

# Laptops and cell phones *Wi-Fi network* User name "guest" Password "NQFguest"



# Improving Diagnostic Accuracy 2016-2017

In-Person Meeting #1

January 10-11, 2017

# Welcome, Introductions, and Overview of Meeting Objectives

## NQF Project Staff

- Helen Burstin, MD, MPH, Chief Scientific Officer
- John Bernot, MD, Senior Director
- Tracy Lustig, DPM, MPH, Senior Director
- Andrew Lyzenga, MPP, Senior Director
- Christy Skipper, MS, Project Manager
- Vanessa Moy, MPH, Project Analyst

# **Disclosures of Interest**

NATIONAL QUALITY FORUM

## **Committee Panel**

- Mark Graber, MD, FACP, Co-Chair
- Missy Danforth, Co-Chair
- Jennifer Campisano, JD
- Michael Dunne, PhD
- Mark Grenache, PhD
- Helen Haskell, MA
- Carlos Higuera-Rueda, MD
- Marilyn Hravnak, RN, PhD, ACNP-BC, FCCM, FAAN
- Mira Irons, MD
- Nicholas Kuzma, MD

- Kathryn McDonald, PhD
- Prashant Mahajan, MD, MPH, MBA
- Lavinia Middleton, MD
- David Newman-Toker, MD, PhD
- Martha Radford, MD
- David Seidenwurm, MD
- Thomas Sequist, MD
- Susan Sheridan, MIM, MBA, DHL
- Hardeep Singh, MD, MPH

## Federal Liaisons (Non-Voting Committee Representatives)

Centers for Medicare & Medicaid Services
 Marsha R. Smith, MD, MPH, FAAP

- Agency for Healthcare Research and Quality
  - Rear Admiral Jeff Brady, MD, MPH
  - Kerm Henriksen, PhD

# **Opening Remarks**

## **Project Objectives**

- Develop a conceptual framework for measuring healthcare organization structures, processes, and outcomes that address the improvement of diagnostic accuracy
- Identify any existing measures or measure concepts consistent with the conceptual framework that could be used to measure baseline status and improvement of healthcare organizational efforts to improve diagnostic accuracy
- Use National Academies of Sciences, Engineering, and Medicine's (NASEM) *Improving Diagnosis in Health Care* report as a guide

## In this Project we will:

- Build on the NASEM report on diagnostic error to identify a measurement framework
- Identify measures in development, testing, and in use
- Identify measure concepts
- Identify significant measure gaps
- Set measurement priorities
- We will not:
  - Develop a new conceptual framework
  - Develop measures
  - Endorse measures

## **Meeting Objectives**

#### Day One:

 Refine and prioritize domains and subdomains of diagnostic accuracy measurement framework

#### Day Two:

- Group discussion on measures, measure concepts, and domains
- Identify gaps in measures and recommendations to address gaps

## **Meeting Ground Rules**

- Acknowledge that you would like to speak by placing your name card in the vertical position
- Always use your microphone for the benefit of remote participants and transcript
- Openly share and respect differing views
- Avoid dominating a discussion and allow others to contribute

Overview & Historical Perspective of the NASEM Diagnostic Accuracy Framework

# Where Failures in the Diagnostic Process Occur

#### - Failure of Engagement

- **┌** Failure in Information Gathering
- Failure in Information Integration
- Failure in Information Interpretation

Failure to Establish an Explanation for the Health Problem Failure to Communicate the Explanation



# **Committee's Conceptual Model**

- Definition of Diagnostic Error
- Overview of the Diagnostic Process
- Work System Factors that Influence the Process
- Outcomes from the Diagnostic Process

# **Definition of Diagnostic Error**

The failure to:

(a) establish an **accurate** and **timely** explanation of the patient's health problem(s)

or

(b) **communicate** that explanation to the patient

# **The Diagnostic Process**



## **The Work System**



# **Diagnostic Team Members**



# **Diagnostic Team Members**



# The Outcomes from the Diagnostic Process



# Where Failures in the Diagnostic Process Occur

#### - Failure of Engagement

- **┌** Failure in Information Gathering
- Failure in Information Integration
- Failure in Information Interpretation

Failure to Establish an Explanation for the Health Problem Failure to Communicate the Explanation



# Excerpts, NAM Chapter 3

...committee's dual focus on improving the diagnostic process and reducing diagnostic errors.

Characterization of diagnostic errors requires understanding (1) which aspects in the diagnostic process are susceptible to failures and

(2) what the contributing factors to these failures are.

The committee used its conceptual model and input from other frameworks to provide a context for the measurement of the causes and risks of diagnostic error. Measurement can focus on diagnostic process steps, the work system components, or both in order to identify causes and risks of diagnostic error.

# TABLE 3-2 Methods for Detecting Failures Across *the Diagnostic Process*

• Where in the Diagnostic Process the Failure Occurred

 $\rightarrow$  Failure to engage in the health care system or in the diagnostic process

#### • Nature of Failure

 $\rightarrow$  Delay in patient presenting  $\rightarrow$  Patient unable to access care

#### • Methods for Detecting Failures

 $\rightarrow$ Analysis of emergency department, urgent care, and other high-risk cohorts  $\rightarrow$ Surveys to determine why and what could be done differently

# TABLE 3-1 Methods for Estimating the Incidence of Diagnostic Errors

#### Data Source

→Medical records

#### Key Features of the Data Source

 $\rightarrow$  Rely on documentation (what was recorded, such as clinical history and interview, physical exam, and diagnostic testing)

#### • Method(s) for Selecting Cases for Review (Denominator)

→Pre-specified criteria (e.g., trigger tool)
→Random sample

#### Method for Determining if Error Occurred (Numerator)

→Implicit review/expert assessment
 →Explicit criteria

# **Related Frameworks**

# THE SAFER DX FRAMEWORK FOR MEASUREMENT AND IMPROVEMENT OF DIAGNOSTIC SAFETY

### HARDEEP SINGH, MD, MPH

HOUSTON VA CENTER FOR INNOVATIONS IN QUALITY, EFFECTIVENESS & SAFETY MICHAEL E. DEBAKEY VA MEDICAL CENTER BAYLOR COLLEGE OF MEDICINE Twitter: @HardeepSinghMD



Baylor College of Medicine

# Why Little Progress in Measurement

- "Basic Science" at the confluence of cognitive science, informatics, human factors, social science, & the 'art' of medicine
- Experts still debating definition of "diagnosis"
   Lack of standards for most "diagnosis" concepts
   Confusion with screening; quality issues
- Operational definitions of diagnostic error harder & especially with evolving diagnosis
   Uncertainty at play; not always black & white

IMPROVING DIAGNOSISIN HEALTH CARE

Comments from frontline "A "diagnosis" is not a static, fixed conclusion; it is a fluid, evolving conclusion based on serial observation and hypothesis building"

"One moves from less certainty to more certainty more or less quickly depending on a number of factors"

docs"Many of the complications introduced by<br/>both medicolegal and quality<br/>improvement efforts come from treating<br/>diagnosis as a black and white situation"

# Safety Begins with Measurement

# Hard to improve if we cannot measure; And....

Harder to measure if we cannot define the problem we are trying to solve!

# **Operational Definition of Diagnostic Error**

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- Case analysis reveals <u>unequivocal evidence</u> of a missed opportunity to make a correct or timely diagnosis (do something different?)
- Missed opportunity is framed within the context of an <u>"evolving" diagnostic process</u>
- The opportunity could be missed by the provider, care team, system, and/or patient

## **Measuring Preventable Harm**



Adapted from Singh Jt Comm J Qual Patient Saf 2014

## Foundation for Rigorous Measurement

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- Few valid and reliable data sources
- Must reflect real-world practice
  - more than just what's in "the doctors head"
  - systems, team members, and patients, all inevitably influence clinicians' thought processes
- Diagnostic performance = individual + system performance so need both provider-centric and system-centric approaches
- Shared accountability beyond clinician/s

Singh BMJQS 2013 Singh & Graber NEJM 2015 Singh & Zwaan Annals of Internal Medicine 2016

## Foundation for Rigorous Measurement

- "Structure"- complex adaptive sociotechnical system - technological and non-technological dimensions
- "Process" diagnosis evolves in distributed dimensions beyond the provider visit
- Outcomes"- safe (correct and timely) diagnosis vs. missed/delayed/wrong/over diagnosis; but should also account for patient and care outcomes

Meyer et al JAMA Intern Med 2013 Singh & Sittig J Gen Intern Med 2014 Singh et al JAMIA 2012 Singh & Graber JAMA 2011

# Safer Dx Measurement Framework

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\* Includes 8 technological and non-technological dimensions

# What Did We Learn After a Decade

- Common diseases missed despite clear evidence to suggest diagnosis (or need to pursue diagnostic evaluation)
- Failure to elicit or act upon key history/exam finding or 'red flags', incl. abnormal results
- □ Poor calibration is key:
  - We struggle between under-diagnosis and overzealous diagnostic pursuits
#### Time Ripe for Retrospective Measurements

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- Signals from administrative data are weaker
  - If validated, could provide clues on possible missed opportunities that warrant additional clinical evaluation
  - Stronger signals to bolster error measurement
    - **Review high-risk cohorts (cancer**  $\sim 1/3$ rd delays)
    - Triggered record reviews (e.g. unexpected hospitalization post PCP/ED visit; missed results)
    - Reports from providers or patients ?

Singh et al Am J Gastro 2009; Singh et al JCO 2010 Singh et al Arch IM 2012 Singh et al BMJQS 2011Singh et al JAMA IM 2012; Singh and Sittig BMJQS 2015; Singh et al Peds 2010

#### Accuracy of the Safer Dx Instrument to Identify Diagnostic Errors in Primary Care

Aymer Al-Mutairi, MD<sup>1,2</sup>, Ashley N. D. Meyer, PhD<sup>1</sup>, Eric J. Thomas, MD, MPH<sup>3,4</sup>, Jason M. Etchegaray, PhD<sup>4,5</sup>, Kevin M. Roy, MD<sup>6</sup>, Maria Caridad Davalos, MD<sup>6</sup>, Shazia Sheikh, MD<sup>7</sup>, and Hardeep Singh, MD, MPH<sup>1</sup>

<sup>1</sup>Houston Veterans Affairs Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Houston, TX, USA; <sup>2</sup>Department of Family & Community Medicine, Baylor College of Medicine, Houston, TX, USA; <sup>3</sup>Department of Internal Medicine, University of Texas Medical School at Houston, Houston, TX, USA; <sup>4</sup>The University of Texas at Houston-Memorial Hermann Center for Healthcare Quality and Safety, Houston, TX, USA; <sup>5</sup>RAND Corporation, Santa Monica, CA, USA; <sup>6</sup>Department of Pediatrics, Section of Critical Care Medicine, Baylor College of Medicine and Texas Children's Hospital, Houston, TX, USA; <sup>7</sup>Department of Medicine, Baylor College of Medicine and Ben Taub Hospital - Harris Health System, Houston, TX, USA.

**IMPORTANCE:** Diagnostic errors are common and harmful, but difficult to define and measure. Measurement of diagnostic errors often depends on retrospective medical record reviews, frequently resulting in reviewer disagreement.

**OBJECTIVES:** We aimed to test the accuracy of an instrument to help detect presence or absence of diagnostic error through record reviews.

**DESIGN:** We gathered questions from several previously used instruments for diagnostic error measurement, then developed and refined our instrument. We tested the accuracy of the instrument against a sample of patient records (n = 389), with and without previously identified diagnostic errors (n = 129 and n = 260, respectively).

RESULTS: The final version of our instrument (titled Safer

**CONCLUSIONS:** The Safer Dx Instrument helps quantify the likelihood of diagnostic error in primary care visits, achieving a high degree of accuracy for measuring their presence or absence. This instrument could be useful to identify high-risk cases for further study and quality improvement.

*KEY WORDS:* diagnostic error; measurement; patient safety; diagnostic safety; primary care; quality improvement.
J Gen Intern Med 31(6):602–8
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#### Approach Diagnostic "Error" as Diagnostic "Safety" ORIGINAL ARTICLE

#### OPEN

#### Measures to Improve Diagnostic Safety in Clinical Practice

Hardeep Singh, MD, MPH, \* Mark L. Graber, MD, †‡§ and Timothy P. Hofer, MD, MSc//¶

**Abstract:** Timely and accurate diagnosis is foundational to good clinical practice and an essential first step to achieving optimal patient outcomes.

infections, and medication errors. The dearth of valid measurement approaches is a major barrier in efforts to study and ultimately improve diagnosis.<sup>9,10</sup>

**TABLE 1.** Candidate Set of Measurement Concepts to Consider for Evaluation of Diagnostic Safety

Measurement Concept	Rationale
Structure	
Web-based decision support tools and online reference materials are available to all providers to aid differential diagnosis.	80% of diagnostic errors in one study had no documented differential diagnosis. <sup>26</sup>
Process	
Proportion of laboratory test results or diagnostic imaging not performed within the expected turnaround time	Delays in diagnostic testing lead to delays in diagnosis and incre chances for iatrogenic injury in the interim. <sup>41</sup>
Outcomes	
Proportion of patients with newly diagnosed colorectal cancer diagnosed within 60 days of first presentation of known red-flags	Nearly a third of patients with colorectal cancer have missed opportunities for an earlier diagnosis. <sup>48,51–53</sup>

To create a foundation for further discussion on evidence for measures for diagnostic safety, 6 questions should be considered:

- What are the appropriate time intervals to diagnose specific conditions of interest that are frequently associated with diagnostic error?
- How can we measure competency in clinical reasoning in realworld practice settings?
- What measurable physician or team behaviors characterize ideal versus suboptimal diagnostic performance?
- What system properties translate into safe diagnostic performance, and how can we measure those?
- How do we leverage information technology, including electronic health records (EHRs), to help measure and improve diagnostic safety?
- How do we leverage patient experiences and reports to measure and improve diagnostic safety?

## "Actionable Measurement"

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- Measurement of diagnostic error ready for QI, learning & research purposes
  - Translate into feedback & learning
- <u>Not</u> ready for public reporting, performance measurement or penalties
- Engage providers, patients & organizations
- Generate evidence to measure diagnostic
   'harm', 'safety', 'reliability', 'uncertainty'

# Lets Only Measure If.... Actionable For Safety

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- For sharp-end outcome measures for missed opportunities, more 'basic science' needed
- For blunt-end measures for system diagnostic performance, need standards and operational definitions (e.g. VA policy on test results)
- Must evaluate measurement burdens and unintended consequences
- □ A "measured" approach (JPS paper; Safer Dx) essential to inform good measures and solutions

Singh, Graber & Hofer Journal of Patient Safety 2016

# Thank you and Acknowledgements

#### □ Funding Agencies:

- **Department of Veterans Affairs**
- Agency for Healthcare Research & Quality
- National Institute of Health
- Multidisciplinary team at VA Health Services **Research Center for Innovation**

Papers: <a href="https://www.researchgate.net/profile/Hardeep\_Singh">https://www.researchgate.net/profile/Hardeep\_Singh</a> Email: <u>Hardeeps@bcm.edu</u> Web: <a href="http://www.houston.hsrd.research.va.gov/bios/singh.asp">http://www.houston.hsrd.research.va.gov/bios/singh.asp</a> Twitter: <u>@HardeepSinghMD</u>

# NQF Measurement Framework Meeting, January, 2017 Unified Conceptual Model for Diagnostic Errors

#### David E. Newman-Toker, MD PhD

Director, Armstrong Institute Center for Diagnostic Excellence Professor of Neurology, Otolaryngology, & Emergency Medicine Johns Hopkins University School of Medicine Johns Hopkins Bloomberg School of Public Health

#### DISCLOSURES

#### I. Grant support

- NIH U01 DC013778-01A1 (NIDCD), 5U01NS080824, (NINDS), U24TR001609-01 (NCATS), AHRQ (pending)
- Siemens/SIDM, Brainscope, Kaiser Permanente
- 2. Research VOG devices loaned by
  - **GN** Otometrics
  - Autronics-Interacoustics
- 3. Founding Board Member SIDM (unpaid)
- 4. 'Diagnosis' career focus (academic COI)

Investigational Use - None

# Diagnostic Errors

NAM Definition of Diagnostic Error

#### **DIAGNOSTIC ERROR is the failure to...**

(a) establish an accurate and timely explanation of the patient's health problem(s) or

(b) communicate that explanation to the patient

# Diagnostic Errors UNIFIED MODEL



Newman-Toker, Diagnosis, 2014



Newman-Toker, Diagnosis, 2014



Newman-Toker, Diagnosis, 2014



# Diagnostic Errors MEASUREMENT MPLICATIONS

## IMPLICATIONS FOR MEASUREMENT

- I. Process defect not required for dx error
- 2. Process defect alone is a 'near miss'
- 3. 'Suboptimal' is similar to 'failed' process
- 4. Overdiagnosis & overtesting may harm
- 5. Harm is a key parameter to measure

Newman-Toker, NQF Measurement Framework

#### BIG DATA FOR NAM-DEFINED DX ERROR & HARMS PROCESS NOT NEEDED TO DEFINE DX ERROR

Look Back Approach: Stroke patients more likely to have been discharged from ED with "benign" dizziness prior ~14 days (N = ~180,000 strokes)



Look Forward Approach: 'Benign' dizziness sent home from ED more likely to return with a stroke within ~30 days, but not heart attack (N = ~30,000 ED dizzy discharges)



# Committee Discussion – Terminology and Definitions

IOM: The failure to: establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient **Graber:** A diagnosis that is wrong, missed, or egregiously delayed, based on retrospective review using a gold standard (Label failure)

DIAGNOSTIC ERROR

Schiff: Any error of ommission or commission during the diagnostic process (Process failure) Singh: A missed opportunity to have made the correct diagnosis based on retrospective review (Process failure)

#### **Terminology and Definitions**

- Diagnostic Error and Diagnostic Accuracy
- Move to a focus on quality?
  - Diagnostic Quality
  - Quality of Diagnosis
  - Quality of the Diagnostic Process
- Do we need to call out "Safety" or rely on IOM definition of quality (and incorporate it into definition)?
  - Safe

Efficient

• Timely

- Effective
- Patient-Centered
   Equitable

## Potential Definitions for Diagnostic Quality

- The degree to which an accurate and timely explanation of a patient's health problems has been (1) established and (2) communicated to the patient.
- The degree to which the healthcare system can be relied upon to establish an accurate and timely explanation of a patient's health problem and to communicate that explanation to the patient.
- The degree to which diagnosis-related systems, processes, and behaviors increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

Definition should also recognize that diagnostic quality can be evaluated across the IOM's six dimensions of quality:

- Safe
- Patient-centered
- Efficient

Effective • Timely

• Equitable

#### Opportunity for Public and Member Comment

# Lunch

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# Review of Proposed Framework for Measuring Diagnostic Quality

#### Proposed Framework for Measurement of Diagnostic Quality

- Purpose:
  - To provide an organizational scheme for identifying and categorizing diagnosis-related measures
  - To facilitate systematic identification of measure gaps
  - To facilitate systematic prioritization of measures and/or measurement areas
  - To serve as a conceptual framework and guidance for future development of diagnosis-related measures

#### Proposed Framework for Measurement of Diagnostic Quality

- Three high-level domains:
  - Structure
    - » Aspects or attributes of the work system in which diagnosis occurs
  - Process
    - » Actions or processes supporting accurate and timely diagnosis
  - Outcome
    - » Outcomes associated with diagnosis or diagnostic performance

Within the structure-process-outcome model, elements of the NASEM framework serve as subdomains

#### **Structure Domain**



#### **Structure Domain**

#### **Subdomains:**

- People ("Diagnostic Team Members" in NASEM report)
- Tasks
- Technologies and Tools
- Organizational Characteristics
- Physical Environment
- External Environment

#### **Process Domain**



#### **Process Domain**

#### **Subdomains**:

- Patient Engagement
- Information Gathering/Diagnostic Evaluation
- Information Interpretation/Hypothesis Generation
- Information Integration/Hypothesis Confirmation & Revision
- Communication of the Diagnosis to the Patient
- Quality Improvement and Learning Activities

#### **Outcome Domain**



#### **Outcome Domain**

#### **Subdomains:**

- Intermediate Outcomes
- Patient/Clinical Outcomes
- Patient Experience
- System Outcomes

# Questions?

## **Environmental Scan**
#### **Environmental Scan Overview**

- To identify measures of diagnostic error and other approaches to assess or monitor the accuracy of diagnosis
- Research Questions:
  - What evidence-based metrics exist for evaluating diagnostic accuracy?
  - What are the current approaches to identifying, learning from, and reducing or avoiding diagnostic errors?
  - What conceptual and measurement gaps exist with respect to diagnostic accuracy?
  - What outcomes might be associated with errors in diagnosis?
  - What are organizations doing to establish a work system that supports the diagnostic process? How are organizations facilitating more effective teamwork and communication among health professionals, patients, and families?

#### **Literature Review**

- Identify existing structure, process, and outcome measures, including those that are in testing, development, or in use to improve diagnostic accuracy
- Information Sources
  - PubMed
  - Grey Literature (i.e., academic or policy literature that is not commercially published)
    - » Government publications (e.g., federal or state agency reports, rules and regulations, etc.)
    - » Reports or publications from foundations, associations, or non-profit groups
    - » Conference papers, abstracts, or proceedings
    - » Key informant interviews
  - Measures Inventory

#### **Measures Inventory**

- AHRQ National Quality Measures Clearinghouse and National Guidelines Clearinghouse
- Health Indicators Warehouse
- CMS Measures Inventory
- NQF Endorsed Measures

#### Keywords

- Diagnostic errors
- Diagnosis errors
- Diagnostic process
- Diagnostic performance
- Diagnostic uncertainty
- Diagnostic accuracy
- Diagnostic safety
- Medical error
- Latent error
- Near misses
- Adverse event
- Misdiagnosis
- Missed diagnosis

- Safety Culture
- Diagnostic failure
- Diagnostic testing
- Diagnostic bias
- Diagnostic delays
- Timely/timeliness

## Results of Environmental Scan: Summary



54 Measures found

See handouts

### Results of Environmental Scan: Structural Measures



Domain

### Results of Environmental Scan: Process Measures



### Results of Environmental Scan: Outcome Measures



### Qualitative Analytics: Measurement Areas



## Qualitative Analytics: Topic Area (Condition/Specialty)



### Committee Discussion – Feedback on Framework and Environmental Scan

#### Questions

#### Framework:

- Does this framework address all aspects of diagnosis that could be subject to measurement?
- Are there elements missing?
- Should any elements be modified or added?
- Will this framework be useful for categorizing and prioritizing measures of diagnostic quality?

- Environmental Scan:
  - Are there any measures that should be included?
  - Are there any measures that should be excluded? Why?

#### Opportunity for Public and Member Comment

## Committee Dinner P.J. Clarke's 1600 K St. NW 6pm – Reservation under NQF

#### Walking Directions from NQF:

Head south on 15th St. NW toward K St.

Turn right onto K St. and the destination is on your left

Walking Directions from Residence Inn:

Head south on 14<sup>th</sup> St. NW toward L St. NW

Turn right onto L St. NW

Turn Left toward K St. NW, turn right onto K St. NW and the destination is on your left

# Adjourn.

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#### Welcome and Day One Recap

January 11, 2017

#### **Meeting Objectives**

Group discussion on measures and domains

 Identity gaps in measures and recommendations to address gaps

#### Brainstorming Exercise – Potential Measures of Diagnostic Quality

#### Groups

#### Group 1

- Mark Graber
- Michael Dunne
- Missy Danforth
- Carlos Higuera-Rueda
- Prashant
  Mahajan
- Martha Radford

#### Group 2

- Helen Haskell
- Marilyn Hravnak
- Lavinia Middleton
- Mira Irons
- Thomas Sequist
- David Newman-Toker

#### Group 3

- Jennifer Campisano
- Mark Grenache
- Nicholas Kuzma
- Kathryn McDonald
- David Seidenwurm
- Hardeep Singh

#### **Discussion Questions**

- What are the most important aspects of diagnosis that should be measured?
- What are things that can be measured now?
- What else is important?

## Review of Breakout Group Discussions

## Lunch

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### Committee Discussion: Revisiting the Framework for Measuring Diagnostic Quality

#### Opportunity for Public and Member Comment

## Break

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#### **Next Steps**

- Web Meeting #2: Post Meeting Follow-up
  January 17, 2017 2-4 PM ET
- 30-Day Comment period on Draft Framework:
  - January 31-March 1, 2017
- Web Meeting #3: Respond and Adjudicate Comments; Revisit Measure Inventory

<sup>D</sup> March 16, 2017 1-3 PM ET