TITLE: Statewide Learning Collaborative to Improve Adherence to Breast Cancer Guidelines

ABSTRACT:
This proposal seeks to establish the Breast Cancer Quality Improvement Collaborative in Illinois (BQIC-IL), a diverse group of Commission on Cancer-accredited hospitals throughout the state working together to improve quality and safety by improving adherence to National Comprehensive Cancer Network (NCCN) Clinical Practice in Oncology guidelines for breast cancer patients. Importantly, BQIC-IL will be a ***first of its kind*** learning collaboration in cancer care that will utilize specific, innovative strategies to engage providers and drive effective quality improvement (QI) in breast cancer care in response to high-quality comparative data. Importantly, BQIC-IL will allow hospitals to advance to the next level of QI beyond merely receiving quality data, namely, ***effectively using quality data*** from customized measures of breast cancer care based on NCCN guidelines. BQIC-IL will use a novel combination of tested strategies of ***mentored implementation to enhance QI*** (e.g., mentors, coaching, interactive educational curriculum, collaborative-wide meetings, site visits) to equip hospitals and individual providers *to* ***identify their local performance gaps in breast cancer care*** in a rigorous fashion based on high-quality, benchmarked data, and then ***implement solutions*** to those problems using established process improvement (PI) methods. Ultimately, hospitals will measurably improve adherence to NCCN guidelines for breast cancer, quality of care, and outcomes while reducing costs arising from unsafe, inefficient, or inappropriate care.

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A. REVIEWER COMMENTS

No reviewer comments were provided following review of the original letter of intent.

B. OVERALL GOALS AND OBJECTIVES

This proposal seeks to establish the Breast Cancer Quality Improvement Collaborative in Illinois (BQIC-IL), a diverse group of hospitals throughout Illinois working together to improve quality, safety, and adherence to National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Breast Cancer ("NCCN Guidelines") patients. Importantly, BQIC-IL will be the ***first of its kind*** for cancer patients that will utilize specific, innovative strategies to engage providers (e.g., mentors/coaches, multimedia interactive education, networking, etc.) and drive effective quality improvement (QI) in breast cancer care in response to high-quality comparative data.

BQIC-IL will allow hospitals to advance to the next level of QI through effective use of registry data to improve care instead of simply receiving it. The collaborative will facilitate ***effective use of quality data*** from customized measures of breast cancer care based on evidence-based best practice guidelines; thus, BQIC-IL will be a *first of its kind learning collaboration in cancer care*. BQIC-IL will use tested strategies of ***mentored implementation to enhance QI*** (e.g., mentors, coaching, collaborative-wide meetings, educational curriculum, site visits) to equip hospitals and individual providers *to* ***identify their local performance gaps in breast cancer care*** in a rigorous manner based on high-quality, benchmarked data, and then ***implement solutions*** to those problems using established process improvement (PI) methods. Ultimately, hospitals will measurably improve adherence to best practice guidelines for breast cancer, quality of care, and outcomes while reducing costs arising from unsafe, inefficient, or inappropriate care.

C. BACKGROUND AND CURRENT ASSESSMENT OF NEED IN TARGET AREA

Breast cancer is the most common cancer in women in the United States, with over 230,000 new cases, and over 40,000 deaths annually.[1] Once breast cancer is diagnosed, patients often undergo a battery of diagnostic tests, staging studies, and specialist referrals. Treatment often involves multiple therapies including surgery, chemotherapy, hormonal therapy, and/or radiotherapy. Surveillance of patients for years after their initial treatment is also required. Widely accepted, high quality, consensus breast cancer management guidelines, most notably the NCCN Guidelines, exist to guide providers in best practices for this increasingly complicated disease.

However, despite the wide availability of the NCCN and other guidelines, hospitals and providers struggle to adhere to recommended practices. Studies show that care is often not adherent with NCCN Guidelines and other best practice breast cancer care guidelines. Multiple studies from our team and others have shown that many cancer care guidelines are followed correctly in only 40-60% of patients.[2-5] There are multiple studies describing variability in breast cancer guideline adherence in areas including imaging, surgical treatment, chemotherapy, molecular therapy, radiation therapy, and post-treatment surveillance.[6-13] Both considerable overutilization and underutilization have been documented.

Without detailed, high-quality comparative data about adherence to guidelines and outcomes, hospitals and providers remain mostly unaware of their performance. Even when provided with comparative data, *physicians often express that they lack the skills and knowledge to use the data to improve care.* Objective measurement tools are central to this effort, and providers need to be equipped to implement local QI and PI efforts. Furthermore, there is often inadequate or no funding from hospitals to implement solutions even if clinicians have identified problems in care using comparative data. Thus, an important need exists to empower hospitals and providers

treating breast cancer patients to identify their local problems with guideline adherence and develop sustainable solutions to those problems.

Statewide QI learning collaboratives have demonstrated success in other medical specialties and conditions,[14-16] but have never been focused on breast cancer care. Thus, there are major opportunities available related to the novelty, implementation, utility, and sustainability of a statewide cancer care QI initiative to improve adherence to the NCCN guidelines. This proposal leverages the previous knowledge and experience of the Northwestern Surgical Outcomes and Quality Improvement Center (SOQIC) with statewide hospital collaboration and cancer-specific QI research by designing and implementing a statewide collaborative of hospitals to improve the quality of care for breast cancer patients in Illinois. Our panel of experts and personnel in SOQIC are highly equipped to carry out this meaningful and challenging work through our previous and ongoing experience creating and coordinating the Illinois Surgical Quality Improvement Collaborative (ISQIC; www.isqic.org), a learning collaborative of 56 hospitals dedicated to improving the quality of surgical care in Illinois.

Hospitals already are required to collect the data needed for quality measurement for breast cancer patients. Reporting basic information about all new cancer cases is a federal requirement. Hospitals accredited by the Commission on Cancer (CoC) must report even more detail about every new cancer patient they see to the National Cancer Data Base (NCDB). The NCDB is a clinical oncology database, jointly sponsored through the American College of Surgeons and the American Cancer Society. More than 1,500 CoC-accredited facilities report to the NCDB. Since 1989, NCDB data have included details regarding patient demographics, comorbidities, cancer diagnoses, treatment, and outcomes. Cases reported to the NCDB represent approximately 70% of newly diagnosed cancer cases nationwide, and the NCDB now has data on more than 35 million cancer patients. As a result, the NCDB is currently considered one of the highest quality risk-adjusted, comparative databases in the world. The NCDB will serve as the common data collection and reporting platform for the proposed breast cancer QI collaborative. Our group has extensively used the NCDB for quality measurement, resulting in more than 100 publications.

The CoC provides feedback to hospitals on seven fairly basic quality measures through the Cancer Quality Improvement Program (CQIP) and the Rapid Quality Reporting System (RQRS) based on NCDB data. Very few measures are reported overall, and thus the data do not reflect the full breadth of the impactful aspects of the NCCN guidelines on cancer patients. As a result, the data are highly underutilized, and hospitals vary considerably in whether they actually use their data and performance reports to enact QI efforts, as evidenced by continued poor guideline adherence nationally and in Illinois. All 72 CoC-accredited hospitals in Illinois would be eligible to participate in an Illinois QI collaborative for breast cancer. The CoC has expressed enthusiasm and support for a statewide oncology collaborative and the Director of Cancer Programs for the American College of Surgeons and the founder of the NCDB, Dr. David Winchester, is a collaborator and mentor on this project. Notably, SOQIC and the CoC/NCDB are located in the same building.

A preliminary analysis of NCDB data from Illinois reveals that, despite feedback of comparative data, variability exists between institutions. For instance, there is a 2.5-fold variation in hospital breast conserving therapy rates statewide. Based on our previous experience and a review of existing breast cancer literature, it is highly likely there is considerable unmeasured variation in

adherence to guidelines statewide, even at CoC hospitals,[13,17] including both inadequate provision of care and inappropriate overutilization of care (Table 1).

Table 1: Potential Novel Breast Cancer Guideline-Based Quality Measures
Primary site image or palpation-guided needle biopsy (core/FNA) performed to establish diagnosis rather than open biopsy
Referral for genetic counseling in appropriate patients
Use of neoadjuvant therapy in appropriate patients
Appropriate utilization of genomic profiling and appropriate treatment in response to genomic profiling results
Use of HER2-directed therapy in HER2 positive patients
Post mastectomy radiation therapy inappropriately utilized in breast cancer patients with small tumors (T1-T2) and negative lymph nodes
Inappropriate use of PET, CT, and radionuclide bone scans in the staging of early breast cancer that is at low risk of spreading

D. TARGET AUDIENCE

The primary audience for this project will be hospitals and physicians in Illinois who care for breast cancer patients at cancer centers that are CoC-accredited and report to the NCDB. Multidisciplinary management of breast cancer patients will be emphasized and cancer QI teams will be encouraged to involve relevant providers from medical oncology, surgical oncology, radiation oncology, pathology, radiology, supportive oncology, and other relevant specialties. There are 72 CoC-accredited Illinois hospitals that would be eligible to participate in a statewide QI collaborative for breast cancer care. Finally, Illinois residents who are diagnosed and treated for breast cancer will directly benefit from the project outcomes. The incidence of new diagnoses of breast cancer in Illinois in 2014 was 10,277; thus, this project can potentially impact up to 20,000 patients over 2 years.[18] Moreover, arming cancer centers with the tools to assess adherence to the NCCN breast cancer guidelines will be transferable to other malignancies.

E. PROJECT DESIGN AND METHODS

E.1. PROJECT CLASSIFICATION: Quality Improvement

E.2 INTRODUCTION

BQIC-IL will be coordinated by the Northwestern University Surgical Outcomes and Quality Improvement Center (SOQIC; www.SOQIC.org). The Principal Investigator (PI; Yang) will serve as the Director of BQIC-IL. The BQIC-IL Coordinating Center will be responsible for development and implementation of all collaborative-wide activities, in consultation with the BQIC-IL Advisory Committee. Specifically, the Coordinating Center will be responsible for recruitment of hospitals, development of novel quality measures reflecting the NCCN guidelines, implementation of an educational QI curriculum, recruitment and training of mentors, development and execution of benchmarked data reports with custom analyses for member hospitals, coordination of an annual statewide breast cancer QI project, conducting hospital site visits, and overall administration of BQIC-IL.

SOQIC has extensive experience in leading large learning collaboratives through its leadership of the Illinois Surgical Quality Improvement Collaborative (ISQIC; www.ISQIC.org), a 56-hospital learning collaborative that has been successful in improving the quality of surgical care in Illinois. SOQIC will utilize its existing relationships with Illinois hospitals through ISQIC to recruit hospitals eligible to participate in BQIC-IL. SOQIC has utilized the lessons learned from the ISQIC experience to develop a stepwise process for creation and implementation of a breast cancer-focused statewide QI learning collaborative.

E.3 SPECIFIC AIMS

SPECIFIC AIM 1: To examine variability in adherence to NCCN Clinical Practice Guidelines in Oncology for Breast Cancer in Illinois. We hypothesize that some hospitals will have statistically and clinically significantly lower guideline adherence rates compared to other hospitals in the state.

SPECIFIC AIM 2: To establish the Breast Cancer Quality Improvement Collaborative in Illinois (BQIC-IL), a QI learning collaborative of Commission on Cancer (CoC)-accredited hospitals in Illinois with the goal of increasing adherence to NCCN Guidelines for breast cancer. Based on our existing quality collaborative with 56 Illinois hospitals, we hypothesize that up to 25 of the 72 CoC-accredited hospitals in Illinois can be recruited to participate in BQIC-IL and, through a novel combination of QI strategies and process measures based on NCCN Guidelines, learn how to *effectively use quality data, utilize mentored implementation to enhance QI efforts in breast cancer*, *identify local performance gaps in breast cancer care*, and *implement solutions* to those problems using established process improvement (PI) methods.

SPECIFIC AIM 3: To evaluate improvement in NCCN Guideline adherence in the BQIC-IL hospitals compared to control hospitals. We hypothesize that participation in BQIC-IL will result in significantly improved adherence to NCCN Guideline-based breast cancer care process measures compared to control hospitals.

E.4. PROJECT OVERVIEW

This proposal seeks to establish the Breast Cancer Quality Improvement Collaborative in Illinois (BQIC-IL), a group of CoC-accredited hospitals throughout the state, **working together to improve NCCN breast cancer guideline adherence statewide** in order to improve quality and safety in breast cancer care. Importantly, BQIC-IL will be the first of its kind for cancer patients that will utilize strategies to drive QI and engage providers in response to high-quality comparative data.

Based on the BQIC-IL Coordinating Center's previous experience with ISQIC, along with a needs assessment of Illinois hospitals, BQIC-IL will combine multiple improvement strategies in a novel combination to better engage providers and have a larger impact on improving breast cancer care. These new approaches will include:

1. Require the **Breast Cancer Quality Improvement Team at each hospital** (described below) to take part in **formal training in QI/PI approaches**.
2. **Augment current registry data with additional data collection evaluating adherence to novel NCCN Guideline-based process measures.** Other accepted guidelines such as those from the American Society of Clinical Oncology (ASCO), CoC, and other oncology-specific professional organizations and societies may also be utilized. **Comparative performance reports** will facilitate provider examination and use of performance data to develop and implement QI projects. We will use our prior experience to explore novel approaches to automate data collection and decrease the data abstraction burden to keep the focus on QI.
3. Provide all hospital QI teams with trained and experienced **local QI mentors/coaches** to guide them through their local and statewide QI projects. The mentors for BQIC-IL will be local, since in our experience, having a local mentor can facilitate a closer more fluid

relationship between the mentor and mentees, resulting in a more productive and successful relationship on both sides.

4. Form the **BQIC-IL Site Visit Team** to make in-person visits to selected hospital sites.
5. Offer **pilot grants** to hospitals attempting to implement solutions based on their performance reports.
6. Require hospitals to participate in annual local (chosen by hospital) and statewide (chosen by Advisory Committee and done by all participating hospitals) **collaborative Breast Cancer Quality Improvement Projects.**
7. **Facilitate leadership engagement** by requiring presentation of BQIC-IL performance reports to each hospital's Board (or Quality Committee of the Board) annually.
8. Require participation in **semi-annual collaborative-wide conferences** where participants will discuss their projects, share experiences, and participate in face-to-face QI/PI training.

By using this novel combination of approaches to improving the quality of breast cancer care, we expect that BQIC-IL will enable hospitals to improve their adoption of multidisciplinary best practices in accordance with the well-established NCCN guidelines for breast cancer. They will be able to identify their local performance gaps in a rigorous fashion based on high-quality, benchmarked data, and implement solutions using established PI methodology. Ultimately, each hospital will measurably increase adherence to diagnosis, treatment, and/or surveillance best-practice guidelines in breast cancer, improve the quality of care provided, and reduce costs arising from unsafe, inefficient, or inappropriate care.

E.5. SPECIFIC PROJECT OBJECTIVES:

E.5.A. PHASE 1: ESTABLISHMENT OF THE COLLABORATIVE

1. Assemble a multi-stakeholder Advisory Committee to help guide BQIC-IL, establish goals, and recruit hospitals. The group will consist of representative physicians, nurses, administrators, and other stakeholders of various oncologic specialties from throughout the state. The CoC (Dr. David P. Winchester), SOQIC, and the NCCN (Dr. William Gradishar) will also be represented on the Advisory Committee. Two additional nationally recognized breast oncologists, Dr. Nora Hansen (Surgical Oncology) and Dr. Jonathan Strauss (Radiation Oncology) have already agreed to serve on the Advisory Committee.

2. Recruit up to 25 of the 72 CoC-accredited eligible hospitals in Illinois. The target accrual will be 25 hospitals with a minimum accrual of 5 hospitals. Notably, the 5 hospitals of Northwestern Memorial HealthCare have already committed to participation in BQIC-IL, and numerous other hospitals in Illinois have expressed interest in joining a statewide cancer QI collaborative.

3. Establish the BQIC-IL Coordinating Center for recruitment of hospitals, identification and development of quality measures for the collaborative, development and implementation of an educational QI curriculum customized to include QI in cancer care, recruitment and training of mentors/coaches, development of benchmarked data reports with custom analyses for member hospitals, development of a site visit team, coordination of an annual statewide QI project, and overall administration of the collaborative.

4. Develop the BQIC-IL QI/PI educational curriculum based on our multimedia interactive ISQIC QI/PI education curriculum. The BQIC-IL educational curriculum will include a focus on multidisciplinary team building for QI and include more clinical content highlighting areas for improvement in breast cancer care. For each quality measure examined, modules will also be

created to educate providers on the evidence for the measure, best practices for ensuring adherence, and strategies for earning multidisciplinary buy-in.

5. Recruit and train QI mentors to assist local QI Teams throughout the QI process. Importantly, the local mentors/coaches will conduct regularly scheduled mentorship calls with the Breast Cancer Quality Improvement Teams they are mentoring, and may make visits to their mentee sites of their own accord, which has occurred in our previous experience.

6. Develop novel process measures that reflect care consistent with best practice guidelines (e.g., NCCN Guidelines), beyond what is currently collected in the NCDB. Process measures (i.e., adherence rates to NCCN Guidelines) offer unique opportunities to identify actionable QI targets and demonstrate early success in improving quality.

7. Create statewide benchmarked comparative data reports reflecting the novel BQIC-IL breast cancer quality process measures and other established breast cancer process and outcome measures already measured in the NCDB. Hospital performance will be benchmarked against both the hospitals in the collaborative (Figure 1) and the more than 1,500 CoC-accredited hospitals nationwide. The selection and creation of the process measures for BQIC-IL will be based on gaps in the provision of optimal breast cancer care according to accepted, evidence-based best practice guidelines, identified utilizing state-specific data with the input of the Advisory Committee. Thus the initial BQIC-IL QI projects will be optimally positioned for improving breast cancer care in Illinois.

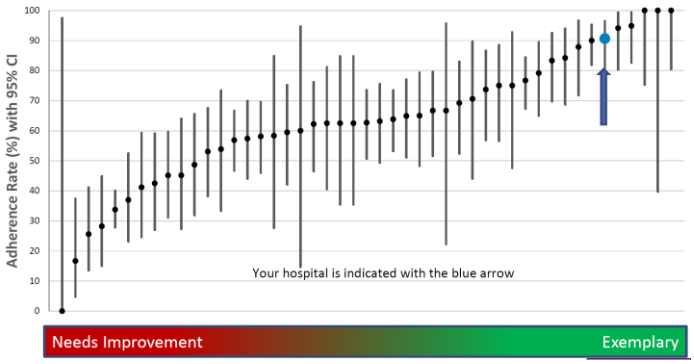


Figure 1: Sample Benchmarked Comparative Data Report

E.5.B. PHASE 2: INITIAL COLLABORATIVE OBJECTIVES

8. Recruit and train local Breast Cancer Quality Improvement Teams that will be responsible for BQIC-IL implementation at each hospital. Each team will consist of at least 3 people.

i. **BQIC-IL Local Champion**: A breast cancer-focused clinician champion for BQIC-IL will be identified. The site leader will preferably be a respected clinical oncologist from Medical Oncology, Radiation Oncology, or Surgical Oncology, ideally the CoC Cancer Liaison or Cancer Quality Committee Chair. The participation of one of these leaders as the BQIC-IL Local Champion will be favored as s/he already has the respect and reputation within their institution to be able to more easily achieve buy-in for the activities of the collaborative across oncology specialties, permitting both a quicker timeline and higher impact for collaborative-related QI activities. The Champion will be expected to report to his/her institution's Cancer Committee (or similar) on an at least quarterly basis as a standing agenda item in order to maintain institutional focus and attention on BQIC-IL's activities. Furthermore, in order to maintain leadership engagement, the Champion will be required to present to his/her hospital's Board on an annual basis.

ii. **BQIC-IL Supporting Clinician**: Ideally from an oncology-related specialty different from that of the Champion, this clinician will partner with the other team members in leading the local work of BQIC-IL at their hospital.

iii. **Cancer Registrar/QI Project Manager**: The registrar is already in place at each hospital per CoC requirements and will be responsible for clinical data abstraction and QI project management locally. NCDB cancer registrars already have some experience in QI project management and will receive further training through the BQIC-IL QI/PI curriculum.

iv. **Optional Participant(s):** Breast cancer-focused clinician representatives from other specialties including Radiology and Pathology, the hospital's QI infrastructure, additional hospital cancer registrars, and/or oncology nurses/midlevel providers.

9. Train the Breast Cancer QI Teams in QI/PI approaches using our formal online multimedia and in-person curriculum.

10. Initiate BQIC-IL site visits to assess hospital quality and safety culture, QI resources, implementation of the quality projects, observe how initiatives are adapted locally, and identify areas for improvement in cancer care at each hospital. The site visits will allow the Coordinating Center to provide more personalized and specific advice and assistance with QI, and draw the attention of hospital leadership to the work of their hospital's Breast Cancer QI Team.

11. Provide sustained support to hospitals for consultation and guidance during statewide QI projects through the experienced, trained QI mentors and the Coordinating Center team.

12. Utilize comparative quality data from the NCDB and additional NCCN breast cancer guideline-specific data collected specifically by BQIC-IL hospitals. Breast cancer best practice guidelines will guide the creation of novel, actionable breast cancer quality measures that will be a hallmark of this collaborative. The Coordinating Center will use this data to generate individual hospital- and Illinois-specific comparative performance reports to determine where areas for improvement in breast cancer care exist. Both national and statewide benchmarks will be used. Hospitals will be particularly alerted to their specific areas of poor performance.

13. Initiate semi-annual collaborative-wide in-person meetings. Each meeting will focus on education in QI/PI in cancer care, sharing improvement efforts, presenting and discussing collaborative projects, and administrative concerns. A keynote speaker who is experienced in cancer care QI will be invited to each meeting. Increasingly more advanced QI/PI training topics will be introduced at these meetings. Attendance of each hospital's QI Team will be required. Awards for exceptional efforts and performance will be offered annually.

E.5.C. PHASE 3: COLLABORATIVE-WIDE QUALITY IMPROVEMENT IN BREAST CANCER CARE

14. Implement statewide annual Breast Cancer Collaborative Care QI Projects, in consultation with the Advisory Committee. We will use data from process measures created based on NCCN guidelines in order to identify areas of poor performance across the state and develop the annual statewide QI projects around one or more of these areas.

- Advisory committee will select the topic for the statewide QI project.
- Coordinating Center will provide support and guidance to member hospitals for the project.
- **PI coaches** from the Coordinating Center will hold bi-monthly group calls with hospitals to assess progress, share experiences, and set goals for advancing their QI projects.
- A **toolkit of interventions with a guide to implementation** that is specific to the topic of the statewide project may be included. This toolkit will serve as an implementation guide that will help hospitals select and customize intervention(s) to address their hospital's local problems while accounting for their QI experience, resources, needs, and barriers. Solutions could include tools such as BQIC-IL "virtual breast cancer tumor boards" to encourage

multidisciplinary oncology care coordination and communication at hospitals which do not have the volume, resources, or expertise to conduct their own multidisciplinary conferences.

15. **Initiate individualized annual local QI projects** based on the comparative BQIC-IL comparative quality performance reports with the assistance of QI mentors.
16. **Demonstrate significant improvement in guideline adherence** to NCCN Guidelines (and any other breast cancer best practices) or outcomes by the end of Year 2 of BQIC-IL.
17. **Demonstrate the effectiveness of statewide collaboration in cancer care QI** among clinicians, hospitals, and professional organizations to improve the quality of breast cancer care.

All educational material, resources, reports, toolkits, and other implementation tools will be made available to all BQIC-IL hospitals free-of-charge through the secure BQIC-IL website. In the spirit of collaborative QI, interested outside parties will be able to access specific BQIC-IL resources upon request on a case-by-case basis subject to review by the Coordinating Center.

F. INNOVATION:

BQIC-IL provides a unique and novel initiative for Illinois hospitals that will create a state-wide multispecialty cancer care QI collaborative. While statewide collaboratives have been successful in other specialties, *no active, large scale, multi-institutional, breast cancer-focused QI collaborative currently exists*. Thus, this proposal is **unique** in that a multidisciplinary breast cancer care QI collaborative combining high-quality comparative data and the mentored QI implementation strategies described in this proposal has never been attempted. BQIC-IL is thus **novel** in its scale and comprehensiveness, representing **the first use of these strategies in a breast cancer-focused QI collaborative**. The expected goal of the collaborative will be to develop a first of its kind breast cancer care quality and safety improvement program that will lead to significant improvements in breast cancer guideline adherence, utilization of coordinated multidisciplinary cancer care, and breast cancer-related morbidity and mortality rates by engaging in data-driven QI initiatives. Importantly, BQIC-IL will serve as a framework for breast cancer QI collaboration in other states.

G. EVALUATION DESIGN:

G.1. SURVEYS, EVALUATION FORMS, AND REPORTS:

BQIC-IL hospitals will initially be evaluated through data from **surveys, evaluation forms, and reports** collected from each hospital using fully tested and refined tools according to a schedule defined through our previous experience with ISQIC.[19-21] These tools assess local QI experiences, resources, barriers, hospital engagement, participation, and implementation intensity (Table 2, Appendix). All hospitals will be required to submit these materials at the initiation of BQIC-IL (baseline) and on at least a semi-annual basis.

Table 2. BQIC-IL Surveys, Evaluations, and Reports

Baseline	Ongoing Basis
Safety Attitudes Questionnaire	Hospital Semiannual Progress Reports
Hospital QI/PIR Resource Self-Assessment Tool	BQIC-IL QI Team Meeting Form
QI Methods Knowledge Application Tool (QIKAT)	Oncology QI Mentor Meeting Call Form/Hospital Evaluation
Hospital Leadership Engagement Survey	

G.2. SITE VISITS:

Site visits also play an important role in evaluation. An interdisciplinary team consisting of an oncologist (PI), a qualitative/mixed-methods evaluation expert (Dr. J. Johnson), and a research coordinator will conduct all site visits. Data will be collected through observation, interviews, focus groups, and artifact collection and analysis. The site visit protocol is adapted from a protocol previously developed, refined, and tested in over 30 hospitals (Appendix) being used in our current, AHRQ-funded study evaluating ISQIC (AHRQ R01HS024516-01, PI: Bilimoria).

G.3. STATISTIAL ANALYSIS:

For the **statistical analysis**, since all hospitals in this study will receive the intervention and because we do not have a contemporaneous control group of hospitals that will not receive the intervention, our basic study design will be a pre-post evaluation. We will test the hypothesis that BQIC-IL's intervention(s) will increase the proportion of breast cancer patients receiving guideline-adherent care. All study variables will be appropriately summarized using univariate statistics. To test for differences in patient populations during the pre- and post-intervention periods, we will use hospital-level cluster-corrected t-tests and chi-squared tests to investigate differences in patient characteristics over study periods.

The **primary outcome measures** will be dichotomous measures indicating whether a breast cancer patient undergoing treatment in a study hospital received (or did not receive) guideline-adherent care. The key explanatory measure will be a dichotomous measure indicating whether an incident patient received treatment at a study hospital during the pre- or post-intervention period. Statistical models will control for patient characteristics in the NCDB, and will also control for hospital characteristics such as bed size, teaching status, volume, and nurse-to-bed ratio.

The first analysis will be an **unadjusted pre-post evaluation**. We will use cluster-corrected chi-square tests of association to test for differences in the proportion of women who receive guideline-adherent care before-and-after intervention. The second analysis will be an **adjusted pre-post evaluation**. To test our hypothesis adjusting for patient and hospital confounders, we will estimate logistic regression models of the general form:

$$logit\{Pr(Adherent = 1|PrePost_i, \mathrm{X}_i)\} = \beta_0 + \beta_1 PrePost_i + X_i'\beta$$

where *Adherent* is a dichotomous outcome indicating receipt of guideline-adherent care (or not), *PrePost* measures whether patient *i* underwent treatment during the post-intervention (vs. pre-intervention) period, and X_i is a vector of patient characteristics and attributes of the hospital in which *i* underwent treatment. Estimates of β_1 that are positive (or odds ratio (OR) >1.00) and statistically significant (p<0.05) will provide support for the effectiveness of our intervention. All models will be estimated with robust clustered variance estimation to account for patient clustering within hospitals. We may also estimate a set of linear probability models (LPMs) that regress each dichotomous outcome on *PrePost*, a vector of patient characteristics, and a set of hospital fixed effects to control for all unmeasured hospital attributes that do not vary within hospitals, but that vary across hospitals. Hospital fixed effects cannot be included in logistic regression models due to the incidental parameters problem.[22] LPMs may be viable in this application because we anticipate rates of guideline-adherent care within the 60-80% range, where the relationship between logits and probabilities should still be roughly linear. The final analysis will be an **adjusted pre-post evaluation with historical controls**. A limitation of our study design is the lack of contemporaneous study controls, which will prevent us from being able to conclude that changes in the proportion of patients receiving guideline-adherent care was due

to our intervention alone, and not due to other secular changes occurring during the study period. To address this limitation, we will match hospitals in our study with other Illinois CoC hospitals that did not participate in our study. We will obtain NCDB data for the same time period and test the hypothesis that the increase in the proportion of patients receiving guideline-adherent care in study hospitals is greater than the increase in non-study hospitals. We will test this hypothesis by estimating difference-in-differences (DD) models of the general form:

$$logit\{Pr(Adherent = 1|PrePost_i, \mathrm{X}_i)\}$$
$$= \beta_0 + \beta_1 PrePost_i + \beta_2 Study_i + \beta_3 PrePost_i * Study_i + X_i'\beta$$

where *Study* measures whether patient *i* underwent treatment in a study hospital (vs. matched control hospital), and *PrePost*Study* is an interaction term between *PrePost and Study*. The DD estimator, β_3 represents the difference between study and matched control hospitals in time period differences in the log odds of receiving guideline-adherent care. A statistically significant ($p<0.05$), positive coefficient will provide support for our hypothesis regarding the effectiveness of our intervention. Again, all models will be estimated with robust clustered variance estimation to account for patient clustering within hospitals.

Because we do not have complete pilot hospital data, we calculated **statistical power** for a two-sample test for differences in proportions (patients receiving treatment in the pre-intervention period vs. post-intervention period) under various assumptions regarding the final number of hospitals in our study (*k* clusters), the average number of breast cancer patients per hospital (*m* cluster size), effect size, baseline rates of guideline-adherent care, and intra-cluster correlations. Alpha was set at 0.05. We calculated scenarios for which we would have ≥80% power to detect an increase in the proportion of patients receiving guideline-adherent care (Appendix).

In the longer term, we also expect to see improvements in breast cancer-specific outcomes in the NCDB. We anticipate that the BQIC-IL implementation protocol, implementation analysis, guideline adherence data, and results over time will be presented at national meetings and published in leading journals. If BQIC-IL is successful after the first two years, a second wave of recruitment from the remainder of the 72 eligible CoC-accredited Illinois hospitals will be considered. The study will also serve as the basis for future research focused on development of a generalizable model for implementation of multidisciplinary QI learning collaboratives in cancer care. The lessons learned from this breast cancer-focused collaborative will inform the creation of successful multi-institutional collaboratives focused on other cancer sites.

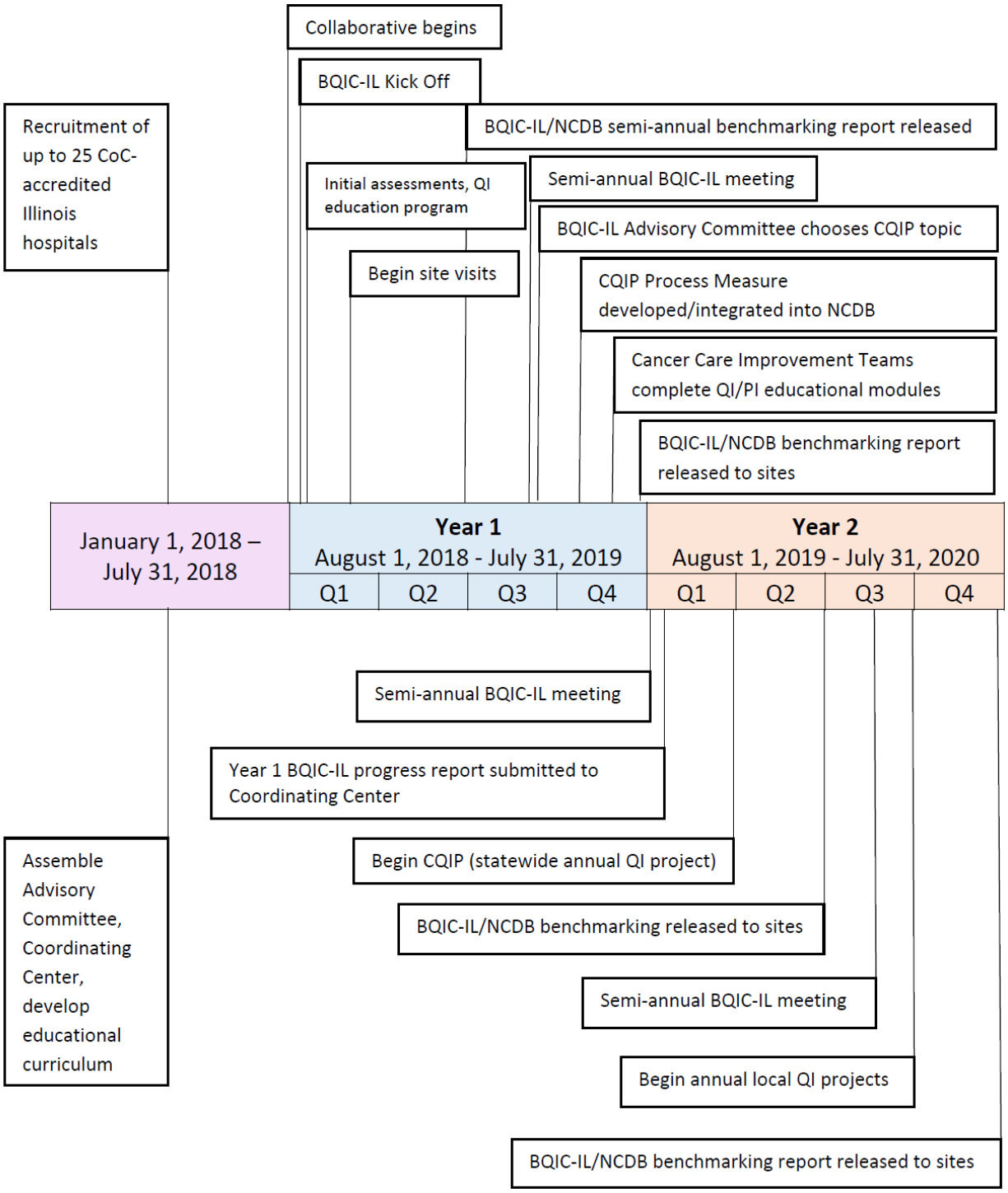
H. DETAILED WORKPLAN AND DELIVERABLES SCHEDULE

It is expected that all 3 phases implementation of BQIC-IL will be successfully completed by the end of two years (Figure 2).

Year 1: Initiation of Phase I. This will include recruitment of hospitals, education/training of Breast Cancer QI teams, initial assessments, and development/implementation of new NCCN Guideline-based process measures. Phase II will be initiated later during Year 1, and will include the first semi-annual meeting, distribution of the first semi-annual benchmarking report to hospitals, and preparation for the first statewide Breast Cancer Collaborative Quality Improvement Project.

Year 2: Continue Phase II and launch of Phase III, including initiation of the Breast Cancer Collaborative Quality Improvement Project and local QI projects of each hospital's own choosing.

Figure 2: Timeline of Expected Workplan and Deliverables Schedule



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