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Remote Symptom Monitoring with Electronic Patient-Reported Outcomes (ePROs) in Oncology

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Presentation to: NIH Collabratory Grand Rounds
March 17, 2023

Symptoms are Common in Cancer

- Interfere with physical function and daily activities
- Lead to avoidable ER/hospital visits, readmissions
- Preclude treatment

Symptom management is a cornerstone of quality care

- But do we adequately detect and manage symptoms?

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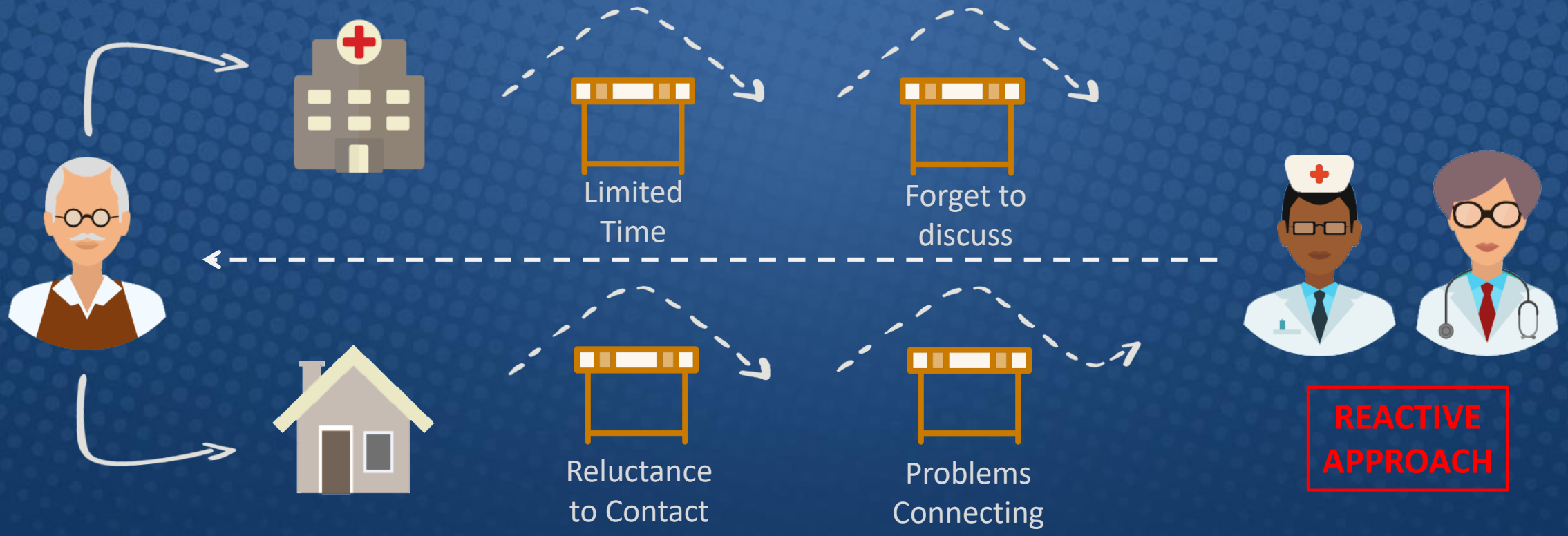
Standard Approach to Symptom Monitoring



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Model for Systematic Symptom Monitoring Using Electronic Patient-Reported Outcomes

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Early 2000s Patient Self-Reporting System

U.S. National Cancer Institute CTCAE Scale - Example: Pain

None	I have not had pain.
Grade 1 (Mild)	I have had mild pain, but it does not interfere with my normal functioning.
Grade 2 (Moderate)	I have had moderate pain, and my pain or my use of pain medications interferes with my normal functioning. But I am still able to carry out my normal daily activities.
Grade 3 (Severe)	I have had severe pain, and my pain or my use of pain medications severely interferes with my normal daily activities.
Grade 4 (Disabling)	My pain has been disabling.

Early Alert Function to Clinicians

Example: Shortness of Breath (Dyspnea)

○ None	I have not had shortness of breath (with exercise or rest).
○ Grade 1 (Mild)	I have been short of breath with exercise, but I can walk up 1 flight of stairs without stopping.
○ Grade 2 (Moderate)	I have been short of breath with exercise but I am not able to walk up 1 flight of stairs or 1 city block without stopping.
◉ Grade 3 (Severe)	I have been short of breath during my normal daily activities (dressing, showering, cleaning, cooking, etc).
○ Grade 4 (Disabling)	I have been short of breath even when I am resting in bed or in a chair.

Email Alert to Clinical Nurse

From: Patient Symptom Tracking <webmaster@mskcc.org>
Date: Wednesday, June 14, 2010 at 2:16 PM
To: Microsoft Office User < [redacted]@mskcc.org>
Subject: Patient Symptom Alert

SYMPTOM REPORTED FROM HOME

Patient Medical Record Number: [redacted]
Date/Time Reported: 07/14/2010 at 2:15 PM

Symptom: DYSPNEA **Grade:** 3

Symptoms that have worsened since 07/07/2010:
Symptom: DYSPNEA from **Grade:** 1 to 3

Link to FULL REPORT

Printed Report to Oncologist at Clinic Visit

STAR SYMPTOM REPORT

Confidential PHI

Patient Name: [redacted]
Patient MRN: [redacted]
Primary Oncologist: [redacted]

Worsened symptoms since July 7:

- Cough: from grade 0 to grade 1

Improved symptoms since July 7:

- Dyspnea: from grade 3 to grade 1
- Fatigue: from grade 2 to grade 1
- Pain: from grade 1 to grade 0

Below is a summary of prior reported symptoms, with most recent reports on top:

DATE	Anorex.	Constip.	Cough	Diarrhea	Dyspnea	Dysur.	Fatigue	Hot Fl.	Nausea	Neurop.	Pain	Vomiting
06/10/10	0	0	1	0	2	0	2	0	2	0	1	0
06/10/10	Clinic/Chemotherapy Visit											
06/20/10	0	0	2	0	1	0	2	0	0	0	1	0
07/01/10	0	0	1	0	1	0	1	0	0	0	1	0
07/01/10	Clinic/Chemotherapy Visit											
07/07/10	0	0	0	0	1	0	1	0	1	0	0	0
07/14/10	0	0	0	0	3	0	2	0	0	0	1	0
07/22/10	0	0	1	0	1	0	1	0	0	0	0	0
07/22/10	Clinic/Chemotherapy Visit											

Feasibility in Routine Cancer Care

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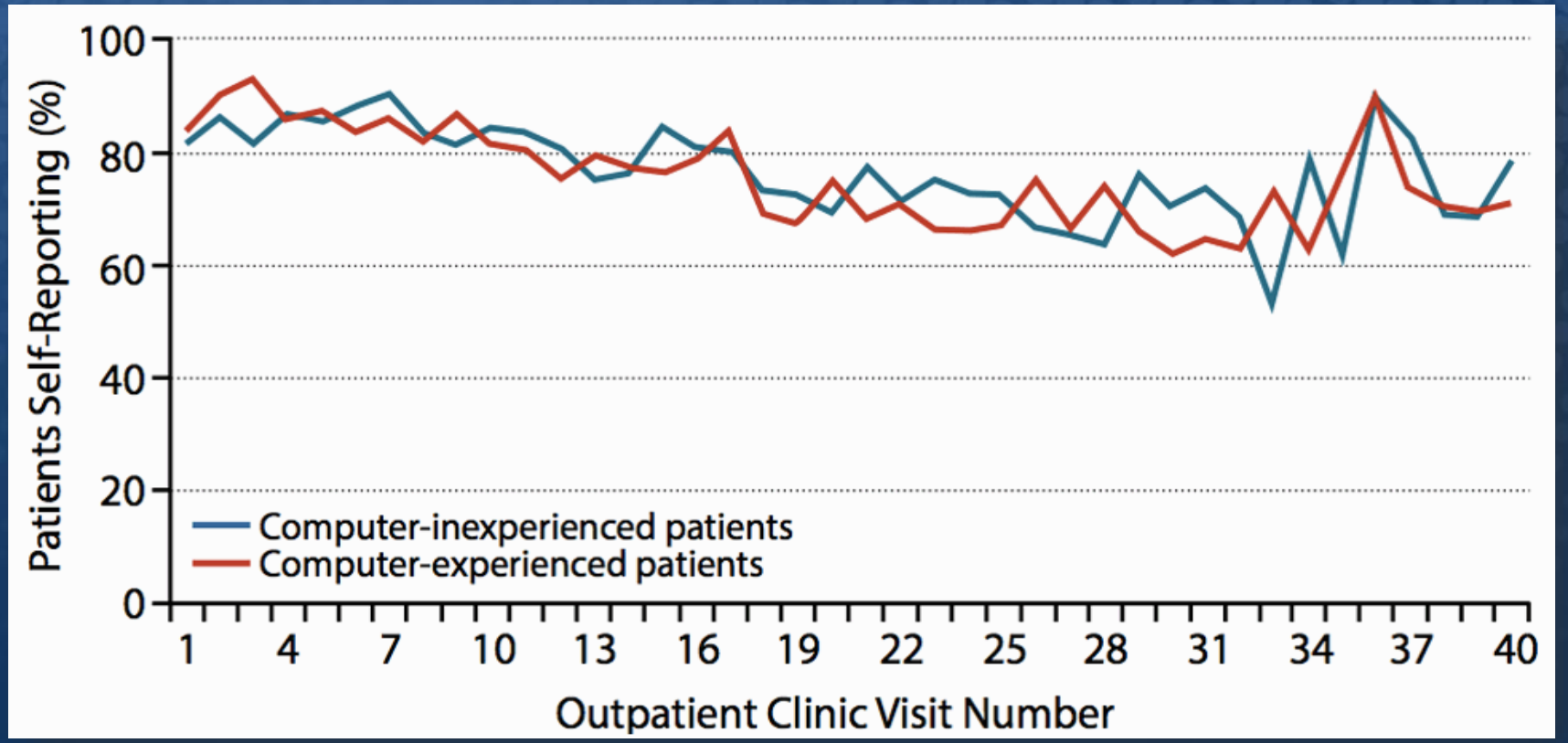
Patients longitudinally self-reporting symptoms (N~700):

- Most patients self-report at any given clinic visit



Basch: J Clin Oncol: 2005, 2007, 2016

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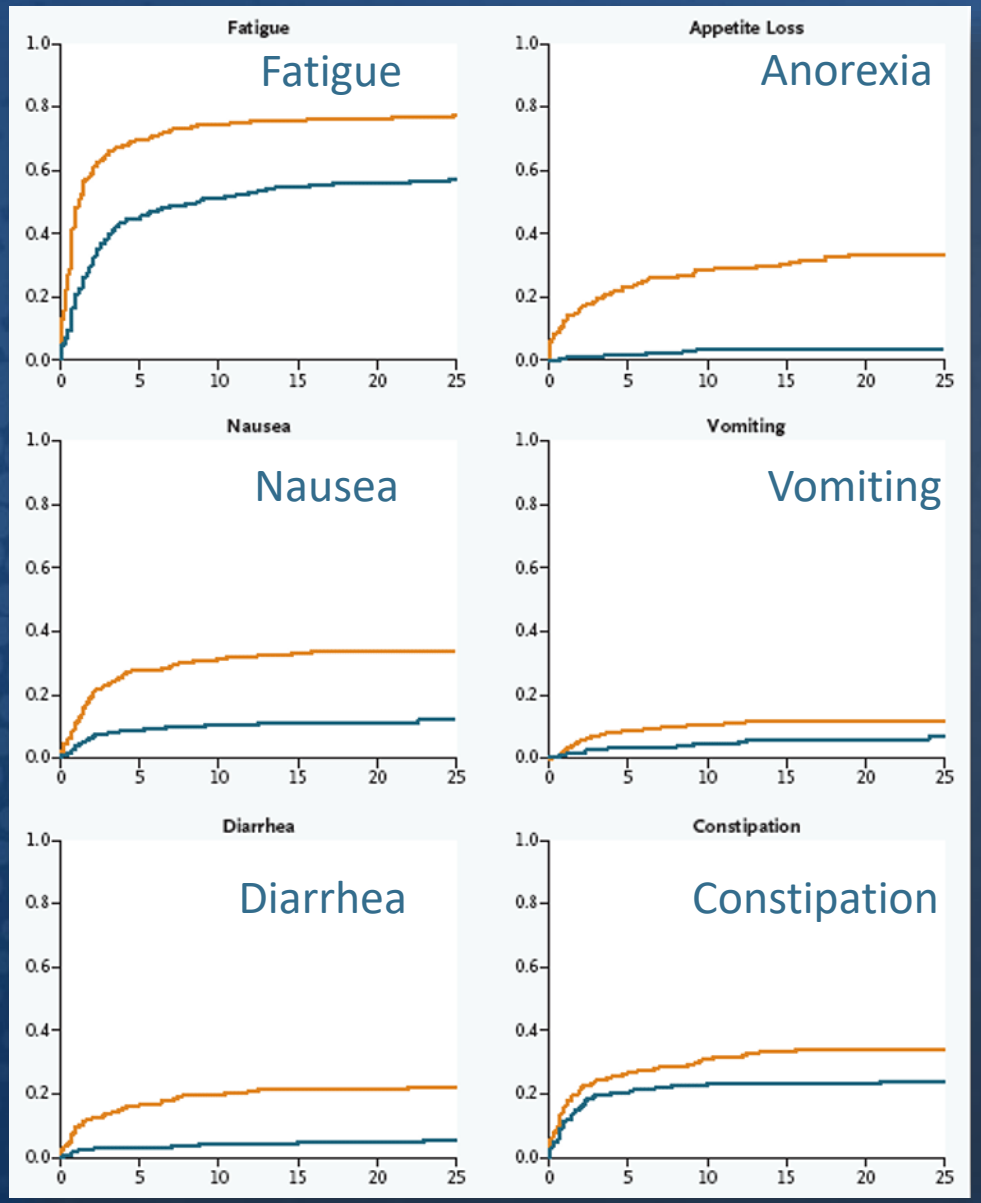
Clinician vs Patient-Reported Symptoms



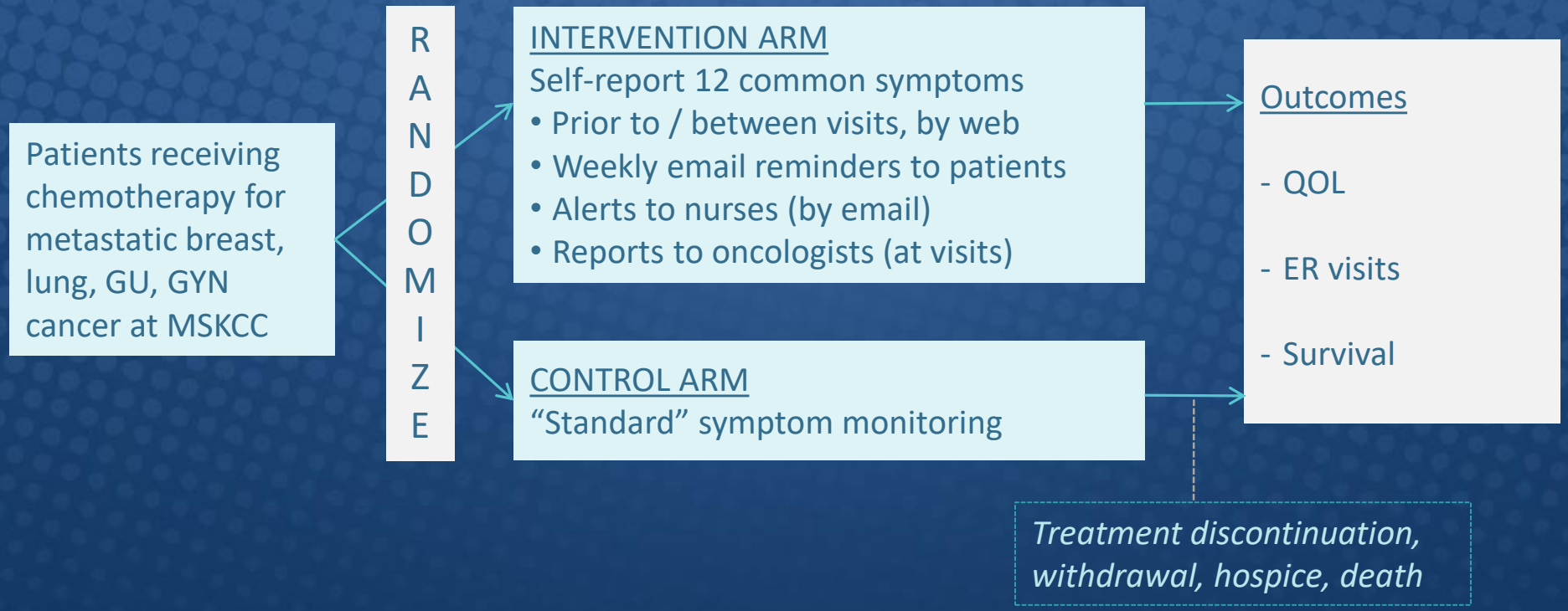
Clinicians miss a substantial number of our patients' symptoms – what are the potential consequences, and opportunities for improvement?

Patient-reported

Clinician-reported

Basch: NEJM, 2010

Large Single-Center "STAR" Study: Impact on Clinical Outcomes

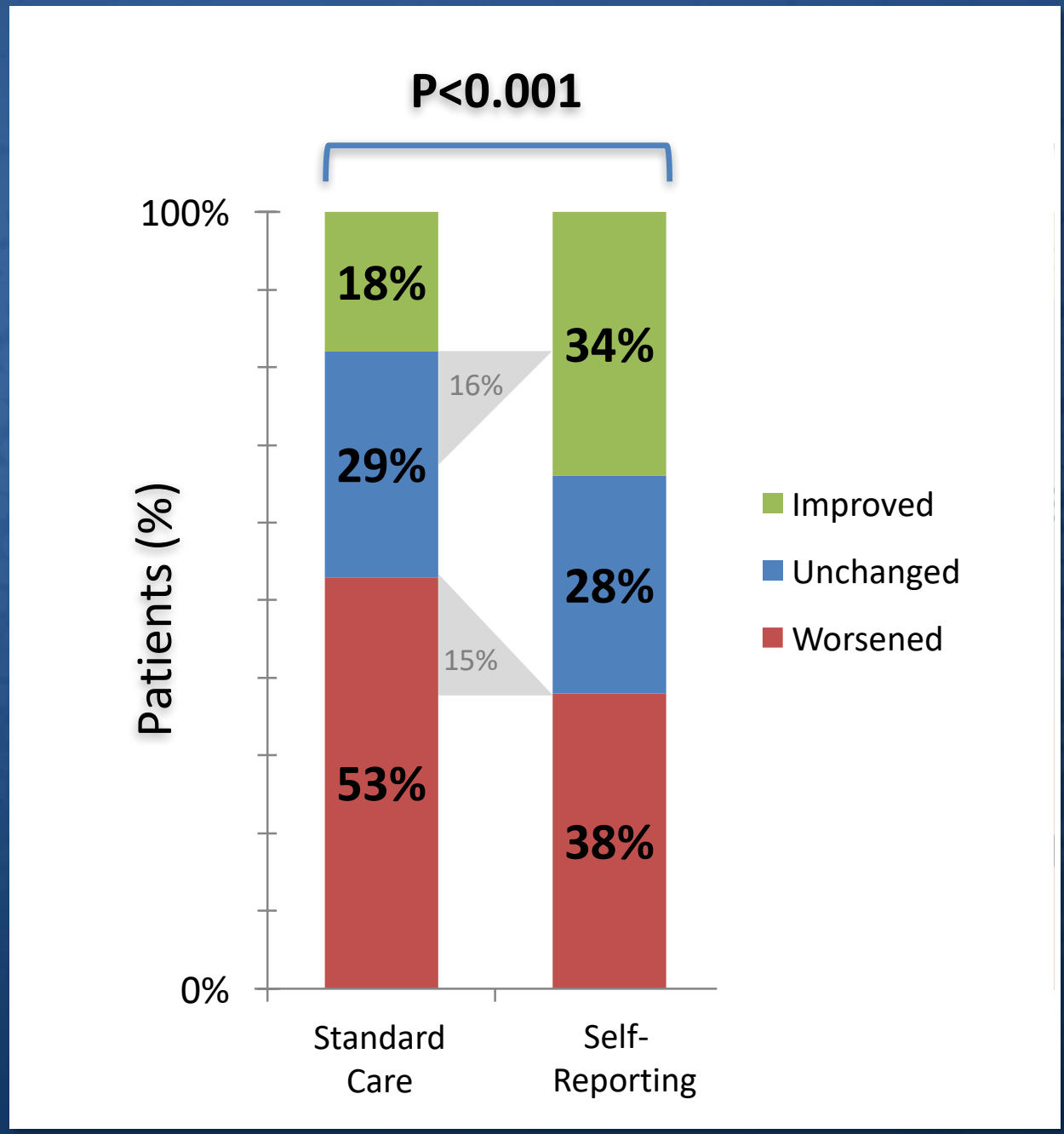


766 patient participants; median follow up 7 years

Basch: JAMA, 2017

Quality of Life

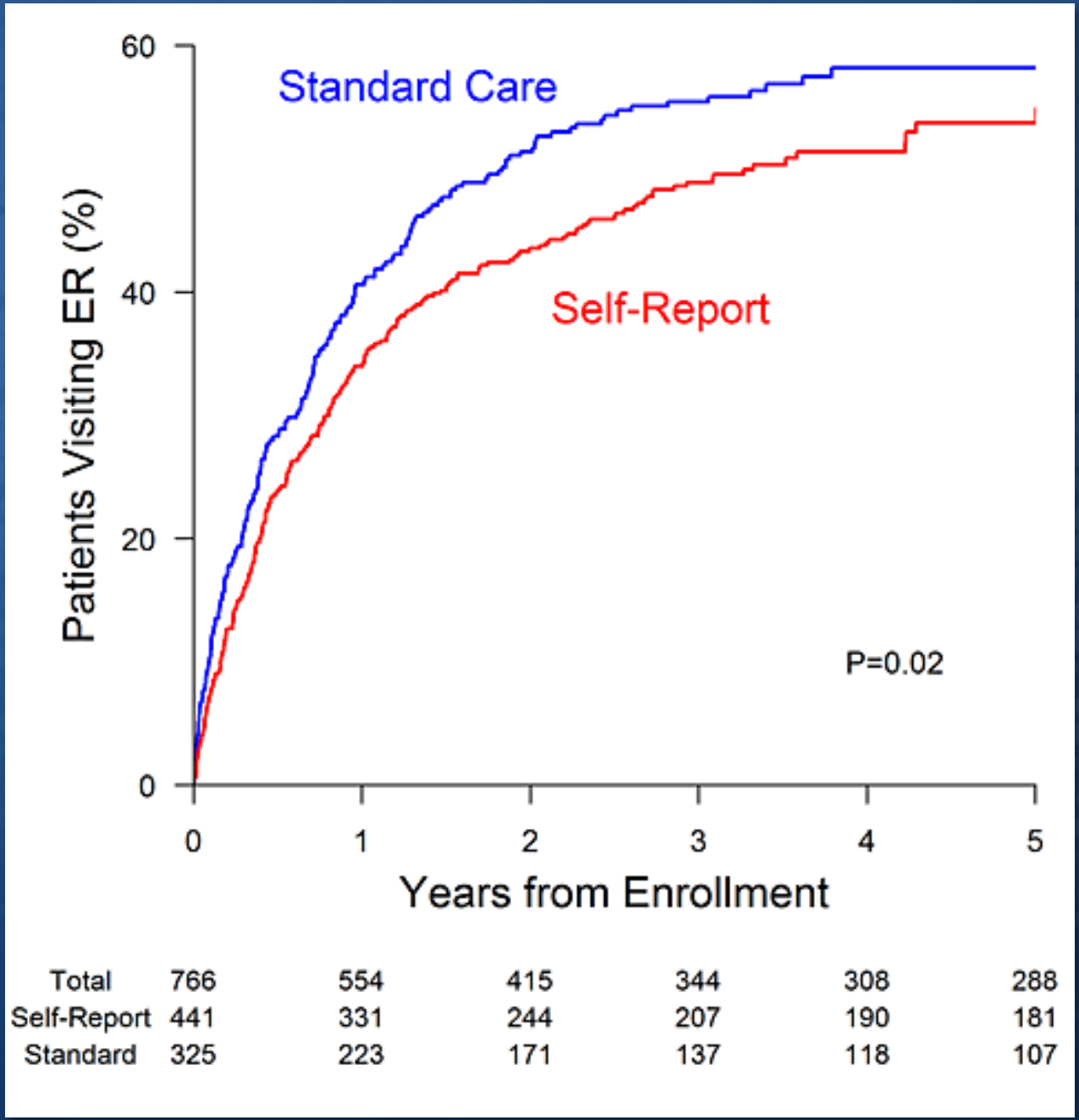
- Assessed at 6 months, compared to baseline
- Compared to standard care, 31% more patients in the self-reporting arm experienced QOL benefits (*P<0.001*)



Basch: JCO, 2017

Emergency Room Visits

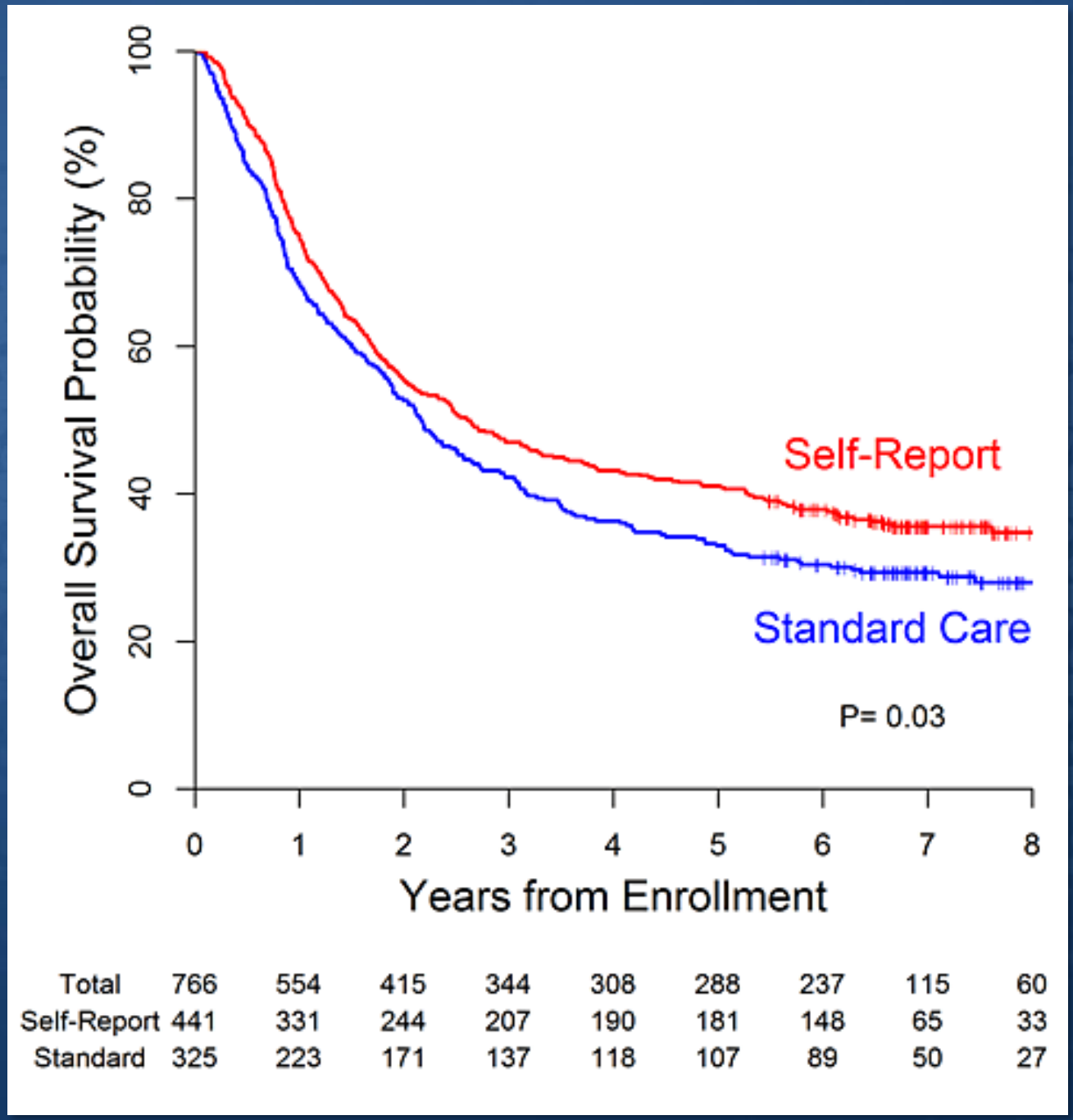
- Compared to standard care, 7% fewer patients in the self-reporting arm visited the Emergency Room, with durable effects throughout the study (*P=0.02*)



Basch: JCO, 2017

Overall Survival

- Compared to standard care, median survival was 5 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%



Basch: JAMA, 2017

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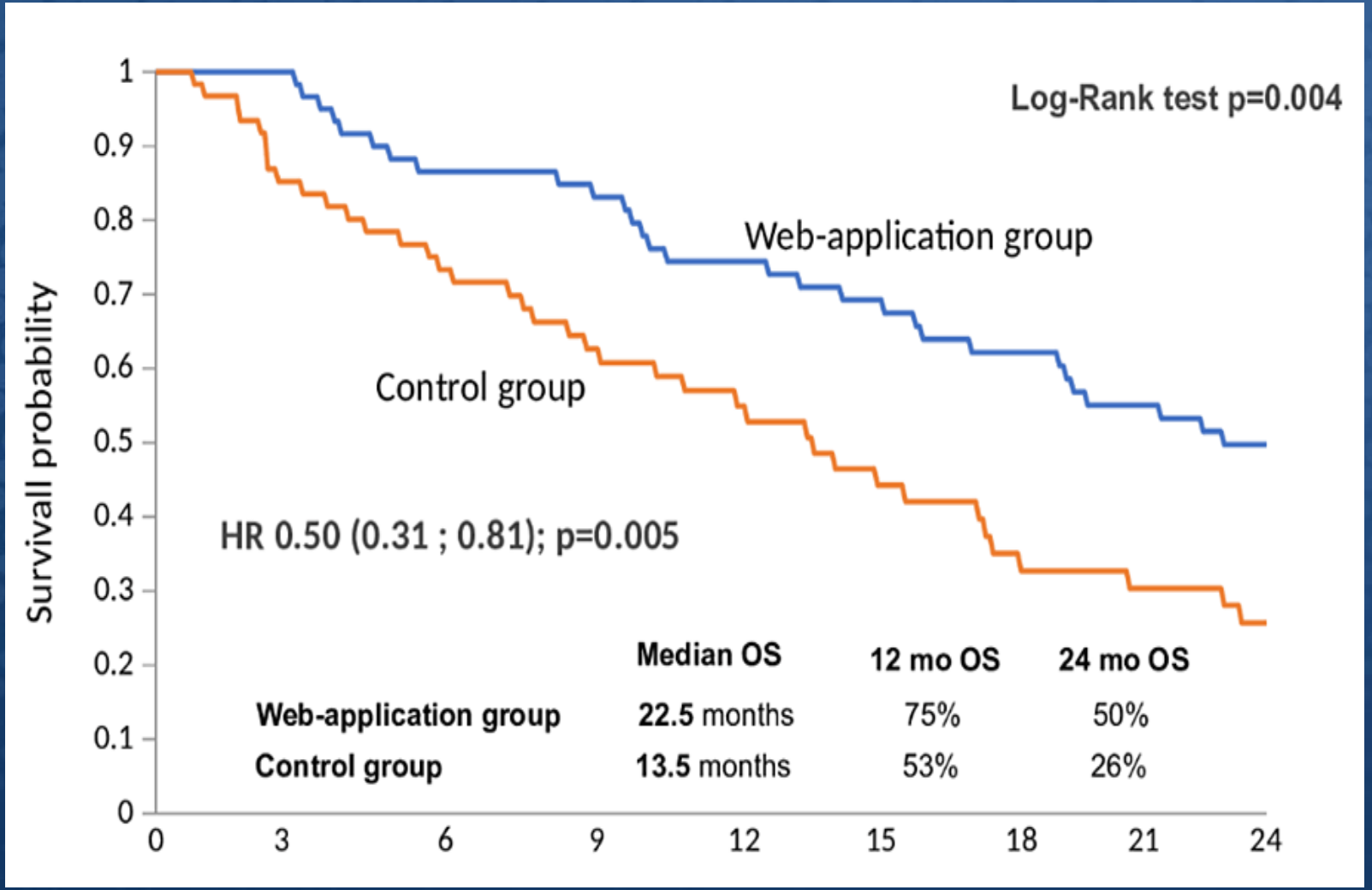
Mechanisms of Action

1. Proactive monitoring prompts clinicians to intervene early, before symptoms worsen and cause serious downstream complications
   - *Nurses acted on >75% of PRO alerts*
2. Symptom control enables patients to stay more functional, which is known to be associated with better survival
   - *Better physical functioning in PRO arm (P=.01)*
3. Symptom monitoring enables control of chemotherapy side effects, enabling more intensive and longer duration of cancer treatment
   - *Longer time on chemotherapy in PRO arm (8 months vs. 6 months)*

Basch: JAMA, 2017

French Lung Cancer RCT



- N=121 @ 5 centers in France
- Weekly PRO monitoring

Results:

- Overall survival: 22.5 vs 13.5 months (P=0.03)
- Optimal treatment 72.4% vs 32.5% (P<0.001)

Denis, Basch: JAMA, 2019

Canadian Population-Based Study (N>128,000)

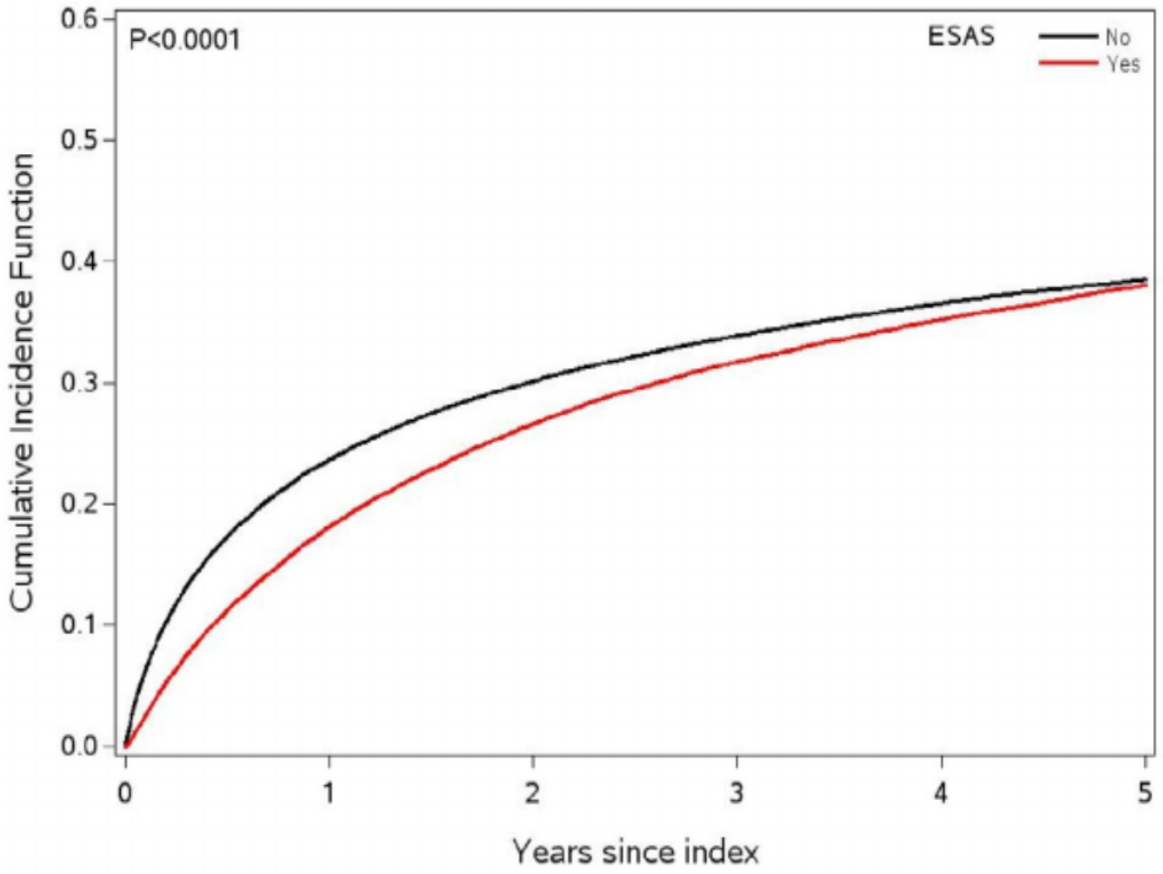


FIGURE 2 Cumulative incidence function of death for patients exposed and unexposed to ESAS

- PROs in clinics across Ontario

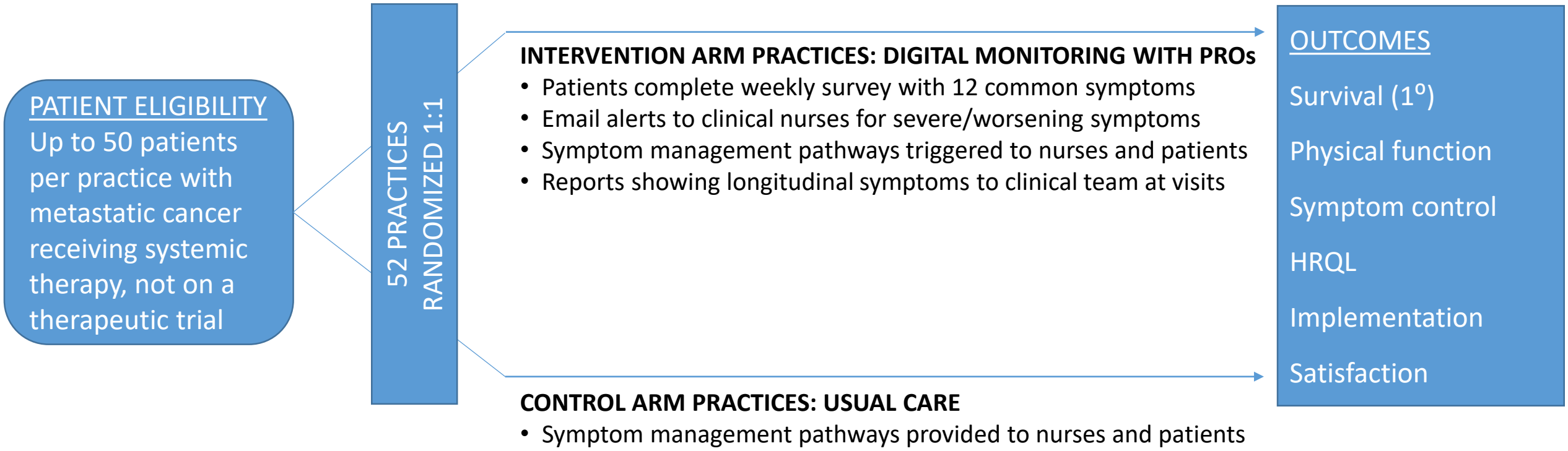
Results:

- 1 year survival: 81.9% vs 76.4% (P=0.0001)
- 8% decrease emergency visits
- 14% decrease hospitalizations

Barbera: Cancer Med, 2020
Barbera: JCO Clin Pract, 2020

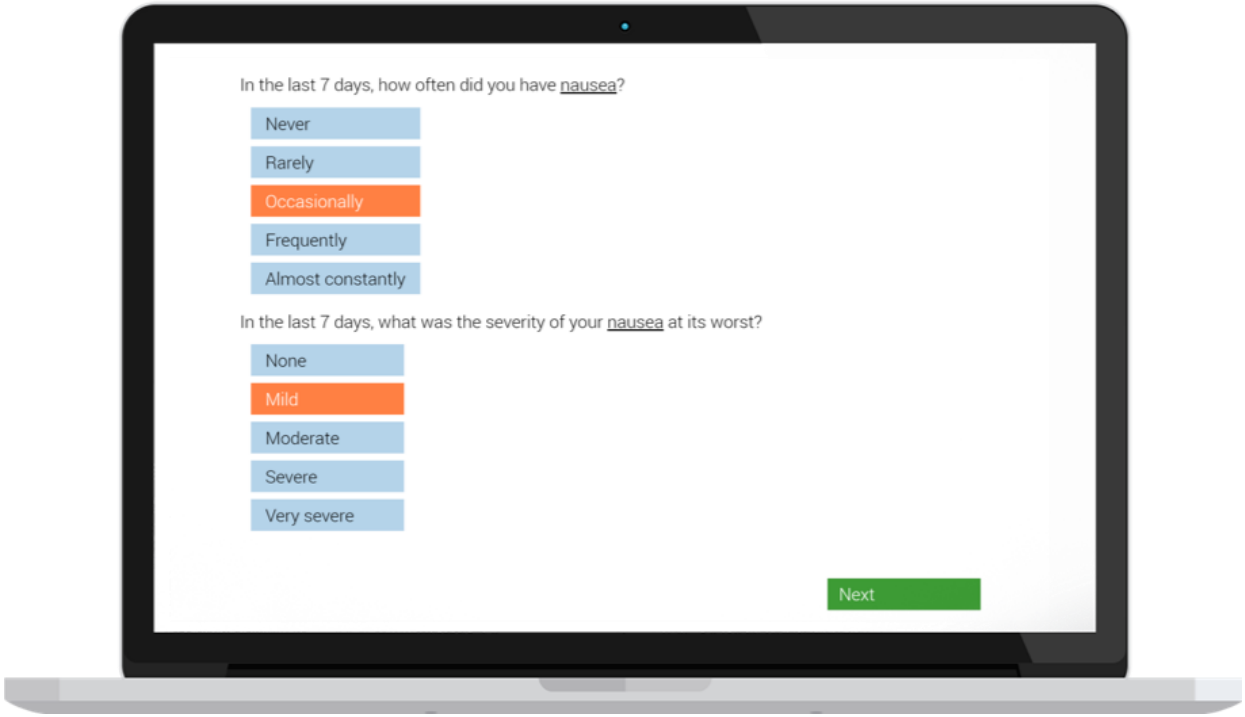
PRO-TECT
Cancer Symptom Study

- Cluster randomized trial at 52 US community oncology practices, across 25 states
- Funded by PCORI, sponsored by Alliance Foundation Trials

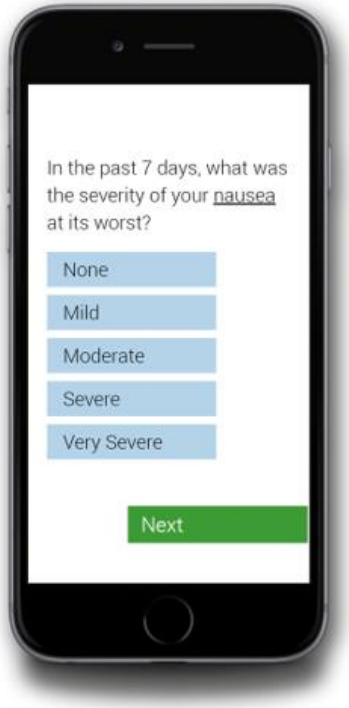


Basch: JAMA 2022

- Weekly PRO survey items from NCI PRO-CTCAE (pain, nausea, vomiting, constipation, diarrhea, dyspnea, insomnia, depression, oral intake), plus patient-reported ECOG performance status, falls, financial toxicity
- Patient choice of interface for completing weekly surveys

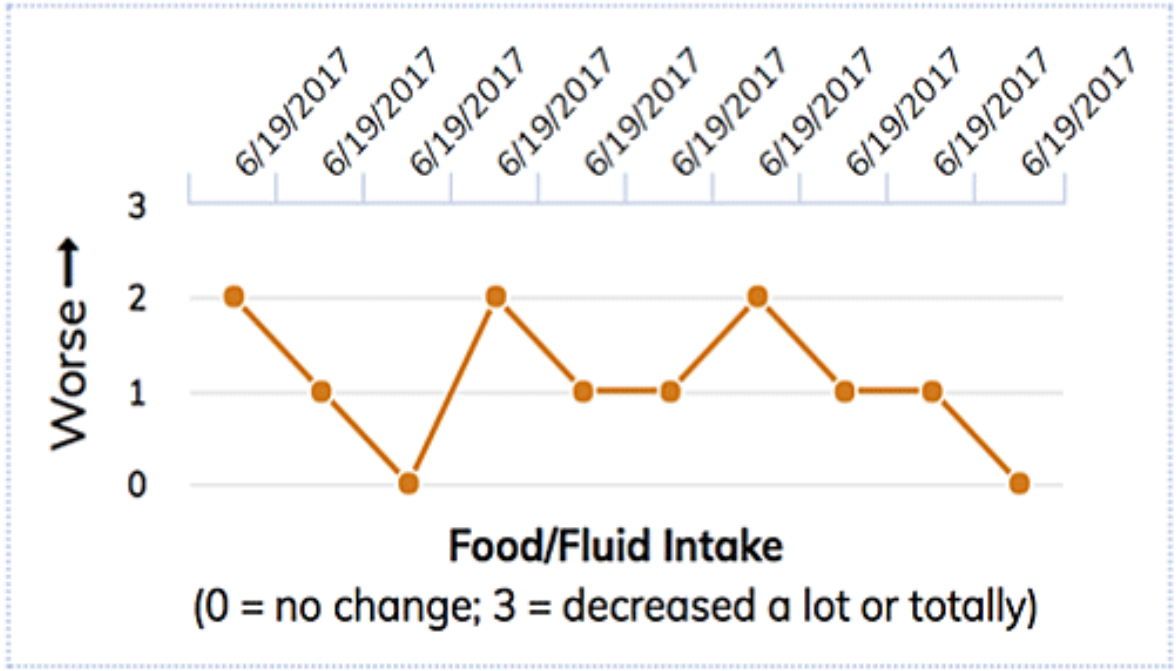


Web



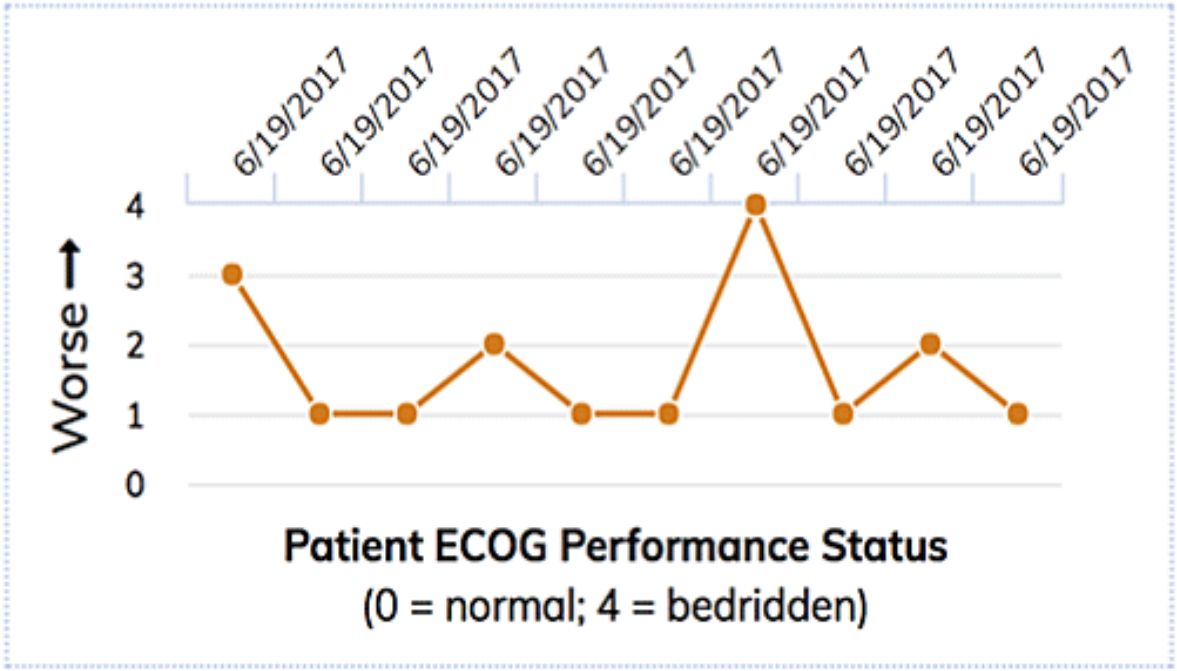
Mobile

Automated Telephone Systems



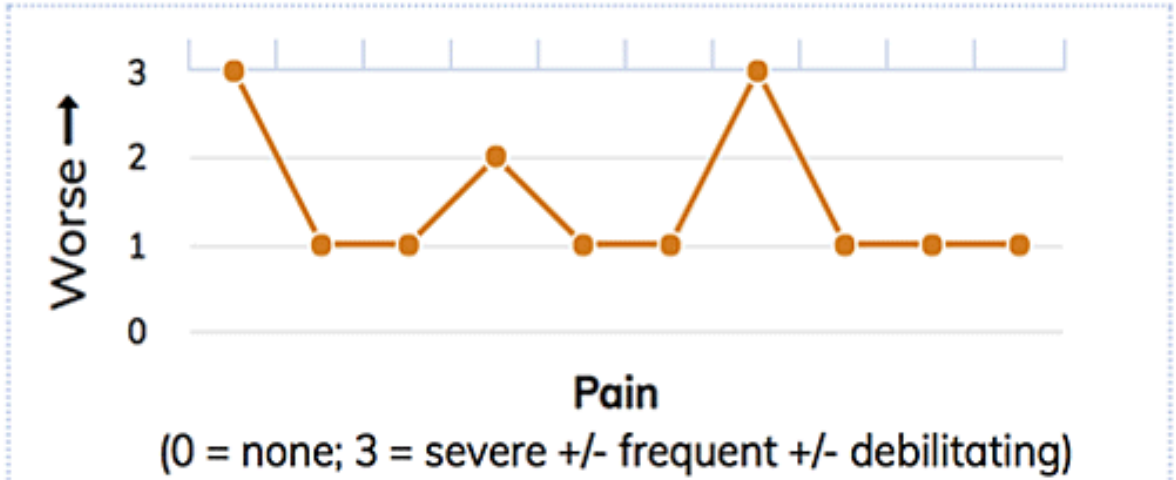
Food/Fluid Intake

(0 = no change; 3 = decreased a lot or totally)



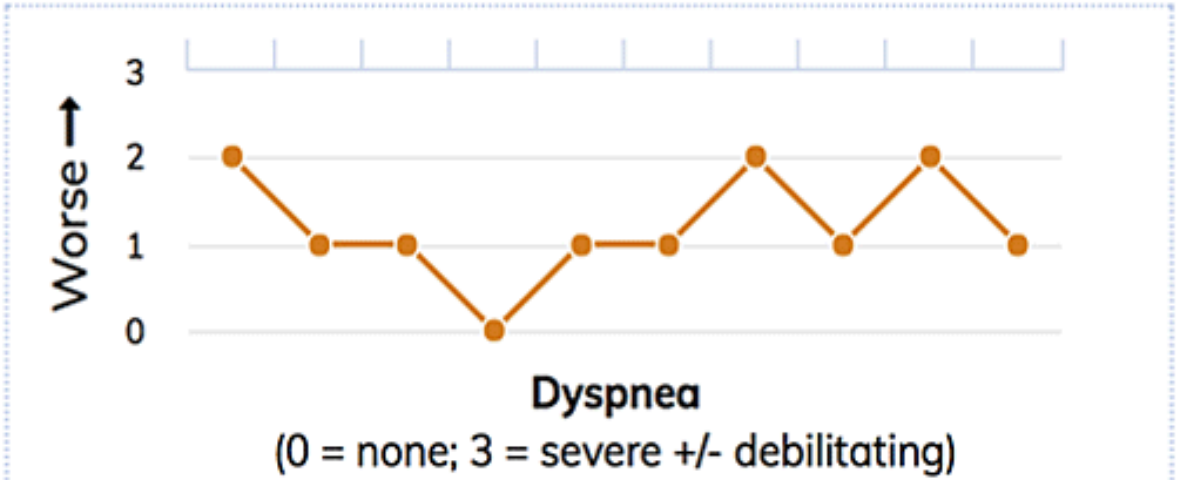
Patient ECOG Performance Status

(0 = normal; 4 = bedridden)



Pain

(0 = none; 3 = severe +/- frequent +/- debilitating)



Dyspnea

(0 = none; 3 = severe +/- debilitating)

What can I do to manage my **sleep problems**?

Tips to help you sleep:

- **Tell your cancer care team about problems that are getting in the way of your sleep.** Getting treatment to lower side effects such as pain or bladder or bowel problems may help you sleep better.
- **Set good bedtime habits.**
  - Go to bed only when sleepy, in a quiet and dark room, and in a comfortable bed.
  - Go to bed and wake up at the same time.
  - Avoid napping if possible.
  - Make sure your bedroom is not overly hot or cold.
  - Stop watching television or using devices with screens a couple of hours before going to bed.
    - Devices like: iPads, laptops, and smart phones.
  - Don't drink or eat a lot starting about 2-3 hours before bedtime.
  - Exercising too close to bedtime may make sleep more difficult.
    - Exercise before 2:00pm promotes sleep.
  - Don't watch the clock at night.
  - Keep out pets who wake you up.

- **Don't stay awake in bed** for more than 5-10 minutes. If you do not fall asleep, get out of bed, sit in a chair in the dark until you are sleepy. It's okay if this happens several times a night.
- **Avoid caffeine after midday.** Also cigarettes, alcohol and some 'over-the-counter' medications may interfere with sleep.
- **Sleep medicine may be prescribed** by your cancer care team for a short period if other strategies don't work.
- **Cognitive behavioral therapy (CBT) and/or relaxation therapy may help.** For example, a CBT therapist can help you learn to change negative thoughts and beliefs about sleep into positive ones.
  - Muscle relaxation, guided imagery, and self-hypnosis may help.

PRO-TECT Cancer Symptom Study — Clinician Symptom Management Pathway — Developed with: carevive systems | ALLIANCE FOUNDATION TRIALS, LLC

PAIN

Pain is common in patients with cancer and impacts patients' functional status and quality of life.

- Cancer patients often have multiple sites of pain.
- Cancer pain is associated with increased emotional distress and risk of developing depression.

Sources of pain in cancer patients include:

- Direct effects of cancer (bone pain, pressure on internal organs, ascites).
- Surgery pain.
- Radiation therapy (mucositis, dermatologic changes, brachytherapy pain, mucosal inflammation).
- Chemotherapy or targeted therapy (arthralgia, myalgia, neuropathy, bowel function changes, mucositis, rash).
- Diagnostic procedures.
- Other health conditions (arthritis, osteoporosis)

Assessment

- Assess pain medication history.
  - What is prescribed, what is the patient actually taking, how it is working?
  - Is the patient taking opioids, and are they long acting, short acting, or both?
  - How long has the patient been on their pain regimen?
- Conduct comprehensive pain assessment:
  - Location of pain (Where does pain originate? Does it radiate to another area of the body?).
  - Intensity of pain (use pain scale of 0-10 with 10 being the worst pain imaginable).
  - Quality of pain (sharp, stabbing, burning, aching).
  - Using scale of 1-10 with 10 being the worst pain imaginable: What is your pain at its best? What is it at its peak? What is your pain after taking your pain medications?
  - Assess for breakthrough pain (Does the pain return or increase in intensity before the next dose?).
  - Onset, duration and aggravating/alleviating factors (When does it start? What makes it worse/better? How often does it occur? How long does it last?)
- Assess for changes in activity level, sleep, general activities of daily living, depression.
- If taking opioids, assess for constipation.

Severity

Grade 1 *Mild*	Grade 2 *Moderate*	Grade 3 *Severe*	Grade 4 *Life Threatening*
Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care, ADL	

Interventions Based on Severity

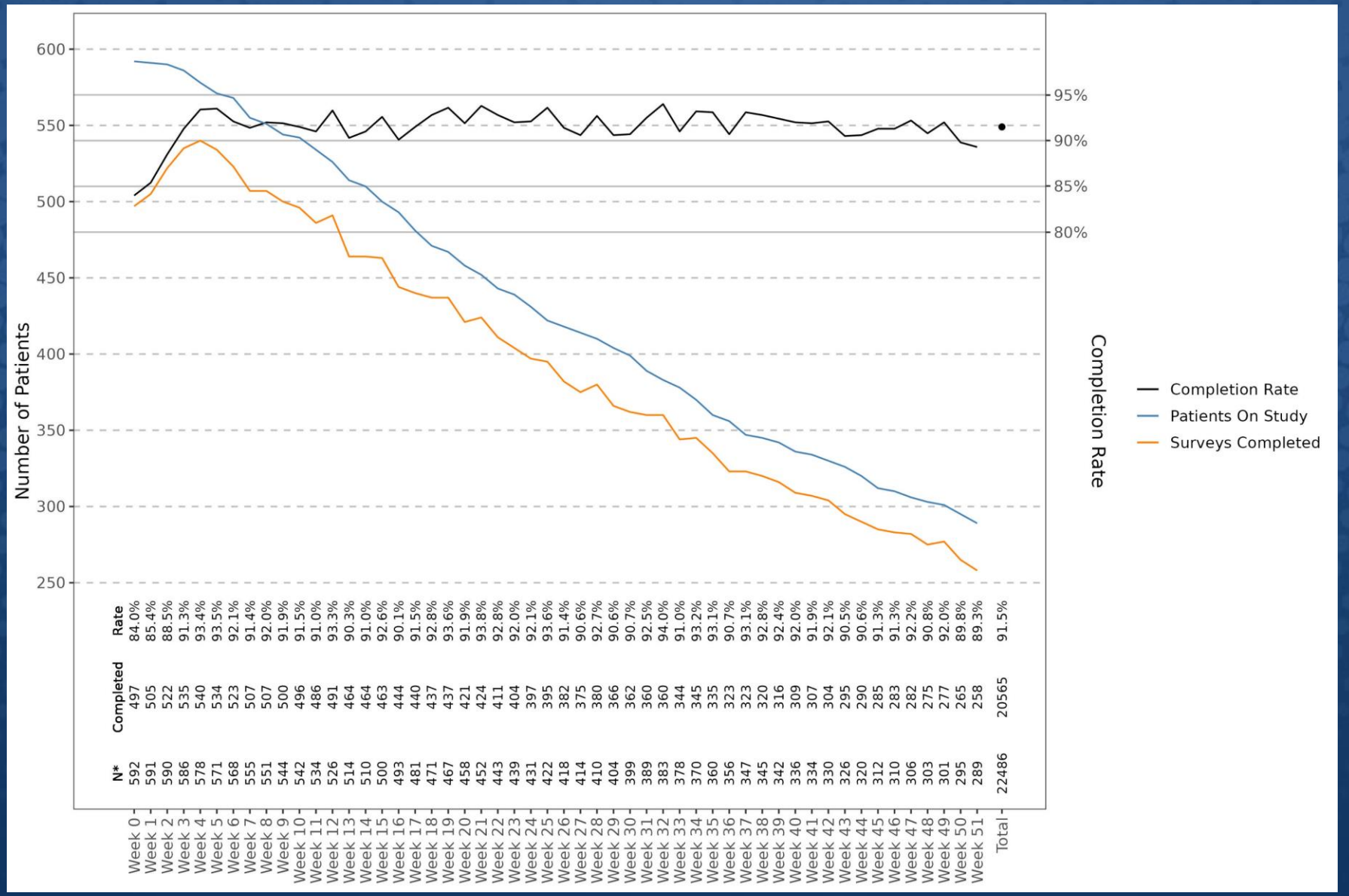
Management of Pain:

1. Non-opioids (acetaminophen, COX-2 inhibitor, NSAID). Note that COX-2 inhibitor (celecoxib, meloxicam) does not inhibit platelet aggregation; NSAID toxic effects can include acute renal failure, gastrointestinal toxicity, cardiovascular toxicity, and CNS toxicity such as memory loss and confusion. NSAIDs should be avoided or used with caution if patient has: stomach or intestinal ulcers; cardiovascular disease and/or hypertension; kidney disease; bleeding disorders; pregnancy; taking other prescription anti-coagulants such as warfarin (Coumadin) or heparin, phenytoin (Dilantin), and/or cyclosporine; use of acetaminophen may cause hepatic injury; use caution with liver disease.
2. Opioids such as morphine when pain persists or increases and cannot be controlled by non-opioids.
3. Non-medication treatments should be offered for all patients with pain. These include emotional support, distraction (music, social engagement), appropriate physical activity (positioning, cushioning, supportive devices, exercise. Physical therapy), and topical application of heat or cold.

Considerations:

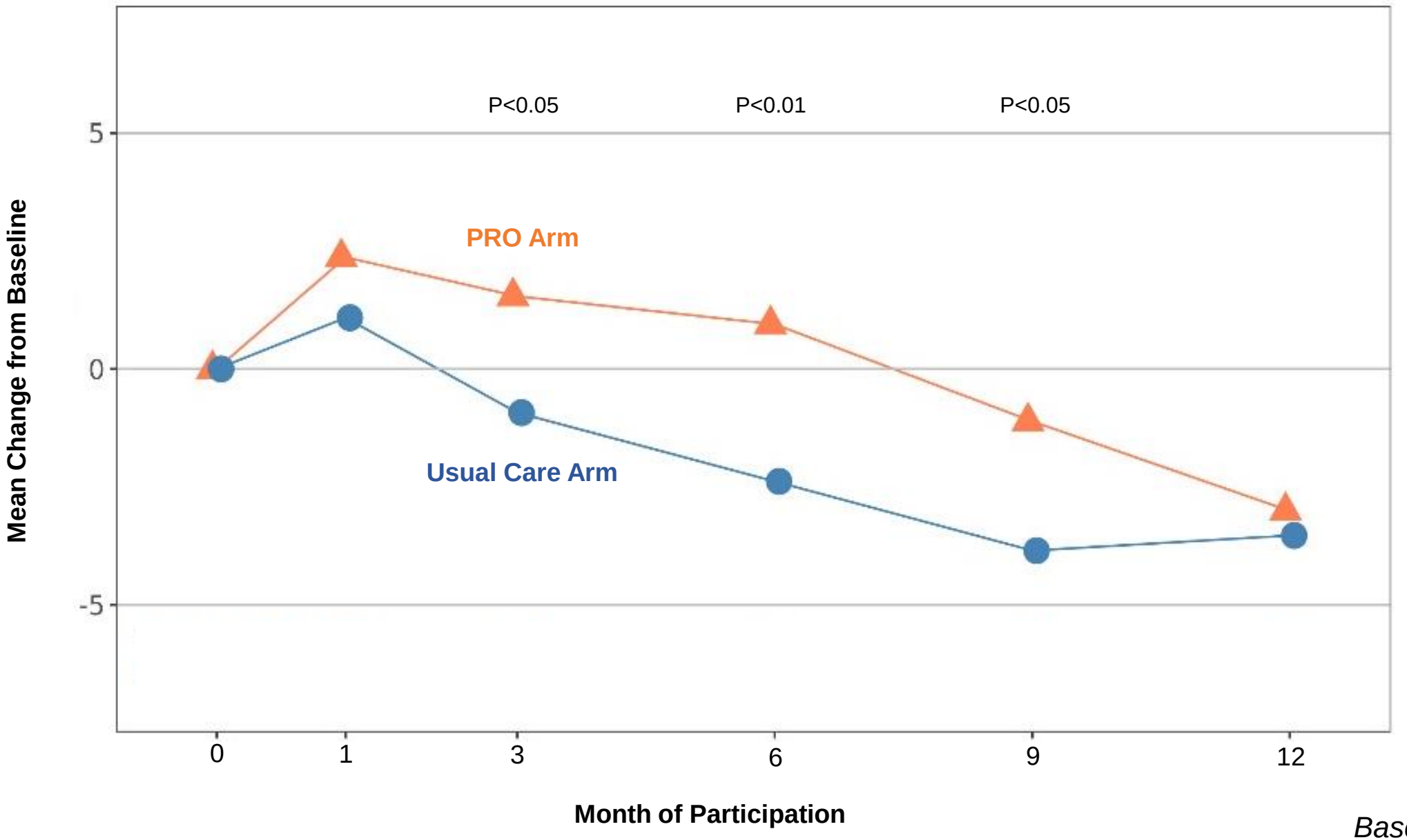
- Pain medication scheduled "around the clock" when pain is constant. Consider long-acting agent.
- Use the simplest route of administration possible.
- Consider additional supportive drugs to address anxiety, depression, or neuropathic pain symptoms.
- Provide patient/family/caregiver education about treatment approaches and safe medication use.
- Consider suggesting a pain diary to monitor characteristics of pain, medication regimen, and response to medication.
- No driving when using opioids.

Adherence with Weekly ePROs: 91.5%



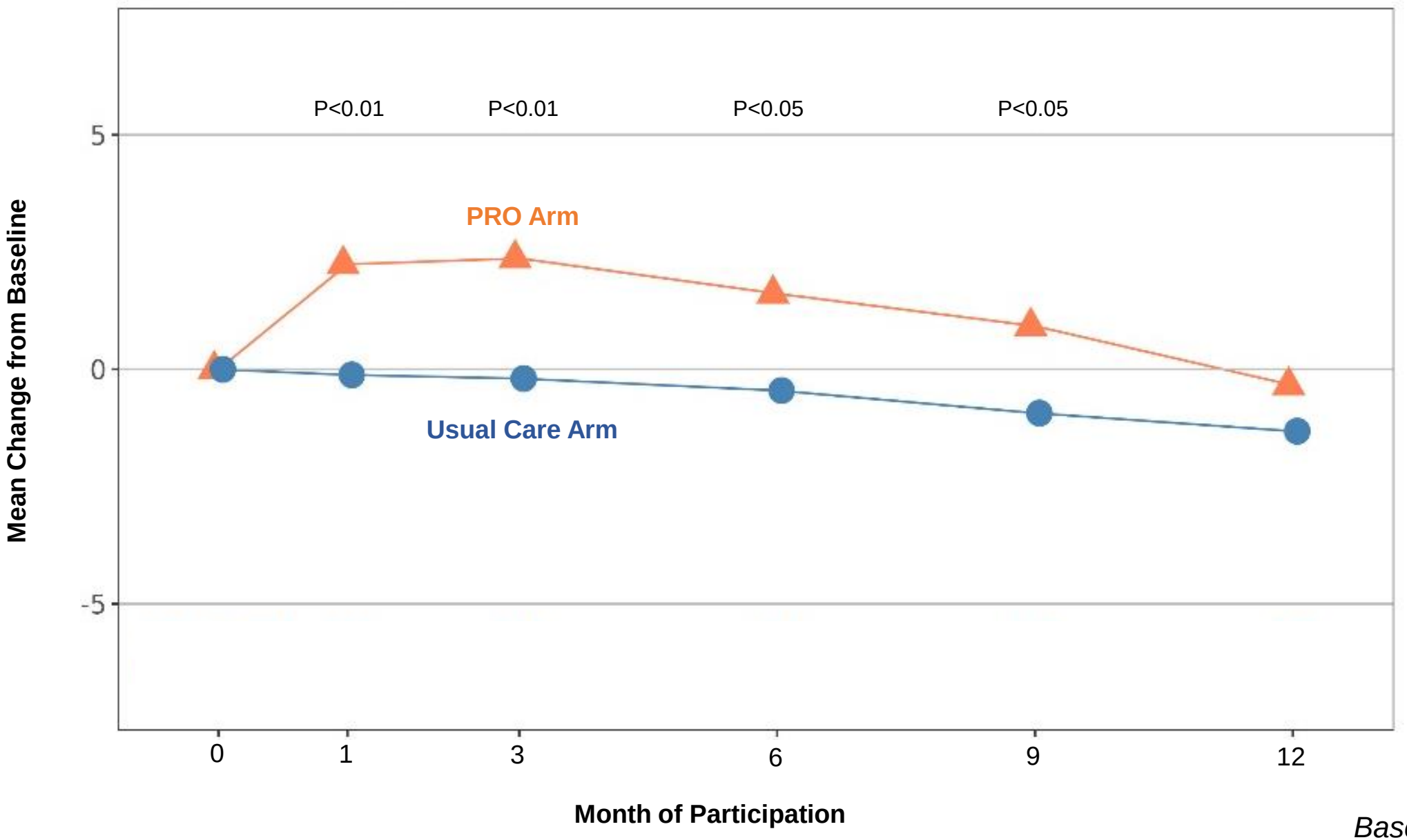
Basch: JAMA 2022

Results: Effects on Patient Physical Functioning



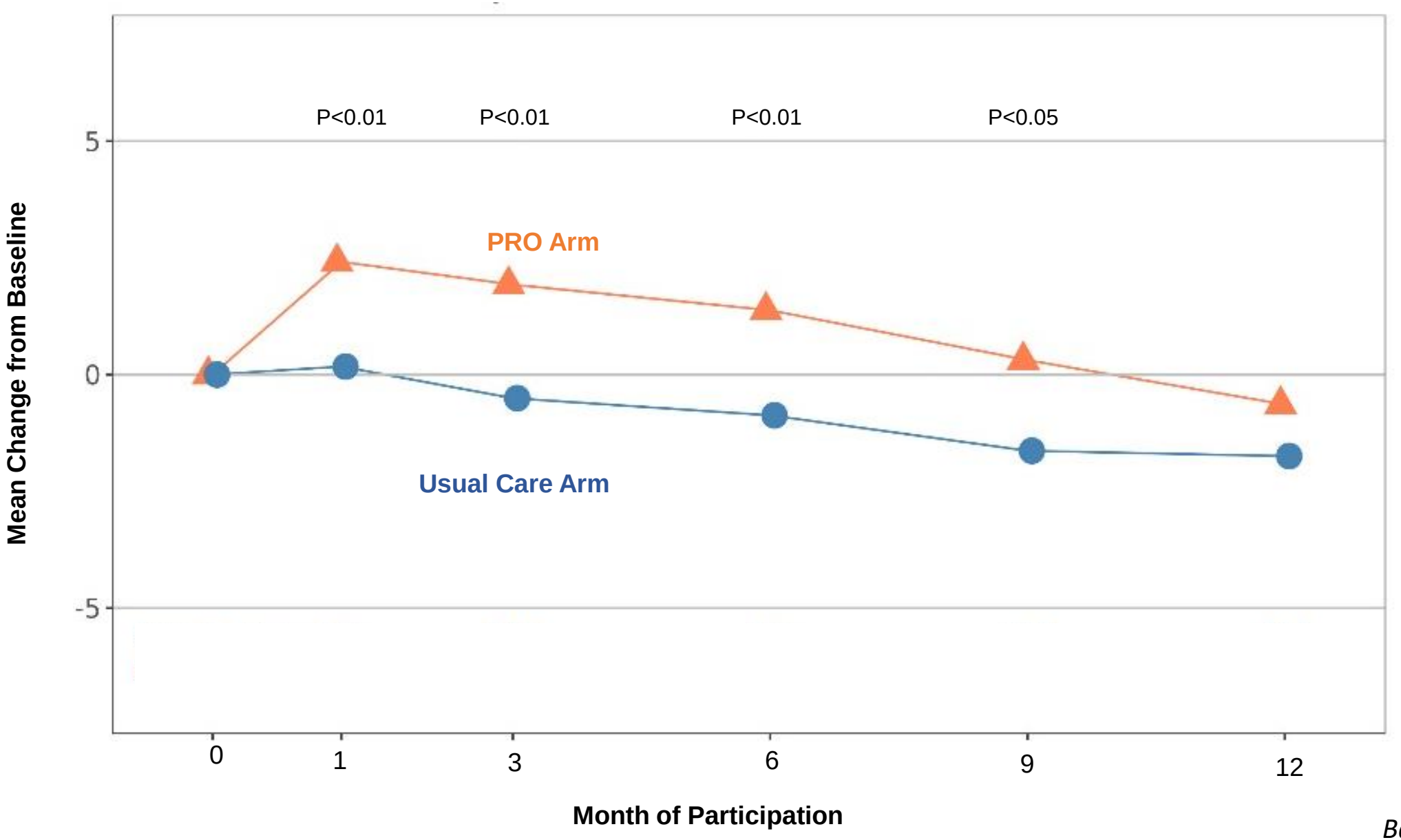
Basch: JAMA, 2022

Results: Effects on Patient Symptom Control



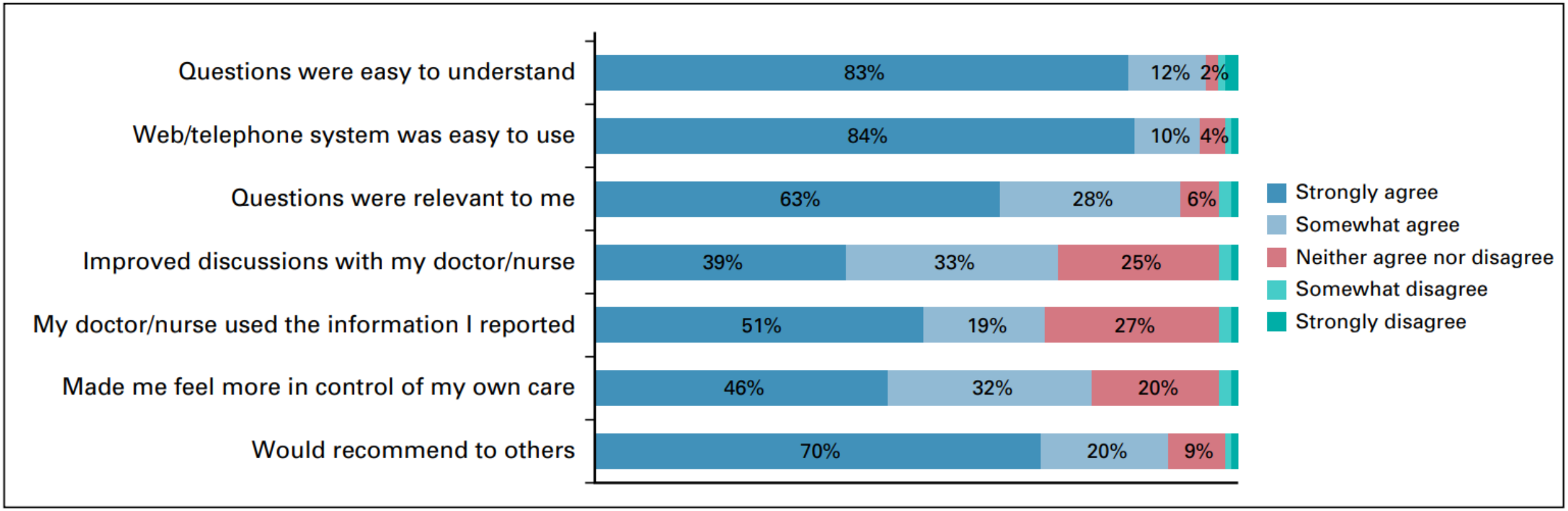
Basch: JAMA, 2022

Results: Effects on Health-Related Quality of Life



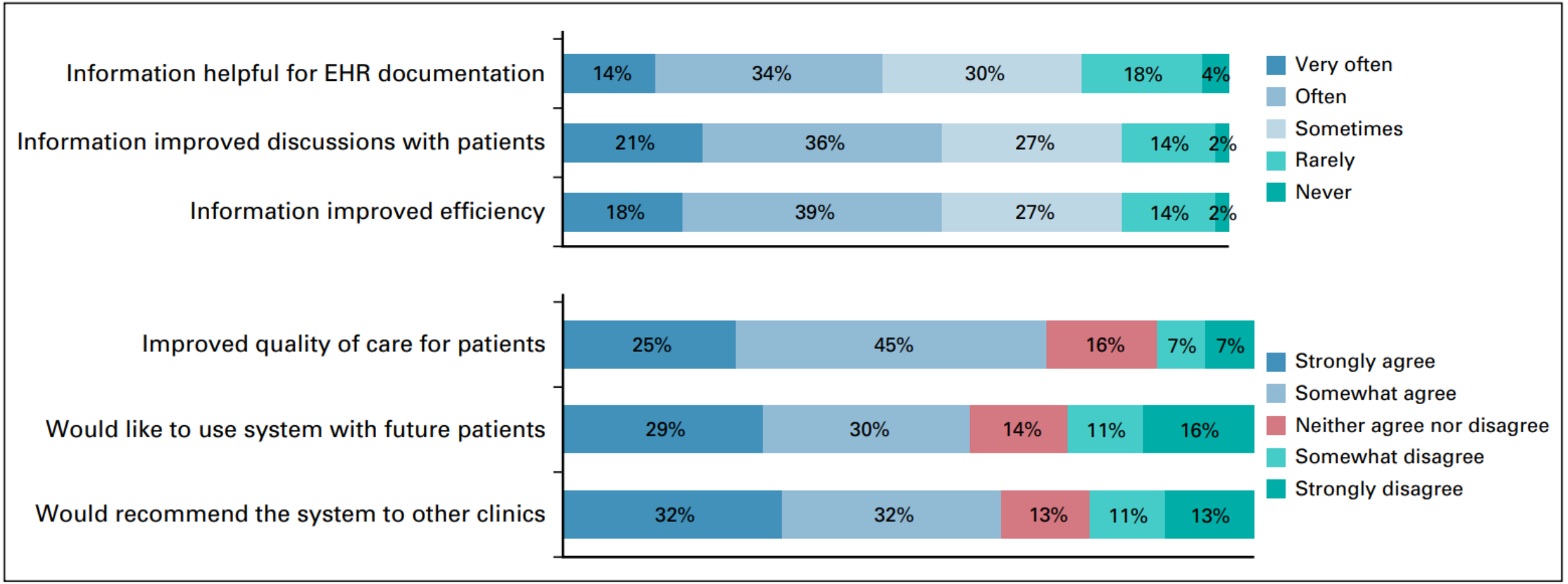
Basch: JAMA, 2022

Patient Impressions of ePRO System



Basch: JCO Cancer Clin Informatics, 2020

Nurse Impressions of ePRO System



Basch: JCO Cancer Clin Informatics, 2020

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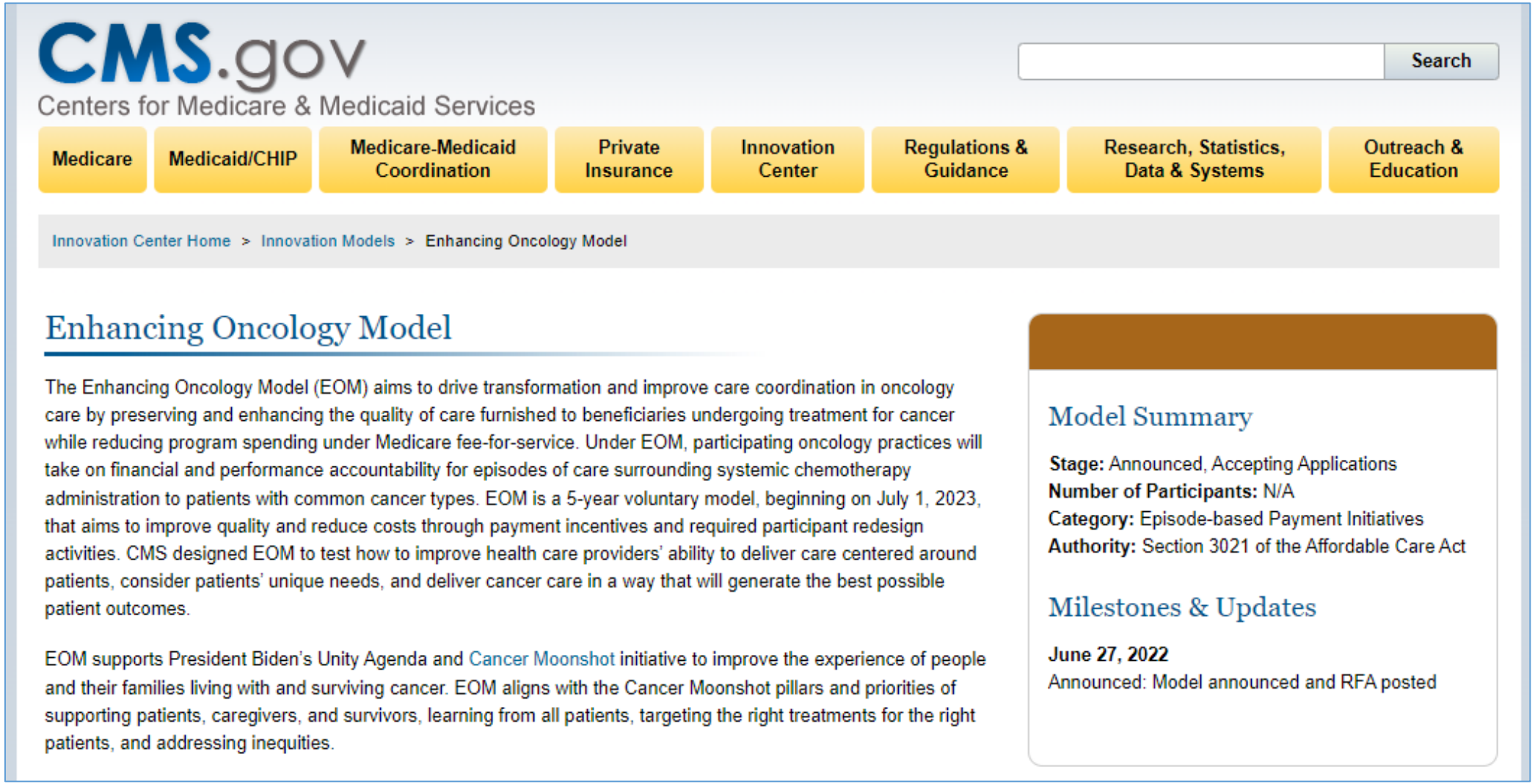
Subsequent Wave of Commercial ePRO Symptom Monitoring Digital Therapeutics in Oncology

Inclusion of ePROs in Value-Based Care Models



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Innovation Center Home > Innovation Models > Enhancing Oncology Model

Enhancing Oncology Model

The Enhancing Oncology Model (EOM) aims to drive transformation and improve care coordination in oncology care by preserving and enhancing the quality of care furnished to beneficiaries undergoing treatment for cancer while reducing program spending under Medicare fee-for-service. Under EOM, participating oncology practices will take on financial and performance accountability for episodes of care surrounding systemic chemotherapy administration to patients with common cancer types. EOM is a 5-year voluntary model, beginning on July 1, 2023, that aims to improve quality and reduce costs through payment incentives and required participant redesign activities. CMS designed EOM to test how to improve health care providers' ability to deliver care centered around patients, consider patients' unique needs, and deliver cancer care in a way that will generate the best possible patient outcomes.

EOM supports President Biden's Unity Agenda and Cancer Moonshot initiative to improve the experience of people and their families living with and surviving cancer. EOM aligns with the Cancer Moonshot pillars and priorities of supporting patients, caregivers, and survivors, learning from all patients, targeting the right treatments for the right patients, and addressing inequities.

Model Summary

Stage: Announced, Accepting Applications
Number of Participants: N/A
Category: Episode-based Payment Initiatives
Authority: Section 3021 of the Affordable Care Act

Milestones & Updates

June 27, 2022
Announced: Model announced and RFA posted

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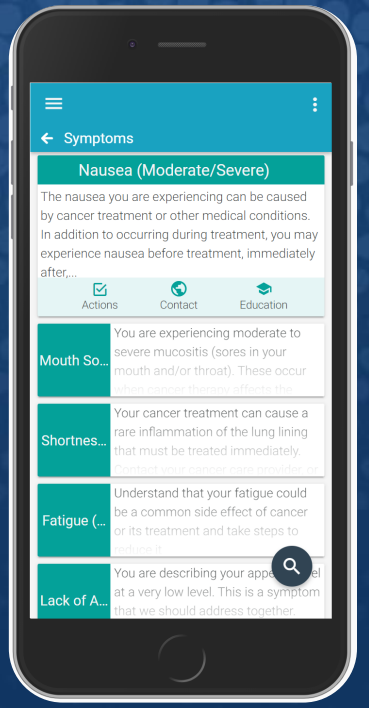
(Immediate) Future Challenges

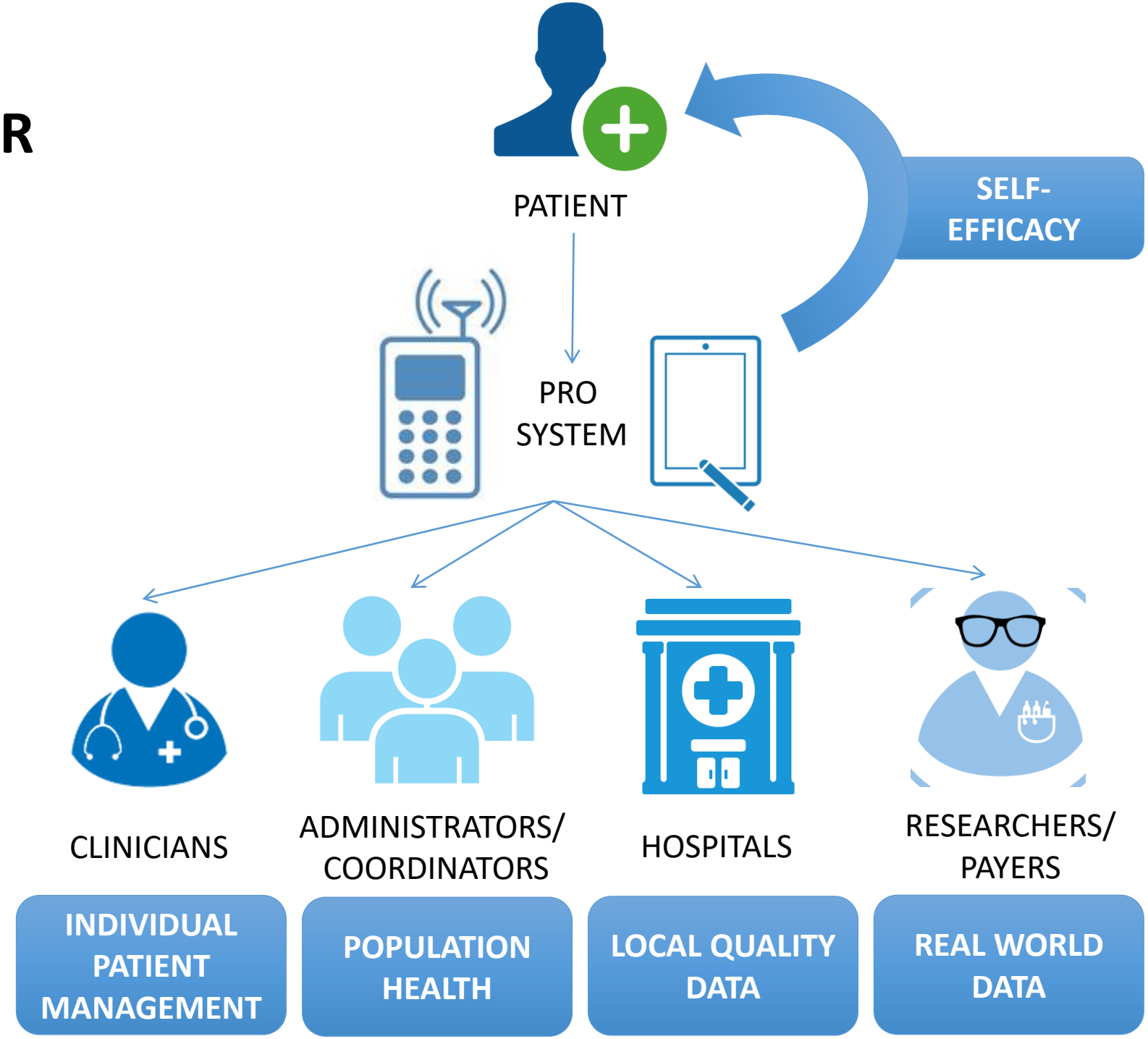
1. Integrating with EMR and other information systems
2. Standardizing implementation (clinical integration)
3. Determining sufficient reimbursement for practices

Currently Planning

- National U.S. demonstration project for PROs
- In partnership with major EMR vendors, oncology professional societies and patient organizations



Value of PRO Data in the EMR



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Use of PROs for Patient Monitoring in Oncology Clinical Trials

	TAXOTERE 75 mg/m2 every 3 weeks	
ADVERSE REACTION	**ANY (%)**	**GRADE 3/4 (%)**
Anemia	67	5
Neutropenia	41	32
Thrombocytopenia	3	1
Infection	32	6
Epistaxis	6	0
Allergic Reactions	8	1
Neuropathy Sensory	30	2
Neuropathy Motor	7	2
Rash/Desquamation	6	0
Alopecia	65	N/A
Nail Changes	30	0
Nausea	41	3
Diarrhea	32	2
Stomatitis/Pharyngitis	20	1
Taste Disturbance	18	0
Vomiting	17	2
Anorexia	17	1
Cough	12	0
Dyspnea	15	3
Cardiac function	10	0
Fatigue	53	5
Myalgia	15	0
Tearing	10	1
Arthralgia	8	1

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Table from Docetaxel Chemotherapy U.S. Drug Label

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Vomiting	17	2
Anorexia	17	1
Cough	12	0
Dyspnea	15	3
Cardiac function	10	0
Fatigue	53	5
Myalgia	15	0
Tearing	10	1
Arthralgia	8	1

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Table from Docetaxel Chemotherapy U.S. Drug Label

Source of Adverse Event Data in Oncology Trials

- "Common Terminology Criteria for Adverse Events" (CTCAE)
- Item library, designed for clinicians to complete
- About 800 items total (10% of items are symptom)

CTCAE/MedDRA Term	CTCAE Grade 1	CTCAE Grade 2	CTCAE Grade 3	CTCAE Grade 4
Mucositis oral	Asymptomatic or mild symptoms; intervention not indicated	Moderate pain; not interfering with oral intake; modified diet indicated	Severe pain; interfering with oral intake	Life-threatening consequences; urgent intervention indicated

Reliability of Clinician-Reporting in Trials

Symptom	ICC	95% CI
Constipation	0.48	0.36; 0.58
Diarrhea	0.58	0.49; 0.66
Dyspnea	0.69	0.62; 0.75
Fatigue	0.50	0.39; 0.59
Nausea	0.52	0.41; 0.60
Neuropathy	0.71	0.65; 0.76
Vomiting	0.46	0.34; 0.56

Atkinson/Basch: Qual Life Res, 2011

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Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events

Developed under contracts to the NCI

(2008-present)

http://appliedresearch.cancer.gov/pro-ctcae

Patient-Centered Structure for Questions

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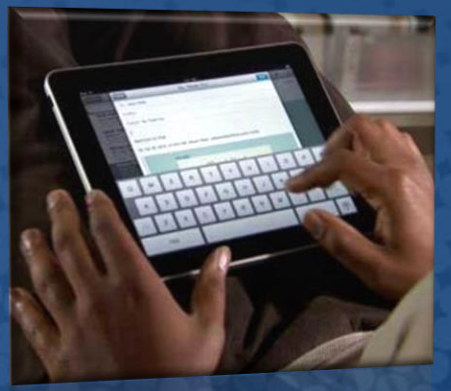
CTCAE/MedDRA Term	CTCAE Grade 1	CTCAE Grade 2	CTCAE Grade 3	CTCAE Grade 4
Mucositis oral	Asymptomatic or mild symptoms; intervention not indicated	Moderate pain; not interfering with oral intake; modified diet indicated	Severe pain; interfering with oral intake	Life-threatening consequences; urgent intervention indicated

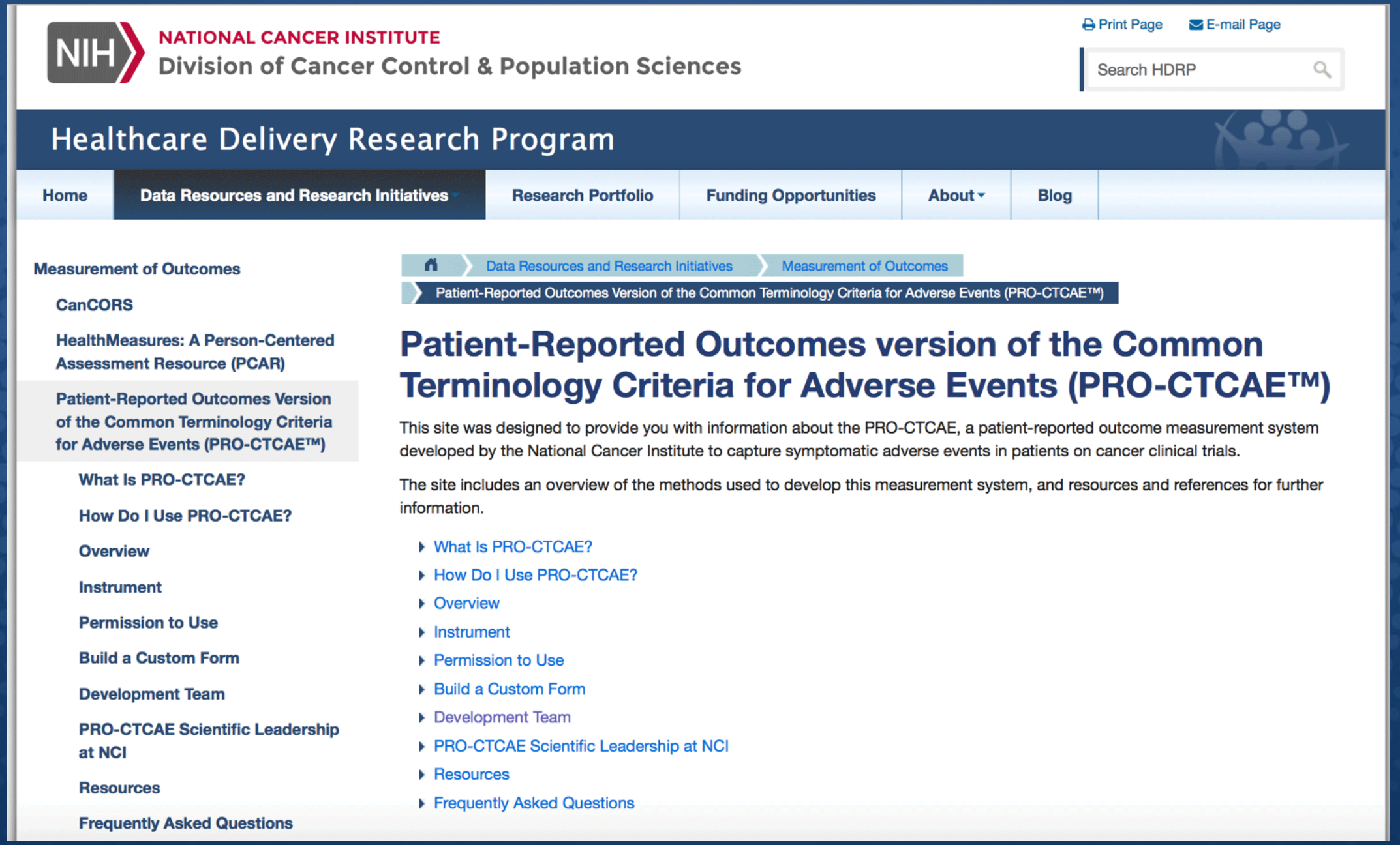
Two Items	Responses
What was the severity of your MOUTH OR THROAT SORES at their worst?	None Mild Moderate Severe Very Severe
How much did MOUTH OR THROAT SORES interfere with your usual activities?	Not at all A little bit Somewhat Quite a bit Very much

Robust Psychometric Evaluation



- 124 items representing 78 Symptomatic Adverse Events
- Extensive qualitative evaluation in diverse populations
- Large national “validation” study demonstrated robust validity, reliability, sensitivity, appropriate recall periods, mode equivalence (paper/electronic)

Basch: JNCI, 2014
Hay/Basch: Qual Life Res, 2014
Dueck/Basch: JAMA Oncol, 2015



http://healthcaredelivery.cancer.gov/pro-ctcae/

Industry Trial Example

Cabozantinib vs. mitoxantrone in metastatic prostate cancer

- 10 PRO-CTCAE AEs
  - Selected by investigators based on expected toxicities
- Reported by patients every 3 weeks from home between visits via automated telephone system
  - Human reminder call if no response after 72 hours
- Average 96% compliance at each time point

Basch: JAMA Oncol 2019

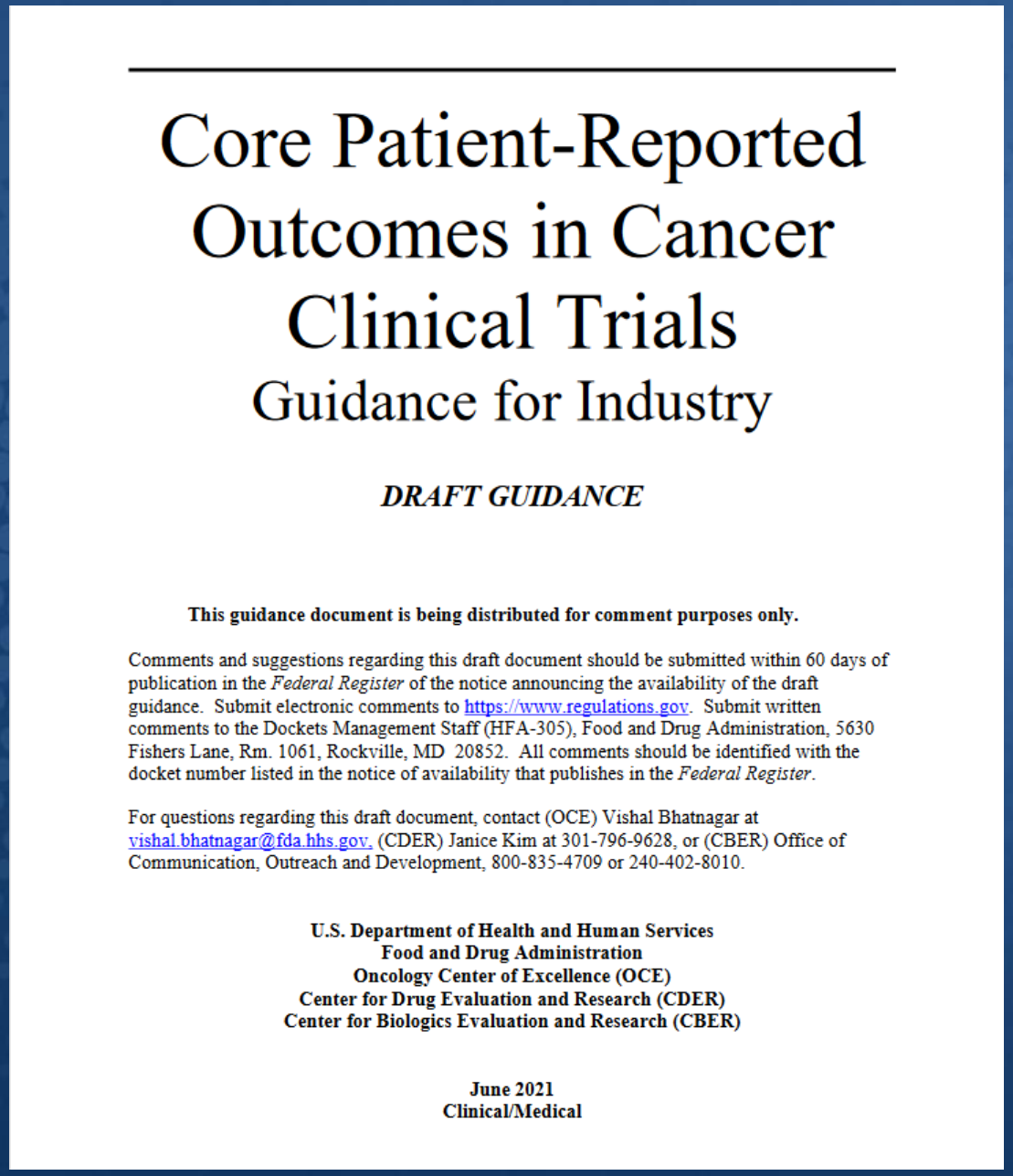
Between-Arm Comparison: CTCAE and PRO-CTCAE

SYMPTOM	INVESTIGATOR-REPORTED *CTCAE Max Grade 3+*			PATIENT-REPORTED *PRO-CTCAE Max 3+*		
	Cabo	**Mito**	***P***	**Cabo**	**Mito**	***P***
Constipation	3.3%	1.8%	1.00	26%	13%	0.04
Decrease appetite	1.7%	5.3%	0.36	38%	15%	0.008
Diarrhea	8.3%	1.8%	0.21	44%	11%	<0.001
Fatigue	18.0%	8.8%	0.18	36%	26%	0.30
Nausea				38%	15%	0.008
Short of breath	--	5.3%	0.11	14%	13%	1.00
Vomiting	1.7%	7.0%	0.20	12%	7%	0.52

# of significant between-arm AE differences:

- By investigator report (CTCAE): 0
- By patient report (PRO-CTCAE): 4

Basch: JAMA Oncol 2019



Core Patient-Reported Outcomes in Cancer Clinical Trials

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE) Vishal Bhatnagar at vishal.bhatnagar@fda.hhs.gov, (CDER) Janice Kim at 301-796-9628, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

June 2021
Clinical/Medical

PRO-CTCAE now widely used in international cancer drug development trials

Included in FDA and EMA guidance

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Conclusions

Patient self-reporting improves symptom monitoring and outcomes in routine cancer care and clinical research

- Expands our understanding of patient experience
- Engages patients

Demonstrates how hard it is to change a simple process, even if it makes a lot of intuitive sense

With Gratitude

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The patients and families participating in this research

PRO-CTCAE 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, Bill Wood, Gita Mody, Angie Smith (Prior: Diana Mehedint)

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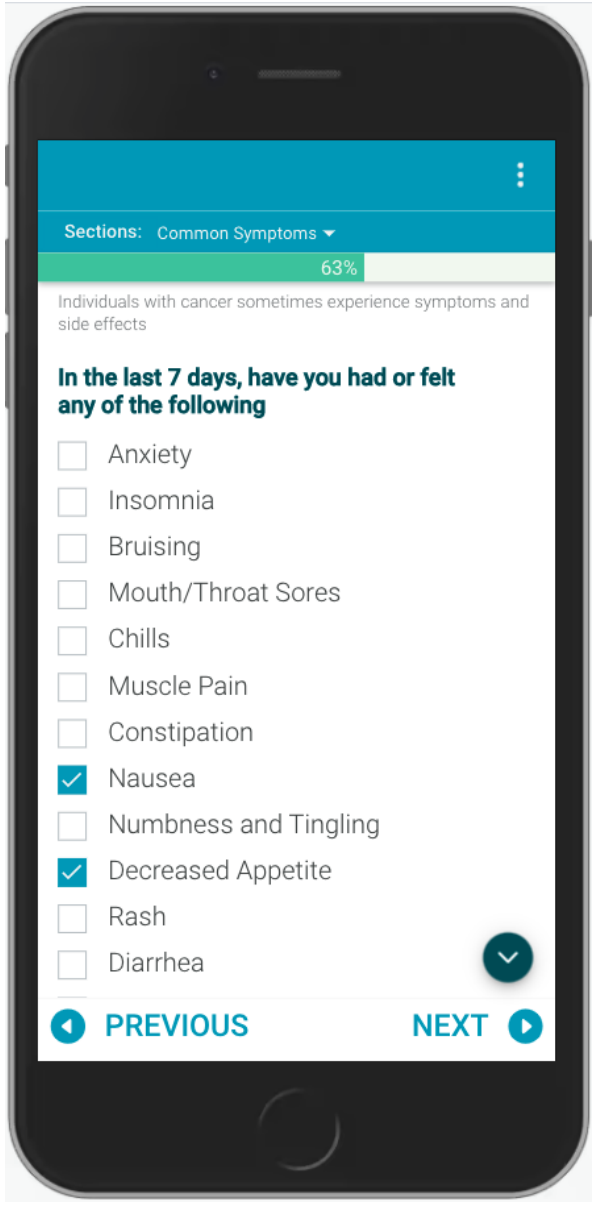
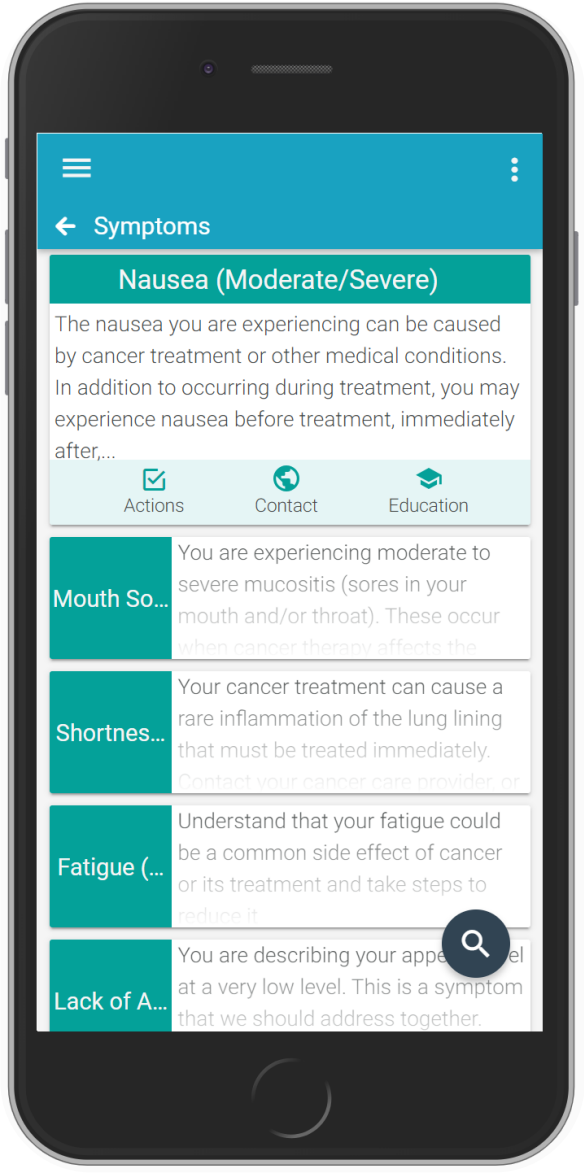
Thank You

APPENDIX: Key Technical Functions for PROs in EHRs

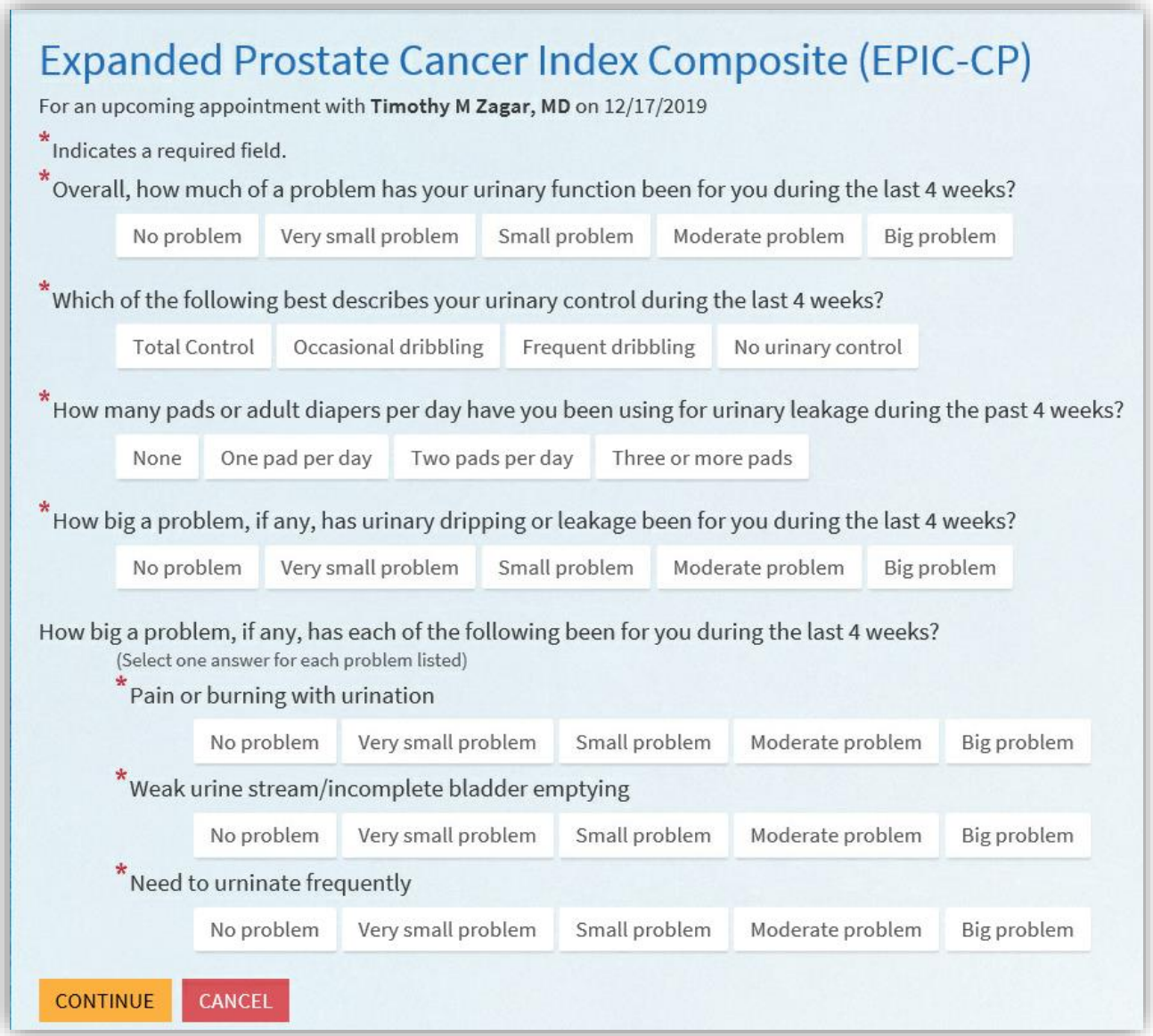
- Administrative interface
  - *Registration form* to enroll patient to initiate PRO reporting
  - *Dashboard* showing patient/panel compliance with PRO reporting
- Clinician interface
  - *Alert notifications*: Inbasket receipt of notifications, with audit trail for clearing alerts
  - *Data visualization*: Ability to view longitudinal data in table and line graph formats
- Patient interface
  - *Automated e-prompts* reminding when to self-report (email, text, phone call)
    - Follow up e-prompt(s) if don't self-report in response to initial e-prompt
  - *PRO surveys* with easy access (this is a major pitfall of native EHR PRO systems)
  - *Alert notifications* triggered to clinicians for severe/worsening symptoms

Example: PRO Patient Interface Interfaced with EMR





Example: PRO patient Interface in Native EMR Functionality



Expanded Prostate Cancer Index Composite (EPIC-CP)

For an upcoming appointment with **Timothy M Zagar, MD** on 12/17/2019

* Indicates a required field.

* Overall, how much of a problem has your urinary function been for you during the last 4 weeks?

No problem | Very small problem | Small problem | Moderate problem | Big problem

* Which of the following best describes your urinary control during the last 4 weeks?

Total Control | Occasional dribbling | Frequent dribbling | No urinary control

* How many pads or adult diapers per day have you been using for urinary leakage during the past 4 weeks?

None | One pad per day | Two pads per day | Three or more pads

* How big a problem, if any, has urinary dripping or leakage been for you during the last 4 weeks?

No problem | Very small problem | Small problem | Moderate problem | Big problem

How big a problem, if any, has each of the following been for you during the last 4 weeks?

(Select one answer for each problem listed)

* Pain or burning with urination

No problem | Very small problem | Small problem | Moderate problem | Big problem

* Weak urine stream/incomplete bladder emptying

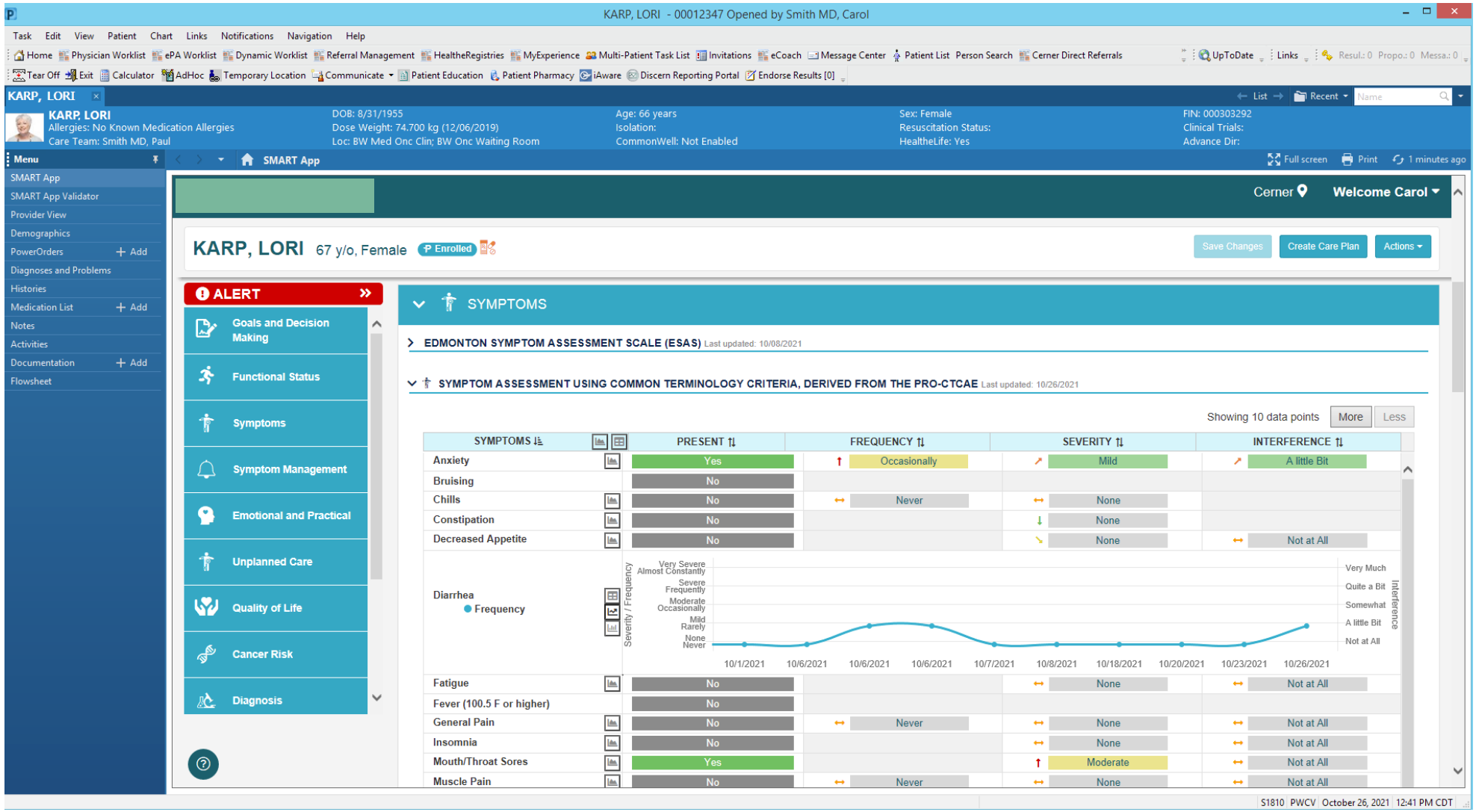
No problem | Very small problem | Small problem | Moderate problem | Big problem

* Need to urinate frequently

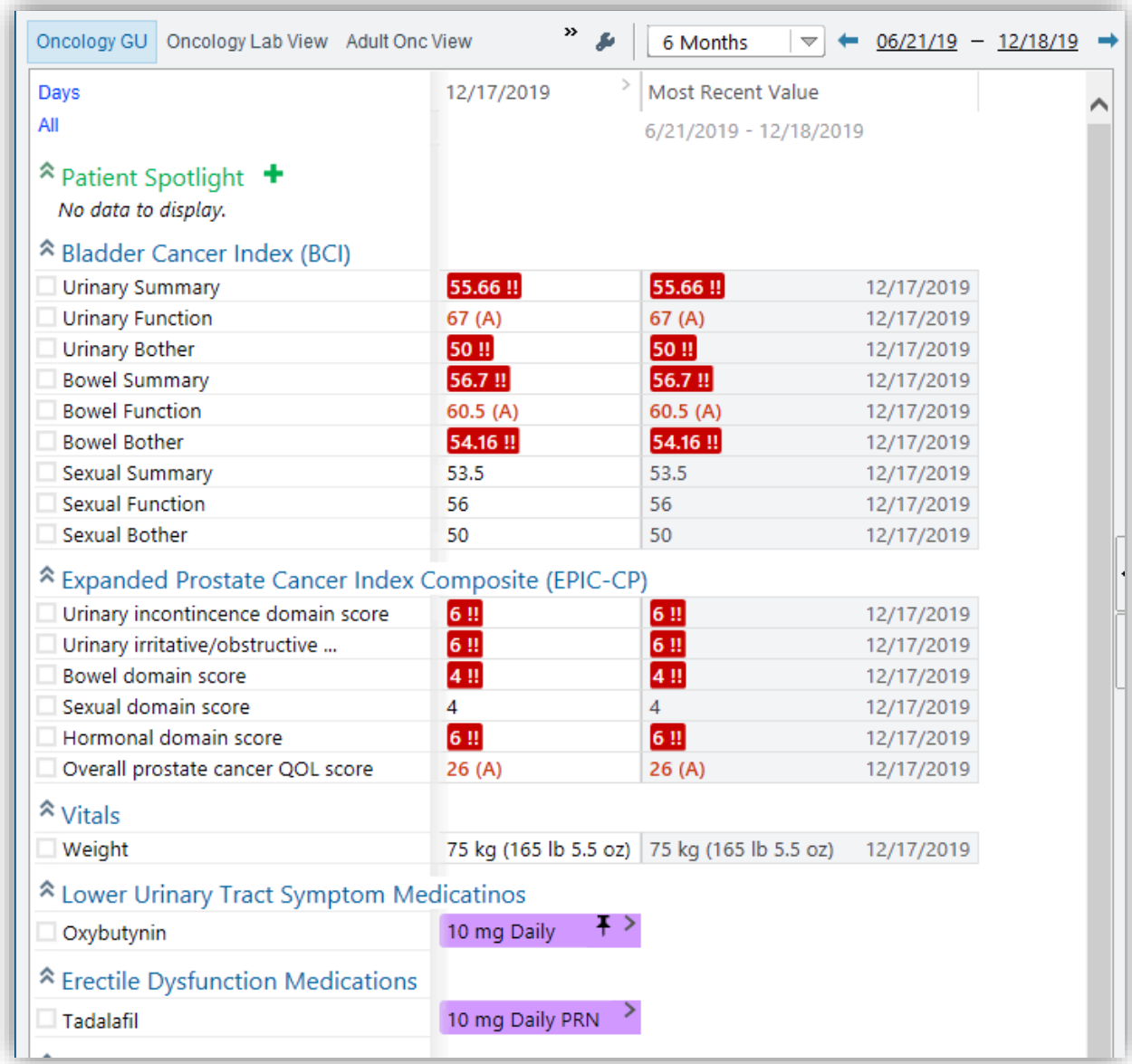
No problem | Very small problem | Small problem | Moderate problem | Big problem

CONTINUE CANCEL

Example: Clinician Visualization of PRO Data in EMR



Example: Clinician Visualization of PRO Data in EMR



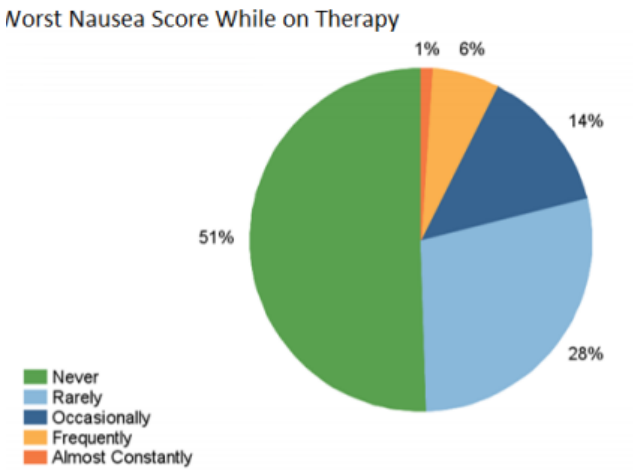
Oncology GU | Oncology Lab View | Adult Onc View | 6 Months | 06/21/19 – 12/18/19

Days All	12/17/2019	Most Recent Value 6/21/2019 - 12/18/2019	
Patient Spotlight			
No data to display.			
Bladder Cancer Index (BCI)			
Urinary Summary	55.66 !!	55.66 !!	12/17/2019
Urinary Function	67 (A)	67 (A)	12/17/2019
Urinary Bother	50 !!	50 !!	12/17/2019
Bowel Summary	56.7 !!	56.7 !!	12/17/2019
Bowel Function	60.5 (A)	60.5 (A)	12/17/2019
Bowel Bother	54.16 !!	54.16 !!	12/17/2019
Sexual Summary	53.5	53.5	12/17/2019
Sexual Function	56	56	12/17/2019
Sexual Bother	50	50	12/17/2019
Expanded Prostate Cancer Index Composite (EPIC-CP)			
Urinary incontincence domain score	6 !!	6 !!	12/17/2019
Urinary irritative/obstructive ...	6 !!	6 !!	12/17/2019
Bowel domain score	4 !!	4 !!	12/17/2019
Sexual domain score	4	4	12/17/2019
Hormonal domain score	6 !!	6 !!	12/17/2019
Overall prostate cancer QOL score	26 (A)	26 (A)	12/17/2019
Vitals			
Weight	75 kg (165 lb 5.5 oz)	75 kg (165 lb 5.5 oz)	12/17/2019
Lower Urinary Tract Symptom Medicatinos			
Oxybutynin	10 mg Daily		
Erectile Dysfunction Medications			
Tadalafil	10 mg Daily PRN		

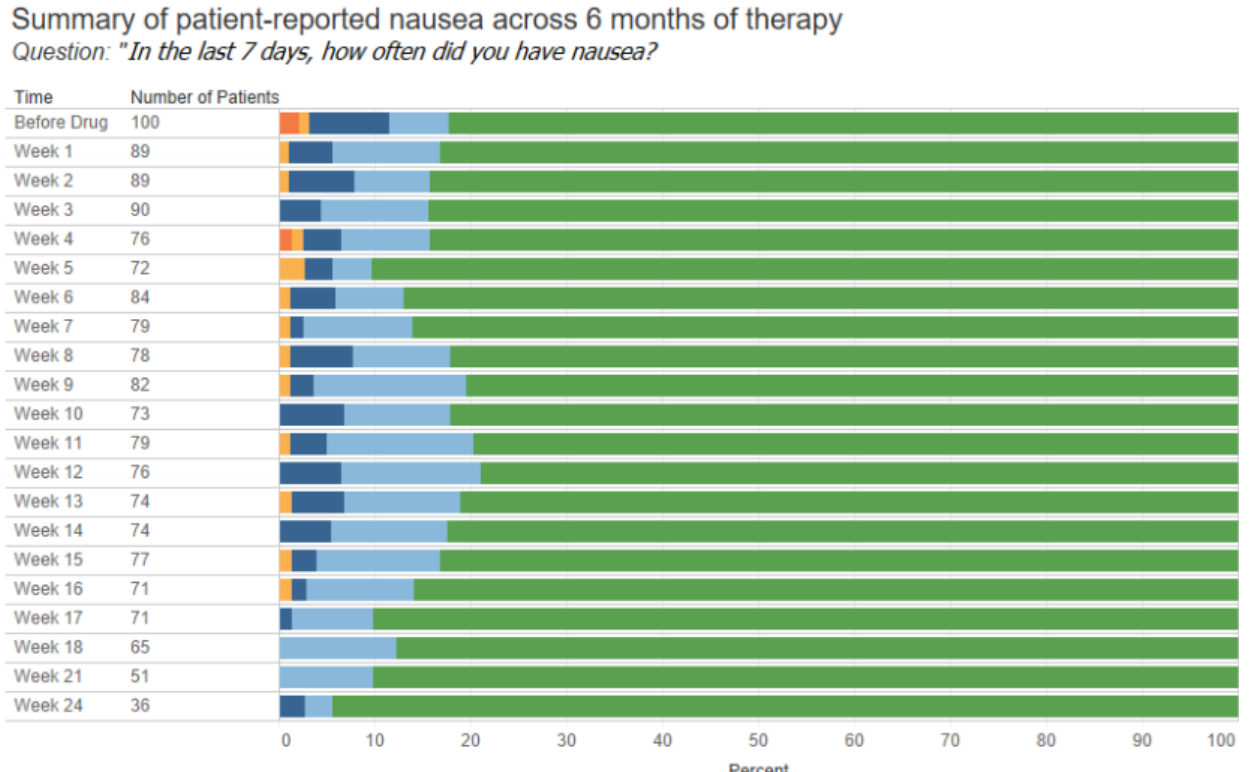
Project Patient Voice

Drug	Indication	Trial Name	Study Design	Blinding Status	Number of patients	Number of PRO patients (with baseline)	PRO Tools Used to Measure Side-effect	FDA Label
Cancer Drug	Patients with Advanced/ Metastatic Cancer	Trial A	Randomized	Double Blind	100	100	PRO-CTCAE	Here

Limitations: Project Patient Voice is intended as one of many tools for patients to use when discussing a drug with their physician. Do not rely on PatientVoice alone to make decisions about medical care. Do not use Patient Voice to substitute for advice from your health care professional. Conclusions about patient experiences with side-effects may be limited because the complete drug side-effect profile may not have been captured by the patient-reported survey.



Worst Nausea Score: This was calculated by finding the worst severity rating score a patient reported any time while the patient was taking the drug



Example: PRO-CTCAE Anorexia