Electronic Patient-Reported Outcomes (ePROs) as Digital Therapeutics

Ethan Basch, MD, MSc

University of North Carolina

Presentation to National Cancer Policy Forum, National Academies of Sciences, Engineering, and Medicine

July 13, 2020

Disclosures

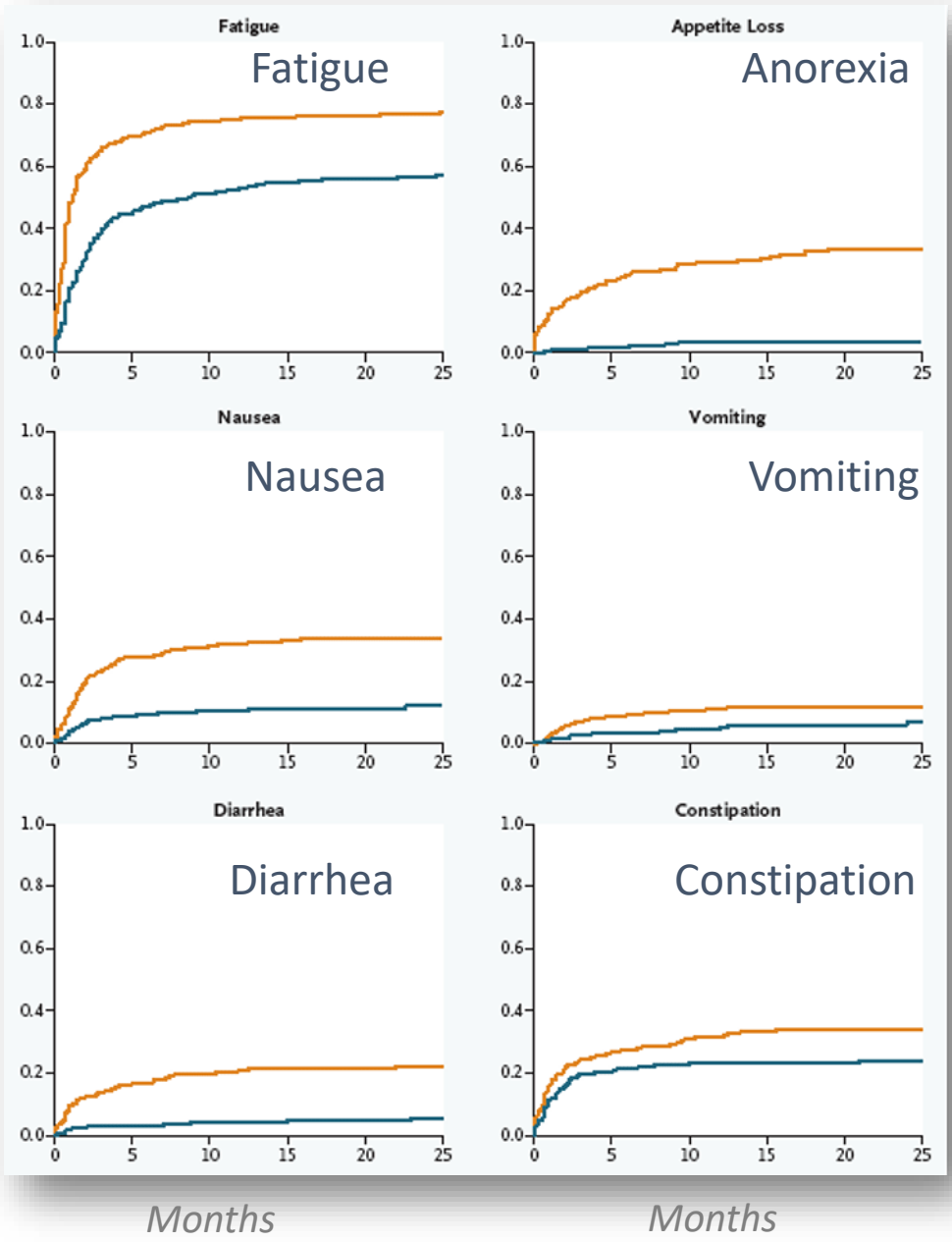
Employer: University of North Carolina

Research Funding: National Cancer Institute; Patient-Centered Outcomes Research Institute

Editorial Board: *JAMA*

Advising/Consulting: Sivan; Navigating Cancer; CareVive; Research Triangle Institute; AstraZeneca

Board of Directors: ASCO



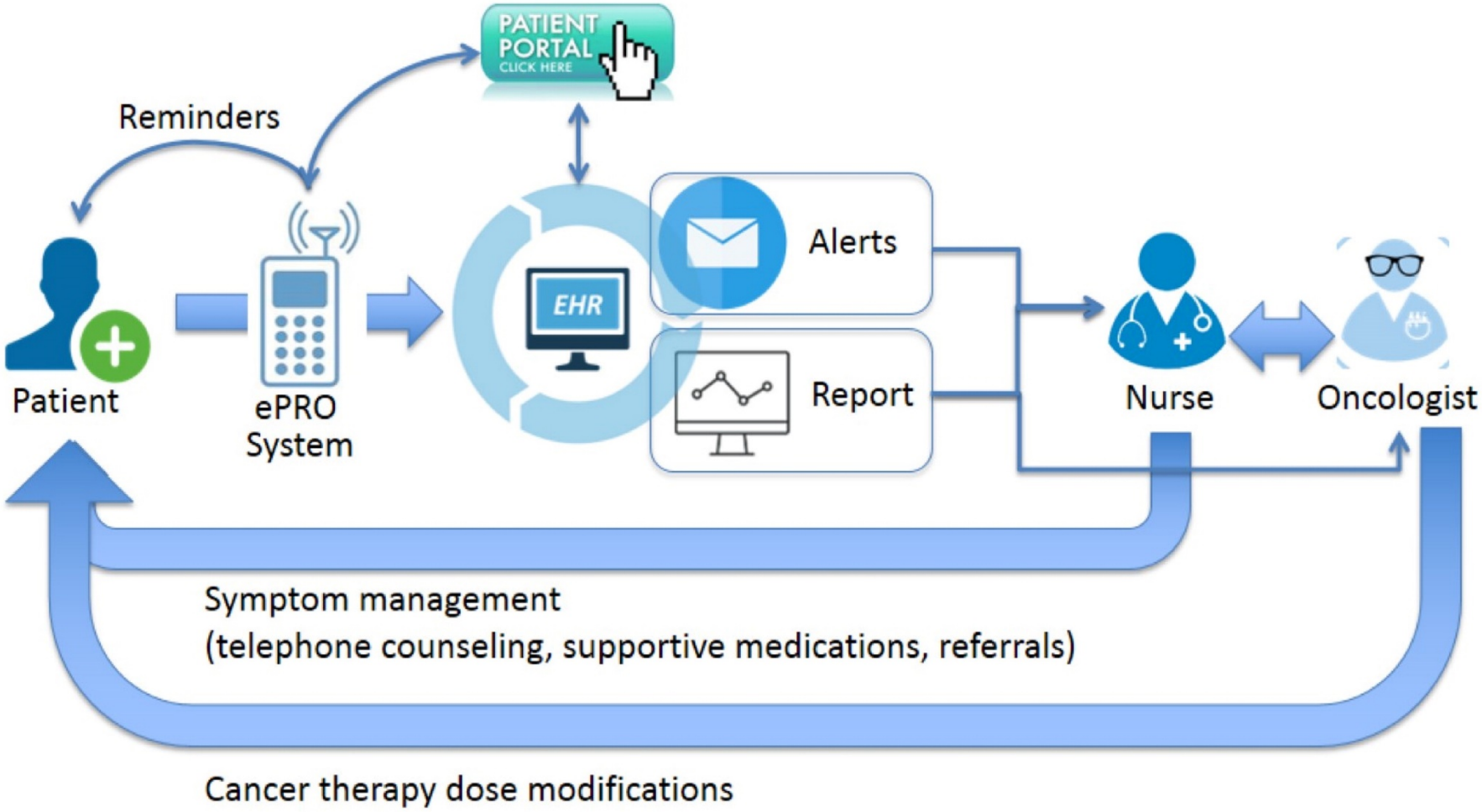
Cumulative incidence of patient vs. clinician reporting of the same symptoms over time, showing under-reporting by clinicians compared to patient self-report

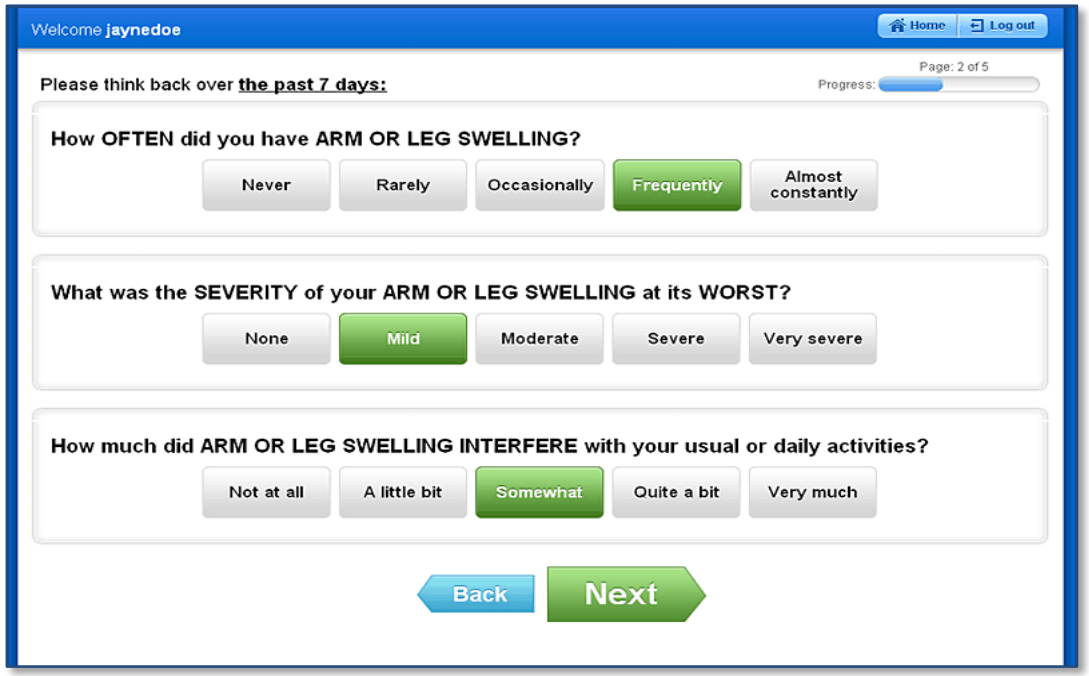
Patient-reported

Clinician-reported

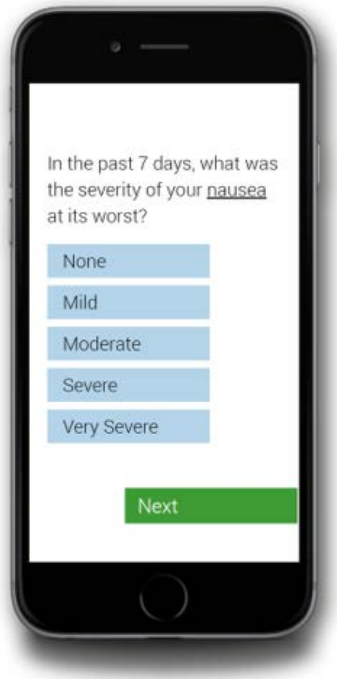
Basch: ***N Engl J Med*** *2010; 362:865-869*

Workflow Model for Implementing ePROs in Oncology Clinical Practice





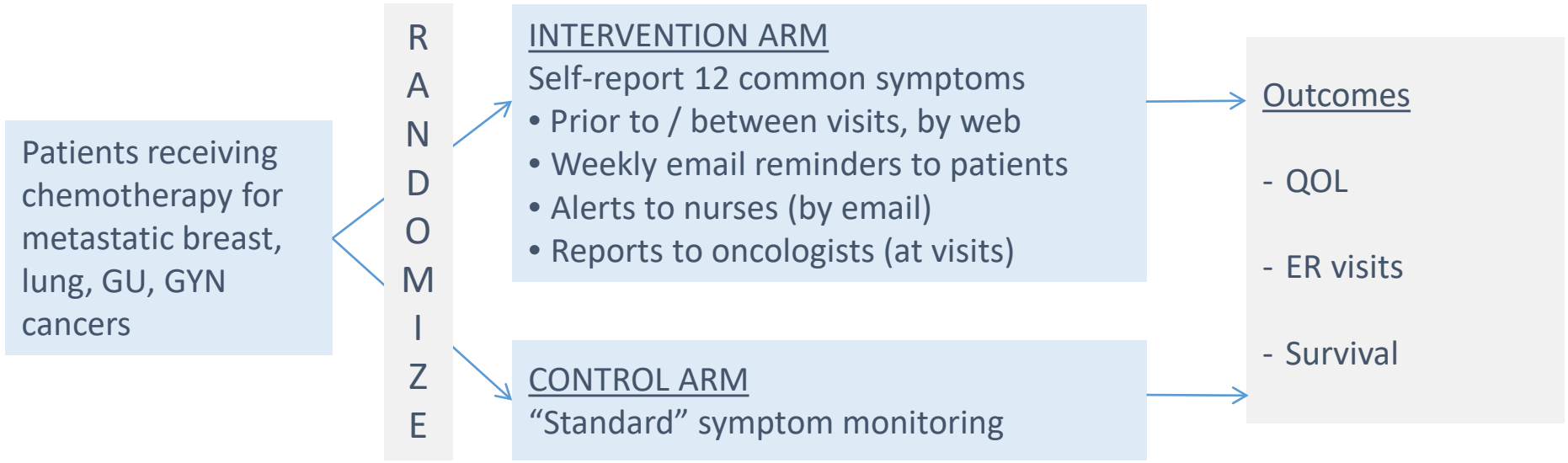
Web



Mobile

Automated Telephone Systems

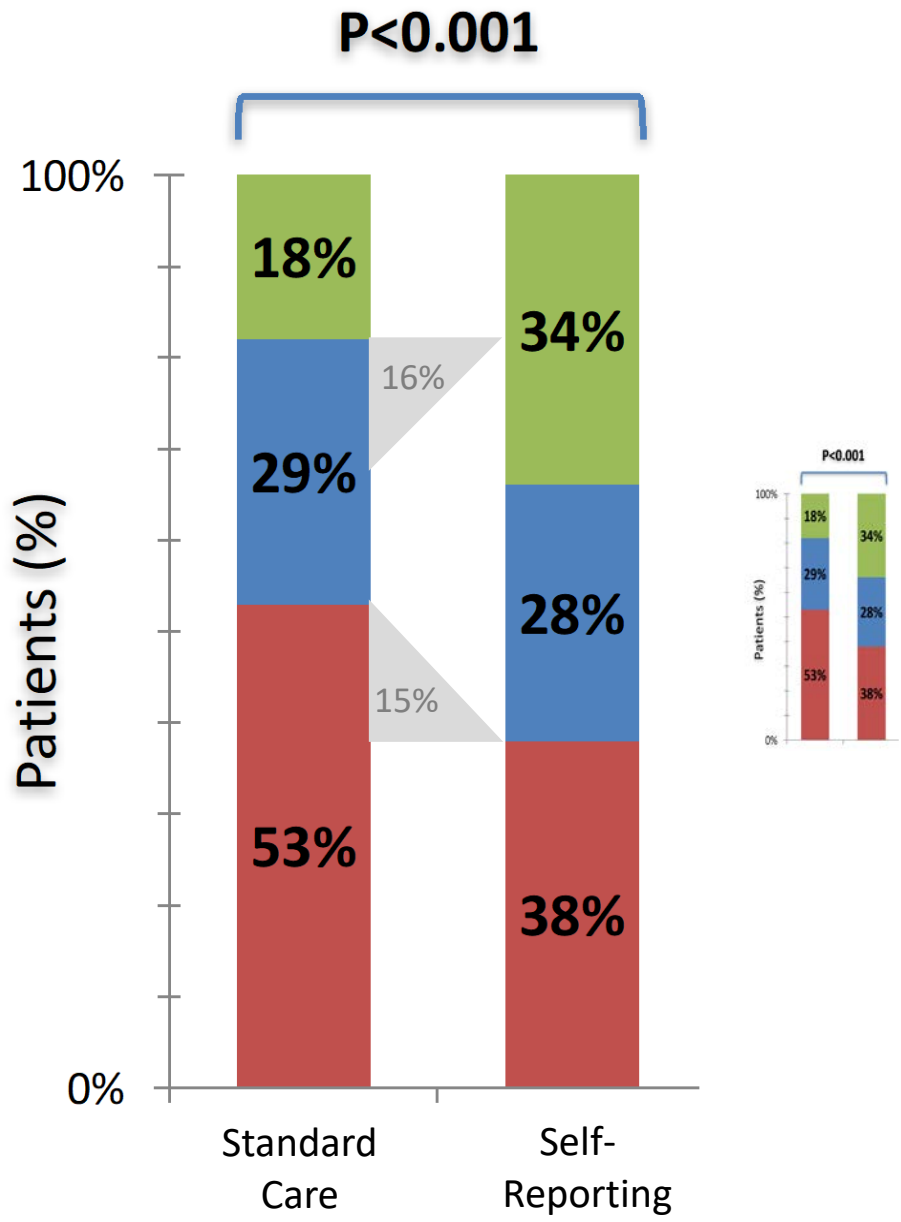
“STAR” Trial: ePRO as a Digital Therapeutic



Basch et al: ***JAMA*** *2017 Jul 11; 318(2): 197–198*
Basch et al: ***J Clin Oncol*** *2016 Feb 20; 34(6): 557–565*

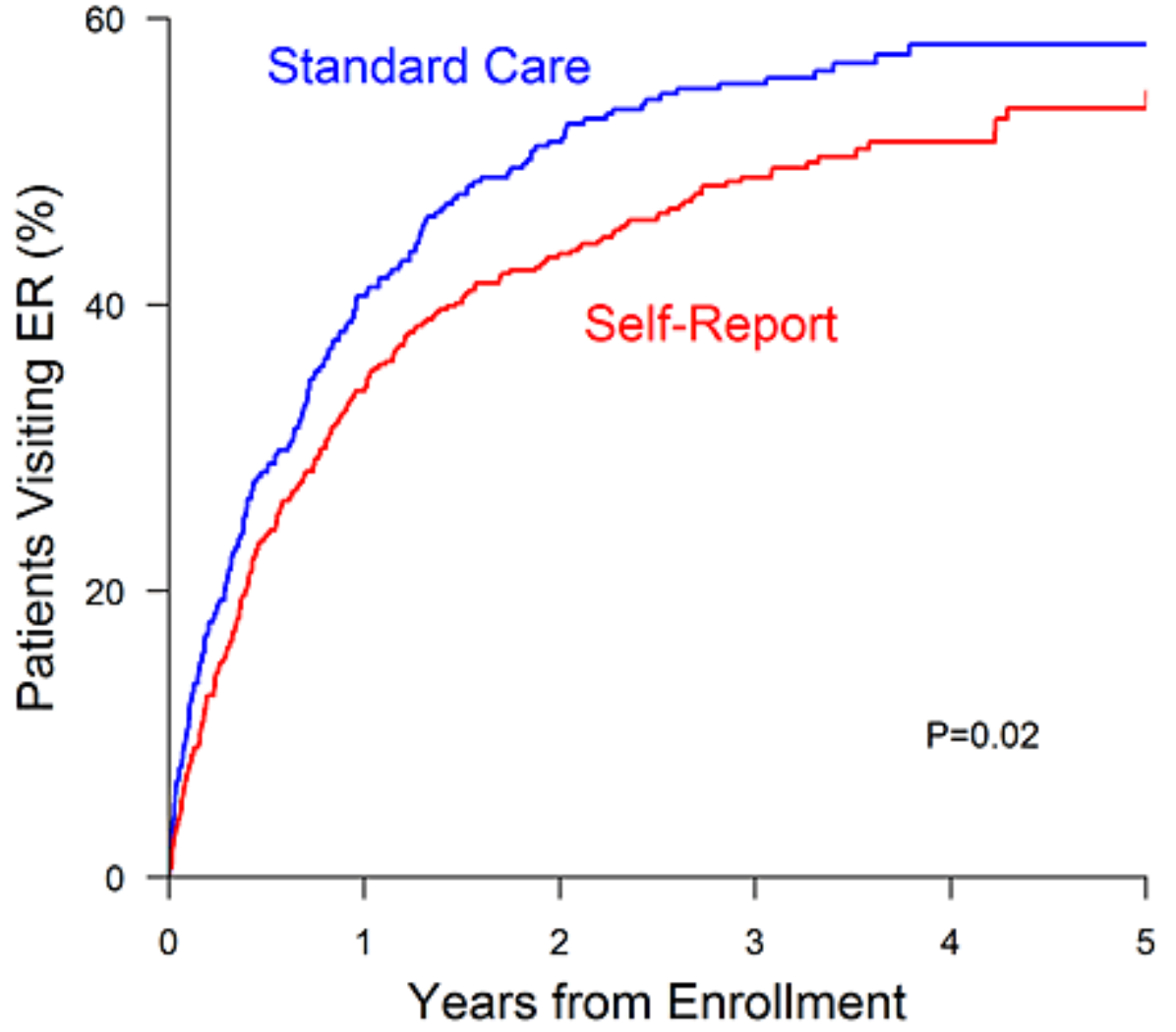
Quality of Life

- Assessed at 6 months, compared to baseline
- Compared to standard care, 31% more patients in the ePRO self-reporting arm experienced QOL benefits (*P<0.001*)



Emergency Room Visits

- Compared to standard care, 7% fewer patients in the ePRO self-reporting arm visited the Emergency Room, with durable effects throughout the study (*P=0.02*)



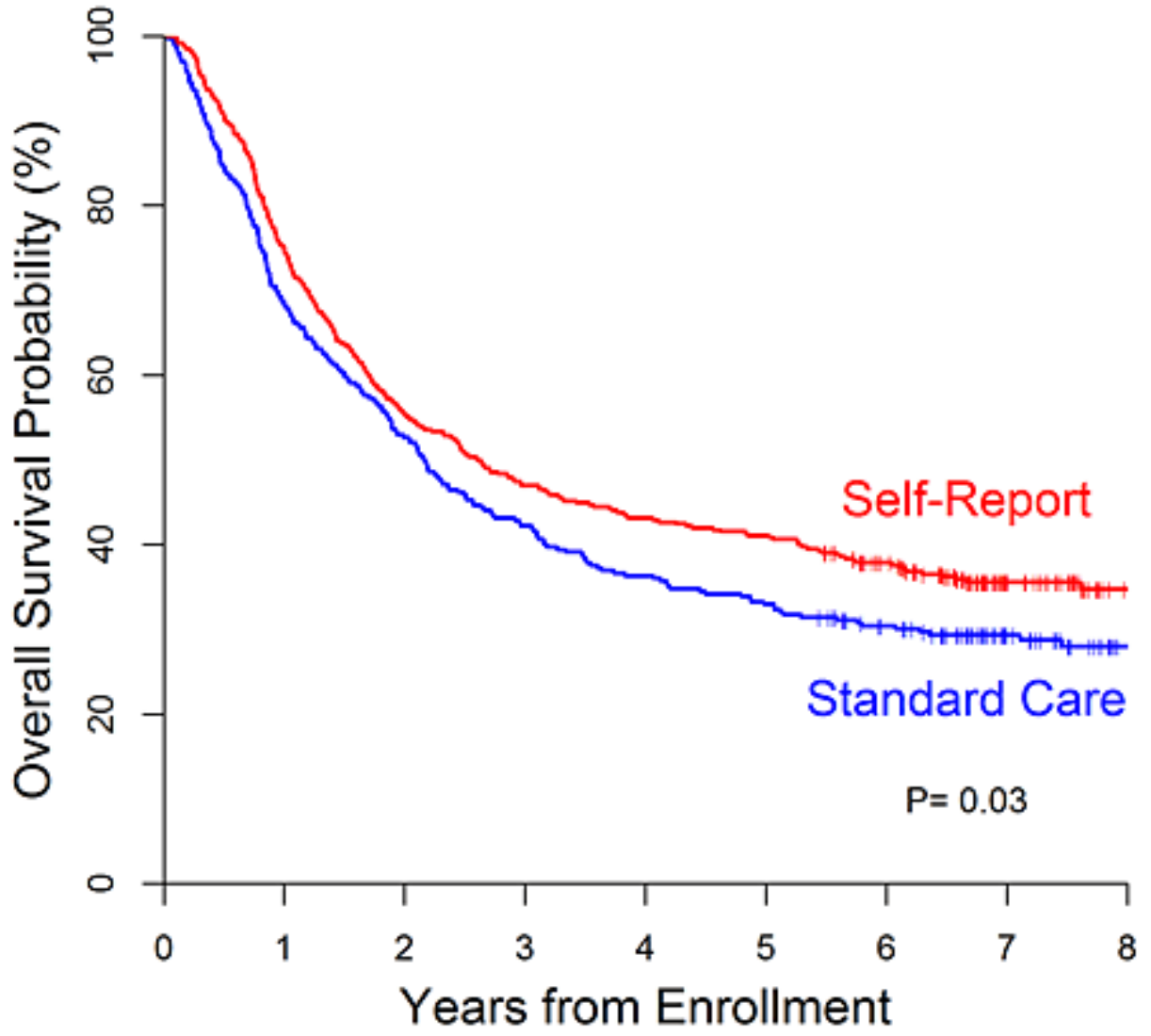
Total	766	554	415	344	308	288
Self-Report	441	331	244	207	190	181
Standard	325	223	171	137	118	107

Overall Survival

- Compared to standard care, median survival was 5.2 months longer among patients in the self-reporting arm (31.2 vs. 26.0 months) (*P=0.03*)
- Remained significant in multivariable analysis:

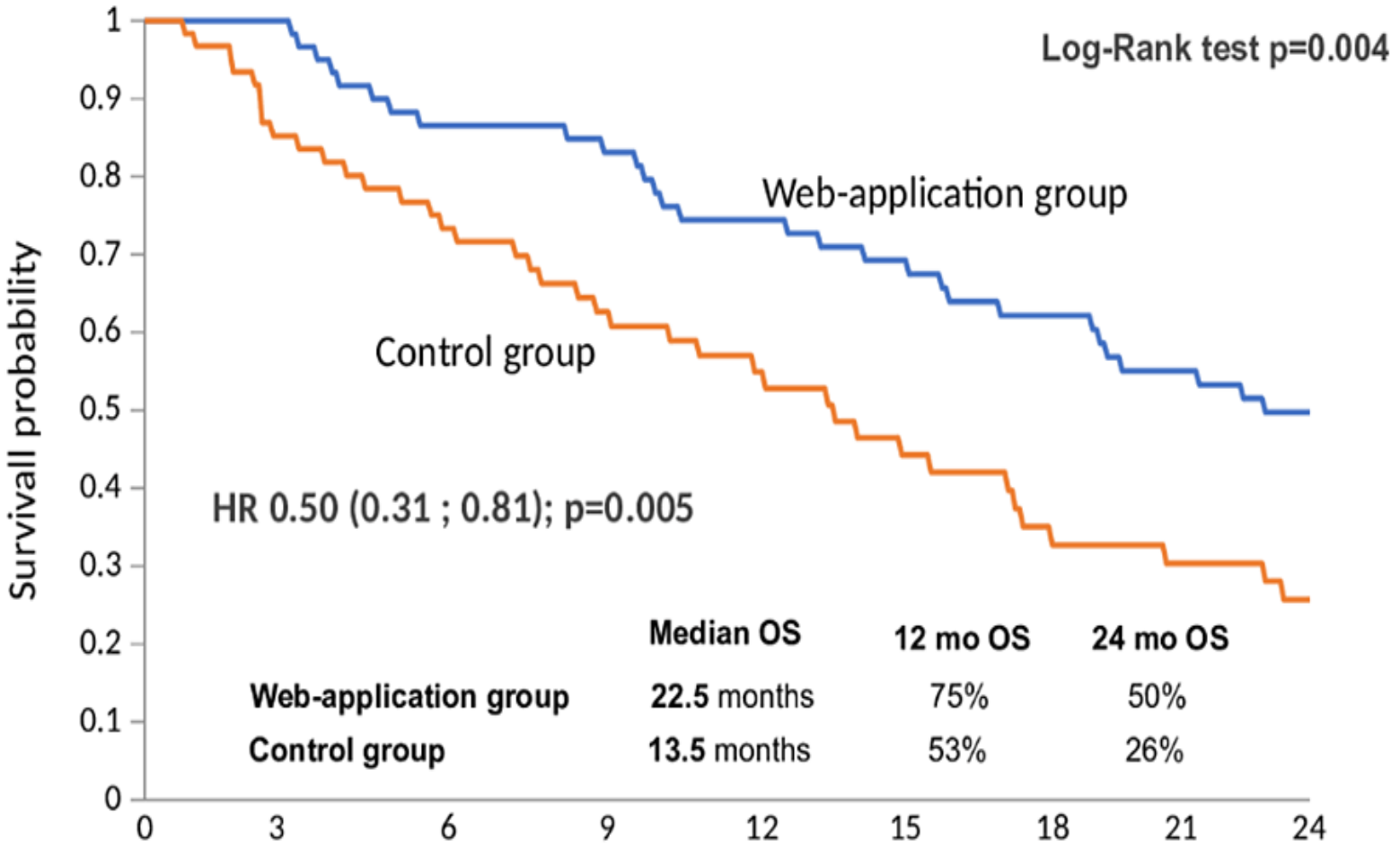
  Adjusted hazard ratio 0.832

  (*95% CI; 0.696, 0.995*)
- 5-year absolute survival benefit of 8%



Total	766	554	415	344	308	288	237	115	60
Self-Report	441	331	244	207	190	181	148	65	33
Standard	325	223	171	137	118	107	89	50	27

Similar Survival Benefits in Subsequent French RCT



Denis et al: ***JAMA****. 2019 Jan 22; 321(3): 306–307*

The impact of routine ESAS use on overall survival: Results of a population-based retrospective matched cohort analysis.

Lisa Catherine Barbera, Rinku Sutradhar, Craig Earle, Nicole Mittmann, Hsien Seow, Doris Howell, ...

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Abstract Disclosures

Abstract

6509

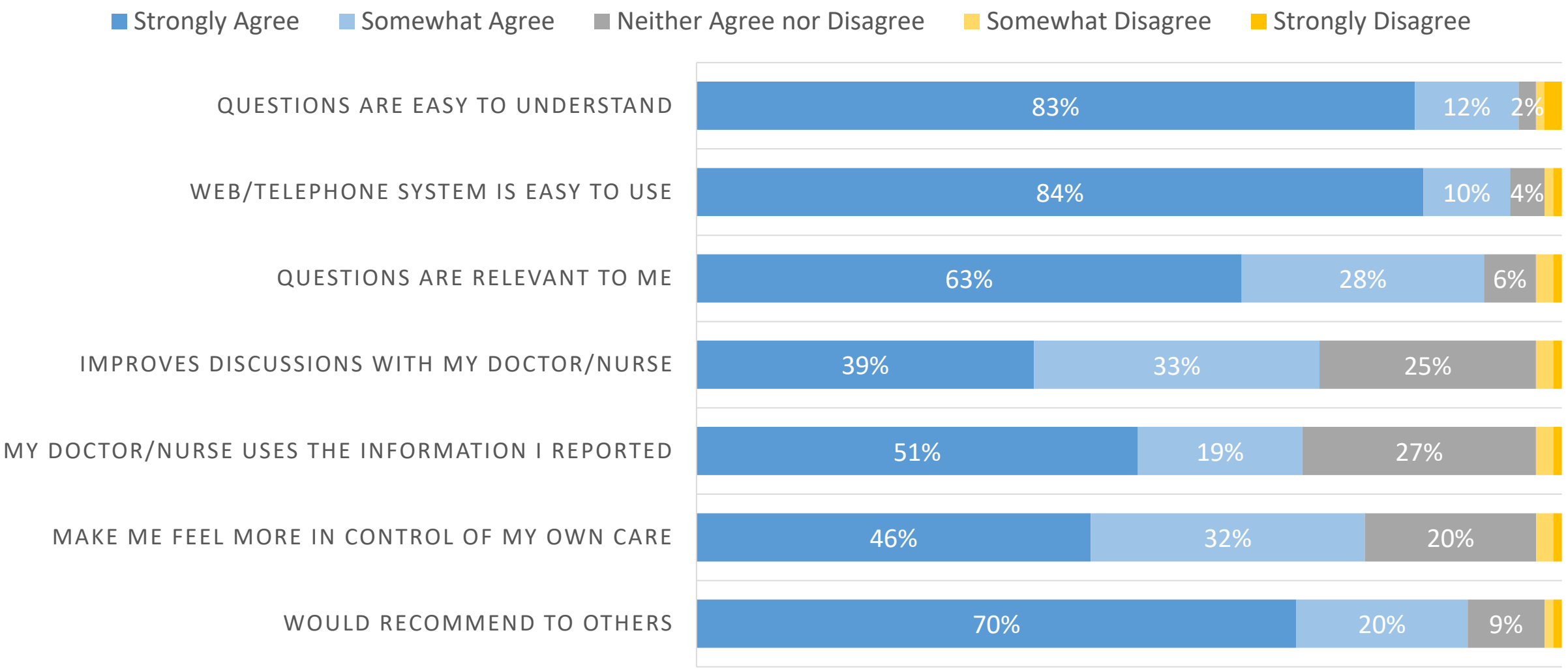
Background: The study objective was to examine the impact of routine Edmonton Symptom Assessment System (ESAS) use on overall survival among adult cancer patients. We hypothesized that patients exposed to ESAS would have better overall survival rates than those who didn't have ESAS. **Methods:** The effect of ESAS screening on survival was evaluated in a retrospective matched cohort study. The cohort included all Ontario patients aged 18 or older who were diagnosed with cancer between 2007 and 2015. Patients completing at least one ESAS assessment during the study were considered exposed. The index date was the day of their first ESAS assessment. Follow up time for each patient was segmented into one of three phases: initial, continuing, or palliative care. Exposed and unexposed patients were matched 1:1 using hard (birth year ± 2 years, cancer diagnosis date ± 1 year, cancer type and sex) and propensity-score matching (14 measures including cancer stage, treatments received, and comorbidity). Matched patients were followed until death or the end of study at Dec 31, 2015. Kaplan-Meier curves and multivariable Cox regression were used to evaluate the impact of ESAS on survival. **Results:** There were 128,893 pairs well matched on all baseline characteristics (standardized difference < 0.1). The probability of survival within the first 5 years was higher among those exposed to ESAS compared to those who were not (73.8% vs. 72.0%, P-value < 0.0001). In the multivariable Cox regression model, ESAS assessment was significantly associated with a decreased mortality risk (HR: 0.49, 95% CI: 0.48-0.49) and this protective effect was seen across all phases. **Conclusions:** ESAS exposure is associated with improved survival in cancer patients, in all phases of care. To the extent possible, extensive matching methods have mitigated biases inherent to observational data. This provides real world evidence of the impact of routine symptom assessment in cancer care.

And in Large Canadian Population-Based Study

ASCO 2019

Barbera et al: ASCO 2019 (JCO 37[15]: suppl (May 20, 2019) 6509-650

Patient Impressions of ePRO System (N=496)



Basch et al: ***JCO Cancer Clinical Informatics****; in press*

Challenges to ePRO Implementation

- Despite evidence, uptake in oncology practices has been slow.
- Main barrier is financial. A clear business model does not yet exist, and payers do not cover use of PROs in practice despite benefits.
- At practice level, implementation requires altering workflow, and deploying adequate staff to train patients, field alerts, monitor and address compliance.

Recommendations

1. CMS and private payers should provide reimbursement for symptom monitoring via PROs in clinical oncology practice, e.g., with a billing code that is substantial enough to support the technology and personnel deployment needs for this care enhancement.
2. Use of ePROs for symptom monitoring should be adopted as a process measure for performance evaluation in oncology.
3. Implementation of ePROs in any given practice should employ QI best practices, as with any complex care enhancement -- with particular attention to engagement of staff, leadership, and patients, and with ongoing monitoring of compliance.

With Gratitude

The patients and families participating in the reported research

PRO Investigators: Deborah Schrag, Charlie Cleeland, Tito Mendoza, Jeff Sloan, Amylou Dueck, Deborah Bruner, Amy Abernethy, Thomas Atkinson, Jennifer Hay, Bryce Reeve, Ben Arnold, Marty Schoen, Antonia Bennett, Ram Chilukuri, Paul Baumgartner
NCI: Lori Minasian, Sandy Mitchell, Ann O'Mara, Andrea Denicoff, Diane St. Germaine

Patient representatives: Diane Paul, Cindy Geoghegan, Patty Spears, Mary Lou Smith, Patrick Gavin, Jane Perlmutter, Alliance Patient Representative Committee

MSK: Lauren Rogak, Alexia Iasonos, Mark Kris, Howard Scher, Paul Sabbatini, Tom Atkinson, Narre Heon, Marwan Shouery, Kevin Shannon, Kai Lin, Charmaine Pun, Roxana Damian, Sharon Bayuga, Jennifer Hay, Glenn Heller, Natalie Barragan (Prior: Cliff Hudis, Mary Shaw, Laura Sit, Allison Barz, Mike Fruscione, Sean Ryan, Dawn Lavene, Liora Stark, Mark Appawu, Lisa Cianci)

UNC: Antonia Bennett, Philip Carr, Angela Stover, Eden Gifford, Mattias Jonsson, Sydney Henson, Jennifer Jansen, Randall Teal, Andrew Shirk, Bill Wood (Prior: Diana Mehedint)

Research networks: Alliance/CALGB; RTOG/NRG; NCCCP (now NCORP)

Funding: NCI U01-CA233046; NCI HHS-N261201000043C; NCI HHS-N261201000063C; NCI ARRA N02-PC-2008-00043; PCORI ME-1507-32079; PCORI IHS-1511-33392; DoD W81XWH 11-1-0639