Northwestern Medicine®

Developing a clinically-relevant, patient-centric health status measure for patients with heart failure built on PROMIS®

Faraz S. Ahmad, MD, MS

Assistant Professor of Medicine (Cardiology)

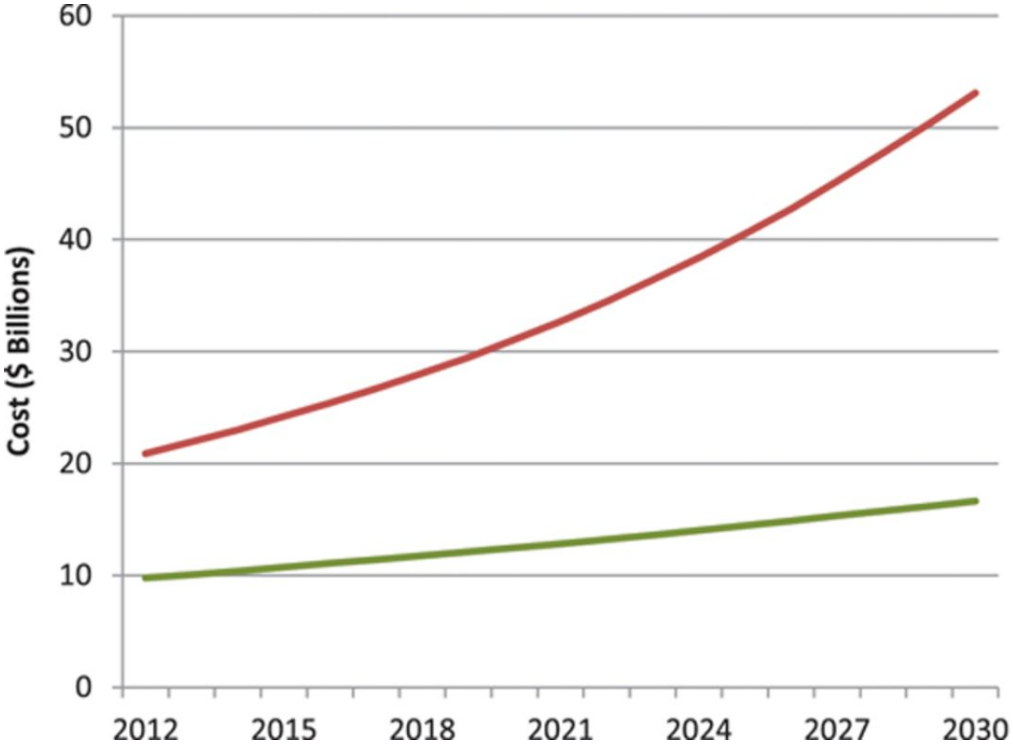
Assistant Professor of Preventive Medicine (Health and Biomedical Informatics)

Center for Health Information Partnerships

Faraz.Ahmad@northwestern.edu

CHiP CENTER FOR HEALTH INFORMATION PARTNERSHIPS

The Heart Failure Epidemic



80% of the costs
related to hospitalizations

Northwestern Medicine®

Heidenreich et al. Circ Heart Fail 2013.

Growing interest in PROMs for routine use and research

Circulation

Cardiovascular Health: The Importance of Measuring Patient-Reported Health Status : A Scientific Statement From the American Heart Association

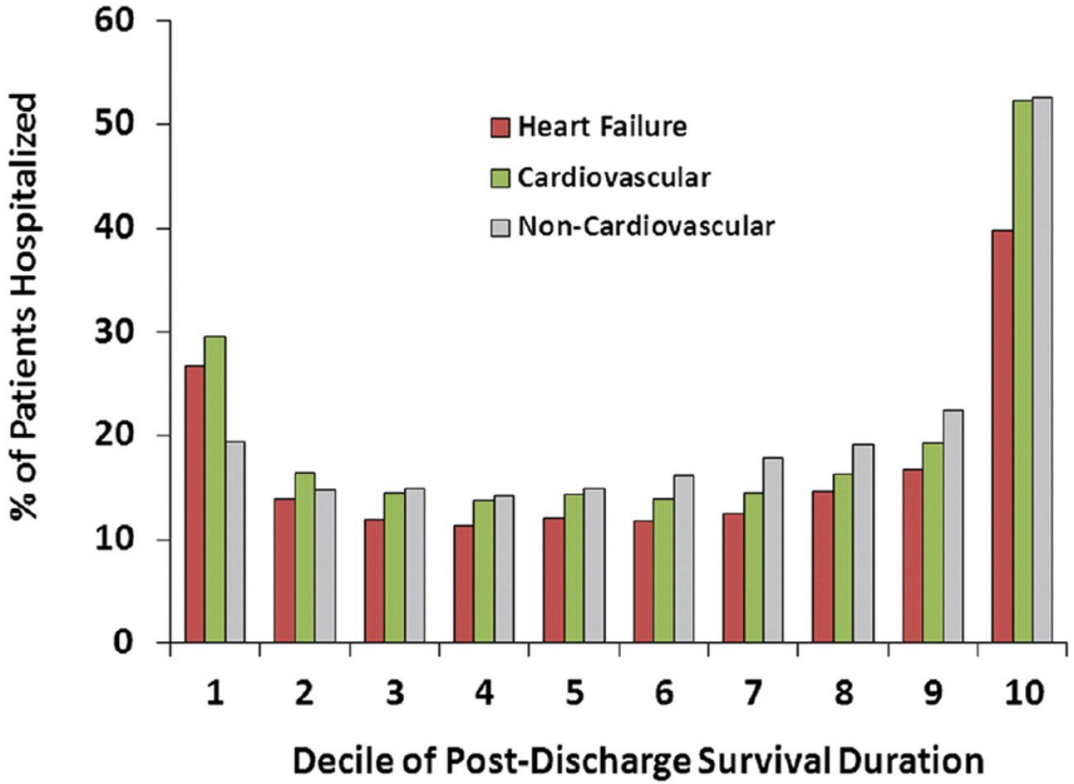
John S. Rumsfeld, Karen P. Alexander, David C. Goff, Jr, Michelle M. Graham, P. Michael Ho, Frederick A. Masoudi, Debra K. Moser, Véronique L. Roger, Mark S. Slaughter, Kim G. Smolderen, John A. Spertus, Mark D. Sullivan, Diane Treat-Jacobson and Julie J. Zerwic

The Learning Healthcare System and Cardiovascular Care

A Scientific Statement From the American Heart Association

Northwestern Medicine®

HF represents the model condition for routinely-collected PROMs



Northwestern Medicine®

Chun et al. Circ Heart Fail 2012.

Gaps in Using PROMs in Patients with Heart Failure

- NYHA Class is a clinician interpretation and unreliable
- A publicly available, clinically relevant measure that quantifies physical, mental, and social health and enables comparisons
  - Kansas City Cardiomyopathy Questionnaire
  - Minnesota Living with Heart Failure Questionnaire
- Best practices to consistently obtain PROMs and integrate into routine care
- Utility of routinely-collected PROMs to improve care and outcomes

Northwestern Medicine®

The PROMIS-Plus-HF Profile Measure

Development

- ✓ In-person focus groups (8 groups; 61 patients) and clinician (n=10) phone interviews to identify content themes
- ✓ Mapping of themes to existing PROMIS domains/items and drafting with cognitive testing of new domains/items

Validation

- ✓ Good psychometric properties (reliability, validity, and responsiveness) in cross-sectional sample of 600 patients and longitudinal sample of 75 patients

Key Properties

- ✓ Complete assessment of physical, mental, and social health
- ✓ Leverages existing, extensively tested PROMIS items with new content specific to heart failure
- ✓ Entire instrument or subsets of domains can be used depending on clinical or research purpose

Northwestern Medicine®

Ahmad et al. *Circ Heart Fail.* 2019. In press.

The PROMIS-Plus-HF

Domain	# of subdomains	# Items Total*
Physical	7	45
Mental	7	24
Social	4	17
Total	18	86

*Estimated completion of 3-5 items per minute

Northwestern Medicine®

PROMIS-Plus-HF-Physical

	Domain includes new items	# Items Total	# Items Existing	# New Items
Dyspnea	No	10	10	0
Fatigue	Yes	11	10	1
Health Behavior Outcomes	Yes	3	0	3
Pain Interference	No	2	2	0
Physical Function	No	10	10	0
Sleep Disturbance	No	6	6	0
Symptoms	Yes	3	0	3
Total		45	38	7

PROMIS-Plus-HF-Mental

	Domain includes new items	# Items Total	# Items Existing	# New Items
Anger	Yes	1	0	1
Anxiety	Yes	5	0	5
Cognitive Ability	No	3	3	0
Cognitive Function	No	3	3	0
Depression	No	6	6	0
Illness Burden	Yes	4	0	4
Life Satisfaction	Yes	2	0	2
Total		24	12	12

PROMIS-Plus-HF-Social

	Domain includes new items	# Items Total	# Items Existing	# New Items
Ability to Participate in Social Roles and Activities	No	6	6	0
Independence	Yes	3	0	3
Satisfaction with Social Roles and Activities	No	6	6	0
Social Isolation	No	2	2	0
Total		17	14	3

Abbreviated Versions

- Create abbreviated research and clinical forms
- Approximately 30 (research form) and 12 (clinical form) questions
- Generate summary scores for physical, mental, and social health
- Potentially generate overall score

Abbreviated Versions

- Approach
  - Reduced to 31 items via review by measurement experts and heart failure expert
    - Preserved coverage of key areas while minimizing redundancy
    - Selected most well-tested PROMIS items
    - Selected items those correlated to overall domain score when able
  - Generate summary scores by domain (0-100) and perform psychometric testing in 600-person sample and separate longitudinal sample (n=185)

The PROMIS-Plus-HF Research Form

Domain	# of Subdomains	# Items Total*
Physical	6	16
Mental	5	10
Social	3	5
Total	14	31

*Estimated completion of 3-5 items per minute

Northwestern Medicine®

Summary of Initial Psychometric Testing

- Evidence of internal consistency (Cronbach's alpha > 0.85)
- No evidence of floor or ceiling effects
- Normal distribution of domain and overall summary scores
- Excellent test-retest reliability (Pearson r > 0.95)
- Additional reliability and validity analyses are ongoing

Northwestern Medicine®

Questions for Audience

- What the is optimal study design to create the clinical short form?
  - Planning survey of clinicians and patients vs modified Delphi method
  - Will use selected psychometric tests
- Is it valuable to create an overall summary score?
- Would linear transformation to 0-100 vs T-score enhance interpretability?
- Would a CAT be valuable to health systems and researchers?
- Would you consider using the clinical form in your health system?
- Any interest in collaboration on a implementation grant to PCORI?

Northwestern Medicine®

Acknowledgements

- K12 Primary Mentors
  - Dr. David Cella
  - Dr. Karl Bilimoria
  - Dr. Susan Yount
  - Dr. Abel Kho
- Additional K12 mentors/collaborators
  - Katie Jackson
  - Dr. Michael Kallen
  - Dr. Kannan Mutharasan
  - Jen Bannon
  - Shruti Cruz
  - Ashley Rego
  - Ann Ibrahim
- NM PRO Members
  - Kristina Davis
  - Kate Thomas
  - Dr. Cynthia Barnard
  - Dr. Justin Starren
  - Dr. Therese Nelson
  - Dr. Nan Rothrock
- Additional PROMIS-Plus-HF co-investigators
  - Dr. Karen Schifferdecker
  - Kathleen Carluzzo
  - Dr. Jill Gelow
  - Dr. Peter McCullough
  - Dr. Stephen Kimmel
  - Dr. Elliot Fisher

Northwestern Medicine®

Validation Strategy

Category	Definition	Study population	Statistical approaches
Reliability			
Internal consistency	Extent of items measuring the same concept	Cross-sectional sample of 600 patients	Cronbach's alpha, inter-item correlation, item-adjusted total correlation, categorical confirmatory factor analysis, item response theory, differential item functioning
Test-retest reliability	Stability of responses over time without any clinical change	Repeat testing within 7 days for 100 participants	Intraclass correlation coefficient
Validity			
Construct and Criterion-Related Validity	Data fit with prior, hypothesized relationships among items and domains and correlation with similar measure	Cross-sectional assessment of 600 patients with heart failure and correlation with KCCQ subdomains and known-groups validity comparisons with PROMIS Global Physical and Mental	Pearson and Spearman correlations, intraclass correlation coefficient, analysis of variance
Responsiveness	Measures show expected changes with interventions over time consistent with pre-determining hypotheses	Longitudinal sample of 75 patients with heart failure before and after one of five different interventions/clinical scenarios	Paired t-test

Adapted from: Cella D, Hahn EA, Jensen SE, et al. Patient-Reported Outcomes in Performance Measurement. September 2015.

Northwestern Medicine®

Developing a clinically-relevant, patient-centric health status measure for patients with heart failure built on PROMIS®

Faraz S. Ahmad, MD, MS

Assistant Professor of Medicine (Cardiology)

Assistant Professor of Preventive Medicine (Health and Biomedical Informatics)

Center for Health Information Partnerships

Faraz.Ahmad@northwestern.edu

CHiP CENTER FOR HEALTH INFORMATION PARTNERSHIPS

K12 Conceptual Model and Future Funding

Step 1

Develop and validate the abbreviated PROMIS-Plus-HF physical, mental, and social measure versions with summary scores

Step 2

Optimize implementation of routinely-collected HF PROMs via a mixed-methods approach and pilot testing with patients

Step 3

Multi-center study testing a combination of the following:

1. Strategies to encourage routine use by patients
2. Strategies to implement into clinical care
3. Evaluate if routine use of PROMs improves risk prediction and patient-centered outcomes

K12 Career Development Award

Future Funding

Northwestern Medicine®

Outcomes (eventually)

- 30-day hospital readmissions
- Use and titration of guideline-directed medical therapy
- Referral to appropriate consultative care
  - Palliative care, cardiac behavioral medicine/psychiatry, social work

Northwestern Medicine®

Short Form vs Computerized Adaptive Testing

Short Form	Computerized Adaptive Testing
✓ More straightforward to develop and understand ✓ Easier to implement into routine care from an informatics perspective ✓ Same items filled out over time ✓ Can overlap items across population ✗ May have higher participant burden	✗ More challenging to develop and understand ✗ Harder to interpret by other ✗ More challenging informatics build ✗ Harder to scale nationally ✓ May minimize participant burden ✓ Very cool

Northwestern Medicine®