

# Patient Centered Outcomes Research and EHRs

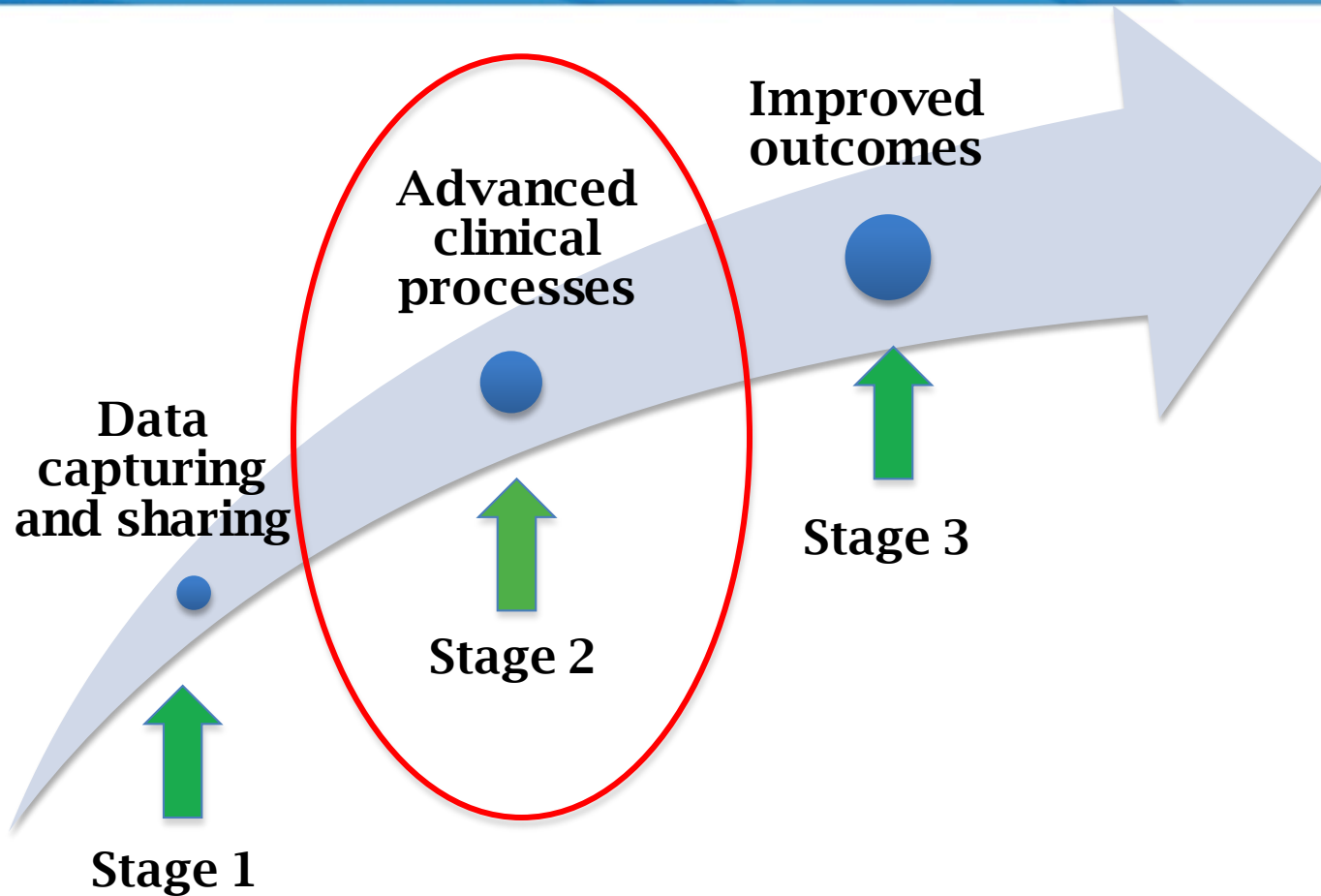
Kevin Larsen MD

Medical Director, Meaningful Use

Office of the National Coordinator of Health IT

November 19, 2013

# Meaningful Use





“I am the expert about me.”

- MU 2 Measures
  - Functional status pre and post hip surgery
  - Functional status pre and post knee surgery
  - Functional status with heart failure over time
  - Functional status with rheumatoid arthritis
  - Depression remission
- Measures in development
  - Change in functional status (delta)
  - Shared care plan goal attainment
  - ADHD outcome





Only those who  
provide care can  
improve care

# Small Data is our Short Term Focus.

Dr. Joe Kimura



- NQF project
- 3 characteristics
  - Meaningful to consumers, built with consumers
  - Care bundles (measures patients through their experience, rather than a single environment or program)
  - Patient Reported Outcomes





current

EHR  
Reporting



# REPORT ONCE- using standards

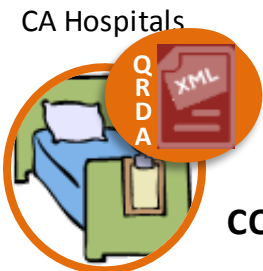
Eligible Providers



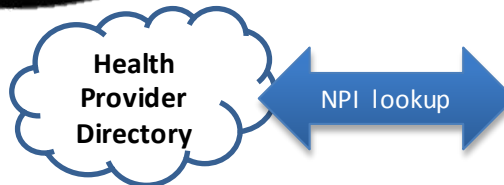
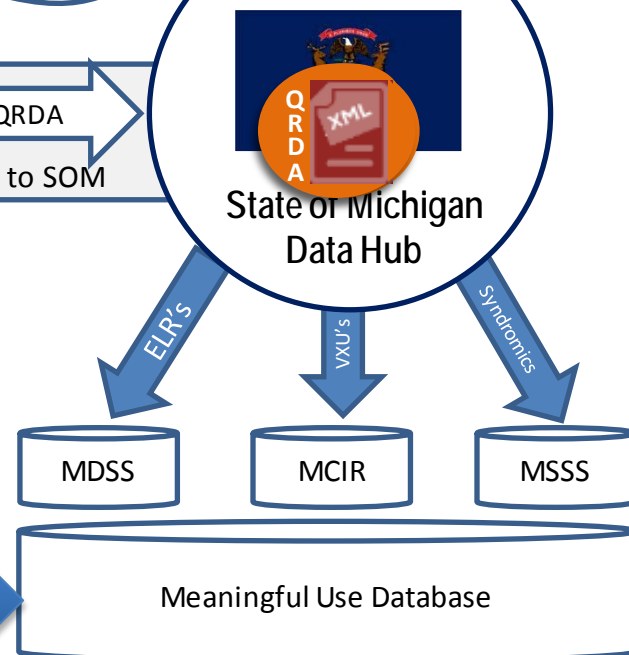
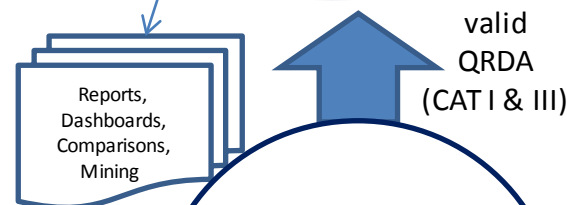
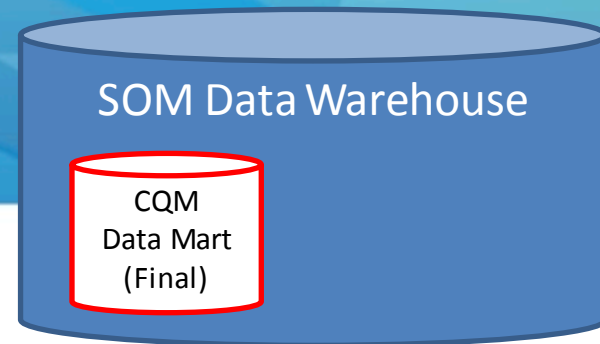
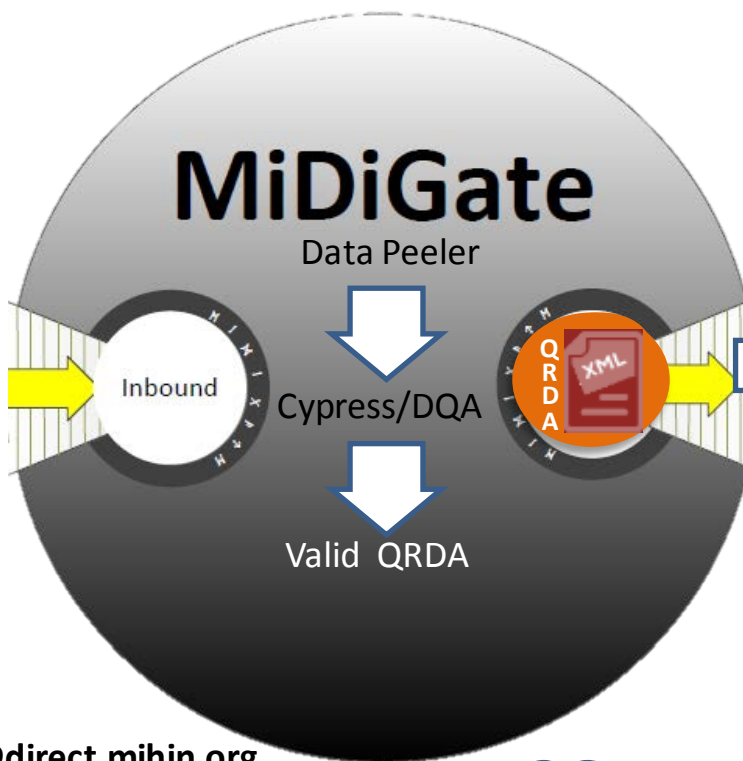
Eligible Hospitals QRDA (CAT I & III)



CA Hospitals QRDA (CAT I & III)



CQMs@direct.mihin.org





# Complex Adaptive System



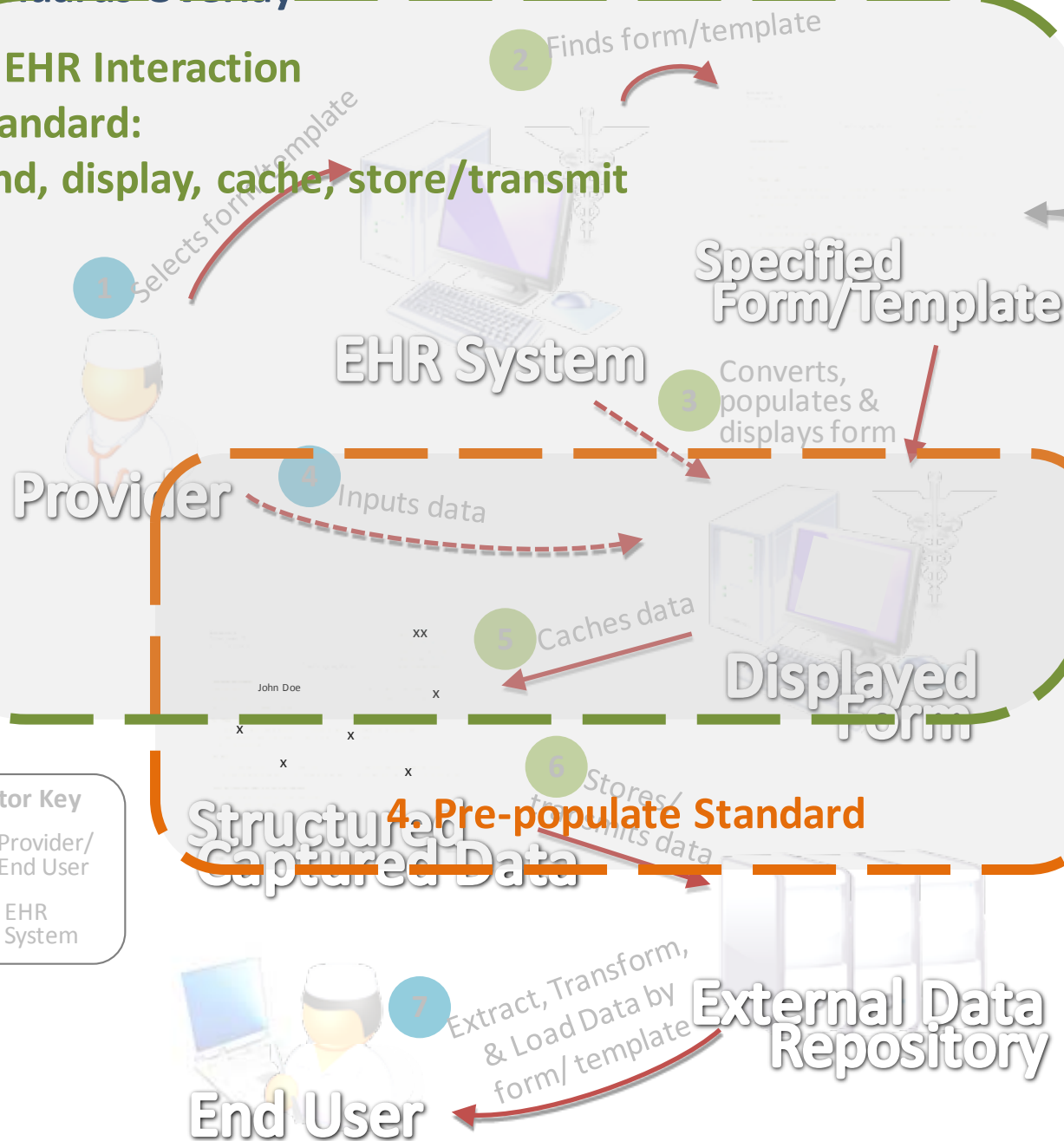
SDC will focus on solving a specific interoperability challenge through the development of **four** new standards that will enable EHRs to capture and store structured data:

1. Standard for the CDEs that will be used to fill the specified templates
2. Standard for the structure or design of the template (container)
3. Standard for how EHRs interact with the template
4. Standard to auto-populate template

# Structured Data Capture Standards Overlay

## 3. EHR Interaction Standard:

Find, display, cache, store/transmit



## CDE Library

### 1. CDE Standard

Clinical Research CDEs

AHRQ CDEs [Common Formats]

Other domain CDEs

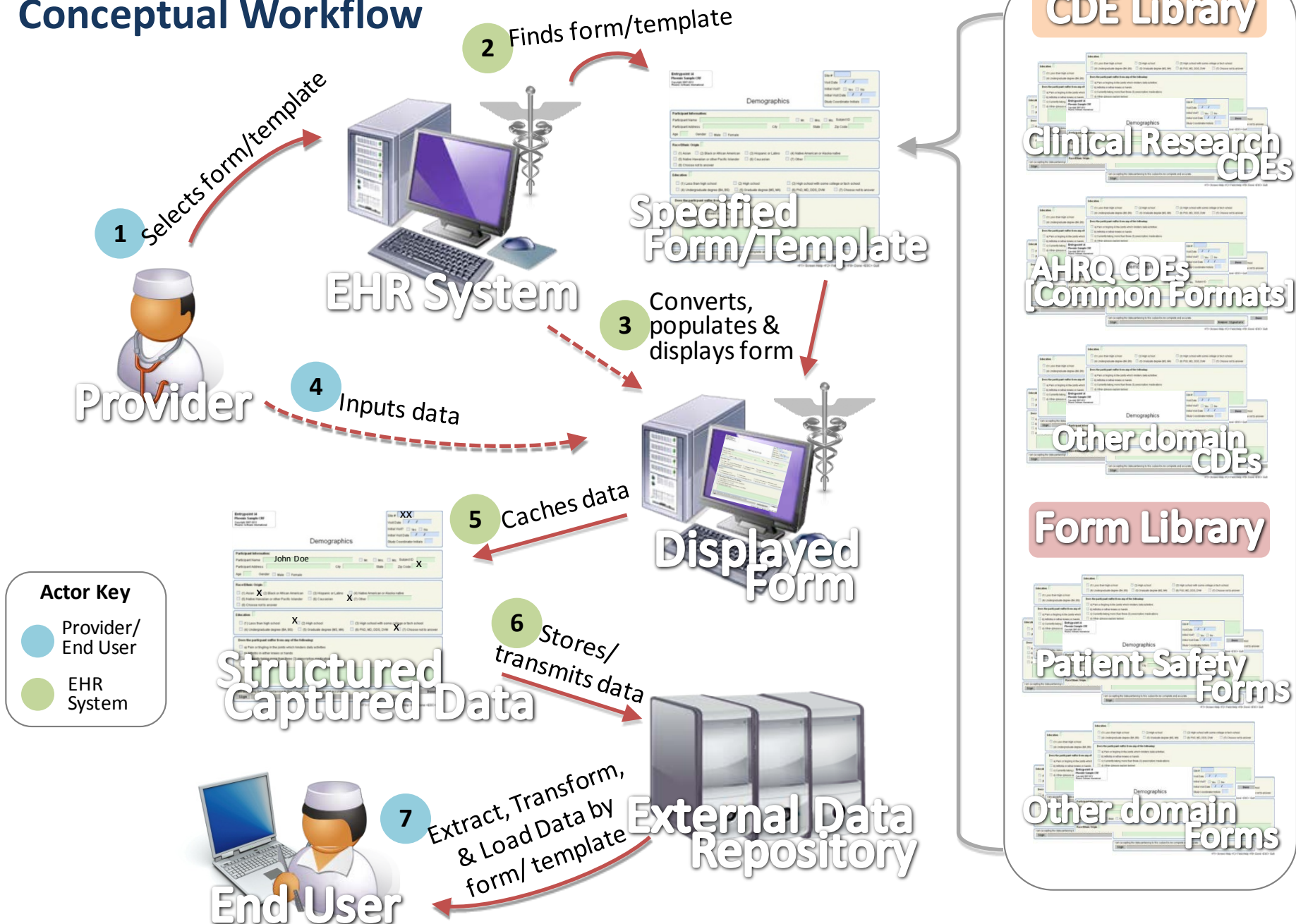
## 2. Structure Form Library Standard

Patient Safety Forms

Other domain Forms



# Structured Data Capture Conceptual Workflow



# Questions?

**Kevin.larsen@hhs.gov**

*For more information about ONC visit: [healthIT.gov](http://healthIT.gov)*

Office of the National  
Coordinator for Health  
Information Technology



**Learn. Act.  
Improve. Spread.**

Accelerating Large-scale Improvement  
in Health Care Quality.

# Patient Reported Outcome Measures in CMS Programs

*Kate Goodrich, MD MHS*

*Director, Quality Measurement and Health Assessment Group*

*Centers for Medicare and Medicaid Services*

# The strategy is to concurrently pursue three aims

## Better Care

Improve overall quality by making health care more patient-centered, reliable, accessible and safe.

## Healthy People / Healthy Communities

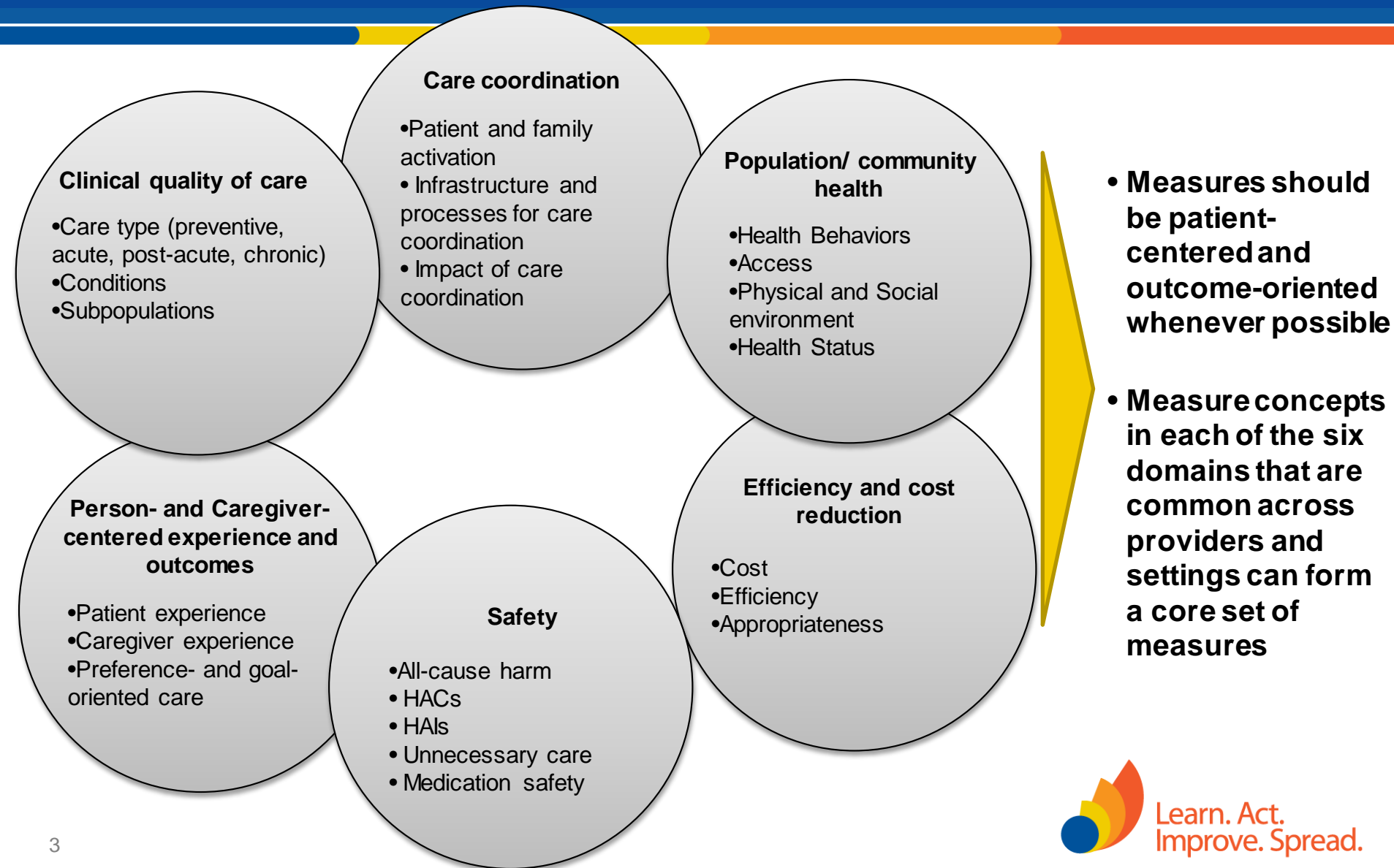
Improve population health by supporting proven interventions to address behavioral, social and environmental determinants of health, in addition to delivering higher-quality care.

## Affordable Care

Reduce the cost of quality health care for individuals, families, employers and government.



# CMS framework for measurement maps to the six National Quality Strategy priorities



# CMS' Vision for Quality Measurement

- Align measures with the National Quality Strategy and Six Measure Domains/Priorities
- Implement measures that fill critical gaps within the 6 domains, particularly patient experience and Patient Reported Outcomes
- Align measures across CMS programs whenever possible
- Parsimonious sets of measures; core sets of measures
- Removal of measures that are no longer appropriate (e.g., topped out)
- Align measures with external stakeholders, including private payers and boards and specialty societies
- Major aim of measurement is improvement over time

# Landscape of Quality Measurement

- **Historically a siloed approach to quality measurement**
  - **Different measures within each quality program**
  - **Different reporting criteria for each quality program**
- **No clear measure development strategy**
- **Typically Disease Specific measures**
- **Confusing and Burdensome to stakeholders**
- **Burdensome to CMS with stovepipe solutions to quality measurement**

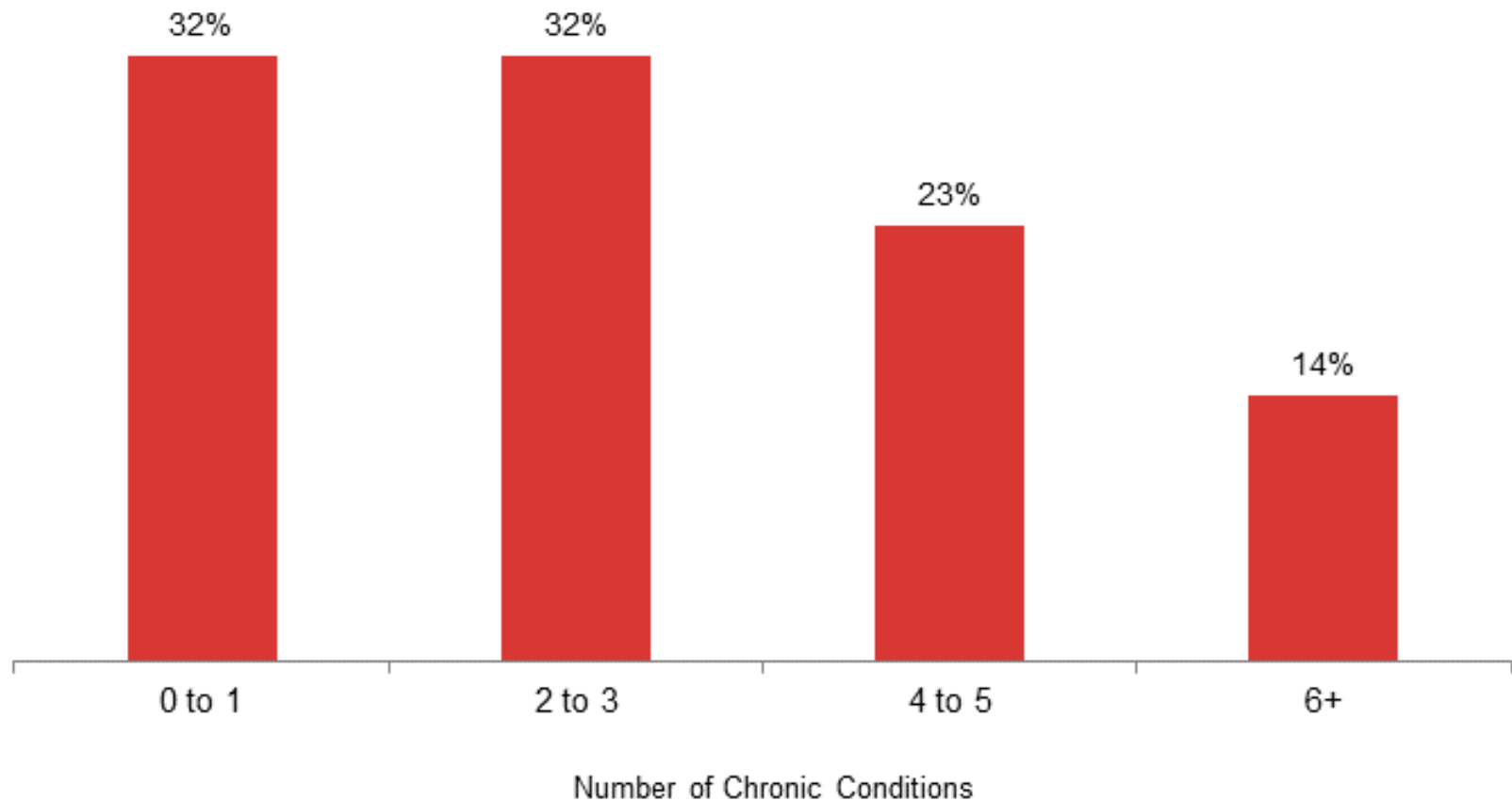
# The Future of Quality Measurement for Improvement and Accountability

- **Meaningful quality measures increasingly need to transition away from setting-specific, narrow snapshots**
- **Reorient and align measures around patient-centered outcomes that span across settings**
- **Measures based on patient-centered episodes of care**
- **Capture measurement at 3 main levels (i.e., individual clinician, group/facility, population/community)**
- **Why do we measure?**
  - **Improvement**

Source: Conway PH, Mostashari F, Clancy C. The Future of Quality Measurement for Improvement and Accountability. JAMA 2013 June 5; Vol 309, No. 21 2215 - 2216



# Percentage of Medicare Beneficiaries with Multiple Chronic Conditions



Source: Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chart book: 2012 Edition Baltimore, MD. 2012.

# Multiple Conditions is the Norm

- 3/4 persons  $\geq 65$  years have multiple conditions
- 1/4 adults  $< 65$  who receive health care have multiple conditions
- 65+ y.o. with  $\geq 2$  conditions  $\rightarrow \sim 80\%$  Medicare costs
- All adults: Majority of health care used by those with  $\geq 2$  conditions

Anderson G (RWJF.org)

- 60% take 5-9 medications
- 20% take 10+ medications



# Most important outcome among older adults with multiple conditions when faced with tradeoff

- Varied in their outcome priority
  - Maintain function: 42%
  - Relief of pain or other symptoms: 32%
  - Keep alive: 27%

Fried TR, Arch Intern Med, 2011; Patient  
Educ Couns, 2010; J Am Geriatr Soc, 2008



# Policy changes that support patient-centered care with MCC

- Replace disease-focused quality metrics with...
- Patient-centered metrics (e.g. ascertain goals, shared decision-making, function, symptoms, appropriate prescribing for health outcome goal)



# Current activities that foster appropriate care for MCC

- Payment and delivery system innovations that foster integration
- **Patient-Reported outcomes (PROs) measure use and development**
- EHRs: care plans and patient-centered outcomes shared across providers for decision making
- A few available quality metrics (e.g. shared decision making)



# Patient Experience of Care Measures

- HCAHPs used for Hospital VBP – weighted at 30% of total score starting in FY 2015
- CG-CAHPS used in the PQRS, ACO and Physician VM programs for groups of 25 or more
  - CMS is exploring expansion of this measure for all clinicians
  - Specialty specific CAHPS? (e.g. S-CAHPS)
- CAHPS measures are in use or in development for every setting of care
  - Post Acute Care (LTCH, IRF, Home Health)
  - In-Center Dialysis
- First caregiver experience measure implemented in the Hospice quality reporting program

# CMS Activities on Patient Reported Outcome Measures

- In 2012, CMS funded the NQF to develop guidance on development of PROMs
- CMS currently uses a number of PROMs in our clinician reporting programs (e.g. depression, functional status)
- CMS and HHS working to identify existing PROMs that can be rapidly incorporated into our quality reporting programs, including the ACO program and CMMI models.
- CMS and ONC are currently developing PROMs for the hospital and outpatient setting
  - Disease-specific functional status
  - General functional status
- CMS now includes patients in all measure development work, in order to understand the outcomes that are most important to patients and families

# Measures Using Patient-Reported Outcomes

Phyllis Torda

November 2013



# Today

**Working on performance measures for assessment of functional status for the following**

- Hip and knee replacement
- Congestive heart failure
- Asthma, rheumatoid arthritis, pain
- **For use in Meaningful Use and other CMS eligible professional programs**



# Complex Chronic Conditions: Heart Failure – Generic Tools

PROM	# of items	Dartmouth-Hitchcock	University of Penn	Cleveland Clinic	Oxford Report¥	Total
PROMIS (global)	10	√	√			2
EQ-5D*	5			√	√	2
SIP	136					0
SF-36*	36				√	1
SF-12*	12				√	0
VR-12	12	√				1

\*Proprietary tools

¥Patient-Reported Outcome Measurement Group, Oxford: A Structured Review of Patient-Reported Outcomes Measures (PROMs) for Heart Failure

# Complex Chronic Conditions: Heart Failure – Generic vs. Condition-Specific Tools

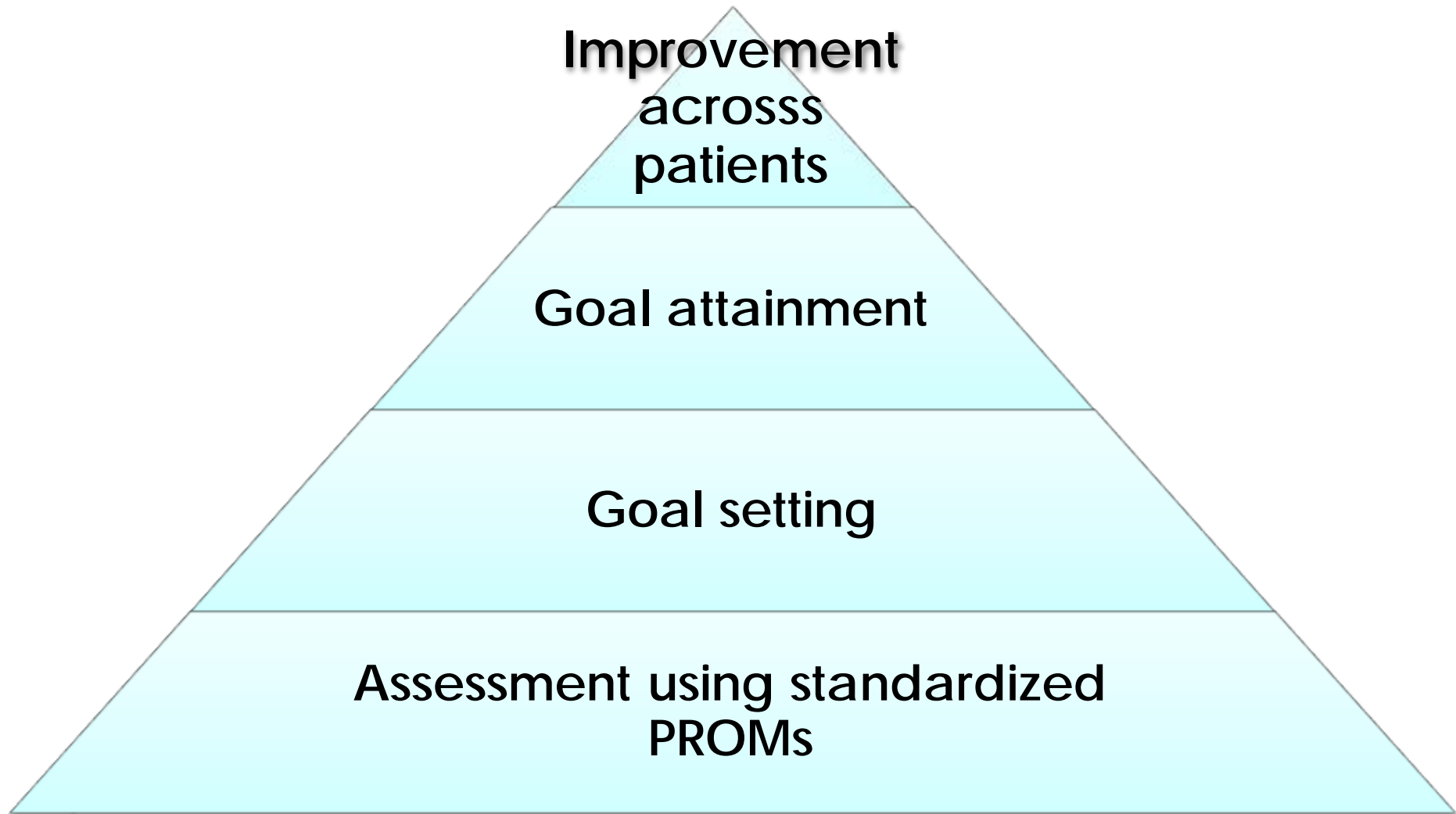
PROM	Dartmouth-Hitchcock	University of Penn	Cleveland Clinic	Total
Generic PROM only		√*		1
Condition-specific PROM only				0
Generic and condition-specific PROM	√		√*	2

\*University of Pennsylvania and Cleveland Clinic are also using the PHQ-9, and Cleveland Clinic is using the GAD-7 for anxiety

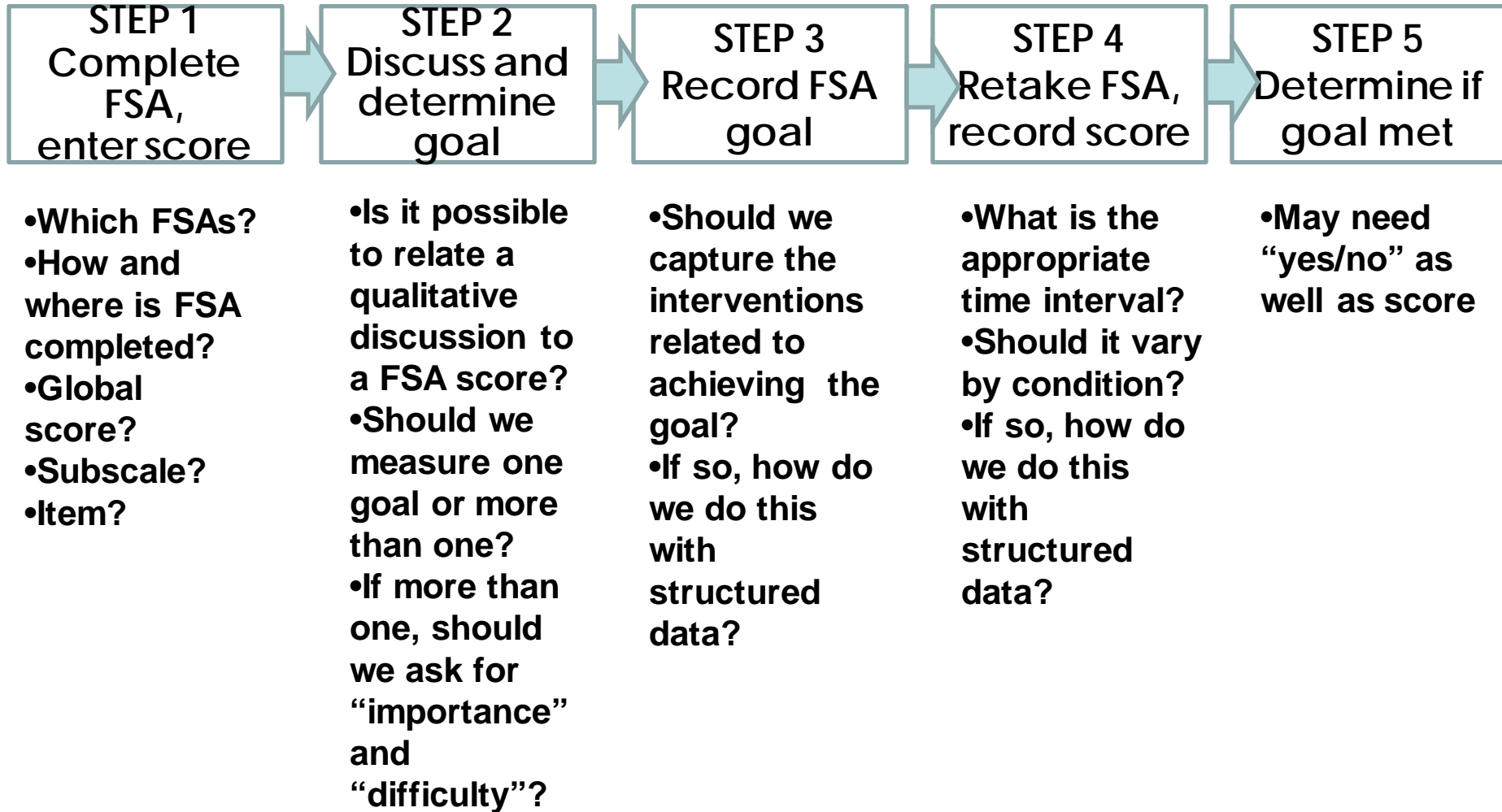
# Key Themes: Use of PROMs

- **Experts provided feedback that standardized functional status assessments are of interest, but generally are not used in clinical practice**
  - When they are used, they are not used systematically
  - These instruments are generally calibrated for individual patient assessment
  - We will need consider risk adjustment to achieve equitable population-level evaluation for outcome measures
- **Expert support for pairing process measure with goal setting tied to functional status assessments**
- **Expert recommendation to specify several assessment tools because using a single assessment tool may affect face validity**
- **Issues may be different for assessment of procedures than for use with chronic conditions**
- **Expert discomfort with outcomes at aggregate level**

# Building to Outcomes: PROM Performance Measures



# Measuring Goal-Setting and Goal-Attainment





# Next Steps

- Explore how to construct outcome measures
- Decide on standardized tools
- Explore licensing options
- Field test
- **Final specifications final specs for potential inclusion in Meaningful Use Stage 3**



# Patient Reported Outcomes: Examples of Measures in MN

- Depression Remission
- Asthma Control
- Orthopedic Functional Status

Collette Pitzen, BSN CPHQ  
MN Community Measurement



## Case Study # 1 Depression

- Condition specific PROM performance measure
- PROM = PHQ-9
  - Tool in public domain
  - 9 question tool, easy to administer & score
  - Valid for diagnostic and assessment over time
- Widely implemented in MN
  - Publically reported since 2009
  - Primary Care and Behavioral Practices
  - 80,000+ patients annually via direct data submission
- Implemented in EMR systems → pop-up, templates-values stored in discrete fields (not dependent on LOINC)
- NQF Endorsed/ e-Measure/ MU 2

### PHQ-9 Scoring

<u>Score</u>	<u>Depression Severity</u>
0 to 4	None/ minimal
5 to 9	Mild
10 to 14	Moderate
15 to 19	Moderately Severe
20 to 27	Severe



## Depression Remission at Six Months

- Patients with diagnosed major depression or dysthymia AND elevated PHQ-9 > 9
- Prospective/ longitudinal, based on index visit

PHQ-9 < 5 (remission) at six months +/- 30 days

Adults 18 + w major depression or dysthymia & PHQ-9 > 9

- Not assessed = not in remission

2/1/2012	3/15/2012	4/10/2012	6/20/2012		7/15/2012		
Diag 296.23 Major depression, severe PHQ-9 = 21	PHQ-9 = 18	PHQ-9 = 12	PHQ-9 = 8		PHQ-9 = 3		
Index Visit				7/2/2012 minus 30 days	Remission	8/1/2012 Six Month Marker	8/31/2012 plus 30 days

# Public Reporting by Clinic



When Health Care Improves, Everyone Wins.

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[ABOUT US](#)

[List all Clinics](#)

## Depression: Remission (Feeling Better)

[Skip to the Data ▶](#)

Ratings by Condition

[Asthma](#)

[Colorectal Cancer Screening](#)

[Depression](#)

[Remission](#)

Depression is more than feeling sad or "blue". Depression can interfere with daily life. Most people who seek treatment can improve to where they feel better and have few symptoms of depression or none at all. This is called being in remission.

[read more](#)

The Depression Remission measure reports on how well clinics help patients with depression reach remission and improve to where they say they have few symptoms of depression or none at all.

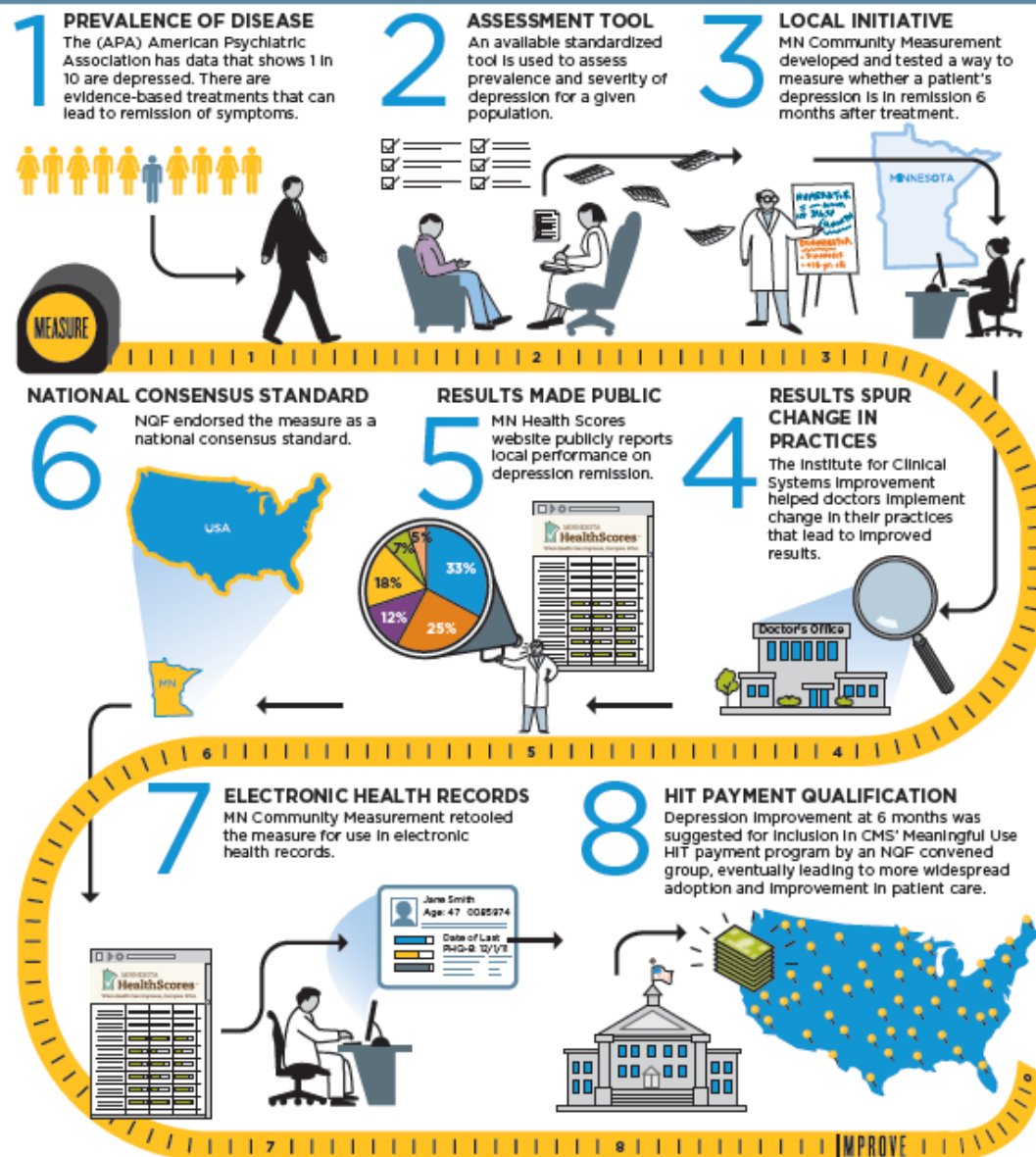
<a href="#">Essentia Health - Aurora Clinic</a>	Aurora	55705	29%	<div><div></div></div>	<a href="#">view profile &gt;</a>	
<a href="#">Aspen Medical Group - Hopkins</a>	Hopkins	55343	28%	<div><div></div></div>	<a href="#">view profile &gt;</a>	
<a href="#">Essentia Health - Deer River Clinic</a>	Deer River	55705	25%	<div><div></div></div>	<a href="#">view profile &gt;</a>	
<a href="#">Allina Health - Prescott</a>	Prescott	54021	24%	<div><div></div></div>	<a href="#">view profile &gt;</a>	
<a href="#">Mayo Clinic - Northwest</a>	Rochester	55901	24%	<div><div></div></div>	<a href="#">view profile &gt;</a>	
<a href="#">Sawtooth Mountain Clinic, Inc</a>	Grand Marais	55604	22%	<div><div></div></div>	<a href="#">view profile &gt;</a>	
<a href="#">Entira Family Clinics - North St. Paul (formerly Family Health Services Minnesota - North St. Paul Clinic)</a>	North St. Paul	55109	21%	<div><div></div></div>	<a href="#">view profile &gt;</a>	
<a href="#">Allina Health - Brooklyn Park</a>	Brooklyn Park	55443	20%	<div><div></div></div>	<a href="#">view profile &gt;</a>	
<a href="#">Hennepin County Medical Center (HCMC) Clinics - St. Anthony Village Clinic</a>	St. Anthony	55418	20%	<div><div></div></div>	<a href="#">view profile &gt;</a>	

[www.mnhealthscores.org](http://www.mnhealthscores.org)

MN Community Measurement

( 4 )





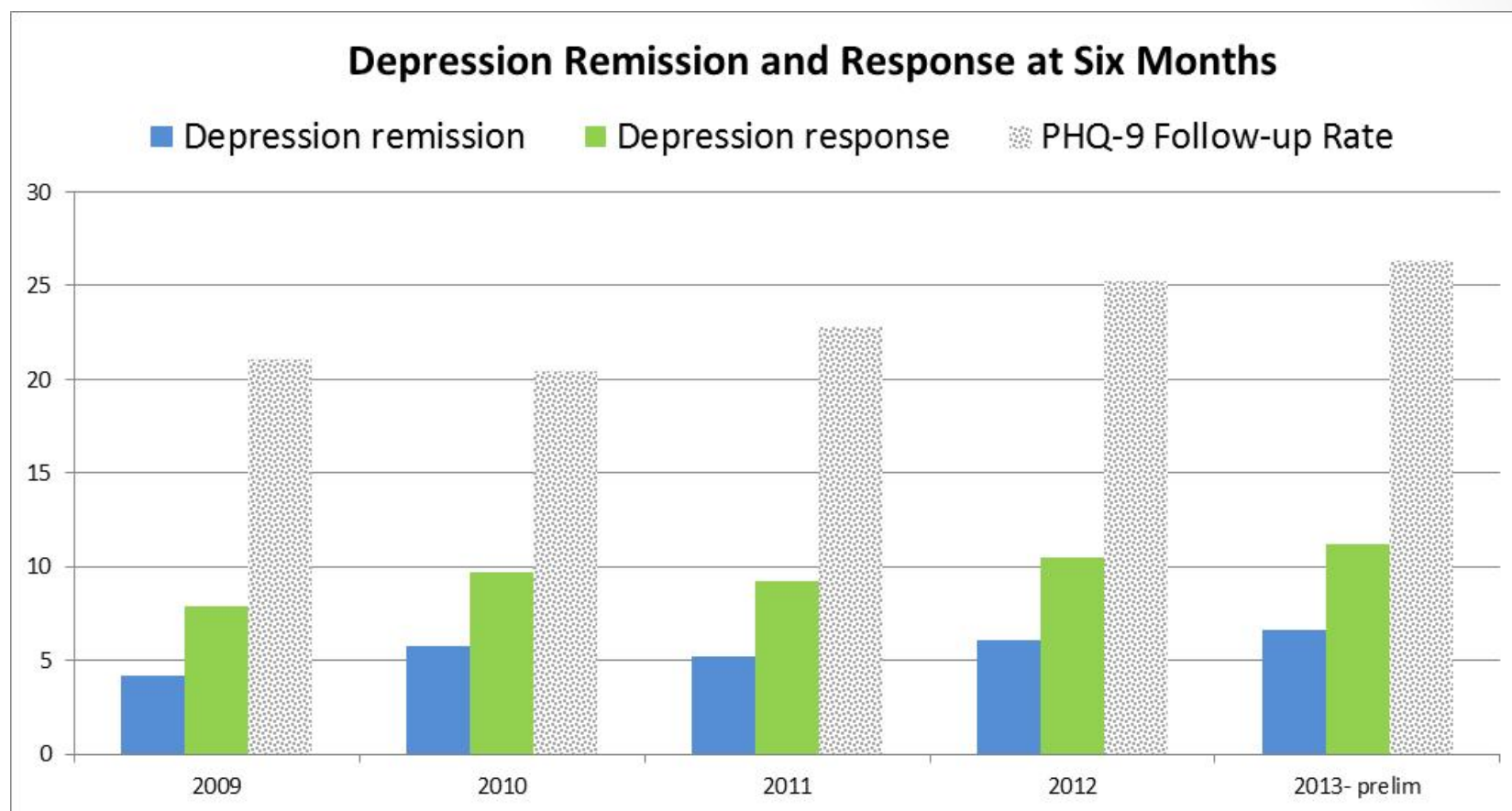
## Illustrated Example of the Lifecycle of a Measure

### Depression Remission at Six Months

Courtesy of the National Quality Forum



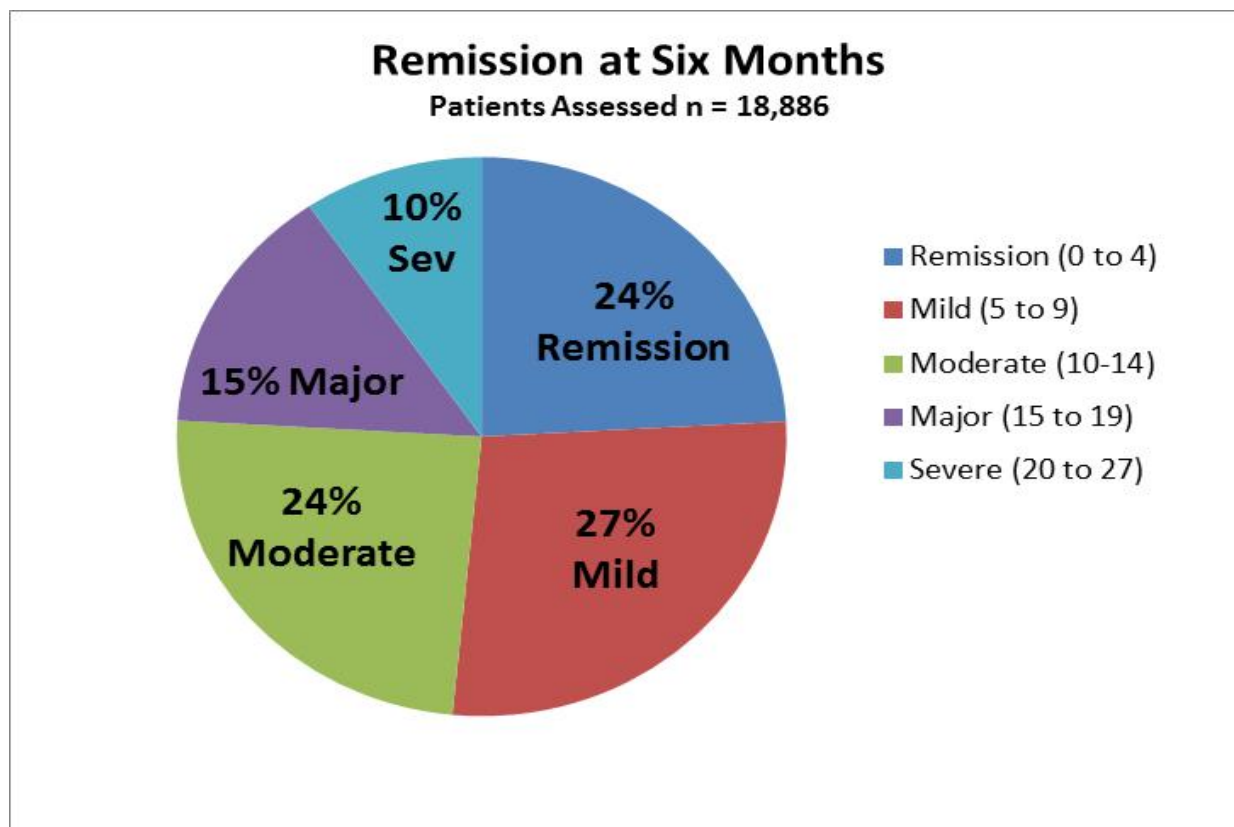
# Depression Remission/ Response and Follow-up Rates at Six Months



Small incremental improvement ... but lost to follow-up is at 72%



# Challenges with Patient Follow-up



Of patients assessed:

- 25% in remission
- 25% major to severe depression symptoms



## Case Study # 2 Asthma

- Condition specific PROM performance measure
- PROM = Three Tools (choice) to indicate if asthma is in control
  - ACT/ C-ACT Asthma Control Test [Score = 20 or >]
  - ACQ Asthma Control Questionnaire [Score = 0.75 or <]
  - ATAQ Asthma Therapy Assessment Questionnaire [Score = 0]
- Less complicated than depression measure
- Most recent assessment in the measurement period in control?
- 76% of population with completed test (↑ from 55%)
  - 99% of practices using ACT or C-ACT

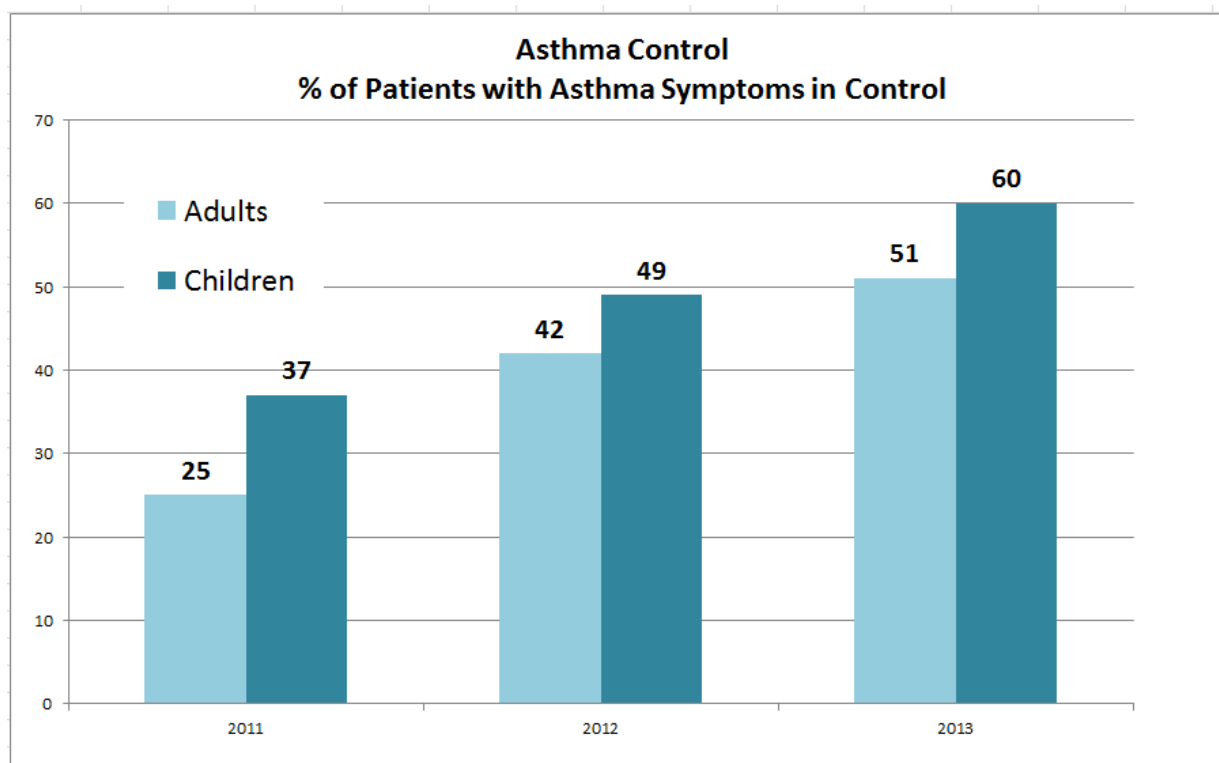


## Optimal Asthma Care- Control Component

### Most recent asthma control test with score in control

Patients age 5 to 50 with a diagnosis of asthma

- Not assessed = not in control
- Rush to implement → low rates first year as groups implementing tools







## Case Study # 3

### Total Knee and Lumbar Spine Surgery

- Condition specific PROM performance measure administered pre-operatively and post-operatively to patients
- Currently in pilot
- Yes, specialists can collect and report data
- Implementation into work flow is key
  - Groups rated tool administration to the patients more difficult than getting the info into or out of EMR
- Issues with proprietary tools



## Orthopedic/ Neurosurgery Measures

- Measuring the average or percent change between pre and post op scores
- For each patient → measure change
- Rates by practice or practice/ location
- Not assessed = not in measure
- Anticipate at least 70% one year capture rate
- Assessing clinical variables for risk adjustment
  - Obesity/ BMI
  - Tobacco Status
  - Pre-operative functional status score

Population	Pre-op	Three Month	One Year	Functional Status	Quality of Life
Total Knee Replacement	✓	✓	✓	Oxford Knee	EQ5D-5L
Lumbar Disc/Laminotomy	✓	✓		Oswestry (ODI) Pain Scale	EQ5D-5L
Lumbar Fusion	✓		✓	Oswestry (ODI) Pain Scale	EQ5D-5L



# Oxford Knee Score

## 3. During the past 4 weeks...

Have you had any trouble getting in and out of a car or using public transportation because of your knee? (whichever you would tend to use)

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

## 4. During the past 4 weeks...

For how long have you been able to walk before pain from your knee becomes **severe**? (with or without a cane)

No pain/more than 30 minutes	16 to 30 minutes	5 to 15 minutes	Around the house only	Not at all/severe pain when walking
<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

## 5. During the past 4 weeks...

After a meal (sitting at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable
<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0



# Oswestry Disability Index

- A low back pain specific functional status tool; gold standard used in the field over 20 years. Tool in public domain.
- Expressed as % disability
  - 20 to 40 moderate disability
  - 40 to 60 severe disability
  - 60 to 80 crippled
  - 80 to 100 bedbound or exaggerating

## 10 Questions related to low back function

- |                  |                            |
|------------------|----------------------------|
| ▪ Pain intensity | ▪ Standing                 |
| ▪ Personal care  | ▪ Sleeping                 |
| ▪ Lifting        | ▪ Sex life (if applicable) |
| ▪ Walking        | ▪ Social life              |
| ▪ Sitting        | ▪ Travelling               |

Valid Tool = at least 8 of 10 questions answered

Valid Version = 2.1a



## Learning Via Pilot

- If a tools are “newer” to the practice
  - Time to implement & build into work flow
  - Follow-up post-op
  - Unfamiliarity / skipping questions
- Public domain tools preferable
  - “Permission to Use” → barriers for electronic admin
- Frequently desired measure point is lengthy
  - One year (nine to fifteen months post-op) post fusion
  - Initial discectomy 3 month follow-up good
- Balance between desire and burden
  - Development work group function, quality of life and pain
  - Needed to narrow variables for RA (started with > 20)

# PROs in EHR: Regulatory Considerations for Use in Clinical Trials

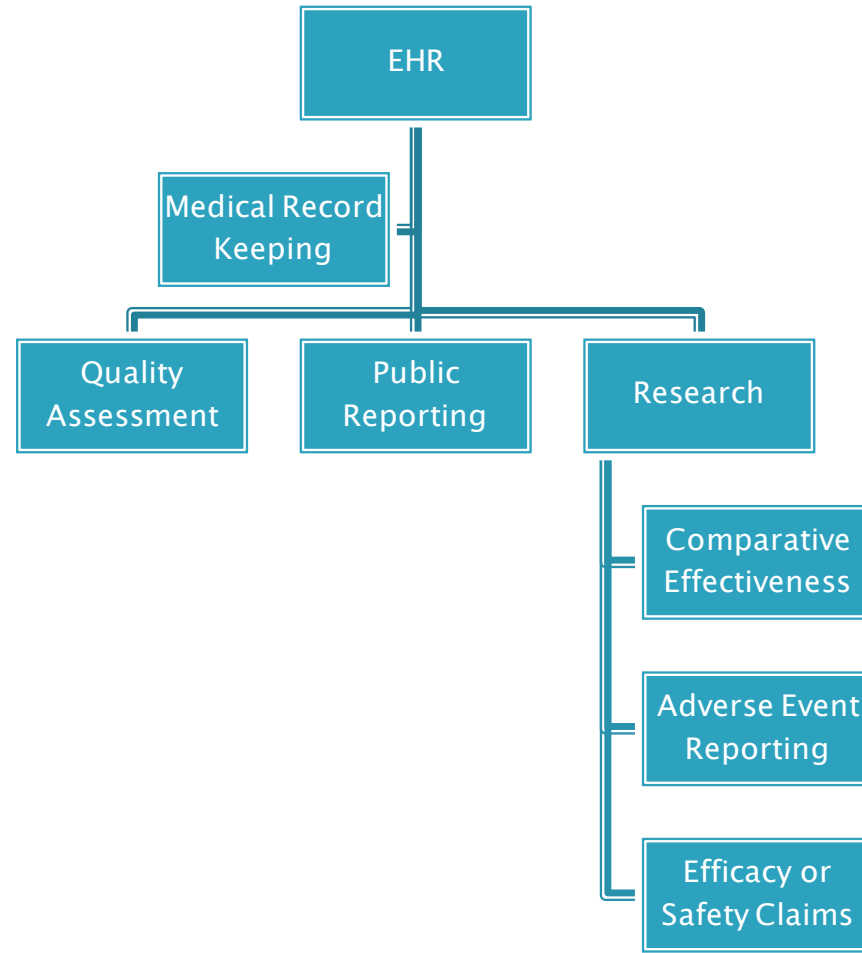
Ann Marie Trentacosti, M.D.  
Medical Lead  
OND/CDER/SEALD  
November 19, 2013



# Outline

- ▶ Instrument Selection: Measuring the Right Thing in the Right Way
- ▶ Special Considerations for Electronic Data Collection

# Evolution of EHR



# FDA PRO Guidance

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## **Guidance for Industry**

### **Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims**

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiological Health (CDRH)

December 2009  
Clinical/Medical

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- ▶ PRO: A measurement based on a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else
- ▶ Defines how the Agency interprets "well-defined and reliable" for PRO measures intended to provide evidence of treatment benefit that support labeling claims

# PRO Instrument

A means to capture data (i.e., a questionnaire) plus all the information and documentation that supports its use

- ▶ Clearly defined methods and instructions for administration or responding
- ▶ Standard format for data collection
- ▶ Well-documented methods for scoring, analysis, and interpretation of results

# PRO Instrument Selection

## “Fit for Purpose”

**Step 1: Define disease population**

**Step 2: Define other aspects of context of use**

**Step 3: Define the concept of interest that will define treatment benefit**

**Step 4: Select or develop well-defined and reliable PRO Measures  
(including data collection method)**



**PRO Instrument**

# Defining Context of Use

**Each of the following variables can impact the adequacy of a PRO to support a claim:**

- **Disease definition including, if appropriate**
  - Disease subtype
  - Disease severity
  - History of previous treatment
- **Patient subpopulations**
  - Patient demographics
  - Reporting ability
  - Culture and language
- **Clinical trial design and objectives**
  - Endpoint positioning
  - Endpoint definitions
  - Analysis plan
  - Methods for interpretation of study results
  - Targeted labeling claim
- **Clinical practice and study setting**
  - Inpatient vs. outpatient
  - Geographic location
  - Clinical practice variation



# Considerations for Mode of Administration Selection

- ▶ Who is the target population?
- ▶ Where will the assessment be completed? (e.g., patient home)
- ▶ What is the timeframe for reporting (immediate or some recall)?
- ▶ Characteristics of the items and response options?
- ▶ Infrastructure of collection of data electronically (e.g., internet connectivity variation)
- ▶ Patient burden and length of instrument or batteries of instruments
- ▶ Multiple languages needed?

# Considerations for Selecting an Appropriate Mode of Administration

Consideration	Paper	Electronic Hand Held Device	Web or browser-based	IVRS
Technology Availability and Acceptance	Paper and Pens available and acceptable to all	Device provided by Sponsor; studies show acceptance across broad spectrum	Must have computer or web-enabled device; studies show acceptance across broad spectrum	Must have phone (or Sponsor provides one); studies show acceptance across broad spectrum
Graphics supported?	Yes	Yes	Yes	No
Large number of questions and/or responses supported?	Yes	Yes	Yes	No
Alarm option to minimize missing data?	No	Yes (multiple alarms possible)	No (although possibility for email reminders)	Yes (incoming phone call)
Logical branching / adaptive questions possible?	No (branching possible, but with patient confusion and burden)	Yes	Yes	Yes
Literacy required?	Yes	Yes	Yes	No (but cognitive load may be higher for auditory vs. visual items)
Out of range data avoided?	No	Yes	Yes	Yes
Transcription errors avoided?	No	Yes	Yes	Yes
Time stamp available?	No	Yes	Yes	Yes

# Special consideration – Translations and Mode of Administration



Thinking about the last 24 hours...

Please rate how difficult it was to stand upright without falling while your eyes were closed.

0 -1-2-3-4-5-6-7-8-9-10  
Not at                      Extremely  
all difficult                      difficult

Մտածում եք, որ վերջին 24 ժամվա ընթացքում...  
Խնդրում ենք գնահատել, թե որքան դժվար էր կանգնել շիտակ, առանց նվազում, մինչդեռ ձեր աչքերը փակ էին.

0 -1-2-3-4-5-6-7-8-9-10  
Ամենեւին Չափազանց  
Դժվար                      դժվար է

# Migration of PRO from Paper to Electronic Mode of Administration

- ▶ Existing instruments that switch from paper to electronic data capture are evaluated as a modified instrument
  - At a minimum documentation of cognitive debriefing should demonstrate that content validity is not altered between the 2 instruments

# Data Collection Method Review

- ▶ Data collection method, procedures and protocols associated with instrument administration mode
  - Instructions to interviewers, self-administration, or supervising self-administration.
- ▶ Data quality control procedures specific to the data collection method or instrument administration mode
  - Case report forms or screen shots of electronic PRO instruments.
- ▶ Comparability of data obtained when using multiple data collection methods or administration modes within a single clinical trial

# When Reviewing Electronic PROs

- ▶ The content of electronic instruments is evaluated the same as in any other PRO instrument
- ▶ Documentation of development and validation needed for review of evidence to support labeling claims
  - PRO Guidance defines the principles of good measurement science for developing PROs
- ▶ Additional documentation may be important to review with electronic assessments
  - Program specifications and rationale for design features (e.g., forced responses, branches, prompts)
  - Usability testing
  - Training materials
  - Documentation related to migration from paper to electronic
- ▶ Electronic data capture does not overcome problems with content validity
  - Capturing the wrong data really well is not useful!



# Source Data

- ▶ Includes all information in original records, certified copies of original records of clinical findings, observations, or other activities used for reconstructing and evaluating the investigation
- ▶ FDA and sponsors have access to source data to ensure adequate protection of rights, welfare, and safety of human subjects
- ▶ Must be attributable, legible, contemporaneous, original, and accurate

# Electronic PRO Instruments

## Sponsors:

- ▶ Must ensure that regulatory requirements for record keeping, transmission, maintenance, storage, and access are met
- ▶ Provide investigators with all information necessary to conduct the trials in accordance with the investigational plan and permitting FDA to access, copy, and verify records and reports relating to the investigation (i.e., source data verification)

# Computerized System Safeguards

- ▶ Internal Security Safeguards
  - Limited Access: limited to authorized individuals only
  - Audit Trails: Use of computer generated stamped audit trails
  - Date/Time Stamp
- ▶ External Security Safeguards
  - Procedures and controls to prevent the altering, browsing, querying, or reporting of data via external software applications

# FDA Guidances

- ▶ Guidance for Industry: Patient–Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Available online:  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf>
- ▶ Guidance for Industry: Computerized Systems Used in Clinical Investigations. Available online:  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf>
- ▶ Guidance for Industry: Part 11, Electronic Records; Electronic Signatures–Scope and Application: Available online:  
<http://www.fda.gov/regulatoryinformation/guidances/ucm125067.htm>
- ▶ Draft Guidance for Industry: Electronic Source Data in Clinical Investigations. Available online:  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf>

# What is the Potential for Using PROs in Performance Measurement?

PCORI PRO Infrastructure  
Workshop  
Atlanta  
November 19, 2013



NATIONAL  
QUALITY FORUM

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# Potential for PROs to Improve Care

- Facilitate person-centered care
- Improve patient-provider communication and decision-making
- Identify patient needs in a timely manner
- Assist clinical providers in care management
- Assist patients with self-care management and monitoring
- Outcomes such as function and symptom relief are reasons for seeking and delivering care
- Therefore, PROs should be considered for performance measurement

# NQF Endorses Performance Measures

- NQF is a voluntary consensus standards setting organization
- Endorses performance measures for use in BOTH improvement and accountability applications (public reporting and payment)
- Endorses PRO-based performance measures, not individual-level PRO instruments, tools, or scales
- Does not develop measures -- evaluates against standard criteria
  - ✓ Importance to measure and report
  - ✓ Scientific acceptability of measure properties
  - ✓ Feasibility
  - ✓ Usability and use
  - ✓ Related and competing measures



# NQF Project – PROs in Performance Measurement

- Guiding Principles
  - Psychometric Soundness
  - Person-Centered
  - Meaningful
  - Amenable to Change
  - Implementable
- PRO domains included
  - health-related quality of life/functional status
  - symptom and symptom burden
  - experience with care (incl. engagement, shared decision-making)
  - Health-related behaviors

# NQF Endorses Performance Measures

## Distinctions among PRO, PROM, and PRO-PM

	Definition	Example: Patients With Clinical Depression
<b>PRO</b> (patient-reported outcome)	The concept of any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.	Symptom: depression
<b>PROM</b> (instrument, tool, single-item measure)	Instrument, scale, or single-item measure used to assess the PRO concept as perceived by the patient, obtained by directly asking the patient to self-report (e.g., PHQ-9).	PHQ-9©, a standardized tool to assess depression
<b>PRO-PM</b> (PRO-based performance measure)	A performance measure that is based on PROM data aggregated for an accountable healthcare entity (e.g., percentage of patients in an accountable care organization whose depression score as measured by the PHQ-9 improved).	Percentage of patients with diagnosis of major depression or dysthymia and initial PHQ-9 score >9 with a follow-up PHQ-9 score <5 at 6 months (NQF #0711)

# Pathway from PRO to NQF-endorsed PRO-PM PRO

## **1. Identify the quality performance issue or problem**

- Include input from all stakeholders including consumers and patients



## **2. Identify outcomes that are meaningful to the target population and are amenable to change**

- Ask persons who are receiving the care and services
- Identify evidence that the outcome responds to intervention



## **3. Determine whether patient-/person-reported information (PRO) is the best way to assess the outcome of interest**

- If a PRO is appropriate, proceed to step 4

# Pathway from PRO to NQF-endorsed PRO-PM PROM

## **4. Identify existing PROMs for measuring the outcome (PRO) in the target population of interest**

- Many PROMs (instrument/ scale/single-item) were developed and tested primarily for research



## **5. Select a PROM suitable for use in performance measurement**

- Identify reliability, validity, responsiveness, feasibility in the target population



## **6. Use the PROM in the real world with the intended target population and setting to:**

- Assess status or response to intervention, provide feedback for self-management, plan and manage care or services, share decision-making
- Test feasibility of use and collect PROM data to develop and test an outcome performance measure

# Pathway from PRO to NQF-endorsed PRO-PM

## PRO-PM

### **7. Specify the outcome performance measure (PRO-PM)**

- Aggregate PROM data such as average change; percentage improved or meeting a benchmark



### **8. Test the PRO-PM for reliability, validity, and threats to validity**

- Analysis of threats to validity, e.g., measure exclusions; missing data or poor response rate; case mix differences and risk adjustment; discrimination of performance; equivalence of results if multiple PROMs specified

# Pathway from PRO to NQF-endorsed PRO-PM

## NQF Endorsement Process

### 9. Submit the PRO-PM to NQF for consideration of NQF endorsement

- Detailed specifications and required information and data to demonstrate meeting [NQF endorsement criteria](#)



### 10. Evaluate the PRO-PM against the [NQF endorsement criteria](#)

- Importance to Measure and Report (including evidence of value to patient/person and amenable to change)
- Scientific Acceptability of Measure Properties (reliability and validity of PROM and PRO-PM; threats to validity)
- Feasibility
- Usability and Use
- Comparison to Related and Competing Measures to harmonize across existing measures or select the best measure

# Pathway from PRO to NQF-endorsed PRO-PM

## NQF Endorsement Process (Cont.)

### 11. Use the endorsed PRO-PM for accountability and improvement

- Refine measure as needed



### 12. Evaluate whether the PRO-PM continues to meet [NQF criteria](#) to maintain endorsement

- Submit updated information to demonstrate meeting all criteria including updated evidence, performance, and testing; feedback on use, improvement, and unintended adverse consequences



**Feedback to step 1**



# Sample of Methodological Questions for Discussion

- What should be considered in choosing an approach to aggregate PROM data for an outcome performance measure (e.g., average/median amount of change; percentage of patients who improve/reach benchmark/have meaningful change)?
- What are the implications of various aggregation approaches on:
  - reliability of the PRO-PM score
  - validity of conclusions about quality?
- Are there any unique considerations for risk adjustment of a PRO-PM (as compared to other quality outcome performance measures)?

## Next steps

- PRO-PMs are ripe for the “measure incubator” concept to fill important measure gaps
  - Select a candidate PRO (e.g., functional status) and take down the pathway
- NQF upcoming projects
  - Measure Gaps – Person-centered care and outcomes
  - CDP endorsement of performance measures – Person and family-centered care
  - Patient engagement “Action Team”

# Resources from NQF Project

- Project Report - **Patient-Reported Outcomes (PROs) in Performance Measurement**
- Commissioned papers
  - **Methodological Issues in the Selection, Administration and Use of Patient-Reported Outcomes in Performance Measurement in Health Care Settings**  
David Cella, Ph.D., Elizabeth A. Hahn, M.A., Sally E. Jensen, Ph.D., Zeeshan Butt, Ph.D., Cindy J. Nowinski, M.D., Ph.D., Nan Rothrock, Ph.D.
  - **Patient-Reported Outcomes in Performance Measurement Commissioned Paper on PRO-Based Performance Measures for Healthcare Accountable Entities**  
Anne Deutsch, RN, PhD, CRRN; Laura Smith, PhD; Barbara Gage, PhD; Cynthia Kelleher, MPH, MBA; Danielle Garfinkel, BA
- Available on NQF website: [PROs in Performance Measurement](#)