17,19,21,22 35:5,9  
 35:20,21 36:1,6,6  
 37:22 38:19 39:2  
 41:11,14 44:7,12  
 45:22 47:3 56:14  
 63:21 64:12,15 65:3,5  
 65:6 67:2 70:4,22  
 71:7 72:6,6,8,17,21  
 73:8 76:1 77:22 83:20  
 94:16 96:17,18 98:21  
 99:14 100:20 101:3  
 102:20 104:4,16,22  
 106:6 109:5,5 111:14  
 122:2,9 131:3 143:16  
 143:19 144:13 152:7  
 158:7,22 171:20  
 177:11,16 192:13  
 193:1,12,14,21  
 197:18 200:6,12  
 204:17 211:1 212:21  
 214:16 215:19,21,22  
 219:8 221:21 222:17  
 224:4 225:13 226:2  
 227:1 229:3 230:17  
 232:10,11,12 234:6  
 243:3 252:21 255:8  
 256:5 260:7 283:6  
 295:21 296:7 300:15  
 300:21 311:12 321:8  
 322:12 332:9 335:5  
 338:12 342:4,4,12  
 343:10 347:14 360:20  
 363:5,12,12 366:2  
 368:5,9,16 369:15,17

371:3 377:13,15  
 378:16 399:3,14,19  
 399:21 406:16 412:19  
 414:13,14,19 415:2  
 419:11,14,15,18  
 420:3  
**patient's** 35:8,10 45:12  
 130:10 142:1 158:1  
 192:3 194:4 242:22  
 414:2  
**patient-centered** 15:1,3  
 15:15 16:18 412:21  
**patient-level** 77:4  
 221:11  
**patient-report** 63:5,17  
 230:3  
**patient-reported** 8:2,11  
 16:17,19,21 19:12  
 21:12 24:10 35:4,7  
 38:9,22 39:7 49:22  
 64:17,20 65:10 87:15  
 191:18 193:4  
**patients** 2:6 4:9,10,12  
 4:13,15,16,18 5:5,9  
 21:1 25:18,22 35:2,16  
 36:13 46:12 61:12  
 62:13 70:4,6 71:2,10  
 72:20 78:8,14,21 79:4  
 79:5,8 80:20,21 82:6  
 83:15 89:6 90:4 98:18  
 100:1,4,7,12 101:6,22  
 102:6 103:10 107:14  
 108:8 110:12 111:10  
 111:11 112:5,10  
 117:22 127:1 128:11  
 128:20 129:14 140:11  
 140:12 142:21 160:6  
 161:17 162:14 179:18  
 192:14 193:9 194:1,2  
 194:6,12,13,15  
 196:12 198:15 199:4  
 200:15 202:9,11  
 203:7,7 204:12 205:8  
 207:19 208:14 209:4  
 209:20,22 210:6,21  
 216:8 218:10,20  
 222:22 223:6,13,16  
 224:10 228:4 231:21  
 232:3,6 234:12,13  
 235:11,15,18 243:3  
 244:13,18 245:5,11  
 245:12 247:15 249:1  
 249:22 250:1 252:5  
 254:15,20 255:4  
 259:15,17 277:20  
 280:10 303:15 309:3  
 315:18 317:21 318:3  
 318:5,9 319:1,1,12

320:13,16,17,18,19  
 320:20 321:21 322:4  
 322:21 323:4,4 324:7  
 328:6,22 329:6  
 331:22 336:4 338:4  
 338:10,17 344:8,19  
 345:5,10,15,18  
 356:12 358:2,7,20  
 359:4 360:10 361:7,9  
 362:17 364:5,8,11,19  
 365:13 372:20,22  
 373:2,6,8,19 374:1,7  
 374:11 382:22 383:1  
 383:6,9 388:7 411:20  
 411:20 415:5 416:8  
 416:10,13 418:6,11  
 418:12 419:1,2,3,22  
 420:6,17,19 421:8,14  
**pause** 183:19 272:15  
 368:1  
**pay** 38:5 47:19 115:19  
**pay-for-performance**  
 57:11 58:12  
**payer** 72:11 73:14  
 74:18 91:7 112:19  
 113:2  
**paying** 114:22  
**payment** 47:17,21 48:6  
 285:11 323:19 333:5  
 334:20,21 335:6,8  
 338:14 345:11 347:22  
 351:13 397:5 410:4  
**payment-based** 174:12  
**PC** 2:12  
**PCORI** 16:17 19:21  
 24:1 25:7  
**pediatrician** 14:18  
**pediatricians** 15:17  
**pediatrics** 14:19 15:4  
 15:15 164:3  
**peer** 383:17  
**peers** 108:16  
**pen** 114:20  
**penalties** 48:7  
**penalty** 48:13  
**pencil** 92:4,6  
**pending** 240:16,17  
**penlight** 101:19  
**Pennsylvania** 1:16  
 139:14  
**people** 13:17 79:17  
 83:14 94:18 95:12,13  
 101:1 106:21 116:7  
 126:21 131:10,14  
 142:10 154:8 160:9  
 162:13 175:18 184:11  
 211:12 218:11,22  
 255:18 271:10 273:11

273:12,17 274:8  
 276:2,19 277:2  
 278:10 279:14,20  
 283:13 285:13 286:8  
 289:5 305:2 307:22  
 308:15,22 309:6,14  
 312:2 316:3 317:19  
 318:6,7 319:4,14  
 326:18 328:3 329:2  
 333:8 343:15,20  
 344:21 377:6 382:10  
 391:10,18 392:4  
 393:16 395:22 399:10  
 400:7 404:18 405:19  
**people's** 103:15  
**perceive** 22:6 106:1,2  
 129:14  
**perceived** 36:5 129:19  
 319:12  
**percent** 5:4,7 51:3,14  
 52:7,8,12,13,15 77:19  
 83:9 89:6,12,21 93:7  
 103:9 119:1,1,2,2,10  
 119:11,11 120:3  
 126:13,14 134:9,9,9  
 134:10,14,14,15,15  
 134:19,19,20,20  
 135:2,2,3,3,8,8,9  
 141:13 147:15 148:13  
 148:17,18,21 149:12  
 149:17 151:8 155:20  
 156:19,22 157:11  
 166:1,1,2,7,8,8,9,18  
 166:19,19,19 167:3,4  
 167:4,4 180:18,19,19  
 180:19 181:9,10,10  
 181:10 182:2,3,3,3,15  
 182:16,16,16 183:5,5  
 207:15 217:1,1,5,6,6  
 217:7,12,13,13,14  
 222:21,21 223:17,19  
 223:19 224:4,8,9,13  
 224:17,18,19 227:10  
 227:11,11,12,18,19  
 227:19,20 230:19,21  
 232:3,5,17,18 240:2,3  
 240:3,4,13,13 244:1,1  
 257:18,18 258:1,2,2,3  
 258:9,9,10,10 261:2,3  
 261:3,4 262:11  
 267:13,13 269:11  
 277:4,6,22 278:3,6,17  
 294:11,11,14,14,15  
 294:15,20,20,20,21  
 296:18,19 298:3,6  
 299:5 300:2 302:16  
 302:17,17,17 311:2,3  
 311:3,3 314:1,1,2,2,7

314:7,8,8,14,15  
 315:17 327:20 332:14  
 332:20,21 341:16  
 342:1 353:20,20,21  
 353:21,22 354:5,5,6,6  
 361:8 375:10,11,14  
 375:14,15,15,18,19  
 375:19,20 380:21,22  
 380:22 381:1,11  
 382:3 384:7,18  
 385:10,19 387:11,12  
 387:12,13,19,20,20  
 387:21 388:3,3,4,4,9  
 388:9 406:8,9,15,16  
 417:14  
**percentage** 36:13 112:5  
 149:5 157:9 174:3  
 209:19 231:21 235:19  
 245:12 265:22 283:3  
 314:11 331:22 341:17  
 358:20 372:16 382:20  
 382:21 383:16  
**percentages** 51:18  
**percentile** 149:16  
 296:17  
**percentiles** 149:15  
**perception** 130:14  
**perfect** 106:14 109:21  
 215:17 412:8  
**perform** 268:1 379:13  
**performance** 8:4,4,9,13  
 19:13,21 20:6 36:10  
 37:16,19,21 38:2,3,5  
 38:22 39:2,8 41:22  
 47:19 58:7 59:22 60:1  
 60:9 64:16,21 65:2  
 77:5,9 79:1,7 83:5  
 90:19 103:1,1 107:21  
 108:1,4,5,10,12,12,15  
 108:17 109:9 110:19  
 119:3,4,6 140:10  
 141:13,15,17 145:3  
 147:11 148:4,9,16  
 159:20 166:13 187:3  
 198:13 201:20 217:2  
 219:4,11,19 247:12  
 248:1,4 257:19  
 266:22 294:12 311:12  
 311:14 326:10 340:5  
 340:8 343:6,17 346:5  
 347:11,17 350:17  
 354:3 356:10 357:1  
 361:15 363:10,13,17  
 367:17 370:21 375:11  
 385:13,15 400:14  
 404:16 405:19 422:4  
**performed** 194:21  
 206:14 208:4 219:14

245:16 246:14  
**performer** 91:13  
**performers** 112:2,3,3,9  
 148:10  
**performing** 194:22  
 199:17 230:20 397:20  
**performs** 311:11  
**period** 53:4 98:8 140:13  
 196:18 210:1 211:22  
 213:20 271:11,20  
 281:7 287:19 300:15  
 308:16 343:12,13,17  
 360:4,9 401:18  
**periodic** 140:21  
**perioperative** 24:6  
 177:7  
**Permanente** 2:9 17:18  
 17:20  
**permission** 264:22  
**person** 1:3 6:7 9:3,7  
 32:8,12,15,16 33:12  
 34:3,7,11,13 38:7  
 46:13 70:14 105:12  
 106:10 128:13 174:17  
 208:19 292:17 301:19  
 311:11 323:13 337:5  
 337:6,9,11,17 343:12  
 356:19 371:21 407:21  
 408:3 413:11 414:19  
 420:3  
**person's** 273:20 280:2  
 323:10 337:10  
**personal** 25:20  
**personally** 10:14 176:7  
**persons** 208:8 215:5  
 372:16  
**perspective** 45:9 47:9  
 85:7 103:6 107:10  
 175:13 179:15 259:7  
 284:5 338:2 349:22  
 394:21 395:6 403:5  
 414:2,3,3  
**perturbations** 296:5  
**Peter** 2:11 18:4 45:6  
 124:1 131:20 156:17  
 208:17 317:11 319:16  
 337:22 351:4 371:19  
**Peter's** 127:8 287:2  
**phase** 1:3 6:17 8:22  
 30:8,20 31:19,20  
 32:18 33:3,7 38:10  
 39:9 40:17 49:19,21  
 50:4 137:8 223:12,15  
 248:8 369:3  
**phased** 225:4  
**phases** 223:10 320:3  
**PhD** 1:15,19,21 2:1,8  
**phenomenon** 136:13

**Philadelphia** 1:16 16:13  
**philosophy** 203:15  
 213:1,11 291:1  
**phone** 66:5 67:5,6  
 138:12,16 265:14  
 316:15 355:11,13  
 356:1 388:12,16  
**photo** 391:2 403:14  
**PHQ** 404:19  
**PHQ-9** 36:7,15 46:10  
 404:10,21 417:11,16  
**physiatrist** 27:4  
**physical** 27:5 34:17,20  
 45:10 46:2,15 65:18  
 70:19 73:13 74:19  
 98:11 100:5 103:11  
 106:20 140:3 215:9  
 263:10 266:19 316:12  
 357:21 365:9 403:20  
 404:6,6 405:12 406:1  
**physician** 2:7 16:7  
 45:16 78:8 139:19  
 185:21 186:6 214:18  
 221:10,12,22 222:11  
 234:4 238:4,16 363:7  
 413:1  
**physician-level** 221:16  
**physician-reported**  
 234:10  
**physicians** 78:7 111:11  
 211:12 234:3,16  
**physiological** 372:7,13  
**physiology** 365:9  
**Physiotherapy** 63:2  
**pick** 30:10 113:14  
 314:19 344:7,9 410:1  
**picked** 85:20 414:18  
 421:7  
**picture** 10:6 285:7  
**piece** 51:10 53:16  
 111:17 172:13 251:9  
 408:21  
**pilot** 198:11 203:1  
 218:3,17 223:15  
 224:8,21 229:7,10  
 232:15 245:22 248:1  
 248:8,12,22 250:15  
 332:18 346:2 347:4  
**pilot-testing** 228:13  
**piloted** 222:18 331:13  
 402:14  
**piloting** 223:6  
**pilots** 223:10 248:20  
 249:13  
**Pitzen** 3:9 189:5,11,16  
 191:3,5,10,12 195:16  
 197:7 199:13 201:5  
 201:14 203:3,9

204:21 206:9,13  
 209:11 212:12,17  
 216:11 223:8 228:11  
 231:22 234:18 242:11  
 248:6 249:15 252:15  
 254:7,13 255:22  
 257:5,10 264:7  
**place** 55:21 89:19 185:9  
 185:10 231:15 312:3  
 322:8 370:4 408:10  
**placed** 93:14  
**plan** 5:5 140:8 141:9  
 150:7,12,17 152:13  
 153:9 154:4 157:21  
 158:10 167:19,22  
 168:22 169:2,12  
 170:4,8 172:19,20  
 173:9,12,16 175:20  
 177:13 178:5,21  
 179:3 180:9 185:10  
 186:1,15,20 188:3  
 210:6,15 211:1  
 231:11 235:8 249:5  
 315:19 319:22 322:7  
 330:11 332:11 333:1  
 333:14,22 334:1,4  
 338:11 341:9 344:6  
 344:16 347:7 349:1  
 349:13,14 352:17  
 369:20,21  
**plane** 11:9  
**planning** 142:17 143:15  
 230:17 320:9  
**plans** 22:4 142:2  
 169:18 177:2 180:7  
 249:2 285:12 353:11  
 362:15 416:6  
**platform** 62:21  
**play** 274:19 285:22  
**plays** 130:17  
**plea** 135:15 415:18  
**please** 12:17 27:21  
 53:18 54:3 118:3,21  
 143:6 152:19 178:15  
 183:14,16 233:10,11  
 242:11 388:14 422:4  
**pleased** 191:16  
**pleasure** 139:14  
**plot** 299:8  
**plug** 215:12  
**plus** 84:16 113:7  
 289:17  
**PM** 50:16 133:20  
**point** 40:12 45:13 48:3  
 58:17 59:16 75:11  
 87:19 89:22 94:3  
 111:16 113:5 118:1  
 137:16 147:21 150:3

154:14 155:18,20  
 156:13 161:14 164:10  
 172:17 174:7,22  
 176:5 188:3,14  
 194:18 205:16 208:16  
 216:6 219:17 233:10  
 235:3 237:5,6,16  
 239:6 253:12 256:9  
 283:21 287:2 297:12  
 297:14 301:13 304:13  
 304:18 307:3 308:14  
 309:16 312:14 313:11  
 313:16 328:21 330:16  
 333:19 337:8 345:17  
 346:2 347:4 348:19  
 349:22 350:11,13  
 351:18 352:2,6 354:8  
 384:2 395:14 396:4  
 402:11 404:15  
**pointed** 246:10,16  
**pointing** 310:9  
**points** 12:6 37:15 38:12  
 38:21 84:6 131:8  
 188:4 199:3,3 207:12  
 246:2 302:22 304:15  
 355:21 368:4 386:10  
 391:20  
**policies** 303:7 305:12  
**policy** 15:10 19:7 65:22  
 122:15 208:20 303:3  
 306:2  
**politely** 246:17  
**Poonam** 3:8 316:10  
 319:7 327:19  
**poor** 283:17 285:9  
**poorly** 383:1  
**populated** 187:14  
**population** 34:2 39:5  
 41:11 44:7 71:1  
 101:16 119:6 144:16  
 148:3 157:11 159:15  
 160:2 192:13 193:1  
 194:9 196:15 197:18  
 200:6 209:19 210:15  
 218:13 219:8 222:18  
 223:18 224:5,14  
 230:13 243:3 244:16  
 252:21 269:21 270:16  
 271:6 277:3,5,9  
 281:22 286:6,17,21  
 291:11 296:5 297:9  
 304:12 318:21 320:16  
 326:10,18 336:9  
 345:9 374:5 383:3,4  
 401:15  
**population's** 400:10  
**populations** 41:14  
 71:13 106:18 160:4

291:9 321:8 329:22  
 330:2 369:10 401:19  
**portal** 229:3 232:13  
**portals** 411:22  
**portfolio** 32:13,16  
 42:14 220:9  
**portion** 113:21 278:13  
**portrayed** 305:9  
**poses** 17:1 20:8  
**position** 381:6 410:4  
**positive** 287:10  
**positives** 101:12  
**possibilities** 81:16  
**possibility** 184:7 281:4  
**possible** 8:9 51:7 71:15  
 104:8,12,14,20 111:4  
 137:9 160:19 193:17  
 204:1 226:8 270:18  
 290:7 334:7 335:5  
 355:18 357:14 393:4  
 403:16  
**post** 218:4 232:18  
 263:14 310:9 316:8  
 351:12 360:7,21  
 361:7  
**post-acute** 21:3 22:3,8  
 32:5 285:16 290:19  
 291:4,8 323:18  
 324:10 333:5 334:20  
 334:21 335:4 338:14  
 346:16 347:22  
**post-op** 206:21 218:12  
 232:16  
**post-operative** 209:21  
 232:5,22  
**post-operatively**  
 222:20 231:19  
**post-public** 241:4  
**post-surgery** 91:11  
 204:5 259:9  
**posted** 137:12,18  
**postop** 244:12  
**postoperational** 243:2  
**postoperative** 191:19  
 193:15,17 194:7  
 196:18 200:14 205:7  
 231:4 244:14 249:9  
 252:7  
**postoperatively** 192:5  
 193:19 194:3 198:21  
 203:6 244:9 253:1  
**potential** 48:4 112:21  
 150:21 167:13 194:16  
 197:2 208:21 220:9  
 234:13 235:22 253:10  
 254:9  
**potentially** 208:1 247:2  
 287:13 288:5 345:2

348:6  
**power** 413:15  
**powered** 160:12  
**powerful** 417:18  
**Powers** 2:11 18:5  
**PQRS** 65:9,12 154:19  
 164:16,20  
**PR-PMs** 56:12  
**practical** 81:13  
**practice** 128:6 140:18  
 144:3 161:2 192:20  
 198:12 206:15 243:19  
 250:5 251:1 260:8  
 305:1 306:2 358:7  
**practice-level** 260:11  
**practices** 18:1 141:5  
 199:20 200:3,19  
 213:4 223:4 229:2,12  
 229:17 243:9 246:3  
 248:11 249:10,16  
 250:17 260:9 284:19  
 284:19  
**practicing** 62:18  
**practitioner** 45:10  
**practitioners** 248:14  
**Pratt** 285:15  
**PRD** 291:19 334:19  
**pre** 209:21 210:15  
 218:12 222:20 230:10  
 232:21 244:12,14  
 249:9 252:22 259:8  
 263:14 360:7,21  
 361:7  
**pre-meeting** 53:17  
**pre-op** 218:4 231:18  
 232:20  
**pre-operative** 210:20  
 228:19 230:15,18  
**precise** 130:5 180:13  
 365:18  
**precisely** 379:18  
**precision** 222:1  
**predict** 72:11 75:22  
 93:6  
**predicted** 67:16 72:14  
 81:4 83:15,16 116:12  
 117:1 140:22  
**predicting** 69:13 76:11  
 276:18  
**prediction** 81:4 82:5  
 351:16  
**predictions** 72:19  
**predictive** 98:17  
**predictor** 75:12 76:12  
 211:18  
**predominant** 126:9,10  
**predominantly** 283:9  
**preference** 280:2

**preferences** 280:6  
**preliminary** 149:22  
**preop** 231:5  
**preoperative** 162:5  
 192:3 194:6 231:3  
 235:7 243:1  
**preoperatively** 198:21  
 244:8 249:5  
**preparation** 149:6  
**prepare** 124:14  
**prepared** 30:15,16  
**preparing** 43:13 124:20  
 409:18  
**prescribe** 46:13  
**prescribed** 287:20  
**prescriptive** 226:13  
**present** 1:11 3:1,19  
 42:14 61:20 76:18  
 87:7 90:22 107:20  
 109:16 142:4 164:22  
 195:3 265:16 269:2  
 315:16  
**presentation** 65:20  
 404:14 413:6  
**presented** 47:14 49:18  
 62:7 63:6 88:3 112:12  
 126:8 196:3,7 244:6  
 308:6  
**presenting** 6:19 23:11  
 80:17 191:16 197:19  
 220:2 253:2 257:7  
 265:19 290:17 317:13  
 345:4 356:11  
**president** 9:10 21:10  
 22:1,13 29:6 356:6,21  
**presiding** 1:10  
**press** 118:12,19 183:16  
 388:14  
**pressure** 266:12 307:14  
 346:22 348:10 379:10  
 405:4,6  
**pressures** 329:2  
**pretty** 46:8 85:9 95:1  
 147:11 172:2 177:5  
 190:13 213:19 264:4  
 273:19 282:22 295:3  
 295:22 296:18 306:15  
 329:15 331:7 344:8  
 382:10 388:22 395:7  
 397:9,20 405:11,16  
 410:7 415:4  
**prevalence** 90:20  
**prevent** 256:4 282:3  
 307:16  
**preventing** 304:7  
**prevention** 267:1  
**previous** 31:19 244:21  
 326:16 379:20 403:13

**previously** 171:18  
 226:19 244:6 316:19  
**previously-published**  
 267:9  
**primarily** 65:14 252:1  
**primary** 61:15 192:15  
 193:2 210:10 211:6  
 223:12,17 224:12  
 229:12 273:21 274:3  
 374:17  
**prime** 49:5  
**prior** 55:13 74:6 75:10  
 76:13 120:8 143:11  
 143:12 193:13 194:9  
 234:5 244:8 249:2  
 266:7 272:2 275:4,4  
 377:20  
**priori** 24:14 71:2  
**priorities** 34:2,6  
**priority** 34:8,9,12 84:18  
 134:5 166:21 217:8  
 249:19 250:2 258:4  
 266:9 294:17 375:16  
**private** 33:21 364:6  
**prize** 151:18  
**PRO** 8:21 50:15 118:17  
 193:5 194:14 225:3,5  
 243:14 257:13  
**pro-based** 36:10 193:5  
 242:21  
**pro-concepts** 36:5  
**PRO-PM** 36:9 39:4 43:7  
 50:5,12 133:21  
**PRO-PMs** 391:21  
 401:22  
**probability** 184:7  
**probably** 10:17 26:7  
 42:17 44:5 47:5 59:3  
 60:19 61:8 70:9 90:7  
 94:1 102:3 115:19  
 132:22 137:15 138:7  
 143:2 151:17 156:1  
 195:12 202:5 204:19  
 207:7 218:20 233:12  
 238:20 259:16 272:6  
 295:12,16 304:20  
 310:13 333:9 345:14  
 364:1 374:11 381:18  
 389:7 394:8 407:9  
**problem** 70:9 81:20  
 104:5 129:21,21  
 130:9 153:6 205:20  
 219:5 259:11  
**problematic** 377:15  
**problems** 96:20 101:21  
 102:15 104:22 155:22  
 172:6 185:11 329:8  
 370:3 382:21

**procedural** 215:3  
 306:13  
**procedure** 90:19  
 192:17 193:3,14  
 197:12 206:8,14  
 211:9 216:3 224:1  
 243:5 244:9 245:3,10  
 245:15 246:16,18  
 247:17,18 249:6  
 250:1 252:8 253:14  
 254:17,22 255:4  
 263:13  
**procedure-wise** 306:12  
**procedures** 22:16  
 192:20 194:21,22  
 196:13 197:4 243:9  
 245:13 246:10,14  
 249:22 421:1  
**proceed** 138:4 191:7  
 241:14  
**proceeding** 188:22  
**process** 4:7 13:10  
 27:18 30:18 33:3 38:8  
 38:18 48:9,20 49:22  
 50:15 51:2 52:3 53:8  
 55:22 60:4,17 61:2,6  
 62:17 63:22,22 65:15  
 66:11 67:15 73:17  
 79:21 116:18 118:18  
 124:12,16 132:1  
 133:17 142:13 143:18  
 144:22 145:6 153:19  
 154:10,13 155:1  
 161:18 162:3,5  
 167:15 175:14 184:20  
 185:3 194:11,14  
 195:13 203:19 212:20  
 216:18 228:13 229:1  
 229:7 230:15 231:1,7  
 231:11 232:1 235:13  
 244:17 247:14 261:19  
 305:1,19 319:20  
 320:2 321:10 325:1  
 330:12,18,21 331:8  
 344:3 350:3 352:15  
 352:17 353:1 354:19  
 361:20,21 363:16  
 364:3 370:9 371:7,11  
 387:1 409:2,4 415:1  
 419:19  
**processes** 63:19  
 203:12 282:16  
**procession** 63:16  
**produce** 58:10  
**product** 23:9 74:4  
 210:11 410:2  
**professional** 12:10  
 192:22

**professor** 7:19 16:14  
 19:10 20:11 23:16  
 357:9  
**prognosis** 269:13  
 288:15  
**program** 21:20 48:12  
 154:19 157:8 164:20  
 283:11 292:4 301:8  
 325:9,22 346:20  
 357:5,7,16 358:4  
 361:18,19,21 362:7  
 363:19 364:4,13  
 365:16,16,20 366:4  
 367:4,17 373:5  
 386:18,22  
**programs** 15:20 33:18  
 33:20,20,21 49:14,15  
 58:10,14 358:4,17  
 359:13 360:22 361:10  
 361:16,22 362:6,12  
 362:14 363:6,14,21  
 363:21 364:2,6 365:1  
 366:3 367:7,14 369:5  
 369:17,22 387:2,2,2  
**progress** 262:19  
 280:11  
**progression** 126:16  
**project** 4:6 31:14,18,21  
 31:22 32:15 42:5,6  
 137:8 226:11 248:10  
**projected** 83:1 273:8  
**projects** 19:20 333:8  
 408:22  
**proliferation** 394:22  
 396:16 417:22  
**prolonged** 414:17  
**PROM** 36:3,11 87:7  
 89:9  
**PROMIS** 8:11 16:19  
 19:16,22 252:19  
 257:1 403:15 404:21  
 411:10  
**promise** 11:12 404:9  
 422:3  
**promote** 21:18  
**promoted** 176:9  
**promoting** 177:6  
**PROMs** 21:18  
**proper** 259:12  
**properly** 197:5  
**properties** 39:19 84:5  
 193:9 243:20 352:18  
**prophecy** 221:19  
**proportion** 76:20  
 108:10 112:10 148:2  
 201:3 268:7 278:4,7,8  
**proportionally** 381:17  
**propose** 321:11

**proposed** 47:17 317:10  
320:11  
**proposition** 410:7  
**PROs** 21:20 46:1  
**prove** 287:4  
**provide** 33:16,18 38:17  
39:4 49:17 62:1 81:7  
82:11 116:9 140:22  
142:15 220:15 225:21  
239:11 250:22 262:15  
355:1 368:14,21  
378:11,15 409:4  
**provided** 57:4 77:4  
113:4,9,10 120:11  
141:12 150:17 165:16  
217:18 226:9 229:6  
239:8 296:21 363:4  
366:13 377:11  
**provider** 22:3 35:10  
46:6 62:9 77:10  
111:19,21 117:8  
141:13 178:4 342:3  
391:15 395:10 398:8  
**providers** 21:2 35:22  
62:6,12,22 63:3 119:6  
140:7 146:6 147:13  
147:14,22 148:3,8,19  
148:21 149:4,5,10  
156:21,22 157:3,5,6  
158:22 160:5 172:9  
179:11 292:9 397:2  
411:22 416:5  
**provides** 270:3  
**providing** 38:15 283:14  
287:13 409:1  
**proving** 283:21  
**provision** 140:8  
**provisional** 240:15  
**provisions** 273:2  
**provocative** 386:7  
**proxy** 210:11 399:20  
**psychometric** 193:9  
243:20 352:17  
**psychometrically** 99:18  
**psychometrician** 23:13  
316:17  
**Psychometricians**  
167:7  
**psychometrics** 64:6  
87:14  
**psychosocial** 100:4  
**PT** 72:3 157:19  
**PT/OT** 62:18  
**public** 4:20 5:19 33:20  
38:4 48:14 55:13  
57:11 65:22 88:16,17  
88:21 89:1,2 93:15  
113:16,17 117:13

120:9 183:11,14,16  
183:18 187:4 188:18  
188:19 213:3 241:3,6  
270:2 316:11 317:4  
325:1,3 354:15  
388:11,14,15  
**publically** 117:13 350:7  
**publically-held** 62:5  
**publications** 64:8 87:14  
**publicly** 195:22 231:10  
231:11 266:21 268:14  
284:7 292:5 297:18  
**publish** 231:15  
**published** 97:19 231:13  
276:17 336:21 404:13  
405:15  
**pull** 59:9,11 84:12  
114:15 149:19,19  
201:15 237:22 276:7  
**pulled** 116:14  
**pulmonary** 5:9 355:17  
356:8,10,13 357:5,11  
357:13,15 358:9,13  
358:17 359:3,10  
360:2,7,21 361:18  
362:5,12 363:20  
364:1,12 365:1  
371:22 372:11 373:3  
373:4,19,22 374:4  
376:18 379:5 382:10  
385:10 386:9 388:7  
**purpose** 49:20 130:13  
154:11 269:9 306:8  
306:19 369:8,14  
378:18,19 400:5  
401:13,15 414:6  
**purposes** 82:9 168:5,12  
275:19 369:11 401:1  
410:4  
**purview** 163:14 397:12  
397:15  
**push** 100:15 253:14  
394:8 406:6  
**pushed** 232:12  
**pushing** 238:14 384:18  
**put** 7:3 16:9 42:9 43:11  
62:10 69:12 97:21  
177:13 187:10 197:16  
200:9 211:1 215:11  
238:6 246:11 274:15  
274:17 278:18 299:16  
306:19 312:7 320:20  
322:8 325:1,4,6  
330:11 336:6 337:15  
380:9 400:16 404:2  
404:12 406:21 421:19  
**puts** 414:5  
**putting** 168:10 177:2

186:7,7 197:5 252:16  
273:9 321:2 386:5  
**Pyles** 2:11 18:5

---

## Q

---

**QI** 398:4  
**QIOs** 285:14  
**QM** 306:7  
**qualified** 15:17 65:11  
**qualify** 213:1 225:1  
323:1  
**qualitative** 167:22  
**quality** 1:1,8,18 2:3  
15:13,21 17:10 19:4  
21:5,10 22:1,14,21,22  
27:9 29:6,11 34:14,16  
34:21 35:12 43:16  
47:15 48:5 55:17 58:9  
58:11 88:16 107:9  
113:4 130:21 138:12  
138:20,22 139:2,4,13  
139:19 153:12 162:17  
168:18 180:8,9 187:4  
196:1 199:7,10 206:3  
210:19 247:13,21  
248:13 251:4 266:8  
266:13 282:15 283:17  
284:16,16 285:9  
286:20 290:3 292:7  
296:14 300:4 301:6  
301:11 304:21 315:17  
319:19 321:12 322:10  
325:9,22 326:3,11  
333:9 344:3,12,15  
345:7 346:20 351:14  
356:22 357:17 359:13  
362:7,15 363:3,6,15  
365:12 367:8,14  
377:12 406:14 410:15  
410:18,20 411:2,7  
**quality-of-life** 210:17  
252:18  
**quantifies** 243:16  
**quantify** 197:16  
**quantifying** 188:12  
**quarter** 189:12 267:14  
267:15 268:5,9,17,17  
269:11 272:3 277:21  
278:5 281:2,8,10  
297:17 298:2,19  
300:14 349:3,8  
**quarterly** 280:21  
408:21  
**quarters** 268:19 297:19  
298:17 300:13,17  
**quartiles** 83:8  
**question** 39:20 41:19  
42:8 43:12 45:18

46:18,19 48:16 67:14  
67:22 70:11 85:3  
88:15 89:5 92:11  
97:21 98:2,3 101:8  
102:9 105:17 107:8  
108:22 113:14 116:4  
117:3,5 120:18  
123:21 124:2,7 125:1  
127:8,12 128:10  
131:21 132:18 143:3  
143:4,6,7 144:19  
145:5 147:10,18  
149:14 153:4 155:6  
160:2,21 162:22  
167:8 168:7 170:17  
171:12 175:2 177:22  
193:7 201:2,6 202:1,5  
204:4 206:10 209:1  
225:10 234:19 238:2  
240:14 243:16 247:9  
254:4,4,8 256:19  
261:19 276:5,9  
280:14 284:3 287:11  
287:22 288:9,11  
291:12,14 303:10,21  
305:16 306:11,13  
308:20 309:13 325:17  
332:12 338:13 339:1  
343:9 344:14 346:15  
361:12 363:19 367:20  
370:10 371:2 376:1  
378:5 394:17 403:21  
407:20 408:12 411:16  
411:17,18 418:14  
420:5  
**questionable** 104:2  
**questionnaire** 73:3  
232:11 256:12 359:12  
**questionnaires** 8:1  
140:17 141:3 259:16  
259:20 377:7  
**questions** 27:15 38:13  
39:11 46:3 56:5 58:21  
96:14 100:18 101:10  
103:16 114:12,14,15  
121:19 124:13 128:14  
131:12 137:6 142:6  
142:10 174:19 177:20  
195:4 199:14 200:20  
214:7 229:9 231:17  
233:3 236:19 257:2,3  
325:12 329:9 359:18  
380:13 381:9 382:13  
382:15 390:10 402:12  
402:18 403:8,9,10  
406:21 407:11,12  
418:17  
**queue** 28:21

**quibble** 274:20  
**quick** 30:6 98:2 118:9  
 121:21 138:15 162:21  
 167:8 211:11 215:17  
 272:16 297:4 376:1  
 384:17  
**quickly** 32:12 51:2  
 81:19 113:13 136:19  
 205:5,13 248:17  
 390:22  
**quite** 8:21 9:1 28:10,18  
 44:18 49:4 95:7 124:4  
 146:20,21 196:19  
 204:7 229:6,14  
 289:21 295:18 324:20  
 336:10 371:18 373:2  
**quorum** 51:3,6,10  
**quote** 151:22  
**quoted** 156:20  
**quotes** 363:5

# R

**R** 76:3 296:18  
**R-squared** 296:19  
**race** 158:22 159:14  
**race/ethnicity** 210:9  
 224:6,9  
**radically** 418:16  
**raise** 302:11 312:15  
**raised** 123:18,18  
 259:11  
**raises** 250:7  
**Rand** 2:11 20:13 24:9  
 59:12  
**random** 298:18  
**randomized** 24:14  
 160:10 178:18 374:15  
**range** 48:4 133:19  
 148:16 151:8 201:22  
 223:20 237:21 332:1  
**ranges** 382:6  
**Ranging** 48:5  
**rankings** 300:3  
**ranks** 295:10 296:17  
**rant** 418:19  
**ranting** 417:19  
**Rasch** 59:2 71:21 86:17  
 104:6 267:19 307:20  
**rate** 77:19 141:13  
 148:12 194:8,12  
 222:20 230:20 231:3  
 231:4,20 232:16,21  
 248:21 253:5,7 271:9  
 271:18 278:2,6,9,16  
 300:16,20 371:4  
 414:15  
**rated** 230:1 386:20  
**rates** 141:15 204:9

213:8 218:11 225:4,5  
 230:11,18 232:20  
 249:7 290:2 311:11  
 319:13,14  
**rating** 229:22 266:10  
 415:14,15 416:20  
**ratings** 266:3  
**rational** 118:16  
**rationale** 38:17 60:16  
 95:21 125:5 142:15  
 196:11 216:16 337:14  
 342:9 384:3  
**raw** 360:12,18  
**re-vote** 354:16  
**re-working** 389:22  
**reach** 54:10 64:20  
 121:10 389:5  
**reached** 52:6,12,17,21  
 53:5  
**reaction** 62:10  
**read** 7:2 43:14 151:20  
 152:4 174:11 218:6  
 331:18 341:3  
**readily** 395:7  
**reading** 74:1 342:2  
 419:21  
**readmission** 319:13  
**ready** 49:4 93:18 189:7  
 190:11 216:14 225:7  
 227:4 233:4 257:11  
 260:18 302:3 310:19  
 313:18 351:3 355:14  
 380:14,15 387:16  
**real** 28:4 30:5 51:2  
 79:22 81:20 109:5  
 132:12 136:19 138:15  
 175:16 205:13 240:19  
 254:8,9 328:9 382:2  
**realistic** 404:1 406:4  
**realize** 94:21 253:3  
 381:19  
**realized** 141:1 412:19  
**really** 7:9 9:1 15:7  
 25:19 26:1 27:18  
 28:18 29:9,18 30:14  
 31:1,4 42:19 45:2,4  
 48:16 52:9 54:13 58:3  
 59:13 68:12 83:2,6  
 85:8 100:9 102:7  
 103:14 104:20 107:2  
 114:11 117:6 125:19  
 125:22 128:5 130:9  
 131:18 139:10,10  
 145:5 146:8 152:4  
 154:15 155:2 159:19  
 169:13 172:14,21  
 173:1,22 176:18  
 177:5 178:7 184:22

187:6 188:13 197:10  
 203:19,22 204:13  
 205:1,7,18 206:4  
 207:4,9,10 208:11  
 213:14 214:17 215:13  
 215:17 221:19 234:2  
 250:9,12 251:3,5,16  
 255:1,3 279:9 281:20  
 286:12 295:15 300:4  
 307:18,21 308:4,11  
 311:12 312:22 313:2  
 318:21,21 320:14  
 321:4 324:15 326:9,9  
 330:6 334:8 336:5  
 338:7,9,22 339:5  
 342:15 344:20 345:15  
 347:3 348:19 349:7  
 349:15 351:15 358:10  
 358:11 361:14,15  
 366:3,17 373:6 381:9  
 383:5,10 387:1 391:3  
 393:19 395:15 396:1  
 399:6 400:3 404:20  
 410:17 411:12 413:3  
 413:7,10,16,16 414:8  
 414:13,16,18 415:2  
 415:18,18,22 416:9  
 416:12 417:9,17  
 418:1  
**reason** 86:19 98:15  
 126:7 130:6 176:4  
 196:16 254:21 273:16  
 288:6 337:8,11 385:3  
 393:9 408:13  
**reasonable** 49:15 222:4  
 225:12 226:5 322:15  
 342:9,10 384:20  
 385:12 404:1  
**reasons** 184:2 254:18  
 285:11,19 373:13  
 379:19 398:4  
**Rebecca** 1:18 24:21  
**recalibrate** 130:2  
**recall** 12:8 54:15 76:4  
**recap** 344:14  
**receive** 287:8  
**received** 12:8,12 16:15  
 65:7,9  
**receiving** 252:9  
**recognition** 16:2 141:2  
**recognize** 151:12  
 154:13 251:19 278:14  
 279:14 297:12  
**recognized** 16:3  
**recognizing** 61:4  
 297:17  
**recommend** 293:17  
**recommendation** 40:3

135:18 293:14 385:18  
**recommendations**  
 33:17,19 57:19  
 109:22 385:22 386:4  
**recommended** 32:22  
 52:14 56:10 101:19  
 358:6  
**recommending** 56:8  
 386:2  
**reconsider** 241:4  
**reconsideration** 59:21  
 60:8 354:16  
**reconsidering** 40:12  
**reconvene** 315:5  
**record** 99:15 118:6  
 136:9 154:5 161:1  
 169:2,12 170:13,21  
 170:22 172:13 190:8  
 274:4 276:12,14  
 315:2 337:8 398:15  
**recorded** 56:15  
**recording** 144:12  
**records** 332:17 360:21  
 366:2 398:14  
**recover** 319:1  
**recovery** 75:13 204:16  
**recuse** 20:17  
**recycled** 285:19  
**red** 311:8  
**Redesign** 17:11  
**reduce** 60:22 63:18  
 244:15 394:22  
**reduced** 99:19 266:13  
**reducing** 304:6  
**reduction** 152:13 335:1  
 335:2  
**reevaluate** 151:13  
**reexamination** 140:21  
**refer** 53:18 158:18  
**refereed** 64:7  
**reference** 58:20 234:4  
 282:10  
**references** 77:4  
**referral** 266:18  
**referred** 35:18 317:22  
**referring** 80:9 122:21  
 340:1  
**refers** 36:3  
**reflect** 30:14 243:22  
 301:11  
**reflected** 43:10 46:1  
 75:20 224:4 234:8  
 313:14  
**reflecting** 200:12  
**reflection** 282:5  
**reform** 323:19 333:5  
 334:20,21 335:8  
 338:14 347:22 351:13



**reforms** 345:11  
**refresher** 54:14  
**refused** 337:11 342:4  
**refusing** 342:10  
**regard** 112:21 145:8  
 266:22 267:22 268:4  
 269:15  
**regarding** 12:6 30:20  
 37:16 40:22 55:9  
 87:19 106:2 120:19  
 226:19 237:16 261:9  
 293:8 354:18  
**regardless** 235:15  
 244:18  
**region** 253:8  
**regions** 95:18 201:21  
**register** 233:15 325:5  
**registered** 316:22  
 317:2  
**registry** 65:12 140:15  
 174:2,4 360:3  
**regularly** 128:8 162:15  
**rehab** 9:14 20:5 56:18  
 62:6 106:20 203:7,8  
 208:20,21 213:20,22  
 214:14 215:1,2,9  
 317:5 324:12 356:8  
 356:10 357:5,11,13  
 357:15 358:9,13,17  
 359:3 360:2,7,21  
 361:18 362:5,12  
 363:20 364:1,12,17  
 365:1 372:11 373:3,5  
 374:8 376:18 379:3,5  
 382:10 385:10 386:9  
 389:11 394:5 400:1  
**rehabilitation** 5:9 18:7  
 20:7 23:1 27:5,9 37:2  
 37:4 64:11 200:14  
 266:18 317:1 355:17  
 356:13 364:15 373:19  
 373:22 374:4 388:8  
 399:2,9 410:19  
**rehab** 379:2  
**rehospitalizations**  
 357:19  
**Reilly** 265:11,13,13  
**reimbursed** 364:11  
**reiterate** 131:8  
**relate** 60:17 104:22  
 252:7  
**related** 5:1,2 15:7 18:2  
 19:8,18,18 34:4 35:12  
 40:5,9,13,19 41:1,8  
 52:20 54:1 85:15 92:7  
 94:2 100:18 102:7  
 105:5 107:8 137:17  
 191:19 211:19 212:4

218:16 243:12,17  
 253:19 269:19 273:7  
 280:14 287:11 303:2  
 303:12 308:8 317:17  
 325:7 326:16 334:4  
 351:5 358:10 384:17  
 406:6 418:15  
**relates** 17:5 102:11  
 107:8 108:16 172:14  
 279:2 358:12  
**relationship** 118:17  
 195:20 216:16  
**relative** 266:7 295:14  
**relatively** 184:11 277:9  
 393:22  
**releasing** 362:11  
**relevance** 406:1  
**relevancy** 101:5  
**relevant** 9:15 12:15,21  
 13:3,13 21:14 84:15  
 139:21 211:3 270:13  
**reliability** 50:2,3 54:20  
 55:4 57:8 58:16,18  
 90:9 112:15 132:4  
 134:11 145:9,9,13,18  
 146:14 151:1,6,7,15  
 167:9 169:9,21  
 180:12 184:3,9,13  
 198:3 199:17 205:14  
 212:4 217:15,19,22  
 218:17 219:3,10,18  
 220:6 221:8,9 225:16  
 227:6 238:4,11,12,16  
 251:2,10 258:12  
 259:2,7 260:4,6,11,19  
 262:2,8,12 267:18  
 268:5 276:21 295:1,2  
 295:4,7,18,21 296:8  
 297:16 302:4,7,7,9,10  
 302:10,12,13 312:8  
 312:16,17 316:20  
 332:3 346:11 349:10  
 359:12 365:17 369:13  
 375:21 376:21 378:2  
 378:12 380:15,16  
**reliable** 57:22 104:16  
 218:5 225:17,19  
 269:5 275:18 297:7  
 333:22 359:2 362:8  
 365:19 366:8,11  
 369:7 374:5 379:21  
**reliably** 235:20  
**rely** 27:18 114:8  
**remain** 244:3  
**remaining** 67:15 355:9  
**Remarks** 4:2  
**remember** 40:1 49:21  
 174:12 184:14 397:16

**reminder** 14:11 27:17  
 28:11 55:2 265:8  
**reminders** 13:16  
**remote** 148:15  
**removal** 30:20  
**remove** 274:13 308:17  
**removed** 323:7  
**render** 119:17  
**rendering** 326:7  
**repeat** 85:15 143:6  
 282:20  
**replace** 404:21  
**replacement** 4:22 20:1  
 192:1,16,17 196:7  
 204:12,15,20 207:7,8  
 209:4 211:7,7 214:12  
 215:6 223:12 224:2  
 235:2 240:8  
**replacements** 198:8  
 199:11 206:22 208:20  
 213:17 223:17  
**replied** 359:11  
**report** 8:2 35:7,19 36:1  
 117:9 148:1 203:13  
 224:9 225:6 231:11  
 235:21 284:7 292:7  
 327:1,21 328:15  
 332:13 333:3 342:17  
 350:7 361:3 374:20  
 386:1,4,6  
**reported** 35:6 36:6  
 56:15 64:16 139:20  
 145:19 148:3,21  
 150:16 164:20 169:9  
 211:9,10 226:22  
 268:14 292:5 297:18  
 300:17 368:6 419:11  
**reporting** 38:5 57:11  
 82:9 139:19 140:12  
 140:13 144:19 145:2  
 147:14 148:8,10,18  
 185:8 187:5 188:1,8  
 194:10 195:22 196:1  
 211:8 213:3 231:8,10  
 248:13 266:21 270:2  
 285:13,18 300:15  
 303:2 325:9,22 327:1  
 327:10 346:20 369:20  
 410:17  
**reports** 82:11 301:14  
**represent** 13:22 14:1,1  
 14:3 18:7,11,20  
 306:10  
**representative** 222:22  
**represented** 6:22 306:3  
 360:22  
**representing** 13:19  
 25:3,21 129:20

**represents** 18:12 123:7  
 358:16 414:2  
**reproduce** 170:2  
**reproducibility** 170:18  
**reproducible** 169:21  
 365:19 366:12,19  
**requested** 116:18  
**requesting** 121:2  
**requests** 112:16  
**require** 61:2 275:8  
 330:22 386:11  
**required** 39:1 140:12  
 151:10 248:14 249:4  
 287:20 310:13 326:4  
 327:7,7 330:20  
 364:22 368:8,15  
 378:22 398:20  
**requirement** 51:3 60:9  
 280:19 308:17 396:12  
**requirements** 55:19  
**requires** 295:10  
**requiring** 203:21  
**research** 8:3,14 12:11  
 13:2 16:8,13,18 17:5  
 17:8,22 18:2 20:14  
 21:13 23:7 27:2 64:4  
 64:19 65:19 66:3  
 76:22 81:5 143:13  
 144:4 243:19 316:11  
 317:4,6 319:3 373:17  
 383:21  
**researcher** 16:15 66:2  
 350:1 408:8  
**reserve** 397:21  
**Residence** 190:17  
**resident** 266:4 280:15  
**resident's** 266:19  
**residents** 5:7 265:22  
 266:6 267:3,7 269:11  
 270:1,4 274:17  
 280:21 283:3 292:3  
 314:11  
**residual** 66:21 67:3,17  
 67:20 72:18 76:15  
**residuals** 66:20 68:12  
**Resnik** 3:10 66:5 67:5,6  
 67:13 68:15 69:5,17  
 70:2,17 71:8,18 72:5  
 72:16 73:7 74:8 75:1  
 75:15 76:17 78:1,4,9  
 78:18 80:8 83:10 87:3  
 87:22 88:19 89:8,16  
 90:6,21 93:4 95:3  
 97:6 98:15 99:4,8  
 106:4 107:20 109:13  
 109:16 111:16 114:19  
 116:5 131:7 135:17  
 136:4

**resolution** 235:5  
**resolved** 101:18  
**resource** 351:21  
**resources** 398:13,20  
**respecify** 174:9  
**respect** 77:18 123:19  
 254:11  
**respectfully** 256:1  
 386:13  
**respecting** 280:6  
**respiratory** 318:11  
 365:8  
**respond** 179:17 237:12  
 239:2 284:3,4 290:11  
 291:13  
**response** 63:19 86:17  
 113:16 133:9 146:2  
 218:10 222:19 247:8  
 250:13 263:19 337:19  
 359:20  
**responsibility** 214:5  
**responsible** 214:22  
**responsive** 130:5  
**rest** 29:22 58:2 85:6  
 108:21 123:9 156:9  
 278:11 291:13 319:2  
**restated** 339:7  
**restaurant** 416:18  
**restore** 286:13  
**restraint** 292:21  
**restratify** 360:14  
**resubmit** 55:12  
**result** 161:20 163:15  
 252:8 368:9  
**resulting** 62:9 269:7  
**results** 80:13 118:22  
 154:6 171:1 172:20  
 191:17 194:17 240:17  
 240:18 245:22 246:3  
 268:6 269:4 289:9  
 368:10  
**resume** 12:18,19  
**resumed** 136:10 190:8  
 315:2  
**retire** 155:20  
**retool** 398:14  
**retraining** 358:5 364:20  
**retrievable** 229:18  
**return** 189:17  
**returned** 232:12,13  
**reverse** 264:17  
**review** 10:15 24:10  
 30:22 31:4 32:14 33:4  
 36:17 38:10,16 39:9  
 74:10 85:4 128:8  
 163:13 179:20 250:15  
 311:19,21,22 319:7  
**reviewed** 32:18,21 33:2

107:18 260:14 290:13  
 383:17  
**reviewer** 145:19  
**reviewers** 25:8 84:22  
 90:16 121:8 125:14  
**reviewing** 41:21 44:13  
 64:15 86:21 319:8  
**reviews** 220:5  
**revised** 301:16  
**revision** 192:16 193:3  
 211:7  
**revisions** 65:14  
**revisit** 61:8 255:12  
**revote** 52:22 53:2,3  
 241:7 294:1,4,7  
**rewrite** 340:22  
**Rezek** 3:11 139:3,3  
 147:20 178:1  
**ribs** 125:12  
**right** 10:9 17:16 27:22  
 42:10,10 57:5 67:3  
 71:8 72:5 73:7 74:20  
 75:15 78:8 82:1 85:17  
 85:22 86:4 90:21  
 114:19 117:15 119:22  
 126:11 132:17 133:14  
 143:20 144:22 147:12  
 147:12 148:20 149:1  
 149:18 150:4 152:5  
 152:20 153:5 154:1,8  
 155:11 156:4,4  
 158:17 159:16 165:13  
 169:17 170:10 171:4  
 171:10 174:18 175:18  
 175:19 177:16 179:10  
 183:10 187:7 189:13  
 189:19 190:16 201:10  
 202:18,18,21 205:14  
 215:7 216:14 228:5  
 230:19 233:1 236:10  
 237:9 238:1,5 254:5  
 257:9 258:19 260:11  
 263:3 264:7 271:7,22  
 274:6 275:16,20  
 278:12 282:7,8 288:8  
 290:11 291:6 301:21  
 303:19 306:16 309:12  
 315:13 316:18 321:10  
 326:22 328:3,7,10  
 331:2,13 336:12  
 338:17 339:16 340:14  
 342:3,8 347:19  
 350:18 365:5,14  
 366:18,20 369:6  
 371:18 374:14 380:12  
 384:9 387:2 388:17  
 389:14 391:5,17  
 392:10 393:20 394:15

400:10 405:14 409:12  
 410:16 413:14,17  
 417:8 418:15  
**right-hand** 69:2,14,18  
 69:18  
**rigidly** 10:18  
**rigor** 313:1,8  
**rigorous** 64:5  
**rise** 246:16  
**risk** 65:2 67:14 68:15  
 71:11 73:17 74:10,14  
 74:15,21 75:17 78:19  
 79:7 81:2 89:1 98:4  
 98:13 102:18 103:4  
 105:15,17 112:17  
 113:2 116:5,6,9,21  
 117:9 203:16 209:2  
 234:7 235:9 245:20  
 251:10 266:12,16  
 269:15,17 270:20  
 279:16 286:17 304:14  
 304:15 308:20 318:14  
 326:2 328:2,3,5,6,9,9  
 373:1  
**risk-adjust** 211:13  
**risk-adjusted** 67:20  
 72:7,18 81:7,8 280:8  
**risk-adjustment** 209:9  
 210:7 211:2 224:16  
 258:19  
**risky** 176:22  
**RN** 1:21 2:3,9 45:12  
**Robert** 29:12  
**role** 15:16 45:4 130:17  
 285:21 351:1 408:1  
**roll** 169:8 255:20  
 336:12 339:16 340:13  
**rolled** 176:13 255:13,17  
**rolls** 344:10  
**room** 1:8 151:18 211:13  
 277:10 388:11 415:20  
**root** 238:10  
**roughly** 93:9  
**round** 273:1 307:3  
**routine** 81:14  
**routinely** 98:10 228:10  
 230:7 232:3  
**RTI** 265:18 291:16  
 316:12,17 317:3  
 355:1  
**rubric** 153:17  
**rulemaking** 57:17 325:5  
**rules** 79:3  
**ruling** 287:3,10  
**run** 53:15 82:4 139:7  
 177:1 210:6 239:8  
 357:20 363:21 364:13  
 365:3,7

**running** 357:5 386:18  
**runs** 361:19 403:8  
**rural** 32:7 158:22  
**rushed** 415:20  
**Russian** 63:8

---

**S**


---

**S** 4:1  
**Sadly** 16:8  
**safe** 337:17  
**safer** 401:16  
**Safety** 21:10 26:19  
**Saliba** 2:10 20:10,10  
 88:14 99:2,5 123:20  
 214:8 265:8  
**salt** 148:5  
**Sam** 27:3 407:19  
**sample** 78:6,16 79:10  
 79:15 82:8,14,19 90:9  
 149:1 169:10,16  
 184:12 203:2 223:3  
 255:16 267:11 278:4  
 278:11 280:15 366:15  
**sampled** 79:18 414:1  
**samples** 89:18  
**sampling** 80:1 164:21  
 280:14,22 288:4  
**SAMPSEL** 30:4 39:21  
 40:10,15,18 49:16  
 54:13 119:22 133:15  
 138:10 147:2,5,8  
 163:12 165:12 166:11  
 180:21 219:20 226:4  
 240:20 242:8 261:5  
 262:7,16,21 293:1  
 331:3 354:8 355:10  
 355:14,20 356:3  
 368:3,13,18 370:5  
 378:3,19 389:17  
 392:14  
**SAMUEL** 1:17  
**sanguine** 79:12  
**Sarah** 30:3 41:7 53:12  
 54:11 59:17 139:6  
 183:8 219:20 310:9  
 370:2 392:11  
**Sarah's** 7:4  
**satisfied** 170:10  
**satisfy** 312:2  
**saves** 12:4  
**saw** 102:14 104:1 231:2  
 268:20 291:18 332:7  
 338:15 340:8  
**saying** 6:14 70:12  
 91:12 102:12 114:16  
 156:21 159:5 172:12  
 173:6 176:21 251:5  
 253:4 256:20 274:11

292:16 312:15 330:9 395:12 402:6 407:20 414:21 421:21 <b>says</b> 49:1 103:20 136:14 151:22 152:2 173:11 277:20 328:13 341:5,8 342:3 382:18 404:17 <b>SBL2</b> 364:18 <b>scale</b> 8:7 36:4 86:15 96:7 98:7 100:6 160:16 194:19 199:5 204:6 207:12 217:21 218:1,18 246:2 252:21 308:9 337:4 359:18 368:19 374:16 405:7,7 <b>scales</b> 97:11 <b>scenario</b> 219:13 <b>scheduled</b> 137:11,13 189:20,22 388:20 389:4 <b>scheduling</b> 11:11 138:2 <b>school</b> 1:13,14,16,21 2:1 7:21 14:20 17:4 400:13,20,21 <b>science</b> 29:18 64:1 65:19 219:16 <b>Sciences</b> 7:20 19:10 <b>scientific</b> 2:15 29:8 54:19 55:4 58:4,5 64:5,7 <b>scientist</b> 178:17,18 317:6 <b>scoliosis</b> 243:13 <b>scoop</b> 312:20 <b>scope</b> 250:5 <b>score</b> 5:17 36:14 39:2,3 67:1,17 69:4,15 71:9 72:7 81:4,7,8 114:17 117:9 152:11 154:7 155:17,19 161:11 187:5 193:6 194:19 199:12 206:4 207:20 207:21 210:16 219:4 219:11,19 228:19,20 230:6 231:3 235:8,10 244:20 259:8,8 264:3 268:11 292:19 331:17 331:20 339:17 340:12 340:13,16 366:19 <b>score-level</b> 260:3 <b>scored</b> 24:11 152:15 243:22 <b>scores</b> 46:11 58:7 70:20 72:18 74:14 78:22 82:6 91:20 92:3 111:12 114:4 115:5	131:13 193:21 198:19 202:11 205:15 210:20 220:6 225:20 231:14 231:16 234:17 252:18 267:12 268:8,13,15 268:17 362:8 365:19 366:12 370:21 <b>scoring</b> 55:2 152:20 193:11 <b>screen</b> 39:15 59:9 147:12 <b>screening</b> 234:4 <b>script</b> 380:2 <b>scrutiny</b> 249:2 259:10 <b>se</b> 25:19 <b>search</b> 209:8 <b>second</b> 48:15 62:22 84:1 111:2 167:17 168:15 203:11 233:12 242:13 303:19,20,20 392:15 407:19 <b>Secretary</b> 320:8 <b>section</b> 276:7,7 278:20 332:16 335:11,12 <b>sections</b> 335:10 <b>see</b> 6:4 10:6 20:7 29:16 42:3,17 44:20 56:20 71:2 76:8,19 80:9 83:18,22 86:18 91:3 98:21 100:19 101:9 108:3,6,9,12 110:5,18 111:2,11 121:19 122:9,22 123:21 124:16 130:15,22 136:4 137:22 146:17 148:13,17 151:14 164:19,21 174:6 180:1 186:20 197:3 204:15 207:2 230:10 241:12,15 247:6 250:4 252:12 268:10 268:14 279:3 282:14 286:5 299:8 300:2 303:14,15,18 307:13 315:5 324:17 331:5 332:5,8 335:3 339:12 346:14 351:4 354:13 355:3 364:17 370:2 376:8 378:22 383:7,9 407:3 408:2,5,6 409:6 410:2 413:11 415:7 415:15 417:1,21 419:13,18 422:2 <b>seeing</b> 107:15 125:6 231:5 232:2,9 256:9 264:5 295:13 299:22 329:4 377:16 <b>seen</b> 59:3 111:10 112:1	121:22 140:13 338:17 399:5 <b>segment</b> 304:12 <b>segue</b> 109:21 <b>selected</b> 25:10 193:7 271:2 383:2 <b>selecting</b> 234:12 <b>selection</b> 33:17 95:15 104:3,4 149:1 196:12 200:15 271:1 303:14 304:10 <b>self</b> 8:1 321:15 322:12 334:12 335:21 340:15 <b>self-care</b> 308:10 <b>self-performance</b> 266:4 311:10 <b>self-report</b> 130:22 131:3 <b>self-reported</b> 24:2 <b>self-selected</b> 148:7 <b>semi-permeable</b> 414:4 <b>send</b> 214:14 228:5 342:16,17 394:10 <b>sending</b> 214:14 <b>senior</b> 15:10 21:10 29:5 31:14 107:4 317:4 <b>seniors</b> 400:13 <b>sense</b> 20:9 41:16 77:10 93:18 123:17 126:1 127:17 128:5 132:9 162:12 166:4 167:14 188:7 201:12 222:7 244:4 246:22 263:11 270:17 271:5 273:12 273:14,14 287:9 304:19 312:6 326:14 336:9 382:3 397:6 <b>sensible</b> 271:3 307:17 <b>sensibly</b> 43:11 <b>sensitive</b> 153:6 <b>sent</b> 121:17 <b>sentence</b> 341:8 <b>sentiment</b> 264:4 <b>separate</b> 88:6 126:17 131:12 409:19 <b>separated</b> 130:6 <b>separately</b> 211:10 <b>separating</b> 106:18 127:5 297:8 <b>serve</b> 15:20 71:13 128:20 158:1 362:3 <b>served</b> 9:4 13:6 37:22 44:8 52:4 64:3 <b>service</b> 1:21 14:4 38:19 115:20 118:19 216:18 <b>services</b> 17:3 20:14 31:21 43:15 139:12 266:19 283:15 284:1	291:8,10 <b>serving</b> 229:10 <b>session</b> 9:12 10:11 139:7 <b>sessions</b> 360:9 <b>set</b> 31:5 34:4 42:10,10 42:20 44:2 46:9 47:1 49:10 63:4 90:5 114:3 215:6 251:20 279:21 301:22 304:22 322:15 326:1 346:18 350:9 350:10 389:15 390:12 395:4 401:2 404:19 407:3,9 418:17 <b>sets</b> 32:17 44:16 255:19 393:5 <b>setting</b> 36:22 37:2 44:6 45:1 46:12 90:1 164:6 164:10 224:3 235:9 279:19 284:14,22 285:2 286:5 290:19 316:7 324:11 342:18 357:20 383:6 385:10 401:18 407:13 410:22 411:3 <b>settings</b> 37:14 44:3,8 44:17 71:5 284:17 290:18 291:4 321:7 323:3 324:15 333:2 335:4,4 346:17 348:6 374:8 392:21 393:6,9 394:4,6 396:5,19 397:1 410:11,14,15 411:5 <b>seven</b> 37:1,9 61:20 63:6 64:20 65:10 166:1 271:10,20 272:7 391:4 <b>severe</b> 320:20 358:7 364:5 374:2 <b>severely</b> 71:3 72:2,2 <b>severity</b> 24:11 <b>sexual</b> 256:19 <b>SF-36</b> 63:13 86:16 401:17 <b>shadowing</b> 30:9 <b>shaking</b> 91:17 <b>shape</b> 6:11 <b>share</b> 75:12 200:4 210:8 220:10 223:13 235:6 248:19 256:7 309:17 393:16 419:14 <b>shared</b> 205:5 239:7 293:6 300:3 <b>SharePoint</b> 59:10 <b>Sharon</b> 1:20 24:17 375:22 <b>she'll</b> 31:11
--	--	--	---

**sheet** 58:18  
**Sherri** 2:3 25:14  
**Sherrie** 2:1 23:12 42:8  
 43:1 61:14,16 66:16  
 85:1 91:16 97:22  
 108:19 109:22 120:11  
 151:16 156:8 162:20  
 173:6 175:8 176:13  
 185:6 200:22 202:14  
 220:16 221:4 241:16  
 259:22 295:19 339:3  
 370:19 402:6 403:2,5  
 403:7 413:20 414:21  
**Sherrie's** 208:21  
**Sherry** 362:21 376:21  
**shift** 345:20  
**shoes** 336:6  
**shoot** 412:8,9  
**shooting** 232:4  
**short** 87:11 88:20 93:5  
 113:17,20 114:5,14  
 115:16 117:7 265:9  
 272:10 274:12 361:2  
 361:5,13 362:18  
 402:22  
**shorten** 389:8  
**shorter** 385:14 402:14  
**shortly** 49:9  
**shoulder** 4:15 96:18  
 102:13,13,15 103:10  
 103:20 104:5 174:17  
 186:19,20 403:19  
**show** 36:20 60:10  
 120:21 122:19 218:3  
 236:7,9,13,15 267:18  
 268:1 307:22 331:16  
**showed** 60:21 111:18  
 169:5 373:21 379:20  
**showing** 121:3 123:2  
 147:1 188:3 267:21  
**shown** 73:4,6,19  
 104:19 150:22 267:14  
 357:16 366:7  
**shows** 37:5,9 88:20  
 91:6 207:12 341:1  
**Shrift** 3:12 138:22  
**sick** 317:21 318:6 323:4  
 324:8 336:4 337:10  
**side** 25:6 69:2,3,14,16  
 69:18,18,22 223:19  
 226:7 253:10 259:17  
 329:2 336:13 396:22  
**sidelines** 23:6  
**sign** 23:20  
**signal** 297:12  
**signal-to** 297:20  
**signal-to-noise** 268:6  
 296:1 297:16 298:10

299:19  
**signed** 157:7,10  
**significance** 159:2  
**significant** 9:1 96:19  
 130:1 133:18 141:17  
 158:20 161:7 202:7  
 204:16 208:1 268:20  
 303:3 360:15  
**significantly** 146:13  
 268:8,11,15 298:4,8  
**signs** 416:1  
**silence** 28:9 233:16  
**similar** 10:21 41:10  
 64:20 99:19 105:21  
 124:4 127:19 129:9  
 202:2 260:13 261:6  
 282:16 290:14 314:19  
 319:21 379:9 389:20  
 394:1,7 398:15  
 402:16 407:2  
**similarities** 242:17  
**similarity** 389:7 391:2  
**similarly** 99:18 114:3  
**simple** 129:6 228:20  
 325:17 402:21 416:19  
 416:20,21  
**simpler** 404:5  
**simplicity** 193:10  
**simply** 60:16 350:11  
**Simultaneous** 76:6  
 368:12  
**single** 38:13 216:2  
 268:5,9 297:16  
**single-item** 36:4  
**sit** 13:16 15:4 17:9 21:4  
 23:9 28:9 336:12,13  
 413:10  
**site** 22:10 59:10 323:18  
**sits** 404:16  
**sitting** 10:10 14:5  
 336:13 349:3  
**situation** 55:7 384:21  
**situations** 144:4  
**six** 28:9 99:13 204:14  
 204:18 208:14 269:13  
 272:8,17 273:16,22  
 274:13 287:19 288:16  
 293:8 302:17 309:15  
 311:3 314:8 317:9  
 337:4,4 341:16  
 353:20 354:5 358:21  
 359:1 360:6 362:11  
 363:17 366:5 372:19  
 373:9,10,11,17  
 374:10,17 379:8,13  
 384:22 385:4,9  
 386:18 387:3,12  
 388:3,9 389:3 391:4

406:10,13  
**six-month** 205:4 310:2  
**Sixteen** 217:5  
**Sixty-eight** 258:8  
**sixty-five** 387:20  
**Sixty-seven** 314:1  
**size** 78:16 82:8 101:11  
 184:12 198:12 201:3  
 202:17 226:20 236:22  
**sizes** 82:14,19  
**sketchy** 307:21  
**ski** 106:19  
**skill** 129:11 255:19  
**skilled** 37:3,8 291:20  
 324:11 415:13 417:1  
**skip** 189:20 315:6  
 336:16,18  
**skipped** 315:6  
**skirted** 420:22  
**skis** 105:3  
**sleeping** 342:4,8  
**slice** 299:15  
**slide** 35:15 36:22 37:5,9  
 39:6 49:20 51:20 57:7  
 58:3 108:6 118:4  
**slides** 31:11 32:11  
 34:10 36:16,19 49:18  
 80:9  
**slight** 281:4  
**slightly** 332:21 421:3  
**slot** 190:1  
**slotted** 10:16  
**slow** 59:18  
**smack** 299:6  
**small** 65:17 81:17,17  
 82:13 89:5 90:3,10,12  
 110:13 148:2 156:3  
 203:2 209:18 296:18  
 393:8 394:2  
**smaller** 78:13 157:9  
 174:5  
**smallest** 238:17  
**smiling** 47:22 48:2  
**Smith** 3:13 265:3,11,15  
 265:17 271:13,17,22  
 272:18 273:4 274:2  
 276:11 277:4,7 278:3  
 279:12 280:12,18  
 281:9,13,16 282:9  
 288:5,10 289:12,20  
 291:6 297:11 300:6  
 303:18 316:19  
**smokers** 224:18,19  
**SNF** 43:20 56:18 348:11  
**snowing** 189:14  
**social** 7:20 19:10 22:18  
 24:21 34:18  
**societies** 141:7

**society** 20:22 235:1  
 379:17  
**socioeconomic** 160:8  
 210:11  
**software** 51:17 81:9  
**soliciting** 399:12  
**Solutions** 2:3  
**somebody** 28:1 66:20  
 103:19 153:5 162:9  
 169:22 170:3,7,8,12  
 170:18 180:5 187:20  
 188:7 205:16 272:14  
 274:14 311:11 323:6  
 327:5,8 328:14 336:6  
 337:7,12 339:16  
 341:19 342:10 348:11  
 381:14 405:2,5,8  
 419:7  
**somebody's** 336:16  
 348:9  
**someone's** 372:6  
**somewhat** 255:10  
 290:14 395:1 416:7  
**Somplasky** 3:14 138:19  
 138:20 164:14,15  
**soon** 251:13 258:22  
 338:21  
**sooner** 205:9  
**Sophia** 3:2 138:18  
 183:20  
**sophisticated** 393:2  
**sorely** 29:15  
**sorry** 7:13 16:17 52:2  
 59:17 69:8 78:12 80:8  
 91:14 93:5 99:8 119:2  
 125:14 132:2 148:14  
 150:2 224:18 261:17  
 264:12 288:10 312:11  
 327:5 329:18 330:20  
 340:11 348:16 349:15  
 351:7 353:6 356:3  
 365:4,6 379:8 393:17  
 414:10 417:19 418:18  
 421:18  
**sort** 7:4 8:10 16:21  
 41:17 42:18 48:20  
 52:8 68:6 77:10 86:18  
 87:2 94:18 103:13  
 120:16 127:14 128:15  
 128:19 148:7,17  
 162:16 169:4 204:6  
 215:3,4 253:15 271:9  
 271:14 273:5 276:14  
 279:19,21 281:20  
 288:14 292:8 334:2  
 349:2 379:2 384:18  
 393:16 397:21 402:10  
 407:20 412:10 416:12

417:6 418:6 420:21  
**sound** 369:6 377:1  
**soundness** 58:5  
**sounds** 61:10 221:19  
 248:7 340:4 369:1  
 418:4  
**source** 103:21 105:20  
 206:7  
**sources** 171:3 173:20  
**Southwestern** 1:17  
**space** 28:22 44:16  
 81:22 379:3 420:20  
**Spanish** 63:7  
**speak** 27:21 28:3 85:3  
 129:2 214:8 257:2  
 356:16 366:6 410:15  
 410:18,20  
**speaking** 76:6 115:21  
 316:3 368:12  
**Spearman-Brown**  
 221:18  
**special** 337:12 407:17  
**specialist** 24:22 26:12  
 27:4  
**specialists** 320:13  
**specialized** 320:21  
 321:3  
**specialties** 197:15  
**specialty** 100:3 141:7  
**specific** 38:21 42:5  
 49:14 52:20 94:5,14  
 95:19 96:14,15 100:9  
 100:9 102:5,6 104:16  
 106:2 121:1 124:19  
 125:8 127:16 129:18  
 153:6 254:17 258:18  
 284:14 323:14 330:1  
 345:6 379:11 380:1,1  
 381:10 385:20 391:21  
 393:5 397:13 399:15  
 399:18 401:1,4,21  
 402:2,2 404:7 408:22  
 412:4 420:16  
**specifically** 25:7 48:11  
 112:18 149:21 173:2  
 185:21 188:12 200:7  
 329:12 385:16 399:1  
 420:18  
**specification** 79:10  
 146:5,10,16 167:9  
 181:3 245:2  
**specifications** 46:5  
 180:13 228:14,15  
 258:16,20 310:3  
 325:1 370:12  
**specificity** 94:9  
**specifics** 125:4  
**specified** 37:7,10 68:16

68:18 103:4 172:1  
 370:15  
**specifies** 78:19  
**specify** 120:20 121:1  
 172:3  
**specs** 384:8  
**speculate** 76:17 382:17  
**speech** 62:18 310:10  
**speed** 112:22  
**spelled** 59:12  
**spend** 128:17 192:10  
**spending** 351:22 390:9  
**spent** 43:3 197:5 319:7  
**spin** 187:10  
**spinal** 245:18 252:4  
 254:5,5 263:7  
**spine** 5:3 63:11 197:18  
 225:2 230:5 242:15  
 243:12 245:3 262:6  
**spiritual** 34:18  
**splines** 80:3 83:1  
**spoke** 413:5  
**spondylolisthesis**  
 245:9,18 246:21  
**sponsored** 374:12  
**spooky** 221:19  
**sports** 71:4 72:3  
**spouse** 399:13,21  
**spread** 18:1 128:4  
 236:21 237:19 238:13  
 366:2  
**spreadsheet** 116:14  
**spring** 248:16 325:3  
**square** 238:10  
**squared** 76:4  
**stability** 295:9 296:11  
**stable** 79:6 108:2  
 268:17  
**staff** 2:14 4:5 6:15 28:7  
 28:8 30:1,15,21 31:3  
 57:3 66:9 121:14  
 219:9 225:10 239:15  
 240:15 241:1 293:10  
 313:3 356:19 367:21  
 386:19 407:1 422:2  
**staffer** 9:21  
**staffing** 303:4 305:20  
**stage** 321:4,9,11  
**staggering** 28:18  
**stairs** 342:21  
**stamping** 176:12  
**stance** 177:5  
**stand** 336:14  
**standard** 22:15 63:4  
 82:18,21 86:8,10,21  
 201:4,8 202:16  
 203:12 207:20 208:7  
 225:13,14,15,18

226:20,21 237:3,7,15  
 237:21 238:7,8,19,20  
 243:21 249:8 295:3  
 303:2 358:7 359:2  
 364:10,22 402:9,21  
 404:3  
**standard-deviation**  
 207:22  
**standardization** 284:21  
 291:18 292:1 311:17  
 317:12 335:3 348:13  
 400:4,22  
**standardize** 290:18  
 312:1  
**standardized** 36:7  
 140:6,16,19 142:16  
 143:14,14 144:1  
 151:22 163:1 167:14  
 172:19 317:14 324:3  
 324:13 334:14 348:5  
 379:11,14,21 395:4  
 396:21 401:17  
**standardizing** 291:2  
**Standards** 1:18  
**standing** 1:3 10:2 16:1  
 233:19 408:14,19  
**standpoint** 47:15,16  
**star** 292:21 303:2  
 388:15 415:14,15  
**start** 14:15,16 32:10  
 50:7,8 61:11 84:8  
 90:17 102:3 109:6  
 117:18 118:3,4,5  
 213:3 215:13 242:6  
 255:3 273:15 315:5  
 369:4 381:14,16  
 384:5,14 393:1 406:8  
 411:11  
**started** 30:7 62:4 63:10  
 64:5 70:16 97:5,5  
 101:19 149:19,19  
 162:7 242:18 346:20  
 347:8 408:13  
**starting** 30:21 62:14  
 66:18 214:20 271:19  
 416:13  
**starts** 118:20 119:9  
 134:7,13,18 135:1,6  
 165:9 166:5,16 167:1  
 180:16 181:7,22  
 182:13 183:3 216:19  
 217:10 227:8,16  
 233:8 239:22 240:9  
 257:14,21 258:6  
 260:22 294:10,14,19  
 302:15 311:1 313:22  
 314:6,14 353:19  
 354:5 374:22 375:13

375:18 380:18 387:11  
 387:19 388:2,8  
**state** 1:20 24:19 63:1  
 66:1 91:17 195:15  
 230:7 235:14 300:20  
 303:1,3,7 357:10  
**state's** 204:9  
**state-based** 305:11  
**stated** 259:6 300:10  
**statement** 187:17 297:5  
 352:10  
**statements** 78:7  
**states** 62:20,20 303:6  
 305:6,7 364:8 391:21  
**statewide** 196:1 203:14  
 248:13  
**statistic** 300:22  
**statistical** 31:6 80:4  
 376:17  
**statistically** 66:21  
 114:17 141:17 158:20  
**statistician** 22:19 24:22  
 114:9 147:19  
**statistics** 199:18  
 224:15 295:18  
**status** 4:9,10,12,13,15  
 4:16,18,21 5:3 24:5  
 32:14 33:4,5,11 35:8  
 35:13,19,20 36:21  
 37:16 38:6 52:21  
 61:12 68:8,17 70:3  
 71:10 72:9 76:12 94:4  
 94:13 95:4,7 112:6  
 117:21 142:1 152:1  
 158:6 160:8 170:7  
 185:9,22 186:17,19  
 191:19,22 192:4,9  
 194:5 195:1 205:8  
 210:11,16 235:7  
 240:7 242:14 243:1,2  
 254:1 263:14 267:4  
 319:12 320:12 392:20  
 397:21 401:19  
**stay** 5:8 11:1 189:17  
 286:11 287:6 422:3  
**staying** 190:17  
**steeped** 8:21  
**steering** 407:22  
**stenosis** 245:18 252:4  
**step** 51:9 203:11  
 264:18 370:8,8 371:7  
**stepped** 7:11  
**steps** 180:7  
**steroid** 263:10  
**Steve** 3:6 355:12 356:6  
**stick** 11:17  
**Stille** 1:9,13 7:6 14:17  
 14:18 46:21 61:10

66:16 84:11 85:17 87:20 88:10 93:16 96:3 97:20 102:2 106:3 107:6 108:19 109:20 115:12 116:3 117:2 118:9,14 119:12,19,21 120:15 122:7,14 123:8 124:1 126:3 127:7 132:15 132:21 133:3 135:10 135:22 136:3,11 138:3 142:7 147:10 148:20 150:1 151:16 153:19 156:4,8,17 158:12 161:12 162:1 162:16 164:12 165:10 167:6 169:7 174:19 176:19 177:17 178:9 178:13,15 180:8 181:12,15,18 182:5,8 182:18,21 183:7,22 184:10 188:17,21 190:13 195:5 202:8 202:18,21 236:20 333:20 341:7,12 393:1,20 394:16 396:8 403:2 407:18 413:14,18 <b>stimulated</b> 45:7 <b>stock</b> 388:18 <b>stop</b> 90:16 100:11 115:13 119:13 124:9 152:16 235:3 247:6 261:6 325:11 328:18 418:18 <b>stopped</b> 55:9 <b>stops</b> 55:5 <b>store</b> 230:1 395:17 <b>story</b> 110:12 361:5 362:18 <b>straight</b> 381:19 <b>straighten</b> 299:20 <b>strategies</b> 139:21 <b>strategy</b> 266:9 282:14 <b>stratification</b> 24:14 106:17 107:4 281:21 <b>stratifications</b> 198:14 <b>stratified</b> 193:2 <b>stream</b> 60:19 <b>street</b> 1:8 190:16 <b>strengthens</b> 341:15 <b>strengths</b> 124:13 <b>strictly</b> 11:3 382:16 <b>strikes</b> 44:9 124:4 306:20 371:21 410:6 <b>striving</b> 402:8 406:4 <b>strong</b> 110:10 144:11 193:8 243:20 358:3	<b>strongly</b> 367:14 <b>struck</b> 28:17 158:13 208:22 419:21 <b>structure</b> 10:21 38:18 41:17 55:22 56:1 118:18 216:18 <b>struggle</b> 271:3 273:15 <b>struggled</b> 199:16 <b>struggling</b> 85:8 161:5 403:1 <b>students</b> 400:11 <b>studies</b> 17:21 104:19 267:9 276:18 383:20 <b>study</b> 89:20 160:11 198:11 203:4 207:18 208:14 211:22 217:20 218:3,17 346:2 347:5 374:18 416:11 <b>stuff</b> 77:11 84:18 88:11 169:15 174:13 202:10 381:12 396:7 408:2 419:22 <b>sub-domains</b> 34:21 <b>sub-group</b> 345:6 <b>subcontractor</b> 195:18 195:20 <b>subgroup</b> 274:12 <b>subject</b> 12:21 13:7,21 221:8,8 259:9 409:1 <b>subjecting</b> 249:20 <b>subjective</b> 277:11 <b>submission</b> 127:3 194:12 229:2 231:16 280:16 326:8 356:15 <b>submit</b> 109:14 111:17 203:22 229:2 260:15 321:13 347:20 <b>submitted</b> 19:13 32:19 33:7 43:14 74:2 91:1 121:9 244:16 249:5 281:2 331:19 354:15 366:1,9 <b>submitting</b> 61:21 <b>subscribe</b> 115:20 116:8 117:14 <b>subscriber</b> 117:10 <b>subscribers</b> 108:2 <b>subsequently</b> 30:11 <b>subset</b> 335:14 <b>subsidize</b> 63:3 <b>substantial</b> 296:11 <b>substantially</b> 123:13 278:1 <b>substituting</b> 7:6 <b>suburb</b> 25:17 <b>success</b> 255:9 <b>successful</b> 229:18 245:4	<b>successfully</b> 63:21 <b>suffer</b> 36:2 <b>sufficient</b> 120:22 159:2 211:13 352:22 353:1 378:16 <b>sufficiently</b> 160:12 308:8 <b>suggest</b> 161:15 171:6 269:4 299:22 314:17 <b>suggested</b> 268:2 413:8 <b>suggesting</b> 131:22 132:3 205:4 256:6 268:21 <b>suggestion</b> 263:5 386:7 386:12 <b>suggests</b> 141:4 143:13 307:16 <b>suitability</b> 182:19,22 240:5 314:10 388:5 <b>suite</b> 73:18 94:7,22 151:22 163:1,19 171:17 <b>sum</b> 228:20 <b>summarize</b> 12:18 24:11 <b>summarized</b> 133:16 <b>summarizing</b> 12:20 <b>summary</b> 38:15 228:19 246:7 270:12 282:11 302:22 <b>summed</b> 193:21 <b>super</b> 409:16 <b>superior</b> 41:3 <b>supplement</b> 8:19 107:21 <b>supplemental</b> 91:2 107:22 347:20 357:22 364:19 <b>supplementary</b> 111:17 <b>support</b> 60:3,11 66:9 118:16 141:7 291:9 291:11 307:2 308:18 352:9 363:4 369:13 <b>supported</b> 377:10 <b>supporting</b> 32:3,6 293:10 308:19 <b>supportive</b> 2:13 96:12 <b>supports</b> 216:16 <b>supposed</b> 154:20 363:9 397:13 403:13 <b>sure</b> 7:17 21:14 28:10 31:10 41:16 44:22 50:17 52:2 54:4 56:2 56:15 57:3,22 58:7,20 59:4 71:22 83:22 91:22 110:21 126:5 137:5 142:22 143:8 143:10 145:14 146:20 146:22 148:11 155:7	162:13 168:17 176:2 178:2 179:11 190:5 195:16 197:3 199:2 199:15 207:11 218:21 221:1,1 228:11 231:22,22 247:11 248:6 273:4 284:2 287:16 289:20 300:6 303:5 304:7 312:10 317:18 333:10 355:21 358:1 361:12 371:18 397:12 418:9 421:6,7 <b>surface</b> 306:16 <b>surgeon</b> 206:14 208:4 212:9 213:16,18 214:2,13,22 215:19 215:20 216:1 226:2 234:7 253:14 <b>surgeons</b> 192:21 205:5 208:3 214:9 232:2 255:16 <b>surgeries</b> 9:13 73:11 234:16 <b>surgery</b> 4:22 5:3 7:8 26:9 41:22 42:15 192:1 207:14 208:12 212:15 230:17 233:18 234:5,6,14 240:8 242:15 245:2 247:17 251:21 252:10 253:7 253:10,17,19 256:16 259:18 418:14 <b>surgical</b> 41:20 42:2 72:10 74:17 75:4,8 200:14 204:7 206:8 211:18 214:21 246:10 374:1 <b>surprised</b> 82:20 159:18 372:3 <b>surprising</b> 278:11 372:5 <b>surprisingly</b> 7:9 <b>surrounding</b> 184:6 <b>survey</b> 22:16 37:20 62:16,21 63:21 73:9 73:18 93:13,14 116:19,21 131:6 311:13 376:16 <b>surveying</b> 137:19 <b>surveyors</b> 285:14 305:20 <b>surveys</b> 37:17 38:13 53:18 62:15,16 63:5 64:12 73:14 99:22 102:1 127:16 <b>survival</b> 273:16 276:18 <b>survive</b> 309:15 <b>survived</b> 318:8
---	---	---	---

**Susie** 13:19  
**suspect** 121:12  
**Sutter** 2:11 18:5  
**Suzanne** 9:20 10:1,4  
 30:7 31:14 39:10 50:6  
 51:21 55:1 392:11  
**Sven** 138:11  
**swallow** 26:9  
**swathe** 254:19  
**sway** 305:11 306:5  
**switch** 236:2  
**symptom** 33:9 35:1,13  
 35:22 72:9 74:16  
 105:13  
**symptoms** 33:8 34:22  
 35:13 204:13 257:7  
 263:12 416:1  
**system** 2:10 8:12 16:20  
 21:19 22:2 66:4 108:3  
 127:15 139:19 152:20  
 161:1 176:3 196:2  
 215:6 234:11 248:14  
 266:10 272:4,5 324:5  
 369:2 389:11  
**system's** 414:3  
**systematic** 38:15  
**systematically** 180:3  
**systems** 24:10 179:20  
 229:17 394:6 397:5  
 411:20

# T

**T** 4:1,1  
**table** 6:10 12:7,14 14:9  
 18:16 54:9 85:5 89:16  
 89:20 90:7,8,10  
 91:4 114:6 293:5  
 335:17 353:10  
**tables** 91:4  
**tabs** 11:4  
**tackling** 246:8  
**tails** 222:12  
**take** 6:12 7:15 11:19  
 12:2 21:15 29:3 30:5  
 40:7 42:13 43:18  
 48:10 52:19 67:7,13  
 70:20 80:14 81:10  
 82:17 91:15 106:21  
 114:13 116:21 118:7  
 127:10 128:8 129:16  
 136:7 138:7 146:3  
 148:4 161:13 165:2  
 196:19 239:5 256:7  
 275:9 284:10 303:19  
 303:19,20 304:18  
 309:3 313:12 314:17  
 338:10 351:6 385:9  
 386:4 388:18 390:21

404:4,4  
**taken** 75:16 76:10  
 89:19 217:20 313:6  
 326:17 349:22  
**takes** 99:10 166:2 194:1  
 317:21 370:9 372:2  
 414:5  
**talk** 6:10 40:8 48:18  
 51:2 54:5,12 58:4  
 61:14 84:14,17 89:13  
 145:15 158:19 165:13  
 168:8,13 177:18  
 196:9 198:1 199:9  
 219:21 228:7 239:16  
 241:22 297:1,2  
 316:19 317:8 392:2  
 392:12,15 394:14  
 403:3,13 412:22  
 413:5 422:3  
**talked** 86:1 125:3,18  
 209:15 256:3 258:13  
 327:16 347:21 358:13  
 391:15 404:11 419:3  
**talking** 32:12 34:10  
 46:19 47:9 49:7,13  
 50:7 54:6 59:1 91:8  
 93:17 132:16 150:3  
 191:20 206:1 207:21  
 261:12 278:6 281:10  
 281:13 282:9 288:13  
 288:14 289:1,15  
 290:5 297:10 304:9  
 308:12 328:18 350:10  
 390:9 411:11,12  
**taps** 338:21  
**Tara** 3:7 274:21 291:13  
 316:6 324:17  
**target** 39:5 192:8  
 244:20 258:19 266:6  
 269:20 272:1 292:17  
 301:19 363:2  
**targeted** 300:15  
**task** 33:22 34:8,11,15  
 161:9 268:1 293:9  
 356:10,19 357:1,12  
**tasks** 105:21 106:2  
 289:10  
**tautologic** 301:4  
**teach** 26:5  
**team** 17:11 30:15 66:6  
 146:4 215:1,5,7,18,20  
 216:2 241:9 315:21  
 316:4 400:2  
**tech** 236:3  
**technical** 43:8 143:1  
 146:3 233:13,20  
 293:9 344:13,17  
**technique** 82:20

**techniques** 200:15  
 374:1 393:5  
**technology** 63:20  
**tee** 402:18  
**teeth** 176:17  
**telephone** 3:19 183:17  
**tell** 7:16 9:8 14:9 83:6  
 110:11 114:9 121:9  
 169:11,15,16 179:1  
 221:7 309:12 329:15  
 342:20 356:5 376:12  
**telling** 21:16 214:13  
**tells** 10:5  
**ten** 78:8,14 101:9 108:7  
 114:15,16 115:3  
 136:6,12 345:19  
 360:9  
**tend** 44:17 160:6,7,7  
 290:3 307:22 382:22  
**tendon** 104:18  
**tends** 160:9 421:13  
**tensions** 400:22  
**tent** 54:9  
**tenth** 127:19  
**TEP** 21:4 320:10,13  
**term** 21:3 22:9 66:19  
 311:9 315:17 317:19  
 318:2 319:19 320:12  
 320:14,16 321:7,22  
 322:21 324:9 325:8  
 326:1 329:15 330:3  
 331:17 332:2 336:3  
 345:12 346:17,19  
 348:12 350:9 394:4,5  
**terminology** 35:16  
 341:1  
**terms** 45:3 53:8 93:10  
 127:9,19 149:3,4  
 150:22 158:14 159:14  
 167:11 198:1,5,8  
 199:5,6 201:7 209:2  
 218:13 222:20 224:6  
 229:9 231:20 235:12  
 242:16 247:5,19,22  
 249:8,19 254:9 256:2  
 259:2 270:15,20  
 286:6 292:18 298:18  
 304:1,3,6 310:14  
 312:4 313:11 323:17  
 330:14 345:7 346:4,5  
 346:11 348:1,7  
 366:13 367:8 398:12  
 406:9  
**terrific** 417:12  
**test** 22:10 63:20 87:12  
 114:13,18 332:22  
 333:2 358:22 359:1,2  
 360:7 366:5 372:1,20

373:9,12,14,17  
 374:10,17 377:5  
 379:9 380:7 385:3,13  
 386:17,19 397:8  
 400:9 406:12  
**test/retest** 90:9 205:13  
**tested** 39:1 113:11  
 114:2 223:3 269:16  
 320:4 359:8,22  
 403:21  
**testing** 49:2 50:2,3,6,12  
 55:18 59:8,14 63:15  
 63:18,19 86:13 97:4  
 115:1 146:17 178:2  
 180:13 181:4 196:20  
 219:3,10,18 220:18  
 220:21 229:7 232:15  
 248:9 259:3,7 260:4  
 260:11,15 267:6  
 269:4 296:10 298:2  
 316:20 334:19 336:2  
 367:18 368:14,15  
 370:14,20 371:2  
 376:16 378:13 409:21  
 421:15  
**tests** 87:11,12 140:19  
 370:15 378:2 385:13  
**Texas** 27:4  
**thank** 6:15,21 7:5,17  
 8:17,22 9:9 11:21  
 17:1 18:3 19:8 25:13  
 27:12 28:13,16 46:22  
 61:19 66:14,17 76:3  
 88:14 116:2 118:8  
 123:22 132:2,11  
 136:6 142:3,4,7 143:5  
 147:9 156:11 162:2  
 178:16 187:8 188:15  
 188:21 191:5 195:2  
 196:20 197:20,22  
 199:13 201:1 216:13  
 236:1 241:8,10 246:4  
 246:6 257:5 263:4,20  
 264:8 265:5,15 270:5  
 270:7,11 273:6  
 278:22 286:1,22  
 287:21 315:15 337:21  
 344:1 353:14 355:3  
 356:14 362:20 385:21  
**thank-yous** 6:8  
**thanks** 17:15 66:8  
 107:6 126:6 158:11  
 326:6  
**Theberge** 9:20 31:13,14  
 51:1 52:2 137:5  
 236:10,16 293:16  
 294:3,6 353:12  
**theme** 259:10 395:3

<b>theory</b> 86:17	405:2,11,20,22	287:9 288:7,10,12,17	101:7 159:12,17
<b>therapeutic</b> 270:17	407:15 408:5 409:18	288:19,22 289:22	161:8 168:10 200:10
<b>therapies</b> 287:6,8	410:16 413:22 414:5	290:4,5 291:7 293:6	207:16 220:22 259:14
<b>therapist</b> 45:11,15 46:2	414:22	294:3 299:13 300:17	295:2 306:16 315:10
46:15 65:18 316:12	<b>think</b> 6:21 10:3,17 11:1	301:12,14 302:11	322:15 336:9 382:7
<b>therapists</b> 103:11 125:7	13:4 15:18 16:22	303:1,3,21 304:2,5,20	392:22
140:3,3 215:10	19:18 24:15 26:22	305:3 308:5,11,21	<b>thoughts</b> 48:17 77:2
338:17 343:21	27:20 28:1 39:22 41:8	309:17 312:16,21	200:5 252:14
<b>therapy</b> 70:19 98:19	42:9 43:5 44:9 45:2,3	313:5,10,15 316:14	<b>threat</b> 269:2
106:20 206:18 207:5	45:19 46:2,9,18 51:16	325:2,11 326:10,14	<b>threats</b> 209:2
207:6 263:10 365:8,9	51:22 53:22 54:6 56:4	327:21 328:18 329:19	<b>three</b> 9:13 33:22 34:1
365:10	56:13 57:8 58:2 59:15	329:22 334:6 335:17	37:7 52:10 53:10
<b>thereof</b> 170:2	61:1 65:14 66:22 69:9	338:18,22 339:7,22	83:12,18 84:4 89:21
<b>they'd</b> 110:1	70:8 73:20 75:1,17	344:20 345:2,9	90:18 97:22 108:8
<b>thing</b> 26:7 39:22 41:8	79:11 81:4 82:3 83:18	349:16,22 351:2	119:8 134:5,12,17,22
44:21 54:1 58:22	85:2,7,9,20,21 86:20	352:10 354:12 361:15	135:5 154:21 165:6
69:12 76:11 83:6	87:3 89:8,12 90:6,13	367:6,22 370:5,18	166:14,22 180:14
97:21 103:13 110:15	93:22 95:1,15,22 97:6	371:7 378:3 379:18	181:5,20 182:11
110:17 111:2 121:21	103:1,14 108:14	380:14 385:3,6,11	193:13 200:8 205:18
133:4 151:3 156:12	109:10 113:8,16	386:6,12 388:22	217:3,9 227:7,14
159:12 167:21 175:18	115:16,21 116:2	389:6,14,18 390:15	233:6 239:20 244:8
175:19 178:12 179:18	117:5,12,14 120:17	390:17 392:14,15	257:20 258:5 260:20
185:15 202:12 204:12	120:19 121:14 122:14	393:4,10 397:11	268:18 269:10 271:21
205:22 207:9 221:18	123:14 124:18,21	398:3,18 399:16	272:3,7 274:18 277:2
247:18 248:20 287:10	126:12,16 127:1	400:4,6,8 401:6,22	277:6 280:20 294:13
295:8,8 297:11,13	128:11,22 129:4	402:5 403:4 404:15	294:18 297:19 300:17
300:7 301:5 305:17	131:7 133:15 135:11	406:4 407:5 409:5	302:14 305:14 310:22
307:11 308:10,13	135:15 138:11 142:12	410:8,12,14 411:4,19	313:21 314:5 320:5
315:12 317:18 323:1	142:22 148:6,20,22	412:1,6 413:9,19,20	332:18,20 343:13,16
326:15 334:2 341:16	150:21 158:19 159:3	414:21 415:10,10	343:18,20 353:17
369:9 371:16 384:20	159:4 160:18 161:12	416:3 417:5,20,21	354:4 360:8 364:13
396:14 397:10 398:22	162:3,11,19 165:17	418:3,4 419:9 421:11	375:12,17 380:17
406:5 414:11 419:10	167:11 168:15 169:13	<b>thinking</b> 42:19 43:18	387:10,18 388:1
419:19 420:16 421:5	172:17,22 173:9	75:9 106:16 127:5,13	389:3 404:9 407:12
421:19	175:8,9,12 176:1,20	127:21 128:2,3	<b>three-month</b> 200:11
<b>things</b> 12:14,20 13:8	177:21 179:14 180:10	132:20,22 179:10	271:11
16:3 21:15 31:3 50:20	184:10,11,16,18,19	210:2 288:21 311:8	<b>three-quarters</b> 268:12
54:3 74:20 75:9 77:18	185:8,15 188:5,11,11	331:13 349:3 370:11	298:6
80:1 83:4 86:18 88:13	190:10 195:5,11	381:22 401:7 406:9	<b>threshold</b> 82:12 271:14
95:10 103:11 105:10	197:8 198:5 202:1,3	411:9,15 412:11	305:22 371:17,19
110:2 120:17 125:22	204:2,11,14,17	<b>third</b> 168:15 240:16	<b>thresholds</b> 55:2 79:2
133:22 152:9 155:16	206:10,22 207:3,8	268:10	299:18
163:4 170:5 177:3	208:6 211:16 212:1	<b>thirty-eight</b> 380:22	<b>throw</b> 226:8
183:8 184:13,15	213:13 214:16,19,20	<b>Thirty-five</b> 387:19	<b>throwaway</b> 289:5
187:6 198:17 206:2	215:12,17 220:19,19	<b>Thirty-two</b> 258:1	<b>thumbprint</b> 110:11
209:14 212:21 226:8	222:16 226:5,10,12	<b>Thomas</b> 2:11 18:4,4	<b>tie</b> 56:21 98:11 354:19
229:22 250:20 251:14	228:2,6 233:19 236:2	43:13 119:14,17,20	<b>tied</b> 150:12 175:19
253:6 256:17 270:12	237:2 239:13,15	124:3 132:2,8,12	340:2
270:21 279:22 284:9	247:19 250:2,4 251:4	156:18 157:13,18	<b>tiered</b> 369:2 370:3
284:12 289:6 292:11	251:9,15 253:11	158:8,11 161:15	<b>tiers</b> 153:9
292:22 299:4,9 300:1	255:5,11,12,15,16	164:6,11 208:18	<b>time</b> 6:18 9:4 10:18
302:2 303:5 307:10	256:20 258:16,18,21	211:11 254:3,8	11:2,4,6,9,12,14 12:5
307:14,15 308:7	261:6,10 263:22	282:20 286:1 297:4	21:15 25:15 26:16
319:10 329:20 335:7	264:3 265:6,7 270:13	338:1 393:17 396:14	28:4 42:12 43:3 44:14
339:5 342:20 346:7	271:1,5 272:9,19,22	409:9	48:3 49:5 50:19 54:7
351:16 353:8 385:22	273:21 274:8 275:17	<b>thoracic</b> 125:12 379:17	55:14 58:17,21 59:2,2
393:8,12 394:2 396:9	277:10,14 279:12	<b>thorough</b> 205:1	59:11 60:14 75:10
397:17 399:7 401:3	280:3 286:3,18,20	<b>thought</b> 45:7 81:11	89:14 97:3,12 99:6,9



101:9,21 107:21  
 108:3,10 116:22  
 120:7 121:11 128:7  
 128:17 136:17,17  
 137:7,10 147:3 155:2  
 156:3 157:4,7 160:17  
 172:16 174:11 183:15  
 188:20 189:13,21  
 192:11 196:17,19  
 200:11 204:6,7,16  
 205:11 213:20 220:13  
 229:14 239:15 242:19  
 244:8 262:19 264:9  
 271:20 272:1,2  
 279:17 280:16 281:8  
 293:15 295:13,13  
 301:19 319:7 321:11  
 322:6 337:8 342:1  
 343:3,18 345:17  
 353:4,7,12 355:21  
 372:1 378:5,6 385:18  
 388:11,13,18 389:1,8  
 390:12 397:18 409:18  
 413:15 417:14,17  
 419:17  
**time-limited** 65:8  
**timeframe** 205:4 232:10  
**timeframes** 205:3  
**timeline** 262:17  
**times** 61:4,8 105:19  
 133:8 152:4 218:9  
 225:15 226:6 228:3,6  
 238:10 331:6 364:13  
 418:11  
**tiny** 51:22 197:7  
**TKR** 194:21  
**TMJ** 125:11  
**to-noise** 297:13  
**tobacco** 210:22 224:16  
**today** 10:11 11:11  
 12:13 17:6 18:16 20:8  
 22:12,20 23:11 28:20  
 30:17 36:18 44:20  
 48:8 53:9 61:21 64:15  
 65:13 104:15,15  
 137:22 142:4 175:10  
 191:21 195:11 248:18  
 253:2 260:16 264:2,9  
 265:16 316:3 317:11  
 356:11 358:15 389:1  
 390:18 395:3 399:7  
 404:19 407:8 419:21  
 421:8  
**toilet** 266:5 308:1  
 336:14  
**toileting** 335:21  
**told** 10:2 348:9  
**tomorrow** 11:8 43:3

189:22 345:3 389:16  
 389:20 390:11 392:1  
 392:17 407:9 419:22  
**tone** 288:8  
**tonight** 190:15  
**tool** 18:10 36:7,15  
 37:20 73:8 86:3 99:19  
 99:21 100:15 117:8  
 140:6 144:1,13,20,20  
 146:1,7 149:6 163:7,8  
 163:16 172:15,19,21  
 173:15 175:19 193:5  
 193:6,7 194:9 225:3,5  
 228:20 230:6,8,16  
 231:12 235:20 243:14  
 243:16,22 244:14  
 247:14 248:21 249:4  
 250:4 252:1 253:4,9  
 256:2 267:2 291:19  
 311:20 334:14,18  
 335:9,10,14,19 337:4  
 368:20 374:3 379:14  
 379:15 410:10  
**toolbox** 385:2  
**toolkit** 380:4  
**tools** 16:2 18:15 37:17  
 59:4,12 86:1,5,8,10  
 86:21 87:6 140:17  
 141:4,8,22 163:11,13  
 167:14 230:3 231:6  
 244:19 256:6 290:18  
 303:8 334:11 395:4  
**toothpaste** 395:18  
**topic** 196:6,6 300:4  
**topped** 397:19  
**total** 4:22 24:9 130:12  
 131:2 148:2 191:22  
 192:15,16 196:7,12  
 198:8 206:22 211:18  
 224:2 240:7 242:17  
 244:6 248:20  
**totally** 273:11,13  
 349:20 409:10 416:20  
**touch** 408:22  
**touched** 107:9 270:12  
**touches** 292:2  
**touchscreen** 101:20  
**touchscreen-based**  
 24:4  
**tough** 326:10 328:20  
**town** 7:10 18:6  
**track** 11:5 397:3 415:7  
**tracked** 161:21 324:15  
**Tracy** 3:5,16 265:6,10  
 265:18 316:15,16  
**tradeoffs** 401:6  
**traditional** 192:7 219:6  
**train** 25:8 26:17

**trained** 66:21 168:18  
**training** 23:13 168:14  
 168:20 312:4 317:1  
 364:16  
**traits** 141:16  
**trajectory** 75:13  
**transfer** 266:5 308:2  
 336:14,14  
**Transferring** 5:12  
**transitioning** 252:19  
**transitions** 285:3  
**translate** 21:16 122:15  
**translation** 247:1  
**transparency** 213:3  
**transparent** 14:14  
**trashed** 400:15  
**treat** 228:8 338:11  
 374:1  
**treating** 94:18 130:15  
 130:16  
**treatment** 27:7 35:1  
 77:21 94:9 131:5  
 172:1 208:10 318:16  
 321:2 338:5 358:8  
 373:21 374:13 395:10  
**treatments** 263:9,12  
 374:16  
**tremendous** 6:22  
**trend** 267:15 286:6  
**trial** 160:16 373:21  
 374:13,14  
**trials** 8:3,15 24:14  
 160:10 178:19 382:2  
**trickier** 168:2 405:13  
**tried** 263:9,12 342:11  
 401:16 402:13  
**tripped** 13:18  
**trouble** 103:5 156:18  
 176:16 282:21 296:9  
 344:2  
**troubled** 275:22 296:8  
**true** 45:22 84:5 115:9  
 116:13 121:12 150:10  
 173:14 205:8,15  
 339:13 340:3 372:10  
**truly** 112:20 279:14  
 306:9 414:12  
**trust** 9:14 417:2,2  
**trusting** 186:6  
**truth** 103:18  
**try** 11:1,5,17 42:9 51:9  
 90:10 99:15 147:21  
 152:4 171:1 197:16  
 201:16 219:9 225:5  
 233:11 263:11 284:5  
 357:14 394:22 400:11  
 410:10 411:4  
**trying** 11:13 66:19

71:21 89:13 91:10,22  
 92:12 102:21 105:18  
 105:21 108:20 186:4  
 209:8 218:9 222:11  
 222:13 226:1 234:17  
 237:22 247:4 250:16  
 269:9 272:5 273:8  
 290:17 301:4 304:1,5  
 318:22 344:20 395:9  
 401:13  
**tubes** 395:17  
**tune** 401:10  
**turn** 11:18 28:14 54:4,5  
 54:8,9,11 138:10  
 161:1 389:13  
**turned** 67:10 413:4  
**tutorial** 118:10  
**twelve** 375:11  
**Twenty** 383:19  
**twenty-five** 381:1 383:2  
**Twenty-four** 375:13  
**twenty-nine** 375:15  
**twice** 348:22  
**two** 6:11 7:12 19:20  
 22:4 31:20 33:7 37:12  
 39:9 40:16 52:1 53:10  
 54:7 71:5 99:11 105:8  
 112:16 118:12,20  
 119:8 121:8 134:5,11  
 134:16,22 135:4  
 157:1 165:6 166:1,14  
 166:22 170:5,13  
 171:3 173:20 174:1  
 180:14 181:5,20  
 182:11 183:2 187:6  
 188:4,9 207:21  
 208:15 213:17 216:19  
 217:3,9 220:2 223:10  
 227:7,14 233:6  
 236:17 239:20 240:9  
 257:14,20 258:5  
 260:20 267:14 271:14  
 289:8 294:10,13,18  
 302:14 310:22 313:21  
 314:5,13 320:7  
 321:22 339:21 343:11  
 344:8 353:17 354:4  
 359:8 364:13,14  
 368:1 374:22 375:12  
 375:17 380:17 385:2  
 385:4,13 386:17  
 387:10,18 388:1,8  
 389:3,8 390:13  
 391:20 392:10 406:11  
 407:11  
**two-point** 202:6 238:19  
**type** 42:2 46:6 59:14  
 73:14 91:7 96:1 98:21

112:12 144:1 154:16  
 193:3 219:5,13 275:5  
 284:8 317:20 323:22  
 329:1 344:11 351:16  
 351:19 368:13 410:21  
**types** 102:15 121:5  
 131:18 211:9 226:15  
 284:11 292:20 338:15  
 344:19 345:14 364:8  
 371:8  
**typical** 209:18  
**typically** 357:20 365:3,7

## U

**uber** 409:15  
**UC** 2:1 23:18  
**UCLA** 20:11 24:9  
**UCLA/JH** 2:10  
**UDS** 23:10  
**uh** 7:4  
**ulcer** 266:13 346:22  
**ulcers** 307:14  
**ultimately** 18:18 206:19  
 207:1 222:15  
**unable** 26:8 80:8  
**unavoidable** 266:14  
 269:7  
**uncle** 170:14  
**uncomfortable** 240:19  
**undergo** 192:15 243:5  
 251:20  
**undergoing** 197:12  
 255:4  
**underlying** 197:9  
 282:16 406:3  
**understand** 17:22  
 69:10 71:15,20,22  
 72:12 73:22 74:15,22  
 80:21 85:9,13 86:8  
 87:22 88:9 90:15  
 91:20 113:15 115:18  
 120:16 121:11 143:9  
 144:18 153:16 155:1  
 167:16 168:4 170:3  
 171:17 173:1 178:19  
 179:9 184:5,22 194:8  
 213:9 238:6 246:19  
 247:4 251:3 262:13  
 271:7 274:11 344:4  
 346:6,10,14 350:2  
 356:1 363:2,15 384:5  
 395:5 409:10,13,13  
**understandability**  
 113:11  
**understanding** 33:1  
 73:22 81:21 144:10  
 151:9 152:19 156:19  
 186:12 212:8 247:15

248:5 262:2 284:13  
 336:22  
**understood** 50:18  
 90:21 94:15 163:17  
 170:20 196:21 237:13  
 238:3  
**undertook** 195:8  
**underwent** 259:18  
**unexpected** 323:14  
 327:6,9  
**unexpectedly** 327:20  
**unexplained** 66:22  
 68:13  
**unfamiliar** 9:20  
**unfortunately** 44:15  
 272:14  
**unidimensional** 104:8  
 104:9 105:1  
**unidimensionality**  
 104:10  
**unidimentionality**  
 86:18  
**uniform** 389:11 400:8  
**uniformly** 179:19  
**unintended** 177:1  
 280:5 303:13 309:2  
**unique** 87:9 401:1  
**unit** 56:17 60:10 110:7  
 110:9 226:1 410:21  
**United** 2:2 62:20  
**units** 56:3 60:5 122:2,3  
 288:1,3 331:17  
**universal** 131:17  
**University** 1:13,14,15  
 1:19,20,21 7:20 14:20  
 17:4 24:19 26:6 317:7  
 357:10  
**unnecessarily** 283:12  
**unreasonable** 208:15  
**unsatisfying** 288:19  
**unstable** 82:14 247:3  
**untested** 371:9  
**unusable** 98:12  
**update** 146:9,15 149:2  
**updated** 376:19  
**upfront** 192:22 209:16  
 210:3  
**upper** 96:1,8 192:14  
 243:4 404:7  
**upset** 283:11  
**urban** 158:21  
**urban/rural** 141:18  
**usability** 54:22 127:14  
 135:4,18 182:6,10  
 239:18,19 261:13  
 314:4 386:21 387:22  
**usable** 237:7  
**use** 8:2 21:17,18 22:8

23:7 37:10 38:3 39:15  
 48:21 56:8 63:3 64:16  
 69:14 74:5 77:9 78:21  
 80:5,17 81:1,20 82:6  
 82:20 83:5 84:1 86:2  
 86:4 90:1 91:10  
 101:22 113:6,7  
 114:22 115:8,16  
 116:10 117:8 119:7  
 125:6 129:9 132:4  
 140:2,5 141:4,8  
 142:16 143:14 144:12  
 144:20 149:11 157:8  
 157:10 160:20 163:7  
 164:1,16 165:2  
 172:15,18 173:8,15  
 176:11 187:4 192:21  
 194:10 208:15 210:22  
 211:3 218:5 229:17  
 236:4 253:5 266:6  
 284:8 285:14 290:22  
 292:21 299:2,11,13  
 314:4 321:17 334:11  
 336:18 350:4,11  
 358:5 362:1,1 369:5  
 369:11 372:20 377:12  
 377:14,22 378:6  
 379:2,5 387:22 394:7  
 394:18 398:5 400:12  
 400:17,20 401:17,18  
 402:17 406:20 409:16  
 417:16 419:12,17  
 421:1  
**useful** 87:1 124:20,21  
 128:16 156:6 172:10  
 199:4 208:6 212:1  
 216:9 292:19 296:14  
 298:16 299:9 304:3  
 326:8 398:6 408:10  
**usefulness** 377:8  
**uses** 79:8 89:2 377:20  
 405:2  
**usually** 221:6 274:5,8  
 318:4  
**UT** 1:17  
**utilization** 149:11 156:2  
 156:13 246:9 284:12  
 351:15  
**utilize** 358:18 387:3  
**utilized** 360:20 363:14  
**utilizing** 141:21 359:8

## V

**VA** 2:10  
**valid** 57:22 104:17  
 131:19 218:5 269:5  
 303:5 359:2 362:8  
 366:8 368:4 369:7,9

369:10 372:20 373:12  
 373:15 374:4 378:5  
 379:21 398:2  
**validated** 8:1 141:21  
 171:18 398:6  
**validating** 409:20  
**validity** 50:2 54:21 55:5  
 55:18,19 57:8 58:16  
 58:18 84:13,15 88:13  
 100:19 103:22 111:3  
 111:13,18 112:12  
 132:4 134:16 171:10  
 171:12 181:2 184:4,9  
 198:3 209:2 212:4  
 217:16,19,22 218:17  
 227:13 251:2 261:13  
 267:19,21 268:21  
 269:3 282:13 295:4  
 296:10 297:2,2  
 299:21 300:7 301:5  
 302:7,8,11,20,21  
 303:10 306:14,14,17  
 306:18,20 307:2,9,11  
 307:21 308:4,6,11  
 310:12,15,21 332:3  
 349:10 359:14 363:5  
 366:14,18 367:6  
 369:14 370:11,14,17  
 370:20 371:2 378:2  
 378:12 380:15 381:3  
 387:7,9  
**valuable** 8:17 128:16  
 270:3  
**value** 39:19 67:16,21  
 68:3,10 69:3,13,15,17  
 69:22 117:1 147:16  
 275:21 286:19 334:8  
 373:10 409:11  
**values** 39:5 76:4 116:12  
**van** 2:12 16:5,6 125:13  
 126:11 127:4 329:9  
 329:19 330:17  
**variability** 76:14 77:6  
 102:14 103:2 104:13  
 221:16 232:17 246:2  
 248:1,4 249:11 251:1  
 255:20 338:15 346:5  
 348:1 415:11  
**variable** 68:5,5,7,20  
 69:19 99:3 246:15  
**variables** 76:10 98:4  
 112:17 115:6 116:6  
 210:13 211:2,3  
 224:16 245:20 296:17  
**variance** 66:22 67:18  
 76:15 93:7 123:2  
 297:9  
**variants** 331:16 338:6

**variation** 67:16 68:13  
75:22 110:8,9,13  
119:5 122:1,4,13,18  
123:5 148:17 194:20  
198:9 201:20 247:20  
250:19 296:19 299:7  
300:2 303:1 305:6,7  
331:21 367:8  
**variations** 198:12  
365:17 393:8  
**varies** 89:8 253:7  
342:15  
**variety** 49:3 232:8  
255:19  
**various** 141:16 371:17  
373:13 406:13 418:11  
**vary** 70:14 82:1 205:15  
400:19  
**varying** 155:21  
**vast** 56:13  
**vehicles** 411:13  
**vendor** 401:8  
**vendors** 401:9  
**ventilator** 320:19  
**ventilators** 318:6,17  
319:15 329:7 345:5  
**verification** 100:22  
**verified** 383:16  
**version** 92:6 94:2  
243:15 272:21  
**versions** 93:5  
**versus** 45:12 71:3  
96:17 105:4 144:7  
203:7 208:12 221:8  
221:16 226:2,2 400:4  
400:12 401:22 406:8  
**vertebrate** 243:7 247:2  
**Verville** 2:12 18:5  
**veteran** 9:21  
**Veterans** 20:12  
**Vice** 21:10 22:1 23:16  
29:6  
**view** 42:17 402:11  
**viewed** 285:8  
**virtually** 373:8  
**virtue** 254:16  
**vision** 264:14 404:1,1  
405:10 410:10  
**visit** 78:15 111:8 140:12  
141:10 158:4  
**Visiting** 1:21 17:3  
**visits** 77:22 78:2 140:10  
323:18  
**vital** 140:17 216:4  
358:17  
**voice** 45:22 330:20  
**volume** 6:19 62:16  
194:21 196:13 197:4

**volunteer** 13:13 333:8  
**volunteers** 333:7  
**vote** 51:16 53:20 54:18  
54:21 84:19 88:12  
92:10 93:19 102:3,3  
117:18,22 118:6,7,21  
120:6 123:16 131:22  
132:19 134:8 135:7  
147:9 162:20 164:12  
176:6 178:10,14  
180:11 181:1,16,18  
182:9,9,21 190:5  
214:7 225:8 227:5  
233:4,15 236:4  
239:18 251:17 257:11  
260:18 302:4,16  
310:4,6,20 313:19  
314:1 351:3,6 353:5  
375:1,4,6,7 380:15  
387:16 420:14  
**voted** 175:5  
**votes** 51:11 54:16  
124:8 216:22 217:5  
217:12 227:10,18  
240:2,12 257:17  
258:1,8 261:2 262:7,9  
294:19 311:2 353:19  
380:19  
**voting** 51:5,8,17 53:6  
118:3,5,11,15,20  
119:3,9 127:9 134:4,6  
134:11,12,16,17,21  
135:1,4,6,21 165:5,9  
166:5,6,13,16,17,21  
167:1,2 175:2 179:8  
180:12,16,17 181:2,7  
181:8,19,22 182:1,10  
182:13,14 183:3,4  
216:15,19,21 217:2,4  
217:8,10,11 227:6,8,9  
227:13,15,17 233:5,8  
233:9 239:19,21  
240:1,5,9,11 257:12  
257:14,16,19,21,22  
258:4,6,7 260:19,21  
261:1,22 265:9  
293:12 294:9,10,12  
294:14,17,19 302:13  
302:15 309:16 310:21  
311:1 313:20,22  
314:4,6,13 353:16,19  
354:5 374:21,22  
375:11,13,16,18  
380:16,18 387:8,9,11  
387:17,19,22 388:2,5  
388:8

---

**W**


---

**wait** 164:19  
**waiting** 134:8 135:7  
260:5  
**walk** 77:15 205:17  
321:18 337:7 358:22  
359:1 360:7 363:17  
366:5 372:17,17,19  
373:9,14,17 374:10  
374:17 377:8 379:9  
379:14,22 385:3,13  
386:19 387:3 406:13  
**walked** 406:7  
**walking** 192:11 336:15  
336:16 372:1,12  
**walks** 362:11  
**want** 6:7 7:5,12 11:6  
12:19 27:15 30:5,14  
31:9 40:13 41:15  
46:21 50:10 56:2,15  
56:20 57:17,21 58:6  
58:15 59:3,10,15,18  
62:1 67:7 69:8 71:15  
74:11 81:7 91:10 95:9  
106:19 107:1 113:15  
122:17 123:10 130:16  
137:2 143:8 147:18  
163:12 168:6 171:6  
184:1 185:18,21  
188:5 189:14 196:14  
197:3 198:1 204:15  
207:14 212:2 214:8  
215:11,13 219:21  
225:1 235:12 237:12  
241:22 246:8 253:5  
253:16 263:8 265:15  
272:6 277:19 278:19  
281:21 287:15 290:22  
297:2 306:21 309:2  
310:16 324:17 328:21  
331:5 337:3 340:21  
346:1 351:4 352:9  
354:13,19 356:14  
362:21 368:1 376:3  
382:16,17 389:19  
390:5,16 394:14  
405:6,8 412:1,12  
418:14  
**wanted** 29:3,20 32:11  
49:16 50:17 77:2 89:4  
94:20 100:11 113:5  
125:2 168:16 174:21  
203:11 205:3 211:5  
212:22 220:11 221:1  
235:6 242:9 245:8  
246:19 255:3 278:17  
280:7 297:13 304:21  
317:18 351:9 379:8  
**Wanting** 186:2

**wants** 241:17 291:13  
388:21  
**warehousing** 283:13  
**warned** 30:19  
**warring** 279:20  
**wars** 401:8  
**wash** 335:22  
**Washington** 1:9 19:6  
26:20  
**wasn't** 9:12 74:1 88:17  
155:2,9 169:4 307:18  
327:5 334:5 337:9,16  
337:16 340:10 341:20  
346:6 396:12  
**waste** 172:16  
**watched** 23:5  
**way** 6:18,20 28:6 45:10  
48:5,6 80:20 86:22  
98:12 104:17 110:16  
140:13 150:10,15  
164:2 172:3 173:22  
174:6,7,16 175:10,11  
176:10,17,20 179:13  
184:22 187:15,20,22  
188:6 194:16 206:1  
215:6 235:21 249:21  
255:10 258:13 270:14  
284:20 289:12,13  
291:18 292:13 293:12  
301:3 306:3 308:4,5,6  
308:9 309:8 331:1  
340:6,9 341:2 344:4  
368:4 371:22 384:8  
385:18 402:21 405:4  
406:6 407:14 409:22  
412:5,11 418:20,22  
419:13  
**ways** 123:4 179:10  
221:6,17 222:2 232:8  
379:11 394:12 404:5  
**we'll** 6:10 11:5 12:3,6  
17:12 22:20 29:8  
40:20 47:5 50:10,21  
52:18 53:20 54:16,18  
54:19,21,22 55:7 58:4  
58:19 59:6,8 61:8,11  
119:12 121:15,19  
131:14 136:7 137:18  
137:21 138:1 189:17  
327:21 332:4 371:9  
390:17  
**we're** 9:18 12:13 14:7  
17:6 24:12 29:15  
44:13 47:8 49:8 50:19  
51:7 53:8 56:11 57:22  
58:6 59:18 70:9 72:1  
72:21 73:3 74:10  
75:13,21 80:16 85:8

86:2,20 91:8,22,22 93:18 105:22 117:18 117:20 118:11,15 119:3 126:5 127:2 128:2,2 130:16 132:16,21 134:8,21 135:7 138:3 139:10 146:19,21 147:22 150:3 160:15 163:6 172:4,7 173:7 176:1,1 185:12 315:4 321:4 322:10 328:16 329:4 329:20 330:8,9 337:18 348:14 349:4 350:16 352:8 353:4 353:12 355:2,5 356:11 367:2,11,16 371:8 374:21,22 377:4,19 380:14,18 391:10,18 392:6,16 393:19 396:18 397:13 398:13 399:2,11 401:7,9 403:12 408:8 410:17 418:10 420:1 421:20 <b>we've</b> 26:9 43:18 46:10 48:16 59:11 63:16,19 93:14 109:10 117:3 121:22 125:3 129:5 145:2 315:9 317:9 320:5,9 323:17 324:19,19 349:8 354:11 356:1 357:4 362:19 371:19 388:22 397:15,19 404:8 408:13 409:12 414:7 418:13 421:21 <b>weakness</b> 132:13 150:21 252:6 253:22 <b>weaknesses</b> 124:13 <b>wealth</b> 29:13 263:15 <b>wearing</b> 336:4 <b>webinar</b> 26:14,17 148:14 <b>webinars</b> 26:20 <b>website</b> 88:22 91:12 92:17,19 93:13,17 115:11,22 116:7,17 116:20 380:5 <b>WEDNESDAY</b> 1:5 <b>weeds</b> 381:5 <b>week</b> 7:8 25:16 29:5 49:12 121:10 137:14 137:21 343:5 364:13 364:13 390:14 <b>weekends</b> 343:20 <b>weeks</b> 9:14 205:18 220:4	<b>weigh-in</b> 251:16 <b>weighing</b> 405:8 <b>weight</b> 292:8 405:9 <b>weighted</b> 300:13 305:13 306:5 <b>weighted-out</b> 305:10 <b>weights</b> 300:22 305:17 <b>weird</b> 169:19 413:3 <b>welcome</b> 6:4 7:12 28:4 29:20,21,22 136:11 191:4 195:4 <b>well-correlated</b> 300:9 <b>well-informed</b> 138:1 <b>well-taken</b> 237:18 301:13 <b>went</b> 53:22 60:20 85:1 91:12 103:10 136:9 149:7 151:8 159:13 170:12 190:8 200:17 213:22 226:13 315:2 339:3 382:15 409:18 <b>weren't</b> 158:1 220:22 232:9 259:18 297:20 309:4 324:1 329:12 <b>Werneke</b> 3:15 65:22 99:6,9 101:2 125:10 130:7 <b>Western</b> 2:4 9:11 <b>Wexner</b> 1:20 24:19 <b>wheelchair</b> 321:17 336:17,19 <b>wheeze</b> 377:2 <b>whichever</b> 56:9 171:21 241:16 <b>whirl</b> 242:6 <b>white</b> 19:11 159:21 224:10 402:11 404:11 <b>white/white</b> 141:19 <b>wide</b> 48:4 193:16 254:19 <b>widely</b> 172:8 243:19 <b>wider</b> 255:19,21 308:22 <b>wiggle</b> 277:10 <b>willing</b> 279:21 <b>willingness</b> 385:8 <b>Wilson</b> 2:16 29:4 <b>win</b> 151:18 <b>window</b> 193:16 <b>wish</b> 54:8 <b>withdrawn</b> 32:20 <b>Womack</b> 96:10 97:2,7,8 97:15 <b>woman</b> 105:4 <b>Women</b> 1:12 15:11 <b>wonder</b> 228:1 237:7 279:7 421:2 <b>wondered</b> 103:6 125:21 198:10 199:8 303:16	<b>wonderful</b> 8:16 66:10 264:8 <b>wondering</b> 39:16 43:22 45:17 128:1 133:7 142:14 143:11 145:10 184:12 204:4 209:6 236:22 262:4 407:1 <b>Wood</b> 29:12 <b>word</b> 175:6 215:18 406:20 <b>word's</b> 216:4 <b>worded</b> 340:11 <b>words</b> 12:17 13:12 72:7 197:6 259:14 394:10 <b>work</b> 7:1 8:8,14,21 9:1 11:14 12:22 13:3,13 14:22 15:16 18:13 19:5 20:13 22:9 24:21 24:22 26:18 27:1,5,18 28:20 30:10 31:19 32:6,8 33:14 46:15 49:19,21 57:18 75:17 96:2 121:14,15 130:10,18 132:13 174:17 191:17 193:8 195:20 197:13 200:5 200:17 203:19 205:2 209:15 210:13 216:12 232:1,2 233:1 234:20 240:22 242:18,19 245:1,8,13 246:19 250:7 255:2 256:8 293:13 303:9 316:21 317:5 342:5 345:8,19 357:3 370:7 383:4 386:11 401:3 409:17 410:2,9 <b>worked</b> 10:1 31:18 219:9 412:18 <b>worker</b> 22:18 <b>workers</b> 89:5,21 90:2,3 <b>workflow</b> 230:15 231:7 <b>workflows</b> 230:3,9 <b>workgroup</b> 30:21 32:6 <b>working</b> 8:6 10:4 25:16 29:9 31:20 127:2 196:10 203:18 215:21 219:22 229:8 233:15 252:18 304:16 315:22 317:3 320:2 324:20 343:21 357:11 389:1 397:7 398:8 399:3 <b>works</b> 11:11 130:1 304:18 335:19 402:15 404:20 <b>worksheet</b> 376:2 <b>world</b> 229:15 382:2 <b>worlds</b> 352:2	<b>worried</b> 82:13 <b>worrisome</b> 299:20 <b>worry</b> 82:13 323:10 326:15 345:16 <b>worse</b> 207:7 290:3 <b>worth</b> 49:7 276:21 298:20 349:16 <b>worthwhile</b> 338:7 <b>wouldn't</b> 115:4 131:19 157:20 179:6 250:14 274:18 276:4 293:22 298:14 338:3 345:18 386:13,14 391:7 410:1 <b>wounds</b> 320:20,22 329:7 410:17 <b>wow</b> 101:8 <b>wrap</b> 117:3 <b>wrist</b> 4:17 95:6 <b>write</b> 7:2 175:20 <b>writeup</b> 246:10 259:12 307:15 <b>writing</b> 19:12 <b>written</b> 340:5,6,9 368:5 <b>wrong</b> 217:18 218:7 274:6 349:20 <b>wrote</b> 8:20 170:8
<b>X</b>			
<b>X</b> 46:6 384:8			
<b>Xing-hua</b> 265:12			
<b>Y</b>			
<b>Yale</b> 220:18			
<b>Ye</b> 178:1			
<b>yeah</b> 78:10 81:15 88:10 148:22 185:5 188:10 315:8 327:15 328:12 328:14 329:19 331:11 335:20 339:15 341:10 351:8,12 355:22 363:1			
<b>year</b> 19:14 21:21 33:22 43:17 50:14 81:22 108:8 112:13 146:18 168:15 192:5,18 193:15,17 194:22 204:5,19 208:4,13 212:10,15 213:17,19 214:2,12,19 215:14 218:5,12 231:16 232:3 243:2,7 244:10 305:21 325:5,10 360:4 404:14			
<b>year's</b> 98:7 298:19			
<b>year-old</b> 106:19			
<b>years</b> 7:22 19:17 25:5 29:10 30:12 32:3 61:9			

63:10,15 89:20 97:15  
 107:4 108:9 113:7  
 136:12 140:11 154:21  
 191:17 196:10,14  
 208:15 223:20,21  
 318:7 345:20 357:6  
 357:12 383:13 386:18  
 412:17  
**Yelp** 416:16,18,22  
 417:2  
**yes-or-no** 273:22  
**yesterday** 43:5 103:9  
 165:14 408:18  
**yield** 366:3  
**York** 1:21 2:4 9:11 17:3  
 17:11 22:3 357:4  
**young** 26:6 113:8  
**younger** 283:10  
**youth** 113:8

---

**Z**


---

**zero** 98:7 119:10  
 134:10 155:8 166:19  
 167:4 180:18 181:9  
 182:3,16 187:15  
 217:13 227:10 240:2  
 258:2,9,10 261:2  
 290:2,7 294:15,21  
 311:2 314:2,2,8  
 353:20 375:14,19,20  
 387:20,21 388:4  
**zero/one** 152:7  
**Zheng** 3:16 265:18  
 286:2  
**zip** 210:9  
**zone** 52:17 166:3  
 180:22 183:8 240:22  
 262:9  
**Zyl** 2:12 16:5,6 125:13  
 126:11 127:4 329:9  
 329:19 330:17

---

**0**


---

**0-48** 194:18  
**0.87** 268:3  
**0.95** 267:19  
**0167** 5:10  
**0174** 5:11  
**0175** 5:12  
**0176** 5:13  
**0177** 5:15  
**02624** 136:7  
**0422** 4:9 5:1 40:7,13  
 61:22 64:22  
**0423** 4:10 61:12 90:18  
 109:3 117:19,21  
**0424** 4:12 107:18  
**0425** 4:13

**0426** 4:15  
**0427** 4:16  
**0428** 4:18 61:22 65:1  
 125:1 126:5  
**0631** 264:11  
**0674** 268:22  
**0688** 5:7 20:18 264:17  
 264:21 265:21 314:11  
**0701** 5:9 355:8,15 388:6  
**08** 298:10  
**09** 296:18

---

**1**


---

**1** 183:17,17 225:15  
 296:18,19 335:17  
 369:3  
**1,000** 364:1  
**1.23** 62:15  
**1.6D** 89:16  
**1:00** 189:12  
**1:10** 189:20  
**10** 19:17 32:22 196:14  
 224:18 243:15 252:19  
 257:1,3  
**10-minute** 314:17  
**10.8** 201:22  
**10:30** 390:4  
**100** 98:7 194:22 224:13  
 232:5 281:18  
**100-point** 246:2  
**101** 286:10  
**1030** 1:8  
**11** 4:3 19:17 32:18,21  
 134:14,19,19 166:7,9  
 217:13 240:3 294:15  
 321:16 354:5  
**11:01** 136:9  
**11:23** 136:10  
**11:45** 189:13  
**1100** 223:15  
**12** 24:3 32:19 51:16  
 62:15 193:7 302:17  
 364:13  
**12-month** 140:13  
**12.9** 201:22  
**12:00** 343:11,12,15  
**12:23** 190:8  
**12:45** 189:13  
**12:57** 190:9  
**121** 360:22  
**136** 4:19  
**14** 4:4 65:16 113:8  
 133:19 199:3 237:5  
 237:17  
**14-percent** 224:20  
**14.3** 267:13  
**15** 10:16 11:3 51:5  
 196:18 236:16 244:10

257:3 390:9,16  
**15-fold** 246:12  
**15-point** 98:6  
**15,000** 62:17  
**15.4** 267:13  
**15th** 1:8  
**16** 135:3,9 166:8,8,19  
 167:4 182:2 201:19  
 217:1,6 227:11  
 255:15  
**16-point** 208:1  
**17** 80:3 199:3 207:12  
 237:6,17 314:14  
 353:21 354:6  
**17-point** 194:18  
**17.2** 246:2  
**18** 65:16 113:7 133:19  
 140:11 192:14 224:4  
 243:4 357:11 412:17  
**183** 4:20  
**19** 51:4  
**190** 4:22  
**1980** 23:4  
**1990** 21:14  
**1995** 62:4 63:10  
**1998** 62:12 64:12  
 217:21 218:19  
**1A** 118:16 131:22  
**1B** 131:22 132:19  
**1C** 133:1 134:4

---

**2**


---

**2** 1:3  
**2,000** 366:1  
**2,668** 360:20  
**2.0** 272:21  
**2.1a** 243:15  
**20** 10:17 11:3 63:15  
 318:7 357:5 386:18  
**20-year** 283:7  
**2000** 374:14  
**2005** 101:18 335:1  
**2006** 320:4  
**2008** 65:8 139:18  
 154:18  
**2009** 139:19 154:18  
**2010** 196:8  
**2011** 65:9 267:16  
 324:21 358:15  
**2012** 141:14 320:4  
 346:21  
**2013** 149:8,14,21  
 156:20 184:17 360:5  
**2014** 146:16 267:14  
 360:5  
**2015** 1:6 21:15  
**21** 1:6 33:5 106:18  
 134:14 135:7 166:18

167:3 180:19 182:15  
 261:3 361:8  
**21-year-old** 105:3  
**22** 26:10 77:7 325:2  
**2287** 5:16 314:20  
**23** 77:8 224:18  
**24** 343:5  
**241** 5:3  
**25** 149:11 156:19,22  
 157:11 358:21 359:5  
 362:16 381:15,19  
 382:4,6 383:7,15  
 384:13  
**250** 381:14  
**26** 56:13 119:10 135:8  
 136:7 149:12 180:19  
 181:10 182:3 227:19  
 240:3 258:2  
**2624** 4:19 5:2 138:5  
 139:15 140:5 183:1  
**2631** 5:4 264:12,17  
 265:1 315:6,7,13,17  
**264** 5:6  
**2643** 5:3 241:14 242:13  
**265** 5:8  
**2653** 4:21 5:1 189:2  
 190:20 191:21 240:6  
**28** 4:5,7 31:5 36:17  
 56:13 119:1,2 311:3  
 353:20  
**2A** 132:6  
**2B** 80:3

---

**3**


---

**3** 132:7 135:21 137:8  
 277:4 278:3  
**3,000** 62:19 207:19  
 208:14  
**3.0** 267:10  
**3:00** 389:4,16  
**3:23** 315:2  
**3:25** 314:16  
**3:30** 264:18 293:2,2,3  
**3:35** 314:18  
**3:38** 315:3  
**30** 97:15 103:9 126:14  
 274:19 298:3 417:14  
**300** 405:18  
**31** 232:16 277:22 278:5  
**32** 134:15,20 181:10  
 182:16 227:19 258:9  
 261:3 274:17 359:10  
**33** 294:20 314:1  
**35** 76:4  
**355** 5:9,10,11,12,14,15  
 5:17  
**36** 223:21  
**37** 76:4 119:10,11 134:8

134:15 135:2,8 227:11,19 <b>388</b> 5:19 <b>39</b> 314:7	<b>68</b> 262:11
<hr/> <b>4</b> <hr/>	<hr/> <b>7</b> <hr/>
<b>4</b> 132:7 135:21 <b>4,186</b> 332:17 <b>4.22</b> 226:22 227:2 238:9 <b>40</b> 52:12,13,15 126:14 230:19,21 384:6 417:14 <b>400</b> 318:1 <b>41</b> 223:19 <b>42</b> 135:2 181:9 240:13 258:2 <b>422</b> 190:3,4,6 <b>44</b> 26:10 294:14,14 <b>45-year-old</b> 283:18 <b>47</b> 134:20 166:7 182:15 183:5 217:13 227:11 261:3 <b>48</b> 207:12	<b>7</b> 33:6 <b>70</b> 126:12 222:21 232:2 232:18 <b>72</b> 119:2 343:6 <b>75</b> 51:3 119:1 <b>77</b> 299:5
<hr/> <b>5</b> <hr/>	<hr/> <b>8</b> <hr/>
<b>5</b> 166:2 217:6 388:19 <b>5:00</b> 389:4 <b>5:15</b> 388:20 <b>5:30</b> 422:7 <b>50</b> 77:19 148:18 207:15 222:21 298:6 353:21 382:9 395:17 <b>500</b> 381:16 <b>50th</b> 149:16 <b>52</b> 52:7 <b>52A</b> 80:3 <b>53</b> 180:18 183:5 <b>54</b> 166:1 <b>55</b> 52:7 <b>56</b> 32:17 <b>58</b> 134:9 182:2 <b>59</b> 223:19	<b>8</b> 207:21 <b>8:30</b> 1:9 <b>8:38</b> 6:2 <b>80</b> 148:16 151:8 382:6 <b>80.9</b> 141:13 <b>80s</b> 374:12 <b>84-year-old</b> 105:4 <b>85-year-old</b> 107:1 <b>87</b> 224:17 <b>89</b> 64:7
<hr/> <b>6</b> <hr/>	<hr/> <b>9</b> <hr/>
<b>6</b> 4:2 294:11,20 <b>6.14</b> 332:19 <b>6.67</b> 332:21 <b>6:00</b> 190:15 <b>60</b> 51:14 52:11,13,13 120:2 166:2 <b>61</b> 294:19 <b>63</b> 166:18 167:3 217:6 240:3 <b>64</b> 4:9,11,12,14,15,17 4:18 <b>64.7</b> 223:20 <b>65</b> 283:10 302:16 <b>67</b> 311:2 354:6	

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In the matter of: Person- and Family-Centered Care  
Phase 2 Standing Committee Meeting

Before: NQF

Date: 01-21-15

Place: Washington, DC

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