

THE NATIONAL QUALITY FORUM

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MEETING OF THE HEALTHCARE ACQUIRED

CONDITIONS AND SERIOUS REPORTABLE EVENTS IN

HEALTHCARE STEERING COMMITTEE

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Wednesday, November 18, 2009

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The Steering Committee convened,
at 9:00 a.m., in Salon A of the Park Ballroom
of the Park Hyatt Washington, located at 1201
24th Street, N.W., Washington, D.C., Gregg
Meyer and Sally Tyler, Co-Chairs, presiding.

PRESENT:

GREGG MEYER, MD, MSc, CO-CHAIR
SALLY TYLER, MPA, CO-CHAIR
LEAH BINDER, MEMBER

PATRICK BRENNAN, MD, MEMBER
TEJAL GANDHI, MD, MPH, MEMBER (via telephone)
CHRISTINE GOESCHEL, RN, MPA, MEMBER
CYNTHIA HOEN, ESQ., MPH, FACHE, MEMBER
HELEN LAU, RN, MHROD, BSN, BMus, MEMBER
(via telephone)
KATHRYN McDONAGH, PhD, RN, FACHE, MEMBER

JOHN MORLEY, MD, MEMBER
DEBORAH NADZAM, PhD, RN, FAAN, MEMBER
MARTHA RADFORD, MD, FACC, FAHA, MEMBER
(via telephone)
STANCEL RILEY, MD, MPA, MPH, MEMBER
DIANE RYDRYCH, MA, MEMBER
DORON SCHNEIDER, MD, MEMBER

PHILIP SCHNEIDER, FASHP, MS, MEMBER
ERIC TANGALOS, MD, FACP, AGSF, CMD, MEMBER
MICHAEL VICTOROFF, MD, MEMBER
PETER ANGOOD, MD, FACS, STAFF
HELEN BURSTIN, MD, STAFF

JENNIFER HURST, MHS, STAFF

LINDSEY TIGHE, STAFF

NOT PRESENT:

SUSAN GENTILLI, MBA, RHIA, CPHQ, MEMBER

KEVIN HIGH, MD, MS, MEMBER

A-G-E-N-D-A

Welcome and Call to Order	5
Peter Angood	5
Sally Tyler	9
Gregg Meyer	12
Introductions and Disclosures	15
Overview and Orientation	33
Helen Burstin	33
Peter Angood	62
Questions and Answers	88
Definition of Serious Reportable Events	106
Vote	147
Regarding leaving "preventable" in the existing footnotes and definition in "unqualified"	
Vote	156
Regarding leaving "serious" in	
Vote	159
Regarding removing "unambiguous"	
Vote	168
Regarding phrase "should never occur"	
Vote	168
Regarding whether "that should not occur" should be in or out of the definition	

A-G-E-N-D-A (CONTINUED)

Vote Regarding whether to leave in "and/or"	180
Vote Regarding whether to leave in "which may or may not have been preventable"	192
Vote Regarding leaving definition of "preventable" as it was originally	201
Vote Regarding the language "Serious describes an event that results in death or loss of a body part, disability, or loss of bodily function, or risk thereof."	212
Vote Regarding the language "Ambiguous refers to an event that is clearly defined and easily identified."	213
Definition of HACs	218
NQF State-Based Reporting Agencies' Perspectives	339

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

2 (8:59 a.m.)

3 DR. ANGOOD: Well, welcome to each
4 of you.

5 My name is Peter Angood. I am a
6 Senior Advisor at the National Quality Forum
7 in regards to patient safety.

8 I want to thank each of you for
9 taking the time out of your busy schedules to
10 join us. We have a busy couple of days.

11 The work of this project fits in
12 well with a variety of other patient-oriented
13 activities that we have within NQF. We will
14 highlight some of that in the next sets of
15 presentations.

16 We have NQF processes here. We
17 have to open the meeting formally. So we will
18 do that.

19 We have the meetings open to the
20 public for comment and listening. That should
21 not hinder your comments.

22 The meeting is recorded, so that

1 we have transcripts as well as a full record
2 of all of the deliberations. That is part of
3 not only our intent of trying to make sure we
4 have accuracy in keeping track of all of the
5 comments, but it is part of our open
6 transparency approaches in terms of all of the
7 NQF activities.

8 But, again, please don't have any
9 hindrances in terms of your comments. We want
10 open and productive dialog. And if there is
11 agreement, great; if there is some
12 disagreement, we need to hear those because we
13 want to hear where the differences of opinions
14 come from.

15 A couple of brief announcements,
16 and then I am going to turn over the meeting
17 to Sally and Gregg.

18 We have as well the need to have
19 full disclosures from each of you as we go
20 around doing the introductions. We need to
21 make sure, as part of our processes, that we
22 are aware of any potential conflicts that you

1 may have as a part of your activities.

2 We will make sure that the follow-
3 up meetings include the reimbursement forms
4 and all of the materials to get your finances
5 back in order.

6 I think all of you have had a copy
7 of the meeting materials forwarded to you.
8 You have some hard copy on the table top. One
9 is the agenda and copies of the PowerPoint
10 slides. Then there's a short page that we
11 will talk about a little bit more in terms of
12 our Technical Advisory Panels, when we have
13 that discussion tomorrow.

14 For those of you who may want a
15 freshened-up thumb drive with all the
16 materials, Lindsey has those in the back, but
17 really none of the materials have changed,
18 other than the PowerPoint slides, but we do
19 have extra copies, if you would like that.

20 The Blackberry and iPhone services
21 and all those things, as you can see if you
22 have looked at your device, there is no

1 reception down here really. So keep your
2 device turned off, please. But we will have
3 breaks during the day, and you can scoot on
4 upstairs and get caught up with your different
5 emails, et cetera.

6 And, Chris, we are just getting
7 started. Just pick any spot that is open.

8 The washrooms are out the hall and
9 in the far left at the very end of the hall.
10 We will leave it up to Sally and Gregg to put
11 the breaks into place.

12 Then one last comment which I
13 forgot to mention about NQF process. We do
14 have in the agenda formal periods where those
15 on the line or who choose to join us in the
16 audience have the opportunity to provide
17 comment on the information that they have
18 heard and to provide inputs to our
19 deliberations as well.

20 We have an interesting set of
21 topics. It is generating a lot of interest on
22 multiple levels, and the work that we do with

1 this Committee I think is going to have a
2 significant impact for American healthcare
3 and, to some degree, internationally as well.
4 Because the activities around the serious
5 reportable events and this new concept of
6 healthcare-acquired conditions is certainly of
7 strong interest for everyone. We will get
8 into more details with that.

9 So, with those as my opening
10 comments, I just wanted to also introduce
11 Helen Burstin, who is Senior Vice President at
12 the National Quality Forum in charge of
13 performance measures. Helen has been
14 instrumental in my getting oriented and
15 acclimated to NQF. It is a pleasure to have
16 Helen here as well.

17 With that, I will turn it over to
18 Gregg and Sally for their introductions and to
19 get the meeting formally started.

20 CO-CHAIR TYLER: Hi. Good morning.

21 I'm Sally Tyler. I am really
22 happy to be here with you all this morning,

1 very happy to co-chair the Steering Committee
2 with Gregg.

3 I have met a couple of you before,
4 but most of you have not. My background is a
5 little bit different from most of everybody
6 else in the room. I'm a health policy
7 analyst, and I work for a labor union.

8 I have previously served on
9 another steering committee for NQF last year
10 on the voluntary reporting standards for
11 hospitals. That was a valuable process for
12 me. I learned a lot, and I also learned a lot
13 about the workings of NQF.

14 One of the things I did notice in
15 that process, though, was that a lot of our
16 discussions were just clinicians talking to
17 clinicians. That would be natural because,
18 generally, those were the people in the room.
19 But I hope, in moving forward with this
20 process -- and this is one of the reasons that
21 I very much wanted to part of this project,
22 because I think this project has such huge

1 implications for the public, for consumers,
2 and for the healthcare workforce, that I hope
3 we remember that we are talking to those
4 people as well. Certainly in our report
5 language, when that becomes final in 2011, but
6 certainly even in our deliberations and
7 discussions here, that we remember that.

8 From time to time I believe there
9 will be members of the public in our
10 discussions as well. But even when they are
11 not in the room, I hope we can remember.

12 So I am not shy about interrupting
13 when we get into much alphabet soup, and I
14 will ask for, you know, "And in plain language
15 that means what?" or "Why is this significant
16 to our project?" So that everybody takes that
17 in the spirit that it is meant, not just to
18 slow down the deliberations, but to make it a
19 little bit more accessible to consumers who
20 are some of the people who are going to be
21 impacted and have a lot to gain by this
22 project. I also think it can really help them

1 gain confidence in our process and raise
2 awareness of this process with the public.

3 So I am really look forward to
4 working with all of you.

5 CO-CHAIR MEYER: Good morning.

6 I am Gregg Meyer, and thank you
7 for participating on this Work Group. I am a
8 general internist and the Senior Vice
9 President for Quality and Safety at Mass
10 General Hospital and the Mass General
11 Physicians Organization.

12 I have had the privilege,
13 actually, to be associated with this work,
14 either directly or indirectly, really, I
15 think, from the very beginning. I would
16 actually draw the timeline back on the work on
17 serious reporting events and the kind of
18 complementary set of safe practices to a
19 report that myself and colleagues had an
20 opportunity to work on for President Clinton
21 that came out of AHRQ. That was the "Doing
22 What Counts" report.

1 Actually, if you go back to the
2 original document from serious reportable
3 events, you will see that that report is
4 emphasized and referenced heavily there. The
5 reason was because, when we were looking at
6 the Institute of Medicine report and what the
7 government ought to do at that time, there was
8 a lot of tension between what ended up being
9 two, again, I think complementary forces.

10 The first one was, what is it that
11 we need to do nationally to improve? And, oh,
12 by the way, we also have an obligation for
13 accountability to the public.

14 The way that that was split was to
15 work with the relatively nascent Quality Forum
16 at that point in time and come up with what
17 became the patient safety practices. And I
18 have had the privilege of chairing that
19 Committee over the last several years and
20 being involved with that group from the
21 beginning, and the complementary set of
22 serious reportable events, which were at the

1 time very much focused in on the accountable
2 side, with a recognition that you need both to
3 move forward.

4 I think we are going to be
5 revisiting some of those conversations over
6 the next day and a half. I think I look
7 forward to a lively discussion. Please speak
8 freely and openly, because that is what will
9 make, I think, this much more interesting.

10 This is going to be tough work. I
11 think that, on the one hand, you can look and
12 say, boy, 2011 seems so far away, but I think
13 that the NQF staff who are with us here today
14 recognize that that moves along very, very
15 quickly. In fact, the task ahead of us I
16 think is relatively formidable.

17 With that said, there is no doubt
18 that this group is up to it. We will commence
19 getting to work today.

20 I am going to be with you in
21 person today. I am going to be, actually, one
22 of those virtual voices on the phone tomorrow

1 because I need to be in Boston in the early
2 afternoon, but I will be here to participate
3 in your deliberations tomorrow. I look
4 forward to that.

5 I am going to start by asking, I
6 am going around and ask everyone to do their
7 introductions. In addition to telling us who
8 you are and where you are from, we also need
9 to hear from you a little about your
10 disclosures. In fact, we are required to hear
11 about your disclosures.

12 So I will begin with that, and I
13 will tell you that what I need to disclose in
14 this forum is that, as mentioned earlier, I
15 have been the Chair of the Patient Safety
16 Practices Committee. I received no
17 remuneration for that.

18 I am actually working on Peter
19 Angood and Helen Burstin to try to fix that
20 thing.

21 (Laughter.)

22 But I have failed so far, much to

1 all of our mutual chagrin.

2 And I also serve on a committee at
3 RAND which is a Technical Advisory Panel,
4 which is under contract to AHRQ to actually
5 look at the evidentiary base in trying to
6 create a grading system for patient safety
7 practices.

8 And that is my disclosure.

9 So, please, if we can go around to
10 the left here.

11 MEMBER GOESCHEL: Wonderful. I am
12 Chris Goeschel. I am a registered nurse, have
13 been a healthcare executive, am now a health
14 services researcher at Johns Hopkins with
15 Peter Pronovost.

16 I have to say that my links to the
17 National Quality Forum started when I
18 petitioned the Michigan Health and Hospital
19 Association to join, and they would not when
20 I was there because it was too expensive.
21 They do now. Yes, they do. No thanks to me;
22 I was gone after they made that decision.

1 (Laughter.)

2 But I would say that I am thrilled
3 to be part of this. Certainly, Peter
4 Pronovost and I have a number of grants
5 through the Agency for Healthcare Research and
6 Quality working on patient safety,
7 specifically in the area of culture change and
8 reducing infections, but I also speak
9 frequently on the topics of quality and
10 safety, both nationally and internationally.
11 And I formerly a Senior Advisor to the World
12 Health Organization Patient Safety Program.

13 I am thrilled to be here.

14 MEMBER NADZAM: I am Debbie
15 Nadzam. I am the Practice Leader for Patient
16 Safety at Joint Commission Resources, although
17 I have also been recently designated the
18 Director of International Quality Measurement.
19 So I guess that is a little bit of a
20 disclosure. We are part of the Joint
21 Commission Enterprise.

22 I am a nurse by background. In

1 terms of my NQF days, my physician colleague
2 at Cleveland Clinic, when I was there, and I
3 convinced Cleveland Clinic to participate.
4 They were one of the early providers. As
5 their representative, I served as Vice Chair
6 for the Research and Quality Council for the
7 first four years.

8 Other disclosure, I am a member of
9 the National Coordinating Council for
10 Medication Error Reporting and Prevention. I
11 don't know that that is relevant.

12 I am very happy and honored to be
13 here. Thank you.

14 MEMBER BRENNAN: Good morning.

15 I am P.J. Brennan. I am the Chief
16 Medical Officer and Senior Vice President of
17 the University of Pennsylvania Health System.

18 My background is infectious
19 diseases. This is my first professional
20 activity with the National Quality Forum.

21 Peter and I worked together at the
22 Joint Commission when I chaired the Sentinel

1 Event Advisory Group, and have been a member
2 of that group for many years.

3 I have no commercial
4 relationships. I currently Chair the
5 Healthcare Infection Control Practices
6 Advisory Committee, a federal advisory
7 committee to HHS and CDC, and participate in
8 a number of nonprofit healthcare boards. I am
9 also a member of the SHEA Board, which is the
10 Society for Healthcare Epidemiology of
11 America. And I am a member of a physician
12 advisory panel, uncompensated, for a local
13 payer in Philadelphia.

14 MEMBER VICTOROFF: I am Michael
15 Victoroff, representing the American Academy
16 of Family Physicians. I am a family
17 physician, but not an officer of that
18 organization.

19 I am from Denver, where I am the
20 Chief Medical Officer of a company called
21 Lynxcare, which is a consumer-facing advocacy
22 organization that does case management for

1 people with complex conditions.

2 I am also a risk management
3 consultant for COPIC Insurance Company. In
4 that role, in around 1992, I wrote one of the
5 original taxonomies for coding errors in
6 medicine, actually, before they were invented
7 by the Institute of Medicine.

8 That taxonomy that we shared with
9 just about everybody, including NQF, looks as
10 though it was one of the germinal centers for
11 classification systems and other event coding
12 systems still in use today.

13 My research and work mostly at
14 COPIC is involved in epidemiology of error,
15 and specifically, research on errors
16 attributable to electronic information
17 systems.

18 I am also a member of the Rocky
19 Mountain Patient Safety Organization, which is
20 one of the PSOs chartered through AHRQ, and I
21 belong to a number of other sort of consumer
22 safety organizations in Colorado.

1 MEMBER RYDRYCH: I am Diane
2 Rydrych, and like Sally, I bring a non-
3 clinical perspective to the group. I also
4 have a background in health policy analysis,
5 and am the Patient Safety Director for the
6 Minnesota Department of Health. So I have
7 been working for the last few years with
8 hospitals and other providers to help them
9 understand and implement the serious
10 reportable events.

11 I don't think I have anything to
12 disclose. I do participate in a number of
13 patient safety coalitions, including the
14 Minnesota Alliance for Patient Safety and
15 others, but none that I think are necessary to
16 disclose here.

17 It is my first opportunity to be
18 on an NQF committee, and I am very much
19 looking forward to the discussion over the
20 next two days.

21 MEMBER TANGALOS: I am Eric
22 Tangalos, one of the three majority

1 Minnesotans here.

2 (Laughter.)

3 And former Chair of the Division
4 of Medicine at Mayo Clinic and First Quality
5 Officer for the Department of Medicine at
6 Mayo.

7 I am here because I think I was
8 nominated by the American Geriatrics Society,
9 where I serve on their Foundation for Health
10 in Aging.

11 I am Policy Chair for the American
12 Medical Directors Association.

13 The disclosure would be that I am
14 still active with NCQA on one of their
15 technical panels, the Joint Commission on a
16 couple of their panels, and have been very
17 active with the MDS 3.0 rollout, which is a
18 CMS project that at times has had contracts
19 with RAND, RTI, and others, and I am still
20 active with that.

21 MEMBER RILEY: Hi. I'm Stancel
22 Riley. This is my first opportunity to serve

1 on an NQF committee, and I am very grateful
2 and honored to be here.

3 For 23 years, I was a cardiac
4 surgeon, and then sort of made a transition to
5 a separate career in health policy and public
6 health. In that role, I served as the
7 Director of what we call the Patient Care
8 Authority in Massachusetts, which basically
9 takes in all the reports from hospitals and
10 looks at them. In that capacity, I have also
11 served on several patient work group
12 committees in the State.

13 And the only other thing I think I
14 might have to disclose is we also have been
15 deemed holder of group causes for the Joint
16 Commission for the entire State. So we work
17 with the Joint Commission on those things.

18 MEMBER McDONAGH: Good morning.

19 My name is Kathy McDonagh. I am
20 also happy to be here. This is my first NQF
21 committee experience as well.

22 My clinical background is in

1 nursing, and I have been an CNO, a COO, and
2 for over 20 years a CEO of hospital systems.
3 I have also done a lot of work with governing
4 boards. I have done some research on how
5 governing board performance impacts hospital
6 outcome. So the theme of all my variety of
7 work has always been on quality and patient
8 safety and how to improve patient care.

9 Currently, I am the Vice President
10 for Executive Relations at Hospira. I made a
11 big jump after 35 years in the world of
12 hospitals to take a new position last year.
13 Hospira is a global healthcare company that
14 makes medical devices, generic
15 pharmaceuticals. Really, all of our product
16 line is focused on patient safety, improving
17 productivity, and reducing costs of medical
18 care.

19 So I am really excited to be able
20 to work at a national level with my C-Suite
21 colleagues, governing board folks, to help
22 people see how we can improve quality and

1 patient safety. So I am glad to be here, and
2 I don't know of any disclosures.

3 MEMBER DORON SCHNEIDER: Good
4 morning. Hi.

5 My name is Doron Schneider, and I
6 am an internist at Abington Memorial Hospital.
7 That is eight miles north of Philadelphia.
8 There I am the Medical Director for our Center
9 for Patient Safety and Healthcare Quality.

10 This is my first NQF meeting. I
11 was nominated by the ACP. For the ACP, I do
12 a lot of activities relative to quality
13 improvement, mostly in physician offices,
14 through several of their programs.

15 I also work with the ABIM to help
16 with some of the PIM activities, and SHM as
17 well for some of their improvement activities.

18 In the past year, I have served on
19 an advisory board for Novo Nordisk for helping
20 them understand insulin safety in hospitals.

21 MEMBER PHILIP SCHNEIDER: And I am
22 Phil Schneider, no relation, though we do a

1 lot alike.

2 (Laughter.)

3 I am a Clinical Professor and
4 Associate Dean of the College of Pharmacy at
5 the University of Arizona at the Phoenix
6 Biomedical Campus. It is a brand-new campus,
7 health sciences center, that has been
8 established in Phoenix. As you know, the
9 University of Arizona is in Tucson, but the
10 State has decided to invest resources, which
11 they have less of now than they did when I
12 decided to go there, to build an academic
13 health sciences program, with the aim of
14 having Arizona serve as a place where
15 biomedical industry would like to locate their
16 companies.

17 I was nominated by the American
18 Society of Health System Pharmacists. My
19 background is pharmacy.

20 And I don't know what the statutes
21 of limitation are for disclosures, because in
22 my capacity at Ohio State University, I had a

1 lot more responsibility for scholarly activity
2 and research and received grants from the
3 Agency for Healthcare Research and Quality,
4 but also did some work with the private
5 sector, helping them evaluate patient safety
6 technologies, including Hospira, but also
7 Cardinal Health and Baxter. So we had a
8 balanced portfolio when it came to our
9 research funding from the private sector.

10 I currently am on scientific
11 advisory boards for two companies. One is
12 called Intelligent Hospital Systems, which is
13 a company in Winnipeg, Canada, not a great
14 place to go for advisory board meetings in the
15 winter. They make a robot that produces IV
16 solutions in hospitals.

17 And the other is a company called
18 SEA Medical, which is producing some
19 technology that helps identify the identity
20 and concentration of medicines that are given
21 through intravenous infusions.

22 MEMBER MORLEY: Good morning.

1 My name is John Morley. I am from
2 New York, the New York State Department of
3 Health. I have been in government for four
4 years, just over four years.

5 Prior to that, as a clinician, my
6 medical practice and experience was in
7 anesthesia, internal medicine, pulmonary and
8 critical care.

9 My role in the Health Department
10 is the Medical Director of the regulatory side
11 of the Department.

12 And to the best of my knowledge, I
13 don't have any conflicts. I don't have enough
14 influence, power, money, or anything.

15 (Laughter.)

16 Thank you.

17 MEMBER RADFORD: Hi. I'm Martha
18 Radford, and I am calling in from New York
19 City.

20 I am the Chief Quality Officer at
21 NYU Langone Medical Center. I have been on at
22 least one other NQF technical panel earlier

1 this year on outcomes. I think I was on one
2 other prior to that, although I guess I am
3 getting Alzheimer's.

4 I have been active on panels with
5 NCQA as well and a long-term member of the
6 ACC, American College of Cardiology/American
7 Heart Association Task Force on Performance
8 Measures and Data Standards. I think one or
9 both of those organizations nominated me to be
10 part of this group, which I am very honored to
11 be.

12 I am a cardiologist, and have no
13 remunerative conflicts of any type, which
14 means that I am living below the Manhattan
15 poverty line.

16 MEMBER LAU: Hi. My name is
17 Helen Lau. I am calling you on the next two
18 days from California on the West Coast.

19 My clinical background is in
20 nursing. Currently, I am a National Program
21 Leader in Quality from Kaiser Permanente.

22 My background, a lot of experience

1 in quality management and also operational
2 background from the hospital to home care
3 area.

4 I have served, from 2001 to 2003,
5 served at the National Malcolm Baldrige
6 Quality Award as an examiner.

7 As far as disclosure, currently, I
8 am also a member on the NQF, the Common Format
9 Expert Panel. Other than that, I have nothing
10 else to disclose.

11 DR. ANGOOD: Is there anyone else
12 on the phone?

13 (No response.)

14 Thanks, Martha and Helen, for
15 jumping in like that.

16 MEMBER RADFORD: Hi. This is
17 Martha again.

18 I just wondered if someone could
19 send the slides to us that are out of the --

20 DR. ANGOOD: Sure. We will see
21 what we can do. We are in kind of a low-
22 frequency area in terms of wireless, but we

1 will ask Lindsey Tighe to pop up and send
2 those in to both you, Martha, and Helen as
3 well.

4 MEMBER RADFORD: I just wanted to
5 say that I will be there tomorrow. I am sorry
6 that I couldn't be there today.

7 DR. ANGOOD: No, that's not a
8 problem at all. Thank you for piping up.

9 Jennifer?

10 MS. HURST: Hi. Good morning.

11 My name is Jennifer Hurst. I'm
12 the Senior Project Manager on the Patient
13 Safety Team.

14 I have no disclosures.

15 I would also like to take the
16 opportunity to introduce you to Lindsey. She
17 is in the back.

18 All of you have received a lot of
19 emails from Lindsey. So thanks so much for
20 your patience.

21 DR. ANGOOD: While Cynthia is
22 getting organized, I will just sort of give a

1 little bit more brief background on my
2 origins.

3 Unfortunately, I did grow up in
4 Winnipeg.

5 (Laughter.)

6 And that's why I don't live there
7 anymore.

8 (Laughter.)

9 MEMBER PHILIP SCHNEIDER: I bet it
10 is nice there in the summer. Our last meeting
11 was in February.

12 (Laughter.)

13 DR. ANGOOD: All two weeks, and it
14 is a dry cold. That's what they always say,
15 too.

16 I come from a surgery background,
17 spent a lot of years doing trauma and critical
18 care and a variety of academic backgrounds,
19 and spent a number of years at the Joint
20 Commission looking at the patient safety
21 activities there, including the National
22 Patient Safety Goals and the Sentinel Event

1 Reporting System.

2 I have been at NQF since the
3 springtime, helping to consolidate and expand
4 the patient safety portfolio.

5 Helen, do you want to do it? Then
6 we will get Cynthia, once she is settled.

7 DR. BURSTIN: Sure. Hi.

8 Helen Burstin. I'm the Senior VP
9 at NQF for Performance Measures for about the
10 last almost three years. Before that, I was
11 at AHRQ for about seven years; spent a fair
12 amount of time with my colleague to my right
13 here, together with John Eisenberg, and had a
14 phenomenal opportunity to really think and
15 build a lot of the patient safety and quality
16 work that we did at AHRQ.

17 Before that, I was at the Brigham
18 in Boston and was head of Quality Measurement
19 and was also an investigator on the Harvard
20 Medical Practice Study as well as the
21 Utah/Colorado Study. So patient safety is
22 sort of in my blood to a certain extent.

1 I also have a very strong interest
2 in HIT.

3 DR. ANGOOD: Cynthia, we are just
4 doing the introductions. Basically, if you
5 could just give a short background on who you
6 are and how you are here, and any disclosures,
7 please.

8 MEMBER HOEN: Sure. I'm sorry I
9 am late. I was doing the Acela taxi thing
10 through the city, but I am glad to get here.

11 My background is in law. I got my
12 JD about 20 years ago and practiced defense
13 for 14 before going in-house with a hospital
14 system. I have my master's in public health.
15 I run risk management and claims management
16 insurance programs. I am very involved with
17 the medical staff as well as the Quality
18 Director and Legislation.

19 CO-CHAIR MEYER: Anyone else join
20 us on the phone who hasn't already had a
21 chance to introduce themselves?

22 (No response.)

1 Okay. Hearing none, we will move
2 forward.

3 What we would like to do is, at
4 the onset of each of the sections that you see
5 listed in your book here, we will try to be
6 pretty explicit about what we want to try to
7 get out of that session, so you can focus on
8 that.

9 The first part of our day is going
10 to be spent with an overview and orientation
11 to this project, and also committee roles, and
12 a bit about where we fit into the NQF
13 framework, which is incredibly important. I
14 think all of you know that the NQF is not just
15 about the content of the products that it
16 produces, but it is very much about the
17 process and doing things the right way.

18 So, with that, I will turn it over
19 to Helen and Peter.

20 DR. BURSTIN: Again, it is a
21 pleasure to be here.

22 I want to run through this very

1 quickly. I think you may have had some of
2 this orientation on your call.

3 What we wanted to do a little bit
4 was give you an orientation to -- I will start
5 out broad and Peter will get specific -- about
6 our work, how it relates, and then
7 specifically, how this particular piece fits
8 into the broader safety portfolio at NQF, but
9 also the broader piece of the more specifics
10 of we are hoping to go.

11 So the next slide, please.

12 So, just to begin, the mission of
13 NQF is something most of you probably know,
14 all about improving healthcare quality.
15 Obviously, over the last two years, really
16 beginning to set the priorities and goals for
17 the nation around performance measurement and
18 improvement, endorsing National Consensus
19 Standards. That is the piece we are sitting
20 on today.

21 The hope is the current, for
22 example, serious reportable events are

1 National Consensus Standards of the NQF. The
2 question is going to be: should we expand,
3 revise those, think about a broader set of
4 those? And that will be the discussion for
5 today.

6 And specifically, the idea is that
7 the measures and other consensus standards,
8 like serious reportable events, that are
9 endorsed by NQF are important for measuring
10 performance, and specifically, are considered
11 appropriate for public reporting, to get at
12 comparisons between providers.

13 And lastly, a modest education and
14 outreach program, and probably soon to be a
15 fourth goal, which is all focused around this
16 issue of translation of what's currently
17 happened to an HIT environment. So, for
18 example, moving the measurement platform away
19 from medical records, even some of the
20 administrative data, to more of a focus on how
21 we can use various electronic data sources to
22 get at better measures.

1 Next, please.

2 So the goals for today will, as I
3 mentioned, orient you to where we are
4 currently, specifically thinking about your
5 role and the TAPs that will follow. We will
6 talk a little bit about the safety work. Then
7 Peter will get into the details around some of
8 the specific questions, the scope of this
9 project; definitions, which is going to be --
10 I think if we come out with nothing today
11 other than with a set of workable definitions
12 to define the next phase of work, we would be
13 very, very pleased. Then, ultimately,
14 thinking about how we would review and update
15 the criteria reviews for SREs, and then create
16 what those criteria might be for a broader set
17 of events.

18 Next.

19 So NQF is a private nonprofit. It
20 is a voluntary consensus standard-setting
21 organization. The standard-setting
22 organization is particularly because of a

1 national act called the National Technology
2 Transfer and Advancement Act that essentially
3 deems NQF as the standards-setting
4 organization for healthcare quality.

5 This is important because, when
6 the federal government is seeking to use
7 healthcare quality standards, they need to use
8 standards that are NQF-endorsed. So that is
9 the reason we try to really bring together
10 these multi-stakeholder groups and try to get
11 the best of standards we all feel comfortable
12 with.

13 Very explicitly, around the table,
14 as you will see, steering committees are
15 always constructed to be multi-stakeholder, to
16 try to get the full range of voices, as Sally
17 mentioned earlier.

18 Over 400 members currently, a
19 broad set of stakeholders across of a variety
20 of councils.

21 Go to the next one. Sorry, that's
22 in there twice. Next. We must be going the

1 wrong way.

2 For those of you who haven't seen
3 our website recently, I would recommend you
4 take a look. It has been revamped and,
5 actually, much easier to use than the old one
6 was, which I could never find anything on.
7 Although after three years, I kind of could
8 find anything, and now I can find nothing
9 because I used all my workarounds. I am
10 handling the new IT.

11 But the thing about having an
12 account there, it is very easy. Anybody can
13 go on and just get so you can track projects,
14 for example. You could easily go on as a
15 member of the Steering Committee, enroll, and
16 then say you want to track this particular
17 Committee, and then easily just go to the
18 website and pull up any of the documents as
19 they come up, just one easier-step shopping
20 for you.

21 Next.

22 So where do you fit? This is the

1 way we organize our projects. We have
2 specific project areas, and we convene a
3 multi-stakeholder steering committee.

4 Then we use technical advisors or
5 work groups or technical panels to do more of
6 the detailed evaluation that feeds into the
7 steering committee. The steering committee is
8 the ultimate deciding group that makes the
9 recommendations to the NQF membership and the
10 public prior to commenting.

11 We will then have a set of draft
12 recommendations, draft consensus standards.
13 We will then have a public comment period,
14 which is remarkably robust. I mean, in our
15 most recent project we did on clinically-
16 enriched administrative measures, we had 800
17 comments.

18 So we consider that a positive
19 sign that the membership and the public are
20 engaged. It makes it a pretty hard job for
21 all of you because you get to look through all
22 of those comments and make a set of your

1 recommendations based on the comments, as to
2 whether or not you want to modify what you
3 would like to do.

4 Ultimately, we will then put those
5 standards out for member voting. It will go
6 to the Consensus Standards Approval Committee
7 and the Board. We always, as is required for
8 all consensus standards organizations, have a
9 30-day appeals period.

10 Next.

11 So, as I mentioned, we have a very
12 formal consensus development process, which we
13 really must adhere to for the sake of
14 maintaining our status. We really try to
15 always, as I mentioned, have multi-stakeholder
16 input, and we always have public and private
17 sector representation.

18 We really are increasingly trying
19 to move, as I will tell you in a moment,
20 moving towards thinking about this full
21 continuum of care. So many of our measures
22 are very siloed into this is a hospital

1 measure; this is an ambulatory measure, and
2 trying to move much sort of care across the
3 continuum.

4 Some of our current safety
5 measures, for example, like surgical site
6 infections, are one example of where that
7 already happens. It goes out 30 days beyond
8 the surgery to begin looking for SSIs.

9 Next.

10 So your role? You, essentially,
11 serve as a proxy for the broad multi-
12 stakeholder group within NQF. You are serving
13 as individuals, though. So, although you have
14 been nominated by others, you are here because
15 of your expertise. We expect you will bring
16 that stakeholder perspective to the table,
17 which we think is very important. Work with
18 us to make sure we do it right.

19 We will have you think about, once
20 we figure out what the criteria are, whether
21 we are going to modify the SRE criteria for
22 this project. You will help us look to ensure

1 that we are, in fact, applying the criteria
2 appropriately, make recommendations to the
3 membership, respond to comments, as I
4 mentioned. The Co-Chairs will actually
5 represent you at the Consensus Standards
6 Approval Committee, and any further directions
7 to the CSAC will come back to you.

8 Next.

9 The role of the TAPs. In this
10 particular project, we are envisioning
11 probably, as Peter will go over with you, to
12 have three Technical Advisory Panels, to allow
13 us to think through the expansion of the
14 serious events, whatever they may be called,
15 to other settings. So perhaps you have been
16 thinking of an ambulatory-oriented group,
17 nursing homes, home health, groups like that.
18 So we will want your thinking in helping us
19 think that through.

20 They will advise you, essentially.
21 They will do the deeper dive in terms of the
22 draft review of the events. They will respond

1 to any questions you may have.

2 Our plan is we would like to try
3 to pull a Chair for each of those panels from
4 this group, so that we can actually have some
5 cohesion between the work of the Steering
6 Committee and the work of the TAPs.

7 Next.

8 Our job? In terms of staff, we
9 will again, as I mentioned, make sure we are
10 adhering to the process. We will organize the
11 meetings to the best of our ability in
12 conference calls; guide you through the steps
13 of the process. We will work to respond to
14 any queries that are out there; maintain
15 documentation on the website and to the
16 public.

17 Really, one of the core features
18 of NQF is transparency. Everything we do,
19 every deliberation of every committee is
20 completely transparent, and that is quite
21 intentional.

22 The person in the back who is

1 taking notes will do, literally, a transcript
2 for us, a legal kind of transcript, which we
3 will have. You will feel comfortable with
4 that.

5 It will get posted on our website,
6 as will a summary of all the Steering
7 Committee deliberations. The reviews of all
8 of our events that you do will all be posted
9 on the website. So, when people come to
10 really make an assessment, they will have all
11 of the information you had to make that
12 determination.

13 Then we will work to make sure you
14 have all the information you need from any
15 submitters of any of these events.

16 Next.

17 So just a tiny bit about where we
18 are moving to in terms of NQF. There's no
19 doubt that performance measurement in general
20 is clearly an evolution, in a lot of different
21 ways. There is definitely a drive towards
22 higher performance.

1 Many of the measures that came in,
2 I think, over the last few years, people have
3 thought perhaps didn't represent the highest
4 level of performance, but perhaps the base
5 level of performance. We are trying to move
6 that bar a bit; seeing more and more of a
7 shift and an interest, especially from our
8 consumer and purchaser colleagues, to get
9 towards composites, to get to a more
10 comprehensive view of what we do. Always
11 trying to remember to ensure that we measure
12 disparities in all we do, as opposed to the
13 after-thought that it often is.

14 NQF has done some work determining
15 a set of criteria that we use for determining
16 which standards should be stratified. This
17 will be something interesting for this group
18 to think about, perhaps not at this meeting,
19 but perhaps at the next one, whether some of
20 those events really are ones where we know
21 there are known disparities, and you would
22 want to make sure you look for stratification.

1 As I mentioned, trying to get more
2 of a cross-site, cross-sectional view of
3 healthcare quality. So thinking about
4 harmonizing measures across sites and
5 providers. Really a struggle, remarkably,
6 because people tend to have fairly entrenched
7 measurement systems within our silos, and
8 breaking those is a pretty significant task,
9 but I think a really important one at the end
10 of day, to make more sense of where we are
11 going.

12 And lastly, trying to promote this
13 sense of shared accountability. This is
14 probably the biggest struggle I think we have
15 in talking to folks who live on the frontlines
16 of healthcare, which is that it is very easy
17 for us to say let's pick the best possible
18 measures we can to get from a very patient-
19 focused viewpoint healthcare quality. But it
20 is inevitable that we come back to this
21 question, "but I can't be solely accountable
22 for that outcome."

1 So the classic example here would
2 be re-admissions. You know, hospitals will
3 say, "I can't own this. You know, there are
4 community providers for whom I need to do a
5 hand off." But, yet, there is no question
6 that measuring re-admissions is the right
7 thing to do.

8 So we are struggling with that,
9 but I think we really, at the end of the day,
10 want to try to get a set of measures that
11 allow us to see that patient-focused view of
12 the world.

13 Increasingly, a focus on outcome
14 measures. We are doing a project currently on
15 outcomes across the top 20 Medicare
16 conditions, as well as a steering committee
17 focused on child health outcomes and mental
18 health outcomes. So we are really trying to
19 move the needle there.

20 We are planning to do a great deal
21 of work on appropriateness and overuse as we
22 go forward.

1 And then, also, launching a
2 project very soon, in the next month or so,
3 for the first time beginning to look at cost
4 and resource use, as coupled with quality
5 measures. It will be a real interesting
6 challenge, I think, for us going forward to
7 begin knitting together what are the
8 appropriate measurement sets across some of
9 these conditions, when you have outcomes,
10 resource use, safety measures, patient
11 satisfaction, patient shared decision making
12 into a real measurement set that would add
13 value from all stakeholders.

14 Next.

15 Actually, I will skip this.

16 We have updated our endorsement
17 criteria last August. Again, they are not
18 directly applicable to these events, but I
19 think they are many of the same concepts that
20 we want you to think about as you are
21 developing or expanding the criteria that we
22 are using for SREs and perhaps this broader

1 category of HACs.

2 We very much tried to strengthen
3 the criteria so that we had a stronger link to
4 the National Priorities that I will mention
5 shortly, higher-level performance measures,
6 greater harmonization as much as possible
7 across sites of care.

8 So perhaps, as you are thinking
9 through SREs or HACs across site-specific, are
10 there opportunities to think about events that
11 would cross sites of care, for example, rather
12 than just be siloed?

13 A greater emphasis on thinking
14 about outcomes of care. And then, if there
15 are more process measures, ensuring there is
16 a fairly tight process-to-outcomes link.

17 Next.

18 These are the criteria that we
19 have currently. Again, you will need to think
20 about how these fit within the context of SREs
21 and HACs.

22 We have now a must-pass criterion

1 of importance to measure and report, which was
2 a change for us. The idea here was, really to
3 put it in the simplest terms, is the juice
4 worth the squeeze? Is it really worth
5 collecting the data? Because at the end of
6 the day there is a known performance gap;
7 there is clear evidence that this measurement
8 focus is important.

9 Then, lastly, there is an
10 opportunity for improvement. There is a gap
11 here. There is a real problem.

12 So, for example, identifying
13 events for which there is a very small number,
14 and perhaps not a great impact on the overall
15 healthcare system, may not be where we want to
16 go, just to think about it in this context.

17 We want to, as much as possible,
18 drive toward high levels of a scientific
19 acceptability of the measurement properties,
20 the reliability and the validity of the
21 measures, and in this case the events. Can
22 you set up specifications for these events in

1 a way that they are replicable across
2 hospitals, across health system, across
3 different pairs and data sources?

4 Usability, ultimately, can the
5 intended end-users of that, whether that is
6 consumers, purchasers, clinicians, whoever it
7 may be, understand and use those results for
8 decision making.

9 Peter will tell you about a
10 parallel effort that is happening in just a
11 couple of weeks, which is a steering committee
12 that will think through a framework for
13 reporting on these kind of events, which we
14 will, obviously, make sure you guys stay
15 connected.

16 And then lastly, feasibility, can
17 we logically implement these measures without
18 undue burden? So that is where we have a
19 great deal of shift toward electronic data
20 collection and EHRs.

21 A real question would be, how much
22 of this kind of work can begin to be built off

1 that platform? It is still unclear, I think.

2 Next.

3 I mentioned disparities. I think
4 a last point here, just to make the point that
5 we have been trying to think about how to make
6 disparities assessment a routine part of
7 measurement, working closely with lots of
8 other stakeholders to think about both the
9 direct methods in terms of how do we ensure,
10 for example, an EHR environment. If you're
11 collecting race, ethnicity, language data, how
12 does that data flow through so that you can,
13 in fact, always have it to marry it to your
14 quality measures, to be able to stratify for
15 disparities, thinking through some of the
16 indirect methods that are currently being used
17 with geographic information systems, for
18 example, to do that.

19 Then, lastly, this concept that we
20 have developed called disparity-sensitive
21 measures, where we have come up with a set of
22 criteria around prevalence, the impact of the

1 condition, the impact of the quality process
2 to narrow the gap, and then, ultimately, the
3 size of the gap as being the ones, in
4 particular, we should always stratify,
5 something for you to think about as you go
6 through the events.

7 Next.

8 This is just a framework we have
9 been thinking through, as we start thinking
10 about care across an episode. These are
11 episodes as we have developed them from the
12 patient perspective, not necessarily from the
13 billing perspective, a billing-free time
14 period when there's no bills.

15 Now this is really from a
16 patient's viewpoint. We have developed these
17 now across multiple conditions. This is the
18 example for acute MI, just trying to think
19 about how care begins to cross the bubbles
20 here of various phases of care, understanding
21 and trying to think about the population at
22 risk, for example, and prevention,

1 understanding patient preferences, as they
2 play in here, and, ultimately, recognizing
3 that there are different outcomes for
4 patients, depending on different trajectories
5 of their care.

6 A patient who has an acute MI and
7 winds up with PCI could wind up for whom
8 really secondary prevention is most important.
9 The patient has a pretty significant hit on
10 their myocardium, a whole different set of
11 outcomes that are going to be especially
12 important that we consider for them.

13 Next.

14 And lastly, I just want to end
15 with a bit of a discussion on the National
16 Priorities before I turn it over to Peter. We
17 have been trying to think through what are the
18 highest leverage areas where we think, if we
19 really work together, we could really make a
20 significant change and drive change and
21 improvement in the healthcare system.

22 Next.

1 So the National Priorities
2 Partnership was established a couple of years
3 ago to specifically set up this goal. There
4 are now 32 leadership organizations. Pretty
5 much all of the major effector arms in
6 healthcare are represented at some macro-
7 level. It is chaired by Don Berwick and Peggy
8 O'Kane.

9 Next.

10 And these are the six National
11 Priorities and Goals on these two slides. I
12 am not surprised on this slide to highlight
13 patient safety, since it was one of the six.
14 But the others are directly relevant, I think,
15 as you think through the kind of events you
16 want to be thinking about.

17 The first is that patients receive
18 well-coordinated care across provider settings
19 and levels of care with a specific focus on
20 some of the issues around medication
21 reconciliation, hospital re-admissions, and
22 perhaps preventable and emergency department

1 visits.

2 The second is a more population
3 health lens to the healthcare system, focusing
4 on ensuring that 100 percent of patients get
5 what is indicated in terms of preventive
6 services, ensuring access to the healthy
7 lifestyle behavior interventions we can do,
8 and then moving towards this concept of more
9 of a population-level health index, which is
10 more of a community-oriented measurement. We
11 don't have very many of those, except for the
12 AHRQ prevention quality indicators, which look
13 at preventable admissions in a community.

14 The safety one is interesting and
15 fits directly into this work. A strong focus
16 here on improving the safety and reliability
17 of the healthcare system with a focus on
18 hospital-level mortality rate. They called it
19 serious adverse events to keep it quite broad,
20 as part of that initial rating group. This
21 was initial.

22 Then, lastly, healthcare-

1 associated infections. Peter will say more
2 about that.

3 Next.

4 These are the remaining three.

5 Engaging patients and families on managing
6 health and making decisions about care.

7 Strong import here around shared decision
8 making. Patient experience of care at every
9 setting.

10 Patient self-management.
11 Guaranteeing appropriate and compassionate
12 care for end-of-life is a particularly
13 important one that has had very little
14 attention to date.

15 And lastly, eliminating waste
16 while ensuring the delivery of appropriate
17 care, which has nine focused areas of overuse
18 that we will be working through over the next
19 year to two.

20 Next.

21 So, just putting it together,
22 thinking about that lens across episodes, and

1 then overlaying in yellow the National
2 Priorities, this is really the vision of where
3 we see our portfolio moving to. We want to
4 see it as sort of a two-dimensional matrix
5 across the high-level, high-impact conditions,
6 as well as these cross-cutting National
7 Priorities and Goals to begin giving us a
8 broad picture as to where we think we need to
9 go to, hopefully, make some significant
10 improvements in the healthcare system.

11 Next.

12 And lastly, just hard to not
13 mention HIT, since I think it is so relevant
14 to where we are at the moment. ARRA, the
15 American Recovery and Reinvestment Act, had a
16 significant amount of dollars at stake, I am
17 sure you all know, \$40 billion, around the use
18 of electronic health records.

19 One of the key capacities that
20 they are going to be assessing is the ability
21 to capture and query information relevant to
22 healthcare quality. So just something to

1 think about as you, again, consider what kind
2 of events can be captured from different data
3 sources.

4 Next.

5 And lastly, this is a great slide
6 that the RWJ Aligning Forces for Quality group
7 came up with that I think just makes the case
8 specifically, as we are thinking about a very
9 broad set of events across a broad set of
10 settings, begin thinking about how we may need
11 to bring together data across a whole range of
12 different settings and information systems, to
13 get at what we want, to get at the data
14 aggregation, to again try to be more patient-
15 centered into what I think they need.

16 I think that is it. Peter, I
17 think it is yours, yes, next.

18 Lastly, NQF just released the
19 quality dataset, which we have been working on
20 over the last year, of those key data types
21 and data elements that should be embedded into
22 EHRs to allow for quality measurement.

1 Next. And I think that's it.

2 There you go. I will turn it over to Peter.

3 CO-CHAIR MEYER: Actually, before
4 you turn it over to Peter, any clarifying
5 questions for Helen? I think the most
6 important thing I want you to focus on is, as
7 I said before, is the importance to process.

8 DR. BURSTIN: Yes.

9 CO-CHAIR MEYER: One of the things
10 that we will be counting on the NQF staff,
11 both Sally and I will be regularly asking to
12 make sure, are we on track; are we going
13 through all of the right steps? Process
14 really matters here.

15 Any questions for Helen at this
16 point?

17 (No response.)

18 Any from the folks on the phone?

19 MEMBER RADFORD: No. Very clear.

20 But thank you.

21 CO-CHAIR MEYER: Peter?

22 DR. ANGOOD: All right, thanks,

1 Gregg. Thanks, Helen.

2 Each time I hear Helen's talk, I
3 continue to learn more. I think, from your
4 perspective, NQF is complicated to learn
5 because it has really got these tight
6 processes, but it is, obviously, also
7 expanding its whole scope of activity on a lot
8 of different fronts. That is an exciting part
9 to be a part of.

10 What I will do in the next couple
11 of minutes is just sort of review some of the
12 aspects of safety, and then we will start to
13 hone this all down into this Committee's work
14 overall.

15 As you can see, the roles of NQF
16 so far in safety, this serious reportable
17 events, a very early program, got a lot of
18 national and international notoriety. The
19 first release was in '03. There was an update
20 in '06. Even before our current contractual
21 work with the Department of Health and Human
22 Services, we were scheduling in to have the

1 serious reportable events updated for 2009,
2 but we have rolled it into this particular
3 scope of work.

4 These 28 SREs really, I think,
5 have taken hold in many, many different ways.
6 It is on the national level. It is in the
7 state levels. It is in regional levels. It
8 is certainly within healthcare systems, and,
9 obviously CMS has taken up some of these as
10 concepts in terms of the payment strategies.
11 So NQF I think had a lot of foresight in terms
12 of bringing these into play.

13 The cross-cutting safety measures,
14 there's about 550-or-so measures within the
15 NQF measures database now. About 20 percent
16 of them are safety-related. That is mostly
17 oriented towards the safe practices and the
18 serious reportable events, but a number of
19 them are oriented as well to specific areas,
20 healthcare-acquired conditions, I'm sorry,
21 infections, and a couple of other focus areas.

22 But there's some incongruities in

1 there as well. We have some gap areas. As we
2 move forward, one of the other pieces of work
3 that we will be doing is to look at expanding
4 the patient safety measures and filling in
5 some of those holes. I will talk more about
6 that in a moment.

7 NQF's safe practices are also a
8 very well-established program now. They have
9 been recently updated for the third time.
10 Those were released in 2009.

11 We have moved into an annual
12 maintenance cycle for these. We recognize
13 that the evidence on the safe practices
14 evolves rapidly enough, and the topics
15 themselves continue to evolve, that the annual
16 maintenance process is important.

17 So we have already done a fairly
18 light but I think thorough review of the just-
19 released 2009 safe practices for 2010. Those
20 will be under final approval by the Board
21 toward the end of the month. Then they will
22 be released at the end of the year, or

1 certainly by January.

2 Then we will do a deeper review of
3 the safe practices again during 2010 for
4 release in 2011. We will probably move to
5 this sort of light year, heavy year, light
6 year, heavy year, to make sure that we are
7 keeping abreast of the field.

8 One of the things I learnt, and
9 many of you have felt it, is with the Patient
10 Safety Goals Program at the Joint Commission,
11 if you tweak them too much too often, you just
12 confuse the field. We want to make sure that
13 we don't do that with the safe practices as
14 well.

15 They have been taken up very well,
16 but what we need to do is really learn how to
17 better at NQF bring the safe practices in with
18 the serious reportable events, in with the
19 measures, so they all weave better together.

20 They kind of sit there as three
21 separate programs, some overlaps, and I think
22 the evolution of NQF is just reflective of how

1 these programs came to be. But there will be
2 a concerted effort on our parts to really
3 weave those three programs together.

4 That also fits in with the
5 National Priorities patient safety activity
6 that Helen mentioned in there. Some early
7 work with NPP is we are going to be focusing
8 on the perioperative environment, specifically
9 looking at, how do we decrease the healthcare-
10 acquired infections in that perioperative
11 environment, as well, how do we decrease the
12 serious reportable events in that
13 perioperative environment? It is not just
14 cutting off the wrong leg. It is the pressure
15 ulcers. It is all those other things.

16 Then, how do we improve or augment
17 the cross-disciplinary team activities in the
18 perioperative environment? We got to that
19 point by looking at the safe practices or the
20 practices of each of the member organizations
21 within NPP and realizing that those were
22 common themes across all of the member

1 organizations.

2 The perioperative environment is
3 just chosen as an initial start point because
4 it is relatively contained in terms of the
5 environment, in terms of the number of
6 disciplines, and the definable types of
7 conditions that are in there.

8 But, as we learn from that, we
9 will be looking, again, for ways to, within
10 the NPP activity, cross over that to the
11 serious reportable events, to the safe
12 practices, to the measures. Then we will move
13 beyond the perioperative environment with NPP
14 there, obviously. But that is just a starting
15 point.

16 The common formats for the patient
17 safety organizations, we have been overseeing
18 the Steering Committee activity in developing
19 those common formats. The first iteration of
20 those common formats are out there. They are
21 still open for public comment. So, if you
22 have interest in these, by all means, seek

1 those out.

2 The development of the common
3 formats has, I think, been important work
4 because it really is trying to make sure the
5 commonality of terms, the approaches, the data
6 is as uniform as it can be, as they go into
7 the reporting structures of the patient safety
8 organizations.

9 There's about 70 PSOs out there
10 now. They are just getting started on their
11 reporting activities. We will be following
12 along with the Agency for Healthcare Research
13 and Quality to see how that evolves.

14 That, too, ties into some of the
15 IT work that Helen just mentioned. I am not
16 going to go into that further, but, obviously,
17 the focus on the national level with
18 electronic health records and HIT overall,
19 clearly, is an important facet in all of this.
20 It, to some degree, will help us with driving
21 these commonalities across these programs as
22 best as we can.

1 Now, having said all of that, the
2 serious reportable events are clear and
3 distinct by themselves. The safe practices
4 are also clear and distinct by themselves, as
5 are the measures. They have different
6 focuses, but we need to just get them to come
7 together more closely.

8 Next slide, please.

9 The Health and Human Services
10 contract is a four-year contract that HHS
11 approached NQF for in January of this year.
12 It is a multi-faceted contract. It has got
13 numerous components to it.

14 We have been rapidly ramping up as
15 an organization in order to get all of these
16 projects off of the ground. Eddie Garcia is
17 a part of that project's work. He is sitting
18 there in the back. So, if you have more ideas
19 from their perspective, don't hesitate to
20 approach Eddie -- he is a very approachable
21 guy -- during the course of the day.

22 The three specific areas for the

1 patient safety component of this large
2 contract are expanding the healthcare-acquired
3 conditions into other environments of care
4 beyond the hospital setting. As we will
5 discuss more, this term, healthcare-acquired
6 condition, is actually undefined. We have
7 opportunity to define that.

8 There's been a lot of discussion,
9 a lot of email traffic, between ourselves and
10 HHS and CMS about this term, but I think we
11 have, to some degree, a clean piece of paper
12 to start with, but there will be context as a
13 result of the serious reportable events, and
14 as well from the HAI world and CMS's hospital-
15 acquired conditions. But we need to make sure
16 that we don't confuse the field as we define
17 this, because there already is some confusion
18 out there.

19 So expanding into non-hospital
20 environments for these so-called HACs, and we
21 need to be careful, and HHS is certainly in
22 agreement with this, that the NQF serious

1 reportable events don't get lost in this
2 process. You can think about them as a subset
3 of the HACs. You can think about them as a
4 slight parallel set, if you would like. But
5 the serious reportable events from NQF carry
6 a lot of value to the healthcare industry.
7 There is general agreement that that program
8 should not be subsumed by these HACs, but more
9 as we discuss through that.

10 The second deliverable is, as I
11 briefly mentioned, the expansion of patient
12 safety measures across a variety of
13 environments of care as well. As we define
14 those environments, then this second
15 deliverable will follow along with those same
16 environments, as we begin that activity in
17 January. That deliverable has not begun as
18 yet, because, in part, we wanted to see how
19 this group's activities came together as well.
20 We will certainly keep you apprised of that
21 work overall.

22 The third deliverable is what

1 Helen briefly mentioned. That is the
2 development of a framework report on all of
3 the issues related to the measurement, the
4 evaluation, and the public reporting of these
5 so-called healthcare-acquired conditions.

6 That is a framework, and NQF does
7 these framework reports from time to time to
8 sort of set out what the issues are and where
9 the field should follow, as we put these
10 things through our consensus development
11 process.

12 A couple of you, John and Diane,
13 were involved in one of our early
14 environmental assessments as part of this
15 third deliverable. That was recognizing that
16 the 27 states and the District of Columbia
17 state-based reporting systems have never
18 really been brought together into the same
19 room to talk about the issues. So we had
20 these folks together -- what? -- just three
21 weeks ago, or thereabouts.

22 We have provided some of the

1 output from that meeting in your materials.
2 Through a fairly busy day of activity, we had
3 some presentations from six of the individual
4 states. We had some breakout sessions with
5 some very focused activity on reporting and
6 the issues related to that.

7 We also had them spend some
8 specific focus time on the serious reportable
9 events. That is some of the information you
10 have got in your packets.

11 So those three deliverables are
12 fairly robust. We've got a set of timelines
13 to, hopefully, wrap up most of the hard-core
14 work by the end of 2010 and the reports by
15 first or perhaps second quarter of 2011.

16 With all of what I have described
17 so far between our NQF-specific safety
18 activities, the NPP, and these three
19 deliverables, we have set up with a Patient
20 Safety Advisory Committee at NQF to just help
21 get some broad-based overview and make sure
22 that we are targeting these programs

1 appropriately and reasonably.

2 May I have the next slide, please?

3 Then the three proposed settings
4 that we have here -- and we will talk more
5 about them -- as we looked at the HHS
6 contract, and trying to get focus for this, we
7 said, well, there's a number of conditions
8 that are out there. You can start with the
9 top 20 CMS conditions. There are a number of
10 environments in which those conditions are
11 taken care of. CMS has the 10 environments
12 that they usually have, but we don't have
13 resources available to run 10 focused
14 Technical Advisory Panels. So we look for
15 ways to bring these environments into similar
16 areas, recognizing that it is far from
17 perfect, but it is certainly a good starting
18 point.

19 So the ambulatory home health
20 environment, the inpatient hospital settings,
21 as it is aggregated, and then the whole issue
22 of sort of extended care with the nursing we

1 have in long-term care facilities, those are
2 the three environments that we are going to
3 try to use for both this first deliverable,
4 this group's activities, as well as for that
5 development and expansion -- not the
6 development, but the expansion. Helen always
7 slaps my wrist when I say, "development",
8 because I have to be clear, NQF does not
9 develop measures, but we expand them and we
10 have the field nudge them along. I have to
11 just delete that one off my lexicon.

12 But the next slide, please.

13 So, in terms of our scope, it is
14 fairly robust. Maintenance review of the
15 existing serious reportable events. That is
16 an important component, and that will be the
17 early part of our work. Then the developing
18 of the definitions and the criteria for these
19 broader-based events. How will we define the
20 healthcare-acquired conditions or the
21 healthcare-associated conditions, and then how
22 does that impact or overlap with the serious

1 reportable events? Then how do we do this in
2 a meaningful way for the field into other
3 environments beyond a hospital setting?

4 As many of you know, the SREs
5 themselves are meant to be fairly
6 generalizable, but we need to review them in
7 terms of the context to specific environments
8 and settings. So, as Gregg said -- next
9 slide, please -- we will have a fair amount of
10 work for us.

11 So, just very briefly, review the
12 criteria of the prior SRE work, clarify the
13 definitions. We will be doing a call for
14 update and maintenance around the SREs, and
15 potentially around the HACs, depending on how
16 that conversation goes.

17 Certainly, as part of the SRE
18 update, we will want to do a call, so that we
19 get the opportunity from the field to also
20 comment on the existing serious reportable
21 events and also have the field with
22 opportunity to input for other new serious

1 reportable events or the opportunity to
2 suggest where some of the serious reportable
3 events should be deleted or removed from the
4 list. That is an important part of the
5 maintenance and update process.

6 The Technical Advisory Panels, we
7 will talk more about those. That is most of
8 tomorrow's discussion. We will get into a bit
9 more detail on that.

10 Next slide, please.

11 Then the applicability to these
12 environments, both for the serious reportable
13 events themselves, but the healthcare-acquired
14 conditions. In fact, a little bit about the
15 TAPs already, and then the evidence around the
16 level of preventability and endorsement of the
17 existing SREs I mentioned briefly, and the
18 additional ones, all for discussion.

19 I will close up with a few
20 comments about the definitions, and then we
21 will come back to them and let ourselves get
22 into the work.

1 So next slide, please.

2 So the current definition is
3 preventable, serious, and unambiguous. These
4 are the types of events that should never
5 occur.

6 Next slide, please.

7 Now, just to refresh everybody,
8 the current listing of these SREs, it is not
9 intended to capture all events that are out
10 there. It is really meant to be those highly-
11 significant events that are of concern to the
12 public, to the healthcare professionals, and
13 to the providers overall. They are meant to
14 be clearly identifiable, clearly measurable,
15 and therefore, feasible to be reported in some
16 type of a reporting system, and the risk of
17 their occurrence is significantly influenced
18 by the policies or the procedures of a
19 particular facility.

20 As we know, that is sometimes
21 difficult in itself because these are uncommon
22 events, but should they occur, there needs to

1 be a lot of focused activity around them.
2 There is an awful lot of discussion out there,
3 well, shouldn't we focus more on the more
4 common things, so that organizations can move
5 towards managing those, as opposed to these
6 rare birds that don't happen?

7 Unfortunately, some of you who are
8 in reporting systems know that these, quote,
9 "rare birds" happen more frequently than we
10 like them to still. It is jut an unfortunate
11 part of where we are at as a healthcare system
12 overall.

13 The criteria -- the next slide --
14 is really, as I mentioned, preventable
15 serious, unambiguous, and any of these
16 following. They are adverse. They are
17 indicative of a healthcare safety problem in
18 their system. They are important for the
19 public and the private, and it is usually
20 preventable. These are not always truly
21 avoidable instances because healthcare is
22 complex overall.

1 The next slide.

2 I am not going to take us through
3 each of these, but we will review them during
4 our further discussions. These are up for, I
5 think, us to -- you know, if we are happy with
6 them, that is fine. If they need to be
7 cleaned up or modified, that is fine, too. We
8 don't have to do all of that this meeting, but
9 it is certainly something that we have to stop
10 and review for ourselves.

11 I think we are close to the last
12 couple of slides.

13 Do you want to stop for a moment?

14 CO-CHAIR MEYER: Yes, one point
15 there of clarification is, actually, my sense
16 is that, if we are going to go out to the
17 field and ask for a call for events, then,
18 actually, we do have to leave this meeting
19 with a pretty clear definition here.

20 DR. ANGOOD: Okay. That is a good
21 technical point. Thanks.

22 CO-CHAIR MEYER: That is going to

1 be a deliverable for us, and, actually, in the
2 not-too-distant future.

3 DR. ANGOOD: No, thank you for
4 that.

5 All right. Next slide then,
6 please.

7 Hospital-acquired conditions, this
8 is the CMS term. Okay? This refers to those
9 conditions deemed reasonably preventable with
10 implementation with evidence-based guidelines.
11 We just have this here. We are not married or
12 wedded to this. This is not our term. But we
13 just wanted to make sure that you were aware
14 of that CMS term.

15 And we do need to make sure that
16 we don't further confuse the field overall, as
17 we move forward with this other version of
18 HACs.

19 Go ahead, Helen.

20 DR. BURSTIN: One point of
21 clarification, if I could. So the HACs are
22 currently a term CMS uses which is attached to

1 a payment issue. I think it is just important
2 to remember that NQF does not engage -- you
3 know, our line stops at implementation.
4 There's no NQF issues around the payment or
5 non-payment. That is for CMS to decide.

6 The reason this definition is
7 important, and the reason CMS just came to us
8 with part of this task, was the idea that the
9 SREs seem -- and feel free, Eddie, to hop up
10 at any time -- that the SREs seem too narrow,
11 and there seemed to be a desire to potentially
12 widen that group of potential events that we
13 would want to be able to report on and
14 consider. So that was the idea.

15 So, starting with the definition
16 of HACs that CMS uses just seems like a good,
17 logical place to begin to understand, and
18 there is a whole series of like terms in both
19 of those: what is preventable? What is
20 largely preventable? What is serious? What
21 is not so serious? So these are the kind of
22 terms we think you will grapple with today.

1 Sorry.

2 DR. ANGOOD: No, that's good.

3 Thanks. I appreciate your making that
4 comment.

5 So the next slide, please.

6 So, as we were putting the work
7 plan together, we felt it was important to at
8 least get some preliminary concepts into
9 place. This language was comfortable for the
10 folks at HHS who reviewed our work plan
11 proposal.

12 I have reread this a number of
13 times. I think it is good guidance, but we
14 need to look for, how do we make this much
15 more in a way of a crisp definition?

16 So "untoward conditions or
17 complications that are acquired by patients
18 during the processes of their care for any
19 given illness that is being managed across a
20 variety of environments of care". That is
21 kind of a lot of words, but I think the
22 concept is in there.

1 They can be across the spectrum
2 from rare to uncommon to common. They may or
3 may not require formalized reporting to
4 different external agencies, but they should,
5 as a minimum, be reviewed internally as part
6 of the QI processes of an organization.

7 We can come back to this. Between
8 Helen and I, we have been talking too much.

9 But take a moment and reflect on
10 this particular slide, as we go through the
11 day, though, and as we try to delineate the
12 differences between the SREs and what this
13 expanded term of HACs is.

14 So some questions that we want you
15 to be thinking about. Are there changes or
16 adjustments to the definitions and criteria
17 for the SREs? The SREs themselves, do we need
18 to change that list? Can we consolidate it
19 and omit, add, those sorts of things?

20 Next slide.

21 Then, sort of the framing
22 questions around the HACs: what is the scope

1 that this definition should encapsulate? What
2 are those differences, as we have mentioned?

3 Then there is this whole set of
4 discussion around acquired versus associated.
5 Acquired has a connotation that there is
6 something related to the processes of care;
7 whereas, associated could be any number of
8 different reasons why a condition shows up. So
9 we need to tease on that one.

10 The folks at HHS don't have a bias
11 at this point in time. I think it is
12 important for us to have open discussion about
13 this nuance because it has huge ramifications,
14 depending on which direction you go towards.

15 Then, while Helen mentioned we
16 don't concern ourselves with the payment
17 strategies, we do need to consider the
18 ramifications on the potential uses of these
19 HACs. As we have felt, and as we made
20 comment, the SREs have been uptaken -- that's
21 not the right word; taken up is the right word
22 -- in a number of venues. There's a lot of

1 infrastructure already in place across the
2 country related to the SREs. So, while we
3 can't predict where those HACs go, it is
4 certainly something that we need to think
5 about.

6 Then the last slide I believe is
7 the relevance related to the CMS top 20
8 conditions. There's other types of
9 conditions, other patient populations in the
10 CMS populations, obviously, pediatrics being
11 an obvious one.

12 Then what are these different
13 types of settings, and how do we consolidate
14 them, as we mentioned? Then the topics could
15 also be expanded potentially into not just
16 conditions and environments, but the
17 procedures related to some of these conditions
18 or whether or not teams of care or individual
19 disciplines of care should have some of these
20 topics related to them.

21 That is a lot more contentious and
22 a lot more sensitive, obviously, but over the

1 course of time, these things have a habit of
2 creeping, and we need to think through some of
3 those ramifications.

4 All right, I think I am done.

5 We have a listing of all of the
6 current SREs, but we are not going to go
7 through that just right now.

8 CO-CHAIR MEYER: Before we move on
9 to questions from the group, have you had any
10 comments from the CMS perspective?

11 DR. BURSTIN: It seems like you
12 should sing with that kind of microphone.

13 (Laughter.)

14 MEMBER RADFORD: If there was a
15 question, then we couldn't hear it. So, if
16 someone could repeat it, that would be great.

17 DR. ANGOOD: There hasn't been a
18 question yet. We are just setting up with
19 another microphone, but we will get it right
20 away.

21 MEMBER RADFORD: Thank you.

22 MR. GARCIA: This is Eddie Garcia

1 from CMS.

2 I think Helen and Peter did a good
3 job of capturing our thinking on HACs. We
4 have hospital-acquired conditions now. Our
5 thinking was to expand the SRE list initially
6 into other settings of care, but then, also,
7 to look at things that are potentially
8 occurring more often and frequently. That
9 could be captured.

10 So we just take this term
11 "healthcare-acquired" to capture different
12 settings of care outside of the hospital and
13 to also gather information on events that are
14 occurring frequently.

15 So I am really glad that the
16 meeting is going on, and we can, hopefully,
17 get to definitions that are useful.

18 Another thing to not complicate
19 this work with is our HAI initiative at the
20 Department, which is looking at healthcare-
21 associated infections, which I am hoping that
22 this HAC term can also be encapsulated

1 underneath as well, with the SRE list.

2 So that is all I have to say.

3 DR. ANGOOD: Yes, and on that last
4 point, I forgot to mention that on that second
5 deliverable, where we are expanding the
6 patient safety-related measures, there will be
7 very specific focused efforts on the HAI as
8 well. That is a part of where we are heading,
9 so, again, helping to bring that harmonization
10 of the HHS's HAI action plan and the scope of
11 activity related to that with the measures, et
12 cetera.

13 MEMBER BRENNAN: Peter, will that
14 be part of the work of one of our Technical
15 Advisory Panels?

16 DR. ANGOOD: No, P.J., we will
17 formally have another steering committee that
18 will begin in January on the measures, and
19 they will have their own Technical Advisory
20 Panels as well.

21 We need, obviously, to keep
22 bringing the information into both groups or

1 all three groups.

2 MEMBER TANGALOS: Yes, well, since
3 we are a steering committee, let me float
4 around at 30,000 feet for just a couple of
5 minutes. Because our task may be much more
6 difficult than the hospital-acquired
7 activities. So a few random thoughts from
8 both discussions, if you will, and then maybe
9 a little bit of a philosophical discourse as
10 well.

11 But, you know, in the hospital we
12 can call people "patients". But when we get
13 into the other environments, it gets very,
14 very difficult to use that term. And not
15 being politically correct, I am actually
16 thinking about how people, individuals,
17 interact with their environments, and where
18 that safety-versus-autonomy question comes up;
19 also, where the question between populations
20 and what is best for a population versus what
21 is best for an individual comes up. I have
22 heard a fair amount of that.

1 I think it is going to be a
2 struggle. I don't have to go back but 24
3 hours to look at the maelstrom that we have
4 right now in front of us regarding breast
5 cancer screening.

6 It really is an issue of
7 population, which is where you want to go with
8 a lot of NQF things, and the individual. We
9 have heard from the individual repeatedly last
10 night with anecdotal stories. We see the
11 patient listed a number of times, the
12 individual here.

13 So I struggle with where this
14 group is going to go in this expanded
15 environment, where it is less clear that we
16 are dealing with a patient as much as we are
17 with an individual, and where they have an
18 autonomy of their own.

19 Of course, my own background, it
20 is expansive, but it is long-term care as
21 well. We will get to one of the reportable
22 events, which is falls, which happens to be in

1 Minnesota right now a huge expos,. It is an
2 incredibly complicated issue between autonomy
3 and safety and where we are with that.

4 So I am sure that NQF has
5 struggled with these things, but it is going
6 to influence all that we do until we finish
7 our work.

8 CO-CHAIR MEYER: Other questions?
9 We apparently have one from the phone.

10 (No response.)

11 Yes, please.

12 MEMBER NADZAM: One of the things
13 that struck me with the transition from
14 hospital to healthcare is that a hospital is
15 a provider setting; healthcare is everything
16 we do. I think that will have an impact on
17 whether acquired or associated is used.
18 Healthcare-associated doesn't attribute any
19 accountability to the provider, whether it is
20 an organization or a clinician. It can be,
21 you know, I am at risk for developing an
22 infection. So I don't know what the right

1 words are, but I am not sure healthcare is the
2 right transition term.

3 DR. BURSTIN: Also, in addition to
4 that, I think it would also be helpful for us
5 to define associated versus acquired, which we
6 didn't do, just to get a better sense of what
7 people's thinking is.

8 The reason this really jumped to
9 me is I was looking at CDC stuff just a couple
10 of days ago and realized that, although some
11 of us still call them healthcare-acquired
12 infections, it is, clearly, healthcare-
13 associated infections, is the preferred CDC
14 term. Yet, it is hospital-acquired conditions
15 on the CMS side.

16 So it just seemed like it was an
17 opportunity to reconcile, and it is a really
18 very different term. So I just think it is
19 one of those other sort of concepts we need to
20 grapple with.

21 CO-CHAIR MEYER: I think that
22 would be a good part of our discussion, that

1 mission later on.

2 Christine?

3 MEMBER GOESCHEL: Chris Goeschel.

4 I have a comment as well.

5 I think, agreeing with everyone in
6 terms of the magnitude of the challenge that
7 is in front of us, I have to applaud the fact
8 that we are having the conversation. Because,
9 as I look at what is on the plate, I have seen
10 many of these dishes in other settings, be it
11 CDC or other settings that we are working in.

12 The real risk to any of this, in
13 my estimation, is that well-intentioned people
14 go down parallel paths and we end up with a
15 duplicity of wisdom at the end of the day that
16 only serves to confuse consumers and CMS and
17 others for whom important decisions are really
18 our responsibility.

19 So I am a bit overwhelmed at the
20 challenge, but glad that all the things that
21 are listed here today are in front of us. I
22 think we have an accountability. So thank

1 you.

2 CO-CHAIR MEYER: Well said. I
3 think one of the things that Peter mentioned,
4 and I think it is worth reflecting on for a
5 moment, is this notion of harmonization and
6 trying to provide what is a relatively clear
7 message to the field, to the people on the
8 frontline in a variety of settings trying to
9 do this work.

10 I am a huge fan of that effort.
11 On the other hand, we want to harmonize, but
12 we don't want to necessarily homogenize these
13 things. That really will be our challenge, I
14 think, over the next day and a half.

15 Other comments? Please, Michael.

16 MEMBER VICTOROFF: I don't know if
17 this is timely, but I have a pedantic,
18 annoying bias. When we begin to parse out
19 nuances of words, there's two ways to express
20 what we mean precisely in general.

21 One is to spend a huge amount of
22 time getting the poetry of the exact selected

1 word for the exact selected concept agreed in
2 the room, but I find that, usually, when you
3 choose the perfect word in the room, it is no
4 longer perfect when it falls into the
5 community. You have a bunch of interpreters
6 and other critics and poets and people
7 performing exegesis on the perfectly-selected
8 word. I think that is self-defeating.

9 So my bias, when we are talking
10 about associated versus acquired versus caused
11 by or resulting from, I can see us getting
12 into -- I will also introduce another bias
13 pretty soon, which is the legalistic prejudice
14 about there's an undercurrent here that we
15 need to be aware of about liability.

16 So my preference for solving the
17 choose-the-perfect-word problem is usually to
18 attach enough footnotes or explanatory
19 material to clumsily and brutally, but
20 clearly, explain what the word discussion is
21 about, rather than just being happy with
22 putting up a perfect piece of poetry.

1 CO-CHAIR MEYER: I think one of
2 the things that is useful, when you look,
3 going back to the 2002 report, you will see
4 that not only did they define the serious
5 reportable events, but they actually defined
6 the words within the definition. I consider
7 that part of the work for us to consider
8 taking on today, is looking at that as well.

9 Any comments? Please, P.J.

10 MEMBER BRENNAN: A question for
11 Helen or Gregg. There are events, I think,
12 that are not outcomes, but process measures
13 that could be good surrogates for outcomes
14 that are very difficult to measure. You know,
15 an action that is clearly proven to prevent an
16 event that may be manifest post-discharge or
17 in another setting of care that would fly in
18 the face of SREs as they are currently
19 defined, without giving examples, would such
20 process measures be suitable or is an event
21 always an outcome?

22 CO-CHAIR MEYER: I will just

1 speak. This is not in my role here as the
2 Chair. This is actually reflecting back on my
3 work on state practices.

4 That is where I think, something
5 like that is where we would fold that into the
6 work on the state practices group. But,
7 again, as Peter was trying to say, we want the
8 two to complement each other, but they won't
9 necessarily 100 percent overlap.

10 I do think that that may be one
11 way to start to parse them out, as folks see
12 processes in the state practices and more on
13 the accountability for the actual outcomes of
14 events in this Committee.

15 DR. BURSTIN: And also, on the
16 measures side, I mean, in some ways, if you
17 looked upon the SREs as being the outcome, it
18 would be very logical to think of what are the
19 linked process measures that you could
20 associate that. Ultimately, as you begin
21 thinking about a measurement set around falls,
22 or whatever the case may be, these would be

1 the sort of interventions that might be well-
2 laid-out in exquisite detail implementation-
3 wise and safe practices. This is how you
4 would measure those processes, and these are
5 the events we are trying to prevent. So I
6 think it actually winds up being a nice,
7 logical procession -- I hope.

8 DR. ANGOOD: Well, yes, just to
9 tie the bow on the box here, so it is the
10 reportable event, it is the practices, and it
11 is the measures, and how do we build that
12 continuum, if you will, because they are
13 needing to be related, but they are separate
14 and distinct.

15 I think, as we deliberate through
16 this group and move through the next year or
17 so, it will help us in those other venues to
18 really move toward how to make these overlap
19 and flow together.

20 MEMBER DORON SCHNEIDER: Just a
21 comment: the tight coupling that occurs in
22 the hospital environment is what I am thinking

1 about, and it is not seen in private care
2 offices. I am not sure how to really phrase
3 it, but I worry a little bit about us defining
4 an event and where it initiated, and some of
5 these events may really span many encounters.
6 Thinking that through is going to be
7 difficult.

8 DR. BURSTIN: Actually, just one
9 thing to add: another incredibly important
10 role of the Steering Committee is to define
11 what is not there and what needs to be
12 developed. So, in fact, you may define events
13 in primary care and then the need to identify
14 the set of processes that go along with them
15 that could be built into linked process
16 measures or safe practices; you're absolutely
17 right.

18 CO-CHAIR MEYER: Other comments or
19 questions?

20 (No response.)

21 I will just make one final comment
22 because it came up today, and it just forced

1 me to reflect back on discussions that we had
2 literally eight or nine years ago now. That
3 was this issue of rare bird, and that some of
4 these are very unusual events. That was
5 always a struggle when we initially thought
6 about really moving this contracted work from
7 AHRQ over to the National Quality Forum.

8 One of the things I would ask us
9 to think about broadly is that we can look at
10 many of these and say these are
11 extraordinarily rare. So, as mine and Helen's
12 former boss, John Eisenberg, was often wont to
13 say is he would note that we could get rid of
14 most of these serious reportable events from
15 American hospitals and healthcare settings
16 next week, and would we really be safer
17 because they are so rare?

18 I think it is a provocative
19 question, but I think the other thing for us
20 to think about is that sometimes what we need
21 to do to address what is a relatively rare
22 event gives us organizational capacity to

1 indirectly impact many other events.

2 So it is a bit of a struggle here.

3 I think it is one that I just want us to keep

4 in mind as we move forward.

5 Please do.

6 MEMBER GOESCHEL: Again, Chris

7 Goeschel.

8 I think, to that end, I agree with

9 you completely. Yet, I think -- and I know it

10 is not the work of the National Quality Forum

11 -- but we nodded earlier, the things that seem

12 to be rare events in our individual

13 organizations or the U.S. health system often

14 are not rare when we look at global

15 healthcare.

16 The world is small, and hospitals

17 and healthcare organizations increasingly are

18 looking at what is happening in the U.S.

19 through organizations like NQF to learn from

20 and not make mistakes. So I think, with that

21 WHO hat on that I wear, I think it is really

22 important and valuable to hold onto this

1 because, you know, Peter talked about the
2 insurers are people that latched onto the
3 serious reportable event list. That list has
4 legs around the world. It may not be our
5 primary focus, but we can't forget it.

6 CO-CHAIR MEYER: So, with that,
7 now I have that we are almost at about 10:30.
8 I think we should restart at 10:45. So we
9 will take that 15-minute break. I think we
10 will need the extra time that we will have by
11 starting a bit earlier. So we will convene
12 again at 10:45. And for those on the phone,
13 again, we will restart at 10:45.

14 Thank you.

15 (Whereupon, the foregoing matter
16 went off the record at 10:29 a.m. and resumed
17 at 10:52 a.m.)

18 CO-CHAIR MEYER: We will go ahead
19 and reconvene now.

20 For those that are the phone, if
21 you, again, could just identify yourselves to
22 us, the Committee members, that would be

1 helpful.

2 MEMBER RADFORD: Hi. This is
3 Martha Radford. I'm here.

4 CO-CHAIR MEYER: Welcome back,
5 Martha.

6 MEMBER RADFORD: Thank you.

7 MS. CANNON: This is Marge Cannon.
8 I'm from CMS, and I work with Eddie.

9 CO-CHAIR MEYER: Okay, thank you.
10 And Helen?

11 MEMBER GANDHI: Gregg, it is Tejal
12 calling in.

13 CO-CHAIR MEYER: Tejal Gandhi.
14 Thank you. Welcome, Tejal.

15 MS. MURPHY: Melinda Murphy, NQF.

16 CO-CHAIR MEYER: Welcome, Melinda.
17 And Helen, are you still on?

18 Okay, I think we lost Helen over the break,
19 but, hopefully, she will rejoin us.

20 As I said before, before each
21 session, we are going to try to be pretty
22 explicit about what we are looking to be able

1 to have as a goal for that discussion. This
2 one is relatively clear.

3 So, from now until around
4 noontime, what we would like to do is we would
5 like to come out of this discussion with
6 either an endorsement of the current or a
7 vision of the current definition of serious
8 reportable events, and have that to the point
9 where, after we hear some public comment, that
10 we will actually be able to take a vote for
11 the sense of the Committee.

12 So this will be a little bit of
13 wordsmithing in real time, and I think we are
14 going to rely on Jennifer to help us keep
15 track of that in real time as we move forward.

16 But, very concretely, we want to
17 come out of this next hour and 15 minutes or
18 so with a clear sense of what this definition
19 will be.

20 Now, as you recognize, there are
21 more than one bites at the apple in the
22 process that Helen and Peter reviewed with

1 you. So, if we don't get something perfectly
2 right or, in retrospect, we think we need to
3 tweak it a bit, there will be opportunities
4 for that built into the process. But this
5 will be what goes out to the field in terms of
6 the call for events.

7 So I would like to begin by,
8 again, calling your attention to a slide that
9 Peter reviewed for us. You will also find
10 that slide in your hard copy in front of you
11 here, and it is labeled as page 11 and it is
12 Slide No. 33.

13 This is the definition of serious
14 reportable events, defined as: "Preventable,
15 serious, and unambiguous adverse events that
16 should never occur."

17 So I would actually like it if we
18 could be reductionist about this, to actually
19 pick off each bit of this as we go along, and
20 begin first by acknowledging that first piece
21 of it, and that is preventable.

22 One of the things I think that is

1 important is that you will see, again, going
2 to your hard copy on page 12 at the bottom,
3 that the slide there defines the definitions
4 of the terms actually used in the serious
5 reportable event definition. And there, you
6 will see the definition of preventable is
7 described as an event that "could have been
8 anticipated and prepared for, but it occurs
9 because of an error or other system failure".

10 One, if you read the report
11 closely, you will actually see that they go on
12 further to use the term "usually preventable".
13 That may, in fact, be something that we want
14 to think about.

15 So I am going to stop there and
16 ask people to begin the conversation here. If
17 you think that this is not the right way to
18 tackle it, please speak up on that first and
19 foremost.

20 MEMBER RADFORD: Hi. This is
21 Martha Radford. I am going to jump in here.

22 This is a huge issue around

1 preventability and an intense gray area for
2 many adverse events that happen. It really
3 has to do with a gradient of contribution to
4 the event from patient risk criteria versus
5 care criteria.

6 There are going to be patients for
7 whom every conceivable prophylactic measure
8 against the anticipatable event is taken who
9 will get it anyway. I think this is the most
10 clearly manifest in VTE prevention, where all
11 of the studies have shown reductions, but
12 never elimination of a hospital-acquired VTE
13 in high-risk groups.

14 So I just want to toss that out
15 there as a remark, which is not to say that we
16 should avoid these types of events. I think
17 we have to deal with it, but just to
18 acknowledge that preventability is never black
19 and white almost.

20 MEMBER PHILIP SCHNEIDER: I think
21 that is probably true. I think there are some
22 adverse drug events that are clearly

1 preventable, like patients getting a drug to
2 which they have a known allergy.

3 And I think about infections and
4 some of the work that I did with the Nutrition
5 Support Service. We tried to minimize central
6 venous catheter infections. But I guess your
7 aim should always be zero, but, you know, the
8 fact is some people will get them.

9 So is it potentially preventable?
10 Would that be an enhancement that would get at
11 this issue that many adverse events will
12 happen, no matter how rigorous or serious our
13 intent is?

14 CO-CHAIR MEYER: I think, just in
15 terms of process, if you could, I will try to
16 keep track of everybody and periodically also
17 pause and go to the phones, but if you could
18 raise your hand, and if that is not working,
19 we will move to the flipping up the cards.
20 But I will try to get folks in order here.

21 Please.

22 MEMBER RYDRYCH: Yes, I would

1 agree with the comment that not all of these
2 events are preventable. We see it mostly with
3 pressure ulcers and falls, where there is that
4 issue of patient autonomy or there might be
5 co-morbidities. We have had very serious
6 trauma patients that developed pressure
7 ulcers, despite best efforts.

8 I do like the idea of potentially
9 preventable because it is a bit more
10 aspirational. There may be events that are
11 not preventable right now with what we know
12 right now, but that may be in the future, as
13 best practices evolve. So getting that idea
14 in there might be a good idea.

15 CO-CHAIR MEYER: Please, Michael.

16 MEMBER VICTOROFF: I will third,
17 pile on.

18 I am congenitally opposed to zero
19 tolerance philosophies because they are not
20 realistic.

21 Also, I am going to interject what
22 may get tiresome later, a liability risk

1 management viewpoint that puts anyone in the
2 position of being associated with an allegedly
3 preventable event, you know, at least one
4 strike and you're out situation in terms of
5 trying to defend it.

6 So I guess I would like to find
7 the language. I don't have it right
8 immediately. But I think, for me, the
9 approach is going to be to qualify the word
10 "preventable" by saying something like under
11 the usual conditions of care or under the best
12 conditions of care, best obtainable, best
13 feasible conditions of care.

14 What I am trying to allow with
15 that language is that sometimes you are not
16 operating under the best possible conditions.
17 I am thinking about times in the clinic when
18 the power has gone out and floods and swarms
19 of attacking killer bees. There's all sorts
20 of less-than-optimal conditions. Maybe
21 optimal, maybe the word "under optimal"
22 conditions, something like that. But I need

1 to see that word "preventable" qualified.

2 CO-CHAIR MEYER: So, so far, we
3 have a call at least to qualify this.

4 We will go to Cynthia and then
5 Doron.

6 MEMBER HOEN: Yes, I think one of
7 the frustrations of the people in the field
8 with dealing with this term is that it somehow
9 needs to be linked to proven best practices.
10 So that, if I implement as a nurse those
11 practices which have been proven to reduce or
12 to prevent that event, that it won't happen
13 unless there's outside influences such that
14 the other members are talking about, the
15 conditions of the environment which would
16 cause it.

17 So, right now, the people that I
18 talk to, there's not a lot credibility to the
19 preventable part of this definition because it
20 is not linked to what can we do to prevent it
21 in the first instance.

22 CO-CHAIR MEYER: Doron?

1 MEMBER DORON SCHNEIDER: I was
2 going to say the same. I think that if we use
3 "potentially", which I like a lot, then we
4 would need a definition of what that is. We
5 can subsume all of these comments into that.

6 Do you see what I'm saying? To
7 have "potentially" be defined as such, under
8 "usual conditions", et cetera, et cetera, with
9 the implementation of appropriate evidence-
10 based care measures, et cetera, et cetera.
11 That is what we are trying to capture with
12 "potentially".

13 MEMBER RADFORD: I do like the
14 "potentially" term, and I will agree that
15 tying potentially into the evidence base might
16 be a good way to proceed.

17 I would hope that perhaps you
18 could share with the Committee the recent
19 evidence base that was referred to in the
20 introduction, the evidence-based review, I
21 should say.

22 MEMBER TANGALOS: All right.

1 Well, I would say that I like the original
2 three words. They have strong cache. They
3 have been used a lot.

4 I think "potentially" will be just
5 an argument in balls and strikes. I would
6 suggest that, if we want to get at this end of
7 it, though, maybe "never" should come out
8 because the never event has its own cache.

9 CO-CHAIR MEYER: We will certainly
10 get to that.

11 MEMBER TANGALOS: No, no, but that
12 is the point, that that is an incredibly
13 important concept right now. If we are
14 talking about some wiggle room, then I would
15 go after the never in that elimination, rather
16 than preventable, serious, and unambiguous,
17 because they have been in play for so long.

18 CO-CHAIR MEYER: Stan?

19 MEMBER RILEY: I guess I am going
20 to argue again for different words here. I
21 think "potentially" opens things up in an
22 incredible way for all kinds of exactly as

1 Eric and I probably are going to say for
2 arguments about it, you know. So exactly what
3 is preventable or not?

4 I think the other problem is I am
5 not sure that we have the tools to say
6 something is potentially preventable, even
7 something as terrible as retained foreign
8 bodies. I mean, you know, there is a huge
9 debate and pages and pages of articles written
10 about, what can you do to prevent them? You
11 know, x-rays don't work. Counts don't work.

12 So everybody has to have some real
13 good tools to be able to do it to make it a
14 preventable event.

15 CO-CHAIR MEYER: I have Philip,
16 Diane, and then P.J.

17 MEMBER PHILIP SCHNEIDER: I guess,
18 as I remember reading about serious reportable
19 events, the "never" part really defines the
20 scope of what is a serious reportable event in
21 a very narrow way. By taking it out or
22 diluting it, you really widely increase the

1 number of events that could be potentially
2 reported.

3 I think of a "never" event as
4 wrong site surgery. I can't think of any, no
5 matter how inevitable it is because of the
6 limits of human performance and human factors,
7 it still should never happen, and we should
8 constantly strive for no wrong site surgery.
9 You should always strive for not leaving
10 foreign bodies in patients after a surgical
11 procedure.

12 So I think we need to be careful.
13 I don't have any objections to "never" being
14 in or out. But if you take it out, you are
15 going to really increase the scope of events
16 that would fall under this definition.

17 And I think there's some value in
18 identifying a number of things, be it a
19 relatively short list, 28 or whatever, that
20 really should never happen, and for people to
21 think about healthcare in a much more vigilant
22 way than they have historically.

1 CO-CHAIR MEYER: Diane?

2 MEMBER RYDRYCH: I think we have
3 to make sure we are thinking about what the
4 purpose of this definition is and what the
5 implications are of making a change to it.

6 My understanding of the reason why
7 the serious reportable events list was adopted
8 was in the hope that states, that other
9 bodies, would begin doing public reporting
10 based on these measures, and that it was an
11 important accountability measure.

12 For us in Minnesota, it probably
13 doesn't matter how we define this because we
14 make it very clear that these are reportable
15 events, whether a facility considers them to
16 be preventable or not. So, whether we say it
17 is potentially preventable, may be
18 preventable, often preventable, it is a never
19 event, it is not a never event, it is still
20 something that we expect to be reported. We
21 still expect for cause analyses. We still
22 expect corrected actions. The facility may

1 determine that it wasn't preventable in their
2 case.

3 But it feels a little bit like
4 when we are talking about the definition here,
5 we are saying that there might be implications
6 to what is reportable if we change this
7 definition. I think we need to be clear on
8 that.

9 CO-CHAIR MEYER: Just one point of
10 clarification before I move on to P.J. and
11 then John.

12 That is that our job here is
13 twofold in terms of the SREs. First of all,
14 it is to look at this definition, but it also
15 is to define the list. So those two go hand-
16 in-hand with each other. So I would argue
17 that this is not necessarily expanding this to
18 5,000 things or reducing it to one or two.

19 MEMBER RYDRYCH: Right. And I
20 think as long as we deal with that as two
21 separate topics or two separate tasks for this
22 group, defining the definition and then

1 defining the list, we are okay. But if we
2 start thinking of changes to this definition,
3 potentially opening up the list to other types
4 of events, then I think we are blurring the
5 areas a little bit more than we probably want
6 to.

7 CO-CHAIR MEYER: P.J.?

8 MEMBER BRENNAN: Gregg, I find it
9 very ambiguous, a very ambiguous definition.
10 And I want to agree with Eric's comments. The
11 ambiguity is created by the fine detail in
12 "preventable", "usually preventable", but then
13 going on to say that they should never occur.
14 So which is it?

15 I worry about setting the bar too
16 low by introducing too many qualifiers in it.
17 So I would prefer to have the fine print and
18 say that it is preventable, it is unambiguous,
19 and it is serious, but take out the language
20 on "never".

21 I mean I agree that it doesn't
22 matter whether it is never or not. It should

1 be reported. It is serious. In fact, I think
2 if you take as an example central-line-
3 associated bloodstream infections versus
4 catheter-related bloodstream infections, as
5 somebody who practices in this field, I think
6 that really all the catheter-related
7 bloodstream infections can be prevented. The
8 central-line-associated is different. Not all
9 of those can be prevented, frankly, because
10 some of those don't come from the line; they
11 come from the intestines of neutropenic
12 patients, for example, and there is not much
13 you can do about that.

14 So I would try to avoid the
15 qualifiers on this.

16 CO-CHAIR MEYER: I think I had
17 John next, and then Deborah and then
18 Christine.

19 Before I do that, just one point
20 of clarification. So, just so everyone is on
21 the same page, so when you were referring to
22 the fine print, what you were referring to is

1 the fact that preventable, if you go to the
2 fine print, actually says "usually
3 preventable" --

4 MEMBER BRENNAN: "Usually", yes.

5 CO-CHAIR MEYER: -- in the current
6 definition?

7 MEMBER BRENNAN: Right. Right.

8 CO-CHAIR MEYER: Okay. John?

9 MEMBER MORLEY: John Morley.

10 I don't disagree with anything
11 that has been said so far. I think there's
12 been some excellent points made.

13 One of the things that caught my
14 attention, particularly Diane's comment about
15 thinking about the goal of this, clearly, the
16 ultimate goal is that this is a tool for
17 safety and for collecting information and for
18 change.

19 But, in the shorter-term, I think
20 this definition is what we use, then, to
21 revise that list of 28 things that is at the
22 end. I am looking at the list now. As I look

1 at the list, I could live with any of these
2 things.

3 I particularly agree with what
4 Diane said about, regardless of what is up
5 here, in New York State we are going to set a
6 bar about what is going to be required to be
7 reported, whether it is potentially
8 preventable or not. We are going to get those
9 reports.

10 But, as I look at this list, I see
11 some things in here that I don't think are 100
12 percent preventable, but I would like to know
13 100 percent of the time that they happen.

14 CO-CHAIR MEYER: Deborah?

15 MEMBER NADZAM: Yes, I was going
16 to say the same thing. I like what Diane
17 said. It makes me think, why should we even
18 have "preventable" in there?

19 I wondered if you might give us
20 some background about how it got in there in
21 the first place.

22 CO-CHAIR MEYER: Boy, I am not

1 sure if my institutional memory on that exact
2 one is clear. I do know that there was a lot
3 of discussion around the "usually", and it was
4 very much along the lines that we have had
5 this morning now, is that there are some
6 things -- I particularly remember one of the
7 examples that came up was around pressure
8 ulcers and the notion that some pressure
9 ulcers in some patients, it stretches the
10 imagination about how it will be potentially
11 preventable.

12 So I can't really say anything
13 more beyond that, though, in terms of the
14 background.

15 DR. ANGOOD: Gregg, if I could
16 just jump in, Melinda Murphy is on the phone.
17 Melinda was involved in the early stages of
18 this.

19 So, Melinda, do you have some
20 institutional memory on the term
21 "preventable", by chance?

22 MS. MURPHY: Well, I was just

1 looking back at the original report. I was
2 not involved in the original report.

3 But there is a section in the
4 commentary that added to the original report
5 about the evidence for preventable that
6 acknowledges that there was not an exhaustive
7 review of the literature on preventability
8 prior to selection of the events.

9 DR. ANGOOD: Thanks. That helps.

10 CO-CHAIR MEYER: Okay. Christine?

11 MEMBER GOESCHEL: Great. Thank
12 you.

13 I would suggest and believe that
14 the list needs to be as it was written,
15 "preventable, serious, unambiguous". As I
16 look at our definition of preventable, having
17 had many discussions around this with
18 organizations, the current definition says,
19 "Describes an event that could have been
20 anticipated and prepared for, but that occurs
21 because of an error or other system failure."

22 As Diane said, there may be things

1 that are on the list that occur, but not
2 because of an error or a system failure, that
3 could have been alluded to.

4 I think the other thing, building
5 on what John said, it seems as though our
6 choice is to tighten the definitions, quote,
7 "shorten the list" or expand the definitions,
8 and see what happens with those. I don't
9 think we want to go there.

10 I think people understand
11 preventable, unambiguous, and serious. I
12 think the opportunity to clarify what is on
13 the list is useful. Beyond that, I think one
14 of the opportunities that we have, as I
15 understand it, is to make certain that,
16 ultimately, reporting is important.

17 But, going back to where we
18 started, the goal isn't reporting. The goal
19 is eliminating these events.

20 So preventable helps me at an
21 organizational level to know where I should
22 focus my efforts. We could go after a lot of

1 things that are serious and reportable, but
2 are not preventable. So I think "preventable"
3 is a very important word.

4 CO-CHAIR MEYER: Sally?

5 CO-CHAIR TYLER: Yes. I think
6 also that "preventable" is an important word.
7 To me, one of the reasons it is important is
8 that it really links back and reminds us of
9 evidence-based care and brings the whole
10 evidence-based process into it.

11 There are things we know to be
12 effective, to make a difference, that should
13 be done. That is something I think that is
14 very important in the public accountability
15 concept, that this should link back to
16 evidence-based care.

17 I also very much agree with -- I
18 hadn't thought about it until Eric brought it
19 up, but the concepts of "preventable" and
20 "never" work at this from different sides. If
21 we modify it to "potentially preventable",
22 then it does certainly -- it is hard for us to

1 say it should never occur. So I think it is
2 a very good point.

3 CO-CHAIR MEYER: Helen?

4 DR. BURSTIN: I was just going to
5 say I did grab the 2002 report yesterday
6 before I left the office, thinking it might
7 come in handy.

8 Just a brief paragraph here about
9 they actually struggled with "unintended"
10 versus "preventable", interestingly enough, in
11 the initial report. They tried to make a
12 distinction between "unintended" and
13 "preventable" as a criterion for events,
14 because "unintended" was considered to be less
15 associated with the implication that someone
16 was to blame for an event, and was also
17 considered to have the advantage of capturing
18 the events that, upon analysis, suggest
19 methods of prevention that would otherwise be
20 unknown.

21 "On the other hand, there was
22 concern that many unintended events are truly

1 not preventable, given current knowledge.
2 Reporting such events to an external body,
3 particularly if the data were eventually
4 summarized for the public, would lead to
5 misunderstanding.

6 "Ultimately, the Steering
7 Committee agreed that 'preventable' was the
8 more relevant concept for the intended
9 purpose, but because few classes of events are
10 always preventable, the Steering Committee
11 concluded that an event be judged 'usually
12 preventable' to qualify for the list.

13 So they certainly make many of
14 their own qualifications in their
15 determination of words as well.

16 CO-CHAIR MEYER: Eric?

17 MEMBER TANGALOS: When you go back
18 to the 2002, I had a flashback of working on
19 a mission statement, any mission statement.
20 I mean tread carefully when you start to
21 revise mission statements. Essentially, that
22 is almost what we are looking at here.

1 CO-CHAIR MEYER: Michael, and then
2 I am going to take the Chairman's prerogative
3 and try to move this --

4 MEMBER VICTOROFF: I think the
5 point about mission statements is very good.
6 I think it is important for me to make sure
7 that we have a very clear slogan expressed in
8 unambiguous terms.

9 The first three adjectives are
10 fine for me with these qualifications in the
11 fine print; I really think the fine print is
12 important when we talk about preventability
13 because preventability is a very large
14 concept. There is a lot packed into it.

15 But I really feel it is important
16 for me to remove the word "never" because not
17 only is it used as a bludgeon by people who
18 are more interested in blame than in problem-
19 solving and in litigation, it is a bludgeon
20 potentially.

21 But it is a trivializer because
22 anything that happens that somebody doesn't

1 like should never happen or never had happened
2 or never did or never could or never might or
3 never should. No one should have their
4 parking ticket not stamped when they leave the
5 hospital. There's all kinds of "nevers".

6 So it ruins the force of the
7 slogan for me by attaching that caboose to it.

8 CO-CHAIR MEYER: I think we have
9 actually heard from just everyone at this
10 point.

11 What I would like to do is just
12 put a proposal just for us to chew on. That
13 is, I think that one of the things that is
14 important here is that there is the existing
15 fine print.

16 Just to remind people, that fine
17 print, again, is on page 12 of your hard copy.
18 It says, "Use of the term 'usually
19 preventable' recognizes that some of these
20 events are not always avoidable, given the
21 complexity of healthcare."

22 I think that that is quite

1 consistent with what we have heard around the
2 table here.

3 To that end, and again, I do think
4 there is a conflict between "preventable" and
5 "never", "potentially preventable" and "never"
6 that we would introduce here.

7 So, if we left it as preventable,
8 but kept the footnote, kept the clarification,
9 would that work for people? Or do people feel
10 that we need to pull the word "usually" right
11 up into the definition, rather than have it
12 down in the footnote?

13 MEMBER BRENNAN: Gregg, you would
14 leave in the final clause on "never"?

15 CO-CHAIR MEYER: I would not.

16 MEMBER BRENNAN: Okay.

17 CO-CHAIR MEYER: Let me just, if I
18 can jump ahead here, what I would say is,
19 "Serious reportable events" -- by the way, we
20 can't change serious reportable events; we are
21 given that -- "defined as preventable," with
22 the footnote "serious" -- I don't think there

1 is going to be any argument about the
2 "serious" -- "and unambiguous adverse events."
3 Full stop.

4 MEMBER BRENNAN: I'm okay with
5 that.

6 MEMBER RYDRYCH: Just a comment.
7 We have really been trying to move away from
8 talking about never events in our State, for
9 all the reasons that people have talked about.

10 But I do wonder, and I don't want
11 to quite be devil's advocate on this. But one
12 of the downsides of talking about "never" is
13 what we have said, that these are not always
14 preventable. I think it is that fear of being
15 labeled publicly, because we have a public
16 report. The fear of a lot of hospitals is,
17 you know, your name shows up in a report; this
18 is something that never should have happened.
19 That anxiety drives a lot of the dynamics in
20 our State. So that is part of why we have
21 moved away from it.

22 But the one silver lining of it is

1 that I think it has also driven a lot of
2 urgency around change for these events. So I
3 do wonder, do we lose some of that urgency of
4 the serious reportable events or some of that
5 sense of priority for them if we take out that
6 clause entirely? Is there a way to modify it
7 that still gets at the importance of reducing
8 the numbers of these events, but still
9 acknowledges that they in many cases should
10 not occur?

11 I would agree that there are some
12 that are "nevers", there are some that are
13 not. I am not sure that that nuance can be
14 captured in one phrase, but I just wanted to
15 make that observation.

16 CO-CHAIR MEYER: I have a response
17 to Diane, but before I do, do others have a
18 response to her comment about just removing --

19 MEMBER GANDHI: Gregg, this is
20 Tejal on the phone.

21 CO-CHAIR MEYER: Yes, please.

22 MEMBER GANDHI: So I still worry

1 about the falls and the pressure ulcers and
2 this issue of preventability really. You
3 know, people at the hospitals who are trying
4 to report, the preventable thing ends up being
5 a real sticking point for many.

6 I just wonder about -- I didn't
7 think "potentially preventable" was going to
8 be good because I think that is just opening
9 it up to way too many things. But I wonder if
10 -- I know there is a footnote, but I just
11 wonder if, instead of having it in the
12 footnote, if the word "usually" was up in the
13 main definition, that might just help quell
14 many of these debates that happen in the
15 hospital about, "Oh, that fall wasn't
16 preventable because...." You know, there is
17 so much debate about that unnecessarily
18 sometimes, I think.

19 I wonder if people will really get
20 to the footnote versus if it was just in the
21 main definition to use the word "usually".

22 MS. CANNON: This is Marge Cannon

1 from CMS. I am one of the medical officers at
2 CMS.

3 I really like "preventable" in
4 there kind of as a standalone, only because it
5 kind of really packs a punch, so that you know
6 that your hospital system is going to go back
7 and look through that case specifically and
8 highlight that case and say, "What did we do
9 or did not do that could have prevented this
10 outcome?"

11 Of course, they will do their own
12 investigation. As a clinician, we all know
13 that there are going to be one or two cases
14 that there is nothing you could have done to
15 prevent it. But I really think that the
16 stronger language -- I agree with taking the
17 "never" out, but I really think the stronger
18 language and the power that prevention packs
19 in highlighting the incident is really
20 valuable and useful in retaining, and maybe
21 not doing a caveat except as a footnote.

22 Just my thought.

1 CO-CHAIR MEYER: I don't think
2 anyone has proposed removing the word
3 "preventable" in total. I think it is a
4 question as to whether or not we qualify it
5 further.

6 MS. CANNON: No, but my thing is I
7 think that it should -- I really like it in
8 there without qualifying it in the main body.

9 CO-CHAIR MEYER: Please,
10 Christine.

11 MEMBER GOESCHEL: Just a quick
12 comment. I would agree with you
13 wholeheartedly. Although I know organizations
14 struggle with this, being perfectly candid,
15 many organizations look and, with any sort of
16 qualifier that says "usually", they will
17 discern that they are different and that
18 theirs were not preventable.

19 I think, for people that are
20 alarmed by the word "preventable", the
21 opportunity to read the footnote is a small
22 amount of effort to begin to look at their own

1 events more systematically perhaps.

2 I think "preventable" to stay the
3 way it is without a qualifier in the
4 definition.

5 CO-CHAIR MEYER: I just did want
6 to respond to Diane, because I think your
7 point is well-taken that we don't want to lose
8 the urgency that is implied by the final
9 tagline there of that should never occur.

10 On the other hand, what I would
11 argue is that the world is a different place
12 in 2009 than it was in 2000 or 2002, in that
13 you and a number of the folks represented
14 around the table here are in states where the
15 reportability piece is there. The reality of
16 it is that these things are not going to go,
17 the urgency is not going to go away, by
18 definition, because of what you are doing.

19 In fact, that is exactly what the
20 original intent of creating this list was, was
21 that states would pick this up and ask people
22 to report on it.

1 So I am not sure that we are going
2 to lose any urgency here. I think that
3 urgency is almost hardwired at this point.

4 MEMBER RYDRYCH: I would say yes
5 and no. And again, I want to say I don't like
6 the "never" term, and we don't use it. But I
7 think we do face in our State a loss of
8 urgency around this in some ways because we
9 have been doing it for a number of years, and
10 because the coverage of our report and our
11 learnings has almost become routine now. It
12 is like, "Oh, here's another report from the
13 Health Department. Look, more of these things
14 happened."

15 Because we have been so successful
16 at giving the message that they are not always
17 preventable and that there is going to always
18 be some level of these events, I think it has
19 ended up sometimes coming back to bite us, and
20 reinforce the idea that there's a level, maybe
21 higher than what it should be, that is okay of
22 these events.

1 So I don't know what the answer is
2 on that clause because I don't like the
3 "should never occur" clause, but I do think
4 that thinking of them all as "nevers",
5 thinking of them all as "preventable" has led
6 to more aggressive action in our State and
7 more aggressive change in our State,
8 especially in the early years, because it was
9 sort of a goal, one we knew we would never
10 achieve, to prevent all of these, but a goal,
11 nonetheless.

12 There may not be any way of
13 putting that into a definition, and it may not
14 be necessary to be in a definition. It may be
15 just one of the caveats that is part of this.

16 But it is certainly a tension that
17 we have experienced. I don't know if other
18 states have as well.

19 MEMBER GANDHI: This is Tejal
20 Gandhi again from Partners.

21 I actually agree with you in the
22 sense that, you know, in the State of

1 Massachusetts or at Partners, about 60 or 70
2 percent of the events reported are falls.
3 Then a large percentage of those after -- I
4 mean everybody does root-cause analysis on all
5 of these, and so on. Many of those are deemed
6 not preventable.

7 I think the message ends up
8 getting blurred because that is sort of the
9 message of, oh, you know, here are the SRE
10 rates, but most of these were falls; many of
11 those were not preventable. Then they lose
12 sight of the retained foreign bodies and the
13 wrong site surgeries, or whatever, because
14 they got diluted by that 70 percent falls
15 issue.

16 So part of me wonders about being
17 inclusive of these events, where I know we
18 want to know about falls, but include things
19 like the falls and pressure ulcers, where
20 there is so much debate about preventability;
21 I think some of the ones that we truly think
22 really should not happen, like the wrong site

1 surgeries, kind of get lost.

2 CO-CHAIR MEYER: We will have an
3 opportunity to talk about specifics on the
4 list, to do that later on this afternoon.

5 MS. MURPHY: Gregg, may I make a
6 comment? This is Melinda.

7 CO-CHAIR MEYER: Please do,
8 Melinda.

9 MS. MURPHY: I looked back in the
10 2002 report and the 2006 report. The term
11 "never" is used in the document. It is,
12 however, used outside of the criteria for
13 identifying the event.

14 So, in 2002, it says, "a serious
15 preventable adverse event sometimes called
16 'never event'", and that is just in the
17 introduction to the document.

18 In 2006, in the criteria for
19 inclusion verbiage, outside the criteria
20 itself, it says, "The listed events described
21 in this report that meet those criteria is not
22 intended to include all events that might

1 possibly be useful to the report and that do
2 not include all events that should never
3 occur."

4 But the term itself is not used
5 inside the criteria.

6 CO-CHAIR MEYER: I think that
7 point is well-taken. I think that one of the
8 things that we will do, after we review the
9 definition here, is go through those criteria.

10 But operationalizing this, in
11 fact, it was not part of the language. So it
12 really calls into question why it was there at
13 all. Again, there are some historical reasons
14 why it was there. Perhaps those have faded.

15 Deborah, and then I am going to
16 try to move this along a bit.

17 MEMBER NADZAM: Yes, I am just
18 recalling that, when this group first got
19 started back in 2001 or 2002, it was called
20 the Never Events Committee, wasn't it? Didn't
21 you all purposely change it, as I recall from
22 Dr. Scheibe's participation on that, I think

1 hearing about it?

2 CO-CHAIR MEYER: The history of
3 the term "never events" is that it actually
4 came out of an early discussion around the
5 contract to create this Committee. At that
6 point, it was Dr. Kaiser's interpretation. He
7 was the one who coined that phrase at that
8 point in time.

9 CO-CHAIR TYLER: I just had a
10 question. I guess I had always been taught
11 that, in coming up with a definition, that you
12 don't use within the definition itself a word
13 that is in the word to be defined. So I am
14 wondering why "serious". It is "serious
15 reportable events", and then we say, "What's
16 a serious reportable event?" "Well, it's
17 serious."

18 I mean that is a bit circular.
19 You know, there is a reason it is not done.
20 It leads to sloppy thinking in some ways. So
21 I am wondering.

22 I know that we actually define now

1 "serious" as well. But I am wondering if that
2 is necessary and if that is the best way to do
3 it.

4 DR. BURSTIN: I just think it
5 would also be helpful that I think it is
6 important to remember that we are going to
7 come back to this after you try to nail down
8 what HACs, whatever this broader term is.

9 I think, again, it would be
10 helpful to sort of think about how these come
11 together logically. So I think it would be a
12 good place to start, but don't forget you will
13 have, I think, another chance at it, once you
14 get the bigger sense of it.

15 CO-CHAIR MEYER: John?

16 MEMBER MORLEY: As I listen and go
17 around in circles in my own mind on the
18 thoughts that go back, I still end up back
19 with what I had said before. The importance
20 of this, even more clearly now to me than five
21 minutes ago, is just that this is a definition
22 that will help me to define that list.

1 The purpose of putting this out
2 there is for transparency, so that the public
3 sees what this Committee was thinking.

4 I don't think that that is
5 something that I am going to use in terms of
6 an argument with an institution about what is
7 reportable or not. It is a serious reportable
8 event. Here's the list. It's reportable.
9 That is it.

10 Whether I am using my old CMO hat
11 or my new regulator hat, I am going to be
12 going with the list and saying: this was what
13 was used to create the list.

14 CO-CHAIR MEYER: I think that is
15 the reality there.

16 So what I would like to do is I
17 would like to try to move us on to actually
18 start to take a look at the criteria here.

19 There are a couple of questions
20 that I think are kind of left on the table on
21 that. Actually, I am going to ask for folks
22 in the room here to go for a hand vote. What

1 I would like to do with those of you on the
2 phone is I will call on you at the end, and we
3 may vote by exception, just to make it easier.

4 The first issue I would just get a
5 sense of the group on is whether or not folks
6 are comfortable with leaving "preventable"
7 with the existing footnotes and definition in
8 unqualified. So it would say, "Defined as
9 preventable".

10 Again, I would ask just for a
11 raise of hands of those who are comfortable
12 with leaving that as is.

13 (Show of hands.)

14 Okay. That is the vast majority
15 here.

16 And those on the phone, do any of
17 you feel that it needs to be qualified?

18 MEMBER GANDHI: Do you mean in the
19 footnote or do you mean in the body?

20 CO-CHAIR MEYER: No, I mean in the
21 definition. No one, I think, has suggested
22 the footnote would change, and I think the

1 footnote is very consistent with the
2 conversation.

3 MEMBER GANDHI: Okay.

4 (No response from those on the
5 phone regarding the vote.)

6 Okay. So I think we have a pretty
7 clear sense there.

8 The next is well-taken. That is
9 Sally's about, is the "serious" redundant? I
10 think probably, if there are any English
11 teachers here, I think they probably would say
12 yes. On the other hand, one could say, boy,
13 it really hammers it home.

14 And, P.J., you have a quick
15 comment on that particular issue before we --

16 MEMBER BRENNAN: Yes. Gregg, in
17 the electronic version of the document that I
18 am looking at, in the Executive Summary,
19 "serious" is defined, and it is unambiguously
20 defined.

21 CO-CHAIR MEYER: It is. It is.

22 MEMBER BRENNAN: If you read that

1 fine print, it is pretty clear, yes.

2 CO-CHAIR MEYER: Deborah, are you
3 wearing your English teacher hat?

4 MEMBER NADZAM: No, I'm not,
5 although when I saw that definition, too, as
6 long as you have it up, I am looking at your
7 screen, that last clause "an event, the
8 occurrence of which is not trivial", it is
9 kind of awkwardly stated. Then we run into
10 what is "trivial".

11 CO-CHAIR MEYER: And just to call
12 that out to people, that is on the bottom of
13 page 12. You will see that that is a
14 definition, using necessary criteria.

15 Sally, please.

16 CO-CHAIR TYLER: Yes, and I guess
17 "serious" bumps up against "adverse", how they
18 differ, how they overlap. Do they replicate
19 each other?

20 "Adverse" is described as a
21 negative consequence of care that results in
22 unintended injury or illness which may or may

1 not have been preventable.

2 CO-CHAIR MEYER: Michael, and then
3 Philip.

4 MEMBER VICTOROFF: Well, just
5 speaking very quickly in favor of not changing
6 it, although I think technically there is a
7 slight pedagogical problem with redundancy.
8 But the use of this, the point of this, I
9 think, going back to what John was saying, why
10 do we care?

11 These are things about which there
12 are actions that could be taken to reduce the
13 rates, not maybe make them vanish from earth,
14 but to reduce the rates because we care about
15 rates. And they are important because they
16 are more important than other things that we
17 could also be working on. So we should
18 prioritize these things because they will,
19 either in magnitude or in quantity, impact the
20 experience of our patients more than the
21 things that we would say are trivial.

22 So, for those kinds of reasons,

1 qualitative reasons, I would just leave it
2 alone.

3 CO-CHAIR MEYER: Okay. Philip?

4 MEMBER PHILIP SCHNEIDER: Well,
5 you know, my sister's a PhD in English. So I
6 am steeped in this stuff.

7 I agree it has a redundancy to it,
8 but if I take it out of either the title or
9 the definition, it bothers me; it is not
10 complete enough.

11 So I am wondering whether we
12 could --

13 CO-CHAIR MEYER: It can't be taken
14 out of the title. We don't have that leisure.

15 MEMBER PHILIP SCHNEIDER: Right.
16 So, therefore, I will just focus on the
17 definition then.

18 One option would be to change
19 "serious" to another word. "Significant"
20 would be one that comes to my mind. Then
21 maybe you would define "significant" in the
22 way that "serious" is defined on page 12.

1 CO-CHAIR TYLER: That was,
2 actually, what I was just going to suggest.
3 I think that would make a good --

4 CO-CHAIR MEYER: Well, how about
5 that?

6 So further comments on that?
7 Okay, I see some head nods around the table on
8 that.

9 Yes, I'm sorry. Please.

10 MEMBER HOEN: From a legal
11 perspective, which I can't leave behind here,
12 I really do not need another word to define in
13 that definition. So to have "serious" in both
14 places, I agree is not the perfect model. I
15 would rather leave it out of the title and
16 have it in the body defined. But to put in
17 another fourth word, which then becomes the
18 subject of definitions, from a legal action,
19 is problematic.

20 CO-CHAIR MEYER: I think the
21 suggestion was that it would say -- "serious
22 reportable events", again, we can't change

1 that piece.

2 MEMBER HOEN: Right.

3 CO-CHAIR MEYER: Defined as
4 "preventable, significant, and unambiguous".

5 MEMBER HOEN: But now I have got
6 to define "significant" and then "serious".
7 That could become debate.

8 CO-CHAIR TYLER: But I think what
9 Philip was suggesting -- and correct me if I
10 am wrong -- that "significant" would be
11 defined as "serious" is defined in our
12 breakout. Right?

13 MEMBER PHILIP SCHNEIDER: That is
14 right. I wouldn't define "serious" anymore.
15 I would change the word "serious" in the
16 definition of terms used to "significant". So
17 there wouldn't be a fourth term. There would
18 only be three.

19 MEMBER DORON SCHNEIDER: Reporting
20 near-misses is important. I just worry about,
21 when we use "significant", you know, it, to
22 me, kind of opens it up to who is it

1 significant for. I need to know, as a safety
2 officer in my institution in the State, that
3 other things are occurring. And "significant"
4 I think opens it up to further problems.

5 MEMBER GANDHI: I would just
6 comment that in the adverse event literature
7 there is often severity classifications, and
8 the classifications are significant, serious,
9 and life-threatening. So "significant" and
10 "serious" are two different classifications in
11 much of the literature around adverse events,
12 particularly adverse drug events. So I think
13 that would lead to some confusion.

14 CO-CHAIR MEYER: Thank you, Dr.
15 Gandhi.

16 Diane?

17 MEMBER RYDRYCH: We might be
18 getting into the territory that Michael talked
19 about before, where we are trying to find the
20 perfect term when we really need to look at
21 how we describe it in our definitions.

22 I think whether we choose

1 "serious" or "significant", it is going to be
2 ambiguous. For events that we are describing
3 as unambiguous, our definitions are always
4 going to be ambiguous on the ground in some
5 sense.

6 I know that we get pushed back
7 sometimes on "serious". Because people don't
8 understand that "which is not trivial" clause,
9 we get pushed back when there is no patient
10 harm. There are cases where people think that
11 should not be a reportable event or something
12 that needs to be learned from if it didn't
13 involve patient harm. So I think we will run
14 into that problem either way.

15 So, despite the redundancy in the
16 definition -- and I will play the English
17 card, too, and say I used to be an English
18 teacher -- despite the redundancy, I would
19 keep the "serious" in there.

20 CO-CHAIR MEYER: I would, again
21 trying to move us to a decision here, I think
22 that Dr. Gandhi's note that "serious" and

1 "significant" are defined very differently in
2 an important way in the safety science
3 literature I think is well-taken.

4 So, with that, what I would put on
5 the table is, basically, a vote, those in
6 favor of leaving serious in as it stands -- we
7 will, actually, look at the specific
8 definitions, by the way. This is the first
9 part. We've got so more work to do after
10 this.

11 So those in favor of leaving
12 "serious" in? And a vote to the no is
13 actually that we would take "serious" out. So
14 those in favor of leaving "serious" in?

15 (Show of hands.)

16 Okay. All right, and again, those
17 on the phone, is there anyone strongly in
18 favor of taking "serious" out, since the
19 majority of folks here in the room voted in
20 favor of leaving it in?

21 MEMBER RADFORD: I would leave it
22 in.

1 CO-CHAIR MEYER: Okay. So we now
2 are left, the next term we have is
3 "unambiguous". Again, I would call to you, on
4 page 12, "unambiguous" is defined as "refers
5 to event that is clearly defined and easily
6 identified".

7 I would say "unambiguous" is an
8 aspirational term for those of us on the
9 frontline trying to figure this out every day,
10 but it did seem to carry some import.

11 MEMBER TANGALOS: I would leave it
12 in. I think it will be a term that will be
13 retired in the next decade. It is an overused
14 -- it is one of those words that gets
15 overused. But I wouldn't change it.

16 CO-CHAIR MEYER: So you are
17 suggesting that we punt this to the 2020
18 update?

19 (Laughter.)

20 MEMBER TANGALOS: Yes. Yes.
21 That's a good idea.

22 CO-CHAIR MEYER: Hard to argue

1 against that.

2 (Laughter.)

3 Stan?

4 MEMBER RILEY: In a way, I guess I
5 agree, but at the same time, being on the
6 frontlines, you know, we get a lot of pushback
7 about "unambiguous". You know, what exactly
8 does that mean?

9 You tell people the definition
10 here, and it still is like there is just a lot
11 of controversy, at least out in the frontline,
12 about "unambiguous".

13 And it is hard to counter
14 arguments about it. Although I have to tell
15 you the truth, I think it should be in there.
16 It just is one of those things that you can
17 expect a lot of pushback from.

18 CO-CHAIR MEYER: Philip?

19 MEMBER PHILIP SCHNEIDER: I think
20 "unambiguous" refers to the event itself
21 rather than the causality, right? Is that
22 right? Because causality is highly ambiguous,

1 but the event itself is usually -- I am not
2 too uncomfortable with --

3 CO-CHAIR MEYER: It refers,
4 specifically in the definition, it refers to
5 the event. To the event.

6 MEMBER PHILIP SCHNEIDER: I am
7 okay with it.

8 CO-CHAIR MEYER: Diane?

9 MEMBER RYDRYCH: Yes, and I would
10 just note I am fine with it, too. But I think
11 part of this comes down to the guidance that
12 is part of the definition of each of the
13 individual 28 events, right? So, if we are
14 looking at potentially modifying the list of
15 the 28, I am assuming modifications of that
16 definitional guidance might be part of that as
17 well, which helps to make them a little bit
18 less ambiguous.

19 CO-CHAIR MEYER: Absolutely.
20 Absolutely.

21 Anyone in favor, again, just a
22 quick vote, anyone in favor of removing the

1 term "unambiguous"?

2 (No response.)

3 Okay. Seeing none.

4 Anyone on the phone in favor of
5 removing the term "unambiguous"?

6 (No response.)

7 CO-CHAIR MEYER: Hearing none --

8 MEMBER GANDHI: I'm good.

9 CO-CHAIR MEYER: Okay. So we will
10 leave it in.

11 And the final point here before we
12 can move on is -- and I will, again, put this
13 in terms that we have had a fair amount of
14 discussion -- is anyone in favor of leaving
15 the clause "that should never occur" as part
16 of this definition?

17 Philip?

18 MEMBER PHILIP SCHNEIDER: I am not
19 opposed to it, but I will say that it kind of
20 reduces the impact factor to the public. If
21 there is an interest, and the issue of urgency
22 comes to my mind, and when you see things that

1 are reported, that catch phrase "never events"
2 establishes a sense that healthcare providers
3 are really interested in making sure that some
4 things really don't happen. I think there is
5 some public relations elements to that
6 statement that we will lose.

7 Having said that, given the nature
8 of what we are going to try to do, the fact
9 that it is almost impossible to make sure that
10 something never happens, I probably would
11 support taking it out. But I do think we are
12 going to lose some of the top spin that is
13 embedded within this definition.

14 CO-CHAIR MEYER: I do think one of
15 the things that we can, as a Committee, really
16 provide a sense of the Committee to the
17 Quality Forum staff is that folks did identify
18 this issue of urgency and the idea that we
19 want to keep the spotlight on this. That is
20 actual work for the NQF to do, to help ensure
21 that that continues.

22 John?

1 MEMBER MORLEY: Right now, I am
2 hearing that there's two choices, essentially;
3 you know, either keep it in or eliminate it
4 entirely.

5 I agree with the comments that
6 were made that it does de-emphasize the
7 statement a bit. Is there a third opportunity
8 to say something along the lines of "that
9 should not occur"? The heat is really
10 attached to that word "never" for lots of
11 reasons. Can it be a third one? And I offer
12 as the third possibility "that should not
13 occur".

14 MEMBER RADFORD: I would also like
15 to see perhaps a little bit of discussion in
16 the document that comes out of this about, you
17 know, the tension in using the term "never
18 events", whichever way we decide, to take it
19 out or leave it in, around this issue of the
20 urgency versus the bludgeon. I think that was
21 well-put.

22 CO-CHAIR MEYER: If I could, we

1 are just going to pause for one moment to
2 welcome Leah Binder.

3 Leah, welcome to our conversation.
4 If you can, Leah, just quickly share your
5 background, and also your conflicts, with the
6 group. Then we can move on in the discussion.

7 I would just remind folks to use
8 the microphone because that is the only way
9 the folks on the phone can hear us.

10 MEMBER BINDER: Okay. I am Leah
11 Binder, and I am CEO of the Leapfrog Group,
12 which represents purchasers of care. We focus
13 on hospital care quality.

14 Conflicts, I am not sure we have
15 conflicts. I don't believe we have any, but
16 we have a strong interest in never events. We
17 did have a major policy on never events that
18 we were the first national organization to
19 issue, which identified the 28 serious adverse
20 events from NQF back in 2006.

21 CO-CHAIR MEYER: Other comments on
22 this? So further discussion on this notion of

1 "that should not occur" versus "that should
2 never occur"?

3 MR. GARCIA: Can I just make a
4 statement on that?

5 CO-CHAIR MEYER: Please do.

6 MR. GARCIA: I would support this
7 change away from "never", the word "never" and
8 changing it to "not", to maintain that urgency
9 on this list of SREs.

10 Then, looking to the next
11 definition on the HACs, to have a broader,
12 expanded list, maybe events that aren't as
13 rare or potentially could occur.

14 I think that is something we need
15 to look at in the discussion. I really think
16 the SRE list is good the way it is. I think
17 we should maintain that urgency with it.

18 CO-CHAIR MEYER: And you feel that
19 using the word "not" would continue to do
20 that --

21 MR. GARCIA: I think so.

22 CO-CHAIR MEYER: -- in a way that

1 would be helpful to it? Okay.

2 Christine?

3 MEMBER GOESCHEL: I don't want to
4 belabor this, but I think, if it helps, for
5 those who do a quick read, to have "not" in
6 there, it is fine. But at my core, and as
7 leaders in this field, the fact is that
8 anything that is adverse and preventable
9 brings with it that it should not occur.

10 So, I mean, I think we don't want
11 to lose sight of the fact that we also need to
12 have NQF staff, as they write the report, make
13 certain that the broader meaning of all of
14 this is not lost.

15 CO-CHAIR MEYER: Okay. Further
16 comments? Leah?

17 MEMBER BINDER: I guess I am
18 jumping right in. So apologies if this is out
19 of context.

20 The term "never" is very
21 important. I know to our constituent the term
22 "never" actually really does matter, has a lot

1 of resonance.

2 If I had to name one thing, one
3 issue in the Leapfrog survey that is of most
4 importance to purchasers, it is the never
5 events policy. The word "never" is a powerful
6 word, and it states that these events are just
7 so catastrophic that they should never occur.
8 I mean it just has a resonance and importance.

9 So removing "never" from the
10 definition, if that is what we are talking
11 about, would have very serious -- it would be
12 a statement, in and of itself, that we have
13 removed the word "never" from something that
14 has had such a powerful impact in the field.

15 CO-CHAIR MEYER: So, just to catch
16 you up, we have actually had a fair amount of
17 discussion around whether that "never" needs
18 to be in there. I think that folks have come
19 to a place where at this point what I would
20 like to do is I would like to move us to
21 making a decision on this, unless people have
22 further discussion.

1 Anyone on the phone have any
2 further comments before we start to get a
3 sense of where the Committee stands?

4 Yes, please, Cynthia.

5 MEMBER HOEN: Just one comment. I
6 think I heard a different opinion on whether
7 that terminology stays in there if we remove
8 pressure ulcers and falls from the list than
9 I do when they are on there. So maybe this is
10 an issue we should leave right now -- I don't
11 know how the rest of the Committee feels --
12 and move on and maybe look at some of those
13 other things.

14 CO-CHAIR MEYER: So I would
15 propose, actually, I think that is an
16 excellent point. I do think that what we
17 ought to do is, at the end of the afternoon,
18 hopefully, if we get through the list, go back
19 and circle back and see if this works. But I
20 would like to still get a sense of the
21 Committee now, just because I think that that
22 is one of the deliverables that we have been

1 asked to work on today.

2 So, if I could call the vote, the
3 first vote is for those who feel that the
4 phrase "that should never occur" should remain
5 in. So that would be keeping the phrase
6 "should never occur".

7 (Show of hands.)

8 Anyone on the phone feel that the
9 term "should never occur" should remain in?

10 (No response.)

11 The second question would be, do
12 those who feel that the term "that should not
13 occur" should be in the definition -- "that
14 should not occur"?

15 (Show of hands.)

16 So we have a bit of a split here.
17 So one, two, three, four, five, six, seven.

18 And on the phone, if you could
19 please let us know if you feel that the term
20 "that should not occur" should remain in?

21 MEMBER GANDHI: This is Tejal.

22 I would be okay with it.

1 MEMBER RADFORD: I would agree
2 with that.

3 CO-CHAIR MEYER: Okay. So let me
4 do this a little bit more formally.

5 So, Martha, "that should not
6 occur", should that be in our out of the
7 definition?

8 MEMBER RADFORD: I have no problem
9 with it being in the definition, but I would
10 like to see a short paragraph of discussion
11 about it.

12 CO-CHAIR MEYER: Okay. Helen, are
13 you with us?

14 (No response.)

15 Okay. And Tejal?

16 MEMBER GANDHI: "That should not
17 occur" is fine with me.

18 CO-CHAIR MEYER: Okay. And any
19 other voting members on the phone?

20 (No response.)

21 Okay. Again, anyone, just so I
22 can clear it up completely here, anyone who

1 feels that that term "that should not occur"
2 should not be in the definition?

3 (Show of hands.)

4 Okay. So one, two, three, four,
5 five.

6 Okay. So, for those on the phones
7 here, the majority are in favor of adding the
8 term "that should not occur". With that said,
9 there was a split vote, and that is something
10 that we try to avoid, whenever possible.

11 I am not sure at this point in
12 time that further discussion of this out of
13 the context of the list itself is going to
14 move us across the finish line.

15 So what I would like to do is I
16 would like us to leave this stand as it
17 currently states here.

18 And for those on the phone, the
19 current definition is: "Serious reportable
20 events defined as preventable, serious, and
21 unambiguous adverse events that should not
22 occur."

1 What I would propose is that, at
2 the end of the day when we review the list, we
3 go back to this and see if this is still
4 working for the group.

5 Okay. The next step, that is
6 great. We have made some progress there. So
7 congratulations to us on that. You know, that
8 works. That works, yes. Okay.

9 If you could just move to the next
10 slide, please, Jennifer?

11 Just to remind you that behind
12 this are the criteria. I do think we should
13 spend a moment and reflect on whether or not
14 there are any changes.

15 It looks like we skipped some
16 there, Jennifer. If you can go back up, just
17 do the PageUp function; it will be easier.
18 Yes. So if you can leave it there?

19 So an event must be unambiguous,
20 usually preventable, serious, and any of the
21 following. So these are the criteria that are
22 up there.

1 If we can go back to that, please?

2 Leave it there for now.

3 So, if people can take a look,
4 again, for those of you with hard copy, this
5 is on page 12, the middle slide there.

6 And the question is, does anybody
7 feel that we need to make any changes to the
8 criteria? These are the criteria that we will
9 use this afternoon to look at the current list
10 and to consider additions or deletions.

11 MEMBER TANGALOS: This is Eric
12 again.

13 Now this "usually" gets in there.
14 I would have to say that is ambiguous.

15 DR. BURSTIN: Just one point of
16 clarification. I underlined "usually
17 preventable". It is not in the book, just for
18 point of discussion. So it is not underlined
19 in the actual SREs, but it is there.

20 MEMBER TANGALOS: But it says,
21 "usually". And I am glad you underlined it.
22 I mean I don't think you needed to; we would

1 have caught it anyway.

2 CO-CHAIR MEYER: And so, Eric,
3 what you are saying is you're saying that, if
4 it said the use of the term "preventable"
5 recognizes that some of these events are not
6 always avoidable, given the complexity of
7 healthcare --

8 MEMBER TANGALOS: Well, that is
9 enough.

10 CO-CHAIR MEYER: That is enough?

11 MEMBER TANGALOS: I mean, for me,
12 the less said, the better. I don't like
13 arguing balls and strikes.

14 CO-CHAIR MEYER: That is a fair
15 statement. It would have to come out from
16 both sides, yes. Yes. Yes, I think that that
17 is fair.

18 Diane?

19 MEMBER RYDRYCH: Just a small
20 grammar comment. Are those really "and/or's"
21 or should they just be "and's"? Because the
22 way we have it written here, it could be

1 adverse or it might not be adverse, but
2 indicative of a problem, or it might not be
3 either one of those, but important for public
4 credibility. I would argue they should
5 probably be "and's".

6 CO-CHAIR MEYER: I think they are.
7 I agree with that. But, with that said, I am
8 interested if other people, you know,
9 different people read it and have different
10 interpretations. Do people look at that
11 differently?

12 So we've got Michael.

13 MEMBER VICTOROFF: I am not quite
14 clear what this slide means. If this were the
15 typical PowerPoint, non-grammatical,
16 typographically illiterate slide that I often
17 use, it is fine. But if this actually is
18 language for a report, then it is illogical,
19 and the fourth bullet doesn't parse with the
20 verb of the subject. So it really needs to be
21 rewritten.

22 This is not an English teacher

1 because I barely speak English, but I was a
2 philosophy major. So this is a logic issue.

3 MEMBER RYDRYCH: I think the
4 fourth one is not intended to be part of the
5 definition. It is more an elaboration of --

6 MEMBER VICTOROFF: Well, okay.
7 So, now looking at the fourth bullet itself,
8 you see the glaring problem logically with it?
9 On the slide, it looks like a bullet. But in
10 the text --

11 CO-CHAIR MEYER: So Helen?

12 DR. BURSTIN: Just to clarify
13 that, it actually is A, B, and C. Then,
14 underneath it, they define usually preventable
15 outside of the scope of the criteria.

16 MEMBER VICTOROFF: Okay. So that
17 problem is solved. But the "and/or" needs to
18 be --

19 CO-CHAIR MEYER: And just to help
20 to orient folks, if you look at your briefing
21 document, under the section on definitions, it
22 states, "To qualify for the SRE list, an event

1 must be unambiguous, usually preventable,
2 serious, and any of the following adverse
3 and/or indicative of a problem in healthcare
4 facilities, safety systems and/or important
5 for public credibility or public
6 accountability."

7 That is where it does stop there.
8 The "usually" is in the paragraph beneath.

9 Please, Cynthia.

10 MEMBER HOEN: Yes, I think that
11 the "and/or" is very important because I think
12 that allows a broader group of conditions to
13 be listed, based upon those criteria. If you
14 say, "and", "and", "and", it is going to be
15 very difficult to define anything that will go
16 into there.

17 MEMBER VICTOROFF: Let me clarify.
18 You can't have "and" alone and you can't have
19 "or" alone. So, if you insist on having a
20 conjunction, it's got to be "and/or". But, in
21 fact, having a conjunction there is not
22 necessary since you have already said that

1 these things are inclusive above.

2 So now, really, that settles my
3 objections. If you are going to put a
4 conjunction at all, it needs to be "and/or",
5 and I could live with that, if we have to. It
6 is not vital.

7 MEMBER RYDRYCH: Is it any of the
8 following or is it all of the following?

9 MEMBER VICTOROFF: Any means
10 "and/or".

11 CO-CHAIR MEYER: Yes, what this
12 says is, just to remind you, the wording here
13 says, "To qualify for the SRE list, an event
14 must be...." Now one could argue to say we,
15 as a Committee, would say that it pretty much
16 ought to be all three of them. With that
17 said, what the criterion says specifically, it
18 says, if it not one of these three, then it
19 can't be on the list. So the current language
20 leaves it open a little bit.

21 And actually, if you could,
22 Jennifer, if you would go to the background

1 document quickly, just to pull that one up?
2 It is a Word document. Let's put that up, and
3 then we will get people to look at that, and
4 I think maybe we can solve this relatively
5 quickly.

6 Maybe not so quickly. So maybe we
7 will go to Deborah, if you can --

8 MEMBER NADZAM: Yes. I think, if
9 it says it can be any of the following, you
10 just need commas in between or nothing.

11 Because something can be adverse, but not
12 indicative of a problem in the healthcare
13 facility.

14 I mean we just went through all
15 that "preventable" and "never" discussion. So
16 I would be for leaving it "any" and dropping
17 the "and/or's". I mean it is almost
18 redundant.

19 CO-CHAIR MEYER: And again, just
20 to remind the group that what we are producing
21 is an NQF consensus-based list. So, to those
22 of you that may have a visceral reaction to

1 say, boy, we are really opening things up by
2 saying you just need one of these three, the
3 reality of it is that the work of this
4 Committee is to decide what is on the list and
5 what is not on the list. So, to me, that is
6 relatively clear.

7 DR. ANGOOD: So, while we are
8 fussing on that, while we are fussing on the
9 technical side, in the briefing document, on
10 page 4 of that in the .pdf, is where --

11 CO-CHAIR MEYER: Right.

12 DR. ANGOOD: -- Gregg is making
13 mention of this.

14 CO-CHAIR MEYER: So I guess I will
15 put the question on the table, is the "and/or"
16 necessary? On that, I am getting a bunch of
17 heads saying, no, they don't really feel it
18 is. But let's project it up here, so
19 everybody is on the same page and we know
20 where we are.

21 Right there. Right there in the
22 middle.

1 So "to qualify for the SRE list".

2 So the question on the table is,
3 do we leave the "and/or" in or out?

4 MEMBER TANGALOS: Again, we have
5 been discussing proper English. My
6 understanding is that that isn't proper
7 English anymore; "and/or" doesn't fit.

8 CO-CHAIR MEYER: Who wants to
9 leave "and/or" in? Raise your hand.

10 (No response.)

11 Seeing none, we will remove
12 "and/or". It will be the bulleted list.

13 I'm sorry. For those on the
14 phone, does anyone feel showing that the term
15 "and/or" -- this is on page 4 of your briefing
16 document, is the paragraph in question. Does
17 anyone feel strongly that we need to leave the
18 term "and/or" in?

19 MEMBER GANDHI: I don't feel
20 strongly either way.

21 CO-CHAIR MEYER: And Helen?

22 DR. BURSTIN: And just for

1 clarity, at the end of the day, I want to be
2 sure you have also grappled with the question
3 of, do you think they should be "and's"? Now
4 that you've gotten past "and/or's", just to be
5 clear, is there any reason for "and's"?

6 MEMBER RYDRYCH: Although, as the
7 person who suggested that, I am going to take
8 that off the table, as I think a little
9 further.

10 CO-CHAIR MEYER: I think that that
11 would in some ways maybe hamstring us a little
12 bit in the future in terms of what we could
13 consider.

14 DR. BURSTIN: I just know we are
15 going to get asked that question. So I was
16 trying to preempt it. Thank you.

17 CO-CHAIR MEYER: It allows it to
18 be open, I think.

19 DR. BURSTIN: Yes.

20 MEMBER PHILIP SCHNEIDER: You
21 know, if you look at page 4, it says, "any of
22 the following". So "any" is inconsistent with

1 "and/or" in a way.

2 CO-CHAIR MEYER: We are making
3 progress. We will move on, if we could.

4 Boy, I am really going to test
5 your skills here, Jennifer, because I am going
6 to ask you -- actually, let's move to the next
7 slide here. PageDown. Yes.

8 So these are the definitions of
9 the terms that are used in the SRE criteria,
10 and some of them are also used in the SRE
11 definition.

12 And again, if people could take a
13 moment to look at these, just to orient folks,
14 it is the last slide on page 12 of your hard-
15 copy handout. There are five terms that are
16 identified here: event, adverse, preventable,
17 serious, and unambiguous.

18 We have had a little bit of a
19 discussion about the term "serious", but let's
20 take these in turn.

21 Anyone have any objections to the
22 current wording of "event" or suggestions for

1 modifying it?

2 Deborah?

3 MEMBER NADZAM: The way it is
4 currently defined, it does not say it has to
5 be a patient outcome. I am thinking of what
6 you said earlier, P.J., about, could a process
7 be an event? So I just put that on the table.
8 Is that the way we still want it?

9 CO-CHAIR MEYER: No, I think that
10 that is okay to put it on the table.

11 Any reactions?

12 MEMBER NADZAM: And actually, some
13 of the criminal --

14 CO-CHAIR MEYER: One could argue
15 that these leaves it open broadly.

16 MEMBER NADZAM: It leaves it open.

17 CO-CHAIR MEYER: And again, at the
18 end of the day, this Committee and its
19 predecessors will be the ones that have to
20 sort out what is and isn't on the list, but it
21 doesn't limit necessarily.

22 Yes, Michael, and then Philip.

1 MEMBER VICTOROFF: Is this the
2 right time to talk about "usually" under the
3 third bullet "preventable"?

4 CO-CHAIR MEYER: We are going to
5 take these in turn.

6 MEMBER VICTOROFF: Okay.

7 CO-CHAIR MEYER: Hold your fire.
8 Philip, anything on "event"?

9 MEMBER PHILIP SCHNEIDER: Yes, my
10 brother here, Doron, mentioned the issue of
11 near-misses. I am wondering, there could be
12 a near-miss that would have really been a
13 disaster.

14 I am wondering, in the context of
15 our overall discussion as it relates to an
16 event, whether an occurrence is something that
17 is a clinical event or whether it is something
18 that could be a near-miss, that was an event,
19 an error that was caught? And where are we
20 going to get that?

21 CO-CHAIR MEYER: So I will hear
22 from Michael on that, and then I have a

1 comment to respond as well.

2 MEMBER VICTOROFF: In our culture
3 in Colorado, we have a practice of occurrence
4 reporting. We require all the doctors insured
5 by our company in Colorado to report
6 occurrences, even those that do not continue
7 trajectory to harm.

8 So, at least in some cultures,
9 those I am familiar with, occurrences comprise
10 near-misses and events for which the normal
11 safety procedures operated properly;
12 nevertheless, something happened that needs to
13 be considered instead.

14 CO-CHAIR MEYER: And just to
15 follow on that comment, I think kind of in the
16 safety science literature, I think the term
17 "occurrence" would be broad enough to include
18 events that did not result in patient harm.
19 So there are no-harm events that you would
20 call an occurrence.

21 So, again, this leaves it very
22 broad still. This allows this to be open to

1 perhaps a broader range of issues to be
2 considered on the SREs.

3 MEMBER BINDER: I just would echo
4 the comments, but I would think an event is
5 serious if it is a near-miss that could have
6 resulted in the things on those lists. That
7 is that serious, in my mind.

8 CO-CHAIR MEYER: So, as currently
9 written, this would allow this Committee and
10 its predecessors to continue to consider those
11 for lists, to be included on the list.

12 MEMBER BINDER: The way the
13 definition is written here for serious, it has
14 to result in death or --

15 CO-CHAIR MEYER: Deborah?

16 MEMBER NADZAM: Yes, I don't know
17 that this is a discussion for right now, but
18 I want to say it and maybe put it on the
19 parking lot, to have a discussion about the
20 term "near-miss".

21 CO-CHAIR MEYER: Close call. Yes,
22 we will have that discussion.

1 DR. ANGOOD: Gregg, if I may, just
2 for context for the group, the third
3 deliverable, which is this framework report on
4 measuring, evaluating, and publicly reporting
5 these healthcare-acquired conditions, as part
6 of our background work, we are certainly
7 discussing the issue of near-misses, close
8 calls, however they want to be framed up. So
9 that will be in there as well.

10 And as we get to the definitions
11 of healthcare-acquired conditions, I think
12 there is need to keep this concept in there as
13 well. I think what I am trying to drive
14 through is this is one of those differentiator
15 points sort of between the NQF SREs as opposed
16 to the whole field of trying to report and
17 create change around these healthcare-acquired
18 conditions.

19 CO-CHAIR MEYER: Any further
20 comments on the term "event"?

21 (No response.)

22 "Adverse", any comments on that?

1 Deborah?

2 MEMBER NADZAM: I am wondering if
3 we need that last clause, "which may or may
4 not have been preventable".

5 CO-CHAIR MEYER: Yes, please.

6 MEMBER McDONAGH: I was going to
7 comment that I think it is important that
8 "which may or may not have been preventable"
9 is in there because we deleted that whole
10 other section of -- what was it?
11 -- "potentially" or that we deleted in the
12 previous slide.

13 But, at any rate, we later
14 describe "preventable", which I think is
15 different from "adverse" because "adverse" may
16 or may not have been preventable.

17 What I am arguing is to leave it
18 in.

19 CO-CHAIR MEYER: You are arguing
20 to leave it in.

21 Michael, and then I am going to
22 try to move us along quickly.

1 MEMBER VICTOROFF: Sorry. To me,
2 it doesn't make sense to have "preventable" in
3 two places, but I have always interpreted this
4 to need the word "actual". If the word
5 "potential" versus "actual" had any place in
6 the entire definition, it would be here
7 because there are near-miss events or
8 psychological harms or other really scary
9 things that almost happened that are very
10 adverse, but they might not actually have
11 occurred.

12 I don't argue strongly for
13 including that, but, to me, that would be much
14 more valuable than to duplicate the language
15 of prevention in this bullet.

16 CO-CHAIR MEYER: Do you have a
17 specific proposal for a qualifier to put on
18 the end there, Michael, or is that --

19 MEMBER VICTOROFF: Not unless
20 there is a strong feeling. I think we could
21 tinker with this all day, but I don't think I
22 can significantly improve it.

1 CO-CHAIR MEYER: Christine?

2 MEMBER GOESCHEL: I need someone
3 to clarify for me why we need unintended
4 injury or illness, since the consequence of
5 care that results in injury or illness is
6 never intended. We never intend to cause
7 injury or illness. Is that an injury? I
8 don't know. I mean I am asking for
9 clarification.

10 CO-CHAIR MEYER: Yes, I think
11 that's a --

12 MEMBER GOESCHEL: Unintended
13 versus intended.

14 MEMBER DORON SCHNEIDER: But
15 doesn't the word "harm" fit there? Describe
16 the "results and harm"?

17 MEMBER RYDRYCH: Except that not
18 all of these events result in harm, though.

19 CO-CHAIR MEYER: Right, not all of
20 these will result in harm.

21 MEMBER RYDRYCH: Right, right.

22 CO-CHAIR MEYER: I think that that

1 is important.

2 Help me out here.

3 MEMBER GOESCHEL: Yes, I just need
4 someone to explain that to me. I trip on
5 that.

6 CO-CHAIR TYLER: I have to add
7 something that may or may not add to the
8 murkiness of that unintended. At another
9 point, we are going to be talking about our
10 list of conditions includes criminal actions.
11 Certainly, there is intended injury in some of
12 those. So that may bring it under the big
13 tent there. At least that would be an
14 exception that would be included.

15 CO-CHAIR MEYER: P.J.?

16 MEMBER BRENNAN: Gregg, I think
17 there are surgical procedures that clearly
18 result in injury that is an unavoidable and
19 even an intended consequence of the surgery,
20 in part to create some desired effect. So I
21 would argue to leave "unintended" in,
22 "unintended injury".

1 CO-CHAIR MEYER: Cynthia?

2 MEMBER HOEN: Yes, just back to
3 the "usually preventable" or "not
4 preventable", the criteria initially starts
5 out with "usually preventable, serious, and
6 any one of the following adverse...." So, by
7 putting in the definition of "adverse", which
8 may or may not have been preventable, we seem
9 to undermine the initial definition that we
10 were working with.

11 CO-CHAIR MEYER: I do think I am
12 anxious to move us -- this is the slide
13 between us and lunch. That is a good sign.

14 (Laughter.)

15 Public comment as well, though,
16 just so you know, to remind us.

17 So the current definition is
18 described as a "negative consequence of care
19 that results in unintended injury or illness
20 which may or may not have been preventable".
21 And the question is, I would like to call the
22 question on whether or not we include the

1 "which may or may not have been preventable",
2 and let's see where we are.

3 So who feels strongly that "which
4 may or may not have been preventable" needs to
5 stay in that definition?

6 (Show of hands.)

7 Okay. So P.J., Philip and
8 -- okay, so four.

9 And on the phone, if I can take a
10 quick roll?

11 Martha, do we leave "which may or
12 may not have been preventable" in the
13 definition of "adverse"?

14 (No response.)

15 Tejal?

16 (No response.)

17 Oh, they're gone.

18 Okay. So what I am taking from
19 that is that -- so just to clarify, how many
20 folks think that that final term "which may or
21 may not have been preventable", that we should
22 strike it from this?

1 (Show of hands.)

2 So what I would propose that this
3 is an issue, again, that I would like to, at
4 the end of the day, after we go through the
5 list, let's go back and revisit this and make
6 sure that we are consistent.

7 What we are tripping up against
8 here is that in the past there have been
9 inconsistencies. There have been
10 inconsistencies between what is on the list
11 and the criterion here, and we will try to
12 clean it up as best we can.

13 So we will strike it for now,
14 based on the sense of the Committee, but we
15 will revisit this one as well, just to make
16 sure we are making them consistent.

17 "Preventable". Let go. Let's
18 hear.

19 (Laughter.)

20 We have had a fair amount of
21 discussion on this already.

22 Please, what I would like you to

1 do is, also, to suggest some wordsmithing for
2 us, if you can.

3 So, Michael?

4 MEMBER VICTOROFF: Let's see, the
5 shortest way I can probably help this is to
6 say there are other causes for events besides
7 error and system failure. To list them all,
8 I am not sure I could.

9 So what I would probably
10 substitute, I would leave the words "but that
11 occurs" and then say, substitute something
12 like "despite the presence of preventive
13 mechanisms", "in the course of optimal care",
14 or "despite adherence to best available
15 guidelines".

16 MEMBER DORON SCHNEIDER: I'm not
17 sure we want to --

18 CO-CHAIR MEYER: Doron, if you can
19 help us with that, please?

20 MEMBER DORON SCHNEIDER: I am not
21 sure we want to bring it down to the level of
22 the event. I mean you are trying to define

1 "preventable". So isn't it that it should
2 capture something about reducing the
3 likelihood of an event due to the application
4 of evidence-based care, you know, some
5 language like that, that really brings the
6 evidence-based medicine into that, as opposed
7 to describing an event?

8 Because you really want to
9 describe here, define the word "preventable".
10 So "preventable" means that, through the
11 application of evidence-based practice, there
12 is reduction in risk for that patient,
13 something like that. That is what
14 "preventable" is.

15 CO-CHAIR MEYER: So, just to
16 follow up on Doron's comment, I call your
17 attention, as Helen pointed out to me, on page
18 13, the top slide there, under the proposed
19 definition for HAC, it says, "Refer to
20 conditions being reasonably preventable with
21 the implementation of evidence-based
22 guidelines."

1 So is there something we can work
2 from that?

3 MEMBER DORON SCHNEIDER: And that
4 is the CMS definition of a hospital-acquired
5 condition.

6 CO-CHAIR MEYER: So that would
7 leave us with "preventable" describes an event
8 that could have been anticipated and prepared
9 for through adherence to -- or through
10 implementation of evidence-based guidelines or
11 evidence-based -- I think "guidelines" is a
12 little reductionist. Evidence-based practice?

13 I know. Let's work on it. I
14 don't think we're there.

15 Cynthia?

16 MEMBER HOEN: Yes, I think I would
17 like to leave what we have and add the
18 evidence-based guidelines. So it would read,
19 "been anticipated and prepared for". Those
20 are the obvious things that we may put on the
21 list that you should have done something
22 about. Or use the HAC language that you just

1 read that I can't see without my glasses.

2 CO-CHAIR MEYER: So what I said
3 was, I said, "Preventable describes an event
4 that could have been anticipated and prepared
5 for through adherence of evidence-based
6 practice."

7 Eric, please help us.

8 MEMBER TANGALOS: Yes, I actually
9 have trouble with that.

10 CO-CHAIR MEYER: Good. Help us
11 out.

12 MEMBER TANGALOS: Well, again,
13 that gives another out there because a lot of
14 bad things can happen where there's no
15 guideline around it. Yet, you know it is a
16 bad thing that happened.

17 CO-CHAIR MEYER: Yes.

18 MEMBER TANGALOS: So I would be a
19 little bit careful. Again, I think the less
20 words, the better, not the more.

21 I am a little surprised on page
22 13, although we are not discussing it right

1 now --

2 CO-CHAIR MEYER: We will get
3 there.

4 MEMBER TANGALOS: Yes, but we have
5 added another word "reasonable".

6 CO-CHAIR MEYER: Yes. Yes. We'll
7 get there. We will get there.

8 So, Eric, help me out. How can we
9 make this --

10 MEMBER TANGALOS: Well, we are in
11 Washington, D.C., and our Founding Fathers
12 created the Constitution, and we have left it
13 alone for the most part.

14 CO-CHAIR MEYER: Yes. So what do
15 you say?

16 MEMBER TANGALOS: Leave it alone.

17 CO-CHAIR MEYER: Leave it alone?

18 Okay.

19 MEMBER PHILIP SCHNEIDER: Is it
20 possible to have an event that could be
21 anticipated and prepared for without having
22 evidence-based practices defined?

1 CO-CHAIR MEYER: Yes, I think that
2 was the point.

3 MEMBER PHILIP SCHNEIDER: Yes.
4 So, in that, I agree with that comment, Eric's
5 comment then.

6 CO-CHAIR MEYER: If I can, again,
7 to move us on, I am going to call the
8 question. So the question here is, those in
9 favor of leaving the definition of
10 "preventable" as it was, as it was stated
11 originally -- so that was Eric's proposal.

12 And again, "Preventable describes
13 an event that could have been anticipated and
14 prepared for but it occurs because of an error
15 or other system failure."

16 I do think we could, in the text
17 of the report, we will have the opportunity to
18 note that there are other things besides an
19 error or system failure -- I think the point
20 well-taken -- other things potentially that
21 could, but I think for this report that is
22 what we will largely concentrate on.

1 So those in favor of leaving it as
2 is, if we can see a show of hands?

3 Okay. And on the phone, Martha?

4 (No response.)

5 Tejal?

6 (No response.)

7 Okay. And those in favor of
8 making some change to it, again, if I could
9 just get a quick show of hands?

10 So, again, we will leave it as is.

11 "Serious", the definition of
12 "serious" is in front of you.

13 Deborah, get us going.

14 MEMBER NADZAM: I just want to
15 point out that, in the 2006 monograph, it is
16 a different definition.

17 CO-CHAIR MEYER: Oh, we don't want
18 that.

19 MEMBER NADZAM: It says, "An event
20 whose occurrence is grave", not trivial, which
21 I like better, but --

22 CO-CHAIR MEYER: I don't know if

1 we can pull up that 2006 language.

2 MEMBER NADZAM: It was in the
3 materials you sent us.

4 CO-CHAIR MEYER: Okay.

5 MEMBER RADFORD: This is Martha
6 here. I am going to have to leave for a bit
7 to go to the meeting that I had to stay back
8 for. I will join up again.

9 CO-CHAIR MEYER: All right.

10 MEMBER RADFORD: Thank you.

11 CO-CHAIR MEYER: Thank you very
12 much.

13 So you are looking --

14 MEMBER NADZAM: It is C2 in the
15 glossary.

16 CO-CHAIR MEYER: C2 in the
17 glossary. That actually is, I believe that
18 is, what you are looking at probably is the
19 2002 report.

20 Let me just look here very quickly
21 because it is important.

22 Yes, it is the 2002 report. So

1 the 2002 report -- yes. Yes, so it changed
2 between 2002 and 2006. In the 2002 report, it
3 says, the final sentence is "An event whose
4 occurrence is grave." Here it says, "An event
5 the occurrence of which is not trivial."

6 MEMBER NADZAM: It conflicts with
7 itself, the monograph, because on page 3 --

8 CO-CHAIR MEYER: You're right.

9 MEMBER NADZAM: -- it has your
10 definition.

11 CO-CHAIR MEYER: At the head of
12 the table, we have just discovered that.
13 Another contribution.

14 But let's talk about that because
15 I do think that, if we can go back and pull up
16 the slide -- yes. So we have had some
17 discussion, but --

18 MEMBER TANGALOS: You get the OCD
19 award of the day.

20 (Laughter.)

21 Actually, it is; it is
22 spectacular.

1 CO-CHAIR MEYER: Let the record
2 reflect that Deborah won that award.

3 (Laughter.)

4 Okay. So the question here is I
5 think the good news is that we have a choice,
6 and that choice is, do we have nothing there
7 at all or do we put in "grave" or do we say,
8 "which is not trivial"? Boy, those are very,
9 very -- I mean it strikes me that they really
10 are really very distant goal posts, those two.

11 Diane?

12 MEMBER RYDRYCH: So, just to
13 clarify, is the intent of that final clause to
14 capture events that we deem serious, but that
15 don't cause patient harm? Because I have
16 always found that last clause to be rather
17 confusing.

18 "When referring to other than an
19 adverse event, an event the occurrence of
20 which is not trivial."

21 And there are some of these events
22 that aren't related to patient harm that

1 wouldn't otherwise be captured in the first
2 part of this definition because they don't
3 involve death or serious disability?

4 So I am assuming that is the
5 intent. But there is a way of talking about
6 it that is a little bit less ambiguous?

7 CO-CHAIR MEYER: Anyone help us
8 out here? Michael?

9 MEMBER VICTOROFF: I am always
10 hesitant here. But this looks like we are
11 debating synonyms for the word "serious". If
12 you go to the dictionary, which I just did,
13 and you look for synonyms for "serious", you
14 get things like "not trivial" or "grave" --
15 (laughter) -- or appealing to the
16 sensibilities of a connoisseur, which probably
17 isn't what we want.

18 (Laughter.)

19 CO-CHAIR MEYER: I do like it.

20 (Laughter.)

21 MEMBER VICTOROFF: Well, you could
22 use it, but I am not proposing it.

1 So we are dickering here over
2 which synonym for "serious". Do we want to
3 redundantly say "serious" means, yes, serious,
4 we really mean serious; we seriously mean
5 really seriously serious?

6 However, the important part of
7 this clause it means for me is for things
8 other than adverse events. So I would almost
9 propose here to just forget the synonymizing,
10 which is a new verb -- (laughter) -- and say,
11 "which entail important consequences for the
12 patient" or "the participants" or "the
13 institution", or something.

14 CO-CHAIR MEYER: It is the
15 "something", that is probably broader than
16 that. Because, again, these criteria and
17 these definitions are putting guardrails
18 around what we can possibly consider.

19 So, to my mind, leaving that
20 broad, with the notion being that, yes, a
21 significant close call is something that we
22 still want to maybe be able to consider here.

1 I think it would be difficult to say it has a
2 consequence to the patient.

3 Diane, you look like you want to
4 -- can you help us out?

5 MEMBER RYDRYCH: Well, I don't
6 know that I have a suggestion. Because I
7 think it is possible to have something that is
8 an adverse event, but that still doesn't
9 involve harm to a patient. It can be a
10 negative consequence of care, but it can be
11 something that is easily addressed and has no
12 harm to the patient.

13 So it almost seems like the clause
14 needs to take out that, when referring to
15 other than an adverse event, and somehow get
16 at -- it describes an event that results in
17 death or serious disability or an event whose
18 occurrence is whatever synonym we choose to
19 use, even when no harm occurs to the patient,
20 which seems to be the intent of it, right? I
21 don't think that is quite right.

22 MEMBER DORON SCHNEIDER: I mean,

1 aren't we trying to model the sentinel event
2 verbiage from the Joint Commission? I mean
3 the sentinel event verbiage really does have
4 that. It is the risk thereof that is clear,
5 I think, that helps you figure out --

6 CO-CHAIR MEYER: So can you help
7 us? Doron, can you help us work through to
8 something that we can react to?

9 P.J.?

10 MEMBER BRENNAN: I think this
11 definition is too long. I would suggest
12 ending it at "loss of bodily function or the
13 risk thereof".

14 CO-CHAIR MEYER: "Loss of bodily
15 function" --

16 MEMBER BRENNAN: "Describes an
17 event that results in death or loss of a body
18 part, disability, or loss of bodily function,
19 or the risk thereof."

20 Now we are getting very close to
21 the sentinel event definition, yes.

22 But why limit it to seven days?

1 Events beyond seven days or --

2 CO-CHAIR MEYER: Eric, and I would
3 like to hear from some of the -- Stan and John
4 and Diane, I am going to cold-call you on that
5 because I do think that that is an issue that
6 you struggle with in terms of the --

7 MEMBER TANGALOS: We could still
8 argue trivial, but I think the bigger issue is
9 above that, because we can't use this
10 definition in the universe that we are
11 expanding into.

12 CO-CHAIR MEYER: That is true.

13 MEMBER TANGALOS: It can't.

14 CO-CHAIR MEYER: That is
15 absolutely true.

16 MEMBER TANGALOS: Setting a time
17 limit is one thing, but discharge from an
18 inpatient facility makes no sense at all.

19 So, if we are to bring this
20 forward into the expanding universe, we have
21 to end it sooner.

22 CO-CHAIR MEYER: So we have to end

1 it sooner, and I am getting a nod of agreement
2 from our CMS colleagues here.

3 I think what that will leave us
4 with, of course, is going to be ongoing,
5 robust discussions with our colleagues to whom
6 we report.

7 So, Stan, you look like you are
8 ready to jump in.

9 MEMBER RILEY: Yes, you know, I
10 guess I agree completely that we need to
11 scratch the time limit there. But I also
12 agree that loss of bodily function, okay, or
13 risk thereof.

14 CO-CHAIR MEYER: Period.

15 MEMBER RILEY: Period, yes. I
16 think that does it all for me.

17 CO-CHAIR MEYER: I think the point
18 is very well-taken.

19 I would like to, if we can, any
20 further comments or wordsmithing on this?

21 (No response.)

22 Please, Sally?

1 CO-CHAIR TYLER: I just have a
2 question because I don't know if that goes
3 enough. Does disability, are you all thinking
4 that that would include psychological harm --

5 CO-CHAIR MEYER: Oh, yes.

6 CO-CHAIR TYLER: -- trauma? So
7 that is inclusive in this definition, right?

8 CO-CHAIR MEYER: Absolutely.
9 Absolutely. That is a nice footnote, but I
10 think we considered that in the very
11 beginning.

12 DR. BURSTIN: That was a footnote.

13 CO-CHAIR MEYER: Yes.

14 DR. BURSTIN: There actually is a
15 definition as well, which we should have
16 included in the original report as well, for
17 disability. So, since disability is in this
18 title, not to footnote the footnotes, but it
19 does specifically say, "Disability means a
20 physical or mental impairment that
21 substantially limits one or more of the major
22 life activities of an individual."

1 So I think that is encompassed.

2 CO-CHAIR MEYER: So I would like
3 to move us to -- those in favor of this
4 language? "Serious describes an event that
5 results in death or loss of a body part,
6 disability, or loss of bodily function, or
7 risk thereof." Full stop. Those in favor of
8 that change?

9 (Show of hands.)

10 Okay. And anyone on the phone?

11 (No response.)

12 Okay. We will leave that as is.

13 We are left with "Ambiguous refers
14 to an event that is clearly defined and easily
15 identified."

16 Any recommendations for a change
17 here?

18 (No response.)

19 Seeing none, those in favor of
20 continuing it?

21 Mike?

22 MEMBER VICTOROFF: No, that's it.

1 CO-CHAIR MEYER: Those in favor of
2 continuing it as is?

3 (Show of hands.)

4 Okay. We have now updated the
5 definition of serious reportable events.

6 We will move briefly to a few
7 moments for public comment. There are no
8 public members here.

9 Anyone on the phone?

10 (No response.)

11 No public members on the phone.

12 DR. BURSTIN: Operator, are all
13 the lines open for the public?

14 THE OPERATOR: Yes, ma'am.

15 DR. BURSTIN: Okay. And if
16 there's any public comment, this would be the
17 time.

18 (No response.)

19 Hearing none --

20 CO-CHAIR MEYER: Right. Hearing
21 none, we have voted through the changes.

22 Again, I think we will want to revisit these

1 at the end of the day or perhaps even at some
2 point tomorrow.

3 And thank you, actually, to those
4 of you who reminded us that we have got to
5 also do the healthcare-acquired conditions
6 work, and we've got to make sure these fit and
7 mesh well there.

8 With that, we are a bit late, 15
9 minutes. It is time for lunch.

10 We will reconvene at 1:00 p.m.

11 Thank you. That was a terrific
12 discussion. Language matters, and clearing up
13 some of the conflicts in the earlier reports
14 alone will be a good contribution from the
15 Committee.

16 So thank you.

17 DR. ANGOOD: Yes, I just want to
18 say thank you as well. That was strong work.
19 Many of us don't naturally gravitate to word-
20 by-word dissections, but this has helped
21 streamline this tremendously.

22 So thank you, and let's enjoy some

1 lunch.

2 (Whereupon, the foregoing matter
3 went off the record at 12:32 p.m. for lunch
4 and resumed at 1:10 p.m.)

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1 which apparently, I heard on good authority,
2 is quite good. That would be for around 6:30
3 p.m. this evening. So, if you are interested
4 in joining others for dinner, let Jennifer
5 know during the break, and she will go ahead
6 and get the proper reservation set up for you.

7 Actually, a very quick show of
8 hands right now would be helpful, if you are
9 interested.

10 (Show of hands.)

11 Very nice.

12 By the way, orientation for the
13 afternoon, I am actually going to ask Jennifer
14 to go back to the slide set and remind folks
15 that, under this contract from HHS, the
16 National Quality Forum is not only asking us
17 to work on the serious reportable events, but
18 they are also asking us to work on HACs. I
19 specifically use the term "HAC" rather than
20 say, "acquired/associated" at this point in
21 time.

22 So, if we can get the slides up in

1 a minute, and actually just go to the HAC
2 definition, the goal of the next conversation,
3 just to orient folks to the hard copy, we are
4 now on page 13. So, beginning on page 13, the
5 goal of the next conversation is for us to
6 actually try to define HACs.

7 Some if you were sitting here
8 during that last conversation and saying, boy,
9 I wish we had a blank slate; we could do so
10 much of a better job, my advice to you is be
11 careful what you wish for because that is what
12 you have right now with healthcare-associated
13 or -acquired conditions, that there is not a
14 definition in place. This group is being
15 asked to develop that. That is our task over
16 the beginning of the afternoon here.

17 With that said, we made some great
18 progress this morning and in some ways may
19 have opened up some opportunities to try to
20 come to some clarity about the way that HACs
21 and SREs can relate to one another.

22 With that, I am going to turn it

1 over to Helen Burstin.

2 DR. BURSTIN: So several of us
3 were sitting here thinking, okay, you guys
4 have now clarified this definition
5 sufficiently that the question is, is there
6 really a need for a second term? I actually
7 did have a brief conversation with Eddie
8 Garcia from CMS.

9 Obviously, one, we understand they
10 are a big, complicated organization. But he
11 has very similar thinking.

12 I mean, really, their major
13 objections to SREs was that they were so, the
14 implication of them being never events meant
15 that you couldn't have a broader set of events
16 potentially that they could use. We have
17 already indicated we are going to expand the
18 SREs beyond the hospital setting.

19 So I guess I would just, before we
20 even sort of jump into trying to divine this
21 thing, can we take a look at this definition
22 with reference to the great work you did this

1 morning, and think about, in fact, whether a
2 second definition is actually needed?

3 MEMBER PHILIP SCHNEIDER: I think
4 I kind of mentioned this earlier, as we were
5 tweaking the definition for serious reportable
6 events, to some extent it dealt with the
7 scope. If you look at the proposed definition
8 for hospital HAC, it seems like that could be
9 an awful lot of events.

10 Can you go back to that hospital-
11 acquired/associated?

12 Because there are many things that
13 are reasonably preventable. I mean you could
14 look at fevers or a lot of things.

15 Again, this gets into the issue of
16 process variation versus really focusing on
17 really serious events in-depth. It may be
18 desirable to look at very frequently-occurring
19 events that shouldn't happen as a measure of
20 variation that should be taken out of
21 healthcare. It is an entirely different
22 approach than looking at serious events that

1 involve root-cause analysis and looking for
2 system causes.

3 So I look at the universe of
4 events that are encompassed by this definition
5 as being huge, even with our new definition
6 for serious events being relatively small.
7 When I get into debates with human factors
8 folks, they have said: I would rather analyze
9 one serious event in some depth to find out
10 where we can make improvements than have
11 databases with a million events, finding out
12 where the errors are most common. We know
13 that heparin errors happen a lot, but let's
14 look at a few of them and find out what the
15 root causes are.

16 So this takes me to an issue that
17 I have debated for my entire life in this
18 safety science area, which is, when do you
19 look at granularity versus when do you look at
20 trends?

21 But the two definitions, as they
22 are currently structured, deal with small

1 numbers of serious events versus large numbers
2 of relatively-common events.

3 CO-CHAIR MEYER: Stan?

4 MEMBER RILEY: I guess, for me, it
5 gives us the opportunity to look at all the
6 rest of the events that actually happen.
7 Serious reportable events, at least in
8 Massachusetts, comprise about 20 percent of
9 the reports that we get. The other 80 percent
10 are these kinds of things.

11 So, without this ability, you
12 know, I think we would be missing a lot.
13 Probably the same thing is true in Minnesota.
14 You know, the SREs are just sort of a small
15 slice of the pie.

16 So I think this gives us a really
17 good opportunity to look at some of the other
18 things that are happening out there. Some of
19 them are really terrible that are going on.

20 So I think, even though it expands
21 the universe a lot, it does give us an
22 opportunity to actually see the kinds of

1 things that are happening out there that we
2 would miss without a broader definition.

3 CO-CHAIR MEYER: Before we go to
4 Michael, I just want to make sure one thing is
5 crystal-clear for everybody, that we have two
6 highly-related but separate tasks with regard
7 to the SREs.

8 The first one was to do the work
9 of this morning. That is, to define the SREs.
10 But also, recognize that within what I think
11 we created were relatively broad definitions.
12 There is the specific list of things that are
13 reportable. Following kind of the spirit of
14 this project from its beginnings, the hope was
15 that states would then take up this list and
16 require reporting on that basis.

17 So the two are separate, highly-
18 related, and then there is this third nuance.
19 I think that Helen kind of begs the
20 provocative question; that is to say, can we
21 kind of within the definition for serious
22 reportable events, you know, consider a

1 broader range of issues that would allow us to
2 accomplish what was being asked here?

3 So, with that clarification, I am
4 going to go to Michael and then Deborah.

5 MEMBER VICTOROFF: To begin to
6 untangle this, a couple of threads I see
7 dangling are that conditions for me are
8 totally different things than events. If we
9 were to honor that difference, which we could,
10 I would leave the events as they are. They
11 have to do with sort of events or things that
12 transpire in the world, whatever processes.

13 Whereas, conditions, to me, I am
14 fairly narrowly trying to understand these as
15 diseases or disabilities or disorders that a
16 human being acquires as a result of a
17 healthcare process. So they are completely
18 different things.

19 I think I like the idea of a
20 parallel list of acquired conditions that a
21 person got because of something that we did to
22 them in the healthcare system. But that,

1 then, opens up two more threads that we didn't
2 have with the reportable events thing.

3 No. 1, we are going to have to
4 grade them for severity again, because nausea
5 is a healthcare-acquired condition when you
6 get chemotherapy, and stomachache is something
7 you get from aspirin. You know, where do we
8 want to go? We need to put some kind of a
9 scale with this, like serious or something
10 equal.

11 But the other one is the big
12 gorilla for me. That is that I understood
13 that CMS wanted this list, or something, to be
14 the foundation of an intervention, something
15 we haven't talked about, which is the non-
16 reimbursable aspect of some of these things,
17 which I also support, the idea that if the
18 hospital or the doctor or the system imposes
19 a condition wrongly on someone that was
20 avoidable, then we ought to stimulate their
21 quality improvement system by not paying them,
22 or whatever, burning the place to the ground,

1 doing some kind of an intervention.

2 So those are threads that we
3 didn't see in the SREs. I like them, but I
4 have a lot of problems with this phrasing.

5 CO-CHAIR MEYER: Let me, before we
6 move to Deborah, just again I think some
7 additional points: one of them is that, for
8 the serious reportable events, one of the
9 things that we have learned over time is, when
10 someone says they want to measure something,
11 the right question to always ask is, for what
12 purpose?

13 The purpose for the serious
14 reportable events is very clear. It is stated
15 in the prior reports. That is to come up with
16 -- it is for accountability, and it is to come
17 up with a list that states would implement for
18 public reporting.

19 There is a lot of ambiguity, I
20 think, right here. I am going to call on our
21 colleague from CMS to see if he can help us
22 out at all. Because I do think, if he can

1 help us frame this consideration by knowing
2 for what purpose they are likely to be used,
3 it will make a difference for us.

4 So any help you can give us, and I
5 don't want to put you on the spot, but I do
6 want to put you on the spot.

7 (Laughter.)

8 MR. GARCIA: I think, originally,
9 you are encompassing what we had hoped for,
10 which is an extension of the SRE list. I
11 think the definition that you have come up
12 with does do that. So you have taken out the
13 inpatient hospital portion and you have taken
14 out this reference to never events, which was
15 politically not feasible for us to use. So
16 you have done away with those references.

17 In parallel to this list now that
18 could be expanded across settings of care and
19 could be expanded to encompass more events
20 potentially, we have this thing called
21 healthcare-acquired conditions, which look at
22 things that are potentially of less -- that

1 are not as rare, that maybe aren't as serious
2 as the serious reportable events.

3 So I think this has taken us down
4 another track that I think we hadn't thought
5 of before and that is just as useful. The
6 HACs, then, would be used for, as you are
7 saying, quality improvement. We could put
8 quality measures off of those. The SREs tend
9 to be, as you know, counts. So I think both
10 are useful. One is for reporting; the other
11 possibly for reporting and for QI.

12 I am not sure if that is helpful
13 or if you have --

14 CO-CHAIR MEYER: For QI and for
15 payment purposes are two different things. So
16 I guess I am, again, putting it kind of back
17 to you in terms of, you know, Michael's
18 statements in terms of, well, it depends a
19 little bit on what it is going to be used for.

20 MR. GARCIA: Sure. Right. I'm
21 sorry, I really shouldn't comment on that.

22 CO-CHAIR MEYER: You have a future

1 in government.

2 (Laughter.)

3 Congratulations.

4 MR. GARCIA: Right.

5 CO-CHAIR MEYER: Speaking from one
6 who knows.

7 (Laughter.)

8 MR. GARCIA: I know that with the
9 healthcare-acquired conditions, they are using
10 that for something like determination. Right
11 now, there aren't discussions to expand that.

12 On the quality improvement side or
13 through our QIO programs, we would look to the
14 evidence base and quality measures that could
15 be generating from this list of HACs in other
16 settings of care.

17 CO-CHAIR MEYER: Deborah, and then
18 I am going to come back to Helen.

19 MEMBER NADZAM: Yes, I was having
20 similar concerns about how are they different
21 and how are they the same, and for what
22 purpose are these lists being developed?

1 On that list of conditions are a
2 variety of hospital-acquired infections
3 currently from SSI to bloodstream, UTIs, et
4 cetera. So they are different, and it doesn't
5 sound like we are willing to move to the point
6 where we would say those HAIs are serious
7 reportable events completely, but they are.

8 It is a slippery slope, I think,
9 for when is a condition, you know it shouldn't
10 have happened and we're not paying for it. I
11 mean it is a slippery --

12 MEMBER VICTOROFF: And if I could
13 just respond, I think this is the nugget of
14 the problem. If we open-endedly define
15 anything you acquired from healthcare, which
16 would mean any iatrogenic effect or any side
17 effect, or even any intended effect like,
18 "What is your condition?"

19 "I've got one leg."

20 "How did you get that?"

21 "Well, you see, I stepped on a
22 landmine and then they sawed it off to prevent

1 the gangrene, and now I have one leg. My
2 healthcare-acquired condition is I've got one
3 leg."

4 So there are some healthcare-
5 acquired conditions that are deliberate,
6 intentional, in fact, beneficial, the best we
7 could do, or a trivial, minor, not important,
8 or expected and anticipated. You are going to
9 get nauseated from your chemo; we are sorry.
10 Your hair is going to fall out. That is an
11 acquired condition. We're sorry.

12 Now, on the one hand, I think it
13 might be very good for quality and for
14 science, for other reasons, to know who's got
15 no hair because of healthcare and who's got no
16 hair because of the wrong genes. That could
17 be important. You know, who's got one leg now
18 because of healthcare? You know, okay.

19 But that is not really a quality
20 measure yet. It is just sort of epidemiology.

21 But if we were, at the same time,
22 to say, healthcare-acquired conditions,

1 inadvertent bad conditions, that we didn't
2 mean them to have that we should have tried to
3 prevent, and we did our best, but now they are
4 all screwed up, and it is our fault, those
5 kind of conditions, for which maybe it is very
6 fair and valid to not to pay us because, okay,
7 you're right, you know, we shouldn't have done
8 that. And we shouldn't make you pay for
9 undoing the error we shouldn't have made
10 anyway. That bunch of things.

11 We really do have a mixed bag
12 here. There's two colored jelly beans in the
13 bag. That is where I don't think we can use
14 the same definition.

15 First of all, this definition is
16 too bland. Healthcare- or hospital-acquired
17 conditions, that won't do it for me. All the
18 jelly beans in the world are in there. And if
19 we just mean bad stuff that we didn't mean to
20 do that we hurt people with inadvertently, and
21 we are really sorry kind of things, this
22 definition doesn't capture that. I think that

1 is in a whole other gang of things that we
2 ought to be thinking about.

3 They are not necessarily events,
4 right? Like there's a fire in a trash can,
5 and that is an event, and that shouldn't have
6 happened. That's maybe reportable. But
7 there's no condition there.

8 Whereas, myocardial toxicity,
9 maybe that is a condition. But the event is
10 tricky.

11 So there really is room for me for
12 two lists, but we've got to be clear what we
13 are doing. Okay?

14 CO-CHAIR MEYER: Helen, you wanted
15 to jump in?

16 DR. BURSTIN: Yes, I was just
17 going to make a point that, first of all, I
18 think it is important to remember that payment
19 issues are outside our scope, really outside
20 our scope. How these get used is really not
21 an issue.

22 The real issue for this group

1 should be, is there a need for a second set of
2 events, whatever we call them, whatever it is,
3 that is potentially reportable or not
4 reportable, serious or perhaps maybe not as
5 serious?

6 But I do think it is important to
7 note, and I just pulled up the list from last
8 year, and I think you added one more SSI. You
9 know, of the current one, two, three, four,
10 five, six, seven, eight HACs, four of them are
11 SREs. So there is already blurriness. So we
12 shouldn't pretend that they are separate.
13 Four of them are SREs. The remaining ones are
14 bloodstream infections, urinary tract
15 infections, a couple of SSIs, and falls.

16 So I guess my question would be,
17 is there an opportunity to think -- I am a
18 lumper by nature; I'll admit that -- you know,
19 is there an opportunity to think about whether
20 there are serious reportable events? And
21 perhaps there are some of those events that
22 get into this issue of always reportable

1 versus events for which there are known
2 strategies to reduce care.

3 I just think there might be an
4 opportunity to think about something, as you
5 think about it from where you sit, Stan: what
6 are the events that are important, 20 percent
7 of which get to you? How many of that
8 remaining 80 percent are the kind of thing
9 that would be important to have a standard
10 definition for, however it may be used in
11 healthcare?

12 CO-CHAIR MEYER: So I am going to
13 go ahead and go to Doron and then to John.

14 MEMBER DORON SCHNEIDER: So the
15 term "hospital-acquired conditions" is being
16 used, to my understanding, by CMS to look at
17 payment withholding. The way I am thinking
18 about it, these hospital-acquired conditions,
19 you know, should be used by the National
20 Quality Forum differently, which really are
21 unintended conditions that are a cause of
22 healthcare, of which the SREs are a subset and

1 I think, you know, HAIs may be a subset of.

2 Because we do want to have
3 reporting of these other events. By
4 definition, if you have a list of things which
5 are serious, then you have a list of things
6 which are not serious. Those are hospital-
7 acquired or -associated, whatever we come up
8 with, conditions.

9 Because, to your point, we are not
10 supposed to be thinking today about payment.
11 We are supposed to be thinking about
12 reporting. So, if we are thinking about
13 reporting and accountability, then it is SREs
14 are serious; these other events are other
15 events. We want near-misses and we want the
16 minor events, and we need to learn from them.

17 DR. ANGOOD: If I may, just on
18 that point -- sorry, Gregg -- we don't have
19 the full context from all of CMS here. Eddie
20 is doing a formidable job of sort of fingering
21 in the dike while we pepper them all morning
22 and afternoon.

1 But the hospital-acquired
2 conditions is not just about money. It
3 actually is part of CMS's incentive strategies
4 to improve quality of care. We just have to
5 help tease that out for perhaps bringing the
6 term back to what its true purposes are, and
7 that is to help improve the safety of quality
8 in healthcare.

9 If this, then, comes back to CMS
10 and they reconfigure, that would be a good
11 outcome. My point being is I don't think we
12 are necessarily beholden by rigidity in CMS,
13 and they are just taking a focus on payment,
14 because we are really trying to improve
15 quality.

16 CO-CHAIR MEYER: John?

17 MEMBER MORLEY: Harmony was never
18 my forte, but I would like to comment in terms
19 of harmony.

20 The first comment is I think how
21 we got to this point, to some significant
22 degree, started with the IOM report 10 years

1 ago. I think this really is about what Peter
2 was talking about in terms of quality and
3 safety.

4 I think reporting for the sake of
5 reporting is of zero value to me. I try to
6 convince the reporters that yell at us, "Why
7 aren't you whacking the hospitals more for not
8 reporting?" that the value in the information
9 that we collect, as we were just hearing a
10 little while ago about collecting information
11 for analysis, is my concern.

12 Now let me go someplace else and
13 come back to there. When I was on the
14 hospital side, one of the struggles that I had
15 was that there was a list that came from the
16 Joint Commission. There was a list, even
17 then, from the NQF. There was a list from the
18 health department. There was a list from our
19 friends at CMS. I needed a list to keep track
20 of the lists.

21 And one of the great things that I
22 see about NQF is that there is an appreciation

1 that we need to have a little more unity, a
2 little more harmony, and less of these lists.

3 The list, actually, is far -- it
4 is easier for me to handle one list of 40
5 things than four lists of 10 things. I would
6 just rather have it all in one.

7 Now, to respond to something that
8 Mike had said, clearly, there is a major
9 difference between events and conditions, but
10 for our purposes today, an event is an event
11 that we care about, unless there is a
12 condition associated with it.

13 So I think the two merge in that
14 respect. I would just as soon have a single
15 list issue that, once again, is very important
16 to me, it is not about just collecting notches
17 on a gun belt, that there was another wrong-
18 sited surgery. I want to know how it
19 happened, why it happened, to try to prevent
20 it from happening again.

21 And those fewer lists that we can
22 have, I think there is a very limited number

1 of resources we all have. When the topic
2 comes up in the press, what has been
3 accomplished in the last 10 years, the answer
4 has been given, well, we really haven't
5 accomplished very much.

6 I would differ a little bit and
7 say that there are clear pockets that we can
8 identify improvement, but they get diluted in
9 the bigger picture. One of the things that I
10 think has been a downside in terms of the last
11 10 years is the variation in what our
12 responses have been, the different things that
13 have been attempted.

14 If there had been more focus on a
15 single list with similar issues being driven
16 from NQF, from the Joint Commission, from the
17 state health departments, from Leapfrog, and
18 from many of the other quality improvement
19 organizations that are out there, I think we
20 would have accomplished more.

21 It is sad to me that something as
22 important as retained foreign bodies or wrong-

1 sited surgeries, that we haven't made more of
2 a dent in those topics in the last 10 years.
3 Maybe Minnesota made a difference in retained
4 foreign bodies; I am not sure. And
5 Pennsylvania is starting to hint at
6 improvement in wrong-sited surgeries, but it
7 has been 10 years on those two topics.

8 Again, from my perspective, I
9 would like to see a simpler list. I am a huge
10 believer in the KISS philosophy, keep it
11 simple; for political correctness, I will say
12 SILLY. But whichever it is, you know, the
13 simpler we can make it, the better, and the
14 more focused we can make it, the better.

15 CO-CHAIR MEYER: P.J.?

16 MEMBER BRENNAN: I am looking at
17 the slide deck that was provided to us from
18 the state meeting, the state-based reporting
19 meeting perspectives on SREs and HACs.
20 Looking at the tables, it makes me ask the
21 question, serious to whom?

22 This strikes me as a matter of

1 degree. I am really struggling with the
2 distinction between conditions and events.

3 So, unless I am reading this list
4 incorrectly, there's a table -- I am not sure
5 which slide it is -- but it was hospital-
6 acquired conditions and it has got HAIs. They
7 seem to be hospital-acquired conditions rather
8 than SREs, but, boy, those are serious
9 conditions. Those are really serious events.

10 You know, 15 to 40 percent of
11 people die of vascular catheter-associated
12 infections. Mediastinitis after a CABG is a
13 horrendous event. Orthopedic procedures with
14 infections are potentially fatal, not because
15 of the infection, but because of the
16 disability that ensues. DVTs and PEs are
17 self-explanatory. Infections after bariatric
18 surgery are catastrophic.

19 So I would like one list, to be
20 honest with you. I am really struggling with
21 the distinction here, and I think it is more
22 a matter of degree than reality.

1 CO-CHAIR MEYER: Let me, just
2 before I jump to others, if I could, I just
3 want to make sure I am hearing this right. So
4 what I am hearing from John and from P.J. is
5 keep one definition and generate one list.
6 That list would include some things that
7 states would be asked for public reporting on,
8 and it would include an additional list of
9 conditions or events, and we can work on that
10 as time goes on, that would be used for other
11 purposes.

12 Is that what I am hearing from
13 you?

14 MEMBER BRENNAN: Yes, yes.

15 CO-CHAIR MEYER: Okay. One of the
16 things I just want to let people know about,
17 and this is not good nor bad; this is just
18 reality. The reality of it is that neither
19 this Committee nor the Quality Forum, nor any
20 of us in our other roles, have the ability to
21 control what is going to be done with these
22 lists.

1 At AHRQ, we used to coin this term
2 called "off-label use". However, we would
3 say, boy, we want to put out these indicators
4 for quality improvement purposes, and that is
5 what they are best suited for, and that is all
6 well and good. The reality is someone can
7 pick them up tomorrow -- they are in the
8 public domain -- and use them for payment
9 purposes. That is America, and I don't think
10 we can change that. So I think it is
11 something just to keep in mind as we work
12 through this.

13 John, I am going to go to you, and
14 then I want to move on to Christine.

15 MEMBER MORLEY: On that very issue
16 about information or the product of this
17 Committee and this work being used for other
18 purposes, it seems pretty clear to me at
19 least, and I am not on the inside on CMS, but
20 they didn't decide not to pay for these things
21 because they wanted to save a ton of money.
22 They didn't save a ton of money. I have seen

1 in some place in writing some of the numbers,
2 and the numbers relative to the budget are
3 incredibly small.

4 They wanted to send a message.
5 What we are about today, and all of this work,
6 is toward changing our culture to say quality
7 isn't an afterthought, a "one more thing".
8 Quality is job one, not that I am a big fan of
9 certain car companies, but there's something
10 to be said about that is our priority. We are
11 changing the culture.

12 That is the message that I got
13 from CMS, is intent to change. There will be
14 multiple other ways that we haven't even
15 thought of yet that people will use this, and
16 I appreciate that, as long as the goal,
17 hopefully, is to drive change, improvement,
18 culture, safety.

19 CO-CHAIR MEYER: Okay. Christine,
20 and then Deborah.

21 MEMBER GOESCHEL: Great. Thank
22 you.

1 First, I need to apologize because
2 I am going to sneak out a little early for
3 something I could not get out of that was
4 preordained.

5 But I need and want to weigh-in
6 strongly on the value of a single list. I
7 agree. I mean we have talked about the need
8 to figure out what other entities are doing
9 above and beyond NQF. For every additional
10 list that we have, it just complicates the
11 challenge.

12 I think the other thing, agreeing
13 particularly with what P.J. and John said, it
14 is that I would hope, as we go after these
15 conditions, or whatever we are looking at,
16 that we start with where evidence lives; that
17 we don't start with the conditions, and then
18 try to find evidence. Because part of the
19 challenge that I think many of us face every
20 day is we identify serious, important issues
21 for which there is not evidence on how to
22 improve, but we make it a top priority.

1 I think somewhere within, although
2 we don't develop measures, I think it gets to
3 part of the linkage that you talked about
4 earlier with the measurement group to make
5 sure that we understand where strong evidence
6 lives, where perhaps the focus for gaps could
7 start there, if that makes any sense at all.

8 I really feel strongly that part
9 of the challenge we face is by identifying
10 things for which there is not evidence. I
11 will use UTIs as a perfect example of what do
12 you measure. There's great debate on that
13 right now.

14 CO-CHAIR MEYER: Deborah?

15 MEMBER NADZAM: Yes, something you
16 said, John, sparked a thought related to the
17 two lists. The SREs are single events. The
18 others are conditions. And are they the same?

19 If you look at the conditions
20 those events describe, it is death or
21 permanent disability, except for the criminal
22 ones perhaps and pressure ulcers, I think.

1 So, again, we have to go to the
2 purpose. They are both for improvement
3 purposes, but is each individual occurrence to
4 be reported for every SSI or for patients who
5 died as a result of an SSI?

6 I know you said something earlier
7 about infections being considered on the SRE
8 list and not included. I would like to see
9 one list, too, but I think they do describe
10 different groups of bad things that happen.

11 CO-CHAIR MEYER: P.J.?

12 MEMBER BRENNAN: I just wanted to
13 respond to something that John said regarding
14 CMS, and perhaps you can speak to this better
15 than I.

16 But value-based purchasing is
17 really part of the Deficit Reduction Act. So
18 we shouldn't be mistaken in thinking that this
19 is -- I don't mean to suggest you were
20 mistaken, but the issue is not just culture
21 change, but cost was clearly a part of that.
22 I realize that this isn't part of our purview,

1 but that is certainly something that has
2 driven CMS's activity I think.

3 I think there is a lot of
4 congressional frustration that they have been
5 able to find so few evidence-based conditions
6 on which to develop a value-based purchasing
7 program. I think there is a lot of impatience
8 to push it in that direction.

9 CO-CHAIR MEYER: Before we move to
10 Leah, just one, again, potentially qualifying
11 issue, that in some ways the choice of term of
12 condition versus event, which I think is one
13 that we are hung on. Yet, when you look at
14 the lists, there seemed to be a fair amount of
15 blend there. I mean it begs the question.

16 Now what we don't have is I don't
17 know the ICD-9 code for a rape on the campus
18 of Mass General. It doesn't exist. I do know
19 there is an ICD-9 code for every single one of
20 CMS's HACs. There is an ICD-9 code for
21 mediastinitis.

22 So to what extent did the coding

1 drive the use of the word "condition" is what
2 I am wondering, because that seems like a
3 pretty logical follow-on. Is that part of
4 this? It may be ancient history.

5 I mean, clearly, to affect it in
6 payment, you need to tie it to codes. It is
7 impossible to do otherwise. But you just
8 wonder how artificial this distinction is or
9 how much it is a product of the use of the
10 list as opposed to some kind of underlying
11 philosophical approach about what makes sense.

12 I am going to go to Leah, and then
13 I will come back to you, Mike.

14 MEMBER BINDER: I would agree with
15 your comments. Actually, that was the point
16 I wanted to raise.

17 I like the idea philosophically of
18 one list. Leapfrog is a very strong proponent
19 of harmonization and reducing the number of
20 measures that hospitals have to collect, so
21 they spend more time actually addressing the
22 issues that are raised by the measures than

1 just collecting a lot of data. So having one
2 list does have an appeal.

3 I also like it philosophically
4 because it focuses on the harm to the patient.
5 A condition or an event makes the list because
6 a patient has suffered terribly in some way.
7 So, therefore, it makes that list. It is a
8 patient-centered approach, I think, to what we
9 are trying to do. So I like that.

10 But I would add, and the next
11 point is very important, these need to be
12 reportable. So we need to make sure that it
13 is pragmatic and feasible to report.

14 CO-CHAIR MEYER: I have Michael
15 and then Doron.

16 MEMBER VICTOROFF: You are
17 touching on something that I thought we would
18 probably get to tomorrow, which involves the
19 reporting systems. I think you are exactly
20 right. My empiric observation is that the
21 reason that we have so-called conditions from
22 CMS is because that is all that they can

1 traffic in really. There is no procedure for
2 let's go hand the baby to the wrong person.
3 Again, there's no CPT for that.

4 There are ICDs for some of these
5 conditions, although the ICDs are neutral with
6 regard to whether they were intentional or
7 they are complications, or whatever.

8 CO-CHAIR MEYER: Right, acquired
9 on admission, yes.

10 MEMBER VICTOROFF: In essence, my
11 global thought about reporting systems is that
12 we don't have an adequate vocabulary,
13 taxonomy, classification within either the CPT
14 or the ICD that is suitable for reporting the
15 kind of events we are talking. So we really
16 need to be thinking about stepping outside of
17 that or using some adjunct codes to the ICD,
18 if we can come up with some, or G codes, or
19 God knows what.

20 But, that being said, I am neutral
21 on the subject of whether we should merge the
22 lists or keep them separate. I don't much

1 care, although I am not a reporter. So, if
2 the reporting faction in here really
3 authoritatively says that, yes, that would
4 really help enormously, then I will defer.

5 But what that simply means to me
6 is that we have to take these conditions and
7 rephrase them rhetorically to say a case in
8 which a patient-acquired condition in the
9 course of medical care, something, something,
10 something. We can do it. It is a little
11 wordsmithing problem.

12 But, then, what that means is we
13 are still going to have to say that the
14 condition was serious because we simply can't
15 create another index of side effects and
16 adverse events with complications in all of
17 healthcare because that would be self-
18 defeating. We have got to retain the fact
19 that we are just talking about the top of a
20 pyramid for now for a pragmatic reason.

21 CO-CHAIR MEYER: Doron?

22 MEMBER DORON SCHNEIDER: So the

1 one thing that we decided on this morning that
2 is relevant to this is the words "the risk
3 thereof". If we think from a reporting
4 standpoint, and we would like to know about
5 these events because that patient almost had
6 a major problem, then that is one angle that
7 that report would go. But CMS is not going to
8 care because it didn't meet that definition of
9 harm to the patient from a patient-centered
10 approach.

11 So I think whatever we come up
12 with here at the end has got to satisfy both
13 of those. It is both the patient-centered
14 approach, that there was harm, or the risk
15 thereof, and there is where the learning is
16 for the organization itself to protect the
17 next patient.

18 CO-CHAIR MEYER: We will go to
19 Philip.

20 MEMBER PHILIP SCHNEIDER: I am
21 trying to get a sense of what we need to do
22 here because I think we would probably agree,

1 from what I have heard, that if you had a Venn
2 diagram method, the big circle is hospital-
3 acquired conditions and then inside that --

4 CO-CHAIR MEYER: Healthcare.

5 MEMBER PHILIP SCHNEIDER: -- yes,
6 the healthcare-associated, HACs, and inside,
7 not outside at all like the ADE ones. The
8 inside is serious reportable events.

9 So, by definition, a hospital-
10 acquired or healthcare-associated condition is
11 a different definition than a serious
12 reportable event.

13 So, then, you are getting into
14 this list and harmonization, and I certainly
15 agree with the frustration that you have with
16 having all these things, but do we have to do
17 that? Or do we simply have to state for the
18 fact that there are preventable negative,
19 adverse events that happen in the healthcare
20 system that people have, some of which are
21 serious reportable events?

22 CO-CHAIR MEYER: Let me just

1 suggest --

2 MEMBER PHILIP SCHNEIDER: So I am
3 trying to get a sense at the end game what we
4 really need to do.

5 CO-CHAIR MEYER: So I think in
6 terms of the Venn diagram that you propose,
7 that sounds like what people are talking
8 about, that HACs are more all-encompassing,
9 and within the HAC is embedded a small circle
10 of SREs.

11 To me, as I think about, well,
12 what's the differentiator, what is defining
13 that smaller circle, to me, it gets back to
14 the purpose. That is, those are the things
15 that we are going to ask states to have public
16 reporting on, doing that.

17 And that is not to say that states
18 won't ask us to report HACs or CMS won't ask
19 us, but in terms of publicly reporting, that
20 it is the smaller circle. I may be off there,
21 and if I am, I want get folks to jump in.

22 Actually, Doron, and I want to go

1 to Christine afterwards because I want to
2 catch her before she has to go.

3 MEMBER DORON SCHNEIDER: I think I
4 am confused. I think that the Venn diagram is
5 very critical. I am sort of with you, but
6 then I am not.

7 Hospital-acquired conditions are
8 everything. If we go down that line, all
9 right, of which the serious stuff is one
10 circle, all right, which is serious reportable
11 events, I see two circles within the whole of
12 these. You've got CMS's list, whatever you
13 want to call it. Right now, it happens to be
14 called healthcare-acquired conditions, right?
15 Then you've got serious reportable events, of
16 which there is, within that Venn diagram of
17 those two, an intersection which now there are
18 only four of the conditions, right?

19 Then the bigger Venn diagram, the
20 bigger circle, is hospital-acquired
21 conditions. So we probably need a different
22 term, so that we don't keep stumbling up

1 against that for all reportable events.

2 So you've got reportable events.

3 Let's just call it that. Then you've got the
4 serious reportable events and CMS's list.

5 That is where I think we have to have the
6 discussion about bringing those two together
7 and creating one. And, at the end of day, we
8 don't have, to your point, control over what
9 CMS does with the list, as far as from a
10 payment perspective.

11 MEMBER LAU: This is Helen on the
12 phone.

13 CO-CHAIR MEYER: Yes?

14 MEMBER LAU: I have been listening
15 to this. I think it is fascinating with the
16 Venn diagram. As you folks are talking, I
17 start seeing more a tree diagram. The
18 healthcare-associated condition is really the
19 top of this tree. Then, there it depends on
20 what setting the serious reportable event is.
21 In the hospital setting, there are certain
22 serious reportable events, and if you talk

1 about nursing homes or home care, the serious
2 reportable event is of a different level. You
3 know, it depends on the perspective.

4 I think, within that level, there
5 are some cross-cutting, you know, an
6 interchange arrow going back and forth. So,
7 for example, aspiration. Aspiration could
8 potentially be a hospital-acquired, a
9 healthcare-acquired condition. Then, because
10 of the aspiration, now the patient could have
11 aspiration pneumonia, and then end up with
12 septic shock, and maybe something else, and
13 die.

14 So kind of start looking at that,
15 okay, so aspiration itself is not an event.
16 It is more like a condition.

17 So, in different care settings,
18 you have a different seriousness of how, if
19 you grade them, you know, different levels.
20 So maybe I am thinking too much. So I think
21 this is what you guys are talking about.

22 I also like the idea of one single

1 list, but how can we have a single list that
2 can cross all care settings? I think that is
3 also the challenge, but maybe there is some
4 common area that can touch different care
5 settings.

6 CO-CHAIR MEYER: Let's go to
7 Christine.

8 MEMBER GOESCHEL: I actually need
9 to listen at this point. Thank you.

10 CO-CHAIR MEYER: Okay. Cynthia?

11 MEMBER HOEN: Yes, picking up on
12 what Doron was saying, if we have the universe
13 of all bad things that happen to people in the
14 hospital, and then the two subsets he was
15 talking about, in my mind, I am now starting
16 to think that one is sort of like criminal
17 policy violations as opposed to those things,
18 almost like Red Rules that we put in place
19 because the Joint Commission says they
20 shouldn't happen.

21 Then there is another subgroup of
22 the sort of clinically-acquired bads that we

1 want to have best practices in place to
2 prevent -- clinical best practices which are
3 scientifically proven. Then, somewhere in the
4 middle, there is the intersection which you
5 were talking about, which may be they don't
6 fall -- the falls, the pressure ulcers, where
7 we are not quite sure what the clinical
8 pathway is, but we also know that we don't
9 want them.

10 CO-CHAIR MEYER: Okay. We are
11 going to go to John and then to Deborah.

12 MEMBER MORLEY: I have to confess
13 that I come to the table here with a very,
14 very clear bias, and I am not sure how
15 accurate it is. But all of the comments that
16 I have had heard pretty clearly have been in
17 terms of the goal is to improve healthcare, to
18 reduce these events from happening.

19 I think there is a clear reason
20 for having two different lists if there are
21 two different goals. So I go back to what was
22 said before, and you were asking CMS, and I am

1 not sure I heard a clear answer. But, if
2 there is a different goal of the two lists,
3 then, clearly, that would be the reason to
4 have the second list.

5 Other than that, for my own
6 purpose, if there is one goal, and I
7 appreciate what the previous speaker on the
8 phone was just saying, Helen, about -- who was
9 on the phone, Helen?

10 CO-CHAIR MEYER: Helen, yes.

11 MEMBER MORLEY: So, in terms of
12 potentially needing something else that
13 addresses the specific issues of home care
14 that may not overlap with hospital care and
15 long-term care and hospice, and the rest of
16 it.

17 But, if the goal is about tracking
18 these cases, in the hope that somebody is
19 actually making changes that reduce the events
20 from happening, then a single list is still
21 what I would like to see.

22 CO-CHAIR MEYER: Deborah?

1 MEMBER NADZAM: I am going to go
2 back to the Venn diagram again, too. I think
3 you could actually start with the circle of
4 all HACs. I mean you could start with
5 everything that is reportable, too, but you
6 could start with all HACs, whatever the "H"
7 and the "A" stand for, a subset of which are
8 so egregious that every single time they occur
9 they must be reported to somebody, if the
10 state so deems that is the law.

11 But it would suggest going back to
12 the definition of SRE and calling it perhaps
13 an HAC that is preventable, serious,
14 unambiguous, and has egregious results, or
15 something like that, making the definition
16 clear, that it is a subset of this larger
17 group of things that can happen that
18 shouldn't.

19 CO-CHAIR MEYER: Peter and then
20 Michael.

21 DR. ANGOOD: Yes, I wanted to
22 address Michael's plea for some type of

1 taxonomy or terminology. That is evolving
2 through a lot of the work at WHO, and there is
3 an existing taxonomy that we have endorsed, et
4 cetera, et cetera, not the least of which is
5 AHRQ's work with the common formats for the
6 PSO reporting strategies. That remains to be
7 seen.

8 So that is not our job, is to sort
9 of get into that. But clarifying the
10 definitions I think is important.

11 Unfortunately, part of what the
12 struggle here is is the confusion that CMS has
13 created by having this little list.

14 Depending, actually, on how you tease it out,
15 it is six out of the ten are true SREs in the
16 CMS list.

17 Then what confuses the folks in a
18 variety of environments is the HAI focus
19 because it is healthcare-associated as well.

20 And yet, actually, a lot of this is from
21 P.J.'s work and others, that the HAI
22 harmonization, actually, has been one of the

1 strongest activities that has occurred and is
2 a good role model, I think, for a lot of
3 activities in healthcare. Because you've got
4 the Joint Committee, you've got NQF, you've
5 got CDC, et cetera, all focusing on this one
6 thing.

7 So, as we look at Venn diagrams or
8 think about them, you can actually put the
9 SREs, the CMS, and the HAIs all inside of that
10 bigger bubble, which is the HACs.

11 To some degree, having said all of
12 this, I think that the CMS and the HAI are
13 kind of distractors in here. We can fit them
14 in over time, but the single list or gradings
15 on a single list, so that you get the really,
16 really serious bad stuff versus all the other
17 things, I think that is partly where we need
18 to try to move.

19 If we create and get a fourth
20 list, CMS, SREs, HAI, and now the HACs, and we
21 are going to add a whole bunch of different
22 environments, we have just created more

1 confusion in the field. So the more
2 simplification, the better off we are, I
3 think.

4 CO-CHAIR MEYER: Michael, and then
5 I want to take stock and see where we are
6 left.

7 MEMBER VICTOROFF: I am very
8 sympathetic with the idea of having one list
9 of bad things. I sense there is a movement
10 toward the list of bad things. So we will
11 call it the BT list.

12 (Laughter.)

13 But we are talking now proposing
14 this new language.

15 But, in the list of bad things,
16 not all mammals are dogs, and I can't make the
17 Venn diagrams work and comprise things
18 including such things as outcomes, diseases
19 and disabilities, latent hazard situations,
20 administrative or behavioral events which may
21 or may not have created harm, like a guy comes
22 into the ER firing a pistol, didn't hurt

1 anybody. So I guess there is no need to
2 report it. I said we discharged a baby to the
3 wrong person who showed up with a court order.

4 So there are a lot of things where
5 it is hard to describe -- now so think about
6 taxonomies and capturing reporting systems.
7 I don't think that you are going to be able to
8 get a good collection of all which we are
9 interested in by saying let's just find a way
10 to screw them into the category of diseases,
11 disorders, and conditions and diagnoses. So
12 every time we see streptococcus, we will know
13 something bad happened. I don't see any way
14 to do that with any of these, even murder, you
15 know, if you are saying murder.

16 So I just think, on my one big
17 master list of every bad thing, there is going
18 to end up being -- there is going to be a
19 spectrum of severity, and there are going to
20 be at least a few, I don't quite know how
21 many, boxes in which there are going to be
22 some near-miss things that are really so

1 terrible we ought to tell everyone, and
2 hazardous conditions, like this EEG machine
3 always read it wrong whenever you set it this
4 way. You know, luckily, it hasn't hurt anyone
5 yet. And this provider is schizophrenic, and
6 we don't have a system in our hospital to
7 identify schizophrenic providers, but we think
8 we should tell you.

9 So I guess I would be open to an
10 unenumerated set of categories within these.
11 I think that is my solution to, yes, some are
12 processes; some are outcomes; some are
13 conditions; some are hazards.

14 I think I would be more open to
15 expanding the categories as we collapse the
16 list.

17 CO-CHAIR MEYER: I just want to
18 take stock for a second. The good news is we
19 have the time for the discussion. Because,
20 actually, the goal of the first two sessions
21 this afternoon that take us up to three
22 o'clock is to help define the healthcare-

1 acquired conditions, and then to discuss the
2 interface between healthcare-acquired
3 definitions and SREs. We are right in the
4 middle of that, so we have got the time to
5 chew on this.

6 With that said, one of the things
7 that I would like to do, though, is to start
8 to try to get us to the point where maybe we
9 can start to come to some agreements around
10 how to proceed.

11 One way to try to capture, to
12 synthesize what people are saying, it is very
13 clear what you hear over again, there is, by
14 and large, with some exceptions, by and large,
15 people think one list is a good thing. People
16 also recognize that this distinction between
17 event and condition is problematic.

18 We also hear that, if there is one
19 list, there may be parts of that list that you
20 would stratify to the here are things that
21 every state ought to do public reporting on;
22 here are things that we all ought to be

1 learning from and know about.

2 Then there are some outliers, and

3 the outliers I think you have defined well.

4 So some of the criminal acts and such just

5 don't seem to fit well with any of these. It

6 begs the question of, you know, we have a

7 chance. We have two tasks. We have to do

8 these definitions, and we have to come up with

9 a list. That list may or may not need to

10 contain those things. Maybe we should think

11 about some other way to handle those, if they

12 are outside of it.

13 But, if we started and said let's

14 look at all events, and I am staring at

15 Helen's keyboard here, but if you say, all

16 events, that they are discrete, auditable, and

17 clearly-defined occurrences, knowing that an

18 occurrence could be a close call, and that you

19 look at those that are adverse, that are

20 preventable, that are unambiguous. So you

21 have events that are adverse, preventable,

22 unambiguous, with the definitions we had

1 earlier.

2 You could then say, from that
3 list, you would say that some of these are so
4 serious, that some of these will be very
5 serious, and of those, some of them ought to
6 be reported.

7 I am trying to see if we can work
8 through a tiered list. I am not sure it is
9 going to be possible. What I do think is
10 points well-taken; if we take the current list
11 of both serious reportable events as it exists
12 from 2006, and then you look at the CMS list
13 of hospital-acquired conditions, and you try
14 to put it into Venn diagrams, not everything
15 fits and not everything overlaps. It doesn't
16 work. So we have to go back and look maybe at
17 the lists, content, in addition to defining
18 the process.

19 Is that congruent with the way
20 people are thinking, or are you saying, wow,
21 we are so far off the ranch, that we've got to
22 reel folks back in?

1 MEMBER LAU: Yes, I agree.

2 MEMBER TANGALOS: Let me just ask,
3 to what end you wish to accomplish this?

4 CO-CHAIR MEYER: Yes, for what
5 purpose?

6 MEMBER TANGALOS: To what ends?
7 If we take John's words about what has
8 happened over the last decade as being not
9 much, selecting out the individual events and
10 then reporting them hasn't taken us very far.

11 CO-CHAIR MEYER: Unless you took a
12 step back and you said -- and I am just going
13 back to 2002, 2001, and the birth of this
14 Committee. The counter-argument is to say,
15 you know something; there are some things that
16 there is an intangible value of accountability
17 that you just need to have it out there, just
18 because you have to.

19 MEMBER TANGALOS: Be that as it
20 may, and I won't argue that point, if we are
21 going to go forward, maybe we are stuck in
22 that world of reporting those events and

1 trying to fix them and prevent them from ever
2 happening. But it doesn't move the field very
3 far forward.

4 CO-CHAIR MEYER: Yes.

5 MEMBER TANGALOS: So, as we look
6 to the future, as we look to what we want to
7 accomplish, can we select targets that really
8 lift all of the ships, that get us to where we
9 want to go, instead of continuing to focus on
10 moments in time that are easily defensible
11 that we have said amongst ourselves, "Yes,
12 this is really bad."?

13 But, other than just fixing that
14 really bad thing, what have we really done for
15 the universe of healthcare? So I would kind
16 of like to have us refocus along that line, if
17 at all possible, as we look at what we want to
18 report.

19 I am not so excited about looking
20 at the individual events that the court system
21 or somebody else is going to pull forward. I
22 want to move everything.

1 CO-CHAIR MEYER: Leah?

2 MEMBER BINDER: I think it is a
3 really interesting point, and I think it is
4 worth reflecting on.

5 What comes to mind is the airline
6 industry. It always comes to mind as sort of
7 an analogy that we face in healthcare. And I
8 am thinking about what the airline industry
9 does with serious reportable events. That is
10 they report them to all of the airlines. So,
11 if there is one event in one airline,
12 everybody knows about it.

13 So that it isn't just one hospital
14 that is learning from an event. It is all the
15 hospitals potentially could learn from the
16 event. Maybe that is an area that we should
17 be looking toward as well.

18 I think you are raising a really
19 important point: how do we move beyond just
20 reporting for the sake of reporting?

21 MR. GARCIA: I need to go, but I
22 am going to be coming back in. I just want to

1 say I really appreciate this conversation that
2 is going on. I will be coming back in to hear
3 where you end up.

4 Thank you.

5 CO-CHAIR MEYER: Thank you.

6 Doron?

7 MEMBER DORON SCHNEIDER: So
8 Pennsylvania has one of the oldest public
9 reporting in the country. It would be
10 interesting to see what P.J. thinks about it,
11 but we have routine lessons learned that are
12 sent down in the form of Patient Safety
13 Authority bulletins. A lot of these are off
14 of near-misses.

15 So I think that we do have an
16 opportunity to enhance reporting in a
17 meaningful way, and it is really up to the
18 states to make or not make the learnings
19 occur.

20 I would just say that, the way you
21 led off this session, I would just make sure
22 that in your diagram there on your computer

1 that, if you have adverse events as the whole,
2 then you are going to miss near-misses. Then
3 we have to then include the risk thereof as
4 well.

5 CO-CHAIR MEYER: Yes, I agree. I
6 agree.

7 P.J.?

8 MEMBER BRENNAN: To just follow up
9 on Doron's comment, Pennsylvania actually has
10 three different reporting systems. The first
11 goes back to the 1980s, and it is the Hospital
12 Performance Report on Hospital Mortality.

13 It is hard to say that that has a
14 big impact. I mean it is hard to see the
15 impact. I think over time there has been a
16 lot of controversy in the State about whether
17 it has been impactful or not or whether it is
18 just the secular trend in improvement that has
19 resulted in reductions in mortality in various
20 categories. But it does get attention from
21 time to time.

22 The Patient Safety Authority is an

1 anonymous reporting system that gets hundreds
2 of thousands of reports. As John pointed out,
3 it is starting to demonstrate improvement in
4 the reduction in wrong site surgery, which
5 happens about once a year at a hospital of
6 about 300 beds across the State.

7 Then there's the HAIs. What has
8 driven a lot of that has just been the public
9 interest in it.

10 So lots of different reports
11 created for lots of different purposes, and
12 outcomes that vary with the system and the
13 attention to it.

14 CO-CHAIR MEYER: We will go to
15 Helen.

16 DR. BURSTIN: Just perhaps a way
17 to synthesize this a bit is to go back to the
18 actual safety goal that was arrived upon by
19 the National Partnership because it is broad
20 and it was intentionally, and Leah was
21 involved in some of this, it was intentionally
22 broad.

1 It said, "All healthcare
2 organizations and their staff will strive to
3 ensure a culture of safety while driving to
4 lower the incidence of healthcare-induced
5 harm, disability, or death toward zero. They
6 will focus relentlessly on continually
7 reducing and seeking to eliminate all
8 healthcare-associated infections and serious
9 adverse events."

10 So there was intentionally a broad
11 net cast, thinking there were logical
12 approaches that you could use to reduce the
13 various entities that could fit that broader
14 categorization.

15 So I just think that, if we are thinking
16 about what's the point, the point is to
17 achieve this. Then I think you could make the
18 case that, depending on how it is useful, you
19 could stratify the list by whatever purpose is
20 needed.

21 I don't want to lose Doron's point
22 about the risks thereof because I think it is

1 a really important piece that, to date, the
2 SREs have not helped us with.

3 CO-CHAIR MEYER: Here's what I
4 propose: I propose that we actually try to
5 put some of this onto paper that we can
6 project up here while all the rest of you take
7 a break for 10 minutes or 15 minutes, and then
8 we come back and try to really come to some
9 decisions here. Because it is a great
10 discussion, but we've got to think our way
11 through this.

12 So let's take a break for a few
13 minutes.

14 Those on the phone, we will be
15 reconvening at approximately 2:25 Eastern
16 Time.

17 Thank you.

18 (Whereupon, the foregoing matter
19 went off the record at 2:12 p.m. and resumed
20 at 2:31 p.m.)

21 CO-CHAIR MEYER: Before I start,
22 if I can just, again, take a quick roll call

1 of those who are on the phone, if you could
2 identify yourselves?

3 MEMBER LAU: Helen Lau from
4 California.

5 CO-CHAIR MEYER: Welcome back.

6 MEMBER RADFORD: Martha Radford
7 from New York.

8 CO-CHAIR MEYER: Great.

9 MS. CANNON: Marge Cannon from CMS
10 in Baltimore.

11 CO-CHAIR MEYER: Okay.

12 MEMBER GANDHI: Tejal Gandhi from
13 Partners Healthcare.

14 CO-CHAIR MEYER: Great.

15 Anyone else on the phone?

16 (No response.)

17 Terrific.

18 Okay. I am going to spend a
19 couple of minutes just trying to talk through
20 what is before you here. This isn't perfect.
21 This is just a starting point.

22 But I would really like us to get

1 in the next half-hour to really try to settle
2 on a few decisions to try to see if we can
3 make this work.

4 So I will do it from here, if I
5 can.

6 So, first of all, what we put here
7 is a Venn diagram. The larger circle there is
8 all adverse events. We need a different name
9 there. So let's think about that, okay?

10 But what we are saying about these
11 events is they are discrete, they are
12 auditable, and they are clearly-defined
13 occurrences or risks thereof. So, in some
14 ways for the safety science folks, they would
15 say occurrence actually already has that in it
16 because occurrence could include a close call.

17 The point here is that this is
18 very all-encompassing. In fact, if you think
19 about it, even those criminal events that are
20 part of the current SRE list from 2002 and
21 2006 fit that. And within that, all of them
22 are adverse, preventable, unambiguous.

1 There is a subset. So, now
2 looking at the Venn diagram, there is a subset
3 of them that meet our definition from this
4 morning. They are preventable. They are
5 serious. They are unambiguous, adverse events
6 that should not occur. Those would be SREs.

7 There is another subset within
8 those, which are the healthcare-associated
9 infections. Right now, there is not a lot of
10 overlap between the HAI list and the serious
11 reportable events.

12 The diagram here is meant to say
13 that maybe there ought to be. We are not
14 presupposing anything, but maybe there ought
15 to be.

16 And I would argue that, if you try
17 to say, what is that border that defines the
18 HAIs that actually would be serious reportable
19 events and those that aren't, from a
20 functional point of view, from a practical
21 point of view, to me, it is pretty clear.

22 What I would say is I would say,

1 you know, those that are SREs are nasty
2 numerators. They are just the single thing
3 that happened is so bad that I have to do a
4 root-cause analysis. That is the tool I use
5 to learn and get better.

6 The rest of those HAIs that are
7 not serious reportable events are those where
8 I rely on the epidemiology tools, too. I look
9 at rates, and it is not the single nasty
10 numerator.

11 Then, in addition to that, we try
12 to note here that there are some adverse
13 events, again, that meet that they are
14 discrete, auditable, and clearly-defined
15 occurrences or risks thereof. Maybe they are
16 the nausea from chemotherapy that we don't
17 want, and they are non-serious. They are not
18 reportable right now.

19 There will be some of those, some
20 healthcare-associated infections; maybe some
21 healthcare-associated infections are to the
22 point where we really don't feel like we need

1 to unleash the tools and the time on them.

2 Then to recognize that, outside of

3 those three, there is still a host of events.

4 That host of events, which we can't define

5 right now, and, in fact, our Technical

6 Advisory Panels, hopefully, will help us with

7 some of them, but some of them may be

8 important enough that we need to spend more

9 time, energy, and effort on them. That is the

10 black hole or the space between the planets

11 right now that is ill-defined.

12 So I wanted to throw that up there

13 and see, first of all, all adverse events,

14 lousy title. We've got to come up with a

15 different name for that.

16 But, beyond that, or if you have

17 an idea of how to improve that, we want to

18 hear that now. But, beyond that, is this

19 model consistent with what we are talking

20 about. What are the flaws in it? What should

21 we change? Because this will help guide us as

22 we start to create lists.

1 So I am going to turn to P.J., and
2 then we will let folks chime in as they wish.

3 MEMBER BRENNAN: Gregg, I think
4 there are events that are not rare that are
5 very serious, too. So I think there is
6 another circle to add there.

7 Maybe it just is a parsing of the
8 list that we currently have.

9 CO-CHAIR MEYER: And that may, in
10 fact, be the definition of what that white
11 matter is.

12 MEMBER BRENNAN: I think so. I
13 think so, yes.

14 CO-CHAIR MEYER: They are not
15 rare --

16 MEMBER BRENNAN: Yes.

17 CO-CHAIR MEYER: -- but they are
18 serious enough.

19 MEMBER BRENNAN: Right.

20 CO-CHAIR MEYER: But they are not
21 very serious.

22 MEMBER BRENNAN: Right, right.

1 Then the other point that I would
2 make is that on HAIs I wouldn't be a lumper.
3 I think that there are some where SREs and the
4 serious or very -- excuse me -- HAIs, some
5 HAIs, and the SRE circles would overlap
6 entirely. I think that bloodstream infections
7 is nearly a complete overlap, and some of the
8 others, where the definitions are ambiguous,
9 there would be a smaller overlap. So I would
10 parse that a bit.

11 CO-CHAIR MEYER: So, within this
12 all adverse events, there is a circle of
13 serious?

14 MEMBER BRENNAN: Yes, yes.

15 CO-CHAIR MEYER: I got that. And
16 SREs are clearly embedded in that circle. The
17 non-serious are, by definition, out of it.
18 Some HAIs are in; some are out. Okay.

19 MEMBER BRENNAN: And just one
20 other point. Excuse me.

21 CO-CHAIR MEYER: Group think isn't
22 easy on a computer.

1 MEMBER BRENNAN: Oh, you can go
2 ahead.

3 CO-CHAIR MEYER: Okay. Deborah?
4 What I am going to do is I am going to try to
5 go around the table. It would just make it
6 easier to keep track of folks.

7 MEMBER NADZAM: Yes, I like it,
8 too. It might be that that larger blue circle
9 is non-SREs, serious, and the white matter is
10 the non-serious.

11 CO-CHAIR MEYER: Right. In fact,
12 yes, that works, actually. That works, and we
13 just would have to have it encompass all of
14 the SREs.

15 DR. ANGOOD: I am sorry. Say that
16 again now.

17 MEMBER NADZAM: The large blue,
18 the largest blue bubble is non-SREs, serious,
19 and I guess not reportable, but they are
20 serious. Then all the other white matter is
21 the non-SRE, non-serious, not reportable.

22 CO-CHAIR MEYER: While I am

1 wordsmithing with Helen here, I am going to go
2 around the table.

3 So, P.J., you're okay?

4 Michael?

5 MEMBER VICTOROFF: I don't see the
6 need for rare. Otherwise, I like this. I
7 have other comments I am going to pull through
8 later.

9 But it seems to me that rare is a
10 value judgment that we don't need. Your rare
11 is not my rare. You know, I run a rehab thing
12 for brain-injured vets, and it is not at all
13 rare to see someone fly off the handle and
14 strangle a nurse, but it is still bad.

15 CO-CHAIR MEYER: Yes, well-taken.

16 MEMBER VICTOROFF: Well, that is a
17 value judgment again. I am sorry.

18 (Laughter.)

19 But it is not that I have never
20 done that.

21 (Laughter.)

22 But, if you remove the word

1 "rare", then I do think I follow the rest of
2 this pretty well. It seems to accomplish
3 everything that we said, except for this one
4 glaring thing that I don't understand you've
5 got to explain.

6 The healthcare-acquired infections
7 I think fits very well; it is perfectly a
8 little, good, blue bubble there. But we were
9 just arguing for an hour about healthcare-
10 acquired conditions. And if what you meant to
11 do was to erase that list from my mind, I
12 thank you. This does everything that I --

13 CO-CHAIR MEYER: That was our --

14 MEMBER VICTOROFF: Am I
15 clarifying? Am I the only one that was stupid
16 about this? But you just erased the list.

17 Let CMS do what they want. What you are
18 saying is that, for NQF purposes, infections
19 are just one of the things that overlap,
20 serious and non-serious, reportable and non-
21 reportable, and wounds could be another thing
22 potentially, and concussions and sprained

1 ankles, and all kinds of other stuff could be
2 serious, not serious, reportable, not
3 reportable.

4 But I like this model, if I am
5 understanding what you did there.

6 CO-CHAIR MEYER: You've got it
7 right.

8 MEMBER VICTOROFF: Okay, and I
9 will have to hear other comments about rare.

10 DR. ANGOOD: Part of the problem
11 is most every topic that we choose to speak
12 about is a spectrum, and to some degree, it is
13 a value judgment.

14 You know, we can get a hugely
15 complicated Venn diagram and our multiple
16 layers of overlap. We are trying to keep it
17 simple.

18 But we do need to recognize in the
19 practical, real world there is this spectrum
20 of events. So some serious HAIs, some not so
21 serious.

22 CO-CHAIR MEYER: And just to put a

1 final point on your comment, Michael, one
2 could well imagine the specter of a report
3 coming from this Committee back to the product
4 of NQF that may not mention the hospital-
5 acquired conditions at all.

6 Diane?

7 MEMBER RYDRYCH: I was just going
8 to agree with Michael's comment on rare. I
9 would probably take "rare" out.

10 CO-CHAIR MEYER: Done.

11 MEMBER RYDRYCH: But I think this
12 is helpful. We talked about this a little bit
13 during the break, that I think we were getting
14 hung on CMS's list rather than focusing on the
15 concept of HAC or bad things, or whatever
16 shorthand we want to use. So I think it is
17 helpful to think of it this way.

18 CO-CHAIR MEYER: We are modifying
19 it -- by the way, you are seeing that the
20 "rare" is still up here -- we are modifying it
21 here. We are not connected up. So we will,
22 at the end of this, have a final that we can

1 throw up and let people see.

2 Let's do it here. You leave that
3 up here. We will do it here. Then we will
4 put it up at the end. We will transfer it
5 over.

6 Cynthia, do you have any comments?

7 MEMBER HOEN: I really like it. I
8 think that we could also use the white matter
9 in the future potentially to draw out
10 additional events as we become more
11 sophisticated in what we learn.

12 CO-CHAIR MEYER: Because those
13 boundaries shouldn't be permanent, although
14 the boundary of an SRE will be a pretty hard
15 list because you need a hard list to be able
16 to effectuate it.

17 Eric?

18 MEMBER TANGALOS: The only thing,
19 in the white matter, why not just leave it
20 adverse events and not include non-serious,
21 non-reportable? Because it gives us better
22 opportunity, and, again, stays away from

1 definitions that we may not need.

2 CO-CHAIR MEYER: Okay.

3 MEMBER RILEY: So now we get to
4 have table mates who are absolute opposites of
5 each other.

6 So my point I think is that you
7 could have non-SREs that can be serious, but
8 they would still be reportable. So that
9 circle would not necessarily be not
10 reportable, particularly if you are going to
11 have the white matter be non-serious and non-
12 reportable.

13 CO-CHAIR MEYER: So one would
14 almost imagine that there would be -- I
15 actually need to jump up here for a second.
16 I will talk once I reach a microphone -- that
17 there would be serious non-SREs that are, and
18 there may be some overlap with HAIs, that are
19 reportable. Then there will be a small set
20 that you won't --

21 MEMBER RILEY: Right.

22 CO-CHAIR MEYER: And one could

1 argue, by the way, going back to one of the
2 earlier comments, that that boundary of what
3 would be reportable and not reportable, there
4 are some things that are serious, they are not
5 SREs, and we don't know what to do about them.

6 MEMBER RILEY: Exactly.

7 CO-CHAIR MEYER: And therefore,
8 you are reporting just for reporting sake.
9 And by the way, it is not a public
10 accountability reason there. So maybe that
11 doesn't -- but I want to try to make sure that
12 we can define these boundaries because, at the
13 end, that is what is going to be important to
14 people like all of us in the room here who try
15 to make this into something real out on the
16 frontline.

17 MEMBER BINDER: I have a couple of
18 questions. I want to get back to the earlier
19 point that was made about hospital-acquired
20 conditions disappearing. Was that the term?

21 What happened to them exactly? I
22 wasn't really clear on what that was.

1 CO-CHAIR MEYER: On which?

2 MEMBER BINDER: What happened to
3 hospital-acquired conditions?

4 CO-CHAIR MEYER: Hospital-acquired
5 conditions are going to be whatever CMS wants.
6 We are not charged -- and again, I turn to
7 Peter and to Helen for this -- but my
8 understanding is that this Committee is not
9 charged with defining the hospital-acquired
10 conditions for CMS. They did not look to the
11 NQF to do that initially, nor do I think that
12 that's what they asked us to do here.

13 But let me make sure that we are
14 not off-track on that.

15 DR. ANGOOD: No, that is correct.
16 I will restate that.

17 We were approached to possibly
18 expand the serious reportable events into
19 other environments and to begin using this
20 term of healthcare-acquired conditions. But
21 at no point has the work of this Committee
22 been charged to look at functions or scope for

1 CMS and their whole hospital-acquired
2 conditions. That is whatever CMS wants to do.

3 And the reason we moved towards
4 getting rid of the HAC, which we spent an hour
5 debating on, was, I think, a reflection on the
6 lack of specificity that HHS and CMS has on
7 healthcare-acquired conditions. It is really
8 an open book, as Gregg said at the beginning.

9 We were getting ourselves confused
10 in that hour of deliberation. So we decided,
11 since it is an open book, let's take that off
12 of the plate and get ourselves back to, what
13 are we really trying to do? We are trying to
14 improve the quality of healthcare.

15 There's all these things that
16 happen. Some of them are really bad. Some of
17 them are in the categories like HAIs already.
18 So we are trying to simplify by this.

19 DR. BURSTIN: And part of the
20 charge from CMS specifically, and HHS, was to
21 expand the list beyond those that were very
22 serious and reportable across multiple

1 environments of care. I think we can do that
2 in this manner without necessarily using their
3 specific term that they are using for payment
4 purposes.

5 MEMBER BINDER: But, presumably,
6 we could pick some of the HACs from the CMS
7 list and include them in this?

8 DR. BURSTIN: Absolutely, yes.

9 MEMBER BINDER: Got it.

10 I just want to reiterate I also
11 believe "rare", I am glad you took that off.

12 DR. BURSTIN: Yes.

13 MEMBER BINDER: You already did.
14 That is good because what is rare in one
15 hospital is not rare in another; it doesn't
16 mean anything, have anything to do with the
17 seriousness of the condition.

18 Then I want to go back to this
19 reportable issue. What does reportable mean?
20 Reportable to whom? Are we talking about
21 reportable in terms of to regulatory
22 authorities? Reportable to states?

1 Reportable to the feds?

2 I am speaking from the purchaser
3 point of view. What we want to see reported
4 is going to be different from what the
5 government wants to see reported. I am not
6 sure that it is the scope of this Committee,
7 or maybe it is, to decide what should be
8 reported and what should not, and what is
9 seriousness enough to be.

10 You know, the reporting issue, in
11 other words, I am not sure that that should be
12 a differentiator regarding serious versus not
13 serious.

14 MEMBER TANGALOS: That is another
15 reason why the white matter piece has to have
16 non-reportable removed from it. It really
17 does.

18 CO-CHAIR MEYER: Yes.

19 MEMBER BINDER: It's gone.

20 MEMBER TANGALOS: It was, yes, and
21 let's think about reporting to the patient,
22 too, or the individual.

1 CO-CHAIR MEYER: The only thing I
2 would say about reportability, I think that
3 point is well-taken. So we will try to remove
4 it here where it is not necessary.

5 I think the thing that we have to
6 remember is that one of our tasks is for the
7 SRE list, that they are, by definition, the
8 recommendations that states would report on
9 them, and Leapfrog and others may use them for
10 reporting, too.

11 So we don't want to exclude other
12 things from being reported, but we definitely
13 have to say these things are what we recommend
14 for an accountability purpose to be reported.
15 That is part of our charge.

16 MEMBER BINDER: So can I clarify
17 that is part of our charge, that what we
18 recommend should be reportable by CMS and
19 states?

20 CO-CHAIR MEYER: No. Our charge
21 is to develop the NQF list --

22 MEMBER BINDER: Right.

1 CO-CHAIR MEYER: -- of serious
2 reportable events. Now that does carry with
3 it and that list was specifically designed for
4 state reporting.

5 MEMBER BINDER: Okay.

6 CO-CHAIR MEYER: CMS and others
7 can do, and Leapfrog, you know, they can do
8 what they wish with the list.

9 MEMBER BINDER: Well, I would say,
10 then, that does not mean that something that
11 we don't put on the list of serious reportable
12 events -- I don't think that we should have
13 the implication that what is not on that list
14 we all believe is not reportable, because we
15 have --

16 CO-CHAIR MEYER: No.

17 MEMBER BINDER: Do you know what I
18 mean? Some of us may think that there are
19 other things that are reportable, and this
20 Committee is really looking at what do we all
21 agree is reportable. That doesn't mean we
22 think that other things aren't reportable.

1 CO-CHAIR MEYER: So the Venn
2 diagram is important here in that there are
3 some things that are SREs that are, we will
4 just say, for accountability purposes, yes, we
5 should absolutely all report on these. There
6 may be other things for other purposes. So
7 you could say, for improvement purposes, we
8 ought to know what is going on with
9 healthcare-acquired infections.

10 We may want to decide, in fact, to
11 parse it out further, again, to try to decide
12 where the boundaries are between healthcare-
13 acquired infections and where SREs are.

14 So I don't want to limit -- I want
15 to try to avoid limiting us in a box.

16 MEMBER BINDER: Yes, I guess I am
17 trying to get at not the white matter, but the
18 large, blue dot, non-SREs, serious, not
19 reportable. There may, in fact, be serious --

20 CO-CHAIR MEYER: Yes, we ditched
21 that.

22 MEMBER BINDER: Oh, you did?

1 CO-CHAIR MEYER: Yes. Yes, we
2 ditched it. We said that there are going to
3 be non-SREs that you still want to report on.

4 Unfortunately, we are not doing it
5 in real-time.

6 For those of you who are on the
7 phone, I am sorry because we are trying to
8 work in real-time with the diagram here to
9 make it clear. As soon as we are through with
10 it, we will send it out to you, so you will
11 have something to react to at least tomorrow
12 for certain.

13 MEMBER LAU: This is Helen on the
14 phone.

15 As you were talking, I started
16 drawing it myself. I really like the white
17 matter, you know, that you have got there.

18 I just wanted to challenge the
19 group, you know, because we talk about this,
20 the series of these dots here, can this be
21 looked at as a three-dimensional Venn diagram?

22 CO-CHAIR MEYER: Yes.

1 MEMBER LAU: Yes?

2 CO-CHAIR MEYER: I think we could
3 make it into a six-dimensional Venn diagram.

4 (Laughter.)

5 However, I think we want to keep
6 it as simple as we can.

7 So, just to update people, again,
8 a work-in-progress, but we are saying that the
9 SREs, by definition, these are reportable,
10 that there are healthcare-associated effects
11 that may or may not bleed into the SREs.
12 There are also non-SREs, but certainly
13 important and reportable. So it gets to your
14 point, Leah, that there are some things we
15 still want to learn about.

16 MEMBER BINDER: It says the same
17 thing as the big circle now, that they are
18 serious and reportable.

19 CO-CHAIR MEYER: Okay. So let's
20 work on that. Okay?

21 So your point is well-taken. We
22 don't want to just say that the only thing

1 that is reportable are SREs. Right? And on
2 the other hand, how do we parse that?

3 Doron, can you make your comment
4 without the diagram up there?

5 MEMBER DORON SCHNEIDER: We were
6 going in order. Did you want to go ahead?
7 Are you sure?

8 MEMBER BINDER: Yes, go ahead.

9 MEMBER DORON SCHNEIDER: Okay. I
10 think that you need another circle all the way
11 around which would be for anticipated. Okay?
12 Because all adverse events is not clear. That
13 gets to like the nausea if you are
14 chemotherapy, et cetera.

15 So, to be exquisitely clear, it is
16 really -- and some of these may become more
17 oval as you have to, then, overlap into this
18 new boundary.

19 But if you had a largest circle,
20 which is all adverse events, and then that
21 circle here becomes unanticipated events, that
22 is really what you are really interested in

1 reporting. Everything in there becomes
2 reportable. If it is unanticipated, it is
3 reportable. All right?

4 The anticipated stuff, we may not
5 care as much, although one may argue, for
6 epidemiology purposes, some people would say
7 you do it. But from a safety, quality
8 perspective, if it is unanticipated, that is
9 the one we want, and another circle outside
10 the whole.

11 Then we can get rid of that big,
12 blue, new circle and have it stay the way it
13 was before. Because then everything else in
14 the white matter is the non-serious -- it is
15 non-serious, it is not necessarily not serious
16 reportable, if you follow me, right? Not
17 SREs, non-serious and reportable.

18 CO-CHAIR MEYER: You are saying
19 reportable for quality improvement purposes?

20 MEMBER DORON SCHNEIDER: Exactly.

21 CO-CHAIR MEYER: Okay.

22 MEMBER DORON SCHNEIDER: So that

1 is what the white matter is. It is not
2 serious, not SRE, but reportable.

3 Then the new concept of a bigger
4 circle would be, you know, everything outside
5 of this sphere is that there are events which
6 are anticipated adverse events because of
7 healthcare.

8 Do you see what I am saying?

9 CO-CHAIR MEYER: I understand what
10 you are saying.

11 Yes, Leah, help.

12 MEMBER BINDER: I think the
13 reportability issue is confusing all of this.
14 I mean I think we should just take it out.
15 Because, for my constituency, we want
16 everything reported.

17 I mean I am not saying that
18 this -- you know, there's no need, I don't
19 think, in this diagram and in this
20 conceptualization for us to weigh-in on what
21 we think should be reportable. I mean I think
22 everything, theoretically, could be reported.

1 Or nothing.

2 But the point is that the key
3 issue is, are they serious or not and
4 preventable? I just think that it is
5 confusing the whole picture.

6 And I do think that there should
7 be a larger circle that is also near-misses.

8 CO-CHAIR MEYER: We are
9 considering near-misses because it is adverse
10 events or risks thereof. So the near-misses
11 are in here. It is just that that part, it
12 has gotten dropped off of the definition above
13 it.

14 So your argument is that
15 everything is potentially reportable for a
16 variety of purposes? I mean it is potentially
17 reportable.

18 There is a small group, which we
19 are calling SREs, which we say should ask to
20 have publicly reported?

21 MEMBER BINDER: Right. I mean I
22 recognize that it is not going to be a

1 consensus of everyone on what events should be
2 reported. On our end of the spectrum, it is
3 going to be everything. I think others would
4 not agree that that is appropriate.

5 CO-CHAIR MEYER: Yes.

6 MEMBER BINDER: But, from a
7 purpose of reaching consensus among the
8 stakeholders, we should be identifying those
9 which all of us agree should be reportable.
10 That doesn't mean the other parts are
11 automatically, we agree, not reportable.
12 Therefore, for a diagram with this, the
13 reportable issue is not key.

14 CO-CHAIR MEYER: Cynthia, I
15 skipped over you, and I want to make sure that
16 I don't miss you. I want to finish out folks
17 here before I go to others.

18 Help yourself.

19 MEMBER McDONAGH: Well, let's see,
20 I thought I had a good sense of it until these
21 circles got added.

22 CO-CHAIR MEYER: Yes.

1 MEMBER McDONAGH: But I do think
2 there is a need to differentiate reportable,
3 and maybe we are saying the same thing, but
4 there is that defined body that we all need to
5 agree upon. But it is confusing to me as
6 these boxes now are not reportable. I am
7 having trouble differentiating a couple of
8 those.

9 MEMBER DORON SCHNEIDER: By
10 definition, a serious event has got to be
11 reportable. That big, blue circle needs to
12 go.

13 CO-CHAIR MEYER: Yes.

14 MEMBER McDONAGH: Right.

15 CO-CHAIR MEYER: So you are saying
16 this circle should go?

17 MEMBER DORON SCHNEIDER: Yes, that
18 one go for sure.

19 That was okay. You could have
20 just have made the other one bigger. Just
21 make the other one bigger.

22 Right, and that is actually okay

1 because that circle that just got bigger,
2 actually, is quantitatively where the most
3 number of reportable events are coming from.

4 CO-CHAIR MEYER: You wouldn't have
5 an overlap with SREs, but that would be,
6 otherwise --

7 (Pause.)

8 So let's make sure that we've got
9 your -- so what you are saying is that all of
10 the white matter there is potentially
11 reportable, too?

12 MEMBER BINDER: Well, again,
13 getting back to reporting to who and all those
14 issues --

15 CO-CHAIR MEYER: Yes.

16 MEMBER BINDER: -- around what is
17 reportability, from our point of view, sure.
18 I mean I am sure there will be disagreements
19 between what Leapfrog would want or a
20 purchaser would see as appropriate to report
21 and what others might see as appropriate to
22 report within that larger circle.

1 CO-CHAIR MEYER: And we are
2 ignoring -- I think, Doron, you made the point
3 saying there's another group of things outside
4 of this that includes things that are
5 anticipated, and we are just going to ignore
6 that.

7 MEMBER DORON SCHNEIDER: Right.
8 So, by definition, everything in that circle
9 now is reportable. Everything in that big
10 circle, including the white matter, is
11 reportable.

12 It could be. That is fine.
13 Because it is unanticipated, an adverse event.

14 I just made the motion to have
15 another circle, which is to capture -- because
16 people are still learning the safety signs.
17 We don't want them to report nausea after
18 chemotherapy, if it is anticipated.

19 CO-CHAIR MEYER: Right. So you
20 are saying there is --

21 MEMBER DORON SCHNEIDER: There is
22 a lot of healthcare-associated side effects,

1 but we are not interested in them as much.

2 CO-CHAIR MEYER: But, to keep it
3 simpler here, I would say, if we focus on the
4 unanticipated, that recognizes --

5 MEMBER DORON SCHNEIDER: Okay.

6 MEMBER PHILIP SCHNEIDER: I am not
7 sure I agree with that. I was struck by a
8 conversation, many of which have been
9 humbling, with Dr. Lucian Lee, who said that
10 all adverse events should be considered
11 preventable.

12 A couple of them that we have
13 focused a lot on that you probably wouldn't
14 necessarily consider reporting. A simple one
15 is vancomycin infusion reactions. You know,
16 it took us a little while to figure out how to
17 prevent those. It turned out it was the rate
18 of infusion.

19 Chemotherapy, I would argue, if I
20 worked in a cancer clinic, I would want to
21 know what the rate of nausea and vomiting are,
22 to compare different kinds of chemotherapy

1 that might have equal efficacy, to pick one
2 that was more comfortable for the patient, or
3 to continue to explore innovative ways to
4 prevent nausea.

5 In our lifetime, we have started
6 to use pretty innovative and out-of-the-box
7 kind of therapies, including haloperidol and
8 GI motility agents and marijuana, and a
9 variety of different things, in an attempt to
10 try to blunt those effects.

11 So I am not talking about putting
12 those in the NQF serious events list, but I am
13 talking about I am not sure there is -- any
14 organization may want to look at something
15 that is undesirable that happens with a
16 patient that is associated with their
17 healthcare, in the interest of improving
18 quality or finding research areas, like
19 genomics.

20 CO-CHAIR MEYER: So that may, in
21 fact, define -- Helen, if you want to jump in
22 here in terms of areas of research?

1 DR. BURSTIN: Just to remember
2 that, really, the purpose of NQF is about
3 public reporting.

4 CO-CHAIR MEYER: Right.

5 DR. BURSTIN: So keep that in
6 mind. You may have lots of things you may
7 choose to internally look at for the sake of
8 internal QI, but would they rise to that list
9 of what you --

10 CO-CHAIR MEYER: And that is the
11 kind of thing to put in the text, to say that,
12 you know, areas for research are we would like
13 to see us push the edge of the envelope and
14 try to find some of these things which we now
15 say we can't do anything about. When we
16 figure out ways to do something about it, when
17 we can, and they move inside this circle.

18 MEMBER PHILIP SCHNEIDER: Right.
19 Well, it wasn't saying what we should include
20 in SREs because that is clearly there.

21 CO-CHAIR MEYER: Yes.

22 MEMBER PHILIP SCHNEIDER: But we

1 are trying to develop this inclusive diagram
2 that includes --

3 CO-CHAIR MEYER: So I would say
4 that that would require some text explanation
5 as well --

6 MEMBER PHILIP SCHNEIDER: Yes.

7 CO-CHAIR MEYER: -- to say what is
8 around that.

9 Sally, and then I am going to go
10 to John.

11 CO-CHAIR TYLER: I was just going
12 to reiterate that because I had had that
13 thought as we were talking along. I mean I
14 think in the report we definitely should
15 underscore that there is a separate and
16 continuing need for data collection around
17 lots of areas, where you are looking at your
18 internal practice and quality, and that those
19 should be ongoing, but they may differentiate
20 from the need for public reporting.

21 So, yes, I definitely would
22 underscore that.

1 CO-CHAIR MEYER: John?

2 MEMBER MORLEY: No.

3 CO-CHAIR MEYER: Okay. A few more
4 comments, and then I want to try to come to
5 closure on this quick.

6 MEMBER RYDRYCH: Okay. I've been
7 holding this for a while.

8 CO-CHAIR MEYER: Fire. Go.

9 (Laughter.)

10 MEMBER RYDRYCH: I have been
11 holding this, so I will let a few of them go.

12 But, given the point that was just
13 made that NQF is really focused on public
14 reporting, I wonder if we are confusing the
15 issue by having reportable there for non-SREs.
16 Because are we then saying we are going to
17 create a whole separate list of non-serious
18 reportable events that are reportable, which
19 seems odd to me.

20 I would almost argue that we
21 shouldn't even have that one, and it should
22 just be part of the unanticipated adverse

1 events circle generally.

2 But my other question is, thinking
3 of the process that this --

4 CO-CHAIR MEYER: Stop there fore a
5 minute just to make sure.

6 MEMBER RYDRYCH: Yes.

7 CO-CHAIR MEYER: So what you are
8 saying is you are saying that NQF is all about
9 reporting and that --

10 MEMBER RYDRYCH: If NQF is about
11 public reporting, then why are we establishing
12 a separate list of things that don't meet the
13 criteria for being serious reportable events,
14 but that we are still saying are reportable?

15 CO-CHAIR MEYER: And our job,
16 actually, here is to create that one list, the
17 SRE list --

18 MEMBER RYDRYCH: Right.

19 CO-CHAIR MEYER: -- as a product
20 of this Committee.

21 MEMBER RYDRYCH: Right, unless we
22 want to clarify that we are talking about

1 internally-reportable or the things that need
2 to be tracked by those facilities.

3 But my other point is related to
4 that; that given the process of this group,
5 there are going to be the technical advisory
6 groups and there is going to be a call for
7 potential events.

8 CO-CHAIR MEYER: Yes.

9 MEMBER RYDRYCH: If we set up
10 something separate like this, are we then
11 saying that the technical advisory groups
12 should not only be considering what might make
13 the list of SREs, but what could also go into
14 this separate box of non-SREs? And do they
15 have to think about what the distinction is
16 between them? And when does something rise to
17 SREs versus when is it in this non-SRE group,
18 but it is still distinguished from the white
19 matter?

20 CO-CHAIR MEYER: What is expected
21 of you under the contract?

22 DR. ANGOOD: Well, I think in

1 terms of what is expected of us at NQF, I
2 think it is still a little bit confusing.
3 That is because of the struggle we are having
4 on the definition and what the needs of HHS
5 are in terms of their perceptions.

6 I think, as Eddie made comment a
7 little bit earlier, their idea initially was
8 to expand the SREs into other environments, or
9 the concept of SREs into other environments.
10 Rather than just continuing to call them SREs,
11 they sort of reacted to this HAC term.

12 So, yes, we still all very much
13 need to look at, how do we maintain the NQF
14 serious reportable event list and the value it
15 provides, but how do we take the concept of it
16 and move it into other environments, so that
17 it becomes meaningful for those other
18 environments?

19 And if it gets taken up in other
20 ways by CMS or others, then that is the market
21 economy.

22 Now Helen I think has some other

1 comments as well, but it is sort of the
2 expansion of the concept into other
3 environments that makes it a meaningful
4 listing, if you will.

5 MEMBER RYDRYCH: But I think in
6 this diagram those would still be SREs, right?
7 They would just be SREs in other settings?

8 I worry that we are creating a
9 second tier here of events that aren't SREs,
10 but that are somehow differentiated from the
11 white matter.

12 DR. ANGOOD: Well, we never even
13 got to the language that we had on one of the
14 slides. It is in the slide packet. I don't
15 have one with me, but it is after -- because
16 we are trying to play with multiple computers
17 up here, page 13, that middle slide, where it
18 talks about the broad-based concept whereby
19 untoward conditions or complications are
20 acquired. That is the language that is in the
21 work plan. That seemed to be what resonated
22 with HHS, as we had been talking about it.

1 But my previous comments are still
2 the same.

3 DR. BURSTIN: The only thing I
4 would add is just, again, what we heard
5 clearly from CMS, and from others, was that
6 SREs was too limiting. People perceived them
7 as never events. It wasn't broad enough to
8 come up with a list of just never events.
9 They wanted that to be broader and
10 encapsulate, and so going back to our
11 conversation right after lunch, go back to
12 events that perhaps are serious, but maybe
13 could not be called never events.

14 That is why we began this
15 conversation in saying, are there really two
16 lists of events here? Have we now codified
17 the definition of SREs to the point where, in
18 fact, we have made them serious, but not never
19 events? And maybe that is good enough, just
20 to remember where we started. Then they
21 wanted to get it expanded to other
22 environments of care.

1 So, you know, if we are making
2 this overly complicated, I just think we don't
3 want to do that. I think we wanted to be able
4 to really encapsulate that broader vision of
5 where we want to go. How you call it and what
6 we wind up with is your decision as the
7 Steering Committee.

8 CO-CHAIR MEYER: And so let me
9 just put something on the table, just for
10 people to think about.

11 The point is well-taken about
12 defining a second list here. But, in fact,
13 if you got rid of the non-serious or the not
14 necessarily not serious reportable, if you got
15 rid of that bubble, and then you said the
16 white matter is defined by an untoward -- by
17 the definition on page 13, which is "untoward
18 conditions or complications acquired by
19 patients," and we would have to broaden the
20 word "patient" apropos the discussion earlier
21 about going to other healthcare environments.

22 Going further, these could be

1 rare, uncommon, or relatively common. "They
2 may or may not require formalized reportable
3 to various reporting agencies, but should be
4 subject to internal organizational review, at
5 a minimum, should they occur."

6 So, Michael, you don't think that
7 defines the white matter?

8 MEMBER VICTOROFF: Well, as bad as
9 that is, yes, it could define the white
10 matter. I don't like almost anything about
11 that definition.

12 CO-CHAIR MEYER: So what should we
13 do?

14 MEMBER VICTOROFF: I would get rid
15 of the lower lefthand bubble, for the reason
16 that we just heard. It doesn't add, and it
17 does complicate life.

18 And I would also remove the
19 language -- I would just leave SREs as SREs
20 because it is an idiosyncratic, local,
21 however, authority list from NQF. And the key
22 to what we are saying about them is that we,

1 to whom you are not going to report anything,
2 suggest that report-collecting agencies of a
3 certain caliber and interest, we strongly urge
4 them to make these among the things
5 universally which they collect, in addition to
6 whatever else they collect.

7 But, since we are not a report-
8 collecting agency, we can't say what is really
9 reportable. We are merely exhorting certain
10 kinds of quality organizations to consider
11 these highly above all, for our reasons.

12 But, when we say, "reportable",
13 and I've got to go back to what Leah was
14 saying, reportable is a local definition
15 everywhere. There are literally -- everything
16 in the white matter, I mean things outside the
17 white matter are reportable somewhere, the
18 Department of Motor Vehicles, and the who
19 knows what, and EPA, and I don't care; NASA
20 wants to hear something.

21 So, even the word "reportable" is
22 something we are going to stumble over if we

1 use it in our diagram. So I would say SREs,
2 we have defined that. You know, "See above."
3 We've got what SREs are.

4 Infections, that is perfect. It
5 is inside there, mostly unanticipated, and
6 some of them are SREs. That clarifies the
7 relationship of reportable events to
8 infections.

9 Then there is another spectrum of
10 them, and there's other dimensions that we can
11 draw through this, among which are the site of
12 care, the locus of care, the degree of
13 severity, and the type of intervention, the
14 sort of outcome. Then measure the impact and
15 the cost to society.

16 I just listed three things that
17 helped me understand why a thing would be
18 reportable. They are the three "I's" that I
19 came up with. They had to do with impact, the
20 presence of an intervention, and our ability
21 to identify precisely the item we are
22 discussing. So it is unambiguous.

1 That is how I read -- I just
2 ambiguated the term unambiguous with those
3 three things, and you don't have to adopt
4 them.

5 But, so far, I think you have to
6 squeeze those into the -- well, I don't mind
7 if they leak outside of unanticipated. I like
8 to see the point of unanticipated. This
9 diagram is pretty good for me right now.

10 CO-CHAIR MEYER: Stan?

11 MEMBER RILEY: So I guess I would
12 argue for replacing that small circle back
13 because I think that is actually the biggest
14 circle, not the overall biggest circle, but
15 the place where most of the events are.

16 That is, they are non-SREs,
17 they're serious, and they are reportable. So
18 that if we just took out the "not" in that
19 part, that is where about 80 of the things
20 that happen are going to actually live.

21 MEMBER VICTOROFF: Could I
22 respond? That is already the white matter.

1 And I think we can annotate the white matter
2 exactly as you said.

3 CO-CHAIR MEYER: So the point here
4 is saying that, actually, anything inside the
5 white matter is reportable?

6 MEMBER RILEY: Is non-SRE and --

7 CO-CHAIR MEYER: And they are not
8 SREs? Does that work?

9 MEMBER RILEY: Yes. I guess the
10 only other thing that I am concerned about is
11 the unanticipated. Is everything inside that
12 white circle going to be serious? Is that
13 what we are going to say?

14 CO-CHAIR MEYER: No.

15 MEMBER RILEY: No?

16 CO-CHAIR MEYER: No.

17 MEMBER RILEY: Okay. Then it is
18 not included in the white circle, what I am
19 saying.

20 MEMBER RYDRYCH: I think the white
21 circle could be serious or not serious,
22 reportable or not reportable, right? It is

1 the all bad things list that Michael talked
2 about, where it is not dependent on harm; it
3 is not dependent on risk of harm.

4 CO-CHAIR MEYER: And this
5 Committee is not going to define reportability
6 outside of the SREs.

7 John?

8 MEMBER MORLEY: Do we care at all
9 -- at all -- about the non-serious reportable
10 adverse events that we are going to define?
11 I mean what we are talking about here is I
12 think we could come up with a list of
13 somewhere between 100 and 1,000 adverse
14 events, but there is a limit of resources.
15 And we are asking them to focus on a certain
16 category. That category is serious reportable
17 adverse events.

18 So do we care about any bubble
19 other than that? At this time?

20 And remember that the 10 or 15 or
21 20 things, whatever number we end up with, is
22 all going to fit into that one bubble.

1 CO-CHAIR MEYER: Yes, I am going
2 to let Eric respond. But before he does, let
3 me just say that what I think -- we could say,
4 boy, we spent two hours talking about a Venn
5 diagram; that's great.

6 But the reality of it is is I
7 think that this Venn diagram, with the
8 definitions that we have done this morning
9 attached to the call to events, will help
10 clarify what people send in to us.

11 And do we care about -- is our job
12 to define all the things in the white matter?
13 The answer is absolutely no. That would (a)
14 be a Herculean, a Sisyphean task, and (b) --
15 Sisyphus rolling the ball up the hill.

16 Eric?

17 MEMBER TANGALOS: Yes, I think
18 that the non-SRE serious reportable right now
19 is going to distract the next groups that get
20 into play.

21 I think we shouldn't spend too
22 much more time here because I think we did our

1 work in redefining the SREs. Although Leah
2 and Leapfrog is wedded to the "never" piece,
3 by taking that word out and changing it a
4 little bit, maybe a little bit more, we have
5 really expanded the scope that we wanted to
6 get to with this particular process.

7 CO-CHAIR MEYER: Doron?

8 MEMBER DORON SCHNEIDER: So we are
9 giving special attention to the HAIs. I just
10 wonder, if we are going down this path at all,
11 if we want to think about, just for clarity's
12 sake, the different categories of SREs that we
13 have, at least prior to this current effort,
14 where you have surgical events, product or
15 device events, care management events, et
16 cetera. Theoretically, you could say that
17 each one of those can be, if we want to be
18 clear --

19 CO-CHAIR MEYER: Absolutely.

20 MEMBER DORON SCHNEIDER: -- their
21 own circle. Then some may be SREs and some
22 wouldn't be SREs, but everything in the white

1 big circle is reportable.

2 CO-CHAIR MEYER: I think the only
3 argument I would make, I would make two
4 arguments for potentially including HAI in the
5 diagram if we sent it out as part of the call.
6 I would use it there, No. 1, because HAIs are
7 special interest kind of nationally. But,
8 beyond that, just for illustrative purposes,
9 to say here's the way one of them overlaps,
10 and, oh, by the way, all of these other things
11 we do the same thing, it just makes it simpler
12 to portray.

13 Deborah, and I am going to try to
14 bring us to a closing point here.

15 MEMBER NADZAM: Okay. Just a
16 quick comment. I think we may need to say
17 something about what very serious means as
18 compared to serious. We may need to go back
19 to that definition. I like the impact. I
20 like the impact.

21 CO-CHAIR MEYER: There, we are
22 taking it out. It is out.

1 MEMBER NADZAM: We are taking what
2 out?

3 MEMBER RYDRYCH: I don't think we
4 even need to say very serious. We already
5 know --

6 MEMBER NADZAM: We are going to
7 take very serious out as well?

8 MEMBER RYDRYCH: I think we could
9 because we already defined SREs.

10 CO-CHAIR MEYER: All right, P.J.?

11 MEMBER BRENNAN: Gregg, I just
12 wondered where actionable fits into this. By
13 way of example, when Pennsylvania started its
14 HAI reporting system, it built initially, but
15 the goal within a very short time was to
16 report all HAIs. There was an enormous effort
17 in that, but at the end of the day there were
18 only four or five that are reported. One of
19 them is multiple HAIs in a single patient. I
20 don't know how to prevent those. There are
21 ways to prevent each one individually, but it
22 is a category that is sort of useless, in my

1 mind, as is much of the rest.

2 However, it informs the purchasers
3 very well of all the things that they are
4 interested in, you know, the whole spectrum of
5 costs related to HAIs. So it is sort of a
6 research tool, but in terms of hospital
7 action, it is really confined to a small
8 subset.

9 So where does actionable fit into
10 this? I think that is an important issue.

11 CO-CHAIR MEYER: Yes, and again, I
12 turn to Peter and Helen, if they have further
13 thoughts on this.

14 If you go back to kind of original
15 definitions of SREs, and I am going to flip
16 through here, one of the issues has been, and
17 this gets back not to the specific criteria
18 for this Committee, but the National Quality
19 Forum as a whole, it is there is supposed to
20 be a feasibility and ability to take action as
21 one of the broad criteria for a National
22 Quality Forum consensus standard.

1 So I would say, certainly, when
2 this goes through the consensus development
3 process and goes through the CSAC and other
4 parts, they are going to look very closely at
5 that actionability piece.

6 I think it would be hard to put
7 something on a serious reportable event list
8 with a notion that we don't have any idea of
9 what to do about it. I think that that gets
10 filtered; that will get filtered out in the
11 process.

12 Leah?

13 MEMBER BINDER: I think, also,
14 actionable, the definition of actionable
15 changes with reporting.

16 CO-CHAIR MEYER: Right, it does.

17 MEMBER BINDER: You know, five
18 years ago, I don't think anyone believed that
19 it was possible to get to no central line
20 infections, right? Well, it is possible when
21 we learn it because we start reporting it, and
22 we start seeing it.

1 So I think that is another element
2 to consider.

3 CO-CHAIR MEYER: Okay. Yes, Helen
4 has a question.

5 DR. BURSTIN: I have a question.
6 It is always fun to kind of have that storm
7 and drama of groups, and we have kind of come
8 back to the reference point.

9 I have a question for John,
10 though. Going back to that list of 40, it
11 would be useful to have that list of 40. Does
12 the expanded definition of SREs we came up
13 with this morning work to fill that list of
14 40? Are you still going to get left with
15 stuff that people are telling you to put on
16 there that doesn't fit?

17 MEMBER MORLEY: I think you could
18 come up with, given the definition that we
19 have now, I think we can come up with 40
20 things.

21 DR. BURSTIN: Okay. I mean not
22 that we have to come up with 40 things.

1 MEMBER MORLEY: Right.

2 DR. BURSTIN: But I just think
3 that it would be helpful just to --

4 MEMBER MORLEY: I think it is
5 broad enough, and there's lots of room.

6 DR. BURSTIN: Right.

7 MEMBER MORLEY: There's lots of
8 places. We have very clearly limited and
9 targeted and started with the low-hanging
10 fruit.

11 DR. BURSTIN: Okay.

12 MEMBER MORLEY: There will be
13 slightly-one-more-shelf-higher fruit.

14 DR. BURSTIN: Okay, great.
15 Because just getting back to that list of the
16 CMS events, and I just pulled those up to
17 remind us, the things that are left on that
18 list that weren't on the initial SRE list
19 include some of the HAIs, which we have now
20 talked about, as well as the only other one,
21 really, that is on here is falls.

22 I guess the question would be,

1 just to kind of play this out one more time
2 for us, if that is how people are thinking
3 about it. Would falls or some subset of falls
4 now fit in the new definition of SREs?

5 MEMBER MORLEY: Yes.

6 DR. BURSTIN: You have answered my
7 question. Thank you.

8 MEMBER RYDRYCH: But they already
9 are SREs, falls. Death or serious disability,
10 serious disability or -- no, serious
11 disability from falls is still a part of it.

12 MEMBER VICTOROFF: What about a
13 busted tibia?

14 MEMBER RYDRYCH: That is a serious
15 disability.

16 CO-CHAIR MEYER: That is a serious
17 disability. Yes, it is.

18 Okay. So I had stopped us there.

19 Be careful what you wish for was
20 the right thing to start the conversation.

21 With that said, where I think we
22 are is we have a definition of serious

1 reportable events from this morning. We have
2 got a kind of conceptual framework, I think,
3 for what we have thought through a lot. I
4 think we will actually have to see a final
5 version, based on this discussion, of the Venn
6 diagram and this notion that everything in
7 that big circle is potentially a part of it.

8 We are going to define a pretty
9 small circle of what is reportable as SREs.
10 We will kind of finish that off and get that
11 out to folks. And maybe we can try to get
12 that to folks tomorrow in a final form.

13 Make sure that we are -- I think
14 that we are in the same place. I just want to
15 make sure everyone leaves tomorrow agreeing
16 that, yes, this is what we said. Because that
17 is going to go out in this call for potential
18 events.

19 Do folks need to take a 10-minute
20 break before we dive into the SRE list? That
21 is the remainder of our afternoon, is to spend
22 time on the SRE list.

1 Just as a word of warning, I am
2 going to put Diane, Stan, and John on the spot
3 a bit, because I want to start a review of the
4 SRE list with actually going through the
5 state-based reporting agencies' feedback that
6 we all have on our reports.

7 So do people need a 10-minute
8 break or can we plow forward?

9 A 10-minute break, raise your
10 hand. Who needs a 10-minute break?

11 Okay, John, take your break and
12 come back.

13 (Laughter.)

14 We're starting without you.

15 Okay. I would ask everybody, if
16 you could pull up your -- and thank you. That
17 was an awesome discussion, and I think in the
18 end we got to a good place.

19 If you could please pull up the
20 slide set on NQF state-based reporting? I
21 actually found this to be pretty provocative.

22 Jennifer, if you can pull that up

1 as well, I think that will be helpful.

2 DR. ANGOOD: So where we are at is
3 in the main .pdf document.

4 CO-CHAIR MEYER: State-based
5 reporting.

6 DR. ANGOOD: State-based reporting
7 agencies' perspectives.

8 CO-CHAIR MEYER: I would like us
9 to go to the first slide that says, "SREs most
10 and least useful".

11 MEMBER RYDRYCH: Although I will
12 say I don't know if either John or I was on
13 that work group, but we might be able to
14 summarize it.

15 CO-CHAIR MEYER: Well, no, you
16 don't have to summarize it.

17 MEMBER RYDRYCH: Okay.

18 CO-CHAIR MEYER: You can react to
19 the feedback that your colleagues gave, I
20 think.

21 Stan, were you at the meeting?

22 MEMBER RILEY: Yes.

1 CO-CHAIR MEYER: Okay.

2 DR. ANGOOD: What occurred is,
3 during one of the breakout sessions at the
4 state-based reporting meeting, where we had 22
5 of the involved states present and several
6 individuals, was to review the existing
7 serious reportable events and to sort of kind
8 of evaluate their usefulness, their impact, et
9 cetera.

10 The handout kind of details
11 through some of the questions that were asked.
12 You know, comment on the criteria and most and
13 least useful, potential new conditions, et
14 cetera.

15 And where Gregg wants us to focus
16 is on some of the actual outputs on the SREs,
17 SRE by SRE by SRE.

18 CO-CHAIR MEYER: Right.

19 DR. ANGOOD: So that is --

20 CO-CHAIR MEYER: So what I suggest
21 process-wise is that we just review the slide
22 set in just five or ten minutes, just so

1 people can all get familiar, and we can hear
2 your perspectives on it.

3 Then we are actually going to go
4 back through the list of SREs as they are in
5 your handout here one by one, and we will do
6 as many as we possibly can.

7 So, just, again, to start the
8 conversation, this is a list of -- on the left
9 side, you will see the SREs listed there.

10 I guess what I would ask the three
11 of you -- and, Stan, if you have any further
12 commentary on this -- and then the other two
13 of you to chime in and say, does this comport
14 with your experience or do you take umbrage
15 with this? And this is not what you have
16 experienced here?

17 This is just for input. We are
18 not making decisions based on this, but this
19 is a good point of input for all of us.

20 So, Stan?

21 MEMBER RILEY: I think it is a
22 great place to start. John and I weren't on

1 this particular Committee. We were on another
2 one at that piece, but we did listen, and I
3 think Diane was there, too, to the
4 presentations.

5 I think there was actually some
6 pushback about some of these things at that
7 time. So this is not necessarily sort of a
8 consensus document. This was that particular
9 breakout group's feelings about things.

10 CO-CHAIR MEYER: So they came up
11 with these five that were the least useful,
12 for the reasons they have here on the right
13 side.

14 MEMBER RILEY: Right.

15 CO-CHAIR MEYER: And, John or
16 Diane, is that your experience?

17 MEMBER MORLEY: I would agree that
18 it has not been particularly useful, the large
19 experience that I have, which is not a large
20 number of cases, fortunately. But there's
21 very clear reasons, in my view, as to why.

22 A little bit the limited number of

1 times that that event happens, but, more
2 importantly, there's a significant reluctance
3 for open discussion and review and analysis,
4 a real root-cause analysis.

5 Now maybe there is a root-cause
6 analysis. Part of the problem is that they
7 are reporting to a regulatory body. Part of
8 the discussion we did have three weeks ago was
9 this whole issue of, what happens to the
10 information? Is it going to be used against
11 us? That type of thing.

12 So we don't get a lot of honest --
13 we get some, for sure; I am not putting
14 everybody in the same category, but
15 particularly the more likely it is for
16 somebody to end up with a blame issue or being
17 put at risk of defending their license or
18 something, the much more likely they are to
19 provide technical information without useful
20 analysis of the cases.

21 CO-CHAIR MEYER: Diane?

22 MEMBER RYDRYCH: I would just say,

1 yes, I wasn't part of this group, either.

2 I agree and disagree with it. I
3 would say it is true that the last three
4 events on this page, we have never had
5 reported in six years. But I don't think that
6 the fact that they haven't happened
7 necessarily means they shouldn't be on the
8 list.

9 I do think the spinal manipulative
10 therapy question, to me, for some of these,
11 there's the question of, is it an individual
12 practitioner or is it a larger system issue?
13 For me, that is kind of the issue with spinal
14 manipulative therapy, is that we are more
15 talking about one practitioner and what they
16 do, rather than a failure in a system of care.

17 We do have some issues with the
18 post-op death classification. I think in
19 Minnesota we agree that just looking at ASA
20 Class 1 is probably too narrow because it is
21 sort of implies that any other patient, the
22 death was anticipated in them, which I don't

1 think was the intent of that event.

2 I think we, generally, would
3 support broadening of that, as the group
4 recommended, to any anticipated interoperative
5 or post-op death, not just Class 1.

6 But I don't know that I would
7 describe these as least useful. I think they
8 might need further clarification, and there
9 can be discussion about adding or removing.

10 CO-CHAIR MEYER: Please, John, and
11 then Stan.

12 MEMBER MORLEY: In things like the
13 manipulative therapy, that is not going to
14 happen in a regulated environment, or
15 virtually not going to happen. We don't get
16 any information from offices or things like
17 that in terms of reporting.

18 CO-CHAIR MEYER: Right. And just
19 remember that the charge of this Committee is
20 to expand beyond hospitals. So that may be
21 something to consider as we --

22 MEMBER MORLEY: Yes.

1 CO-CHAIR MEYER: Which may have
2 been ahead of its time.

3 MEMBER MORLEY: Yes, and I would
4 appreciate that. I would say, though, that,
5 as we talk about that, one of the struggles
6 that we have with current reporting systems is
7 the amount of reporting that we get.

8 In New York, we have about 34
9 reportable events. I have forgotten the exact
10 number now. The ones that are most serious I
11 think, like a wrong-sited surgery, I would
12 suggest -- and I can't say for certain -- that
13 we have between 90 and 95 percent of wrong-
14 sited surgeries reported to us.

15 Another category is thromboembolic
16 disease. I would say we get about 10 or 20
17 percent of those cases reported to us. That
18 is in a regulated environment.

19 So the point that I want to make
20 is, if you go to the nursing home, I suspect
21 that we would see a little less reporting, and
22 home care, a lot less, and a non-regulated

1 environment --

2 CO-CHAIR MEYER: Stan?

3 MEMBER RILEY: So I guess that I
4 would have to agree with Lucien Lee, who says
5 that all reporting is voluntary, whether it is
6 mandated or not. So that is certainly there.

7 I think, for us, I agree that
8 these are rare events for us to have reported,
9 but just, for instance, the licensed
10 healthcare impersonator, because of the
11 environment that we happen to be in, we have
12 research assistants or researchers who
13 sometimes are from foreign countries. They
14 already have gotten an MD there. All of a
15 sudden, they are participating in the
16 patient's care. So that actually is one of
17 the things that we have particularly seen.

18 So I agree that just because we
19 see them rarely doesn't mean they need to be
20 taken off the list.

21 CO-CHAIR MEYER: Okay. And we are
22 not making that judgment here.

1 P.J., we want to move to the next
2 slide, and then we will move on.

3 MEMBER BRENNAN: Okay. Gregg, on
4 the first one, I think it meets the standard
5 of being unambiguous, which is the advantage
6 of it. I would certainly agree that there are
7 unanticipated deaths that occur in other
8 classes, but Class 1 is clearly one that is
9 unambiguous, I think.

10 The second item, these sort of
11 contamination events don't cause death very
12 often in the short-term, but all of those
13 patients injured in Nevada, for example, with
14 hep C are certainly at risk of death or liver
15 transplantation down the road.

16 The problem is we are, I think,
17 ahead of the curve here with this one --

18 CO-CHAIR MEYER: Yes.

19 MEMBER BRENNAN: -- because there
20 is no real reporting mechanism for these
21 practices.

22 CO-CHAIR MEYER: If we could,

1 let's move to the next slide, the next slide
2 down.

3 Again, I would just like the state
4 reporting folks to react to this most and
5 least useful list.

6 Does that comport with your
7 experience? Or any commentary on these here?

8 DR. ANGOOD: So, then, the context
9 of this is the subgroup was asked sort of, in
10 addition to those ones that you just reviewed,
11 sort of what were some of the more useful
12 types of SREs, and then kind of what was the
13 least useful overall, separate from that list
14 you just looked at a moment ago.

15 MEMBER RYDRYCH: And I would just
16 say I don't tend to think of these events in
17 terms of most useful or least useful. So this
18 doesn't really resonate for me personally.

19 CO-CHAIR MEYER: Okay.

20 MEMBER RYDRYCH: I think we have
21 found all of them to be useful. As long as
22 you are actually looking at the data and

1 really using it to identify those system
2 breakdowns and identify what can be put in
3 place, they can all be useful, whether they
4 are more or less rare. I don't find events
5 that report death to be more useful than those
6 that are no-harm events, or any of the others.

7 MEMBER RILEY: And I guess I
8 agree. You know, I think that the best
9 learning probably is from the ones that aren't
10 deaths. So I would agree with that.

11 And I think that criminal
12 activities are actually useful to learn from.
13 I mean, you know, with your experience not
14 very long ago, I am certain --

15 CO-CHAIR MEYER: Three weeks ago.

16 MEMBER RILEY: -- that you learned
17 a lot from that shooting at your place.

18 CO-CHAIR MEYER: Folks, just so we
19 are not talking in code, about three weeks
20 ago, we had a mental health provider in one of
21 our psychiatry offices who a patient attempted
22 to stab to death in her office, barricaded

1 herself in the office, and as he was stabbing
2 her to death, a legally-armed off-duty
3 security officer broke down the door and shot
4 the perpetrator dead, saving the life of our
5 psychiatrist, who is now home after four
6 surgeries. But this is the real world. This
7 is the real world.

8 Yes, I don't think anybody at Mass
9 General had any problem with that being
10 reported to the Department of Public Health,
11 OSHA, the State police, you know, Interpol,
12 whoever we could get to help us on that one.

13 DR. ANGOOD: But that actually
14 brings up the point about this term "useful",
15 and it is probably the wrong piece of
16 language. But what drives reporting more are
17 these types of topics versus what drives
18 reporting less, partly because of the
19 frequency.

20 It was interesting in the
21 discussion, some of the states, Florida, in
22 particular, as I remember it, the criminal

1 activity was actually a big part of their
2 profile of the State-based reporting. And
3 other states it was, clearly, "No, I haven't
4 seen one in five years" type of stuff.

5 So I think for us to continue to
6 use this word "useful" is the wrong term, but
7 it is what drives reporting is more the issue
8 here.

9 CO-CHAIR MEYER: Right.

10 Leah, do you have any comments on
11 it? Because you also have a lot of experience
12 with this list as well. Any comments from
13 kind of the Leapfrog experience to say, boy,
14 this is what has been very useful, less
15 useful, or --

16 MEMBER BINDER: No, not entirely.
17 The word "useful", I would just echo what
18 everyone's -- useful to whom, for what? But
19 that would be my only question.

20 CO-CHAIR MEYER: Okay. John?

21 MEMBER MORLEY: I confess that,
22 when I first looked at it, I was interpreting

1 it the way Peter described it in terms of
2 useful, that it does trigger more reporting
3 and more response from the institution. So I
4 thought yes.

5 Then, as I heard Stan and Diane's
6 comments, I agree that it is not always useful
7 in that sense. But it is a clearer line for
8 delineation for the institution to report, to
9 understand it, what their response needs to be
10 in terms of a root-cause analysis, and so
11 forth.

12 DR. ANGOOD: So I think it gets
13 back to that sense of urgency that we were
14 trying to get at earlier. What will drive
15 people to report as opposed to kind of let it
16 slide into this voluntary mode?

17 CO-CHAIR MEYER: Sally?

18 CO-CHAIR TYLER: Yes, I just
19 wanted to say one thing. Because I wasn't on
20 this working group, obviously, and I don't
21 understand the term "useful" and "least
22 useful" at all. So that doesn't work for me.

1 So maybe it is a different term that might
2 work. So I am not really sure what people are
3 trying to get at there.

4 But I know, from our members, in
5 terms of healthcare workforce, frontline
6 workforce, particularly around events to
7 report criminal activities, they certainly
8 feel like violence and assault is vastly
9 underreported. There's a lot of confusion,
10 you know, frequently not demonstrated or
11 explained to them how to report and who to
12 report to. When they do report to one
13 supervisor up, they don't feel like it goes up
14 the ladder. Nothing ever happens to it, and
15 there are no system changes that are put in
16 place because of it.

17 In particular, I think, in mental
18 health settings, some people feel that the
19 response they get is you have to expect some
20 level of violence. You have to expect to be
21 assaulted at some point. It is very
22 frustrating.

1 So I don't think they would find
2 the term "least useful" a good term. I don't
3 know, you know, again, what we are trying to
4 get at here. But, certainly, it is vastly
5 underreported, at least according to the
6 healthcare workforce certainly.

7 CO-CHAIR MEYER: Okay. With that,
8 what I would like to do is I would like people
9 -- Jennifer, if you can pull up the first of
10 the slides of the specific SREs, and it is the
11 surgical event slide?

12 What I would like us to do is --
13 and that is on page 15 of your handout -- I
14 would like us to actually march through these.

15 Let me just make sure that we have
16 the proper context here. What we are going to
17 do now is we are going to provide some input
18 to the existing list of SREs. Remember that
19 we are only a small part of the process. So
20 what will come after this meeting is, in that
21 call for events, it will be asking people to
22 react to the list. So there will be a broad

1 base.

2 So we are not going to be making a
3 decision this afternoon. We are going to be
4 providing input, but we are not going to be
5 making a decision on each of these.

6 But it will be a chance for us to
7 get a sense of the Committee early on about
8 the existing list. Then what will happen,
9 through both the TAP and through the public
10 call, is that we will have an opportunity to
11 get further input on the existing list and
12 some advice about whether or not the list
13 needs to be expanded.

14 So that part of it, the list
15 expansion part, is not going to be covered, I
16 don't think, during this day and a half. But
17 we did want to at least get your initial
18 reactions to the existing list.

19 Having no other way to do that, I
20 would like to go through these one by each.
21 Again, if you have a strong reaction to this
22 one way or the other, what I would like to do

1 is we would like to get your reaction down
2 kind of on paper. So we can make sure it is
3 part of the process here.

4 So we are going to start with the
5 surgical events because of the order.

6 So Michael is just aching to jump
7 in.

8 MEMBER VICTOROFF: My minor simple
9 change is to change that to "procedure". We
10 just published a paper where we identified
11 that, of all of the wrong site procedures,
12 more than half of them were done by non-
13 surgical specialists.

14 CO-CHAIR MEYER: Right,
15 interventional radiology.

16 MEMBER VICTOROFF: Well, I'm
17 sorry, ours were internal medicine.

18 (Laughter.)

19 But we are willing to compete on
20 any -- point made.

21 CO-CHAIR MEYER: Yes.

22 MEMBER VICTOROFF: Surgery is

1 probably too narrow a word, and I think the
2 word "procedure" covers everything.

3 CO-CHAIR MEYER: So you would say
4 procedural events as the major heading, and
5 below that, in terms of SRE 1A, procedure
6 performed on the wrong body part?

7 MEMBER VICTOROFF: Yes.

8 DR. ANGOOD: Gregg, please may I
9 make a quick comment?

10 CO-CHAIR MEYER: Yes.

11 DR. ANGOOD: Before we get too
12 much further into this, I want to just review
13 some of the questions that we had posed in the
14 introductory comments earlier this morning for
15 framing it again.

16 We have gone through the
17 definition and the criteria. That is now
18 very, very helpful, and it has consolidated
19 that.

20 So, as we go through this, in the
21 overall process, you know, are there changes
22 to the list, the consolidations? Are there

1 SREs that will be added or those that need to
2 be omitted? You don't have to do all of that
3 today, but that is the long-range purpose in
4 here.

5 So I, personally, and this is just
6 a personal comment, but, you know, in this
7 first cluster, that is one that might, as an
8 example, be consolidated a little bit. It
9 doesn't have to be, but that is just one that
10 we might want to think about. And there may
11 be others as we move forward.

12 So, rather than just getting
13 nitpicky one by one by one, think broadly as
14 well. But there are processes that we have to
15 go through.

16 CO-CHAIR MEYER: Deborah?

17 MEMBER NADZAM: Can one of you
18 explain the exclusion that occurs in 1A and
19 1C, emergent situations? It is in this one as
20 well. I don't know exactly where.

21 CO-CHAIR MEYER: "Excludes
22 emergent situations that occur in the course

1 of surgery and/or whose exigency precludes
2 obtained informed consent."

3 MEMBER NADZAM: I guess I am
4 puzzled by the informed consent and emergent
5 and --

6 CO-CHAIR MEYER: I will give you a
7 very concrete clinical example. Maybe it
8 might help.

9 A patient comes in with chest
10 trauma after a motor vehicle accident and is
11 having trouble breathing. We need to put a
12 chest tube into that patient to allow that
13 patient's lungs to reinflate and circulation
14 to proceed unimpeded.

15 We put the chest tube in in the
16 wrong side. We guess wrong, to start with.
17 We end up putting them in on both sides of
18 that patient. That first one wouldn't be a
19 wrong site surgery.

20 On the other hand, a patient comes
21 in for an outpatient diagnosis of a collection
22 of fluid in their chest. Clearly, there are

1 on the x-ray -- this is done as an outpatient
2 -- it is on the left side. They put in the
3 chest tube on the right side. I would say
4 that is wrong site.

5 So I think the idea was that, I
6 would argue that the problem whenever you put
7 any exclusions is that people want to
8 interpret that broadly, but I would say it is
9 pretty narrow.

10 But I think in some of these, boy,
11 I put the chest tube in the wrong site. Yes,
12 but it is in the middle of a trauma code, and
13 I just put it in the other side right after
14 that. So be it.

15 Where I put the chest tube in the
16 wrong side and the patient was coming in for
17 an elective diagnostic procedure, that is
18 wrong site. That is wrong site, and it is
19 tough.

20 MEMBER RYDRYCH: And I would just
21 clarify that. I mean, for us, that chest tube
22 would still be reportable because we would

1 look at, what was the intent? If you guessed
2 wrong, you just weren't sure which side, and
3 you put it on the left, that is not
4 reportable. But if you intended the right,
5 and put it on the left -- but I think the
6 reason for that exclusion is that the only way
7 to get at intent is to look at the informed
8 consent sometimes.

9 We, at least in the early years,
10 ran into problems with people saying, well,
11 sometimes there isn't informed consent. That
12 was sort of the loophole a little bit. If
13 there was no informed consent, therefore, it
14 couldn't be wrong.

15 So we try to get at intent a
16 little bit more broadly.

17 CO-CHAIR MEYER: Let me just,
18 again, trying to think broadly about this, the
19 world has changed. When this list first
20 appeared, I can tell you, the anxiety around
21 the 2002 list was off the chart because people
22 had all sorts of ideas about what was going to

1 be done with this and what the implications
2 would be, and what would it mean when you put
3 this out in the public domain.

4 That is why it is in place to
5 let's be more precise and let's have more
6 exclusions. Now one could argue and say, boy,
7 2009 is different than 2002, and maybe we can
8 live with the fact that, boy, that chest tube
9 in the emergency room may end up getting
10 reported. So be it. No one is going to lose
11 their job over it.

12 DR. ANGOOD: Well, and I think
13 that is an important point to make, Gregg. A
14 number of years, too many institutions were
15 not very good with informed consent, and they
16 oftentimes classified something as emergent
17 when it was just kind of urgent. So I think
18 the more we can tighten it down, because there
19 is a tolerance for tighter processes now
20 compared to five and even ten years ago, so I
21 think there's room to get rid of some of this
22 language.

1 CO-CHAIR MEYER: John, and then
2 back to you, Mike.

3 MEMBER MORLEY: To follow up on
4 Mike's comments, New York's experience has
5 been very, very clear. We have two reportable
6 codes, what we call a 911 and a 912. The 911
7 is a wrong-sited surgery. By definition, it
8 is surgery and it is in the operating room.
9 A 912 is a procedure.

10 So part of the point I want to
11 make, I agree with changing to procedure.
12 There is an opportunity or a consideration for
13 having a second code for procedure. That is
14 what New York has done maybe.

15 But I would like to really request
16 and urge at this point -- I wasn't going to
17 mention this until later -- that there is a
18 consideration for expanding it yet one more
19 level. Procedure -- in New York, by the way,
20 the numbers are 20 for wrong-sited surgery,
21 just New York State, 20 wrong-sited surgeries
22 per year, approximately 100 wrong-sited

1 procedures per year.

2 And besides radiologists, the
3 other category that is increasing is
4 anesthesiologists doing a block on the wrong
5 side, and the surgeon comes in and says, "No,
6 we're doing the other side," but the block is
7 in. We call that a 912. That is 100 of those
8 versus 20 wrong-sited surgeries.

9 The other category that I would
10 say I would like to see added, and I am saying
11 it earlier than I had planned, would be
12 radiation, which is not considered by some a
13 procedure.

14 We had an event in the papers
15 recently, a high-profile case of a pregnant
16 woman in the ER who is asked -- someone calls
17 her first name. So she steps up and gets a CT
18 scan and she is pregnant. The wrong patient
19 got the CT scan.

20 We have a number of radiology
21 issues. Some of those are radiation therapy
22 on the wrong site.

1 So it gets a little fuzzy in terms
2 of how some people interpret that term
3 "procedure". "Well, I wasn't using a
4 scalpel." "Well, I wasn't using a needle."
5 Radiology is also an issue for us.

6 CO-CHAIR MEYER: So I think that
7 is great. It is the kind of feedback to put
8 in. Well said.

9 We will go to Diane, and then to
10 Doron.

11 MEMBER VICTOROFF: I don't see any
12 reason here, even after the explanation for
13 this middle sentence here, "Exclude the
14 emergent" and something, something, "informed
15 consent" --

16 CO-CHAIR MEYER: Yes. We should
17 just ditch -- that was the point we were
18 making. Maybe we are mature enough now to get
19 rid of the exclusion.

20 MEMBER VICTOROFF: You know, I am
21 sort of in the let-the-chips-fall kind of
22 sentiment, and let us report too much, of

1 which some of them are excusable and
2 explainable and defensible and some aren't,
3 and that is someone else's problem.

4 CO-CHAIR MEYER: Diane, then
5 Doron, and then Leah.

6 MEMBER RYDRYCH: Mine will be
7 short because I am just going to echo what
8 John said. Those are big areas where we see
9 issues as well, wrong-sited blocks and
10 radiation therapy.

11 CO-CHAIR MEYER: We do, too.

12 MEMBER RYDRYCH: And a lot of our
13 wrong site, wrong body part, wrong patient are
14 outside of the OR.

15 I would just say maybe another
16 thing that NQF should think about is more
17 specifically defining what is an invasive
18 procedure. We have a standard list that we
19 use or a list of codes that are considered to
20 be invasive procedures that includes radiation
21 therapy. But, to the extent that the
22 additional specifications can be clearer on

1 that, rather than just saying, "includes
2 endoscopies and other invasive procedures", I
3 think we will see a lot more consistency
4 across states and a lot less confusion about
5 what should be in there and what shouldn't.

6 CO-CHAIR MEYER: Stan is nodding
7 in agreement.

8 MEMBER RILEY: Yes. I agree
9 completely. You know, that is exactly the
10 kinds of things that we are seeing, and the
11 more consistency across states, that would
12 really be helpful.

13 CO-CHAIR MEYER: Doron, and then
14 Leah.

15 MEMBER DORON SCHNEIDER: This may
16 not be easily identifiable, but the consent
17 being done incorrectly, in that the body part
18 was done, the surgery was done correctly, et
19 cetera, et cetera. But if you think about the
20 patient partnership, the National Priorities
21 of capturing the patient voice and ensuring
22 that they are a decision maker in their care,

1 you know, having everything go correctly, but
2 the patient not understand that that was
3 occurring is another variation, that that was
4 going to occur.

5 CO-CHAIR MEYER: Are you arguing
6 that, in addition to the procedural list, with
7 the exclusions, maybe adding radiation and
8 radiology procedures, and the rest, that even
9 separate from that -- so the patient got the
10 procedure done on the right body part, and the
11 procedure was supposed to be done on the left
12 side, it was done on the left side, but the
13 consent said my right side, you would count
14 that as --

15 MEMBER DORON SCHNEIDER: Well,
16 either the consent wasn't done at all, you
17 know, the consent wasn't done or it didn't
18 list death or it didn't list the correct list
19 of --

20 MEMBER RYDRYCH: Or the consent
21 was incorrect.

22 MEMBER DORON SCHNEIDER: Or the

1 consent was incorrect. I think that would
2 align us very nicely with the priorities, the
3 National Priorities, just to consider.

4 CO-CHAIR MEYER: And I would argue
5 that this is, again, where there is, putting
6 on my other hat that I wear, that this is
7 something that the State Practice Committee
8 feels very strongly about, and we have a very
9 specific safe practice on this specific issue.

10 And whether or not we want to
11 consider that would be a serious reportable
12 event as well is something I think that we
13 should at least take into consideration.

14 Leah?

15 MEMBER BINDER: Just to go back on
16 the point about the language "an emergency
17 basis" or patient consent, I agree that that
18 should be removed. I just want to make the
19 point of why.

20 I think that this should be based
21 on the harm to the patient. It should be a
22 patient-centered experience. So, if a patient

1 has wrong site surgery, they don't care
2 whether it happened in the emergency room or
3 outpatient, it is a catastrophic event in your
4 life and in your family's life.

5 So the burden should be on the
6 providers to report it and to prove that it
7 couldn't have been prevented.

8 CO-CHAIR MEYER: Well said. Okay.

9 Any other comments on this? This
10 is terrific.

11 Again, we are providing our input
12 into the process. Others will have the same
13 opportunity.

14 Mike, before we leave this one?

15 MEMBER VICTOROFF: This is
16 microscopic on D. The way we state leaving
17 foreign bodies in people is a foreign body --

18 CO-CHAIR MEYER: Let me go
19 through.

20 So I am not sure we are done. But
21 we will pull up 1B here.

22 1B, again, I think some of these

1 changes carry through to all of the surgical
2 procedures.

3 Anything else that we want to add
4 to 1B again? Changes to procedure --

5 MEMBER VICTOROFF: Okay, B is
6 wrong because it shouldn't have anything to do
7 with documented informed consent. It should
8 be the patient's clinical indication.

9 CO-CHAIR MEYER: Right.

10 MEMBER RYDRYCH: And that same
11 thing is on the first one, but we didn't talk
12 about it.

13 MEMBER VICTOROFF: Right Yes,
14 exactly. Those both should be changed because
15 the question -- it is not that that is a
16 question, but that is another question.

17 CO-CHAIR MEYER: Right. So, if
18 the patient signed off and said, "My informed
19 consent says go ahead and remove my right
20 hand," and actually the right thing to do is
21 the left hand, but you remove the right hand,
22 you still did the wrong thing.

1 MEMBER VICTOROFF: But it should
2 be the patient's indication.

3 CO-CHAIR MEYER: Yes.

4 MEMBER VICTOROFF: And then we
5 have like let's put that on the list of
6 possible things to add to defects in the
7 informed consent, which is another topic for
8 another day.

9 CO-CHAIR MEYER: And again, I
10 think if we enjoin that conversation, we would
11 want to pull up the safe practices when that
12 comes because I think they cover that pretty
13 well.

14 Other comments on surgery or
15 procedure performed on the wrong patient?

16 Again, many of these roll through
17 all of the procedures, the comments that you
18 just made, which is great.

19 MEMBER VICTOROFF: Does this also
20 comprise identity theft? I don't want to
21 contaminate it, if it is unwanted, but we have
22 a large number of people who use false

1 credentials or identification to obtain
2 medical services by fraud.

3 CO-CHAIR MEYER: Yes.

4 MEMBER VICTOROFF: Or, you know,
5 never mind the fraud; they are pretending to
6 be their cousin because they've got a Medicaid
7 card.

8 CO-CHAIR MEYER: Yes.

9 MEMBER VICTOROFF: Whether we
10 include that anecdote in this or not doesn't
11 matter to me, but we should specify whether it
12 is.

13 CO-CHAIR MEYER: So let me just
14 say, to put some color commentary on that, we
15 had a situation six months ago, or about six
16 or eight months ago. We had a patient come in
17 with appendicitis and ended up bringing that
18 patient to the operating room.

19 Before the patient underwent the
20 procedure, we discovered that there was a
21 mismatch between our blood specimen then and
22 the prior blood specimen. I mean while they

1 were ordering the ABO-compatible blood, and
2 that was how we discovered it was her cousin's
3 insurance card. Fortunately, they didn't have
4 the same blood type for them.

5 I would argue that maybe -- and
6 this is a real issue; this is as real as any
7 of the other criminal events there. And, boy,
8 there are lots of good reasons for it. These
9 are people who are desperate. They don't have
10 insurance.

11 But, with that said, one could
12 think that maybe that is something, a place
13 where we would want to expand the criminal
14 list. It is a tough thing to raise.

15 MEMBER VICTOROFF: Can I intensify
16 that, just one more anecdote?

17 CO-CHAIR MEYER: It's tough.

18 MEMBER HOEN: This is a big can of
19 worms.

20 CO-CHAIR MEYER: It is. This is
21 going right up against CMS HIPAA Red Rules.

22 MEMBER HOEN: Yes, and this is a

1 bigger issue than I think that we can possibly
2 tackle.

3 I've got information that shows
4 the number of people who access healthcare,
5 primarily, 85 percent of them, with made-up
6 Social Security numbers. I don't consider
7 that to be identity theft or fraud. They are
8 simply trying to access healthcare. They
9 think that they can't get it unless they give
10 that number because that is the first thing
11 that they ask when they walk in the door.

12 So I think this is a big can of
13 worms. It has to be addressed. There are
14 specific instances like you have just talked
15 about. I have only had that happen a couple
16 of times, where they actually presented
17 somebody else's insurance card or
18 identification.

19 More often than not, it is
20 illegals trying to access healthcare with
21 made-up Social Security numbers.

22 MEMBER MORLEY: Ditto in New York.

1 CO-CHAIR MEYER: Yes.

2 MEMBER MORLEY: Ten years ago, I
3 ran the pre-anesthesia screening clinic, and
4 we encountered it. I think it is a very real
5 problem, but I would like to see this clearly
6 more clinical, more adverse event, quality,
7 safety. And while those are very real issues,
8 I would certainly agree that I don't think it
9 is appropriate for this purpose.

10 CO-CHAIR MEYER: Okay. Let's move
11 on to the next one.

12 This is the wrong procedure
13 performed on a patient. And again, we have
14 put in the caveats there about getting rid of
15 the exclusions and broadening the definition
16 of procedures.

17 Any comments?

18 MEMBER VICTOROFF: Get rid of the
19 informed consent.

20 CO-CHAIR MEYER: And get rid of
21 the informed consent piece, yes.

22 MEMBER RYDRYCH: Yes, I think that

1 has some implications for the implementation
2 guidance, too, in terms of what you are saying
3 about where surgery begins or when surgery
4 begins or when it ends, not just changing it
5 to say surgery or invasive procedure, but
6 there are other ways you would probably want
7 to specify that as well.

8 CO-CHAIR MEYER: Do you have any
9 ideas about how we can prime the pump to get
10 input on that? Diane?

11 MEMBER RYDRYCH: I don't know
12 because that is one we are really struggling
13 with in Minnesota right now, is when does a
14 procedure end, and we have been going back and
15 forth on that for a long time.

16 CO-CHAIR MEYER: We are as well.

17 MEMBER RYDRYCH: So I don't really
18 have an answer.

19 MEMBER VICTOROFF: Just to add
20 something, this is a poisonous complication
21 here. I don't know what to do with it.

22 But, in our taxonomy, we have

1 several categories of you didn't do the right
2 thing here. Sometimes it is because of a
3 clinical judgment where you chose, you
4 deliberately chose a procedure, but it wasn't
5 under guidelines or standard of care the
6 correct procedure for the indicated condition
7 or it was obsolete, or you shouldn't have made
8 that -- that was the wrong approach to take to
9 the organ. I mean there's a lot of fuzziness
10 under this where you could say, well, that was
11 the wrong procedure, like you should have done
12 a two-level fusion, you know, and what you did
13 was a -- and I am not sure we want to capture
14 the clinical nuances of judgment here.

15 And I am not sure that this
16 language actually articulates the other thing
17 that we do want to capture, which is you came
18 down for a shoulder reduction, and you got a
19 knee reduction, because we're dumb.

20 CO-CHAIR MEYER: Yes, I think it
21 raises on general issue. I am going to let
22 Stan respond to this as well.

1 One general issue is, and some of
2 us talked about this during one of the breaks,
3 we are never going to come up with the perfect
4 list. There are always going to be
5 conversations between people like myself and
6 healthcare organizations, people like Stan,
7 and the Commonwealth of Massachusetts, about,
8 is this right or not?

9 So we can't get rid of the
10 discussions. I think trying to get rid of as
11 much ambiguity, using the word again, as we
12 possibly can is great, but we are not going to
13 get to zero. So thinking it makes it so.

14 MEMBER DORON SCHNEIDER: The way
15 the language is, it says, "The event is
16 intended to capture the insertion of the wrong
17 medical implant into the correct surgical
18 site." That's a little different.

19 CO-CHAIR MEYER: Yes, it is a
20 little different. I can tell you the
21 specifics, the specific issue that came up
22 that led to that language. It has to do with

1 the wrong intraocular lens, the wrong strength
2 of intraocular lens being inserted. You know,
3 you have a cataract extraction on the left
4 eye. Yes, they did the left eye, but they put
5 the wrong lens in. That is why that added
6 language was there.

7 MEMBER RYDRYCH: And I would just
8 say, from our perspective, we have certainly
9 had that case, that type of case, a number of
10 them, which we have considered a wrong
11 procedure. We have also had patients who
12 specified a saline breast implant and got
13 silicone. And we have had cases with
14 orthopedic procedures where it was the wrong
15 material. Someone had an allergy to a certain
16 type of material, and then a different kind of
17 implant or different size was put in. To us,
18 it falls into that category and reflects a
19 breakdown in the system.

20 DR. ANGOOD: And in the data
21 collection systems out there, orthopedics,
22 ophthalmology, device-oriented specialties are

1 the ones that lead the list in terms of these
2 types of wrong-sited -- wrong surgeries.

3 Sorry.

4 CO-CHAIR MEYER: Other comments on
5 this one?

6 (No response.)

7 Can we move to D? So this is
8 retention of a foreign object in a patient
9 after a procedure. We just shortened that.
10 We just get to after a procedure.

11 MEMBER VICTOROFF: We use the
12 language "foreign body unintentionally" left
13 in a patient after a procedure.

14 CO-CHAIR MEYER: Right. So there
15 are many times they leave --

16 MEMBER VICTOROFF: Yes, we leave,
17 deliberately leave pacemakers in and stuff,
18 but -- yes, we would just move the language
19 from the right column to the left column, to
20 be part of the definition.

21 CO-CHAIR MEYER: In that center
22 column, are those the additional specs?

1 DR. ANGOOD: Yes, equivalent.

2 CO-CHAIR MEYER: Yes. This is a
3 little bit of NQF inside baseball. But, in
4 fact, the actual piece of this that applies to
5 the National Technology Transfer and
6 Advancement Act is both the definition and the
7 additional specifications.

8 So, if you are seeing it in the
9 first two columns, it is, essentially, that is
10 the stuff you have to do. People will
11 sometimes shorten it just to the definitions,
12 but the real meat is in the combination of the
13 two.

14 MEMBER RYDRYCH: And I would just
15 say, again, on the guidance or on further
16 defining it, being specific about labor and
17 delivery I think is important here because
18 that is an area where we have seen a lot of
19 retained objects, and a lot of people don't
20 consider vaginal deliveries to be invasive
21 procedures, but we do.

22 The other area that I think we

1 want to be clear on is device fragments and
2 things that break off inside the body.
3 Sometimes we find that people don't consider
4 them to be those, like, you know, a catheter
5 sheath or something else to be a retained
6 object. And maybe it just needs to be
7 clarified a little bit in the implementation
8 guidance because I think people tend to think
9 of sponges and clamps and not much else there.

10 CO-CHAIR MEYER: So I think that
11 that's --

12 MEMBER RILEY: I was going to say,
13 the other thing is, with all the laparoscopic
14 things, you know, pieces of staplers or things
15 like that, that get left in, even though the
16 whole instrument is pulled out, and they don't
17 see it until two or three days later, whenever
18 they check. So that is huge.

19 CO-CHAIR MEYER: Okay. Doron?

20 MEMBER DORON SCHNEIDER: Well,
21 there is language exactly to that. It is
22 right there. It says excludes that, "objects

1 not present prior to surgery that are
2 intentionally left in, when the risk of
3 removal exceeds the risk of retention, such as
4 microneedles or broken screws." Doesn't that
5 capture that?

6 CO-CHAIR MEYER: Not exactly.

7 MEMBER DORON SCHNEIDER: It is an
8 exclusion.

9 CO-CHAIR MEYER: Yes, I think the
10 classic example would be a patient comes in
11 and has an epidural block done. The catheter
12 sheath shears, and they are left with a piece
13 of catheter in them. I mean it is actually
14 something that you don't want to leave behind.

15 MEMBER HOEN: We have actually had
16 a couple of cases where it was wound packing
17 that was left in a patient, and the wound
18 closed over it, and later had to go back and
19 extract it.

20 So I would suggest that that
21 should be an area also --

22 CO-CHAIR MEYER: That is.

1 Can we talk about this microneedle
2 issue? So the point here is that, as many of
3 you know, some of the needles that we use are
4 literally you need almost a microscope just to
5 see them. They are incredibly small.

6 If the needle count is off at the
7 end of the procedure, you have to ask yourself
8 a question: do you go on a safari in
9 somebody's abdomen to try to literally find
10 the needle in a haystack or do you leave it
11 behind?

12 And if you do leave it behind, is
13 it a serious reportable event or not? And I
14 know what the language says here, but, to my
15 mind, the failure in terms of a lesson
16 learned, it is the process broke down. You
17 left something behind. But that may be a
18 little bit too harsh.

19 MEMBER DORON SCHNEIDER: But if
20 there's no harm?

21 CO-CHAIR MEYER: It is hard to
22 know. What the surgeons will say is, they'll

1 say, "Boy, some of these things are as small
2 as the staples we leave in people, not a big
3 deal."

4 So I would love to get a sense of
5 the Committee. I am not sure where I am on
6 it. I think I am more leaning on these are
7 serious reportable events still because we've
8 got to learn from them, but maybe I am off the
9 ranch on this.

10 So I want to hear from Stan and
11 from Diane.

12 MEMBER RILEY: I guess I sort of
13 agree with a piece of that. Certainly, 70 and
14 80 needles, if you are doing coronary, for
15 instance, gosh, they are hard to find even in
16 the pericardium when you are looking straight
17 at it.

18 MEMBER GANDHI: Yes, and our
19 surgeons tell us that a lot of them get sucked
20 up in the drains and things like that, and you
21 just never find them. So you don't even know
22 that you have left it behind.

1 CO-CHAIR MEYER: So what I am
2 trying to parse out here is, clinically, you
3 can make a very rational decision and say, the
4 benefit of taking it out isn't worth the risk
5 of trying to go and find it. But you decide
6 not to take it out. You close the patient up.
7 Is that a serious reportable event or not?

8 MEMBER GANDHI: Right, and you
9 could make an argument that that was
10 deliberately left in or left hanging,
11 depending on how you want to phrase it.

12 CO-CHAIR MEYER: But your needle
13 count was off.

14 MEMBER GANDHI: Yes, the needle
15 count was off, but, again, they are saying
16 they may or may not be in the patient. They
17 could be anywhere.

18 MEMBER BRENNAN: You don't know
19 for sure.

20 CO-CHAIR MEYER: Yes, and these
21 are so small. You are talking about a 70
22 needle. Finding a 70 needle in somebody's

1 chest with a radiograph, even with a CT scan,
2 is not easy. You can't do it.

3 MEMBER GANDHI: It is not
4 possible.

5 DR. ANGOOD: Do you inform the
6 patient, too?

7 CO-CHAIR MEYER: If it is me, you
8 are.

9 DR. ANGOOD: If it is an adverse
10 event, are they going to worry about it?

11 CO-CHAIR MEYER: No, this is what
12 makes it fun.

13 So, Diane, what is your
14 experience?

15 MEMBER RYDRYCH: Well, I think
16 this is exactly the question we have been
17 struggling with, actually. Because we want to
18 not penalize people if their process worked
19 and they identified that the object was likely
20 to have been retained before the surgery was
21 over. That means their process did the right
22 thing, and we don't want to punish that.

1 We do exclude microneedles and we
2 exclude things from reportability if, for
3 example, in the case of a broken pin during a
4 hip procedure, if you discover that it broke
5 off before you closed, and you made a decision
6 I am not going to take it out because it is
7 not going to cause any harm or it will just be
8 too tough on the patient to take it out. We
9 don't consider that to be reportable. Your
10 process worked. You identified that it was
11 retained beforehand.

12 CO-CHAIR MEYER: So, getting to
13 Peter's point, my needle count is off. I say
14 I'm missing a 70 needle; we're going to close
15 up.

16 MEMBER RYDRYCH: That is the exact
17 question we have been struggling with. We
18 have hours of phone calls with hospitals and
19 the hospital association and the health
20 department about this just over the last
21 couple of weeks, trying to decide if there was
22 something -- you think it was possibly

1 retained. Maybe you have to leave the OR to
2 get a better image, and then you have to come
3 back in. Does that count as being retained or
4 not? To be honest, we don't have the answer.
5 I lean towards saying yes.

6 CO-CHAIR MEYER: Let me hear from
7 P.J. Do you want to jump in here?

8 MEMBER BRENNAN: No, go ahead.

9 CO-CHAIR MEYER: Michael?

10 MEMBER VICTOROFF: Let's not
11 confound, again, the problem of whether there
12 really is a good remedy or whether it is
13 actually excellent medical judgment to proceed
14 a certain way.

15 And the other totally separate
16 problem, whether this is information that we
17 or some other patient in the future might wish
18 to capture for epidemiologic purposes or
19 safety purposes.

20 And I, as the person in the
21 recovery room, have the right, I would to say,
22 to hear that you made a judgment in my behalf,

1 and it is almost certainly right because you
2 are a genius. And this little piece of
3 needle, first of all, it is probably up in the
4 suction somewhere, and in our study of
5 thousands of people where we reported this and
6 tracked it, these were the outcomes. So this
7 is what I have to tell you about it because we
8 have tons of information about it, and that's
9 why I know I made the right decision.

10 On the other hand, we could simply
11 say, "Don't worry, honey. Some stuff
12 happened, but I did all the right things
13 because I am a really smart surgeon, and you
14 don't have to worry about us reporting what
15 you don't know about because it probably isn't
16 relevant."

17 So pick one.

18 CO-CHAIR MEYER: John, and then
19 our surgical friend to my right. John?

20 MEMBER MORLEY: I would lean very
21 clearly toward saying it was a reportable
22 event because I would want to know about it

1 myself as a patient. I would want to be able
2 to track it.

3 It would concern me a great deal
4 if half the hospitals in my State had it
5 happen once or twice, and there's another
6 hospital, one hospital, that it happened 47
7 times. So that is one value to tracking it.

8 There's another value. I think
9 the patient needs to know about it. I think
10 it could potentially be a very interesting
11 finding for the next surgeon that comes into
12 that abdomen who gets stuck with it.

13 MEMBER RADFORD: Just to clarify
14 my own thinking on this -- this is Martha
15 speaking -- you know, the goal of these
16 reportable events is to report and to form
17 kind of a database around things that are
18 reported.

19 I mean, to me, some of this is
20 edging toward health services research, which
21 is not a bad thing, and maybe that is one of
22 the goals of these reporting requirements.

1 So I just want to hear other
2 people's points of view on that.

3 DR. ANGOOD: This is Peter Angood.

4 That is a good point, Martha. My
5 comments are, you know, there's, again, a
6 spectrum of need here. Certainly, on a case-
7 by-case basis, you can make an argument for
8 saying, "Well, it is this little, wee, bitty
9 needle, and it is too much fuss to go and find
10 it, and it is not going to bother the patient
11 anyway. So we will just move on past."

12 But you want to make sure, still,
13 that there are processes in place to serve as
14 a checking mechanism that things are actually
15 being done. If the processes aren't in place,
16 then slippage occurs.

17 So I think it is important to have
18 this as part of the process check. The
19 outcome patient-by-patient may not make much
20 difference.

21 I think the point about the
22 greater good and collecting the information is

1 pivotally important, as well as the patient
2 outcomes, in terms of the knowledge base.

3 MEMBER RADFORD: Yes, I would just
4 urge people to be somewhat evidence-based here
5 and to be sure that we have some evidence
6 that -- I mean I am just picking on these
7 small needles just because people complain to
8 me about it.

9 We have some evidence that there
10 is, you know, harm and that something can be
11 done about it. I don't know. I mean the
12 person, the organization that reports one a
13 year versus 47, they could just not even be
14 counting. In fact, I have heard about
15 organizations that stopped counting.

16 CO-CHAIR MEYER: Yes, I think that
17 that point is an important one.

18 One thing I would argue is that
19 the policies and procedures that you have that
20 will mitigate the risk of leaving something
21 small behind, one would hope would have some
22 impact on your risk of leaving something more

1 significant and potentially harmful behind.

2 So one of the real things that we
3 struggle with in safety science is no harm, no
4 foul, which is kind of a classic way to think,
5 and sometimes you get yourself in trouble if
6 you say, boy, they weren't harmed; we don't
7 really need to pay attention to it. In fact,
8 the next time it happens, it happens
9 differently, and the Swiss cheese is lined up
10 worse, and it hurts somebody badly.

11 Doron?

12 MEMBER DORON SCHNEIDER: So, when
13 this was written, this was excluded. You say,
14 "Objects not present prior to surgery that are
15 intentionally left in when the risk of removal
16 exceeds the risk of retention, such as
17 microneedles or broken screws."

18 Now I would argue that we should
19 take that exclusion out because it is now
20 ambiguous. We should make it unambiguous, so
21 that if you start a surgery, you have intended
22 things that you leave in. If there's anything

1 that is unintentionally left in, it gets
2 reported. That is unambiguous.

3 CO-CHAIR MEYER: And the patient
4 gets informed?

5 I am sure, by the way -- again, we
6 are just part of this process. So, whatever
7 input we have on this, we will certainly be
8 hearing from the American College of Surgeons
9 and the Society of Thoracic Surgeons, and
10 others, during the public comment period.

11 Leah?

12 MEMBER BINDER: There's two issues
13 with this, too. There's whether or not a
14 small needle, whether it was left in or not.
15 Then whether it is appropriate for a surgeon
16 to respond in one way or another, whether it
17 is responsible to search for it, and all of
18 that.

19 But this document is getting at,
20 was there harm done? Was something serious
21 done? Not what was the clinical remedy and
22 whether that is appropriate. In other words,

1 the harm to the patient in this case of
2 leaving a small item in is harm to the
3 patient, period, regardless of the fact that
4 it might not have been feasible or clinically
5 appropriate to try to remove the needle.

6 CO-CHAIR MEYER: And let me remind
7 folks that one of the things we did with that
8 definition this morning, which we did say that
9 there were some close calls that were
10 important enough that they ought to be
11 considered here.

12 John, and then I think we will
13 move on after this. It is a great discussion.

14 MEMBER MORLEY: I wanted to agree
15 with what Doron had said, that taking that out
16 would be a good thing.

17 If I may ask a very quick question
18 for personal -- we have an argument going on
19 in New York. If a thoracic surgeon does
20 thoracic surgery, closes the patient. The
21 patient goes to the ICU, and the following day
22 goes to remove the pulmonary artery catheter

1 and can't, and learns it has been sewn in, is
2 that a retained foreign body?

3 MEMBER RILEY: I guess I think the
4 answer to that one is yes, mostly because, as
5 a thoracic surgeon, you know, you can staple
6 across the pulmonary artery and you can see
7 the Swan-Ganz catheter in the artery. So the
8 answer is you probably know that it is there,
9 and you should do something about it. So I
10 would say yes.

11 MEMBER MORLEY: By the way, Dr.
12 Ganz passed away two days ago.

13 CO-CHAIR MEYER: It's not easy.
14 There will be discussions, no matter what we
15 say. There will be some interesting
16 discussions.

17 Leah, and then P.J.

18 MEMBER BINDER: Just a quick
19 point. I can't read the comments that are
20 being typed. I just want to make certain.

21 Diane made a point that I think we
22 should definitely include in this, and I don't

1 know if it is there or not. It is about
2 objects left, vaginal deliveries and the
3 objects left in. That is a very important
4 point that I want to make sure we keep mindful
5 of.

6 CO-CHAIR MEYER: Okay. P.J.?

7 MEMBER BRENNAN: Gregg, I just
8 want to come back to my earlier point. The
9 reporting here would occur on discovery, not
10 on miscount.

11 CO-CHAIR MEYER: Right.

12 MEMBER BRENNAN: So, at the end of
13 a case, if you have a miscount, that is not
14 the basis for a report.

15 CO-CHAIR MEYER: It isn't, and I
16 think it really gets to one of the scarier
17 aspects of all of this. That is, if we say,
18 yes, these are reportable, are people going to
19 stop doing counts of microneedles? And the
20 world can respond in perverse ways.

21 MEMBER BRENNAN: There are a lot
22 of things that aren't counted that can be left

1 behind.

2 CO-CHAIR MEYER: Absolutely.

3 MEMBER BRENNAN: Sheaths.

4 MEMBER RILEY: So I was just going
5 to say that, in part of the vaginal delivery
6 piece, almost all those sponges in the past
7 have not been radiopaque, so that they
8 couldn't be seen.

9 One of the changes that we have
10 seen, at least in Massachusetts, is now they
11 have changed to using the ones that are
12 radiopaque. So I think just knowing that has
13 made an important difference.

14 CO-CHAIR MEYER: Let's move on.
15 So I think we've got some good comments that
16 are going to stir up some reaction from the
17 field.

18 If we can move on to 2?

19 As a process check, just so people
20 recognize it, we are required to have a period
21 of public comment. My understanding is there
22 are no public commentators in the room.

1 Are there any on the phone?

2 (No response.)

3 No public commentators on the
4 phone.

5 DR. ANGOOD: Operator, could you
6 just check and see if there are any open
7 lines, other than the individuals who are part
8 of our Committee?

9 THE OPERATOR: There are none.

10 DR. ANGOOD: Thank you very much.

11 CO-CHAIR MEYER: So what I am
12 proposing that we do is we actually roll
13 through as many of these as we possibly can.
14 I would like to hold close to our adjournment
15 time. I am hoping we can have maybe 15
16 minutes or so to run over a bit, to get
17 through more of these. We will need to go
18 through the rest of these tomorrow morning.
19 This is important work for us to get through
20 today.

21 So if we can go to 1E? And this
22 is one, again, that there was some discussion

1 on. First of all, for those of you, just to
2 make sure everyone is onboard, ASA, American
3 Society of Anesthesiologists, Class 1, these
4 are the lowest-risk patients. These are
5 patients who generally are relatively healthy
6 going into their procedure.

7 So, Diane?

8 MEMBER RYDRYCH: And I am not
9 going to comment on that because I think I
10 already made my vote for expanding it beyond
11 ASA Class 1.

12 But I think what has always been a
13 little confusing for me about this one is,
14 when you look at the implementation guidance,
15 it is not clear whether this is really
16 intended to just capture anesthesia-related
17 events or if it really is unanticipated deaths
18 during or after surgery due to other factors.

19 Because the discussion is mostly
20 about anesthesia and it is intended to capture
21 events after administration of anesthesia,
22 whether or not the planned surgical procedure

1 was carried out. So I think there is some
2 confusion there about what the intent was,
3 whether we are really trying to capture
4 reaction to anesthesia or deaths associated
5 with the anesthesia as opposed to the broader
6 category of surgical deaths that may or may
7 not have been associated with the anesthesia.

8 DR. ANGOOD: My sense is that it
9 has been primarily designed towards the
10 anesthetic-related deaths in otherwise healthy
11 individuals, but it can be complicated.

12 CO-CHAIR MEYER: Stan?

13 MEMBER RILEY: So I guess I was
14 going to say that the ones that we have had
15 reported to us, almost all of them have been
16 from C-sections. The mother is an ASA 1, and
17 then the procedure ends up a disaster, and
18 there's a death or some serious disability, a
19 hysterectomy. So those are the ASA 1's we
20 went through.

21 MEMBER RYDRYCH: Yes, and I will
22 just say we haven't had very many of these

1 reported, but the ones that we have had
2 reported have not all been anesthesia-related,
3 which is an argument for clarifying I think.

4 CO-CHAIR MEYER: Doron, and then
5 John.

6 MEMBER DORON SCHNEIDER: Just a
7 question about, is there overlap here between
8 this one and death associated with medical
9 error, in a sense of PCA errors around
10 C-sections? I just throw that out there as,
11 could that fall into two categories?

12 CO-CHAIR MEYER: Potentially, yes.
13 John?

14 MEMBER MORLEY: I agree with Diane
15 that I would suggest that it be expanded from
16 ASA Class 1, which, by definition, is somebody
17 that takes no medications and is healthy, to
18 include ASA 2's. I would hope that it would
19 go as far as including anyone that has had an
20 elective procedure.

21 I am just reviewing in my mind, I
22 have been reviewing our codes for unexpected

1 death in New York State recently. So I am
2 thinking we have had a number of cases of
3 patients that have had a hemorrhage and died
4 of surgical complications, hemorrhage, died
5 within 24 hours.

6 And finally, the same comments
7 that have been made about procedure before, so
8 that it is clear that this includes endoscopy,
9 should be considered.

10 CO-CHAIR MEYER: And
11 interventional radiology.

12 MEMBER MORLEY: Correct. Yes.

13 CO-CHAIR MEYER: Other comments on
14 this one?

15 I am sure we will hear a great
16 deal of feedback based on these comments from
17 the field as well.

18 MEMBER TANGALOS: Well, have the
19 radiologists and the endoscopists been getting
20 a free pass on this? Or are they being
21 reported now anyway?

22 CO-CHAIR MEYER: You know, my

1 guess is that varies state to state. I can
2 tell you in the Commonwealth of Massachusetts,
3 if we had a patient who died immediately post-
4 endoscopy, and Stancel Riley didn't hear about
5 it, Gregg Meyer would be hearing from Stancel
6 Riley.

7 But I don't think that that is --
8 and again, this would make it a little bit
9 more universal, getting to one of the points
10 you made earlier, that getting some uniformity
11 across states has a value of its own.

12 MEMBER RYDRYCH: Yes.

13 MEMBER MORLEY: In New York, the
14 answer to that would be there's variation from
15 institution. Some institutions, clearly
16 indicated surgery, and some are better
17 reporters than others.

18 CO-CHAIR MEYER: I think the
19 notion of expansion will be provocative, and
20 let's see what we hear.

21 Diane?

22 MEMBER RYDRYCH: Well, just one

1 other comment on anesthesia. You know, when
2 I look at the implementation guidance, I
3 actually don't even remember ever seeing that
4 before, the associated with administration,
5 anesthesia, whether or not the planned
6 surgical procedure was carried out. And I
7 probably just missed it over the years.

8 But that is something that I would
9 be amazed if that was ever really reported.

10 I mean that is going to be a very, very rare
11 event, but I don't think there's clarity about
12 that; that if anesthesia were administered,
13 the surgery never happened, the patient died.
14 I don't think there would be understanding of
15 that as a reportable type of event.

16 I don't know. Do you, John?

17 CO-CHAIR MEYER: So we may want
18 some clarifying.

19 MEMBER RYDRYCH: It would be?

20 CO-CHAIR MEYER: Yes.

21 MEMBER RYDRYCH: Well, maybe that
22 is just us then. We need to clarify that.

1 CO-CHAIR MEYER: So we get some
2 clarifying language there.

3 As soon as Jennifer is done typing
4 that one out, we will move to No. 2, product
5 or device events.

6 Again, I open it up for comments
7 here.

8 Stan?

9 MEMBER RILEY: So I guess this
10 brings up something that is being done now for
11 breast reconstruction following surgery for
12 cancer. There is a non-sterile biologic
13 called Alloderm. Alloderm is used to make
14 just a much nicer result, but it is an
15 unsterile product.

16 One of the things that has
17 happened with the use of this product is the
18 number of breast infections have gone from
19 about 6 percent to about 20-odd percent. So
20 it is one of those things that you go, ooh,
21 wow, that's important to know about.

22 So I think this is a really

1 important area for picking up things that you
2 are not sure about until you just sort of see
3 them and they go, oh, wow, this is bad.

4 CO-CHAIR MEYER: And did those
5 come to you under this SRE?

6 MEMBER RILEY: No, actually, they
7 didn't come to us under this SRE. They came
8 to us under sepsis. Whenever we saw what the
9 real problem was, we, then, reclassified them
10 as this.

11 CO-CHAIR MEYER: Other comments on
12 this one?

13 MEMBER MORLEY: Question? I don't
14 know how this is interpreted in terms of a
15 fairly relatively common issue across the
16 country, which is IMED or IVAC infusion pumps
17 and errors with that. Do you get those
18 reports, do you think, with this?

19 I think it happens more commonly
20 than we see those reports, just because it is
21 not always thought of. In terms of the
22 reportable events, one of the things that I

1 have said in defense of hospitals is that
2 there's only a certain number of reports that
3 they can keep track of with the resources that
4 they have as well as we have. So I am not
5 sure that is one of the ones that is enough of
6 a priority that people actually appreciate it.

7 You know, even if we came up with
8 a list of 100 things, I don't think hospitals
9 could come up, any healthcare facility could
10 come up with the resources to track and find
11 all of those events that happen.

12 MEMBER PHILIP SCHNEIDER: John, is
13 that related to infections or is that related
14 to dosage errors?

15 MEMBER MORLEY: Dosage errors.

16 MEMBER PHILIP SCHNEIDER: Because
17 that would fall under SRE 4A, I would think.

18 CO-CHAIR MEYER: Yes, if you had
19 death from --

20 MEMBER MORLEY: Well, I am
21 thinking it is both, actually, but it is a
22 dosage issue. You know, as the pumps have

1 gotten smarter and people rely on them more,
2 they just sort of -- things happen.

3 CO-CHAIR MEYER: Yes, Michael?

4 MEMBER VICTOROFF: Could I ask how
5 attached we are to the term "serious
6 disability"? I am not sure that completely
7 captures stuff like 300 people in Denver that
8 were exposed to hepatitis C because a nurse
9 was diverting Demerol and she used
10 contaminated needles, and several of those
11 people are going to get hepatitis C. I don't
12 know if everyone is going to agree that
13 getting hepatitis C is a disability.

14 Or a person who was put in a coma
15 and sent to ICU because of a morphine dose who
16 came out fine. They didn't die. They weren't
17 disabled. They came fine. They spent three
18 days in ICU on a vent.

19 So do you guys call those
20 disabilities?

21 MEMBER RYDRYCH: That is a can of
22 worms, too, though. I mean that is something

1 we have worked on a lot, is trying to define
2 what serious disability means, and we do have
3 a whole algorithm for people to work through.
4 You know, was there a fracture? Was there a
5 head injury? Was the person transitioned to
6 a higher level of care for 48 hours or more?
7 Did it affect activities of daily living for
8 seven days or more? So we have a whole bunch
9 of criteria that we look at.

10 Whether we capture hep C,
11 something like that, I honestly don't know if
12 that would be captured there, but I think that
13 is one of the challenges for the states that
14 do this, is trying to figure out what exactly
15 some of those terms mean. We probably all do
16 it just a little bit differently, I would
17 imagine.

18 CO-CHAIR MEYER: On this in
19 particular, I would actually ask for John,
20 Diane, Stan, and for you to talk to your
21 colleagues and some of the physicians around
22 the country.

1 But to the extent that you have
2 operationalized certain definitions to help
3 people work through algorithms to say, yes,
4 this is -- so my answer to both of yours would
5 be, in our institution, yes and yes, that we
6 would consider those to be reportable.

7 But I think that it would be great
8 to get them into the NQF and get those part of
9 it. It sounds like they may be very valuable,
10 and we want to learn from your experience. To
11 the extent that we can codify it as additional
12 specs here, or even field guidance, it would
13 be terrific.

14 DR. BURSTIN: And actually, one of
15 the criticisms we have gotten about the SREs
16 over the years is their lack of specificity.
17 So I think if there is a way for us to add the
18 specifications, not just guidance, but the
19 actual specifications, I think, again, why
20 does every state have to reinvent that? Why
21 does Leapfrog have to reinvent that each time?
22 That should be what is value-added of NQF.

1 MEMBER RYDRYCH: Well, too, I
2 think even the term "serious disability" is
3 sometimes problematic, and we sort of try to
4 move toward serious injury sometimes.
5 Particularly with falls, we have had cases
6 where -- one example, and it seems far-
7 fetched, but it was true, was a case where
8 someone was a paraplegic and was in a
9 wheelchair, fell out of the wheelchair, broke
10 a hip. It didn't actually affect their
11 activities, the broken hip, but it was a
12 serious injury to the patient.

13 So, depending on how you define
14 disability in terms of limiting someone's
15 activities, if their activities were limited
16 ahead of time, I would argue, absolutely, that
17 is still a serious harm, a serious disability.
18 But there were some who argued against it. So
19 that becomes a difficult area, too, sometimes.

20 MEMBER VICTOROFF: Well, the
21 reason I raised that, and this may not be a
22 discussion you want to have, but serious

1 disability doesn't do for me what serious
2 health impact does or serious health
3 consequence.

4 Let me just give you one, not on
5 this subject, example, but it speaks to
6 disability. I once lost a breast biopsy
7 specimen from a woman. I just did a breast
8 biopsy, and the courier put it on the roof of
9 their car and drove away, and they and a lot
10 of other tubes and stuff -- the woman never
11 found out if she had or didn't have a normal
12 breast biopsy.

13 The impact on her was significant
14 because we changed her plan of care and we did
15 surveillance and all that kind of stuff. But
16 no one could say whether she actually had
17 cancer there or not. So we really wouldn't
18 know for years whether she had a disability.

19 So I want to capture weird stuff
20 like that, and the hepatitis C and the broken
21 hip, and the things that I would call profound
22 health impact, life-changing impacts, that

1 really I don't think even a generous English
2 professor would call them disabilities.

3 CO-CHAIR MEYER: And I think, you
4 know, if you look at the actual report from
5 the NQF, you will see that there are box
6 definitions of things like disability. But
7 the reality of it is that, when this gets out
8 into the field, there's a lot of -- and so I
9 think to the extent that we can try to not
10 only refine the list of SREs, but really to
11 try to work on the additional specs and make
12 them more user-friendly out in the field, I
13 think we would take a far step forward.

14 So, again, I would ask the folks
15 who are involved in this on the state side to
16 really help us out and give us whatever
17 materials you have, get them into the process,
18 because I think we will all be better off for
19 it.

20 DR. BURSTIN: And it sounds like
21 we have to at least define serious disability
22 since that's not defined in the report, and it

1 is in all the SREs.

2 CO-CHAIR MEYER: Yes.

3 Okay, the next one is patient
4 death or serious disability associated with
5 the use or function of a device in patient
6 care in which the device -- can you go
7 back? -- in which the device is used or
8 functions other than as intended.

9 So, Deborah?

10 MEMBER NADZAM: Okay, this might
11 be a little bit of a bizarre question on this
12 one, for what is not stated. I don't know if
13 this is where it belongs. And I don't know
14 the full outcome or number of cases that this
15 would happen in, other than I know it happens.

16 Adult equipment being used on
17 children. Well, I don't know how often it
18 lead to harm. I mean we know that adult
19 equipment on children doesn't work as well as
20 pediatric equipment on children.

21 MEMBER RYDRYCH: Does that fall
22 under 2B, using a device other than as

1 intended?

2 MEMBER NADZAM: That is why I am
3 asking. Yes, that is where we are, on 2B.

4 MEMBER RYDRYCH: I'm sorry.

5 MEMBER NADZAM: No, no.

6 CO-CHAIR MEYER: We are on 2B.

7 MEMBER VICTOROFF: Well, if they
8 died or got disabled, right, then it would
9 definitely come under this. But they just
10 used it and got away with it, and there was no
11 health situation --

12 MEMBER NADZAM: Well, yes, then,
13 right. Right.

14 MEMBER VICTOROFF: -- then they
15 wouldn't come under this. Are you saying --

16 MEMBER NADZAM: I guess I am
17 wondering about the need to call it out, to
18 pull out the issue of equipment.

19 MEMBER DORON SCHNEIDER: The
20 question of reportability and the risk
21 thereof, I mean this falls into the risk
22 thereof, even if they didn't have harm

1 associated with it. And that is the same that
2 goes with contaminated endoscopes, or whatever
3 the examples were before, you know, about the
4 disability. It is the risk thereof. They
5 were exposed to the biologic or the
6 contaminated device. So, even though it is
7 not currently a disability, they certainly
8 were exposed to a risk.

9 MEMBER NADZAM: Is it appropriate
10 to include it in comments, I guess is what I
11 am asking, because it is so underappreciated,
12 I think, that this could be a place to make a
13 statement about it, that it would include this
14 sort of misuse of equipment.

15 CO-CHAIR MEYER: Let me, just
16 before we hear from John, turn this on its
17 head a little bit or make it a little bit more
18 complicated.

19 There is the use of equipment for
20 imaging for adults on children, exposing
21 children to very high doses and inappropriate
22 doses of radiation. It is a real national

1 safety issue. Does that fall in here or not?

2 John?

3 MEMBER MORLEY: To your question,
4 I would say, if it happened at Cedars-Sinai,
5 yes.

6 (Laughter.)

7 Otherwise, probably not.

8 I think, to the question about
9 information that is reportable, if you go back
10 to the goal, the goal is to make things safer.
11 You know, every time you ask the question, it
12 comes up all the time because there are gray
13 cases.

14 You know, as Gregg was saying
15 earlier, we aren't going to eliminate some
16 level of discussion that is going to take
17 place.

18 But if the people in the
19 discussion ask the question, well, are we
20 trying to make things safer, will this
21 information cause people to learn and to make
22 changes, in the case that you are describing,

1 Deb, I would say, yes, I would clearly want it
2 reported. Then I would want to be able to put
3 that into an annual report, which we in New
4 York refer to as the "try annual report". We
5 try to annually put out a report.

6 (Laughter.)

7 And we have not been successful in
8 the last two or three years, but we are about
9 to be successful.

10 But putting that information out,
11 people will learn from that. I think they
12 will also learn the difference of whether it
13 has happened once or 21 or 31 or 101 times.
14 It will make a difference to them.

15 MEMBER RYDRYCH: And I will just
16 say, now that I have caught up to which event
17 we are on, I would say that would be
18 reportable for us as well, if it met that
19 threshold of death or serious disability.

20 But I just wanted to clarify
21 something that Doron said about risk thereof.
22 You know, we talked about how we were defining

1 these events to include death or disability or
2 risk thereof, but we are not saying that we
3 are applying that threshold of risk thereof to
4 each individual event, correct? Because that
5 would mean expanding all of these beyond death
6 or serious disability to include no harm and
7 near-misses. And that is not what we are
8 saying, right?

9 CO-CHAIR MEYER: No, but I think
10 we have the leeway, right, but we have the
11 leeway in specific instances to do that,
12 though.

13 MEMBER RYDRYCH: In specific
14 instances, yes. Okay.

15 CO-CHAIR MEYER: And move to 2C,
16 if we can.

17 MEMBER RYDRYCH: How do we
18 determine which ones we do that for?

19 CO-CHAIR MEYER: In this
20 conversation, based on the input from the
21 field. I think that will come.

22 DR. BURSTIN: I'm sorry. Just to

1 follow up with that, I am still not clear
2 because I did hear what was said, and it made
3 me think the same thing. So how do they all
4 begin with death or disability if we are
5 talking about a risk therein?

6 So we need to make -- I think it
7 would be helpful, rather than to do it on an
8 individual event basis, to actually have some
9 sort of principle, some logic of when you
10 would apply "or risk therein" because,
11 otherwise, it feels very haphazard.

12 CO-CHAIR MEYER: "Risk thereof".

13 DR. BURSTIN: Sorry. "Risk
14 thereof."

15 CO-CHAIR MEYER: Cynthia?

16 MEMBER HOEN: If you go back to
17 our first definition, it is what, preventable
18 -- I'll find it here -- "preventable, serious,
19 and any of the following: adverse", da-da,
20 da-da-da-da.

21 So why are we changing the
22 definition for the products issues as opposed

1 to the other issues that are listed? Because
2 now it is just death or serious disability
3 versus serious, which included the at-risk
4 issues.

5 CO-CHAIR MEYER: To my mind, I
6 think that Doron's comment is a provocative
7 one of saying, should we also do that for
8 this? I think that my interpretation of the
9 way the definition is written is that we have
10 the ability to consider close calls. I think
11 that Helen's is, well, we ought to have some
12 sort of principles about when we would do
13 that.

14 On the other hand, I also have a
15 sense that, right now, at least in the States
16 of Minnesota, New York, and Massachusetts, we
17 have probably taken away 50 percent of the
18 FTEs working on event reporting right now, and
19 that there is a certain workload that can be
20 accommodated as well.

21 So, to my mind, we can't make this
22 all inclusive.

1 MEMBER RYDRYCH: Considering that
2 we only have half an FTE in Minnesota, you
3 have lost twice as much as we have by meeting
4 here.

5 (Laughter.)

6 MEMBER PHILIP SCHNEIDER: You have
7 a full half?

8 (Laughter.)

9 CO-CHAIR MEYER: You two can have
10 an offline conversation about that. Diane is
11 a better negotiator.

12 MEMBER VICTOROFF: Yes, job-
13 sharing.

14 Although I was in total
15 concordance with what Doron was saying about
16 the white matter and the larger white matter
17 in the world, and I am very open to tomorrow
18 hearing about new additions to the list that
19 comprise near-miss events, if we can define a
20 couple that are unambiguous, and all that sort
21 of stuff, you know, yay for that. I am for
22 that.

1 But I think that is a different
2 matter than imposing and expanding the Venn
3 diagram for these guys to include near-misses,
4 which currently I don't understand them to be
5 at all. I understand the SREs to just be the
6 blue dot in the Venn diagram, meaning, yes,
7 they died, and that is all that is reportable
8 for now.

9 But if tomorrow you want to bring
10 a near-miss thing that you can really define
11 and you like, I will probably support it.

12 MEMBER RYDRYCH: I wonder if we
13 just want to -- I hate to go back to the
14 morning, but the place where we added in "risk
15 thereof" was in our definition of "serious".
16 So, I wonder, is it just a matter of making a
17 small change there? Instead of saying serious
18 includes event that result in death, however
19 we worded it, do we change it just slightly,
20 so we say that serious means events that can
21 result in, which captures the deaths, the
22 serious disabilities, the no-harms, but

1 doesn't say that they all have to be linked to
2 it?

3 CO-CHAIR MEYER: Yes, that works.

4 We will rework that language --

5 MEMBER RYDRYCH: Okay.

6 CO-CHAIR MEYER: -- and get that
7 back to folks. Okay. We will do it offline.
8 Okay, that is helpful.

9 Other comments? I just want to go
10 to 2C, and 2C is air embolism.

11 Here it is interesting. I guess
12 this is one where I would appreciate it if the
13 NQF staff could help reach out to the
14 neurosurgical field and see if this exclusion
15 needs to be there still. So this has been
16 there since this initial list.

17 The exclusion says, "Excludes
18 death or serious disability associated with
19 neurosurgical procedures known to present a
20 high risk of intravascular air embolism."

21 And I am not familiar enough with
22 the state-of-the-art in neurosurgery to know

1 if that is still the case in 2009 or not, but
2 I think we should ask their opinion, unless
3 somebody here knows that.

4 MEMBER MORLEY: The big issue is
5 when they do a sitting craniotomy, which they
6 still do. It is pretty rare, but they still
7 do sitting craniotomies. So, yes. But I am
8 not sure that I would agree it should be an
9 exclusion. I still would be interested to
10 know how often it happens.

11 CO-CHAIR MEYER: So, if we
12 could --

13 MEMBER MORLEY: It is a rare event
14 that they do the surgery. It is an even rarer
15 event that you get the air embolism. But it
16 is a high-risk procedure for getting an air
17 embolism.

18 CO-CHAIR MEYER: So it just makes
19 one wonder whether or not that exclusion
20 should still be there or not. And we should
21 ask for specific feedback from the field.

22 MEMBER VICTOROFF: Just returning

1 to the philosophy we had before, childbed
2 fever used to be a really high risk for
3 vaginal delivery. And we were just, oh, well,
4 you know, the informed consent says you could
5 die because I didn't wash my hands, so
6 whatever.

7 I don't think the fact that a
8 thing is a high risk necessarily means that it
9 shouldn't be counted and accounted for.

10 CO-CHAIR MEYER: So, trying to be
11 consistent with what we said before, there
12 seems to be a lot of nods about that. Okay,
13 and we will let them push back.

14 MEMBER RYDRYCH: And it gets back
15 to the Class 1/Class 2 question with the
16 surgical deaths as well.

17 CO-CHAIR MEYER: It does. Yes, it
18 does.

19 MEMBER RYDRYCH: Are we saying
20 that the higher risk needs to be excluded?

21 CO-CHAIR MEYER: Yes. Yes. Fair
22 enough.

1 MEMBER RYDRYCH: Okay.

2 CO-CHAIR MEYER: Other comments on
3 this one?

4 (No response.)

5 Great. I would still like to
6 forge ahead, if people can stay with us for a
7 little while longer.

8 The next one is patient protection
9 events. And the first one here is infants
10 discharged to the wrong person.

11 So, Deborah, let's here.

12 MEMBER NADZAM: Is this intended
13 to mean a neonate, a newborn?

14 CO-CHAIR MEYER: Yes.

15 MEMBER NADZAM: What about other
16 infants and children given to the wrong
17 person?

18 CO-CHAIR MEYER: You know, my
19 understanding of this, when this first came
20 up, was that people were thinking about a
21 newborn baby. The language "infant" is
22 interesting. Why isn't a "minor" the language

1 there? And the answer is I can't answer that.
2 I don't know if others have any more history
3 on this one or not.

4 MEMBER NADZAM: If it is meant to
5 be newborn, it should say, "newborn", I guess.
6 Otherwise, I think it needs clarification.

7 MEMBER VICTOROFF: How about
8 another dependent person, like a dependent
9 adult?

10 MEMBER NADZAM: Yes.

11 MEMBER VICTOROFF: I mean we could
12 easily rephrase this to be more comprehensive.

13 CO-CHAIR MEYER: So you are
14 proposing to broaden this and to say a
15 dependent?

16 MEMBER VICTOROFF: Yes, an
17 incompetent or dependent person, e.g.,
18 newborn, disabled person, cognitively-impaired
19 person discharged to the custody of a
20 guardian, an inappropriate guardian or
21 inappropriate --

22 CO-CHAIR MEYER: Flashing back to

1 the movie "Rain Man".

2 MEMBER RYDRYCH: I guess I haven't
3 thought about this one that much because we
4 have never had one of these, but how do we
5 define wrong person? I think we sort of
6 intuitively know what that means, but how do
7 we define wrong person in an unambiguous way
8 for the purposes of this list?

9 CO-CHAIR MEYER: Let's hear.

10 MEMBER TANGALOS: Well, I would be
11 careful about wrong person, too. Let's say
12 somebody brought a kid in after a beating, and
13 they are the wrong person to get that baby
14 back.

15 MEMBER VICTOROFF: Maybe we could
16 say unauthorized. We have to maybe narrow it
17 legalistically and say, clearly, the problem
18 with the infant is what is meant by wrong is
19 illegal, unauthorized. And I guess I would be
20 willing to give up all the other wrongs if we
21 could have that.

22 CO-CHAIR TYLER: But I am not

1 sure. I think Eric's point was that it could
2 be the legal guardian that brings someone in,
3 but the legal person may be responsible for
4 the injury, so you wouldn't want to discharge
5 them to that person. So legal may not be
6 the --

7 MEMBER VICTOROFF: We can't
8 capture that. So we just have to get the
9 wrong driver's licenses.

10 CO-CHAIR MEYER: Cynthia, let's
11 hear.

12 MEMBER HOEN: Yes, I think the
13 concern here was that people wanted to get
14 little babies so they could put them up for
15 adoption or they could have them. That is
16 what we were trying to protect from.

17 It gets to be a really sticky
18 legal wicket that I am not sure hospitals are
19 prepared to deal with with respect to what the
20 wrong person is. Who is the legal guardian?
21 Do they have a legal guardian? Did the legal
22 guardian send the person over? I don't have

1 enough resources to check all that stuff out.

2 At some point, we have to rely upon what

3 people tell us who have been involved in the

4 care all along.

5 CO-CHAIR MEYER: So you are
6 arguing to keep this and narrow it to newborn?

7 MEMBER HOEN: That's right.

8 MEMBER TANGALOS: I think to make
9 this one unambiguous, you tighten it up. You
10 make it the newborn.

11 MEMBER RYDRYCH: Yes, and I wonder
12 if we maybe seek legal advice on how to word
13 it, so that it is clearer than wrong person.

14 CO-CHAIR MEYER: Leah?

15 MEMBER BINDER: I'm shocked. I
16 mean I would definitely want to expand this
17 one. If you trust your child's life to a
18 hospital, I definitely want the hospital 100
19 percent accountable for who they are
20 discharging my child to. There are custody
21 disputes. There are all kinds of problems
22 that happen that hospitals, yes, it's tough,

1 but, yes, they've got to be responsible for
2 it. It is catastrophic if they release to the
3 wrong person.

4 So I would definitely support an
5 expansion, recognizing it is going to be
6 difficult to word it, but that is still an
7 important point, I think.

8 CO-CHAIR MEYER: Are there any
9 groups that folks can think of that we should
10 specifically ask the Quality Forum to reach
11 out to, to help us clarify this?

12 We've got a strong case by some to
13 say narrow/tighten. We've got a good case to
14 say, no, let's expand this.

15 Is there a group that we should
16 specifically solicit --

17 MEMBER TANGALOS: Point well-
18 taken. Maybe this just needs to be divided.
19 Get the infant piece taken care of, which I
20 think could be relatively easy, and then
21 discuss the other part, which is going to be
22 difficult. So two different --

1 CO-CHAIR MEYER: Okay. Patient
2 death or serious disability associated with
3 patient elopement, and excludes events
4 involving competent adults.

5 Comments on this one?

6 MEMBER TANGALOS: Is the depressed
7 patient that slips out of a facility competent
8 or not?

9 CO-CHAIR MEYER: If they have
10 capacity, they are medically, legally
11 competent.

12 MEMBER TANGALOS: And then they go
13 out and commit suicide.

14 CO-CHAIR MEYER: If they have
15 capacity, they are medically, legally
16 competent. I am not saying that this
17 exclusion is right. I am just saying I think
18 that that's probably the way that it would be
19 interpreted.

20 MEMBER MORLEY: I think you would
21 find that that information would be
22 appropriately recorded in the chart, or should

1 be appropriately recorded, in terms of
2 somebody with a little depression because they
3 are sad for some reason versus the patient who
4 was admitted for severe clinical depression.

5 And I was, actually, thinking
6 about asking the question -- the attorneys I
7 know frequently have changed me from saying,
8 "competent" to "having capacity". I don't
9 know how standardized that is, but --

10 CO-CHAIR MEYER: I think "having
11 capacity" will probably be the 2009 language.

12 MEMBER MORLEY: So you want to
13 change that to --

14 CO-CHAIR MEYER: I think this
15 would probably be 2002 language, yes.

16 MEMBER RYDRYCH: Well, I think the
17 intent here was, if I am correct, was to
18 differentiate between somebody who is
19 competent to make a decision to leave against
20 medical advice versus somebody who --

21 CO-CHAIR MEYER: Right, and that
22 is capacity.

1 MEMBER RYDRYCH: Right. Versus
2 somebody who takes off without going through
3 that process. Right?

4 MEMBER VICTOROFF: This says
5 elopement. I mean they just sign anything and
6 everybody said, "Okay, whatever, I guess
7 you're competent." This implies that a
8 procedure was circumvented.

9 MEMBER TANGALOS: No, I think this
10 starts to get into that new universe.

11 CO-CHAIR MEYER: Eric, I am asking
12 you --

13 MEMBER TANGALOS: No, no.

14 CO-CHAIR MEYER: We are not
15 talking just about hospitals --

16 MEMBER TANGALOS: We are not
17 talking about the hospital anymore.

18 CO-CHAIR MEYER: We're not.

19 MEMBER TANGALOS: Now we are
20 talking about people entrusted to assisted
21 living, some kind of step-down. The elopement
22 terminology is very classic in the nursing

1 home, but I am not even thinking nursing home.

2 I am thinking assisted living.

3 And I am not convinced that we are

4 getting at what we want to get at. Yes, we

5 can say they are competent or they have the

6 capacity to do this, but, boy, we lose a lot

7 of people that wander off. And how competent

8 or what capacity they maintain in that

9 independent environment is really uncertain

10 because it is a cascade of activities, too.

11 They are looking good at one moment in time.

12 They are in their environment. It's fine.

13 And just like errors, there is a cascade of

14 activities.

15 We had the Minnesota woman in her

16 fifties with early Alzheimer's disease fairly

17 much unrecognized who drove all the way west

18 and died. We filled her car with gas, did

19 this, that, and the other thing; got

20 directions in the wrong way.

21 So it is not particularly easy

22 here.

1 CO-CHAIR MEYER: Leah? Let me just
2 get to Leah, then Diane, and then Deborah.

3 MEMBER BINDER: I think this is
4 one of those where on a case-by-case basis it
5 isn't necessarily the fault, so to speak, of
6 the providers. You're not tying people down,
7 and they are adults and they have a right.
8 So, in an individual instance, a disappearance
9 or an elopement may be justifiable by the
10 provider.

11 Nonetheless, this is an instance
12 where counting the incidence of this is very
13 important. When we see variation among
14 facilities or among hospitals, that is very
15 significant. That is where we know there is
16 a very -- if a nursing home has, you know, 50
17 of these in a year, we should be really
18 focusing on them. And we are only going to
19 know it if they report it.

20 So I would see this, even though
21 this may not be the fault of the providers in
22 every single case, nonetheless, the reporting

1 is essential because it is very serious in the
2 aggregate.

3 CO-CHAIR MEYER: Go ahead.

4 MEMBER RYDRYCH: And just a
5 comment and a clarification. I agree with
6 what Michael said. I do think that this
7 implies that the process of signing a document
8 to leave against medical advice was
9 circumvented, and maybe that needs to be
10 noted, to differentiate between those
11 situations.

12 But a clarification, too. I agree
13 with what Eric is saying about how this
14 differs in long-term care settings. I am just
15 questioning, as this group and as the advisory
16 groups start to talk about expanding these
17 serious reportable events into other settings,
18 are we necessarily -- we are not necessarily
19 saying that these exact events are going to
20 translate; in some cases, they may.

21 CO-CHAIR MEYER: Some will and
22 some won't.

1 MEMBER RYDRYCH: In some cases,
2 they may morph a little bit. So there may
3 still be an event that is related to
4 elopement, but it necessarily has to be worded
5 a little bit differently, if it is applying to
6 long-term care, than it does to the inpatient
7 setting. We may need to have different
8 caveats for each one.

9 I mean I think Eric's point is
10 true, but we won't necessarily be
11 transplanting this one to the other setting.

12 CO-CHAIR MEYER: So let me go to
13 Deborah, Doron, and then to Cynthia.

14 MEMBER NADZAM: Yes, on the
15 version that you sent to us, there's a phrase
16 at the end that is not up there. After
17 "disappearance", it says, "for more than four
18 hours". Is that still in?

19 CO-CHAIR MEYER: So, probably you
20 may be looking at 2002.

21 DR. BURSTIN: No, in 2002, it was
22 in.

1 MEMBER RYDRYCH: Is it not there
2 anymore?

3 CO-CHAIR MEYER: So, 2006, it is
4 not?

5 MEMBER RYDRYCH: I think that was
6 removed.

7 MEMBER NADZAM: Because that was
8 my question.

9 CO-CHAIR MEYER: What you see up
10 here is 2006.

11 MEMBER NADZAM: Okay. Good.

12 MEMBER RYDRYCH: I think it was
13 removed because it was the harm to the patient
14 that was important, not the amount of time
15 being gone.

16 MEMBER NADZAM: Right, right,
17 right.

18 CO-CHAIR MEYER: This is the 2006
19 version. What you got through the email and
20 what you have is 2002. So, yes, there are a
21 few places, this and with falls, there were
22 important omissions and additions.

1 Okay. Sorry. So Deborah, Doron,
2 and then Cynthia.

3 MEMBER DORON SCHNEIDER: I was
4 going to make that point also on the other
5 end, which is that the association -- there is
6 no time element here in the sense of, yes, I
7 mean it is very ambiguous to me to a certain
8 extent because it could be associated, you
9 know, not necessarily in the first 24 hours.
10 It could be down the line. So I think there
11 is a little level of ambiguity there.

12 And because it is a harm event,
13 and I don't think we are going after what you
14 really were after, which was your rate of
15 elopement, because the harm is not that
16 frequent. That may be one where we do the
17 "risk thereof", if we decide to go down that
18 dialog tomorrow.

19 MEMBER RILEY: So the only thing
20 that I was going to say about this, too, is
21 this may be an opportunity to sort of put the
22 definition for capacity in, where people can

1 clearly understand exactly what that whole
2 sentence means, and that it is completely
3 different than competency.

4 CO-CHAIR MEYER: We would need
5 some legal help with that.

6 Cynthia?

7 MEMBER HOEN: I have seen a number
8 of cases where they have used as the standard
9 of care such that you had a person who you
10 believed was legally competent who left, who
11 eloped from the hospital and committed
12 suicide, and they hold this out as a standard.

13 I think that is really a
14 negligence issue. Did you fail in the
15 hospital to appropriately categorize them? I
16 mean I would be completely comfortable with
17 this if they eloped from a secured area, from
18 a psych unit, from a psych hospital, from the
19 Alzheimer's unit of a care facility. But just
20 for a general open hospital, elopement is
21 awful ambiguous.

22 CO-CHAIR MEYER: I don't think we

1 are going to solve this one. So I think what
2 we are going to end up doing is probably
3 hearing a fair amount from the field and
4 revisiting this.

5 MEMBER TANGALOS: Well, I would
6 like to expand it a little bit before we even
7 leave this. At Mayo, we have a big deal about
8 code pink. All right? A big deal. I don't
9 know where it fits.

10 It hinges on abduction. I mean we
11 are never sure if a kid is lost or an older
12 adult is lost. But it is a big deal.

13 And I am sure, I mean, if we are
14 going to expand events, I am thinking about
15 the outpatient setting for the most part, but
16 where do we put that?

17 CO-CHAIR MEYER: There is a
18 criminal event. We will come to the criminal
19 events, the abduction piece.

20 MEMBER TANGALOS: Yes, but I am
21 saying that I think every facility ought to
22 have some program in place, not to get to the

1 criminal event.

2 CO-CHAIR MEYER: And that is where
3 the nexus would be between this work and the
4 safe practices.

5 MEMBER TANGALOS: Very good.

6 CO-CHAIR MEYER: Exactly.

7 MEMBER TANGALOS: Very good.

8 CO-CHAIR MEYER: So let's go to
9 3C, patient suicide or attempted suicide
10 resulting in serious disability while being
11 cared for in a healthcare facility.

12 Note the word there, "healthcare
13 facility". So it is very broad.

14 And it goes on to say, "Define
15 those events that result from patient actions
16 after admission in a healthcare facility.
17 Excludes deaths resulting from self-inflicted
18 injuries that were the reason for admission to
19 the healthcare facility."

20 Any comments on that one? Stan?

21 MEMBER RILEY: I guess I think we
22 should remove the exclusion. You know, they

1 may have come into the hospital for I don't
2 know. What if it is a self-mutilator and
3 something happens that way? So I am not sure
4 that that exclusion is useful.

5 CO-CHAIR MEYER: Yes, I think what
6 was around the exclusion was the notion that
7 somebody comes in after out in the field
8 taking a horrible overdose of tricyclics or
9 acetaminophen, of Tylenol, and you do your
10 best for them. They die. That seems to me
11 that that is not something that -- Diane?

12 MEMBER RYDRYCH: I only have one
13 tiny comment on this one, and it is related to
14 the exclusion. What about cases where there's
15 somebody in the ED? Because we are saying it
16 excludes after admission.

17 CO-CHAIR MEYER: Yes, and I think
18 that did come up later in this. That is why
19 it says, that is why I pointed out it says,
20 "healthcare facility". The emergency
21 department is assumed in that.

22 So, if someone walks up, going up

1 the entry ramp to Mass General and slits their
2 wrists, or if somebody comes through the
3 emergency room and checks in, and gets checked
4 into the emergency room, slits their wrists
5 there, we are.

6 MEMBER RYDRYCH: But we are
7 defining that as admission into a healthcare
8 facility, once you're in the ED?

9 CO-CHAIR MEYER: Right, and that
10 is why the wording here is specific; it says,
11 "healthcare facility", because this came up.

12 MEMBER HOEN: Admission is a
13 complicated word, though.

14 CO-CHAIR MEYER: Admission is a
15 complicated word. I mean I note that was
16 specifically why that was worded that way.

17 MEMBER TANGALOS: In trying to do
18 good with the programs, where do we include
19 investigations of drowning? And the reason I
20 bring it up is that is the modus operandi for
21 old people to finish their lives. That is
22 what they do. They drown themselves.

1 CO-CHAIR MEYER: Have any of the
2 states here seen a hospital-reported drowning?

3 MEMBER TANGALOS: It is not
4 hospitals. It is at CCRCs where they wheel
5 themselves into the Jacuzzi.

6 CO-CHAIR MEYER: More to come in
7 our expansion discussion tomorrow.

8 (Laughter.)

9 You have to include Jacuzzis.

10 Yes, Michael?

11 MEMBER VICTOROFF: Just to follow
12 on that, I think, as I have been fantasizing
13 about these translating to other environments,
14 I have come up with cases where I think you
15 have to have a separate footnote for what does
16 this mean in this kind of facility.

17 CO-CHAIR MEYER: Yes.

18 MEMBER VICTOROFF: You know, on a
19 cruise ship, this would mean, you know --

20 CO-CHAIR MEYER: Okay.

21 MEMBER VICTOROFF: And I think
22 that we are going to have to do that.

1 CO-CHAIR MEYER: And you will see
2 in some of the other NQF products they do --
3 so Safe Practices says this is what it means
4 in a hospital; this is what it means in a
5 long-term care facility. So that sometimes
6 can be explanatory language around this.

7 Okay. At this point in time, it
8 is almost five o'clock. We have a fair amount
9 of work still to do. So, just to remind
10 folks, what is left are care management
11 events, environmental events, and criminal
12 events. We are approximately halfway through
13 the list.

14 At this point, I feel like I have
15 already begged your indulgence long enough by
16 holding you over. On the other hand, I also
17 recognize that Sally, to my right here, is
18 going to be the onsite Chair tomorrow morning
19 who will inherent my failure to take you over
20 the finish line.

21 MEMBER TANGALOS: I would make a
22 suggestion, though. We shouldn't end on a

1 vision of an old person wheeling themselves
2 into a Jacuzzi.

3 (Laughter.)

4 We should end on a high note
5 somehow.

6 CO-CHAIR MEYER: I am looking to
7 you.

8 MEMBER RYDRYCH: Give us a better
9 image, please.

10 CO-CHAIR MEYER: Just before we
11 close, Peter or Helen, do you have any further
12 business?

13 DR. ANGOOD: No further comment,
14 really, other than to thank you all for really
15 a heavy load of work today, I think clarifying
16 this, our redefinition, getting us a bit more
17 clarity around this HAC concept, and kind of
18 getting that squared away, basically.

19 CO-CHAIR MEYER: Anyone left on
20 the phone? Do we have anyone left on the
21 phone?

22 (No response.)

1 DR. ANGOOD: Nobody.

2 CO-CHAIR MEYER: Okay.

3 DR. ANGOOD: So I think it has
4 been a great afternoon, a great day. Thank
5 you very much.

6 Dinner is at the Blue Duck Tavern
7 for 7:00, and the reservation is under NQF for
8 National Quality Forum.

9 CO-CHAIR MEYER: So, to finish on
10 a high note, to quote the sage of sages of
11 epidemiology, who is Mary Poppins, if you
12 didn't know it, "Well begun is half done."

13 (Laughter.)

14 Thank you for your work today.

15 7:00 p.m., it got changed to 7:00.

16 All right, thank you very much.

17 Hang in there.

18 (Whereupon, at 4:59 p.m., the
19 above-entitled matter was adjourned for the
20 day, to reconvene the next day, Thursday,
21 November 19, 2009.)

22

A				
abdomen 387:9 394:12	accountability 13:13 48:13 93:19 95:22 99:13	actions 118:22 150:12 191:10 449:15	333:9 334:14,14 383:22 384:7 415:11 418:11	80:16 107:15 109:2,22 110:11 133:2 142:15
abduction 448:10 448:19	118:11 127:14 176:6 226:16	active 22:14,17,20 29:4	additions 172:10 427:18 445:22	149:17,20 154:6 154:11,12 163:19 165:8 170:21
ability 45:11 60:20 222:11 243:20 325:20 333:20 426:10	236:13 272:16 294:10 299:14 301:4	activities 5:13 6:7 7:1 9:4 25:12,16 25:17 32:21 67:17 69:11 72:19 74:18 76:4 91:7 211:22 265:1,3 351:12 355:7 414:7 416:11,15,15 441:10,14	address 102:21 263:22	174:1,1 176:2 178:11 182:16 187:22 188:15,15 189:10 192:6,7 193:13 204:19 206:8 207:8,15 253:16 255:19 270:19,21 276:1 278:9 281:8,22 282:5 283:12 284:13 286:12 292:20 304:12,20 306:6 307:9 311:13 312:10 316:22 328:10,13 328:17 378:6 390:9 425:19
ABIM 25:15	accountable 14:1 48:21 436:19	activity 18:20 27:1 63:7 67:5 68:10 68:18 72:16 74:2 74:5 80:1 90:11 249:2 353:1	addressed 207:11 377:13	278:9 281:8,22 282:5 283:12 284:13 286:12 292:20 304:12,20 306:6 307:9 311:13 312:10 316:22 328:10,13 328:17 378:6 390:9 425:19
Abington 25:6	accounted 431:9	acts 270:4	addresses 262:13	advice 218:10 357:12 436:12 439:20 443:8
able 24:19 54:14 83:13 105:22 106:10 116:13 206:22 249:5 267:7 292:15 322:3 340:13 394:1 423:2	accuracy 6:4 accurate 261:15 Acela 34:9 acetaminophen 450:9	actual 99:13 161:20 172:19 189:4,5 277:18 341:16 384:4 415:19 418:4	adequate 252:12 adhere 42:13 adherence 195:14 197:9 198:5	206:8 207:8,15 253:16 255:19 270:19,21 276:1 278:9 281:8,22 282:5 283:12 284:13 286:12 292:20 304:12,20 306:6 307:9 311:13 312:10 316:22 328:10,13 328:17 378:6 390:9 425:19
above-entitled 455:19	achieve 140:10 278:17	acute 55:18 56:6	adhering 45:10	advise 44:20
ABO-compatible 376:1	aching 358:6	add 50:12 85:19 101:9 191:6,7 197:17 251:10 265:21 285:6 321:4 323:16 373:3 374:6 379:19 415:17	adjectives 130:9	Advisor 5:6 17:11
abreast 66:7	acknowledge 109:18	add 50:12 85:19 101:9 191:6,7 197:17 251:10 265:21 285:6 321:4 323:16 373:3 374:6 379:19 415:17	adjoined 455:19	advisors 41:4
absolute 293:4	acknowledges 125:6 134:9	added 125:4 199:5 234:8 308:21 360:1 366:10 382:5 428:14	adjourned 455:19	advisory 7:12 16:3 19:1,6,6,12 25:19 27:11,14 44:12 74:20 75:14 78:6 90:15,19 284:6 318:5,11 443:15
absolutely 101:16 159:19,20 209:15 211:8,9 297:8 301:5 329:13 330:19 402:2 416:16	acknowledging 107:20	adding 170:7 346:9 370:7	adjournment 403:14	advocacy 19:21
acquired 1:6 67:10 71:15 84:17 86:4 86:5 93:17 94:5 97:10 218:13 224:20 230:15 231:5,11 236:7 242:6 252:8 255:3 255:10 269:1 289:10 291:5 301:13 320:20 322:18	ACP 25:11,11	addition 15:7 94:3 271:17 283:11 324:5 350:10 370:6	adjunct 252:17	advocate 133:11
acquired 1:6 67:10 71:15 84:17 86:4 86:5 93:17 94:5 97:10 218:13 224:20 230:15 231:5,11 236:7 242:6 252:8 255:3 255:10 269:1 289:10 291:5 301:13 320:20 322:18	acquired 1:6 67:10 71:15 84:17 86:4 86:5 93:17 94:5 97:10 218:13 224:20 230:15 231:5,11 236:7 242:6 252:8 255:3 255:10 269:1 289:10 291:5 301:13 320:20 322:18	additional 78:18 226:7 243:8 246:9 292:10 368:22	adjustments 85:16	affect 250:5 414:7 416:10
acquired/associa... 217:20 220:11	acquired/associa... 217:20 220:11		administered 409:12	afternoon 15:2 142:4 167:17 172:9 216:17 217:13 218:16 236:22 268:21 338:21 357:3 455:4
acquires 224:16	acquires 224:16		administration 404:21 409:4	afterthought 245:7
act 39:1,2 60:15 248:17 384:6	act 39:1,2 60:15 248:17 384:6		administrative 37:20 41:16 266:20	
action 90:10 98:15 140:6 152:18 333:7,20	action 90:10 98:15 140:6 152:18 333:7,20		admission 252:9 449:16,18 450:16 451:7,12,14	
actionability 334:5	actionability 334:5		admissions 58:13	
actionable 332:12	actionable 332:12		admit 234:18	
			admitted 439:4	
			adopt 326:3	
			adopted 118:7	
			adoption 435:15	
			adult 419:16,18 433:9 448:12	
			adults 421:20 438:4 442:7	
			Advancement 39:2 384:6	
			advantage 128:17 349:5	
			adverse 58:19	

after-thought 47:13	agreement 6:11 71:22 72:7 210:1 369:7	ambiguated 326:2	and/or's 173:20 178:17 181:4	400:4,8 408:14 415:4 433:1,1
agencies 4:22 85:4 323:3 324:2 339:5 340:7	agreements 269:9	ambiguity 120:11 226:19 381:11 446:11	anecdotal 92:10	answered 337:6
agency 17:5 27:3 69:12 324:8	AGSF 2:12	ambiguous 4:13 120:9,9 155:2,4 158:22 159:18 172:14 205:6 212:13 286:8 397:20 446:7 447:21	anecdote 375:10 376:16	Answers 3:8
agenda 7:9 8:14	ahead 14:15 82:19 104:18 132:18 216:16 217:5 235:13 287:2 304:6,8 347:2 349:17 373:19 392:8 416:16 432:6 443:3	ambulatory 43:1 75:19	anesthesia 28:7 404:20,21 405:4,5 405:7 409:1,5,12	anticipatable 109:8
agents 313:8	AHRQ 12:21 16:4 20:20 33:11,16 58:12 102:7 244:1	ambulatory-orie... 44:16	anesthesia-related 404:16 406:2	anticipated 108:8 125:20 197:8,19 198:4 199:21 200:13 231:8 304:11 305:4 306:6 311:5,18 345:22 346:4
aggregate 443:2	AHRQ's 264:5	America 19:11 244:9	anesthesiologists 366:4 404:3	anxiety 133:19 363:20
aggregated 75:21	aim 26:13 110:7	American 9:2 19:15 22:8,11 26:17 29:6 60:15 102:15 398:8 404:2	anesthetic-related 405:10	anxious 192:12
aggregation 61:14	air 429:10,20 430:15,16	amount 33:12 60:16 77:9 91:22 96:21 137:22 160:13 166:16 194:20 249:14 347:7 445:14 448:3 453:8	angle 254:6	anybody 40:12 172:6 267:1 352:8
aggressive 140:6,7	airline 274:5,8,11	analogy 274:7	Angood 2:13 3:3,8 5:3,5 15:19 30:11 30:20 31:7,21 32:13 34:3 62:22 81:20 82:3 84:2 88:17 90:3,16 100:8 124:15 125:9 179:7,12 187:1 214:17 236:17 263:21 287:15 290:10 295:15 318:22 320:12 340:2,6 341:2,19 350:8 352:13 354:12 359:8,11 364:12 382:20 384:1 390:5,9 395:3,3 403:5,10 405:8 454:13 455:1,3	anymore 32:7 153:14 180:7 440:17 445:2
Aging 22:10	airlines 274:10	analyses 118:21	ankles 290:1	anyway 109:9 173:1 232:10 395:11 407:21
ago 34:12 57:3 73:21 94:10 102:2 145:21 238:1,10 334:18 344:8 350:14 351:14,15 351:20 364:20 375:15,16 378:2 400:12	alarmed 137:20	analysis 21:4 128:18 141:4 221:1 238:11 283:4 344:3,4,6 344:20 354:10	annote 327:1	apologies 165:18
agree 103:8 111:1 114:14 120:10,21 123:3 127:17 134:11 136:16 137:12 140:21 151:7 152:14 158:5 162:5 169:1 174:7 200:4 210:10,12 246:7 250:14 254:22 255:15 272:1 276:5,6 291:8 300:21 308:4,9,11 309:5 312:7 343:17 345:2,19 348:4,7,18 349:6 351:8,10 354:6 365:11 369:8 371:17 378:8 388:13 399:14 406:14 413:12 430:8 443:5,12	algorithm 414:3	ancient 250:4	announcements 6:15	apologize 246:1
agreeed 97:1 129:7	algorithms 415:3	and's 173:21 174:5 181:3,5	annoying 96:18	apparently 93:9 217:1
agreeing 95:5 246:12 338:15	align 371:2	and/or 4:3 175:17 176:3,4,11,20 177:4,10 179:15 180:3,7,9,12,15 180:18 182:1 361:1	annual 65:11,15 423:3,4	appeal 251:2
	aligning 61:6		annually 423:5	appealing 205:15
	alike 26:1		anonymous 277:1	appeals 42:9
	allegedly 112:2		answer 140:1 240:3 262:1 329:13 379:18 392:4	appeared 363:20
	allergy 110:2 382:15			appendicitis 375:17
	Alliance 21:14			applaud 95:7
	Alloderm 410:13 410:13			apple 106:21
	allow 44:12 49:11 61:22 112:14 186:9 224:1 361:12			applicability 78:11
	allows 176:12 181:17 185:22			applicable 50:18
	alluded 126:3			application 196:3 196:11
	all-encompassing 256:8 281:18			applies 384:4
	alphabet 11:13			apply 425:10
	Alzheimer's 29:3 441:16 447:19			applying 44:1 424:3 444:5
	amazed 409:9			appreciate 84:3 245:16 262:7 275:1 347:4 412:6 429:12

appreciation 238:22	209:8 272:20 282:16 294:1	aspirational 111:10 157:8	at-risk 426:3	13:1 31:17 44:7 45:22 48:20 70:18
apprised 72:20	305:5 312:19	aspirin 225:7	audience 8:16	78:21 85:7 92:2
approach 70:20 112:9 220:22 250:11 251:8 254:10,14 380:8	316:20 326:12 362:6 364:6 371:4 376:5 396:18 397:18 416:16	assault 355:8	auditable 270:16 281:12 283:14	98:3 99:2 102:1 105:4 125:1
approachable 70:20	argued 416:18	assaulted 355:21	augment 67:16	126:17 127:8,15 129:17 136:6 139:19 142:9
approached 70:11 295:17	arguing 173:13	assessing 60:20	August 50:17	143:19 145:7,18 145:18 150:9
approaches 6:6 69:5 278:12	argument 115:5 133:1 146:6	assessment 46:10 54:6	authoritatively 253:3	155:6,9 163:20 167:18,19 171:3 171:16 172:1
appropriate 37:11 50:8 59:11,16 114:9 308:4 310:20,21 378:9 398:15,22 399:5 421:9	307:14 331:3 389:9 395:7 399:18 406:3	assessments 73:14	authorities 297:22	192:2 194:5 202:7 203:15 216:8,15 217:14 220:10
appropriately 44:2 75:1 438:22 439:1 447:15	arguments 116:2 158:14 331:4	assistants 348:12	authority 23:8 217:1 275:13 276:22 323:21	228:16 229:18 237:6,9 238:13 250:13 256:13 259:6 261:21 263:2,11 271:16
appropriateness 49:21	Arizona 26:5,9,14	assisted 440:20 441:2	automatically 308:11	271:22 272:12,13 274:22 275:2 276:11 277:17
approval 42:6 44:6 65:20	arms 57:5	associate 26:4 99:20	autonomy 92:18 93:2 111:4	279:8 280:5 291:3 294:1,18 296:12 297:18 310:13 321:10,11 324:13
approximately 279:15 365:22 453:12	ARRA 60:14	associated 12:13 59:1 86:4,7 89:21 93:17 94:5,13 97:10 112:2 121:3 128:15 236:7 239:12 313:16 405:4,7 406:8 409:4 419:4 421:1 429:18 438:2 446:8	avoid 109:16 121:14 170:10 301:15	326:12 331:18 333:14,17 335:8 335:10 336:15 339:12 342:4 354:13 365:2 371:15 379:14 386:18 392:3 401:8 419:7 422:9 425:16 428:13 429:7 431:13,14 433:22 434:14
apropos 322:20	arrived 277:18	association 16:19 22:12 29:7 391:19 446:5	avoidable 80:21 131:20 173:6 225:20	433:22 434:14
area 17:7 30:3,22 109:1 221:18 260:4 274:16 384:18,22 386:21 411:1 416:19 447:17	arrow 259:6	assuming 159:15 205:4	award 30:6 203:19 204:2	background 10:4 17:22 18:18 21:4 23:22 26:19 29:19 29:22 30:2 32:1 32:16 34:5,11 92:19 123:20 124:14 163:5 177:22 187:6
areas 41:2 56:18 59:17 64:19,21 65:1 70:22 75:16 120:5 313:18,22 314:12 315:17 368:8	artery 399:22 400:6,7	attach 97:18	aware 6:22 82:13 97:15	
argue 115:20 119:16 138:11 157:22 174:4 177:14 183:14 189:12 191:21	articles 116:9	attached 82:22 162:10 329:9 413:5	awareness 12:2	
	articulates 380:16	attaching 131:7	awesome 339:17	
	artificial 250:8	attacking 112:19	awful 80:2 220:9 447:21	
	ASA 345:19 404:2 404:11 405:16,19 406:16,18	attempt 313:9	awkwardly 149:9	
	asked 168:1 181:15 218:15 224:2 243:7 295:12 341:11 350:9 366:16	attempted 240:13 351:21 449:9	A-F-T-E-R-N-O-... 216:1	
	asking 15:5 62:11 190:8 217:16,18 261:22 328:15 356:21 420:3 421:11 439:6 440:11	attention 59:14 107:8 122:14 196:17 276:20 277:13 330:9 397:7	A-G-E-N-D-A 3:1 4:1	
	aspect 225:16	attorneys 439:6	a.m 1:19 5:2 104:16,17	
	aspects 63:12 401:17	attributable 20:16		
	aspiration 259:7,7 259:10,11,15	attribute 93:18		
			B	
			b 175:13 329:14 373:5	
			babies 435:14	
			baby 252:2 267:2 432:21 434:13	
			back 7:5,16 12:16	

backgrounds 32:18	beginning 12:15	418:18 427:11	442:3	block 366:4,6
bad 198:14,16	13:21 36:16 50:3	454:8	biologic 410:12	386:11
232:1,19 243:17	211:11 218:4,16	beyond 43:7 68:13	421:5	blocks 368:9
248:10 260:13	296:8	71:4 77:3 124:13	biomedical 26:6,15	blood 33:22 375:21
265:16 266:9,10	beginnings 223:14	126:13 209:1	biopsy 417:6,8,12	375:22 376:1,4
266:15 267:13,17	begins 55:19 379:3	219:18 246:9	bird 102:3	bloodstream 121:3
273:12,14 283:3	379:4	274:19 284:16,18	birds 80:6,9	121:4,7 230:3
288:14 291:15	begs 223:19 249:15	296:21 331:8	birth 272:13	234:14 286:6
296:16 323:8	270:6	346:20 404:10	bit 7:11 10:5 11:19	bludgeon 130:17
328:1 394:21	begun 72:17	424:5	17:19 32:1 35:12	130:19 162:20
411:3	455:12	bias 86:10 96:18	36:3 38:6 46:17	blue 216:22 287:8
badly 397:10	behalf 392:22	97:9,12 261:14	47:6 56:15 78:8	287:17,18 289:8
bads 260:22	behavior 58:7	big 24:11 191:12	78:14 91:9 95:19	301:18 305:12
bag 232:11,13	behavioral 266:20	219:10 225:11	101:3 103:2	309:11 428:6
balanced 27:8	beholden 237:12	245:8 255:2	104:11 106:12	455:6
Baldrige 30:5	belabor 165:4	267:16 276:14	107:3,19 111:9	blunt 313:10
ball 329:15	believe 11:8 87:6	303:17 305:11	119:3 120:5	blurred 141:8
Ballroom 1:19	125:13 163:15	309:11 311:9	143:16 144:18	blurriness 234:11
balls 115:5 173:13	202:17 297:11	331:1 338:7 353:1	159:17 162:7,15	blurring 120:4
Baltimore 280:10	300:14	368:8 376:18	168:16 169:4	BMus 2:6
bar 47:6 120:15	believed 334:18	377:12 388:2	177:20 181:12	board 19:9 24:5,21
123:6	447:10	430:4 448:7,8,12	182:18 198:19	25:19 27:14 42:7
barely 175:1	believer 241:10	bigger 145:14	202:6 205:6 214:8	65:20
bariatric 242:17	belong 20:21	209:8 240:9	228:19 240:6	boards 19:8 24:4
barricaded 351:22	belongs 419:13	257:19,20 265:10	277:17 286:10	27:11
base 16:5 47:4	belt 239:17	306:3 309:20,21	291:12 319:2,7	bodies 116:8
114:15,19 229:14	beneath 176:8	310:1 377:1	330:4,4 339:3	117:10 118:9
357:1 396:2	beneficial 231:6	biggest 48:14	343:22 360:8	141:12 240:22
baseball 384:3	benefit 389:4	326:13,14	363:12,16 384:3	241:4 372:17
based 42:1 114:10	Berwick 57:7	billing 55:13	385:7 387:18	bodily 4:11 208:12
118:10 176:13	best 28:12 39:11	billing-free 55:13	403:16 408:8	208:14,18 210:12
194:14 338:5	45:11 48:17 69:22	billion 60:17	414:16 419:11	212:6
342:18 371:20	91:20,21 111:7,13	bills 55:14	421:17,17 444:2,5	body 4:10 129:2
407:16 424:20	112:11,12,12,16	Binder 2:3 163:2	448:6 454:16	137:8 147:19
basically 23:8 34:4	113:9 145:2	163:10,11 165:17	bite 139:19	152:16 208:17
156:5 454:18	194:12 195:14	186:3,12 250:14	bites 106:21	212:5 309:4 344:7
basis 223:16	231:6 232:3 244:5	274:2 294:17	bitty 395:8	359:6 368:13
371:17 395:7	261:1,2 351:8	295:2 297:5,9,13	bizarre 419:11	369:17 370:10
401:14 425:8	450:10	298:19 299:16,22	black 109:18	372:17 383:12
442:4	bet 32:9	300:5,9,17 301:16	284:10	385:2 400:2
Baxter 27:7	better 37:22 66:17	301:22 303:16	Blackberry 7:20	book 35:5 172:17
beans 232:12,18	66:19 94:6 173:12	304:8 306:12	blame 128:16	296:8,11
beating 434:12	198:20 201:21	307:21 308:6	130:18 344:16	border 282:17
beds 277:6	218:10 241:13,14	310:12,16 334:13	bland 232:16	boss 102:12
bees 112:19	248:14 266:2	334:17 353:16	blank 218:9	Boston 15:1 33:18
began 321:14	283:5 292:21	371:15 398:12	bleed 303:11	bother 395:10
begged 453:15	392:2 408:16	400:18 436:15	blend 249:15	bothers 151:9

bottom 108:2 149:12	332:11 349:3,19 389:18 392:8	broad-based 74:21 320:18	314:1,5 321:3 335:5,21 336:2,6	227:20 244:2 257:14 321:13
boundaries 292:13 294:12 301:12	401:7,12,21 402:3	broke 352:3 387:16 391:4 416:9	336:11,14 337:6 415:14 418:20	410:13 calling 28:18 29:17
boundary 292:14 294:2 304:18	brief 6:15 32:1 128:8 219:7	broken 386:4 391:3 397:17 416:11	424:22 425:13 444:21	105:12 107:8 263:12 307:19
bow 100:9	briefing 175:20 179:9 180:15	417:20	business 454:12	calls 45:12 143:12
box 100:9 301:15 318:14 418:5	briefly 72:11 73:1 77:11 78:17 213:6	brother 184:10	busted 337:13	187:8 366:16
boxes 267:21 309:6	Brigham 33:17	brought 73:18 127:18 434:12	busy 5:9,10 74:2	391:18 399:9
boy 14:12 123:22 148:12 179:1	bring 21:2 39:9 43:15 61:11 66:17	brutally 97:19	by-case 395:7	426:10
182:4 204:8 218:8	75:15 90:9 191:12	BSN 2:6	by-word 214:20	campus 26:6,6 249:17
242:8 244:3 329:4	195:21 209:19	BT 266:11	C	Canada 27:13
353:13 362:10	331:14 428:9	bubble 265:10 287:18 289:8	C 5:1 175:13 349:14 413:8,11	cancer 92:5 312:20
364:6,8 376:7	451:20	322:15 323:15	413:13 414:10	410:12 417:17
388:1 397:6 441:6	bringing 64:12 90:22 237:5 258:6	328:18,22	417:20	candid 137:14
brain-injured 288:12	375:17	bubbles 55:19	CABG 242:12	Cannon 105:7,7
brand-new 26:6	brings 127:9 165:9 196:5 352:14	budget 245:2	caboose 131:7	135:22,22 137:6
break 104:9 105:18 217:5 279:7,12	410:10 435:2	build 26:12 33:15 100:11	cache 115:2,8	280:9,9
291:13 338:20	broad 36:5 39:19 43:11 58:19 60:8	building 126:4	caliber 324:3	capacities 60:19
339:8,9,10,11	61:9,9 185:17,22	built 53:22 101:15 107:4 332:14	California 29:18 216:7 280:4	capacity 23:10
385:2	206:20 223:11	bullet 174:19 175:7 175:9 184:3	call 3:2 23:7 36:2 77:13,18 81:17	26:22 102:22
breakdown 382:19	277:19,22 278:10	189:15	91:12 94:11 107:6	438:10,15 439:8
breakdowns 351:2	321:7 333:21	bulleted 180:12	113:3 147:2	439:11,22 441:6,8
breaking 48:8	336:5 356:22	bulletins 275:13	149:11 157:3	446:22
breakout 74:4 153:12 341:3	449:13	bumps 149:17	168:2 185:20	capture 60:21 79:9
343:9	broaden 322:19 433:14	bunch 97:5 179:16 232:10 265:21	186:21 192:21	89:11 114:11
breaks 8:3,11 381:2	broadening 346:3 378:15	414:8	196:16 200:7	196:2 204:14
breast 92:4 382:12 410:11,18 417:6,7	broader 36:8,9 37:3 38:16 50:22	burden 53:18 372:5	206:21 216:4	232:22 269:11
417:12	145:8 164:11	burning 225:22	226:20 234:2	311:15 380:13,17
breathing 361:11	165:13 176:12	Burstin 2:14 3:7 9:11 15:19 33:7,8	257:13 258:3	381:16 386:5
Brennan 2:4 18:14 18:15 90:13 98:10	186:1 206:15	35:20 62:8 82:20	266:11 270:18	392:18 404:16,20
120:8 122:4,7	219:15 223:2	88:11 94:3 99:15	279:22 281:16	405:3 414:10
132:13,16 133:4	224:1 278:13	101:8 128:4 145:4	318:6 319:10	417:19 435:8
148:16,22 191:16	321:9 322:4 405:5	172:15 175:12	322:5 329:9 331:5	captured 61:2 89:9
208:10,16 241:16	broader-based 76:19	180:22 181:14,19	338:17 356:21	134:14 205:1
243:14 248:12	broadly 102:9 183:15 360:13	211:12,14 213:12	357:10 365:6	414:12
276:8 285:3,12,16	362:8 363:16,18	213:15 219:1,2	366:7 413:19	captures 413:7
285:19,22 286:14		233:16 277:16	417:21 418:2	428:21
286:19 287:1		296:19 297:8,12	420:17	capturing 89:3
			called 19:20 27:12 27:17 39:1 44:14	128:17 267:6
			54:20 58:18	369:21
			142:15 143:19	car 245:9 417:9
				441:18
				card 155:17 375:7
				376:3 377:17
				cardiac 23:3

Cardinal 27:7	carniotomies 430:7	catheter-associat...	129:13 140:16	439:7 455:15
cardiologist 29:12	carried 405:1	242:11	187:6 191:11	changes 85:15
Cardiology/Ame...	409:6	catheter-related	249:1 255:14	120:2 171:14
29:6	carry 72:5 157:10	121:4,6	303:12 334:1	172:7 213:21
cards 110:19	300:2 373:1	caught 8:4 122:13	348:6 349:6,14	262:19 334:15
care 23:7 24:8,18	cascade 441:10,13	173:1 184:19	355:7 356:4,6	355:15 359:21
28:8 30:2 32:18	case 19:22 52:21	423:16	378:8 382:8	373:1,4 402:9
42:21 43:2 51:7	61:7 99:22 119:2	causality 158:21,22	388:13 393:1	422:22
51:11,14 55:10,19	136:7,8 253:7	cause 113:16	395:6 398:7 421:7	changing 150:5
55:20 56:5 57:18	278:18 366:15	118:21 190:6	cetera 8:5 90:12	164:8 245:6,11
57:19 59:6,8,12	382:9,9 391:3	204:15 235:21	114:8,8,10,10	330:3 365:11
59:17 71:3 72:13	395:6 399:1	349:11 391:7	230:4 264:4,4	379:4 425:21
75:11,22 76:1	401:13 416:7	422:21	265:5 304:14	charge 9:12 296:20
84:18,20 86:6	422:22 430:1	caused 97:10	330:16 341:9,14	299:15,17,20
87:18,19 89:6,12	437:12,13 442:22	causes 23:15 195:6	369:19,19	346:19
92:20 98:17 101:1	cases 134:9 136:13	221:2,15	chagrin 16:1	charged 295:6,9,22
101:13 109:5	155:10 262:18	caveat 136:21	Chair 15:15 18:5	chart 363:21
112:11,12,13	343:20 344:20	caveats 140:15	19:4 22:3,11 45:3	438:22
114:10 127:9,16	347:17 382:13	378:14 444:8	99:2 453:18	chartered 20:20
149:21 150:10,14	386:16 407:2	CCRCs 452:4	chaired 18:22 57:7	check 385:18
163:12,13 190:5	416:5 419:14	CDC 19:7 94:9,13	chairing 13:18	395:18 402:19
192:18 195:13	422:13 443:20	95:11 265:5	Chairman's 130:2	403:6 436:1
196:4 207:10	444:1 447:8	Cedars-Sinai 422:4	challenge 50:6 95:6	checked 451:3
227:18 229:16	450:14 452:14	center 25:8 26:7	95:20 96:13	checking 395:14
235:2 237:4	case-by-case 442:4	28:21 383:21	246:11,19 247:9	checks 451:3
239:11 253:1,9	cast 278:11	centered 61:15	260:3 302:18	cheese 397:9
254:8 259:1,17	cataract 382:3	centers 20:10	challenges 414:13	chemo 231:9
260:2,4 262:13,14	catastrophic 166:7	central 110:5	chance 34:21	chemotherapy
262:15 297:1	242:18 372:3	334:19	124:21 145:13	225:6 283:16
305:5 321:22	437:2	central-line 121:2	270:7 357:6	304:14 311:18
324:19 325:12,12	catch 161:1 166:15	central-line-asso...	change 17:7 52:2	312:19,22
328:8,18 329:11	257:2	121:8	56:20,20 85:18	chest 361:9,12,15
330:15 345:16	categories 268:10	CEO 24:2 163:11	118:5 119:6	361:22 362:3,11
347:22 348:16	268:15 276:20	certain 33:22	122:18 132:20	362:15,21 364:8
369:22 372:1	296:17 330:12	126:15 165:13	134:2 140:7	390:1
380:5 414:6	380:1 406:11	245:9 258:21	143:21 147:22	chew 131:12 269:5
417:14 419:6	categorization	302:12 324:3,9	151:18 152:22	Chief 18:15 19:20
436:4 437:19	278:14	328:15 347:12	153:15 157:15	28:20
443:14 444:6	categorize 447:15	351:14 382:15	164:7 187:17	child 49:17 436:20
447:9,19 453:5,10	category 51:1	392:14 400:20	201:8 212:8,16	childbed 431:1
cared 449:11	267:10 328:16,16	412:2 415:2	244:10 245:13,17	children 419:17,19
career 23:5	332:22 344:14	426:19 446:7	248:21 284:21	419:20 421:20,21
careful 71:21	347:15 366:3,9	certainly 9:6 11:4,6	358:9,9 428:17,19	432:16
117:12 198:19	382:18 405:6	17:3 64:8 66:1	439:13	child's 436:17
218:11 337:19	catheter 110:6	71:21 72:20 75:17	changed 7:17 203:1	chime 285:2 342:13
434:11	385:4 386:11,13	77:17 81:9 87:4	363:19 373:14	choice 126:6 204:5
carefully 129:20	399:22 400:7	115:9 127:22	402:11 417:14	204:6 249:11

choices 162:2	clarified 219:4 385:7	240:7 244:18 261:14,19 262:1 263:16 269:13 282:21 294:22 302:9 304:12,15 330:18 343:21 365:5 385:1 404:15 407:8 425:1	53:6	coalitions 21:13
choose 8:15 97:3 154:22 207:18 290:11 314:7	clarifies 325:6		Clinton 12:20	Coast 29:18
choose-the-perfe... 97:17	clarify 77:12 126:12 175:12 176:17 190:3 193:19 204:13 299:16 317:22 329:10 362:21 394:13 409:22 423:20 437:11		close 78:19 81:11 186:21 187:7 206:21 208:20 270:18 281:16 389:6 391:14 399:9 403:14 426:10 454:11	code 249:17,19,20 351:19 362:12 365:13 448:8
chose 380:3,4			closed 386:18 391:5	codes 250:6 252:17 252:18 365:6 368:19 406:22
chosen 68:3	clarifying 62:4 264:9 289:15 406:3 409:18 410:2 454:15	clearer 354:7 368:22 436:13	closely 54:7 70:7 108:11 334:4	codified 321:16
Chris 8:6 16:12 95:3 103:6	clarity 181:1 218:20 409:11 454:17	clearing 214:12	closes 399:20	codify 415:11
Christine 2:5 95:2 121:18 125:10 137:10 165:2 190:1 244:14 245:19 257:1 260:7	clarity's 330:11	clearly 4:14 46:20 69:19 79:14,14 94:12 97:20 98:15 109:10,22 122:15 145:20 157:5 191:17 212:14 239:8 248:21 250:5 261:16 262:3 286:16 314:20 321:5 336:8 349:8 353:3 361:22 378:5 393:21 408:15 423:1 434:17 447:1	closing 331:14	coding 20:5,11 249:22
circle 167:19 255:2 256:9,13,20 257:10,20 263:3 281:7 285:6 286:12,16 287:8 293:9 303:17 304:10,19,21 305:9,12 306:4 307:7 309:11,16 310:1,22 311:8,10 311:15 314:17 317:1 326:12,14 326:14 327:12,18 327:21 330:21 331:1 338:7,9	Class 345:20 346:5 349:8 404:3,11 406:16 431:15	clearly-defined 270:17 281:12 283:14	closure 316:5	cognitively-imp... 433:18
circles 145:17 257:11 286:5 308:21	classes 129:9 349:8	Cleveland 18:2,3	clumsily 97:19	cohesion 45:5
circular 144:18	classic 49:1 386:10 397:4 440:22	clinic 18:2,3 22:4 112:17 312:20 378:3	cluster 360:7	coin 244:1
circulation 361:13	classification 20:11 252:13 345:18	clinical 21:3 23:22 26:3 29:19 184:17 261:2,7 361:7 373:8 378:6 380:3 380:14 398:21 439:4	CMD 2:12	coined 144:7
circumvented 440:8 443:9	classifications 154:7,8,10	clinically 41:15 389:2 399:4	CMO 146:10	cold 32:14
city 28:19 34:10	classified 364:16	clinically-acquired 260:22	CMS 22:18 64:9 71:10 75:9,11 82:8,14,22 83:5,7 83:16 87:7,10 88:10 89:1 94:15 95:16 105:8 136:1 136:2 197:4 210:2 219:8 225:13 226:21 235:16 236:19 237:9,12 238:19 244:19 245:13 248:14 251:22 254:7 256:18 258:9 261:22 264:12,16 265:9,12,20 271:12 280:9 289:17 295:5,10 296:1,2,6,20 297:6 299:18 300:6 319:20 321:5 336:16 376:21	cold-call 209:4
claims 34:15	clause 132:14 134:6 140:2,3 149:7 155:8 160:15 188:3 204:13,16 206:7 207:13	clinician 28:5 93:20 136:12	CMS's 71:14 237:3 249:2,20 257:12 258:4 291:14	collapse 268:15
clamps 385:9	clean 71:11 194:12	clinicians 10:16,17	CNO 24:1	colleague 18:1 33:12 226:21
clarification 81:15 82:21 119:10 121:20 132:8 172:16 190:9 224:3 346:8 433:6 443:5,12	cleaned 81:7			colleagues 12:19 24:21 47:8 210:2 210:5 216:20 340:19 414:21

combination 384:12	77:20 84:4 86:20 95:4 100:21	429:9 432:2 438:5 449:20	commonalities 69:21	451:13,15
come 6:14 13:16	101:21 106:9	commercial 19:3	commonality 69:5	complicates 246:10
32:16 38:10 40:19	111:1 122:14	Commission 17:16	commonly 411:19	complication 379:20
44:7 46:9 48:20	133:6 134:18	17:21 18:22 22:15	Commonwealth	complications
54:21 70:6 78:21	137:12 142:6	23:16,17 32:20	381:7 408:2	84:17 252:7
85:7 106:5,17	148:15 154:6	66:10 208:2	community 49:4	253:16 320:19
115:7 121:10,11	167:5 173:20	238:16 240:16	58:13 97:5	322:18 407:4
128:7 145:7,10	185:1,15 188:7	260:19	community-orie...	component 71:1
166:18 173:15	192:15 196:16	commit 438:13	58:10	76:16
218:20 226:15,16	200:4,5 213:7,16	committed 447:11	companies 26:16	components 70:13
227:11 229:18	228:21 237:18,20	committee 1:9,18	27:11 245:9	comport 342:13
236:7 238:13	276:9 291:1,8	9:1 10:1,9 13:19	company 19:20	350:6
250:13 252:18	304:3 319:6	15:16 16:2 19:6,7	20:3 24:13 27:13	composites 47:9
254:11 261:13	331:16 341:12	21:18 23:1,21	27:17 185:5	comprehensive
269:9 270:8 279:8	359:9 360:6	35:11 40:15,17	compare 312:22	47:10 433:12
279:8 284:14	398:10 402:21	41:3,7,7 42:6 44:6	compared 331:18	comprise 185:9
316:4 321:8	404:9 409:1 426:6	45:6,19 46:7	364:20	222:8 266:17
328:12 335:7,18	443:5 450:13	49:16 53:11 68:18	comparisons 37:12	374:20 427:19
335:19,22 339:12	454:13	74:20 90:17 91:3	compassionate	computer 275:22
356:20 375:16	commentary 125:4	99:14 101:10	59:11	286:22
381:3 392:2 401:8	342:12 350:7	104:22 106:11	compete 358:19	computers 320:16
411:5,7 412:9,10	375:14	114:18 129:7,10	competency 447:3	conceivable 109:7
420:9,15 424:21	commentators	143:20 144:5	competent 438:4,7	concentrate 200:22
448:18 450:1,18	402:22 403:3	146:3 161:15,16	438:11,16 439:8	concentration
452:6,14	commenting 41:10	167:3,11,21	439:19 440:7	27:20
comes 91:18,21	comments 5:21 6:5	177:15 179:4	441:5,7 447:10	concept 9:5 54:19
151:20 159:11	6:9 9:10 41:17,22	183:18 186:9	complain 396:7	58:8 84:22 97:1
160:22 162:16	42:1 44:3 78:20	194:14 214:15	complement 99:8	115:13 127:15
237:9 240:2	88:10 96:15 98:9	243:19 244:17	complementary	129:8 130:14
266:21 274:5,6	101:18 114:5	265:4 272:14	12:18 13:9,21	187:12 291:15
361:9,20 366:5	120:10 152:6	291:3 295:8,21	complete 151:10	306:3 319:9,15
374:12 386:10	162:5 163:21	298:6 300:20	286:7	320:2,18 454:17
394:11 422:12	165:16 167:2	317:20 322:7	completely 45:20	concepts 50:19
450:7 451:2	186:4 187:20,22	328:5 333:18	103:9 169:22	64:10 84:8 94:19
comfortable 39:11	210:20 250:15	343:1 346:19	210:10 224:17	127:19
46:3 84:9 147:6	261:15 288:7	357:7 371:7 388:5	230:7 369:9 413:6	conceptual 338:2
147:11 313:2	290:9 292:6 294:2	403:8	447:2,16	conceptualization
447:16	316:4 320:1 321:1	committees 23:12	complex 20:1 80:22	306:20
coming 139:19	353:10,12 354:6	39:14	complexity 131:21	concern 79:11
144:11 274:22	359:14 365:4	Committee's 63:13	173:6	86:16 128:22
275:2 291:3 310:3	372:9 374:14,17	common 30:8	complicate 89:18	238:11 394:3
362:16	378:17 383:4	67:22 68:16,19,20	323:17	435:13
commas 178:10	395:5 400:19	69:2 80:4 85:2	complicated 63:4	concerned 327:10
commence 14:18	402:15 407:6,13	221:12 260:4	93:2 219:10	concerns 229:20
comment 5:20 8:12	407:16 410:6	264:5 323:1	290:15 322:2	concerted 67:2
8:17 41:13 68:21	411:11 421:10	411:15	405:11 421:18	concluded 129:11

concordance 427:15	341:13	364:15 367:15	constantly 117:8	contracted 102:6
concrete 361:7	conference 45:12	369:16 370:13,16	constituency 306:15	contracts 22:18
concretely 106:16	confess 261:12 353:21	370:17,20 371:1	constituent 165:21	contractual 63:20
concussions 289:22	confidence 12:1	371:17 373:7,19	Constitution 199:12	contribution 109:3 203:13 214:14
condition 55:1 71:6 86:8 197:5 225:5	confined 333:7	374:7 378:19,21	constructed 39:15	control 19:5 243:21 258:8
225:19 230:9,18	conflict 132:4	431:4	consultant 20:3	controversy 158:11 276:16
231:2,11 233:7,9	conflicts 6:22 28:13 29:13 163:5,14,15	consequence 149:21 190:4	consumer 20:21 47:8	convene 41:2 104:11
239:12 249:12	203:6 214:13	191:19 192:18	consumers 11:1,19 53:6 95:16	convened 1:18
250:1 251:5 253:8	confound 392:11	207:2,10 417:3	consumer-facing 19:21	conversation 77:16 95:8 108:16 148:2
253:14 255:10	confuse 66:12 71:16 82:16 95:16	consequences 206:11	contain 270:10	163:3 218:2,5,8
258:18 259:9,16	confused 257:4 296:9	consider 41:18 56:12 61:1 83:14	contained 68:4	219:7 275:1 312:8
269:17 297:17	confuses 264:17	86:17 98:6,7	contaminate 374:21	321:11,15 337:20
380:6	confusing 204:17 306:13 307:5	172:10 181:13	contaminated 413:10 421:2,6	342:8 374:10
conditions 1:8 9:6	309:5 316:14	186:10 206:18,22	contamination 349:11	424:20 427:10
20:1 49:16 50:9	319:2 404:13	223:22 312:14	content 35:15 271:17	conversations 14:5 381:5
55:17 60:5 64:20	confusion 71:17 154:13 264:12	324:10 335:2	contentious 87:21	convince 238:6
68:7 71:3,15 73:5	266:1 355:9 369:4	346:21 371:3,11	context 51:20 52:16 71:12 77:7	convinced 18:3 441:3
75:7,9,10 76:20	405:2	377:6 384:20	165:19 170:13	COO 24:1
76:21 78:14 82:7	congenitally 111:18	385:3 391:9 415:6	184:14 187:2	Coordinating 18:9
82:9 84:16 87:8,9	congratulations 171:7 229:3	426:10	236:19 350:8	COPIC 20:3,14
87:16,17 89:4	congressional 249:4	consideration 227:1 365:12,18	356:16	copies 7:9,19
94:14 112:11,12	congratulations 171:7 229:3	371:13	continually 278:6	copy 7:6,8 107:10 108:2 131:17
112:13,16,20,22	congratulations 171:7 229:3	considered 37:10 128:14,17 185:13	continue 63:3 65:15 164:19	172:4 182:15 218:3
113:15 114:8	congressional 249:4	186:2 211:10	185:6 186:10	core 45:17 165:6
176:12 187:5,11	congruent 271:19	248:7 312:10	313:3 353:5	coronary 388:14
187:18 191:10	conjunction 176:20 176:21 177:4	366:12 368:19	CONTINUED 4:1	correct 91:15 153:9 295:15 370:18
196:20 214:5	connected 53:15 291:21	382:10 399:11	continues 161:21	380:6 381:17
218:13 224:7,13	connoisseur 205:16	407:9	continuing 212:20 213:2 273:9	407:12 424:4 439:17
224:20 227:21	connotation 86:5	considering 307:9 318:12 427:1	315:16 319:10	corrected 118:22
229:9 230:1 231:5	consensus 36:18 37:1,7 38:20	considers 118:15	continuum 42:21 43:3 100:12	correctly 369:18 370:1
231:22 232:1,5,17	41:12 42:6,8,12	consistency 369:3 369:11	contract 16:4 70:10 70:10,12 71:2	correctness 241:11
235:15,18,21	44:5 73:10 308:1	consistent 132:1 148:1 194:6,16	75:6 144:5 217:15	cost 50:3 248:21 325:15
236:8 237:2 239:9	308:7 333:22	284:19 431:11	318:21	costs 24:17 333:5
242:2,6,7,9 243:9	334:2 343:8	consolidate 33:3 85:18 87:13		Council 18:6,9
246:15,17 247:18	consensus-based 178:21	consolidated 359:18 360:8		
247:19 249:5	consent 361:2,4 363:8,11,13	consolidations 359:22		
251:21 252:5				
253:6 255:3 257:7				
257:14,18,21				
267:11 268:2,13				
269:1 271:13				
289:10 291:5				
294:20 295:3,5,10				
295:20 296:2,7				
320:19 322:18				

councils 39:20	104:6,18 105:4,9	209:14,22 210:14	331:2,21 332:10	434:22 435:10
count 370:13 387:6	105:13,16 110:14	210:17 211:1,5,6	333:11 334:16	436:5,14 437:8
389:13,15 391:13	111:15 113:2,22	211:8,13 212:2	335:3 337:16	438:1,9,14 439:10
392:3	115:9,18 116:15	213:1,20 216:3,8	340:4,8,15,18	439:14,21 440:11
counted 401:22	118:1 119:9 120:7	216:11 222:3	341:1,18,20	440:14,18 442:1
431:9	121:16 122:5,8	223:3 226:5	343:10,15 344:21	443:3,21 444:12
counter 158:13	123:14,22 125:10	228:14,22 229:5	346:10,18 347:1	444:19 445:3,9,18
counter-argument	127:4,5 128:3	229:17 233:14	348:2,21 349:18	447:4,22 448:17
272:14	129:16 130:1	235:12 237:16	349:22 350:19	449:2,6,8 450:5
counting 62:10	131:8 132:15,17	241:15 243:1,15	351:15,18 353:9	450:17 451:9,14
396:14,15 442:12	134:16,21 137:1,9	245:19 247:14	353:20 354:17,18	452:1,6,17,20
countries 348:13	138:5 142:2,7	248:11 249:9	356:7 358:14,21	453:1 454:6,10,19
country 87:2 275:9	143:6 144:2,9	251:14 252:8	359:3,10 360:16	455:2,9
411:16 414:22	145:15 146:14	253:21 254:18	360:21 361:6	Co-Chairs 1:22
counts 12:22	147:20 148:21	255:4,22 256:5	363:17 365:1	44:4
116:11 228:9	149:2,11,16 150:2	258:13 260:6,10	367:6,16 368:4,11	co-morbidities
401:19	151:3,13 152:1,4	261:10 262:10,22	369:6,13 370:5	111:5
couple 5:10 6:15	152:20 153:3,8	263:19 266:4	371:4 372:8,18	CPHQ 2:21
10:3 22:16 53:11	154:14 155:20	268:17 272:4,11	373:9,17 374:3,9	CPT 252:3,13
57:2 63:10 64:21	157:1,16,22	273:4 274:1 275:5	375:3,8,13 376:17	craniotomy 430:5
73:12 81:12 91:4	158:18 159:3,8,19	276:5 277:14	376:20 378:1,10	create 16:6 38:15
94:9 146:19 224:6	160:7,9 161:14	279:3,21 280:5,8	378:20 379:8,16	144:5 146:13
234:15 280:19	162:22 163:21	280:11,14 285:9	380:20 381:19	187:17 191:20
294:17 309:7	164:5,18,22	285:14,17,20	383:4,14,21 384:2	253:15 265:19
312:12 377:15	165:15 166:15	286:11,15,21	385:10,19 386:6,9	284:22 316:17
386:16 391:21	167:14 169:3,12	287:3,11,22	386:22 387:21	317:16
427:20	169:18 173:2,10	288:15 289:13	389:1,12,20 390:7	created 120:11
coupled 50:4	173:14 174:6	290:6,22 291:10	390:11 391:12	199:12 223:11
coupling 100:21	175:11,19 177:11	291:18 292:12	392:6,9 393:18	264:13 265:22
courier 417:8	178:19 179:11,14	293:2,13,22 294:7	396:16 398:3	266:21 277:11
course 70:21 88:1	180:8,21 181:10	295:1,4 298:18	399:6 400:13	creating 138:20
92:19 136:11	181:17 182:2	299:1,20 300:1,6	401:6,11,15 402:2	258:7 320:8
195:13 210:4	183:9,14,17 184:4	300:16 301:1,20	402:14 403:11	credentials 375:1
253:9 360:22	184:7,21 185:14	302:1,22 303:2,19	405:12 406:4,12	credibility 113:18
court 267:3 273:20	186:8,15,21	305:18,21 306:9	407:10,13,22	174:4 176:5
cousin 375:6	187:19 188:5,19	307:8 308:5,14,22	408:18 409:17,20	creeping 88:2
cousin's 376:2	189:16 190:1,10	309:13,15 310:4	410:1 411:4,11	criminal 183:13
cover 374:12	190:19,22 191:6	310:15 311:1,19	412:18 413:3	191:10 247:21
coverage 139:10	191:15 192:1,11	312:2 313:20	414:18 418:3	260:16 270:4
covered 357:15	195:18 196:15	314:4,10,21 315:3	419:2 420:6	281:19 351:11
covers 359:2	197:6 198:2,10,17	315:7,11 316:1,3	421:15 424:9,15	352:22 355:7
co-chair 2:2,2 9:20	199:2,6,14,17	316:8 317:4,7,15	424:19 425:12,15	376:7,13 448:18
10:1 12:5 34:19	200:1,6 201:17,22	317:19 318:8,20	426:5 427:9 429:3	448:18 449:1
62:3,9,21 81:14	202:4,9,11,16	322:8 323:12	429:6 430:11,18	453:11
81:22 88:8 93:8	203:8,11 204:1	326:10 327:3,7,14	431:10,17,21	crisp 84:15
94:21 96:2 98:1	205:7,19 206:14	327:16 328:4	432:2,14,18	criteria 38:15,16
98:22 101:18	208:6,14 209:2,12	329:1 330:7,19	433:13,22 434:9	43:20,21 44:1

47:15 50:17,21 51:3,18 54:22 76:18 77:12 80:13 85:16 109:4,5 142:12,18,19,21 143:5,9 146:18 149:14 171:12,21 172:8,8 175:15 176:13 182:9 192:4 206:16 317:13 333:17,21 341:12 359:17 414:9	currently 19:4 24:9 27:10 29:20 30:7 37:16 38:4 39:18 49:14 51:19 54:16 82:22 98:18 170:17 183:4 186:8 221:22 230:3 285:8 421:7 428:4 curve 349:17 custody 433:19 436:20 cutting 67:14 cycle 65:12 Cynthia 2:5 31:21 33:6 34:3 113:4 167:4 176:9 192:1 197:15 260:10 292:6 308:14 425:15 435:10 444:13 446:2 447:6 C-sections 405:16 406:10 C-Suite 24:20 C2 202:14,16	171:2 181:1 183:18 189:21 194:4 203:19 214:1 246:20 258:7 332:17 357:16 374:8 399:21 455:4,20 455:20 days 5:10 18:1 21:20 29:18 43:7 94:10 208:22 209:1 385:17 400:12 413:18 414:8 da-da 425:19 da-da-da-da 425:20 dead 352:4 deal 49:20 53:19 109:17 119:20 221:22 388:3 394:3 407:16 435:19 448:7,8,12 dealing 92:16 113:8 dealt 220:6 Dean 26:4 death 4:10 186:14 205:3 207:17 208:17 212:5 247:20 278:5 337:9 345:18,22 346:5 349:11,14 351:5,22 352:2 370:18 405:18 406:8 407:1 412:19 419:4 423:19 424:1,5 425:4 426:2 428:18 429:18 438:2 deaths 349:7 351:10 404:17 405:4,6,10 428:21 431:16 449:17 Deb 423:1 debate 116:9	135:17 141:20 153:7 247:12 debated 221:17 debates 135:14 221:7 debating 205:11 296:5 Debbie 17:14 Deborah 2:8 121:17 123:14 143:15 149:2 178:7 183:2 186:15 188:1 201:13 204:2 224:4 226:6 229:17 245:20 247:14 261:11 262:22 287:3 331:13 360:16 419:9 432:11 442:2 444:13 446:1 decade 157:13 272:8 decide 83:5 162:18 179:4 244:20 298:7 301:10,11 389:5 391:21 446:17 decided 26:10,12 254:1 296:10 deciding 41:8 decision 16:22 50:11 53:8 59:7 155:21 166:21 322:6 357:3,5 369:22 389:3 391:5 393:9 439:19 decisions 59:6 95:17 279:9 281:2 342:18 deck 241:17 decrease 67:9,11 deem 204:14 deemed 23:15 82:9 141:5	deems 39:3 263:10 deeper 44:21 66:2 defeating 253:18 defects 374:6 defend 112:5 defending 344:17 defense 34:12 412:1 defensible 273:10 368:2 defer 253:4 Deficit 248:17 definable 68:6 define 38:12 71:7 71:16 72:13 76:19 94:5 98:4 101:10 101:12 118:13 119:15 144:22 145:22 151:21 152:12 153:6,14 175:14 176:15 195:22 196:9 218:6 223:9 230:14 268:22 284:4 294:12 313:21 323:9 328:5,10 329:12 338:8 414:1 416:13 418:21 427:19 428:10 434:5,7 449:14 defined 4:15 98:5 98:19 107:14 114:7 132:21 144:13 147:8 148:19,20 151:22 152:16 153:3,11 153:11 156:1 157:4,5 170:20 183:4 199:22 212:14 270:3 309:4 322:16 325:2 332:9 418:22 defines 108:3 116:19 282:17 323:7
--	--	--	--	---

defining 101:3 119:22 120:1 256:12 271:17 295:9 322:12 368:17 384:16 423:22 451:7	255:11 263:12,15 282:3 285:10 286:17 299:7 303:9 307:12 309:10 311:8 319:4 321:17 322:17 323:11 324:14 331:19 334:14 335:12,18 337:4,22 359:17 365:7 378:15 383:20 384:6 399:8 406:16 425:17,22 426:9 428:15 446:22	delineation 354:8 deliverable 72:10 72:15,17,22 73:15 76:3 82:1 90:5 187:3 deliverables 74:11 74:19 167:22 deliveries 384:20 401:2 delivery 59:16 384:17 402:5 431:3 Demerol 413:9 demonstrate 277:3 demonstrated 355:10 dent 241:2 Denver 19:19 413:7 department 21:6 22:5 28:2,9,11 57:22 63:21 89:20 139:13 238:18 324:18 352:10 391:20 450:21 departments 240:17 dependent 328:2,3 433:8,8,15,17 depending 56:4 77:15 86:14 264:14 278:18 389:11 416:13 depends 228:18 258:19 259:3 depressed 438:6 depression 439:2,4 depth 221:9 describe 154:21 188:14 190:15 196:9 247:20 248:9 267:5 346:7 described 74:16 108:7 142:20 149:20 192:18 354:1 describes 4:10	125:19 197:7 198:3 200:12 207:16 208:16 212:4 describing 155:2 196:7 422:22 designated 17:17 designed 300:3 405:9 desirable 220:18 desire 83:11 desired 191:20 desperate 376:9 despite 111:7 155:15,18 195:12 195:14 detail 78:9 100:2 120:11 detailed 41:6 details 9:8 38:7 341:10 determination 46:12 129:15 229:10 determine 119:1 424:18 determining 47:14 47:15 develop 76:9 218:15 247:2 249:6 299:21 315:1 developed 54:20 55:11,16 101:12 111:6 229:22 developing 50:21 68:18 76:17 93:21 development 42:12 69:2 73:2,10 76:5 76:6,7 334:2 device 7:22 8:2 330:15 385:1 410:5 419:5,6,7 419:22 421:6 devices 24:14 device-oriented 382:22	devil's 133:11 de-emphasize 162:6 diagnoses 267:11 diagnosis 361:21 diagnostic 362:17 diagram 255:2 256:6 257:4,16,19 258:16,17 263:2 275:22 281:7 282:2,12 290:15 301:2 302:8,21 303:3 304:4 306:19 308:12 315:1 320:6 325:1 326:9 329:5,7 331:5 338:6 428:3 428:6 diagrams 265:7 266:17 271:14 dialog 6:10 446:18 Diane 2:10 21:1 73:12 116:16 118:1 123:4,16 125:22 134:17 138:6 154:16 159:8 173:18 204:11 207:3 209:4 291:6 339:2 343:3,16 344:21 367:9 368:4 379:10 388:11 390:13 400:21 404:7 406:14 408:21 414:20 427:10 442:2 450:11 Diane's 122:14 354:5 dickering 206:1 dictionary 205:12 die 242:11 259:13 413:16 431:5 450:10 died 248:5 407:3,4 408:3 409:13 420:8 428:7
---	---	--	--	--

441:18	397:9 414:16	disagreement 6:12	164:15 166:17,22	Ditto 377:22
differ 149:18 240:6	444:5	disagreements	169:10 170:12	dive 44:21 338:20
difference 127:12	differs 443:14	310:18	172:18 178:15	diverting 413:9
224:9 227:3 239:9	difficult 79:21 91:6	disappearance	182:19 184:15	divided 437:18
241:3 395:20	91:14 98:14 101:7	442:8 444:17	186:17,19,22	divine 219:20
402:13 423:12,14	176:15 207:1	disappearing	194:21 203:17	Division 22:3
differences 6:13	416:19 437:6,22	294:20	214:12 258:6	doctor 225:18
85:12 86:2	dike 236:21	disaster 184:13	268:19 279:10	doctors 185:4
different 8:4 10:5	diluted 141:14	405:17	322:20 338:5	document 13:2
46:20 53:3 56:3,4	240:8	discern 137:17	339:17 344:3,8	142:11,17 148:17
56:10 61:2,12	diluting 116:22	discharge 209:17	346:9 352:21	162:16 175:21
63:8 64:5 70:5	dimensions 325:10	435:4	399:13 403:22	178:1,2 179:9
85:4 86:8 87:12	dinner 216:20	discharged 267:2	404:19 416:22	180:16 340:3
89:11 94:18	217:4 455:6	432:10 433:19	422:16,19 452:7	343:8 398:19
115:20 121:8	direct 54:9	discharging 436:20	discussions 10:16	443:7
127:20 137:17	direction 86:14	disciplines 68:6	11:7,10 81:4 91:8	documentation
138:11 154:10	249:8	87:19	102:1 125:17	45:15
167:6 174:9,9	directions 44:6	disclose 15:13	210:5 229:11	documented 373:7
188:15 201:16	441:20	21:12,16 23:14	381:10 400:14,16	documents 40:18
220:21 224:8,18	directly 12:14	30:10	disease 347:16	dogs 266:16
228:15 229:20	50:18 57:14 58:15	disclosure 16:8	441:16	doing 6:20 12:21
230:4 240:12	Director 17:18	17:20 18:8 22:13	diseases 18:19	32:17 34:4,9
248:10 255:11	21:5 23:7 25:8	30:7	224:15 266:18	35:17 49:14 65:3
257:21 259:2,17	28:10 34:18	disclosures 3:5	267:10	77:13 118:9
259:18,19 260:4	Directors 22:12	6:19 15:10,11	dishes 95:10	136:21 138:18
261:20,21 262:2	disabilities 224:15	25:2 26:21 31:14	disorders 224:15	139:9 226:1
265:21 276:10	266:19 413:20	34:6	267:11	233:13 236:20
277:10,11 281:8	418:2 428:22	discourse 91:9	disparities 47:12	246:8 256:16
284:15 298:4	disability 4:11	discover 391:4	47:21 54:3,6,15	302:4 366:4,6
312:22 313:9	205:3 207:17	discovered 203:12	disparity-sensitive	388:14 401:19
330:12 355:1	208:18 211:3,17	375:20 376:2	54:20	448:2
364:7 381:18,20	211:17,19 212:6	discovery 401:9	disputes 436:21	dollars 60:16
382:16,17 428:1	242:16 247:21	discrete 270:16	dissections 214:20	domain 244:8
437:22 444:7	278:5 337:9,10,11	281:11 283:14	distant 204:10	364:3
447:3	337:15,17 405:18	discuss 71:5 72:9	distinct 70:3,4	Don 57:7
differentiate 309:2	413:6,13 414:2	269:1 437:21	100:14	door 352:3 377:11
315:19 439:18	416:2,14,17 417:1	discussing 180:5	distinction 128:12	Doron 2:11 25:3,5
443:10	417:6,18 418:6,21	187:7 198:22	242:2,21 250:8	100:20 113:5,22
differentiated	419:4 421:4,7	325:22	269:16 318:15	114:1 153:19
320:10	423:19 424:1,6	discussion 7:13	distinguished	184:10 190:14
differentiating	425:4 426:2	14:7 21:19 37:4	318:18	195:16,18,20
309:7	429:18 438:2	56:15 71:8 78:8	distract 329:19	197:3 207:22
differentiator	449:10	78:18 80:2 86:4	distractors 265:13	208:7 235:13,14
187:14 256:12	disabled 413:17	86:12 94:22 97:20	District 73:16	251:15 253:21,22
298:12	420:8 433:18	106:1,5 124:3	ditch 367:17	256:22 257:3
differently 156:1	disagree 122:10	144:4 160:14	ditched 301:20	260:12 275:6,7
174:11 235:20	345:2	162:15 163:6,22	302:2	304:3,5,9 305:20

305:22 309:9,17 311:2,7,21 312:5 330:7,8,20 367:10 368:5 369:13,15 370:15,22 381:14 385:19,20 386:7 387:19 397:11,12 399:15 406:4,6 420:19 423:21 427:15 444:13 446:1,3 Doron's 196:16 276:9 278:21 426:6 dosage 412:14,15 412:22 dose 413:15 doses 421:21,22 dot 301:18 428:6 dots 302:20 doubt 14:17 46:19 downside 240:10 downsides 133:12 Dr 5:3 30:11,20 31:7,21 32:13 33:7 34:3 35:20 62:8,22 81:20 82:3,20 84:2 88:11,17 90:3,16 94:3 99:15 100:8 101:8 124:15 125:9 128:4 143:22 144:6 145:4 154:14 155:22 172:15 175:12 179:7,12 180:22 181:14,19 187:1 211:12,14 213:12,15 214:17 219:2 233:16 236:17 263:21 277:16 287:15 290:10 295:15 296:19 297:8,12 312:9 314:1,5 318:22 320:12 321:3 335:5,21	336:2,6,11,14 337:6 340:2,6 341:2,19 350:8 352:13 354:12 359:8,11 364:12 382:20 384:1 390:5,9 395:3 400:11 403:5,10 405:8 415:14 418:20 424:22 425:13 444:21 454:13 455:1,3 draft 41:11,12 44:22 drains 388:20 drama 335:7 draw 12:16 292:9 325:11 drawing 302:16 drive 7:15 46:21 52:18 56:20 187:13 245:17 250:1 354:14 driven 134:1 240:15 249:2 277:8 driver's 435:9 drives 133:19 352:16,17 353:7 driving 69:20 278:3 dropped 307:12 dropping 178:16 drove 417:9 441:17 drown 451:22 drowning 451:19 452:2 drug 109:22 110:1 154:12 dry 32:14 Duck 216:22 455:6 due 196:3 404:18 dumb 380:19 duplicate 189:14 duplicity 95:15 DVTs 242:16 dynamics 133:19	D.C 1:21 199:11 <hr/> E <hr/> E 5:1,1 earlier 15:14 28:22 39:17 103:11 104:11 183:6 214:13 220:4 247:4 248:6 271:1 294:2,18 319:7 322:20 354:14 359:14 366:11 401:8 408:10 422:15 early 15:1 18:4 63:17 67:6 73:13 76:17 124:17 140:8 144:4 246:2 357:7 363:9 441:16 earth 150:13 easier 40:5 147:3 171:17 239:4 287:6 easier-step 40:19 easily 4:15 40:14 40:17 157:5 207:11 212:14 273:10 369:16 433:12 Eastern 279:15 easy 40:12 48:16 286:22 390:2 400:13 437:20 441:21 echo 186:3 353:17 368:7 economy 319:21 ED 450:15 451:8 Eddie 70:16,20 83:9 88:22 105:8 219:7 236:19 319:6 edge 314:13 edging 394:20 education 37:13 EEG 268:2	effect 191:20 230:16,17,17 effective 127:12 effector 57:5 effects 253:15 303:10 311:22 313:10 effectuate 292:16 efficacy 313:1 effort 53:10 67:2 96:10 137:22 284:9 330:13 332:16 efforts 90:7 111:7 126:22 egregious 263:8,14 EHR 54:10 EHRs 53:20 61:22 eight 25:7 102:2 234:10 375:16 Eisenberg 33:13 102:12 either 12:14 106:6 150:19 151:8 155:14 162:3 174:3 180:20 252:13 340:12 345:1 370:16 elaboration 175:5 elective 362:17 406:20 electronic 20:16 37:21 53:19 60:18 69:18 148:17 element 335:1 446:6 elements 61:21 161:5 eliminate 162:3 278:7 422:15 eliminating 59:15 126:19 elimination 109:12 115:15 eloped 447:11,17 elopement 438:3 440:5,21 442:9	444:4 446:15 447:20 else's 368:3 377:17 email 71:9 445:19 emails 8:5 31:19 embedded 61:21 161:13 256:9 286:16 embolism 429:10 429:20 430:15,17 emergency 57:22 364:9 371:16 372:2 450:20 451:3,4 emergent 360:19 360:22 361:4 364:16 367:14 emphasis 51:13 emphasized 13:4 empiric 251:20 encapsulate 86:1 321:10 322:4 encapsulated 89:22 encompass 227:19 287:13 encompassed 212:1 221:4 encompassing 227:9 encountered 378:4 encounters 101:5 ended 13:8 139:19 375:17 endorsed 37:9 264:3 endorsement 50:16 78:16 106:6 endorsing 36:18 endoscopes 421:2 endoscopies 369:2 endoscopists 407:19 endoscopy 407:8 408:4 ends 135:4 141:7 272:6 379:4 405:17
---	--	--	--	--

end-of-life 59:12	73:14 453:11	errors 20:5,15	183:7 184:8,16,17	102:4,14 103:1,12
end-users 53:5	environments 71:3	221:12,13 406:9	184:18 186:4	106:8 107:6,14,15
energy 284:9	71:20 72:13,14,16	411:17 412:14,15	187:20 195:22	109:2,16,22
engage 83:2	75:10,11,15 76:2	441:13	196:3,7 197:7	110:11 111:2,10
engaged 41:20	77:3,7 78:12	especially 47:7	198:3 199:20	116:19 117:1,15
Engaging 59:5	84:20 87:16 91:13	56:11 140:8	200:13 201:19	118:7,15 120:4
English 148:10	91:17 264:18	ESQ 2:5	203:3,4 204:19,19	125:8 126:19
149:3 151:5	265:22 295:19	essence 252:10	207:8,15,16,17	128:13,18,22
155:16,17 174:22	297:1 319:8,9,16	essential 443:1	208:1,3,17,21	129:2,9 131:20
175:1 180:5,7	319:18 320:3	essentially 39:2	212:4,14 221:9	132:19,20 133:2,8
418:1	321:22 322:21	43:10 44:20	233:5,9 239:10,10	134:2,4,8 138:1
enhance 275:16	452:13	129:21 162:2	242:13 249:12	139:18,22 141:2
enhancement	envisioning 44:10	384:9	251:5 255:12	141:17 142:20,22
110:10	EPA 324:19	established 26:8	258:20 259:2,15	143:2,20 144:3,15
enjoin 374:10	epidemiologic	57:2	269:17 274:11,14	152:22 154:11,12
enjoy 214:22	392:18	establishes 161:2	274:16 309:10	155:2 159:13
enormous 332:16	epidemiology	establishing 317:11	311:13 319:14	161:1 162:18
enormously 253:4	19:10 20:14	estimation 95:13	334:7 344:1 346:1	163:16,17,20
enriched 41:16	231:20 283:8	et 8:5 90:11 114:8,8	356:11 366:14	164:12 166:5,6
enroll 40:15	305:6 455:11	114:10,10 230:3	371:12 372:3	170:20,21 173:5
ensues 242:16	epidural 386:11	264:3,4 265:5	378:6 381:15	185:10,18,19
ensure 43:22 47:11	episode 55:10	304:14 330:15	387:13 389:7	189:7 190:18
54:9 161:20 278:3	episodes 55:11	341:8,13 369:18	390:10 393:22	195:6 204:14,21
ensuring 51:15	59:22	369:19	409:11,15 423:16	206:8 209:1 213:5
58:4,6 59:16	equal 225:10 313:1	ethnicity 54:11	424:4 425:8	217:17 219:14,15
369:21	equipment 419:16	evaluate 27:5 341:8	426:18 428:18	220:6,9,17,19,22
entail 206:11	419:19,20 420:18	evaluating 187:4	430:13,15 444:3	221:4,6,11 222:1
Enterprise 17:21	421:14,19	evaluation 41:6	446:12 448:18	222:2,6,7 223:22
entire 23:16 189:6	equivalent 384:1	73:4	449:1	224:8,10,11 225:2
221:17	ER 266:22 366:16	evening 217:3	events 1:8 3:10 9:5	226:8,14 227:14
entirely 134:6	erase 289:11	event 4:10,14 19:1	12:17 13:3,22	227:19 228:2
162:4 220:21	erased 289:16	20:11 32:22 98:16	21:10 36:22 37:8	230:7 233:3 234:2
286:6 353:16	Eric 2:12 21:21	98:20 100:10	38:17 44:14,22	234:20,21 235:1,6
entities 246:8	116:1 127:18	101:4 102:22	46:8,15 47:20	236:3,14,15,16
278:13	129:16 172:11	104:3 108:5,7	50:18 51:10 52:13	239:9 242:2,9
entrenched 48:6	173:2 198:7 199:8	109:4,8 112:3	52:21,22 53:13	243:9 247:17,20
entrusted 440:20	209:2 292:17	113:12 115:8	55:6 57:15 58:19	252:15 253:16
entry 451:1	329:2,16 440:11	116:14,20 117:3	61:2,9 63:17 64:1	254:5 255:8,19,21
envelope 314:13	443:13	118:19,19 125:19	64:18 66:18 67:12	257:11,15 258:1,2
environment 37:17	Eric's 120:10 200:4	128:16 129:11	68:11 70:2 71:13	258:4,22 261:18
54:10 67:8,11,13	200:11 435:1	142:13,15,16	72:1,5 74:9 76:15	262:19 266:20
67:18 68:2,5,13	444:9	144:16 146:8	76:19 77:1,21	270:14,16,21
75:20 92:15	error 18:10 20:14	149:7 154:6	78:1,3,13 79:4,9	271:11 272:9,22
100:22 113:15	108:9 125:21	155:11 157:5	79:11,22 81:17	273:20 274:9
346:14 347:18	126:2 184:19	158:20 159:1,5,5	83:12 89:13 92:22	276:1 278:9 281:8
348:1,11 441:9,12	195:7 200:14,19	171:19 175:22	98:5,11 99:14	281:11,19 282:5
environmental	232:9 406:9	177:13 182:16,22	100:5 101:5,12	282:11,19 283:7

283:13 284:3,4,13	196:6,11,21	367:13 391:1,2	90:5 119:17	expressed 130:7
285:4 286:12	197:10,11,12,18	excluded 397:13	209:11,20 268:15	exquisite 100:2
290:20 292:10,20	198:5 199:22	431:20	365:18 404:10	exquisitely 304:15
295:18 300:2,12	249:5 396:4	excludes 360:21	424:5 428:2	extended 75:22
304:12,20,21	evidentiary 16:5	385:22 429:17	443:16	extension 227:10
306:5,6 307:10	evolution 46:20	438:3 449:17	expands 222:20	extent 33:22 220:6
308:1 310:3	66:22	450:16	expansion 44:13	249:22 368:21
312:10 313:12	evolve 65:15	exclusion 360:18	72:11 76:5,6	415:1,11 418:9
316:18 317:1,13	111:13	363:6 367:19	320:2 357:15	446:8
318:7 320:9 321:7	evolves 65:14 69:13	386:8 397:19	408:19 437:5	external 85:4 129:2
321:8,12,13,16,19	evolving 264:1	429:14,17 430:9	452:7	extra 7:19 104:10
325:7 326:15	exact 96:22 97:1	430:19 438:17	expansive 92:20	extract 386:19
328:10,14,17	124:1 347:9	449:22 450:4,6,14	expect 43:15	extraction 382:3
329:9 330:14,15	391:16 443:19	exclusions 362:7	118:20,21,22	extraordinarily
330:15 336:16	exactly 115:22	364:6 370:7	158:17 355:19,20	102:11
338:1,18 341:7	116:2 138:19	378:15	expected 231:8	eye 382:4,4
345:4 347:9 348:8	158:7 251:19	excusable 368:1	318:20 319:1	e.g 433:17
349:11 350:16	294:6,21 305:20	excuse 286:4,20	expensive 16:20	
351:4,6 355:6	327:2 360:20	executive 16:13	experience 23:21	F
356:21 358:5	369:9 373:14	24:10 148:18	28:6 29:22 59:8	FAAN 2:8
359:4 376:7 388:7	385:21 386:6	exegesis 97:7	150:20 342:14	FACC 2:9
394:16 404:17,21	390:16 414:14	exhaustive 125:6	343:16,19 350:7	face 98:18 139:7
410:5 411:22	447:1 449:6	exhorting 324:9	351:13 353:11,13	246:19 247:9
412:11 424:1	examiner 30:6	exigency 361:1	365:4 371:22	274:7
427:19 428:20	example 36:22	exist 249:18	390:14 415:10	facet 69:19
432:9 438:3	37:18 40:14 43:5	existing 3:12 76:15	experienced 140:17	FACHE 2:5,7
443:17,19 448:14	43:6 49:1 51:11	77:20 78:17	342:16	facilities 76:1 176:4
448:19 449:15	52:12 54:10,18	131:14 147:7	Expert 30:9	318:2 442:14
453:11,11,12	55:18,22 121:2,12	264:3 341:6	expertise 43:15	facility 79:19
eventually 129:3	247:11 259:7	356:18 357:8,11	explain 97:20	118:15,22 178:13
everybody 10:5	332:13 349:13	357:18	191:4 289:5	209:18 412:9
11:16 20:9 79:7	360:8 361:7	exists 271:11	360:18	438:7 447:19
110:16 116:12	386:10 391:3	expand 33:3 37:2	explainable 368:2	448:21 449:11,13
141:4 179:19	416:6 417:5	76:9 89:5 126:7	explained 355:11	449:16,19 450:20
223:5 274:12	examples 98:19	219:17 229:11	explanation 315:4	451:8,11 452:16
339:15 344:14	124:7 421:3	295:18 296:21	367:12	453:5
440:6	exceeds 386:3	319:8 346:20	explanatory 97:18	FACP 2:12
everyone's 353:18	397:16	376:13 436:16	453:6	FACS 2:13
evidence 52:7	excellent 122:12	437:14 448:6,14	explicit 35:6	fact 14:15 15:10
65:13 78:15 114:9	167:16 392:13	expanded 85:13	105:22	44:1 54:13 78:14
114:15,19 125:5	exception 147:3	87:15 92:14	explicitly 39:13	95:7 101:12
229:14 246:16,18	191:14	164:12 227:18,19	explore 313:3	108:13 110:8
246:21 247:5,10	exceptions 269:14	321:21 330:5	expos 93:1	121:1 122:1
396:5,9	excited 24:19	335:12 357:13	exposed 413:8	138:19 143:11
evidence-based	273:19	406:15	421:5,8	161:8 165:7,11
82:10 114:20	exciting 63:8	expanding 50:21	exposing 421:20	176:21 220:1
127:9,10,16 196:4	exclude 299:11	63:7 65:3 71:2,19	express 96:19	231:6 253:18

255:18 281:18 284:5 285:10 287:11 301:10,19 313:21 321:18 322:12 345:6 364:8 384:4 396:14 397:7 399:3 431:7 faction 253:2 factor 160:20 factors 117:6 221:7 404:18 faded 143:14 FAHA 2:9 fail 447:14 failed 15:22 failure 108:9 125:21 126:2 195:7 200:15,19 345:16 387:15 453:19 fair 33:11 77:9 91:22 160:13 166:16 173:14,17 194:20 232:6 249:14 431:21 448:3 453:8 fairly 48:6 51:16 65:17 74:2,12 76:14 77:5 224:14 411:15 441:16 fall 117:16 135:15 231:10 261:6 406:11 412:17 419:21 422:1 falls 92:22 97:4 99:21 111:3 135:1 141:2,10,14,18,19 167:8 234:15 261:6 336:21 337:3,3,9,11 382:18 416:5 420:21 445:21 false 374:22 familiar 185:9 342:1 429:21 families 59:5	family 19:16,16 family's 372:4 fan 96:10 245:8 fantasizing 452:12 far 8:9 14:12 15:22 30:7 63:16 74:17 75:16 113:2 122:11 239:3 258:9 271:21 272:10 273:3 326:5 406:19 416:6 418:13 fascinating 258:15 FASHP 2:12 fatal 242:14 Fathers 199:11 fault 232:4 442:5 442:21 favor 150:5 156:6 156:11,14,18,20 159:21,22 160:4 160:14 170:7 200:9 201:1,7 212:3,7,19 213:1 fear 133:14,16 feasibility 53:16 333:20 feasible 79:15 112:13 227:15 251:13 399:4 features 45:17 February 32:11 federal 19:6 39:6 feds 298:1 feedback 339:5 340:19 367:7 407:16 430:21 feeds 41:6 feel 39:11 46:3 83:9 130:15 132:9 147:17 164:18 168:3,8,12,19 172:7 179:17 180:14,17,19 247:8 283:22 355:8,13,18 453:14	feeling 189:20 feelings 343:9 feels 119:3 167:11 170:1 193:3 371:8 425:11 feet 91:4 fell 416:9 felt 66:9 84:7 86:19 fetch 416:7 fever 431:2 fevers 220:14 fewer 239:21 field 66:7,12 71:16 73:9 76:10 77:2 77:19,21 81:17 82:16 96:7 107:5 113:7 121:5 165:7 166:14 187:16 266:1 273:2 402:17 407:17 415:12 418:8,12 424:21 429:14 430:21 448:3 450:7 fifties 441:16 figure 43:20 157:9 208:5 246:8 312:16 314:16 414:14 fill 335:13 filled 441:18 filling 65:4 filtered 334:10,10 final 11:5 65:20 101:21 132:14 138:8 160:11 193:20 203:3 204:13 291:1,22 338:4,12 finally 407:6 finances 7:4 find 40:6,8,8 97:2 107:9 112:6 120:8 154:19 221:9,14 246:18 249:5 267:9 314:14 351:4 356:1 385:3	387:9 388:15,21 389:5 395:9 412:10 425:18 438:21 finding 221:11 313:18 389:22 394:11 fine 81:6,7 120:11 120:17 121:22 122:2 130:10,11 130:11 131:15,16 149:1 159:10 165:6 169:17 174:17 311:12 413:16,17 441:12 fingering 236:20 finish 93:6 170:14 308:16 338:10 451:21 453:20 455:9 fire 184:7 233:4 316:8 firing 266:22 first 13:10 18:7,19 21:17 22:4,22 23:20 25:10 35:9 50:3 57:17 63:19 68:19 74:15 76:3 107:20,20 108:18 113:21 119:13 123:21 130:9 143:18 147:4 156:8 163:18 168:3 205:1 223:8 232:15 233:17 237:20 246:1 268:20 276:10 281:6 284:13 340:9 349:4 353:22 356:9 360:7 361:18 363:19 366:17 373:11 377:10 384:9 393:3 404:1 425:17 432:9,19 446:9 fit 35:12 40:22	51:20 180:7 190:15 214:6 265:13 270:5 278:13 281:21 328:22 333:9 335:16 337:4 fits 5:11 36:7 58:15 67:4 271:15 289:7 332:12 448:9 five 145:20 168:17 170:5 182:15 234:10 332:18 334:17 341:22 343:11 353:4 364:20 453:8 fix 15:19 273:1 fixing 273:13 flashback 129:18 Flashing 433:22 flaws 284:20 flip 333:15 flipping 110:19 float 91:3 floods 112:18 Florida 352:21 flow 54:12 100:19 fluid 361:22 fly 98:17 288:13 focus 35:7 37:20 49:13 52:8 57:19 58:15,17 62:6 64:21 69:17 74:8 75:6 80:3 104:5 126:22 151:16 163:12 237:13 240:14 247:6 264:18 273:9 278:6 312:3 328:15 341:15 focused 14:1 24:16 37:15 48:19 49:17 59:17 74:5 75:13 80:1 90:7 241:14 312:13 316:13 focuses 70:6 251:4 focusing 58:3 67:7 220:16 265:5
--	---	---	---	---

291:14 442:18	fore 317:4	106:15 209:20	friends 238:19	392:17
fold 99:5	foregoing 104:15	272:21 273:3,21	front 92:4 95:7,21	fuzziness 380:9
folks 24:21 48:15	215:2 279:18	339:8 360:11	107:10 201:12	fuzzy 367:1
62:18 73:20 84:10	foreign 116:7	418:13	frontline 96:8	
86:10 99:11	117:10 141:12	forwarded 7:7	157:9 158:11	G
110:20 138:13	240:22 241:4	foul 397:4	294:16 355:5	G 5:1 252:18
146:21 147:5	348:13 372:17,17	found 204:16	frontlines 48:15	gain 11:21 12:1
156:19 161:17	383:8,12 400:2	339:21 350:21	158:6	game 256:3
163:7,9 166:18	foremost 108:19	417:11	fronts 63:8	Gandhi 2:4 105:11
175:20 182:13	foresight 64:11	foundation 22:9	fruit 336:10,13	105:13 134:19,22
193:20 217:14	forge 432:6	225:14	frustrating 355:22	140:19,20 147:18
218:3 221:8	forget 104:5 145:12	Founding 199:11	frustration 249:4	148:3 154:5,15
256:21 258:16	206:9	four 18:7 28:3,4	255:15	160:8 168:21
264:17 271:22	forgot 8:13 90:4	168:17 170:4	frustrations 113:7	169:16 180:19
281:14 285:2	forgotten 347:9	193:8 234:9,10,13	FTE 427:2	280:12,12 388:18
287:6 308:16	form 275:12	239:5 257:18	FTEs 426:18	389:8,14 390:3
338:11,12,19	338:12 394:16	332:18 352:5	full 6:1,19 39:16	Gandhi's 155:22
350:4 351:18	formal 8:14 42:12	444:17	42:20 133:3 212:7	gang 233:1
399:7 418:14	216:18	fourth 37:15	236:19 419:14	gangrene 231:1
429:7 437:9	formalized 85:3	152:17 153:17	427:7	Ganz 400:12
453:10	323:2	174:19 175:4,7	fun 335:6 390:12	gap 52:6,10 55:2,3
follow 7:2 38:5	formally 5:17 9:19	265:19	function 4:12	65:1
72:15 73:9 185:15	90:17 169:4	four-year 70:10	171:17 208:12,15	gaps 247:6
196:16 276:8	Format 30:8	fracture 414:4	208:18 210:12	Garcia 70:16 88:22
289:1 305:16	formats 68:16,19	fragments 385:1	212:6 419:5	88:22 164:3,6,21
365:3 425:1	68:20 69:3 264:5	frame 227:1	functional 282:20	219:8 227:8
452:11	former 22:3 102:12	framed 187:8	functions 295:22	228:20 229:4,8
following 69:11	formerly 17:11	framework 35:13	419:8	274:21
80:16 171:21	formidable 14:16	53:12 55:8 73:2,6	funding 27:9	gas 441:18
176:2 177:8,8	236:20	73:7 187:3 338:2	further 44:6 69:16	gather 89:13
178:9 181:22	forms 7:3	framing 85:21	81:4 82:16 108:12	general 12:8,10,10
192:6 223:13	forte 237:18	359:15	137:5 152:6 154:4	46:19 72:7 96:20
399:21 410:11	forth 259:6 354:11	frankly 121:9	163:22 165:15	249:18 352:9
425:19	379:15	fraud 375:2,5	166:22 167:2	380:21 381:1
follow-on 250:3	fortunately 343:20	377:7	170:12 181:9	447:20 451:1
footnote 132:8,12	376:3	free 83:9 407:20	187:19 210:20	generalizable 77:6
132:22 135:10,12	forum 1:2 5:6 9:12	freely 14:8	301:11 322:22	generally 10:18
135:20 136:21	13:15 15:14 16:17	frequency 30:22	333:12 342:11	317:1 346:2 404:5
137:21 147:19,22	18:20 102:7	352:19	346:8 357:11	generate 243:5
148:1 211:9,12,18	103:10 161:17	frequent 446:16	359:12 384:15	generating 8:21
452:15	217:16 235:20	frequently 17:9	454:11,13	229:15
footnotes 3:12	243:19 333:19,22	80:9 89:8,14	fusion 380:12	generic 24:14
97:18 147:7	437:10 455:8	355:10 439:7	fuss 395:9	generous 418:1
211:18	forward 10:19 12:3	frequently-occur...	fussing 179:8,8	genes 231:16
force 29:7 131:6	14:3,7 15:4 21:19	220:18	future 82:2 111:12	genius 393:2
forced 101:22	35:2 49:22 50:6	freshened-up 7:15	181:12 228:22	genomics 313:19
forces 13:9 61:6	65:2 82:17 103:4	friend 393:19	273:6 292:9	GENTILLI 2:21

geographic 54:17	42:5 44:11 49:22	406:19 410:20	116:1 117:15	331:13 332:6
Geriatrics 22:8	52:16 55:5 60:9	411:3 419:6 422:9	120:13 123:5,6,8	333:15 334:4
germinal 20:10	62:2 69:6,16	425:16 428:13	123:15 126:17	335:10,14 338:8
getting 8:6 9:14	81:16 82:19 85:10	429:9 438:12	128:4 130:2 133:1	338:17 339:2,4
14:19 29:3 31:22	86:14 87:3 88:6	443:3 444:12	135:7 136:6,13	342:3 344:10
69:10 96:22 97:11	92:2,7,14 95:14	446:17 449:8	138:16,17 139:1	346:13,15 356:16
110:1 111:13	101:14 104:18	goal 37:15 57:3	139:17 143:15	356:17 357:2,3,4
141:8 154:18	107:19 108:11	106:1 122:15,16	145:6 146:5,11,12	357:15 358:4
179:16 208:20	110:17 113:4	126:18,18 140:9	146:21 150:9	363:22 364:10
210:1 255:13	115:15 119:15	140:10 204:10	152:2 155:1,4	365:16 368:7
291:13 296:4,9	122:1 126:9,22	218:2,5 245:16	161:8,12 163:1	370:4 376:21
310:13 336:15	129:17 136:6	261:17 262:2,6,17	170:13 176:14	379:14 380:21
360:12 364:9	138:16,17 143:9	268:20 277:18	177:3 181:7,15	381:3,4,12 385:12
378:14 391:12	145:16,18 146:22	332:15 394:15	182:4,5 184:4,20	390:10 391:6,7,14
398:19 407:19	167:18 171:3,16	422:10,10	188:6,21 191:9	395:10 399:18
408:9,10 413:13	172:1 176:15	goals 32:22 36:16	200:7 201:13	401:18 402:4,16
430:16 441:4	177:22 178:7	38:2 57:11 60:7	202:6 209:4 210:4	404:6,9 405:14
454:16,18	194:4,5,17 202:7	66:10 261:21	216:16,21 217:13	409:10 413:11,12
GI 313:8	203:15 205:12	394:22	218:22 219:17	422:15,16 437:5
give 31:22 34:5	216:16 217:5,14	God 252:19	222:19 224:4	437:21 440:2
36:4 123:19	218:1 220:10	goes 43:7 77:16	225:3 226:20	442:18 443:19
222:21 227:4	223:3 224:4 225:8	107:5 211:2	228:19 229:18	446:4,13,20 448:1
361:6 377:9 417:4	235:13,13 238:12	243:10 276:11	231:8,10 233:17	448:2,14 450:22
418:16 434:20	244:13 246:14	334:2,3 355:13	235:12 243:21	452:22 453:18
454:8	248:1 250:12	399:21,22 421:2	244:13 246:2	good 9:20 12:5
given 27:20 84:19	252:2 254:7,18	449:14	250:12 253:13	18:14 23:18 25:3
129:1 131:20	256:22 257:2,8	Goeschel 2:5 16:11	254:7 256:15	27:22 31:10 75:17
132:21 161:7	260:6 261:11,21	16:12 95:3,3	259:6 261:11	81:20 83:16 84:2
173:6 240:4	263:1 271:16	103:6,7 125:11	263:1,11 265:21	84:13 89:2 94:22
316:12 318:4	272:21 273:9	137:11 165:3	267:7,17,18,19,21	98:13 111:14
335:18 432:16	274:21 277:14,17	190:2,12 191:3	271:9 272:12,21	114:16 116:13
gives 102:22	287:1,5 288:1	245:21 260:8	273:21 274:22	128:2 130:5 135:8
198:13 222:5,16	297:18 304:6,8	going 6:16 9:1	275:2 276:2	145:12 152:3
292:21	308:17 309:12,16	11:20 14:4,10,20	280:18 285:1	157:21 160:8
giving 60:7 98:19	309:18 315:9	14:21 15:5,6	287:4,4 288:1,7	164:16 192:13
139:16 330:9	316:8,11 318:13	34:13 35:9 37:2	291:7 293:10	198:10 204:5
glad 25:1 34:10	321:11 322:5	38:9 39:22 43:21	294:1,13 295:5	214:14 217:1,2
89:15 95:20	324:13 331:18	48:11 50:6 56:11	298:4 301:8 302:2	222:17 231:13
172:21 297:11	333:14 338:17	60:20 62:12 67:7	304:6 307:22	237:10 243:17
glaring 175:8 289:4	340:9 342:3	69:16 76:2 81:2	308:3 311:5 315:9	244:6 265:2 267:8
glasses 198:1	347:20 357:20	81:16,22 88:6	315:11 316:16	268:18 269:15
global 24:13	359:20 360:15	89:16 92:1,14	318:5,6 321:10	289:8 297:14
103:14 252:11	367:9 370:1	93:5 98:3 101:6	322:21,22 324:1	308:20 321:19
glossary 202:15,17	371:15 372:18	105:21 106:14	324:22 326:20	326:9 339:18
go 6:19 13:1 16:9	373:19 386:18	108:1,15,21 109:6	327:12,13 328:5	342:19 356:2
26:12 27:14 36:10	387:8 389:5 392:8	111:21 112:9	328:10,22 329:1	364:15 376:8
39:21 40:13,14,17	395:9 403:17,21	114:2 115:19	329:19 330:10	392:12 395:4,22

399:16 402:15	10:2 12:6 63:1	guardrails 206:17	454:17	270:11 288:13
437:13 441:11	77:8 98:11 105:11	guess 17:19 29:2	HACs 4:19 51:1,9	handling 40:10
445:11 449:5,7	120:8 124:15	110:6 112:6	51:21 71:20 72:3	handout 182:15
451:18	132:13 134:19	115:19 116:17	72:8 77:15 82:18	341:10 342:5
gorilla 225:12	142:5 148:16	144:10 149:16	82:21 83:16 85:13	356:13
gosh 388:15	179:12 187:1	158:4 165:17	85:22 86:19 87:3	hands 147:11,13
gotten 181:4	191:16 236:18	179:14 210:10	89:3 145:8 164:11	156:15 168:7,15
307:12 348:14	285:3 296:8	219:19 222:4	217:18 218:6,20	170:3 193:6 194:1
413:1 415:15	332:11 341:15	228:16 234:16	228:6 229:15	201:2,9 212:9
governing 24:3,5	349:3 359:8	267:1 268:9	234:10 241:19	213:3 217:8,10
24:21	364:13 401:7	287:19 301:16	249:20 255:6	431:5
government 13:7	408:5 422:14	326:11 327:9	256:8,18 263:4,6	handy 128:7
28:3 39:6 229:1	ground 70:16	336:22 342:10	265:10,20 297:6	Hang 455:17
298:5	155:4 225:22	348:3 351:7 361:3	HAI 71:14 89:19	hanging 389:10
grab 128:5	group 12:7 13:20	361:16 388:12	90:7,10 264:18,21	haphazard 425:11
grade 225:4 259:19	14:18 19:1,2 21:3	400:3 405:13	265:12,20 282:10	happen 80:6,9
gradient 109:3	23:11,15 29:10	408:1 410:9	331:4 332:14	109:2 110:12
grading 16:6	41:8 43:12 44:16	420:16 421:10	hair 231:10,15,16	113:12 117:7,20
gradings 265:14	45:4 47:17 58:20	429:11 433:5	HAIs 230:6 236:1	123:13 131:1
grammar 173:20	61:6 83:12 88:9	434:2,19 440:6	242:6 265:9 277:7	135:14 141:22
grants 17:4 27:2	92:14 99:6 100:16	449:21	282:18 283:6	161:4 198:14
granularity 221:19	119:22 143:18	guessed 363:1	286:2,4,5,18	220:19 221:13
grapple 83:22	147:5 163:6,11	guidance 84:13	290:20 293:18	222:6 248:10
94:20	171:4 176:12	159:11,16 379:2	296:17 330:9	255:19 260:13,20
grappled 181:2	178:20 187:2	384:15 385:8	331:6 332:16,19	263:17 296:16
grateful 23:1	218:14 233:22	404:14 409:2	333:5 336:19	326:20 346:14,15
grave 201:20 203:4	247:4 263:17	415:12,18	half 14:6 96:14	348:11 357:8
204:7 205:14	286:21 302:19	guide 45:12 284:21	357:16 358:12	377:15 394:5
gravitate 214:19	307:18 311:3	guideline 198:15	394:4 427:2,7	412:11 413:2
gray 109:1 422:12	318:4,17 340:13	guidelines 82:10	455:12	419:15 436:22
great 6:11 27:13	345:1 346:3	195:15 196:22	halfway 453:12	happened 37:17
49:20 52:14 53:19	354:20 437:15	197:10,11,18	half-hour 281:1	131:1 133:18
61:5 88:16 125:11	443:15	380:5	hall 8:8,9	139:14 185:12
171:6 218:17	groups 39:10 41:5	gun 239:17	haloperidol 313:7	189:9 198:16
219:22 238:21	44:17 90:22 91:1	guy 70:21 266:21	hammers 148:13	230:10 233:6
245:21 247:12	109:13 248:10	guys 53:14 219:3	hamstring 181:11	239:19,19 267:13
279:9 280:8,14	318:6,11 329:19	259:21 413:19	hand 14:11 49:5	272:8 283:3
329:5 336:14	335:7 437:9	428:3	96:11 110:18	294:21 295:2
342:22 367:7	443:16	<hr/>	119:15 128:21	345:6 372:2
374:18 381:12	group's 72:19 76:4	H	138:10 146:22	393:12 394:6
394:3 399:13	343:9	H 263:6	148:12 180:9	409:13 410:17
407:15 415:7	grow 32:3	habit 88:1	231:12 252:2	422:4 423:13
432:5 455:4,4	Guaranteeing	HAC 89:22 196:19	304:2 339:10	happening 53:10
greater 51:6,13	59:11	197:22 217:19	361:20 373:20,21	103:18 222:18
395:22	guardian 433:20	218:1 220:8 256:9	373:21 393:10	223:1 239:20
Gregg 1:21 2:2 3:4	433:20 435:2,20	263:13 291:15	426:14 453:16	261:18 262:20
6:17 8:10 9:18	435:21,22	296:4 319:11	handle 239:4	273:2

happens 43:7 92:22 126:8 130:22 161:10 257:13 277:5 313:15 344:1,9 355:14 397:8,8 411:19 419:15 430:10 450:3	harsh 387:18 Harvard 33:19 hat 103:21 146:10 146:11 149:3 371:6 hate 428:13 haystack 387:10 hazard 266:19 hazardous 268:2 hazards 268:13 head 33:18 152:7 203:11 414:5 421:17 heading 90:8 359:4 heads 179:17 health 10:6 16:13 16:18 17:12 18:17 21:4,6 22:9 23:5,6 26:7,13,18 27:7 28:3,9 34:14 44:17 49:17,18 53:2 58:3,9 59:6 60:18 63:21 69:18 70:9 75:19 103:13 139:13 238:18 240:17 351:20 352:10 355:18 391:19 394:20 417:2,2,22 420:11	232:16 235:11,22 237:8 253:17 255:4,19 261:17 265:3 268:22 273:15 274:7 278:1 280:13 289:9 296:14 301:12 306:7 313:17 322:21 348:10 355:5 356:6 377:4,8,20 381:6 412:9 449:11,12,16,19 450:20 451:7,11	434:9 435:11 heard 8:18 91:22 92:9 131:9 132:1 167:6 217:1 255:1 261:16 262:1 321:4 323:16 354:5 396:14 hearing 35:1 144:1 160:7 162:2 213:19,20 238:9 243:3,4,12 398:8 408:5 427:18 448:3 Heart 29:7 heat 162:9 heavily 13:4 heavy 66:5,6 454:15 Helen 2:6,14 3:7 9:11,13,16 15:19 29:17 30:14 31:2 33:5,8 35:19 62:5 62:15 63:1 67:6 69:15 73:1 76:6 82:19 85:8 86:15 89:2 98:11 105:10 105:17,18 106:22 128:3 169:12 175:11 180:21 196:17 216:6,9,12 219:1 223:19 229:18 233:14 258:11 262:8,9,10 277:15 280:3 288:1 295:7 302:13 313:21 319:22 333:12 335:3 454:11	191:2 195:5,19 198:7,10 199:8 205:7 207:4 208:6 208:7 226:21 227:1,4 237:5,7 253:4 268:22 284:6,21 306:11 308:18 329:9 352:12 361:8 415:2 418:16 429:13 437:11 447:5 helped 214:20 279:2 325:17 helpful 94:4 105:1 145:5,10 165:1 217:8 228:12 291:12,17 336:3 340:1 359:18 369:12 425:7 429:8 helping 25:19 27:5 33:3 44:18 90:9 helps 27:19 125:9 126:20 159:17 165:4 208:5 hemorrhage 407:3 407:4 hep 349:14 414:10 heparin 221:13 hepatitis 413:8,11 413:13 417:20 Herculean 329:14 hesitant 205:10 hesitate 70:19 HHS 19:7 70:10 71:10,21 75:5 84:10 86:10 217:15 296:6,20 319:4 320:22 HHS's 90:10 Hi 9:20 22:21 25:4 28:17 29:16 30:16 31:10 33:7 105:2 108:20 high 2:22 52:18 421:21 429:20
hard 7:8 41:20 60:12 107:10 108:2 127:22 131:17 157:22 158:13 172:4 182:14 218:3 267:5 276:13,14 292:14,15 334:6 387:21 388:15 hardwired 139:3 hard-core 74:13 harm 155:10,13 185:7,18 190:15 190:16,18,20 204:15,22 207:9 207:12,19 211:4 251:4 254:9,14 266:21 278:5 328:2,3 371:21 387:20 391:7 396:10 397:3 398:20 399:1,2 416:17 419:18 420:22 424:6 445:13 446:12,15 harmed 397:6 harmful 397:1 harmonization 51:6 90:9 96:5 250:19 255:14 264:22 harmonize 96:11 harmonizing 48:4 harmony 237:17 237:19 239:2 harms 189:8	healthcare 1:6,9 9:2 11:2 16:13 17:5 19:5,8,10 24:13 25:9 27:3 36:14 39:4,7 48:3 48:16,19 52:15 56:21 57:6 58:3 58:17,22 60:10,22 64:8 67:9 69:12 72:6 79:12 80:11 80:17,21 89:20 93:14,15 94:1,12 102:15 103:15,17 117:21 131:21 161:2 173:7 176:3 178:12 220:21 224:17,22 230:15 231:4,15,18	healthcare-acqui... 9:6 64:20 71:2,5 73:5 76:20 78:13 89:11 94:11 187:5 187:11,17 214:5 225:5 227:21 229:9 231:2,22 257:14 259:9 269:2 289:6 295:20 296:7 301:9 healthcare-associ... 76:21 93:18 218:12 255:6,10 258:18 264:19 278:8 282:8 283:20,21 303:10 311:22 healthcare-induc... 278:4 healthy 58:6 404:5 405:10 406:17 hear 6:12,13 15:9 15:10 63:2 88:15 106:9 163:9 184:21 194:18 209:3 269:13,18 275:2 284:18 290:9 324:20 342:1 388:10 392:6,22 395:1 407:15 408:4,20 421:16 425:2	278:4 288:1 295:7 302:13 313:21 319:22 333:12 335:3 454:11 Helen's 63:2 102:11 270:15 426:11 help 11:22 21:8 24:21 25:15 43:22 69:20 74:20 100:17 106:14 135:13 145:22 161:20 175:19	

431:2,8 454:4 455:10 higher 46:22 139:21 414:6 431:20 higher-level 51:5 highest 47:3 56:18 highlight 5:14 57:12 136:8 highlighting 136:19 highly 79:10 158:22 223:17 324:11 highly-related 223:6 high-impact 60:5 high-level 60:5 high-profile 366:15 high-risk 109:13 430:16 hill 329:15 hinder 5:21 hindrances 6:9 hinges 448:10 hint 241:5 hip 391:4 416:10 416:11 417:21 HIPAA 376:21 historical 143:13 historically 117:22 history 144:2 250:4 433:2 hit 34:2 37:17 56:9 60:13 69:18 HOEN 2:5 34:8 113:6 152:10 153:2,5 167:5 176:10 192:2 197:16 260:11 292:7 376:18,22 386:15 425:16 435:12 436:7 447:7 451:12 hold 64:5 103:22 184:7 403:14 447:12	holder 23:15 holding 316:7,11 453:16 hole 284:10 holes 65:5 home 30:2 44:17 75:19 148:13 259:1 262:13 347:20,22 352:5 441:1,1 442:16 homes 44:17 259:1 homogenize 96:12 hone 63:13 honest 242:20 344:12 392:4 honestly 414:11 honey 393:11 honor 224:9 honored 18:12 23:2 29:10 hop 83:9 hope 10:19 11:2,11 36:21 100:7 114:17 118:8 223:14 246:14 262:18 396:21 406:18 hoped 227:9 hopefully 60:9 74:13 89:16 105:19 167:18 216:14 245:17 284:6 hoping 36:10 89:21 403:15 Hopkins 16:14 horrendous 242:13 horrible 450:8 hospice 262:15 Hospira 24:10,13 27:6 hospital 12:10 16:18 24:2,5 25:6 27:12 30:2 34:13 42:22 57:21 71:4 71:14 75:20 77:3 89:12 91:11 93:14	93:14 100:22 131:5 135:15 136:6 163:13 219:18 220:8,10 225:18 227:13 236:6 238:14 242:5 255:2,9 258:21 260:14 262:14 268:6 274:13 276:11,12 277:5 291:4 297:15 333:6 391:19 394:6,6 436:18,18 440:17 447:11,15,18,20 450:1 453:4 hospitals 10:11 21:8 23:9 24:12 25:20 27:16 49:2 53:2 102:15 103:16 133:16 135:3 238:7 250:20 274:15 346:20 391:18 394:4 412:1,8 435:18 436:22 440:15 442:14 452:4 hospital-acquired 82:7 89:4 91:6 94:14 109:12 197:4 230:2 232:16 235:15,18 237:1 242:7 257:7 257:20 259:8 271:13 294:19 295:3,4,9 296:1 hospital-level 58:18 hospital-reported 452:2 host 284:3,4 hour 106:17 289:9 296:4,10 hours 92:3 329:4 391:18 407:5 414:6 444:18	446:9 huge 10:22 86:13 93:1 96:10,21 108:22 116:8 221:5 241:9 385:18 hugely 290:14 human 63:21 70:9 117:6,6 221:7 224:16 humbling 312:9 hundreds 277:1 hung 249:13 291:14 Hurst 2:15 31:10 31:11 hurt 232:20 266:22 268:4 hurts 397:10 Hyatt 1:20 hysterectomy 405:19 <hr/> I <hr/> iatrogenic 230:16 ICD 252:14,17 ICDs 252:4,5 ICD-9 249:17,19 249:20 ICU 399:21 413:15 413:18 idea 37:6 52:2 83:8 83:14 111:8,13,14 139:20 157:21 161:18 224:19 225:17 250:17 259:22 266:8 284:17 319:7 334:8 362:5 ideas 70:18 363:22 379:9 identifiable 79:14 369:16 identification 375:1 377:18 identified 4:15 157:6 163:19	182:16 212:15 358:10 390:19 391:10 identify 27:19 101:13 104:21 161:17 216:5 240:8 246:20 268:7 280:2 325:21 351:1,2 identifying 52:12 117:18 142:13 247:9 308:8 identity 27:19 374:20 377:7 idiosyncratic 323:20 ignore 311:5 ignoring 311:2 illegal 434:19 illegals 377:20 illiterate 174:16 illness 84:19 149:22 190:4,5,7 192:19 illogical 174:18 illustrative 331:8 ill-defined 284:11 image 392:2 454:9 imagination 124:10 imagine 291:2 293:14 414:17 imaging 421:20 IMED 411:16 immediately 112:8 408:3 impact 9:2 52:14 54:22 55:1 76:22 93:16 103:1 150:19 160:20 166:14 276:14,15 325:14,19 331:19 331:20 341:8 396:22 417:2,13 417:22 impacted 11:21 impactful 276:17 impacts 24:5
--	--	--	--	---

417:22	234:6 235:6,9	include 7:3 141:18	independent 441:9	325:4,8 334:20
impairment 211:20	239:15 240:22	142:22 143:2	index 58:9 253:15	410:18 412:13
impatience 249:7	246:20 251:11	185:17 192:22	indicated 58:5	infectious 18:18
impersonator	264:10 274:19	211:4 243:6,8	219:17 380:6	influence 28:14
348:10	279:1 284:8	276:3 281:16	408:16	93:6
implant 381:17	294:13 301:2	292:20 297:7	indication 373:8	influenced 79:17
382:12,17	303:13 333:10	314:19 336:19	374:2	influences 113:13
implement 21:9	364:13 384:17	375:10 400:22	indicative 80:17	inform 390:5
53:17 113:10	395:17 396:1,17	406:18 421:10,13	174:2 176:3	information 8:17
226:17	399:10 401:3	424:1,6 428:3	178:12	20:16 46:11,14
implementation	402:13 403:19	451:18 452:9	indicators 58:12	54:17 60:21 61:12
82:10 83:3 100:2	410:21 411:1	included 186:11	244:3	74:9 89:13 90:22
114:9 196:21	437:7 442:13	191:14 211:16	indirect 54:16	122:17 238:8,10
197:10 379:1	445:14,22	248:8 327:18	indirectly 12:14	244:16 344:10,19
385:7 404:14	importantly 344:2	426:3	103:1	346:16 377:3
409:2	imposes 225:18	includes 191:10	individual 74:3	392:16 393:8
implication 128:15	imposing 428:2	311:4 315:2	87:18 91:21 92:8	395:22 422:9,21
219:14 300:13	impossible 161:9	368:20 369:1	92:9,12,17 103:12	423:10 438:21
implications 11:1	250:7	407:8 428:18	159:13 211:22	informed 361:2,4
118:5 119:5 364:1	improve 13:11 24:8	including 20:9	248:3 272:9	363:7,11,13
379:1	24:22 67:16	21:13 27:6 32:21	273:20 298:22	364:15 367:14
implied 138:8	189:22 237:4,7,14	189:13 266:18	345:11 424:4	373:7,18 374:7
implies 345:21	246:22 261:17	311:10 313:7	425:8 442:8	378:19,21 398:4
440:7 443:7	284:17 296:14	331:4 406:19	individually 332:21	431:4
import 59:7 157:10	improvement	inclusion 142:19	individuals 43:13	informs 333:2
importance 52:1	25:13,17 36:18	inclusive 141:17	91:16 341:6 403:7	infrastructure 87:1
62:7 134:7 145:19	52:10 56:21	177:1 211:7 315:1	405:11	infusion 312:15,18
166:4,8	225:21 228:7	426:22	indulgence 453:15	411:16
important 35:13	229:12 240:8,18	incompetent	industry 26:15	infusions 27:21
37:9 39:5 43:17	241:6 244:4	433:17	72:6 274:6,8	inherent 453:19
48:9 52:8 56:8,12	245:17 248:2	incongruities 64:22	inevitable 48:20	initial 58:20,21
59:13 62:6 65:16	276:18 277:3	inconsistencies	117:5	68:3 128:11 192:9
69:3,19 76:16	301:7 305:19	194:9,10	infant 432:21	336:18 357:17
78:4 80:18 83:1,7	improvements	inconsistent 181:22	434:18 437:19	429:16
84:7 86:12 95:17	60:10 221:10	incorrect 370:21	infants 432:9,16	initially 89:5 102:5
101:9 103:22	improving 24:16	371:1	infection 19:5	192:4 295:11
108:1 115:13	36:14 58:16	incorrectly 242:4	93:22 242:15	319:7 332:14
118:11 126:16	313:17	369:17	infections 17:8	initiated 101:4
127:3,6,7,14	inadvertent 232:1	increase 116:22	43:6 59:1 64:21	initiative 89:19
130:6,12,15	inadvertently	117:15	67:10 89:21 94:12	injured 349:13
131:14 145:6	232:20	increasing 366:3	94:13 110:3,6	injuries 449:18
150:15,16 153:20	inappropriate	increasingly 42:18	121:3,4,7 230:2	injury 149:22
156:2 165:21	421:21 433:20,21	49:13 103:17	234:14,15 242:12	190:4,5,7,7
174:3 176:4,11	incentive 237:3	incredible 115:22	242:14,17 248:7	191:11,18,22
188:7 191:1	incidence 278:4	incredibly 35:13	278:8 282:9	192:19 414:5
202:21 206:6,11	442:12	93:2 101:9 115:12	283:20,21 286:6	416:4,12 435:4
231:7,17 233:18	incident 136:19	245:3 387:5	289:6,18 301:9,13	innovative 313:3,6

inpatient 75:20 209:18 227:13 444:6	397:21 404:16,20 419:8 420:1 432:12	internationally 9:3 17:10	invented 20:6	430:4 447:14
input 42:16 77:22 342:17,19 356:17 357:4,11 372:11 379:10 398:7 424:20	intense 109:1	internist 12:8 25:6	invest 26:10	issues 57:20 73:3,8 73:19 74:6 83:4 186:1 224:1 233:19 240:15 246:20 250:22 262:13 310:14 333:16 345:17 366:21 368:9 378:7 398:12 425:22 426:1,4
inputs 8:18	intensify 376:15	interoperative 346:4	investigation 136:12	item 325:21 349:10 399:2
inserted 382:2	intent 6:3 110:13 138:20 204:13 205:5 207:20 245:13 346:1 363:1,7,15 405:2 439:17	Interpol 352:11	investigations 451:19	iteration 68:19
insertion 381:16	intentional 45:21 231:6 252:6	interpret 362:8 367:2	investigator 33:19	IV 27:15
inside 143:5 244:19 255:3,6,8 265:9 314:17 325:5 327:4,11 384:3 385:2	intentionally 277:20,21 278:10 386:2 397:15	interpretation 144:6 426:8	involve 155:13 205:3 207:9 221:1	IVAC 411:16
insist 176:19	interact 91:17	interpretations 174:10	involved 13:20 20:14 34:16 73:13 124:17 125:2 277:21 341:5 418:15 436:3	I's 325:18
instance 113:21 348:9 388:15 442:8,11	interchange 259:6	interpreted 189:3 411:14 438:19	involves 251:18	<hr/> J <hr/>
instances 80:21 377:14 424:11,14	interest 8:21 9:7 34:1 47:7 68:22 160:21 163:16 277:9 313:17 324:3 331:7	interpreting 353:22	involving 438:4	Jacuzzi 452:5 454:2
Institute 13:6 20:7	interested 130:18 161:3 174:8 216:20 217:3,9 267:9 304:22 312:1 333:4 430:9	interrupting 11:12	in-depth 220:17	Jacuzzis 452:9
institution 146:6 154:2 206:13 354:3,8 408:15 415:5	interesting 8:20 14:9 47:17 50:5 58:14 274:3 275:10 352:20 394:10 400:15 429:11 432:22	intersection 257:17 261:4	in-house 34:13	January 66:1 70:11 72:17 90:18
institutional 124:1 124:20	interject 111:21	intervention 225:14 226:1 325:13,20	IOM 237:22	JD 34:12
institutions 364:14 408:15	internal 28:7 314:8 315:18 323:4 358:17	interventions 58:7 100:1	iPhone 7:20	jelly 232:12,18
instrument 385:16	internally 85:5 314:7	intestines 121:11	issue 37:16 75:21 83:1 92:6 93:2 102:3 108:22 110:11 111:4 135:2 141:15 147:4 148:15 160:21 161:18 162:19 163:19 166:3 167:10 175:2 184:10 187:7 194:3 209:5 209:8 220:15 221:16 233:21,22 234:22 239:15 244:15 248:20 249:11 297:19 298:10 306:13 307:3 308:13 316:15 333:10 344:9,16 345:12 345:13 353:7 367:5 371:9 376:6 377:1 380:21 381:1,21 387:2 411:15 412:22 420:18 422:1	Jennifer 2:15 31:9 31:11 106:14 171:10,16 177:22 182:5 217:4,13 339:22 356:9 410:3
instrumental 9:14	interface 269:2	intraocular 382:1,2	iPhone 7:20	job 41:20 45:8 89:3 119:12 218:10 236:20 245:8 264:8 317:15 329:11 364:11 427:12
insulin 25:20	interject 111:21	intravascular 429:20	issue 37:16 75:21 83:1 92:6 93:2 102:3 108:22 110:11 111:4 135:2 141:15 147:4 148:15 160:21 161:18 162:19 163:19 166:3 167:10 175:2 184:10 187:7 194:3 209:5 209:8 220:15 221:16 233:21,22 234:22 239:15 244:15 248:20 249:11 297:19 298:10 306:13 307:3 308:13 316:15 333:10 344:9,16 345:12 345:13 353:7 367:5 371:9 376:6 377:1 380:21 381:1,21 387:2 411:15 412:22 420:18 422:1	John 2:8 28:1 33:13 73:12 102:12 119:11 121:17 122:8,9 126:5 145:15 150:9 161:22 209:3 235:13 237:16 243:4 244:13 246:13
insurance 20:3 34:16 376:3,10 377:17	interestingly 128:10	intravenous 27:21	iPhone 7:20	
insured 185:4	interface 269:2	introduce 9:10 31:16 34:21 97:12 132:6	iPhone 7:20	
insurers 104:2	interject 111:21	introductions 3:5 6:20 9:18 15:7 34:4	iPhone 7:20	
intangibile 272:16	internal 28:7 314:8 315:18 323:4 358:17	introductions 3:5 6:20 9:18 15:7 34:4	iPhone 7:20	
Intelligent 27:12	internally 85:5 314:7	introductions 3:5 6:20 9:18 15:7 34:4	iPhone 7:20	
intend 190:6	internally-report... 318:1	introductions 3:5 6:20 9:18 15:7 34:4	iPhone 7:20	
intended 53:5 79:9 129:8 142:22 175:4 190:6,13 191:11,19 230:17 363:4 381:16	international 17:18 63:18	introductions 3:5 6:20 9:18 15:7 34:4	iPhone 7:20	

247:16 248:13 261:11 277:2 315:10 316:1 328:7 335:9 339:2 339:11 340:12 342:22 343:15 346:10 353:20 365:1 368:8 393:18,19 399:12 406:5,13 409:16 412:12 414:19 421:16 422:2	Kathy 23:19 keep 8:1 58:19 72:20 90:21 103:3 106:14 110:16 155:19 161:19 162:3 187:12 238:19 241:10 243:5 244:11 252:22 257:22 287:6 290:16 303:5 312:2 314:5 401:4 412:3 436:6 keeping 6:4 66:7 168:5 kept 132:8,8 KEVIN 2:22 key 60:19 61:20 307:2 308:13 323:21 keyboard 270:15 kid 434:12 448:11 killer 112:19 kind 12:17 30:21 40:7 46:2 53:13 53:22 57:15 61:1 66:20 83:21 84:21 88:12 136:4,5 142:1 146:20 149:9 153:22 160:19 185:15 220:4 223:13,19 223:21 225:8 226:1 228:16 232:5,21 235:8 250:10 252:15 259:14 265:13 273:15 313:7 314:11 331:7 333:14 335:6,7 337:1 338:2,10 341:7,10 345:13 350:12 353:13 354:15 358:2 364:17 367:7,21 382:16 394:17 397:4 417:15 440:21 452:16	454:17 kinds 115:22 131:5 150:22 222:10,22 290:1 312:22 324:10 369:10 436:21 KISS 241:10 knee 380:19 knew 140:9 knitting 50:7 know 11:14 18:11 25:2 26:8,20 35:14 36:13 47:20 49:2,3 60:17 77:4 79:20 80:8 81:5 83:3 91:11 93:21 93:22 96:16 98:14 103:9 104:1 110:7 111:11 112:3 116:2,8,11 123:12 124:2 126:21 127:11 133:17 135:3,10,16 136:5 136:12 137:13 140:1,17,22 141:9 141:17,18 144:19 144:22 151:5 153:21 154:1 155:6 158:6,7 162:3,17 165:21 167:11 168:19 171:7 174:8 179:19 181:14,21 186:16 190:8 192:16 196:4 197:13 198:15 201:22 207:6 210:9 211:2 216:19 217:5 221:12 222:12,14 223:22 225:7 228:9,17 229:8 230:9 231:14,17 231:18 232:7 234:9,18 235:19 236:1 239:18 241:12 242:10	243:16 248:6 249:17,18 254:4 259:3,5,19 261:8 267:12,15,20 268:4 270:1,6 272:15 283:1 288:11 290:14 294:5 298:10 300:7,17 301:8 302:17,19 306:4 306:18 312:15,21 314:12 322:1 325:2 332:5,20 333:4 334:17 340:12 341:12 346:6 351:8,13 352:11 355:4,10 356:3,3 359:21 360:6,20 367:20 369:9 370:1,17 375:4 379:11,21 380:12 382:2 385:4,14 387:3,14 387:22 388:21 389:18 393:9,15 393:22 394:9,15 395:5 396:10,11 400:5,8 401:1 407:22 409:1,16 410:21 411:14 412:7,22 413:12 414:4,11 417:18 418:4 419:12,13 419:15,17,18 421:3 422:11,14 423:22 427:21 429:22 430:10 431:4 432:18 433:2 434:6 439:7 439:9 442:15,16 442:19 446:9 448:9 449:22 450:2 452:18,19 455:12 knowing 227:1 270:17 402:12 knowledge 28:12	129:1 396:2 known 47:21 52:6 110:2 235:1 429:19 knows 229:6 252:19 274:12 324:19 430:3
Johns 16:14 John's 272:7 join 5:10 8:15 16:19 34:19 202:8 joining 216:20 217:4 Joint 17:16,20 18:22 22:15 23:15 23:17 32:19 66:10 208:2 238:16 240:16 260:19 265:4 judged 129:11 judgment 288:10 288:17 290:13 348:22 380:3,14 392:13,22 juice 52:3 jump 24:11 108:21 124:16 132:18 210:8 219:20 233:15 243:2 256:21 293:15 313:21 358:6 392:7 jumped 94:8 jumping 30:15 165:18 justifiable 442:9 jut 80:10	<hr/> K <hr/> Kaiser 29:21 Kaiser's 144:6 KATHRYN 2:7			<hr/> L <hr/> labeled 107:11 133:15 labor 10:7 384:16 lack 296:6 415:16 ladder 355:14 laid-out 100:2 landmine 230:22 Langone 28:21 language 4:9,13 11:5,14 54:11 84:9 112:7,15 120:19 136:16,18 143:11 174:18 177:19 189:14 196:5 197:22 202:1 212:4 214:12 266:14 320:13,20 323:19 352:16 364:22 371:16 380:16 381:15,22 382:6 383:12,18 385:21 387:14 410:2 429:4 432:21,22 439:11,15 453:6 laparoscopic 385:13 large 71:1 130:13 141:3 222:1 269:14,14 287:17 301:18 343:18,19 374:22 largely 83:20 200:22 larger 263:16 281:7 287:8 307:7 310:22 345:12 427:16

largest 287:18 304:19	400:17 436:14 442:1,2	387:10,12 388:2 392:1 397:22 439:19 443:8 448:7	Legislation 34:18 legs 104:4 leisure 151:14 lens 58:3 59:22 382:1,2,5 lesson 387:15 lessons 275:11 less-than-optimal 112:20 let's 48:17 178:2 179:18 182:6,19 193:2 194:5,17 195:4 197:13 203:14 214:22 221:13 252:2 258:3 260:6 267:9 270:13 279:12 281:9 292:2 296:11 298:21 303:19 308:19 310:8 350:1 364:5 364:5 374:5 378:10 392:10 402:14 408:20 432:11 434:9,11 435:10 437:14 449:8	323:17 352:4 372:4,4 436:17 lifestyle 58:7 lifetime 313:5 life-changing 417:22 life-threatening 154:9 lift 273:8 light 65:18 66:5,5 likelihood 196:3 limit 183:21 208:22 209:17 210:11 301:14 328:14 limitation 26:21 limited 239:22 336:8 343:22 416:15 limiting 301:15 321:6 416:14 limits 117:6 211:21 Lindsey 2:16 7:16 31:1,16,19 line 8:15 24:16 29:15 83:3 121:10 170:14 257:8 273:16 334:19 354:7 446:10 453:20 lined 397:9 lines 124:4 162:8 213:13 403:7 lining 133:22 link 51:3,16 127:15 linkage 247:3 linked 99:19 101:15 113:9,20 429:1 links 16:16 127:8 list 78:4 85:18 89:5 90:1 104:3,3 117:19 118:7 119:15 120:1,3 122:21,22 123:1 123:10 125:14 126:1,7,13 129:12 138:20 142:4
lastly 37:13 48:12 52:9 53:16 54:19 56:14 58:22 59:15 60:12 61:5,18 latched 104:2 late 34:9 214:8 latent 266:19 Lau 2:6 29:16,17 216:6,7,10 258:11 258:14 272:1 280:3,3 302:13 303:1 laughter 15:21 17:1 22:2 26:2 28:15 32:5,8,12 88:13 157:19 158:2 192:14 194:19 203:20 204:3 205:15,18 205:20 206:10 227:7 229:2,7 266:12 288:18,21 303:4 316:9 339:13 358:18 422:6 423:6 427:5 427:8 452:8 454:3 455:13 launching 50:1 law 34:11 263:10 layers 290:16 lead 129:4 154:13 383:1 419:18 Leader 17:15 29:21 leaders 165:7 leadership 57:4 leads 144:20 Leah 2:3 163:2,3,4 163:10 165:16 249:10 250:12 274:1 277:20 303:14 306:11 324:13 330:1 334:12 353:10 368:5 369:14 371:14 398:11	leak 326:7 lean 392:5 393:20 leaning 388:6 Leapfrog 163:11 166:3 240:17 250:18 299:9 300:7 310:19 330:2 353:13 415:21 learn 63:3,4 66:16 68:8 103:19 236:16 274:15 283:5 292:11 303:15 334:21 351:12 388:8 415:10 422:21 423:11,12 learned 10:12,12 155:12 226:9 275:11 351:16 387:16 learning 254:15 270:1 274:14 311:16 351:9 learnings 139:11 275:18 learns 400:1 learnt 66:8 leave 4:3,5 8:10 81:18 131:4 132:14 151:1 152:11,15 156:21 157:11 160:10 162:19 167:10 170:16 171:18 172:2 180:3,9,17 188:17,20 191:21 193:11 195:10 197:7,17 199:16 199:17 201:10 202:6 210:3 212:12 224:10 292:2,19 323:19 372:14 383:15,16 383:17 386:14	leaves 177:20 183:15,16 185:21 338:15 leaving 3:12,14 4:7 117:9 147:6,12 156:6,11,14,20 160:14 178:16 200:9 201:1 206:19 372:16 396:20,22 399:2 led 140:5 275:21 381:22 Lee 312:9 348:4 leeway 424:10,11 left 8:9 16:10 128:6 132:7 146:20 157:2 199:12 212:13 266:6 335:14 336:17 342:8 362:2 363:3 363:5 370:11,12 373:21 382:3,4 383:12,19 385:15 386:2,12,17 387:17 388:22 389:10,10 397:15 398:1,14 401:2,3 401:22 447:10 453:10 454:19,20 lefthand 323:15 leg 67:14 230:19 231:1,3,17 legal 46:2 152:10 152:18 435:2,3,5 435:18,20,21,21 436:12 447:5 legalistic 97:13 legalistically 434:17 legally 438:10,15 447:10 legally-armed 352:2	level 24:20 47:4,5 57:7 64:6 69:17 78:16 126:21 139:18,20 195:21 259:2,4 355:20 365:19 414:6 422:16 446:11 levels 8:22 52:18 57:19 64:7,7 259:19 leverage 56:18 lexicon 76:11 liability 97:15 111:22 license 344:17 licensed 348:9 licenses 435:9 life 211:22 221:17	

145:22 146:8,12	350:5,13 353:12	240:6 246:2	453:5	241:16,20 246:15
146:13 159:14	356:18,22 357:8	253:10 264:13	look 12:3 14:6,11	259:14 273:19
164:9,12,16 167:8	357:11,12,14,18	289:8 291:12	15:3 16:5 40:4	274:17 282:2
167:18 170:13	359:22 363:19,21	312:16 319:2,7	41:21 43:22 47:22	300:20 315:17
171:2 172:9	368:18,19 370:6	330:4,4 343:22	50:3 58:12 65:3	345:19 350:22
175:22 177:13,19	370:18,18,18	347:21 360:8	75:14 84:14 89:7	388:16 441:11
178:21 179:4,5	374:5 376:14	363:12,16 367:1	92:3 95:9 98:2	444:20 454:6
180:1,12 183:20	381:4 383:1 412:8	381:18,20 384:3	102:9 103:14	looks 20:9 23:10
186:11 191:10	418:10 427:18	385:7 387:18	119:14 122:22	171:15 175:9
194:5,10 195:7	429:16 434:8	393:2 395:8	123:10 125:16	205:10
197:21 223:12,15	453:13	404:13 408:8	136:7 137:15,22	loophole 363:12
224:20 225:13	listed 35:5 92:11	414:16 419:11	139:13 146:18	lose 134:3 138:7
226:17 227:10,17	95:21 142:20	421:17,17 432:7	154:20 156:7	139:2 141:11
229:15 230:1	176:13 325:16	435:14 439:2	164:15 167:12	161:6,12 165:11
234:7 236:4,5	342:9 426:1	444:2,5 446:11	172:3,9 174:10	278:21 364:10
238:15,16,17,18	listen 145:16 260:9	448:6	175:20 178:3	441:6
238:19 239:3,4,15	343:2	live 32:6 48:15	181:21 182:13	loss 4:10,11 139:7
240:15 241:9	listening 5:20	123:1 177:5	202:20 205:13	208:12,14,17,18
242:3,19 243:5,6	258:14	326:20 364:8	207:3 210:7	210:12 212:5,6
243:8 246:6,10	listing 79:8 88:5	lively 14:7	219:21 220:7,14	lost 72:1 105:18
248:8,9 250:10,18	320:4	liver 349:14	220:18 221:3,14	142:1 165:14
251:2,5,7 255:14	lists 186:6,11	lives 246:16 247:6	221:19,19 222:5	417:6 427:3
257:12 258:4,9	229:22 233:12	451:21	222:17 227:21	448:11,12
260:1,1 262:4,20	238:20 239:2,5,21	living 29:14 414:7	229:13 235:16	lot 8:21 10:12,12
264:13,16 265:14	243:22 247:17	440:21 441:2	247:19 249:13	10:15 11:21 13:8
265:15,20 266:8	249:14 252:22	load 454:15	265:7 270:14,19	24:3 25:12 26:1
266:10,11,15	261:20 262:2	local 19:12 323:20	271:12,16 273:5,6	27:1 29:22 31:18
267:17 268:16	271:17 284:22	324:14	273:17 283:8	32:17 33:15 46:20
269:15,19,19	321:16	locate 26:15	295:10,22 313:14	63:7,17 64:11
270:9,9 271:3,8	literally 46:1 102:2	located 1:20	314:7 319:13	71:8,9 72:6 80:1,2
271:10,12 278:19	324:15 387:4,9	locus 325:12	334:4 363:1,7	84:21 86:22 87:21
281:20 282:10	literature 125:7	logic 175:2 425:9	404:14 409:2	87:22 92:8 113:18
285:8 289:11,16	154:6,11 156:3	logical 83:17 99:18	414:9 418:4	114:3 115:3 124:2
291:14 292:15,15	185:16	100:7 250:3	looked 7:22 75:5	126:22 130:14
296:21 297:7	litigation 130:19	278:11	99:17 142:9	133:16,19 134:1
299:7,21 300:3,8	little 7:11 10:5	logically 53:17	302:21 350:14	158:6,10,17
300:11,13 313:12	11:19 15:9 17:19	145:11 175:8	353:22	165:22 186:19
314:8 316:17	32:1 36:3 38:6	long 115:17 119:20	looking 13:5 21:19	198:13 220:9,14
317:12,16,17	59:13 78:14 91:9	149:6 208:11	32:20 43:8 67:9	221:13 222:12,21
318:13 319:14	101:3 106:12	245:16 350:21	67:19 68:9 89:20	226:4,19 249:3,7
321:8 322:12	119:3 120:5	351:14 379:15	94:9 98:8 103:18	251:1 264:2,20
323:21 328:1,12	159:17 162:15	453:15	105:22 122:22	265:2 267:4
334:7 335:10,11	169:4 177:20	longer 97:4 432:7	125:1 129:22	275:13 276:16
335:13 336:15,18	181:8,11 182:18	long-range 360:3	148:18 149:6	277:8 282:9
336:18 338:20,22	197:12 198:19,21	long-term 29:5	159:14 164:10	311:22 312:13
339:4 342:4,8	205:6 228:19	76:1 92:20 262:15	175:7 202:13,18	338:3 344:12
345:8 348:20	238:10 239:1,2	443:14 444:6	220:22 221:1	347:22 351:17

353:11 355:9	majority 21:22	249:18 352:8	99:16 116:8	453:3,4
368:12 369:3,4	147:14 156:19	451:1	120:21 129:20	meant 11:17 77:5
380:9 384:18,19	170:7	Massachusetts	141:4 144:18	79:10,13 219:14
388:19 401:21	maker 369:22	23:8 141:1 222:8	147:18,19,20	282:12 289:10
414:1 417:9 418:8	making 50:11 53:8	381:7 402:10	158:8 165:10	433:4 434:18
431:12 441:6	59:6,8 84:3 118:5	408:2 426:16	166:8 172:22	measurable 79:14
lots 54:7 162:10	161:3 166:21	master 267:17	173:11 178:14,17	measure 43:1,1
277:10,11 314:6	179:12 182:2	master's 34:14	190:8 195:22	47:11 52:1 98:14
315:17 336:5,7	194:16 201:8	material 97:19	204:9 206:4,4	100:4 109:7
376:8	262:19 263:15	382:15,16	207:22 208:2	118:11 220:19
lousy 284:14	322:1 342:18	materials 7:4,7,16	219:12 220:13	226:10 231:20
love 388:4	348:22 357:2,5	7:17 74:1 202:3	230:11,16 232:2	247:12 325:14
low 30:21 120:16	367:18 428:16	418:17	232:19,19 246:7	measurement
lower 278:4 323:15	Malcolm 30:5	mates 293:4	248:19 249:15	17:18 33:18 36:17
lowest-risk 404:4	mammals 266:16	matrix 60:4	250:5 263:4	37:18 46:19 48:7
low-hanging 336:9	Man 434:1	matter 104:15	276:14 297:16,19	50:8,12 52:7,19
Lucian 312:9	managed 84:19	110:12 117:5	300:10,18,21	54:7 58:10 61:22
Lucien 348:4	management 19:22	118:13 120:22	306:14,17,21	73:3 99:21 247:4
luckily 268:4	20:2 30:1 34:15	165:22 215:2	307:16,21 308:10	measures 9:13 29:8
lumper 234:18	34:15 112:1	241:22 242:22	310:18 315:13	33:9 37:7,22
286:2	330:15 453:10	279:18 285:11	324:16 328:11	41:16 42:21 43:5
lunch 192:13 214:9	Manager 31:12	287:9,20 292:8,19	335:21 348:19	47:1 48:4,18
215:1,3 321:11	managing 59:5	293:11 298:15	351:13 362:21	49:10,14 50:5,10
lungs 361:13	80:5	301:17 302:17	364:2 375:22	51:5,15 52:21
Lynxcare 19:21	mandated 348:6	305:14 306:1	380:9 386:13	53:17 54:14,21
	Manhattan 29:14	310:10 311:10	394:19 396:6,11	64:13,14,15 65:4
	manifest 98:16	318:19 320:11	409:10 413:22	66:19 68:12 70:5
	109:10	322:16 323:7,10	414:15 419:18	72:12 76:9 90:6
M	manipulative 345:9	324:16,17 326:22	420:21 424:5	90:11,18 98:12,20
MA 2:10	345:14 346:13	327:1,5 329:12	432:13 433:11	99:16,19 100:11
machine 268:2	manner 297:2	375:11 400:14	436:16 440:5	101:16 114:10
macro 57:6	march 356:14	427:16,16 428:2	444:9 446:7	118:10 228:8
made-up 377:5,21	Marge 105:7	428:16 455:19	447:16 448:10,13	229:14 247:2
maelstrom 92:3	135:22 280:9	matters 62:14	451:15 452:16,19	250:20,22
magnitude 95:6	marijuana 313:8	214:12	meaning 165:13	measuring 37:9
150:19	market 319:20	mature 367:18	428:6	49:6 187:4
main 135:13,21	married 82:11	Mayo 22:4,6 448:7	meaningful 77:2	meat 384:12
137:8 340:3	marry 54:13	ma'am 213:14	275:17 319:17	mechanism 349:20
maintain 45:14	Martha 2:9 28:17	MBA 2:21	320:3	395:14
164:8,17 319:13	30:14,17 31:2	McDONAGH 2:7	means 11:15 29:14	mechanisms
441:8	105:3,5 108:21	23:18,19 188:6	68:22 174:14	195:13
maintaining 42:14	169:5 193:11	308:19 309:1,14	177:9 196:10	mediastinitis
maintenance 65:12	201:3 202:5	MD 2:2,4,4,8,9,10	206:3,7 211:19	242:12 249:21
65:16 76:14 77:14	216:15 280:6	2:11,12,13,13,14	253:5,12 331:17	Medicaid 375:6
78:5	394:14 395:4	2:22 348:14	345:7 390:21	medical 18:16
major 57:5 163:17	Mary 455:11	MDS 22:17	414:2 428:20	19:20 22:12 24:14
175:2 211:21	Mass 12:9,10	mean 41:14 96:20	431:8 434:6 447:2	24:17 25:8 27:18
219:12 239:8				
254:6 359:4				

28:6,10,21 33:20	96:16 98:10	210:15 212:22	337:5,8,12,14	431:14,19 432:1
34:17 37:19 136:1	100:20 103:6	216:6,10 220:3	340:11,17,22	432:12,15 433:4,7
253:9 375:2	105:2,6,11 108:20	222:4 224:5	342:21 343:14,17	433:10,11,16
381:17 392:13	109:20 110:22	229:19 230:12	344:22 346:12,22	434:2,10,15 435:7
406:8 439:20	111:16 113:6	235:14 237:17	347:3 348:3 349:3	435:12 436:7,8,11
443:8	114:1,13,22	241:16 243:14	349:19 350:15,20	436:15 437:17
medically 438:10	115:11,19 116:17	244:15 245:21	351:7,16 353:16	438:6,12,20
438:15	118:2 119:19	247:15 248:12	353:21 358:8,16	439:12,16 440:1,4
Medicare 49:15	120:8 122:4,7,9	250:14 251:16	358:22 359:7	440:9,13,16,19
medication 18:10	123:15 125:11	252:10 253:22	360:17 361:3	442:3 443:4 444:1
57:20	129:17 130:4	254:20 255:5	362:20 365:3	444:14 445:1,5,7
medications 406:17	132:13,16 133:4,6	256:2 257:3	367:11,20 368:6	445:11,12,16
medicine 13:6 20:6	134:19,22 137:11	258:11,14 260:8	368:12 369:8,15	446:3,19 447:7
20:7 22:4,5 28:7	139:4 140:19	260:11 261:12	370:15,20,22	448:5,20 449:5,7
196:6 358:17	143:17 145:16	262:11 263:1	371:15 372:15	449:21 450:12
medicines 27:20	147:18 148:3,16	266:7 272:1,2,6	373:5,10,13 374:1	451:6,12,17 452:3
meet 142:21 254:8	148:22 149:4	272:19 273:5	374:4,19 375:4,9	452:11,18,21
282:3 283:13	150:4 151:4,15	274:2 275:7 276:8	376:15,18,22	453:21 454:8
317:12	152:10 153:2,5,13	280:3,6,12 285:3	377:22 378:2,18	members 11:9
meeting 1:6 5:17	153:19 154:5,17	285:12,16,19,22	378:22 379:11,17	39:18 104:22
5:22 6:16 7:7	156:21 157:11,20	286:14,19 287:1,7	379:19 381:14	113:14 169:19
9:19 25:10 32:10	158:4,19 159:6,9	287:17 288:5,16	382:7 383:11,16	213:8,11 355:4
47:18 74:1 81:8	160:8,18 162:1,14	289:14 290:8	384:14 385:12,20	membership 41:9
81:18 89:16 202:7	163:10 165:3,17	291:7,11 292:7,18	386:7,15 387:19	41:19 44:3
241:18,19 340:21	167:5 168:21	293:3,21 294:6,17	388:12,18 389:8	Memorial 25:6
341:4 356:20	169:1,8,16 172:11	295:2 297:5,9,13	389:14,18 390:3	memory 124:1,20
427:3	172:20 173:8,11	298:14,19,20	390:15 391:16	mental 49:17
meetings 5:19 7:3	173:19 174:13	299:16,22 300:5,9	392:8,10 393:20	211:20 351:20
27:14 45:11	175:3,6,16 176:10	300:17 301:16,22	394:13 396:3	355:17
meets 349:4	176:17 177:7,9	302:13 303:1,16	397:12 398:12	mention 8:13 51:4
Melinda 105:15,16	178:8 180:4,19	304:5,8,9 305:20	399:14 400:3,11	60:13 90:4 179:13
124:16,17,19	181:6,20 183:3,12	305:22 306:12	400:18 401:7,12	291:4 365:17
142:6,8	183:16 184:1,6,9	307:21 308:6,19	401:21 402:3,4	mentioned 15:14
member 2:3,4,4,5,5	185:2 186:3,12,16	309:1,9,14,17	404:8 405:13,21	38:3 39:17 42:11
2:6,7,8,8,9,10,10	188:2,6 189:1,19	310:12,16 311:7	406:6,14 407:12	42:15 44:4 45:9
2:11,12,12,13,21	190:2,12,14,17,21	311:21 312:5,6	407:18 408:12,13	48:1 54:3 67:6
2:22 16:11 17:14	191:3,16 192:2	314:18,22 315:6	408:22 409:19,21	69:15 72:11 73:1
18:8,14 19:1,9,11	195:4,16,20 197:3	316:2,6,10 317:6	410:9 411:6,13	78:17 80:14 86:2
19:14 20:18 21:1	197:16 198:8,12	317:10,18,21	412:12,15,16,20	86:15 87:14 96:3
21:21 22:21 23:18	198:18 199:4,10	318:9 320:5 323:8	413:4,21 416:1,20	184:10 220:4
25:3,21 27:22	199:16,19 200:3	323:14 326:11,21	419:10,21 420:2,4	merely 324:9
28:17 29:5,16	201:14,19 202:2,5	327:6,9,15,17,20	420:5,7,12,14,16	merge 239:13
30:8,16 31:4 32:9	202:10,14 203:6,9	328:8 329:17	420:19 421:9	252:21
34:8 40:15 42:5	203:18 204:12	330:8,20 331:15	422:3 423:15	mesh 214:7
62:19 67:20,22	205:9,21 207:5,22	332:1,3,6,8,11	424:13,17 425:16	message 96:7
88:14,21 90:13	208:10,16 209:7	334:13,17 335:17	427:1,6,12 428:12	139:16 141:7,9
91:2 93:12 95:3	209:13,16 210:9	336:1,4,7,12	429:5 430:4,13,22	245:4,12

met 10:3 423:18	190:19,22 191:15	312:2 313:20	418:3 419:2 420:6	microscopic 372:16
method 255:2	192:1,11 195:18	314:4,10,21 315:3	421:15 424:9,15	middle 172:5
methods 54:9,16	196:15 197:6	315:7 316:1,3,8	424:19 425:12,15	179:22 261:4
128:19	198:2,10,17 199:2	317:4,7,15,19	426:5 427:9 429:3	269:4 320:17
Meyer 1:22 2:2 3:4	199:6,14,17 200:1	318:8,20 322:8	429:6 430:11,18	362:12 367:13
12:5,6 34:19 62:3	200:6 201:17,22	323:12 326:10	431:10,17,21	Mike 212:21 239:8
62:9,21 81:14,22	202:4,9,11,16	327:3,7,14,16	432:2,14,18	250:13 365:2
88:8 93:8 94:21	203:8,11 204:1	328:4 329:1 330:7	433:13,22 434:9	372:14
96:2 98:1,22	205:7,19 206:14	330:19 331:2,21	435:10 436:5,14	Mike's 365:4
101:18 104:6,18	208:6,14 209:2,12	332:10 333:11	437:8 438:1,9,14	miles 25:7
105:4,9,13,16	209:14,22 210:14	334:16 335:3	439:10,14,21	million 221:11
110:14 111:15	210:17 211:5,8,13	337:16 340:4,8,15	440:11,14,18	mind 103:4 145:17
113:2,22 115:9,18	212:2 213:1,20	340:18 341:1,18	442:1 443:3,21	151:20 160:22
116:15 118:1	216:3,8,11 222:3	341:20 343:10,15	444:12,19 445:3,9	186:7 206:19
119:9 120:7	223:3 226:5	344:21 346:10,18	445:18 447:4,22	244:11 260:15
121:16 122:5,8	228:14,22 229:5	347:1 348:2,21	448:17 449:2,6,8	274:5,6 289:11
123:14,22 125:10	229:17 233:14	349:18,22 350:19	450:5,17 451:9,14	314:6 326:6 333:1
127:4 128:3	235:12 237:16	351:15,18 353:9	452:1,6,17,20	375:5 387:15
129:16 130:1	241:15 243:1,15	353:20 354:17	453:1 454:6,10,19	406:21 426:5,21
131:8 132:15,17	245:19 247:14	356:7 358:14,21	455:2,9	mindful 401:4
134:16,21 137:1,9	248:11 249:9	359:3,10 360:16	MHROD 2:6	mine 102:11 368:6
138:5 142:2,7	251:14 252:8	360:21 361:6	MHS 2:15	minimize 110:5
143:6 144:2	253:21 254:18	363:17 365:1	MI 55:18 56:6	minimum 85:5
145:15 146:14	255:4,22 256:5	367:6,16 368:4,11	Michael 2:13 19:14	323:5
147:20 148:21	258:13 260:6,10	369:6,13 370:5	96:15 111:15	Minnesota 21:6,14
149:2,11 150:2	261:10 262:10,22	371:4 372:8,18	130:1 150:2	93:1 118:12
151:3,13 152:4,20	263:19 266:4	373:9,17 374:3,9	154:18 174:12	222:13 241:3
153:3 154:14	268:17 272:4,11	375:3,8,13 376:17	183:22 184:22	345:19 379:13
155:20 157:1,16	273:4 274:1 275:5	376:20 378:1,10	188:21 189:18	426:16 427:2
157:22 158:18	276:5 277:14	378:20 379:8,16	195:3 205:8 223:4	441:15
159:3,8,19 160:7	279:3,21 280:5,8	380:20 381:19	224:4 251:14	Minnesotans 22:1
160:9 161:14	280:11,14 285:9	383:4,14,21 384:2	263:20 266:4	minor 231:7
162:22 163:21	285:14,17,20	385:10,19 386:6,9	288:4 291:1 323:6	236:16 358:8
164:5,18,22	286:11,15,21	386:22 387:21	328:1 358:6 392:9	432:22
165:15 166:15	287:3,11,22	389:1,12,20 390:7	413:3 443:6	minute 218:1 317:5
167:14 169:3,12	288:15 289:13	390:11 391:12	452:10	minutes 63:11 91:5
169:18 173:2,10	290:6,22 291:10	392:6,9 393:18	Michael's 228:17	106:17 145:21
173:14 174:6	291:18 292:12	396:16 398:3	263:22 291:8	214:9 279:7,7,13
175:11,19 177:11	293:2,13,22 294:7	399:6 400:13	Michigan 16:18	280:19 341:22
178:19 179:11,14	295:1,4 298:18	401:6,11,15 402:2	microneedle 387:1	403:16
180:8,21 181:10	299:1,20 300:1,6	402:14 403:11	microneedles 386:4	miscount 401:10
181:17 182:2	300:16 301:1,20	405:12 406:4,12	391:1 397:17	401:13
183:9,14,17 184:4	302:1,22 303:2,19	407:10,13,22	401:19	mismatch 375:21
184:7,21 185:14	305:18,21 306:9	408:5,18 409:17	microphone 88:12	missed 409:7
186:8,15,21	307:8 308:5,14,22	409:20 410:1	88:19 163:8	missing 222:12
187:19 188:5,19	309:13,15 310:4	411:4,11 412:18	293:16	391:14
189:16 190:1,10	310:15 311:1,19	413:3 414:18	microscope 387:4	mission 36:12 95:1

129:19,19,21 130:5 mistaken 248:18 248:20 mistakes 103:20 misunderstanding 129:5 misuse 421:14 mitigate 396:20 mixed 232:11 mode 354:16 model 152:14 208:1 265:2 284:19 290:4 modest 37:13 modifications 159:15 modified 81:7 modify 42:2 43:21 127:21 134:6 modifying 159:14 183:1 291:18,20 modus 451:20 moment 42:19 60:14 65:6 81:13 85:9 96:5 163:1 171:13 182:13 350:14 441:11 moments 213:7 273:10 money 28:14 237:2 244:21,22 monograph 201:15 203:7 month 50:2 65:21 months 375:15,16 Morley 2:8 27:22 28:1 122:9,9 145:16 162:1 237:17 244:15 261:12 262:11 316:2 328:8 335:17 336:1,4,7 336:12 337:5 343:17 346:12,22 347:3 353:21 365:3 377:22	378:2 393:20 399:14 400:11 406:14 407:12 408:13 411:13 412:15,20 422:3 430:4,13 438:20 439:12 morning 9:20,22 12:5 18:14 23:18 25:4 27:22 31:10 124:5 218:18 220:1 223:9 236:21 254:1 282:4 329:8 335:13 338:1 359:14 399:8 403:18 428:14 453:18 morph 444:2 morphine 413:15 mortality 58:18 276:12,19 mother 405:16 motility 313:8 motion 311:14 motor 324:18 361:10 Mountain 20:19 move 14:3 35:1 42:19 43:2 47:5 49:19 65:2 66:4 68:12 80:4 82:17 88:8 100:16,18 103:4 106:15 110:19 119:10 130:3 133:7 143:16 146:17 155:21 160:12 163:6 166:20 167:12 170:14 171:9 182:3,6 188:22 192:12 200:7 212:3 213:6 226:6 230:5 244:14 249:9 265:18 273:2,22 274:19 314:17	319:16 349:1,2 350:1 360:11 378:10 383:7,18 395:11 399:13 402:14,18 410:4 416:4 424:15 moved 65:11 133:21 296:3 movement 266:9 moves 14:14 movie 434:1 moving 10:19 37:18 42:20 46:18 58:8 60:3 102:6 MPA 2:2,5,10 MPH 2:4,5,10 MSc 2:2 multi 43:11 multiple 8:22 55:17 245:14 290:15 296:22 320:16 332:19 multi-faceted 70:12 multi-stakeholder 39:10,15 41:3 42:15 murder 267:14,15 murkiness 191:8 Murphy 105:15,15 124:16,22 142:5,9 must-pass 51:22 mutual 16:1 myocardial 233:8 myocardium 56:10	331:15 332:1,6 360:17 361:3 419:10 420:2,5,12 420:16 421:9 432:12,15 433:4 433:10 444:14 445:7,11,16 nail 145:7 name 5:5 23:19 25:5 28:1 29:16 31:11 133:17 166:2 281:8 284:15 366:17 narrow 55:2 83:10 116:21 345:20 359:1 362:9 434:16 436:6 narrowly 224:14 narrow/tighten 437:13 NASA 324:19 nascent 13:15 nasty 283:1,9 nation 36:17 national 1:2 5:6 9:12 16:17 18:9 18:20 24:20 29:20 30:5 32:21 36:18 37:1 39:1,1 51:4 56:15 57:1,10 60:1,6 63:18 64:6 67:5 69:17 102:7 103:10 163:18 217:16 235:19 277:19 333:18,21 369:20 371:3 384:5 421:22 455:8 nationally 13:11 17:10 331:7 natural 10:17 naturally 214:19 nature 161:7 234:18 nausea 225:4 283:16 304:13 311:17 312:21	313:4 nauseated 231:9 NCQA 22:14 29:5 nearly 286:7 near-miss 184:12 184:18 186:5,20 189:7 267:22 427:19 428:10 near-misses 153:20 184:11 185:10 187:7 236:15 275:14 276:2 307:7,9,10 424:7 428:3 necessarily 55:12 96:12 99:9 119:17 183:21 233:3 237:12 293:9 297:2 305:15 312:14 322:14 343:7 345:7 431:8 442:5 443:18,18 444:4,10 446:9 necessary 21:15 140:14 145:2 149:14 176:22 179:16 299:4 need 6:12,18,20 13:11 14:2 15:1,8 15:13 39:7 46:14 49:4 51:19 60:8 61:10,15 66:16 70:6 71:15,21 77:6 81:6 82:15 84:14 85:17 86:9 86:17 87:4 88:2 90:21 94:19 97:15 101:13 102:20 104:10 107:2 112:22 114:4 117:12 119:7 132:10 152:12 154:1,20 164:14 165:11 172:7 178:10 179:2 180:17 187:12 188:3 189:4 190:2
N				
N 5:1				
Nadzam 2:8 17:14 17:15 93:12 123:15 143:17 149:4 178:8 183:3 183:12,16 186:16 188:2 201:14,19 202:2,14 203:6,9 229:19 247:15 263:1 287:7,17				

190:3 191:3	354:9 357:13	434:4 448:11	non-regulated	68:13 74:18
210:10 219:6	385:6 394:9	nevers 131:5	347:22	NQF 4:21 5:13,16
225:8 234:1	429:15 431:20	134:12 140:4	non-reportable	6:7 8:13 9:15
236:16 239:1	433:6 437:18	nevertheless	292:21 298:16	10:9,13 14:13
246:1,5,7 250:6	443:9	185:12	non-serious 283:17	18:1 20:9 21:18
251:11,12 252:16	negative 149:21	new 9:5 24:12 28:2	286:17 287:10,21	23:1,20 25:10
254:21 256:4	192:18 207:10	28:2,18 40:10	289:20 292:20	28:22 30:8 33:2,9
257:21 260:8	255:18	77:22 123:5	293:11 305:14,15	35:12,14 36:8,13
265:17 267:1	negligence 447:14	146:11 206:10	305:17 316:17	37:1,9 38:19 39:3
270:9 272:17	negotiator 427:11	221:5 266:14	322:13 328:9	41:9 43:12 45:18
274:21 281:8	neither 243:18	280:7 304:18	non-SRE 287:21	46:18 47:14 61:18
283:22 284:8	neonate 432:13	305:12 306:3	318:17 327:6	62:10 63:4,15
288:6,10 290:18	net 278:11	337:4 341:13	329:18	64:11,15 66:17,22
292:15 293:1,15	neurosurgery	347:8 365:4,14,19	non-SREs 287:9,18	70:11 71:22 72:5
304:10 306:18	429:22	365:21 377:22	293:7,17 301:18	73:6 74:20 76:8
309:2,4 315:16,20	neurosurgical	399:19 407:1	302:3 303:12	83:2,4 92:8 93:4
318:1 319:13	429:14,19	408:13 423:3	316:15 318:14	103:19 105:15
331:16,18 332:4	neutral 252:5,20	426:16 427:18	326:16	161:20 163:20
338:19 339:7	neutropenic 121:11	440:10	non-sterile 410:12	165:12 178:21
346:8 348:19	Nevada 349:13	newborn 432:13,21	noontime 106:4	187:15 238:17,22
360:1 361:11	never 3:18 40:6	433:5,5,18 436:6	Nordisk 25:19	240:16 246:9
387:4 395:6 397:7	73:17 79:4 107:16	436:10	normal 185:10	265:4 289:18
403:17 409:22	109:12,18 115:7,8	news 204:5 268:18	417:11	291:4 295:11
420:17 425:6	115:15 116:19	nexus 449:3	north 25:7	299:21 313:12
444:7 447:4	117:3,7,13,20	nice 32:10 100:6	notches 239:16	314:2 316:13
needed 172:22	118:18,19 120:13	211:9 217:11	note 102:13 155:22	317:8,10 319:1,13
220:2 238:19	120:20,22 127:20	nicely 371:2	159:10 200:18	323:21 339:20
278:20	128:1 130:16	nicer 410:14	234:7 283:12	368:16 384:3
needing 100:13	131:1,1,2,2,2,3	night 92:10	449:12 451:15	415:8,22 418:5
262:12	132:5,5,14 133:8	nine 59:17 102:2	454:4 455:10	429:13 453:2
needle 49:19 367:4	133:12,18 136:17	nitpicky 360:13	noted 443:10	455:7
387:6,10 389:12	138:9 139:6 140:3	nod 210:1	notes 46:1	NQF's 65:7
389:14,22,22	140:9 142:11,16	nodded 103:11	notice 10:14	NQF-endorsed
391:13,14 393:3	143:2,20 144:3	nodding 369:6	notion 96:5 124:8	39:8
395:9 398:14	160:15 161:1,10	nods 152:7 431:12	163:22 206:20	NQF-specific 74:17
399:5	162:10,17 163:16	nominated 22:8	334:8 338:6	nuance 86:13
needles 387:3	163:17 164:2,7,7	25:11 26:17 29:9	408:19 450:6	134:13 223:18
388:14 396:7	165:20,22 166:4,5	43:14	notoriety 63:18	nuances 96:19
413:10	166:7,9,13,17	non 21:2 225:15	not-too-distant	380:14
needs 79:22 101:11	168:4,6,9 178:15	289:20 293:11	82:2	nudge 76:10
113:9 125:14	190:6,6 219:14	358:12	November 1:13	nugget 230:13
147:17 155:12	227:14 237:17	nonprofit 19:8	455:21	number 17:4 19:8
166:17 174:20	288:19 320:12	38:19	Novo 25:19	20:21 21:12 32:19
175:17 177:4	321:7,8,13,18	non-grammatical	no-harm 185:19	52:13 64:18 68:5
185:12 193:4	330:2 345:4 375:5	174:15	351:6	75:7,9 84:12 86:7
207:14 309:11	381:3 388:21	non-hospital 71:19	no-harms 428:22	86:22 92:11 117:1
319:4 339:10	409:13 417:10	non-payment 83:5	NPP 67:7,21 68:10	117:18 138:13

139:9 239:22	68:14 69:16 87:10	346:16 351:21	339:11,15 340:17	427:17 447:20
250:19 310:3	87:22 90:21 219:9	offline 427:10	341:1 348:21	opened 218:19
328:21 343:20,22	354:20	429:7	349:3 350:19	opening 9:9 120:3
347:10 364:14	occur 3:18,21 79:5	off-duty 352:2	353:20 356:7	135:8 179:1
366:20 374:22	79:22 107:16	off-label 244:2	372:8 373:5	openly 14:8
377:4,10 382:9	120:13 126:1	off-track 295:14	378:10 385:19	opens 115:21
407:2 410:18	128:1 134:10	oftentimes 364:16	401:6 419:3,10	153:22 154:4
412:2 419:14	138:9 140:3 143:3	oh 13:11 135:15	424:14 429:5,7,8	225:1
447:7	160:15 162:9,13	139:12 141:9	431:12 432:1	open-endedly
numbers 134:8	164:1,2,13 165:9	193:17 201:17	438:1 440:6	230:14
222:1,1 245:1,2	166:7 168:4,6,9	211:5 287:1	445:11 446:1	operandi 451:20
365:20 377:6,21	168:13,14,20	301:22 331:10	452:20 453:7	operated 185:11
numerator 283:10	169:6,17 170:1,8	411:3 431:3	455:2	operating 112:16
numerators 283:2	170:22 263:8	Ohio 26:22	old 40:5 146:10	365:8 375:18
numerous 70:13	275:19 282:6	okay 35:1 81:20	451:21 454:1	operational 30:1
nurse 16:12 17:22	323:5 349:7	82:8 105:9,18	older 448:11	operationalized
113:10 288:14	360:22 370:4	120:1 122:8	oldest 275:8	415:2
413:8	401:9	125:10 132:16	omissions 445:22	operationalizing
nursing 24:1 29:20	occurred 189:11	133:4 139:21	omit 85:19	143:10
44:17 75:22 259:1	265:1 341:2	147:14 148:3,6	omitted 360:2	Operator 213:12
347:20 440:22	occurrence 79:17	151:3 152:7	onboard 404:2	213:14 403:5,9
441:1 442:16	149:8 184:16	156:16 157:1	once 33:6 43:19	ophthalmology
Nutrition 110:4	185:3,17,20	159:7 160:3,9	145:13 239:15	382:22
NYU 28:21	201:20 203:4,5	163:10 165:1,15	277:5 293:16	opinion 167:6
N.W 1:21	204:19 207:18	168:22 169:3,12	394:5 417:6	430:2
	248:3 270:18	169:15,18,21	423:13 451:8	opinions 6:13
	281:15,16	170:4,6 171:5,8	ones 47:20 55:3	opportunities
O	occurrences 185:6	175:6,16 183:10	78:18 141:21	51:10 107:3
O 5:1	185:9 270:17	184:6 193:7,8,18	183:19 234:13	126:14 218:19
object 383:8 385:6	281:13 283:15	199:18 201:3,7	247:22 255:7	opportunity 8:16
390:19	occurring 89:8,14	202:4 204:4	347:10 350:10	12:20 21:17 22:22
objections 117:13	154:3 370:3	210:12 212:10,12	351:9 383:1	31:16 33:14 52:10
177:3 182:21	occurs 100:21	213:4,15 216:14	402:11 405:14	71:7 77:19,22
219:13	108:8 125:20	219:3 231:18	406:1 412:5	78:1 94:17 126:12
objects 384:19	195:11 200:14	232:6 233:13	424:18	137:21 142:3
385:22 397:14	207:19 360:18	243:15 245:19	ongoing 210:4	162:7 200:17
401:2,3	395:16	259:15 260:10	315:19	222:5,17,22
obligation 13:12	OCD 203:18	261:10 280:11,18	onset 35:4	234:17,19 235:4
observation 134:15	odd 316:19	281:9 286:18	onsite 453:18	275:16 292:22
251:20	offer 162:11	287:3 288:3 290:8	ooh 410:20	357:10 365:12
obsolete 380:7	office 128:6 351:22	293:2 300:5	open 5:17,19 6:5,10	372:13 446:21
obtain 375:1	352:1	303:19,20 304:9	8:7 68:21 86:12	opposed 47:12 80:5
obtainable 112:12	officer 18:16 19:17	304:11 305:21	177:20 181:18	111:18 160:19
obtained 361:2	19:20 22:5 28:20	309:19,22 312:5	183:15,16 185:22	187:15 196:6
obvious 87:11	154:2 352:3	316:3,6 327:17	213:13 268:9,14	250:10 260:17
197:20	officers 136:1	331:15 335:3,21	296:8,11 344:3	354:15 405:5
obviously 36:15	offices 25:13 101:2	336:11,14 337:18	403:6 410:6	425:22
53:14 63:6 64:9				

opposites 293:4	orthopedics 382:21	100:18 149:18	panels 7:12 22:15	326:19 331:5
optimal 112:21,21 195:13	OSHA 352:11	262:14 282:10	22:16 29:4 41:5	337:11 338:7
option 151:18	ought 13:7 167:17 177:16 225:20	286:5,7,9 289:19	44:12 45:3 75:14	344:6,7 345:1
order 3:2 7:5 70:15 110:20 267:3	233:2 268:1	290:16 293:18	78:6 90:15,20	353:1 356:19
304:6 358:5	269:21,22 271:5	304:17 310:5	284:6	357:14,15 358:3
ordering 376:1	282:13,14 301:8	406:7	paper 71:11 279:5 358:2,10	359:6 365:10
organ 380:9	399:10 426:11	overlaps 66:21 271:15 331:9	papers 366:14	368:13 369:17
organization 12:11 17:12 19:18,22	448:21	overlying 60:1	paragraph 128:8	370:10 383:20
20:19 38:21,22	outcome 24:6	overly 322:2	169:10 176:8	395:18 398:6
39:4 70:15 85:6	48:22 49:13 98:21	overseeing 68:17	180:16	402:5 403:7 415:8
93:20 163:18	99:17 136:10	overuse 49:21 59:17	parallel 53:10 72:4 95:14 224:20	437:21 448:15
219:10 254:16	183:5 237:11	overused 157:13,15	227:17	participants 206:12
313:14 396:12	325:14 395:19	overview 3:6 35:10 74:21	paraplegic 416:8	participate 15:2 18:3 19:7 21:12
organizational 102:22 126:21	419:14	overwhelmed 95:19	Park 1:19,20	participating 12:7 348:15
323:4	outcomes 29:1 49:15,17,18 50:9	o'clock 268:22 453:8	parking 131:4 186:19	participation 143:22
organizations 20:22 29:9 42:8	51:14 56:3,11	O'Kane 57:8	parse 96:18 99:11 174:19 286:10	particular 36:7 40:16 44:10 55:4
57:4 67:20 68:1	98:12,13 99:13		301:11 304:2	64:2 79:19 85:10
68:17 69:8 80:4	266:18 268:12	P	389:2	148:15 330:6
103:13,17,19	277:12 393:6	P 5:1	parsing 285:7	343:1,8 352:22
125:18 137:13,15	396:2	pacemakers 383:17	part 4:10 6:2,5,21 7:1 10:21 17:3,20	355:17 414:19
240:19 278:2	outliers 270:2,3	packed 130:14	29:10 35:9 54:6	particularly 38:22 59:12 122:14
324:10 381:6	outpatient 361:21 362:1 372:3	packet 320:14	58:20 63:8,9	123:3 124:6 129:3
396:15	448:15	packets 74:10	70:17 72:18 73:14	154:12 246:13
organize 41:1 45:10	output 74:1	packing 386:16	76:17 77:17 78:4	293:10 343:18
organized 31:22	outputs 341:16	packs 136:5,18	80:11 83:8 85:5	344:15 348:17
orient 38:3 175:20 182:13 218:3	outreach 37:14	page 7:10 107:11 108:2 121:21	90:8,14 94:22	355:6 416:5
orientation 3:6 35:10 36:2,4	outside 89:12 113:13 142:12,19	131:17 149:13	98:7 113:19	441:21
217:12	175:15 233:19,19	151:22 157:4	116:19 133:20	partly 265:17 352:18
oriented 9:14 64:17 64:19	252:16 255:7	172:5 179:10,19	140:15 141:16	Partners 140:20 141:1 280:13
original 13:2 20:5 115:1 125:1,2,4	270:12 284:2	180:15 181:21	143:11 156:9	partnership 57:2 277:19 369:20
138:20 211:16	305:9 306:4 311:3	182:14 196:17	159:11,12,16	parts 67:2 269:19 308:10 334:4
333:14	324:16 326:7	198:21 203:7	160:15 175:4	pass 407:20
originally 4:8 200:11 227:8	328:6 368:14	218:4,4 320:17	187:5 191:20	passed 400:12
origins 32:2	313:6	322:17 345:4	199:13 205:2	path 330:10
orthopedic 242:13 382:14	oval 304:17	356:13	206:6 208:18	paths 95:14
	overall 52:14 63:14 69:18 72:21 79:13	PageDown 182:7	212:5 237:3	pathway 261:8
	80:12,22 82:16	pages 116:9,9	246:18 247:3,8	patience 31:20
	184:15 326:14	PageUp 171:17	248:17,21,22	
	350:13 359:21	pairs 53:3	250:3 264:11	
	overdose 450:8	panel 16:3 19:12 28:22 30:9	281:20 290:10	
	overlap 76:22 99:9		296:19 299:15,17	
			307:11 316:22	

patient 5:7 13:17 15:15 16:6 17:6 17:12,15 20:19 21:5,13,14 23:7 23:11 24:7,8,16 25:1,9 27:5 31:12 32:20,22 33:4,15 33:21 48:18 50:10 50:11 55:12 56:1 56:6,9 57:13 59:8 59:10 61:14 65:4 66:9 67:5 68:16 69:7 71:1 72:11 74:19 87:9 90:6 92:11,16 109:4 111:4 155:9,13 183:5 185:18 196:12 204:15,22 206:12 207:2,9,12 207:19 251:4,6 254:5,9,17 259:10 275:12 276:22 298:21 313:2,16 322:20 332:19 345:21 351:21 361:9,12,18,20 362:16 366:18 368:13 369:20,21 370:2,9 371:17,21 371:22 373:18 374:15 375:16,18 375:19 378:13 383:8,13 386:10 386:17 389:6,16 390:6 391:8 392:17 394:1,9 395:10 396:1 398:3 399:1,3,20 399:21 408:3 409:13 416:12 419:3,5 432:8 438:1,3,7 439:3 445:13 449:9,15	121:12 124:9 150:20 248:4 322:19 349:13 382:11 404:4,5 407:3 patient's 55:16 348:16 361:13 373:8 374:2 patient-acquired 253:8 patient-by-patient 395:19 patient-centered 251:8 254:9,13 371:22 patient-focused 49:11 patient-oriented 5:12 PATRICK 2:4 pause 110:17 163:1 310:7 pay 232:6,8 244:20 397:7 payer 19:13 paying 225:21 230:10 payment 64:10 83:1,4 86:16 228:15 233:18 235:17 236:10 237:13 244:8 250:6 258:10 297:3 PCA 406:9 PCI 56:7 pdf 179:10 340:3 pedagogical 150:7 pedantic 96:17 pediatric 419:20 pediatrics 87:10 Peggy 57:7 penalize 390:18 Pennsylvania 18:17 241:5 275:8 276:9 332:13 people 10:18 11:4	11:20 20:1 24:22 46:9 47:2 48:6 91:12,16 95:13 96:7 97:6 104:2 108:16 110:8 113:7,17 117:20 126:10 130:17 131:16 132:9,9 133:9 135:3,19 137:19 138:21 149:12 155:7,10 158:9 166:21 172:3 174:8,9,10 178:3 182:12 216:19 232:20 242:11 243:16 245:15 255:20 256:7 260:13 269:12,15,15 271:20 292:1 294:14 303:7 305:6 311:16 321:6 322:10 329:10 335:15 337:2 339:7 342:1 354:15 355:2,18 356:8,21 362:7 363:10,21 367:2 372:17 374:22 376:9 377:4 381:5 381:6 384:10,19 385:3,8 388:2 390:18 393:5 396:4,7 401:18 402:19 412:6 413:1,7,11 414:3 415:3 422:18,21 423:11 432:6,20 435:13 436:3 440:20 441:7 442:6 446:22 451:21 people's 94:7 395:2 pepper 236:21 perceived 321:6 percent 58:4 64:15 99:9 123:12,13	141:2,14 222:8,9 235:6,8 242:10 347:13,17 377:5 410:19,19 426:17 436:19 percentage 141:3 perceptions 319:5 perfect 75:17 97:3 97:4,22 152:14 154:20 247:11 280:20 325:4 381:3 perfectly 107:1 137:14 289:7 perfectly-selected 97:7 performance 9:13 24:5 29:7 33:9 36:17 37:10 46:19 46:22 47:4,5 51:5 52:6 117:6 276:12 performed 359:6 374:15 378:13 performing 97:7 pericardium 388:16 period 41:13 42:9 55:14 210:14,15 398:10 399:3 402:20 periodically 110:16 periods 8:14 perioperative 67:8 67:10,13,18 68:2 68:13 permanent 247:21 292:13 Permanente 29:21 perpetrator 352:4 person 14:21 45:22 181:7 224:21 252:2 267:3 392:20 396:12 413:14 414:5 432:10,17 433:8 433:17,18,19 434:5,7,11,13	435:3,5,20,22 436:13 437:3 447:9 454:1 personal 360:6 399:18 personally 350:18 360:5 perspective 21:3 43:16 55:12,13 63:4 70:19 88:10 152:11 241:8 258:10 259:3 305:8 382:8 perspectives 4:22 241:19 340:7 342:2 perverse 401:20 PEs 242:16 Peter 2:13 3:3,8 5:5 15:18 16:15 17:3 18:21 35:19 36:5 38:7 44:11 53:9 56:16 59:1 61:16 62:2,4,21 89:2 90:13 96:3 99:7 104:1 106:22 107:9 238:1 263:19 295:7 333:12 354:1 395:3 454:11 Peter's 391:13 petitioned 16:18 pharmaceuticals 24:15 Pharmacists 26:18 pharmacy 26:4,19 phase 38:12 phases 55:20 PhD 2:7,8 151:5 phenomenal 33:14 Phil 25:22 Philadelphia 19:13 25:7 Philip 2:12 25:21 32:9 109:20 116:15,17 150:3 151:3,4,15 153:9
--	---	---	--	--

153:13 158:18,19 159:6 160:17,18 181:20 183:22 184:8,9 193:7 199:19 200:3 220:3 254:19,20 255:5 256:2 312:6 314:18,22 315:6 412:12,16 427:6 philosophical 91:9 250:11 philosophically 250:17 251:3 philosophies 111:19 philosophy 175:2 241:10 431:1 Phoenix 26:5,8 phone 14:22 30:12 34:20 62:18 93:9 104:12,20 124:16 134:20 147:2,16 148:5 156:17 160:4 163:9 167:1 168:8,18 169:19 170:18 180:14 193:9 201:3 212:10 213:9,11 216:5,12 258:12 262:8,9 279:14 280:1,15 302:7,14 391:18 403:1,4 454:20,21 phones 110:17 170:6 phrase 3:18 101:2 134:14 144:7 161:1 168:4,5 389:11 444:15 phrasing 226:4 physical 211:20 physician 18:1 19:11,17 25:13 physicians 12:11 19:16 414:21 pick 8:7 48:17 107:19 138:21	244:7 297:6 313:1 393:17 picking 260:11 396:6 411:1 picture 60:8 240:9 307:5 pie 222:15 piece 36:7,9,19 71:11 97:22 107:20 138:15 153:1 279:1 298:15 330:2 334:5 343:2 352:15 378:21 384:4 386:12 388:13 393:2 402:6 437:19 448:19 pieces 65:2 385:14 pile 111:17 PIM 25:16 pin 391:3 pink 448:8 piping 31:8 pistol 266:22 pivotaly 396:1 place 8:11 26:14 27:14 83:17 84:9 87:1 123:21 138:11 145:12 166:19 189:5 218:14 225:22 245:1 260:18 261:1 326:15 338:14 339:18 342:22 351:3,17 355:16 364:4 376:12 395:13,15 421:12 422:17 428:14 448:22 places 152:14 189:3 336:8 445:21 plain 11:14 plan 45:2 84:7,10 90:10 216:21 320:21 417:14	planets 284:10 planned 366:11 404:22 409:5 planning 49:20 plate 95:9 296:12 platform 37:18 54:1 play 56:2 64:12 115:17 155:16 320:16 329:20 337:1 plea 263:22 please 6:8 8:2 14:7 16:9 34:7 36:11 38:1 70:8 75:2 76:12 77:9 78:10 79:1,6 82:6 84:5 93:11 96:15 98:9 103:5 108:18 110:21 111:15 134:21 137:9 142:7 149:15 152:9 164:5 167:4 168:19 171:10 172:1 176:9 188:5 194:22 195:19 198:7 210:22 216:5 339:19 346:10 359:8 454:9 pleased 38:13 pleasure 9:15 35:21 plow 339:8 pneumonia 259:11 pockets 240:7 poetry 96:22 97:22 poets 97:6 point 13:16 54:4,4 62:16 67:19 68:3 68:15 75:18 81:14 81:21 82:20 86:11 90:4 106:8 115:12 119:9 121:19 128:2 130:5 131:10 135:5 138:7 139:3 143:7	144:6,8 150:8 160:11 166:19 167:16 170:11 172:15,18 191:9 200:2,19 201:15 210:17 214:2 216:12,15 217:20 230:5 233:17 236:9,18 237:11 237:21 250:15 251:11 258:8 260:9 269:8 272:20 274:3,19 278:16,16,21 280:21 281:17 282:20,21 283:22 286:1,20 291:1 293:6 294:19 295:21 298:3 299:3 303:14,21 307:2 310:17 311:2 316:12 318:3 321:17 322:11 326:8 327:3 331:14 335:8 342:19 347:19 352:14 355:21 358:20 364:13 365:10,16 367:17 371:16,19 387:2 391:13 395:4,21 396:17 400:19,21 401:4,8 435:1 436:2 437:7 437:17 444:9 446:4 453:7,14 pointed 196:17 277:2 450:19 points 122:12 187:15 226:7 271:10 395:2 408:9 poisonous 379:20 police 352:11 policies 79:18 396:19 policy 10:6 21:4	22:11 23:5 163:17 166:5 260:17 political 241:11 politically 91:15 227:15 pop 31:1 Poppins 455:11 population 55:21 58:2 91:20 92:7 populations 87:9 87:10 91:19 population-level 58:9 portfolio 27:8 33:4 36:8 60:3 portion 227:13 portray 331:12 posed 359:13 position 24:12 112:2 positive 41:18 possibility 162:12 possible 48:17 51:6 52:17 112:16 170:10 199:20 207:7 271:9 273:17 334:19,20 374:6 390:4 possibly 143:1 206:18 228:11 295:17 342:6 377:1 381:12 391:22 403:13 post 408:3 posted 46:5,8 posts 204:10 post-discharge 98:16 post-op 345:18 346:5 potential 6:22 83:12 86:18 189:5 318:7 338:17 341:13 potentially 77:15 83:11 87:15 89:7 110:9 111:8 114:3
--	--	---	---	--

114:7,12,14,15 115:4,21 116:6 117:1 118:17 120:3 123:7 124:10 127:21 130:20 132:5 135:7 159:14 164:13 188:11 200:20 219:16 227:20,22 234:3 242:14 249:10 259:8 262:12 274:15 289:22 292:9 307:15,16 310:10 331:4 338:7 394:10 397:1 406:12 poverty 29:15 power 28:14 112:18 136:18 powerful 166:5,14 PowerPoint 7:9,18 174:15 practical 282:20 290:19 practice 17:15 28:6 33:20 185:3 196:11 197:12 198:6 315:18 371:7,9 practiced 34:12 practices 12:18 13:17 15:16 16:7 19:5 64:17 65:7 65:13,19 66:3,13 66:17 67:19,20 68:12 70:3 99:3,6 99:12 100:3,10 101:16 111:13 113:9,11 121:5 199:22 261:1,2 349:21 374:11 449:4 453:3 practitioner 345:12 345:15 pragmatic 251:13 253:20	precise 364:5 precisely 96:20 325:21 precludes 361:1 predecessors 183:19 186:10 predict 87:3 preempt 181:16 prefer 120:17 preference 97:16 preferences 56:1 preferred 94:13 pregnant 366:15 366:18 prejudice 97:13 preliminary 84:8 preordained 246:4 prepared 108:8 125:20 197:8,19 198:4 199:21 200:14 435:19 prerogative 130:2 presence 195:12 325:20 present 2:1,19 341:5 386:1 397:14 429:19 presentations 5:15 74:3 343:4 presented 377:16 President 9:11 12:9 12:20 18:16 24:9 presiding 1:22 press 240:2 pressure 67:14 111:3,6 124:7,8 135:1 141:19 167:8 247:22 261:6 presumably 297:5 presupposing 282:14 pretend 234:12 pretending 375:5 pretty 35:6 41:20 48:8 56:9 57:4 81:19 97:13	105:21 148:6 149:1 177:15 244:18 250:3 261:16 282:21 289:2 292:14 313:6 326:9 338:8 339:21 362:9 374:12 430:6 prevalence 54:22 prevent 98:15 100:5 113:12,20 116:10 136:15 140:10 230:22 232:3 239:19 261:2 273:1 312:17 313:4 332:20,21 preventability 78:16 109:1,18 125:7 130:12,13 135:2 141:20 preventable 3:12 4:5,8 57:22 58:13 79:3 80:14,20 82:9 83:19,20 107:14,21 108:6 108:12 110:1,9 111:2,9,11 112:3 112:10 113:1,19 115:16 116:3,6,14 118:16,17,18,18 119:1 120:12,12 120:18 122:1,3 123:8,12,18 124:11,21 125:5 125:15,16 126:11 126:20 127:2,2,6 127:19,21 128:10 128:13 129:1,7,10 129:12 131:19 132:4,5,7,21 133:14 135:4,7,16 136:3 137:3,18,20 138:2 139:17 140:5 141:6,11 142:15 147:6,9 150:1 153:4 165:8	170:20 171:20 172:17 173:4 175:14 176:1 178:15 182:16 184:3 188:4,8,14 188:16 189:2 192:3,4,5,8,20 193:1,4,12,21 194:17 196:1,9,10 196:14,20 197:7 198:3 200:10,12 220:13 255:18 263:13 270:20,21 281:22 282:4 307:4 312:11 425:17,18 prevented 121:7,9 136:9 372:7 prevention 18:10 55:22 56:8 58:12 109:10 128:19 136:18 189:15 preventive 58:5 195:12 previous 188:12 262:7 321:1 previously 10:8 pre-anesthesia 378:3 primarily 377:5 405:9 primary 101:13 104:5 prime 379:9 principle 425:9 principles 426:12 print 120:17 121:22 122:2 130:11,11 131:15 131:17 149:1 prior 28:5 29:2 41:10 77:12 125:8 226:15 330:13 375:22 386:1 397:14 priorities 36:16 51:4 56:16 57:1	57:11 60:2,7 67:5 369:20 371:2,3 prioritize 150:18 priority 134:5 245:10 246:22 412:6 private 27:4,9 38:19 42:16 80:19 101:1 privilege 12:12 13:18 probably 36:13 37:14 44:11 48:14 66:4 109:21 116:1 118:12 120:5 148:10,11 161:10 174:5 195:5,9 202:18 205:16 206:15 222:13 251:18 254:22 257:21 291:9 312:13 345:20 351:9 352:15 359:1 379:6 393:3 393:15 400:8 409:7 414:15 422:7 426:17 428:11 438:18 439:11,15 444:19 448:2 problem 31:8 52:11 80:17 97:17 116:4 130:18 150:7 155:14 169:8 174:2 175:8 175:17 176:3 178:12 230:14 253:11 254:6 290:10 344:6 349:16 352:9 362:6 368:3 378:5 392:11,16 411:9 434:17 problematic 152:19 269:17 416:3 problems 154:4
---	--	--	---	--

226:4 363:10 436:21 procedural 359:4 370:6 procedure 117:11 252:1 358:9 359:2 359:5 362:17 365:9,11,13,19 366:13 367:3 368:18 370:10,11 373:4 374:15 375:20 378:12 379:5,14 380:4,6 380:11 382:11 383:9,10,13 387:7 391:4 404:6,22 405:17 406:20 407:7 409:6 430:16 440:8 procedures 79:18 87:17 185:11 191:17 242:13 358:11 366:1 368:20 369:2 370:8 373:2 374:17 378:16 382:14 384:21 396:19 429:19 proceed 114:16 269:10 361:14 392:13 process 8:13 10:11 10:15,20 12:1,2 35:17 42:12 45:10 45:13 51:15 55:1 62:7,13 65:16 72:2 73:11 78:5 98:12,20 99:19 101:15 106:22 107:4 110:15 127:10 183:6 220:16 224:17 271:18 317:3 318:4 330:6 334:3 334:11 356:19 358:3 359:21 372:12 387:16	390:18,21 391:10 395:18 398:6 402:19 418:17 440:3 443:7 processes 5:16 6:21 63:6 84:18 85:6 86:6 99:12 100:4 101:14 224:12 268:12 360:14 364:19 395:13,15 procession 100:7 process-to-outco... 51:16 process-wise 341:21 produces 27:15 35:16 producing 27:18 178:20 product 24:15 244:16 250:9 291:3 317:19 330:14 410:4,15 410:17 productive 6:10 productivity 24:17 products 35:15 425:22 453:2 professional 18:19 professionals 79:12 professor 26:3 418:2 profile 353:2 profound 417:21 program 17:12 26:13 29:20 37:14 63:17 65:8 66:10 72:7 249:7 448:22 programs 25:14 34:16 66:21 67:1 67:3 69:21 74:22 229:13 451:18 progress 171:6 182:3 218:18 project 5:11 10:21 10:22 11:16,22 22:18 31:12 35:11	38:9 41:2,15 43:22 44:10 49:14 50:2 179:18 223:14 279:6 projects 40:13 41:1 70:16 project's 70:17 promote 48:12 Pronovost 16:15 17:4 proper 180:5,6 217:6 356:16 properly 185:11 properties 52:19 prophylactic 109:7 proponent 250:18 proposal 84:11 131:12 189:17 200:11 propose 167:15 171:1 194:2 206:9 256:6 279:4,4 proposed 75:3 137:2 196:18 220:7 proposing 205:22 266:13 403:12 433:14 protect 254:16 435:16 protection 432:8 prove 372:6 proven 98:15 113:9 113:11 261:3 provide 8:16,18 96:6 161:16 344:19 356:17 provided 73:22 241:17 provider 57:18 93:15,19 268:5 351:20 442:10 providers 18:4 21:8 37:12 48:5 49:4 79:13 161:2 268:7 372:6 442:6 442:21	provides 319:15 providing 357:4 372:11 provocative 102:18 223:20 339:21 408:19 426:6 proxy 43:11 PSO 264:6 PSOs 20:20 69:9 psych 447:18,18 psychiatrist 352:5 psychiatry 351:21 psychological 189:8 211:4 public 5:20 11:1,9 12:2 13:13 23:5 34:14 37:11 41:10 41:13,19 42:16 45:16 68:21 73:4 79:12 80:19 106:9 118:9 127:14 129:4 133:15 146:2 160:20 161:5 174:3 176:5 176:5 192:15 213:7,8,11,13,16 226:18 243:7 244:8 256:15 269:21 275:8 277:8 294:9 314:3 315:20 316:13 317:11 352:10 357:9 364:3 398:10 402:21,22 403:3 publicly 133:15 187:4 256:19 307:20 published 358:10 pull 40:18 45:3 132:10 178:1 202:1 203:15 273:21 288:7 339:16,19,22 356:9 372:21 374:11 420:18 pulled 234:7	336:16 385:16 pulmonary 28:7 399:22 400:6 pump 379:9 pumps 411:16 412:22 punch 136:5 punish 390:22 punt 157:17 purchaser 47:8 298:2 310:20 purchasers 53:6 163:12 166:4 333:2 purchasing 248:16 249:6 purpose 118:4 129:9 146:1 226:12,13 227:2 229:22 248:2 256:14 262:6 272:5 278:19 299:14 308:7 314:2 360:3 378:9 purposely 143:21 purposes 228:15 237:6 239:10 243:11 244:4,9,18 248:3 277:11 289:18 297:4 301:4,6,7 305:6 305:19 307:16 331:8 392:18,19 434:8 purview 248:22 push 249:8 314:13 431:13 pushback 158:6,17 343:6 pushed 155:6,9 put 8:10 42:4 52:3 73:9 131:12 152:16 156:4 160:12 177:3 178:2 179:15 183:7,10 186:18 189:17 197:20
---	---	--	---	---

204:7 225:8 227:5 227:6 228:7 244:3 260:18 265:8 271:14 279:5 281:6 290:22 292:4 300:11 314:11 322:9 334:6 335:15 339:2 344:17 351:2 355:15 361:11,15 362:2,6 362:11,13,15 363:3,5 364:2 367:7 374:5 375:14 378:14 382:4,17 413:14 417:8 423:2,5 435:14 446:21 448:16 puts 112:1 putting 59:21 84:6 97:22 140:13 146:1 192:7 206:17 228:16 313:11 344:13 361:17 371:5 423:10 puzzled 361:4 pyramid 253:20 P.J 18:15 90:16 98:9 116:16 119:10 120:7 148:14 183:6 191:15 193:7 208:9 241:15 243:4 246:13 248:11 264:21 275:10 276:7 285:1 288:3 332:10 349:1 392:7 400:17 401:6 p.m 214:10 215:3,4 216:2 217:3 279:19,20 455:15 455:18	Q	quell 135:13 queries 45:14 query 60:21 question 37:2 48:21 49:5 53:21 88:15,18 91:18,19 98:10 102:19 137:4 143:12 144:10 168:11 172:6 179:15 180:2,16 181:2,15 192:21,22 200:8,8 204:4 211:2 219:5 223:20 226:11 234:16 241:21 249:15 270:6 317:2 335:4,5,9 336:22 337:7 345:10,11 353:19 373:15,16,16 387:8 390:16 391:17 399:17 406:7 411:13 419:11 420:20 422:3,8,11,19 431:15 439:6 445:8 questioning 443:15 questions 3:8 38:8 45:1 62:5,15 85:14,22 88:9 93:8 101:19 146:19 294:18 341:11 359:13 quick 137:11 148:14 159:22 165:5 193:10 201:9 216:4 217:7 279:22 316:5 331:16 359:9 399:17 400:18 quickly 14:15 36:1 150:5 163:4 178:1 178:5,6 188:22 202:20 quite 45:20 58:19 131:22 133:11	174:13 207:21 217:2 261:7 267:20 quote 80:8 126:6 455:10	R	R 5:1 race 54:11 Radford 2:9 28:17 28:18 30:16 31:4 62:19 88:14,21 105:2,3,6 108:20 108:21 114:13 156:21 162:14 169:1,8 202:5,10 280:6,6 394:13 396:3 radiation 366:12 366:21 368:10,20 370:7 421:22 radiograph 390:1 radiologists 366:2 407:19 radiology 358:15 366:20 367:5 370:8 407:11 radiopaque 402:7 402:12 Rain 434:1 raise 12:1 110:18 147:11 180:9 250:16 339:9 376:14 raised 250:22 416:21 raises 380:21 raising 274:18 ramifications 86:13,18 88:3 ramp 451:1 ramping 70:14 ran 363:10 378:3 ranch 271:21 388:9 RAND 16:3 22:19 random 91:7 range 39:16 61:11	186:1 224:1 rape 249:17 rapidly 65:14 70:14 rare 80:6,9 85:2 102:3,11,17,21 103:12,14 164:13 228:1 285:4,15 288:6,9,10,11,13 289:1 290:9 291:8 291:9,20 297:11 297:14,15 323:1 348:8 351:4 409:10 430:6,13 rarely 348:19 rarer 430:14 rate 58:18 188:13 312:17,21 446:14 rates 141:10 150:13,14,15 283:9 rating 58:20 rational 389:3 reach 293:16 429:13 437:10 reaching 308:7 react 208:8 302:11 340:18 350:4 356:22 reacted 319:11 reaction 178:22 357:21 358:1 402:16 405:4 reactions 183:11 312:15 357:18 read 108:10 137:21 148:22 165:5 174:9 197:18 198:1 268:3 326:1 400:19 reading 116:18 242:3 ready 210:8 real 50:5,12 52:11 53:21 95:12 106:13,15 116:12 135:5 233:22
---	----------	--	---	----------	---	--

290:19 294:15 344:4 349:20 352:6,7 376:6,6 378:4,7 384:12 397:2 411:9 421:22 realistic 111:20 reality 138:15 146:15 179:3 242:22 243:18,18 244:6 329:6 418:7 realize 248:22 realized 94:10 realizing 67:21 really 7:17 8:1 9:21 11:22 12:3,14 24:15,19 33:14 36:15 39:9 42:13 42:14,18 45:17 46:10 47:20 48:5 48:9 49:9,18 52:2 52:4 55:15 56:8 56:19,19 60:2 62:14 63:5 64:4 66:16 67:2 69:4 73:18 79:10 80:14 89:15 92:6 94:8 94:17 95:17 96:13 100:18 101:2,5 102:6,16 103:21 109:2 116:19,22 117:15,20 121:6 124:12 127:8 130:11,15 133:7 135:2,19 136:3,5 136:15,17,19 137:7 141:22 143:12 148:13 152:12 154:20 161:3,4,15 162:9 164:15 165:22 173:20 174:20 177:2 179:1,17 182:4 184:12 189:8 196:5,8 204:9,10 206:4,5 208:3 219:6,12	220:16,17 222:16 222:19 228:21 231:19 232:11,21 233:11,19,20 235:20 237:14 238:1 240:4 242:1 242:9,20 247:8 248:17 252:1,15 253:2,4 256:4 258:18 265:15,16 267:22 273:7,12 273:14,14 274:3 274:18 275:1,17 279:1,8 280:22 281:1 283:22 292:7 294:22 296:7,13,16 298:16 300:20 302:16 304:16,22 304:22 314:2 316:13 321:15 322:4 324:8 330:5 333:7 336:21 350:18 351:1 355:2 365:15 369:12 379:12,17 392:12 393:13 397:7 401:16 404:15,17 405:3 409:9 410:22 417:17 418:1,10 418:16 428:10 431:2 435:17 441:9 442:17 446:14 447:13 454:14,14 real-time 302:5,8 reason 13:5 39:9 83:6,7 94:8 118:6 144:19 181:5 251:21 253:20 261:19 262:3 294:10 296:3 298:15 323:15 363:6 367:12 416:21 439:3 449:18 451:19	reasonable 199:5 reasonably 75:1 82:9 196:20 220:13 reasons 10:20 86:8 127:7 133:9 143:13 150:22 151:1 162:11 231:14 324:11 343:12,21 376:8 recall 143:21 recalling 143:18 receive 57:17 received 15:16 27:2 31:18 reception 8:1 reclassified 411:9 recognition 14:2 recognize 14:14 65:12 106:20 223:10 269:16 284:2 290:18 307:22 402:20 453:17 recognizes 131:19 173:5 312:4 recognizing 56:2 73:15 75:16 437:5 recommend 40:3 299:13,18 recommendations 41:9,12 42:1 44:2 212:16 299:8 recommended 346:4 reconcile 94:17 reconciliation 57:21 reconfigure 237:10 reconstruction 410:11 reconvene 104:19 214:10 455:20 reconvening 279:15 record 6:1 104:16 204:1 215:3	279:19 recorded 5:22 438:22 439:1 records 37:19 60:18 69:18 recovery 60:15 392:21 Red 260:18 376:21 redefining 330:1 redefinition 454:16 reduce 113:11 150:12,14 235:2 261:18 262:19 278:12 reduces 160:20 reducing 17:8 24:17 119:18 134:7 196:2 250:19 278:7 reduction 196:12 248:17 277:4 380:18,19 reductionist 107:18 197:12 reductions 109:11 276:19 redundancy 150:7 151:7 155:15,18 redundant 148:9 178:18 redundantly 206:3 reel 271:22 refer 196:19 423:4 reference 219:22 227:14 335:8 referenced 13:4 references 227:16 referred 114:19 referring 121:21 121:22 204:18 207:14 refers 4:14 82:8 157:4 158:20 159:3,4 212:13 refine 418:10 reflect 85:9 102:1 171:13 204:2	reflecting 96:4 99:2 274:4 reflection 296:5 reflective 66:22 reflects 382:18 refocus 273:16 refresh 79:7 regard 223:6 252:6 regarding 3:12,14 3:16,18,20 4:3,5,7 4:9,13 92:4 148:5 248:13 298:12 regardless 123:4 399:3 regards 5:7 regional 64:7 registered 16:12 regularly 62:11 regulated 346:14 347:18 regulator 146:11 regulatory 28:10 297:21 344:7 rehab 288:11 reimbursable 225:16 reimbursement 7:3 reinflate 361:13 reinforce 139:20 reinvent 415:20,21 Reinvestment 60:15 reiterate 297:10 315:12 rejoin 105:19 relate 218:21 related 73:3 74:6 86:6 87:2,7,17,20 90:11 100:13 204:22 223:18 247:16 318:3 333:5 412:13,13 444:3 450:13 relates 36:6 184:15 relation 25:22 relations 24:10 161:5
---	---	---	---	--

relationship 325:7	remind 131:16	251:13 254:7	283:18 287:19,21	423:2
relationships 19:4	163:7 171:11	256:18 267:2	289:20,21 290:2,3	reporter 253:1
relative 25:12	177:12 178:20	273:18 274:10	293:8,10,12,19	reporters 238:6
245:2	192:16 217:14	276:12 291:2	294:3,3 295:18	408:17
relatively 13:15	336:17 399:6	299:8 301:5 302:3	296:22 297:19,19	reporting 4:21
14:16 68:4 96:6	453:9	310:20,22 311:17	297:20,21,22	10:10 12:17 18:10
102:21 106:2	reminded 214:4	315:14 324:1,7	298:1 299:18	33:1 37:11 53:13
117:19 178:4	reminds 127:8	332:16 351:5	300:2,11,14,19,21	69:7,11 73:4,17
179:6 221:6	removal 386:3	354:8,15 355:7,11	300:22 301:19	74:5 79:16 80:8
223:11 323:1	397:15	355:12,12 367:22	303:9,13,18 304:1	85:3 118:9 126:16
404:5 411:15	remove 130:16	372:6 394:16	305:2,3,16,17,19	126:18 129:2
437:20	167:7 180:11	401:14 418:4,22	306:2,21 307:15	153:19 185:4
relatively-common	288:22 299:3	423:3,4,5 442:19	307:17 308:9,11	187:4 223:16
222:2	323:18 373:19,21	reportability	308:13 309:2,6,11	226:18 228:10,11
release 63:19 66:4	399:5,22 449:22	138:15 299:2	310:3,11 311:9,11	236:3,12,13 238:4
437:2	removed 78:3	306:13 310:17	316:15,18,18	238:5,8 241:18
released 61:18	166:13 298:16	328:5 391:2	317:13,14 319:14	243:7 251:19
65:10,19,22	371:18 445:6,13	420:20	322:14 323:2	252:11,14 253:2
relentlessly 278:6	removing 3:16	reportable 1:8 3:9	324:9,12,14,17,21	254:3 256:16,19
relevance 87:7	134:18 137:2	9:5 13:2,22 21:10	325:7,18 326:17	264:6 267:6
relevant 18:11	159:22 160:5	36:22 37:8 63:16	327:5,22,22 328:9	269:21 272:10,22
57:14 60:13,21	166:9 346:9	64:1,18 66:18	328:16 329:18	274:20,20 275:9
129:8 254:2	remuneration	67:12 68:11 70:2	331:1 334:7 338:1	275:16 276:10
393:16	15:17	71:13 72:1,5 74:8	338:9 341:7 347:9	277:1 294:8,8
reliability 52:20	remunerative	76:15 77:1,20	362:22 363:4	298:10,21 299:10
58:16	29:13	78:1,2,12 92:21	365:5 371:11	300:4 305:1
reluctance 344:2	repeat 88:16	98:5 100:10	387:13 388:7	310:13 312:14
rely 106:14 283:8	repeatedly 92:9	102:14 104:3	389:7 391:9	314:3 315:20
413:1 436:2	rephrase 253:7	106:8 107:14	393:21 394:16	316:14 317:9,11
remain 168:4,9,20	433:12	108:5 116:18,20	401:18 409:15	323:3 332:14
remainder 338:21	replacing 326:12	118:7,14 119:6	411:22 415:6	334:15,21 339:5
remaining 59:4	replicable 53:1	127:1 132:19,20	422:9 423:18	339:20 340:5,6
234:13 235:8	replicate 149:18	134:4 144:15,16	428:7 443:17	341:4 344:7
remains 264:6	report 11:4 12:19	146:7,7,8 152:22	reported 79:15	346:17 347:6,7,21
remark 109:15	12:22 13:3,6 52:1	155:11 170:19	117:2 118:20	348:5 349:20
remarkably 41:14	73:2 83:13 98:3	213:5 217:17	121:1 123:7 141:2	350:4 352:16,18
48:5	108:10 125:1,2,4	220:5 222:7	161:1 248:4 263:9	353:2,7 354:2
remedy 392:12	128:5,11 133:16	223:13,22 225:2	271:6 298:3,5,8	393:14 394:22
398:21	133:17 135:4	226:8,14 228:2	299:12,14 306:16	401:9 426:18
remember 11:3,7	138:22 139:10,12	230:7 233:6 234:3	306:22 307:20	442:22
11:11 47:11 83:2	142:10,10,21	234:4,20,22	308:2 332:18	reports 23:9 73:7
116:18 124:6	143:1 165:12	251:12 255:8,12	345:5 347:14,17	74:14 123:9
145:6 233:18	174:18 185:5	255:21 257:10,15	348:8 352:10	214:13 222:9
299:6 314:1	187:3,16 200:17	258:1,2,4,20,22	364:10 393:5	226:15 277:2,10
321:20 328:20	200:21 202:19,22	259:2 263:5	394:18 398:2	339:6 396:12
346:19 352:22	203:1,2 210:6	271:11 274:9	405:15 406:1,2	411:18,20 412:2
356:18 409:3	211:16 237:22	282:11,18 283:7	407:21 409:9	report-collecting

324:2	148:4 160:2,6	retired 157:13	156:16 158:21,22	453:17 455:16
represent 44:5 47:3	168:10 169:14,20	retrospect 107:2	159:13 162:1	rigidity 237:12
representation	180:10 187:21	returning 430:22	165:18 167:10	rigorous 110:12
42:17	193:14,16 201:4,6	revamped 40:4	179:11,21,21	Riley 2:10 22:21,22
representative 18:5	210:21 212:11,18	review 38:14 44:22	184:2 186:17	115:19 158:4
represented 57:6	213:10,18 216:13	63:11 65:18 66:2	190:19,21,21	210:9,15 222:4
138:13	280:16 354:3,9	76:14 77:6,11	198:22 202:9	293:3,21 294:6
representing 19:15	355:19 383:6	81:3,10 114:20	203:8 207:20,21	326:11 327:6,9,15
represents 163:12	403:2 432:4	125:7 143:8 171:2	211:7 213:20	327:17 340:22
request 365:15	454:22	323:4 339:3 341:6	217:8 218:12	342:21 343:14
require 85:3 185:4	responses 240:12	341:21 344:3	226:11,20 228:20	348:3 351:7,16
223:16 315:4	responsibility 27:1	359:12	229:4,10 232:7	369:8 385:12
323:2	95:18	reviewed 84:10	233:4 243:3	388:12 400:3
required 15:10	responsible 398:17	85:5 106:22 107:9	247:13 251:20	402:4 405:13
42:7 123:6 402:20	435:3 437:1	350:10	252:8 257:9,10,13	408:4,6 410:9
requirements	rest 167:11 222:6	reviewing 406:21	257:14,18 269:3	411:6 446:19
394:22	262:15 279:6	406:22	282:9 283:18	449:21
reread 84:12	283:6 289:1 333:1	reviews 38:15 46:7	284:5,11 285:19	rise 314:8 318:16
research 17:5 18:6	370:8 403:18	revise 37:3 122:21	285:22,22 287:11	risk 4:12 20:2
20:13,15 24:4	restart 104:8,13	129:21	290:7 293:21	34:15 55:22 79:16
27:2,3,9 69:12	restate 295:16	revisit 194:5,15	299:22 304:1	93:21 95:12 109:4
313:18,22 314:12	result 71:13 185:18	213:22	305:3,16 307:21	111:22 196:12
333:6 348:12	186:14 190:18,20	revisiting 14:5	309:14,22 311:7	208:4,13,19
394:20	191:18 224:16	448:4	311:19 314:4,18	210:13 212:7
researcher 16:14	248:5 410:14	rework 429:4	317:18,21 320:6	254:2,14 276:3
researchers 348:12	428:18,21 449:15	rewritten 174:21	321:11 326:9	328:3 344:17
reservation 216:22	resulted 186:6	re-admissions 49:2	327:22 329:18	349:14 386:2,3
217:6 455:7	276:19	49:6 57:21	332:10 334:16,20	389:4 396:20,22
resonance 166:1,8	resulting 97:11	rhetorically 253:7	336:1,6 337:20	397:15,16 420:20
resonate 350:18	449:10,17	RHIA 2:21	341:18 343:12,14	420:21 421:4,8
resonated 320:21	results 4:10 53:7	rid 102:13 296:4	346:18 353:9	423:21 424:2,3
resource 50:4,10	149:21 190:5,16	305:11 322:13,15	358:14 362:3,13	425:5,10,12,13
resources 17:16	192:19 207:16	323:14 364:21	363:4 370:10,13	428:14 429:20
26:10 75:13 240:1	208:17 212:5	367:19 378:14,18	373:9,13,17,19,20	431:2,8,20 446:17
328:14 412:3,10	263:14	378:20 381:9,10	373:21 376:21	risks 278:22 281:13
436:1	resumed 104:16	right 33:12 35:17	379:13 380:1	283:15 307:10
respect 239:14	215:4 279:19	43:18 49:6 62:13	381:8 383:14,19	RN 2:5,6,7,8
435:19	retain 253:18	62:22 82:5 86:21	385:22 389:8	road 349:15
respond 44:3,22	retained 116:7	86:21 88:4,7,19	390:21 392:21	robot 27:15
45:13 138:6 185:1	141:12 240:22	92:4 93:1,22 94:2	393:1,9,12,19	robust 41:14 74:12
230:13 239:7	241:3 384:19	101:17 107:2	401:11 420:8,13	76:14 210:5
248:13 326:22	385:5 390:20	108:17 111:11,12	420:13 424:8,10	Rocky 20:18
329:2 380:22	391:11 392:1,3	112:7 113:17	426:15,18 436:7	role 20:4 23:6 28:9
398:16 401:20	400:2	114:22 115:13	438:17 439:21	38:5 43:10 44:9
response 30:13	retaining 136:20	119:19 122:7,7	440:1,3 442:7	99:1 101:10 265:2
34:22 62:17 93:10	retention 383:8	132:10 151:15	445:16,16,17	roles 35:11 63:15
101:20 134:16,18	386:3 397:16	153:2,12,14	448:8 451:9	243:20

roll 193:10 216:4 279:22 374:16 403:12 rolled 64:2 rolling 329:15 rollout 22:17 roof 417:8 room 10:6,18 11:11 73:19 97:2,3 115:14 146:22 156:19 233:11 294:14 336:5 364:9,21 365:8 372:2 375:18 392:21 402:22 451:3,4 root 221:15 root-cause 141:4 221:1 283:4 344:4 344:5 354:10 routine 54:6 139:11 275:11 RTI 22:19 ruins 131:6 Rules 260:18 376:21 run 34:15 35:22 75:13 149:9 155:13 288:11 403:16 RWJ 61:6 Rydrych 2:10 21:1 21:2 110:22 118:2 119:19 133:6 139:4 154:17 159:9 173:19 175:3 177:7 181:6 190:17,21 204:12 207:5 291:7,11 316:6,10 317:6,10 317:18,21 318:9 320:5 327:20 332:3,8 337:8,14 340:11,17 344:22 350:15,20 362:20 368:6,12 370:20 373:10 378:22	379:11,17 382:7 384:14 390:15 391:16 404:8 405:21 408:12,22 409:19,21 413:21 416:1 419:21 420:4 423:15 424:13,17 427:1 428:12 429:5 431:14,19 432:1 434:2 436:11 439:16 440:1 443:4 444:1 445:1 445:5,12 450:12 451:6 454:8 <hr/> S s 5:1 264:21 sad 240:21 439:3 safari 387:8 safe 12:18 64:17 65:7,13,19 66:3 66:13,17 67:19 68:11 70:3 100:3 101:16 371:9 374:11 449:4 453:3 safer 102:16 422:10,20 safety 5:7 12:9 13:17 15:15 16:6 17:6,10,12,16 20:19,22 21:5,13 21:14 24:8,16 25:1,9,20 27:5 31:13 32:20,22 33:4,15,21 36:8 38:6 43:4 50:10 57:13 58:14,16 63:12,16 64:13 65:4 66:10 67:5 68:17 69:7 71:1 72:12 74:17,20 80:17 93:3 122:17 154:1 156:2 176:4 185:11,16 221:18 237:7 238:3	245:18 275:12 276:22 277:18 278:3 281:14 305:7 311:16 378:7 392:19 397:3 422:1 safety-related 64:16 90:6 safety-versus-aut... 91:18 sage 455:10 sages 455:10 sake 42:13 238:4 274:20 294:8 314:7 330:12 saline 382:12 Sally 1:22 2:2 3:4 6:17 8:10 9:18,21 21:2 39:16 62:11 127:4 149:15 210:22 315:9 354:17 453:17 Sally's 148:9 Salon 1:19 satisfaction 50:11 satisfy 254:12 save 244:21,22 saving 352:4 saw 149:5 411:8 sawed 230:22 saying 112:10 114:6 119:5 146:12 150:9 173:3,3 179:2,17 218:8 228:7 260:12 262:8 267:9,15 269:12 271:20 281:10 289:18 303:8 305:18 306:8,10 306:17 309:3,15 310:9 311:3,20 314:19 316:16 317:8,8,14 318:11 321:15 323:22 324:14 327:4,19 363:10 366:10	369:1 379:2 389:15 392:5 393:21 395:8 420:15 422:14 424:2,8 426:7 427:15 428:17 431:19 438:16,17 439:7 443:13,19 448:21 450:15 says 122:2 125:18 131:18 137:16 142:14,20 172:20 177:12,13,17,18 178:9 181:21 196:19 201:19 203:3,4 226:10 253:3 260:19 303:16 340:9 348:4 366:5 373:19 381:15 385:22 387:14 429:17 431:4 440:4 444:17 450:19,19 451:10 453:3 scale 225:9 scalpel 367:4 scan 366:18,19 390:1 scarier 401:16 scary 189:8 schedules 5:9 scheduling 63:22 Scheibe's 143:22 schizophrenic 268:5,7 Schneider 2:11,12 25:3,5,21,22 32:9 100:20 109:20 114:1 116:17 151:4,15 153:13 153:19 158:19 159:6 160:18 181:20 184:9 190:14 195:16,20 197:3 199:19 200:3 207:22	220:3 235:14 253:22 254:20 255:5 256:2 257:3 275:7 304:5,9 305:20,22 309:9 309:17 311:7,21 312:5,6 314:18,22 315:6 330:8,20 369:15 370:15,22 381:14 385:20 386:7 387:19 397:12 406:6 412:12,16 420:19 427:6 446:3 scholarly 27:1 science 156:2 185:16 221:18 231:14 281:14 397:3 sciences 26:7,13 scientific 27:10 52:18 scientifically 261:3 scoot 8:3 scope 38:8 63:7 64:3 76:13 85:22 90:10 116:20 117:15 175:15 220:7 233:19,20 295:22 298:6 330:5 scratch 210:11 screen 149:7 screening 92:5 378:3 screw 267:10 screwed 232:4 screws 386:4 397:17 SEA 27:18 search 398:17 second 58:2 72:10 72:14 74:15 90:4 168:11 219:6 220:2 234:1 262:4 268:18 293:15 320:9 322:12
--	---	--	---	---

349:10 365:13	258:17 291:19	sensitive 87:22	153:14,15 154:8	387:13 388:7
secondary 56:8	334:22 369:10	sent 202:3 275:12	154:10 155:1,7,19	389:7 398:20
section 125:3	384:8 409:3	331:5 413:15	155:22 156:6,12	405:18 413:5
175:21 188:10	seek 68:22 436:12	444:15	156:13,14,18	414:2 416:2,4,12
sections 35:4	seeking 39:6 278:7	sentence 203:3	163:19 166:11	416:17,17,22
sector 27:5,9 42:17	seen 40:2 95:9	367:13 447:2	170:19,20 171:20	417:1,2 418:21
secular 276:18	101:1 244:22	sentiment 367:22	176:2 182:17,19	419:4 423:19
secured 447:17	264:7 348:17	sentinel 18:22	186:5,7,13 192:5	424:6 425:18
security 352:3	353:4 384:18	32:22 208:1,3,21	201:11,12 204:14	426:2,3 428:15,17
377:6,21	402:8,10 447:7	separate 23:5	205:3,11,13 206:2	428:20,22 429:18
see 7:21 13:3 24:22	452:2	66:21 100:13	206:3,3,4,5	438:2 443:1,17
30:20 35:4 39:14	sees 146:3	119:21,21 223:6	207:17 212:4	449:10
49:11 60:3,4	select 273:7	223:17 234:12	213:5 217:17	seriously 206:4,5
63:15 69:13 72:18	selected 96:22 97:1	252:22 315:15	220:5,17,22 221:6	seriousness 259:18
92:10 97:11 98:3	selecting 272:9	316:17 317:12	221:9 222:1,7	297:17 298:9
99:11 108:1,6,11	selection 125:8	318:10,14 350:13	223:21 225:9	serve 16:2 22:9,22
111:2 113:1 114:6	self 253:17	370:9 392:15	226:8,13 228:1,2	26:14 43:11
123:10 126:8	self-defeating 97:8	452:15	230:6 234:4,5,20	395:13
149:13 152:7	self-explanatory	sepsis 411:8	236:5,6,14 241:21	served 10:8 18:5
160:22 162:15	242:17	septic 259:12	242:8,9 246:20	23:6,11 25:18
167:19 169:10	self-inflicted	series 83:18 302:20	253:14 255:8,11	30:4,5
171:3 175:8 193:2	449:17	serious 1:8 3:9,14	255:21 257:9,10	serves 95:16
195:4 198:1 201:2	self-management	4:9 9:4 12:17	257:15 258:4,20	Service 110:5
222:22 224:6	59:10	13:2,22 21:9	258:22 259:1	services 7:20 16:14
226:3,21 230:21	self-mutilator	36:22 37:8 44:14	263:13 265:16	58:6 63:22 70:9
238:22 241:9	450:2	58:19 63:16 64:1	271:4,5,11 274:9	375:2 394:20
248:8 257:11	send 30:19 31:1	64:18 66:18 67:12	278:8 282:5,10,18	serving 43:12
262:21 266:5	245:4 302:10	68:11 70:2 71:13	283:7 285:5,18,21	session 35:7 105:21
267:12,13 271:7	329:10 435:22	71:22 72:5 74:8	286:4,13 287:9,18	275:21
275:10 276:14	Senior 5:6 9:11	76:15,22 77:20,22	287:20 289:20	sessions 74:4
281:2 284:13	12:8 17:11 18:16	78:2,12 79:3	290:2,2,20,21	268:20 341:3
288:5,13 292:1	31:12 33:8	80:15 83:20,21	293:7,17 294:4	set 8:20 12:18
298:3,5 306:8	sense 48:10,13	98:4 102:14 104:3	295:18 296:22	13:21 36:16 37:3
308:19 310:20,21	81:15 94:6 106:11	106:7 107:13,15	298:12,13 300:1	38:11,16 39:19
314:13 325:2	106:18 134:5	108:4 110:12	300:11 301:18,19	41:11,22 47:15
326:8 338:4 342:9	140:22 145:14	111:5 115:16	303:18 305:15	49:10 50:12 52:22
347:21 348:19	147:5 148:7 155:5	116:18,20 118:7	306:2 307:3	54:21 56:10 57:3
366:10 367:11	161:2,16 167:3,20	120:19 121:1	309:10 313:12	61:9,9 72:4 73:8
368:8 369:3 378:5	189:2 194:14	125:15 126:11	317:13 319:14	74:12,19 86:3
385:17 387:5	209:18 247:7	127:1 132:19,20	321:12,18 322:14	99:21 101:14
400:6 403:6	250:11 254:21	132:22 133:2	326:17 327:12,21	123:5 217:6,14
408:20 411:2,20	256:3 266:9	134:4 142:14	327:21 328:16	219:15 234:1
418:5 429:14	308:20 354:7,13	144:14,14,16,17	329:18 331:17,18	268:3,10 293:19
442:13,20 445:9	357:7 388:4 405:8	145:1 146:7 148:9	332:4,7 334:7	318:9 339:20
453:1	406:9 426:15	148:19 149:17	337:9,10,10,14,16	341:22
seeing 47:6 160:3	446:6	151:19,22 152:13	337:22 341:7	sets 5:14 50:8
180:11 212:19	sensibilities 205:16	152:21 153:6,11	347:10 371:11	setting 59:9 71:4

77:3 88:18 93:15 98:17 120:15 209:16 219:18 258:20,21 444:7 444:11 448:15 settings 44:15 57:18 61:10,12 75:3,20 77:8 87:13 89:6,12 95:10,11 96:8 102:15 227:18 229:16 259:17 260:2,5 320:7 355:18 443:14,17 settle 281:1 settled 33:6 settles 177:2 seven 33:11 168:17 208:22 209:1 234:10 414:8 severe 439:4 severity 154:7 225:4 267:19 325:13 sewn 400:1 share 114:18 163:4 shared 20:8 48:13 50:11 59:7 sharing 427:13 SHEA 19:9 shears 386:12 sheath 385:5 386:12 Sheaths 402:3 shift 47:7 53:19 ship 452:19 ships 273:8 SHM 25:16 shock 259:12 shocked 436:15 shooting 351:17 shopping 40:19 short 7:10 34:5 117:19 169:10 332:15 368:7 shorten 126:7 384:11	shortened 383:9 shorter-term 122:19 shortest 195:5 shorthand 291:16 shortly 51:5 short-term 349:12 shot 352:3 shoulder 380:18 show 147:13 156:15 168:7,15 170:3 193:6 194:1 201:2,9 212:9 213:3 217:7,10 showed 267:3 showing 180:14 shown 109:11 shows 86:8 133:17 377:3 shy 11:12 side 14:2 28:10 94:15 99:16 179:9 229:12 230:16 238:14 253:15 311:22 342:9 343:13 361:16 362:2,3,13,16 363:2 366:5,6 370:12,12,13 418:15 sides 127:20 173:16 361:17 sight 141:12 165:11 sign 41:19 192:13 440:5 signed 373:18 significant 9:2 11:15 48:8 56:9 56:20 60:9,16 79:11 151:19,21 153:4,6,10,16,21 154:1,3,8,9 155:1 156:1 206:21 237:21 344:2 397:1 417:13 442:15 significantly 79:17	189:22 signing 443:7 signs 311:16 silicone 382:13 SILLY 241:12 siloed 42:22 51:12 silos 48:7 silver 133:22 similar 75:15 219:11 229:20 240:15 simple 241:11 290:17 303:6 312:14 358:8 simpler 241:9,13 312:3 331:11 simplest 52:3 simplification 266:2 simplify 296:18 simply 253:5,14 255:17 377:8 393:10 sing 88:12 single 239:14 240:15 246:6 247:17 249:19 259:22 260:1 262:20 263:8 265:14,15 283:2,9 332:19 442:22 sister's 151:5 Sisyphean 329:14 Sisyphus 329:15 sit 66:20 235:5 site 43:5 117:4,8 141:13,22 277:4 325:11 358:11 361:19 362:4,11 362:18,18 366:22 368:13 372:1 381:18 sited 239:18 241:1 347:14 sites 48:4 51:7,11 site-specific 51:9 sitting 36:19 70:17	218:7 219:3 430:5 430:7 situation 112:4 375:15 420:11 situations 266:19 360:19,22 443:11 six 57:10,13 74:3 168:17 234:10 264:15 345:5 375:15,15 six-dimensional 303:3 size 55:3 382:17 skills 182:5 skip 50:15 skipped 171:15 308:15 slaps 76:7 slate 218:9 slice 222:15 slide 36:11 57:12 61:5 70:8 75:2 76:12 77:9 78:10 79:1,6 80:13 81:1 82:5 84:5 85:10 85:20 87:6 107:8 107:10,12 108:3 171:10 172:5 174:14,16 175:9 182:7,14 188:12 192:12 196:18 203:16 217:14 241:17 242:5 320:14,17 339:20 340:9 341:21 349:2 350:1,1 354:16 356:11 slides 7:10,18 30:19 57:11 81:12 217:22 320:14 356:10 slight 72:4 150:7 slightly 428:19 slightly-one-mor... 336:13 slippage 395:16 slippery 230:8,11	slips 438:7 slits 451:1,4 slogan 130:7 131:7 slope 230:8 sloppy 144:20 slow 11:18 small 52:13 103:16 137:21 173:19 221:6,22 222:14 245:3 256:9 293:19 307:18 326:12 333:7 338:9 356:19 387:5 388:1 389:21 396:7,21 398:14 399:2 428:17 smaller 256:13,20 286:9 smart 393:13 smarter 413:1 sneak 246:2 Social 377:6,21 society 19:10 22:8 26:18 325:15 398:9 404:3 solely 48:21 solicit 437:16 solution 268:11 solutions 27:16 solve 178:4 448:1 solved 175:17 solving 97:16 130:19 somebody 121:5 130:22 262:18 263:9 273:21 344:16 377:17 397:10 406:16 430:3 434:12 439:2,18,20 440:2 450:7,15 451:2 somebody's 387:9 389:22 someone's 416:14 someplace 238:12 somewhat 396:4
---	---	--	--	--

soon 37:14 50:2 97:13 239:14 302:9 410:3	61:3 so-called 71:20 73:5 251:21	specimen 375:21 375:22 417:7	51:9,20 64:4 77:4 77:14 78:17 79:8	stakeholder 43:12 43:16
sooner 209:21 210:1	space 284:10	specs 383:22 415:12 418:11	83:9,10 85:12,17 85:17 86:20 87:2	stakeholders 39:19 50:13 54:8 308:8
sophisticated 292:11	span 101:5	spectacular 203:22	88:6 98:18 99:17 119:13 164:9	stamped 131:4
sorry 31:5 34:8 39:21 64:20 84:1 152:9 180:13 189:1 228:21 231:9,11 232:21 236:18 287:15 288:17 302:7 358:17 383:3 420:4 424:22 425:13 446:1	sparked 247:16 speak 14:7 17:8 99:1 108:18 175:1 248:14 290:11 442:5	specter 291:2 spectrum 85:1 267:19 290:12,19 308:2 325:9 333:4 395:6	172:19 186:2 187:15 218:21 219:13,18 222:14 223:7,9 226:3 228:8 234:11,13 235:22 236:13 241:19 242:8 247:17 256:10 264:15 265:9,20 269:3 279:2 282:6 283:1 286:3,16 287:14 294:5 301:3,13 303:9,11 304:1 305:17 307:19 310:5 314:20 318:13,17 319:8,9,10 320:6 320:7,9 321:6,17 323:19,19 325:1,3 325:6 327:8 328:6 330:1,12,21,22 332:9 333:15 335:12 337:4,9 338:9 340:9 341:16 342:4,9 350:12 356:10,18 360:1 415:15 418:10 419:1 428:5	Stan 115:18 158:3 209:3 210:7 222:3 235:5 326:10 339:2 340:21 342:11,20 346:11 348:2 354:5 369:6 380:22 381:6 388:10 405:12 410:8 414:20 449:20
sort 20:21 23:4 31:22 33:22 43:2 60:4 63:11 66:5 73:8 75:22 85:21 94:19 100:1 137:15 140:9 141:8 145:10 183:20 187:15 219:20 222:14 224:11 231:20 236:20 257:5 260:16,22 264:8 274:6 319:11 320:1 325:14 332:22 333:5 341:7 343:7 345:21 349:10 350:9,11 363:12 367:21 388:12 411:2 413:2 416:3 421:14 425:9 426:12 427:20 434:5 446:21	speaks 417:5 special 330:9 331:7 specialists 358:13 specialties 382:22 specific 36:5 38:8 41:2 57:19 64:19 70:22 74:8 77:7 90:7 156:7 189:17 223:12 262:13 297:3 333:17 356:10 371:9,9 377:14 381:21 384:16 424:11,13 430:21 451:10	spent 32:17,19 33:11 35:10 296:4 329:4 413:17	269:3 279:2 282:6 283:1 286:3,16 287:14 294:5 301:3,13 303:9,11 304:1 305:17 307:19 310:5 314:20 318:13,17 319:8,9,10 320:6 320:7,9 321:6,17 323:19,19 325:1,3 325:6 327:8 328:6 330:1,12,21,22 332:9 333:15 335:12 337:4,9 338:9 340:9 341:16 342:4,9 350:12 356:10,18 360:1 415:15 418:10 419:1 428:5	Stancel 2:10 22:21 408:4,5
sorts 85:19 112:19 363:22	specifically 17:7 20:15 36:7 37:6 37:10 38:4 57:3 61:8 67:8 136:7 159:4 177:17 211:19 217:19 296:20 300:3 368:17 437:10,16 451:16	sphere 306:5 spin 161:12 spinal 345:9,13 spirit 11:17 223:13 split 13:14 168:16 170:9	320:7,9 321:6,17 323:19,19 325:1,3 325:6 327:8 328:6 330:1,12,21,22 332:9 333:15 335:12 337:4,9 338:9 340:9 341:16 342:4,9 350:12 356:10,18 360:1 415:15 418:10 419:1 428:5	stand 170:16 263:7 standalone 136:4 standard 235:9 333:22 349:4 368:18 380:5 447:8,12
sound 230:5 sounds 256:7 415:9 418:20	specifications 52:22 368:22 384:7 415:18,19	sponges 385:9 402:6	350:12 356:10,18 360:1 415:15 418:10 419:1 428:5	standardized 439:9 standards 10:10 29:8 36:19 37:1,7 39:7,8,11 41:12 42:5,6,8 44:5 47:16
soup 11:13 sources 37:21 53:3	specificity 296:6 415:16 specifics 36:9 142:3 381:21 specified 382:12 specify 375:11 379:7	spot 8:7 227:5,6 339:2	350:12 356:10,18 360:1 415:15 418:10 419:1 428:5	standards-setting 39:3 standard-setting 38:20,21 standpoint 254:4 stands 156:6 167:3 staple 400:5 staplers 385:14 staples 388:2 staring 270:14 start 15:5 36:4 55:9 63:12 68:3 71:12 75:8 99:11 120:2 129:20 145:12 146:18 167:2 246:16,17 247:7 258:17 259:14 263:3,4,6 269:7,9
		spotlight 161:19 sprained 289:22 springtime 33:3 squared 454:18 squeeze 52:4 326:6 SRE 43:21 77:12 77:17 89:5 90:1 141:9 164:16 175:22 177:13 180:1 182:9,10 227:10 248:7 263:12 281:20 286:5 292:14 299:7 306:2 317:17 336:18 338:20,22 339:4 341:17,17,17 359:5 411:5,7 412:17 SREs 38:15 50:22	350:12 356:10,18 360:1 415:15 418:10 419:1 428:5 SSI 230:3 234:8 248:4,5 SSIs 43:8 234:15 stab 351:22 stabbing 352:1 staff 2:13,14,15,16 14:13 34:17 45:8 62:10 161:17 165:12 278:2 429:13 stages 124:17 stake 60:16	

279:21 284:22	243:7 256:15,17	storm 335:6	struggles 238:14	125:13 128:18
334:21,22 337:20	275:18 297:22	straight 388:16	347:5	152:2 195:1
339:3 342:7,22	299:8,19 341:5	strangle 288:14	struggling 49:8	208:11 248:19
358:4 361:16	352:21 353:3	strategies 64:10	242:1,20 379:12	256:1 263:11
397:21 443:16	369:4,11 408:11	86:17 235:2 237:3	390:17 391:17	324:2 341:20
started 8:7 9:19	414:13 426:15	264:6	stuck 272:21	347:12 386:20
16:17 69:10	452:2	stratification 47:22	394:12	406:15
126:18 143:19	state-based 4:21	stratified 47:16	studies 109:11	suggested 147:21
216:17 237:22	73:17 241:18	stratify 54:14 55:4	study 33:20,21	181:7
270:13 302:15	339:5,20 340:4,6	269:20 278:19	393:4	suggesting 153:9
313:5 321:20	341:4 353:2	streamline 214:21	stuff 94:9 151:6	157:17
332:13 336:9	state-of-the-art	Street 1:21	232:19 257:9	suggestion 152:21
starting 68:14	429:22	strength 382:1	265:16 290:1	207:6 453:22
75:17 83:15	status 42:14	strengthen 51:2	305:4 335:15	suggestions 182:22
104:11 241:5	statutes 26:20	streptococcus	353:4 383:17	suicide 438:13
260:15 277:3	stay 53:14 138:2	267:12	384:10 393:11	447:12 449:9,9
280:21 339:14	193:5 202:7	stretches 124:9	413:7 417:10,15	suitable 98:20
starts 192:4 440:10	305:12 432:6	strike 112:4 193:22	417:19 427:21	252:14
state 23:12,16	stays 167:7 292:22	194:13	436:1	suited 244:5
26:10,22 28:2	steeped 151:6	strikes 115:5	stumble 324:22	summarize 340:14
64:7 99:3,6,12	steering 1:9,18	173:13 204:9	stumbling 257:22	340:16
123:5 133:8,20	10:1,9 39:14	241:22	stupid 289:15	summarized 129:4
139:7 140:6,7,22	40:15 41:3,7,7	strive 117:8,9	subgroup 260:21	summary 46:6
154:2 240:17	45:5 46:6 49:16	278:2	350:9	148:18
241:18 255:17	53:11 68:18 90:17	strong 9:7 34:1	subject 152:18	summer 32:10
263:10 269:21	91:3 101:10 129:6	58:15 59:7 115:2	174:20 252:21	supervisor 355:13
276:16 277:6	129:10 322:7	163:16 189:20	323:4 417:5	support 110:5
300:4 350:3	step 171:5 272:12	214:18 247:5	submitters 46:15	161:11 164:6
352:11 365:21	418:13	250:18 357:21	subset 72:2 235:22	225:17 346:3
371:7 372:16	stepped 230:21	437:12	236:1 263:7,16	428:11 437:4
394:4 407:1 408:1	stepping 252:16	stronger 51:3	282:1,2,7 333:8	supposed 236:10
408:1 415:20	steps 45:12 62:13	136:16,17	337:3	236:11 333:19
418:15	366:17	strongest 265:1	subsets 260:14	370:11
stated 149:9 200:10	step-down 440:21	strongly 156:17	substantially	sure 6:3,21 7:2
226:14 419:12	sticking 135:5	180:17,20 189:12	211:21	30:20 33:7 34:8
statement 129:19	sticky 435:17	193:3 246:6 247:8	substitute 195:10	43:18 45:9 46:13
129:19 161:6	stimulate 225:20	324:3 371:8	195:11	47:22 53:14 60:17
162:7 164:4	stir 402:16	struck 93:13 312:7	subsume 114:5	62:12 66:6,12
166:12 173:15	stock 266:5 268:18	structured 221:22	subsumed 72:8	69:4 71:15 74:21
421:13	stomachache 225:6	structures 69:7	successful 139:15	82:13,15 93:4
statements 129:21	stop 81:9,13 108:15	struggle 48:5,14	423:7,9	94:1 101:2 116:5
130:5 228:18	133:3 176:7 212:7	92:2,13 102:5	sucked 388:19	118:3 124:1 130:6
states 73:16 74:4	317:4 401:19	103:2 137:14	suction 393:4	134:13 139:1
118:8 138:14,21	stopped 337:18	209:6 264:12	sudden 348:15	161:3,9 163:14
140:18 166:6	396:15	319:3 397:3	suffered 251:6	170:11 181:2
170:17 175:22	stops 83:3	struggled 93:5	sufficiently 219:5	194:6,16 195:8,17
223:15 226:17	stories 92:10	128:9	suggest 78:2 115:6	195:21 214:6

223:4 228:12,20	358:5,13 373:1	276:10 347:6	319:19 348:20	199:10,16 203:18
241:4 242:4 243:3	381:17 393:19	382:21	426:17 437:18,19	209:7,13,16 272:2
247:5 251:12	404:22 405:6	S-E-S-S-I-O-N	takes 11:16 23:9	272:6,19 273:5
261:7,14 262:1	407:4 409:6	216:1	182:20 221:16	292:18 298:14,20
271:8 275:21	431:16		406:17 440:2	329:17 407:18
294:11 295:13	surprised 57:12	T	talk 7:11 38:6 63:2	434:10 436:8
298:6,11 304:7	198:21	table 7:8 39:13	65:5 73:19 75:4	437:17 438:6,12
308:15 309:18	surrogates 98:13	43:16 132:2	78:7 113:18	440:9,13,16,19
310:8,17,18 312:7	surveillance 417:15	138:14 146:20	130:12 142:3	448:5,20 449:5,7
313:13 317:5	survey 166:3	152:7 156:5	184:2 203:14	451:17 452:3
338:13,15 344:13	SUSAN 2:21	179:15 180:2	258:22 280:19	453:21
355:2 356:15	suspect 347:20	181:8 183:7,10	293:16 302:19	TAP 357:9
358:2 363:2	Swan-Ganz 400:7	203:12 242:4	347:5 373:11	TAPs 38:5 44:9
372:20 380:13,15	swarms 112:18	261:13 287:5	387:1 414:20	45:6 78:15
388:5 389:19	Swiss 397:9	288:2 293:4 322:9	443:16	targeted 336:9
395:12 396:5	sympathetic 266:8	tables 241:20	talked 104:1 133:9	targeting 74:22
398:5 401:4 404:2	synonym 206:2	tackle 108:18 377:2	154:18 225:15	targets 273:7
407:15 411:2	207:18	tagline 138:9	246:7 247:3	task 14:15 29:7
412:5 413:6 430:8	synonymizing	take 24:12 31:15	291:12 328:1	48:8 83:8 91:5
435:1,18 448:11	206:9	40:4 81:2 85:9	336:20 377:14	218:15 329:14
448:13 450:3	synonyms 205:11	89:10 104:9	381:2 423:22	tasks 119:21 223:6
surgeon 23:4 366:5	205:13	106:10 117:14	talking 10:16 11:3	270:7 299:6
393:13 394:11	synthesize 269:12	120:19 121:2	48:15 85:8 97:9	taught 144:10
398:15 399:19	277:17	130:2 134:5	113:14 115:14	Tavern 216:22
400:5	system 16:6 18:17	146:18 151:8	119:4 133:8,12	455:6
surgeons 387:22	26:18 33:1 34:14	156:13 162:18	166:10 191:9	taxi 34:9
388:19 398:8,9	52:15 53:2 56:21	172:3 181:7	205:5 238:2	taxonomies 20:5
surgeries 141:13	58:3,17 60:10	182:12 184:5	252:15 253:19	267:6
142:1 241:1,6	79:16 80:11,18	193:9 207:14	256:7 258:16	taxonomy 20:8
347:14 352:6	103:13 108:9	219:21 223:15	259:21 260:15	252:13 264:1,3
365:21 366:8	125:21 126:2	253:6 266:5	261:5 266:13	379:22
383:2	136:6 195:7	268:18,21 271:10	284:19 297:20	teacher 149:3
surgery 32:16 43:8	200:15,19 221:2	272:7 279:6,12,22	302:15 313:11,13	155:18 174:22
117:4,8 191:19	224:22 225:18,21	291:9 296:11	315:13 317:22	teachers 148:11
239:18 242:18	255:20 268:6	306:14 319:15	320:22 328:11	team 31:13 67:17
277:4 347:11	273:20 277:1,12	332:7 333:20	329:4 345:15	teams 87:18
358:22 361:1,19	332:14 345:12,16	338:19 339:11	351:19 389:21	tease 86:9 237:5
365:7,8,20 369:18	351:1 355:15	342:14 371:13	425:5 440:15,17	264:14
372:1 374:14	382:19	380:8 389:6 391:6	440:20	technical 7:12 16:3
379:3,3,5 386:1	systematically	391:8 397:19	talks 320:18	22:15 28:22 41:4
390:20 397:14,21	138:1	418:13 422:16	Tangalos 2:12	41:5 44:12 75:14
399:20 404:18	systems 20:11,12	453:19	21:21,22 91:2	78:6 81:21 90:14
408:16 409:13	20:17 24:2 27:12	taken 64:5,9 66:15	114:22 115:11	90:19 179:9 284:5
410:11 430:14	48:7 54:17 61:12	75:11 86:21 109:8	129:17 157:11,20	318:5,11 344:19
surgical 43:5	64:8 73:17 80:8	150:12 151:13	172:11,20 173:8	technically 150:6
117:10 191:17	176:4 251:19	220:20 227:12,13	173:11 180:4	technologies 27:6
330:14 356:11	252:11 267:6	228:3 272:10	198:8,12,18 199:4	technology 27:19

39:1 384:5	terminology 167:7	279:17 289:12	354:19 368:16	272:15 289:19
Tejal 2:4 105:11,13	264:1 440:22	337:7 339:16	373:11,20,22	291:15 294:4
105:14 134:20	terms 6:6,9 7:11	403:10 454:14	376:14 377:10	296:15 299:12,13
140:19 168:21	18:1 30:22 44:21	455:4,14,16	380:2,16 385:13	300:19,22 301:3,6
169:15 193:15	45:8 46:18 52:3	thanks 16:21 30:14	390:22 394:21	303:14 311:3,4
201:5 216:15	54:9 58:5 64:10	31:19 62:22 63:1	396:18 399:16	313:9 314:6,14
280:12	64:11 68:4,5 69:5	81:21 84:3 125:9	425:3 428:10	317:12 318:1
telephone 2:4,6,9	76:13 77:7 83:18	theft 374:20 377:7	431:8 441:19	324:4,16 325:16
tell 15:13 42:19	83:22 95:6 107:5	theirs 137:18	446:19	326:3,19 328:1,21
53:9 158:9,14	108:4 110:15	theme 24:6	things 7:21 10:14	329:12 331:10
268:1,8 363:20	112:4 119:13	themes 67:22	23:17 35:17 62:9	333:3 335:20,22
381:20 388:19	124:13 130:8	theoretically	66:8 67:15 73:10	336:17 343:6,9
393:7 408:2 436:3	146:5 153:16	306:22 330:16	80:4 85:19 88:1	346:12,16 348:17
telling 15:7 335:15	160:13 181:12	therapies 313:7	89:7 92:8 93:5,12	369:10 374:6
ten 264:15 341:22	182:9,15 209:6	therapy 345:10,14	95:20 96:3,13	385:2,14,14 388:1
364:20 378:2	228:17,18 237:18	346:13 366:21	98:2 102:8 103:11	388:20 391:2
tend 48:6 228:8	238:2 240:10	368:10,21	107:22 115:21	393:12 394:17
350:16 385:8	256:6,19 261:17	thereabouts 73:21	117:18 119:18	395:14 397:2,22
tension 13:8 140:16	262:11 297:21	thereof 4:12 208:4	122:13,21 123:2	399:7 401:22
162:17	313:22 319:1,5	208:13,19 210:13	123:11 124:6	410:16,20 411:1
tent 191:13	333:6 346:17	212:7 254:3,15	125:22 127:1,11	411:22 412:8
term 71:5,10 82:8	350:17 354:1,10	276:3 278:22	131:13 135:9	413:2 417:21
82:12,14,22 85:13	355:5 359:5 367:1	281:13 283:15	138:16 139:13	418:6 422:10,20
89:10,22 91:14	379:2 383:1	307:10 420:21,22	141:18 143:8	think 7:6 9:1 10:22
94:2,14,18 108:12	387:15 396:2	421:4 423:21	150:11,16,18,21	11:22 12:15 13:9
113:8 114:14	411:14,21 414:15	424:2,3 425:12,14	154:3 158:16	14:4,6,9,11,12,16
124:20 131:18	416:14 439:1	428:15 446:17	160:22 161:4,15	21:11,15 22:7
139:6 142:10	terrible 116:7	thing 15:20 23:13	167:13 177:1	23:13 29:1,8
143:4 144:3 145:8	222:19 268:1	34:9 40:11 49:7	179:1 186:6 189:9	33:14 35:14 36:1
153:17 154:20	terribly 251:6	62:6 89:18 101:9	197:20 198:14	37:3 38:10 43:17
157:2,8,12 160:1	terrific 214:11	102:19 123:16	200:18,20 205:14	43:19 44:13,19
160:5 162:17	280:17 372:10	126:4 135:4 137:6	206:7 220:12,14	47:2,18 48:9,14
165:20,21 168:9	415:13	166:2 198:16	222:10,18 223:1	49:9 50:6,19,20
168:12,19 170:1,8	territory 154:18	209:17 219:21	223:12 224:8,11	51:10,19 52:16
173:4 180:14,18	test 182:4	222:13 223:4	224:18 225:16	53:12 54:1,3,5,8
182:19 185:16	text 175:10 200:16	225:2 227:20	226:9 227:22	55:5,18,21 56:17
186:20 187:20	314:11 315:4	235:8 245:7	228:15 232:10,21	56:18 57:14,15
193:20 217:19	thank 5:8 12:6	246:12 254:1	233:1 236:4,5	60:8,13 61:1,7,15
219:6 235:15	18:13 28:16 31:8	265:6 267:17	238:21 239:5,5	61:16,17 62:1,5
237:6 244:1	62:20 82:3 88:21	269:15 273:14	240:9,12 243:6,16	63:3 64:4,11
249:11 257:22	95:22 104:14	283:2 288:11	244:20 247:10	65:18 66:21 69:3
294:20 295:20	105:6,9,14 125:11	289:4,21 292:18	248:10 255:16	71:10 72:2,3 81:5
297:3 319:11	154:14 181:16	299:1,5 303:17,22	256:14 260:13,17	81:11 83:1,22
326:2 352:14	202:10,11 214:3	309:3 314:11	263:17 265:17	84:13,21 86:11
353:6 354:21	214:11,16,18,22	321:3 325:17	266:9,10,15,17,18	87:4 88:2,4 89:2
355:1 356:2,2	216:10 245:21	327:10 331:11	267:4,22 269:6,20	92:1 93:16 94:4
367:2 413:5 416:2	260:9 275:4,5	337:20 344:11	269:22 270:10	94:18,21 95:5,22

96:3,4,14 97:8	185:15,16 186:4	298:21 299:2,5	411:18,19 412:8	162:7,11,12 184:3
98:1,11 99:4,10	187:11,13 188:7	300:12,18,22	412:17 414:12	187:2 223:18
99:18 100:6,15	188:14 189:20,21	303:2,5 304:10	415:7,17,19 416:2	thoracic 398:9
102:9,18,19,20	190:10,22 191:16	306:12,14,19,21	418:1,3,9,13,18	399:19,20 400:5
103:3,8,9,20,21	192:11 193:20	306:21 307:4,6	421:12 422:8	thorough 65:18
104:8,9 105:18	197:11,14,16	308:3 309:1 311:2	423:11 424:9,21	thought 47:3 102:5
106:13 107:2,22	198:19 200:1,16	315:14 318:15,22	425:3,6 426:6,8	127:18 136:22
108:14,17 109:9	200:19,21 203:15	319:2,6,22 320:5	426:10 428:1	228:4 245:15
109:16,20,21	204:5 207:1,7,21	322:2,3,10 323:6	430:2 431:7 433:6	247:16 251:17
110:3,14 112:8	208:5,10 209:5,8	326:5,13 327:1,20	434:5 435:1,12	252:11 308:20
113:6 114:2 115:4	210:3,16,17	328:12 329:3,7,17	436:8 437:7,9,20	315:13 338:3
115:21 116:4	211:10 212:1	329:21,22 330:11	438:17,20 439:10	354:4 411:21
117:3,4,12,17,21	213:22 220:1,3	331:2,16 332:3,8	439:14,16 440:9	434:3
118:2 119:7,20	222:12,16,20	333:10 334:6,9,13	442:3 443:6 444:9	thoughts 91:7
120:4 121:1,5,16	223:10,19 224:19	334:18 335:1,17	445:5,12 446:10	145:18 333:13
122:11,19 123:11	226:6,20,22 227:8	335:19 336:2,4	446:13 447:13,22	thousands 277:2
123:17 126:4,9,10	227:11 228:3,4,9	337:21 338:2,4,13	448:1,21 449:21	393:5
126:12,13 127:2,5	230:8,13 231:12	339:17 340:1,20	450:5,17 452:12	threads 224:6
127:13 128:1	232:13,22 233:18	342:21 343:3,5	452:14,21 454:15	225:1 226:2
130:4,6,11 131:8	234:6,8,17,19	345:5,9,18 346:1	455:3	three 21:22 33:10
131:13,22 132:3	235:3,4,5 236:1	346:2,7 347:11	thinking 38:4,14	40:7 44:12 59:4
132:22 133:14	237:11,20 238:1,4	348:7 349:4,9,16	42:20 44:16,18	66:20 67:3 70:22
134:1 135:7,8,18	239:13,22 240:10	350:16,20 351:8	48:3 51:8,13	73:20 74:11,18
136:15,17 137:1,3	240:19 242:21	351:11 352:8	54:15 55:9,9	75:3 76:2 91:1
137:7,19 138:2,6	244:9,10 246:12	353:5 354:12	57:16 59:22 61:8	115:2 130:9
139:2,7,18 140:3	246:19 247:1,2,22	355:17 356:1	61:10 85:15 89:3	153:18 168:17
141:7,21,21 143:6	248:9 249:2,3,7	357:16 359:1	89:5 91:16 94:7	170:4 177:16,18
143:7,22 145:4,5	249:12 251:8,19	360:10,13 362:5	99:21 100:22	179:2 234:9
145:9,10,11,13	254:3,11,22 256:5	362:10 363:5,18	101:6 112:17	268:21 276:10
146:4,14,20	256:11 257:3,4	364:12,17,21	118:3 120:2	284:3 325:16,18
147:21,22 148:6	258:5,15 259:4,20	367:6 368:16	122:15 128:6	326:3 342:10
148:10,11 150:6,9	260:2,16 261:19	369:3,19 371:1,12	140:4,5 144:20	344:8 345:3
152:3,20 153:8	263:2 264:10	371:20 372:22	146:3 183:5 211:3	351:15,19 385:17
154:4,12,22	265:2,8,12,17	374:10,12 376:12	219:3,11 233:2	413:17 423:8
155:10,13,21	266:3 267:5,7,16	377:1,9,12 378:4	235:17 236:10,11	three-dimensional
156:3 157:12	268:7,11,14	378:8,22 380:20	236:12 248:18	302:21
158:15,19 159:10	269:15 270:3,10	381:10 384:17,22	252:16 259:20	threshold 423:19
161:4,11,14	271:9 274:2,3,18	385:8,8,10 386:9	271:20 274:8	424:3
162:20 164:14,15	275:15 276:15	388:6 390:15	278:11,15 317:2	thrilled 17:2,13
164:16,21 165:4	278:15,17,22	391:22 394:8,9	337:2 381:13	thromboembolic
165:10 166:18	279:10 281:9,18	395:17,21 396:16	394:14 407:2	347:15
167:6,15,16,21	285:3,5,12,13	397:4 399:12	412:21 432:20	throw 284:12 292:1
171:12 172:22	286:3,6,21 289:1	400:3,21 401:16	439:5 441:1,2	406:10
173:16 174:6	289:7 291:11,13	402:12,15 404:9	448:14	thumb 7:15
175:3 176:10,11	291:16,17 292:8	404:12 405:1	thinks 275:10	Thursday 455:20
178:4,8 181:3,8	293:6 295:11	406:3 408:7,18	third 65:9 72:22	tibia 337:13
181:10,18 183:9	296:5 297:1	409:11,14 410:22	73:15 111:16	ticket 131:4

tie 100:9 250:6	tiresome 111:22	376:14,17 391:8	128:11 232:2	49:18 54:5 55:18
tier 320:9	title 151:8,14	436:22	trigger 354:2	55:21 56:17 69:4
tiered 271:8	152:15 211:18	toxicity 233:8	trip 191:4	75:6 96:6,8 99:7
ties 69:14	284:14	track 6:4 40:13,16	tripping 194:7	100:5 112:5,14
Tighe 2:16 31:1	today 14:13,19,21	62:12 106:15	trivial 149:8,10	114:11 133:7
tight 51:16 63:5	20:12 31:6 36:20	110:16 228:4	150:21 155:8	135:3 154:19
100:21	37:5 38:2,10	238:19 287:6	201:20 203:5	155:21 157:9
tighten 126:6	83:22 95:21 98:8	394:2 412:3,10	204:8,20 205:14	181:16 187:13,16
364:18 436:9	101:22 168:1	tracked 318:2	209:8 231:7	195:22 208:1
tighter 364:19	236:10 239:10	393:6	trivializer 130:21	219:20 224:14
time 5:9 11:8,8	245:5 360:3	tracking 262:17	trouble 198:9	237:14 251:9
13:7,16 14:1	403:20 454:15	394:7	309:7 361:11	254:21 256:3
33:12 50:3 55:13	455:14	tract 234:14	397:5	271:7 273:1
63:2 65:9 73:7,7	tolerance 111:19	traffic 71:9 252:1	true 109:21 209:12	280:19 290:16
74:8 83:10 86:11	364:19	trajectories 56:4	209:15 222:13	296:13,13,18
88:1 96:22 104:10	tomorrow 7:13	trajectory 185:7	237:6 264:15	301:17 302:7
106:13,15 123:13	14:22 15:3 31:5	transcript 46:1,2	345:3 416:7	315:1 320:16
144:8 158:5	214:2 244:7	transcripts 6:1	444:10	354:14 355:3
170:12 184:2	251:18 302:11	transfer 39:2 292:4	truly 80:20 128:22	356:3 363:18
209:16 210:11	338:12,15 403:18	384:5	141:21	377:8,20 381:10
213:17 214:9	427:17 428:9	transition 23:4	trust 436:17	389:2,5 391:21
217:21 226:9	446:18 452:7	93:13 94:2	truth 158:15	405:3 414:1,14
231:21 243:10	453:18	transitioned 414:5	try 15:19 35:5,6	422:20 431:10
250:21 263:8	tomorrow's 78:8	translate 443:20	39:9,10,16 42:14	435:16 451:17
265:14 267:12	ton 244:21,22	translating 452:13	45:2 49:10 61:14	tube 361:12,15
268:19 269:4	tons 393:8	translation 37:16	76:3 85:11 105:21	362:3,11,15,21
273:10 276:15,21	tool 122:16 283:4	transparency 6:6	110:15,20 121:14	364:8
276:21 279:16	333:6	45:18 146:2	130:3 143:16	tubes 417:10
284:1,9 328:19	tools 116:5,13	transparent 45:20	145:7 146:17	Tucson 26:9
329:22 332:15	283:8 284:1	transpire 224:12	161:8 170:10	turn 6:16 9:17
337:1 338:22	top 7:8 49:15 75:9	transplantation	188:22 194:11	35:18 56:16 62:2
343:7 347:2	87:7 161:12	349:15	218:6,19 238:5	62:4 182:20 184:5
379:15 397:8	196:18 246:22	transplanting	239:19 246:18	218:22 285:1
403:15 415:21	253:19 258:19	444:11	265:18 269:8,11	295:6 333:12
416:16 422:11,12	topic 240:1 290:11	trash 233:4	271:13 279:4,8	421:16
441:11 445:14	374:7	trauma 32:17	281:1,2 282:16	turned 8:2 312:17
446:6 453:7	topics 8:21 17:9	111:6 211:6	283:11 287:4	tweak 66:11 107:3
timeline 12:16	65:14 87:14,20	361:10 362:12	294:11,14 299:3	tweaking 220:5
timelines 74:12	119:21 241:2,7	tread 129:20	301:11,15 313:10	twice 39:22 394:5
timely 96:17	352:17	tree 258:17,19	314:14 316:4	427:3
times 22:18 84:13	toss 109:14	tremendously	331:13 338:11	two 13:9 21:20
92:11 112:17	total 137:3 427:14	214:21	363:15 387:9	27:11 29:17 32:13
344:1 377:16	totally 224:8	trend 276:18	399:5 416:3 418:9	36:15 57:11 59:19
383:15 394:7	392:15	trends 221:20	418:11 423:4,5	96:19 99:8 119:15
423:13	touch 260:4	tricky 233:10	trying 6:3 16:5	119:18,20,21
tinker 189:21	touching 251:17	tricyclics 450:8	42:18 43:2 47:5	136:13 154:10
tiny 46:17 450:13	tough 14:10 362:19	tried 51:2 110:5	47:11 48:1,12	162:2 168:17

170:4 189:3	111:7 124:8,9	undefined 71:6	192:19 235:21	47:15 50:4,10
204:10 221:21	135:1 141:19	underappreciated	unintentionally	53:7 60:17 76:3
223:5,17 225:1	167:8 247:22	421:11	383:12 398:1	91:14 108:12
228:15 232:12	261:6	undercurrent	union 10:7	114:2 122:20
233:12 234:9	ultimate 41:8	97:14	unit 447:18,19	131:18 135:21
239:13 241:7	122:16	underlined 172:16	unity 239:1	139:6 144:12
247:17 257:11,17	ultimately 38:13	172:18,21	universal 408:9	146:5 150:8
258:6 260:14	42:4 53:4 55:2	underlying 250:10	universally 324:5	153:21 163:7
261:20,21 262:2	56:2 99:20 126:16	undermine 192:9	universe 209:10,20	172:9 173:4
268:20 270:7	129:6	underneath 90:1	221:3 222:21	174:17 197:22
321:15 329:4	umbrage 342:14	175:14	260:12 273:15	205:22 207:19
331:3 342:12	unambiguous 3:16	underreported	440:10	209:9 217:19
365:5 384:9,13	79:3 80:15 107:15	355:9 356:5	University 18:17	219:16 227:15
385:17 398:12	115:16 120:18	underscore 315:15	26:5,9,22	232:13 244:2,8
400:12 406:11	125:15 126:11	315:22	unknown 128:20	245:15 247:11
423:8 427:9	130:8 133:2 153:4	understand 21:9	unleash 284:1	250:1,9 278:12
437:22	155:3 157:3,4,7	25:20 53:7 83:17	unnecessarily	283:4 291:16
twofold 119:13	158:7,12,20 160:1	126:10,15 155:8	135:17	292:8 299:9 313:6
two-dimensional	160:5 170:21	219:9 224:14	unqualified 3:13	325:1 331:6 353:6
60:4	171:19 176:1	247:5 289:4 306:9	147:8	368:19 374:22
two-level 380:12	182:17 263:14	325:17 354:9,21	unrecognized	383:11 387:3
tying 114:15 442:6	270:20,22 281:22	370:2 428:4,5	441:17	410:17 419:5
Tylenol 450:9	282:5 325:22	447:1	unsterile 410:15	421:19
Tyler 1:22 2:2 3:4	326:2 349:5,9	understanding	untangle 224:6	useful 89:17 98:2
9:20,21 127:5	397:20 398:2	55:20 56:1 118:6	untoward 84:16	126:13 136:20
144:9 149:16	427:20 434:7	180:6 235:16	320:19 322:16,17	143:1 228:5,10
152:1 153:8 191:6	436:9	290:5 295:8	unusual 102:4	278:18 335:11
211:1,6 315:11	unambiguously	402:21 409:14	unwanted 374:21	340:10 341:13
354:18 434:22	148:19	432:19	update 38:14 63:19	343:11,18 344:19
type 29:13 79:16	unanticipated	understood 225:12	77:14,18 78:5	346:7 350:5,11,13
263:22 325:13	304:21 305:2,8	underwent 375:19	157:18 303:7	350:17,17,21
344:11 353:4	311:13 312:4	undesirable 313:15	updated 50:16 64:1	351:3,5,12 352:14
376:4 382:9,16	316:22 325:5	undoing 232:9	65:9 213:4	353:6,14,15,17,18
409:15	326:7,8 327:11	undue 53:18	upstairs 8:4	354:2,6,21,22
typed 400:20	349:7 404:17	unenumerated	uptaken 86:20	356:2 450:4
types 61:20 68:6	unauthorized	268:10	urge 324:3 365:16	usefulness 341:8
79:4 87:8,13	434:16,19	unexpected 406:22	396:4	useless 332:22
109:16 120:3	unavoidable	unfortunate 80:10	urgency 134:2,3	user-friendly
350:12 352:17	191:18	Unfortunately 32:3	138:8,17 139:2,3	418:12
383:2	uncertain 441:9	80:7 264:11 302:4	139:8 160:21	uses 82:22 83:16
typical 174:15	unclear 54:1	uniform 69:6	161:18 162:20	86:18
typing 410:3	uncomfortable	uniformity 408:10	164:8,17 354:13	usual 112:11 114:8
typographically	159:2	unimpeded 361:14	urgent 364:17	usually 75:12 80:19
174:16	uncommon 79:21	unintended 128:9	urinary 234:14	97:2,17 108:12
	85:2 323:1	128:12,14,22	Usability 53:4	120:12 122:2,4
U	uncompensated	149:22 190:3,12	use 20:12 37:21	124:3 129:11
ulcers 67:15 111:3	19:12	191:8,21,22	39:6,7 40:5 41:4	131:18 132:10

135:12,21 137:16 159:1 171:20 172:13,16,21 175:14 176:1,8 184:2 192:3,5 Utah/Colorado 33:21 UTIs 230:3 247:11 U.S 103:13,18	vehicle 361:10 Vehicles 324:18 Venn 255:1 256:6 257:4,16,19 258:16 263:2 265:7 266:17 271:14 281:7 282:2 290:15 301:1 302:21 303:3 329:4,7 338:5 428:2,6 venous 110:6 vent 413:18 venues 86:22 100:17 verb 174:20 206:10 verbiage 142:19 208:2,3 version 82:17 148:17 338:5 444:15 445:19 versus 86:4 91:20 94:5 97:10,10 109:4 121:3 128:10 135:20 162:20 164:1 189:5 190:13 220:16 221:19 222:1 235:1 249:12 265:16 298:12 318:17 352:17 366:8 396:13 426:3 439:3,20 440:1 vets 288:12 Vice 9:11 12:8 18:5 18:16 24:9 Victoroff 2:13 19:14,15 96:16 111:16 130:4 150:4 174:13 175:6,16 176:17 177:9 184:1,6 185:2 189:1,19 195:4 205:9,21 212:22 224:5 230:12 251:16	252:10 266:7 288:5,16 289:14 290:8 323:8,14 326:21 337:12 358:8,16,22 359:7 367:11,20 372:15 373:5,13 374:1,4 374:19 375:4,9 376:15 378:18 379:19 383:11,16 392:10 413:4 416:20 420:7,14 427:12 430:22 433:7,11,16 434:15 435:7 440:4 452:11,18 452:21 view 47:10 48:2 49:11 282:20,21 298:3 310:17 343:21 395:2 viewpoint 48:19 55:16 112:1 vigilant 117:21 violations 260:17 violence 355:8,20 virtual 14:22 virtually 346:15 visceral 178:22 vision 60:2 106:7 322:4 454:1 visits 58:1 vital 177:6 vocabulary 252:12 voice 369:21 voices 14:22 39:16 voluntary 10:10 38:20 348:5 354:16 vomiting 312:21 vote 3:11,14,15,17 3:19 4:2,4,6,9,13 106:10 146:22 147:3 148:5 156:5 156:12 159:22 168:2,3 170:9 404:10	voted 156:19 213:21 voting 42:5 169:19 VP 33:8 VTE 109:10,12	303:5,15,22 304:6 305:9 306:15 308:15,16 310:19 311:17 312:20 313:14,21 316:4 317:22 322:3,5 330:11,17 338:14 339:3 347:19 349:1 357:17 359:12 360:10 362:7 365:10 371:10,18 373:3 374:11,20 376:13 379:6 380:13,17 385:1 386:14 388:10 389:11 390:17,22 392:7 393:22 394:1 395:1,12 400:20 401:4,8 409:17 415:10 416:22 417:19 423:1,2 428:9,13 429:9 435:4 436:16,18 439:12 441:4 wanted 9:10 10:21 31:4 36:3 72:18 82:13 134:14 225:13 233:14 244:21 245:4 248:12 250:16 263:21 284:12 302:18 321:9,21 322:3 330:5 354:19 399:14 423:20 435:13 wants 180:8 295:5 296:2 298:5 324:20 341:15 warning 339:1 wash 431:5 Washington 1:20 1:21 199:11 washrooms 8:8 wasn't 119:1 135:15 143:20 294:22 314:19
V			W	
vaginal 384:20 401:2 402:5 431:3 valid 232:6 validity 52:20 valuable 10:11 103:22 136:20 189:14 415:9 value 50:13 72:6 117:17 238:5,8 246:6 272:16 288:10,17 290:13 319:14 394:7,8 408:11 value-added 415:22 value-based 248:16 249:6 vancomycin 312:15 vanish 150:13 variation 220:16 220:20 240:11 370:3 408:14 442:13 varies 408:1 variety 5:12 24:6 32:18 39:19 72:12 84:20 96:8 230:2 264:18 307:16 313:9 various 37:21 55:20 276:19 278:13 323:3 vary 277:12 vascular 242:11 vast 147:14 vastly 355:8 356:4		walk 377:11 walks 450:22 wander 441:7 want 5:8 6:9,13 7:14 33:5 35:6,22 40:16 42:2 44:18 47:22 49:10 50:20 52:15,17 56:14 57:16 60:3 61:13 62:6 66:12 77:18 81:13 83:13 85:14 92:7 96:11,12 99:7 103:3 106:16 108:13 109:14 115:6 120:5,10 126:9 133:10 138:5,7 139:5 141:18 161:19 165:3,10 181:1 183:8 186:18 187:8 195:17,21 196:8 201:14,17 205:17 206:2,22 207:3 213:22 214:17 223:4 225:8 226:10 227:5,6 236:2,15 236:15 239:18 243:3,16 244:3,14 246:5 256:21,22 257:1,13 261:1,9 266:5 268:17 273:6,9,17,22 274:22 278:21 283:17 284:17 289:17 291:16 294:11,18 297:10 297:18 298:3 299:11 301:10,14 301:14 302:3		

321:7 345:1	wear 103:21 371:6	233:12 271:21	135:19 250:8	210:20 253:11
354:19 365:16	wearing 149:3	279:10 284:14	316:14 330:10	288:1
367:3,4 370:16,17	weave 66:19 67:3	310:8 325:3 388:7	428:12,16 430:19	work 5:11 8:22
380:4	website 40:3,18	402:15 437:12,13	436:11	10:7 12:7,13,16
waste 59:15	45:15 46:5,9	whacking 238:7	wondered 30:18	12:20 13:15 14:10
way 13:12,14 35:17	wedded 82:12	wheel 452:4	123:19 332:12	14:19 20:13 23:11
40:1 41:1 53:1	330:2	wheelchair 416:9,9	Wonderful 16:11	23:16 24:3,7,20
77:2 84:15 99:11	Wednesday 1:13	wheeling 454:1	wondering 144:14	25:15 27:4 33:16
108:17 114:16	wee 395:8	whichever 162:18	144:21 145:1	36:6 38:6,12 41:5
115:22 116:21	week 102:16	241:12	151:11 184:11,14	43:17 45:5,6,13
117:22 132:19	weeks 32:13 53:11	white 109:19	188:2 250:2	46:13 47:14 49:21
134:6 135:9 138:3	73:21 344:8	285:10 287:9,20	420:17	53:22 56:19 58:15
140:12 145:2	351:15,19 391:21	292:8,19 293:11	wonders 141:16	63:13,21 64:3
151:22 155:14	weigh-in 246:5	298:15 301:17	wont 102:12	65:2 67:7 69:3,15
156:2,8 158:4	306:20	302:16 305:14	word 86:21,21 97:1	70:17 72:21 74:14
162:18 163:8	weird 417:19	306:1 310:10	97:3,8,20 112:9	76:17 77:10,12
164:16,22 173:22	welcome 3:2 5:3	311:10 318:18	112:21 113:1	78:22 84:6,10
180:20 182:1	105:4,14,16 163:2	320:11 322:16	127:3,6 130:16	89:19 90:14 93:7
183:3,8 186:12	163:3 216:8 280:5	323:7,9 324:16,17	132:10 135:12,21	96:9 98:7 99:3,6
195:5 205:5	well-coordinated	326:22 327:1,5,12	137:2,20 144:12	102:6 103:10
217:12 218:20	57:18	327:18,20 329:12	144:13 151:19	105:8 110:4
235:17 251:6	well-established	330:22 427:16,16	152:12,17 153:15	116:11,11 127:20
267:9,13 268:4	65:8	wholeheartedly	162:10 164:7,19	132:9 156:9
269:11 270:11	well-intentioned	137:13	166:5,6,13 178:2	161:20 168:1
271:19 275:17,20	95:13	wicket 435:18	189:4,4 190:15	179:3 187:6 197:1
277:16 279:10	well-put 162:21	widely 116:22	196:9 199:5	197:13 208:7
291:17,19 294:1,9	well-taken 138:7	widen 83:12	205:11 214:19	214:6,18 216:17
304:10 305:12	143:7 148:8 156:3	wiggle 115:14	250:1 288:22	216:18 217:17,18
331:9,10 332:13	200:20 210:18	willing 230:5	322:20 324:21	219:22 223:8
354:1 357:19,22	271:10 288:15	358:19 434:20	330:3 339:1 353:6	243:9 244:11,17
363:6 365:19	299:3 303:21	wind 56:7 322:6	353:17 359:1,2	245:5 264:2,5,21
372:16 381:14	322:11	winds 56:7 100:6	381:11 436:12	266:17 271:7,16
392:14 397:4	went 104:16 178:14	Winnipeg 27:13	437:6 449:12	281:3 295:21
398:5,16 400:11	215:3 279:19	32:4	451:13,15	302:8 303:20
415:17 426:9	405:20	winter 27:15	worded 428:19	320:21 327:8
434:7 438:18	weren't 336:18	wireless 30:22	444:4 451:16	330:1 335:13
441:17,20 450:3	342:22 363:2	wisdom 95:15	wording 177:12	340:13 354:22
451:16	397:6 413:16	wise 100:3	182:22 451:10	355:2 403:19
ways 46:21 64:5	west 29:18 441:17	wish 218:9,11	words 84:21 94:1	414:3 415:3
68:9 75:15 96:19	We'll 199:6	272:3 285:2 300:8	96:19 98:6 115:2	418:11 419:19
99:16 139:8	we're 197:14	337:19 392:17	115:20 129:15	449:3 453:9
144:20 181:11	230:10 231:11	withholding 235:17	157:14 195:10	454:15 455:14
218:18 245:14	339:14 366:6	woman 366:16	198:20 254:2	workable 38:11
249:11 281:14	380:19 391:14	417:7,10 441:15	272:7 298:11	workarounds 40:9
313:3 314:16	440:18	won 204:2	398:22	worked 18:21
319:20 332:21	we've 74:12 156:9	wonder 133:10	wordsmithing	312:20 390:18
379:6 401:20	174:12 214:6	134:3 135:6,9,11	106:13 195:1	391:10 414:1

workforce 11:2 355:5,6 356:6	writing 245:1	years 13:19 18:7 19:2 21:7 23:3 24:2,11 28:4,4 32:17,19 33:10,11 34:12 36:15 40:7 47:2 57:2 102:2 139:9 140:8 237:22 240:3,11 241:2,7 334:18 345:5 353:4 363:9 364:14,20 378:2 409:7 415:16 417:18 423:8	1:00 214:10 1:10 215:4 216:2 10 75:11,13 237:22 239:5 240:3,11 241:2,7 279:7 328:20 347:16 10-minute 338:19 339:7,9,10 10:29 104:16 10:30 104:7 10:45 104:8,12,13 10:52 104:17 100 58:4 99:9 123:11,13 328:13 365:22 366:7 412:8 436:18 101 423:13 106 3:9 11 107:11 12 3:4 108:2 131:17 149:13 151:22 157:4 172:5 182:14 12:32 215:3 1201 1:20 13 196:18 198:22 218:4,4 320:17 322:17 14 34:13 147 3:11 15 3:5 106:17 214:8 242:10 279:7 328:20 356:13 403:15 15-minute 104:9 156 3:14 159 3:15 168 3:17,19 18 1:13 180 4:2 19 455:21 192 4:4 1980s 276:11 1992 20:4	431:15 2B 419:22 420:3,6 2C 424:15 429:10 429:10 2's 406:18 2:12 279:19 2:25 279:15 2:31 279:20 20 24:2 34:12 49:15 64:15 75:9 87:7 222:8 235:6 328:21 347:16 365:20,21 366:8 20-odd 410:19 2000 138:12 2001 30:4 143:19 272:13 2002 98:3 128:5 129:18 138:12 142:10,14 143:19 202:19,22 203:1,2 203:2 272:13 281:20 363:21 364:7 439:15 444:20,21 445:20 2003 30:4 2006 142:10,18 163:20 201:15 202:1 203:2 271:12 281:21 445:3,10,18 2009 1:13 64:1 65:10,19 138:12 364:7 430:1 439:11 455:21 201 4:6 2010 65:19 66:3 74:14 2011 11:5 14:12 66:4 74:15 2020 157:17 21 423:13 212 4:9 213 4:13 218 4:19 22 341:4 23 23:3
working 12:4 15:18 17:6 21:7 54:7 59:18 61:19 95:11 110:18 129:18 150:17 171:4 192:10 354:20 426:18	written 116:9 125:14 173:22 186:9,13 397:13 426:9	yell 238:6		
workings 10:13	wrong 40:1 67:14 117:4,8 141:13,22 153:10 231:16 239:17 240:22 252:2 267:3 268:3 277:4 347:13 352:15 353:6 358:11 359:6 361:16,16,19 362:4,11,16,18,18 363:2,14 366:4,18 366:22 368:13,13 368:13 372:1 373:6,22 374:15 378:12 380:8,11 381:16 382:1,1,5 382:10,14 383:2 432:10,16 434:5,7 434:11,13,18 435:9,20 436:13 437:3 441:20	yell 238:6	Z	
workload 426:19	wrongly 225:19	yellow 60:1	zero 110:7 111:18 238:5 278:5 381:13	
works 167:19 171:8,8 287:12,12 429:3	wrongs 434:20	yesterday 128:5	\$	
work-in-progress 303:8	wrong-sited 241:6 347:11 365:7,20 365:21,22 366:8 368:9 383:2	York 28:2,2,18 123:5 280:7 347:8 365:14,19,21 377:22 399:19 407:1 408:13 423:4 426:16	\$40 60:17	
world 17:11 24:11 49:12 71:14 103:16 104:4 138:11 224:12 232:18 272:22 290:19 352:6,7 363:19 401:20 427:17	wrote 20:4	York's 365:4	0	
worms 376:19 377:13 413:22	X		03 63:19 06 63:20	
worry 101:3 120:15 134:22 153:20 320:8 390:10 393:11,14	x-ray 362:1		1	
worse 397:10	x-rays 116:11		1 225:3 331:6 345:20 346:5 349:8 404:3,11 405:16 406:16	
worth 52:4,4 96:4 274:4 389:4	Y		1A 359:5 360:18 1B 372:21,22 373:4 1C 360:19 1E 403:21 1's 405:19 1,000 328:13 1/Class 431:15	
wouldn't 153:14,17 157:15 205:1 286:2 310:4 312:13 330:22 361:18 417:17 420:15 435:4	yay 427:21			
wound 386:16,17	year 10:9 24:12 25:18 29:1 59:19 61:20 65:22 66:5 66:5,6,6 70:11 100:16 234:8 277:5 365:22 366:1 396:13 442:17			
wounds 289:21				
wow 271:20 410:21 411:3				
wrap 74:13				
wrist 76:7				
wrists 451:2,4				
write 165:12				
			2	
			2 402:18 410:4	

24 92:2 407:5 446:9	70 69:9 141:1,14			
24th 1:21	388:13 389:21,22			
27 73:16	391:14			
28 64:4 117:19				
122:21 159:13,15				
163:19				
3	8			
3 203:7	8:59 5:2			
3C 449:9	80 222:9 235:8			
3.0 22:17	326:19 388:14			
30 43:7	800 41:16			
30,000 91:4	85 377:5			
30-day 42:9	88 3:8			
300 277:6 413:7	9			
31 423:13	9 3:4			
32 57:4	9:00 1:19			
33 3:6,7 107:12	90 347:13			
339 4:21	911 365:6,6			
34 347:8	912 365:6,9 366:7			
35 24:11	95 347:13			
4				
4 179:10 180:15				
181:21				
4A 412:17				
4:59 455:18				
40 239:4 242:10				
335:10,11,14,19				
335:22				
400 39:18				
47 394:6 396:13				
48 414:6				
5				
5 3:2,3				
5,000 119:18				
50 426:17 442:16				
550-or-so 64:14				
6				
6 410:19				
6:30 217:2				
60 141:1				
62 3:8				
7				
7:00 455:7,15,15				