

Patient-Reported Outcomes (PROs) in Cancer Care

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Learning Objectives

- Describe what patient reported outcomes (PROs) are and how are they used in cancer care
- Describe the clinical outcomes PROs can improve when completed remotely outside the clinic (at home) and in clinic
- Apply understanding of PROs via an implementation case study at NC Cancer Hospital

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Part I:

PRO Background



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COVID-19 and PROs



Management of cancer and health after the clinic visit: A call to action for self-management in cancer care

Doris Howell, Deborah K Mayer, et al.

JNCI: Journal of the National Cancer Institute, djaa083, <https://doi.org/10.1093/inci/djaa083>

Published: 11 June 2020

JNCI JOURNAL of the NATIONAL CANCER INSTITUTE

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PRO Measurement

- Patient-Reported Outcome measure (PRO):
Measurement based on report that comes directly from patient about status of patient's health condition **without amendment or interpretation of patient's response**
 - New FDA guidance in 2020



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Common PROs and PREMs

PROs

- Symptoms
- Functional status
- Quality of life
- Self-efficacy for managing condition



PREMs

- Satisfaction with care
- CAHPS



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Example PRO Items

Welcome jaynedoe Home | Log out

Please think back over the **past 7 days**: Progress

How OFTEN did you have ARM OR LEG SWELLING?

What was the SEVERITY of your ARM OR LEG SWELLING at its WORST?

How much did ARM OR LEG SWELLING INTERFERE with your usual or daily activities?

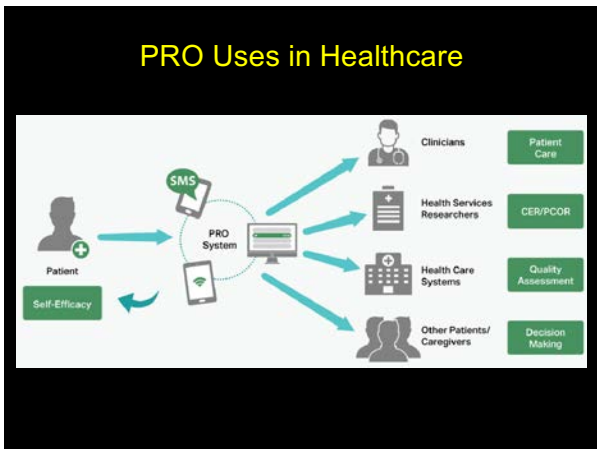
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PHQ-9 Items

Over the last 2 weeks, how often have you been bothered by any of the following problems? (rate "1" to indicate your answer)

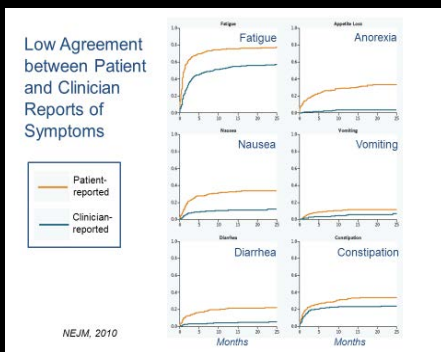
	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3

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Why Are PROs Important in Health Care?



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How Long Do Patients Have to Talk?

JGIM CrossMark

ORIGINAL RESEARCH
Eliciting the Patient's Agenda- Secondary Analysis of Recorded Clinical Encounters

Naykky Singh Ospina, MD, MSc^{1,2}, Karl A. Phillips, MD³, Rene Rodriguez-Gutierrez, MD, MSc^{2,4,5}, Ana Castaneda-Guarderas, MD⁶, Michael R. Giordano, Pharm D, PhD⁷, Megan E. Branda, MS⁸, and Victor M. Montori, MD, MSc²

- Analyzed recorded consultations
- 112 patients and 66 physicians between 2008-15
 - Specialty care: 51 visits, primary care: 61 visits
- Median encounter: 30 min (range: 4 - 80 min.)

Singh Ospina, et al. JGIM 2019;34(1):36-40.

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How Long Do Patients Have to Talk?



Clinician interrupted after median of **11 seconds** (interquartile range 7-22 s)

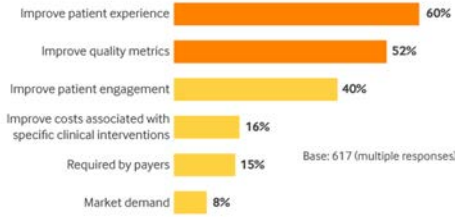
Singh Ospina, et al. JGIM 2019;34(1):36-40.

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Why are Health Systems Interested in PROs?

Better Patient Experience and Quality Are the Top Reasons to Collect and Use PROMs

What are the top two reasons for health care organizations to collect and use Patient-Reported Outcome Measures (PROMs)?

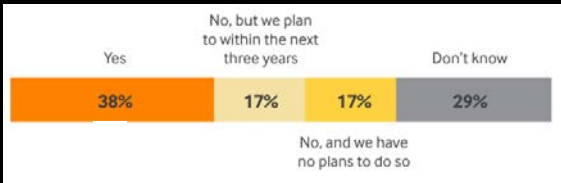


NEM Catalyst (catalyst.nem.org) © Massachusetts Medical Society

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PRO Usage in Clinics Growing

Does your organization use a Patient-Reported Outcome Measures (PROMs) system?

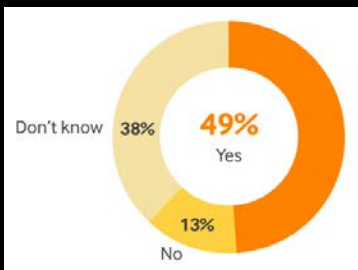


NEM Catalyst (catalyst.nem.org) © Massachusetts Medical Society

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Among Sites Using PROs, Worth it to Implement?

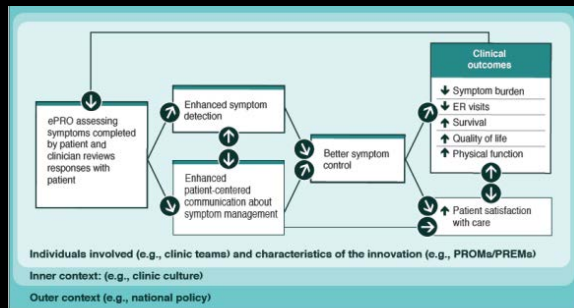
Is the effort involved in collecting, processing, and implementing PROMs worth the result?



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How do PROs Improve Outcomes?



Stover, 2020

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Part II:

Remote PROs outside the clinic



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PRO Randomized Trial at MSK

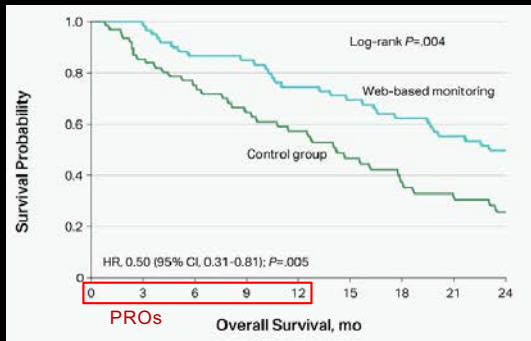


PRO Intervention Group:

- Remained on chemo longer (8.2 v 6.3 months)
- More likely to survive at 1 and 5 years
- Less likely to visit ER: 35% v 41%

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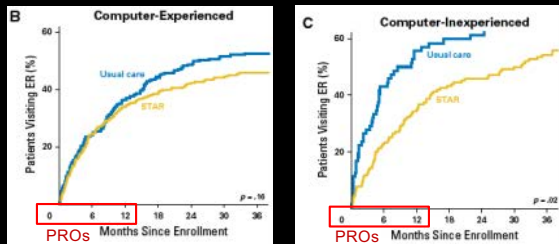
PROs Improve Survival



Basch E, et al. JAMA. 2017;318(2):197-198.

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PROs Improve ER Rates



Basch E, et al. JCO. 2016;34(6):557-565.

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UNC's National PRO Trial

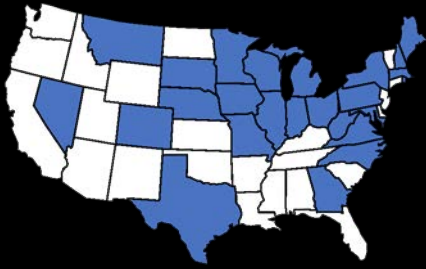


- 52 community cancer centers randomized to usual care or home PROs with alerts to clinicians
- All adult patients receiving chemotherapy
- 1,200 patients enrolled
- Follow up continues up to 12 months

Stover AM, et al. Qual Life Res. 2019;28(Suppl 1):S1.

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UNC's National PRO Trial



Reflects Typical Chemo Population:

- 58% Women
- 78% White
- 41% ≤ High School
- Average Age: 62

- 22% Lung
- 21% Breast
- 11% GI
- 10% Head/Neck
- 8% Prostate
- 28% Other

[clinicaltrials.gov: NCT03249090](https://clinicaltrials.gov/NCT03249090) Stover AM, et al. Qual Life Res. 2019;28(Suppl 1):S1.

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Symptoms Assessed in PRO-TECT

Symptom
Pain
Diarrhea
Constipation
Nausea, Vomiting
Physical Function
Eating/Drinking
Fatigue
Insomnia
Dyspnea
Depression
Falls

Stover AM, et al. Qual Life Res. 2019;28(Suppl 1):S1.

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Intervention Arm

• PROs Completed by Patients at Home
 • Between Visits
 • Any Web-Enabled Device

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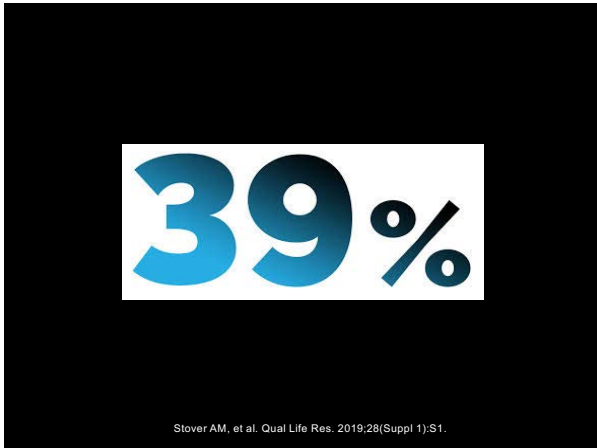
• Automated Alerts for Concerning Symptoms
 • Printouts of Symptoms at Visits

↓

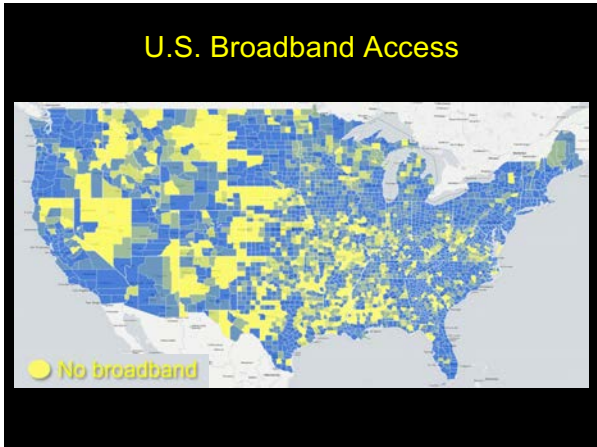
• Contact Patient to Grade Symptom(s)
 • Decide if Clinical Action is Needed

Stover AM, et al. Qual Life Res. 2019;28(Suppl 1):S1.

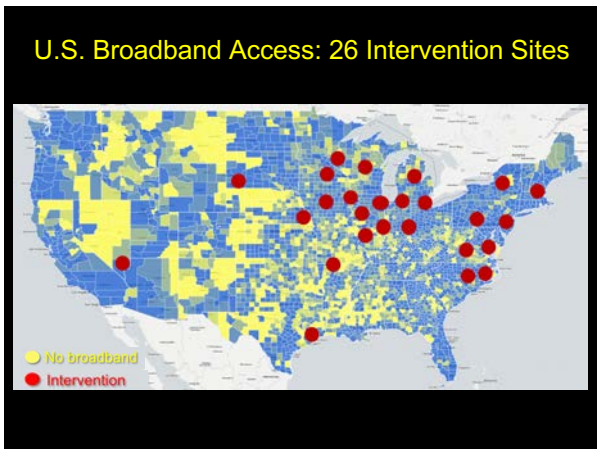
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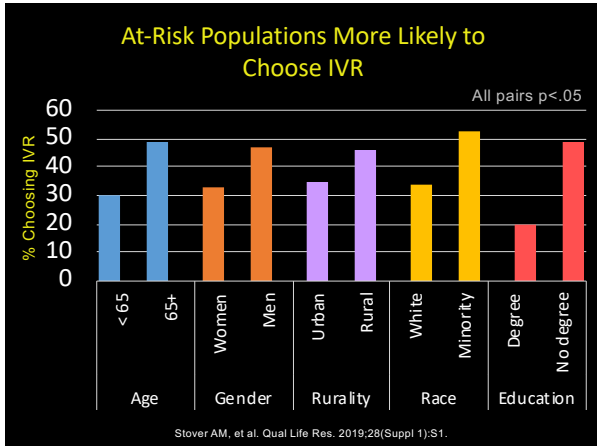
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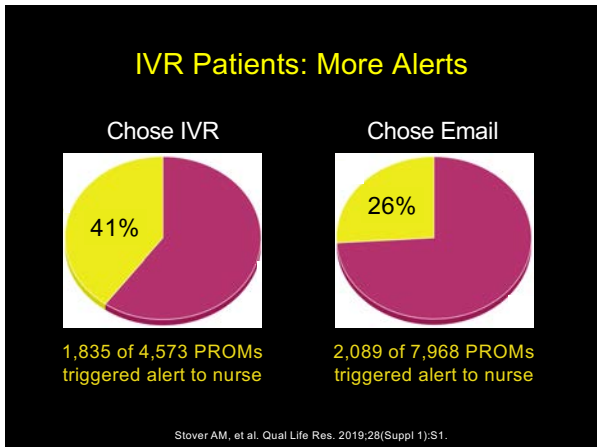
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Part III:

PROs Completed in the Waiting Room and the PRO Rollout at NC Cancer Hospital

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ESAS in Canadian Oncology Clinics

- In 2007, Cancer Care Ontario implemented PROs in waiting rooms
- Matched each cancer patients to a patient with cancer who did not complete PROs
- Results from 2007-2015
- 128,893 matched patient pairs

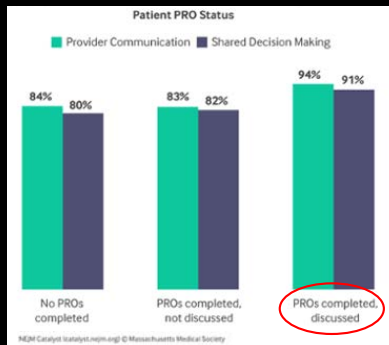
SUMMARY ANSWER: Patients exposed to ESAS are 8% less likely to visit the ED and 14% less likely to be hospitalized.

JCO Oncology Practice

Barbera L, et al. JCO OP. 2020;in press. DOI: 10.1200/JOP.19.00660.

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PROs Improve Satisfaction with Care



- UPMC began collecting PROs in Epic in 2017
- Portal or office-based tablet
- 273 active clinic locations live
- Correlation between discussing PROs and top-box satisfaction scores

Freel, et al. NJEM Catalyst. 2018

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Using an Implementation Science Approach to Implement and Evaluate Patient Reported Outcome Measures (PROM) Initiatives in Routine Care Settings

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Loite Haverman, PhD³
Hedy A. van Oers, PhD³
Joanne Greenhalgh, PhD⁴
Caroline M. Potter, DPhil⁵

On behalf of the ISOQOL PROMs/PREMs in Clinical Practice Implementation Work Group⁶

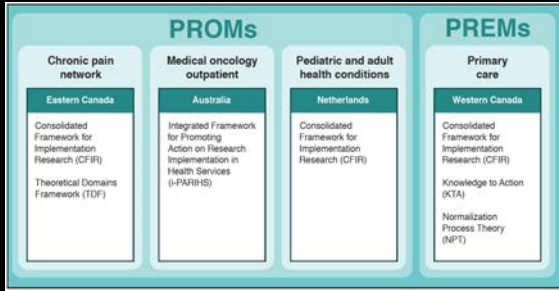


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5. Nuffield Department of Population Health, University of Oxford, UK
6. See Appendix 1

Stover et al. Qual Life Res. 2020; in press.

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PRO Case Studies



Stover et al. Qual Life Res. 2020; in press.

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Common PRO Barriers

- Unsure which PROs to use
- Technology limitations of capturing PROs
 - Displaying results for clinicians in a useful way
 - Not linked to EHR
- Uncertainty about ease and benefit of using PROs
- Perceived increase in workload
- Competing demands within established clinical workflows
- Cost and time to implement



Stover et al. Qual Life Res. 2020; in press.

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Lessons Learned from Case Studies

- In cross-study comparisons:
 - Barriers remarkably consistent across care settings
 - Tailor implementation to clinic resources
- PRO clinic initiatives more likely to be more successful if:
 - Purposefully designed integration
 - Substantive engagement with stakeholders (clinicians, patients)
 - Leverage existing EHR technology
 - Clinic evaluates implementation



Stover et al. Qual Life Res. 2020; in press.

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Steps to Realizing Integrated PRO System

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Melanie Calvert et al.
BMJ 2019;364:bmj.k5267

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User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice
Version 2, January 2015

Produced on behalf of the International Society for Quality of Life Research by (in alphabetical order):

Neil Aaronson, PhD
Thomas Oliver, MD
James Cunningham, PhD
Richard Hays, MD
Richard Hays, MD
Richard Hays, MD
Ralph Rosen, PhD
Richard Serlin, PhD
Clare Traylor, PhD

International Society for Quality of Life Research

Implementing Patient-Reported Outcome Measures in Clinical Practice: A Companion Guide to the ISOQOL User's Guide
Version 1, January 2015

Produced on behalf of the International Society for Quality of Life Research by (in alphabetical order):

Ray A-H Chan, PhD
David J. Cella, PhD
Kathie Hays, PhD
Ralph Rosen, PhD
Lorenz Steiner, MD

International Society for Quality of Life Research

www.isoqol.org

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Not All PROs are Free

Examples of proprietary PROs:

- Beck Depression Inventory (BDI)
- Brief Pain Inventory (BPI)
- EQ-5D
- SF-12, SF-36
- Morisky medication adherence scale

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PROMIS is Free!





<http://www.healthmeasures.net>

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NCCH PRO Rollout




- UNC Health multimillion investment in PROs & personnel
- In Feb. 2017, UNC Center for Health Innovation and UNC Health's Information Services Department began joint effort to develop unified strategy
 - Broad organizational support
 - Robust governance process
- New Epic@UNC functionalities:
 - HIPAA-compliant, secure tablet-based ePRO collection
 - Visualizations and decision support for clinicians

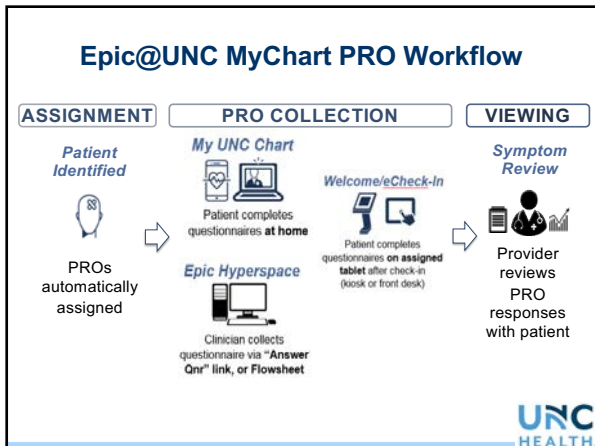
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UNC PRO Rollout Process at a Clinic

- Library of PROs in Epic
- Workflow/PRO needs assessment with coaches
- ISD completes build in Epic
- Tip sheet(s) and decision support available
- Train clinic to use PROs
- PDSA cycles
- Coaches send monthly reports to clinic


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Take Home Messages

- In cancer care, PROs improve:
 - Communication about symptoms
 - Symptom burden
 - Survival
 - ER rates
 - Satisfaction with care....





...But improved care doesn't happen automatically

- Clinic teams need trained to interpret and discuss PROs with patients during visits
- Get PRO implementation help for clinics

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Outcomes Breakfast: Every Tuesday

- unclineberger.org/outcomes
- Tuesdays at 8am: Carolina Club
- Email Eden Gifford to get on listserv
- @corp_UNC 



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- Stover AM, Haverman L, van Ders H, et al. Using an implementation science approach to implement and evaluate Patient-Reported Outcome Measures (PROM) initiatives in routine care settings. *Qual Life Res*. 2020; in press
- "User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice" Version 2, International Society for Quality of Life Research (ISOQOL). January 2019. <https://www.isoqol.org/user-content/uploads/2019/03/20190301UsersGuideVersion2.pdf>

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Questions?

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