What is ACCORDS?

Adult and Child Center for Outcomes Research and Delivery Science

ACCORDS is a ‘one-stop shop’ for pragmatic research:

- A multi-disciplinary, collaborative research environment to catalyze innovative and impactful research
- Strong methodological cores and programs, led by national experts
- Consultations & team-building for grant proposals
- Mentorship, training & support for junior faculty
- Extensive educational offerings, both locally and nationally

ACCORDS Upcoming Events

December 18, 2023 Zoom	**Statistical Methods for Pragmatic Research** Factorial Designs for Optimizing Intervention Development *Presented by:* Maren Olsen, PhD (Duke)
January 10, 2024 10am MT Zoom	**D&I Science Graduate Certificate Program Informational Webinar** Learn about the upcoming application cycle, program requirements, and key competencies.
January 10, 2024 Bushnell Auditorium, Zoom	**Ethics, Challenges, & Messy Decisions in Shared Decision Making** Who's Sharing What? The Challenges of Adolescent Shared Decision Making *Presented by:* Ellen Lipstein, MD (Cincinnati Children's Hospital)
January 22, 2024 AHSB 2200/2201, Zoom	**Statistical Methods for Pragmatic Research** Missing Data and Statistical Methods *Presented by:* Jun Ying, PhD
February 7, 2024 Bushnell Auditorium, Zoom	**Ethics, Challenges, & Messy Decisions in Shared Decision Making** Financial Toxicity and the Importance of Cost Discussions During Shared Decision Making *Presented by:* Mary Politi, PhD (Washington University in St. Louis)
February 26, 2024 Zoom	**Statistical Methods for Pragmatic Research** Latent Class Analysis: Assumptions and Extensions *Presented by:* Rashelle Musci, PhD (Johns Hopkins Bloomberg School of Public Health)

*all times 12-1pm MT unless otherwise noted

COPRH Con

Colorado Pragmatic Research in Health Conference

Innovations in Pragmatic Research Methods

From Data to Equity, Policy, and Sustainability

June 5 - 7, 2024 | 10am-3pm MT

Registration is open now at www.COPRHCon.com

ACCORDS
ADULT AND CHILD CENTER FOR OUTCOMES RESEARCH AND DELIVERY SCIENCE
UNIVERSITY OF COLORADO
CHILDREN'S HOSPITAL COLORADO

Ethics, Challenges, and Messy Decisions in Shared Decision-Making

2023-2024 Seminar Series

Sarah Tevis, MD

Clara Lee, MD

Shared Decision Making in Breast Surgery

Shared Decision Making in Breast Surgery

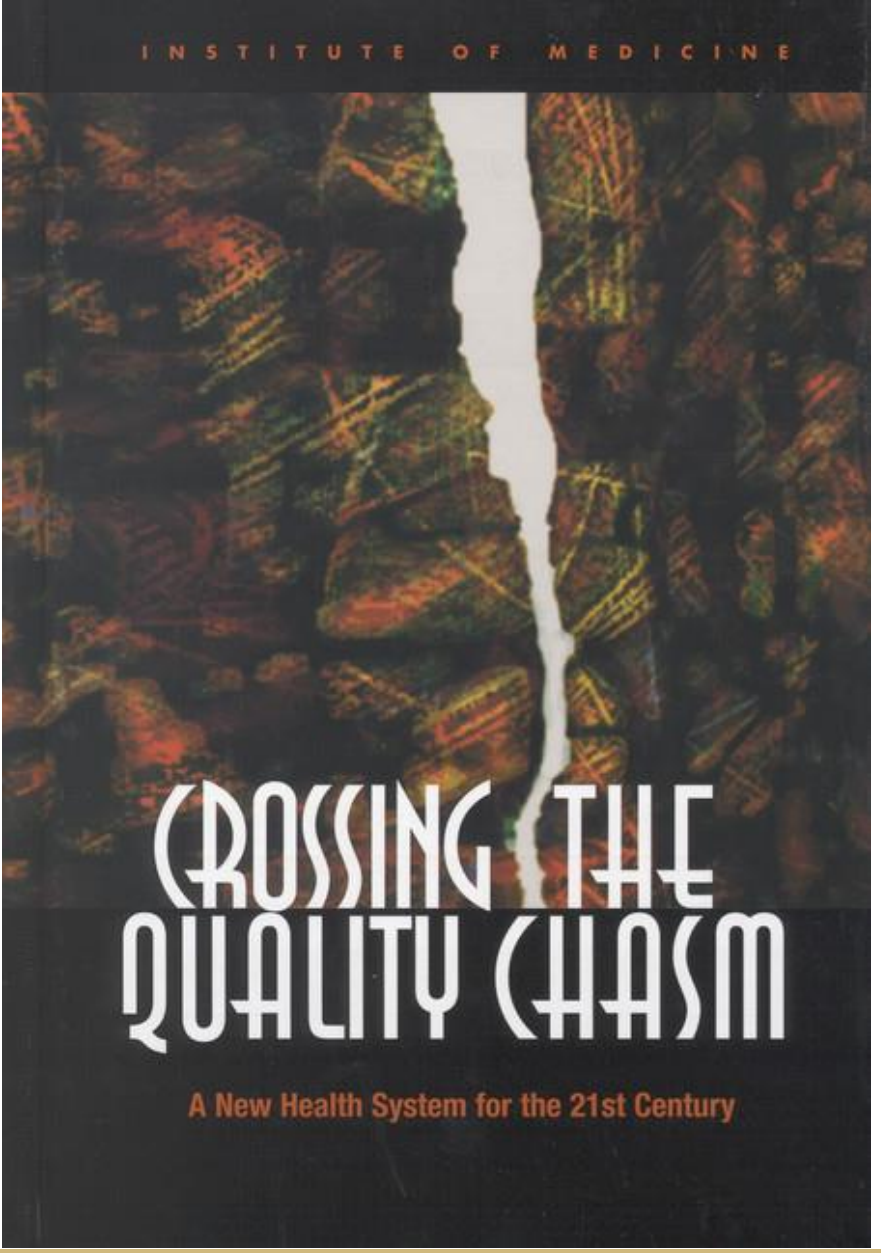
Dr. Clara Lee, Professor of Surgery

Dr. Sarah Tevis, Associate Professor of Surgery

Disclosures

- Funding Sources: Paul Calabresi K12 (K12CA086913), Doris Duke Foundation (2020141), Association for Academic Surgery Joel J. Roslyn Award

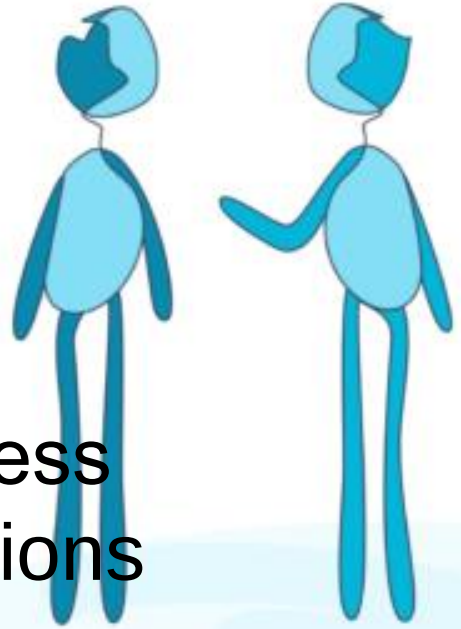
- No other disclosures



"care that is respectful of and responsive to individual patient preferences, needs, and values"…

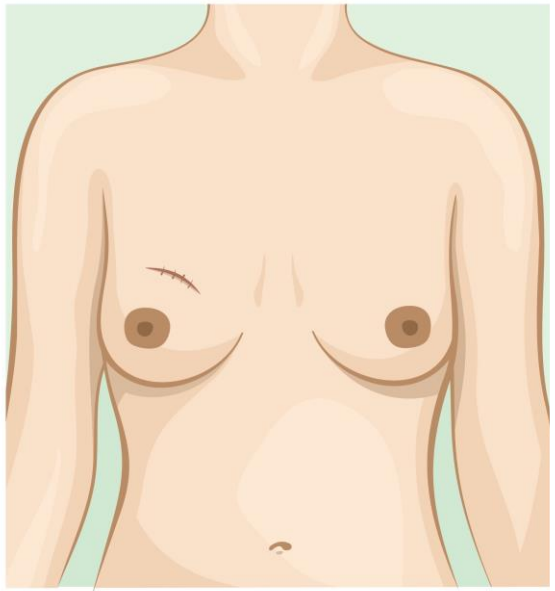
and that ensures "that patient values guide all clinical decisions

What Matters To You?

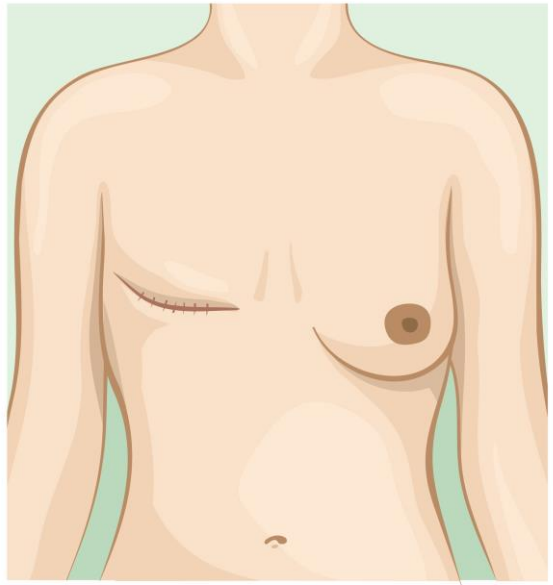


- Increase clinician's awareness
- More meaningful conversations
- Customized plans of care

Institute *for* Healthcare Improvement



LUMPECTOMY



MASTECTOMY

The NEW ENGLAND JOURNAL of MEDICINE

Twenty-Year Follow-up of a Randomized Trial Comparing Total Mastectomy, Lumpectomy, and Lumpectomy plus Irradiation for the Treatment of Invasive Breast Cancer

Bernard Fisher, M.D., Stewart Anderson, Ph.D., John Bryant, Ph.D., Richard G. Margolese, M.D., Melvin Deutsch, M.D., Edwin R. Fisher, M.D., Jong-Hyeon Jeong, Ph.D., and Norman Wolmark, M.D.

- Fantastic Evidence
  - Overall survival
  - Disease free survival
  - Locoregional recurrence
- Paucity of Evidence
  - Physical well-being
  - Psychological well-being
  - Sexual health
  - Cosmetic outcomes

Table 1. Existing Decision Aids for Patients Choosing Lumpectomy or Mastectomy

Existing Decision Aids	Diagnosis	Adjuvant Treatments	Surgery Description	Equivalent Survival	Reconstruction Options	Post-op Recovery	Long-term QOL
A Patchwork of Life*	X	X	X	X	X		
Healthwise*	X	X	X	X	X	X	
National Cancer Institute	X	X	X	X	X	X	
Take-home booklet	X	X	X	X	X	X	
Jewellery Box	X	X	X	X	X	X	
Decision Board	X	X	X	X	X	X	
Options for Treating Breast Cancer	X	X	X	X	X	X	
Early Stage Breast Cancer: Choosing Your Surgery Video	X	X	X	X	X	X	
Interactive Breast Cancer CDROM	X	X	X	X	X		

* Breast surgery DAs included in the Ottawa Hospital Research Institute DA inventory

Challenges to Incorporating QOL

Little data on longitudinal outcomes

How do patients want this information?

Patients want to know about “patients like me”

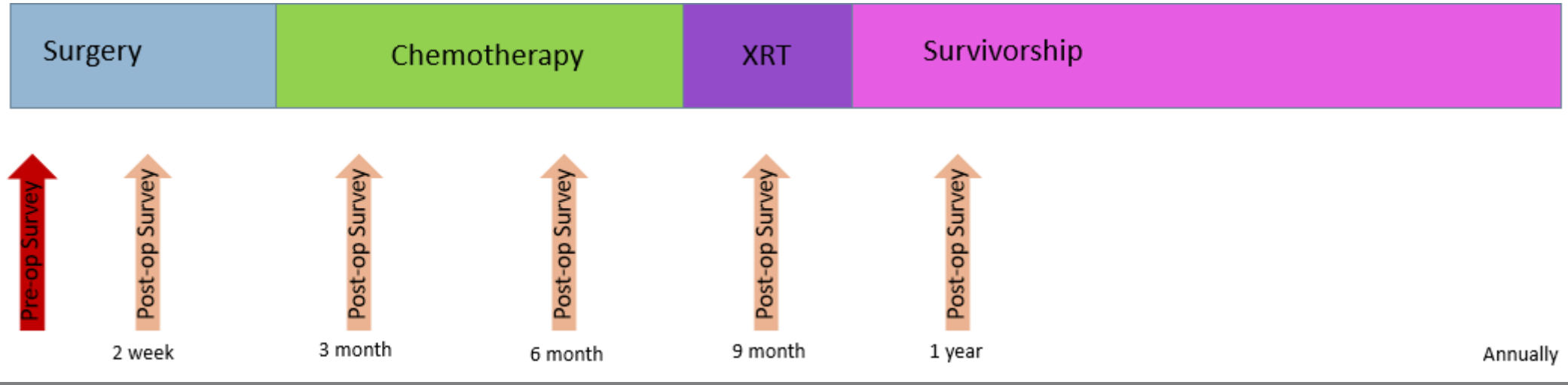
Patient Reported Outcome Measures (PROs)

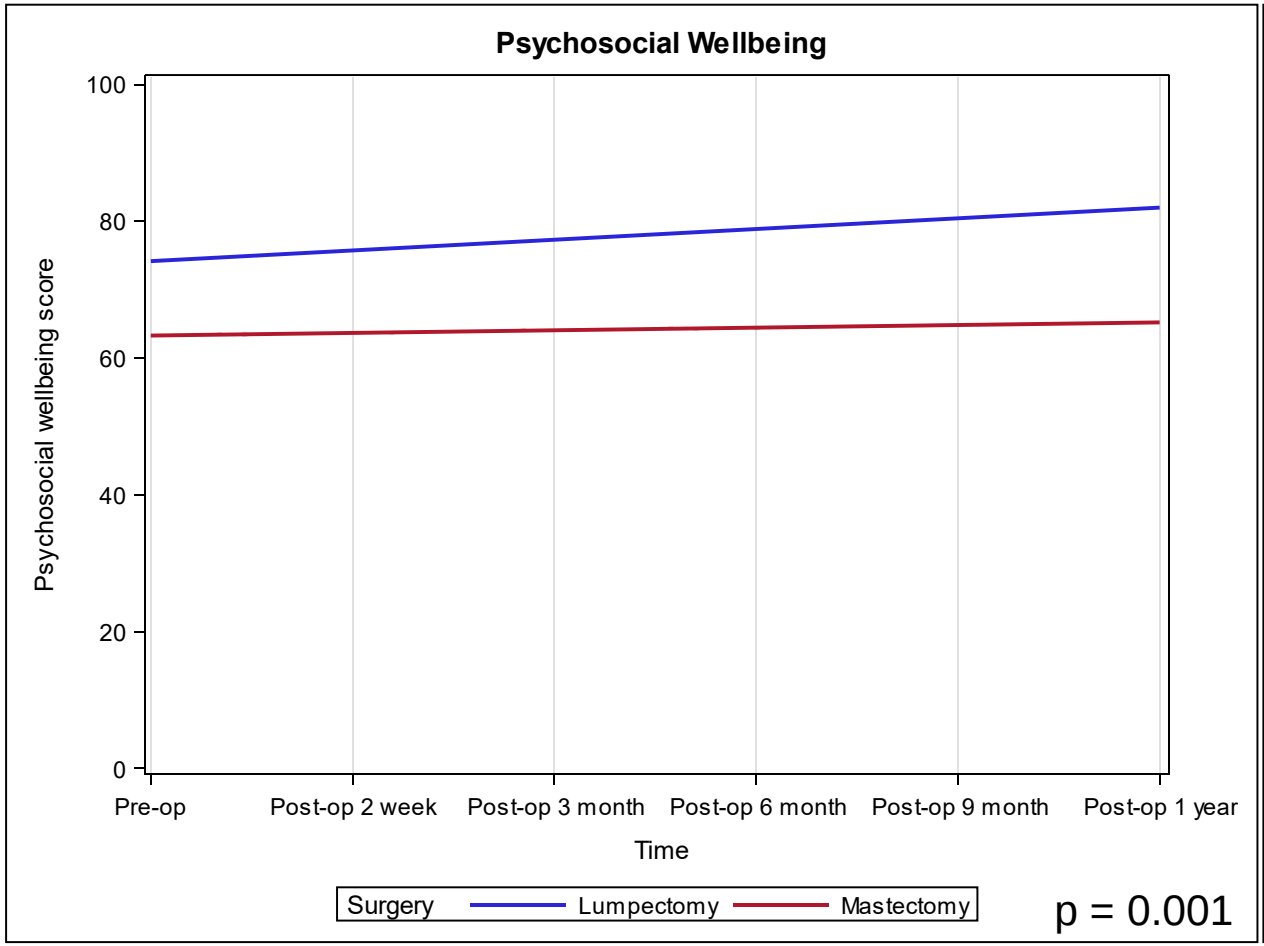
Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.

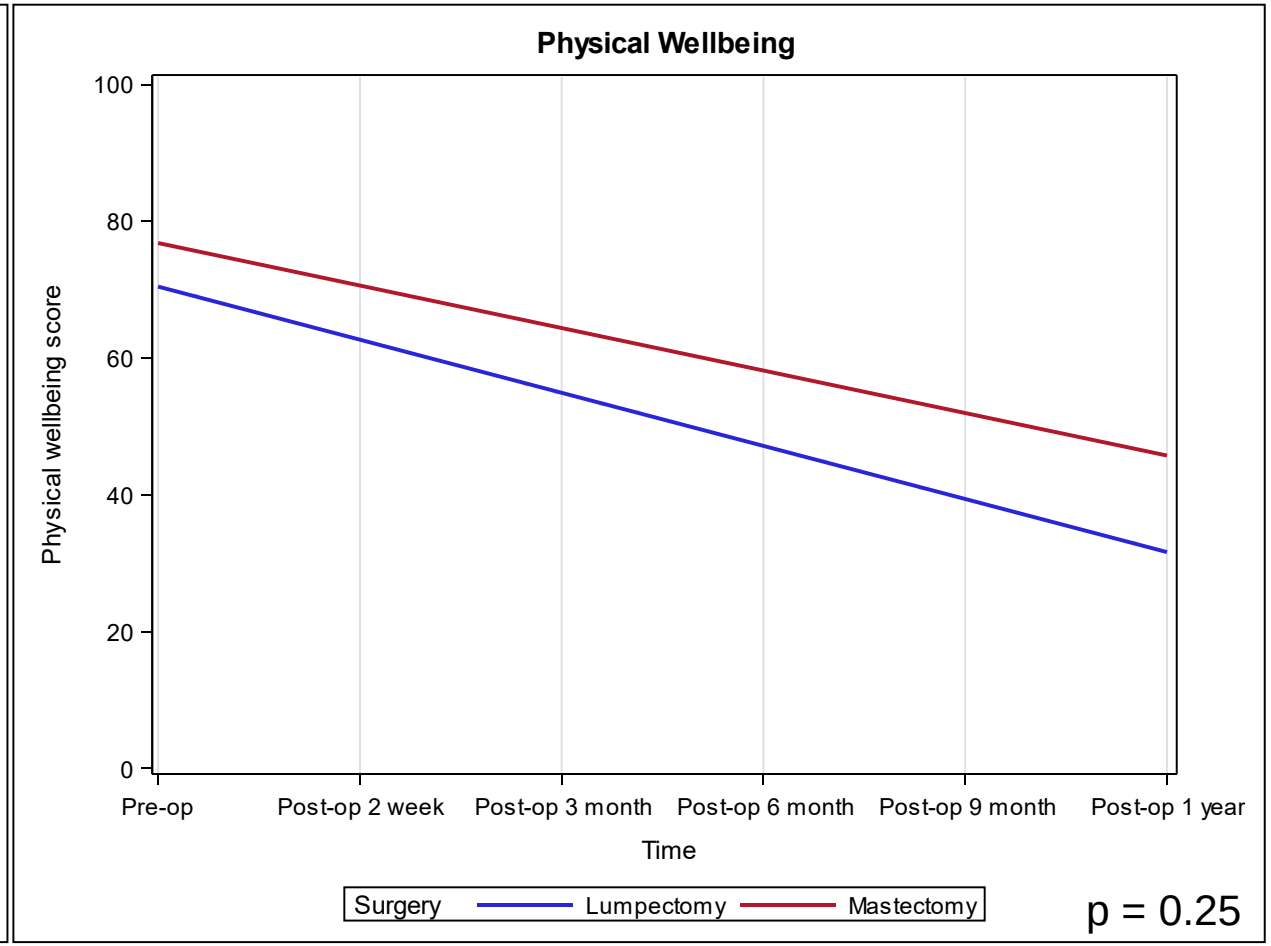
- U.S. Food and Drug Administration

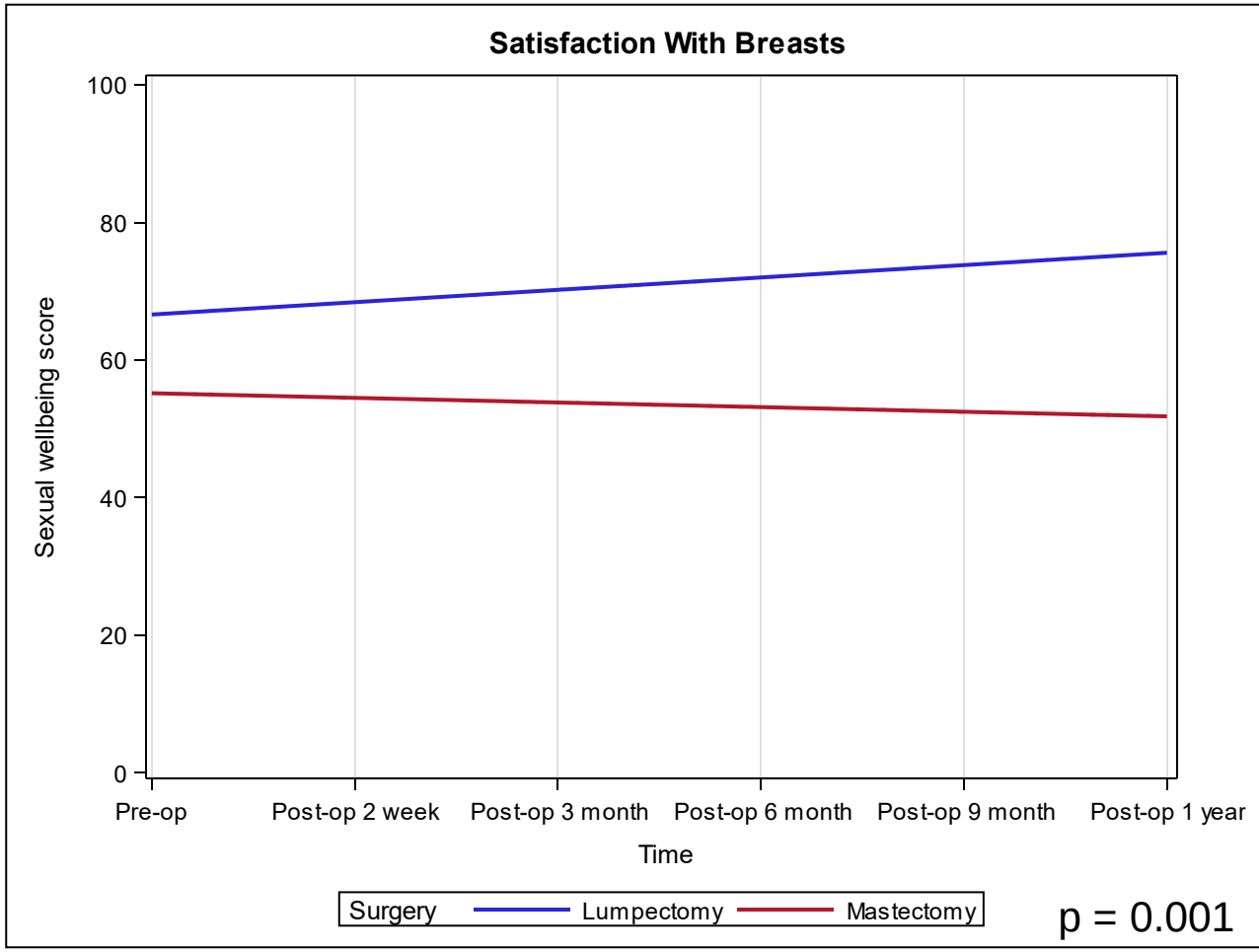
Little data on longitudinal outcomes

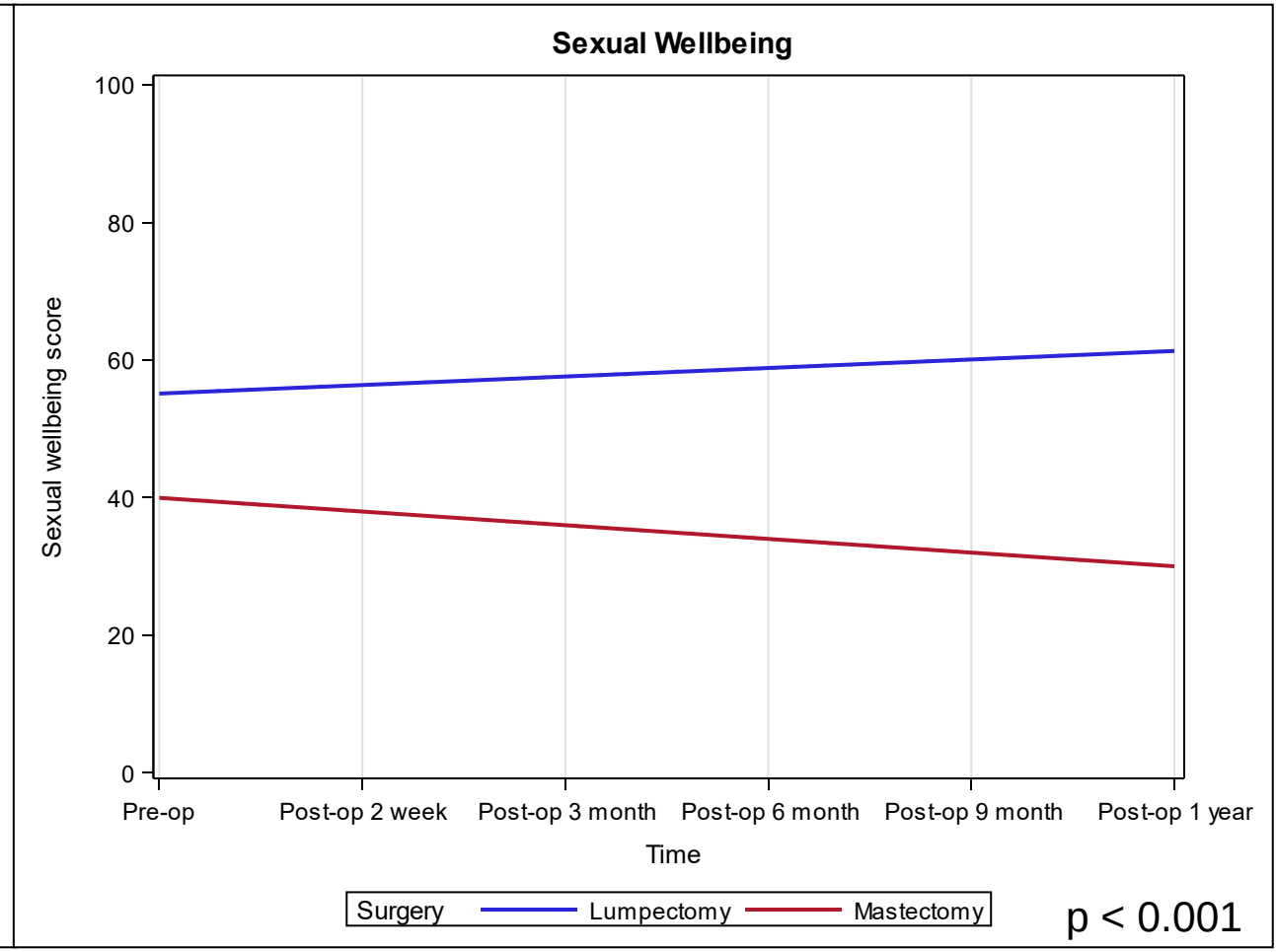
Figure 1.
BREAST-Q conceptual framework. (Pusic A, Klassen A, Scott A, et al. Development of a new patient-reported outcome measure for breast surgery: the BREAST-Q. with permission.)




Psychosocial Wellbeing
Psychosocial wellbeing score
100
80
60
40
20
0
Pre-op
Post-op 2 week
Post-op 3 month
Post-op 6 month
Post-op 9 month
Post-op 1 year
Time
Surgery
Lumpectomy
Mastectomy
p = 0.001


Physical Wellbeing
Physical wellbeing score
100
80
60
40
20
0
Pre-op
Post-op 2 week
Post-op 3 month
Post-op 6 month
Post-op 9 month
Post-op 1 year
Time
Surgery
Lumpectomy
Mastectomy
p = 0.25


Satisfaction With Breasts
Sexual wellbeing score
100
80
60
40
20
0
Pre-op
Post-op 2 week
Post-op 3 month
Post-op 6 month
Post-op 9 month
Post-op 1 year
Time
Surgery
Lumpectomy
Mastectomy
p = 0.001


Sexual Wellbeing
Sexual wellbeing score
100
80
60
40
20
0
Pre-op
Post-op 2 week
Post-op 3 month
Post-op 6 month
Post-op 9 month
Post-op 1 year
Time
Surgery
Lumpectomy
Mastectomy
p < 0.001

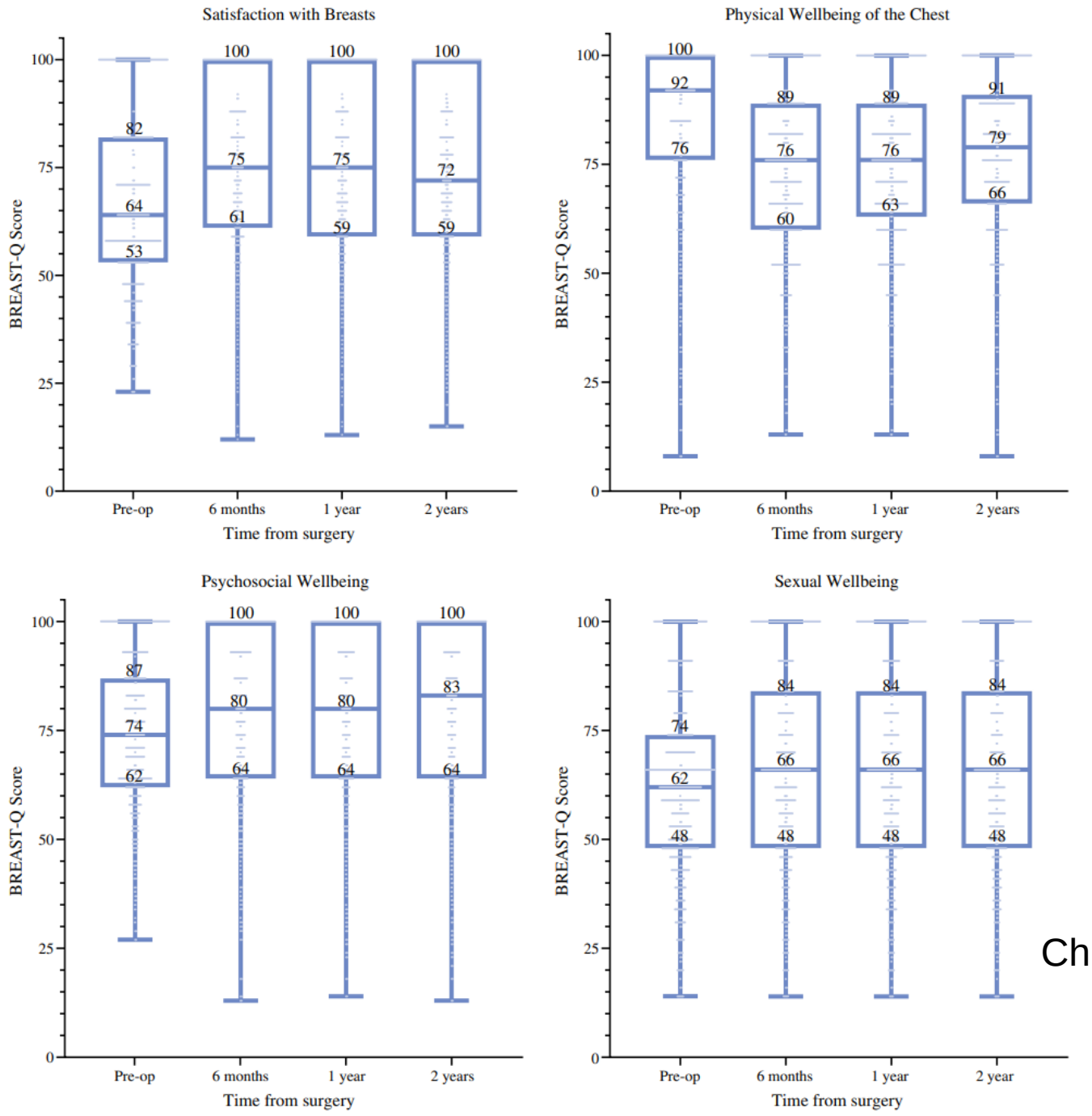


FIG. 1 Breast-conserving therapy BREAST-Q scores from baseline to 2 years after surgery

Chu et al. *Ann Surg Onc* 2023

Can we include PROs in shared decision making?

- Concerns
  - How much data is enough?
  - Will patients understand?
  - Will clinicians be receptive?
- Potential solutions
  - MSKCC, Denver Health
  - Pilot study of data displays
  - Qualitative study

BREAST CANCER SURGERY

What is a lumpectomy?

Many women diagnosed with breast cancer will be offered lumpectomy, which may be referred to as breast-conserving surgery.
A lumpectomy is the removal of the cancer with a small margin of surrounding healthy breast tissue.

What is a maste

A mastectomy is an op
reconstruction remove
appear flat after simpl

LUMPECT	Surgery:	Surgery:
Cancer Outcome		
Similar Survival	Less invasive procedure	More invasive procedure
	Shorter recovery time	Longer recovery time
10-year recurrence risk:	Unlikely to need drains unless combined with reconstruction	Will need drains
	More likely to require radiation after surgery	Less likely to require radiation after surgery
	Higher rate of needing a second cancer surgery if a portion of cancer is left behind after the first surgery	Lower rate of needing a second cancer surgery for cancer left behind in the breast

What might my life look like with each OPTION?

The numbers below are from recent medical studies, where patients have reported how they felt about their **quality of life 6 months after surgery.**

However, no one can know what will happen to any one person.

Life after Lumpectomy

Breast Appearance

Nearly 7 in 10 patients return to pre-surgery satisfaction with breast appearance

Emotional Health

About 8 in 10 patients return to pre-surgery emotional health

Life after Mastectomy

Breast Appearance

Nearly 3 in 10 patients return to pre-surgery satisfaction with breast appearance

Emotional Health

About 6 in 10 patients return to pre-surgery emotional health

What is a meaningful difference?

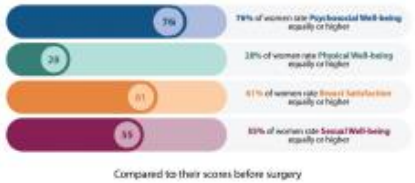
How do patients want this information?

- MSKCC study from 2011-2021
- Lumpectomy patients
- Used 0.2 SD
  - Baseline
  - Change from baseline to 1 year
- Minimal Important Difference (Baseline) = 3 – 4
- Minimal Important Difference (Δ) = 4 - 5

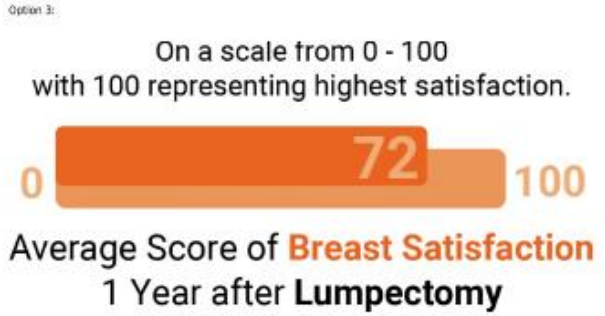
Chu et al. *Ann Surg Onc* 2023.

Option 1:

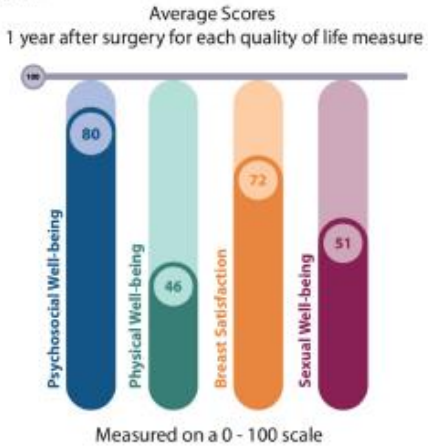
Option 2:



Option 3:

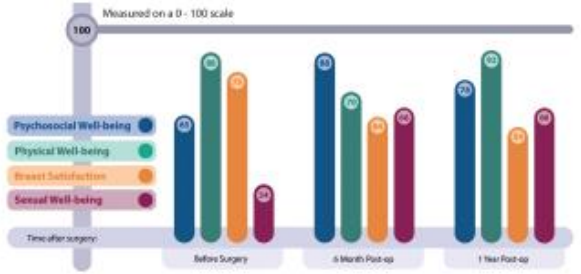


Option 4:



Option 5:

Option 6:



Preliminary Findings

- Patient preferences varied
- Patients favored:
  - Simplicity
  - Reading ease
  - Timepoints over recovery

What (non-surgical) factors impact PROs?

- Patient demographics
- Disease factors
- Axillary surgery
- Reconstructive surgery
- Baseline PROs
- Patient distress
- Receipt of supportive services

Patients want to know about “patients like me”

Variables associated with PROs at 6 months after surgery

↓ Physical well-being (6 months)	↓ Satisfaction with breasts (6 months)	↓ Sexual well-being (6 months)
Older age	Lower satisfaction with breasts	High practical distress
More axillary surgery		
Lower physical well-being		
High emotional distress		
High health related distress		
High practical distress		

Future Goals

- Pilot test our decision aid
- Web-based decision aid “patients like you”
  - Collaborate with MSKCC
  - Integrates baseline information and treatment plan
  - Provides individualized expected long-term PROs

Clinician and Patient Engagement with a Breast Reconstruction Decision Support Tool (BREASTChoice)

Clara N. Lee, MD, MPP
University of North Carolina Chapel Hill

Overview

The BREASTChoice tool

Questions related to electronic health record integration

Future directions

Project Funded by the Agency for Healthcare Research and Quality (AHRQ) R18 HS026699

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The Ohio State University

The Breast Reconstruction Decision

- Breast reconstruction choices:
  - Reconstruction vs. not
  - Timing (Immediate vs. delayed)
  - Type (Implant vs. autologous)
- Risk of complications from immediate reconstruction:
  23% in first 1-2 years (range 5-52%)
- 70% of patients have knowledge deficits about risks
- Clinicians often think the complication risk is 2-5%
- Number of procedures: from 2-19, including “revisions”

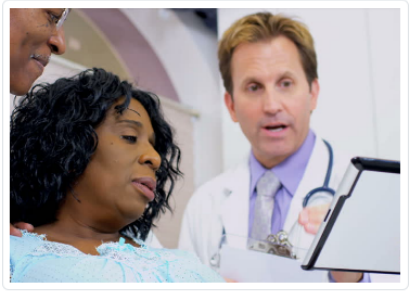
Welcome to the Breast Reconstruction Education and Support Tool (B.R.E.A.S.T. Choice)

A woman who is having her breast removed as part of her breast cancer treatment may think about having breast reconstruction.

Breast reconstruction is surgery that can rebuild the shape and look of the breast.

There are many choices to make when thinking about **breast reconstruction**:

- Should I have breast reconstruction at all?
- If I want to have breast reconstruction, what type of breast reconstruction should I have?
- Should I start the process when I am having my breast removed, or later, after I am done with cancer treatment?



Whether to have breast reconstruction depends on your goals and what matters most to you. It is not needed for breast cancer treatment, but can help some women feel better about their body after breast cancer surgery.

As you learn about breast reconstruction, you can follow the order of the tool, or you can skip around to the sections that are most useful to you.

Should I have breast reconstruction?

Women of any age, race, or body type can consider **breast reconstruction**. But, it is not right for everyone. Below you can learn more about the pros and cons of breast reconstruction.

Pros of Breast Reconstruction	Cons of Breast Reconstruction
Your breasts might look more balanced when wearing a bra, swimsuit, or clothes.	Whether in clothes or not, a reconstructed breast is not a perfect match for a natural breast.
You regain breast shape without having to wear a breast form (prosthesis).	It often involves longer surgery and more than one surgery.
It might help you feel more comfortable with your body and "feel like yourself" again after your breast is removed.	After each surgery, there is a chance of an infection, swelling, pain, poor wound healing, or loss of blood to the tissue. Some of these can be treated with pills or creams. Others may need to be treated with more surgery.

Keep in mind breast reconstruction has little or no effect on finding breast cancer in the future. It also has little or no effect on the chance of breast cancer coming back in the future.

What matters to you as you think about what type of breast reconstruction might be the right choice for you?

1. How important is it to you to heal quickly from reconstruction?

2. How important is it that your breast feels and moves like a natural breast?

3. How concerned are you about possibly needing to replace implants later on?

4. How concerned are you about scarring in other areas of your body if you take tissue or muscle from that area for reconstruction?

5. How concerned are you about weakness in other areas of your body if you take tissue or muscle from that area for reconstruction?

6. How important is it to you to use your own tissues to create a breast?

Your Risk from Having Breast Reconstruction Surgery

Breast reconstruction can help some women feel better about their body after their breast is removed. It can also increase the chance of having a major wound infection, wound opening, or tissue damage. This chance is higher if women start the process at the time their breast is removed for cancer, compared to delaying reconstruction. With no risk factors, 1-2 out of 100 women have a major wound infection, wound opening, or tissue damage after a mastectomy alone. With no risk factors, 7 out of 100 women have a major wound infection, wound opening, or tissue damage after a mastectomy plus immediate breast reconstruction.

To help you understand your own risks from breast reconstruction done at the time your breast is removed, we reviewed your current health. With the same risk factors you have, **15** out of 100 women have a major wound infection, wound opening, or tissue damage. Your risk is higher because you have a number of conditions that have been related to complications and delayed wound healing. Click here to learn more about those conditions. Talk to your doctor about how this might affect your choice.

What does my risk mean?

Your risk shows the chance of having a major wound opening, wound infection or tissue damage compared to a person who has no risk factors. The risk estimate comes from looking at thousands of women and their outcomes from breast reconstruction. It's just an estimate. No one knows who will or will not have one of these outcomes. Talk to your doctor or nurse if you want to learn ways to lower your risk.

This information about risk comes from data in your health record. Please click here to review and check your health data that make up this risk. Please answer all of these questions if some are missing, so we can give you a good estimate of your risk.

Your Chance of Wound Infection, Wound Opening, or Tissue Damage after Breast Reconstruction

7 out of 100 women have these outcomes after breast reconstruction, even with no risk factors.

15 out of 100 women with the same risk factors as you have these outcomes after breast reconstruction.

BREASTChoice Risk Prediction Model

- Developed + validated in >17,000 people; updated 2020 with institutional data, 6 month follow-up, favorable concordance statistic
- BMI
- Smoking or e-cigs (w/in past 6 months)
- Previous chest radiation
- Diabetes
- Congestive Heart Failure
- Hypertension (chronic)
- Depression (treated in past 2 years)
- Psychosis (ever)

RANDOMIZED CONTROLLED TRIAL

A Randomized Controlled Trial Evaluating the *BREASTChoice* Tool for Personalized Decision Support About Breast Reconstruction After Mastectomy

*Mary C. Politi, PhD,** ✉ *Clara N. Lee, MD, MPP,*†‡§ *Sydney E. Philpott-Streiff, MPH,**
Randi E. Foraker, PhD, MA,¶ *Margaret A. Olsen, PhD, MPH,**|| *Corinne Merrill, BSN, RN,***
*Yu Tao, MS,** *and Terence M. Myckatyn, MD***

Objective: To evaluate a web-based breast reconstruction decision aid, *BREASTChoice*.

Summary and Background Data: Although postmastectomy breast reconstruction can restore quality of life and body image, its morbidity remains substantial. Many patients lack adequate knowledge to make informed choices. Decisions are often discordant with patients' preferences.

Methods: Adult women with stages 0–III breast cancer considering postmastectomy breast reconstruction with no previous reconstruction were randomized to *BREASTChoice* or enhanced usual care (EUC).

Results: Three hundred seventy-six patients were screened; 120 of 172 (69.8%) eligible patients enrolled. Mean age = 50.7 years (range 25–77). Most were Non-Hispanic White (86.3%) and had a college degree (64.3%). Controlling for health literacy and provider seen, *BREASTChoice* users had higher knowledge than those in EUC (84.6% vs. 58.2% questions correct; $P <$ usability (mean score = 6.3/7). Participants completed *BREASTChoice* in about 27 minutes.

Conclusions: *BREASTChoice* can improve breast reconstruction decision quality by improving patients' knowledge and providing them with personalized risk estimates. More research is needed to facilitate point-of-care decision support and examine *BREASTChoice's* impact on patients' decisions over time.

Keywords: breast reconstruction, decision aids, risk prediction, shared decision making

(*Ann Surg* 2020;271:230–237)

Over 330,000 women are diagnosed with breast cancer each year,[1] and about 40% undergo mastectomy surgery as part of

Politi et al., 2020, Ann. Surg.

Patients + Clinicians Support Using the Tool: Benefits

"It was good at gathering and pulling my thoughts together in one place. That is definitely…going to help . . . most women . . . right at the time when they get their diagnosis . . . their brain is all over the place…." [Patient #150]

" A lot of times… they don't realize that they're a high-risk patient…If they went into their consultation already knowing that, that would be good." [Clinician #134]

"I think it gives the patient a realistic outline of pros and cons of what their selected choices are, and sort of takes away the overwhelming information that they may seek if they were Googling this information. It's just giving a very straightforward, "This is your pro. This is your con." [Clinician #129]

Boateng, Lee, Foraker, Myckatyn, Spilo, Goodwin, Lee, Politi, 2021. *Medical Decision Making PP*.

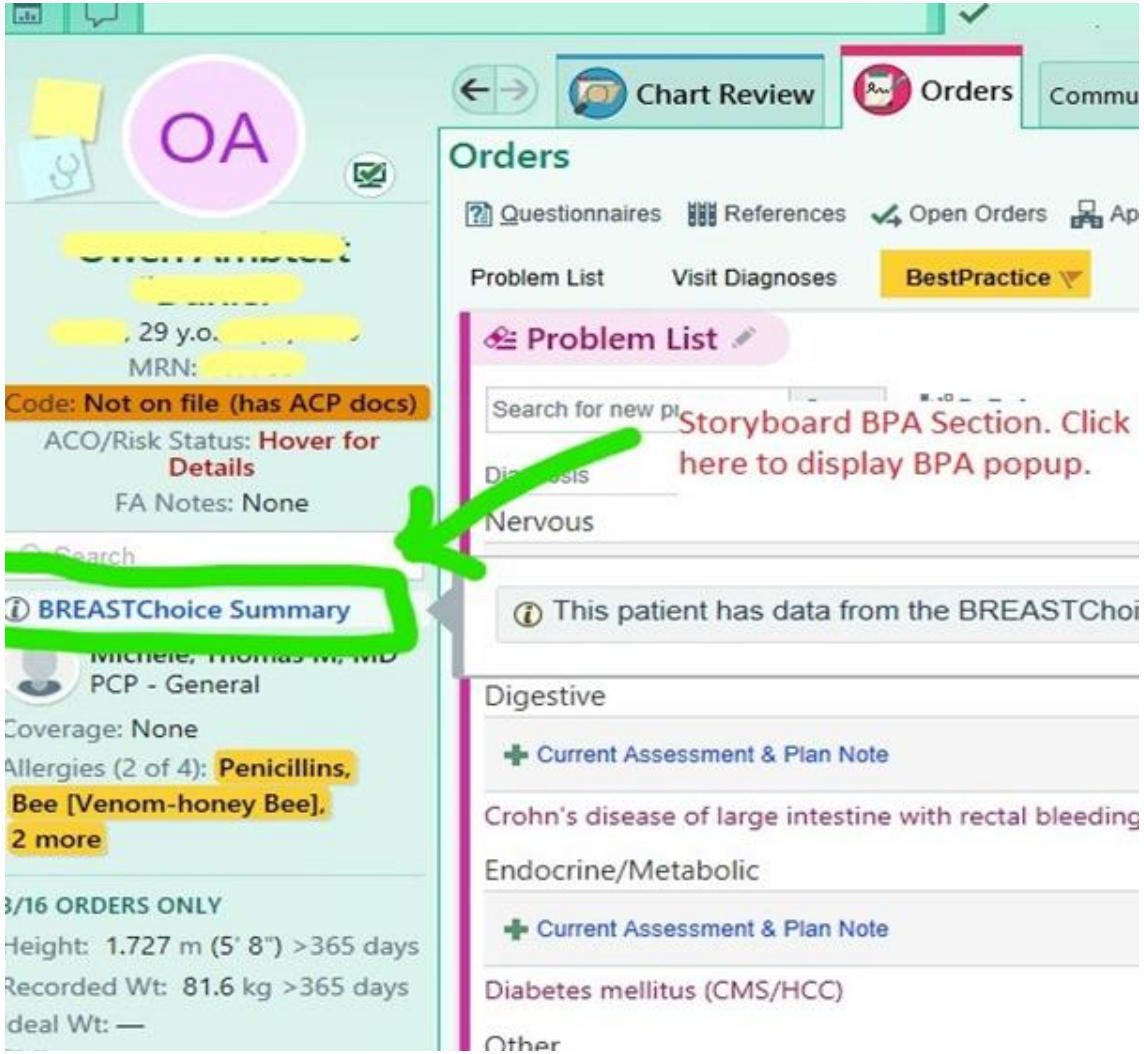
Clinician Role

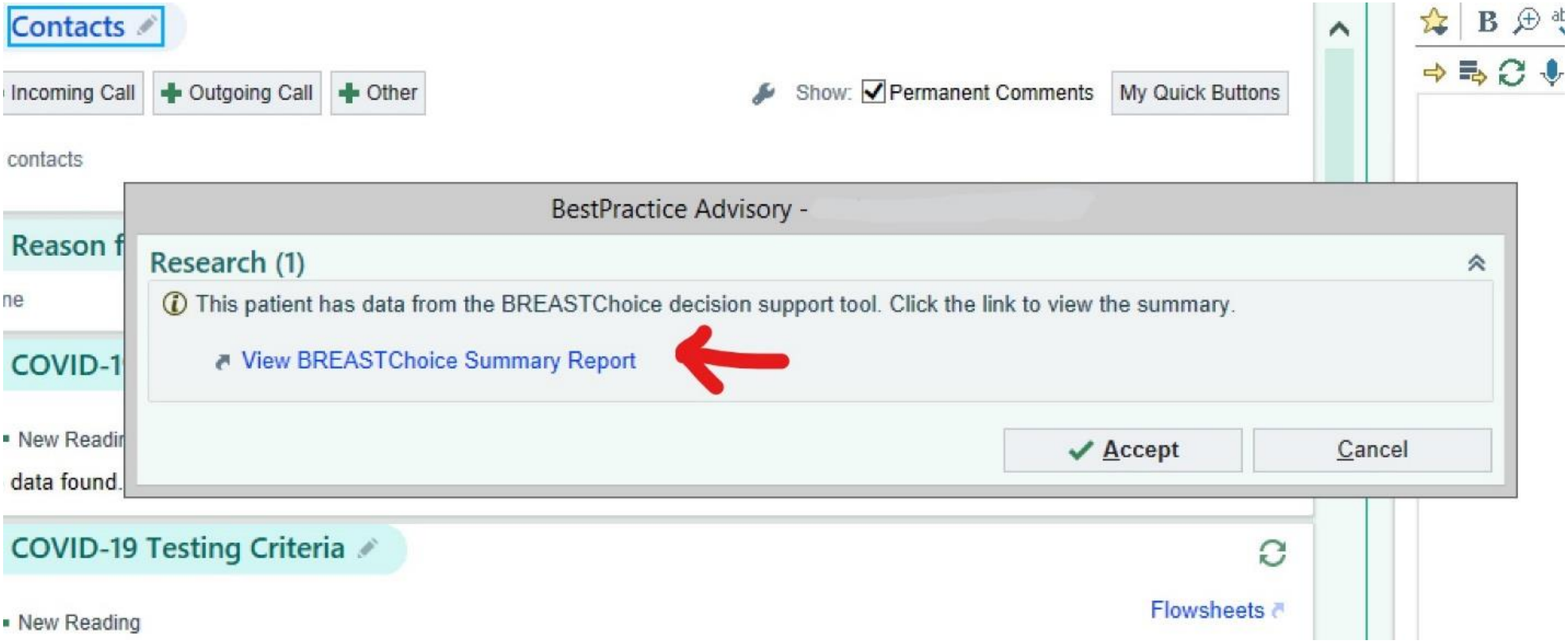
- WU : click on BREASTChoice summary under patients' name.
- OSU: pop up BPA (less work at first), but needed to "accept" (extra step)

- Skills: reviewing information using SDM (brief training)

- Benefits:
  - Patient outcomes from earlier RCT (knowledge, activation)
  - Clinician knowledge of risk and patient preferences
  - Shared decision making process
  - Possibility for better match between risk, preferences and choice

Clinicians Suggested Location for Summary: WU




Contacts
Incoming Call
Outgoing Call
Other
Show:
Permanent Comments
My Quick Buttons
contacts
BestPractice Advisory -
Research (1)
This patient has data from the BREASTChoice decision support tool. Click the link to view the summary.
View BREASTChoice Summary Report
Accept
Cancel
Reason f
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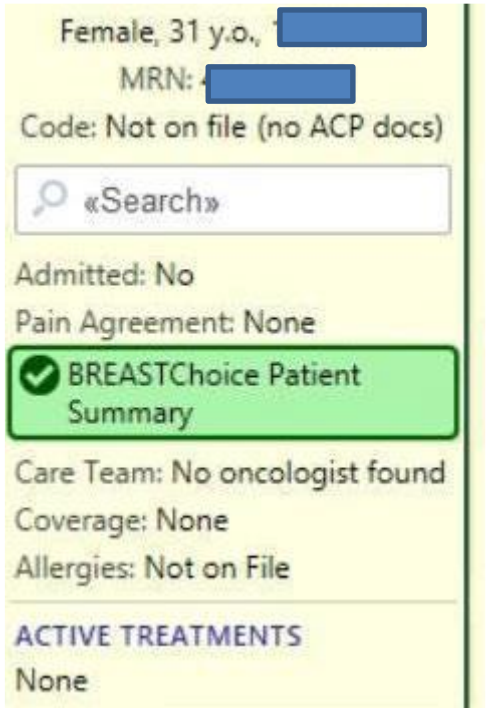
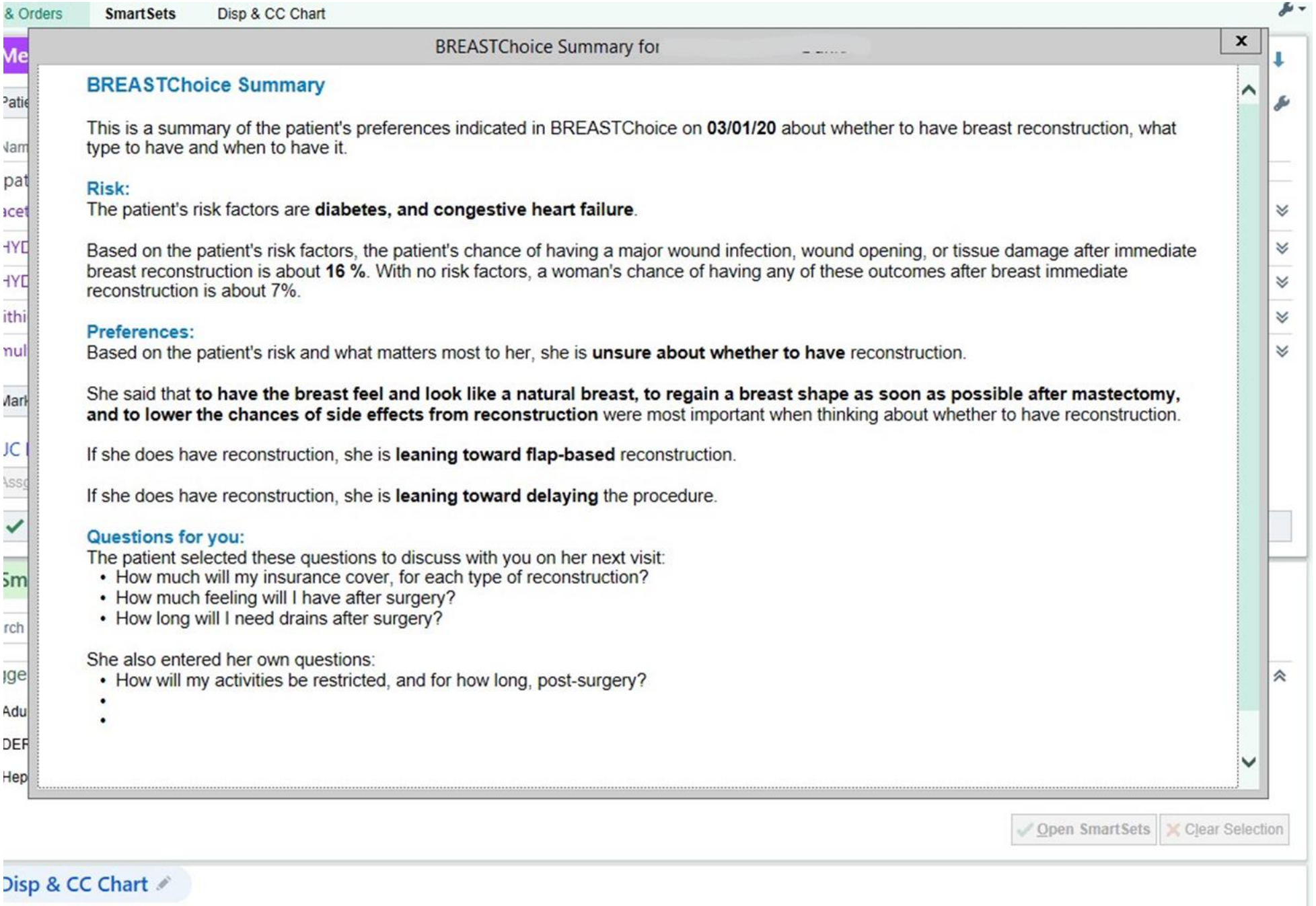
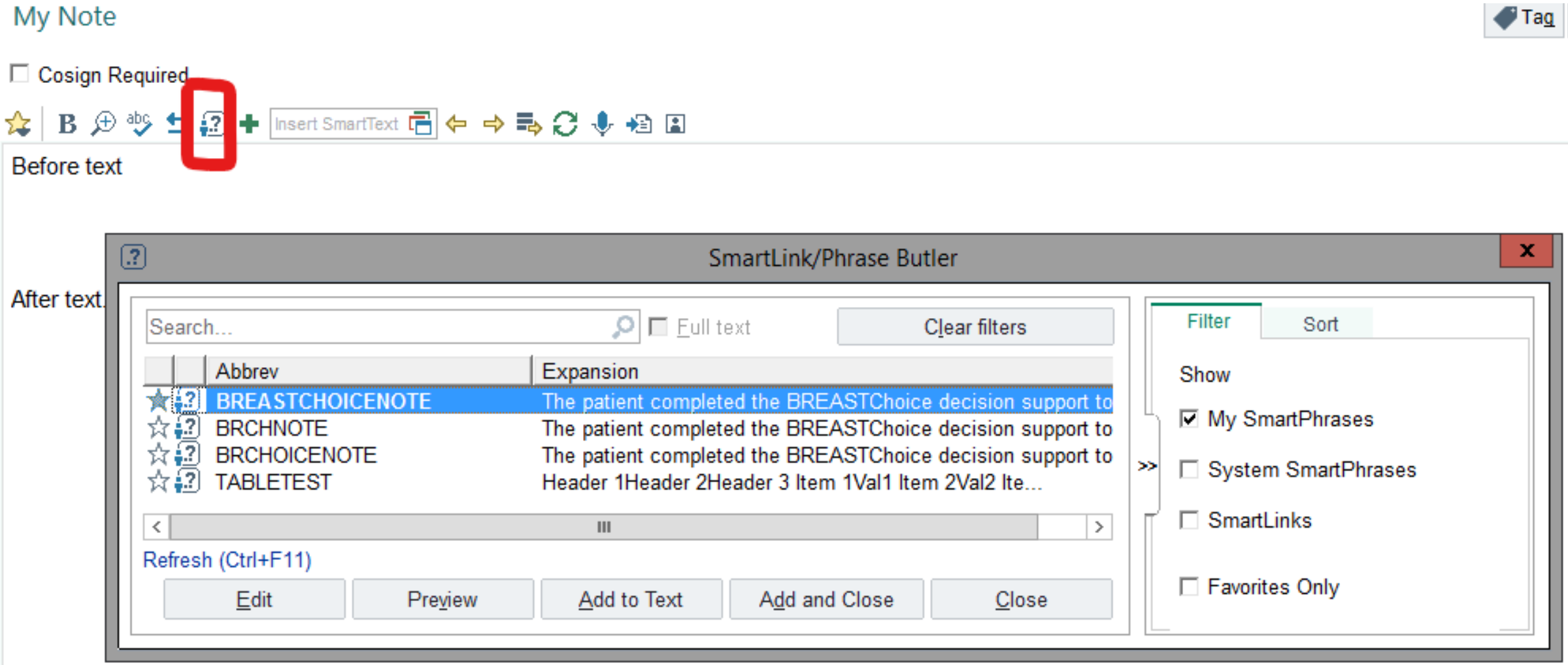
COVID-1
New Readir
data found.
COVID-19 Testing Criteria
New Reading
Flowsheets

OSU: Accept/Dismiss: Extra Step




& Orders
SmartSets
Disp & CC Chart
BREASTChoice Summary for
BREASTChoice Summary
This is a summary of the patient's preferences indicated in BREASTChoice on 03/01/20 about whether to have breast reconstruction, what type to have and when to have it.
Risk:
The patient's risk factors are diabetes, and congestive heart failure.
Based on the patient's risk factors, the patient's chance of having a major wound infection, wound opening, or tissue damage after immediate breast reconstruction is about 16 %. With no risk factors, a woman's chance of having any of these outcomes after breast immediate reconstruction is about 7%.
Preferences:
Based on the patient's risk and what matters most to her, she is unsure about whether to have reconstruction.
She said that to have the breast feel and look like a natural breast, to regain a breast shape as soon as possible after mastectomy, and to lower the chances of side effects from reconstruction were most important when thinking about whether to have reconstruction.
If she does have reconstruction, she is leaning toward flap-based reconstruction.
If she does have reconstruction, she is leaning toward delaying the procedure.
Questions for you:
The patient selected these questions to discuss with you on her next visit:
How much will my insurance cover, for each type of reconstruction?
How much feeling will I have after surgery?
How long will I need drains after surgery?
She also entered her own questions:
How will my activities be restricted, and for how long, post-surgery?
Open SmartSets
Clear Selection
Disp & CC Chart

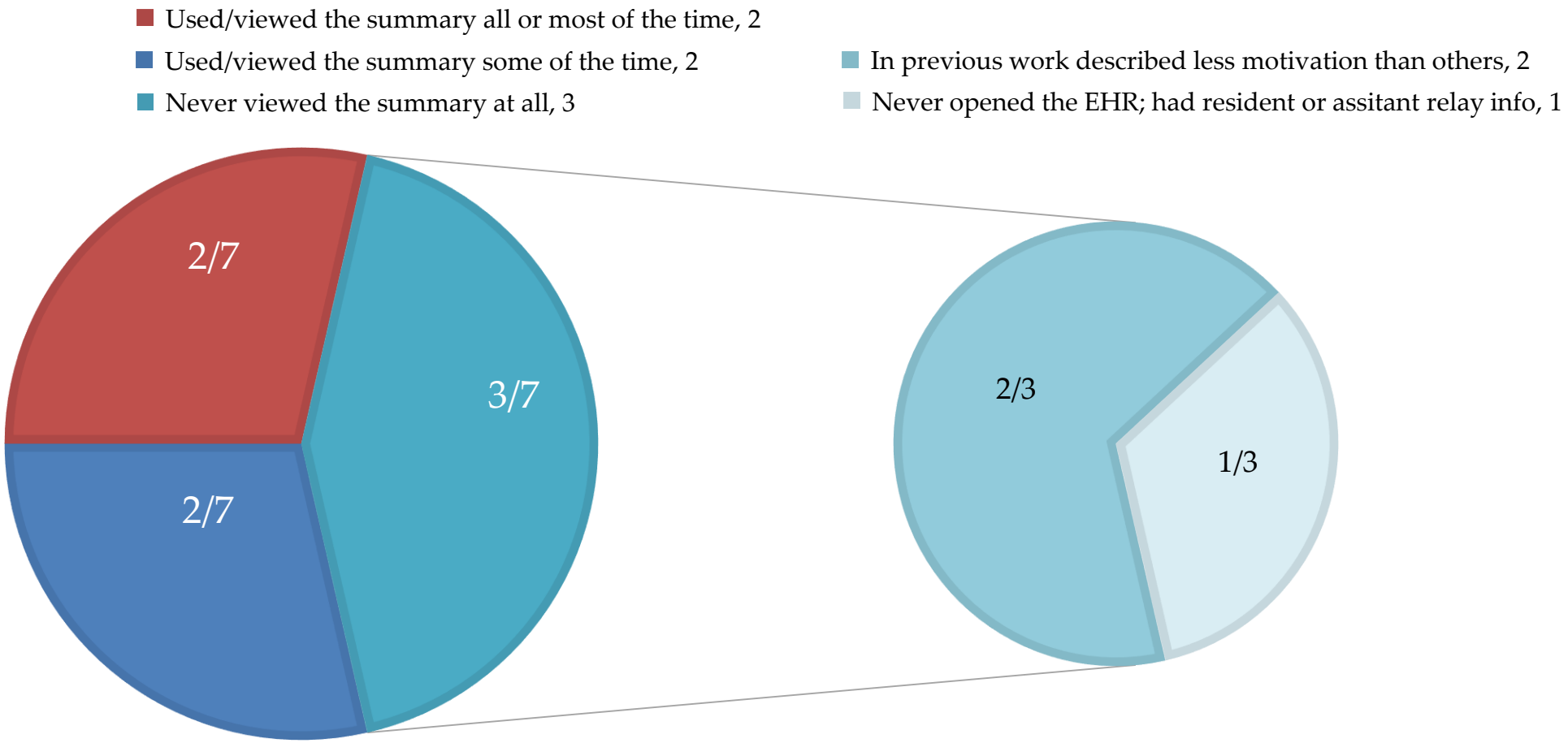
Smart Phrase: Minimize Work



Results: Did Clinicians Engage With BREASTChoice?

All clinicians (N=7 at WU; N=15 at OSU) completed training, supported study

At WU, motivation and workflow impacted use



Results: Did Clinicians Engage With BREASTChoice?

At OSU, technology challenges impacted engagement

- All but 1 accepted the BPA to view it at some point
  - But at first, delay in programming led to paper-based printout
  - Then, ~half initially dismissed the BPA before additional training
  - End of study, bug in program stopped completing summary

Summary: Selected Patient Outcomes: ITT

	BREASTChoice (n=156)	Control (n=165)	Unadjusted Analysis	Adjusted Stratified Analysis	
DQI Knowledge					
Mean (SD)	70.6 (13.2)	67.4 (14.7)		**By site: p=0.04**	**By age: p=0.04 By race: p=0.04**
Median (IQR)	66.7 (66.7-77.8)	66.7 (55.6-77.8)	p=0.08		
Proportion of high-risk (32%+) patients choosing reconstruction	**n=16**	**n=13**	-28.6%		
Chose reconstruction	10 (71.4%)	11 (100.0%)	(-57.9%, 0.8%)		
Chose no reconstruction	4 (28.6%)	0 (0.0%)	p=0.056	-	-
Knowledge as assessed in *BREASTChoice* tool	**n=147**	**n=154**	-18.2%		
(Range 27.3-100%) Mean (SD)	84.7 (13.8)	66.5 (15.8)	(-14.8, -21.6) **p<0.001**	**p<0.001**	**p<0.001**
Exploratory Outcome					
CollaboRATE Top Score Method	**n=141**	**n=156**	3.7%		
Less than every effort was made	78 (55.3%)	92 (59.0%)	(-7.6%, 14.9%)		
Every effort was made	63 (44.7%)	64 (41.0%)	p=0.53	p=0.26	p=0.37

Summary: Selected Patient Outcomes: PP

	BREASTChoice (n=156)	Control (n=165)	Unadjusted Analysis	Stratified Analysis	
DQI Knowledge Mean (SD) Median (IQR)	71.4 (12.8) 66.7 (66.7-77.8)	67.4 (14.7) 66.7 (55.6-77.8)	**p=0.03**	**By site: p=0.01**	**By age: p=0.02** **By race: p=0.01**
Proportion of high-risk (32%+) patients choosing reconstruction Chose reconstruction Chose no reconstruction	**n=13** 8 (66.7%) 4 (33.3%)	**n=13** 11 (100.0%) 0 (0.0%)	-33.3% (-64.3%, 2.4%) **p=0.04**	-	-
Knowledge as assessed in *BREASTChoice* tool (Range 27.3-100%) Mean (SD)	**n=147** 84.7 (13.8)	**n=154** 66.5 (15.8)	-18.2% (-14.8, -21.6) **p<0.001**	**p<0.001**	**p<0.001**
Exploratory Outcome					
CollaboRATE Top Score Method Less than every effort was made Every effort was made	**n=135** 73 (54.1%) 62 (45.0%)	**n=156** 92 (59.0%) 64 (41.0%)	4.9% (-6.5%, 16.3%) p=0.40	p=0.19	p=0.27

Summary: Patient Outcomes

- Improved knowledge about reconstruction, and reconstruction type, timing, and complication risks.

- In PP analyses (those in the *BREASTChoice* group who accessed the intervention), fewer high-risk patients chose to have immediate reconstruction, a higher risk procedure than delayed or no reconstruction.

- *BREASTChoice* did not decrease decisional conflict, improve the match between preferences and surgical choice (match was high in both groups), or increase shared decision-making (also high in both groups)

Summary: Implementation Challenges

- Implementation of digital tools can vary
  - Clinician can fill in or view information solo
  - Clinician can engage with patient** (this is our goal)
  - Clinician/care team can send to patient to fill in or view solo
- Digital tools do not always support collaborative decision discussions
- Alert fatigue and EHR fatigue can be a barrier, even with stakeholder engagement and planning. Status quo is easier.
- How do we go from verbal support for an idea to use and change?

Barriers/Ideas to Address in Future Work

- How can BPA's work without the "alert fatigue?"
- How does BPA design affect clinician use?
- How can patient-facing tools also include clinician components?
- How can we build upon existing workflows, with clinical champions?
  - Build into residency training?

Questions/Follow-Up

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