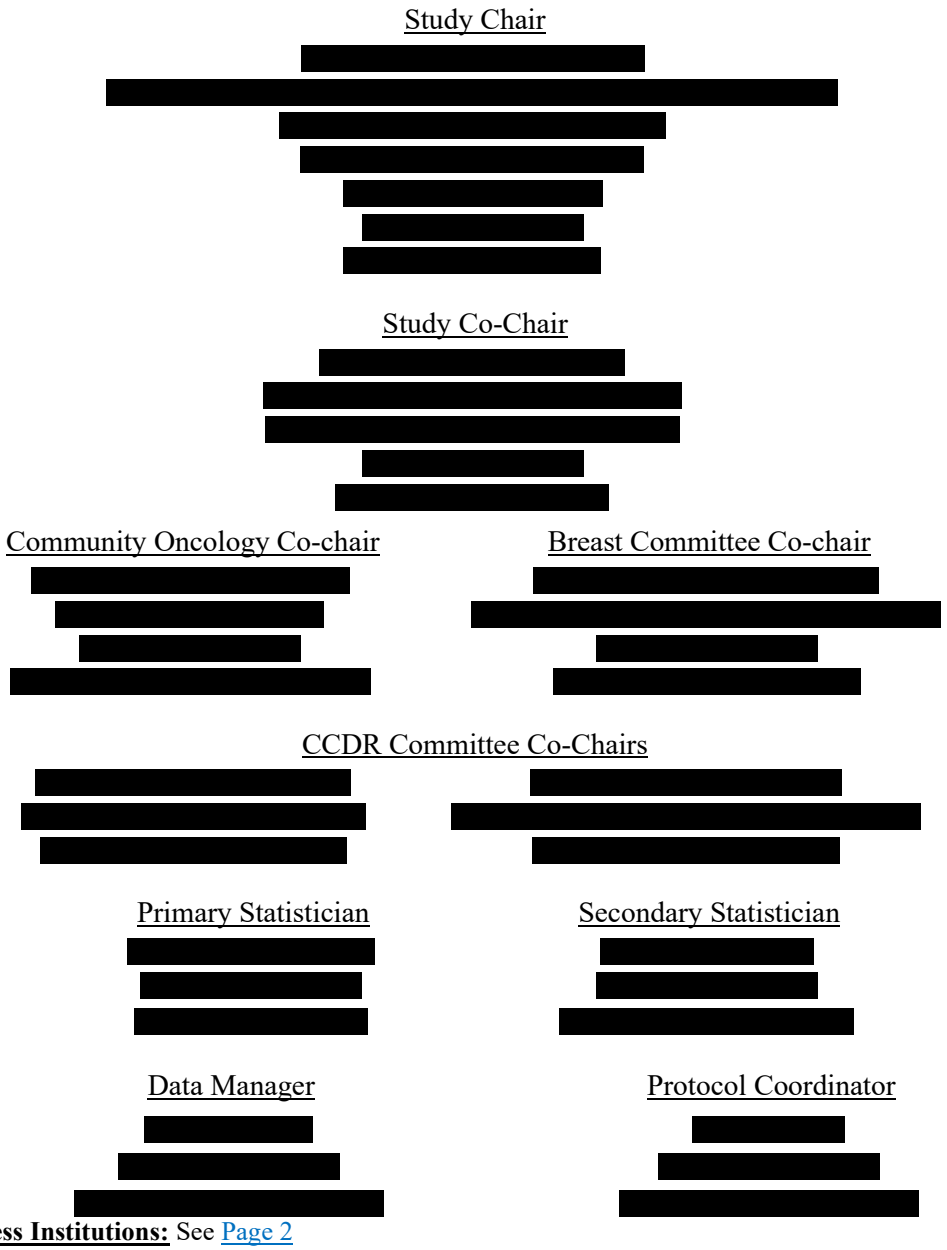
ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

ALLIANCE A231901CD

IMPROVING PATIENT-CENTERED COMMUNICATION IN BREAST CANCER: A RCT OF A SHARED DECISION ENGAGEMENT SYSTEM (SHARES)

A limited access study

ClinicalTrials.gov Identifier: NCT04549571



Limited Access Institutions: See Page 2

Participating Organizations:
NCORP Affiliates/Sub-Affiliates of the Alliance (lead), ECOG- ACRIN, NRG, and SWOG NCORP Research Bases.

Limited access institutions

Adena Regional Medical Center, OH182
Ascension Medical Group Southeast Wisconsin - Mayfair Road, WI169
Aspirus Regional Cancer Center, WI028
Aurora Cancer Care-Grafton, WI194
Aurora West Allis Medical Center, WI108
Baptist Memorial Hospital for Women, TN143
Beebe Health Campus, DE040
Columbia University Medical Center, NY024
Genesis Healthcare System Cancer Care Center, OH327
Helen F. Graham Cancer Center, DE028
Lewis Cancer and Research Pavilion at Saint Joseph's/Candler, GA106
Spectrum Health at Butterworth Campus, MI132
St. Ann's Hospital, OH188
Good Samaritan Regional Health Center, IL148
Marshfield Medical Center-EC Cancer Center-Eau Claire, WI208
Kaiser Permanente-Vallejo, CA154
Kaiser Permanente Moanalua Medical Center, HI007
Maine Medical Center- Scarborough Campus, ME018
Northern Westchester Hospital, NY047
Sanford Broadway Medical Center, ND003
Montefiore Medical Center—Einstein Campus, NY313
Gundersen Lutheran Medical Center, WI029
Novant Health Breast Surgery - Greensboro, NC297
ThedaCare Regional Cancer Center, WI212
West Michigan Cancer Center, MI080

Study Resources:

Expedited Adverse Event Reporting [redacted]	**Medidata Rave® iMedidata portal** [redacted]
OPEN (Oncology Patient Enrollment Network) [redacted]	**Biospecimen Management System** [redacted]

Protocol Contacts:

A231901CD Nursing Contact

[redacted]

Protocol-related questions may be directed as follows:	
Questions	**Contact (via email)**
Questions regarding patient eligibility, treatment, and dose modification:	Study Chair, Nursing Contact, Protocol Coordinator, and (where applicable) Data Manager
Questions related to data submission, RAVE or patient follow-up:	Data Manager
Questions regarding the protocol document and model informed consent:	Protocol Coordinator
Questions related to IRB review	Alliance Regulatory Inbox [redacted]
Questions regarding CTEP-AERS reporting:	Alliance Pharmacovigilance Inbox [redacted]

CANCER TRIALS SUPPORT UNIT (CTSU) ADDRESS AND CONTACT INFORMATION

For regulatory requirements:	For patient enrollments:	For data submission:
Regulatory documentation must be submitted to the Cancer Trials Support Unit (CTSU) via the Regulatory Submission Portal. (Sign in at [redacted] and select the Regulatory > Regulatory Submission.) Institutions with patients waiting that are unable to use the Portal should alert the CTSU Regulatory Office immediately by phone or email: [redacted] to receive further instruction and support. Contact the CTSU Regulatory [redacted] for regulatory assistance.	Refer to the patient enrollment section of the protocol for instructions on using the Oncology Patient Enrollment Network (OPEN). OPEN is accessed at [redacted] Contact the CTSU Help Desk with any OPEN related questions by phone or email: [redacted]	Data collection for this study will be done exclusively through Medidata Rave. Refer to the data submission section of the protocol for further instructions. **For CRC/CRP interviews** do **not** submit study data or forms to the CTSU. Do **not** copy the CTSU on data submissions.

The most current version of the **study protocol and all supporting documents** must be downloaded from the protocol-specific page located on the CTSU members' website [redacted]

Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the Roster Maintenance application and in most cases viewable and manageable via the Roster Update Management System (RUMS) on the CTSU members' website.

For clinical questions (i.e., patient eligibility or treatment-related) see the Protocol Contacts, Page 3.

For non-clinical questions (i.e., unrelated to patient eligibility, treatment, or clinical data submission) Contact the CTSU Help Desk by phone or email:
CTSU General Information Line – [redacted] All calls and correspondence will be triaged to the appropriate CTSU representative.

IMPROVING PATIENT-CENTERED COMMUNICATION IN BREAST CANCER: A RCT OF A SHARED DECISION ENGAGEMENT SYSTEM (SHARES)

Patient Eligibility Criteria (see Section 3.2)

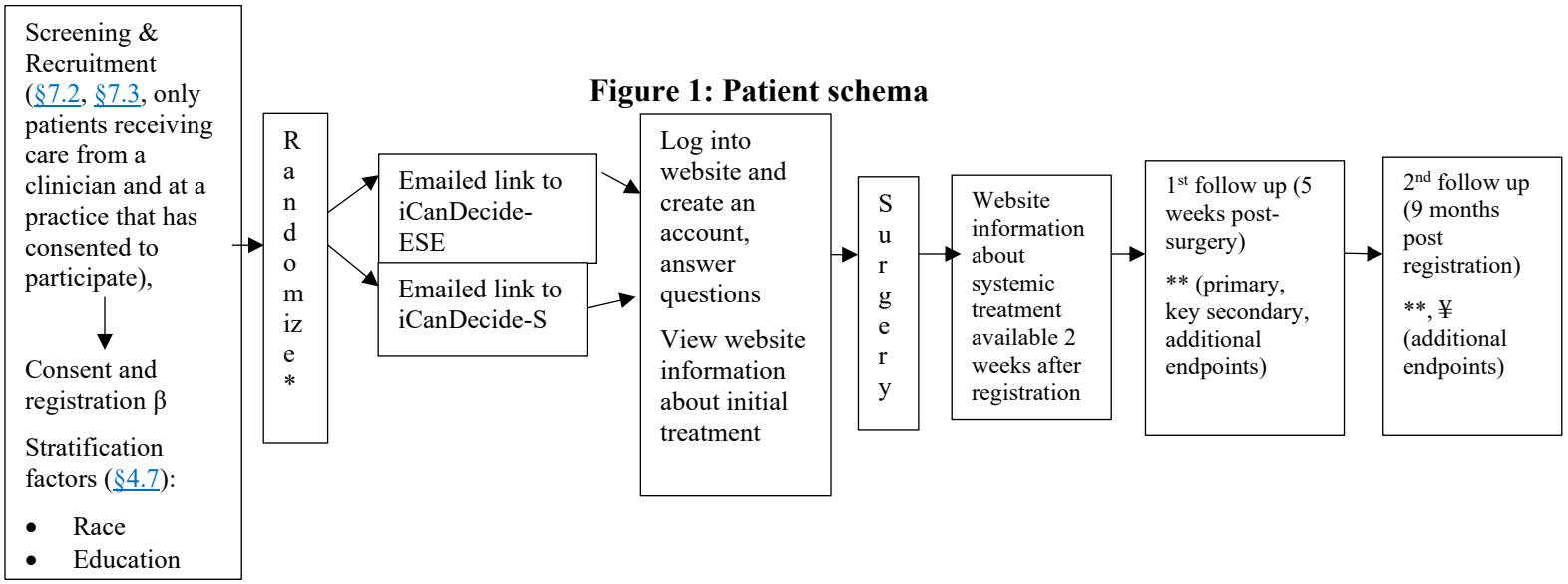
Required Initial Laboratory Values

None

- Women newly diagnosed with stage 0-III breast cancer (See §3.2.1).
- Planning breast surgery as a component of their definitive treatment
- Receives care from a clinician and at a practice that has consented to participate in the clinician dashboard practice-level intervention. (See §3.2.3)
- Patients who are visually impaired are not eligible. (See §3.2.4)
- Patients with impaired decision-making capacity (such as with a diagnosis of dementia or memory loss) are not eligible for this study.
- Patients must be able to read and speak English or Spanish.
- Age 21-84 years

This study will cross a patient-level randomization of an emotional support enhanced version of the iCanDecide breast cancer treatment decision tool (iCanDecide-ESE) vs. standard iCanDecide (iCanDecide -S) with a stepped wedge trial of a clinician dashboard (CDB) to promote patient centered communication.

Figure 1: Patient schema



β Patients may be consented and registered either **before** or **after** their surgical consult (as long as this occurs prior to making a treatment decision - although ideally patients should be consented before treatment decision making, they could still be consented **before** the surgical plan is finalized (as defined by institutional policies), if the surgeon believes the patient would benefit from the iCanDecide tool)

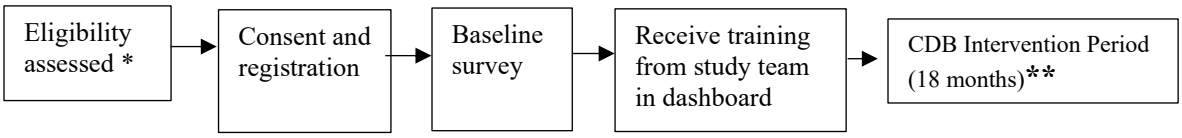
* Patient is emailed an activation link by the University of Michigan research team following randomization.

** Both "follow-up" surveys to be completed on an electronic device (or via paper booklet for those without devices).

¥ A subset of patients from both arms (who consent to participate in the optional process evaluation) will be contacted for a qualitative telephone interview by the University of Michigan research team.

Figure 2: Clinician schema

Eligibility (See Section 3.3): **Breast surgeons and their designee(s) (e.g., physician assistants, nurse practitioners, clinical nurse specialists, or nurses) that participate in the treatment decision-making process.** At least one surgeon at a practice must agree to participate and sign consent. S/he may then also identify a nurse, PA or APP (Advanced Practice Provider) with whom s/he works that is involved in the delivery of the care of the same patients to participate. Henceforth, in this protocol they will be referred to as "**clinicians**."

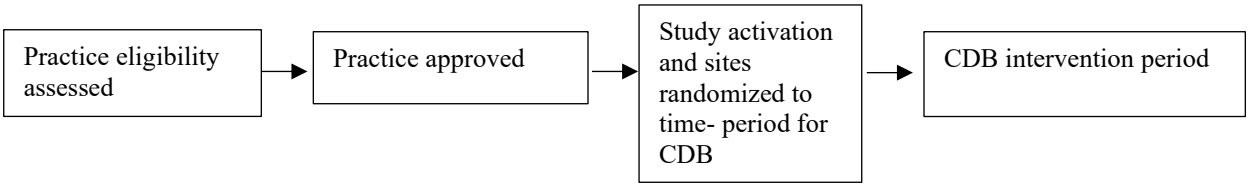


* Following confirmation of eligibility, clinicians will be consented and registered. At the Practice Orientation Visit (in person or virtually), CDB training will be offered.

** Clinicians will be asked to use the clinician dashboard (CDB) beginning in the month to which their practice was randomized and continuing to the end of the study. Follow up surveys will be conducted at 9 and 18 months following clinician registration.

Figure 3: Practice schema*

Eligibility (See Section 3.4): Surgical practice with an NCORP affiliation, and a corresponding CTEP ID



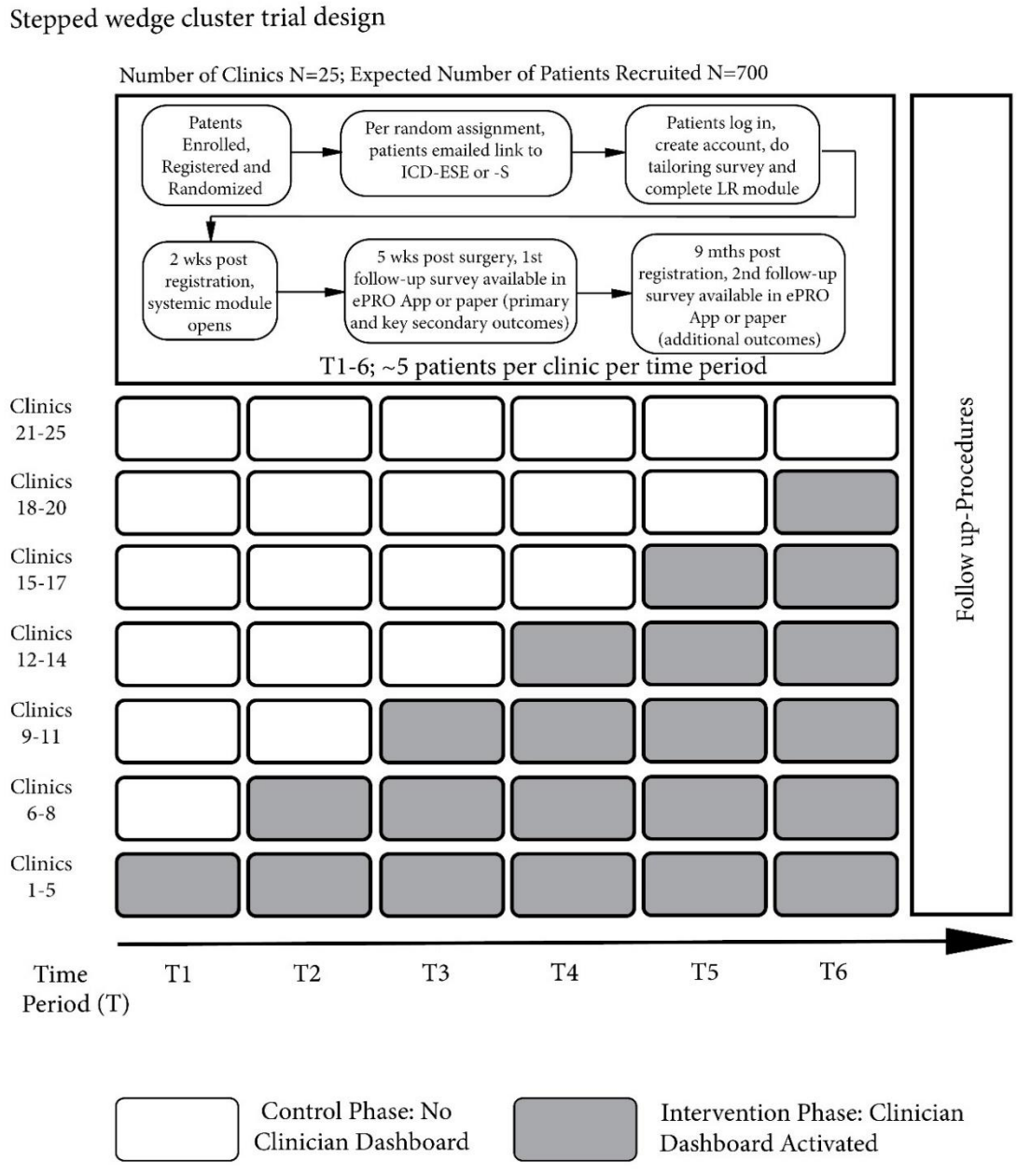
Practice eligibility (See Section 3.4)

- does breast cancer surgery
- not currently enrolling to A231701CD and
- at least one surgeon agrees to use the CDB. (See Section 3.3.1)

* Practices are identified by the study team prior to study activation and provided a description of the study. Approved practices will be randomized to timing of the dashboard intervention at the time that the study is activated. Practice randomization will be done by the Alliance Statistics and Data Center and there are no stratification or grouping factors that will be applied. See Figure 4 for full study schema.

Per the randomization scheme below, some practices may initiate the CDB right away, while others may initiate the CDB later or perhaps be randomized to "no CDB" period.

Figure 4: Depicts full study schema



Please refer to the full protocol text for a complete description of the eligibility criteria and study intervention plan.

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1.0 BACKGROUND

1.1 Introduction

Advances in precision medicine have given cancer doctors new evaluative tools to better individualize treatments for patients with curable breast cancer. At the same time, patients face a growing complexity of information related to a myriad of treatment decisions. The rapid cascade of decisions after diagnosis triggers powerful reactions to the disease threat and arduous management plan that cancer doctors must address. The National Coalition for Cancer Survivorship suggests that a diagnosis of cancer will create a "…state of crisis in nearly all individuals" magnified by the fact that most patients are ill-prepared for the emotional and cognitive demands associated with their diagnosis[1] [2]. In this context, advances in precision medicine cannot optimally improve health without parallel progress in patient-centered communication (PCC).

1.2 Patients need help to manage the complexity of information.

Although having an accurate understanding about treatment trade-offs is a key component of an informed decision, patients' knowledge is surprisingly low. In part, this is due to the complex and often overwhelming nature of the clinical information and treatment decisions a patient must make. Several breast cancer decision tools aimed exclusively at the patient have been developed and tested. In general, these patient-facing tools have been modestly successful at improving knowledge about treatment options. Indeed, our patient-facing decision tool ("iCanDecide") was effective in improving knowledge about complex treatment tradeoffs using an innovative "knowledge building" approach. We systematically built knowledge by first educating patients with very simple information about key facts related to their treatment; we found that 60% of patients in the intervention arm had high knowledge (using a categorical measure of knowledge divided into high vs. low, with high knowledge defined as 80% of knowledge items correct) 4 weeks after enrollment and treatment, compared with 42% who viewed a static version without knowledge building ($P<0.001$)[3]. Importantly, knowledge deficits are especially concerning in more vulnerable groups, such as those with lower educational attainment and racial/ethnic minorities (particularly those who are non-native English speakers)[4, 5]. We believe this knowledge building approach should be the standard of care for educating patients, and particularly for those most vulnerable to low knowledge where gains are most needed. However, with patient input we identified two additional strategies that merit inclusion in patient decision support tools: 1) supporting the emotional aspects of diagnosis, and 2) more directly engaging clinicians in the process of supporting shared decision-making.

1.3 Tools need to address and support patients' emotional needs.

The powerful role of emotion in decision-making has been well documented. This stems from the fact that decision-making at its core includes both emotional and rational processes [6, 7]. Moreover, failure to acknowledge emotion in decision-making may lead to suboptimal decisions that, while anchored in facts, may not be aligned with the individual's sense of self. Two underlying mechanisms for how emotions may influence medical decision-making are particularly important for this study. First, psychological processes, such as affective forecasting (i.e., trying to predict how one will feel in the future, leading to making decisions to avoid regretting something in the future") and catastrophizing (i.e., weighing what might happen) can lead to quick decisions favoring more extensive treatment that may not be medically necessary, and bias decisions away from patients' underlying values [8, 9]. Second, anxiety, distress and worry—always present with a cancer diagnosis—can make it difficult to accurately comprehend risk and benefit information. This is especially true in certain groups where knowledge deficits are biggest, such as those of lower educational attainment and racial/ethnic minorities [4-6, 10,

11]. Worry contributes to feelings of lack of control, and has been associated with choices for extensive treatment, reduced quality of life, financial toxicity, and distress [12-14]. We have found that when faced with a cancer diagnosis, many patients express a default preference to "get the cancer out" and an urgency for surgical treatment (e.g. to "achieve peace of mind") with low knowledge about the risks and benefits. This combination of worry and low knowledge can translate to choices for extensive treatment. Tools that address these underlying emotional drivers can allow patients to better process cognitive information and manage their worry, potentially helping them realize peace of mind with less extensive options.

1.4 Tools need to help clinicians identify their patients' cognitive and emotional needs.

A key gap in existing decision tools is that they have been developed for stand-alone use by a patient. Thus, the very tools designed to support shared decision-making place the onus on patients to bring up what they have learned from the tool with their clinicians. Yet, patients are often unaware of the gaps they have in their knowledge or about how their emotions may be influencing their treatment choices. Research has identified the need to provide clinicians with feedback regarding continued threats to poor decision-making, but to date, no patient decision tools have been integrated within a system to do this. Further, clinicians do not have tools that capture both cognitive and emotional needs of their patients. With pilot funding from our cancer center, our team has already developed and is testing a Clinician Dashboard (CDB) prototype that feeds back the patient experience with our current version of iCanDecide, including remaining knowledge deficits, values for treatment options, degree of anxiety and distress, and assessment of patient centered and overall communication with their clinicians. The CDB allows clinicians to identify patients who need follow up, or "circling back" with the goal of addressing these deficits and supporting patient-clinician communication.

1.5 Shared tools are needed to support patient-centered communication.

While our prior work showed the promise of iCanDecide, it revealed the need to broaden the concept of decision quality to focus on improving key aspects of PCC. Importantly, improving the process of decision-making and conceptualization of decision quality to encompass the full range of components of PCC as identified by the NCI and our own work may ultimately lead patients to feel more comfortable making treatment choices for less extensive but equally effective treatment. Doing so may also translate to longer term positive outcomes for patients, such as quality of life (QoL) and financial outcomes [15, 16]. Patients and clinicians need to be empowered to manage both the cognitive and emotional aspects of, and to share, these decisions. To this end, we propose to formally evaluate a Shared Decision Engagement System (SharES) that integrates the patient-facing, emotional support enhanced iCanDecide tool with a CDB. By partnering with the Alliance NCORP Research Base within the NCI Community Oncology Research Program (NCORP), we will be well positioned not only for successful completion of the proposed trial but for scalability and longer term dissemination throughout the NCORP network.

1.6 Conceptual framework

Our conceptual framework (Fig.5), describes the process by which SharES will impact key components of patient-centered communication (PCC) and the outcomes that will be achieved if successful. Our framework is informed by Lerner's framework for the role of emotion in decision making, Feldman-Stewart's model for patient-professional communication, and our preliminary studies[11, 17]. SharES will directly address 3 core focus areas that are aligned with the NCI's components of PCC and the areas that are not well met by existing decision tools. This will be done through enhancements to iCanDecide as well as through CDB features. Cognitive processing of information will be better through the support of patients' response to

emotion and enable them to manage their cancer-related worry. These primary focus areas will translate to improvements in knowledge, self-efficacy and worry, the primary outcomes of the SharES trial. We believe that, by addressing these areas, SharES will also support overall decision-making and relationship building, which will be assessed through the secondary outcomes of global constructs of PCC, specifically patient-clinician communication (the Health Care Climate questionnaire), Subjective Decision Quality (scale developed by our team in prior studies assessing patient-reported domains of satisfaction with information, involvement, time, process and regret with decision-making), and Patient Assessment of Cancer Communication Experiences (PACE), and values concordant treatment. We hypothesize that both components of SharES will have direct additive effects on these components of PCC. We will further assess the perception of the components of SharES from the perspective of patients and clinicians in our process evaluation.

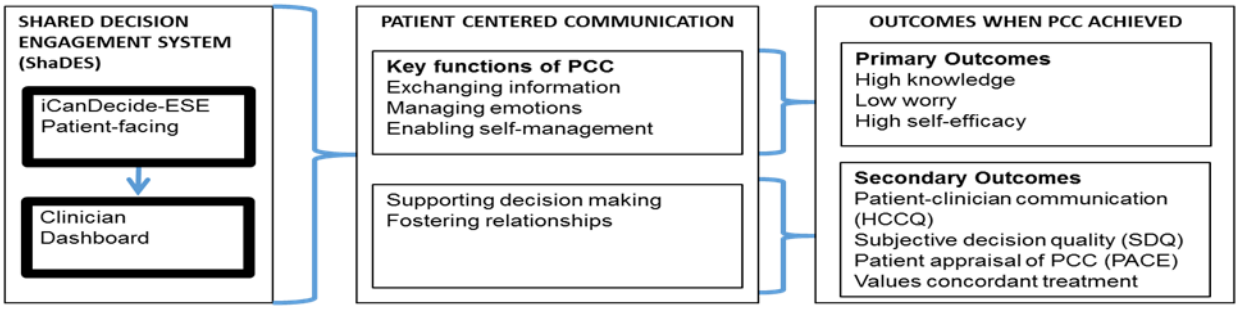


Figure 5. Conceptual Framework: Summary of how SharES will impact primary, key secondary and additional secondary outcomes

1.7 Gaps addressed in this study

This study will address two key gaps related to improving decision quality and outcomes in breast cancer and improve patient centered communication (PCC). We identified 2 major areas to enhance its impact and to fully support PCC: 1) helping manage the flood of patient emotional responses to a breast cancer diagnosis; and 2) closing the PCC loop by better connecting clinicians to the patient experience with the tool. The emotional responses (including anxiety and distress) can produce a sense of urgency in decision-making and distract patients from information processing (and knowledge attainment) and from their own underlying values. In addition, to achieve PCC, clinicians need to exchange information and help manage emotions. However, these issues have not been adequately addressed in existing tools. Therefore, we aim to enhance iCanDecide to engage patients both emotionally and cognitively, and to integrate it into breast oncology workflow by linking patient feedback to a Clinician Dashboard (CDB) already developed by our team.

1.8 Design considerations and preliminary data

Our team has conducted multiple RCT's of patient facing and clinician facing interventions. This includes the prior study on which SharES is based, the iCanDecide RCT. In fact, the control patient-facing intervention in SharES is the evidence-based intervention from the iCanDecide RCT. In preparing for SharES we considered several considerations. We recognize that this project is ambitious in nature, including an evaluation of both patient-facing and clinician-facing interventions in a multi-level trial. We have carefully thought through the potential challenges.

Will clinics enroll and clinicians use the CDB? We have spent the past 3 years laying the groundwork for this study with Alliance. To address this question, we engaged in extensive pilot work to understand breast surgeons' perceptions of the CDB and received extremely positive response from our Alliance survey of clinicians, as well as from 7 practices in the iCanDecide

trial and 2 additional practices. We engaged 9 surgeons and 2 nurse practitioners at these practices to use the CDB, as they desired to improve their communication skills wanted to use the CDB. All used the CDB and gave positive feedback and suggestions for refinement. Further, in preparation for this work, we conducted a survey in 2017 at the Alliance meeting which found strong interest from surgeons and providers among the 50 respondents in joining SharES when offered as a CCDR study, and using the CDB specifically. For the SharES study, we will follow the approaches used in our prior work to invite and engage surgeons in use of the CDB.

Can we enroll 700 patients? In the iCanDecide Trial[3], we exceeded our recruitment goals and had to turn away several clinics that wanted to enroll patients. We had extremely positive responses from patients who did enroll, and many asked to share the tool with friends and family. Practices need to identify only 5 patients per month, with only 4 enrolling in the study to meet our goals, a number very feasible based on experience.

Were other study designs considered? Several designs were considered for this complex study that includes both a patient-facing and a clinic-facing intervention randomization. The stepped wedge "minimax" design is preferred over a fully individually randomized design because it ensures that clinicians do not have some patients for whom they use the CDB and others that they do not. It maximizes power while having a true control set of clinics that never receive the CDB. We felt that a cross over design, that assumes the clinic effect goes away, was not feasible because there might be a carryover effect from using the CDB that would remain (e.g. enhanced clinician ability to deliver PCC). We strongly feel that the proposed design is the most effective for evaluating both intervention components separately and together.

1.9 Study Design Overview

This study is a multi-level trial of SharES that has two interventions in a factorial or crossed design: 1) an individually randomized patient-level RCT to evaluate the standard version (iCanDecide-S) vs. a version with innovative emotional support enhancements (iCanDecide-ESE), and 2) a clinic-level stepped-wedge cluster randomized trial to test a Clinician Dashboard (see Section 12.1 and Fig. 4). In a post-test design with primary and secondary outcomes obtained from patient report 5 weeks post patient surgery, we will evaluate the components of SharES in 700 patients (600 evaluable) in 25 practices. The study will take 5 years, with trial field work taking 18 months.

2.0 OBJECTIVES

(See also Table in Appendix XII)

Because this study includes two interventions (the patient-facing decision tool and the clinician facing dashboard), there are several objectives, since the intent is to measure the impact of each intervention separately on the primary, key secondary and additional endpoints, at 2 time points. The 1st follow up assessment (5 weeks post patient surgery) is when primary and key secondary endpoints/objectives are assessed. The 2nd follow up assessment (9 months post registration) is when additional objectives are assessed. The table in Appendix XII outlines these objectives and endpoints.

2.1 Co-primary Objectives

There are 2 co-primary objectives for this study, which relate to evaluating the impact of each of the 2 components of the SharES intervention (patient facing iCanDecide tool, clinician dashboard) on the primary outcome/endpoint knowledge about locoregional treatment, measured at **the 1st follow up assessment** 5 weeks post patient surgery:

1. To demonstrate that the enhanced iCanDecide (iCanDecide-ESE) intervention is more effective than the standard version (iCanDecide-S) resulting in higher patient knowledge about locoregional treatment risks and benefits.
2. To demonstrate that the activation of the clinician dashboard (CDB) is more effective than not using a CDB, resulting in higher patient knowledge about locoregional treatment risks and benefits.

2.2 Secondary Objectives

2.2.1 Key Secondary Objectives

There are 2 key secondary objectives for this study, which relate to evaluating the impact of each of the 2 components of the SharES intervention (patient facing iCanDecide tool, clinician dashboard) on the **two** key secondary outcomes/endpoints self-efficacy and cancer worry measured at **the first follow up assessment** 5 weeks post patient surgery:

1. To demonstrate that the enhanced iCanDecide (iCanDecide-ESE) intervention is more effective than the standard version (iCanDecide-S), resulting in higher patient-reported breast cancer self-efficacy and lower patient reported cancer worry.
2. To demonstrate that the activation of the clinician dashboard (CDB) is more effective than not using a CDB, resulting in higher patient-reported breast cancer self-efficacy.

2.2.2 Additional Secondary Objectives

The additional secondary objectives relate to evaluating the impact of each of the 2 components of the SharES intervention (patient facing iCanDecide tool, clinician dashboard) on the **three** patient centered communication outcomes/endpoints patient-clinician communication, subjective decision quality, and patient centered communication measured at **the 1st follow up assessment** 5 weeks post patient surgery:

1. To evaluate whether the enhanced iCanDecide (iCanDecide-ESE) intervention is more effective than the standard version (iCanDecide-S), resulting in better appraisal of global patient centered communication related to locoregional treatment, specifically: higher scores on patient-clinician communication (surgeon), subjective decision quality for locoregional treatment, patient centered communication and values concordant treatment.

2. To evaluate whether the activation of the Clinician Dashboard (CDB) is more effective than not using a CDB, resulting in better appraisal of global patient centered communication, specifically, higher scores on patient-clinician communication, (for surgeon), subjective decision quality for locoregional treatment, patient centered communication and values concordant treatment.

2.3 Exploratory objectives (related to the 2nd follow up assessment)

The exploratory objectives relate to evaluating the impact of each of the 2 components of the SharES intervention (patient facing iCanDecide tool, clinician dashboard) on the outcomes/endpoints measured at **the 2nd follow up assessment** 9 months post patient registration that relate to two domains 1) systemic treatment decision making (knowledge regarding systemic treatment, self-efficacy, and cancer worry, global patient appraisal of patient centered communication (patient-clinician communication for the oncologist, appraisal of PCC, subjective decision quality for systemic treatment), and 2) overall Quality of Life (QoL). The timing of the 9 month assessment was set based on prior work, to ensure sufficient time following systemic treatment to answer questions regarding systemic treatment decision making, and to assess overall QoL further out in time following both locoregional and systemic treatment (vs. assessing QoL in the midst of treatment). These exploratory objectives are:

Exploratory objectives related to systemic treatment decision making

2.3.1 To evaluate whether the enhanced iCanDecide (iCanDecide-ESE) intervention is more effective than the standard version (iCanDecide-S) resulting in higher patient knowledge about systemic treatment decision making, higher breast cancer self-efficacy and lower cancer worry.

2.3.2 To evaluate whether the activation of the clinician dashboard (CDB) is more effective than not using a CDB, resulting in higher patient knowledge about systemic treatment decision making, higher breast cancer self-efficacy and lower cancer worry.

2.3.3 To evaluate whether the enhanced iCanDecide (iCanDecide-ESE) intervention is more effective than the standard version (iCanDecide-S) resulting in higher global patient appraisal of patient centered communication (patient-clinician communication for the oncologist, appraisal of PCC, subjective decision quality for systemic treatment).

2.3.4 To evaluate whether the activation of the clinician dashboard (CDB) is more effective than not using a CDB, resulting in higher patient appraisal of patient centered communication (patient-clinician communication for the oncologist, appraisal of PCC, subjective decision quality for systemic treatment).

Exploratory objectives related to Quality of life

2.3.5 To evaluate whether the enhanced iCanDecide (iCanDecide-ESE) intervention is more effective than the standard version (iCanDecide-S) resulting in higher patient reported Quality of Life.

2.3.6 To evaluate whether the activation of the clinician dashboard (CDB) is more effective than not using a CDB, resulting in higher patient reported Quality of Life.

2.4 Other exploratory Objectives

2.4.1 **Synergistic effects:** To explore potential synergistic effects of the two interventions combined (i.e., interaction of iCanDecide-ESE and CDB effects) on primary and key secondary objectives.

2.4.2 **Mediation analysis:** To examine mediators of the primary endpoint (knowledge about locoregional treatment) and key secondary endpoints (cancer worry, self-efficacy) and to examine the association between primary and key secondary endpoints and global appraisal of PCC (additional endpoints) assessed at the 1st follow up assessment.

2.4.3 **Process evaluation:** To conduct a process evaluation guided by the Consolidated Framework for Implementation Research (CFIR) of the two intervention components (patient facing decision tool, clinician dashboard) including qualitative feedback from both patients and clinicians regarding their user experience and paradata (e.g., time on page) to inform scalability and future implementation of the system. We will also collect quantitative data via clinician surveys that will assess attitudes regarding the impact of the CDB intervention. Further detail on the Process Evaluation (eligibility, data collection methods, analysis) is provided in Section 7.3.6. and 8.2.3.

3.0 PATIENT SELECTION

For questions regarding eligibility criteria, see the Study Resources page. Please note that the Study Chair cannot grant waivers to eligibility requirements.

3.1 On-Study Guidelines

This clinical trial can fulfill its objectives only if patients appropriate for this trial are enrolled. All relevant medical and other considerations should be taken into account when deciding whether this protocol is appropriate for a particular patient.

3.2 Patient Eligibility Criteria

Use the spaces provided to confirm a patient's eligibility by indicating Yes or No as appropriate. It is not required to complete or submit the following pages.

___ **3.2.1 Women newly diagnosed with stage 0-III breast cancer.** Although men are recommended to undergo surgery to treat breast cancer, male breast cancer is relatively rare and decision making for breast cancer surgery is quite different between men and women.

___ **3.2.2 Planning breast surgery as a component of their definitive treatment.**

___ **3.2.3 Receives care from a clinician and at a practice that has consented to participate in the clinician dashboard practice-level intervention.**

Practices/clinicians will consent initially at the initiation of the study. (See Section 3.3.1) Patients will then be identified and recruited in those practices. If a practice has more than one clinician doing breast surgery, patients will be recruited from those clinicians who consent (one or more). Patients of clinicians who have not consented will not be eligible.

___ **3.2.4 Patients who are visually impaired are not eligible, as they must be able to access the study intervention on a website at home or in clinic and view the decision aid.**

___ **3.2.5 Patients with impaired decision-making capacity (such as with a diagnosis of dementia or memory loss) are not eligible for this study.**

___ **3.2.6 Patients must be able to speak English or Spanish with the fluency required to have a direct discussion around treatment decision-making (i.e. without interpreter)**. ***Sites seeking to enroll Spanish- speaking patients must have Spanish speaking staff on site or through the use of a translation service to be able to conduct the informed consent discussion in Spanish.***

___ **3.2.7 Age 21-84 years.**

3.3 Clinician Stakeholder (Surgeons and Clinic Staff) Eligibility Criteria

3.3.1 Clinicians eligible for this study include: breast surgeons and their designee(s) (e.g., physician assistants, nurse practitioners, clinical nurse specialists, or nurses) that participate in the treatment decision-making process. At least one surgeon at a practice must agree to participate and sign consent. S/he may then also identify a nurse, PA or APP with whom s/he works that is involved in the delivery of the care of the same patients to participate. **Henceforth, in this protocol they will be referred to as "clinicians."**

3.3.2 Clinicians must agree to have their patients recruited for the entire time the study is open at their practice, which will include time periods in which the clinicians will and time periods in which they will not have access to the CDB. (See Figure 4 for full study schema).

3.4 Practice Eligibility

The study will utilize the National Cancer Institute Community Oncology Research Program (NCORP). Eligible clinics will be surgical practices where initial locoregional treatment (breast surgery) decision-making is done. Twenty-five surgical clinics will be recruited to participate across NCORP to obtain a representative and diverse cohort of patients.

3.4.1 Practices that annually provide surgical care for over 100 patients newly diagnosed with breast cancer are eligible to participate in this study.

3.4.2 Practices currently enrolling to Alliance A231701CD are not eligible to participate in this study.

3.4.3 Eligible practices must have at least one surgeon who agrees to participate in the study. See Section 3.3.1.

3.5 CRA/Research Staff Eligibility

3.5.1 Participants must have worked on the SharES study to participate in these interviews.

4.0 PATIENT REGISTRATION

4.1 Investigator and Research Associate Registration with CTEP

Food and Drug Administration (FDA) regulations require sponsors to select qualified investigators. National Cancer Institute (NCI) policy requires all individuals contributing to NCI-sponsored trials to register with their qualifications and credentials and to renew their registration annually. To register, all individuals must obtain a Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) account at [redacted]. Investigators and clinical site staff who are significant contributors to research must register in the [redacted] (RCR). The RCR is a self-service online person registration application with electronic signature and document submission capability.

RCR utilizes five person registration types.

- Investigator (IVR) — MD, DO, or international equivalent;
- Non Physician Investigator (NPIVR) — advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD);
- Associate Plus (AP) — clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications such as the Roster Update Management System [RUMS], OPEN, Rave, acting as a primary site contact, or with consenting privileges;
- Associate (A) — other clinical site staff involved in the conduct of NCI-sponsored trials; and
- Associate Basic (AB) — individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems.

RCR requires the following registration documents:

Documentation Required	IVR	NPIVR	AP	A	AB
FDA Form 1572	✓	✓			
Financial Disclosure Form	✓	✓	✓		
NCI Biosketch (education, training, employment, license, and certification)	✓	✓	✓		
GCP training	✓	✓	✓		
Agent Shipment Form (if applicable)	✓				
CV (optional)	✓	✓	✓		

IVRs and NPIVRs must list all clinical practice sites and Institutional Review Boards (IRBs) covering their practice sites on the FDA Form 1572 in RCR to allow the following:

- Addition to a site roster;
- Selection as the treating, credit, or drug shipment investigator or consenting person in OPEN;
- Ability to be named as the site-protocol Principal Investigator (PI) on the IRB approval; and
- Assignment of the Clinical Investigator (CI) task on the Delegation of Tasks Log (DTL).

In addition, all investigators acting as the Site-Protocol PI (investigator listed on the IRB approval), consenting/treating/drug shipment investigator in OPEN, or as the CI on the DTL must be rostered at the enrolling site with a participating organization.

Refer to the [redacted] page on the [redacted] for additional information. For questions, please contact the **RCR Help Desk** by email at [redacted].

Note: All participating surgeons, (as consenting and treating providers), will need to be rostered.

Clinicians designated by the surgeon (see Section 3.3.1) who will not be consenting patients will be considered research subjects. Rostering is not required for these individuals.

4.2 CTSU Site Registration Procedures

Permission to view and download this protocol and its supporting documents is restricted and is based on the person and site roster assignment housed in the Roster Maintenance application and in most cases viewable and manageable via the Roster Update Management System (RUMS) on the Cancer Trials Support Unit (CTSU) members' website.

This study is supported by the NCI CTSU.

IRB Approval

As of March 1, 2019, all U.S.-based sites must be members of the NCI Central Institutional Review Board (NCI CIRB) in order to participate in Cancer Therapy Evaluation Program (CTEP) and Division of Cancer Prevention (DCP) studies open to the National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) Research Bases. In addition, U.S.-based sites must accept the NCI CIRB review to activate new studies at the site after March 1, 2019. Local IRB review will continue to be accepted for studies that are not reviewed by the CIRB, or if the study was previously open at the site under the local IRB. International sites should continue to submit Research Ethics Board (REB) approval to the CTSU Regulatory Office following country-specific regulations.

Sites participating with the NCI CIRB must submit the Study Specific Worksheet (SSW) for Local Context to the CIRB using IRBManager to indicate their intent to open the study locally. The NCI CIRB's approval of the SSW is automatically communicated to the CTSU Regulatory Office, but sites are required to contact the CTSU Regulatory Office at [redacted] to establish site preferences for applying NCI CIRB approvals across their Signatory Network. Site preferences can be set at the network or protocol level. Questions about establishing site preferences can be addressed to the CTSU Regulatory Office by email or calling [redacted]

In addition, the Site-Protocol Principal Investigator (PI) (i.e., the investigator on the IRB/REB approval) must meet the following criteria for the site to be able to have an Approved status following processing of the IRB/REB approval record:

- Have an active CTEP status;
- Have an active status at the site(s) on the IRB/REB approval (*applies to US and Canadian sites only*) on at least one participating organization's roster;
- If using NCI CIRB, be active on the NCI CIRB roster under the applicable CIRB Signatory Institution(s) record;
- Include the IRB number of the IRB providing approval in the Form FDA 1572 in the RCR profile;

- List all sites on the IRB/REB approval as Practice Sites in the Form FDA 1572 in the RCR profile; and
- Have the appropriate CTEP registration type for the protocol.

4.2.1 Additional site registration requirements

Additional site requirements to obtain an approved site registration status include:

- An active Federal Wide Assurance (FWA) number;
- An active roster affiliation with the Lead Protocol Organization (LPO) or a Participating Organization (PO);
- An active roster affiliation with the NCI CIRB roster under at least one CIRB Signatory Institution (US sites only); and
- Compliance with all applicable protocol-specific requirements (PSRs).

4.2.2 Protocol-Specific Requirements for A231901CD Site Registration

Limited access information

This is a limited access study. Institutions will be identified prior to activation.

Institutional randomization

Each of the 25 participating clinics will be randomized to timing of dashboard intervention at start of study, with the understanding that some may initiate the CDB right away, while others may initiate the CDB later or even be randomized to "no CDB" period. See Figure 4. The Alliance Statistics and Data Center will randomize institutions once an institution is interested and eligible to participate. There are no stratification factors that will be applied.

Patients will be enrolled at participating clinics during the full duration of the study and all enrolled patients will receive a version of the decision support tool. These patient-level activities are not influenced by the timing of the clinic-level randomization to the CDB.

Practice Survey of Site-Level Attributes

For the sites participating in the NCORP Cancer Care Delivery Research (CCDR) trials, the enrolling NCORP affiliate/subaffiliate will complete the *NCORP Practice Survey of Site-Level Attributes Form* and submit it to the CTSU Regulatory Office as a *Specific Sites only* submission using the Regulatory Submission Portal located in the Regulatory section of the CTSU members' website. The form will collect various attributes about the enrolling NCORP affiliate/subaffiliate. All questions on the form must be complete and the distribution for the analytic cases question must equal 100%. (See form for directions.) The form must be received and completed for site registration approval in the Regulatory application. The *NCORP Practice Survey of Site-Level Attributes Form* requirement is submitted once for participation on all NCORP CCDR trials, but expires two years after it is received. NCORP sites will need to resubmit the Practice Survey Form to the CTSU to continue to enroll to CCDR trials.

4.2.3 Downloading Site Registration Documents

Download the site registration forms from the protocol-specific page located on the CTSU members' website. Permission to view and download this protocol and its supporting documents is restricted to institutions and their associated investigators and staff on a participating roster. To view/download site registration forms:

- Log in to the CTSU members' website [redacted]);

- Click on *Protocols* in the upper left of the screen:
    - Enter the protocol number in the search field at the top of the protocol tree; or
    - Click on the By Lead Organization folder to expand, then select *Alliance*, and protocol number *A231901CD*.
- Click on *Documents, Protocol Related Documents,* and use the *Document Type* filter and select *Site Registration* to download and complete the forms provided. (Note: For sites under the CIRB, IRB data will load automatically to the CTSU.)

4.2.4 Submitting Regulatory Documents

Submit required forms and documents to the CTSU Regulatory Office using the Regulatory Submission Portal on the CTSU members' website.

To access the Regulatory Submission Portal log in to the CTSU members' website, go to the *Regulatory* section and select *Regulatory Submission*.

Institutions with patients waiting that are unable to use the Regulatory Submission Portal should alert the CTSU Regulatory Office immediately by phone or email: [redacted] to receive further instruction and support.

4.2.5 Checking Site's Registration Status

Site registration status may be verified on the CTSU members' website.

- Click on *Regulatory* at the top of the screen;
- Click on *Site Registration;* and
- Enter the sites 5-character CTEP Institution Code and click on Go:
    - Additional filters are available to sort by Protocol, Registration Status, Protocol Status, and/or IRB Type.

Note: The status shown only reflects institutional compliance with site registration requirements as outlined within the protocol. It does not reflect compliance with protocol requirements for individuals participating on the protocol or the enrolling investigator's status with NCI or their affiliated networks.

4.3 Patient Registration Requirements

4.3.1 Informed consent

The patient must be aware of the neoplastic nature of her disease and willingly consent after being informed of the study intervention, the experimental nature of the intervention, alternatives, potential benefits, side-effects, risks, and discomforts. Current human protection committee approval of this protocol and a consent form is required prior to patient consent and registration.

4.3.2 Patient-reported outcomes

This study includes the use of the mandatory patient completed measures. The measures are available in English and Spanish. Participation in Alliance A231901CD is restricted to patients who are able to speak, read and understand these languages. It is preferred that patients complete questionnaires using ePRO, but paper questionnaire booklets will also be available if needed for patients who choose not to use a device.

Electronic patient reported outcomes (ePRO): This study includes the use of ePRO, (electronic patient-reported outcomes). After the patient is registered to the trial, the Clinical Research Professional (CRP) will complete a second registration to the Patient Cloud application. The consent form will specify that there will be two account creations in this study: 1) patient cloud and 2) iCanDecide. The CRP will create a unique patient registration code by accessing the Patient Cloud through iMedidata Rave. Patients (with assistance from CRPs) will need to download the Patient Cloud ePRO app on their own device and use the unique registration code given by the CRP to create an account. Once completed, the patient will be able to complete the submission of patient reported outcomes electronically.

Prior to registration, the patient should be asked about the availability of an electronic device and willingness to complete the patient-reported questionnaires on the device. The patient should be informed that the same method of completion must be used by the patient throughout the duration of the study for all time points. See Appendix I for further instructions on setting up Patient Cloud.

The patient will be requested and provided instruction to contact the study team should she no longer have a device during the study, or obtains a new device. The CRP will assist on a 1:1 basis in these scenarios (E.g. providing a paper booklet if needed, helping re-install patient cloud on new device).

If sites intend to use a shared institutional device, the CRP can assist the patient with access and registration to the Patient Cloud ePRO app, with the patient completing the electronic data submission independently. Detailed instructions are included in Appendix I. If patients will be using devices supplied by the institution, CRPs will need to help the patient log into the device.

Patient questionnaire booklets

Patient questionnaire booklets are to be ordered prior to the registration of any patients. Patient completed booklets can be ordered by downloading and completing the CTSU supply request form (located under the site registration documents section of the A CTSU web site) and submitting it through the CTSU regulatory portal. Samples of the booklets are found in Appendices III- V, which are to be used for reference and IRB submission only. They are not to be used for patient completion.

4.3.3 Protected health information

For local site HIPAA documentation, please note that the following personal health information (PHI) will be released outside of the Alliance. In order to be able to send an activation link and gift cards to all participants (both patients and clinicians), the following information will be collected, and destroyed upon completion of the study:

- **Email address:** Upon patient/non-patient registration in OPEN, the patient's email address (es) and the clinician's email address will be sent to the University of Michigan research team.
- **Patient ID and date of surgery:** The OPEN generated patient ID and date of surgery of the patient (once available) will be sent to the University of Michigan research team in order for them to distribute gift cards.
- **Patient ID and name:** Upon Clinician consent and registration in OPEN, the clinician's name and patient ID (generated after registration in OPEN) will be sent to the University of Michigan research team, to initiate access to the CDB.

- **Telephone number:** For patients and clinicians who choose to participate in the process evaluation at the end of the study, their phone numbers will be collected and sent to the University of Michigan research team.

As described in Section 7.0, the University of Michigan team will be notified when a patient enrolls and will be able to obtain their email address in order to send the randomized link (iCanDecide-ESE or iCanDecide-S).

4.4 Patient Enrollment

The Oncology Patient Enrollment Network (OPEN) is a web-based registration system available on a 24/7 basis. OPEN is integrated with CTSU regulatory and roster data and with the LPOs' registration/randomization systems or the Theradex Interactive Web Response System (IWRS) for retrieval of patient registration/randomization assignment. OPEN will populate the patient enrollment data in NCI's clinical data management system, Medidata Rave.

Requirements for OPEN access:

- Active CTEP registration with the credentials necessary to access secure NCI/CTSU IT systems;
- To perform enrollments or request slot reservations: Must be on an LPO roster, ETCTN corresponding roster, or participating organization roster with the role of Registrar. Registrars must hold a minimum of an Associate Plus (AP) registration type;
- If a Delegation of Tasks Log (DTL) is required for the study, the registrars must hold the OPEN Registrar task on the DTL for the site; and
- Have an approved site registration for the protocol prior to patient enrollment.

To assign an Investigator (IVR) or Non-Physician Investigator (NPIVR) as the treating, crediting, consenting, drug shipment (IVR only), or receiving investigator for a patient transfer in OPEN, the IVR or NPIVR must list the IRB number used on the site's IRB approval on their Form FDA 1572 in RCR. If a DTL is required for the study, the IVR or NPIVR must be assigned the appropriate OPEN-related tasks on the DTL.

Prior to accessing OPEN, site staff should verify the following:

- Patient has met all eligibility criteria within the protocol stated timeframes; and
- All patients have signed an appropriate consent form and Health Insurance Portability and Accountability Act (HIPAA) authorization form (if applicable).

Note: The OPEN system will provide the site with a printable confirmation of registration and treatment information. You may print this confirmation for your records.

Access OPEN at [redacted] or from the OPEN link on the CTSU members' website. Further instructional information is in the OPEN section of the CTSU website at [redacted] For any additional questions, contact the CTSU Help Desk at [redacted]

4.5 Institutional Registration/ Randomization

Each of the 25 participating practices will agree to participate (identifying at least one surgeon to use the CDB) and be randomized to a designated CDB intervention period (understanding that that one group will be randomized to "never use" the CDB). See Figure 4.

Non-patient <*Provider*> enrollments, for this trial will be completed using OPEN. All OPEN access requirements also apply to non-patient enrollments.

Prior to enrollment, site staff should verify the following:

- Non-patient participant (Practice) has met all eligibility criteria within the protocol stated timeframes

In the OPEN credentialing screen, select the registration type of *Non-Patient* and select the applicable non-patient type <*Provider*>. Complete the non-patient enrollment prerequisite questions (if applicable) and the associated eligibility checklist and submit the enrollment.

The OPEN system will provide a printable confirmation of the non-patient registration and additional instructions as needed. You may print this confirmation for your records.

Non-patient enrollments should be linked to the patient enrollment. Go to the history screen and select the patient enrollment. On the summary screen, click on Link or Unlink Non-patients. Select the non-patient at the site that the patient enrollment should be associated with and click *Save*.

4.6 Provider (Clinician) registration procedures

Clinicians will be identified during the practice selection process. (See Section 3.3.1). Following local IRB approval of this study, clinicians will be consented to participate in practice implementation activities (learning to use the CDB), baseline survey, follow up surveys, and audio recording of the process evaluation interview should they participate.

Non-patient <*Provider*> enrollments, for this trial will be completed using OPEN. All OPEN access requirements also apply to non-patient enrollments.

Prior to enrollment, site staff should verify the following:

- Non-patient participant has met all eligibility criteria within the protocol stated timeframes; and
- All non-patients have signed an appropriate consent form and HIPAA authorization form (if applicable).

In the OPEN credentialing screen, select the registration type of *Non-Patient* and select the applicable non-patient type <*Provider, Other Professional Discipline, Institution and/or Caregiver*>. Complete the non-patient enrollment prerequisite questions (if applicable) and the associated eligibility checklist and submit the enrollment.

The OPEN system will provide a printable confirmation of the non-patient registration and additional instructions as needed. You may print this confirmation for your records.

Non-patient enrollments should be linked to the patient enrollment. Go to the history screen and select the patient enrollment. On the summary screen, click on Link or Unlink Non-patients. Select the non-patient at the site that the patient enrollment should be associated with and click *Save*.

Note: Once the clinician (provider/other professional discipline) is enrolled in OPEN, the site coordinator should send the clinician's OPEN generated patient ID and the first and last name to [redacted] within 5 business days of registration.

They may also provide the above information to the UM SharES team at [redacted] and leave a voicemail.

4.7 Site CRCs/CRAs registration procedures

CRCs/CRAs who have worked on the A231901CD study will be identified and will be contacted regarding participating in qualitative process interviews (see Section 8.4).

Non-patient <*Other Professional Discipline* > enrollments, for this trial will be completed using OPEN. All OPEN access requirements also apply to non-patient enrollments.

Prior to enrollment, site staff should verify the following:

- Non-patient participant has met all eligibility criteria within the protocol stated timeframes; and
- All non-patients have signed an appropriate consent form and HIPAA authorization form (if applicable).

In the OPEN credentialing screen, select the registration type of *Non-Patient* and select the applicable non-patient type *<Other Professional Discipline>*. Complete the non-patient enrollment prerequisite questions (if applicable) and the associated eligibility checklist and submit the enrollment.

The OPEN system will provide a printable confirmation of the non-patient registration and additional instructions as needed. You may print this confirmation for your records.

4.8 Stratification Factors and Intervention Assignments

The randomization routine for patient randomization is found in Section 12.2 (Statistical Considerations).

Practice randomization is done at time of identification of 25 participating surgical clinics as described in Section 8.0 (See Figure 3). There are no planned stratification factors for practices.

4.8.1 Stratification Factors

Patients will be stratified before randomization by factors that may be associated with differential impact of the intervention components:

- Race (White; African American; Other).
- Education status (≤ High School, some college, college grad or more)

There are no stratification factors for the clinician dashboard.

4.8.2 Intervention Assignments

The grouping factors are as follows:

Patient level: iCanDecide + emotional support enhancements (iCanDecide -ESE) vs. iCanDecide standard version (iCanDecide -S).

Clinic Level: Clinician Dashboard (CDB) currently in use at the site (mark one):

- **Yes**
- **No (usual care)**

4.9 Procedures for Double-Blinding the Patient Intervention Assignment

After the patient intervention assignment has been ascertained by randomization, following registration in OPEN, the University of Michigan research team will be notified of the assignment. The patient will be emailed the activation link to the decision tool website based on the randomization assignment. From the patient perspective, the decision tool website will be called iCanDecide regardless of the arm to which they are randomized (iCanDecide-ESE vs iCanDecide-S). Patient participants will follow their link to a general "iCanDecide" website and will not know whether their link goes to the intervention (iCanDecide-ESE) or control (iCanDecide-S). Clinicians at practices will know that their patients will have access to a patient-facing decision tool component, but Clinicians will not know to which arm the patient is randomized. *This is because both versions of iCanDecide populate the same information into*

the CDB (the clinician facing dashboard). The enhanced content of the ESE version is available to the patient, but does not populate differently into the CDB, allowing clinicians to remain blinded to the patient-level randomization arm. There is no planned "unblinding" of the patient-facing component.

The practice staff will not be involved in delivering the intervention or assessment of outcomes.

Practices will be randomized to the CDB intervention period at the time of study activation. Because of this, the practices and their clinicians will know when they are using the CDB so the clinician level intervention will not be blinded.

5.0 STUDY CALENDARS

5.1 Patient-level Study Calendar

	At time of Surgical Consultation†	5 weeks post-surgery*	9 months post registration	9-12 months post registration
Consent and Registration	X			
Randomized to iCanDecide-ESE vs. iCanDecide-S	X (1)			
Tailoring Survey	X (2)			
First follow up survey		X (3)		
Second follow up survey			X (3)	
Process evaluation interviews				X (4)

† Registration may occur before or after surgical consultation, as long as patient is consented prior to making a treatment decision.

* **Patients who choose ePRO** will be asked to enter their date of surgery into Patient Cloud, or the site coordinator will be queried by the data manager to enter the date of surgery on the form, "Complete this form with your Date of Surgery" within the "ePRO (5 weeks Post Surgery)" folder in Medidata Rave. (See Section 7.3.4 for instructions).

1 Patient will be sent an activation link for creation of account for the iCanDecide website by UM research team.

2 Web-based: The tailoring survey is delivered by UM research team via iCanDecide website as part of the intervention, following randomization; see Appendix XI. These questions are completed on the iCanDecide website.

3 To be completed using ePRO or paper booklets. See Section 4.3.2 to register patients to the ePRO patient cloud and Appendices I and II for further instructions. To review a copy of the measures, see Appendices III and IV. **For patients who choose to use paper booklets**, the site coordinator must remind the patient to complete the booklets. See Section 7.3.5 for information about reminders sent to participants to improve response rates.

4 Administered by UM research team to a subset of patients who consent to the optional interview.

5.2 Practice and Clinician Level Study Calendar

	Prior to 1st Patient enrollment	Baseline	Month 9 post clinician registration	Month 18 post clinician registration	Post CDB Intervention
Practice survey (clinic characteristics)	X				
Clinician recruitment	X				
Clinician training	X (1)				
Baseline clinician survey		X (2)			
1st clinician survey (regardless of time period of intervention)			X (3)		
2nd clinician survey (regardless of time period of intervention)				X (3)	
Clinician process evaluation interviews					X (4)

1 Clinicians will be trained about 4 weeks before their practice begins use of the CDB. (See Section 8.1.2).

2 To be completed within 2 weeks of clinician registration via paper booklets; see Appendix V to review copy of the survey.

3 To be completed on paper booklets, See Appendix VI for copy of the survey. Reminders will be sent by the study team. (See Section 11.3.1)

4 To be completed by telephone by the UM research team, only for clinicians who agree to participate in the optional interviews.

6.0 DATA SUBMISSION

6.1 Data Submission to the Alliance

6.1.1 Data submission schedule

A Data Submission Schedule (DSS) is available on the Alliance study webpage, within the Case Report Forms section.

The Data Submission Schedule is also available on the CTSU site within the study-specific Case Report Forms folder.

6.1.2 Medidata Rave

Medidata Rave is the clinical data management system being used for data collection for this trial/study. Access to the trial in Rave is controlled through the CTEP-IAM system and role assignments.

Requirements to access Rave via iMedidata:

- Active CTEP registration with the credentials necessary to access secure NCI/CTSU IT systems; and
- Assigned a Rave role on the LPO or PO roster at the enrolling site of: Rave CRA, Rave Read Only, Rave CRA (LabAdmin), Rave SLA, or Rave Investigator.

Rave role requirements:

- Rave CRA or Rave CRA (Lab Admin) role must have a minimum of an Associate Plus (AP) registration type;
- Rave Investigator role must be registered as a Non-Physician Investigator (NPIVR) or Investigator (IVR); and
- Rave Read Only or Rave SLA role must have at a minimum an Associate (A) registration type.

Refer to [redacted] for registration types and documentation required.

Upon initial site registration approval for the study in the Regulatory application, all persons with Rave roles assigned on the appropriate roster will be sent a study invitation email from iMedidata. To accept the invitation, site staff must either click on the link in the email or log in to iMedidata via the CTSU members' website under *Data Management > Rave Home* and click to *accept* the invitation in the *Tasks* pane located in the upper right corner of the iMedidata screen. Site staff will not be able to access the study in Rave until all required Medidata and study-specific trainings are completed. Trainings will be in the form of electronic learnings (eLearnings) and can be accessed by clicking on the eLearning link in the *Tasks* pane located in the upper right corner of the iMedidata screen. If an eLearning is required for a study and has not yet been taken, the link to the eLearning will appear under the study name in the *Studies* pane located in the center of the iMedidata screen; once the successful completion of the eLearning has been recorded, access to the study in Rave will be granted, and a *Rave EDC* link will replace the eLearning link under the study name.

Non-patient enrollments will be populated in a substudy associated with the main study in Medidata Rave. Upon initial site registration approval for the main study in the Regulatory application, all persons with Rave roles at the participating sites will receive an invitation to the main study and all associated substudies in Rave. To accept the invitation to the

substudy, follow the same instructions identified for accepting the invitation to the main study. All non-patient data will be entered in the Rave substudy.

Site staff who have not previously activated their iMedidata/Rave account at the time of initial site registration approval for the study in the Regulatory application will receive a separate invitation from iMedidata to activate their account. Account activation instructions are located on the CTSU website in the *Data Management* section under the Rave resource materials (*Medidata Account Activation and Study Invitation Acceptance*). Additional information on iMedidata/Rave is available on the CTSU members' website in the *Data Management > Rave* section or by contacting the CTSU Help Desk at [redacted]

6.1.3 Data collection summary table

Since this study involves multiple levels of data collection submitted on different platforms, the following table illustrates the process:

Data collection type	Who is Collecting	Where to submit
Clinician baseline survey (paper booklet)	Site staff collects paper booklets	Medidata Rave
Clinician 1st and 2nd follow up assessments (9, 18 months) (paper booklets)	Site staff collects paper booklets	Medidata Rave
Patient tailoring survey responses (part of the iCanDecide intervention for both arms)	UM research team on website	Patient enters into website after account creation
Patient first follow up –5 weeks post-surgery (patient cloud ePRO or paper booklets)	Patients provide responses in ePRO, or site staff enters data for paper booklets	Medidata Rave
Patient 2nd follow up – 9 months post registration (patient cloud ePRO or paper booklets)	Patients provide responses in ePRO, or site staff enters data for paper booklets	Medidata Rave
Clinic level data (clinic characteristics) (Section 10.7)	Site staff	Medidata Rave
Aggregate data related to screening and enrollment (including non-participants)	Site staff	Medidata Rave
List of patients who decline participation with limited demographics (de-identified)	Site staff	UM data center
Process evaluation: Audio files of qualitative telephone interviews (subset of patients)	UM research team	UM research team to upload PDF transcripts to Medidata Rave
Process evaluation: Audio files of qualitative telephone interviews (subset of clinicians)	UM research team	UM research team to upload PDF transcripts to Medidata Rave
iCanDecide paradata, data on iCanDecide website usage	UM research team	UM data center
CDB paradata, data on CDB usage	UM research team	UM data center
Process evaluation: Audio files of qualitative telephone or Zoom interviews (including non-participants [i.e., consenting CRAs/CRCs])	UM research team	UM data center

6.1.4 Data Quality Portal

The Data Quality Portal (DQP) provides a central location for site staff to manage unanswered queries and form delinquencies, monitor data quality and timeliness, generate reports, and review metrics.

The DQP is located on the CTSU members' website under Data Management. The Rave Home section displays a table providing summary counts of Total Delinquencies and Total Queries. DQP Queries, DQP Delinquent Forms, DQP Form Status and the DQP Reports modules are available to access details and reports of unanswered queries, delinquent forms, forms with current status, and timeliness reports. Site staff should review the DQP modules on a regular basis to manage specified queries and delinquent forms.

The DQP is accessible by site staff who are rostered to a site and have access to the CTSU website. Staff who have Rave study access can access the Rave study data via direct links available in the DQP modules.

CTSU Delinquency Notification emails are sent to primary contacts at sites twice a month. These notifications serve as alerts that queries and/or delinquent forms require site review, providing a summary count of queries and delinquent forms for each Rave study that a site is participating in. Additional site staff can subscribe and unsubscribe to these notifications using the CTSU Report and Information Subscription Portal on the CTSU members' website.

To learn more about DQP use and access, click on the Help Topics button displayed on the Rave Home, DQP Queries, DQP Delinquent Forms, DQP Form Status, and DQP Reports modules.

6.2 Data Transmission between the Alliance and University of Michigan

All practice and patient level data collected by site staff will be entered into Medidata Rave. This section describes transmission of data that is collected outside Rave, and the security of this data transmission.

6.2.1 Data submission from the University of Michigan to Alliance Statistics and Data Center

The University of Michigan Center for Health Communications Research (CHCR) will host the websites for patient (iCanDecide-ESE and S) and clinician (CDB). CHCR is a 20-year center with deep experience in web based tool development and data transfer. CHCR will create a study portal using an encrypted channel.

Audio recordings from patient and clinician process evaluations will be transcribed to text and linked to the de-identified study ID.

The UM research team (Study Chair and Co-Chair) will be conducting the process evaluation interviews via telephone and they will be audio recorded. These audio files will then reside with the UM research team.

The audio-files will then be transcribed in their entirety. Although identifying information may exist on the audio files, transcriptionists will strip all identifying information once transcribed and will only have access to the subject ID that is assigned by study staff (no access to the patient-subject log or other identifying information). Study staff members or outside contractors with a business associate agreement who have been approved by UM Legal Services/Privacy Officer for HIPAA compliance will be used for transcription. After data analysis is complete and manuscripts have been accepted for publication, the audio

recordings will be destroyed and the de-identified transcripts will be stored indefinitely on a secure server.

The transcripts will be uploaded into Medidata Rave in pdf format by the UM research team.

6.2.2. Data submission from the Alliance Statistics and Data Center to the University of Michigan

Once the primary analysis is complete and the primary manuscript is published, the final and complete de-identified datasets may be sent to the University of Michigan research team via the Alliance data sharing policy.

6.3 Submission of Patient Completed Measures

It is strongly recommended that patients are encouraged and offered the option of completing the measures using ePRO (5 week and 9-month follow up surveys).

Paper booklets should be offered only to those patients who are not willing and/or are unable to use an electronic device for completion of questionnaires. Booklets must be given to patients to complete at home and patients should be instructed to return the booklets by mail within 2 months of completion or to return the booklets at their regularly scheduled clinic visit. Institutions must provide patients with sufficient self-addressed stamped envelopes for this purpose. Site staff will enter patient responses into Rave upon receipt of the completed booklets.

6.3.1 Medidata patient cloud ePRO registration

This study includes the use of Medidata Patient Cloud electronic patient-reported outcomes (ePRO). After the patient is registered to the trial via OPEN and if the patient is willing to participate in electronic data collection, practice staff will then complete a registration for the patient to the Patient Cloud ePRO through iMedidata. Note: Site staff must have already completed required eLearning for the Patient Cloud ePRO application to register a patient and information about the training is in the ePRO Appendix (Appendix I). The registration to the Patient Cloud ePRO will create a unique patient registration code that site staff will provide to the patient. The patient participants (with assistance from practice staff) will be instructed to download the Patient Cloud ePRO app onto her own device (IOS or Android, phone or tablet) and use the unique patient registration code to create an account. Once the patient's account is set up, the patient will be able to complete the submission of patient reported outcomes electronically for the trial.

Submission of measures completed using the patient cloud app: Data from the patients' responses are submitted directly from the device into the Rave database. There are no documents to audit. The electronic responses are the source documentation.

6.3.2 Paper booklets

Patient-completed questionnaire booklets for this study are to be ordered prior to the registration of any patients (see Section 4.3). Samples of questionnaire booklets are available in Appendix III- V for reference and IRB submission only. They are not to be used for patient completion. Booklets must be given to patients to complete and patients should be instructed to return the booklets to site staff either in person or by mail and site staff will enter patient responses into Medidata Rave. At visits in which booklets are to be completed, the booklet should be given to the patient before any discussion of the patient's health status or test results. The PRO submission schedule is provided in the Study Calendar.

6.3.3 Patient Language Considerations

The patient surveys are available in English and Spanish. Participation in Alliance A231901CD is restricted to patients who are able to speak and understand these languages. The translated measures are available on the A231901CD CTSU and Alliance study pages. Ad-hoc translation of patient-completed measures is not permitted.

7.0 PATIENT INTERVENTION

This is a patient-level randomization of iCanDecide-emotional support enhancement (iCanDecide -ESE) vs. iCanDecide-standard (iCanDecide -S) imbedded within a practice-level stepped wedge randomization of the clinician dashboard (CDB) over time.

For questions regarding intervention, please see the study contacts page.

7.1. Patient facing iCanDecide intervention (iCanDecide -ESE vs. iCanDecide -S) and tailoring survey

The patient facing decision tool used in this study is called iCanDecide and was developed by [redacted] the study team and experts in the UM Center for Health Communications Research[18]. The tool was originally developed to be used on a desktop or laptop computer, and has been updated to be mobile optimized so it can be easily used on a mobile device (iPhone or Android). As part of this project, it will be translated into Spanish.

Tailoring survey: The **tailoring survey, which is part of the intervention,** is done immediately after patients create an account on the iCanDecide platform, following registration and randomization. This survey is part of the patient-facing web platform and includes a brief question set that allows for tailoring of content within the iCanDecide decision tool (Appendix XI). At the time of login into the iCanDecide decision tool, we will collect information from all patients. However, this data will only be used to tailor information and content for patients randomized to the iCanDecide-ESE arm. These data include: maximizer-minimizer scale, worry level, whether patient has seen her surgeon (yes/no), and her desired role in decision making (patient-driven, shared, doctor-driven), her personality with regard to medical care (do you prefer to do everything, do you prefer to "act now"). Answers to these questions will be used to tailor content and use normalizing statements (e.g., "It is completely normal to have a high level of worry at the time of diagnosis and it is important to find ways to manage this worry (such as modules they will be directed to in the tool)".

There is no data collected in this first tailoring survey that is used for primary outcomes analysis. Data obtained from this survey will be sent to Alliance via the process described in Section 6.2.

Decision tool: The standard iCanDecide decision support tool (iCanDecide-S) was previously tested and shown effective for improving knowledge about breast cancer treatment decision making and preparing patients to make a treatment decision[19]. iCanDecide- ESE, the new intervention being tested is an "emotional support enhanced" version of the standard, proven-effective, iCanDecide. This previously tested version is being used as the control, or "standard" (S) version for this study.

In the initial trial of the iCanDecide tool, all patients (100%) in the intervention arm (which is the current standard arm for SharES) completed at least one use of the locoregional module tool, while 93% of patients in the control arm (standard website) completed at least one use. Patients took on average 46 minutes (SD: 27 minutes) to view the iCanDecide intervention, and 21 minutes (SD: 17 minutes) to view the control. Nearly 90% of patients in both arms of this trial reported that the tool was easy to use.

Each version of iCanDecide (both the –ESE and the –S version) has 5 general sections, corresponding to an expanded version of Elwyn's shared decision-making model (connect, choice, options, decision and summary). The proven effective iCanDecide-S version has been updated to include new content related to breast cancer treatment, including genetic testing. The iCanDecide-ESE version includes additional features that support the key functions of PCC outlined in our conceptual framework for each of the 5 sections. These include two modules specifically designed to address the emotions, worry and distress associated with a breast cancer diagnosis: 1) expectation management and 2) worry management. Each of these new sections includes established methods for emotional regulation and worry management (e.g., cognitive behavioral therapy, use of norm reinforcement, mindfulness). Users of both versions move through sections in a linear way. The iCanDecide -ESE version will include all the content delivered in the iCanDecide -S version, but will use established strategies to support the two emotional support components: expectation and worry management.

Both versions of iCanDecide populate the same information into the CDB that is viewable by surgeons/clinicians at the surgical practice. Patients may create PDF versions of any sections of either version of the tool, that are printable and able to be shared with other cancer clinicians (medical, radiation oncologists) or family members.

Both the patient and the practice and clinicians will be blinded as to which arm the patient is assigned to, according to Section 4.8.

More detail regarding the intervention components can be found in Appendix XI.

IT support: Patients registered for the study will have access to IT/technical support from the U-M Center for Health Communications Research through a 1-800 number and email option, provided on the log in page.

7.2. Screening for eligibility

Patient eligibility for this study begins at the time of their first scheduled surgical consultation, among those patients of surgeons who have consented to participate. Patients of consented surgeons will be eligible regardless of what time period the surgeon/practice is randomized to use of the CDB.

Each week, surgeons, clinical personnel, and the practice's research coordinator, will pre-screen patients coming to see clinic surgeons who have consented. Screening will occur through contact with service teams as well as through medical chart review.

7.3. Patient consent, enrollment and follow up

7.3.1. Patient consent process

Practice staff will recruit eligible patients when a surgery consult is scheduled and maintain a log of all patients who are offered participation. Eligible patients will be those patients of clinicians (See Section 3.3.1) who have consented to this study.

In person recruitment: Eligible patients will be identified and introduced to the study in person at participating practices by research personnel. They will be consented on site. If meeting the patient in person is not feasible, the site may follow NCI CIRB SOPs to implement a **remote consenting** process. Patients should be informed that the study involves creation of an account on the iCanDecide website and an account that will generate an App on the patient's device (ePRO – patient cloud) for collection of follow up data. Following consent, participants will be registered in OPEN.

Mail or email recruitment (optional): Some practices may choose to mail or email a letter introducing the study to patients in advance of their arrival to clinic. This would likely be

for logistical reasons and planning of clinical workflow. This letter would invite patients to contact the research coordinator in advance of the clinic appointment to learn more about the study. This letter would allow contact with the patient prior to their presentation in clinic to enroll and follow the steps outlined above for randomization and account creation.

Optional patient recruitment flyers for sites to use will be posted on the study specific website.

Importantly, patients can be registered either before or after their surgical consult (as long as the patient is consented prior to making a treatment decision and registered prior to receiving surgery) depending on clinic preference and workflow, as the tool content is specifically tailored to the timing of the surgical consult.

7.3.2 Creation of account and delivery of intervention following patient registration/randomization

After registration, the below steps will occur:

- The patient's randomization assignment (iCanDecide-ESE vs. -S) after applying the stratification factors in Section 4.7 will be sent to the UM team from CTSU OPEN. **Neither the patient, her surgeon nor the practice will know to which arm the patient is assigned (See Section 4.8).**
- The website activation link specific to the patient's randomization (iCanDecide-ESE vs. -S) will be emailed to the patient's email address that was collected at the time of registration by the UM research team.
- **Patient log in:** Patients will then log in and create a study account (using their email and making their own password). Patients will do this at home or on their mobile device, as this allows the most flexibility for viewing the tool (see note below). For patients who prefer using the clinic iPad, they may need to return to the clinic at a later time.
- **Tailoring Survey:** Following the first account creation, patients will complete a short tailoring survey (see above) as part of the intervention content delivery (Appendix XI). This survey provides needed information for content that is delivered in both versions (ESE and S); for example, whether the patient is leaning toward a particular treatment. This survey does not collect information used for primary analyses.
- **Internet access:** Patients who report difficulty with internet access at home, or who do not have a computer or device will be offered the option of viewing the intervention in clinic on an iPad, after account creation (note, this may require a return visit to the clinic). It may also be viewed on a device owned by a friend or family member, or in a public library. Patients who require this option will need to receive follow up assessments via paper booklets. As noted above, participants will be encouraged to do the intervention from home or on their mobile device.
- Both versions of iCanDecide will be available in English and Spanish.

Note addressing "dose" of intervention: After initial account set up, patients may use the website as many times as they choose. They may use it just once or return to it multiple times. The website may be used on a laptop, home computer or mobile phone (purposely developed to be mobile optimized so it can be used on either an iPhone or Android). Patient participants who view the tool on a device provided by the clinic, a friend or family member or in the library may receive a lesser "dose" of the intervention. The opportunity to include

patients with differential access is felt to be more important than limiting the study only to patients with their own devices. The type of device used will be collected (personal, friend/family, library, clinic iPad) and included in analyses to address this issue. We will also be able to gauge dose from "paradata" (user experience data obtained from the website itself).

7.3.3. Study team procedures following patient randomization

Following randomization in OPEN, the study chairs and University of Michigan coordinators (rostered with Alliance) will have access to OPEN which will contain a cumulative report. The report will be in EXCEL format, and will include the Alliance study number. The fields in this report will include: patient ID, patient email address, enrollment date, arm assignment, enrolling site name, treating investigator (surgeon) name, CTEP ID of the treating investigator and Grouping Factor. Language should also be collected here, in order to deliver the appropriate language intervention to the patient. The institution CTEP ID where patient enrollment occurred will also be sent to the UM research team. The study chairs and UM designee will be alerted to participant enrollment via NCI CRISP notifications on the CTSU website. Once the University of Michigan team members log in to OPEN, they will download the cumulative EXCEL file. The University of Michigan team will then activate an email to the participant that includes the link to the correct version of the website, based on study arm assignment. This will happen within one business day (24 hours) of a notification of participant enrollment. (See Section 7.3.2 for delivery of intervention process). If the UM team observes that the patient has not logged in and created an account on iCanDecide, a reminder email will be sent every day, with up to 4 email reminders total. After the 4th reminder email, patients may still log in and create an account, but there will be no further reminders from the U-M team. Any registered patient will receive the 1st and 2nd follow up survey assessments. We will follow an intention to treat approach, using all available data, regardless whether patients created an account on iCanDecide or viewed/used the tool. We are really testing a "strategy" rather than the effectiveness of the tool. As such, a tool may only be effective if patients are able to access/use it. Therefore, all patients should receive the follow-up questionnaires.

7.3.4 Surgical consultation and surgery

As noted above (Section 7.3.1), patients may be registered to the study before or after their surgical consultation— (as long as patient is consented prior to making a treatment decision and registered prior to receiving surgery).

Patients must have completed the surgery before completing the follow up surveys.

Site coordinator: If the surgery date is not scheduled at the time of enrollment, please contact the patient within 48-72 hours to see if there is further information regarding a scheduled surgery.

If the receipt of neoadjuvant therapy is not known at the time of registration, please contact the patient within 12 weeks to see if there is further information regarding the receipt of neoadjuvant therapy. If the patient will receive neoadjuvant therapy, please contact the patient in 12 weeks to see if the patient has completed neoadjuvant therapy and has received surgery. If unknown, please return and answer this question in Medidata Rave once the decision has been made about receipt of neoadjuvant therapy. The date of surgery must be entered in Rave as soon as this information is known.

Note: The site coordinator should contact the UM study team as soon as they have the patient's date of surgery, and send them this information along with the Patient ID, by

email to [redacted]. They may also provide the above information to the UM SharES team at [redacted], and leave a voicemail.

7.3.5. Patient Surveys

There are **two follow up surveys (quantitative)** to assess the study objectives.

- The **1st follow up survey** is done 5 weeks post-surgery (assessment of the primary, key secondary and additional secondary endpoints/outcomes).

  For patients who complete the survey using the ePRO (Patient Cloud) application:

  At 5 weeks following the date of surgery, the first follow-up survey will be activated in Patient Cloud and will stay active until 12 weeks following the date of surgery. All participants will receive notification when the survey becomes available at 5 weeks post-surgery and the expectation is that the survey is completed at 5 weeks post-surgery. However, patients will receive automatic notifications once 50%, 75%, and 90% of the remaining time has elapsed until the survey is completed. The UM study team will be given information on patient completion by the Alliance Statistics and Data Management Center, in order to email the e-gift card to participants.

  For patients who complete the survey using paper booklet:

  At 5 weeks following the date of surgery, the first follow-up survey is expected to be completed. Because the expectation is to complete the survey at 5 weeks post-surgery, the site coordinator will notify the patient via email or telephone once the patient reaches the 5-week mark post-surgery. Further, all participants will be sent two reminder emails by the site coordinator, one at 8 weeks after surgery and another at 12 weeks after surgery. The UM study team will be given information on patient completions by the Alliance Statistics and Data Management Center, in order to email the e-gift card to participants.

- The **2nd follow up survey** is done about 9 months post-registration and assesses additional secondary outcomes.

  For patients who complete the survey using the ePRO (Patient Cloud) application:

  At 9 months following the date of patient registration, the second follow up survey will be activated in Patient Cloud and will stay active until 11months following the date of patient registration. All participants will receive notification when the survey becomes available at 9 months post registration and the expectation is that the survey is completed at 9 months post-registration. However, patients will receive automatic notifications once 50%, 75%, and 90% of the remaining time has elapsed until the survey is completed. The UM study team will be given information on patient completion by the Alliance Statistics and Data Management Center, in order to email the e-gift card to participants.

  For patients who complete the survey using paper booklet:

  At 9 months following the date of patient registration, the second follow-up survey is expected to be completed. Because the expectation is to complete the survey at 9 months post-registration, the site coordinator will notify the patient via email or telephone once the patient reaches the 9-month mark post- registration. Further, all participants will be sent two reminder emails by the site coordinator, one at 10 months post registration and another at 11 months post registration. The UM study

team will be given information on patient completions by the Alliance Statistics and Data Management Center, in order to email the e-gift card to participants.

For both follow up surveys, patients will complete these measures using the ePRO (Patient Cloud) application. This will be installed on their device at the time of registration. It will take about 25 minutes to complete the surveys. The follow up assessments will be described in the consent form including time taken to complete, and made clear that patients need to create an account and place this application on their device. Those who are not able/willing to use their mobile device will have the option of completing assessments on a paper booklet sent via regular mail.

7.3.6 Qualitative patient interviews: optional process evaluation component

Following completion of the stepped wedge trial component, an optional qualitative process evaluation will be done, with both patients and clinicians (See Section 3.3.1). Process evaluation is essential to understand how the interventions were used and how SharES could be adapted for broader dissemination and implementation.

As done in [redacted] prior intervention trial work,[19, 20] in this study, we will apply the Consolidated Framework for Implementation Research (CFIR) to identify and assess contextual factors that influence adoption and implementation[21] of SharES. The CFIR includes 39 constructs relating to 5 domains. We will give particular emphasis to elements contained within domain #1 (i.e., +/- characteristics of the intervention) and #5 (engaging of key stakeholders in implementation process) to understand key constructs of reach, engagement, satisfaction, and effectiveness of both components of SharES.

Interview procedures:

The UM research team (study chair and co-chair) will re-contact a random sample of patients in both arms via email, who consented to be re-contacted to participate in the optional process evaluation at the time of registration and initial consent. We anticipate contacting 5-8 patients in study time period (CDB intervention period) by group (intervention/control) for a total of 35-40 patient participants.

The UM research team (study chair and co-chair, project coordinator) will then conduct telephone interviews. Guiding questions, developed by the study team based on CIFR domains mentioned above, are included in Appendix VIII. Interviews will be audio recorded with consent. The UM team will also review paradata of usage of both arms of the tool (time on tool, pages viewed, completeness).

Qualitative analysis:

Interview recordings will be transcribed at UM. Transcripts will be reviewed by the study team (Chair, co-chair and investigators) for key dimensions related to the potential for dissemination using qualitative analysis software (NVivo). We are not planning a formal qualitative evaluation, as our numbers of interviewees in each group (patients, clinicians) will be too low to generate a clear set of themes. Rather, the goal of these qualitative process evaluation interviews is to inform refinement and preparation of each component of the SharES system, based on input from user stakeholders, for implementation.

7.4. Patient Incentives

Patients will be given a $20 e-gift card following the creation of an account on the iCanDecide website. Patients will be provided a log-in link by email by the UM research team (following consent and enrollment), to create an iCanDecide account. Patients will also receive a $20 e-gift card for each follow-up assessment. The incentives for each follow up survey will be electronic

gift cards that can be emailed upon completion of the survey. An additional $20 will be sent electronically for those who participate in the qualitative interviews. The maximum incentive would be $80 per patient.

Research Activity	**Amount**	**Incentive delivery coordinated and sent by the University of Michigan (UM) Team**
Patient consent and registration	$20	E-gift ($20) delivered via email to patient after creation of account
Patient follow-up surveys at 5 weeks and 9 months	$20	E-gift ($20) delivered via email to patient by UM team for each of two surveys completed
Patient qualitative interviews (telephone by UM study team)	$20	E-gift ($20) delivered via email to patient by UM team after interview

7.5 Collection of limited data for non-consenting patients

Aggregate Data: Site staff will collect the total number of patients who were offered participation in the study, and the total number of new patients seen in the clinic per month. These data will be collected until the study is closed to accrual. This data will be submitted in Medidata Rave and used to calculate reach of the intervention (e.g., participation rate, enrollment rate).

Screening logs: Practices will develop and maintain a separate log of the following information:

If patients decline to participate in a research activity, the research coordinator will record limited information about them including age, race, ethnicity and reason for declining. These data points will be collected so that we may assess whether participants are categorically different than non-participants. This data is completely de-identified. As these patients have declined research, they will not be approached for future research activities. This decline applies only to that specific research activity and any subsequent research activities. The decline does not apply to any prior data collection unless specified by the patient. Every 3 months, these de-identified data will be sent to the University of Michigan study team via email as an Excel .xlsx spreadsheet, or as a scan of a paper document.

8.0. PRACTICE LEVEL INTERVENTION

8.1 Clinician Dashboard (CDB)

The Clinician Dashboard (CDB) is a web platform viewable by clinicians (see Section 3.3.1) that populates with information following the patient's use of either version of iCanDecide (iCanDecide-ESE and iCanDecide-S versions). The CDB provides clinicians an online platform that summarizes their own patients': 1) lingering knowledge deficits (incorrect items on the selected knowledge questions), 2) values that are misaligned with planned treatment, and 3) an indicator of the emotional state of the patient (score ≥ 4 on the distress thermometer, determined to be clinically meaningful anxiety). It also offers a write-in for unanswered questions. Importantly, the CDB will alert clinicians to the emotional state of the patient and help to identify reasons for it. The CDB is configured so that it can be used before or after the patient's first visit (or both) and can be used by surgeons or other clinicians who engage in treatment decision-making (See Section 3.3.1).

CDB training will be conducted about 4 weeks before the practice begins use of the CDB, with the study chairs making future practice visits as needed. In our pilot work and Alliance survey, surgical practices expressed strong interest in using the CDB.

After activation of the CDB at each clinic, participating clinicians will receive alerts when a patient has completed the patient-level intervention (iCanDecide -ESE or S). These alerts will be sent via email and will simply let them know a patient has completed the tool, and will not include any PHI. The clinician may then log into the CDB using the secure and password protected account to view their patients' reports. These reports will be listed in the CDB starting with the most recent. This process will continue for the duration of the CDB intervention period for that clinic. Clinicians will utilize the CDB for patient care as they find useful.

Rationale for clinician enrollment to surgeons and designees: Although the SharES trial will be deployed in surgical practices (where most patients initiate breast cancer care), we recognize the key role of radiation and medical oncologists in treatment decision-making and will engage them in several important ways. First, both tool versions have information on radiotherapy as well as a comprehensive module on systemic treatment, including knowledge building, values clarification and patient activation. While it is not feasible to deploy a formal dashboard for radiation and medical oncologists in this study (as well as breast surgeons), all patients have options to either 1) print out a PDF summary of any lingering issues and questions for bringing to upcoming radiation or medical oncology visits, 2) enter an email or fax number of their to have this PDF directly sent to another provider. Second, because radiation and some medical oncologists may be involved in locoregional treatment planning, patients will have a similar option of having the summary page of the locoregional module also printed, emailed or faxed to providers. Finally, we will collect patient-reported appraisal of radiation and medical oncologist engagement in both follow-up assessments to illuminate strategies to incorporate oncologists into an integrated dashboard system. Our process evaluation will also assess strategies for CDB integration across specialties.

More detail on the intervention components can be found in Appendix XI.

Technical Support: At the time of study registration, clinicians will create a secure and password protected account for their own participant's output. Clinicians are notified via email after one of their patients has viewed iCanDecide (iCanDecide -ESE or iCanDecide -S) and the platform releases alerts to notify clinicians of issues noted above. The alerts do not include any PHI, but only alert that a patient has completed iCanDecide. In preparation for this project, we conducted pilot testing of this CDB in 9 surgical practices, with 9 surgeons and 2 nurse practitioners who used the CDB easily and found it was useful for their practice.

Clinicians in the study will have access to IT/technical support from the U-M Center for Health Communications Research through a 1-800 number and email option provided on the log in page.

8.1.1 Prior to CDB intervention period—Usual Care

After study activation, the 25 participating practices will be randomized to time period for use of the clinician-level intervention (the clinician dashboard CDB) in groups of 3-5 (See Section 12.1 and Figure 4). When not in their identified CDB intervention period, sites will continue to provide breast cancer surgical care per their usual care. [Note: during this time, patients may be enrolling into the patient level intervention, see Section 7.0].

8.1.2 Clinic level planning

Surgical practices will be enrolled and randomized to start the intervention in different time periods. To optimize power (see Section 12.0 for sample size calculations), we use a specific stepped wedge design in which of the 25 anticipated clinics participating in this study, 5 will use the CDB the entire time, 5 will never use it, and the remainder will be active for varying periods (Fig. 4). For a clinic intervention like the CDB, the stepped wedge design is preferred over individually randomizing patients, ensuring that clinicians do not have some patients for whom they get CDB and others for whom they do not. It maximizes power, while eventually including most of the clinics in the intervention, through a staggered role out that puts less strain on the central study support team than if all intervention practices were activated at once.

Practice Orientation Visits: Any surgical practice affiliated with an NCORP site, with a clinician willing to use the CDB (See Section 3.3.1) and identify approximately 5 patients every 12 weeks (and ideally register) can participate. The study team will conduct Practice Orientation Visits (in person or via virtual means, such as Zoom) to meet with clinicians at practices, give an overview of the study and use of the CDB and answer questions about SharES as a CCDR offering through Alliance (which are required for affiliated sites). At least one clinician per practice must be willing to use the CDB and be able to enroll patients. Those interested and willing must also agree to then be randomized to use CDB during one of the 6 study periods, or to be one of the 5 practices that do not receive it as described above (See also Section 12.1).

At the time of study activation, the 25 participating practices will be randomized to time period for use of the clinician-level intervention (CDB) in groups of 3-5 (See Section 12.1 and Figure 4).

CDB Training: Practice clinicians will be oriented to the CDB by study co- chairs 4 weeks prior to their CDB intervention period. During the entire 18-month study period, patients will be registered and randomized to the patient-level intervention at all 25 practices. Practices are encouraged to approach 5 or more patients per clinic per time period and register 4 of these patients during this time if possible. In our pilot work and Alliance survey, surgical practices expressed strong interest in using the CDB. Participating clinics will receive iPads for use by patient or clinicians. They will also receive $1,000.

8.2 Clinician enrollment, consent and follow up

8.2.1 Clinician enrollment and consent

Lists of NCORP surgical practices and surgical personnel will be used to invite surgeons to participate in the study. Practice invitation will be done at Alliance meetings, and by outreach from the UM study chairs with Alliance CCDR support. All prospective clinician participants will be contacted by the Study chair or co-chair in person (at meetings), or via

phone. Surgeons will be provided information about the study and asked if s/he would be interested in scheduling an in-person or virtual (e.g., Zoom) meeting with the study team to discuss the study.

Breast surgeons and designees (i.e., clinicians, see Section 3.3.1) from NCORP surgical practices willing to participate in use of the clinician dashboard may participate together for the same or different patients. Each clinician will be counted as individual participants and complete baseline and follow up surveys. We anticipate between 1-3 clinicians per practice will participate for a total of up to 75.

S/he must agree to utilize the CDB for patient care as they find useful, if and when randomized. Each clinician who intends to use the CDB will create a secured and password protected account, allowing them to access the CDB. It will take about 15 minutes for this training.

Surgeon/Clinician consent is for participation to use the CDB, allowing their patients to be randomized to the iCanDecide-ESE or S decision tool, a baseline survey, and follow up surveys. They may separately consent to be re-contacted regarding participating in qualitative process interviews.

8.2.2 Clinician Surveys

Clinician participants will complete 3 surveys. Each of these surveys is identical and expected to take about 10 minutes to complete. Measures are listed in Appendix V.

Baseline Survey: Prior to beginning patient enrollment, all participating clinicians at the site will complete a baseline survey. Completion of the baseline survey must be done within 2 weeks of clinician registration and is **required** for further study participation and use of the CDB.

Follow up Surveys: Clinicians will also complete the same survey at two additional time points (one at 9 months and one at 18 months post-registration).

Booklet completion: To maximize responses to the surveys, these will be done via paper booklet (since asking surgeons to do them via ePRO on their mobile device is likely to result in low response rate). Paper booklets will include questions listed in Appendix VI. At each survey point, if no response is received, the study team will send up to 5 reminders to the participants via email, with the goal of completing the surveys within 8 weeks of being sent initially.

8.2.3 Qualitative clinician interviews: optional process evaluation

As noted in Section 7.3.6, following completion of the stepped wedge trial component, an optional qualitative process evaluation will be done, with both patients and clinicians (Section 3.3.1). Process evaluation is essential to understand how the interventions were used and how SharES could be adapted for broader dissemination and implementation.

Interview Procedures:

The UM research team (study chair and co-chair) will re-contact a random sample of clinicians who consented to be re-contacted to participate in the optional process evaluation at the time of registration and initial consent if they are willing to participate in a 30-minute telephone interview to understand more about how the CDB worked in the clinical setting using the CIFR domains noted earlier in Section 7.3.6. A subset of 1-2 clinicians (surgeon or other clinician) per practice will be invited to participate in these interviews. The UM research team (study chair and co-chair, project coordinator) will then conduct telephone interviews Guiding questions, developed by the study team based on CIFR domains

mentioned above , are included in Guiding questions are included in Appendix IX. (e.g., how did the CDB help you to support your patients' needs, and what were its best/worst features? How often did you use the CDB? When did you use the CDB (before/after seeing a patient)? How easy/difficult would it be for you/your practice to implement tools as part of routine care?)

Interviews are expected to take 20 minutes. These will be audio-recorded with consent.

Qualitative analysis:

Interview recordings will be transcribed at UM. Transcripts will be reviewed by the study team (Chair, co-chair and investigators) for key dimensions related to the potential for dissemination using qualitative analysis software (NVivo). We are not planning a formal qualitative evaluation, as our numbers of interviewees in each group (patients, clinicians) will be too low to generate a clear set of themes. Rather, the goal of these qualitative process evaluation interviews is to inform refinement and preparation of each component of the SharES system, based on input from user stakeholders, for implementation.

8.3 Incentives – Clinics and clinicians

8.3.1 Clinics

Participating clinics will receive iPads for use by patient or/and clinicians. They will also receive $1,000. This will be given through the University of Michigan team who will coordinate the distribution of site incentives.

8.3.2 Clinicians

Clinicians will receive $50 for participation that will be given after consent, registration and completion of baseline survey. Those who participate in process evaluation qualitative interviews will receive additional $50. They will be sent these gift cards electronically as well. We will make every effort to deliver the incentive to clinicians as we have done successfully in prior work with clinicians. However, some clinicians may be unable to accept their incentive due to local laws or institutional policies preventing receipt of funds from external sources. The study team may not able to direct their incentive to another source (e.g., donation) due to legalities surrounding incentive delivery.

Research Activity	**Amount**	**Incentive delivery coordinated by the University of Michigan (UM) Team**
Clinician enrollment and consent	$50	E-gift ($50) emailed by UM team to clinician after enrollment/consent
Clinician qualitative interviews (telephone by UM study team)	$50	E-gift ($50) emailed to clinician by UM team after interview

8.4 Qualitative site staff interviews: optional process evaluation

The study team will interview all consenting Clinical Research Coordinators (CRCs) or Clinical Research Associates (CRAs) study to understand how the study has been implemented at different sites in the NCORP network. From the 25 participating clinics, the target total sample size of participating CRCs/CRAs is 15-20.

Please note: Participants must have worked on the SharES study to participate in these interviews.

8.4.1 CRC/CRA Consent

All CRCs/CRAs will be contacted regarding participating in qualitative process interviews. Should they choose to participate they will sign consent.

8.4.2 Interview Procedures

The UM research team (i.e., study chair and co-chair) will contact all CRCs/CRAs who have worked on the SharES study to see if they would like to consent to an optional process evaluation in a 30-minute telephone or Zoom interview to understand more about how the study was implemented at the sites. The UM research team (i.e., study chair, study co-chair, and project coordinator) will then conduct telephone or Zoom interviews. Guiding questions, developed by the study team are available on the CTSU website.

Interviews are expected to take about 30 minutes. These will be audio-recorded with consent.

8.4.3 Incentive – CRC/CRA

Clinical Research Coordinators and Associates will receive $50 for participating that will be given after consent and completion in the process evaluation qualitative interview. They will be sent these gift cards electronically. We will make every effort to deliver the incentive to CRAs/CRCs as we have done successfully in prior work with clinicians. However, some CRAs/CRCs may be unable to accept their incentive due to local laws or institutional policies preventing receipt of funds from external sources. The study team may not be able to direct their incentive to another source (e.g., donation) due to legalities surrounding incentive delivery.

8.4.4 Qualitative analysis

Interview recordings will be transcribed at UM. Transcripts will be reviewed by the study team (i.e., study chair, co-chair, and investigators) for key dimensions related to the potential for dissemination using qualitative analysis software (NVivo). We are not planning a formal qualitative evaluation, as our numbers of interviewees in each group (patients, clinicians, CRCs/CRAs) will be too low to generate a clear set of themes. Rather, the goal of these qualitative process evaluation interviews is to inform refinement and preparation of each component of the SharES system, based on input from user stakeholders, for implementation.

9.0 ADVERSE EVENTS

We do not anticipate any additional adverse events related to participation in this study beyond usual care.

If a participant reports feeling distressed as a result of study participation, either as a result of being completing a study survey or being audio recorded (as part of the optional process evaluation interview), they may choose not to continue or to complete them and/or speak with the site staff. Participants experiencing any physical or psychological complications related to their treatment should discuss this with their treating physician.

10.0 MEASURES

All data are being collected for purposes of research. Data will not be available to clinic staff and will not be used to guide clinical decision making.

The SharES study includes both patient-facing and clinician-facing interventions that will be evaluated in the multi-level trial. All primary and secondary outcomes for this trial and listed below are patient reported and relate to loco regional breast cancer treatment decision making and obtained

via participant survey at 5 weeks post surgery. A second survey sent 9 months post registration will assess the same outcomes as they relate to breast cancer systemic treatment, and reassess them related to loco regional treatment. It will take about 25 minutes to complete the patient survey at every time point.

Clinician surveys will be done as part of the aim of process evaluation as will qualitative interviews with patients and clinicians.

10.1 Primary Outcomes/Endpoints (collected 5 weeks post surgery) (Appendix III)

There is one primary outcome/endpoint for this study: patient knowledge about the risks and benefits of locoregional treatment.

There are two key secondary outcomes/endpoints: patient cancer worry and self-efficacy for making a treatment decision. All the patient facing measures are included in Appendices III and IV.

Our power calculations are based on knowledge.

Given the primary and key secondary endpoints likely have different intraclass correlation coefficients (ICCs), we are relying on a "near minimax" stepped wedge/parallel hybrid design for the cluster intervention, providing close to the maximal possible efficiency across a range of ICCs from 0 to 0.2. We focus on knowledge as the primary endpoint for power and sample size. We estimate our ability to detect a small to moderate effect size (or 2 out of 3 women getting 1 additional knowledge question correct for our optimal design of 25 clinics and 700 subjects, other scenarios in human subjects). We have demonstrated we can recruit 25 clinics, and that clinics can invite 5 patients per month (to enroll 4). For the individual intervention, we will recruit 350 per group (N=700) which will produce at least an 80% power (alpha =0.05) to detect differences of .35 standard deviations between intervention and control subjects for the clinic level intervention and 0.25 standard deviations for the individual level intervention across a wide range of ICCs (0.01 to 0.20). The interaction effect between the two interventions would have to be at least 0.5 standard deviations (~1 additional question correct) for each subject and comparable to our effect size in our current intervention for us to detect it at conventional significance levels.

10.1.1 5-item Breast Cancer Locoregional Knowledge Measure (Primary)

Self-reported knowledge about locoregional treatment (respondents answer questions concerning general breast cancer morbidity and mortality, primary breast surgery (lumpectomy vs mastectomy). (Source: iCanDecide Survey) [3]

This measure is included in the follow up survey 5 weeks after patient surgery (locoregional).

Measured as: Patient-reported knowledge measured at 5 weeks post patient surgery, and defined as the percentage of correct answers (range: 0-100%) from a 5-item scale previously developed and pilot tested; higher percentages indicate increase knowledge of treatment risks and benefits.[3]

10.1.2 Breast Cancer Self-Efficacy Scale (Key secondary)

This is a 11-item validated scale designed to assess breast cancer patients' overall feelings of control of their cancer and worry about their cancer[22]. This is measured at the follow-up survey 5 weeks after surgery.

Measured as: Patient-reported self-efficacy measured at 5 weeks post patient surgery, and defined as the composite score obtained from the 11-item (each rated on a 5-point Likert

scale: “strongly disagree” to “strongly agree”) validated scale designed to assess breast cancer patients’ overall feelings of control of their cancer and worry about their cancer (range: 11 to 55); higher scores indicate increased self-efficacy.

10.1.3 Cancer Worry scale (Key secondary)

This is an 8-item validated scale[23] assessing the degree of cancer-related worry, measured at the follow up survey 5 weeks after surgery.

Measured as: Patient-reported cancer worry is measured at 5 weeks post patient surgery, and defined as the total score obtained from the 8-item (each rated on a 4-point Likert scale: “never” to “almost always”) validated Cancer Worry Scale[23] assessing the degree of cancer-related worry (range: 8 to 40); higher scores indicate more frequent worries about cancer.

10.2 Additional secondary outcomes/endpoints

There are 4 additional secondary outcomes/endpoints for this study that each assesses additional aspects of patient centered communication collected at the 1st follow up assessment (5 weeks post patient surgery).

10.2.1. Health Care Climate Questionnaire (HCCQ) (surgeon)

A 6-item scale assessing patient perceptions of their communication with their clinicians (surgeons) using the validated health care climate questionnaire and adapted by our team for cancer[24]. Higher scores indicate more positive appraisal of communication. The HCCQ regarding surgeons will be assessed in the survey 5 weeks following surgery. The HCCQ regarding medical oncologists will be assessed in the 9-month post registration survey.

Measured as: Patient-clinician communication (focused on surgeon) measured at 5 weeks post patient surgery and 9 months post-registration, and defined as the total score obtained from the 6-item (each rated on a 6-point Likert scale: “not at all” to “very true”) validated HCCQ (range: 6-36); higher scores indicate more autonomy supportive communication.

10.2.2 Patient Assessment of cancer Communication experiences (PACE)

A 16-item scale developed specifically to measure patient report of Patient Centered Communication[25], the patient appraisal of cancer communication experiences. There is an additional question that asks the patient “Overall, how would you rate your experiences with communication related to your cancer care, from the time there was a suspicion that you might have cancer, through the present?”

Measured as: Patient-reported communication, and defined as the total score obtained from the first 16 item (a-p) (each rated on a 4-point Likert scale: “never” to “always”) validated PACE (range: 16 to 64); higher scores indicate more positive communication. 1 “overall” item assessed separately on a scale from 1 to 4 (“never” to “always”). N/A responses removed (see source).

10.2.3 Subjective Decision Quality (SDQ) (locoregional treatment)

A 5-item scale assessing patient-reported measure of decision quality regarding locoregional treatment[26]. The instrument covers five domains of decision quality: regret and satisfaction, as well as perceived adequacy of information, time, and involvement. Higher scores indicated better subjective decision quality. The SDQ for locoregional treatment will be assessed in the survey 5 weeks following surgery.

10.2.4 Emotional Support Measures to assess values concordant treatment

We will use three single item measures developed by our team to assess the importance of "doing everything", "obtaining peace of mind" and "avoiding worry about the cancer coming back"[14].

It is measured as: percentage who indicate quite/very important for each factor (a), (b), and (c).

10.2.5 Help using iCanDecide and Brief Health literacy screener

These two are short process measures vs actual covariates in that they may be used to help us understand how the interventions did/did not work, from the patient's perspective, and to see if this changes over time. Although they are *not* one of the additional outcomes, they are included here for consistency as they collected at the follow up assessment time points.

The Brief health literacy screen measure[27] will used in the tailoring variables (as part of the intervention- see Appendix XI), and also asked at the 1st and 2nd follow up assessments (Appendices III and IV).

The patient facing tool focuses on helping patients make breast cancer treatment decisions. After viewing the tool, the patient may make an initial treatment decision (with or without communicating with their surgeon). This initial decision may then have to change as a result of further communication with the surgeon, and/or additional testing or factors that may sway the patient toward or require a different surgery than that originally planned. For instance, if lumpectomy is the initial surgery chosen, and after surgery the margins are not clean, the patient may desire or require a mastectomy. Only capturing the final surgery (which can be done via medical chart review) misses the chance to know what the original decision was, in the case it had to change. However it is not feasible to collect initial surgery information from the medical chart. For this reason, a question about whether the surgery the patient ultimately got was the same surgery she first decided to have after viewing iCanDecide website will be asked at the end of the 1st follow up assessment. This question is included in Appendix III, before the Brief Health literacy screener.

10.3 Exploratory Outcomes/Endpoints (collected 5 weeks post surgery and 9 months post registration)

We have exploratory outcome related assessments that will be collected at the 2nd follow up (9 months post patient registration) related to the impact of the interventions overall and specifically on systemic treatment decision making, and overall.

10.3.1 4-item Breast Cancer systemic treatment Knowledge Measure

Self-reported knowledge about systemic treatment decision making.

Measured as: Patient-reported knowledge related to systemic therapy measured at 9 months post patient registration, and defined as the percentage of correct answers (range 0-100%) from a 4-item scale; higher percentages indicate increased knowledge of treatment risks and benefits related to systemic therapy. Patients with DCIS will **not** be offered the systemic module.

*The previously described key secondary outcomes/endpoints breast cancer self-efficacy and cancer worry will be re-assessed at 9 months post patient registration, and are considered additional secondary outcomes/endpoints.

10.3.2 Breast cancer self-efficacy and worry

These items will be re-assessed at 9 months using the same measures described above.

10.3.3 Appraisal of patient centered communication

- The HCCQ focused specifically on the medical oncologist using the same items described above. (not offered to DCIS patients as it is not applicable)
- The PACE assessment of patient reported patient centered communication will be asked at 9 months as well using the same item described above.
- The subjective decision quality (SDQ) regarding systemic treatment. The systemic module will not be offered to the DCIS patients.

10.3.4 Distress Thermometer

This is a visual analog scale represented as a thermometer with points from 0-10 and is anchored such that a score of 0 represents no distress and 10 represents extreme distress. Respondents are asked to indicate where on the thermometer they would rate the amount of distress they have experienced in the past 7 days, including today. This will be assessed at both the first (5 weeks post-surgery) and second (9 months post registration) follow up. This has been obtained from the National Comprehensive Cancer Center website[28].

10.3.5 Quality of Life FACT-B QoL measure

The Functional Assessment of Cancer Therapy-B (FACT-B) is a Quality of Life scale for patients with breast cancer, and includes physical and emotional well-being sub-scales[29]. It assesses the degree to which the respondent has been bothered by the side effects of treatment within the past 7 days and uses a 5-point Likert Scale.

This will be assessed at the second follow up (9 months post-registration- 5 domains, 36 items). This measure is being used with permission from FACIT [redacted]).

10.3.6 Emotional Support Measures to assess values concordant treatment

We will use three single item measures described above. [14]

10.4 Paradata regarding iCanDecide website usage

The University of Michigan team will be responsible for supporting collection of data regarding use of both the patient-facing tool (both iCanDecide -ESE and iCanDecide -S versions) and CDB. For both versions of iCanDecide we will collect information on website completion and total time, "drill downs" into sub-sections, return to website, time on page, whether pages were printed out, and whether first accessed before or after surgical consult (or both). For the CDB, we will collect frequency of access, time spent per access, and "click-throughs." These exposure paradata will help determine "dose" of intervention. However, the total time spent on the website and CDB cannot be accurately known if the user does not log out after use.

10.5 Clinician-reported processes measures (Appendix VI)

We will conduct assessments at enrollment/baseline; 9 months and 18 months post clinician registration to assess clinicians' perceptions of their ability to deliver patient centered communication. The surveys will take about 10-15 minutes to complete at each time point.

10.5.1 PPOS- Patient-Practitioner Orientation Scale

18-item clinician directed measure with two sub-scales, sharing and caring, which reflect different aspects of clinicians' appraisal of their ability to provide patient-centered care[30]. This measure is included at baseline, 9 and 18-month follow up surveys, as a continuous scale.

10.5.2 Health Care Climate Questionnaire (HCCQ)

An adapted 6-item measure of the original patient-reported HCCQ obtained from clinicians[24]. The clinician HCCQ measures are adapted to align with patient measures.

10.6 Patient, Clinician and Clinic Characteristics

Patient characteristics: The following data will need to be abstracted from the patient's medical records, and entered into Medidata Rave:

Clinical (AJCC stage, estrogen/progesterone receptor and HER2/neu) and treatment factors (surgery, radiation, systemic therapy, hormonal therapy) from medical records.

Medical record abstraction needs to occur any time before the 2nd follow up assessment. (following surgery and within 9 months of registration). The following will be collected in the OPEN form during registration: race, education, date of birth and language.

Clinician characteristics: We will obtain type of clinician (surgeon, NP, PA, etc.) gender, race, ethnicity, fellowship training, percent of practice that is breast, and years in practice. This will be included in the clinician baseline survey, following registration. (See Appendix VI).

Clinic characteristics: We will obtain limited clinic factors including number of staff, presence of a navigator, annual breast cancer volume, and payer mix. This will be collected by each site's coordinator. We will collect information on: number of surgeons that treat breast cancer, number of direct care staff (nurses, medical assistants, APPs, other), whether there is a navigator on site, total number of new breast cancer patients seen annually, payer mix, geographic location, affiliation with academic center, and whether clinicians participate in a tumor board. This needs to be completed prior to the first patient enrollment. (See Appendix VII).

10.7 Overview of Measures

Measures will be obtained in this study from patient report, medical record, clinician report and clinic staff report. Following completion of the trial, there will be a process evaluation consisting of qualitative interviews with patient and clinician participants.

10.7.1 Patient measures (Appendices III and IV)

Measure	Tailoring survey integrated in website	First follow up survey (5 weeks post-surgery <12 weeks of surgery)	Second follow up survey (9 months post registration <11 months of registration)	Medical record (before second follow up survey)
Breast Cancer Knowledge Measure		X (locoregional)	X (systemic)	
Breast Cancer Self-Efficacy Scale		X	X	
Cancer Worry Scale	X	X	X	
Health Care Climate Questionnaire (patient version)		X (surgeon)	X (med. Onc)	
Subjective Decision Quality		X (locoregional)	X (systemic)	
Patient Assessment of cancer Communication (PACE)		X	X	
Distress Thermometer	X	X	X	
FACT B (5 domains, 36 items)			X	
Emotional Support Measures		X	X	
Had help using website by friend/family		X	X	
Planned vs. Actual Surgery		X		
Brief Health Literacy Screen	X	X	X	
English/Spanish preference	X			
Patient Characteristics	X			X
Treatment received				X

10.7.2 Clinician measures

Measure	Enrollment survey (≤2 weeks of enrollment)	9 month survey (≤8 weeks)	18 month survey (≤ 8 weeks)
Patient Practitioner Orientation Scale	X	X	X
Health Care Climate Questionnaire (adapted for clinician)	X	X	X
Surgeon Characteristics	X		

10.7.3 Clinic measures

Measure	Prior to first patient enrollment	Monthly
Clinic characteristics survey	X	
Reach of Intervention (number of new breast cancer patients/number of patients offered participation)		X

10.8 Process evaluation

See sections 7.3.6 (patient process evaluation) and 8.2.3 (clinician process evaluation) and Appendices VIII and IX.

11.0 END OF INTERVENTION

11.1 Duration of Protocol Intervention

Patient level intervention begins at registration and continues until 12 months after registration for patients who consent to participate in the qualitative interviews.(9-month follow up survey is the last study related activity for patient participants, with the optional process evaluation happening in the following 3 months).

Practice and clinic level intervention begin at surgeon/practice enrollment and will continue until 19 months following site registration.

Please see the study calendar (Section 5.0) and the intervention sections (Sections 7.0 and 8.0) for intervention and following up periods.

11.2 Criteria for Discontinuation of Protocol Intervention

In the absence of delays due to adverse event(s), study participation may be discontinued if one of the following criteria applies:

- Patient decides to withdraw from the study
- Patient non-compliance
- Termination of the study by sponsor
- Patient does not receive surgery within 12 weeks of registration (if not receiving neoadjuvant chemotherapy)
- Patient does not receive surgery within 6 weeks of completing neoadjuvant systemic chemotherapy (if receiving neoadjuvant chemotherapy)

- Patient develops metastatic disease.

The reason(s) for discontinuation, the reason(s) for study removal, and the corresponding dates must be documented in the Case Report Form (CRF).

11.3 Follow-up

11.3.1 Duration of Follow-up

Patients: Following registration and enrollment where informed consent was obtained, the tailoring survey is completed following randomization and creation of account. From that point, the 1st follow up survey is sent 5 weeks after surgery via patient cloud ePRO or paper based if the patient chose to use paper booklets. All participants will be sent reminders (see Section 7.3.5). The same process will be used for the 2nd follow up survey, which is available for completion 9 months post registration.

Consented participants will have chart review performed after completion of their breast cancer treatment.

Clinicians: Following consent and the enrollment survey, participating clinicians (surgeons and APPs) will be given a brief paper-based survey 9 months and 18 months post registration. If no response is received, the study team will send reminders to the participants via email or telephone (maximum of 5 attempts), with the goal of completing the surveys within 8 weeks of being sent initially.

11.3.2 Lost to follow up/ Follow-up for Patients/Clinicians/Practices who Stop Study Intervention Early

Patients: Patients will be considered lost to follow up if attempts to reach them for the first or second follow-up surveys are unsuccessful. Based on prior work, we anticipate high retention (low loss to follow up) to the 1st follow up survey 5 weeks post-surgery, and slightly more loss for the second follow up 9 months post registration.

However, consented patients will still have their chart review performed, unless the patient explicitly decides to withdraw from the study and withdraws consent. There will be no further follow up, other than medical chart review as stated above.

Clinicians: Clinicians will be considered lost to follow up if attempts to reach them for the 9 or 18-month post registration surveys are unsuccessful (despite 5 reminders: see section 11.3.1). Based on prior work and connections to practices in this study we anticipate high retention of clinicians. There will be no further follow up with these clinicians.

11.4 Extraordinary Medical Circumstances

If, at any time, the constraints of this protocol are detrimental to the patient's health and/or the patient no longer wishes to continue, study participation shall be discontinued. In this event:

- Document the reason(s) for discontinuation of therapy on data forms.
- Follow the patient for protocol endpoints as required by the Study Calendar.

11.5 Managing ineligible patients and registered patients who never receive protocol intervention

Definition of ineligible patient

A study participant who is registered to the trial but does not meet all of the eligibility criteria is deemed to be ineligible.

Follow-up for ineligible patients who continue with study participation

Patients who are deemed ineligible after registering may continue with the intervention, provided the treating physician, study chair, and executive officer agree there are no safety concerns if the patient continues study participation. All study related procedures and data submission are to continue as if the patient were eligible. Notification of the local IRB may be necessary per local IRB policies.

Follow-up for ineligible patients who discontinue study intervention

For patients who are deemed ineligible after registering to the trial, who start study participation, but then discontinue intervention, the same data submission requirements are to be followed as for those patients who are eligible and who discontinue study participation.

Follow-up for patients who are registered, but who never start study intervention

For all study participants who are registered to the trial but who never receive study intervention (regardless of eligibility), the follow-up requirements are specified below:

Baseline, off study data submission required.

12.0 STATISTICAL CONSIDERATIONS

12.1 Study Design Overview

This is a patient-level randomization of iCanDecide-ESE vs. iCanDecide-S imbedded within a practice-level stepped wedge randomization of the clinician dashboard (CDB) over time. There are two co-primary objectives for this study, which relate to evaluating the impact of the two components of the SharES intervention (patient facing tool, clinician dashboard) on the primary endpoint knowledge measured at 5 weeks post patient surgery. The two co-primary objectives are:

1. To demonstrate that the enhanced iCanDecide (iCanDecide-E) intervention is more effective than the standard version (iCanDecide-S) resulting in higher patient knowledge of treatment risks and benefits.
2. To demonstrate that the activation of the clinician dashboard (CDB) is more effective than not using a CDB, resulting in higher patient knowledge of treatment risks and benefits.

Patient level assessments are done at time of registration/randomization, 5 weeks post-surgery (1st follow up, primary and key and additional secondary endpoints) and 9 months post registration (additional secondary endpoints). Clinician assessments are done at time of clinic enrollment (baseline, following registration) and at 9 months and 18 months. The overall design of these activities is shown in Figure 4, overall study schema.

Surgical practices will be enrolled through Alliance and randomized to start the intervention in different time periods of 6 total time periods. To optimize power, we use a specific stepped wedge design in which of the 25 anticipated clinics participating in this study, 5 will be randomized to use the CDB the entire time, 5 will be randomized to never use it, and the remainder will be randomized in groups of 3 to start using it for different amounts of time (Figure 4).

During each time period (12 weeks), each practice needs to enroll and register *approximately* 5 patients (realizing this will vary by clinic and by time period), for about 28-30 total patients (this equates to around 750 total, understanding there will be variation in what practices are able to do). Based on pilot work, we believe enrolling 5 patients in 12 weeks is very reasonable (a maximum of 12 patients per practice every 12 weeks). However, recognizing this may vary,

most practices will need to meet a minimum enrollment of 3 patients during the respective time periods. To avoid drawing an overly large number of participants from a single practice, we have established a maximum of 70 per practice; those that are nearing this maximum will consult with the study team before proceeding with recruitment. We are targeting to register and randomize 700 patients, so have allowed for variation by clinic and time period. To register (and randomize) 700 patients, clinical research assistants will need to approach more, as we anticipate about 75% of those approached will register (thus, we anticipate approaching around 930 patients; if 75% agree we will register and randomize the necessary 700). We then anticipate approximately 15% attrition (at the 5-week post-surgery survey) for a final N of 600 with evaluable data on primary and key secondary endpoints.

12.2. Description of Randomization Routine

12.2.1 Practice-level randomization

Twenty-five surgical practices will be identified for participation. In this design, some clinics may have the CDB activated in the first time period, while other clinics may have the CDB activated at a later time period or even be randomized to a "no dashboard" period (Figure 4). In Figure 4, a group of five clinics will be allocated to receive the CDB for the entire duration of the study (first step; T1-6) and a group of five clinics will be allocated to control with no CDB. Groups of three clinics will be allocated to one of the five steps that have the CDB activated at a later time period, namely, at T2, T3, T4, T5, or T6. Simply stated, mostly groups of three will be randomized to each step, but five clinics each will be randomized to the first step and no intervention. Clinic-level randomization will not be stratified. The first time period begins for each clinic based on the date when the first patient at that clinic was registered. Each time period is 12 weeks in duration; therefore, the anticipated start date of time periods 2 through 6 for each clinic will be derived from the date when the first patient at the respective clinic was registered. The potential for an asynchronous start, therefore, is expected and it recognizes that site-level activation procedures will invariably be different between sites.

12.2.2 Patient-level randomization

After a patient is registered they will be assigned to one of the two arms (iCanDecide-S; iCanDecide-ESE) in a 1:1 ratio utilizing a dynamic allocation algorithm based on the methods by Pocock and Simon[31]. The goal of the algorithm is to maintain arm balance with respect to the following stratification factors: race (non-Hispanic White; non-Hispanic African American; Other – including Hispanic) and education status (≤ High School; some college; college graduate or more). These two stratification factors were chosen because they are clinically meaningful prognostic factors assumed to have a powerful effect on the study outcomes, particularly the primary outcome knowledge. In order to ensure that arm assignment is not deterministic, a level of randomness has been added to the algorithm such that patients will be assigned to the arm that leads to more imbalance 10% of the time. Dynamic allocation is a common approach in cancer clinical trials where we desire arms to be balanced across several prognostic factors. The method is considered robust because it ensures excellent arm balance overall and within the stratification factor levels, even with a large number of stratification factors [32].

12.3 Statement for Primary Endpoint

12.3.1 Primary Endpoint

The primary endpoint is patient-reported knowledge of locoregional treatment risks and benefits measured at 5 weeks post patient surgery, and defined as the percentage of correct answers (range 0-100%) from a 5-item scale previously developed and pilot tested [3];

higher percentages indicate increased knowledge of locoregional treatment risks and benefits.

12.3.2 Analysis Plan for Primary Endpoint

There are two co-primary objectives for this study, which relate to evaluating the impact of the two components of the SharES intervention (patient facing decision tool, clinician dashboard) on patient knowledge of treatment risks and benefits. We will follow an intention to treat approach, using all available data, regardless of group assignment or whether patients viewed the patient facing decision tool. The data as collected will have a nested structure: patients nested within surgeons, within surgical clinics and regions of the country. Descriptive analyses will summarize patient, surgeon, and clinic characteristics. When reporting this summary data, we will report as "NR-Not reported" any cell where the number of patients is less than five to avoid inadvertent patient identification.

As described in above and in Figure 4, we are testing two interventions, one randomized at the individual level (i) and one at the clinic level (j), rolled out to clinics over 6 trial time periods (k). The interventions are fully crossed (with intervention and control patients within both intervention and control clinics for every time period), leading to the following linear mixed model for the continuous primary outcome (y) patient knowledge: $y_{ijk} = \beta_0 + \theta_1 x_{1ijk} + \theta_2 x_{2jk} + \beta_k t_k + u_j + e_{ijk}$. Here, y_{ijk} denotes the response corresponding to individual i at time period k from clinic j ($i = 1, \dots, m_{jk}; j = 1, \dots, 25;\ k = 1, \dots, 6$). The variable x_{1ijk} (=0, 1) denotes the intervention status of patient i enrolled in clinic j at time period k. The variable x_{2jk} (=0, 1) denotes the intervention status of this patient's clinic j at the k^{th} time period. The variable t_k (=0, 1) is the indicator for time period k and the term β_k represents the corresponding fixed categorical effect to model the underlying secular trend (k in 1, …, 5, $\beta_6 = 0$ for identifiability). The random effect u_j is a random intercept for clinic j and represents the time invariant deviation of the j^{th} clinic from the population average. The term e_{ijk} is the patient error term. The term β_0 is the intercept. The terms θ_1 and θ_2 represent the intervention effect of iCanDecide-E and the intervention effect of the CDB, respectively. The model assumes that an underlying time effect is the same for each clinic. To allow for potential clinic-level fluctuations of the time effect related to the roll out of the CDB, the random effect $(ut)_{jk}$ (i.e. a clinic effect interacting with time) will be included in sensitivity analysis (see Section 12.3.3). Additionally, we will include another level in the multilevel model to account for potential nesting in surgeon in sensitivity analyses (see Section 12.3.3). This model is adapted to a factorial design by adding an individual-level intervention to the model for a stepped wedge design[33].

Co-primary Objective #1: The analysis effectively reduces to a typical multi-site, patient level randomized control trial (RCT) of iCanDecide-S vs. ESE. [33] We will compare the interventions on patient knowledge, obtained at the 1st follow up (5 week) assessment post-patient surgery. We will use an intent-to-treat among all participants who complete that assessment. [34] The effect of the individual/patient-level intervention will be quantified by the coefficient θ_1 and the standard error of the coefficient will define the confidence interval for the intervention effect. For this and the following models we will examine residual plots from the mixed model to assess model assumptions. We will compare differences in time invariant patient factors obtained at initial login between the intervention and control groups to assess the success of randomization.

Co-Primary Objective #2: The primary estimate of the effect of the CDB cluster-level intervention on the primary outcome knowledge obtained at the 1st follow up (5 week)

assessment, is then quantified simply by the coefficient θ_2 with the confidence interval defined by the standard error of the coefficient estimated by the model. As one of the most effective ways to improve the statistical power in cluster randomized trials, [35] the two patient-level stratification factors (race; education status) as well as an indicator for Hispanic/Latina (yes; no) that are expected to be strongly associated with the outcome knowledge will be included in the model as supportive analysis (See Section 12.3.3).

Although a single model is estimated to address the two co-primary objectives, a fixed-sequence testing strategy will be applied to control the Type I error rate at 0.05 across the two corresponding primary comparisons. The iCanDecide-E vs iCanDecide-S comparison will be tested first at the significance level $\alpha = 0.05$. The two-sided *P*-value testing the null hypothesis of no difference versus the two-sided alternative that there is a difference will be obtained from the model based on a t-statistic for the regression coefficient θ_1. Provided that the result achieves statistical significance at the 0.05 level, the CDB vs no CDB will be tested at the 5% significance level. In a similar fashion, the two-sided *P*-value testing the null hypothesis of no difference versus the two-sided alternative that there is a difference will then be obtained from the model based on a t-statistic for the regression coefficient θ_2. Both tests are important clinically; however, the pre-specified testing order of two comparisons was determined by the likelihood of success.

12.3.3 Planned Supplemental Analysis for Primary Endpoint

To assess the robustness of the results obtained from the primary analysis, several supplemental analyses are planned. Although we expect the effects to be additive, we will test for any synergistic effect of the two interventions by including an interaction between the individual and the cluster level to estimate the amount by which the effect of having both interventions is greater than the additive sum of the components delivered. Because the study was not prospectively powered to detect such an interaction effect, assessing the possibility of synergism is exploratory. To allow for interpretation of the magnitude of any synergism between the interventions, as well as an indication of the imprecision of the results for the interaction, the regression coefficient and 95% confidence interval for the interaction term will be reported.

In sensitivity analyses, the primary analysis will be repeated to allow for potential clinic-level fluctuations of the time effect related to the roll out of the CDB. In addition, the primary analysis will be repeated to allow for another level in the multilevel model to account for potential surgeon effects. Also, the primary analysis will be repeated to include the two patient-level stratification factors race and educational status, as well as other potential confounding variables.

The primary endpoint patient knowledge is defined as the percentage of correct answers. As a supplemental analysis, patient knowledge will be dichotomized as "high" and "low" corresponding to the percentage correct being $\geq$ 80% and $<$ 80%, respectively. A generalized linear mixed effects model for a binary response will be applied and we will adopt the conceptual approach represented and described earlier by the linear mixed effects model above.

12.4 Power and Sample Size for primary outcome/endpoint analysis

As this is a factorial model, it can be shown that the standard error of the coefficient θ_1 for individual level intervention is the same as for a multisite individual level trial. If we consider a standard parallel cluster randomized trial (CRT), the standard error for θ_2 which describes the cluster level intervention effect, would be larger by a design factor of $1 - (n_1 - 1)\rho$ where ρ represents the intraclass correlation coefficient ICC= $\sigma_u^2/(\sigma_u^2 + \sigma_e^2)$.[33, 36] Hence, the sample

size requirement is largest for the cluster level intervention effect and would be prohibitive for a standard CRT across the potential range of the ICC from .01-.20 that we anticipate based on data from the prior iCanDecide RCT. The stepped-wedge design can dramatically improve the efficiency of a cluster randomized intervention when the ICC is higher although it can be less efficient than a parallel CRT when the ICC is very small. Given the three different outcomes of interest (primary outcome: knowledge, and two key secondary outcomes: self-efficacy and cancer worry) (See Section 12.6.1) with likely different ICCs that we plan to analyze and the uncertainty about the ICC for outcomes for which ICCs have not been described, we are relying on a "near minimax" stepped-wedge/parallel hybrid design as described by Hemming and Girling (2016)[36]. This design provides close to the maximal possible efficiency across a range of ICCs from 0 to 0.2. Using software that they provide we can estimate the sample size requirements for this design.

In the iCanDecide trial from our prior work we have already measured the primary outcome, knowledge, using an 8 item scale and this provides very relevant parameter estimates for our sample size calculation. The ICC was quite high for this variable at about 0.15 representing a substantial amount of variation in the average knowledge score across the clinics enrolled in the trial, although including the baseline characteristic of patient education level reduces this ICC by almost half. The effect size for the decision tool was 0.5 standard deviations, described by Cohen (1988) as a "moderate" effect size, which was equivalent to a little less than 1 additional question being answered correctly by those who received the intervention. Thus, we conducted a calculation of the sample size required to detect a somewhat smaller effect size that results in only 2 out of 3 women getting an additional question correct, which represents a small to moderate standardized effect size of 0.35. For several combinations of clinic numbers and patients per time period per clinic we present the estimates of our power to detect this effect in Table 1.

Thus for the stepped-wedge design testing the clinic level intervention the optimal design is to recruit 25 clinics and a target total sample size of 700 patients (600 evaluable). We have shown already the ability to recruit about 25 clinics and this target gives us the best power and a reasonable target enrollment of patients per clinic.

We expect about 15% will not complete the first follow-up (5 weeks post patient surgery), based on our prior iCanDecide trial. This attrition will result in at least a final N of 600 (3-5 per clinic per period). This will allow us to have at least an 80% power (alpha =0.05) to detect differences of .35 standard deviations between intervention and control subjects for the clinic level intervention and 0.25 standard deviations for the individual-level intervention across a wide range of ICCs (0.01 to 0.20). The interaction effect between the two interventions would have to be at least 0.5 standard deviations, or about 1 additional question correct for each subject and comparable to our effect size in our current intervention, for us to be able to detect it at conventional significance levels.

Table 1. Power to detect a small to moderate standardized effect size of 0.35 standard deviations in the outcome.

Clinics	Subjects per Clinic per period	ICC	Power	N completed	N recruited (15% above target)	Number recruited per clinic
20	5	.02	0.92	600	690	36
20	5	.08	0.84	600	690	36
20	5	.14	0.82	600	690	36
20	5	.2	0.82	600	690	36
25	4	.02	0.94	600	690	29
25	4	.08	0.87	600	690	29
25	4	.14	0.84	600	690	29
25	4	.2	0.84	600	690	29
30	3	.02	0.93	540	621	22
30	3	.08	0.85	540	621	22
30	3	.14	0.82	540	621	22
30	3	.2	0.82	540	621	22

12.5 Accrual Time and Study Duration

Our final sample size is 600 patients having completed the first follow up (5 week post-patient surgery) survey. Based on our prior work with similar studies, ongoing work being done with the Alliance to recruit patients to CCDR studies, and the low burden of the study on patients, we estimate that about 70% of the patients approached will be formally recruited into the study and enroll. However, this may vary by practice. Thus, we have based our enrollment on enrolling up to 5 patients per clinic per time period (Figure 4), with the understanding that recruitment may not be static over time period and may vary by clinic. Our proposed schema allows for this variation and variable recruitment and enrollment rates, with a general target of ~5 per clinic per time period. This would equate to approaching 1,050 patients with a participation rate of ~67% (lower than expected). This allows for variation per clinic per time period and the rate of participation by clinic to obtain our N of 700 recruited, enrolled and consented. This also allows for the potential of under-recruitment by some clinics. Our planned stepped wedge design includes 6 periods of approximately 12 weeks (total ~18 months).

While we do not anticipate under-accrual and have allowed for the possibility of variation by site, significant under-recruitment could adversely impact sample size and study conclusions. To proactively address this potential concern we have applied this rule: In a time period, if the current accrual for a given site is < 2/3 of the stated accrual goal for that site at the end of the time period, then the time period will be extended by 3 weeks for that site. This rule is to be applied at the time period-by-site level, independent of the previous history at that (or any other) site of transition time to the intervention. Only one extension is possible at the wave-by-site level, so that the maximum time period length is 15 weeks.

A critical component of this rule is that the accrual process will be supported by ongoing, uniformly applied recruitment monitoring and support from the Alliance and the University of Michigan team. This will serve to encourage a steady rate of accrual across time.

This rule was selected as it best balanced statistical validity with need to meet accrual goals and complete study in a timely fashion. It also was able to address both situational and chronic low accrual at practices.

12.6 Statement for Key Secondary Endpoints

12.6.1 Key Secondary Endpoints

There are two key secondary endpoints, both measured at the 1st follow up (5 weeks post patient surgery):

1. Patient-reported self-efficacy measured at 1st follow up, 5 weeks post-surgery, and defined as the composite score obtained from the 11-item (each rated on a 5-point Likert scale: "strongly disagree" to "strongly agree") validated scale designed to assess breast cancer patients' overall feelings of control of their cancer and worry about their cancer (range: 11 to 55); higher scores indicate increased self-efficacy.
2. Patient-reported cancer worry measured at 1st follow up, 5 weeks post patient surgery, and defined as the total score obtained from the 8-item (each rated on a 4-point Likert scale: "never" to "almost always") validated Cancer Worry Scale assessing the degree of cancer-related worry (range: 8 to 40); higher scores indicate more frequent worries about cancer.

12.6.2 Analysis Plan for Key Secondary Endpoints

The two key secondary endpoints may provide supportive information about the effectiveness of the iCanDecide-E and CDB on the primary endpoint. Stated differently, the first two key secondary endpoints characterize these two effects related to the primary endpoint but may extend our understanding of those effects. The collection of these two key secondary endpoints constitutes a family of key secondary endpoints. A gatekeeping statistical strategy will be used to control the Type I error rate at 0.05 across the primary and this key secondary family of endpoints such that when both effects on the primary endpoint are demonstrated, this family of key secondary endpoints will be examined and may contribute important supportive information about the effectiveness of the interventions.

We are testing two interventions, one randomized at the individual level and one at the clinic level, rolled out to clinics over six trial time periods. Therefore, the secondary family of tests comprises four tests (two for each secondary endpoint) that will be conducted and will be tested with the Holm procedure [37]. The primary analysis described above in Section 12.3.2 for the primary family will be applied to the secondary family. Briefly, the linear mixed model described in detail in Section 12.3.2 will be separately fit for each continuous outcome (self-efficacy; cancer worry). The self-efficacy (or cancer worry) effect of the individual-level intervention will be quantified by the coefficient θ_1 and the standard error of the coefficient will define the confidence interval for the intervention effect on self-efficacy (or cancer worry). Furthermore, the two-sided *P*-value testing the null hypothesis of no difference versus the two-sided alternative that there is a difference will be obtained from the model based on a t-statistic for the regression coefficient θ_1. The estimate of the effect of the CDB cluster-level intervention on self-efficacy (or cancer worry) will be quantified by the coefficient θ_2 with the confidence interval defined by the standard error of the coefficient estimated by the model. Furthermore, the two-sided *P*-value testing the null hypothesis of no difference versus the two-sided alternative that there is a difference will then be obtained from the model based on a t-statistic for the regression coefficient θ_2.

12.7 Statement for Additional Secondary Endpoints

12.7.1 Additional Secondary Endpoints

There are four additional secondary endpoints that will be evaluated in an explorative fashion to contextualize and to further aid our understanding of the potential effects of the interventions on patient-centered communication (PCC) measured at the 1st follow up (5 weeks post patient surgery) as well as concordance between emotional support measures obtained at 5 weeks post patient surgery and treatment received:

1. Patient-clinician communication (surgeon) and defined as the total score obtained from the 6-item (each rated on a 6-point Likert scale: "not at all" to "very true") validated Health Care Climate Questionnaire (range: 6-36); higher scores indicate more autonomy supportive communication.
2. Subjective Decision Quality regarding locoregional treatment, and defined as an overall decision making score obtained from the 5-item validated scale designed to measure decision quality (range: 5-35); higher scores indicate greater subjective decision quality increase
3. Appraisal of patient-centered communication, and defined as the total score obtained from the 16-item (each rated on a 4-point Likert scale: "never" to "always") validated scale (range: 16-64); higher scores indicate more positive communication.
4. Concordance between emotional support measures obtained at 1st follow up assessment and treatment received.

12.7.2 Analysis Plan for Additional Secondary Endpoints

The first three additional secondary endpoints are continuous in nature and will be descriptively summarized. Additionally, the primary analysis described above in Section 12.3.2 for the primary endpoint will be applied to the first three additional secondary endpoints. Regarding the last additional secondary endpoint, the study will also assess the level of concordance between the three emotional support measures obtained at 5 weeks post patient surgery and treatment received; therefore, the corresponding outcome will be a binary outcome reflecting whether the treatment received was concordant or not with the patient's emotional support measures. A similar modeling approach to the primary analysis will be applied; however, a logistic random effects model will be used for this binary outcome. Because of the potential for Type I error due to multiple testing, findings for analyses of these additional secondary endpoints should be interpreted as exploratory. These exploratory analyses are intended to complement and further contextualize the results from the primary analyses.

12.8 Missing Data

We measure our primary endpoint, key secondary endpoints, and PCC endpoints by patient report in the first (5 weeks post-surgery follow-up survey. We anticipate will have minimal missing-ness at this time point based on our prior iCanDecide trial for which we obtained 92% complete follow up survey data at the same measurement time point. However, to decrease missing data from follow-up survey, assessment burden and drop-out, we have limited the number of survey questions and provided incentives. We have included flexible means of contacting patients, including email (primary modality), telephone, or by regular mail if desired. If data are missing on predictor variables of interest, data will be imputed using multiple imputation (MI) techniques (MI using chained equations).[38] MI produces valid statistical estimates under missingness at random (MAR), while also accounting for additional uncertainty

arising from missing data. We will perform sensitivity analyses to determine the degree to which results are sensitive to the MAR assumption. We will also account for survey non-response using an inverse probability weighting approach if we should find that there is differential survey non-response between the intervention and usual care groups according to patient characteristics that also influence the outcomes of interest.

We will consider patients as participants if they complete enrollment and the baseline tailoring survey and only consider them to have dropped out if they withdraw consent. If a participant withdraws consent, we will document: 1) the reason for dropout; 2) who decided the participant would drop out; and 3) whether the dropout involves some or all types of participation.

12.9 Analysis Plan for Exploratory Objectives

We have two exploratory objectives: 1) assesses the impact of the 2 interventions on exploratory endpoints collected at the 2nd follow up assessment (9 months post patient registration), that will also be evaluated in an exploratory fashion to better understand and characterize the intervention effects observed in the primary and secondary analyses; and 2) mediation analyses.

12.9.1 Effect of interventions on exploratory outcomes

There are several exploratory endpoints that will be evaluated in an explorative fashion to contextualize and to further aid our understanding of the potential effects of the interventions on systemic treatment decisions and longer term that will be collected at the 2nd follow up assessment (9 months post patient registration):

1. Patient-reported knowledge related to systemic therapy, and defined as the percentage of correct answers (range 0-100%) from a 4-item scale; higher percentages indicate increased knowledge of treatment risks and benefits related to systemic therapy.
2. Patient-reported self-efficacy and defined as the composite score obtained from the 11-item (each rated on a 5-point Likert scale: “strongly disagree” to “strongly agree”) validated scale designed to assess breast cancer patients’ overall feelings of control of their cancer and worry about their cancer (range: 11 to 55); higher scores indicate increased self-efficacy.
3. Patient-reported cancer worry defined as the total score obtained from the 8-item (each rated on a 4-point Likert scale: “never” to “almost always”) validated Cancer Worry Scale assessing the degree of cancer-related worry (range: 8 to 40); higher scores indicate more frequent worries about cancer.
4. Patient appraisal of patient centered communication relative to systemic treatment (HCCQ focused on medical oncologist, PACE, SDQ focused on systemic treatment).
5. Quality of Life using the FACT-B: The Functional Assessment of Cancer Therapy-B (FACT-B) is a Quality of Life scale (5 domains, 36 items) for patients with breast cancer, and includes physical and emotional well-being sub-scales. It assesses the degree to which the respondent has been bothered by the side effects of treatment within the past 7 days and uses a 5-point Likert Scale. This measure is being used with permission from FACIT ([redacted]).
6. Distress thermometer.

We will evaluate the effect of the intervention on other continuous outcomes of interest (not primary or secondary outcomes or objectives). The corresponding data from these

exploratory endpoints will be summarized descriptively. For continuous outcome measures, the analyses will follow that described above for the additional secondary endpoints.

12.9.2 Mediation Analysis

We will use mediation analyses, [39-41] to examine whether intervention effects on primary and key secondary outcomes/endpoints (knowledge about locoregional treatment, self-efficacy, and cancer worry), if observed, can be explained by changes in two of the additional secondary outcome/endpoint variables. Specifically, we will examine whether changes in patient report of communication with their clinicians (HCCQ-surgeon) and patient appraisal of cancer communication experiences (PACE) account for intervention effects on the aforementioned outcomes. We will also examine whether short-term primary outcomes of locoregional treatment knowledge, self-efficacy and cancer worry may mediate changes in longer-term assessments, specifically QoL assessed at the 2nd follow up. Mediation will be tested in a three-step process[40]. First, the mediator must be affected by the independent variable (IV) of intervention. Second, the intervention must be shown to affect outcomes. Finally, it must be shown that when the dependent variable is regressed on both the independent and mediator(s), the association between IV and outcomes is attenuated. We will estimate the direct and indirect effects of the mediating variables on primary outcomes and the structural relationships (or paths) linking them using the causal inference approaches to measure the direct and indirect effects.

12.10 Study monitoring

This study will be monitored by the Alliance Data Safety Monitoring Board (DSMB), an NCI-approved functioning body. Reports containing efficacy and administrative information will be provided to the DSMB every six months as per NCI guidelines.

The study team will monitor accrual of patients at regular intervals, to ensure that sites reach their accrual goals.

Required submission of patient demographic data for this study will be submitted automatically via OPEN.

12.11 Study reporting

Results Reporting on [redacted] At study activation, this study will have been registered within the [redacted] website. The Primary and Key Secondary Endpoints along with other required information for this study will be reported on [redacted]

13.0 INCLUSION OF WOMEN AND MINORITIES

DOMESTIC PLANNED ENROLLMENT REPORT					
Racial Categories	**Ethnic Categories**				**Total**
	Not Hispanic or Latino		**Hispanic or Latino**		
	Female	**Male**	**Female**	**Male**	
American Indian/ Alaska Native	7	0	0	0	7
Asian	21	0	0	0	21
Native Hawaiian or Other Pacific Islander	6	0	0	0	6
Black or African American	140	0	17	0	157
White	469	0	32	0	501
More Than One Race	8	0	0	0	8
Total	651	0	49	0	700

14.0 GENERAL REGULATORY CONSIDERATIONS

14.1 Waiver of elements of informed consent—patients

We request a waiver of the specific element of consent regarding medical injury to patient. This study does not involve medical treatment, and it is not expected that patients will suffer medical injury due to participation in this trial. We have therefore removed the "What happens if I am injured because I took part in this study" section of the NCI Model Consent Template. Omission of this information does not constitute greater than minimal risk and would not adversely affect the patient. **This waiver is not required per the CIRB's review and determination.**

In addition, patients will not be informed which patient facing decision tool they are randomized to, at the time of informed consent. Omission of this information does not constitute greater than minimal risk and would not adversely affect the patient. Because the study compares the effect of the decision aids on patient engagement, it is necessary to blind the patient and the practice to the intervention assignment.

Following study completion, if effective, all practices will be offered both patient-facing and clinician-facing components.

14.2 Waiver of elements of informed consent—clinicians

We request a waiver of specific elements of consent regarding medical treatment, medical risks, costs, and injury to surgeon/advance practice provider participants. This study does not involve medical treatment of surgeons or advance practice providers, and these elements of informed consent would not apply to the non-patients participating in this study. We have therefore removed these sections from the model consent form. Omission of this information does not constitute greater than minimal risk and would not adversely affect the participant.

A waiver is not required per the CIRB's review and determination.

14.3 Waiver of elements of informed consent—Clinical Research Coordinators and Clinical Research Associates

We request a waiver of specific elements of consent regarding medical treatment, medical risks, costs, and injury to CRC and CRA participants. This study does not involve medical treatment of CRCs and CRAs, and these elements of informed consent would not apply to the non-patients participating in this study. We have therefore removed these sections from the model consent form. Omission of this information does not constitute greater than minimal risk and would not adversely affect the participant.

14.4 Security of audio- recorded data, from the optional process evaluation interviews

Audio-recording of the interviews done in the process evaluation will be shared with the University of Michigan (UM). Although PHI will not be intentionally sent to UM, it is possible that PHI will be shared through the audio-recordings. All audio-recordings will be transcribed in full. Study staff members or outside contractors with a business associate agreement who have been approved by UM Legal Services/Privacy Officer for HIPAA compliance will be used for transcription. Although identifying information may exist on the audio files, transcriptionists will strip all identifying information once transcribed and will only have access to the subject ID that is assigned by study staff (no access to the patient-subject log or other identifying information). The de-identified transcripts will be used in data analysis by the research team. After data analysis is complete and manuscripts have been accepted for publication, the audio recordings will be destroyed and the de-identified transcripts will be stored indefinitely on a secure server.

Data collected as part of the patient website (e.g., "paradata" regarding usage of site components) will reside on a server at UM.

14.5 IRB terminations

Until institutions receive a formal notice from the Alliance regarding termination to patient follow-up, institutions must not close this trial with the IRB of record for the study. Please contact the Alliance Regulatory team at [redacted] with any questions.

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APPENDIX I ELECTRONIC PATIENT-REPORTED OUTCOMES (EPRO) INSTRUCTIONS

1.0 Introduction

Electronic collection of patient-reported outcomes is preferred but not mandatory. Patients will need to use their own device (IOS or Android phone or tablet). Short term data will only appear on the patient's device until responses are completed. The patient data will import directly into the database once the patient clicks the submit button and will no longer be on the patient's device.

Sites can use a site-specific tablet for different study participants. If a site-specific tablet is used, CRAs need to setup the tablet for multiple users.

Site staff access

Site users of ePRO and the Patient Cloud require the same access as those using Rave. Access to the trial in the Patient Cloud is granted through the iMedidata application to all persons with the appropriate roles assigned in Regulatory Support System (RSS). To access the Patient Cloud via iMedidata, the site user must have an active CTEP-IAM account and the appropriate Rave role (Rave CRA, Read-Only, Site Investigator) on either the LPO or participating organization roster at the enrolling site.

Upon initial site registration approval for the study in RSS, all persons with Rave roles assigned on the appropriate roster will be sent a study invitation e-mail from iMedidata. To accept the invitation, site users must log into the Select Login using their CTEP-IAM user name and password, and click on the "accept" link in the upper right-corner of the iMedidata page. Please note, site users will not be able to access the study in the Patient Cloud until all required Medidata and study specific trainings are completed. Trainings will be in the form of electronic learnings (eLearnings), and can be accessed by clicking on the link in the upper right pane of the iMedidata screen.

Users who have not previously activated their iMedidata/Rave account at the time of initial site registration approval for the study in RSS will also receive a separate invitation from iMedidata to activate their account. Account activation instructions are located on the CTSU website, Rave tab under the Rave resource materials (Medidata Account Activation and Study Invitation Acceptance).

Additional information on iMedidata/Rave is available on the CTSU members' website under the Rave tab at [redacted] or by contacting the CTSU Help Desk at [redacted]

2.0 Security

All data are encrypted on the device (128 bit on file +https transfer) and the app requires a user to have a username and password. If the user is idle for too long (5 minutes inactivity time), the app will time out and the user will need to log in again.

The data will only reside on the device for a short period of time. Once the user clicks "submit," the data is securely transferred over https between the device and internal relay. No identifying information is stored in iMedidata (only email address is stored).

The Patient information (email/password) does not reside in Medidata Rave EDC and the patient accounts are hidden in iMedidata from sites and sponsors in the Patient Cloud Relay.

The ePRO application is Part 11 compliant and acts as a gateway between device and Medidata Clinical Cloud (MCC).

Messages and information communicated to and from the Patient Cloud are encrypted and therefore this information cannot be read if intercepted while in transit.

3.0 CRP Training for ePRO

Please visit the Medidata Learning Tool for reference information on Patient Cloud ePRO for CRAs.

4.0 Checklist for activities prior to consenting a patient

- Site staff must have already completed required eLearning for the Patient Cloud ePRO application. See last bullet with hyperlink to training video library. Contact the Study data manager to request appropriate Rave access to register patients in Patient Cloud ePRO
- Accept study invitation at [redacted]

  Note: you must be rostered in RSS and have received an invitation to Patient Cloud ePRO
- Verify the IOS or Android operating system is using the most current version
- Verify Patient Cloud ePRO app is using the most current version
- Refer to [redacted] to review Quick reference guides

5.0 Instructions for ePRO patient registration

Please visit the Medidata Learning Tool for additional screen shots and video tutorials on how to register participants to the study.

i. The patient registration process starts in iMedidata. Begin by clicking on the Patient Cloud Registration link for this study

ii. The patient management app will display, select your STUDY and SITE from the drop downs and click Launch.

iii. Now the first patient can be registered. Create a subject ID and select a Country / Language from the drop down, (these are the only required data fields). The patient initials are optional, but may help in identifying which subject ID maps with which activation code. When finished, click Add.

iv. The patient added will appear at the top of the table and will include the date the patient was added, the subject ID, initials, (if included) and a unique auto-generated activation code. The activation code is unique for each patient and linked to the subject ID, it is not interchangeable. In addition, there is a status section, which determines if the patient has registered. When the patient has registered the status will change from invited to registered.

6.0 Patient Users

To use the Patient Cloud ePRO, patients will need to use their own device (IOS, Android phone or tablet). Short term data will only appear on the patient's device until responses are completed and submitted. The patient data will import directly into the database once the patient selects the "Submit" button and will no longer be visible on the patient's device.

Patient compliance: The patient data imports directly from her/his device into the Rave database. There are no documents to audit. The electronic responses are the source documentation.

Patient Instructions for Accessing the Patient Cloud App using their personal device

Downloading the Patient Cloud ePRO App:

If you are using your personal device, and you do not have the Patient Cloud ePRO app, use the following instructions. When downloading the app, you must use the Apple ID or Google account associated with the device. If the Patient Cloud ePRO app is already on the device, or if you are using a provider's device, you can skip this section.

You will need an email address that you agree to use for this purpose. The e-mail address is needed to identify you on the Patient Cloud Application and for you to receive notifications to let you know when forms are due. Your e-mail address will only be used for this survey study, and will not be used for mail or marketing purposes.

If you decide to use the electronic method to complete the questionnaires, and do not have an e- mail address, you may sign up for one at no charge at many different websites. A few sites that are commonly used and will allow you to create an email address very easily are Yahoo, Gmail, and Outlook.

For iOS:

1. An Apple ID is required for downloading the Patient Cloud ePRO app.
2. Tap the App Store icon.
3. Search for Medidata Patient Cloud and follow the installation instructions.

Note: Patient Cloud ePRO is listed as an iPhone App in the App store. When using an iPad, please view the search results under iPhone apps.

For Android:

1. A Google account is required for downloading the Patient Cloud ePRO app
2. Tap the Play Store icon.
3. Search for Medidata Patient Cloud and follow the installation instructions.

Registering on the App:

You must register in order to complete and submit your study forms. When you register, you will create a username, which is your email address, and a password that allows you to log in to the Patient Cloud ePRO app.

Note: You must have an activation code to begin this process. If you do not have an activation code, please contact your provider.

There are two possible ways to register. Your provider may have sent you a link to a web address where you may register from any web browser, including the one on your device. The other way to register is on the Patient Cloud ePRO app.

1. If registering from the Patient Cloud app, tap Register on the bottom of the log in page. If registering on the web, open the URL [redacted] on a web browser.
2. Enter your activation code and tap Activate.
3. On the next page, read the instructions and tap Next.
4. Read the privacy notice and tap I agree. Then tap OK to confirm.
5. Enter and confirm your email address. Tap Next.
6. Enter and confirm your password. Tap Next.
7. Choose a security question by scrolling through the dropdown menu to display the question of your choice.
8. Enter your security question response.
9. Tap Create my account to complete your registration.

If you registered on the Patient Cloud ePRO app, it automatically logs you out. If you registered on the web, you are presented with the option to download the Patient Cloud ePRO app. You can then proceed to log in with the credentials you created.

Logging in to the App after registration:

1. Enter your Email and Password that you created during the registration process. (If you previously set a PIN code, just enter your four-digit PIN.)
2. Tap Log in.

Note: If you do not remember your password, tap Forgot Password, and follow the instructions provided.

Setting a PIN Code:

The first time you log in to the Patient Cloud ePRO app, you are given the option to create a PIN code. A PIN code allows you to bypass the step of entering your email and password every time you need to log in to the Patient Cloud ePRO app. Instead, you can enter a four-digit PIN.

1. If you wish to set a PIN code the first time you log in, tap Yes when prompted.
2. Note: You can also set your PIN at a later time by tapping the options menu on the top left of most pages and selecting Set PIN.
3. Enter a four-digit PIN.
4. Re-enter the four-digit PIN to confirm.

If you forget your PIN code, tap Forgot PIN and you can access the app using your email and password. You may reset your PIN by tapping the options menu on the top left of most pages and selecting Set PIN.

Resetting Your Password:

You can reset your password by using the options menu at the top left of most pages.

1. Tap the options menu icon.
2. Tap Reset Password.
3. Follow the instructions to reset your password.

Completing and Submitting Forms:

Once logged in, forms related to your study display on the Tasks page. If you are enrolled in multiple studies, select the appropriate study first, and then select a form. New forms can appear on the Tasks page at any time, depending on how the study is designed.

There are two types of forms displayed on the Task List page:

- *Scheduled Forms* (with a  icon): These forms have a "Due Date" indicator in them so you are aware of the last day by which you will need to complete the form. If the form is due in less than one day, you will see the due time in hours.
- *Anytime Forms* (with a  icon): These forms have "Last Completed Time" indicator on them which tells the most recent date or time when you completed the form. If you start a form, but do not complete it, you will see an 'Incomplete" status beneath the form name, along with a half-moon icon

1. Select the appropriate form.
2. Follow the on-screen instructions until you reach the end of the form where you are given the opportunity to review and change your responses prior to submitting.
3. Review your responses by scrolling down the list.
4. If you need to change an answer, tap the question to go back and change the answer.
5. When you are ready to submit, tap Submit Your Data.

Note: Once a form is submitted, you will be unable to edit any of your responses. In some cases, you may be asked to acknowledge your submission by entering your password

APPENDIX II EPRO FLOW CHART FOR PATIENTS (VERSION 1.0)

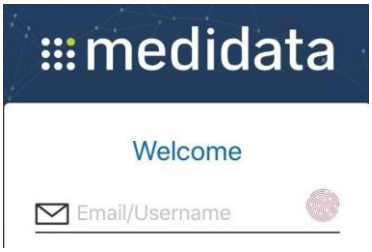
Download the Patient Cloud app

Create a username and password for the Patient Cloud app by selecting the 'Have an Activation Code?' option on the login screen. Use the activation code from your clinic.

Log in to the Patient Cloud app

See your forms on the main screen

Complete, review, and submit your forms



Tip: Your username must be in email format (for example, jodiesmith20@email.com).

Tip: When a form is due, you will see the alarm clock with the date the form will close



For help with the Patient Cloud app, please ask your study team!

APPENDIX III 1ST FOLLOW UP: PATIENT SURVEYS AT 5 WEEKS FOLLOWING SURGERY

PATIENT INFORMATION SHEET 5 WEEKS (for patient completed booklets)

You have been given a booklet to complete for this study. The booklet contains some questions about your knowledge, worries and communication with your doctor as a patient receiving treatment for cancer. Your answers will help us to better understand how the treatment you are receiving is affecting the way you feel.

Note: The title of the measure will not be displayed for patients, and the text in red is the title patients will see. Please see the actual PDF version of the booklets submitted separately for review to see what will be given to the patients.

This booklet is to be completed about one or two months after you receive surgery. This booklet contains the following sets of questions.

(Section Title:) How You Are Feeling
- a) Distress thermometer

(Section Title:) Questions About Breast Cancer
- b) Breast cancer self-efficacy scale
- c) Cancer worry scale
- d) Breast cancer knowledge measure for locoregional treatment

(Section Title:) Making Decisions
- e) Subjective Decision Quality
- f) Health Care Climate Questionnaire
- g) PACE

(Section Title:) A Few More Questions
- h) Emotional support measure
- i) Help using website
- j) Planned vs. Actual Surgery
- k) Brief literacy screen

1. Directions on how to complete this set of questions are written on the top of the page.

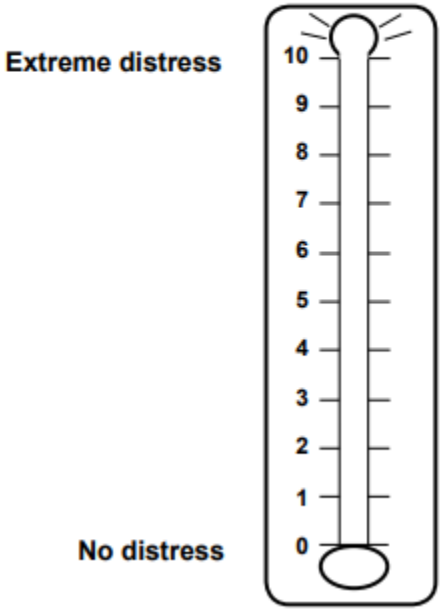
2. It is very important that you return the booklet to us.
3. Please hand the completed surveys to the site coordinator or use the stamped and addressed envelope provided to mail the completed survey to the site coordinator.

Thank you for taking the time to help us.

How you are feeling

Distress Thermometer

Instructions: Please circle the number (0–10) that best describes how much distress you have been experiencing in the past week including today.



Source: National Comprehensive Cancer Network. NCCN Distress Thermometer and Problem List for Patients. 2016;

Questions About Breast Cancer

Breast Cancer Self-Efficacy Scale

The following questions relate to how confident you are about dealing with your breast cancer. Please indicate how much you agree or disagree with each statement.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
a. I am able to ask for help when I have problems related to my breast cancer.	○	○	○	○	○
b. I am able to deal with the fact that I had breast cancer.	○	○	○	○	○
c. I am able to deal with physical symptoms from having breast cancer.	○	○	○	○	○
d. I am able to ask for help for problems related to breast cancer without feeling guilty.	○	○	○	○	○
e. I am able to handle any fears I have about breast cancer returning.	○	○	○	○	○
f. I am able to successfully handle life situations since I had breast cancer.	○	○	○	○	○
g. I am able to have a productive work life even though I had breast cancer.	○	○	○	○	○
h. I am able to successfully work toward my personal goals since I had breast cancer.	○	○	○	○	○
i. I am able to successfully deal with my emotions since I had breast cancer.	○	○	○	○	○
j. I am able to identify changes in my body that may be related to a return of my breast cancer.	○	○	○	○	○
k. I am comfortable calling my healthcare provider if I notice a symptom that may be related to a return of my breast cancer.	○	○	○	○	○

Source: Champion VL[1], Ziner KW, Monahan PO, Stump TE, Cella D, Smith LG, Bell CJ, Von Ah D, Sledge GW. Development and psychometric testing of a breast cancer survivor self-efficacy scale. Oncol Nurs Forum. 2013 Nov;40(6):E403-10. doi: 10.1188/13.ONF.E403-E410.

Cancer Worry Scale

People sometimes report that they have worries about cancer. Please answer the questions by ticking the box that best applies to you. Please indicate the extent to which you have experienced these worries ***during the past week****.*

		Almost never	Sometimes	Often	Almost always
1	**How often have you thought about your chances of getting cancer (again)?**	☐	☐	☐	☐
2	**Have these thoughts affected your mood?**	☐	☐	☐	☐
3	**Have these thoughts interfered with your ability to carry out your daily activities?**	☐	☐	☐	☐
4	**How concerned are you about the possibility of one day getting cancer (again)?**	☐	☐	☐	☐
5	**How often do you worry about developing cancer?**	☐	☐	☐	☐
6	**How much of a problem is this worry?**	☐	☐	☐	☐
7	**How often do you worry about the chance of family members developing cancer?**	☐	☐	☐	☐
8	**How concerned are you about the possibility that you will ever need surgery (again)?**	☐	☐	☐	☐

Cancer Worry Scale-Eng. (8 items), © E.M.A. Bleiker, NKI-AVL, Amsterdam, The Netherlands, 2012

5-item Breast Cancer Knowledge Measure for locoregional treatment

Locoregional knowledge measure

Now a few questions about breast cancer:

1. Which treatment gives women a better chance of surviving breast cancer?
   - ○ Lumpectomy with radiation
   - ○ Mastectomy
   - ○ There is no difference between these two treatment options
   - ○ Don't know

2. On average, which treatment results in a higher chance of having cancer come back in the breast that had the cancer?
   - ○ Lumpectomy with radiation
   - ○ Mastectomy

- ◯ There is no difference between these two treatment options
- ◯ Don't know

3. On average, which treatment results in a higher chance of the cancer coming back anywhere in the body after being treated?
   - ◯ Lumpectomy with radiation
   - ◯ Mastectomy
   - ◯ There is no difference between these two treatment options
   - ◯ Don't know
4. After which surgery is it more likely that women will need to have another operation to remove more breast tissue?
   - ◯ Lumpectomy
   - ◯ Mastectomy
   - ◯ There is no difference between these two treatment options
   - ◯ Don't know
5. For most women, which treatment has a longer recovery time?
   - ◯ Lumpectomy and radiation
   - ◯ Mastectomy
   - ◯ There is no difference between these two treatment options
   - ◯ Don't know

Source: iCanDecide Survey (Hawley et al., JCO 2018. P01 CA163233)

Making Decisions

Subjective Decision Quality (SDQ) for locoregional treatment

E1. Please rate the **amount of information** you had when the following decisions were made:

	Not enough		Just right		Too much	N/A
a. Whether or not to have a breast MRI	○	○	○	○	○	○
b. Whether or not to have a blood or saliva test to see if you have a genetic mutation that increases risk of breast cancer (BRCA1 or BRCA2)	○	○	○	○	○	○
c. Which type of surgery to have	○	○	○	○	○	○
d. Whether or not to have radiation therapy	○	○	○	○	○	○

E2. Please rate the **amount of involvement** you had to make the following decisions:

	Not enough		Just right		Too much	N/A
a. Whether or not to have a breast MRI	○	○	○	○	○	○
b. Whether or not to have a blood or saliva test to see if you have a genetic mutation that increases risk of breast cancer (BRCA1 or BRCA2)	○	○	○	○	○	○
c. Which type of surgery to have	○	○	○	○	○	○
d. Whether or not to have radiation therapy	○	○	○	○	○	○

E3. Please rate the **amount of time** you had to make the following decisions:

	Not enough		Just right		Too much	N/A
a. Whether or not to have a breast MRI	○	○	○	○	○	○

b. Whether or not to have a blood or saliva test to see if you have a genetic mutation that increases risk of breast cancer (BRCA1 or BRCA2)	○	○	○	○	○	○
c. Which type of surgery to have	○	○	○	○	○	○
d. Whether or not to have radiation therapy	○	○	○	○	○	○

E4. How **satisfied** are you with the decision about…

	Not at all satisfied	A little satisfied	Somewhat satisfied	Quite satisfied	Totally satisfied	N/A
a. Whether or not to have a breast MRI	○	○	○	○	○	○
b. Whether or not to have a blood or saliva test to see if you have a genetic mutation that increases risk of breast cancer (BRCA1 or BRCA2)	○	○	○	○	○	○
c. Which type of surgery to have	○	○	○	○	○	○
d. Whether or not to have radiation therapy	○	○	○	○	○	○

E5. How **regretful** are you with the decision about…

	Not at all regretful	A little regret	Somewhat regretful	Quite regretful	Totally regretful	N/A
a. Whether or not to have a breast MRI	○	○	○	○	○	○
b. Whether or not to have a blood or saliva test to see if you have a genetic mutation that increases risk of breast cancer (BRCA1 or BRCA2)	○	○	○	○	○	○
c. Which type of surgery to have	○	○	○	○	○	○
d. Whether or not to have radiation therapy	○	○	○	○	○	○

Health Care Climate Questionnaire (HCCQ) for surgeon

For the next set of questions, please think about the surgeon who was most involved in your surgery.

I feel that my surgeon…

	Not at all true	A little true	Somewhat true	Quite true	Very true
a. Provided me with choices and options for my breast cancer treatment.	○	○	○	○	○
b. Understood how I saw things with respect to my breast cancer.	○	○	○	○	○
c. Expressed confidence in my ability to make decisions.	○	○	○	○	○
d. Listened to how I would like to handle my breast cancer treatment.	○	○	○	○	○
e. Encouraged me to ask questions.	○	○	○	○	○
f. Tried to understand how I saw things before offering an opinion.	○	○	○	○	○

Patient Assessment of cancer communication experiences (PACE)

The next section asks about your experiences with communication during cancer care.

Please mark the extent to which each statement reflects your experiences with communication with doctors, nurses and other healthcare professionals during your cancer care, from the time there was a suspicion that you might have cancer, through the present.

	Never	Sometimes	Usually	Always	N/A
a. I was treated with sensitivity and respect.	○	○	○	○	○
b. I felt known as a person.	○	○	○	○	○
c. I felt listened to.	○	○	○	○	○
d. I felt comfortable asking questions and voicing my concerns.	○	○	○	○	○
e. I felt that everyone worked together as a team in taking care of me.	○	○	○	○	○
f. My wishes were respected.	○	○	○	○	○
g. I got the information I needed, when I needed it.	○	○	○	○	○
h. I got clear, understandable information.	○	○	○	○	○
i. I knew whom to contact if I had a question or concern.	○	○	○	○	○
j. I felt comfortable bringing up anything that was on my mind.	○	○	○	○	○
k. I got consistent information from all my physicians and nurses; everyone was on the same page.	○	○	○	○	○
l. My cancer care team helped me cope with any uncertainty or unknowns.	○	○	○	○	○
m. My cancer care team helped me cope with difficult feelings, like fear, anxiety, and feeling down.	○	○	○	○	○
n. I felt optimism and hope from my physicians and nurses.	○	○	○	○	○

o. I was involved in making decisions as much as I wanted.	○	○	○	○	○
p. I knew whom in the health care system I could reach out to if I was worried that something had gone wrong with my care.	○	○	○	○	○

	Excellent	Very good	Good	Fair	Poor
Overall, how would you rate your experiences with communication related to your cancer care, **from the time there was a suspicion that you might have cancer, through the present?** [b]	○	○	○	○	○

Source: Mazor KM, Street RL, Jr., Sue VM, Williams AE, Rabin BA, Arora NK. Assessing patients' experiences with communication across the cancer care continuum. Patient Educ Couns. 2016;99(8):1343- 1348.

A Few More Questions

Emotional Support Measures to assess values concordant treatment

D8. **When decisions were being made about your treatments**, how important was it to you that your treatments…

	Not at all important	A little important	Somewhat important	Quite important	Very important
a. Kept you from worrying about the cancer coming back	○	○	○	○	○
b. Were the most extensive possible	○	○	○	○	○
c. Gave you peace of mind	○	○	○	○	○

Source: iCanCare survey P01CA163233 (used in publications, eg., **Hawley ST**, Griffith KA, Hamilton AS, Ward KC, Morrow M, Janz NK, Katz SJ, Jagsi R. The association between patient attitudes and values and the strength of consideration for contralateral prophylactic mastectomy in a population-based sample of breast cancer patients. Cancer. 2017 Dec 1;123(23):4547-4555. doi: 10.1002/cncr.30924. Epub 2017 Aug 15.

Help using iCanDecide

Did you have help using iCanDecide?

☐ No, I used the website by myself

☐ Yes, I had help from a friend or family member

How did you access iCanDecide?

☐ Mobile phone

☐ Home desktop or laptop

☐ Clinic iPad

☐ Other

If other, specify _____

How helpful did you find iCanDecide in your treatment decision making?

☐ Not at all helpful

☐ A little helpful

☐ Somewhat helpful

☐ Quite helpful

☐ Very helpful

Planned vs. Actual Surgery

Is the surgery you ultimately got the same surgery you first decided to have after viewing iCanDecide?

☐ Yes, I got the same surgery I planned to have

☐ No, I got a different surgery

If no, what did you originally plan to have?

☐ Lumpectomy

☐ Single mastectomy

☐ Something else (please explain): _____

Brief health literacy screen[27]

"How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" Possible responses are 1-Never, 2-Rarely, 3-Sometimes, 4-Often, and 5-Always.

APPENDIX IV 2ND FOLLOW UP: PATIENT SURVEYS AT 9 MONTHS FOLLOWING REGISTRATION

PATIENT INFORMATION SHEET 9 MONTHS (for patient completed booklets)

You have been given a booklet to complete for this study. The booklet contains some questions about your knowledge, worries and communication with your doctor as a patient receiving treatment for cancer. Your answers will help us to better understand how the treatment you are receiving is affecting the way you feel.

Note: The title of the measure will not be displayed for patients, and the text in red is the title patients will see.

This booklet is to be completed 9 months after you enroll to the study.

(Section Title:) How You Are Feeling

a) Distress thermometer

(Section Title:) Questions About Breast Cancer

b) Breast cancer self-efficacy scale
c) Cancer worry scale
d) Breast cancer knowledge measure for systemic treatment (not for DCIS patients)

(Section Title:) Making Decisions

e) Subjective Decision Quality (SDQ) (not for DCIS patients)
f) Health Care Climate Questionnaire (HCCQ), for medical oncologist (not for DCIS patients)
g) PACE- Patient Assessment of Cancer communication Experiences

(Section Title:) A Few More Questions

h) FACT-B QoL
i) Help using website
j) Brief literacy screen

1. Directions on how to complete this set of questions are written on the top of the page.

2. Please return your booklet when you are finished.

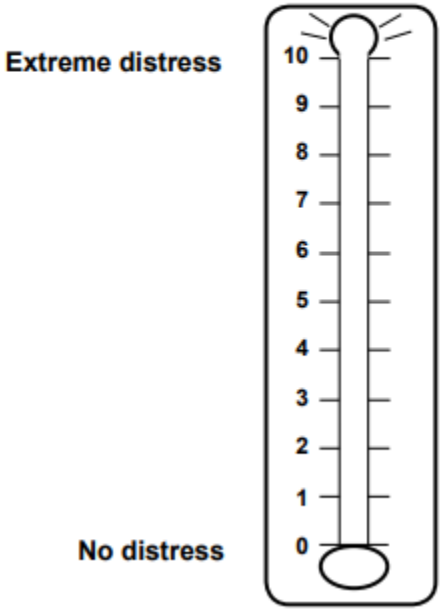
3. Please hand the completed survey to the site coordinator or use the stamped and addressed envelope provided to mail the completed survey to the site coordinator.

Thank you for taking the time to help us.

How You Are Feeling

Distress Thermometer

Instructions: Please circle the number (0–10) that best describes how much distress you have been experiencing in the past week including today.



Source: National Comprehensive Cancer Network. NCCN Distress Thermometer and Problem List for Patients. 2016;

Questions about Breast Cancer

Breast Cancer Self Efficacy scale

The following questions relate to how confident you are about dealing with your breast cancer. Please indicate how much you agree or disagree with each statement.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
a. I am able to ask for help when I have problems related to my breast cancer.	○	○	○	○	○
b. I am able to deal with the fact that I had breast cancer.	○	○	○	○	○
c. I am able to deal with physical symptoms from having breast cancer.	○	○	○	○	○
d. I am able to ask for help for problems related to breast cancer without feeling guilty.	○	○	○	○	○
e. I am able to handle any fears I have about breast cancer returning.	○	○	○	○	○
f. I am able to successfully handle life situations since I had breast cancer.	○	○	○	○	○
g. I am able to have a productive work life even though I had breast cancer.	○	○	○	○	○
h. I am able to successfully work toward my personal goals since I had breast cancer.	○	○	○	○	○
i. I am able to successfully deal with my emotions since I had breast cancer.	○	○	○	○	○
j. I am able to identify changes in my body that may be related to a return of my breast cancer.	○	○	○	○	○
k. I am comfortable calling my healthcare provider if I notice a symptom that may be related to a return of my breast cancer.	○	○	○	○	○

Source: Champion VL[1], Ziner KW, Monahan PO, Stump TE, Cella D, Smith LG, Bell CJ, Von Ah D, Sledge GW. Development and psychometric testing of a breast cancer survivor self-efficacy scale. Oncol Nurs Forum. 2013 Nov;40(6):E403-10. doi: 10.1188/13.ONF.E403-E410.

Cancer Worry Scale

*People sometimes report that they have worries about cancer. Please answer the questions by ticking the box that best applies to you. Please indicate the extent to which you have experienced these worries **during the past week**.*

		Almost never	Sometimes	Often	Almost always
1	How often have you thought about your chances of getting cancer (again)?	☐	☐	☐	☐
2	Have these thoughts affected your mood?	☐	☐	☐	☐
3	Have these thoughts interfered with your ability to carry out your daily activities?	☐	☐	☐	☐
4	How concerned are you about the possibility of one day getting cancer (again)?	☐	☐	☐	☐
5	How often do you worry about developing cancer?	☐	☐	☐	☐
6	How much of a problem is this worry?	☐	☐	☐	☐
7	How often do you worry about the chance of family members developing cancer?	☐	☐	☐	☐
8	How concerned are you about the possibility that you will ever need surgery (again)?	☐	☐	☐	☐

Cancer Worry Scale-Eng. (8 items), © E.M.A. Bleiker, NKI-AVL, Amsterdam, The Netherlands, 2012

4 item Breast Cancer Knowledge Measure for systemic treatment

Now a few questions about breast cancer:

1. Can breast cancer cells be present in other parts of the body even if the surgeon removes all of the tumor from the breast?

○ Yes	○ No	○ Don't know

2. For most women with early breast cancer, how much would waiting several weeks to make a treatment decision about chemotherapy and hormone therapy affect their chances of survival?

○ A little or not at all	○ Somewhat	○ A lot	○ Don't know

3. Without chemotherapy or hormone therapy, about how many women with early stage breast cancer will be cancer free in ten years?

○ Less than half	○ About half	○ More than half	○ Don't know

4. On what kinds of tumors does hormone therapy work best?

○ Hormone receptor (ER or PR) positive tumors

○ Hormone receptor (ER or PR) negative tumors

○ It works the same on both kinds of tumors

○ Don't know

Source: iCanDecide Survey

Making Decisions

Subjective Decision Quality for Systemic treatment:

E1. Please rate the **amount of information** you had when the following decisions were made:

	Not enough		Just right		Too much	N/A
a. Whether or not to have your tumor sent for the Oncotype Dx test	○	○	○	○	○	○
b. Whether or not to have chemotherapy	○	○	○	○	○	○
c. Whether or not to have hormonal therapy	○	○	○	○	○	○

E2. Please rate the **amount of involvement** you had to make the following decisions:

	Not enough		Just right		Too much	N/A
a. Whether or not to have your tumor sent for the Oncotype Dx test	○	○	○	○	○	○
b. Whether or not to have chemotherapy	○	○	○	○	○	○
c. Whether or not to have hormonal therapy	○	○	○	○	○	○

E3. Please rate the **amount of time** you had to make the following decisions:

	Not enough		Just right		Too much	N/A
a. Whether or not to have your tumor sent for the Oncotype Dx test	○	○	○	○	○	○
b. Whether or not to have chemotherapy	○	○	○	○	○	○
c. Whether or not to have hormonal therapy	○	○	○	○	○	○

E4. How **satisfied** are you with the decision about…

	Not at all satisfied	A little satisfied	Somewhat satisfied	Quite satisfied	Totally satisfied	N/A
a. Whether or not to have your tumor sent for the Oncotype Dx test	○	○	○	○	○	○
b. Whether or not to have chemotherapy	○	○	○	○	○	○
c. Whether or not to have hormonal therapy	○	○	○	○	○	○

E5. How **regretful** are you with the decision about…

	Not at all regretful	A little regret	Somewhat regretful	Quite regretful	Totally regretful	N/A
a. Whether or not to have your tumor sent for the Oncotype Dx test	○	○	○	○	○	○
b. Whether or not to have chemotherapy	○	○	○	○	○	○
c. Whether or not to have hormonal therapy	○	○	○	○	○	○

Source:
Resnicow K[1], Abrahamse P[2], Tocco RS[3], Hawley S[4,5], Griggs J[6], Janz N[7], Fagerlin A[8,9], Wilson A[10], Ward KC[11], Gabram SG[12], Katz S[13]. Development and psychometric properties of a brief measure of subjective decision quality for breast cancer treatment. BMC Med Inform Decis Mak. 2014 Dec 5;14:110. doi: 10.1186/s12911-014-0110-x.

Health Care Climate Questionnaire (HCCQ) for medical oncologist

For the next set of questions, please think about the medical oncologist who was most involved in the decision about whether or not you had or plan to have chemotherapy

I feel that my medical oncologist…

	Not at all true	A little true	Somewhat true	Quite true	Very true
a. Provided me with choices and options for my breast cancer treatment.	○	○	○	○	○
b. Understood how I saw things with respect to my breast cancer.	○	○	○	○	○
c. Expressed confidence in my ability to make decisions.	○	○	○	○	○
d. Listened to how I would like to handle my breast cancer treatment.	○	○	○	○	○
e. Encouraged me to ask questions.	○	○	○	○	○
f. Tried to understand how I saw things before offering an opinion.	○	○	○	○	○

Source: Shumway D[1], Griffith KA[2], Jagsi R[2], Gabram SG[3], Williams GC[4], Resnicow K[5]. Psychometric properties of a brief measure of autonomy support in breast cancer patients. BMC Med Inform Decis Mak. 2015 Jul 9;15:51. doi: 10.1186/s12911-015-0172-4. [Adapted from HCCQ: Williams GC. Health care climate questionnaire: https://selfdeterminationtheory.org/pas-health-care-climate]

Patient appraisal of cancer communication experiences (PACE)

The next section asks about your experiences with communication during cancer care. Please mark the extent to which each statement reflects your experiences with communication with Kaiser Permanente doctors, nurses and other healthcare professionals during your cancer care, from the time there was a suspicion that you might have cancer, through the present.

	Never	Sometimes	Usually	Always	N/A
a. I was treated with sensitivity and respect.	○	○	○	○	○
b. I felt known as a person.	○	○	○	○	○
c. I felt listened to.	○	○	○	○	○
d. I felt comfortable asking questions and voicing my concerns.	○	○	○	○	○
e. I felt that everyone worked together as a team in taking care of me.	○	○	○	○	○
f. My wishes were respected.	○	○	○	○	○
g. I got the information I needed, when I needed it.	○	○	○	○	○
h. I got clear, understandable information.	○	○	○	○	○
i. I knew whom to contact if I had a question or concern.	○	○	○	○	○
j. I felt comfortable bringing up anything that was on my mind.	○	○	○	○	○
k. I got consistent information from all my physicians and nurses; everyone was on the same page.	○	○	○	○	○
l. My cancer care team helped me cope with any uncertainty or unknowns.	○	○	○	○	○
m. My cancer care team helped me cope with difficult feelings, like fear, anxiety, and feeling down.	○	○	○	○	○
n. I felt optimism and hope from my physicians and nurses.	○	○	○	○	○

o. I was involved in making decisions as much as I wanted.	○	○	○	○	○
p. I knew whom in the health care system I could reach out to if I was worried that something had gone wrong with my care.	○	○	○	○	○

	Excellent	Very good	Good	Fair	Poor
Overall, how would you rate your experiences with communication related to your cancer care, **from the time there was a suspicion that you might have cancer, through the present?** [b]	○	○	○	○	○

Source: Mazor KM, Street RL, Jr., Sue VM, Williams AE, Rabin BA, Arora NK. Assessing patients' experiences with communication across the cancer care continuum. Patient Educ Couns. 2016;99(8):1343- 1348.

A Few More Questions

Emotional Support Measures to assess values concordant treatment

D8. **When decisions were being made about your treatments**, how important was it to you that your treatments…

	Not at all important	A little important	Somewhat important	Quite important	Very important
d. Kept you from worrying about the cancer coming back	○	○	○	○	○
e. Were the most extensive possible	○	○	○	○	○
f. Gave you peace of mind	○	○	○	○	○

Source: iCanCare survey P01CA163233 (used in publications, eg., **Hawley ST**, Griffith KA, Hamilton AS, Ward KC, Morrow M, Janz NK, Katz SJ, Jagsi R. The association between patient attitudes and values and the strength of consideration for contralateral prophylactic mastectomy in a population-based sample of breast cancer patients. Cancer. 2017 Dec 1;123(23):4547-4555. doi: 10.1002/cncr.30924. Epub 2017 Aug 15.

A Few More Questions

Quality of Life (FACT-B) (Version 4)

Below is a list of statements that other people with your illness have said are important. **Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.**

	PHYSICAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4

GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4

GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
B1	I have been short of breath	0	1	2	3	4
B2	I am self-conscious about the way I dress	0	1	2	3	4
B3	One or both of my arms are swollen or tender	0	1	2	3	4
B4	I feel sexually attractive	0	1	2	3	4
B5	I am bothered by hair loss	0	1	2	3	4
B6	I worry that other members of my family might someday get the same illness I have	0	1	2	3	4
B7	I worry about the effect of stress on my illness	0	1	2	3	4
B8	I am bothered by a change in weight	0	1	2	3	4
B9	I am able to feel like a woman	0	1	2	3	4
P2	I have certain parts of my body where I experience pain	0	1	2	3	4

English (Universal) 16 November 2007

Copyright 1987, 1997

Help using iCanDecide

Did you have help using iCanDecide?

☐ No, I used the website by myself

☐ Yes, I had help from a friend or family member

Brief health literacy screen[27]:

"How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" Possible responses are 1-Never, 2-Rarely, 3-Sometimes, 4-Often, and 5-Always.

APPENDIX V CLINICIAN INFORMATION SHEETS

You have been given a booklet to complete for this study. The booklet contains some questions to be completed at baseline, 9 months and 18 months when you are enrolled as a clinician. Your answers will help us to better understand how to support patients in making their decision about breast cancer surgery/treatment.

Note: The title of the measure will not be displayed for clinicians, and the text in red is the title clinicians will see. Please see the booklets submitted separately, which will be distributed to the clinicians.

1. Section Title: About You **Clinician Characteristics**

(Section Title:) Perspectives about Treatment and Communication

2. **Patient practitioner orientation scale (PPOS)**
3. **Health Care Climate Questionnaire (adapted for clinicians)**

2. It is very important that you return the booklet to us.

3. Please hand the completed survey to the site coordinator.

APPENDIX VI CLINICIAN MEASURES (BASELINE, 9 MONTHS AND 18 MONTHS POST REGISTRATION) AND CLINICIAN CHARACTERISTICS (BASELINE)

Clinician characteristics: (at Baseline only)

1. What type of health care provider are you?

- ◯ Medical doctor (MD)
- ◯ Nurse practitioner (NP)
- ◯ Physician assistant (PA)
- ◯ Other (please specify): _

2. What is your gender?

◯	◯
Male	Female

3. How many years have you been in practice since completing your residency or fellowship training?

_____ years

4. Have you received fellowship training in breast surgery?

◯	◯
Yes	No

5. Which of the following best describes your race? **Please mark ALL that apply.**

- ◯ White
- ◯ Black or African-American
- ◯ American Indian or Alaska Native
- ◯ Native Hawaiian or other Pacific Islander
- ◯ Asian Indian
- ◯ Chinese
- ◯ Filipino
- ◯ Japanese
- ◯ Korean
- ◯ Vietnamese
- ◯ Other Asian (please explain): _
- ◯ Other Race (please explain): _

6. Are you of Hispanic, Latino, or Spanish origin?

◯ Yes, Mexican, Mexican-American, or Chicano

◯ Yes, Puerto Rican

◯ Yes, Cuban

◯ Yes, another Hispanic, Latino, or Spanish origin (please explain): _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

◯ No

7. **In the past 12 months,** approximately what percentage (%) of your <u>new</u> patients were…

a. _____ % Breast cancer (including DCIS) patients

b. _____ % Other (non-breast) oncology patients

c. _____ % Patients without cancer

100 % Total for the past 12 months

Patient-Practitioner Orientation Scale (PPOS)

18-item clinician directed measure with two sub-scales, sharing and caring, which reflect different aspects of clinicians' appraisal of their ability to provide patient-centered care.

	Strongly disagree	Moderately disagree	Slightly disagree	Slightly agree	Moderately agree	Strongly agree
1. The doctor is the one who should decide what gets talked about during a visit.						
2. Although health care is less personal these days, this is a small price to pay for medical advances.						
3. The most important part of the standard medical visit is the physical exam.						
4. It is often best for patients if they do not have a full explanation of their medical condition.						
5. Patients should rely on their doctor's knowledge and not try to find out about their conditions on their own.						
6. When doctors ask a lot of questions about a patient's background, they are prying too much into personal matters.						
7. If doctors are truly good at diagnosis and treatment, the way they relate to patients is not that important.						
8. Many patients continue asking questions even though they are not learning anything new.						
9. Patients should be treated as if they were partners with the doctor, equal in power and status.						
10. Patients generally want reassurance rather than information about their health.						
11. If a doctor's primary tools are being open and warm, the doctor will not have a lot of success.						
12. When patients disagree with their doctor, this is a sign that the						

doctor does not have the patient's respect and trust.						
13. A treatment plan cannot succeed if it is in conflict with a patient's lifestyle or values.						
14. Most patients want to get in and out of the doctor's office as quickly as possible.						
15. The patient must always be aware that the doctor is in charge.						
16. It is not that important to know a patient's culture and background in order to treat the person's illness.						
17. Humor is a major ingredient in the doctor's treatment of the patient.						
18. When patients look up medical information on their own, this usually confuses more than it helps.						

Source: Trapp S, Stern M. Critical synthesis package: Patient-Practitioner Orientation Scale (PPOS). MedEdPORTAL Publications. 2013;9:9501.

Health Care Climate Questionnaire (HCCQ) (existing measure)

An adapted 6-item measure of the original patient-reported HCCQ obtained from clinicians.

Over the past month, overall, I think my breast cancer patients felt that I….

	Not at all true	A little true	Somewhat true	Quite true	Very true
a. Provided choices and options for their treatment.	○	○	○	○	○
b. Understood how they saw things with respect to their breast cancer.	○	○	○	○	○
c. Expressed confidence in their ability to make decisions.	○	○	○	○	○
d. Listened to how they would like to handle their breast cancer treatment.	○	○	○	○	○
e. Encouraged them to ask questions.	○	○	○	○	○
f. Tried to understand how they saw things before offering an opinion.	○	○	○	○	○

Source: Shumway D[1], Griffith KA[2], Jagsi R[2], Gabram SG[3], Williams GC[4], Resnicow K[5]. Psychometric properties of a brief measure of autonomy support in breast cancer patients. BMC Med Inform Decis Mak. 2015 Jul 9;15:51.

APPENDIX VII CLINIC MEASURES

Number of direct care staff in clinic (nurses, medical assistants, mid-level providers, etc.) _ _ _ _ _ _

Does your clinic make a patient navigator available to patients? *(check one)* ☐Yes ☐No

Does your clinic teach residents or fellows? *(check one)* ☐Yes ☐No

How many surgeons who treat patients with breast cancer work in this surgical clinic? _ _ _ _ _ _

Do providers at this surgical clinic participate in any type of breast cancer tumor board? *(check one)* ☐ Yes ☐No

Number of new breast cancer patients seen annually? _ _ _ _ _ _

PAYER MIX

Private Insurance _ _ _. _ _%

Medicare _ _ _. _ _%

Medicare and Private Insurance _ _ _. _ _%

Medicaid _ _ _. _ _%

Medicaid and Medicare _ _ _. _ _%

Military or Veterans Sponsored NOS_ _ _. _ _%

Military Sponsored (Including Champus & Tricare) _ _ _. _ _%

Veterans Sponsored _ _ _. _ _%

Self Pay (No Insurance) _ _ _. _ _%

No Means of Payment (No Insurance) _ _ _. _ _%

Other _ _ _. _ _%

Unknown_ _ _. _ _%

APPENDIX VIII PROCESS EVALUATION PATIENT INTERVIEW GUIDING QUESTIONS

1. Did you use iCanDecide on your laptop, phone or other method?

2. How easy or difficult was it to use iCanDecide?
    a. What was easy to use?
    b. What was hard to use?

3. What did you like best/least about the website?
    a. What did you like the most?
    b. What did you like the least?

4. Did you feel that the website helped to address emotional issues you faced?

5. Did your clinician follow up with you after you viewed the website?

    If yes, was that helpful? Probe for what was/was not helpful

6. Did you generate a summary for both your surgeon and oncologist?

APPENDIX IX PROCESS EVALUATION CLINICIAN INTERVIEW QUESTIONS (FOR PARTICIPANTS)

1. How did the CDB help you to support your patients' needs, and what were its best/worst features?

2. How often did you use the CDB?

3. When did you use the CDB (before/after seeing a patient)?

4. Do you think a tool to help patients manage worry would be helpful to you?

5. Did you feel that using the CDB helped you provide more patient centered care? (why/why not)

6. How easy/difficult would it be for you/your practice to implement tools as part of routine care?
   Patient-facing tools?

   Clinician-facing tools?

7. Do you see a potential for decision support tools to be integrated into the EMR? Why/why not?

APPENDIX X PATIENT THANK YOU LETTERS

Guidance for Disseminating
Thank You Letters to Trial Participants

Trial Participant Thank You Letter

We ask that the physician use the template to prepare a letter thanking the participant for enrolling in this Alliance trial. The template is intended as a guide and can be downloaded from the study page on the Alliance website at [redacted] As this is a personal letter, physicians may elect to further tailor the text to their situation.

This small gesture is a part of a broader program being undertaken by Alliance and the NCI to increase awareness of the importance of clinical trials and improve accrual and follow-through.

We appreciate your help in this effort.

Sample Template

[PARTICIPANT NAME] [DATE] [PARTICIPANT ADDRESS]

Dear [PARTICIPANT SALUTATION],

Thank you for agreeing to take part in this important research study. With the help of people like you who participate in clinical trials, we will achieve our goal of effectively treating and ultimately curing cancer.

There are many reasons why individuals choose to participate in a clinical trial. Sometimes it is because they want access to a specific medication or because they want to do whatever they can to help someone else with cancer. Whatever your reason for participating, you are making a contribution towards finding better treatments and ultimately eliminating this disease for future patients.

You will receive high quality care while participating in this clinical trial. My research staff and I will maintain very close contact with you. This will allow me to provide you with the best care while learning as much as possible to help you and other participants.

On behalf of [INSTITUTION] and the Alliance for Clinical Trials in Oncology, we thank you again for your participation in this clinical trial and look forward to partnering with you.

Sincerely, [PHYSICIAN NAME]

APPENDIX XI INTERVENTION COMPONENTS IN DETAIL

Baseline tailoring variables:
At the time of login following initial patient registration, we will collect information from all patients, but will only use it for tailoring of information and content visible on the website in both arms.

1) Are you leaning toward a particular treatment at this time?
    a. Mastectomy (with or without reconstruction)
    b. Bilateral mastectomy (with or without reconstruction)
    c. Lumpectomy (with or without radiation)
    d. I am not leaning toward anything right now
2) How do want to make decisions with your cancer doctors?
    a. I want to make the decision myself
    b. I want to make the decision with input from my doctor
    c. I want to share the decision
    d. I want my doctor to make the decision with input from me
    e. I want my doctor to make the decision
3) How worried are you about your cancer and its treatment?
    a. 10-pt scale from not very worried to extremely worried
4) What type of person are you? (1-item max-min scale, Scherer et al.)

Sometimes, medical action is clearly necessary, and sometimes it is clearly NOT necessary. Other times, reasonable people differ in their beliefs about whether medical action is needed.

In situations where it's not clear, do you tend to lean towards **taking action** or do you lean towards **waiting and seeing** if action is needed?

Importantly, there is no "right" way to be.

Please answer on the 1-6 scale below:

I lean **strongly** toward **waiting and seeing**	I **lean** toward **waiting and seeing**	I lean **somewhat** toward **waiting and seeing**	I lean **somewhat** toward **taking action**	I **lean** toward **taking action**	I lean **strongly** toward **taking action**
1	2	3	4	5	6

Brief health literacy screen[27]:

"How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" Possible responses are 1-Never, 2-Rarely, 3-Sometimes, 4-Often, and 5-Always.

The Shared Treatment Deliberation System (SharES) consists of two interventions; the patient-facing iCanDecide tool (ESE vs. S) and the Clinician Dashboard (CDB). These will be tested in a patient randomized controlled trial to evaluate the patient facing tool, nested within a stepped wedge trial of the CDB. Further detail on each of the interventions is below.

I. Patient-facing interventions overview:

Both versions of iCanDecide (ESE and S) have 5 general sections, corresponding to an expanded version of Elwyn's shared decision-making model: connect, choice, options, decision and summary. Each section includes factual information about 9 "key facts" related to breast cancer treatment, developed with input from breast cancer clinicians for the proven-effective S version [3]. The ESE version includes additional features that support the key functions of patient centered communication (PCC), specifically to support the emotions that may be triggered with a breast cancer diagnosis. The ESE version includes all the content delivered in the S version, but applies established strategies to support two key emotional support components: expectation and worry management.

a) Expectation management: This module addresses key underlying "heuristics" (psychological shortcuts) that patients use to make emotionally and cognitively challenging decisions, including affective forecasting, misprediction of positive feelings following treatment, and catastrophizing [8, 9]. This module is intended to help patients accept and respond to their emotions, to better understand how their emotions may influence their decision process. We anticipate that helping patients accept and respond to emotions will translate to higher breast cancer self-efficacy. As a result, patients may feel more accepting of less extensive treatment.

b) Worry management: As shown in our prior work, worry and fear about recurrence are drivers of initial treatment decision-making and follow-up care that also impair QoL [12, 13, 16, 42, 43]. Despite the importance of managing worry [12, 42, 43], specific worry support management strategies have not been incorporated into traditional decision tools. This module intends to help patients recognize that worry is natural, how it influences their decision process, and provide strategies for self-managing worry. We anticipate better worry management will translate to lower cancer worry. This is done by providing tailored suggestions for management using strategies below. The worry management module will be available throughout the decision-making process since patient feedback has indicated that worry is ongoing throughout decision making and treatment.

Specific emotional support strategies to address expectations and worry: The iCanDecide - ESE version uses established strategies to support patients to manage expectations and worry in their decision making. How these strategies link to the intended target is outlined in **Table 1**.

a) Tailoring to Maximizer-Minimizer preferences: Using a measure co-developed by co-I Brian Zikmund-Fisher, we will assess patients underlying preferences for maximizing treatment (i.e.,

Table 1. ICD-S and ICD-E Strategies

	Section 1: Connect	Section 2: Choice	Section 3: Options	Section 4: Decision	Section 5: Summary
ICD-S	Focus: Cognitive (facts and values clarification)	Basic choice	Knowledge. Building for key facts	Values clarification	Knowledge and values summary and clinician f/u
ICD-E Expectation management	Focus: Cognitive plus Feelings -Normalizing	-Min-max reflection and guide	-Realistic previews	-Values clarification -Min-max reminder and reflection	Summary of values, feelings and initial treatment choice/leaning
Worry management		-CBT reframe unhelpful thoughts	-CBT body scan -Positivity -Active coping	-CBT decision strength inventory -Positivity -Active coping	CBT booster sessions by email, and return visits to site

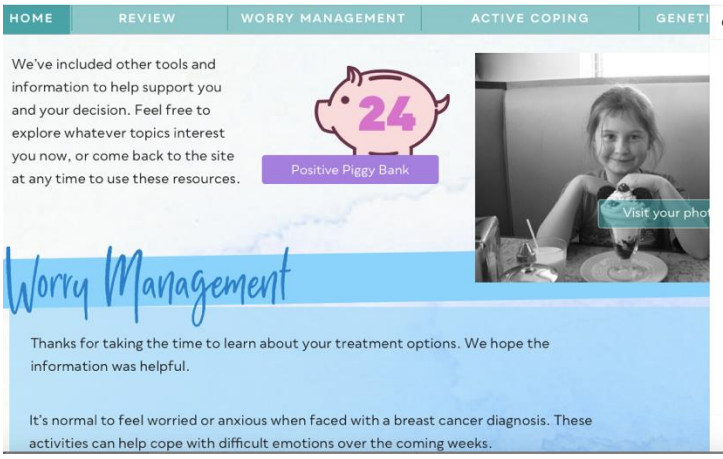
"doing everything") versus more minimal, wait-and-see approaches and provide tailored feedback to help patients understand how these preferences may influence their decision-making. Making patients aware of these tendencies may help them to clarify their preferences with their providers and to reflect critically on their reactions to different treatment approaches before making a final treatment choice [44]. The ESE version presents and tailors messaging based upon the patient's minimizer/maximizer score assessed at log in. The section will use motivational interviewing strategies to ask the patient to consider how their minimizer/maximizer tendency might influence their decision-making (e.g., ***"General preferences for more vs. less care do not always guide us to the best choices. In this case, you might also want to consider…"***).

b) Use of norm-reinforcing statements: These statements are used to help individuals faced with distressing situations understand that their feelings are normal and acceptable, and are encouraged as a method for helping people feel more comfortable (vs. labeling feelings as "bad")[45]. The ESE version uses such statements to help patients understand that their feelings and emotions are normal and manageable (instead of overwhelming and signaling danger). (***e.g., "Feeling overwhelmed by a new diagnosis is totally normal, but there are many resources that can help you manage these feelings."***)

c) Use of realistic previews: Building on prospect theory and gain/loss framing [46], the ESE version provides a complete, "warts and all," description of both positive and negative outcomes ("what I wish I had known stories") that may come from possible treatment choices. The use of such previews, in text or video format, has been shown to translate to higher satisfaction and lower turnover with difficult jobs, as the employees understand what they are getting into when they begin working [47, 48]. Their potential in medical decision-making was recently highlighted.

d) Cognitive Behavioral Therapy (CBT) approaches: CBT is intended to build skills that enable individuals to be aware of thoughts and emotions, how situations influence emotions, and acknowledge and improve dysfunctional thoughts and behaviors [49] [50]. There is a rich literature on CBT as a method for helping patients to self-manage disease, typically focused on symptoms self-management [51-53]. This includes work by study Chair ([redacted] has applied a CBT-based intervention to promote symptom self-management in Veterans with prostate cancer [54]. The integration of CBT into the context of a decision support tool grew from qualitative work led by study Chair [redacted] where patients indicated worry and emotions are often high and can be debilitating. iCanDecide-ESE offers basic principles of CBT (e.g., teaching how to recognize and contain emotion without it having to control decisions) [50] [49]and adoption of specific behavioral strategies (e.g., re-framing unhelpful thoughts, mindfulness body scan, positivity and active coping) [55]. With feedback from breast cancer survivors, we have enhanced the patient-facing tool with CBT-based approaches during and following diagnosis to manage and cope with worry and engage in positive thinking and active coping (example screenshot provided in **Fig. 1**).

Figure 1. Worry Management Enhancement



Additional patient intervention features: To ensure the broadest reach, we will deploy a mobile version of the tool (both intervention and control) so that patients may view it on their mobile

devices. Although most patients used iCanDecide on their home computers (vs. clinic iPads), we want to ensure all patients have access to the study and >80% of adults in our target age group have mobile devices.[56-58]. To allow access across mobile platforms, we use Apache Cordova, a mobile application development framework that enables software programmers to build applications for cross platform mobile devices using CSS3, HTML5, and JavaScript instead of relying on platform-specific operating systems such as Android or iOS. To ensure patients who are primary Spanish speakers can participate we will provide a Spanish version developed using established protocols (e.g., forward and backward translation).

II. Clinician-facing Dashboard Overview:

We have built and pilot-tested the Clinician Dashboard (CDB) prototype to provide surgeons (or clinicians involved in locoregional breast cancer treatment conversations) an online platform that summarizes their patients' disposition following viewing of a patient-facing decision tool with specific regard to:1) lingering knowledge deficits related to upcoming treatment (incorrect items on the selected knowledge questions for each of the 9 key facts), 2) values/priorities that are misaligned with planned treatment, and 3) an indicator of the emotional state of the patient (score ≥ 4 on the distress thermometer, determined to be clinically meaningful anxiety). It also provides a write-in for unanswered questions. Importantly, the CDB will alert clinicians to the emotional state of the patient and help to identify reasons for it. The CDB is configured so that it can be used before or after the patient's first visit (or both) and can be used by surgeons or other clinicians who engage in locoregional treatment decision-making (e.g., advanced practice providers). Clinicians are notified via email after their patient has viewed iCanDecide (ESE or S) and the platform releases alerts to notify clinicians of issues noted above. Clinicians are encouraged to follow up (or "circle back") with patients via phone or additional consultation. In preparation for this project, we conducted pilot testing of this CDB in 9 surgical practices, with 9 surgeons and 2 nurse practitioners. Practices continued to offer the original iCanDecide linked to the CDB. We found all providers (surgeons and NP's) used the CDB and reported it being very useful in their treatment discussions.

APPENDIX XII OBJECTIVES, SOURCE OF DATA AND TIMING OF DATA COLLECTION

Endpoint Name	Grant Aim #	Protocol Aim #	Respondent Type	Timing	Endpoint Measure	Appendix
Knowledge of locoregional treatment risks and benefits*	1,2,3	2.1.1 & 2.2.2 **And** 2.4.1 & 2.4.2	Patient	5 weeks post surgery	Locoregional treatment knowledge scale	III
Knowledge of systemic treatment risks and benefits	1,2	2.3.1 & 2.3.2	Patient	9 months post registration	Systemic treatment knowledge module	IV
Breast cancer self-efficacy^	1,2,3	2.2.1.1 & 2.2.1.2 **And** 2.3.1 & 2.3.2 **And** 2.4.1 & 2.4.2	Patient	5 weeks post surgery **And** 9 months post registration	Breast cancer self - efficacy scale	III, IV
Cancer Worry^	1,2,3	2.2.1.1 & 2.2.1.2 **And** 2.3.1 & 2.3.2 **And** 2.4.1 & 2.4.2	Patient	5 weeks post surgery **And** 9 months post registration	Cancer Worry scale	III,IV
Patient appraisal of <u>global</u> patient centered communication (PCC) *<u>related to locoregional treatment</u>*: consisting of 4 measures a-d)	1,2	2.2.2.1 & 2.2.2.2	Patient	5 weeks post surgery	*Specific items for each global measure below*	III

a) Patient-clinician (surgeon) communication+	1,2	2.2.2.1 & 2.2.2.2	Patient	5 weeks post surgery	Healthcare climate questionnaire (HCCQ-surgeon)	V
b) Appraisal of PCC+	1,2	2.2.2.1 & 2.2.2.2	Patient	5 weeks post surgery	PACE	III, IV
c) Subjective decision quality for locoregional treatment+	1,2	2.2.2.1 & 2.2.2.2	Patient	5 weeks post surgery	SDQ scale-locoregional	III
d) Values-concordant treatment for locoregional+	1,2	2.2.2.1 & 2.2.2.2	Patient	5 weeks post surgery	3 patient-reported values measures for locoregional treatment	III
Patient appraisal of <u>global</u> patient centered communication (PCC) *<u>related to systemic treatment</u>*: consisting of 4 measures (a-d)	1,2	2.3.3 & 2.3.4	Patient	9 months post registration	*Specific items for each global measure below*	IV
a) Patient-clinician (oncologist) communication++	1,2	2.3.3 & 2.3.4	Patient	9 months post registration	Healthcare climate questionnaire (HCCQ-oncologist)	VI
b) Appraisal of PCC++	1,2	2.3.3 & 2.3.4	Patient	9 months post registration	PACE	IV
c) Subjective decision quality for systemic treatment++	1,2	2.3.3 & 2.3.4	Patient	9 months post registration	SDQ scale-systemic	IV

d) Values-concordant treatment for systemic treatment++	1,2	2.3.3 & 2.3.4	Patient	9 months post registration	3 patient-reported values measures for systemic treatment	IV
Quality of Life++	1,2	2.3.5 & 2.3.6		9 months post registration	FACT-B	IV
Process Evaluation	4	2.4.3	Patient and Clinician (qualitative interviews)	Following completion of trial	Qualitative interviews guided by CIFR framework	VIII, IX

*** Primary endpoint/objective; ^Key secondary endpoint/objective; +Additional endpoint/objective; ++ Exploratory endpoint/objective**