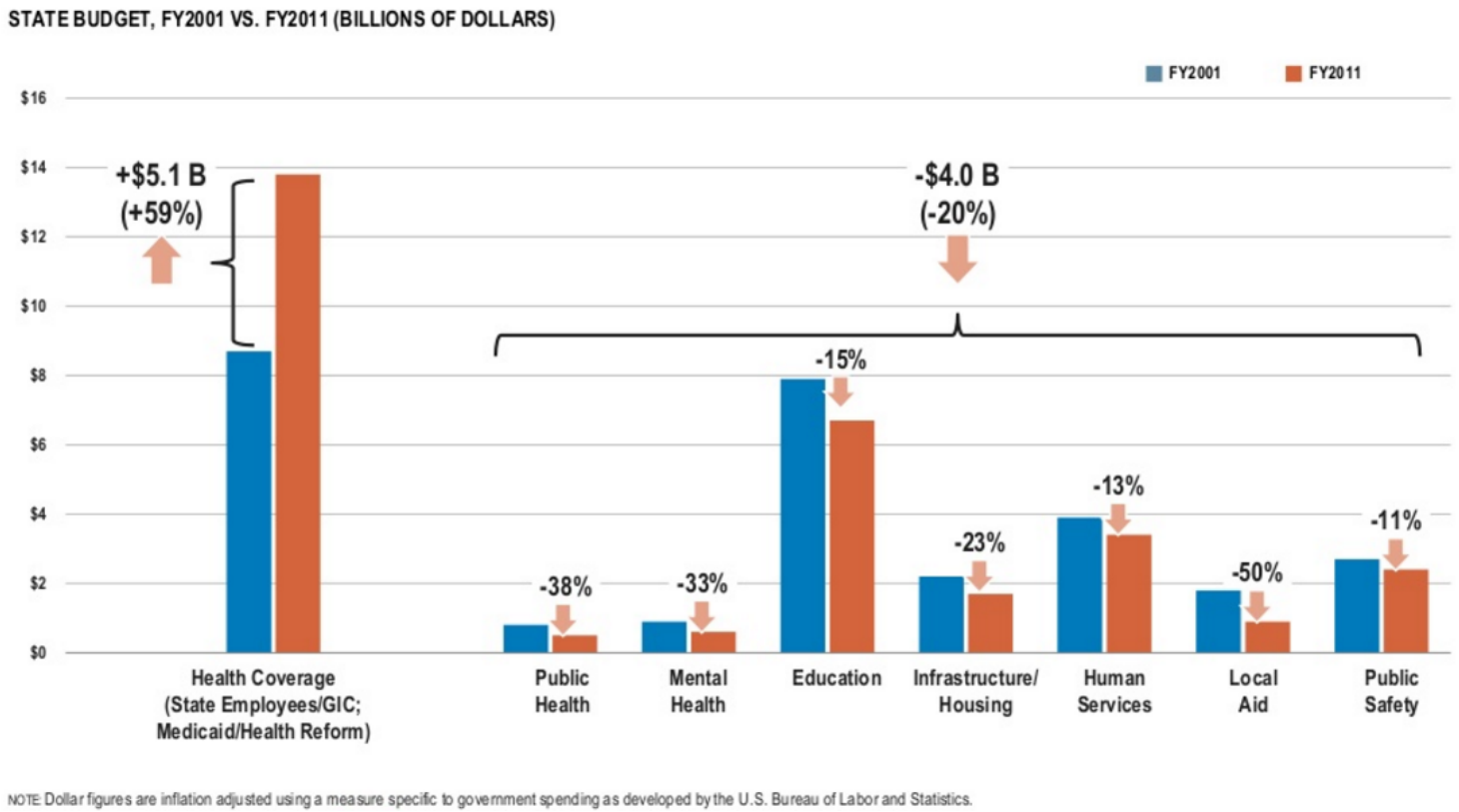
CMS/Payer Perspectives

Understanding Disparities in Access to Genomic Medicine

Sean Tunis MD, MSc | June 27, 2018

CENTER FOR MEDICAL TECHNOLOGY POLICY

Affordability is Center Stage



Source: Mass Budget and Policy Center

Framing workshop topic

- Reducing disparities in access to genomic medicine
- Reducing health disparities through targeted use of genomic medicine

What are payers thinking?

- Coverage decisions
- Value-based payment
- Population health

Coverage Decisions
(Medical Necessity)

Medicare Guidelines for Evaluation of DX Tests

- **Question 1:** *Is the evidence adequate to determine whether the test provides more accurate diagnostic information?*

- **Question 2:** *If the test changes accuracy, is the evidence adequate to determine how the changed accuracy affects health outcomes?*

ORIGINAL RESEARCH ARTICLE | Genetics inMedicine

Generating and evaluating evidence of the clinical utility of molecular diagnostic tests in oncology

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Purpose: Enthusiasm for molecular diagnostic (MDx) testing in oncology is constrained by the gaps in required evidence regarding its impact on patient outcomes (clinical utility (CU)). This effectiveness guidance document proposes recommendations for the design and evaluation of studies intended to reflect the evidence expectations of payers, while also reflecting information needs of patients and clinicians.

Methods: Our process included literature reviews and key infor-

The guidance also describes circumstances under which alternatives to RCTs could be considered, specifying conditions under which test developers could use prospective-retrospective studies with banked biospecimens, single-arm studies, prospective observational studies, or decision-analytic modeling techniques that make a reasonable case for CU.

Conclusion: Using a process driven by multiple stakeholders, we developed a common framework for designing and evaluating stud-

Advance online publication 3 December 2015. doi:10.1038/gim.2015.162

Evidence for MDx Testing

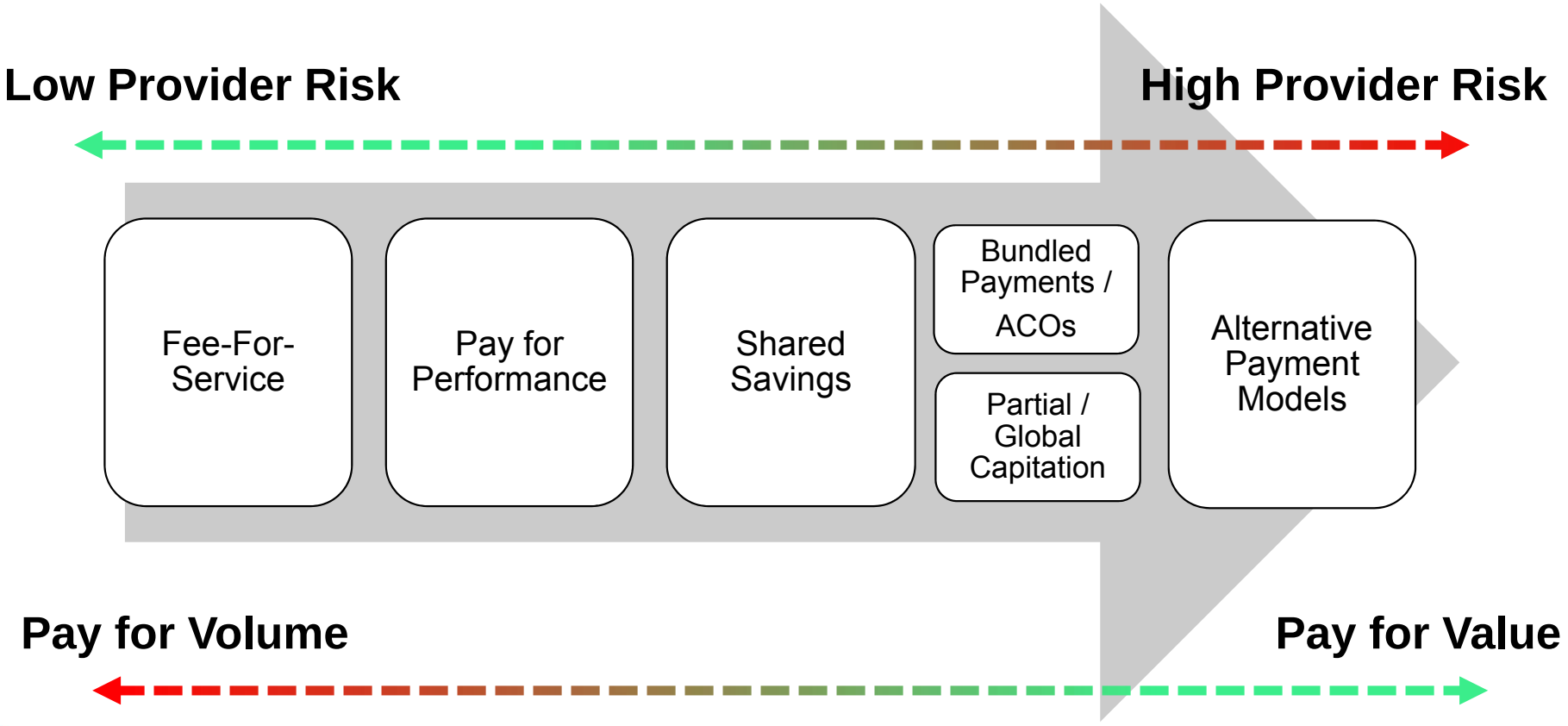
Clinical Utility

Selected Recommendations

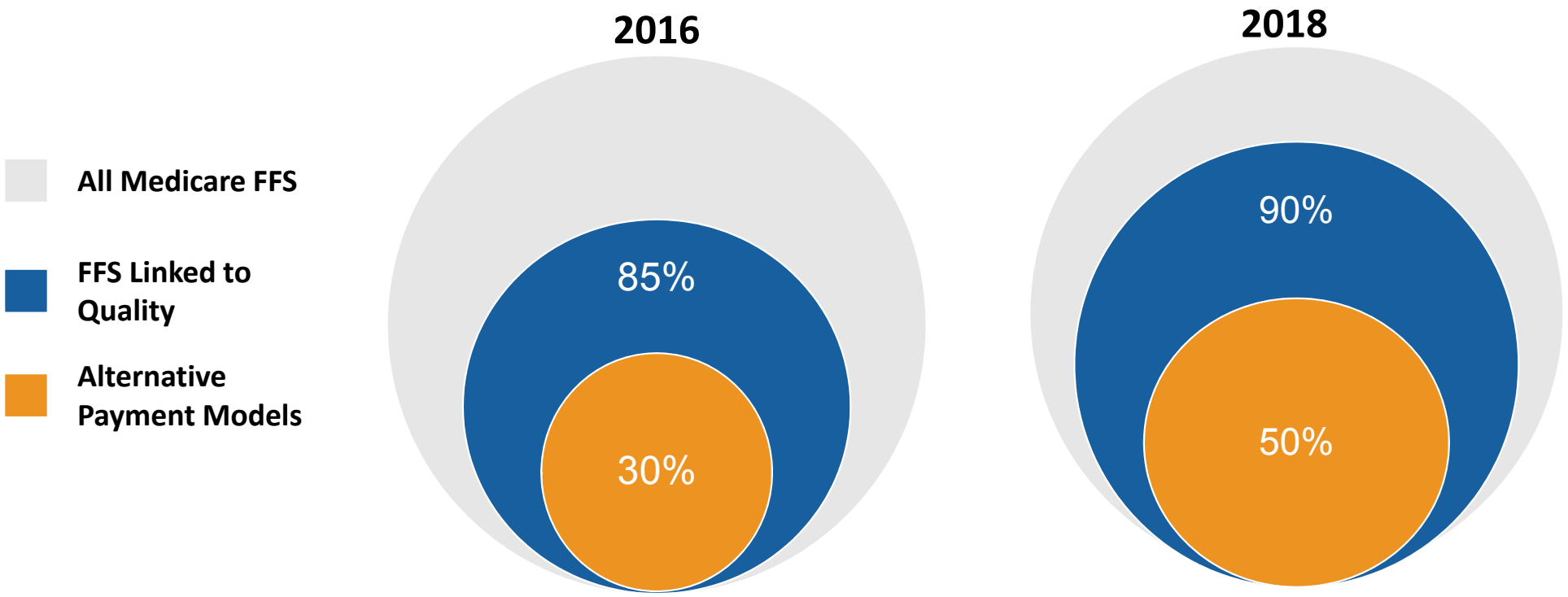
- Change in pt management insufficient
- RCTs generally preferred whenever feasible
- Observational studies may be adequate in specific circumstances, and when RCTs not reasible
- Decision modeling may show the relationship between test results and downstream patient outcomes

Value-based Payment
(shifting risk to providers)

Evolution of Healthcare Payment Models



Current Landscape - Medicare



Population Health

U.S. Department of Health and Human Services

Agency for Healthcare Research and Quality

Advancing Excellence in Health Care • www.ahrq.gov

National Healthcare Quality and Disparities Report

Chartbook on Effective Treatment

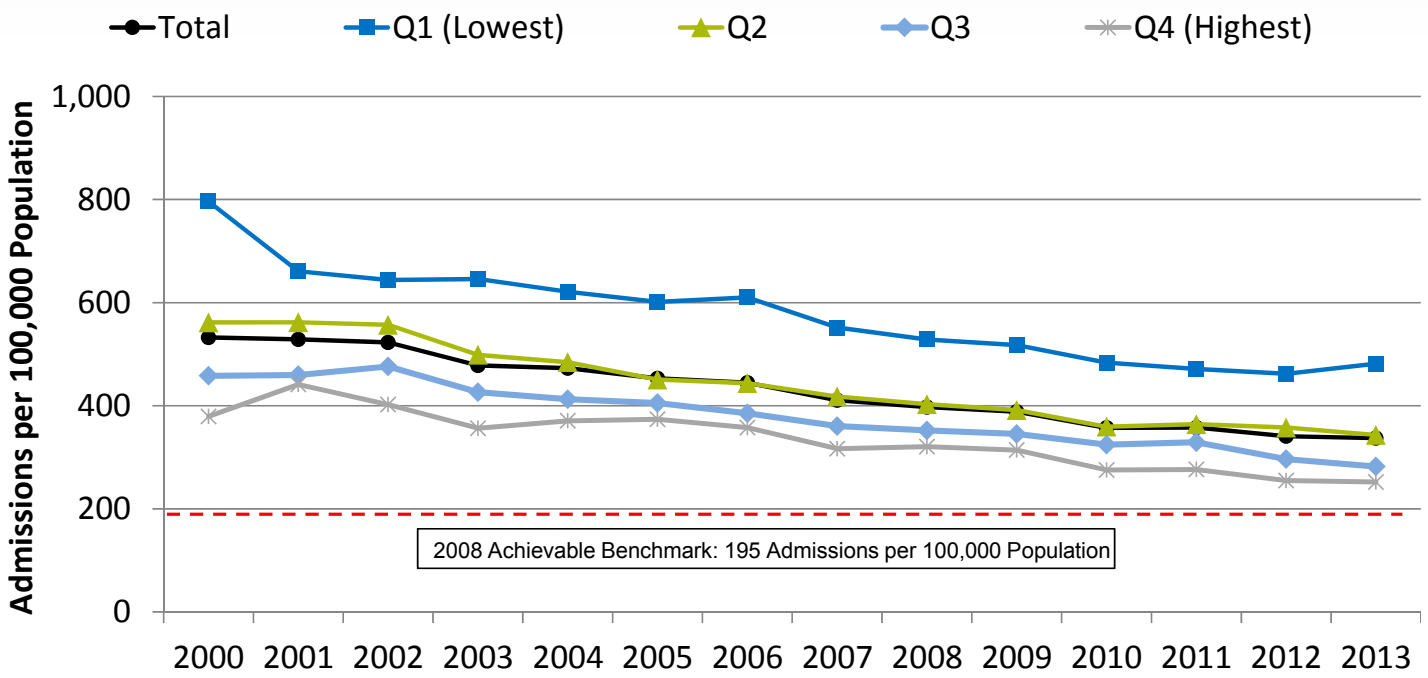
September 2016

This presentation contains notes. Select View, then Notes page to read them.

Conditions Covered

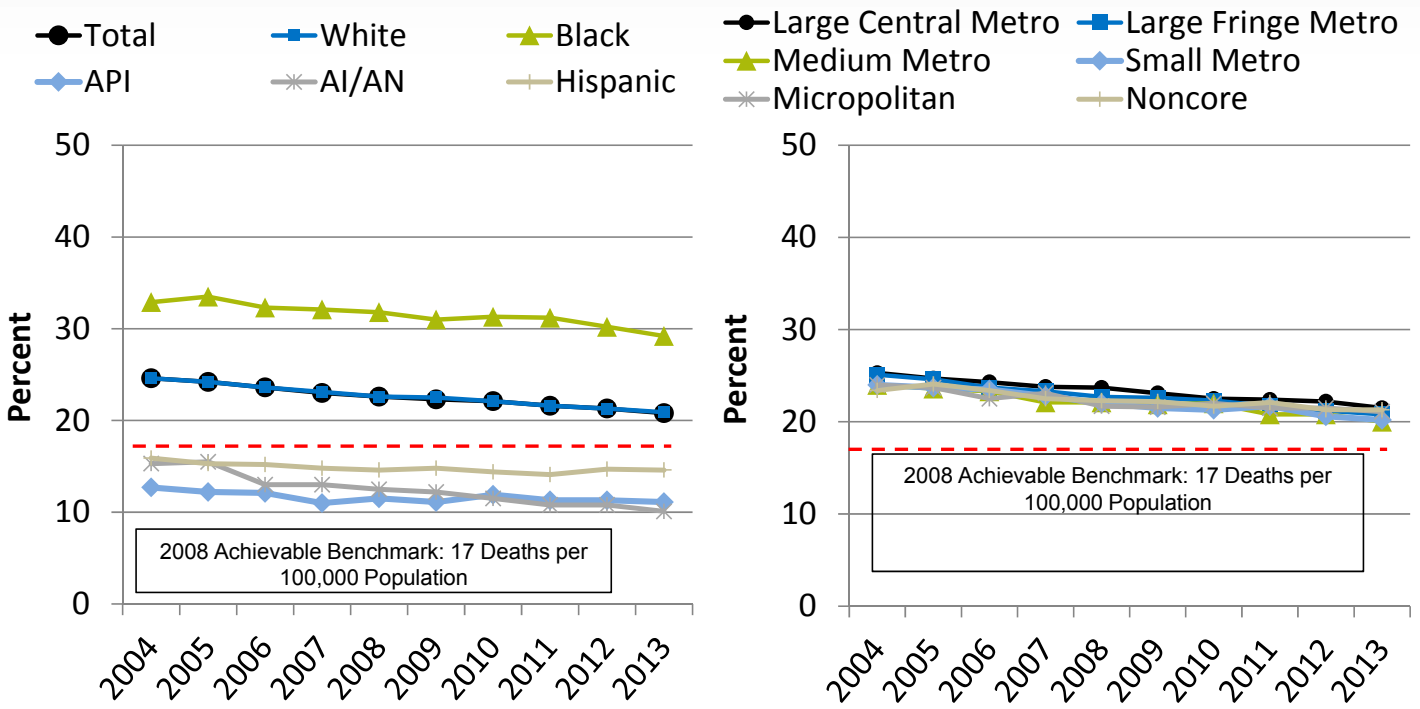
- This chartbook is organized around eight conditions that are the leading causes of mortality and morbidity in the United States:
  - Cardiovascular disease
  - Cancer
  - Chronic kidney disease
  - Diabetes
  - HIV and AIDS
  - Mental health and substance abuse
  - Musculoskeletal diseases
  - Respiratory diseases

Adult admissions with congestive heart failure by income



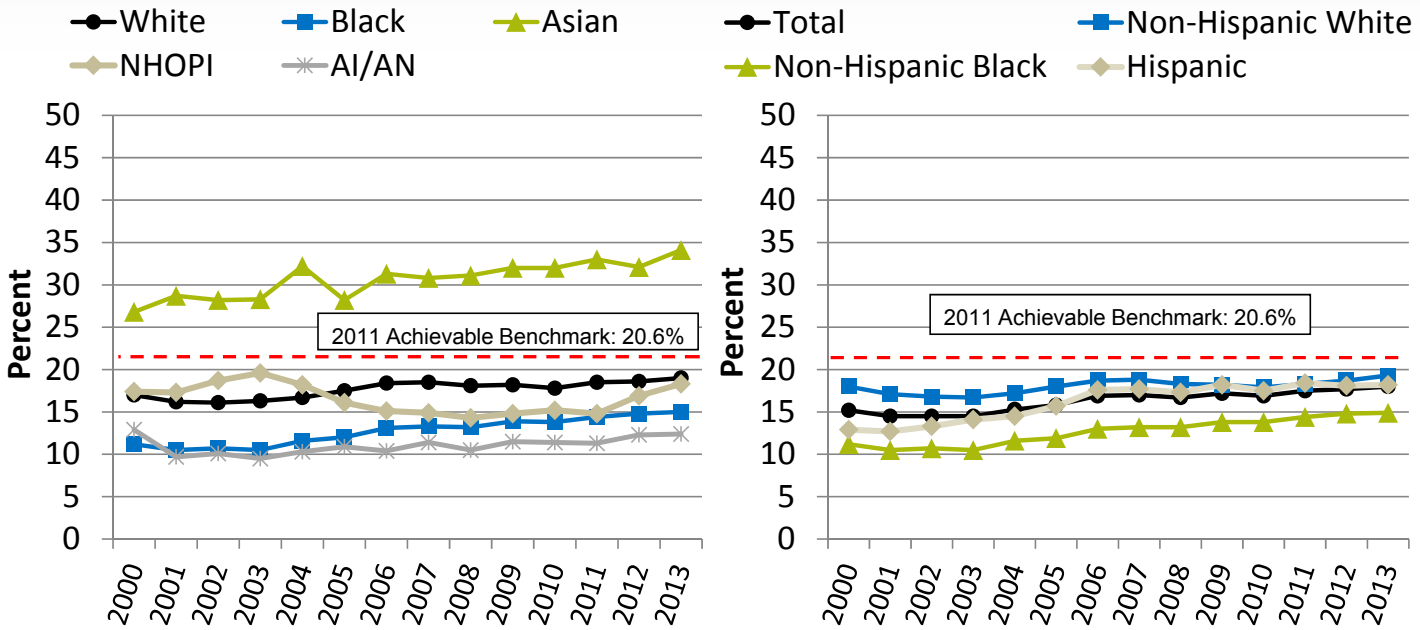
Key: Q = quartile.
Source: Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, Nationwide (2000-2011) and National (2012-2013) Inpatient Sample and AHRQ Quality Indicators, version 4.4.
Denominator: U.S. resident population age 18 and over.
Note: For this measure, lower rates are better. Area income is based on the median income of a patient's ZIP Code of residence.

Age-adjusted breast cancer deaths by race/ethnicity



Key: API = Asian or Pacific Islander; AI/AN = American Indian or Alaska Native.
Source: Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System—Mortality, 2004-2013.
Denominator: U.S. population.
Note: For this measure, lower rates are better. Total rate is age adjusted to the 2000 U.S. standard population.

Dialysis patients receiving transplant by race



Key: NHOPI = Native Hawaiian or Other Pacific Islander; AI/AN = American Indian or Alaska Native.
Source: U.S. Renal Data System, 2000-2013. https://www.usrds.org/2015/view/v2_02.aspx.
Note: Hispanic includes all races. The cohort includes patients from 2000-2013 who were younger than 70 at the initiation of ESRD. Percentages are calculated as the number of patients placed on the deceased donor organ waiting list or receiving a deceased donor transplant within 1 year of initiation, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded), and are estimated using the Kaplan-Meier methodology.

Addressing Disparities in GM

To increase level of interest from payers / providers in promoting access to genomic medicine

- Focus on major public health priorities
- Look for empirical evidence of disparities in care
- Identify in what way genomic medicine could help
- Link to or create quality / value-based payment initiatives
- Generate some evidence to demonstrate better outcomes and value