

Multiple Chronic Conditions: Including people
with representative comorbidities:

*“Treating an Illness Is One Thing. What About a Patient
With Many?”*

Cynthia M. Boyd, MD MPH
Associate Professor
Department of Medicine
and Department of Health Policy and Management
Johns Hopkins University

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Disclosure of Interests (last 5 years)

Cynthia M. Boyd, MD MPH

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“Treating an Illness Is One Thing. What About a Patient With Many?”



http://hab.hrsa.gov/livinghistory/issues/aging_6.htm



Image: Brendan Smialowski for the New York Times, March 31, 2009

It's Not Easy Living with Multiple Chronic Conditions

Time	Medications	Non-pharmacologic Therapy	All Day	Periodic
7 AM	Ipratropium MDI Alendronate 70mg weekly	Check feet Sit upright 30 min. Check blood sugar	Joint protection Energy conservation	Pneumonia vaccine, Yearly influenza vaccine
8 AM	Eat Breakfast HCTZ 12.5 mg Lisinopril 40mg Glyburide 10 mg ECASA 81 mg Metformin 850mg Naproxen 250mg Omeprazole 20mg Calcium + Vit D 500mg	2.4gm Na, 90mm K, Adequate Mg, ↓ cholesterol & saturated fat, medical nutrition therapy for diabetes, DASH	Exercise (non-weight bearing if severe foot disease, weight bearing for osteoporosis) Muscle strengthening exercises, Aerobic Exercise ROM exercises	All provider visits: Evaluate Self-monitoring blood glucose, foot exam and BP Quarterly HbA1c, biannual LFTs Yearly creatinine, electrolytes, microalbuminuria, cholesterol <u>Referrals:</u> Pulmonary rehabilitation
12 PM	Eat Lunch Ipratropium MDI Calcium+ Vit D 500 mg	Diet as above	Avoid environmental exposures that might exacerbate COPD Wear appropriate footwear	Physical Therapy DEXA scan every 2 years Yearly eye exam
5 PM	Eat Dinner	Diet as above	Albuterol MDI prn Limit Alcohol Maintain normal body weight	Medical nutrition therapy <u>Patient Education:</u> High-risk foot conditions, foot care, foot wear Osteoarthritis COPD medication and delivery system training Diabetes Mellitus
7 PM	Ipratropium MDI Metformin 850mg Naproxen 250mg Calcium 500mg Lovastatin 40mg			
11 PM	Ipratropium MDI			
<i>Boyd et al. JAMA 2005;294:716-724</i>				

How Applicable are Clinical Practice Guidelines (CPGs) for People with MCCs?

- Reviewed 9 CPGs for chronic conditions
- Most single disease CPGs fail to give adequate guidance for older patients with MCCs

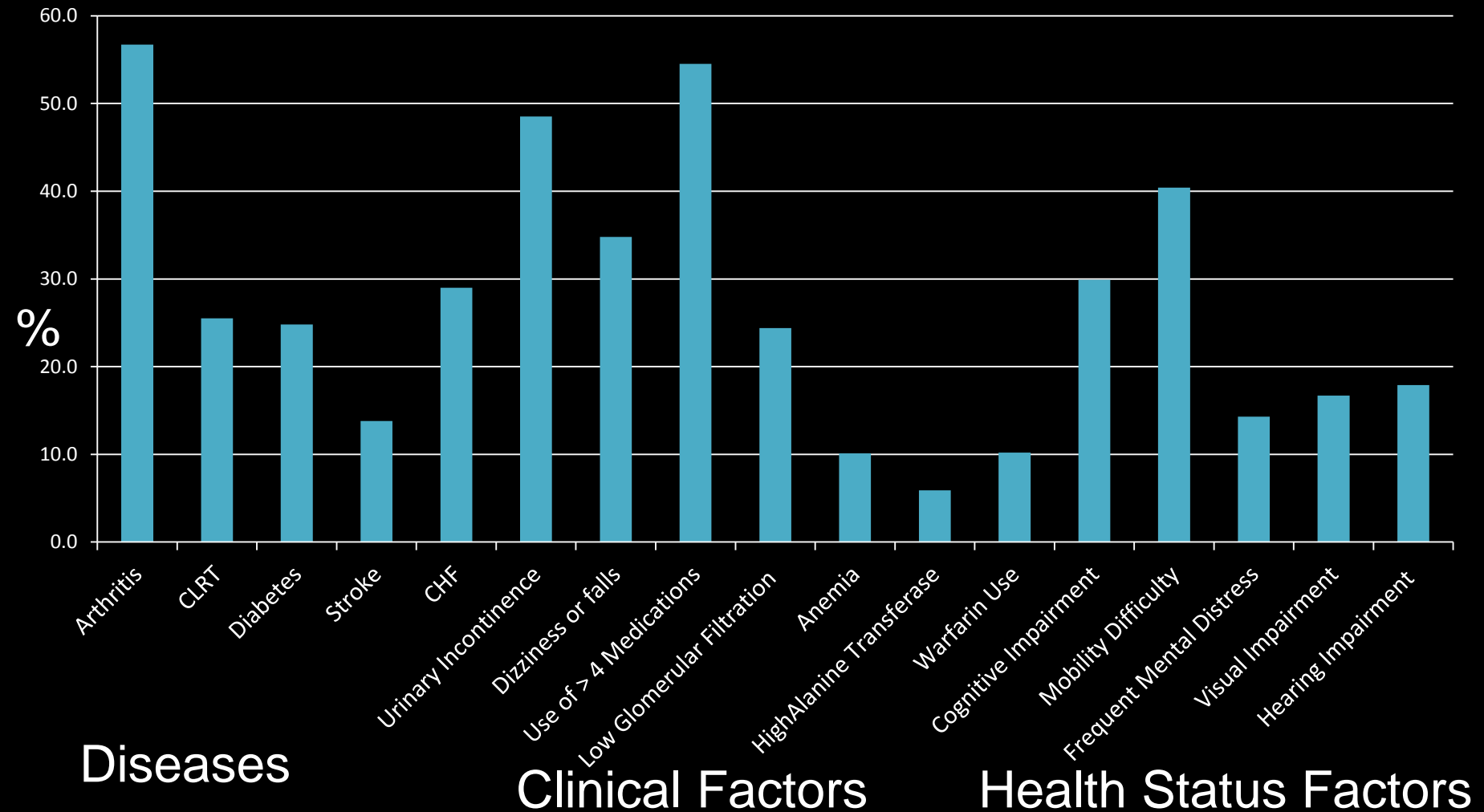
Issue	Is Criteria Addressed?
Attention	Limited
Quality of Evidence	Limited
Specific recommendations	Most address treatment of index disease in presence of single other conditions
Time needed to treat	Limited
Quality of life	Limited
Trade-offs in goals of therapy	Not at all
Patient preferences	Limited
Burden	Limited

Multiple Chronic Conditions is Common

Percentage of Major Chronic Disease in Isolation Among Women Aged 65 or Older: NHANES, 1999-2004

	Arthritis	Coronary Heart Disease	Chronic Lower Respiratory Tract Disease	Diabetes	Stroke
% with only 1 disease of 5 possible diseases	47%	17%	19%	17%	15%

Prevalence of Comorbidities in Adults with Coronary Heart Disease Aged ≥ 45 in NHANES, 1999-2004



Disparities in Multiple Chronic Conditions

Table 1 Characteristics of the 5% highest cost patients compared with the remaining population receiving VA care in 2010

	High-cost patients* n=261 699 %‡	Remaining population† n=4 972 295 %‡
Age, mean (SD)	63 (13)	63 (16)
<45	7	14
45–64	52	41
65+	41	45
Male sex		
Race/ethnicity		
White, non-hisp	70%	72%
Black, non-hisp	21%	14%
Hispanic		
Other		
Unknown		
Marital status		
Single	6%	5%
Married		
Separated/divorced		
Homeless during study		
Insurance status		
None	46	41
Major medical/HMO/PPO/champus/indemnity	8	18
Medicare/Medicare supplement	44	39
All other	2	2
Died during year of study		
Multimorbidity		
≥3 Chronic conditions	≥ 3 77%	26%
≥5 Chronic conditions		
≥3 Body systems affected by conditions	≥ 5 41%	7%
≥5 Body systems affected by conditions		
Annual healthcare costs, mean (SD), median		
Total	72 976 (64 040), 52 807	4267 (5252), 2257
Inpatient care	42 179 (58 679), 26 979	398 (2167), 0
Outpatient care	19 182 (30 269), 12 699	2840 (3433), 1566
Pharmacy services	4525 (13 141), 1738	812 (1499), 337
VA-sponsored contract care	7090 (20 490), 0	213 (1258), 0

*High-cost patients represent the 5% highest cost patients who received inpatient or outpatient care in the VA healthcare system between 1 October 2009 and 30 September 2010. Numbers represent percentages within each category unless otherwise indicated.

†p Values for t tests (mean age, costs) and χ^2 tests (all other characteristics) were <0.001 for all comparisons between high-cost patients and the remaining population.

‡Unless otherwise specified.

HMO, Health Maintenance Organization; PPO, Preferred Provider Organization; VA, Veterans Affairs.

What Do Clinicians Need to Best Care for the People with MCCs?

- Maximize use of therapies likely to benefit
- Minimize use of therapies unlikely to benefit or likely to harm
- An understanding of what outcomes matter most
- Incorporate patient preferences and values regarding burdens, risks, and benefits

Individualized Decisions

Do Screen/treat

Likelihood
of Benefit

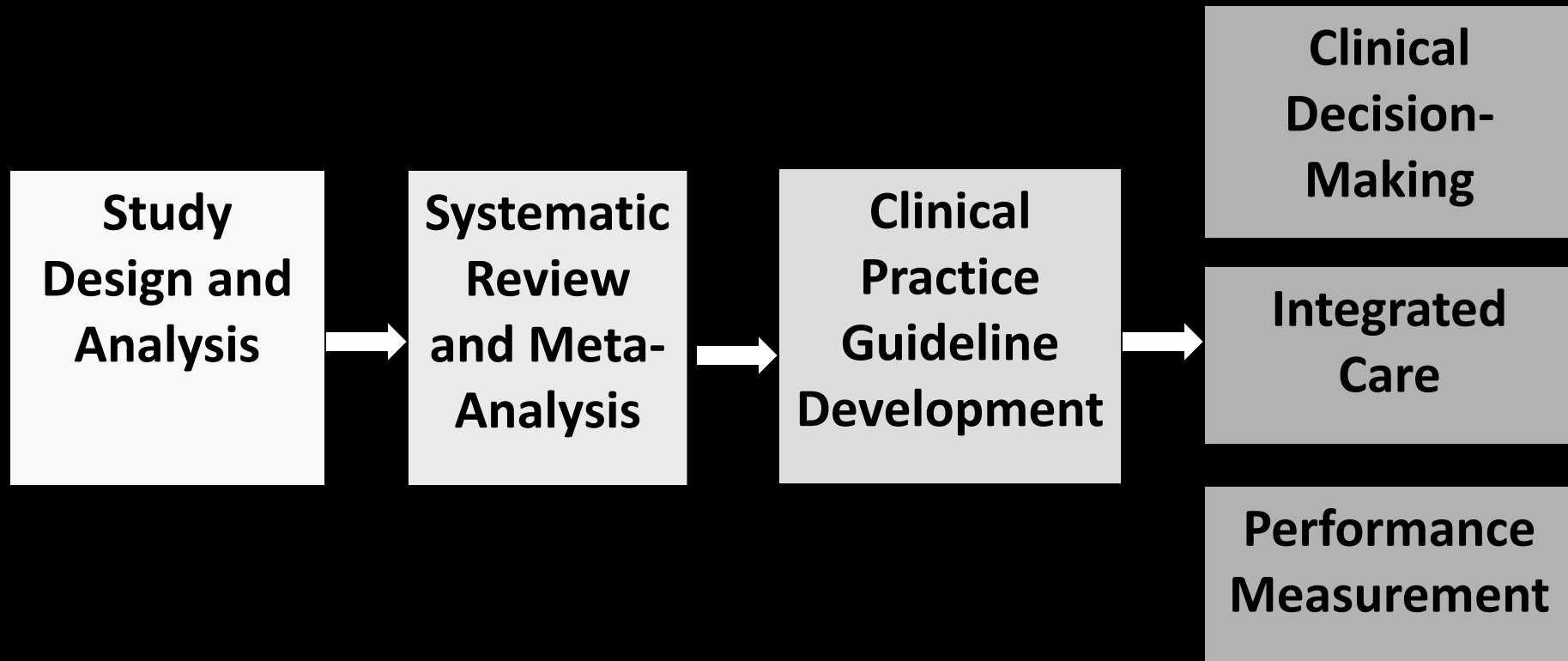


Don't Screen/treat

Likelihood
of Harm

Patient Preferences
(moveable fulcrum)

How can we better address people with MCCs across translational path?



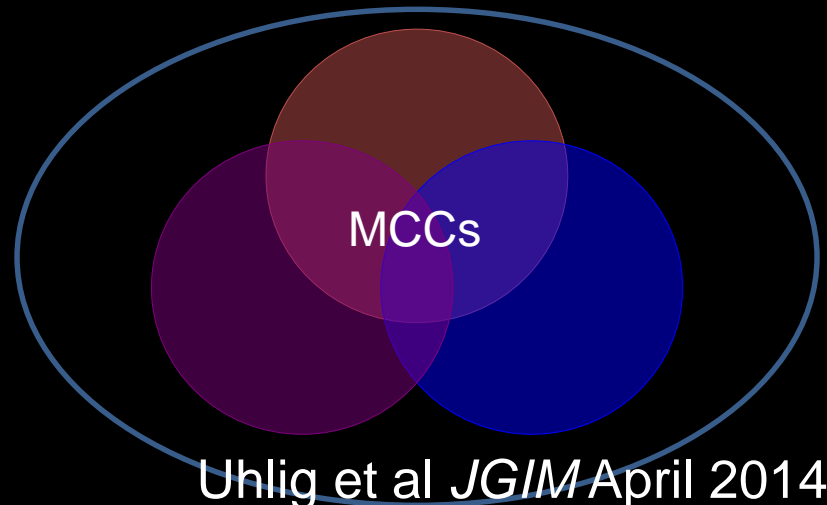
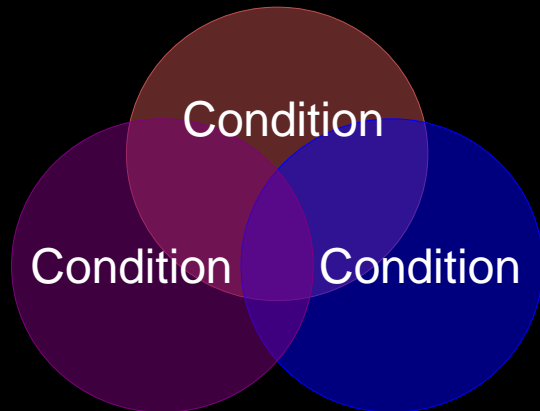
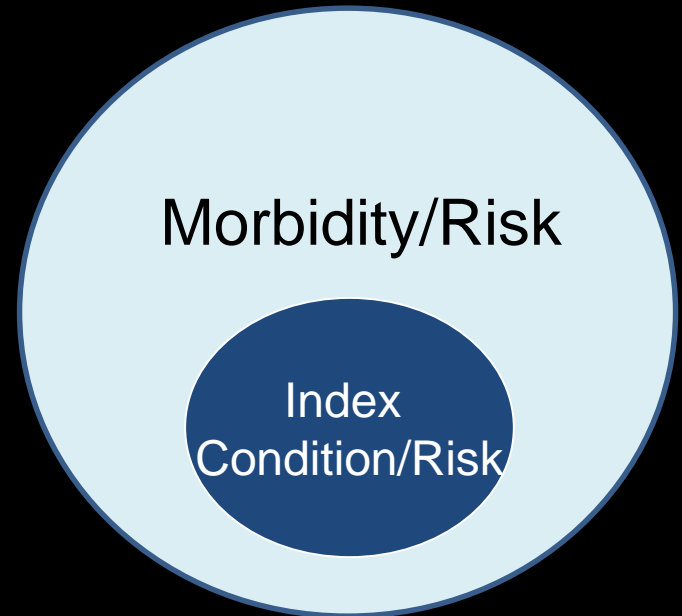
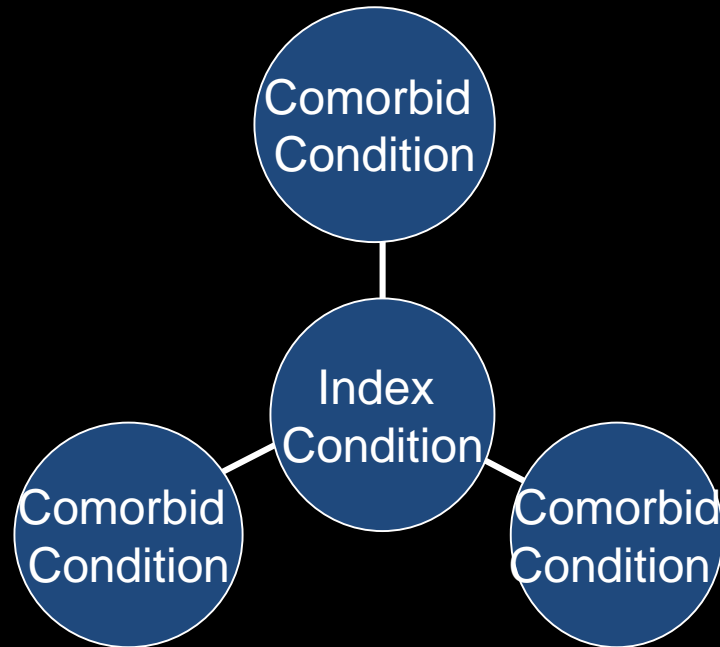
AHRQ R21, EPC Methods, NIH CTSA, NQF via HHS, NIA

JGIM Supplement, 2014. Boyd and Kent, Uhlig et al, Trikalinos et al, and Weiss et al.

What comorbidities matter?

- Prevalence
- Important interactions
 - condition-condition
 - condition-treatment
 - treatment-treatment

Choosing Topics: Focus



Outcomes

- Evaluating interventions requires meaningful outcomes
- No standard quality metrics or outcomes to guide care for the MCC population
- Minimal evidence associating recommended MCC care processes with outcomes
- New interest in outcomes that reflect patient-centered constructs

Slide courtesy of Elizabeth Bayliss

Measuring Outcomes in People with MCCs

- Deciding what outcomes matter to people
 - More likely to be less disease-specific
- Surrogates may have a different relationship to patient-important outcomes in people with MCCs
- Risks of outcomes may be different in people with MCCs
- A hard look at exclusion criteria may point to what outcomes should be measured

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In addition.... Outcomes relevant to MCCs should be:

- Relevant to patients
- Relevant to health care systems
- Relevant to clinicians
- Easy to collect, store, and extract
- “Validated”
 - Associated with other meaningful constructs
 - Sensitive to change over time
- Likely to be a function of the intervention

Two commonly used outcomes for studies of multimorbidity

- Disease-specific outcomes
- Utilization
 - Hospital
 - Emergency services
 - Primary care
 - Specialty care

Informing Patient-Centered Care of People with Multiple Chronic Conditions: PCORI Methods Project

With our stakeholder team of investigators,

- identify high-priority clinical questions and outcomes for people with MCCs, and
- synthesize the evidence base to support the development of clinical practice guidelines that can better inform patient-centered care for people with multiple chronic conditions.
- develop methods guidance

Example outcome domains important to complex patients

- Pain
- Function
- Energy
- Mortality
- Treatment burden
 - Medication side effects
 - Lifestyle modification
- Others....

Patient-reported outcomes (PROs)

- Assess function and well-being (and others)
- Relevant across conditions
- Collection is labor intensive
- Limited evidence associating PROs with clinical interventions
- Systematic collection for pragmatic trials requires substantial organization and infrastructure

Slide courtesy of Elizabeth Bayliss

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Addressing Comorbidities in PICO Questions

Population: Define conditions of interest

Intervention and Comparators: effect modification

Outcomes: choice & ranking of relevant outcomes

harms, burdens, benefits

non-disease specific and disease specific

linkage between surrogate and clinical outcomes

“Effect of treatment on the final outcome may be small even if there are strong associations between treatment and the surrogate and between the surrogate and the patient-important outcome”

Walter SD et al 2012 Sep;65(9):940-5

Timeframe for considering outcomes:

risk prediction

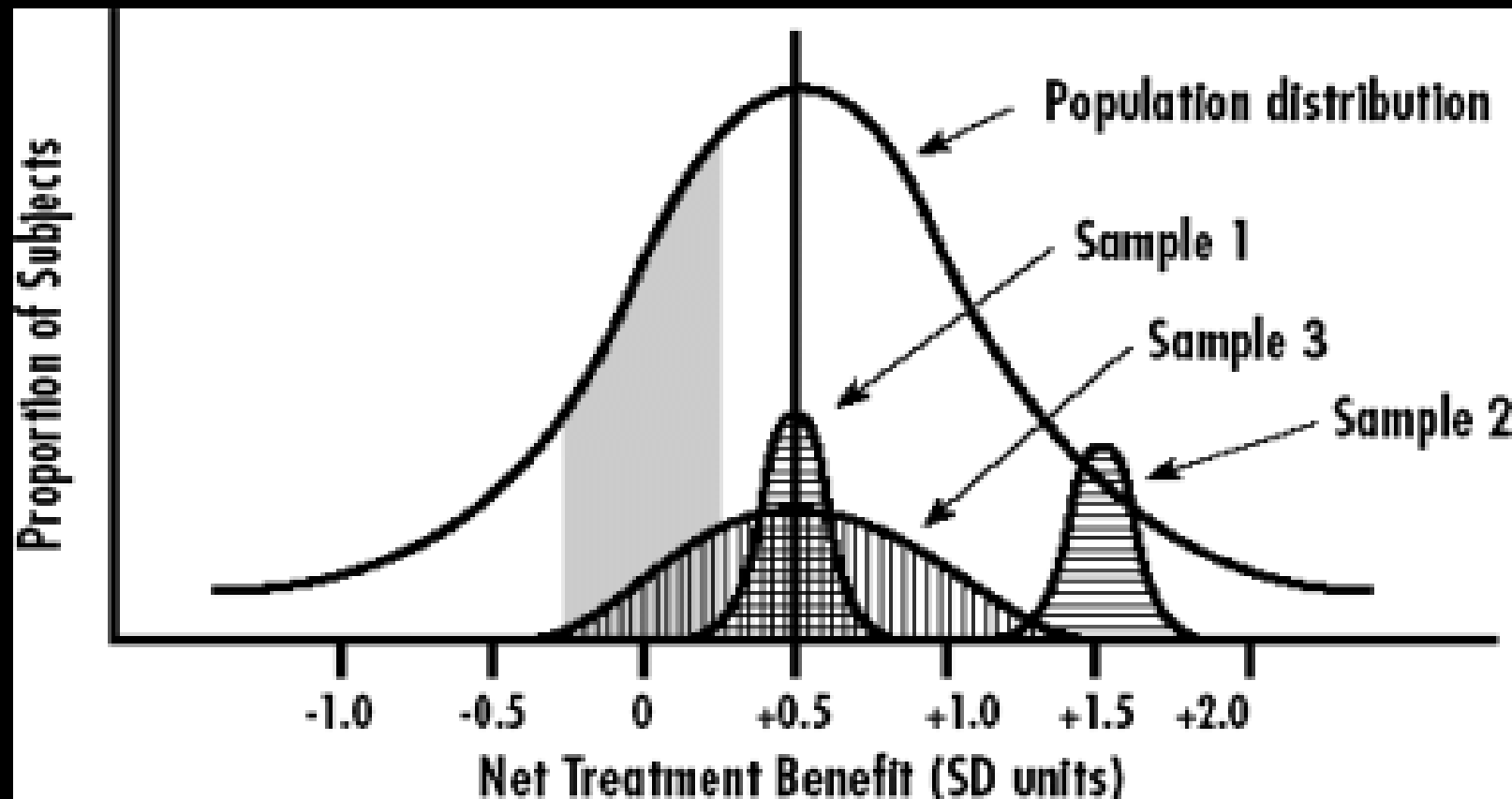
tradeoffs

Trikalinos et al JGIM April 2014,

Uhlig et al JGIM April 2014

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Sample 1: centered, but fails to reflect the diversity of the population

Sample 2: individuals who much more net benefit from the treatment than does average member of population

Sample 3: broadly representative of the population in terms of risk, responsiveness, and vulnerability

Measuring Outcomes in People with MCCs

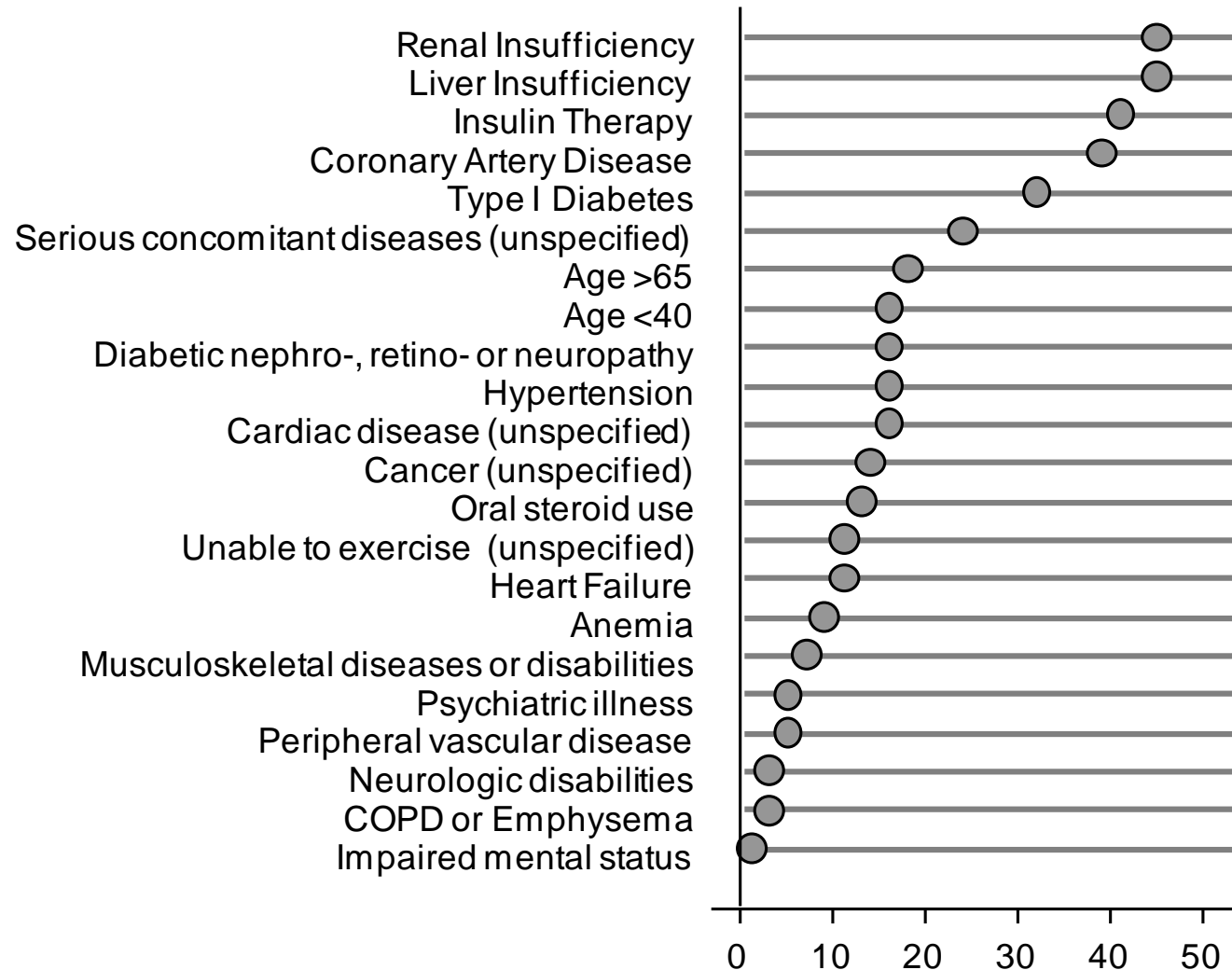
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How can inclusion/exclusion criteria help us understand what outcomes matter to people with MCCs?

- survey of trials reporting on drug and non-drug interventions in patients with four common chronic diseases
 - COPD, heart failure, stroke and type II diabetes mellitus.
- Not a systematic review
- based the selection of randomized controlled trials (RCTs) on 11 Cochrane Reviews that systematically identified and summarized RCTs
 - effectiveness of diuretics, metformin, anticoagulants, long-acting beta agonists alone or in combination with inhaled corticosteroids, lipid lowering agents, and the non-drug interventions exercise and diet for each of the four diseases

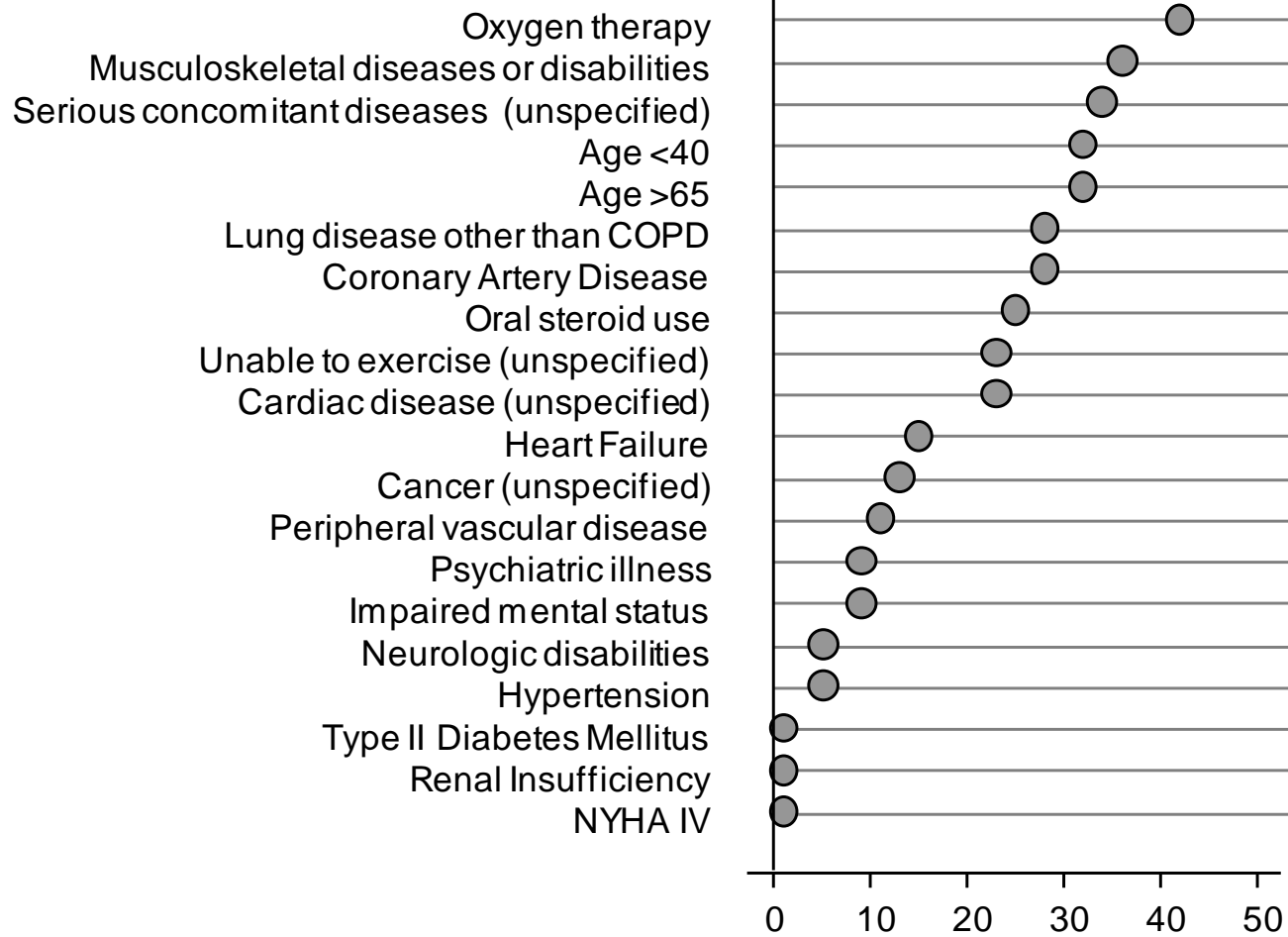
Diabetes trials

% of trials excluding patients with specific comorbidities



COPD trials

% of trials excluding patients with specific comorbidities



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Image: Brendan Smialowski for the New York Times, March 31, 2009

Thank you

cyboyd@jhmi.edu

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- PCORI Methods Portfolio
- Stakeholders and Co-investigators

cyboyd@jhmi.edu

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Puhan et al. Effective Health Care 2013

Giovannetti et al. AJMC 2013

Dugoff et al. J Healthcare Quality 2013

Yu et al BMC Medicine 2013

- National Quality Forum
 - Multiple Chronic Conditions Measurement Framework
 - http://www.qualityforum.org/Projects/Multiple_Chronic_Conditions_Measurement_Framework.aspx
- COMET (Core Outcome Measures in Effectiveness Trials)
 - <http://www.comet-initiative.org/>

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Yu et al Thorax 2014

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Goodman et al Ann Fam Med 2014

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Weiss et al JGIM 2014

Boyd and Kent JGIM 2014

Domains of high quality MCC care

Relative salience as quality measure	Measurement Feasibility	
	<u>Higher</u>	<u>Lower</u>
	Functional assessment Advance Directive on record Depression screen Medication reconciliation Annual flu vaccine System contact after care transition	Drug-Drug interactions Shared decision making Goal setting Assess social support Continuity of care Tailored communication of treatment plans Inappropriate use of care** (e.g. over use of screening colonoscopy, pap, PSA) Redundant or wasteful care** (e.g. duplicate tests)

**Requires specific denominator.

How to Evaluate the Evidence Base

- patients representative of the actual population (often multimorbid)

- the number of trials with explicit age exclusions ↓

While trial enrollment of older patients ↑,

- still well below levels that older patients are affected

Lee PY et al. *JAMA*. 2001;286:708-713, Van Spall et al *JAMA* 2006

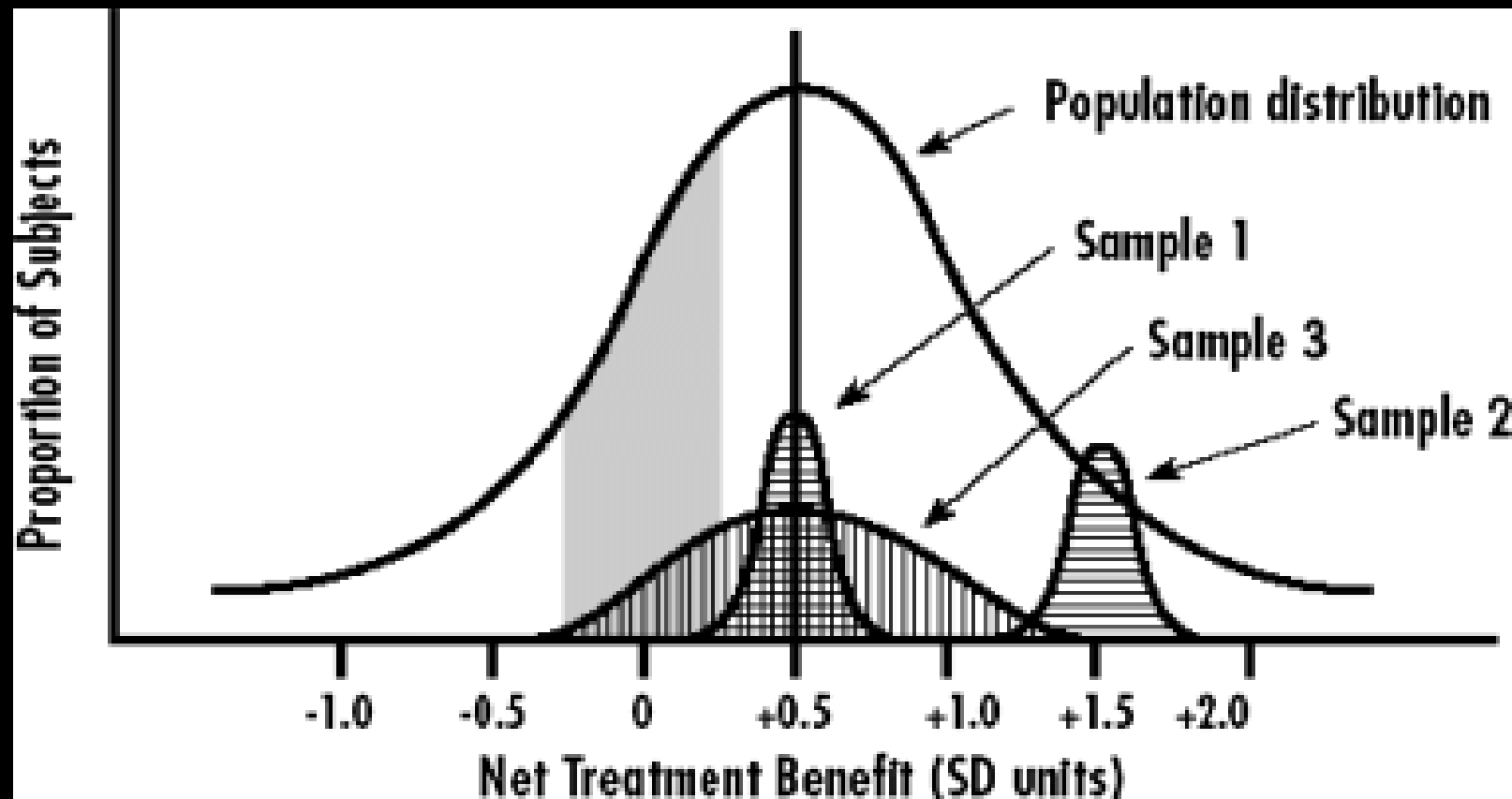
- number of heart failure trials excluding participants with specific comorbidities ↑ from 1985 to 1999

Heiat A, et al *Arch Intern Med*. 2002;162:1682-1688.

- exclusion/inclusion criteria less important than who is the “average” patient in a trial

- Kravitz R et al. *Milbank Quarterly* 82: Dec 2004

Kent and Kitsios, *Trials* 2009



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