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

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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.

Pakhomov SV, et al. Am J Manag Care 2008;14:530-9.
Basch E. N Engl J Med 2017; 376;2:105-8.
Atkinson TM, et al. Qual Life Res. 2012;21(7):1159-64.
Laugsand EA, et al. Health Qual Life Outcomes. 2010;8:104.
Fromme EK, et al. J Clin Oncol. 2004;22(17):3485-90.

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
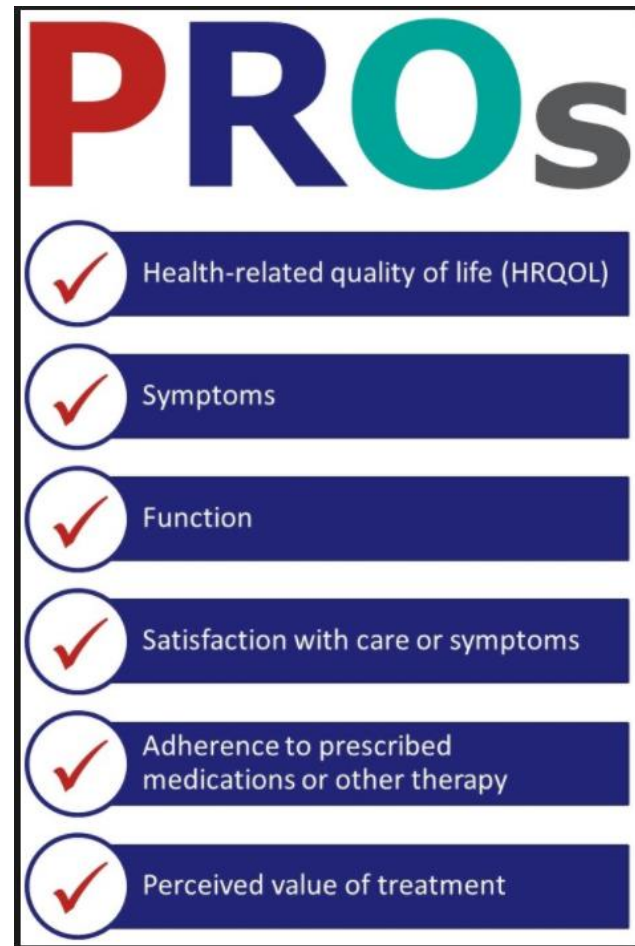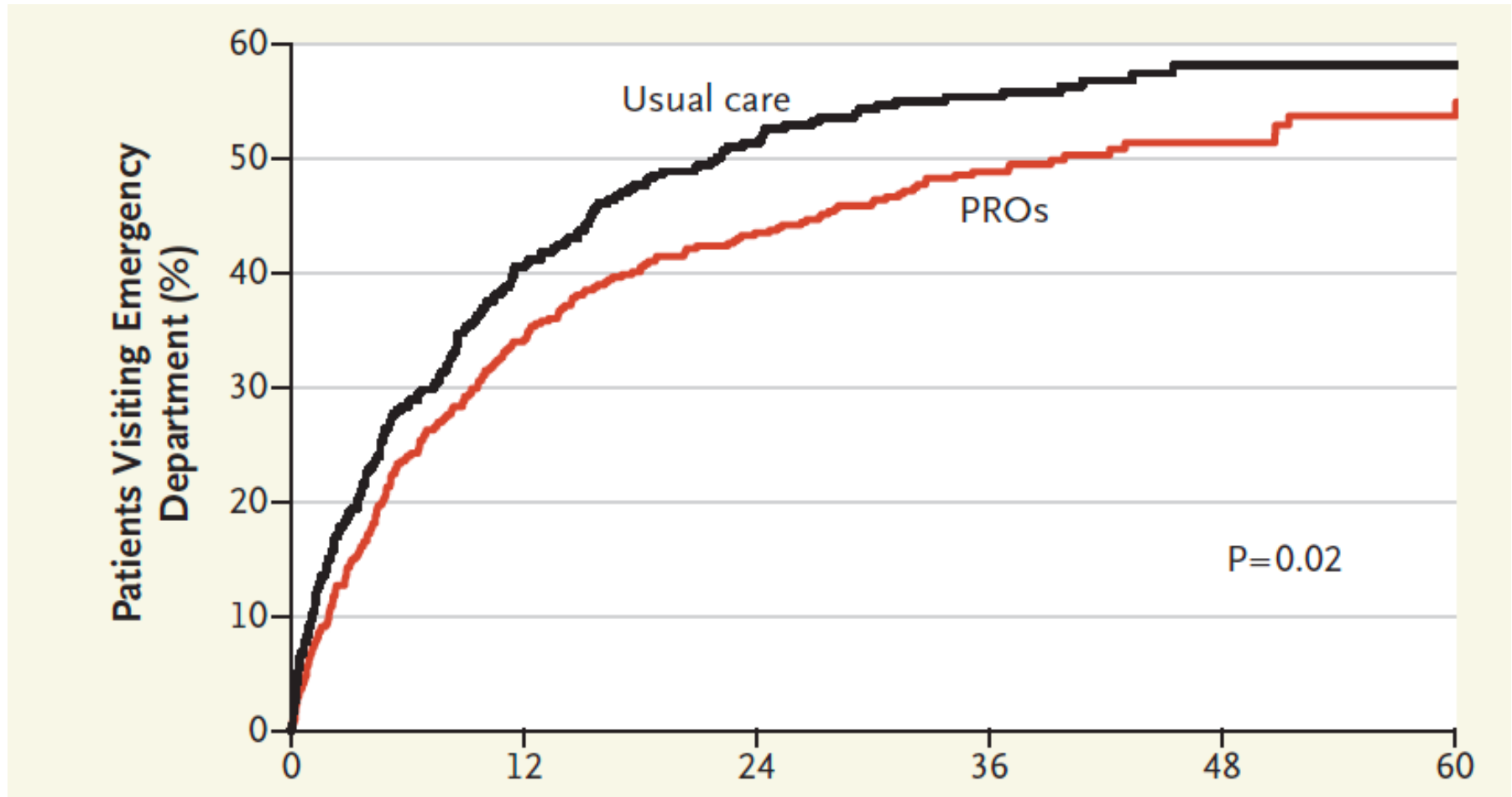
Speight J, et al. BMJ 2010; 340:c2921.
https://www.nihcollaboratory.org/cores/Pages/PRO.aspx
Snyder CF, et al. Qual Life Res 2012;21:1305-14.
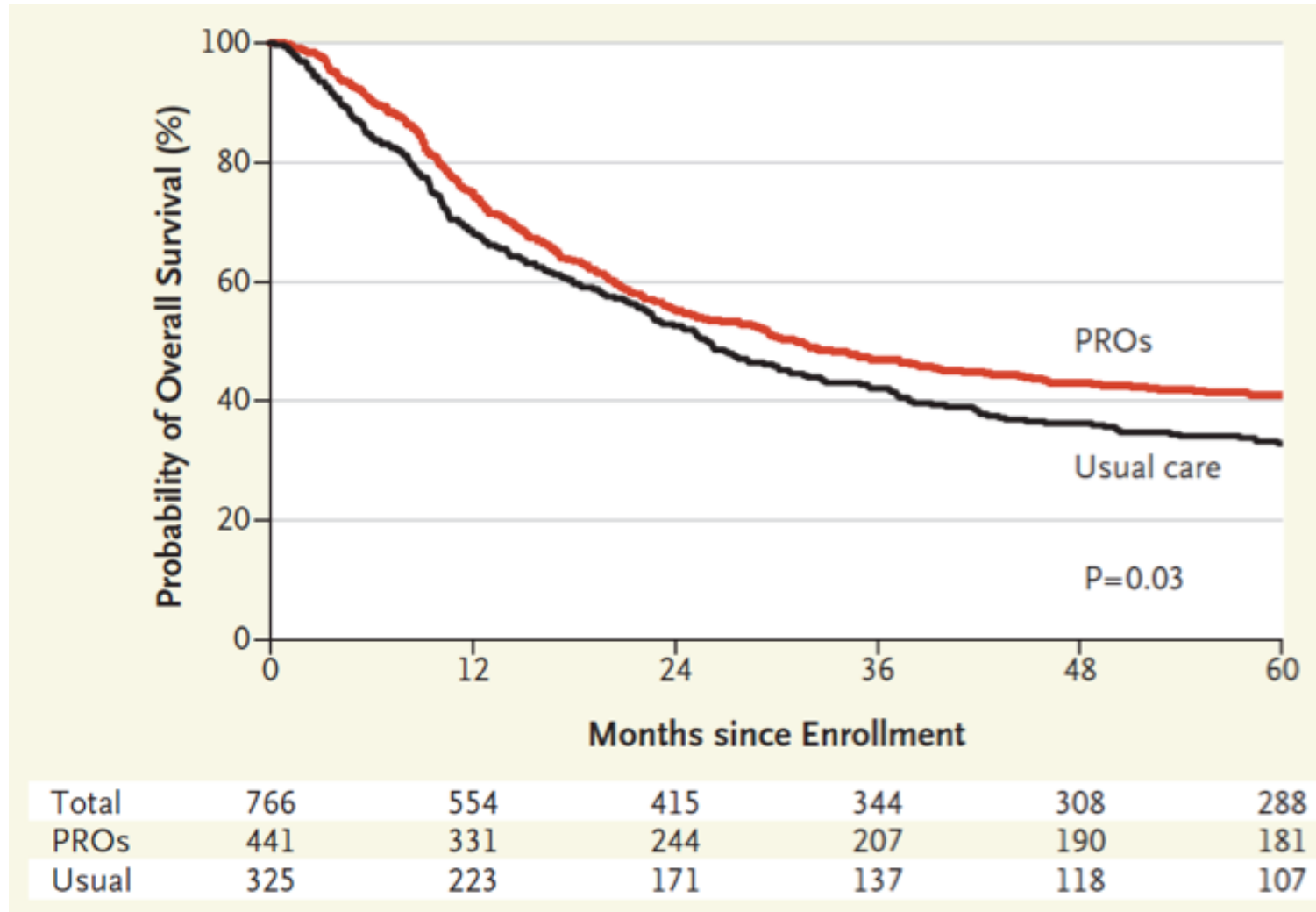Chen et al. BMC Health Services Research 2013, 13:211.

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

Basch E, et al. J Clin Oncol 2016; 34:557-565.   Basch E. N Engl J Med 2017; 376;2:105-8.

Benefits we can measure:
Fewer ER Visits

Basch E, et al. J Clin Oncol 2016; 34:557-565.

Basch E. N Engl J Med 2017; 376;2:105-8.

Benefits we can measure:
Improved OS

Total	766	554	415	344	308	288
PROs	441	331	244	207	190	181
Usual	325	223	171	137	118	107

Basch E, et al. J Clin Oncol 2016; 34:557-565.   Basch E. N Engl J Med 2017; 376;2:105-8.

Benefits we can measure: Improved OS

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

Total	766	554	415	344	308	288
PROs	441	331	244	207	190	181
Usual	325	223	171	137	118	107

P=0.03

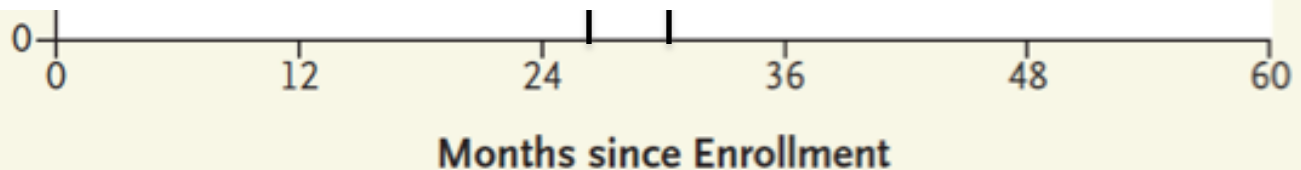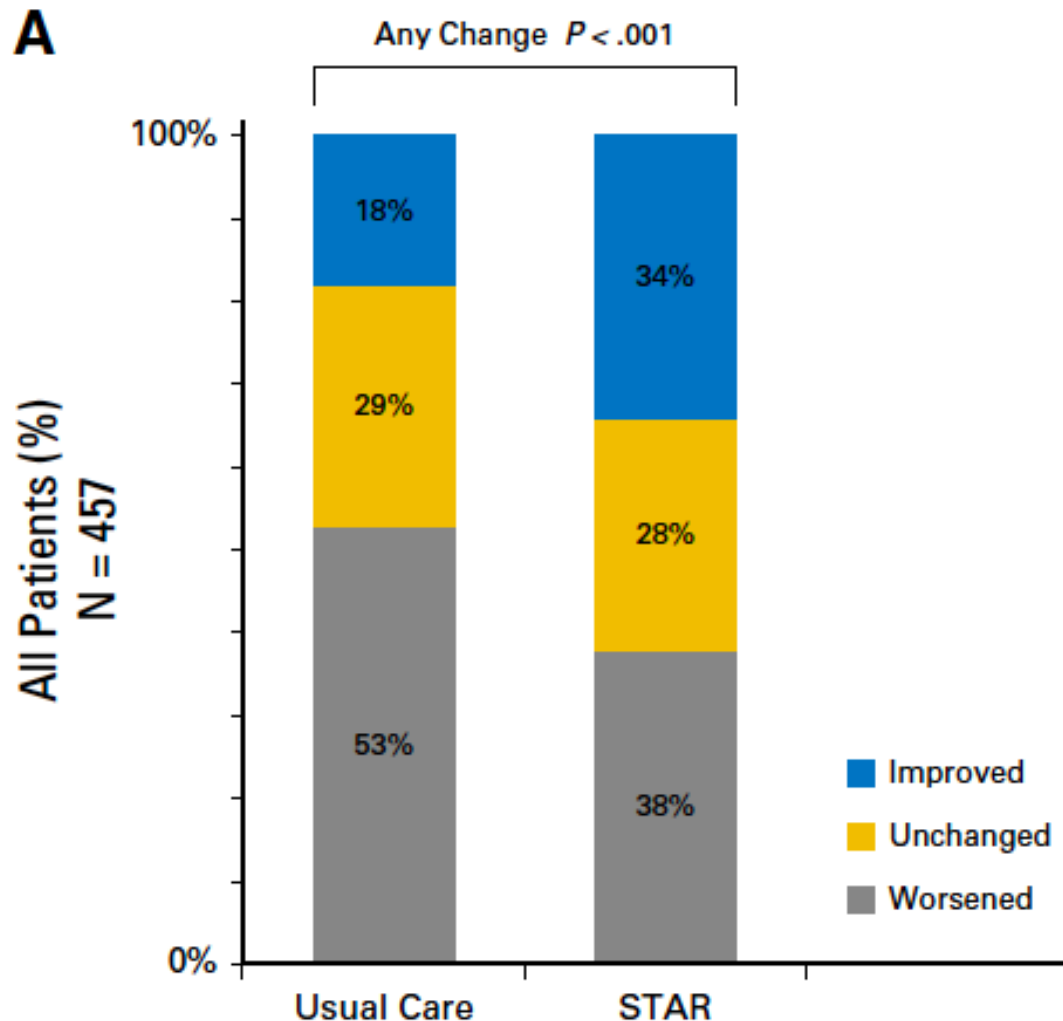Basch E, et al. J Clin Oncol 2016; 34:557-565.   Basch E. N Engl J Med 2017; 376;2:105-8.
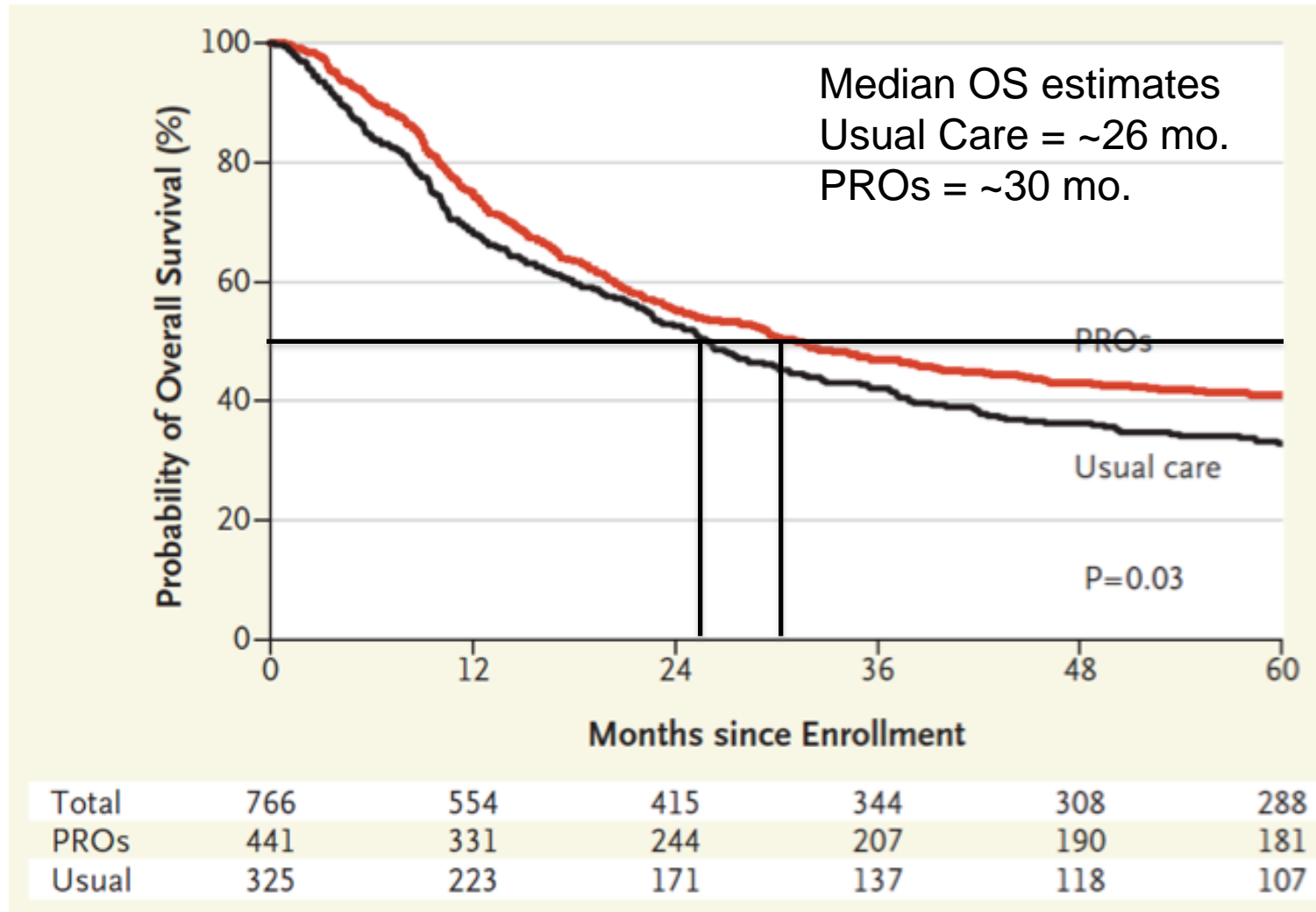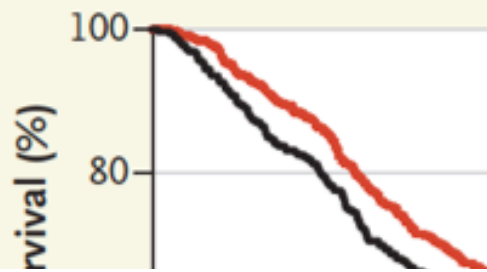
Median OS estimates
Usual Care = ~26 mo.
PROs = ~30 mo.

Toxic therapies have been approved on a smaller survival benefit.

Total	766	554	415	344	308	288
PROs	441	331	244	207	190	181
Usual	325	223	171	137	118	107

Basch E, et al. J Clin Oncol 2016; 34:557-565.   Basch E. N Engl J Med 2017; 376;2:105-8.

Change in QOL at 6 months

A   Any Change *P* < .001

Legend:
- Improved
- Unchanged
- Worsened

Usual Care: 18% Improved, 29% Unchanged, 53% Worsened
STAR: 34% Improved, 28% Unchanged, 38% Worsened

All Patients (%) N = 457

Basch E, et al. J Clin Oncol 2016; 34:557-565.

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.

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.

Stover A, et al. eGEMS 2015; 3(1):Article 17.
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.

Basch E, et al. J Clin Oncol 2016; 34:557-565.
Stover A, et al. eGEMS 2015; 3(1):Article 17.
Chen J, et al. BMC Health Services Research 2013, 13:211.
Jensen RE, et al. Med Care. 2015;53(2):153-9.
Veilikova G, et al. J Clin Oncol 2004;22:714-24.

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.

Stover A, et al. eGEMS 2015; 3(1):Article 17.
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

Eton DT, et al. Mayo Clinic 2012. http://www.mayo.edu/research/documents/harmonizing-and-consolidating-the-measurement-of-patient-reported-information-at-health-care-institutions-a-position-statement-of-the-mayo-clinic/doc-20078615. Accessed 3/2/17

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

Kronke K, et al. J Clin Epidemiol 2015;68(9):1085-92.
Trowbridge R, et al. Acad Med 1997;72(9):790-800.

PROs in Clinical Practice

Prostate Cancer

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

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

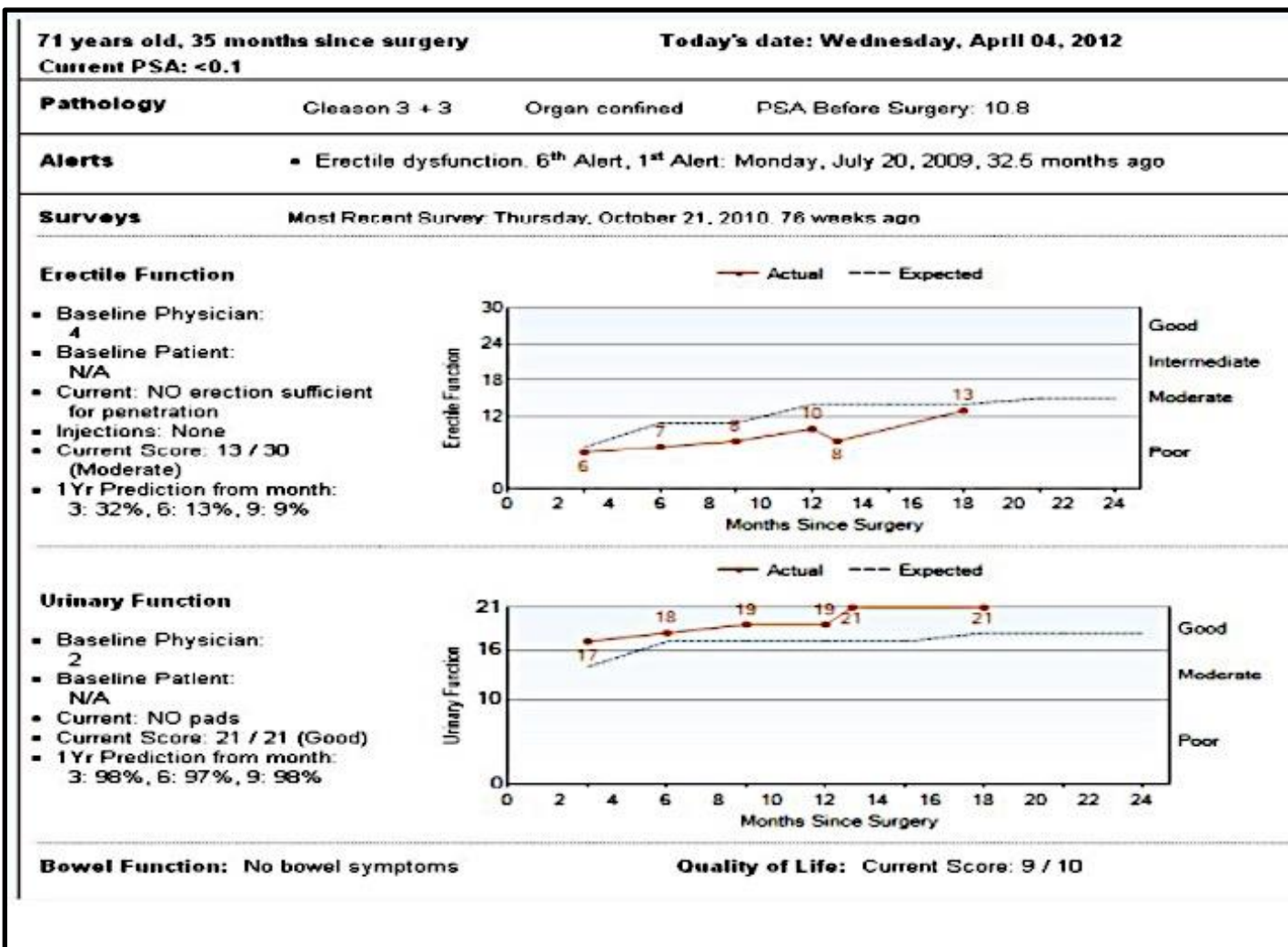# ICHOM Standard Set for Advanced PCa

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

MSKCC STAR system

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.