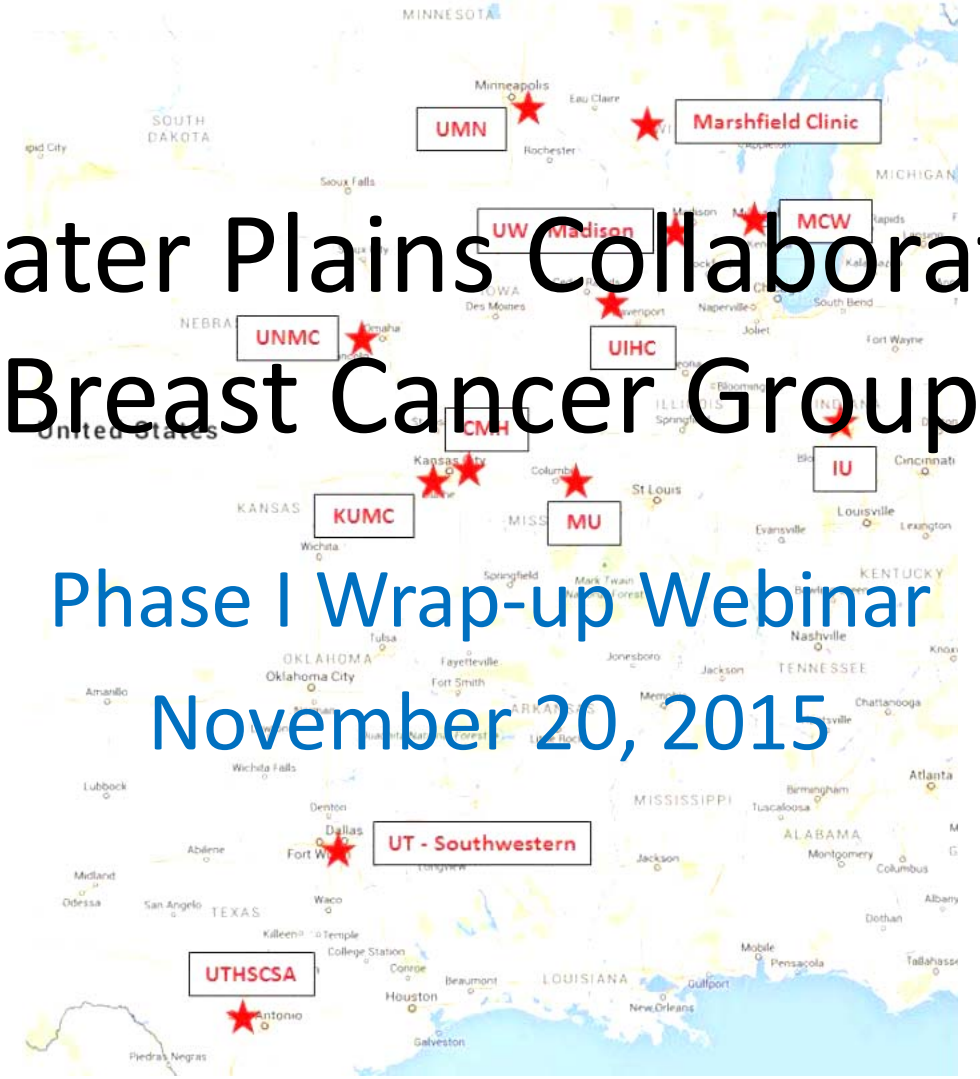
Greater Plains Collaborative Breast Cancer Group



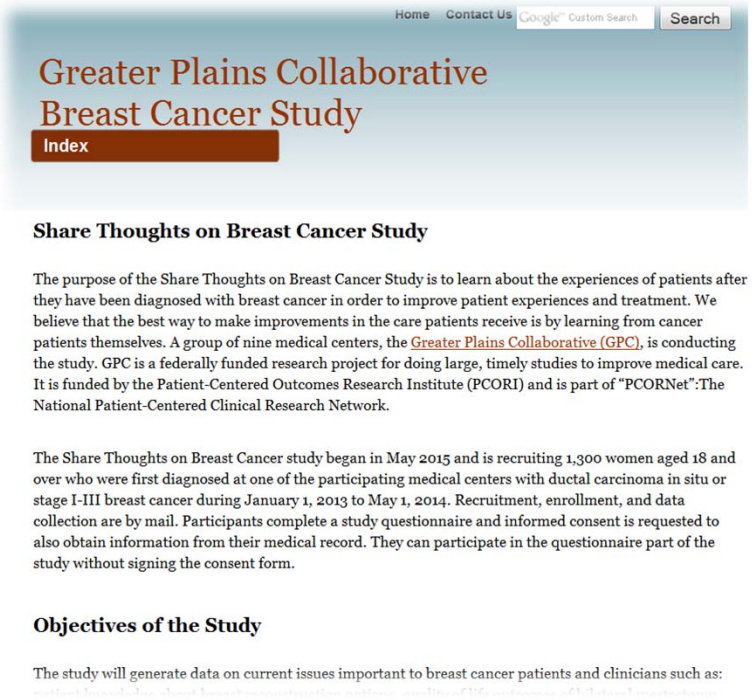
Phase I Wrap-up Webinar

November 20, 2015

Agenda

1. Recap of Phase 1
2. GPC Breast Cancer Datamart update
3. Forming writing groups – discuss draft policy for paper writing
4. Phase 2 plan for building the GPC breast cancer research agenda

Share Thoughts on Breast Cancer Study



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Greater Plains Collaborative
Breast Cancer Study

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Share Thoughts on Breast Cancer Study

The purpose of the Share Thoughts on Breast Cancer Study is to learn about the experiences of patients after they have been diagnosed with breast cancer in order to improve patient experiences and treatment. We believe that the best way to make improvements in the care patients receive is by learning from cancer patients themselves. A group of nine medical centers, the Greater Plains Collaborative (GPC), is conducting the study. GPC is a federally funded research project for doing large, timely studies to improve medical care. It is funded by the Patient-Centered Outcomes Research Institute (PCORI) and is part of "PCORNet":The National Patient-Centered Clinical Research Network.

The Share Thoughts on Breast Cancer study began in May 2015 and is recruiting 1,300 women aged 18 and over who were first diagnosed at one of the participating medical centers with ductal carcinoma in situ or stage I-III breast cancer during January 1, 2013 to May 1, 2014. Recruitment, enrollment, and data collection are by mail. Participants complete a study questionnaire and informed consent is requested to also obtain information from their medical record. They can participate in the questionnaire part of the study without signing the consent form.

Objectives of the Study

The study will generate data on current issues important to breast cancer patients and clinicians such as:

RECAP OF PHASE 1

All study materials and operating procedures available at:
http://www.public-health.uiowa.edu/herce/research/gpc/index.html

Share Thoughts on Breast Cancer Study
Principal Investigators

Coordinating Site

University of Iowa Holden Comprehensive Cancer Center:
- Elizabeth Chrischilles, PhD
- Ingrid Lizarraga, MBBS

Participating Sites

Marshfield Clinic:
- Robert Greenlee, PhD, MPH
- Adedayo A. Onitilo, MD, PhD, MSCR, FACP

Medical College of Wisconsin:
- Joan Neuner, MD, MPH

University of Kansas Medical Center:
- Jennifer Klemp, PhD, MPH

University of Minnesota:
- Anne Blaes, MD

University of Nebraska Medical Center:
- Ann Berger, PhD

University of Texas Southwestern Medical Center:
- Barbara Haley, MD

University of Texas San Antonio Medical Center:
- Amelie G. Ramirez, Ph.D., MPH

University of Wisconsin Carbone Cancer Center:
- Amy Trentham-Dietz, PhD
- Lee Gravatt Wilke, MD, FACS

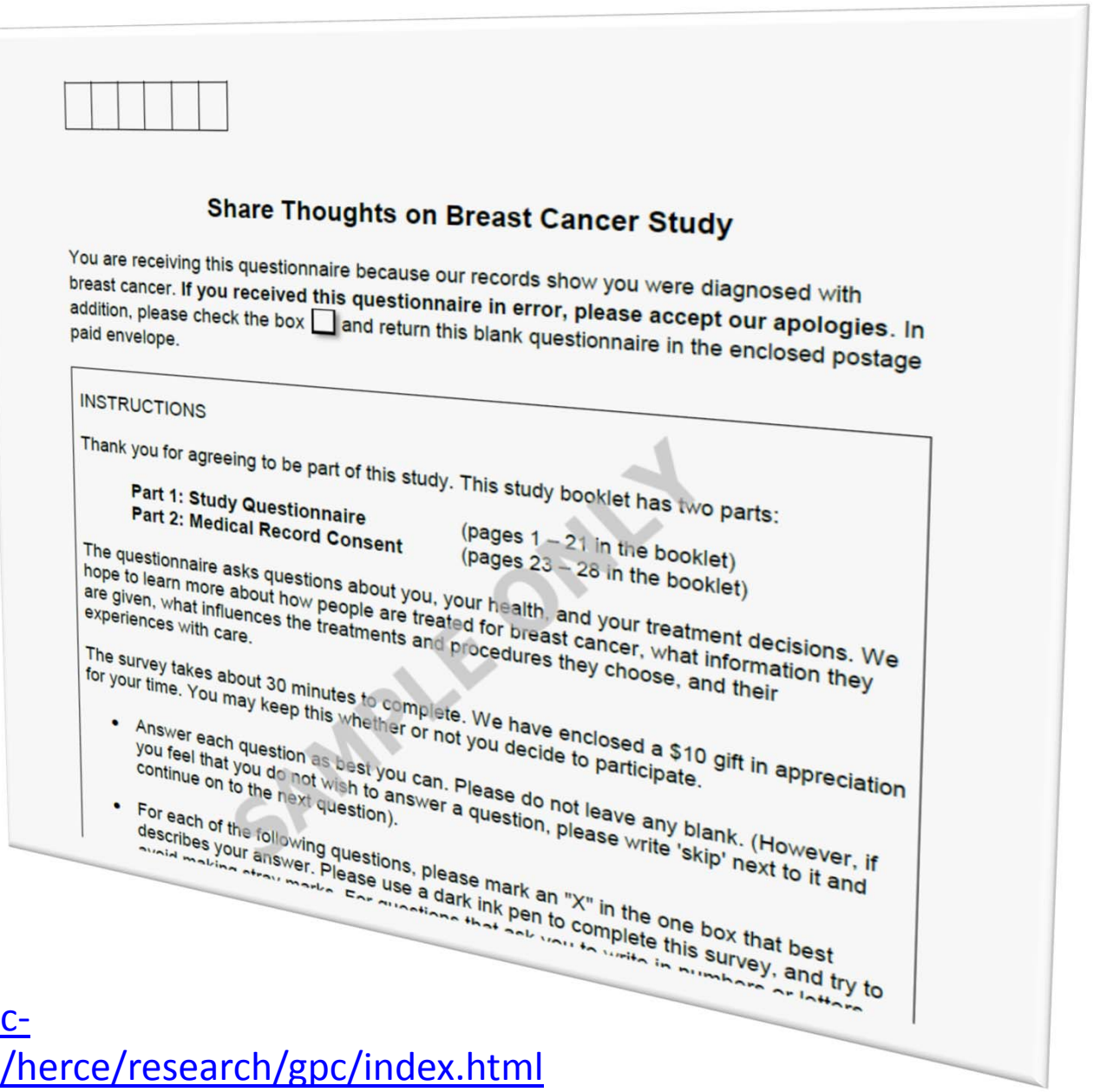
Greater Plains Collaborative Breast Cancer Group

Share Thoughts on Breast Cancer Study
Patient Collaborations

- Four focus group sessions at 8/2014 LEK
  - Recommended signed consent
  - Endorsed mailed questionnaire
  - Re-oriented survey to maximize patient-reported outcomes
  - Notes from patients posted on GPC website
- Participated in webinars
- Edits to cover letter
- Edits to questionnaire, deleted many items

Share Thoughts on Breast Cancer Study
Specific Aims

- Phase 1 specific aims encompassed cohort characterization and survey
  - Aim 1 – Select a cohort
  - Aim 2 – Demonstrate ability to answer research questions via multicenter mailed questionnaire with high participation
  - Aim 3 – Generate data on current issues important to breast cancer patients and clinicians
  - Aim 4 – Validate EHR algorithms using tumor registry gold standard
  - Aim 5 – Demonstrate linkage of survey and i2b2-derived data



Share Thoughts on Breast Cancer Study

You are receiving this questionnaire because our records show you were diagnosed with breast cancer. **If you received this questionnaire in error, please accept our apologies**. In addition, please check the box ☐ and return this blank questionnaire in the enclosed postage paid envelope.

INSTRUCTIONS

Thank you for agreeing to be part of this study. This study booklet has two parts:

Part 1: Study Questionnaire (pages 1 – 21 in the booklet)
Part 2: Medical Record Consent (pages 23 – 28 in the booklet)

The questionnaire asks questions about you, your health, and your treatment decisions. We hope to learn more about how people are treated for breast cancer, what information they are given, what influences the treatments and procedures they choose, and their experiences with care.

The survey takes about 30 minutes to complete. We have enclosed a $10 gift in appreciation for your time. You may keep this whether or not you decide to participate.

- Answer each question as best you can. Please do not leave any blank. (However, if you feel that you do not wish to answer a question, please write 'skip' next to it and continue on to the next question).
- For each of the following questions, please mark an "X" in the one box that best describes your answer. Please use a dark ink pen to complete this survey, and try to avoid making stray marks. For questions that ask you to write in numbers or letters

SAMPLE ONLY

http://www.public-health.uiowa.edu/herce/research/gpc/index.html

Share Thoughts on Breast Cancer Study
Questionnaire Domains

- Cross-sectional survey 12- 30 months after diagnosis
  - Patient-reported outcomes
    - FACT-B, Quick DASH, neuropathy, heart failure, shoulder diagnoses, fear of recurrence
  - BMI change
  - Treatments and interventions received including genetic testing, survivorship care plan elements and breast reconstruction
  - Factors considered when making surgery, chemo decisions
  - Shared decision-making x treatment type
  - Preferred decision-making role
  - Patient experiences of care (Care coordination and physician communication)
  - Recalled decisional uncertainty and decision support, perceived decision effectiveness
  - PCORNet interest in research participation items

Share Thoughts on Breast Cancer Study
Sample Paper Topics

- The role of patient preferences and shared decision-making in management decisions associated with high inter-institutional variability
- What do patients know about their breast reconstruction options?
- Which patients receive autologous fat grafting?
- Prevalence and correlates of long-term effects
  - upper limb morbidity, neuropathy, heart failure, fatigue
- Outcomes of bilateral mastectomy
- Prevalence and correlates of gene testing

Share Thoughts on Breast Cancer Study
Selection Criteria

- Sample selection based on tumor registry data in i2b2 warehouse
- Inclusion criteria:
  - women
  - age 18 or older
  - diagnosed during 1/1/2013 – 5/1/2014
  - first primary breast cancer
  - microscopically confirmed
  - in situ or invasive
- Exclusions:
  - prior breast cancer diagnosis
  - metastatic at diagnosis
  - only histology is lobular carcinoma in situ
  - known to be deceased

Protocol Implementation: Sites used Standard Operating Procedures and participated in weekly webinars

Greater Plains Collaborative Breast Cancer Study

Operating Procedures

Share Thoughts on Breast Cancer Study Operating Procedures

Critical Tasks

Tracking Database Screenshots

SOP for Breast Cancer Study Data

Staff Assignments for Study Implementation

Steps for Mailing

Steps for Mail Merge

Distress Protocol

Letter for Missing Consent Information

Letter for Missing Future Use Consent Information

Letter for Missing Survey Responses

Telephone Script for Missing Information

Honest Broker Study ID Memo

Mailing Video

https://www.youtube.com/watch?v=6oEA0sOI2qE

Participant Materials: Mostly uniform with some customized features

- Uniform questionnaire and consent documents
- Incentives
  - Cash – 4 sites
  - Target gift card – 2 sites
  - Visa gift card – 2 sites
- Cover letters
  - Letterhead
    - Cancer Center – 2 sites
    - Medical Center – 4 sites
    - Medical College – 1 site
    - University CTSI – 1 site
  - Signatures
    - Physician only – 3 sites
    - Physician co-sign – 3 sites
    - PhD only – 1 site
    - PhD and institutional official – 1 site

Share Thoughts on Breast Cancer Study
Survey Status as of 11/13/15

- Sites launched their mailings within a 40 day span
  - 6/19/2015 – 7/29/2015
- 1,987 questionnaires were mailed
  - **1,219 completed (61.35%) (range 52.4-70.8%))**
  - 841 (69%) with signed consent for medical records
  - 772 (63.3%) agreed “that information from this study that does not identify me can be used for research in the future”
  - 632 (51.9%) were “willing to have my name and contact information given to researchers who might want to contact me about future studies.”

Challenges Overcome

- Activating a large diverse network
  - Marshaling local talents while meeting deadlines
  - Getting people engaged to act as team
- Legal/regulatory foundation is brand new
  - IRB Reliance Agreement
  - Data Sharing Agreement
- Competing and complementary PCORNet demands
  - Central PCORI needs (e.g. Common Data Model) versus GPC needs (eg. tumor registry)

Accomplishments

- Patient input substantially directed questionnaire content and study procedures
- 8 of 9 sites deferred IRB oversight to UIOWA
- Cash handling procedures did not require SSN for the $10 cash/gift card at any site
- >50 % response rate at every site.

Upcoming

- Complete Phase 1 aims
  - Aim 4 – Validate EHR algorithms using tumor registry gold standard
  - Aim 5 – Demonstrate linkage of survey and i2b2-derived data
- Launch Phase 2 work
  - Form paper-writing groups, analyze data and publish findings
  - Webinars and future in-person meeting
  - Invite new members, enhance cancer centers involvement
  - Feasibility and preliminary analyses for new grant topics

GPC BREAST CANCER DATAMART UPDATE

FORMING WRITING TEAMS

Publication Policies - *Why*

1. Assure that manuscripts resulting from the Phase 1 GPC *Share Thoughts on Breast Cancer Study* are published in a timely manner;
2. Maintain uniform, high standards for GPC publications and assure that the underlying analyses are consistent with each other;
3. Track the progress of articles and presentations and disseminate this information to GPC members;
4. Prevent duplication of effort in analyses and the preparation of manuscripts;
5. Assure that authorship, with its associated responsibilities and credit, is distributed equitably among members of the GPC-BCG;
6. Prevent disputes over the right to pursue research questions and over authorship, and facilitate the resolution of disputes.
7. Anticipate future collaborative studies of the GPC-BCG as well as products from the Phase 1 study

Writing Teams and Publications Committee

Proposed

- Publications Committee
  - one GPC-BCG member from each GPC institution
- GPC Breast Cancer Study
  - policies meant to cover Phase 1 and future data
- Anyone from a GPC member institution* may submit a writing team proposal for data analysis leading to a manuscript
  - Template for proposing a manuscript
  - Lead author submits proposal including an initial list of writing team members and statistician

*Some restrictions may apply to manuscripts proposing to use *Share Thoughts on Breast Cancer Study* data

  - Informed consent covers analysis of data only by the original 8 institutions, will obtain IRB opinion on “authorship without analysis”

Review and Decisions

Proposed

- Full Publications Committee receives proposals for data analysis leading to manuscripts for review
  - Chair will summarize review in communication with other members of the Leadership Committee
    - Small subcommittee drawn from the Publications Committee
  - Review should generally require 2 weeks
  - Leadership Committee makes decision though it may involve the GPC-BCG
- All GPC-BCG members notified of approved proposals and invited to contact lead author if interested in participating
  - Publications Leadership Committee will participate in decisions about writing team membership if needed

Other Aspects of Publication Policies

Proposed

- Monitoring Progress
- Manuscript Review
  - by Publications Committee
  - Final authorship
  - Recognizing the wider GPC-BCG
  - High priority manuscripts
  - PCORI review
- Abstracts
- Ancillary Studies
- Acknowledging funding source
- Acknowledging the GPC

Proposed

PHASE 2 PLAN FOR BUILDING THE GPC BREAST CANCER RESEARCH AGENDA

Phase II Wish List

Proposed

- Demonstrate a model for creating a research partnership that goes beyond single studies
- Build out a model for engaging a wide variety of stakeholders
  - GPC-BCG site PIs, NCI-designated Cancer Centers, CTSAs, clinicians, health services researchers, patient groups
  - Regular webinars, web office, milestones, policies, informatics support
  - Pilot grants
  - **In-person meeting!**
- Identify funding targets
  - For agendas in CER and clinical epidemiology, healthcare-delivery research
- Develop an initial PCOR proposal to PCORI

Steps/Tasks In First Year

Proposed

- Obtain resource commitment - November
- Identify Leadership Committee and establish publication policies - December
- Begin submitting writing team proposals - January
- Engage and invite new members - January
- Launch sharing of Phase 1 Data - January
- Identify funding opportunities - February
- Develop pilot grant opportunities - March
- In-person meeting including patients - April
- PCORI LOI submission - July or November

Related Phase 2 Milestones

- Transition to sustainable cancer epidemiology cohort (milestones 2.7 and 2.11.1)
- Expand collaborations (milestone 2.6)
- Demonstrate patient engagement policies and compensation (milestone 2.2)

NCI Cancer Centers at GPC Institutions

- Indiana
  - Indiana University Melvin and Bren Simon Cancer Center
- Iowa
  - Holden Comprehensive Cancer Center
- Kansas
  - University of Kansas Cancer Center
- Minnesota
  - Masonic Cancer Center
- Nebraska
  - Fred and Pamela Buffett Cancer Center
- Texas
  - Cancer Therapy & Research Center (UT San Antonio)
  - Harold C. Simmons Cancer Center (UT Southwestern)
- Wisconsin
  - University of Wisconsin Carbone Cancer Center