

A. Cover Page

Title: Optimizing Delivery of Neoadjuvant Chemotherapy to Breast Cancer Patients who are Appropriate Candidates at Johns Hopkins

Abstract: Neoadjuvant chemotherapy (NACT) is frequently administered to women with stage II-III breast cancer prior to surgery and can confer many benefits. One of the greatest challenges of NACT delivery is the coordination required across specialties such as surgical oncology, medical oncology, radiation oncology, radiology, and pathology. Communication gaps among these providers directly affect patients causing treatment delays, increased anxiety, and inferior outcomes. National organizations such as the National Comprehensive Cancer Network (NCCN) and our own institution- the Johns Hopkins Medical Institute (JHMI) have guidelines for the proper delivery of NACT. Despite this, in the JHMI breast cancer clinics, there are lengthy treatment delays between initial visit and initiation of NACT, significant practice variation in pre-treatment staging evaluation, and inconsistent referrals for genetic counseling. We aim to optimize delivery of NACT to patients with breast cancers who are appropriate candidates by executing a new clinical pathway at three JHMI sites- Johns Hopkins Hospital in Baltimore City, Greenspring Station in Baltimore County, and Sibley Memorial Hospital in Washington, DC. This clinical pathway will implement the NACT best practices guideline we developed internally with input from a multidisciplinary working group. Our primary aim is to determine if this pathway shortens time from first visit to first dose of NACT for our patients. We will also ascertain if our patients are getting stage-appropriate pre-treatment evaluation and timely referrals. If successful, this pathway will be disseminated to other sites within JHMI and other academic and community cancer centers.

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D. Main Section

Introduction

Neoadjuvant chemotherapy (NACT) is commonly administered to women with stage II-III breast cancer prior to surgery. Patients can receive many benefits including breast conserving surgery (BCS) rather than mastectomy, smaller lumpectomy improving cosmesis, sentinel lymph node biopsy (SLNB) rather than axillary lymph node dissection (ALND), and avoidance of nodal irradiation. They have time to undergo genetic testing and decide about the type of surgery, and may receive important prognostic information after surgery in the form of pathologic complete response (pCR). Patients who are appropriate candidates should have the opportunity to receive NACT.¹⁻⁵

One of the greatest challenges to delivering NACT and performing surgery is the coordination required across specialties such as surgical oncology, medical oncology, radiation oncology, radiology, and pathology. According to two recent studies, surgical wait times for patients with breast cancer in the US are increasing.^{6,7} The growing complexity of preoperative care pathways is a major contributor. Treatment delays increase patient frustration and anxiety, are symbolic of communication gaps within the care team, and may impact outcomes. Longer time to surgery and longer time to first systemic therapy in patients receiving NACT have been shown to lead to poorer outcomes.⁸⁻¹⁰

A better roadmap for delivering NACT and other complicated multi-disciplinary care is badly needed. Multi-disciplinary care remains rare in the US- a recent study using the Survival, Epidemiology, and End Results (SEER) database found that out of 88,865 patients with breast cancer, only 2.9% received multi-disciplinary care prior to surgery.¹¹ There is scant instruction and few published experiences on how to implement a multi-disciplinary model to increase coordination among providers. A clinical pathway to implement a best practices guideline with integration of patient navigators and a systematic checklist could greatly improve multi-disciplinary care and delivery of NACT. This pathway and these tools will help by clarifying responsibilities, improving communication, and standardizing procedures. More cooperation could reduce treatment delays and increase standardization of care.

Overall Goals and Objectives

Overall Goals

The overall goal of this project is to implement a new clinical pathway to improve delivery of NACT to patients with breast cancer in the JHMI Breast Cancer clinics. This clinical pathway will assist breast cancer providers from multiple disciplines (Surgical Oncology, Medical Oncology, and Radiation Oncology, Radiology, and Pathology) adhere to an internal best practices guideline for management of patients with stage II-III breast cancer who are appropriate candidates for NACT. The pathway will include a flowchart posted in the clinics, companion education about the best practices algorithm, an electronic checklist which can be edited by multiple providers, and patient navigators to oversee the checklist and ensure tasks are getting completed in a timely manner. We believe that executing this pathway will facilitate communication among providers, ensure patients are receiving standardized guideline-based care, and shorten time between a patient's first visit and her first dose of NACT. This will

improve our patients' experiences while receiving NACT and also our providers' ease of delivering NACT. Dissemination of this pathway may improve NACT delivery for patients at other breast cancer centers and also may inform delivery of multi-disciplinary care across our own institution and other cancer centers.

Key Objectives

Primary Objective

(1) To reduce time from first visit to first dose of NACT to 21 days or fewer within 12 months of pathway implementation. We will implement a new clinical pathway to optimize delivery of NACT for patients with breast cancer who are appropriate candidates. By improving communication across specialties, and coordination of care, this pathway will decrease time between first visit and first dose of NACT.

Secondary Objectives

(2) To increase the number of patients who receive stage-appropriate pre-treatment evaluation to 80% or more within 12 months of pathway implementation. This pathway includes a best practices guideline with succinct recommendations for pre-NACT and preoperative evaluation. We will improve standardization of care and increase the number of patients with stage-appropriate evaluation pre-treatment, rather than evaluation that is more conservative or more aggressive than recommended by national guidelines.

(3) To increase the number of patients with appropriate referrals for genetic counseling to 80% or more within 12 months of pathway implementation. This pathway contains a specific prompt to refer a patient for genetic counseling if warranted. Timely referral is important because results of genetic testing may influence the type of surgery a woman chooses and clinical trial eligibility. Out of the patients who are candidates for genetic counseling, we aim that 80% of them will have appropriate referrals to genetic counseling with completed appointment within 30 days of first visit.

(4) To establish compliance with an editable EPIC checklist of 70% or greater within 12 months of pathway implementation. EPIC is our electronic medical record. One component of our clinical pathway is an electronic checklist that can be used by multiple providers to facilitate communication. We aim that 70% of patients or more will have a checklist opened and completed (90% or more of checklist filled).

Current Assessment of Needs

Our Experience to Date

At Johns Hopkins, we have internal algorithms for proper management of patients receiving NACT which have been refined by a multidisciplinary team over a decade. These were developed based on national guidelines such as NCCN as well as relevant research studies.¹² They are reviewed and revised periodically and have been published.¹³ Despite our attempts to adopt these best practices for our patients receiving NACT, our patients still experience treatment delays and care that is not standardized. Some reasons for delays cited by providers include confusion within the care team about whether a patient is a candidate for NACT, uncertainty about which tests need to be performed (MRI, additional biopsies) prior to NACT, logistical challenges like port placement, and inconsistent responsibilities among providers regarding ordering scans and placing referrals. For example, some breast surgeons

will place referrals for genetic counseling and order CT and bone scans while others will defer to Medical Oncology. There is also significant practice variation in the care patients receive. Some patients with relatively early stage disease (e.g. T2N0) will receive a pre-treatment CT scan in the absence of symptoms; this is not recommended by NCCN or internally. Some patients will not get referred for genetic counseling or fertility evaluation although they are candidates for those services.

Treatment Delays

The target timeframe for surgery or NACT after a patient with breast cancer first visits clinic or first has a mammogram is unknown. Several groups have found that longer times to surgery and NACT can lead to measurable tumor growth and have an adverse impact on outcomes.⁸⁻

^{10,14} Patient anxiety with increased wait times is another important consideration, and generally, shorter waiting times lead to greater patient satisfaction.¹⁵ Contributors to longer wait times include requiring multiple consultations, requiring repeat biopsies after initial diagnosis, and needing additional imaging such as MRI, among other factors.^{16,17}

Standardization of Care

There are no universally established benchmarks for high quality multi-disciplinary breast cancer care. Many groups including the NCCN, the American Society of Clinical Oncology (ASCO), and the European Society of Breast Cancer Specialists (EUSOMA) have published recommendations for quality care and several institutions have analyzed their compliance.^{16,18-}

²¹ For straightforward criteria that are easy to evaluate (e.g. reporting HER2neu status or receiving endocrine therapy for hormone-receptor positive breast cancer), targeting compliance of 80-100% is feasible.

Other indicators such as appropriate referrals to genetic counseling are more challenging to measure. One group set their target for genetic counseling referrals as 5% of all patients evaluated.¹⁶ Without performing chart reviews to determine how many patients should have been referred, the value of reaching this target is unknown, and the ideal threshold remains unclear.

Our Model Site

With many unknowns in ideal targets as we try and improve delivery of NACT across our institution, one JHMI breast cancer clinic can serve as a model. The JHMI breast cancer clinics consist of eight different sites. Of these, three sites- Johns Hopkins Hospital (JHH) in Baltimore City, Sibley Memorial Hospital (SMH) in Washington DC, and Greenspring Station (GSS) in Baltimore County have surgical oncology, medical oncology, radiation oncology, and imaging services. We recently piloted a single day multidisciplinary clinic (MDC) for patients with stage II-III breast cancer at GSS; this is our only site which currently has this capacity and only for one half-day a week. This clinic is run by one surgical oncologist, one medical oncologist, and one radiation oncologist. Patients are able to see multiple providers and a patient navigator in one visit and our preliminary data (described in more detail below) show that time to first dose of NACT is significantly shortened. Anecdotally, providers feel their communication with each other is improved and the entire care team understands which steps should take place prior to NACT and prior to eventual breast surgery. The MDC experience has led to more streamlined care and serves as a useful benchmark as we try to improve delivery of NACT at other JHMI sites.

Quantitative Summary

We compared treatment times for patients seen at JHH (which is our highest volume site) to patients seen at the single day GSS MDC. We conducted a review of patients' charts using EPIC, our medical record. We keep a secure IRB-approved database of all patients who receive therapy within JHMI which facilitated this data collection. We searched for patients with stage II-III breast cancer who were seen in the JHH breast cancer clinic or the GSS single day MDC and received NACT in 2016-2017. We identified 55 such patients at JHH and 33 patients at GSS. The mean time from first visit to first dose of NACT was 27.7 days at JHH and 17 days at the single day MDC at GSS. Other data we would collect prior to implementation of our clinical pathway are how many of these 88 patients received stage-appropriate pre-treatment evaluation and how many received appropriate referrals for genetic counseling.

Target Audience

This clinical pathway will be implemented at three JHMI breast cancer clinic sites- JHH, SMH, and GSS. Each of these sites contains surgical oncologists, medical oncologists, radiation oncologists, radiologists, pathologists, and patient navigators who provide comprehensive care for our breast cancer patients. This group is our target audience. Together, these sites see >200 patients with stage II-III breast cancer in a year. Most of these patients are potential candidates for NACT and will benefit from implementation of this clinical pathway.

We already have meaningful buy-in from our target audience. We created a working group consisting of surgical oncologists, medical oncologists, a radiation oncologist, a radiologist, and a pathologist to establish a best practices guideline and an internal algorithm for patients who are candidates for NACT across the JHMI breast cancer clinics. These recommendations were discussed at individual department meetings and at multi-disciplinary Breast Cancer Tumor Board and further refined to form the basis of the clinical pathway we propose here. Discussion in each of these settings convinced us that this clinical pathway is timely and necessary. Providers strongly feel that the delivery of NACT should be more streamlined and standardized and cite difficulty coordinating care as a major barrier. They are eager to participate in a clinical pathway that could mitigate this problem.

We have 5 patient navigators embedded at the three sites. They already have a key role in quality improvement projects, community outreach, education, promoting access to care, and improving coordination of care. They are also engaged in this project to improve delivery of care to our patients. Of note, our patient navigators provide invaluable care but 4 of the 5 are currently funded through short-term grants or discretionary funds and are not directly supported by our institution. This project and its outcomes could help obtain sustainable funding from our institution for this important patient resource.

The most direct beneficiaries of our clinical pathway will be the approximately 200 patients seen at JHH, SMH, and GSS each year who are candidates for NACT. If successful, this model may be implemented at other JHMI sites. We have 3 additional sites with surgery and imaging only and 2 more sites with imaging only currently. This model will also be disseminated across the Johns Hopkins Clinical Research Network (JHCRN). We also plan to publish our experience and outcomes, potentially benefitting many more patients.

Project Design and Methods

Our goal is to implement a new clinical pathway to optimize delivery of NACT to patients with breast cancer who are appropriate candidates. The steps required to efficiently and effectively deliver NACT are numerous and require much coordination among providers from different disciplines. Our pathway includes a best practices guideline with associated algorithms, an electronic checklist, and oversight by patient navigators.

Development of the Best Practices Guideline

The steps we have already taken include establishing a multi-disciplinary working group (as described above) to create a guideline for best practices for NACT delivery and associated algorithms. This guideline is specific and includes how to select appropriate patients for NACT, when to screen for clinical trials, what pre-treatment staging evaluation to obtain, when to order a breast MRI, what axillary evaluation to perform, which referrals to place, and when to follow-up with certain providers. The guideline also assigns specific responsibilities to members of the care team. The best practices guideline has been presented to individual departments and at our multi-disciplinary Breast Cancer Tumor Board and further refined based on these discussions. It is ready for internal dissemination and implementation.

Creation of an Electronic Checklist

Systematic checklists have significantly improved surgical safety and can have other applications like increasing safety and efficiency in radiation oncology and pediatric oncology clinics.^{22,23} We designed a checklist as part of our clinical pathway to keep track of which tasks have been completed and which are pending. We plan to convert this paper checklist into an electronic form embedded within our medical record. All providers involved in the care of a patient will have access to this checklist and can check off items. At the previous meetings described, providers felt strongly that this would be an effective way to communicate which tasks were pending and which were done instead of using a mixture of the medical record, email, phone calls, and in-person communication as is currently done.

Our institution's medical record is EPIC and we have an EPIC development team on site. This team was trained by EPIC but is employed by JHMI. Their purpose is to develop tools and capabilities within the EPIC system to better adapt it to the needs of JHMI providers. We have had several fruitful meetings with this team to describe our clinical pathway and its overall goals, as well as review the checklist we have composed. The EPIC team is currently working to determine which tools within EPIC can be used to convert this checklist to electronic form and which features will need to be built from scratch.

Oversight by Patient Navigators

Patient navigators can significantly improve the quality of care patients receive by increasing efficiency and standardization, and decreasing costs. Investigators at the University of Alabama showed that geriatric cancer patients who were matched with lay navigators received better care at reduced costs compared to those without navigators.²⁴ A Canadian group showed that nurse navigators significantly decreased the time from first imaging to surgery for patients with breast cancer.²⁵ As noted above, a total of five patient navigators are already present at our three clinic sites- JHH, SMH, and GSS. They are already familiar with quality improvement through their active roles in other initiatives and are empowered to advocate for our patients. They will receive training in this pathway and its goals. They will be integral improving the care our patients receive by acting as the liaisons across departments. They will manage the

checklist and ensure that tasks are getting completed.

Implementation

All three sites- JHH, SMH, and GSS, will benefit greatly from implementation of this pathway. JHH and SMH do not currently have a single day MDC for breast cancer patients. Although GSS already has an MDC and has made strides in reducing time from first patient visit to first dose of NACT, this clinic only occurs for one half-day each week and does not benefit patients seen on other days. Additionally, this pathway can also help standardize delivery of care even within the MDC. We will conduct education sessions on this pathway at the JHH, SMH, and GSS breast cancer clinics with providers, clinical staff, and nurses. We will post copies of this pathway throughout the work areas in the clinics and include reminders to use the EPIC checklist. We will periodically review the pathway and seek feedback about its implementation to refine targets, troubleshoot issues, and determine how it could even better assist our patients and providers.

Future Plans

The future plans for our institution include new buildings with more space at the JHH and GSS sites. We anticipate that the JHH and SMH sites will have the capacity for an MDC for two half-days each week by the end of 2018, and that the GSS site will have capacity for an MDC for two additional half-days each week by the end of 2019. With a total of 6 half days, we initially plan to see patients with stage II-III breast cancer within these MDCs but hope to expand this model to all ~1000 new invasive breast cancer patients seen at our institution each year.

These plans for expansion make implementation of our clinical pathway even more important. Currently, only three of our providers are involved in an MDC model, and as discussed above, delivery of NACT is not standardized. This clinical pathway will give all providers who see breast cancer patients across our institution more experience with a multi-disciplinary care model. This pathway will also increase standardization of treatment and further refine our delivery of NACT. If successful, this pathway can be implemented within all future breast cancer MDCs across our institution to deliver high-quality care from day one.

Evaluation Design

Analysis of Primary Objective

Our primary objective is to decrease time from first visit to first dose of NACT. We chose this as our primary outcome measure for several reasons. As others have noted, treatment delays are often used as a quality indicator for patients with breast cancer and can be indicative of poor communication across specialties or inequities in accessing services. Furthermore, we have a significant disparity in treatment time at our own institution between patients who are seen at MDC and those who are not. Reducing this time would be the most direct indicator that our intervention is effective.

We will utilize data from EPIC, our medical record, to assess our clinical pathway. We already keep a secure IRB-approved database of all patients seen across our clinics who receive therapy within JHMI which will facilitate this evaluation. We will conduct a comprehensive chart review of patients with stage II-III breast cancer who may be considered for NACT from January 1, 2017 to December 31, 2018 and calculate time from first appointment to first dose of NACT (measured in days). The majority of first appointments are with the surgical oncologist. We hypothesize that the time from first visit to first dose of NACT will be reduced to shorter than

21 days at JHH and SMH with the implementation of the proposed clinical pathway within two years. Currently, the mean time from first visit to first dose of NACT is 27.7 days at JHH (and only 17 days at GSS). We are targeting an approximately 25% reduction in mean time to first dose of NACT. If we treat at least 83 patients, we will have 80% power to determine that the time to the first dose of NACT is 21 days or fewer with a type I error rate of 5%.

We will compare the average time from first visit to first dose of NACT at all three sites. We will also compare average time to first dose of NACT over time (2018 vs. 2017). These comparisons will help us determine the impact of our intervention. For example, if time from first visit to first dose of NACT is increasing or decreasing at all three sites, we may examine other factors. We would also expect the time to shorten from 2017 to 2018 as more care team members gain familiarity with this clinical pathway.

Analyses of Secondary Objectives

Our secondary objectives include increasing the number of patients with stage-appropriate pre-treatment evaluation. We chose this as an outcome measure because anecdotally, this is where there is large variation in care across our institution. Patients will get staging evaluation that is either too aggressive or too conservative according to national and internal guidelines. This can lead to increased time before therapy, increased cost, and increased anxiety. We set our compliance target at 80% based on published compliance rates for general quality measures for breast cancer care at other institutions. We will continue to collect data during the first 3 months of the grant period and adjust this target if needed. We will perform chart reviews of patients with stage II-III disease and determine how many received appropriate pre-treatment evaluation.

We also want to increase number of patients with appropriate visits to genetic counseling. We chose this as an outcome measure because an advantage of receiving NACT is more opportunity for genetic counseling which may impact a patient's decision about type of surgery and impact clinical trial eligibility.²⁶ Ensuring timely referral is important so patients have ample time to receive and contemplate results. We set our compliance target at 80%, but choosing a target is challenging as discussed previously. We will continue to collect data during the first 3 months of the grant period and adjust this if needed. We will perform chart reviews of patients with stage II-III disease and determine how many should have been referred for genetic counseling according to NCCN criteria.²⁷ We will determine how many of these patients were referred for genetic counseling.

Finally, we want to develop compliance with the electronic checklist and target that 70% (95% confidence interval 60%-80% with 83 patients) of patients have 90% or more of checklist completed at time of surgery within the first year. We set this as a conservative compliance target, but published experiences suggest higher compliance with checklists is feasible. We will perform frequent reviews of the data at three month intervals to troubleshoot the process and seek feedback if our target is not being met. We will reset target if needed.

Dissemination of Results

We will share the results of this project internally and with other institutions that are part of the JHCRN by presenting our experience. The JHCRN includes 5 academic and community sites in Maryland, Pennsylvania, and Virginia which may be interested in adopting a multi-disciplinary clinical pathway to facilitate delivery of NACT. We will also compile and submit a manuscript of our experience and outcomes for publication. NACT offers many advantages to patients and we

anticipate that many cancer centers both with and without physical capacity for an MDC will be interested in implementing a clinical pathway to facilitate NACT delivery.

Conclusion

Breast cancer care including delivery of NACT is becoming increasingly complex. Clinical pathways are important because they can improve communication among multi-disciplinary providers, decrease wait times, increase compliance with guidelines, and may reduce disparities by setting universally accepted standards for care. Unfortunately, there are few published roadmaps to implement clinical pathways.

We plan to implement a new clinical pathway to optimize delivery of NACT to patients who are appropriate candidates across the JHMI clinics. This pathway includes a best practices guideline, an associated electronic checklist, and oversight from patient navigators. We believe this will improve coordination, reduce treatment delays, and increase standardization of care. We aim to disseminate our experiences and outcomes both across our institution and across our field to benefit not only our own patients, but many more patients with breast cancer and the providers who take care of them.

Detailed Workplan and Deliverables

Task	Date Completed
Finish collecting baseline data re: pre-treatment evaluation and referrals	March 31, 2018
Finalize and post clinical pathway guidelines in clinics	March 31, 2018
Build and test electronic checklist within EPIC	March 31, 2018
Train patient navigators about clinical pathway	March 31, 2018
Conduct education sessions in JHH, SMH, GSS clinics	April 30, 2018
Perform first review of time from first visit to first NACT	July 31, 2018
Perform first review of pre-treatment staging evaluations	July 31, 2018
Perform first review of genetic counseling appointments	July 31, 2018
Perform first review of electronic checklist usage	July 31, 2018
Solicit feedback from patient navigators and providers in group settings about pathway implementation (weekly meeting, Tumor Board)	August 31, 2018
Make changes to pathway, conduct additional education sessions based on feedback	September 30, 2018
Perform second data review	December 31, 2018
Present first year data from pathway internally and publicly announce new targets	January 31, 2019
Continue to review data and make adjustments every 3 months	April 1, July 1, Oct 1, 2019
Start formulating plans to disseminate results	July 1, 2019
Present experience at San Antonio Breast Cancer Symposium and complete manuscript describing experience and outcomes	December 31, 2019

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