Clinical Effectiveness and Decision Science Advisory Panel Meeting

November 30th, 2018

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Housekeeping

- **Today's webinar is open to the public and is being recorded**
  - Meeting materials can be found on the PCORI website www.pcori.org
  - Comments may be submitted via chat; No public comment period is scheduled
- Please remember to speak loudly and clearly into a microphone. State your name and affiliation when you speak.
- Please avoid technical language in your discussion.

Conflict of Interest Statement

Disclosures of conflicts of interest of members of this Committee are publicly available on PCORI's website and are required to be updated annually. Members of this Committee are also reminded to update conflict of interest disclosures if the information has changed by contacting your staff representative.

If this Committee will deliberate or take action on a manner that presents a conflict of interest for you, please inform the Chair so we can discuss how to address the issue. If you have questions about conflict of interest disclosures or recusals relating to you or others, please contact your staff representative.

Agenda Overview

Time	Duration	Agenda Item
9:00 – 9:30 am	(30 min)	**Welcome and Introductions**
9:30 – 9:45 am	(15 min)	**Overview and Meeting Activities**
9:45 – 10:45 am	(1 hour)	**Presentation & Discussion – Dr. Barbara Biesecker**
10:45 – 11:00 am	(15 min)	**BREAK**
11:00 am – 12:00 pm	(1 hour)	**Presentation & Discussion – Dr. Danielle Loeb**
12:00 – 12:45 pm	(45 min)	**LUNCH and Acknowledgements**
Small/Large Group Discussion Sessions		
12:45 – 1:00 pm	(15 min)	**Orientation to Small Group Discussions**
1:00 – 2:00 pm	(1 hour)	**Small Group Sessions**
2:00 – 2:15 pm	(15 min)	**BREAK**
2:15 – 3:15 pm	(1 hour)	**Large Group Discussion**
3:15 – 3:30 pm	(15 min)	**Adjourn**

Welcome & Introductions

David Hickam, MD, MPH
Program Director, CEDS
Patient Centered Outcomes Research Institute

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Welcome from PCORI

David Hickam, MD, MPH
Program Director, Science

Department: Clinical Effectiveness and Decision Science

David Hickam, MD, MPH, is a Program Director of the Clinical Effectiveness and Decision Science program at the Patient-Centered Outcomes Research Institute (PCORI). He is responsible for developing PCORI's research program that evaluates comparisons among alternative clinical strategies, methodologies, and communication and dissemination research.

Panel Member Introductions

- Rafael Alfonso-Cristancho, MD, MSc, PhD
- Ashish Atreja, MD, MPH
- Nancy Blake, PhD, RN, NEA-BC, CCRN
- Janice Buelow, RN, PhD, FAAN
- Zeeshan Butt, PhD
- Giovanna Devercelli, PhD
- Neela Goswami, MD, MPH
- Felix Fernandez, MD, MSc
- Lawrence Goldberg, MD
- Melissa Hicks
- Jeff Hersh, MD, PhD
- Kate Houghton, MPA
- LaRita B. Jacobs, MA
- Emilie Johnson, MD, MPH
- Robin Karlin, MS
- Clifford Ko, MD, MS, MSHS
- Susan Lin, ScD, OTR/L, FAOTA
- Lauren McCormack, PhD, MSPH (Chair)
- Helen Osborne, M.Ed., OTR/L
- Ruth M. Parker, MD, MACP
- Nancy Perrin, PhD
- Michael Pignone, MD, MPH, FACP
- Janice T. Radak
- Frank Rider, MS
- Andrew Rosenberg, JD, MP
- Michael Schneider, DC, PhD
- Sandi W. Smith, PhD
- Danny van Leeuwen, MPH, RN, CPHQ (Co-Chair)
- Robert J. Volk, PhD
- Maureen White, MD, MS, MBA
- Nancy White, DPT
- Cornell Wright, MPA

Overview & Activities

Lauren McCormack, PhD, MSPH
Danny van Leeuwen, Opa, RN, MPH

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Overview and Activities

Lauren McCormack, PhD, MSPH
Vice President, Public Health Research Division, RTI International
Representation: Researcher
CEDS Advisory Panel Chair

Danny van Leeuwen, Opa, RN, MPH, CPHQ
Owner, Health Hats
Representation: Patients, Caregivers, and Patient Advocates
CEDS Advisory Panel Co-Chair

Overview - Previous CEDS Meeting Spring 2018

- The day-long meeting was devoted to three major activities:
  - Presentations that provided historical context on the CDR and APDTO funding portfolios and highlighted some key initiatives and activities completed by the former CDR and APDTO panelists;
  - A review of the PCORI methodology standards and discussion of ways to assure the scientific integrity of patient centered outcomes research though identifying and preventing methodological problems; and
  - Active discussions about priorities for PCORI's research programs in future years, with a focus on strategies to maximize the usefulness of PCORI-funded research projects.

Overview – Spring 2018 Discussions

Panelists broke into small group sessions, they were asked to reflect on past initiatives of the former panels and consider the following questions:

1. Based on the themes of the portfolio of funded projects, what are the priorities for future directions, areas in need of further growth, important gaps and emerging trends in American health care?
2. Are there areas of overlap between the CDR and APDTO portfolios that should be considered and/or combined when thinking about future priorities?
3. What future research priorities or areas of focus would address lessons learned, methodological challenges, and the overall value of our funded research?
4. Are there other types of portfolio analysis that would be useful in helping us set future research priorities?

Overview – Spring 2018 Topics, Themes and the Future

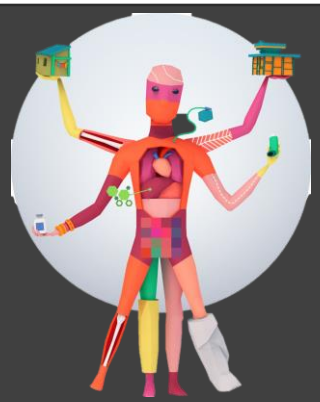
- From the notes captured during the breakout sessions and large group discussion, a list of topics emerged.
- From this list, two topics were identified as highest priority for discussion at this meeting as well as an overarching theme within the context of CEDS
- Theme:
  - Evidence-based decision making
- Sub-theme:
  - addressing the various levels of uncertainty as they relate to evidence-based decision making
- Topics:
  - Genomics/personalized medicine
  - Complex patients

Overview – Present CEDS Meeting Fall 2018

Evidence-based Decision Making

Genomics / Personalized Medicine

Uncertainty around whether to screen and the results received.



Complex Patients

Integration of physical and behavioral health and how uncertainty is addressed during treatments and disease.

Public Health and Healthcare

Present discussion → **Future impact**

Today's meeting

We have taken those topics and themes that emerged from the May 2018 meeting, and have brought them to the forefront of discussion for the activities today:

- Presentations in the field of genomics/personalized medicine and complex patients from:
  - Dr. Barbara Biesecker
  - Dr. Danielle Loeb
- Small group breakout sessions
- Large group discussion

Communication of Clinical Uncertainties: Results form a Systematic Literature Review

Barbara Biesecker, PhD, MS
Distinguished Fellow, RTI International

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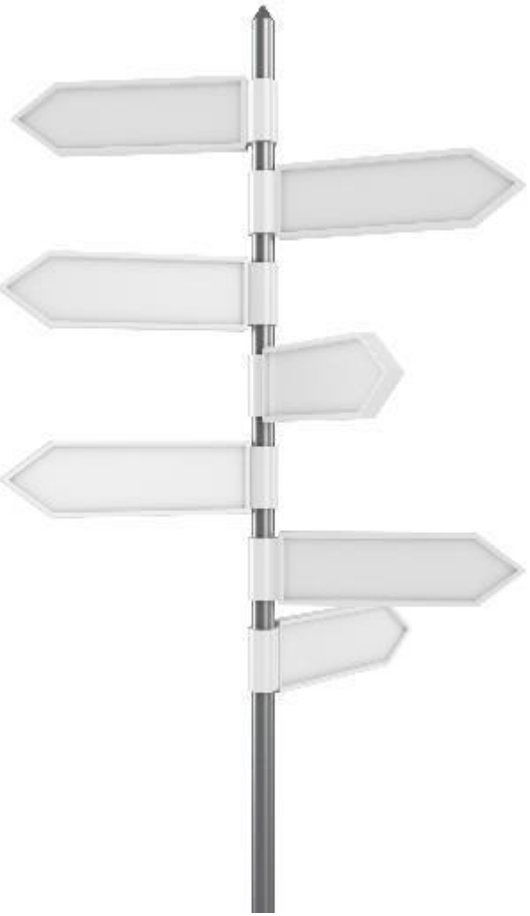
1.

Evidence to inform best practices in communication of clinical uncertainties is a recognized research gap

Why is it Important to Understand how Uncertainties are Communicated

- How providers communicate uncertainties may influence patient perceptions
- Theory suggests patients perceive clinical uncertainties as threat or opportunity
- The interaction between providers and patients around uncertainties may affect health-related outcomes
- The most effective ways to communicate clinical uncertainties are unknown



PCORI's Mission and Strategic Goals

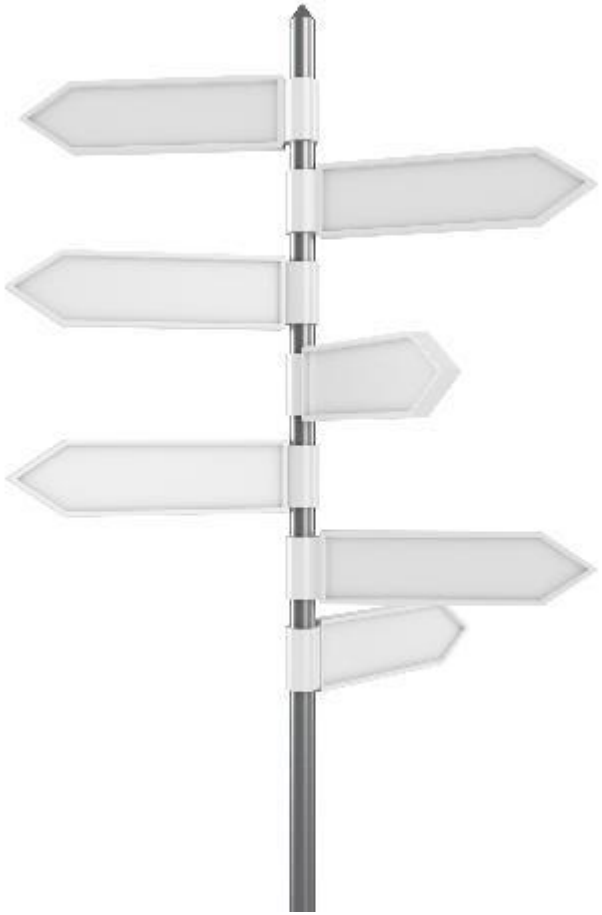
PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from **research guided by patients, caregivers, and the broader healthcare community.**

Our Strategic Goals:

- Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions
- Speed the implementation and use of patient-centered outcomes research evidence
- Influence research funded by others to be more patient-centered

Communicating Uncertainties

- Pervade all aspects of medicine and clinical care
- Patients and clinicians grapple with uncertainty
- Individuals manage uncertainties differently
- Perceptions of uncertainty affect health outcomes
- Evidence is needed to maximize positive patient outcomes and to help establish best practices



Uncertainties Defined

Babrow and colleagues published a taxonomy of uncertainty in 1998 in *Health Communication* outlining five forms of uncertainty in medicine.

1) Complexity—arising from the multicausality, contingency, reciprocity, or unpredictability of a phenomenon
2) Qualities of information—its clarity, accuracy, completeness, volume, ambiguity, consistency, applicability, or trustworthiness
3) Probability—referring to one's belief in a specific probability or a range of probabilities
4) Structure of information—i.e., its order or integration
5) Lay epistemology—people's beliefs about a phenomenon.

Uncertainties Defined

- Uncertainty is the subjective perception of ignorance (Han, et al, 2011).
- Uncertainty has many conceptual meanings not often distinguished.
- Uncertainty is not a monolithic phenomenon.
- There are multiple varieties of uncertainty, which may have distinct psychological effects and warrant different courses of action.

Han and Colleagues' Taxonomy of Medical Uncertainties:

Dimensions:

Source-Probability, Ambiguity and Complexity

Issues-Scientific, Practical and Personal

Locus-Stakeholders

PCORI Stakeholders

2.

Research Question:

What does existing evidence tell us about communicating clinical uncertainties?

Systematic Literature Review (Ongoing)

We conducted a SLR of studies that assess communication of clinical uncertainties

Inclusion Criteria:

- Data on provider communication
- Quantitative and qualitative methods
- Data ascertained by self-report, observation and coding/analysis of communication
- Any clinical setting

Exclusion Criteria:

- Data on patient communication (to be analyzed in the future)
- Commentaries/Clinical Guidelines/Best Practices

Databases searched

Searches by two librarians were executed at different institutions using same search terms.

Search Terms:

- Communication of uncertainty about health
- Communication of uncertainty interventions
- Conveying uncertainty in medicine
- Communication of uncertainty about health risk/illness

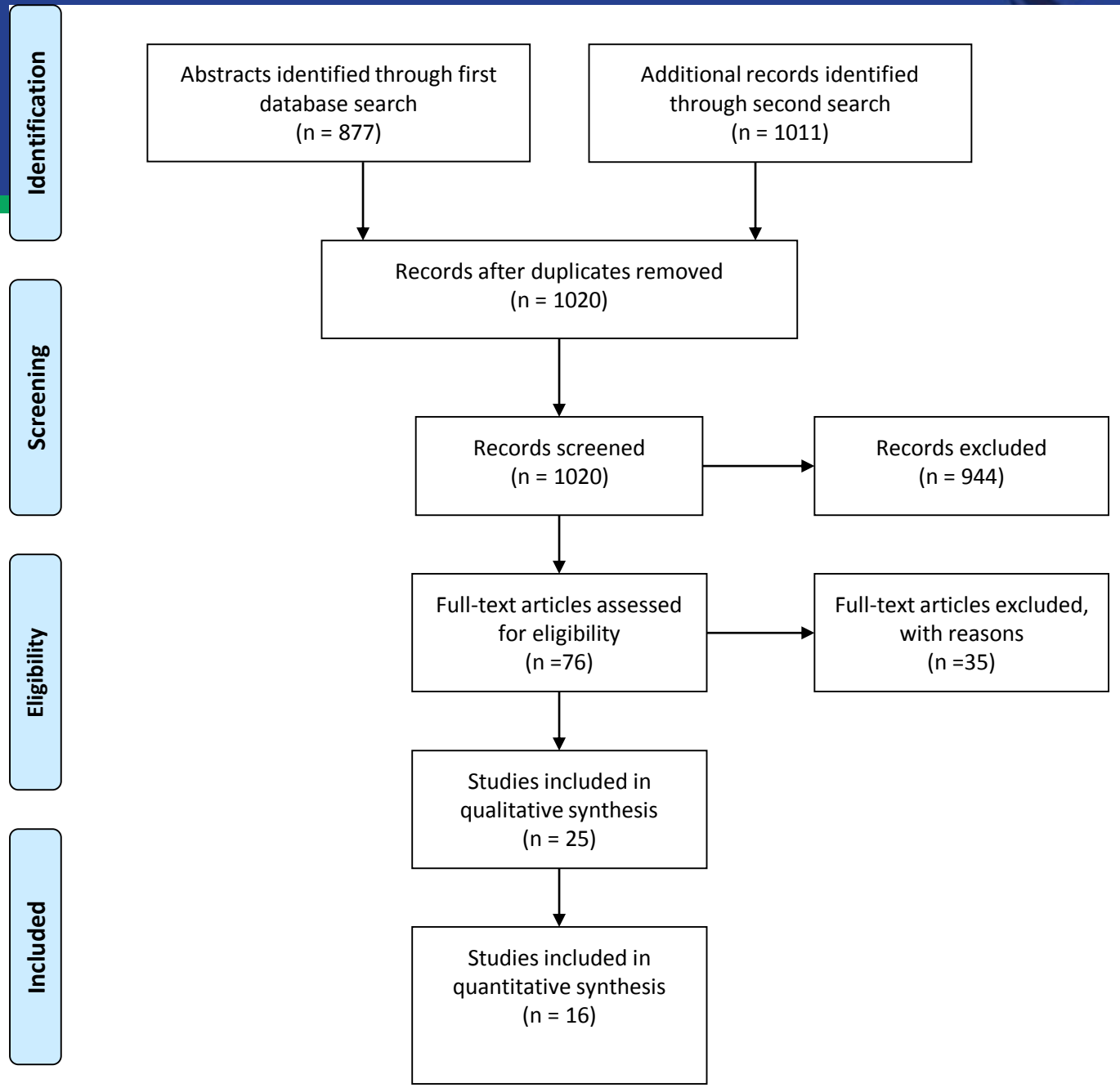
Databases:

- PubMed, Web of Science, PsycINFO, Communication Source and Cochrane Reviews

Dates:

- Studies published from 1/1/1990—6/1/2018

PRISMA Flow Diagram



Review of Search Outcomes

1020 abstracts were identified by the search

Two investigators independently assessed whether each abstract met inclusion criteria/discrepancies were deliberated and then reconciled by consensus

41 abstracts were selected

3656 providers and 4530 patients were assessed within these 41 studies

Final Studies Selected for Review:

- 25 qualitative studies
- 16 quantitative studies

Quantitative Studies Selected (N=16)

- One was an **intervention study** to train physicians in skills to communicate uncertainty effectively
- Eight were **observational studies** of communication
- Seven were **self-reports** of communication of uncertainty between providers and patients

Settings included:

- Primary Care
- Oncology-often advanced cancer care
- Emergency Medicine

Quantitative Outcomes

Outcomes from these studies fell into four categories:

- Providers avoidance of communicating clinical uncertainties
- Effects on patient satisfaction when providers do communicate uncertainty
- The relation between provider characteristics and communication of uncertainty
- The types of uncertainty communicated

Quantitative Outcomes

Five studies demonstrated provider avoidance of communicating uncertainty

- This was associated with less knowledge or confidence in understanding the uncertainties
- In three studies where factors associated with avoidance were not assessed

Patients were less satisfied with provider communication of uncertainty when they did not expect it and more satisfied when they did.

Provider characteristics that led to less communication of uncertainties were:

- ambiguity aversion
- empathy
- decisional conflict about treatments
- discomfort with scientific uncertainty
- anticipation of negative responses from patients

Quantitative Outcomes

Types of uncertainties communicated:

- Communication of aleatory (intrinsic) uncertainty occurred more often than epistemic (limited data)

[This may reflect greater provider comfort in conveying what cannot be changed]

- Verbal conveyance of uncertainty by providers was more threatening to patients than nonverbal

Qualitative Studies Selected (N=25)

- Eleven were analyses of recorded clinical **sessions**
- Ten were analyses of recorded **interviews** with providers
- Three were analyses of **focus groups**
- One was an **ethnographic** analysis
- Findings were analyzed to describe communication or management of clinical uncertainties

Settings included:

- Primary Care
- Oncology-general and cancer genetic counseling
- Medical genetics
- Obstetrics
- Cardiology
- Critical care
- Acute stroke care

Qualitative Outcomes

Outcomes from the qualitative studies fell into the same four categories and more:

- Recognition of the challenges in communicating uncertainties
- Using a strategy of pairing good news with uncertain or bad news to promote a positive frame
- Prioritizing information over uncertainties
- Partnering with patients around uncertainties and decision-making
- Relational factors leading to more expressions of uncertainty
- Prognostic change prompting discussion of uncertainties

Self-reports of communicating clinical uncertainties exceeded direct evidence.

3.

State of the Science is Chaotic

Hypotheses Derived from Initial Data

Hypothesis 1

- Physicians' practices of pairing uncertain clinical information with relatively good information leads to more realistic perceptions of uncertainties

Hypothesis 2

- The potential health-threatening nature of uncertainties and provider characteristics interact to lead to avoiding communication of uncertainties

Hypothesis 3

- Relational factors between providers and patients enhance communication of clinical uncertainties

Hypothesis 4

- Providers more often communicate aleatory uncertainties that cannot be changed as it is less threatening to perceptions of their competence

Study Quality Limiting

PRISMA CHECKLIST PLUS

- Risk of Bias
- Less Rigorous Methods-descriptive cross-sectional and small
- Underpowered to assess associations
- Variety of settings where the implications of uncertainties vary widely

Limitations to Data Syntheses

- Variations in the study design and outcomes preclude meta-analysis
- Many of the findings are exploratory and inadequate even to generate hypotheses
- Not all clinical specialties are represented by the studies
- Inconsistency in clinical uncertainties
- Studies of patient perceptions of communication of uncertainties were not included

Patient-Reported Communication of Uncertainties

Next Effort: Conduct a Systematic Literature Review from Patient Perspective

- Patient's experiences in recorded sessions when uncertainties are communicated
- Patient-reported outcomes from clinical uncertainties
- Patient preferences—Study of prostate screening
- Patient characteristics that affect perceptions of uncertainties
- Role of clinical uncertainties in patient outcomes

PCORI Pays Particular Attention to Specific Populations

- Racial and ethnic minorities
- Older adults
- Low-income
- Residents of rural areas
- Women
- Children
- Patients with low health literacy/numeracy and limited English proficiency
- Lesbian, gay, bisexual, transgender (LGBT) persons
- Veterans and members of the armed forces and their families
- Individuals with special healthcare needs, including individuals with disabilities, individuals with multiple chronic diseases, individuals with rare diseases, and individuals whose genetic makeup affects their medical outcomes

4.

Better Research Through Engagement

Communication of Uncertainties

A Topic Area Consistent with PCORI's Pragmatic Studies

- Patient perceptions of uncertainties affect their psychological wellbeing and health
- Patient resources vary in their interest and responses to uncertainty
- Patient-centered decisions and interactions with providers are affected
- Prioritizing studies that test strategies to communicate uncertainties may lay the groundwork for more extensive research on interaction effects and positive health outcomes

Thank You!

RTI Investigators:

Beth Boyea, MS

Holly Peay, MS, PhD

Ryan Paquin, PhD

Megan Lewis, PhD

BREAK
10:45 – 11 AM

Up Next: Presentation & Discussion
Danielle Loeb, MD, MPH

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Potential Impacts of Patient Complexity on Medical Decision-making and Implications for Research

PCORI Clinical Effectiveness and Decision Science (CEDS) Advisory Panel

Danielle Loeb, MD, MPH
Assistant Professor of Medicine
University of Colorado School of Medicine

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Agenda

Definitions: Comorbidity, Multimorbidity, Complexity

Role of Mental Illness in Complexity

Why it Matters

Measurement issues

Re-Organizing Care

- Complex Adaptive Systems
- Patient–centered Approaches

Gaps in Research

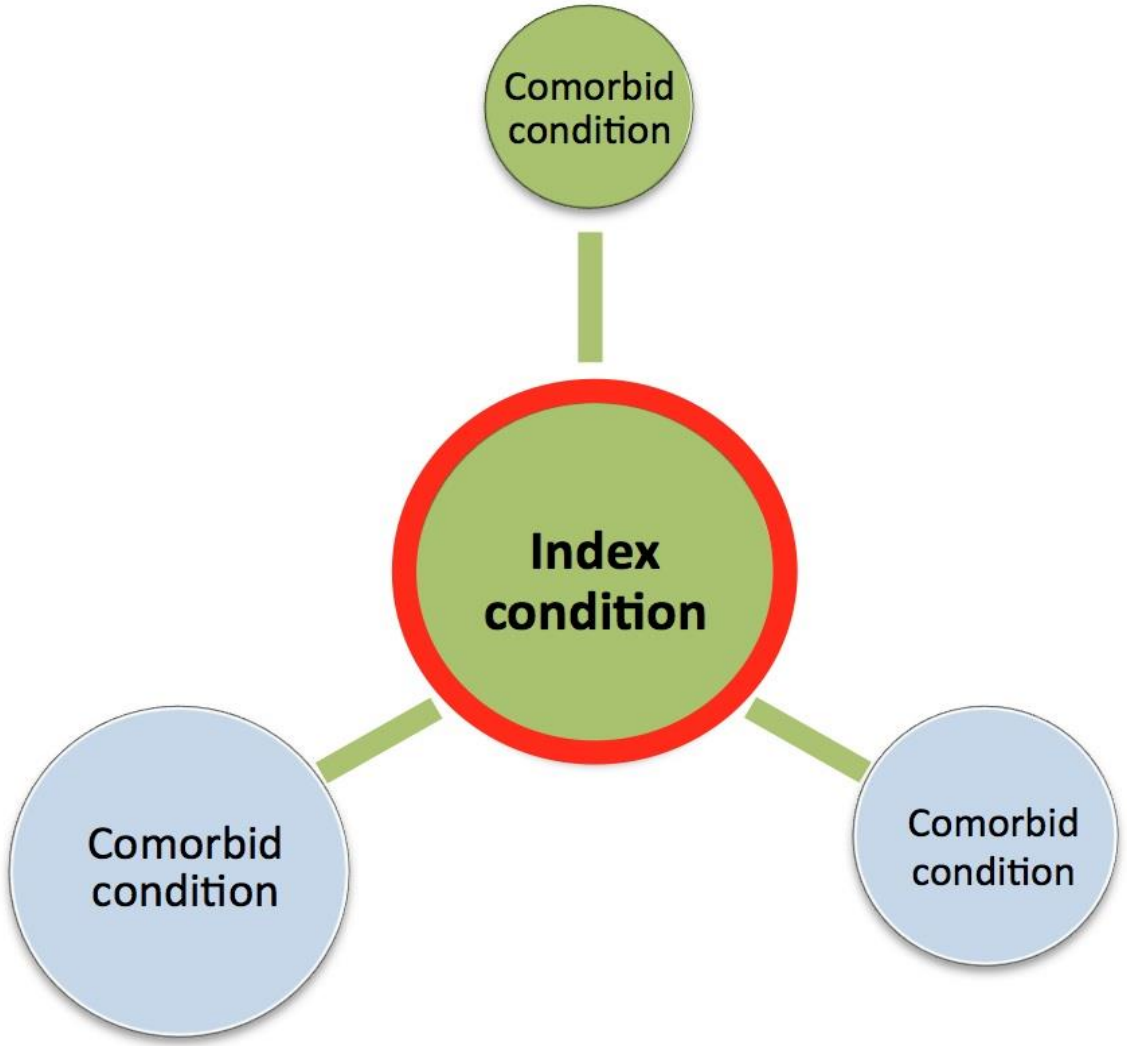
Role of PCORI?

Definitions

Comorbidity
Multimorbidity
Complexity

Comorbidity

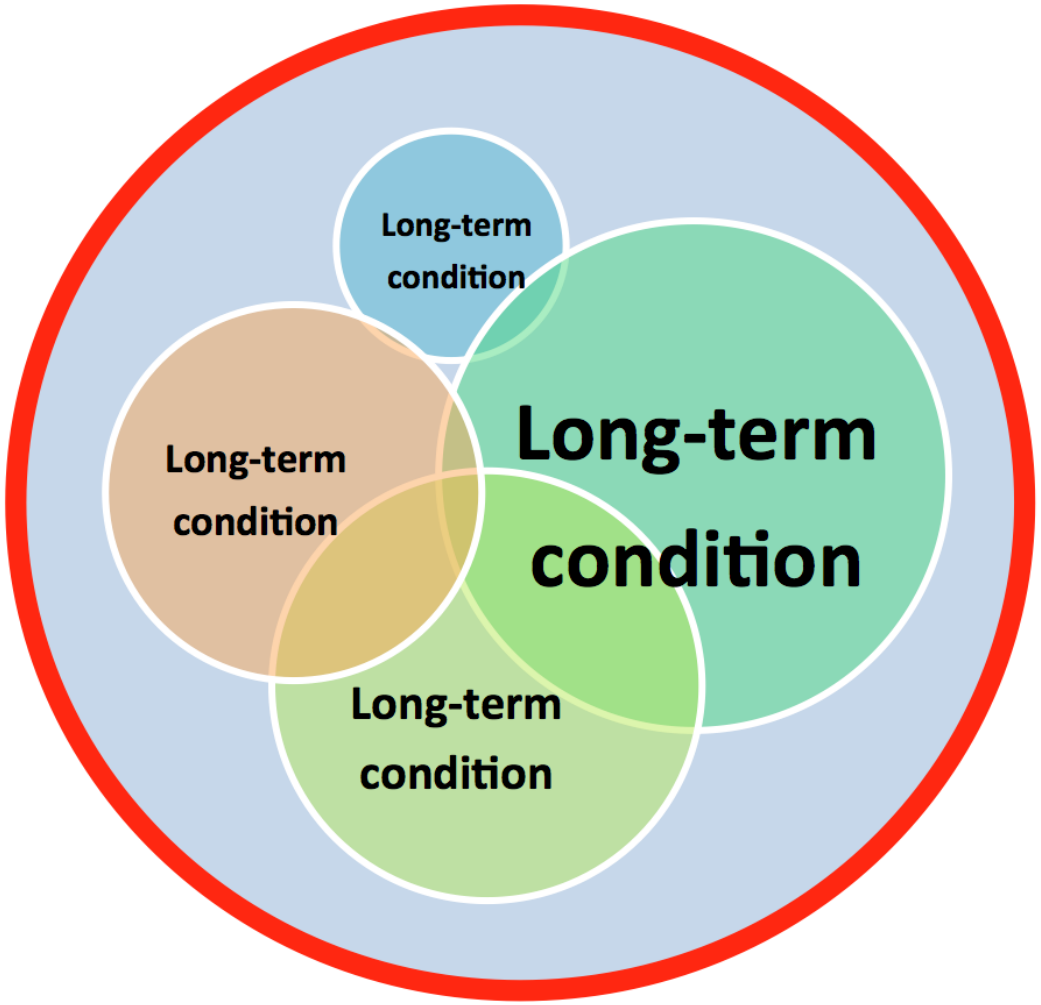
- Index Disease + One or More Comorbid Condition or Diseases Affecting Its Course and Treatment
- Diseases may affect the course and treatment of the index disease to varying degrees



Boyd and Martin. Public Health Reviews, Vol. 32, No 2, 451-474. 2011.
Mercer, et.al. 2014; Chichester: John Wiley & Sons, Ltd.

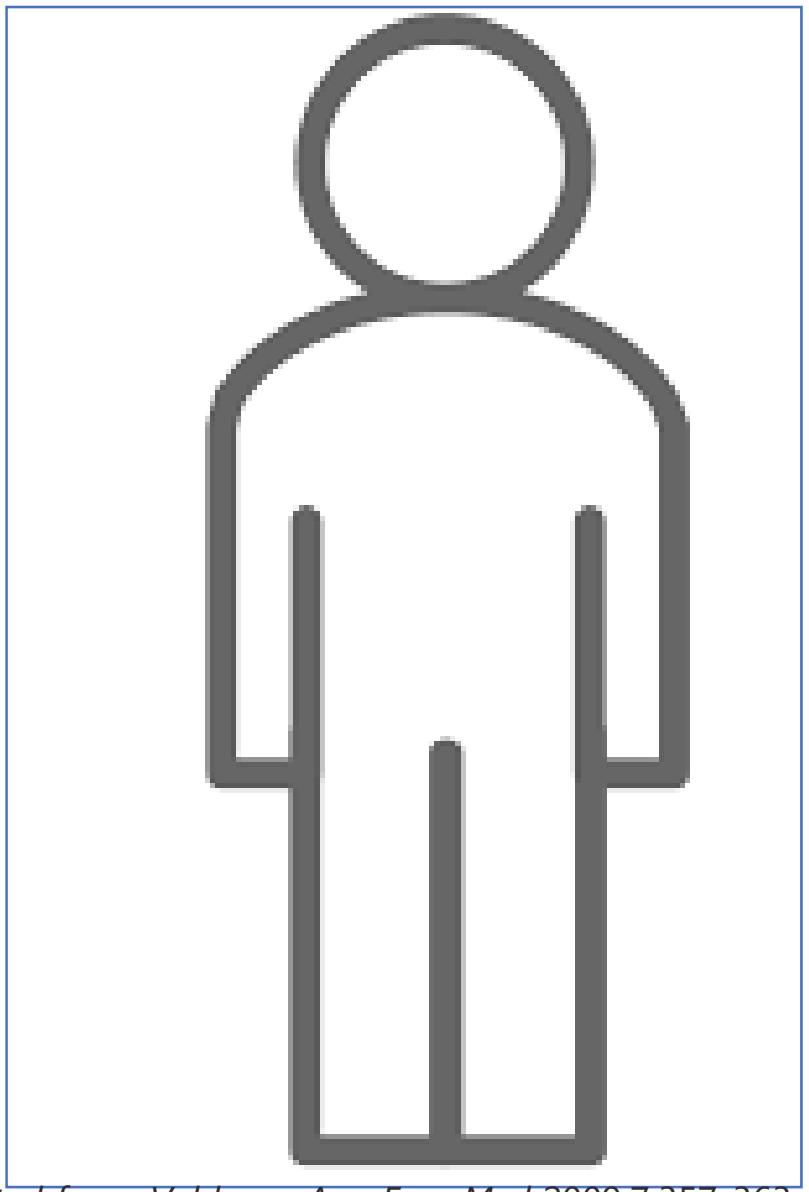
Multimorbidity

- Conditions include traditional diseases
- May reflect conditions such as disability, falls, hearing impairment
- Conditions may overlap to varying degrees
- Intersecting conditions exist within a context of biological health and reserves
- Social, educational, cultural, economic and environmental circumstances will affect management of the multimorbid conditions
- Individual values and priorities for their life and healthcare



Boyd and Martin. Public Health Reviews, Vol. 32, No 2, 451-474. 2011.
Mercer, et.al. 2014; Chichester: John Wiley & Sons, Ltd.

Model of Patient Complexity



Disease 1 (index)

Disease 2

. . . . .

Disease n

Comorbidity (of index disease)

Multimorbidity

Sex

Age

Frailty

Other health related individual attributes

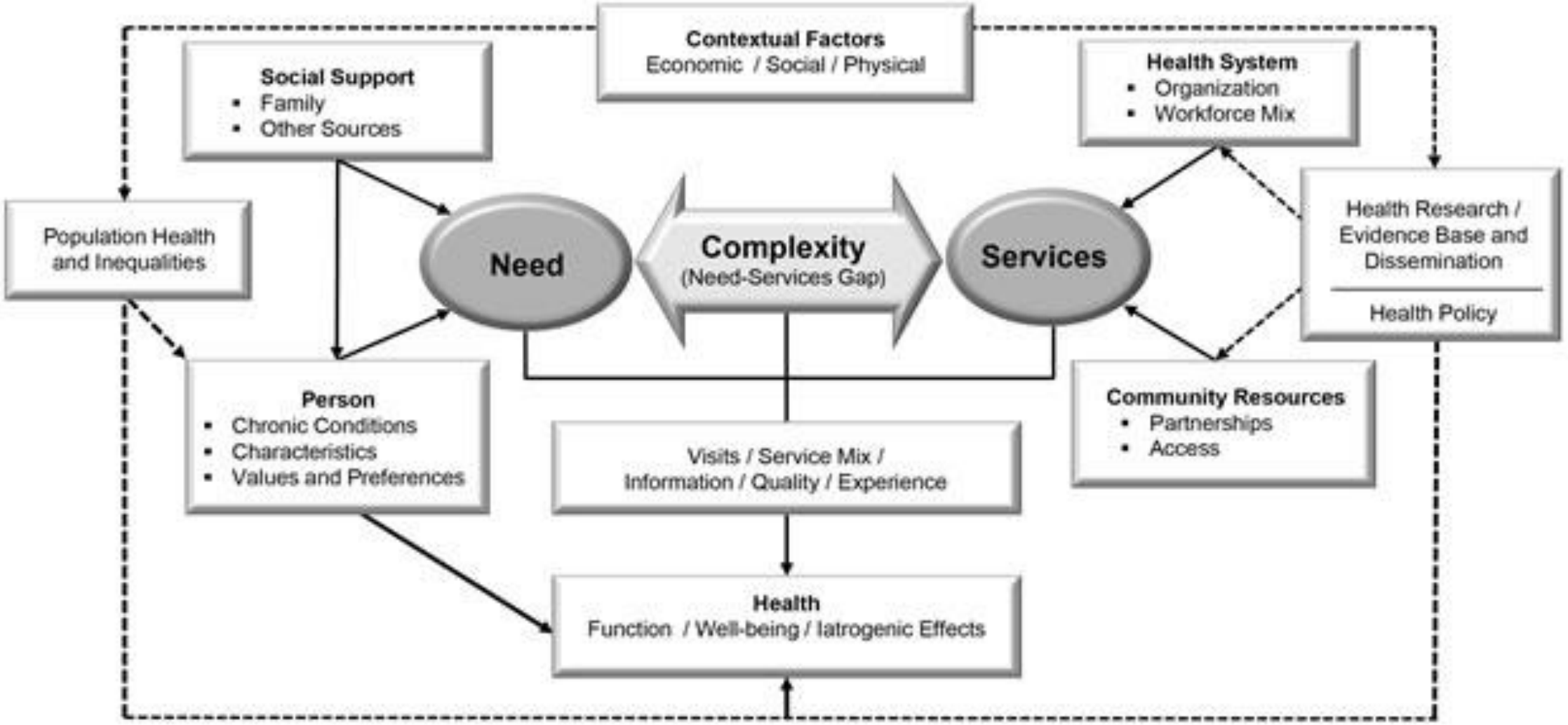
Morbidity Burden

Non-health related individual attributes

Patient's Complexity

Adapted from: Valderas, Ann Fam Med 2009;7:357-363.

AHRQ Conceptual Model of Complexity



Grembowski D, Schaefer J, Johnson KE, et al. *Med Care*. Mar 2014;52 Suppl 3:S7-S14.

Role of Mental Illness in Complexity

A Qualitative Study

Role of Mental Illness in Complexity: A qualitative study

- Qualitative study of primary care physician experiences of managing complex patients using semi-structured in-depth interviews
- Internal medicine primary care physicians
- Two university clinics and three community health clinics associated with the University of Colorado School of Medicine
- Participants were given a working definition of complexity

Complexity Defined

A "complex patient" is defined as a person with **two or more chronic conditions**, where each condition may influence the care of the other condition.

Other factors, such as age, race, gender and psychosocial issues, may also influence the morbidity associated with this patient's chronic conditions.

Based on AHRQ FOA: Optimizing Prevention and Healthcare Management for the Complex Patient (R21)

Demographics

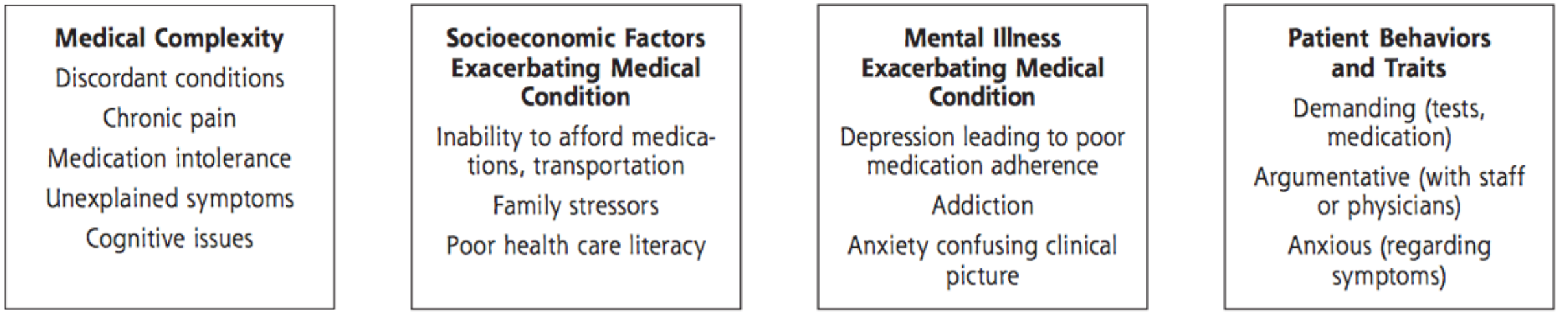
Participant Characteristics (n=15)	
Age in y, mean (range)	38 (29-52)
Female, n (%)	9 (60)
Race/ethnicity, n (%)	
White Non-Hispanic, n (%)	12 (80)
Asian, n (%)	2 (13)
White Hispanic, n (%)	1 (7)
Site of Practice	
Community Health v. University, n (%)	7 (47)
Time since residency completion in y, mean (range)	8 (<1-24)
Time in primary care practice in y, mean (range)	7 (<1-24)

PCPs described highly complex patients with multidimensional needs

There is a 52 year old guy who I've seen for a couple of years. He has diabetes, hypertension, gout, hyperlipidemia, peptic ulcer disease, asthma. His med list is at least 2 pages long. He was homeless and had depression and schizoaffective for his mental illnesses. When I first saw him, he had only been out of jail for a couple weeks…

Provider view of Complexity

Figure 1. Typology of complex patients.



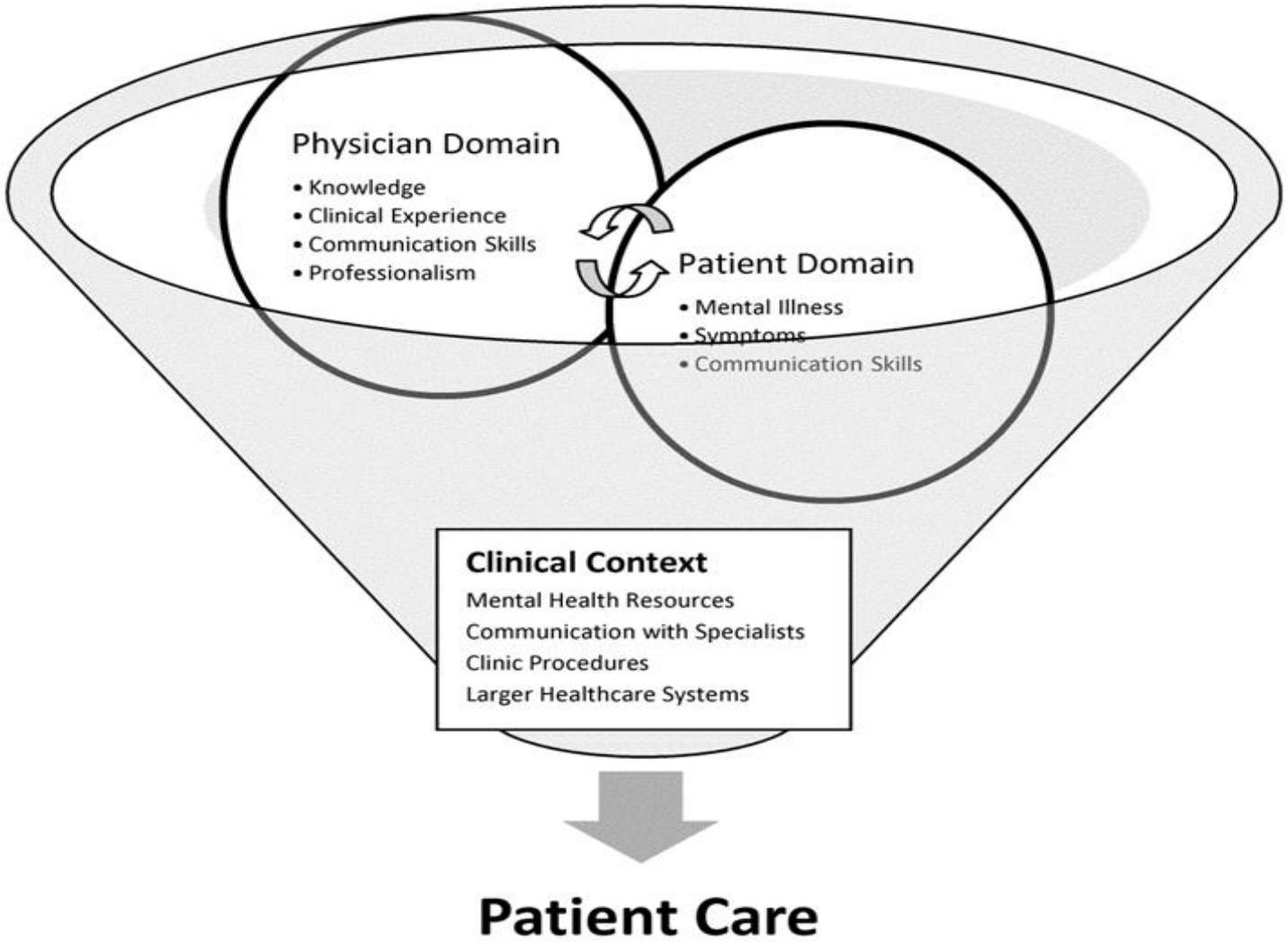
Loeb, et.al., *Ann Fam Med.* Sep 2015;13(5):451-455.

Role of Mental Illness in Patient Complexity

I think if the mental health problem is active, then that makes treating all the other medical problems that much more difficult…They may have a paranoid ideation about medicines or about physicians. Or they may be depressed so it is too difficult for them to go to the pharmacy to pick up a new medicine. Or they may be so anxious that they can't deal with one more new problem. (I-5)

Loeb, et.al., J Gen Intern Med; Feb 2012.

Role of Mental Illness in Patient Complexity



Loeb, et.al., J Gen Intern Med;

Why It Matters

Costs: multimorbidity

Healthcare expenses increase with the number of medical illnesses

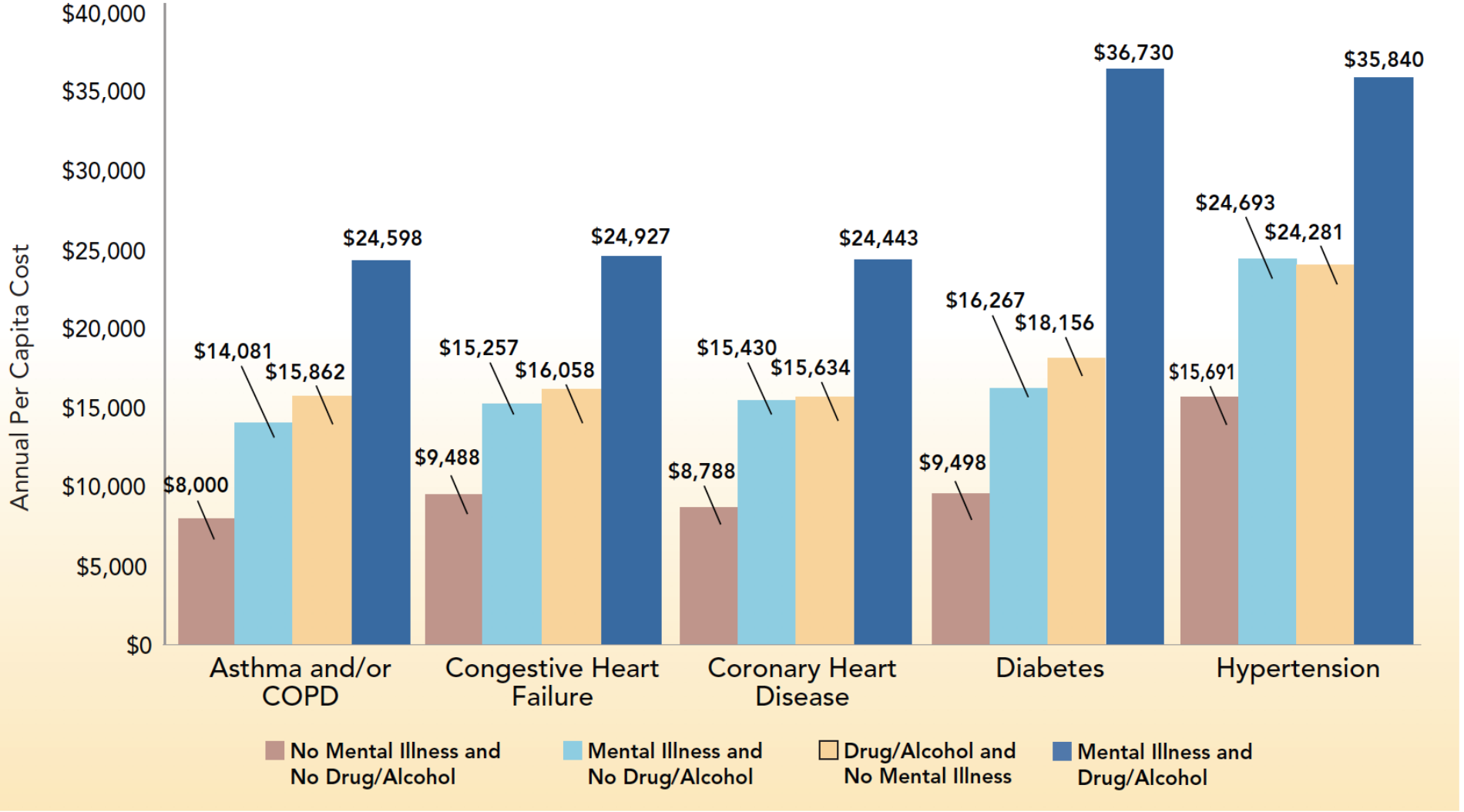
Relationship between multisystem multimorbidity and mean annual healthcare utilisation† among high-cost VA patients

Number of body systems affected by chronic conditions	n	Primary care visits	Specialty care visits	Mental health visits‡	Emergency visits	Hospital admissions
1	30 772	3.1	3.0	15.4	1.2	1.0
2	54 837	4.5	3.7	14.9	1.6	1.3
3	66 610	5.6	4.4	14.5	1.9	1.5
4	53 937	6.7	5.2	14.1	2.3	1.8
5	30 509	7.8	5.9	14.6	2.8	2.0
6	12 566	9.1	6.7	14.2	3.4	2.3
7+	4419	10.5	7.7	15.1	4.0	2.6
Average difference§		1.5*	0.7*	−0.2	0.4*	0.2*

Zulman, et.al., *BMJ open* vol. 5,4 e007771. 2015

Cost of Multimorbidity in Medicaid Patients: The role of Mental Illness

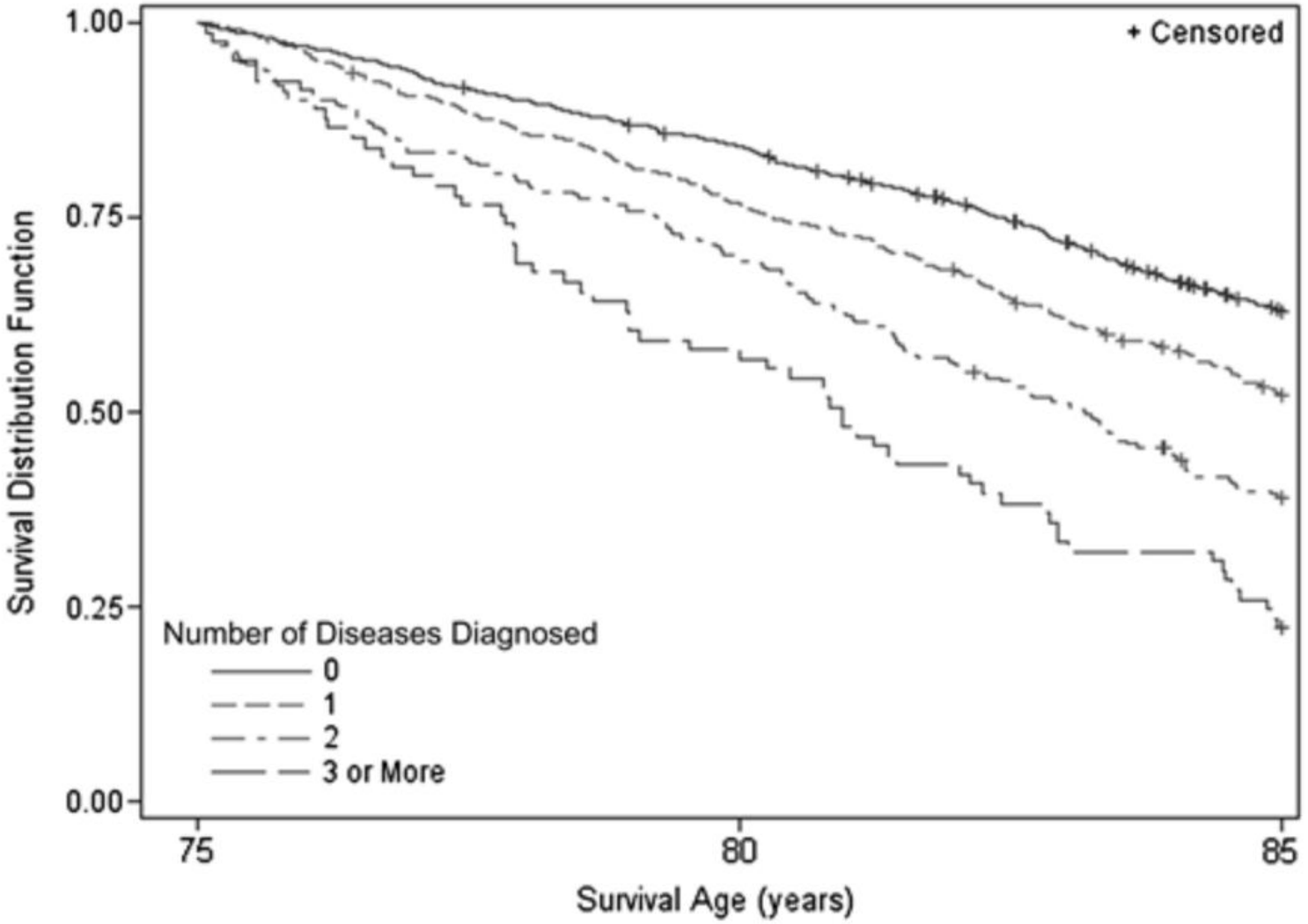
Mental Illness and Addiction further increase costs



Boyd, et.al., Brief. 2010. http://bit.ly/2B9y1K5

Multimorbidity and mortality

More chronic illnesses = lower survival rates

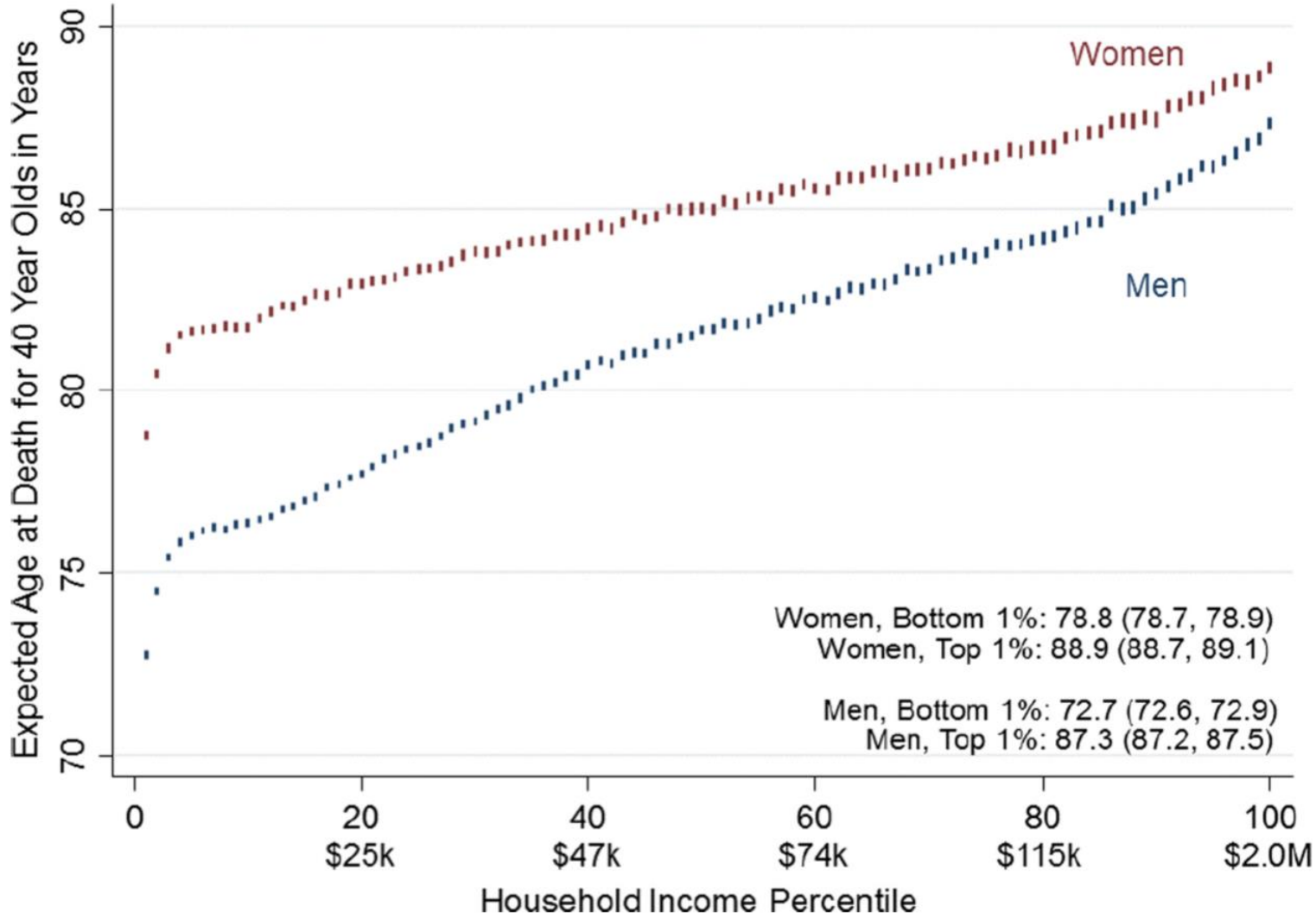


Tate et.al., Gerontologist. 2013 Feb;53(1):133-41.

Socio-Economic Status

Add only one factor of Complexity:

Socio-Economic Status leads to earlier age of death



Chetty et.al., JAMA. 2016 Apr 26;315(16):1750-66.

Quality of Life/ Patient Burden

Multimorbidity associated with:

- Poor health-related quality of life
- Significant issues with self-care
- Challenges with their medical care, including
  - Difficulty getting questions answered between appointments
  - Lack of time to discuss their concerns during appointments
  - Disagreement among specialists
  - Polypharmacy and medication side effects

Fortin et. al.,*Qual Life Res* 2006, **15**(1):83-91.
Bayliss et. al., *Annals of family medicine* 2007, **5**(5):395-402.
Parchman et. A.l, Medical care. , 2005, Vol.43(11), p.1123-1129

Medical Decision-Making Medical Multimorbidity

Following guideline concordant care for patients with multiple conditions becomes challenging due to conflicting guidelines

Table 4. Potential Treatment Interactions for a Hypothetical 79-Year-Old Woman with 5 Chronic Diseases

		Type of Interaction		
Type of Disease	Medications With Potential Interactions	Medication and Other Disease	Medications for Different Diseases	Medication and Food
Hypertension	Hydrochlorothiazide, lisinopril	Diabetes: diuretics increase serum glucose and lipids*	Diabetes medications: hydrochlorothiazide may decrease effectiveness of glyburide	NA
Diabetes	Glyburide, metformin, aspirin, and atorvastatin	NA	Osteoarthritis medications: NSAIDs plus aspirin increase risk of bleeding Diabetes medications: glyburide plus aspirin may increase the risk of hypoglycemia; aspirin may decrease effectiveness of lisinopril	Aspirin plus alcohol: increased risk of gastrointestinal tract bleeding Atorvastatin plus grapefruit juice: muscle pain, weakness Glyburide plus alcohol: low blood sugar, flushing, rapid breathing, tachycardia Metformin plus alcohol: extreme weakness and heavy breathing Metformin plus any type of food: medication absorption decreased
Osteoarthritis	NSAIDs	Hypertension: NSAIDs: raise blood pressure†; NSAIDs plus hypertension increase risk of renal failure	Diabetes medications: NSAIDs in combination with aspirin increase risk of bleeding Hypertension medications: NSAIDs decrease efficacy of diuretics	NA
Osteoporosis	Calcium, alendronate	NA	Diabetes medications: calcium may decrease efficacy of aspirin; asprin plus alendronate can cause upset stomach Osteoporosis medications: calcium may lower serum alendronate level	Alendronate plus calcium: take on empty stomach (>2 h from last meal) Alendronate: avoid orange juice Calcium plus oxalic acid (spinach and rhubarb) or phytic (bran and whole cereals): eating these foods may decrease amount of calcium absorbed (>2 h from last meal)
Chronic obstructive pulmonary disease	Short-acting β-agonists	NA	NA	NA

Boyd et.al., JAMA. 2005 Aug 10;294(6):716-24.

Patient Burden: Medical Multimorbidity

Patients with multiple conditions have a high burden to keep up with medications and other self-care guidelines

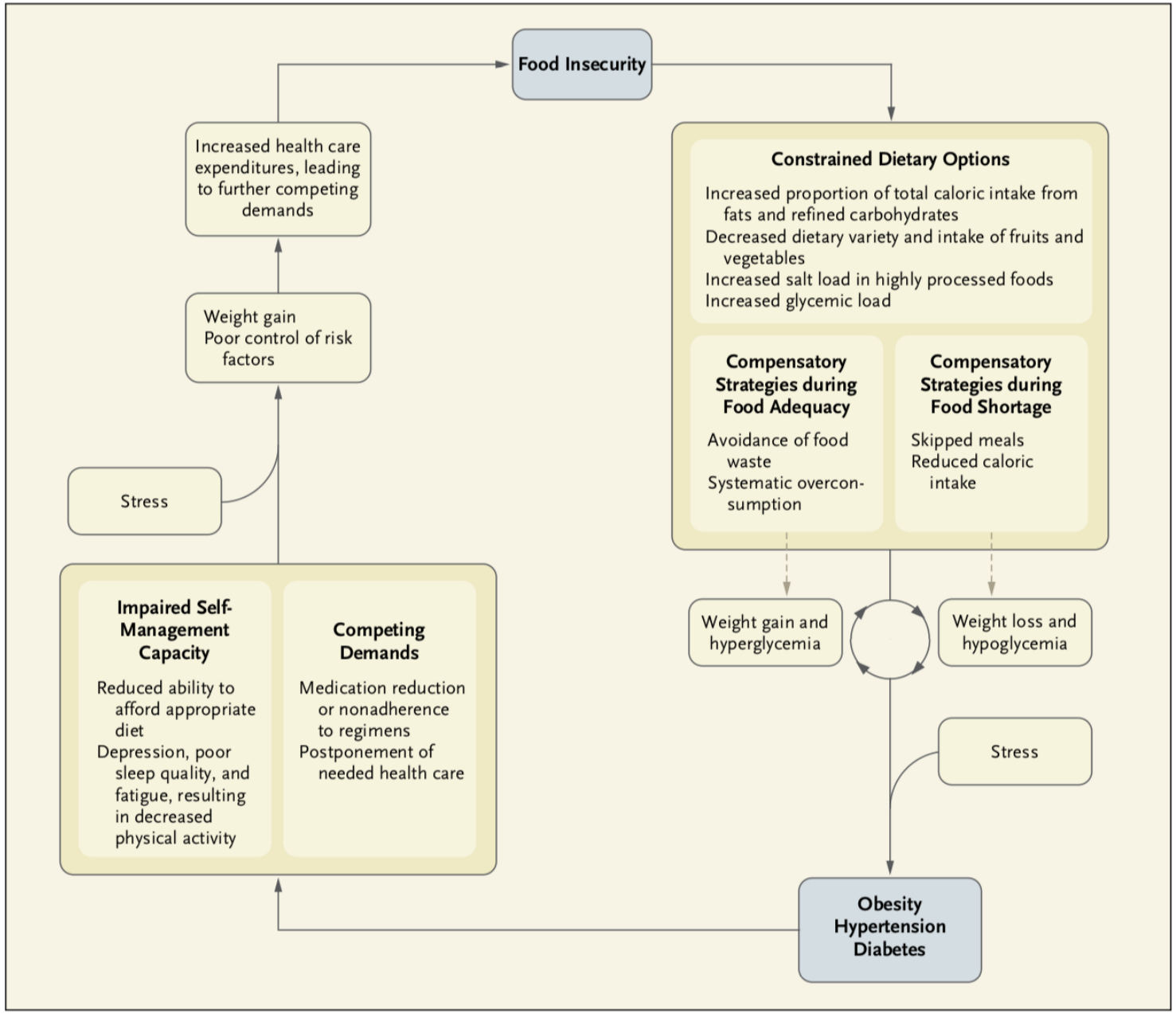
Table 3. Treatment Regimen Based on Clinical Practice Guidelines for a Hypothetical 79-Year-Old Woman With Hypertension, Diabetes Mellitus, Osteoporosis, Osteoarthritis, and COPD*

Time	Medications†	Other
7:00 AM	Ipratropium metered dose inhaler 70 mg/wk of alendronate	Check feet Sit upright for 30 min on day when alendronate is taken Check blood sugar
8:00 AM	500 mg of calcium and 200 IU of vitamin D 12.5 mg of hydrochlorothiazide 40 mg of lisinopril 10 mg of glyburide 81 mg of aspirin 850 mg of metformin 250 mg of naproxen 20 mg of omeprazole	Eat breakfast 2.4 g/d of sodium 90 mmol/d of potassium Low intake of dietary saturated fat and cholesterol Adequate intake of magnesium and calcium Medical nutrition therapy for diabetes‡ DASH‡
12:00 PM		Eat lunch 2.4 g/d of sodium 90 mmol/d of potassium Low intake of dietary saturated fat and cholesterol Adequate intake of magnesium and calcium Medical nutrition therapy for diabetes‡ DASH‡
1:00 PM	Ipratropium metered dose inhaler 500 mg of calcium and 200 IU of vitamin D	
7:00 PM	Ipratropium metered dose inhaler 850 mg of metformin 500 mg of calcium and 200 IU of vitamin D 40 mg of lovastatin 250 mg of naproxen	Eat dinner 2.4 g/d of sodium 90 mmol/d of potassium Low intake of dietary saturated fat and cholesterol Adequate intake of magnesium and calcium Medical nutrition therapy for diabetes‡ DASH‡
11:00 PM	Ipratropium metered dose inhaler	
As needed	Albuterol metered dose inhaler	

Boyd et.al., JAMA. 2005 Aug 10;294(6):716-24.

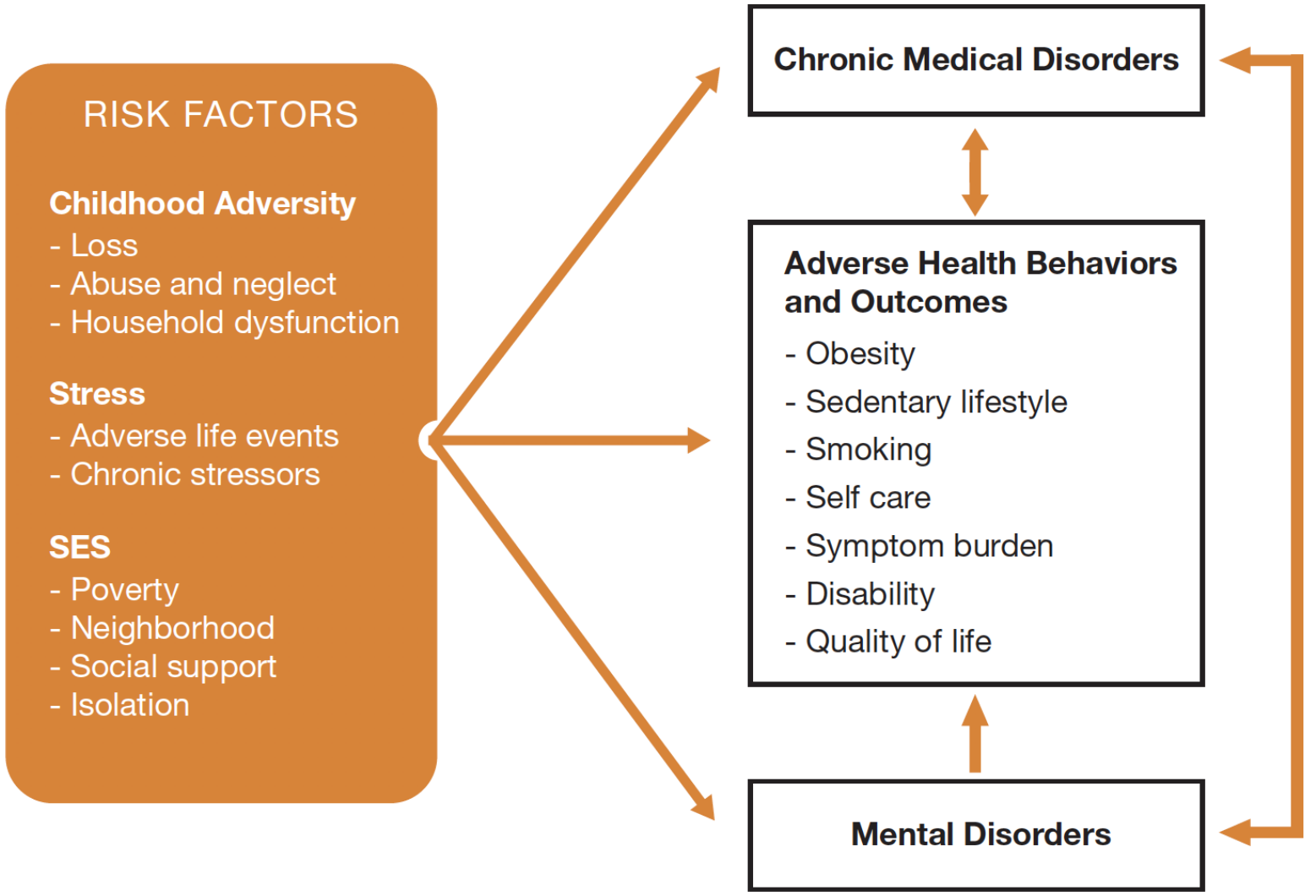
Complexity example:

Again, just one additional factor… Food Insecurity… exacerbates challenges to self-care of medical issues!



Seligman et.al., N Engl J Med.2010 Jul 1;363(1):6-9.

Complexity model: How Mental Illness Complicates Medical Illness



RWJ. Research Synthesis Report. Feb 2011; No. 21.

Katon et.al., Biol Psychiatry. 2003 Aug 1;54(3):216-26.

Measurement Issues

Multimorbidity Measures

Many measures!

Some count illnesses, some count medications, some count specific illnesses, some account for severity… none are perfect

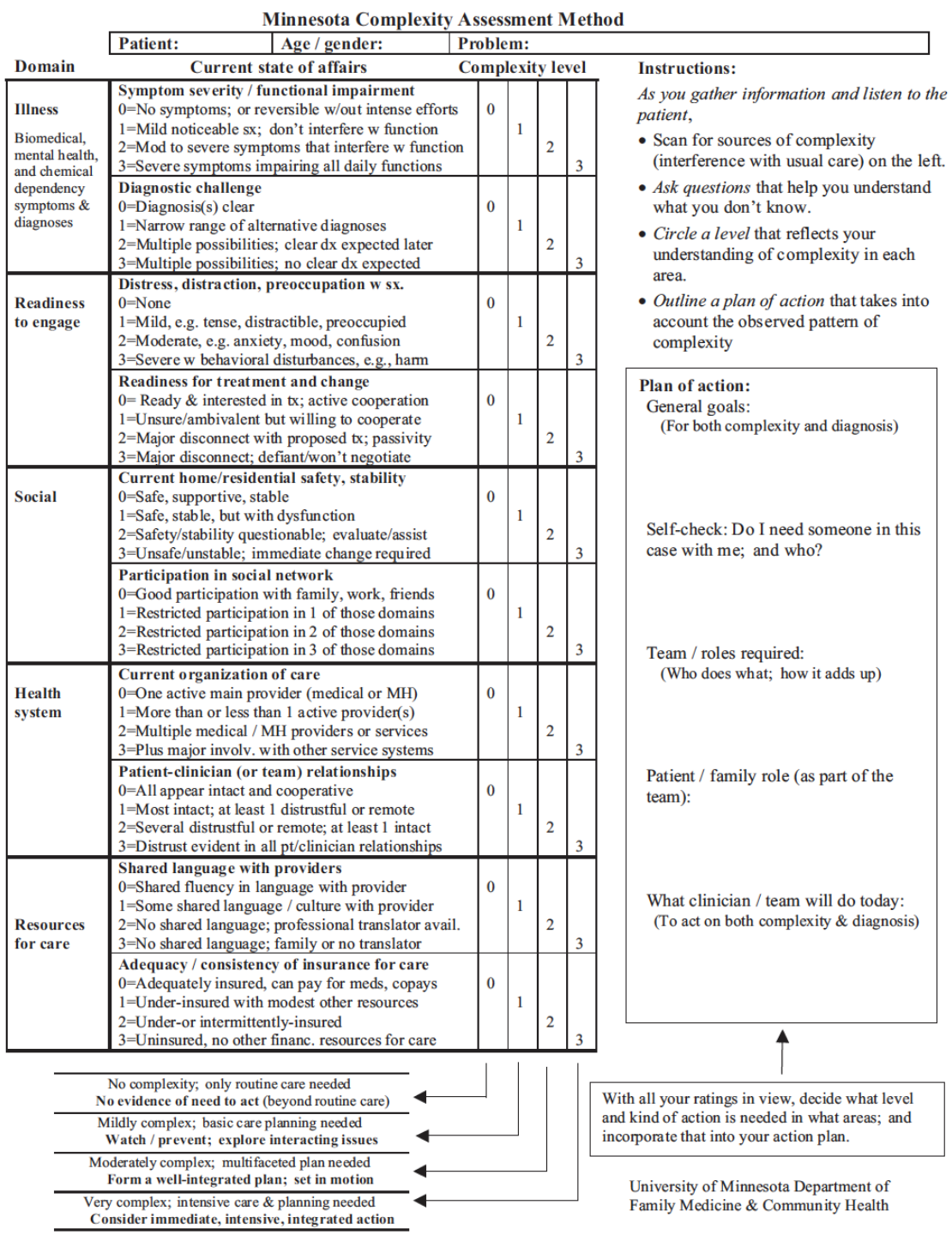
Measure	Chronic condition list/description	Percent endorsement
Count measures		
Canadian Institutes of Health Research (CIHR) List[27,a]	1. Hypertension, 2. depression/anxiety, 3. chronic musuloskeletal conditions causing pain or limitation, 4. osteoarthritis and other arthritis, 5. osteoporosis, 6. asthma, chronic obstructive pulmonary disease or chronic bronchitis, 7. cardiovascular disease, 8. heart failure, 9. stroke and transient ischemic attack (TIA), 10. stomach problem, 11. colon problem, 12. chronic liver disease, 13. diabetes, 14. thyroid disorder, 15. any cancer within the last 5 years, 16. chronic kidney disease or failure, 17. chronic urinary problem, 18. dementia, 19. hyperlipidemia, 20. human immunodeficiency virus.	78.6
Centers for Disease Control and Prevention (CDC) List[28,29]	1. Hypertension, 2. congestive heart failure, 3. coronary artery disease (e.g., ischemic heart disease, coronary heart disease, etc.), 4. cardiac arrhythmias, 5. hyperlipidemia, 6. stroke or transient ischemic attack, 7. arthritis, 8. asthma, 9. autism spectrum disorder, 10. cancer (all but skin), 11. chronic kidney disease, 12. chronic obstructive pulmonary disease, 13. dementia, 14. depression, 15. diabetes, 16. hepatitis, 17. HIV, 18. osteoporosis, 19. schizophrenia, 20. substance abuse (drug or alcohol).	71.4
Health Systems Performance Research Network (HSPRN) List[30]	1. Acute myocardial infarction, 2. rheumatoid arthritis, 3. osteoarthritis arthritis, 4. asthma, 5. cancer, 6. cardiac arrythmia, 7. coronary heart failure, 8. chronic obstructive pulmonary disease, 9. dementia, 10. depression, 11. diabetes, 12. hypertension, 13. osteoporosis, 14. renal failure, 15. stroke, 16. coronary syndrome (excluding myocardial infarction).	42.9
Index measures		
Charlson Comorbidity Index[31]	The original index recognizes 19 conditions identified using International Classification of Diseases (ICD) 9/10 codes, which are weighted to reflect severity and then summed to create a total score. The index uses medical and self-report electronic records and has been extensively validated in hospital and specialist settings. A number of variations exist (including adaptations using administrative data) that appear to perform equally well in predicting a range of outcomes (mortality, healthcare costs, hospital length of stay).	92.9
Elixhauser Comorbidity Index (EI)[32]	The original index recognizes 30 conditions identified using ICD 9 codes. The index uses administrative data and predicts a range of health-related outcomes (mortality, length of stay, cost). The index has been extensively validated for use with administrative data.	71.4
Adjusted Clinical Groups (ACG) System[33]	This index uses a case-mix adjustment system that groups patients into clinically-cogent groups using age, sex and diagnosis codes (ICD 9/10 or Read Code). It uses medical records or insurance claims data, has been validated in multiple settings, and predicts a range of outcomes including morbidity burden and health service use and costs.	71.4
Cumulative Index Illness Rating Scale (CIRS)[34]	This index classifies conditions into 1 of 14 organ domains, which are each rated (0–4) for severity and summed to obtain a total score (0–56). The index uses medical records data, has been validated in family practice, and is used to predict medical burden.	71.4
Cluster measures		
Prevalence-based approach	Identify the most prevalent combination of conditions (e.g., dyads, triads) stratified by age and gender	92.9
Cost-based approach	Identify the most costly combination of conditions (e.g. dyads and triads) stratified by age and gender	64.3
Cluster-based approach	Identify the clusters of conditions using statistical methods such as factor analysis, cluster analysis or latent class analysis	64.3

Griffith et.al., J Comirb. 2018 Sep 3;8(1):2235042X18795306.

Complexity Measure

Additional Factors in the Minnesota Complexity Assessment Method

- Readiness to change
- Housing
- Social Network
- Healthcare system
- Insurance



Minnesota Complexity Assessment Method

Patient: | Age / gender: | Problem:

Domain	Current state of affairs	Complexity level			
Illness Biomedical, mental health, and chemical dependency symptoms & diagnoses	**Symptom severity / functional impairment** 0=No symptoms; or reversible w/out intense efforts 1=Mild noticeable sx; don't interfere w function 2=Mod to severe symptoms that interfere w function 3=Severe symptoms impairing all daily functions	0	1	2	3
	Diagnostic challenge 0=Diagnosis(s) clear 1=Narrow range of alternative diagnoses 2=Multiple possibilities; clear dx expected later 3=Multiple possibilities; no clear dx expected	0	1	2	3
Readiness to engage	**Distress, distraction, preoccupation w sx.** 0=None 1=Mild, e.g. tense, distractible, preoccupied 2=Moderate, e.g. anxiety, mood, confusion 3=Severe w behavioral disturbances, e.g., harm	0	1	2	3
	Readiness for treatment and change 0= Ready & interested in tx; active cooperation 1=Unsure/ambivalent but willing to cooperate 2=Major disconnect with proposed tx; passivity 3=Major disconnect; defiant/won't negotiate	0	1	2	3
Social	**Current home/residential safety, stability** 0=Safe, supportive, stable 1=Safe, stable, but with dysfunction 2=Safety/stability questionable; evaluate/assist 3=Unsafe/unstable; immediate change required	0	1	2	3
	Participation in social network 0=Good participation with family, work, friends 1=Restricted participation in 1 of those domains 2=Restricted participation in 2 of those domains 3=Restricted participation in 3 of those domains	0	1	2	3
Health system	**Current organization of care** 0=One active main provider (medical or MH) 1=More than or less than 1 active provider(s) 2=Multiple medical / MH providers or services 3=Plus major involv. with other service systems	0	1	2	3
	Patient-clinician (or team) relationships 0=All appear intact and cooperative 1=Most intact; at least 1 distrustful or remote 2=Several distrustful or remote; at least 1 intact 3=Distrust evident in all pt/clinician relationships	0	1	2	3
Resources for care	**Shared language with providers** 0=Shared fluency in language with provider 1=Some shared language / culture with provider 2=No shared language; professional translator avail. 3=No shared language; family or no translator	0	1	2	3
	Adequacy / consistency of insurance for care 0=Adequately insured, can pay for meds, copays 1=Under-insured with modest other resources 2=Under-or intermittently-insured 3=Uninsured, no other financ. resources for care	0	1	2	3

Instructions:

As you gather information and listen to the patient,

- Scan for sources of complexity (interference with usual care) on the left.
- *Ask questions* that help you understand what you don't know.
- *Circle a level* that reflects your understanding of complexity in each area.
- *Outline a plan of action* that takes into account the observed pattern of complexity

Plan of action:

General goals:
(For both complexity and diagnosis)

Self-check: Do I need someone in this case with me; and who?

Team / roles required:
(Who does what; how it adds up)

Patient / family role (as part of the team):

What clinician / team will do today:
(To act on both complexity & diagnosis)

No complexity; only routine care needed
No evidence of need to act (beyond routine care)

Mildly complex; basic care planning needed
Watch / prevent; explore interacting issues

Moderately complex; multifaceted plan needed
Form a well-integrated plan; set in motion

Very complex; intensive care & planning needed
Consider immediate, intensive, integrated action

With all your ratings in view, decide what level and kind of action is needed in what areas; and incorporate that into your action plan.

University of Minnesota Department of Family Medicine & Community Health

Peek, et. Al. Families, Systems, & Health © 2009 American Psychological Association; 2009, Vol. 27, No. 4, 287–302

Complexity Measure

A look at one domain of the

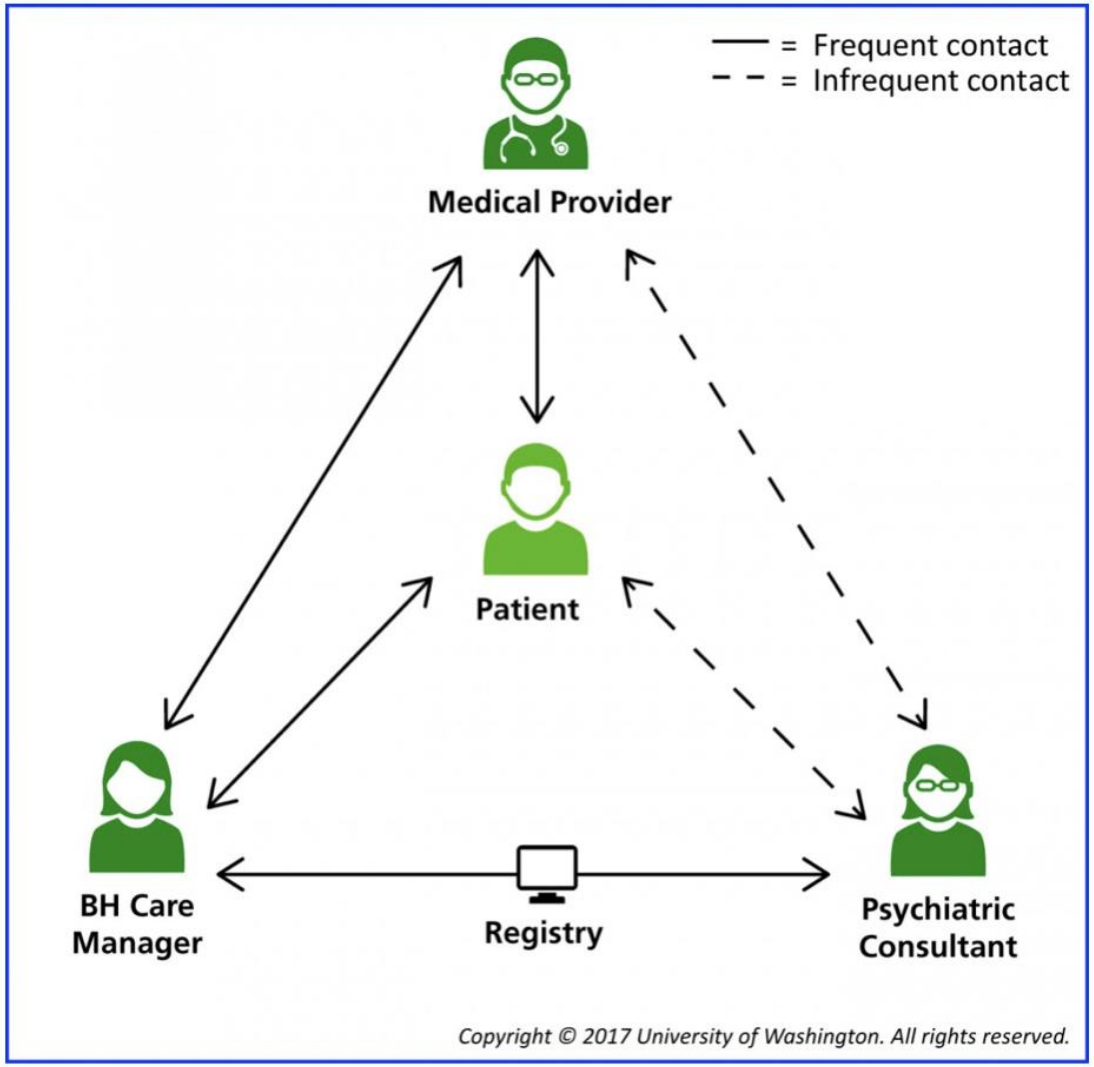
Minnesota Complexity Assessment Method

Social	**Current home/residential safety, stability** 0=Safe, supportive, stable 1=Safe, stable, but with dysfunction 2=Safety/stability questionable; evaluate/assist 3=Unsafe/unstable; immediate change required	0	1	2	3
	Participation in social network 0=Good participation with family, work, friends 1=Restricted participation in 1 of those domains 2=Restricted participation in 2 of those domains 3=Restricted participation in 3 of those domains	0	1	2	3

Peek, et. Al. Families, Systems, & Health © 2009 American Psychological Association; 2009, Vol. 27, No. 4, 287–302

Reorganizing Care for Complexity

Collaborative Care Model for comorbidity



Collaborative Care Works!
But has limited application

- Overwhelming evidence in improving outcomes for Depression and/or Anxiety
- Co-morbid: Coronary Artery Disease, Diabetes, Hypertension, Hyperlipidemia
- But… what about
  - Multimorbidity?
  - Other non-cardiovascular medical illnesses?
  - Food insecurity, transportation issues, legal concerns…

Promise of PCMH

https://nwmphn.org.au/about-nwmphn/primary-health-care-system/person-centred-medical-home/

Mixed Results: Positive

	Total Studies	Cost Reductions	Fewer ED Visits	Fewer Inpatient Admissions	Fewer Readmissions	Improvement in Population Health	Improved Access	Increase in Preventive Services	Improvement in Satisfaction
PEER-REVIEW/ACADEMIA									
Reported outcomes	(n=13)	61% (n=8)	61% (n=8)	31% (n=4)	13% (n=1)	31% (n=4)	31% (n=4)	31% (n=4)	23% (n=3)
INDUSTRY REPORTS									
Reported outcomes	(n=7)	57% (n=4)	57% (n=4)	57% (n=4)	29% (n=2)	29% (n=2)	14% (n=1)	29% (n=2)	14% (n=1)

https://www.pcpcc.org/sites/default/files/resources/Executive%20Summary%20Only%20with%20Evidence.pdf

Mixed Results: mixed

	No Equivalent Recognition Sites (N = 97)	Level 1, 2, or 3 Equivalent Recognition Sites (N = 707)	Difference (Level 1, 2, or 3 Equivalent Recognition – No Equivalent Recognition)	95% Confidence Interval
Utilization, per 1000 beneficiaries per year				
FQHC visits	4705	4933	**228**	**176, 278**
Non-FQHC primary care visits	417	414	−3	−19, 11
Specialist visits	2993	3173	**181**	**124, 232**
ED visits	942	1007	**64**	**35, 89**
Inpatient admissions	346	340	−6	−22, 6
Inpatient ACSC admissions	44	47	3	−2, 7
Inpatient readmissions, percentage points	14.2	14.8	0.6	−0.5, 1.6
Continuity of Care, points				
Provider-level continuity	0.69	0.66	**−0.03**	**−0.04, −0.02**
Practice-level continuity	0.83	0.85	**0.02**	**0.01, 0.03**
Process, percentage points				
All four recommended diabetes tests	20.6	25.2	**4.6**	**2.5, 6.7**
HbA1c test	84.3	86.4	2.1	−1.1, 5.3
LDL test	78.1	80.8	**2.8**	**0.4, 5.1**
Eye exam	43.5	44.3	0.8	−1.9, 3.6
Nephropathy test	50.5	58.2	**7.7**	**4.1, 11.3**
Lipid test for patients with ischemic vascular disease	76.1	77.4	1.3	−1.1, 3.8

Timble et.al., J Gen Intern Med. 2017 Sep;32(9):997-1004.

Complex Leadership Theory

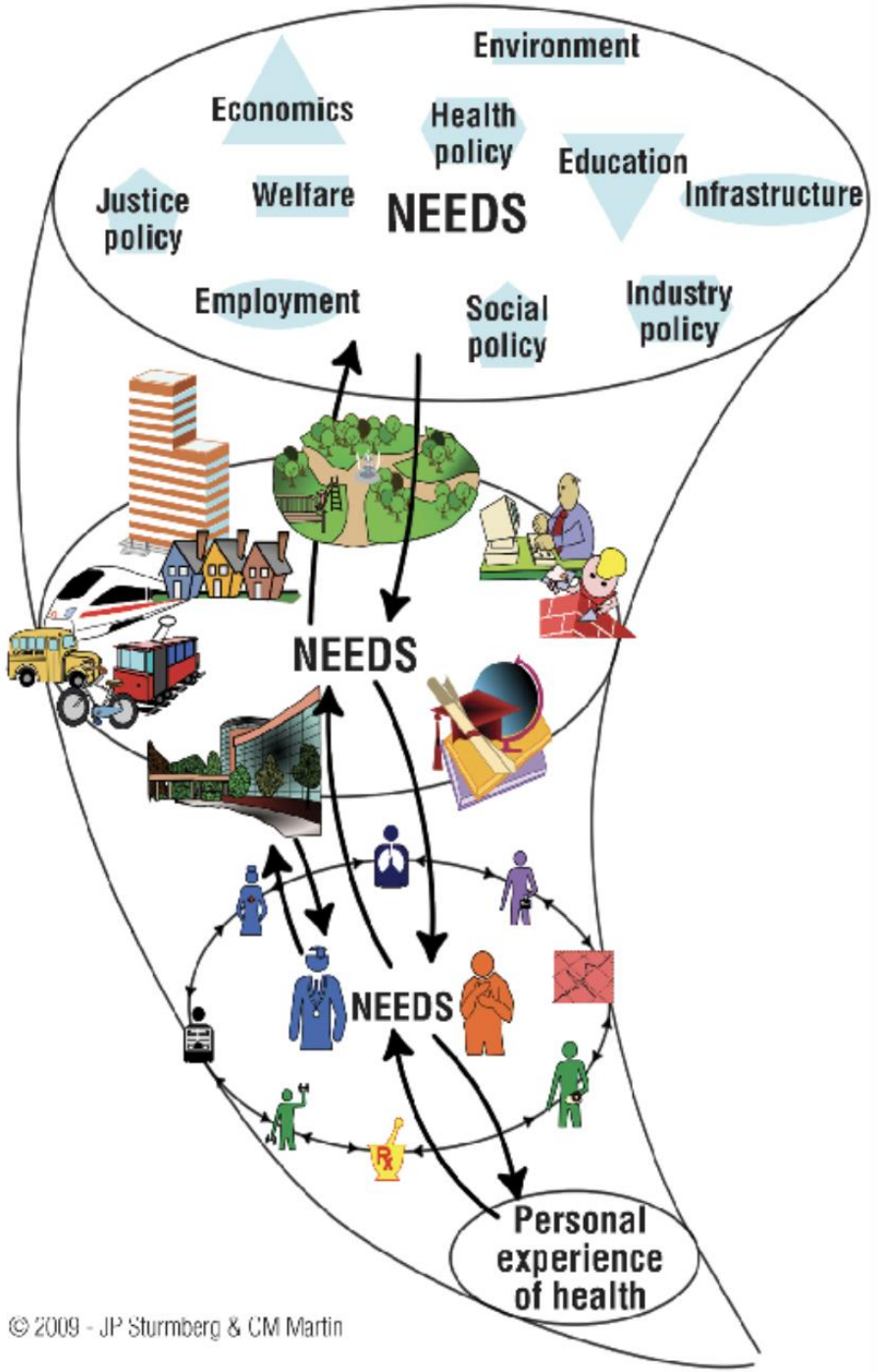
"Complex adaptive systems are neural-like networks of interacting, interdependent agents who are bonded in a cooperative dynamic by common goal, outlook, need, etc."

Uhl-Bien et.al, *The leadership quarterly*, *18*(4), 298-318. 2007

Example: Patient-Centered Vortex

Uses Complex Adaptive Theory

- Patient-centered
- Healthcare organized around patient needs
- Accounts for complexity
- Accounts for need for constant changes to system to adjust to patient needs



Sturmberg, et. al., Med J Aust 2010; 193 (8): 474-478.

Gaps in Research

- Limited data on younger people with multimorbidity
- Modifiable factors to predict risk and target in interventions
- Health services/systems to serve patients with multimorbidity and complexity

Role of PCORI

Discussion

Lunch
12:00 – 12:45 PM

Up Next: Acknowledgements

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Acknowledgements
12:00 – 12:45 PM

Up Next: Orientation to Small Group Discussions
Lauren McCormack
Danny van Leeuwen

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Fall 2018 Acknowledgments

- In recognition of time served as a PCORI Advisory Panel Member, we would like to acknowledge the following members whose terms are ending this fall:

- Clifford Ko
- Giovanna Devercelli
- Janice Buelow
- LaRita B. Jacobs
- Lauren McCormack , Chair
- Michael Pignone
- Robert Volk

Orientation to Small Group Discussions

Lauren McCormack, PhD, MSPH
Danny van Leeuwen, Opa, RN, MPH

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Small Group Discussions

The color sticker on your name tag indicates the group you are in.

There is one facilitator and one PCORI staff note-taker for each group.

<u>The groups/room assignments are as follows:</u>

Yellow Group |

Facilitator: Robert Volk

Blue Group |

Facilitator: Nancy Perrin

Green Group |

Facilitator: Cornell Wright

Small Group Discussion Questions

1. How can we integrate the notion of “complex patients” into a research agenda?
2. How can we use the AHRQ model of complex patients (i.e., Need-Services gap) to help create a new paradigm for comparative effectiveness research?
3. Many different uncertainties were raised in the articles on clinical genetic testing. How should we prioritize the research needs to help decrease the different uncertainties?
4. How would the rapid change in genetic testing technology affect the many uncertainties around the use of this technology?
5. How can we integrate interprofessional/health care team communications into the CEDS research agenda, especially as it relates to complex patients?

BREAK
2:00 – 2:15 PM

Up Next: Large group Discussion
Lauren McCormack
Danny van Leeuwen

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Large Group Discussion
Report Back from the Small Group Sessions

Lauren McCormack, PhD, MSPH
Danny van Leeuwen, Opa, RN, MPH

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Large Group Discussion

- Reconvene to present a summary of what was discussed during small groups:
  - Yellow
  - Blue
  - Green

Small Group Discussion Questions

1. How can we integrate the notion of “complex patients” into a research agenda?
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5. How can we integrate interprofessional/health care team communications into the CEDS research agenda, especially as it relates to complex patients?

Wrap-up, Next Steps, Debrief

Lauren McCormack, PhD, MPH

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Adjourn