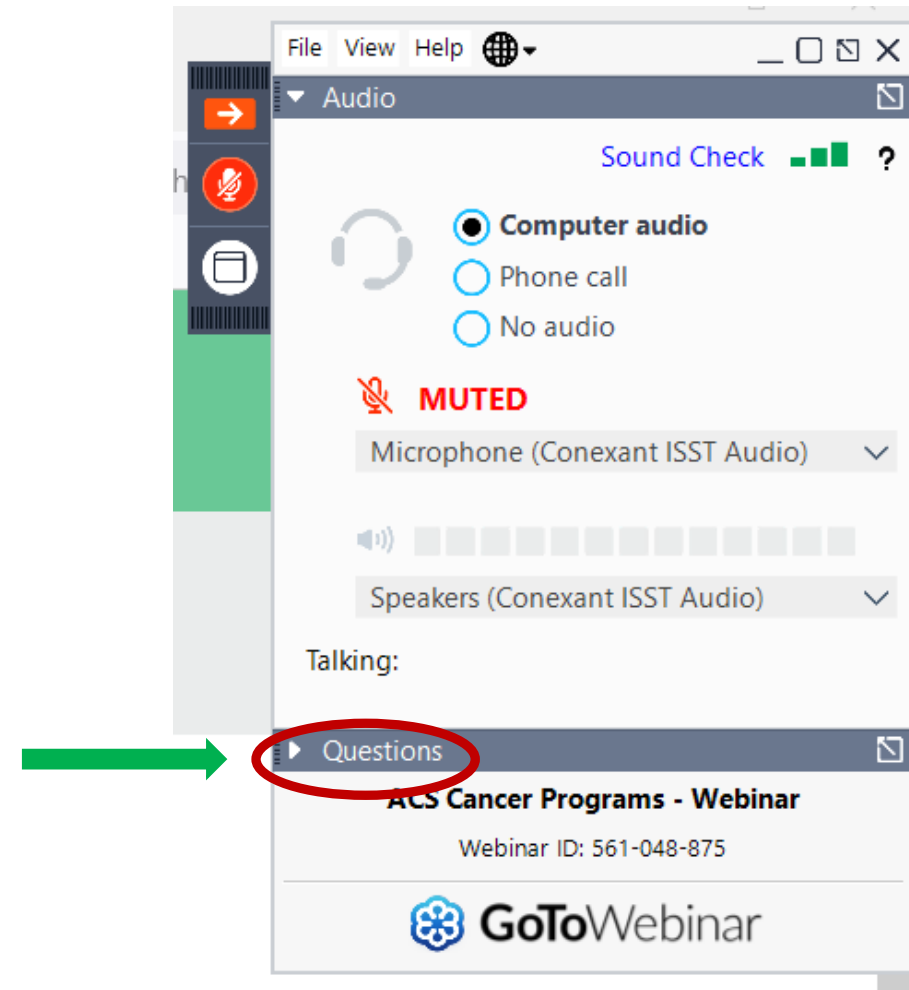


Breaking Barriers: Systemic Strategies and Solutions

November 17, 2023

Logistics

- All participants are muted during the webinar
- Questions – including technical issues you may be experiencing – should be submitted through the question pane
- Questions will be answered as time permits; additional questions and answers will be posted on the website
- Please complete the post-webinar evaluation you will receive via email



Introducing our Moderator



Dr. Laurie Kirstein, MD, FACS
Attending Breast Surgeon
Memorial Sloan Kettering Cancer Center
Associate Professor
Cornell University Medical College
New Jersey

Introducing Our Panelist



Lauren Janczewski, MD, MS
ACS Cancer Program Scholar



Bruce G. Haffty, MD
Associate Vice Chancellor Cancer Programs
Rutgers Biomedical and Health Sciences
Professor and Chair, Department of Radiation
Oncology
Rutgers Robert Wood Johnson and New Jersey
Medical Schools
Rutgers Cancer Institute of New Jersey



**Sharon Gentry, MSN, RN, HON-ONN-CG,
AOCN, CBCN**
Program Director Academy of Oncology
Nurse & Patient Navigators
Editor in Chief Journal of Oncology
Navigation & Survivorship®
Editor in Chief CONQUER: the journey
informed™



Elizabeth Wick, MD
Professor of Surgery
Division of Oncology
Vice Chair of Quality and Safety
Co-Chair, Department of Surgery
research Committee

Agenda for today

- Welcome
- Data Review
- Approaching QI, Thoughts on Problem Solving
- Breast Cancer Fractionation
- Importance of Nurse Navigation
- Q and A



Breaking Barriers

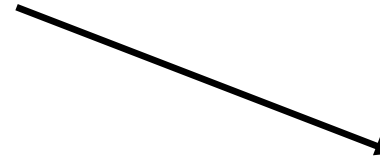
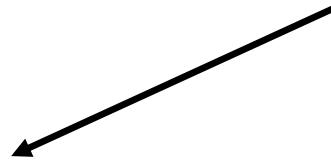
Data Collection Round 4

11/17/2023

Lauren Janczweski MD, MS

Participating Programs

329 total programs



93.2%

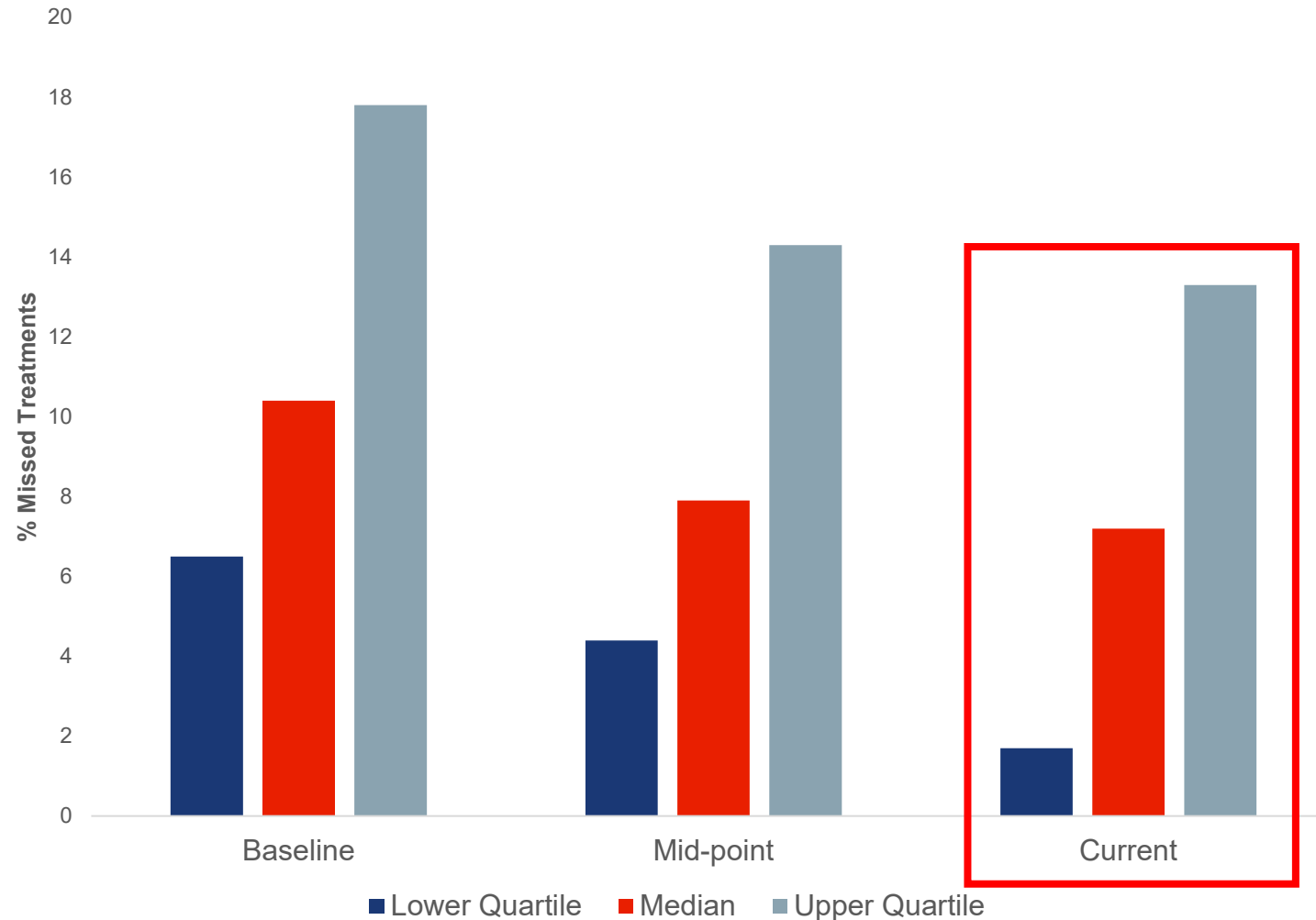
have been able to identify the most common barriers for why patients miss scheduled radiation treatments

93.2%

have been able to prioritize which barriers will have the most impact on reducing missed appointments at your organization/program

Participating Programs

- **77.2% of programs** reported patients with 3 or more missed treatments
- Median percent of patients who missed 3 or more radiotherapy treatments = **7.2% [IQR 1.7%-13.3%]**

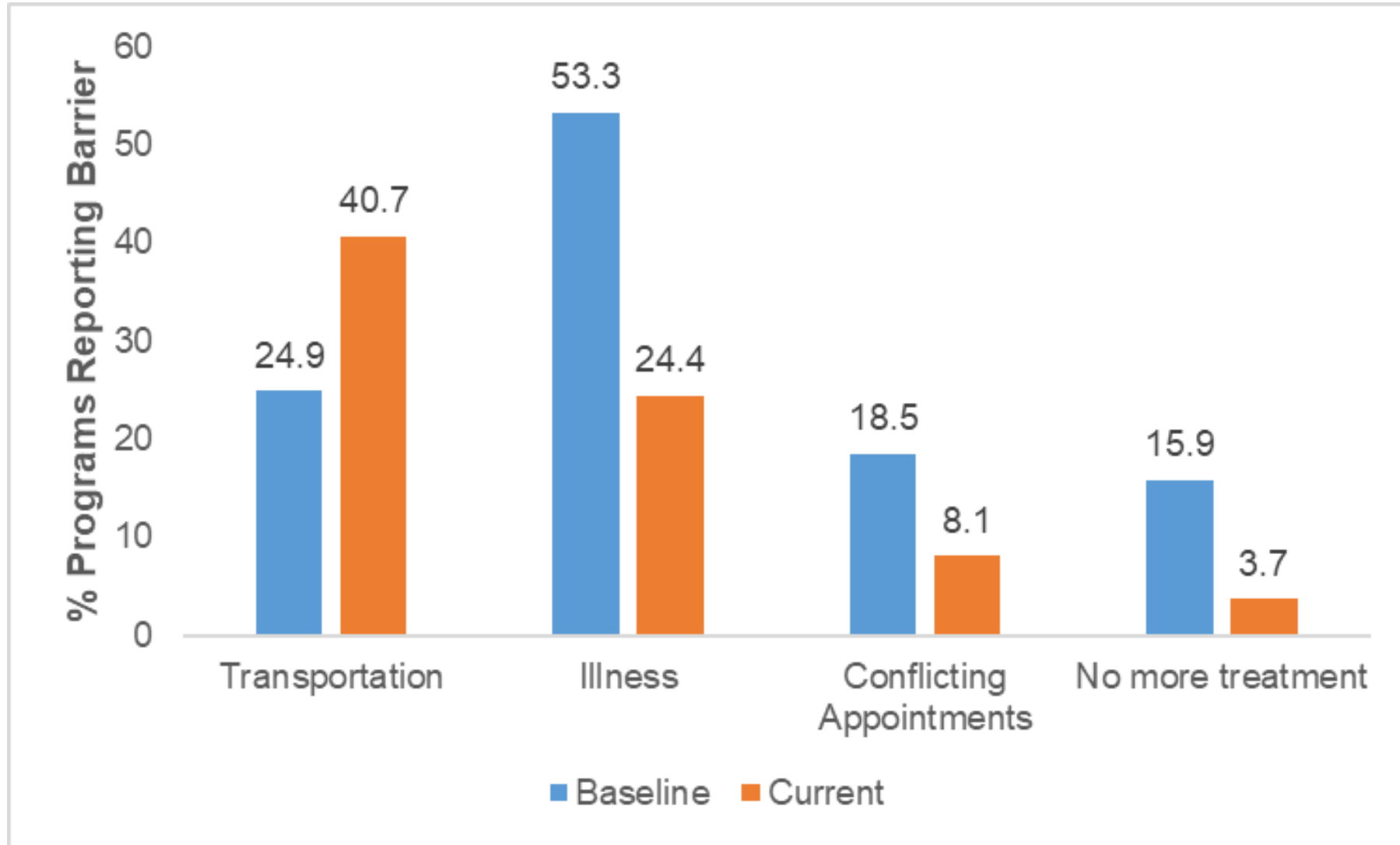


Missed Radiotherapy Treatments by Disease Site

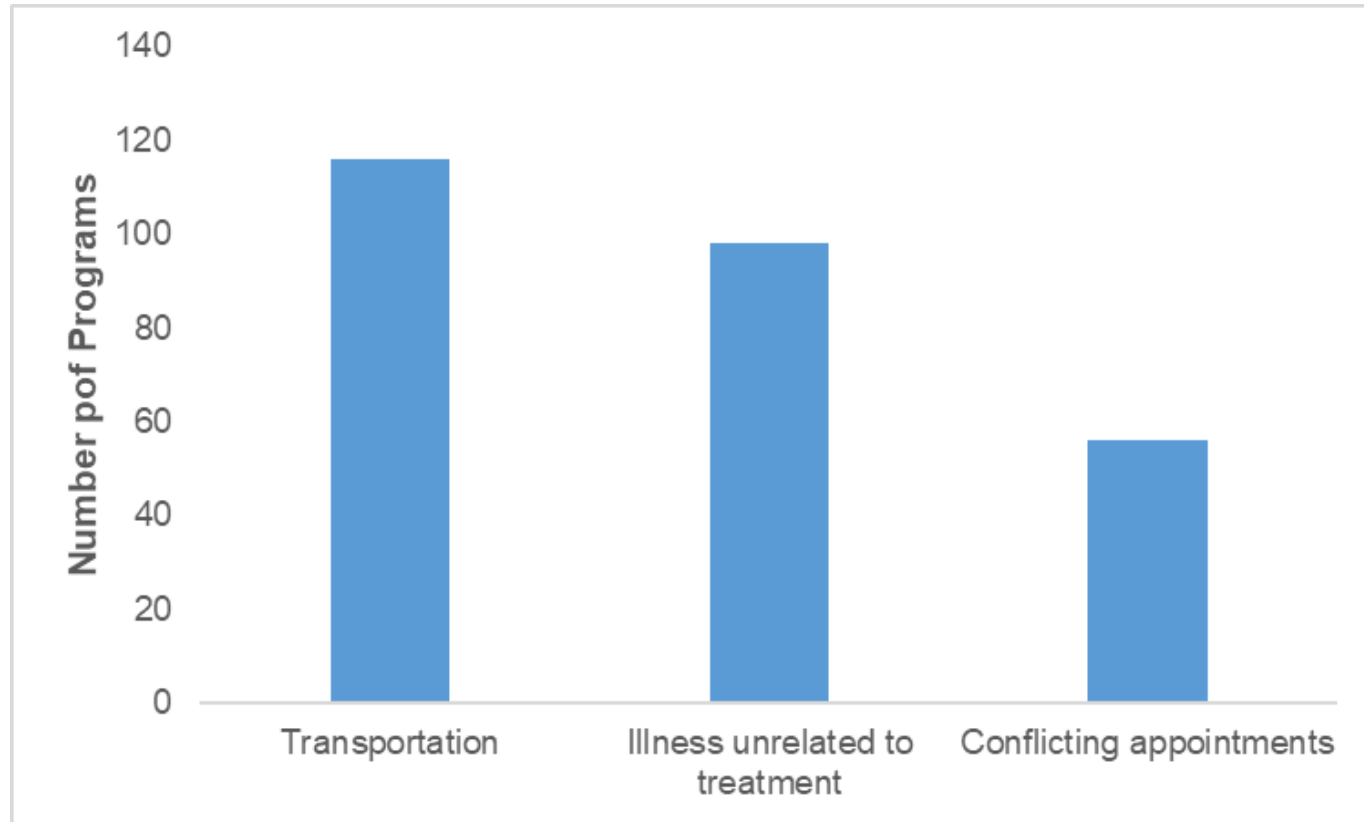
Total number of patients who missed 3 or more treatments = 689 (7.7%)

Disease Site	Programs (N, %)	Patients (N, %)
Breast	48 (14.6%)	75 (4.7%)
Upper GI	73 (22.2%)	32 (11.1%)
GYN	82 (24.9%)	51 (12.7%)
H&N	145 (44.1%)	158 (10.7%)
Prostate	147 (44.7%)	114 (4.5%)
Lung	142 (43.2%)	150 (12.1%)
Rectum	78 (23.7%)	31 (9.6%)
Other	104 (31.6%)	78 (7.1%)

Reasons for Missed Radiotherapy



Barriers Chosen to be Addressed



70.6% of programs already have a plan to address these barriers!

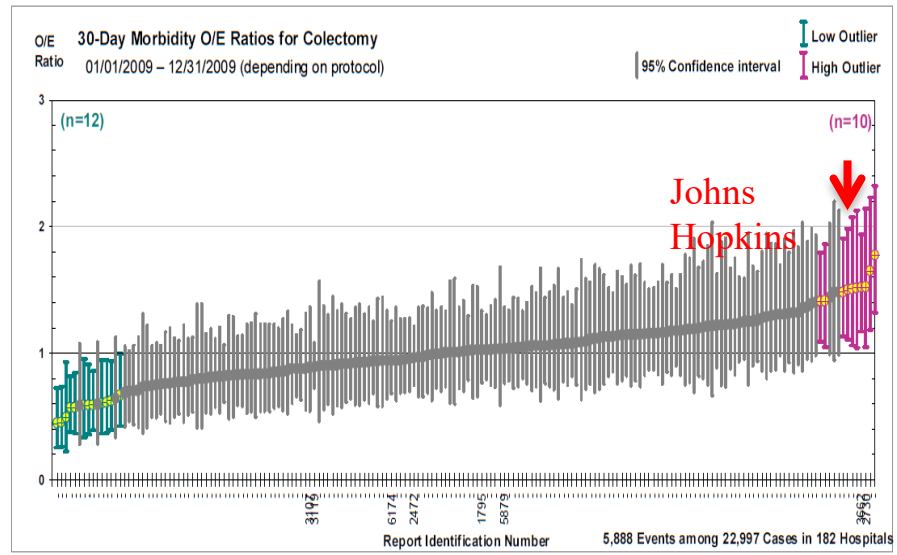
61.1% of programs have already identified programmatic and/or community referrals

Approaching QI, Thoughts on Problem Solving

Elizabeth Wick, MD, FACS UCSF

Surgical Site Infection Prevention

OUTCOMES



JHU Colorectal SSI Rate 2009, 30%

Comprehensive Unit Based Safety Program

1. Improve **patient safety awareness** and **systems thinking at the unit level**
2. **Empower staff** to identify and resolve patient safety issues
3. **Integrate safety practices into daily work** of all staff members
4. Create a patient safety **partnership between executives and frontline** caregivers
5. Provide tools to help CUSP teams **investigate and learn from defects** and improve teamwork and safety culture



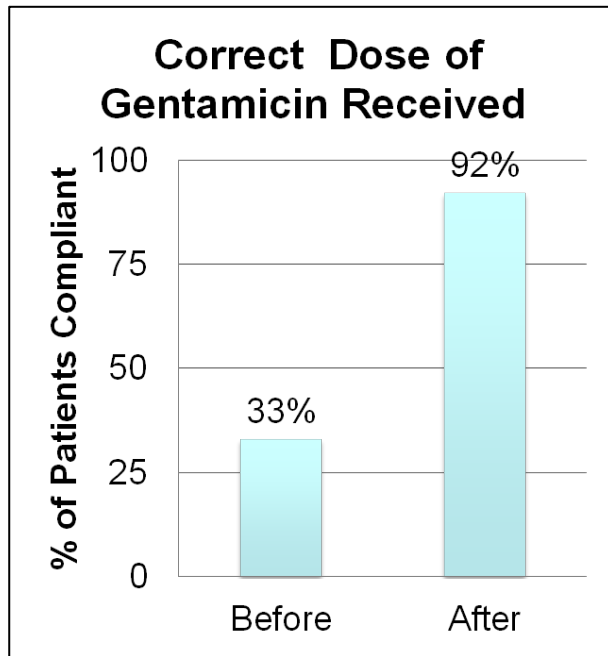
Identifying defects

How will the next patient be harmed or have an SSI?

What can we do to prevent the next patient from harm or SSI?

2011

Gentamicin



Despite >95% compliance on SCIP

- Increased amount of gentamicin available in the room
- Added dose calculator in anesthesia record
- Educated surgery, anesthesia and nursing in grand rounds

Wick et al. JACS 2011

TEAM for Problem Solving

- Who touches every patient?
- What resources are there adhoc?
 - Social workers, case management, community health workers, PMD, oncologists
 - Techs, registration, navigators
- Don't forget patients and families!

Learning from Defects

Contributing Factors	Importance to Current Event, 1 (Low) to 5 (High)	Importance to Future Events, 1 (Low) to 5 (High)



Do we send reminders? Did we reach the patient with the reminder? Is the reminder a text or call? Do we talk about next appointment at prior appointment? Is there a TEAM behind supporting the patient? Once it happens once, do we change how we approach the patient?

1. Patients are missing radiation because of lack of ride?
Brainstorm!!!

Why are patients not getting what they need?

- Staff Safety Assessment: AHRQ
 - <https://www.ahrq.gov/hai/cusp/toolkit/staff-safety-assessment.html>
- Learning from Defects: AHRQ

Conclusions

- QI is hard
- Listen to the frontline
- Simple solutions are sometimes the best
- MEASURE – what you think is happening probably isn't
 - Even the smallest things!
 - Can measure with small audit tools, don't have to the EHR reports
- Lean on the community of others trying to do similar things
- We re-invent the wheel too often!

RUTGERS

Cancer Institute
of New Jersey

Barriers to Radiation Treatment
Potential Solutions in Breast Cancer Fractionation

Bruce G. Haffty, MD

Professor and Chair

Department of Radiation Oncology

Rutgers, The State University of New Jersey

Cancer Institute of New Jersey, Robert Wood Johnson

Medical School and New Jersey Medical School

Barriers to Radiation

- Multiple Studies in Numerous Disease Sites Demonstrate that Interruptions/compliance with the course of Radiation Can Impact outcomes
- Preliminary Studies From this ongoing Barriers Project Confirms that missing 3 or more radiation treatments remains a significant issue in patients undergoing radiation therapy
- Recognizing the possibility of compliance issues with radiation and intervening with appropriate solutions is an important goal

Potential Barriers

- Economic Issues
 - Work Schedule conflicting with RT Schedule
 - Cost of transportation
- Social Issues
 - Child-Care
 - Family Care-Patient is primary caretaker for family member
 - Dependence of family/friends for transportation
 - History of compliance with health care-prior compliance with chemotherapy or surgical schedule
- Travel Distance Issues
 - Daily trips to radiation are inconvenient and costly due to distance
- General Issues
 - Any hesitation or subtle messages from patient that they are not pleased with the idea of coming to radiation daily can signal a barrier to compliance with radiation

Potential Solutions to Barriers

- Socio-Economic Issues
 - Engage Social Workers Immediately for potential solutions
- Travel Distance Issues
 - Consider Solutions including referral to facilities that are closer or providing travel solutions
 - Consider alternate radiation schedules
- General Issues
 - Whatever the reason for hesitation on the part of the patient for potentially not being compliant with daily radiation, consider either social worker intervention, more in-depth discussions regarding the importance of compliance with the radiation schedule, or if appropriate consider alternative radiation schedules
- While this presentation will focus on alternate schedules in breast cancer, shorter course of radiation in multiple disease sites have been or are in the process of being studied

Potential Solutions in Breast Cancer-Alternate Fractionation/Radiation Schedules

- While 5-6 weeks of daily radiation has been the standard for years, this course of treatment has been a significant issue for many patients.
- In fact, many patients in the past have elected mastectomy over breast conservation, simply to avoid the issue of coming for daily radiation treatments over 5-6 weeks
- However, currently there are alternative options for appropriately selected patients that can help to avoid interruptions in the radiation schedule
- For any patient, particularly those where one anticipates potential interruptions in treatment, alternate radiation schedules should be considered

Example of how alternative schedules can impact outcomes in breast cancer

- The following slide is courtesy of Charles Shelton, MD a radiation oncologist in rural NC
- They performed a retrospective review of breast cancer patients treated in a previous era where 5-6 weeks was the predominant schedule, to more recently when 3-4 week courses of radiation were employed

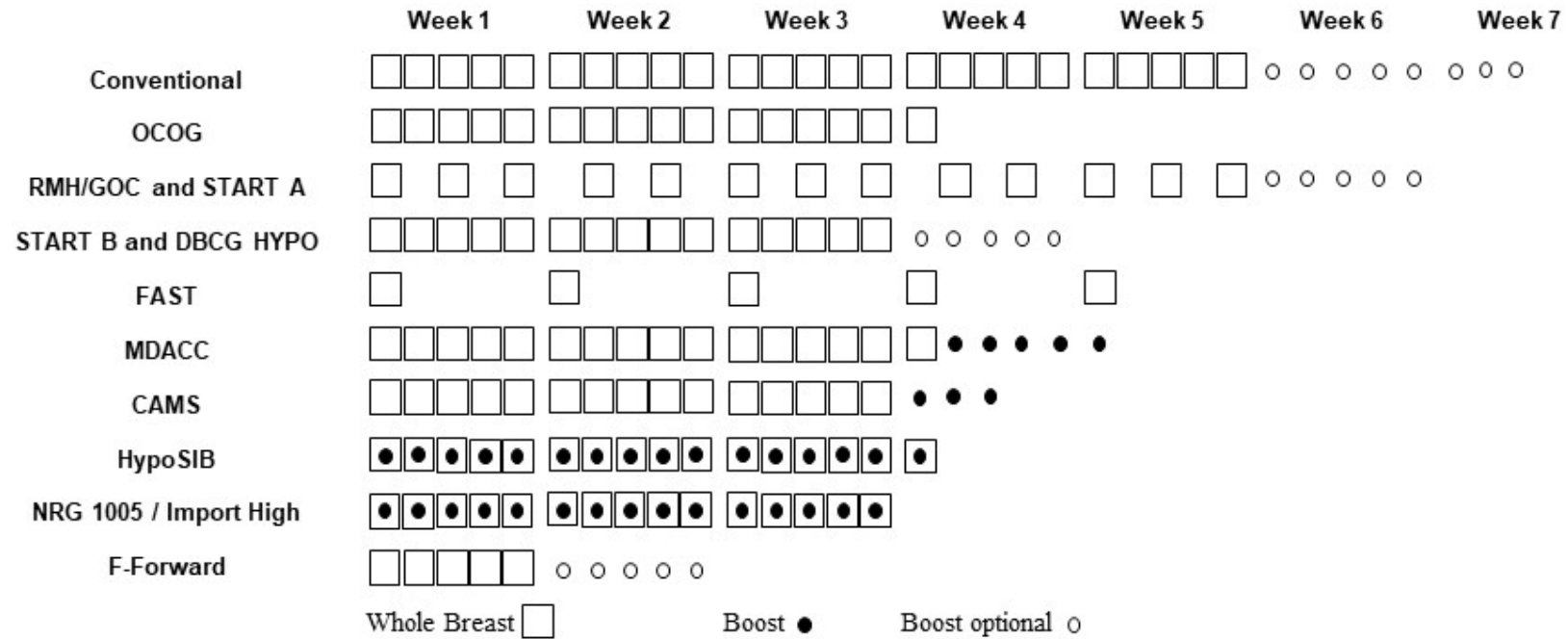
Highlights

- Use of accelerated RT was adopted quickly in rural areas with ~80% of eligible patients being treated with this regimen following lumpectomy (~15 tx) compared to historic 30 tx
- Overall BCT rates also increased as a result of increased access to less treatments (baseline 48% BCT rates, 79% post implementation) and are now in line with national rates
- Missed appointments due to patient barriers (defined as a single missed tx) were half as many using accelerated regimens (16% vs 33%) improving timeliness and compliance.

Whole Breast Fractionation Approaches

Trial	Years Conducted	Patients (Number)	Whole Breast Fractionation (Gy/Fractions)	Boost Timing	Boost used	Boost Fractionation (Gy/Fractions)	RNI used	10-Year IBTR* (%)	Reference
Moderate hypofractionated WBRT									
RMH/GOC	1986-1998	1,410	50/25 42.9/13 39/13	Sequential only	74%	14/7	21%	12% 10% 15%	(36)
OCOG	1993-1996	1,234	50/25 42.5/16	N/A	N/A	N/A	None	7% 6%	(37)
START A	1998-2002	2,236	50/25 41.6/13 39/13	Sequential only	61%	10/5	14%	7% 6% 8%	(9)
START B	1999-2001	2,215	50/25 40/15	Sequential only	43%	10/5	7%	5% 4%	(9)
DBCg HYPO	2009-2014	1,854	50/25 40/15	Sequential only	23%	10/5	None	3% 3% (9 year)	(19)
IMPORT HIGH	2009-2015	2617	40/15 36-40/15 36-40/15	Sequential	100%	16/8 8/15 13/15	Allowed	1.9% 2.0% 3.2% (5-year)	(24)
CAMS	2010-2015	734	50/25 43.5/15	Sequential only	100%	10/5 vs. 8.7/3	4% 3%	2% 1% (5-year)	(38)
MDACC	2011-2014	287	50/25 42.56/16	Sequential only	99%	10/5 or 14/7 vs. 10/4 or 12.5/5	None	1% 1% (3-year)	(18)
NRG RTOG 1005	2011-2014	2,354	50/25 or 42.7/16 40/15	Sequential vs. Concurrent	100%	12/6 or 14/7 vs. 8/15 concurrent	None	2% 3% (7-year)	(23)
Ultra-hypofractionated WBRT									
UK FAST	2004-2007	915	50/25 30/5 28.5/5	N/A	N/A	N/A	None	1% 1% 1%	(30)
UK FAST-Forward	2011-2014	4,096	40/15 27/5 26/5	Sequential only	25%	10/5 or 16/8	None	2% 2% 1% (5 year)	(31)

Selected Fractionation Schedules



Whole Breast Fractionation Options (Without RNI)

- Given the acceptable local control rates and acceptable toxicity profile, any of these fractionation schemes appear to be reasonable options
- Most common in the US currently are the Canadian Fractionation Scheme, the START B Scheme or the Simultaneous Integrated Boost of NRG 1005
- Fast Forward has gained traction in the UK and in the US mainly in older women. Conservative folks caution regarding the relatively short-term follow-up
 - Follow-up from FAST Forward is only 5 years
 - Across all clinical assessments for normal tissue compared to standard fractionation (40 Gy/15 Fx) the odds ratio was 1.55 ($p < .001$) for 27 Gy in 5 fractions and 1.12 ($p = .12$) for 26 Gy in 5 fractions.

Hypofractionation in RNI

- Although conventional fractionation remains the acceptable standard for treating the regional lymphatics hypofractionation of the regional lymphatics has been successfully done throughout the years.
- British Columbia Pre-menopausal PMRT Randomized Trial
 - 37.5 Gy in 16 Fractions of 2.34 Gy
- START A and START B-RNI Administered to 14% of Patients
 - 42.9 Gy in 3.3 Gy Fractions x13 over 5 weeks START A
 - 41.6 Gy in 3.2 Gy Fractions x 13 over 5 weeks START A
 - 40 Gy in 2.6 Gy Fractions x 15 over 3 weeks START B

Rutgers Hypo-fractionation Trial

- Prospective Phase II Trial (NCT01417286)
- 69 Patients enrolled between December 2011 and December 2014 at Rutgers CINJ and Huntsman University of Utah
- Stage II A to IIc disease post-mastectomy with or without reconstruction (41 or 69% of patients had reconstruction)
- Treated PMRT 4995 Gy/3 Weeks (3.33 Gy/11 Fx/ to chest wall and nodes + 3.33Gy/4 Fx Boost)
- Primary Endpoint-total greater than Grade 2 Toxicity Rate below 9%
- Secondary Endpoint-Recurrence Rate between 3.7 and 14.5%
- Reconstruction Complications Attributed to Radiation -24%

Alliance Phase II Randomized Trial (A221505)

Matt Poppe PI Atif Khan Bruce Haffty Co PI

RT-CHARM

P
R
E
R
E
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T
E
R*

→ Mastectomy with
nodal
evaluation/dissection
n
→ +/- adjuvant
chemotherapy with
planned breast
reconstruction

R
A
N
D
O
M
I
Z
E*

→ **Conventional PMRT:**
50Gy/2Gy Chest wall and/or
Reconstructed Breast with
50Gy/2Gy to regional nodes**
over 5-6 weeks.

→ **Hypofractionated PMRT:**
42.56Gy/2.66Gy to Chest wall
and/or Reconstructed Breast
with 42.56Gy/2.66Gy to
regional
nodes** over 3-4 weeks.

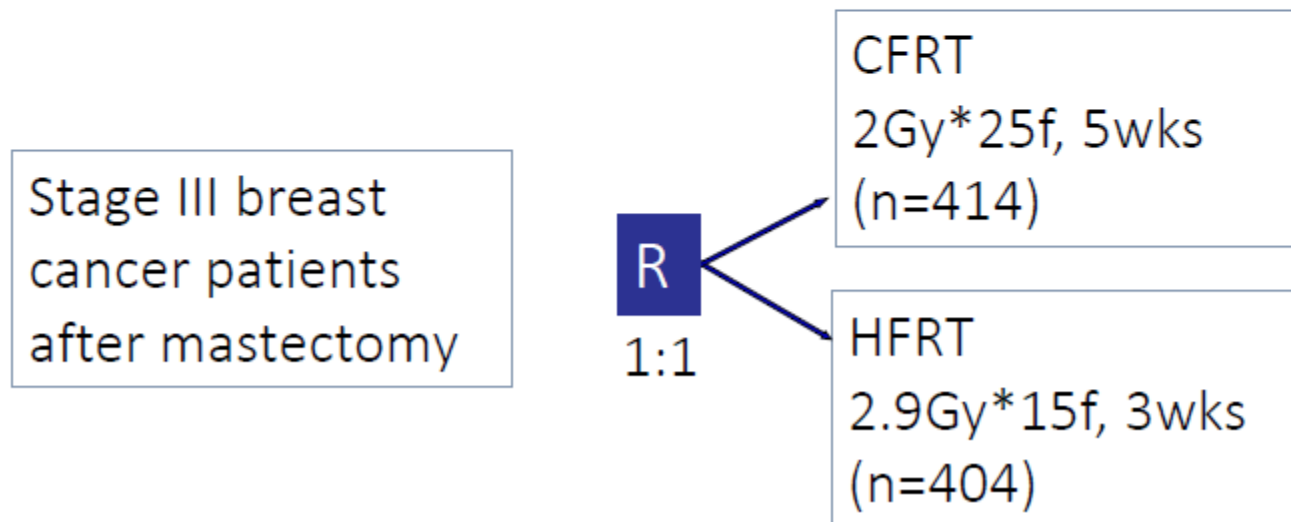
Reached Accrual Goal-Now Closed

Randomized Trial-Hypofractionation (43.5 gy/15Fx/3wks) vs. Standard Fractionation (50 Gy/25Fx/5Wks) Post-Mastectomy: Wang, et al. Lancet Oncology 2019.

Method

A randomized phase III non-inferior trial comparing HFRT and CFRT
(Noninferiority margin: 5% difference in 5-yr LRR rate)

Target sample = 820 (June 2008 - June 2016)



Randomized Trial-Hypofractionation vs. Standard Fractionation Post-Mastectomy: Wang et al. Lancet Oncology 2019

- LRR Primary Endpoint Median FU 52 Months
- No Difference in LRR (8.4% vs. 6.0%) , DM (21.3% vs. 24.3%), DFS (75.1% vs. 74.6%) or OS (84.9% vs. 87.1%) at 5 Years
- No Difference in lymphedema, shoulder disorder, pneumonitis between arms
- Fewer G3 skin reactions in hypofractionation
- No Brachial Plexopathy
- **Notably patients did not have reconstruction**

FABREC Trial Comparing Hypofractionation (16 treatments) to Standard Fractionation (25 Treatments) Post Mastectomy with Reconstruction: Preliminary results reported at ASTRO 2023

- Primary outcome and toxicity profile of Hypofractionation comparable to Standard Fractionation
- Improvement in specific QOL domains with HF, especially among younger patients
- Fewer treatment breaks with HF
- Less financial toxicity with HF
- Results support the use of HF PMRT for patients with implant-based reconstruction

European Society for Radiotherapy and Oncology Advisory Committee in Radiation Oncology Practice consensus recommendations on patient selection and dose and fractionation for external beam radiotherapy in early breast cancer LANCET 2022

- The results from this European Society for Radiotherapy and Oncology Advisory Committee in Radiation Oncology Practice consensus state that moderately hypofractionated radiotherapy can be offered to any patient for whole breast, chest wall (with or without reconstruction), and nodal volumes.
- Results of RT-CHARM from Alliance and FABREC (Similar randomized comparison as RT-CHARM) will hopefully also demonstrate the safety and efficacy of moderate hypofractionation to the reconstructed chest wall and regional lymphatics
- Notably FAST FORWARD (26 Gy in Five Daily Fractions) did include a subset of patients with regional nodal radiation who were randomized-Results Not Yet Reported

PARTIAL BREAST RADIATION

- Partial Breast Radiation has emerged as an acceptable option for selected patients with early-stage node negative breast cancer and DCIS
- Multiple fractionation schemes have emerged, based on randomized trials that demonstrate acceptable local control rates and acceptable toxicity compared to whole breast radiation
- The use of partial breast radiation has significantly increased over the past few years as patients have embraced the convenience and radiation oncologists have become more comfortable with this approach based on the outcomes reported in randomized trials.

Key External Beam APBI Trials

Trial	Patient #	Dose Fractionation	FU	Findings
NSABP-39	4216	50 Gy in 25 vs 38.5 Gy 10 Fractions BID	10 Yrs	1% difference in IBTR/No difference in adverse events
RAPID-OCO	2135	50 Gy/25 or 42.5 Gy 16 vs. 38.5 Gy 10 Fractions BID	8.6 Yrs	PBI non-inferior local control Toxicity/cosmesis poorer with PBI
IMPORT-LO	2018	40 Gy/15 vs. 40 Gy in 15 PBI	6 yrs	PBI non-inferior with improved toxicity/cosmesis
Florence	520	50 Gy in 25 vs. 30 Gy (IMRT) in 5 Fractions QOD	10 Years	PBI non-inferior with improved toxicity/cosmesis
IRMA	3309	50/25 or 42.5/16 or 40/15 vs. 38.5 Gy in 10 fractions BID	5.6 yrs	Increased toxicity and inferior cosmesis with PBI

External Beam APBI

- Based on the inferior cosmesis/toxicity associated with the 38.5 Gy in 10 Fractions BID I and many others are not routinely employing this fractionation scheme any longer
- There are a number of acceptable schemes from the randomized trials as well as Phase II studies
- Given the convenience, and favorable long-term outcomes from the FLORENCE trial, I favor this approach for patients considering partial breast radiation
 - Patients are treated with 30 Gy in 5 Fractions with IMRT Every Other Day
 - Recent Data from the Florence Group Suggests that 30 Gy in 5 Fractions can be done daily with acceptable outcomes

Radiation vs. Hormonal Therapy: EUROPA Trial

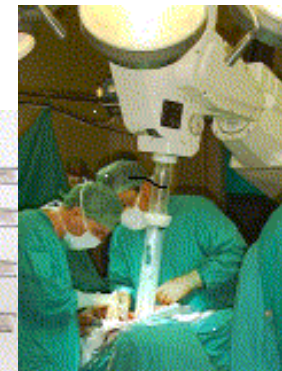
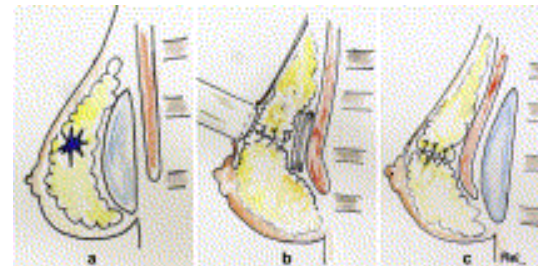
- **Exclusive endocrine therapy or partial breast irradiation for women aged ≥ 70 years with luminal A-like early stage breast cancer (NCT04134598 - EUROPA): Randomized controlled trial comparing health related quality of life by patient reported outcome measures**
- **Plan for > 900 patients in this randomized study**
 - Patients will receive either Exclusive Endocrine Therapy
 - Or exclusive Partial Breast Rt over 1-3 weeks
 - **MY PREDICTION: Radiation Arm will Win!**

Partial Breast Radiation-Brachytherapy

- Partial breast radiation can also be accomplished through interstitial implants or balloon based catheter techniques over 2-5 days
 - Interstitial brachytherapy has been compared to whole breast in a randomized trial with favorable outcomes (Strnad et al. Lancet, 2016)
 - Mammosite Registry trial included 1449 patients treated with single catheter balloon based brachytherapy delivered over 5 days demonstrating favorable outcomes and good cosmesis (Shah, Vicini et al. 2013)
 - Triumph single arm study included 200 patients treated with single catheter balloon based brachytherapy delivered over 2 days with favorable outcomes and good cosmesis. (Yashar, Khan, Haffty, Kuske, 2023).

Data from Intraoperative Randomized Trials

- Europeans accumulating large body of maturing data from randomized trials with **intraoperative single fraction treatment**.
 - TARGIT –Intraoperative using single orthovoltage source in the operating room at lumpectomy
 - ELIOT-Intraoperative electrons delivered in the operating room at lumpectomy



Intraoperative Radiation

- Both the Targit Trial and the Eliot Trial are randomized trials comparing whole breast radiation over 4-6 weeks following lumpectomy to intra-operative treatment with a single fraction of radiation delivered in the OR at the time of lumpectomy
- Both trials have mature data with long term followup and demonstrate acceptable outcomes in selected patients
- Local recurrence rates are slightly higher in the intraoperative arm than whole breast RT but are acceptable

Conclusions

- Multiple factors should be considered in evaluation of patients undergoing radiation that may signal potential lack of compliance with the radiation treatment schedule
 - Work Schedule Conflicts
 - Childcare or Family Care Issues
 - Distance
 - Socio-economic Issues
 - History of non-compliance with medical care
- For patients with breast cancer where compliance with the schedule may be an issue alternate fractionation schedules, if appropriate may be considered:
 - For patients requiring post-mastectomy or regional nodal radiation consider 3–4-week schedules as opposed to 5–6-week schedules
 - For selected patients who meet criteria consider 1–2-week courses of partial breast radiation external beam or brachytherapy or 1-week whole breast RT

The background of the slide features a large, semi-transparent watermark of the Rutgers University seal. The seal is circular and contains a sunburst design in the center, with the words "RUTGERS UNIVERSITY" and "THE STATE UNIVERSITY OF NEW JERSEY" around the perimeter.

RUTGERS

Cancer Institute
of New Jersey

Thank You!

Bruce G. Haffty, MD

Involving navigators throughout the care continuum as patients move through treatment

Sharon Gentry, MSN, RN, HON-ONN-CG, AOCN, CBCN

Academy of Oncology Nurse & Patient Navigators Program Director

Editor-In-Chief for Journal of Oncology Navigation & Survivorship® (JONS) and CONQUER: the patient voice™ publications

sharon.gentry@amplity.com

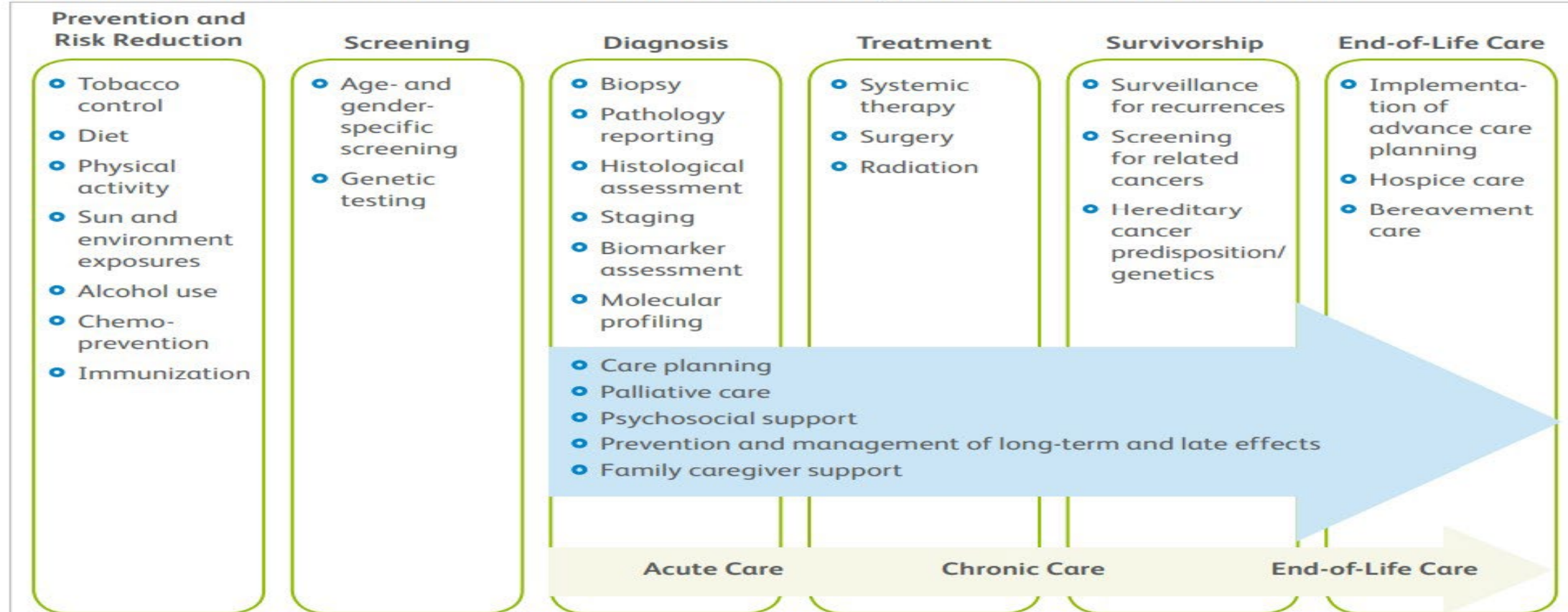
Navigation metrics show value



- ✓ Clinical Outcomes
- ✓ Patient Experience
- ✓ Return on Investment (ROI)

Navigation is a Solution for Health Equity

FIGURE 2. Domains of the Cancer Care Continuum with Examples of Activities in Each Domain



The blue arrow identifies components of high-quality cancer care that should span the cancer care continuum from diagnosis through end-of-life care. The green arrow identifies 3 overlapping phases of cancer care, which are a way of conceptualizing the period of the cancer care continuum that is the focus of this report.

Source: Johnston D, Strusowski T, Bellomo C, Burhansstipanov L. Navigation across the continuum of care. In: Shockney LD (ed). *Team-Based Oncology Care: The Pivotal Role of Oncology Navigation*. Chapter 5. Cham, Switzerland: Springer International; 2018:85-110. Adapted from material originally developed by the National Cancer Institute. Reprinted with permission.

Return on investment (ROI)- Business performance metrics

Making the case for nurse navigators

Method – Gap analysis on why patients were leaving the healthcare system

The retention of 212 patients resulted in an increased diagnostic imaging procedures alone and \$125,000 in total net revenues. Incorporating all the services the 212 patients would generate in non-cancer services, as well as the breast cancer services, the potential total net revenues would be \$350,000.

Esther Muscari Desimini, Janine A. Kennedy, Meg F. Helsley, Karen Shiner, Chris Denton, Toni T. Rice, Barbara Stannard, Patrick W. Farrell, Peter A. Marmorstein & Margaret G. Lewis (2011) Making the Case for Nurse Navigators, *Oncology Issues*, 26:5, 26-33, DOI: 10.1080/10463356.2011.11883604

Using a nurse navigation pathway in the timely care of oncology patients

A medical oncologist could see an additional patient each day due to the time reduction associated with the navigation visit. \$485,312 total cost savings and revenue (4 med oncs; new patient consult was reduced by 24 minutes = medical oncologist could see an additional patient each day due) And time between oncology referral to the start of treatment was reduced by 7 days; 75% patients have advance directives completed

Journal of Oncology Navigation & Survivorship June 2014 Vol 5, No 3

Navigators reduce no-shows

Method - Each patient is contacted at least once a month, with the most at-risk patients being contacted as often as three times a week.

In 3 months, the reduction in no-shows in those receiving radiation therapy equaled a navigator's annual salary. The overall return on investment was \$5 for every \$1 spent

Also, readmissions were cut by one-third, with a similar reduction in emergency visits

Managed Healthcare Executive March 1, 2013

Navigator's Unique View & Perspective



Looking Ahead: What to Expect



Upcoming Data Collection



Data was Released Oct 15- Due Oct 30

Patients seen August 15- Oct 15

More in depth questions about barriers

- Transportation
- Conflicting appointments
- Does not wish to continue treatment
- Patient Sick

If you need to change your primary contact: email cancerqi@facs.org

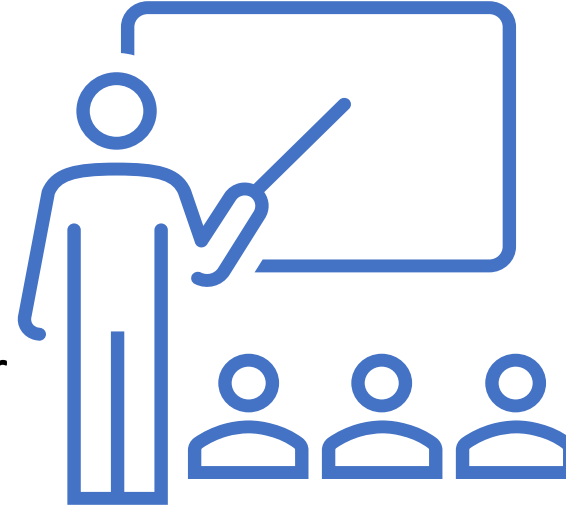


Final Data Collection December 15-30th

Beginning in 2024

Expectations in 2024

- Identify at least one barrier
- Develop a problem statement and goal
- Implement an intervention from the toolkit
- Report Data (via REDCap)
- Meet with small group cohort based on barrier



Reminders

ACS Cancer Conference 2024

February 22-24, 2024 | Austin, TX

<https://www.facs.org/quality-programs/cancer-programs/2024-ac-s-cancer-conference/>

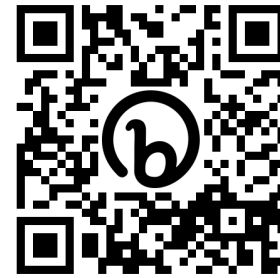


Q and A

Reach out to cancerqi@facs.org



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facs.org/quality-programs/cancer-programs/



ACS Cancer Programs



@AmColSurgCancer