Patient-Reported Outcomes (PROs): Optimizing use in clinical practice

Alicia K. Morgans, MD, MPH
Assistant Professor of Medicine
Division of Hematology/Oncology
Vanderbilt University Medical Center
March 10, 2017
Disclosures

• Advisory Board/Consulting: Genentech, Janssen, Bayer

• None of these are related to today’s talk.
Why use Patient Reported Outcomes (PROs)?

- Up to 50% of symptoms are undetected by treatment teams in routine clinical care.
- Undetected symptoms lead to increased ER visits and hospital admissions, and poorer patient satisfaction, medication adherence, quality of life (QOL), and disease outcomes.

PROs respond to this need

- “Outcomes reported directly by patients without interpretation by clinicians”
- Brief surveys completed by patients at/between visits describing symptoms
  - Can be directed to clinical team and imported directly into EMR

Chen et al. BMC Health Services Research 2013, 13:211.
PROs benefit numerous stakeholders

- Patient/Provider - patient level
  - Timely symptom management, improves health outcomes, med adherence, QOL, and patient-clinician communication
- Health care system - aggregate level
  - Improves patient satisfaction, enables quality improvement initiatives
- Payers and Policy makers - aggregate level
  - Prevent ER visits/hospitalization, reduce healthcare utilization

Benefits we can measure:
Fewer ER Visits

![Graph showing the comparison of patients visiting the emergency department between Usual care and PROs. The graph indicates that PROs have fewer ER visits compared to Usual care, with a statistical significance of P=0.02.]

Benefits we can measure: Improved OS

![Graph showing comparison between PROs and Usual care in terms of Probability of Overall Survival over Months since Enrollment with P=0.03.](image)

Benefits we can measure: Improved OS

Median OS estimates
Usual Care = ~26 mo.
PROs = ~30 mo.

Toxic therapies have been approved on a smaller survival benefit.
Change in QOL at 6 months

Barriers to PRO integration
Barriers to integration

- Altering workflow/decreased efficiency
- Overburdening existing staff
- Unclear value added in day to day practice
- Concerns regarding who deals with urgent issues
- Cost of systems for PRO capture
- Expense of additional dedicated FTEs
- Patient acceptance, burden

Locklear T, et al. NIH Collaboratory/Health Care Systems Research Collaboratory. [https://www.nihcollaboratory.org/Products/Strategies-for-Overcoming-Barriers-to-PROs.pdf](https://www.nihcollaboratory.org/Products/Strategies-for-Overcoming-Barriers-to-PROs.pdf).
Overcoming barriers: Time limitations

- ≥90% of clinicians report unchanged duration of office visits.
- Noted PRO lessened documentation burden – completed some of review of systems.
- Recommendations:
  - Integrate PRO into EMR when possible.
  - Ensure PRO report is in clinic room when physician arrives – like vital sign or lab value.

Locklear T, et al. NIH Collaboratory/Health Care Systems Research Collaboratory.
Overcoming barriers: Unclear benefit, potential risk

- Management of symptoms in real time improves QOL, patient satisfaction, well-being, survival.

- Recommendation:
  - Electronic systems should include built-in triggers for supportive services and alerts for urgent concerns.

Overcoming barriers: Patient burden

- 92% of patients found PRO completion improved care.
- 87% wanted to complete/review PROs at future visits.
- 87% would recommend PRO completion to other patients.

Recommendation:
- Short surveys that trigger action are key to mitigate respondent burden.

Locklear T, et al. NIH Collaboratory/Health Care Systems Research Collaboratory.
Patient reported outcome measures (PROMs) in prostate cancer: Which ones to use?
Multiple options exist

- Disease specific
  - FACT-P, EORTC PR25, EPIC-26, others
- General measures
  - Depression/anxiety - PHQ-9
  - General QOL - SF-36, EQ-5D, FACT-G
  - Advanced cancer QOL - EORTC QLQ-C30
  - Pain - BPI
  - Fatigue - FACIT-Fatigue, BFI
- Standardize collection or harmonize measures with validated crosswalk of scores
Features of successful PROMs

- Simple and brief
  - 6th grade reading level, intuitive rating scale
  - Ideally ~5 mins
- Developed with patient input
- Reliable and valid, sensitive to clinical change
- Easy to score
- Translations available

Actionability and Accessibility

• Easy to use thresholds prompt specific action
  • Referral to support services (social work, dietician)
  • Change in medication regimen (pain or depression medications)
• Requires physician and patient to have access to necessary services

PROs in Clinical Practice
Development of a Standardized Set of Patient-centered Outcomes for Advanced Prostate Cancer: An International Effort for a Unified Approach

Alicia K. Morgans\textsuperscript{a,1,*}, Annelotte C.M. van Bommel\textsuperscript{b,c,1}, Caleb Stowell\textsuperscript{b}, Janet L. Abrahm\textsuperscript{d}, Ethan Basch\textsuperscript{e}, Justin E. Bekelman\textsuperscript{f}, Donna L. Berry\textsuperscript{d}, Alberto Bossi\textsuperscript{g}, Ian D. Davis\textsuperscript{h}, Theo M. de Reijke\textsuperscript{i}, Louis J. Denis\textsuperscript{j,k}, Sue M. Evans\textsuperscript{l}, Neil E. Fleschner\textsuperscript{m}, Daniel J. George\textsuperscript{n}, Jim Kiefert\textsuperscript{o}, Daniel W. Lin\textsuperscript{p}, Andrew G. Matthew\textsuperscript{m}, Ray McDermott\textsuperscript{q}, Heather Payne\textsuperscript{r}, Ian A.G. Roos\textsuperscript{s}, Deborah Schrag\textsuperscript{d}, Thomas Steuber\textsuperscript{t}, Bertrand Tombal\textsuperscript{u}, Jean-Paul van Basten\textsuperscript{v}, Jacobus J.M. van der Hoeven\textsuperscript{w}, David F. Penson\textsuperscript{a,x}.
ICHOM Standard Set for Advanced PCa

Treatment approaches covered

- Hormonal therapy
- Chemotherapy
- Immunotherapy
- Radiopharmaceuticals
- Radiation
- Interventions for complications of local progression

Patient Reported Outcome Measures

- EORTC QLQ-C30
- EPIC-26
- 3 supplemental questions on sexual function

© 2015 ICHOM. All rights reserved. When using this set of outcomes, or quoting therefrom, in any way, we solely require that you always make a reference to ICHOM as the source so that this organization can continue its work to define more standard outcome sets.
### MSKCC STAR system

**Pathology**
- Gleason 3 + 3
- Organ confined
- PSA Before Surgery: 10.8

**Alerts**
- Erectile dysfunction. 6th Alert, 1st Alert: Monday, July 20, 2009, 32.5 months ago

**Surveys**
- Most Recent Survey: Thursday, October 21, 2010, 76 weeks ago

#### Erectile Function
- Baseline Physician: 4
- Baseline Patient: N/A
- Current: NO erection sufficient for penetration
- Injections: None
- Current Score: 13 / 30
  - (Moderate)
- 1Yr Prediction from month:
  - 3: 32%, 6: 13%, 9: 9%

#### Urinary Function
- Baseline Physician: 2
- Baseline Patient: N/A
- Current: NO pads
- Current Score: 21 / 21 (Good)
- 1Yr Prediction from month:
  - 3: 98%, 6: 97%, 9: 98%

**Bowel Function:** No bowel symptoms

**Quality of Life:** Current Score: 9 / 10

---

Memorial Sloan Kettering Cancer Center STAR patient reported outcomes report.  
[https://www.mskcc.org/amplio-system/patient-reported-outcomes](https://www.mskcc.org/amplio-system/patient-reported-outcomes)
Summary

- PRO use in the advanced prostate cancer setting may improve overall survival and quality of life – addressing two of the most urgent needs for this incurable population.

- Integration of PROs into practice requires:
  - Defining the purpose of data collection and choosing appropriate measures
  - Integrating PRO measures into the EMR to enhance rather than reduce clinician efficiency
  - Defining thresholds for action and ensuring appropriate services are available to automatically support patient needs.