NRG ONCOLOGY

Advancing Research. Improving Lives.™

Cancer Care Delivery Research Meeting

Mary Cooley, PhD
Sarah Hawley, PhD

NRG 2025 Summer Meeting

July 24, 2025

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Deputy NCORP PI

Julie Bauman, MD, MPH

Director, George Washington University Cancer Canter

Associate Dean of Cancer and Professor of Medicine at George Washington School of Medicine and Health

Open NRG NCORP CCDR Trials

Study #	Title	Accrual
NRG-CC012CD	Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment (SYMON) A. Sikorski, T. Badger, T. Crane	**Participants: 150** **Personnel: 48** **Practices: 13**

*Accrual as of 7/23/25

Pipeline of NRG CCDR Concepts for Review

Title
Implementing a prostate cancer decision aid in NCORP practices (Ron Chen, MD)
Physical activity monitoring (Nitin Ohri, MD; Julian Hong, MD)
Developing and testing of a toolkit to optimize guideline-based biomarker testing and treatment for NSCLC (Mary Cooley, PhD)

New Process for NCORP-Funded Pilot Projects

Goal: *To prepare investigators to develop pilot projects aligned with NCORP priorities that could lead to a larger NCORP trials*

LOI and Workshop

- Required to be eligible for application to the NCORP Pilot Project RFA
- Investigators submit a 2-page LOI proposing a pilot study to be performed at their own institution
- NCORP committee chairs review LOIs and select those best aligned with NCORP priorities, which could form the basis for future Phase II – III NCORP trials
- Selected investigators are invited to attend a 1-hour workshop during the winter NRG winter meeting and paired with a mentor

Applications to the NCORP Pilot Grant RFA

- The request for funding application (RFA) for NCORP pilot projects will be released each Spring. This is for participants with LOIs selected in the fall and participating in the January workshop.
- While LOI selection and workshop participation do not guarantee pilot funding, the activities are designed to facilitate successful submissions.

Be on the lookout for the next funding cycle:
LOI and application announcement in August 2025!

NRG Health Care Access Fellowship Program

The Health Care Access Fellowship Program outlines three strategic, high-level goals to provide a broader perspective in clinical trials research:

1. Increase young researchers' involvement with NRG, with an emphasis recruitment of researchers with a passion for improving health care access.

2. Mentor selected early-stage NRG Oncology investigators in clinical trials education and training. The program provides networking opportunities and pathways to leadership.

3. Develop successful clinical trials scientists who can compete in grant writing opportunities.

Announcement released July 18, 2025

Applications due September 19, 2025

Read more about this opportunity at:
https://www.nrgoncology.org/HealthCareAccessFellowship

NCORP Disease Site Liaisons

Disease Site	Liaison
Brain	Melin Khandekar
Breast	Mylin Torres
Cervix	Kate Mills
GI colorectal/non-colorectal	Jordan Kharofa
GU	Andrew McDonald
H&N	Beth Beadle
Lung	Nitin Ohri
Ovarian	Kathryn Pennington
Uterine Corpus	Britt Erickson

Thank You to our Patient Advocates

Laurel Pracht

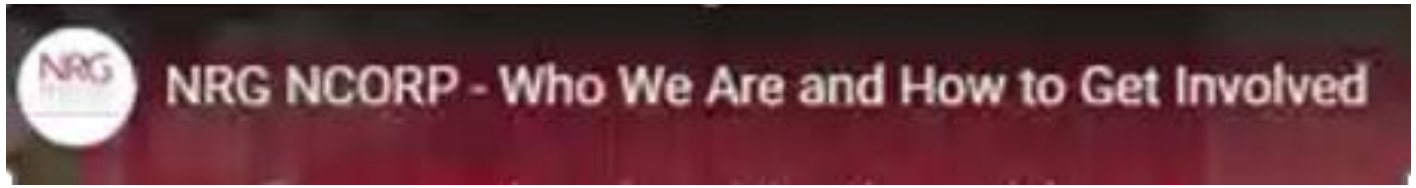
Tambre Leighn

Thank You to our CTN/CRA Liaisons

Michele Harmon

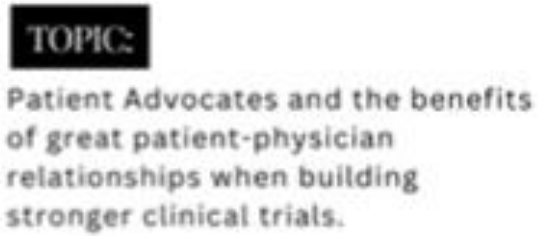
Mary Gulzow

NRG Oncology NCORP Resources



@NRGOnc

@NRGOnc.bsky.social



YouTube

https://www.youtube.com/@NRGOnc

Learning Modules Available in CLASS

https://www.nrgoncology.org/Committees-Programs/NRG-NCORP-Research-Base

Join us at the Advanced Practice Practitioners (APP) Symposium!

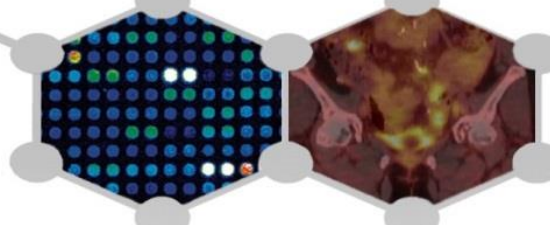
Friday, July 25, 2025

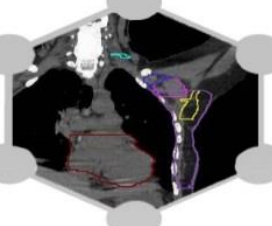
8:15 – 9:45am

Join us at NCORP Town Hall!

Friday, July 25, 2025

10:00 – 11:30am





NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG-CC012CD: Managing symptoms and psychological distress during oral anti-cancer treatment (SYMON)

Tracy E. Crane, PhD, RDN
Alla Sikorskii, PhD, FAPOS
Terry Badger, PhD, RN, PMHCNS-BC, FAPOS, FAAN

July 24, 2025

Disclosures

- Nothing to disclose

Study Team

Grant/Sponsor Acknowledgements:
R01 CA279472 (Sikorskii/Crane/Badger)

Alla Sikorskii, PhD
Study Chair, PI
Michigan State University

Tracy Crane, PhD
Study Co-Chair, MPI
University of Miami

Terry Badger, PhD
Study Co-Chair, MPI
University of Arizona

Stephanie Pugh, PhD
Statistician
NRG Stats & Data Management

Vamsi Krishna Vasireddy, DO
NCORP Community Chair
Carle Cancer Institute

Melyssa Foust, MSN, RN
Nursing Co-Chair
Upstate Carolina NCORP

Jamillah Gross-Caldwell
Study Coordinator
Michigan State University

Grey Freylersythe
Study Coordinator
University of Miami

NRG ONCOLOGY™

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Specific Aims

- Test the **effectiveness of ATSM+TIPC versus active control** on **symptom toxicity index** (primary, summary of 22 Patient Reported Outcomes Common Terminology Criteria for Adverse Events, PRO-CTCAE) and **unscheduled health services use** (secondary)
- Evaluate **implementation outcomes** at the practice personnel level: time, actions taken on symptom reports, intervention acceptability and appropriateness for clinics
- Estimate **cost of delivery of ATSM+TIPC** and **active control** and **cost savings for ATSM+TIPC** versus **active control** as a **result of reduced unscheduled health services use**

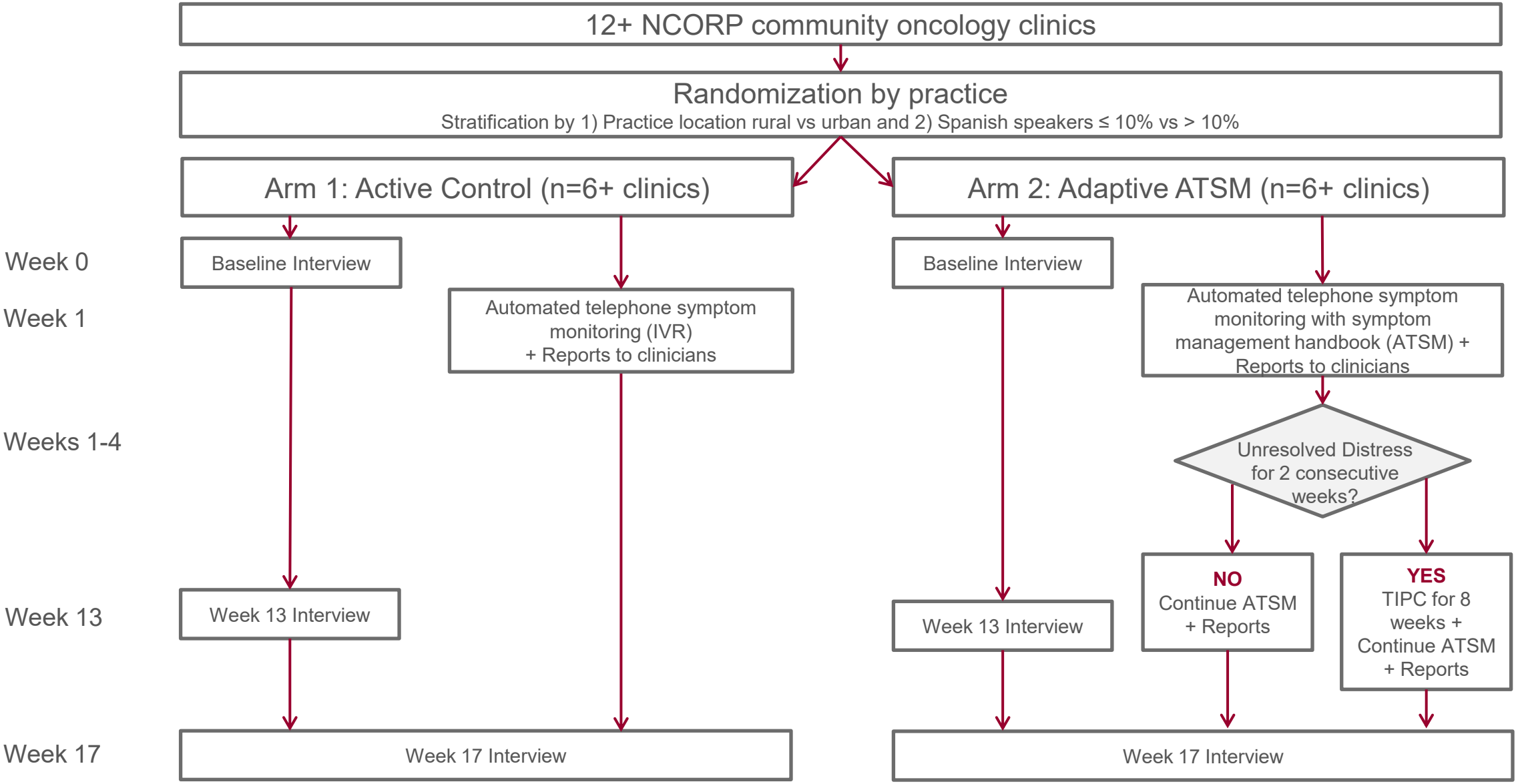
NRG ONCOLOGY™

Design: Hybrid type 1 Implementation Trial

- Automated Telephone Symptom Management (ATSM) + need-based addition of Telephone Interpersonal Counseling (TIPC) intervention, total duration 12 weeks
- **ATSM** is delivered by the automated voice response (IVR) technology, with referral to a printed Handbook for elevated symptoms, summary symptom reports to providers
- **TIPC** designed to address depression and anxiety, 8 weekly sessions delivered by social worker concurrent with ATSM
- **Active control**: symptom monitoring via the IVR with summaries to providers

NRG ONCOLOGY™

Study Schema



Study Population

Clinics (n = 12+)

- Not offering systematic symptom management program to all patients
- Have a licensed behavioral health specialist or be willing to work with contracted TIPC intervener
  - TIPC delivery training (~20 hrs)
- Enroll up to 45 survivors on oral anti-cancer agents per clinic, ~2 per month x 2 yrs of participation

Practice Personnel (+/- 4 per clinic)

- Report on intervention acceptability and appropriateness at months 12 & 25
- Provide monthly data on feasibility and actions taken on symptom reports via brief survey collected from the provider(s) identified by the clinic

NRG ONCOLOGY™

Study Population: Patients

- Aged 18 or older survivor can have **any cancer** treated with **new** oral agent(s) *including checkpoint inhibitors* (Protocol V2)
  - Can be receiving sex hormone inhibitor *in conjunction* with other oral treatment, but not solely
  - Can be receiving radiation or other treatments concurrently
- Started a new course of treatment within the past **8 weeks** or anticipated to start within the next **4 weeks** of registration (Protocol V2)
- Speak and understand **English or Spanish**
- Have access to a telephone and be able to hear and press buttons on the phone during the call
- Not currently receiving competing supportive care or current behavioral counseling

NRG ONCOLOGY™

Study Intervention

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM

My Wellness Research

PARTICIPANTS FROM CLINICS RANDOMIZED TO INTERVENTION

Any Symptoms of 0-4 → Report sent to provider

Symptoms of 2-4 → Participant directed to Handbook

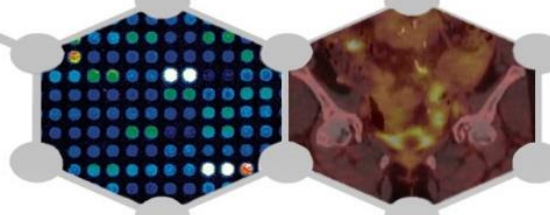
Psychological Symptoms of 3-4 for 2 consecutive weeks (in weeks 1-4 only) → Referral for 8-wk TIP-C sent on the participant's behalf

Rave Medidata

PARTICIPANTS FROM CLINICS RANDOMIZED TO CONTROL

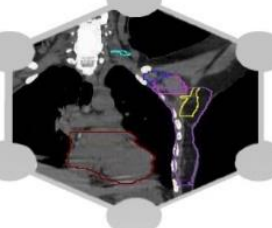
Any Symptoms 0-4 → Report sent to provider

NRG ONCOLOGY™



NRG ONCOLOGY

Advancing Research. Improving Lives.™



Study Updates

Enrollment Summary

Study Activation May 1, 2024

Approved LOIs: n=15 (target n=12+)

- 13 active sites
  - 1 closed KS118
  - 2 additional new sites added July 2025:
    - Medical University of South Carolina, University of Hawai'I

Accruals

- Opened to accrual 10/4/2024
- Patient Enrollments: n=150 (target n=516, 43+ per site)
- Non-Patient Enrollments: n=48 (target n=60, +/-4 per site)

NRG ONCOLOGY™

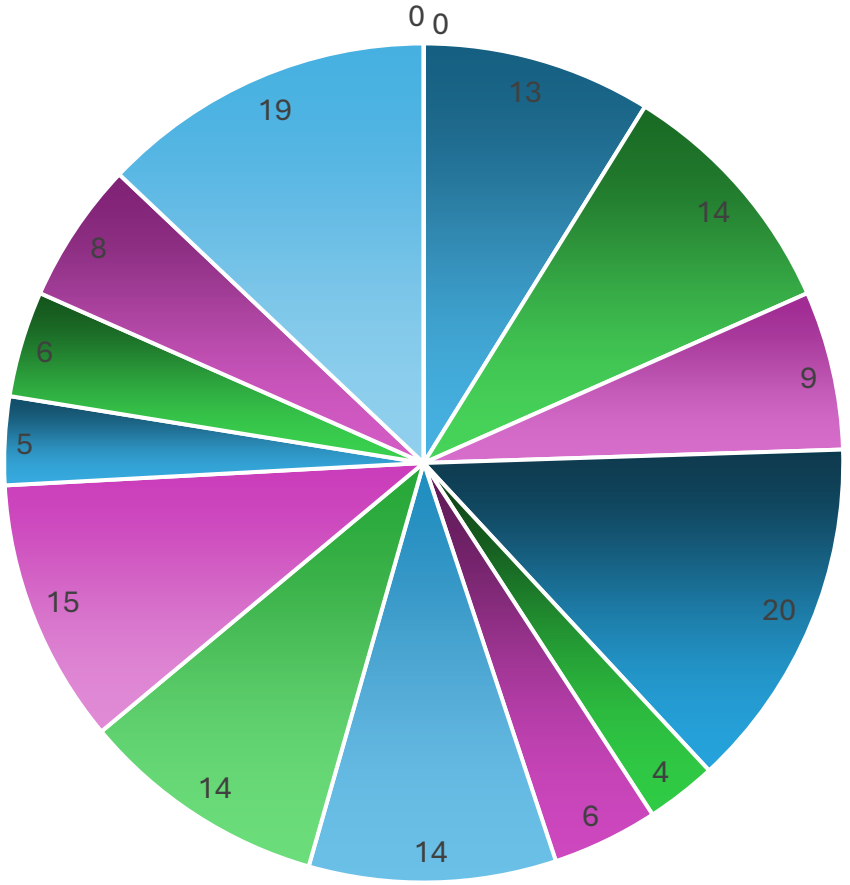
Geographic Distribution

Active Control	Cancer Center at St. Joseph's/CommonSpiri...
	Cancer Research of Wisconsin and Northern...
	Georgia Cares Minority Underserved NCORP
	Lake Regional Health System/Ozarks NCOR...
	Medical University of South Carolina MUSC -...
	Stroger Hospital of Cook County Minority Un...
	University of New Mexico Comprehensive C...
Adaptive ATSM	AnMed Cancer Center/Upstate Carolina NC...
	CARTI - Central Arkansas Radiation Therapy ...
	Carle Cancer Center NCORP
	LSU University Medical Center/Gulf South N...
	Prisma Health Cancer Institute/NCORP of th...
	Puerto Rico Minority Underserved NCORP
	Hawaii Minority Underserved NCORP
Closed	Central Care Cancer Center - Garden City/Oz...

NRG ONCOLOGY™

June 24, 2024

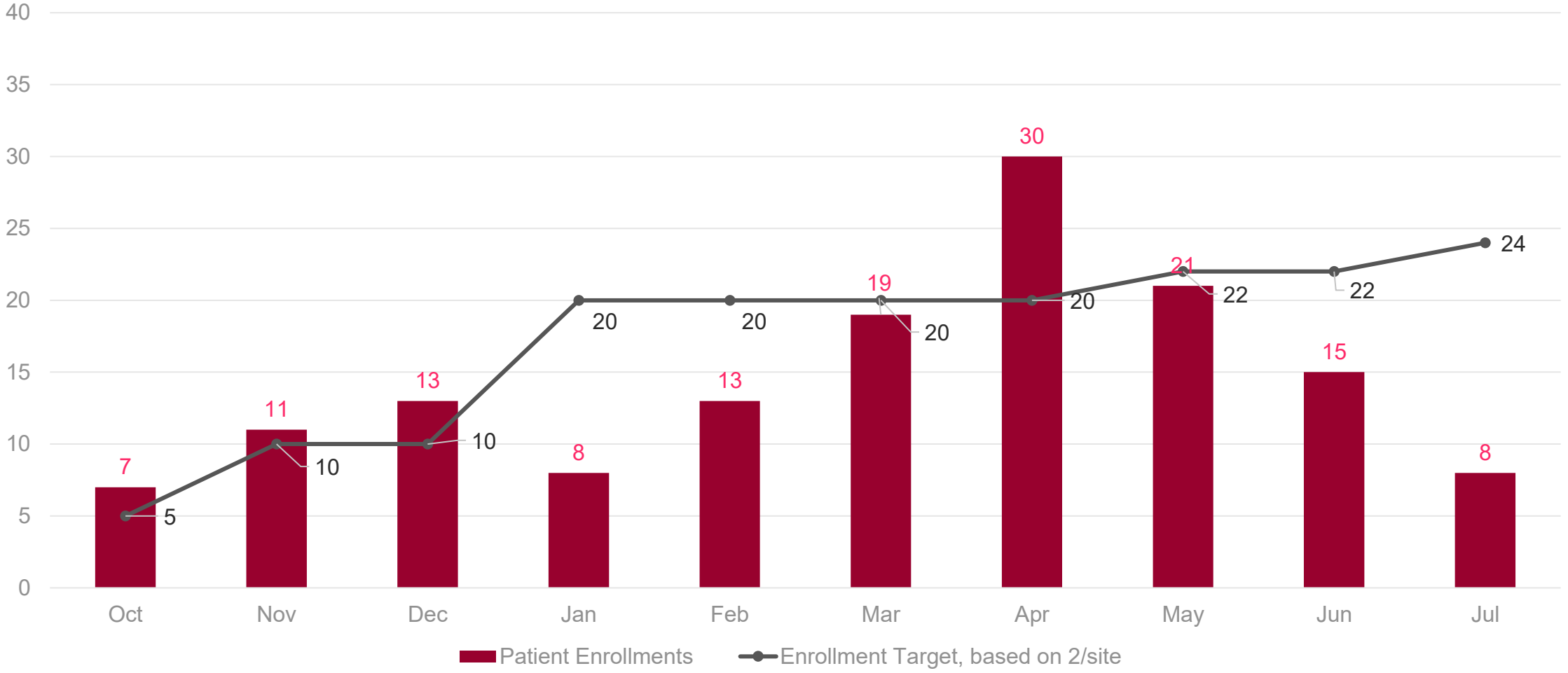
Patient Enrollments by Site (n=147)



- AZ151 St. Josephs n=13
- GA020 GA CaRes n=14
- IL042 Stroger n=9
- **IL168 Carle n=20**
- KS114 Central Care Ozarks - CLOSED
- LA29 LSU n=6
- MO200 Lake Regional Ozarks AF n=14
- NM004 UNM n=14
- SC064 Anmed Upstate Carolina n=15
- PR046 Puerto Rico n=5
- SC045 Prisma Health n=6
- AR020 CARTI n=8
- **WI028 Aspirus CROWN n=19**
- SC008 MUSC n=0 - NEW
- HI005 Uhawai'i n=0 - NEW

NRG ONCOLOGY™

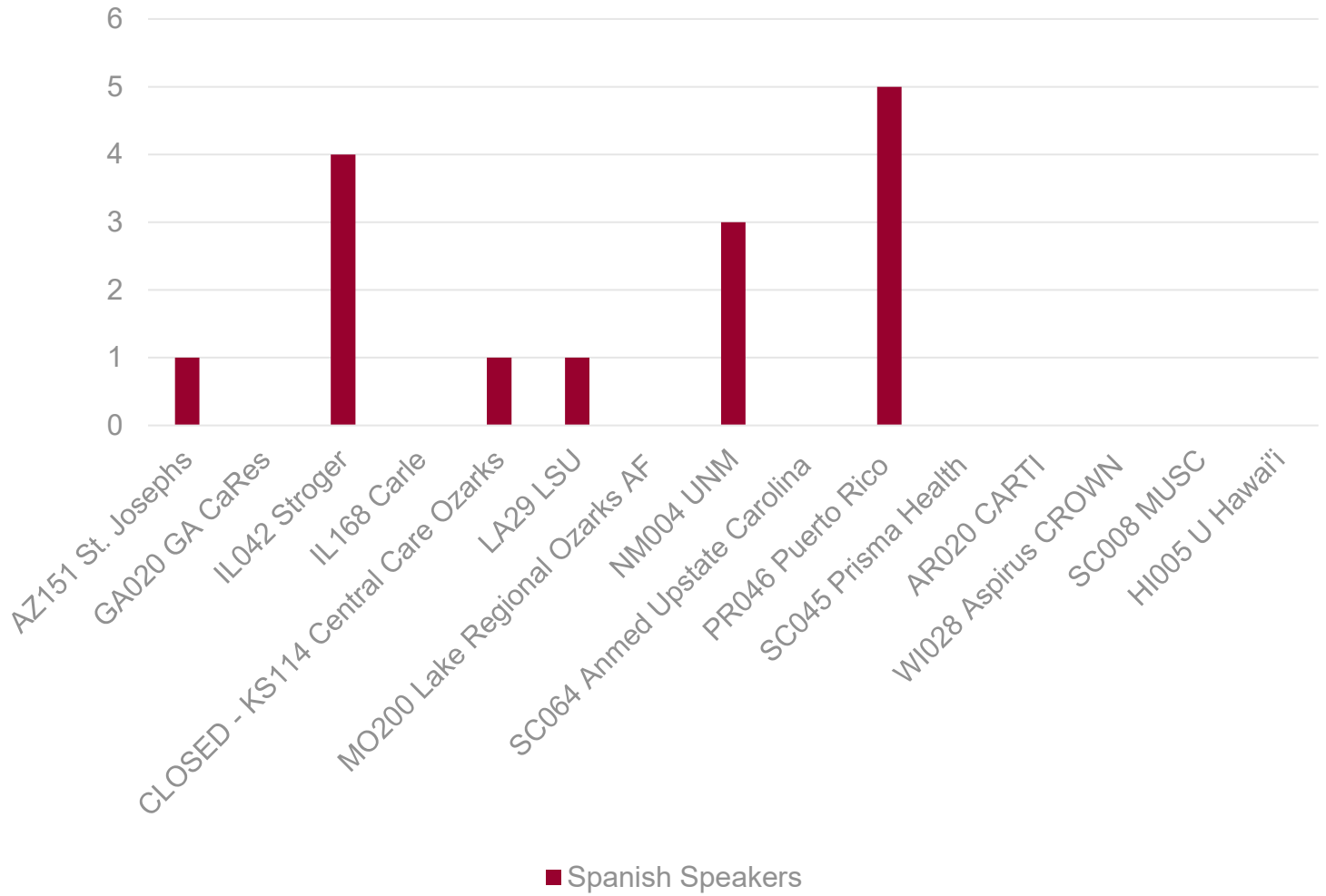
Patient Enrollments by Month (n=147)



NRG ONCOLOGY™

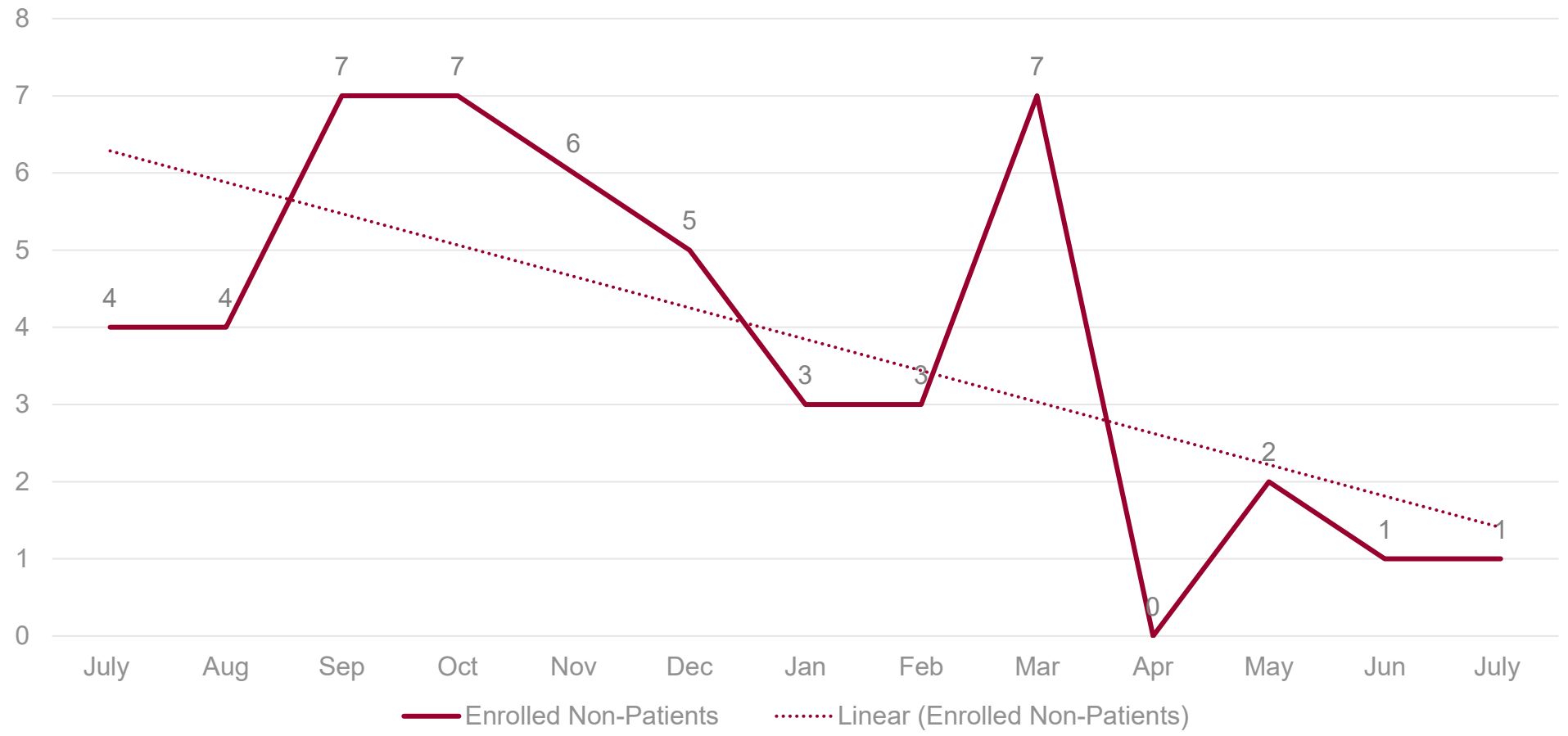
Spanish Speakers Enrollment by Site (n=15)

- Protocol target 15% Spanish speakers
  - N=78/516 target
- Enrollments to date
  - N=15



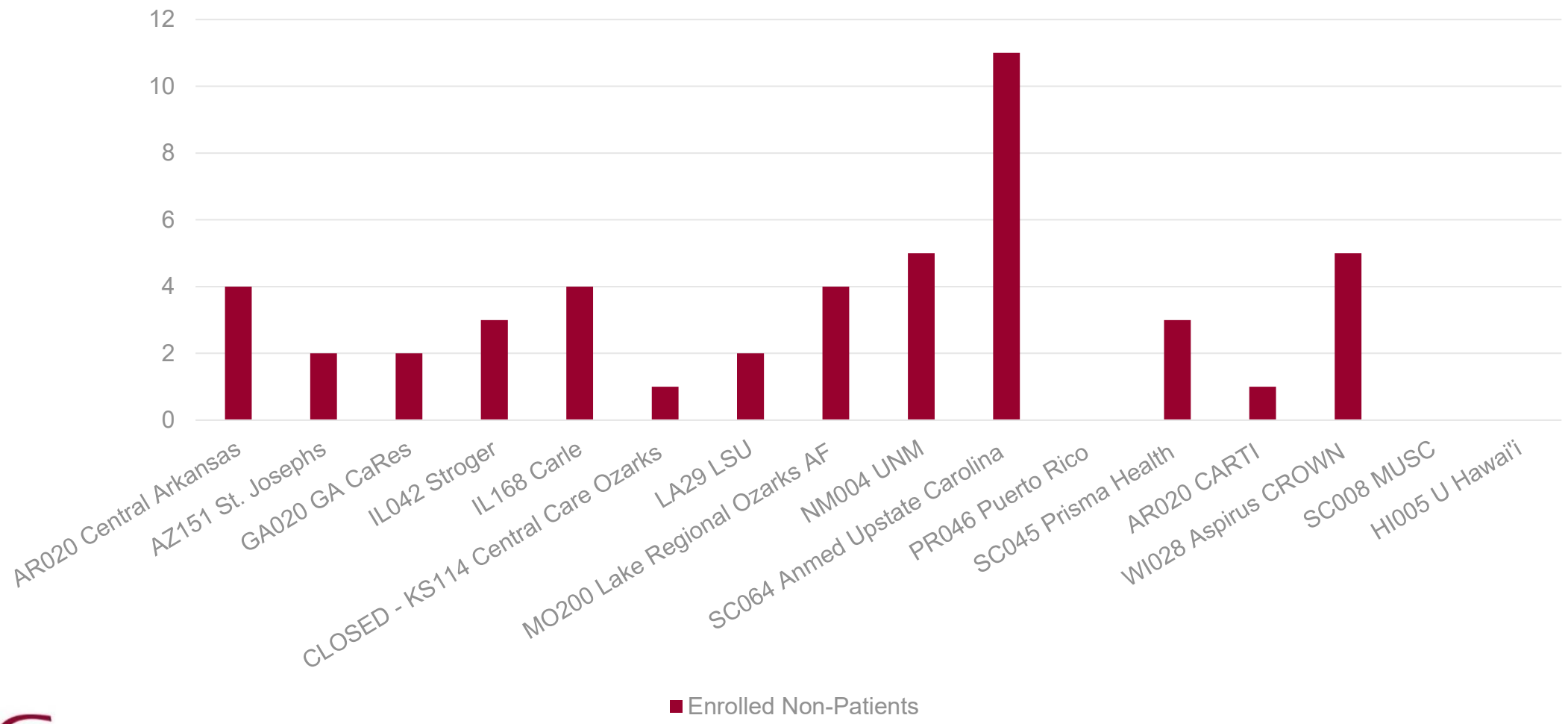
NRG ONCOLOGY™

Non-Patient Enrollments by Month (n=50)



NRG ONCOLOGY™

Non-Patient Enrollments by Site (n=50)



NRG ONCOLOGY™

Questions?

Contact information:

symon@miami.edu
Study Coordinators: Grey Freylersythe & Jamillah Gross-Caldwell

Alla Sikorskii – sikorska@msu.edu
Tracy Crane - tecrane@med.miami.edu
Terry Badger – tbadger@arizona.edu.edu
Melyssa Foust - MFoust@Gibbscc.org

Effectiveness and implementation of a multilevel intervention to improve longer-term breast cancer survivorship care: the *Connected Breast Cancer Care Transitions* study

Archana Radhakrishnan, MD, MHS

Lauren Wallner, PhD, MPH

Sarah Hawley, PhD, MPH

University of Michigan

2025 NRG Oncology Summer Meeting

CanSORT

ROGEL CANCER CENTER
MICHIGAN MEDICINE

Disclosures

- No disclosures

Longer-term survivorship care

- How to best deliver high-quality, comprehensive care to longer-term survivors (>5 years after diagnosis) remains a challenge

- International & national societies recommend transitioning lower-risk, longer-term survivors to primary care

- Existing team-based care models that include primary care are inadequate
  - Focused on immediate period after cancer treatment
  - Patient-level barriers not adequately addressed
  - Operationalizing clinician collaboration is difficult

- Lack of effective and scalable interventions that specifically address gaps in team-based cancer survivorship care for longer-term survivors

Pollock LA, Cancer 2009; Earle CC, Cancer 2004; Snyder CF, JCO 2008; Snyder CF, JCO 2009; Emery JD, BJUI 2017; Mittman N, JCO 2018

Connected Breast Cancer Care Transitions (CBCT)

- Multi-level intervention targeted toward longer-term breast cancer survivors, their medical oncologists and PCPs

- Patients:
  - Support care transitions to primary care for longer-term survivorship
    - Improve knowledge on appropriateness of primary care roles
  - Improve knowledge on extended endocrine therapy & self-management of symptoms

- Clinicians: facilitate transition between oncology and primary care teams
  - Improve inter-clinician (team) communication
  - Operationalize transition to primary care

CanSORT

Funded by NIH/NCI (K07 CA201052, K08 CA245237), UM Rogel Cancer Center (P30 CA 46592)

ROGEL CANCER CENTER
MICHIGAN MEDICINE

CBCT Content

Patient-level

- Patient-facing website tailored to:
  - Patients' baseline preferences and expectations about clinician roles in longer-term survivorship care
  - Clinical information
  - Evolving roles of clinicians over time
  - Needs about extended endocrine therapy

Clinician-level

- Direct communication between oncology & primary care around
  - Transition to primary care
  - Guideline-concordant survivorship care

CanSORT

Funded by NIH/NCI (K07 CA201052) and UM Rogel Cancer Center (P30 CA 46592)

ROGEL CANCER CENTER
MICHIGAN MEDICINE

Preparatory work

2 phases

1. Prior work to develop and evaluate a patient-facing tool (ConnectedCancerCare) in a pilot RCT (described further in next slides)

2. Current work planned through supplemental funding:
   - Adapt the existing content of ConnectedCancerCare to focus on supporting care transitions to primary care > 5 years after treatment

   - Conduct pre-implementation planning to identify a clinician-facing implementation strategy with oncology and primary care clinicians to support transitioning care for longer-term survivors

CONNECTED cancercare

Improving the delivery of team-based survivorship care after primary breast cancer treatment through a multi-level intervention: a pilot randomized controlled trial

Clinical trial | Published: 07 July 2021

Volume 189, pages 81–92, (2021) Cite this article

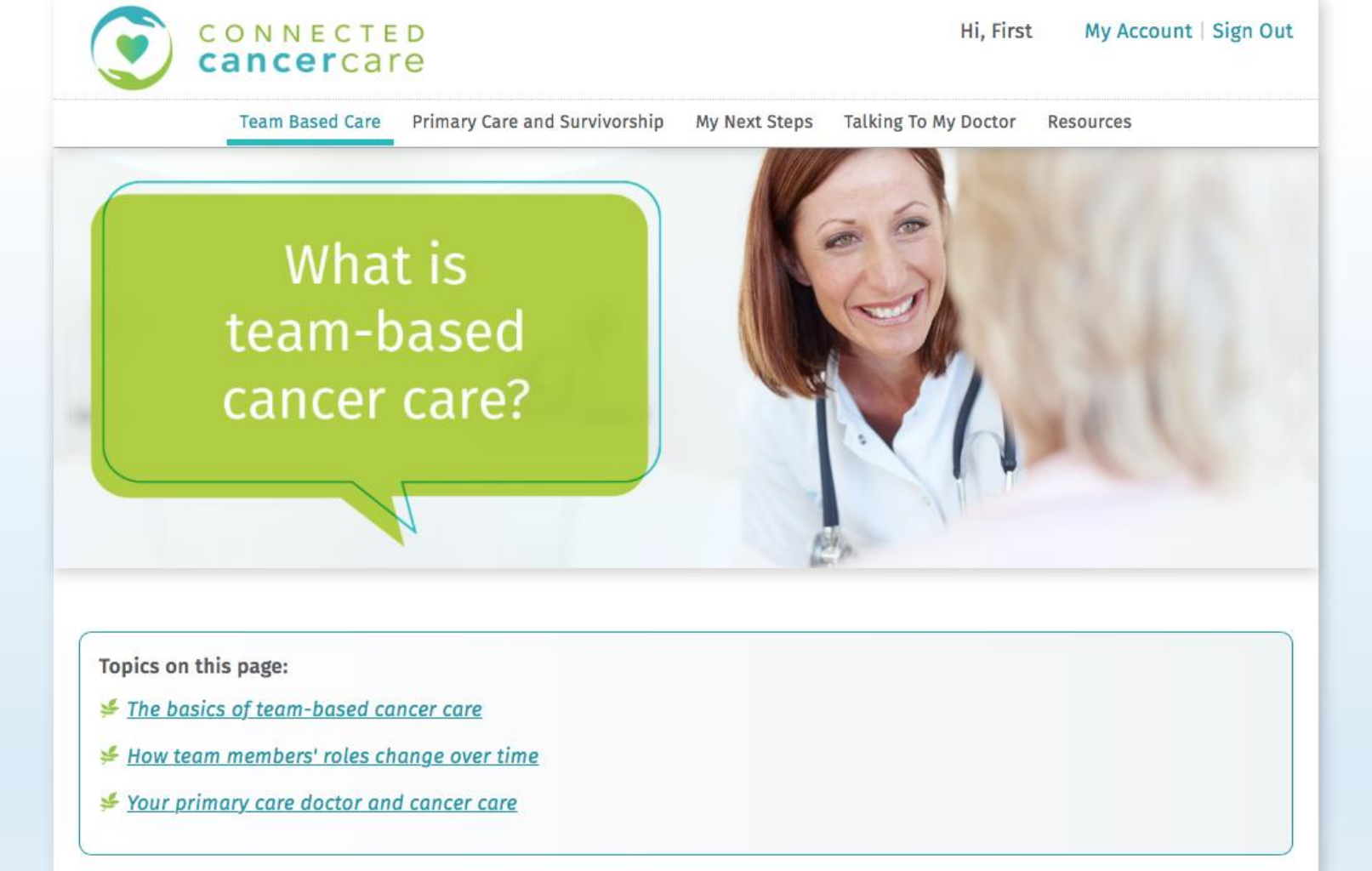
Lauren P. Wallner ✉, Paul Abrahamse, Joan G. Gargaro, Archana Radhakrishnan, Megan A. Mullins, Lawrence C. An, Jennifer J. Griggs, Anne F. Schott, John Z. Ayanian, Anne E. Sales, Steven Katz & Sarah T. Hawley

CanSORT

Funded by NIH/NCI (K07 CA201052) and UM Rogel Cancer Center (P30 CA 46592)

ROGEL CANCER CENTER
MICHIGAN MEDICINE

ConnectedCancerCare



Funded by NIH/NCI (K07 CA201052) and UM Rogel Cancer Center (P30 CA 46592)

CONNECTED cancercare

Hi, First My Account | Sign Out

Team Based Care | Primary Care and Survivorship | My Next Steps | Talking To My Doctor | Resources

What can my primary care provider do now?

The topics on this page cover how your primary care doctor can help you:

- *Watch for breast cancer recurrence*
- *Manage your symptoms and side effects*
- *Maintain a healthy lifestyle*
- *Coordinate your care*
- *Screen for other cancers*

Treatment

During treatment, you worked closely with your oncologist to treat your breast cancer while your primary care doctor played a smaller role.

Oncology care:

- Helped you understand your options and make decisions about treatment
- Gave you the treatment that was the best fit for you

Primary care:

- Helped you manage other health concerns and preventive care

You:

- Talked to your oncologist about your treatment preferences
- Kept track of the treatment you received and side effects you experienced

Transition

Now you are moving into survivorship. You, your oncologist, and your primary care doctor work together to help this transition go smoothly.

Oncology care:

- Helps you and your primary care doctor understand the treatment you had
- Helps you plan your ongoing care

Primary care:

- Learns about your treatment
- Helps you plan your ongoing care

You:

- Talk with both doctors about your treatment and your concerns
- Share the list of activities on your ***My Next Steps*** page with your primary care doctor

Ongoing Care/Survivorship

Going forward, you and your primary care doctor will work side-by-side to coordinate your ongoing care with the rest of your team.

Oncology Care:

- Continues to see you for check-ups and concerns about recurrence as needed

Primary Care:

- Gives you most of the care you need to stay healthy
- Refers you to specialists
- Communicates with your oncologist and refers you back to them if needed

You:

- Keep track of your appointments
- Monitor your pain and symptoms
- Continue to talk with your doctors about your concerns

CanSORT

CONNECTED cancercare

Hi, First My Account | Sign Out

Team Based Care | Primary Care and Survivorship | My Next Steps | Talking To My Doctor | Resources

What are my next steps?

The topics on this page help you keep track of the things you will need to know and do moving forward, like:

- *When to have your follow-up appointment*
- *Your diagnosis and treatment summary*
- *Your next steps in ongoing care*

My Appointment

Schedule an appointment with your primary care doctor between February 1, 2018 and May 4, 2018.

My primary care doctor

John Doe
1231231234

My oncologist

Jane Doe
1234567890

CanSORT

ROGEL CANCER CENTER
MICHIGAN MEDICINE

Longer-term objective

- Evaluate the **effectiveness** of Connected Breast Cancer Care Transitions (CBCT) on transitioning longer-term breast cancer survivors to primary care

- Assess barriers and facilitators to the **implementation** of CBCT across diverse community-based practice settings

Preliminary specific aims

- Aim 1: Assess the effectiveness of CBCT on transitioning longer-term breast cancer survivors from oncology practices to primary care

- Aim 2: Assess the effectiveness of CBCT on patient-centered survivorship care. We will collect patient-reported outcomes related to knowledge about survivorship care (including extended endocrine therapy), ability to self-manage symptoms, and receipt of guideline-concordant survivorship care

- Aim 3: Identify factors that affect the implementation of CBCT across diverse community-based practices

Study design

Effectiveness-implementation study (hybrid type 1)

Effectiveness

- Cluster RCT of CBCT vs. usual care (e.g., static SCP)
- Randomized at medical oncology practice level

Implementation

- Process evaluation with stakeholders at multiple levels
  - Clinician interviews
  - Patient interviews
  - Paradata from website

Study population

- Oncology Practices
  - NCORP medical oncology practices with integrated primary care available (i.e., shared EMR)
- Patients
  - Women with early-stage breast cancer (stages 0-II) who are > 5 years post-treatment and being seen by a medical oncology provider at eligible NCORP practice for follow-up care
  - English or Spanish speaking
- N of practices and patients still need to be determined

Trial outcomes

	Domain	Items	When assessed
Primary	Transition to primary care	* Patient reported willingness to transition to primary care for oncology/ survivorship management * Patient reported interest/intention to transition	4 weeks post enrollment
		Patient reported use of PCP for some oncology care reason	12 months post enrollment
		EMR assessment of use of primary care	12 months post enrollment
Secondary	Patient reported survivorship care	* Patient reported knowledge about extended endocrine therapy * Ability to self-manage symptoms from endocrine therapy	
Exploratory	*Receipt of guideline concordant surveillance care*	*Patient report of care received* *EMR assessment of care received*	*12-18 months*

Trial process outcomes

- Implementation: multi-modal ascertainment via EMR, process, survey, interviews
  - Reach (patient-level)
  - Adoption (clinician-level)
  - Implementation (fidelity)
  - Maintenance (sustainability)
  - Acceptability
  - Feasibility
  - Appropriateness

Study team at University of Michigan

Archana Radhakrishnan, MD
*primary care physician
*cancer survivorship care delivery
*implementation science

Lauren Wallner, PhD
*team-based cancer care
*multilevel interventions
*implementation science

N. Lynn Henry, MD, PhD
*medical oncologist
*breast cancer care delivery
*symptom management

Sarah Hawley, PhD
*cancer care delivery trials
*NCORP PI
*health intervention development & evaluation

CanSORT

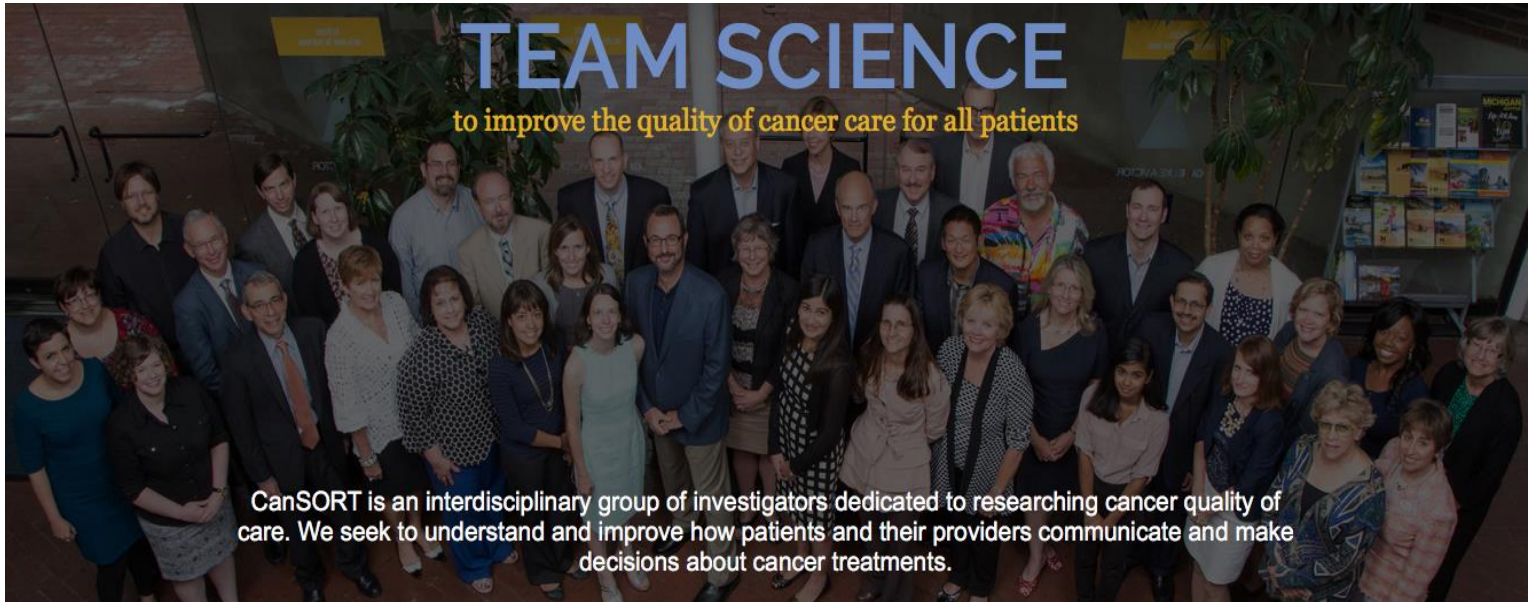
ROGEL CANCER CENTER
MICHIGAN MEDICINE

Thank you!...and some questions for you

- How does your practice typically handle transitioning long term breast cancer patients to primary care (if you do)?
- Is your practice part of a system where primary care is integrated (e.g, shared EMR)?
  - How easy is this to use?
  - Any suggestions if you are not part of such a system?
- Is this project something your practice would have interest in?
- We would like to develop a brief practice survey so that may be coming sometime soon! Meanwhile, **please reach out to us with thoughts about this study**

Thank you!

arra@umich.edu
lwallner@umich.edu
sarahawl@umich.edu



Acknowledgement: NCI (P01 CA163233, K07 CA201052, K08 CA245237); Rogel Cancer Center Research and Career Development Grants; Center for Health Communications Research (P30 CA 46592)

CanSORT

ROGEL CANCER CENTER
MICHIGAN MEDICINE

NRG ONCOLOGY

Advancing Research. Improving Lives.™

Implementing a Prostate Cacner Decision Aid in NCORP Practices

Ronald Chen, MD MPH
University of Kansas Cancer Center

NCI National Clinical Trials Network — a National Cancer Institute program

NCI Community Oncology Research Program — A program of the National Cancer Institute of the National Institutes of Health

Disclosures

- Paid consultant for Astellas, Novartis

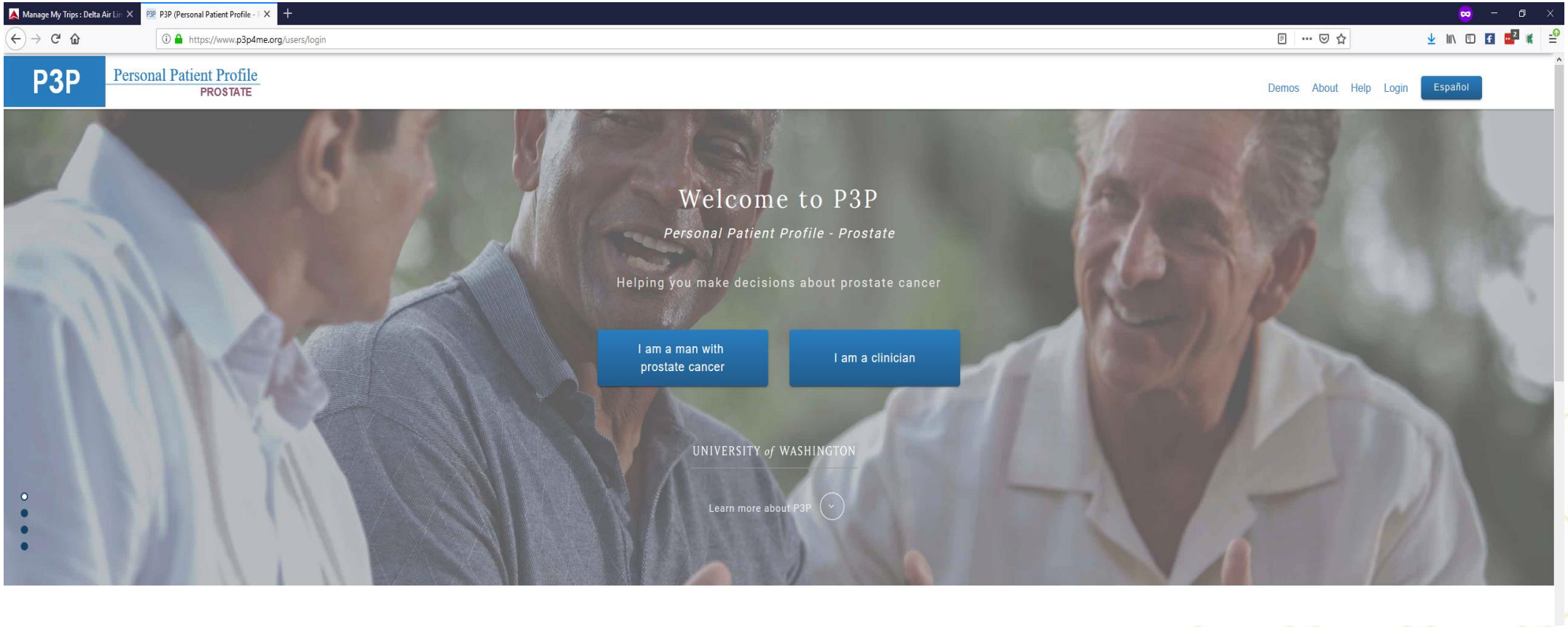
Localized Prostate Cancer – Many Choices

- About 300,000 men are diagnosed with prostate cancer in US each year – most have localized disease
- Patients have multiple choices, ranging from active surveillance to many treatment options (surgery, radiation, focal therapy, etc)
  - These choices have tradeoffs related to efficacy and quality of life impact
- Need for decision aid:
  - Most patients do not receive multidisciplinary consultation to learn about different options
  - Physicians often do not have time to discuss all the tradeoffs of different options, and/or to elucidate patient preferences
  - Many patients do “research” and want to learn about their options: need high quality information to inform their decisions

P3P (Personal Patient-Profile-Prostate)

- Interactive Web-based decision support system in English and Spanish that works on all devices
- Synthesizes medical facts with patient factors (beliefs, preferences, concerns)
- Multi-media education and coaching based on patient priorities
- Prepares a man for the *options consultation* with the clinician and decision

P3P (Personal Patient-Profile-Prostate)

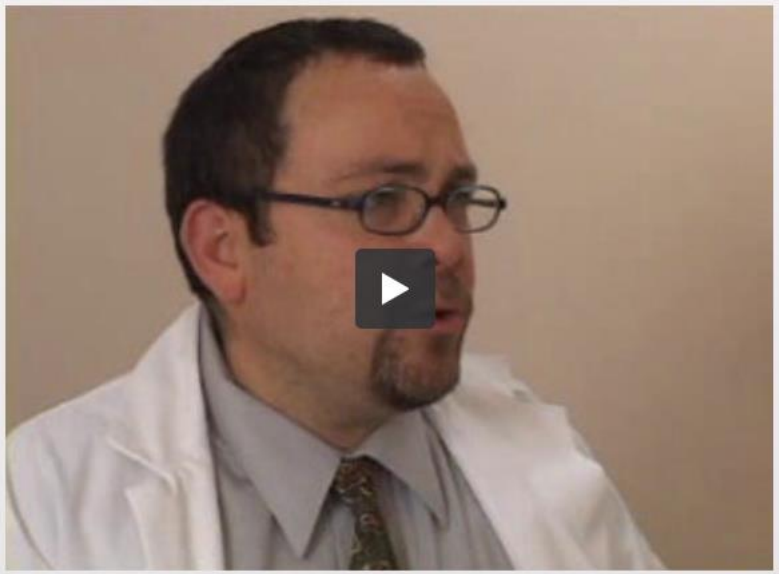


www.p3p4me.org

P3P: Components

- Assess current (baseline) symptoms: EPIC-26
- What is important to you in making a decision
  - Sexual, urinary, bowel function; ability to work and do activities
  - Influence from family, partner, friends
- Videos and texts about different treatments and impact on QOL
  - Modeling how patients can bring up topics during consultation
- Understanding statistics: text and graphic
- Top information topics: text (print-out)
- Education: prostate cancer diagnosis (Gleason, risk group, etc), treatment options, side effects, websites

P3P: Components



TALK TO YOUR DOCTOR

There are several ways to deal with an erection problem if it happens. Your doctor is used to talking about this. Be sure to tell your doctor if you are worried how prostate cancer treatment may affect your body sexually. For example, you might say:

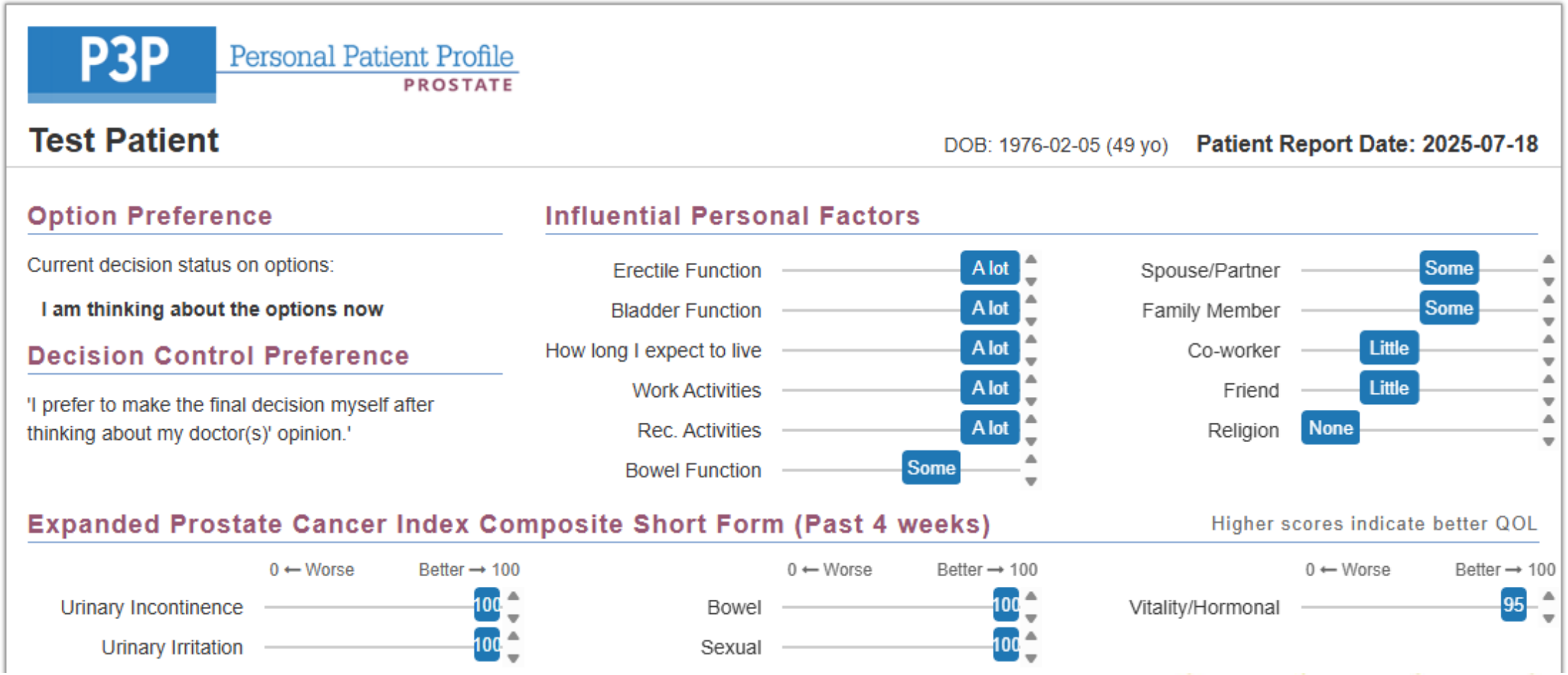
> **"Doctor, I'm worried about being able to have my usual sexual activity because ... (say your own thoughts). Tell me how prostate cancer treatments could affect how my body works sexually."**

INCONTINENCE AFTER SURGERY

After surgery, about 14 out of 100 men will lose some ability to control their urine for the rest of their lives.

The other about 86 men will get urine control back at some point after surgery.

P3P: Components



P3P Personal Patient Profile PROSTATE

Test Patient

DOB: 1976-02-05 (49 yo) **Patient Report Date: 2025-07-18**

Option Preference

Current decision status on options:

I am thinking about the options now

Decision Control Preference

'I prefer to make the final decision myself after thinking about my doctor(s)' opinion.'

Influential Personal Factors

Erectile Function	A lot
Bladder Function	A lot
How long I expect to live	A lot
Work Activities	A lot
Rec. Activities	A lot
Bowel Function	Some
Spouse/Partner	Some
Family Member	Some
Co-worker	Little
Friend	Little
Religion	None

Expanded Prostate Cancer Index Composite Short Form (Past 4 weeks)

Higher scores indicate better QOL

	0 ← Worse Better → 100
Urinary Incontinence	100
Urinary Irritation	100
Bowel	100
Sexual	100
Vitality/Hormonal	95

P3P: Prior Randomized Trials

- Two multi-site randomized trials completed (P3P vs routine care)
- P3P reduced decisional conflict
  - I know which options are available to me
  - I'm clear about the best choice for me
  - I feel I have made an informed choice
  - I am satisfied with my decision…
- Reduced decisional regret in Black men

Berry, Urol Oncol 31:1012-21, 2013
Berry, J Urol 199:89-97, 2018
Berry, Urol Oncol 493:e9-15, 2021.

Possible NCORP Trial

- Cluster randomization by participating site
  - No decision aid vs P3P implemented through urology practice
    - Landscape survey 2017: 133 NCORP practices have access to urology

- Outcomes:
  - Uptake of P3P and use/completion
  - PrepDM (preparation for decision making): effect of educational material on preparing you for a decision
  - Receipt of multidisciplinary consultation
  - Treatment (management) choice, and alignment with patient preferences
  - Decisional regret

Expanded access surveillance paradigm in HPV mediated oropharyngeal squamous cell carcinoma

NRG CCDR, July 2025

Molly E. Heft-Neal, MD

Assistant Professor

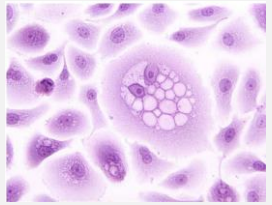
Department of Otolaryngology-Head and Neck Surgery

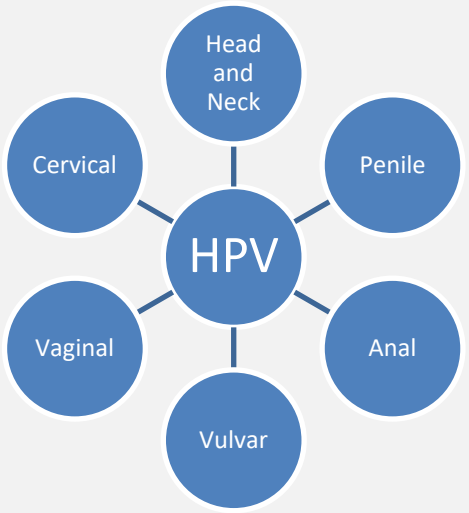
Disclosures

- I have no disclosures
- Mentors: Dr. Swiecicki and Dr. Brenner are Co-inventors of a patent pending related to HPV ctDNA assay technology

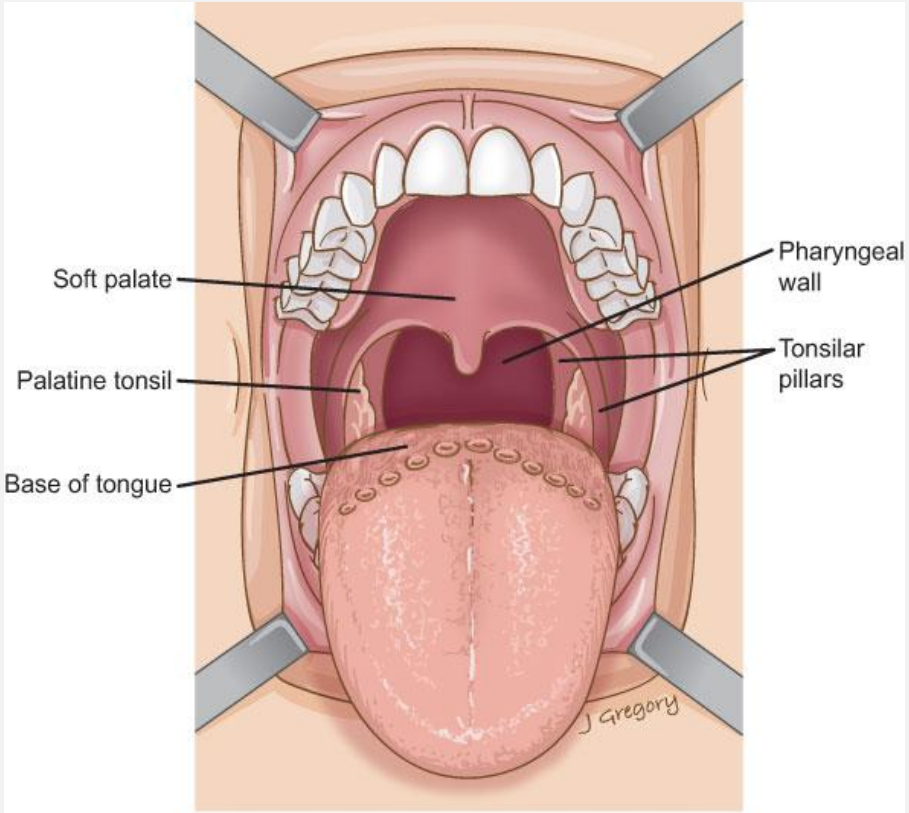
Human Papilloma Virus (HPV) + Oropharynx Squamous Cell Carcinoma

HPV infection causes changes in cell and can lead to cancer





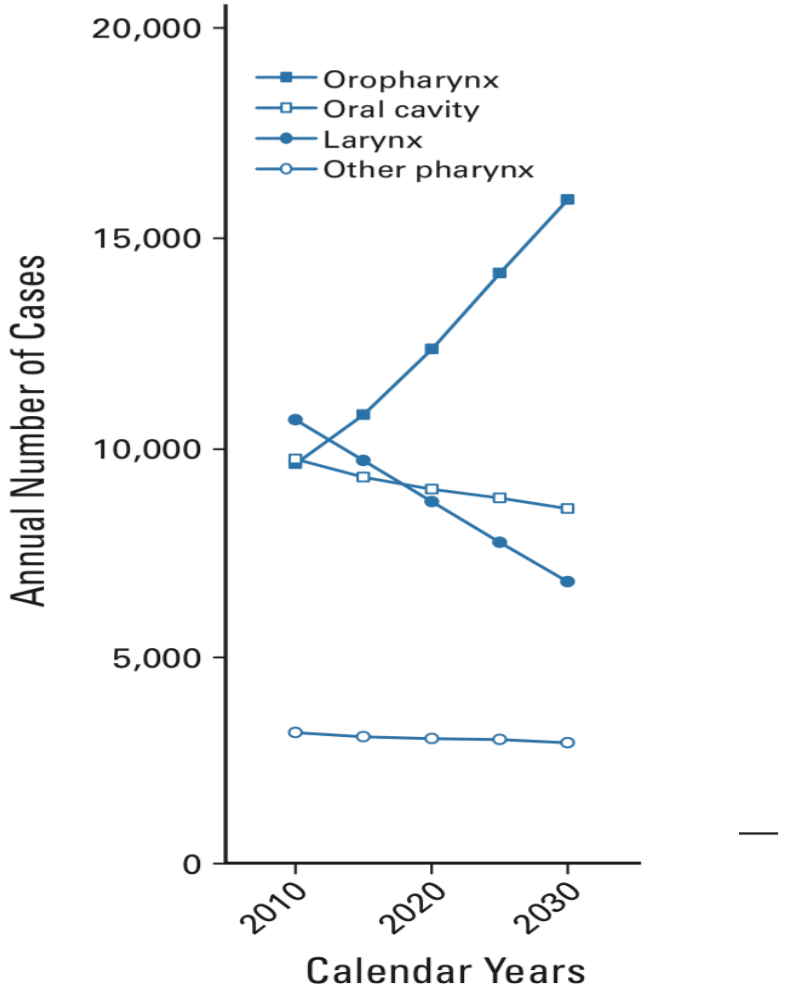
Oropharynx



Men, 50-60 yrs, non-smokers

Increasing Incidence & Stagnant Vaccine Implentation

- 4.5% of all cancers related to HPV – Oropharynx has surpassed cervical as the most common HPV related cancer
- 1998 to 2004: HPV + OPSCC increased 225%
- By 2030 half of all head and neck cancers will be related to HPV

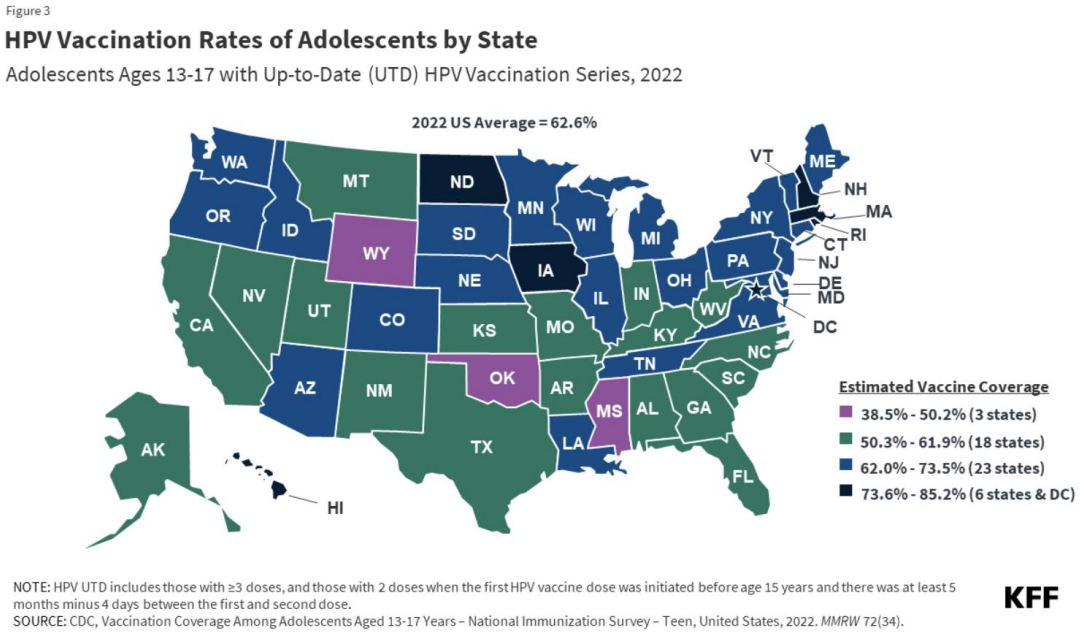


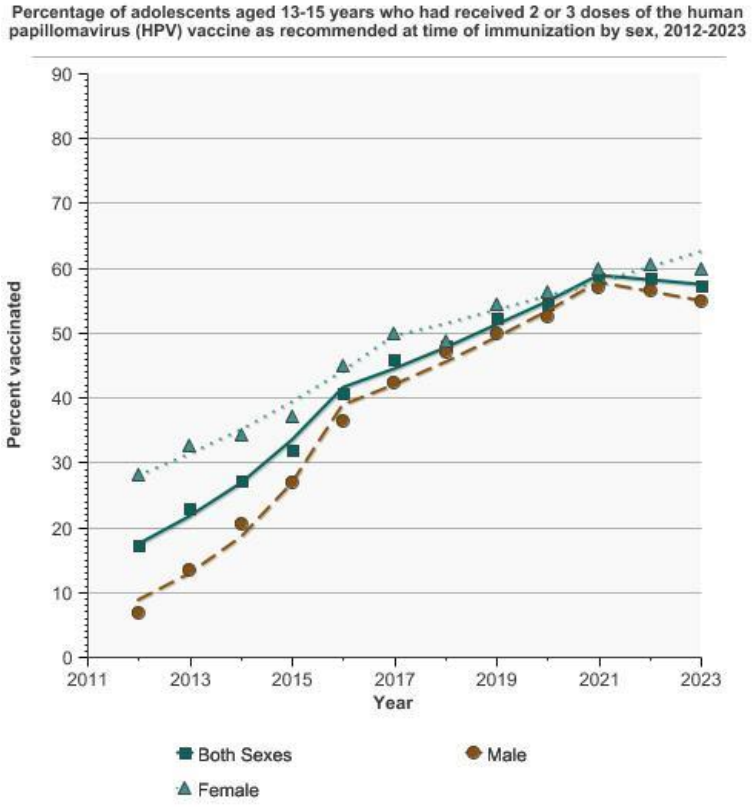
Chaturvedi et al, JCO 2011

Increasing Incidence & Stagnant Vaccination Rates

2019 Adolescents & HPV vaccine

- 54% up to date
- 71% had received more than one dose

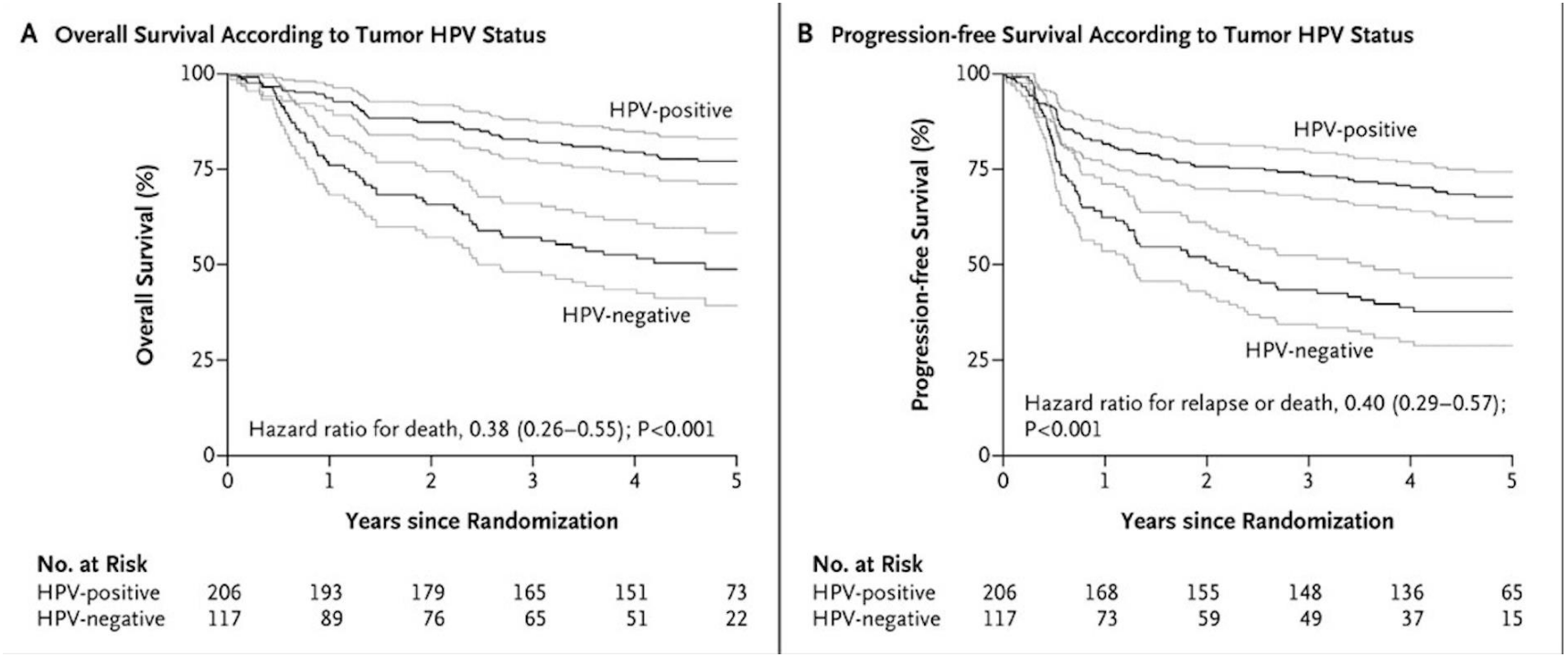




Roman BR, Aragones A, J Surg. Oncol. (2021)
Images – KFF (left), CDC (Right)

Excellent Oncologic Outcomes & Increasing Number of Survivors

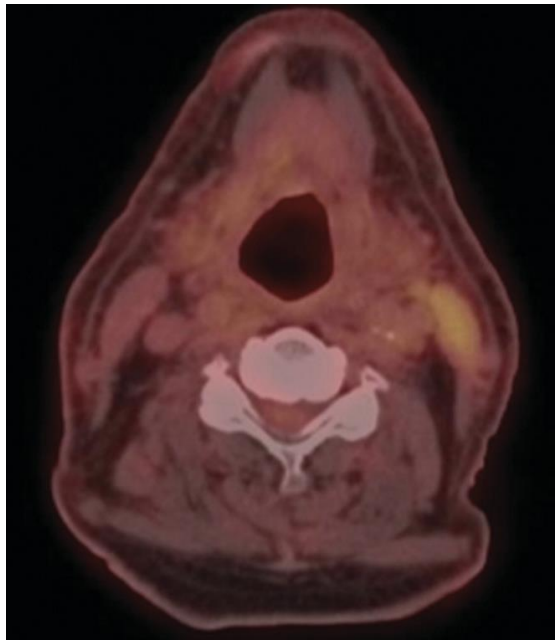
Treatment includes Surgery +/- radiation/CRT based on pathologic risk factors or radiation/CRT alone



There are an estimated 480,000 head and neck cancer survivors in the United States

Ang et al, NEJM 2010

Post-treatment Surveillance



Current NCCN Guidelines:

- 3-month post-treatment imaging: PET CT vs CT neck and chest

If Negative: H&P exam (including a complete ***head and neck exam***; and mirror and ***fiberoptic examination***)

- Year 1, every 1–3 mo
- Year 2, every 2–6 mo
- Years 3–5, every 4–8 mo
- >5 years, every 12 mo

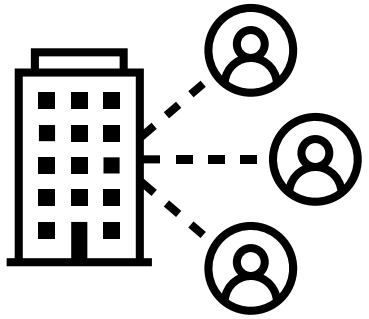
*Based on HPV negative cancer

*most recurrences identified by the patient

Goel, Moore, Sumer, Khan, Sher and Subramaniam, American Journal of Roentgenology (2017)

The Burden of Survivorship

- Discontinuation of cancer follow up in head and neck ~22%
  - Associated with increased distance traveled (>100 miles)
  - Results in missed work/lost income
- Medical Expenditure Panel Survey
  - Compared to other primary tumor sites - Head and neck cancer patients more likely to be:
    - Minority race
    - Lower socioeconomic status
    - Lower education
    - Increased comorbidities



Seaman et al, Cancer (2022)
Massa et al, JAMA Oto (2019)

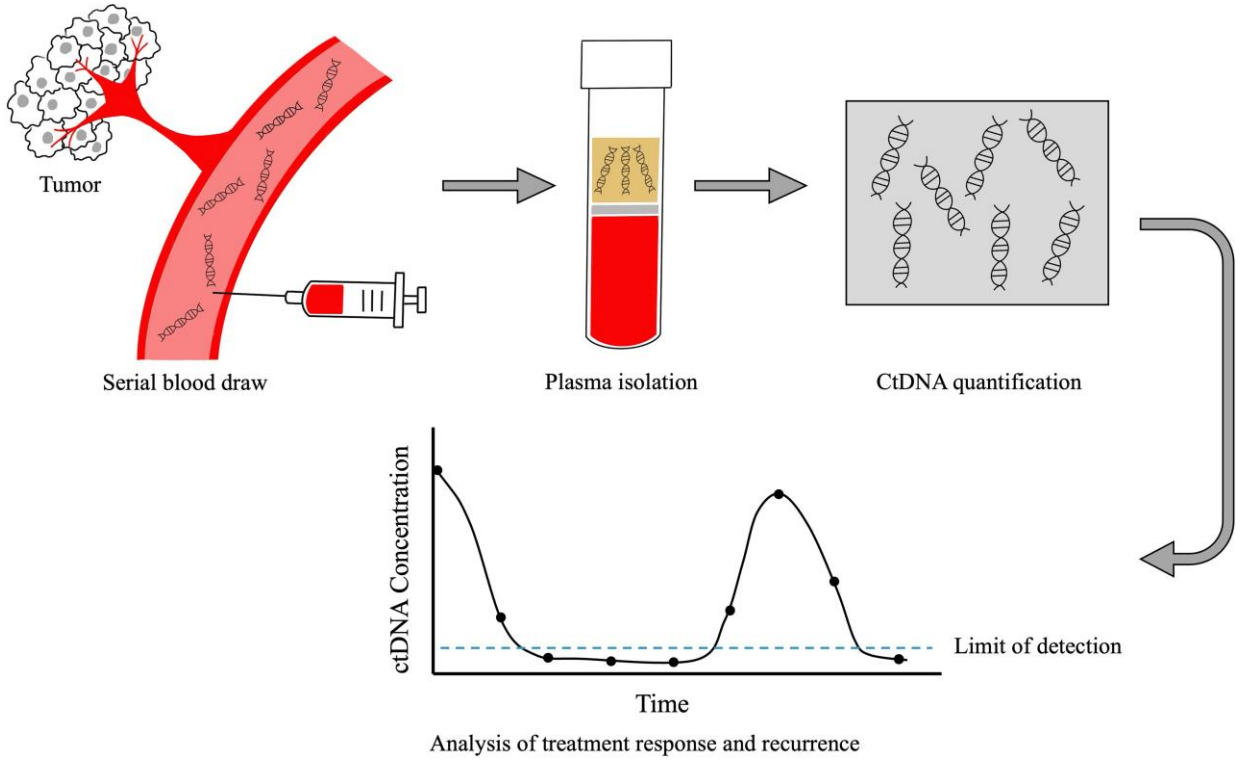
Adjusting the Guidelines for HPV+ OPSCC?

- Adherence to guideline based follow up does not improve outcomes for HPV+ disease
- HPV + OPSCC patients surveyed → 61% interested in decreased in person visits
- Electronic patient reported outcomes measures are a sensitive measure for detecting recurrence

Masroor et al, JAMA Oto (2019)
Gharzai et al, Int Journal Rad Oncol (2020)
Edwards et al, Head and Neck (2024)

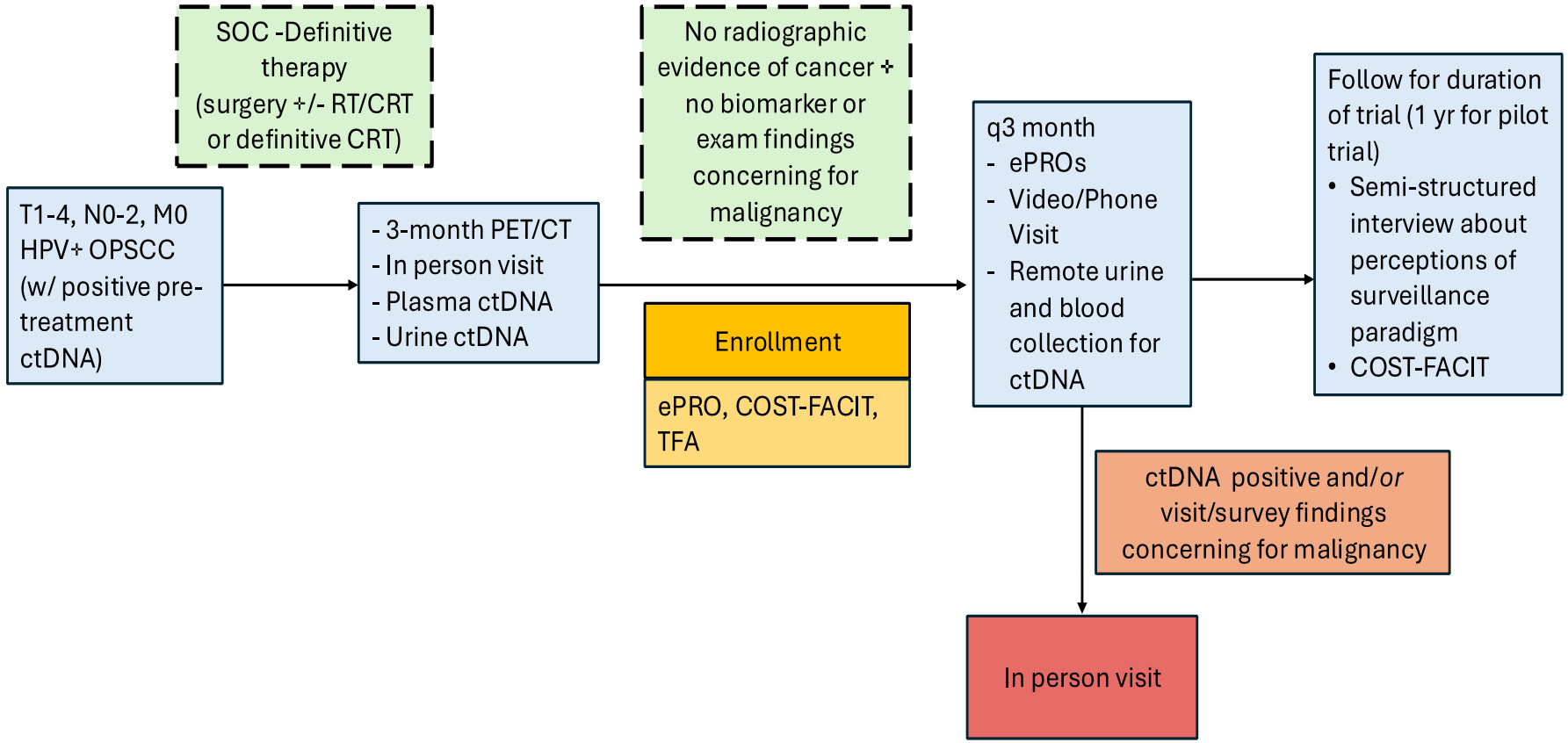
Circulating HPV Tumor DNA (HPV ctDNA)

- 82-98% of HPV+ OPSCC will have a positive blood test for HPV ctDNA
- In a recent prospective trial - 74% of recurrences had + HPV ctDNA (44% of which were asymptomatic/normal imaging), 33% confirmed suspicious findings
- 27% false negative rate, in those that had positive pre-treatment 85% sensitivity



Proposed Paradigm: Telemedicine + Liquid biomarker:

Pairing ePROS, telemedicine visits, and remote collection of blood/urine for HPV ctDNA



Study Details

Eligibility:

- T1-T4, N0-N2, M0 HPV + oropharynx squamous cell carcinoma (diagnosed via p16+ or HPV-in situ testing)
- Positive pre-treatment blood or urine HPV ctDNA
- Within 24 months from treatment completion

Study:

- Q3 month ePRO at time of telemedicine physician/APP visit
  - European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-H&N35 (EORTC C30/HN35
- Q3 month urine and blood collection
  - Blood and urine collection kits mailed to patient with pre-labeled return
  - Run at UM CLIA certified lab

Study Endpoints

Primary Endpoint:

- Feasibility of ePRO and telemedicine – compliance > 75%
- Feasibility of remote blood/urine collection – goal > 75% of specimens

Secondary Endpoints:

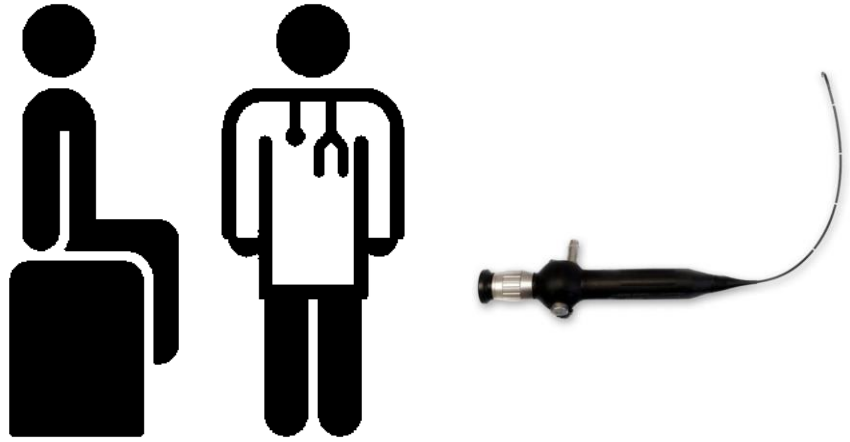
- Financial toxicity measured by COST (COmprehensive Score for financial Toxicity) Patient –Reported Outcome Measure
- Patient perception of surveillance paradigm (semi-structured interviews)

Exploratory Outcomes:

- Performance of plasma and urine ctDNA (Sensitivity, specificity, NPV, PPV)
- Overall, disease free and disease specific survival

Future Directions

- Phase II trial comparing standard of care surveillance to robust remote surveillance paradigm



Questions & Feedback

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN