Johns Hopkins University

Development of a Strategy to Implement an Oncology Clinical Research Program at a Rural Hospital

A Capstone Paper Submitted to the
Krieger School of Arts and Sciences
Advanced Academic Programs
in Partial Fulfillment of the Degree of the
Master of Science in Research Administration

by

Stefanie S. Miller

Baltimore, Maryland
May 2019

Abstract

The purpose of this Capstone Project was to design a strategy for implementing an oncology clinical research program at a rural hospital cancer center. The rural cancer center is part of a large healthcare system (Healthcare System) that encompasses several hospitals located throughout northern Illinois. Healthcare System administrators prioritized development of a research program at the rural hospital as part of an institution initiative to expand access to oncology clinical trials in the community and rural settings. The author of this project was tasked with the responsibility of developing a strategy for building this research program at the rural cancer center. The project was accomplished by conducting a literature review, completing a needs assessment, and reviewing hospital analytic data. The literature review was used to identify best practices for opening and managing clinical research programs and to identify concerns specific to rural hospitals. The needs assessment was completed with key individuals in the oncology and research departments in the Healthcare System to gather information to ensure that the proposed strategy met the requirements of the oncology physicians and oncology and research leadership. The information from the literature review was then combined with feedback from the needs assessment and hospital analytic data to create a strategy that will provide a foundation for an oncology research program at the rural hospital that meets the needs of the patients, physicians, and Healthcare System administrators.

Based on the literature review, needs assessment responses, and the rural hospital analytic data, a strategy was proposed that includes the following recommendations: (1) institute a feasibility committee at the rural hospital to determine

which trials to include in the clinical trial portfolio, (2) include studies in the portfolio that are likely to accrue, are less complex, and focus on chemotherapy treatments, (3) initially open breast, lung, and prostate studies, (4) staff the research program at the rural cancer center with a clinical research nurse on a consistent part-time basis, (5) educate the clinical staff on research activities to promote collaboration, and (6) track study metrics to monitor research personnel workload. The goal of this strategy is to build an initial research program that will succeed in the current environment at the rural cancer center, which is naive to research. Ultimately, the strategy should be modified as the research program grows and investigators gain experience to bring on additional and more complex trials. Extra research staff should be hired as needed. While the strategy proposed in this project is designed specifically for a small rural cancer center, the recommendations may still apply to other larger programs since having effective processes for choosing appropriate trials and providing adequate staffing support are applicable for all clinical research programs.

Table of Contents

Illustrations

Figures

Table

Glossary

Commission on Cancer. "…a consortium of professional organizations dedicated to improving survival and quality of life for cancer patients through standard-setting, which promotes cancer prevention, research, education, and monitoring of comprehensive quality care."[1] The consortium accredits facilities complying with the established standards.[2]

Community Cancer Program. A category of cancer program achieved through the Commission on Cancer accreditation program. "The facility accessions more than 100 but fewer than 500 newly diagnosed cancer cases each year and provides a full range of diagnostic and treatment services, but referral for a portion of diagnosis or treatment may occur."[3]

Comprehensive Cancer Center. "A cancer research center that gets support from the National Cancer Institute (NCI) to do cancer research and provide services directly to cancer patients. Scientists and doctors at these centers do basic laboratory research and clinical trials, and they study the patterns, causes, and control of cancer in groups of people. Also, they take part in multicenter clinical trials, which enroll patients from many parts of the country."[4]

Cooperative Group Trials. "A group of researchers, cancer centers, and community doctors who are involved in studies that test new ways to screen, prevent, diagnose, and treat cancer. Clinical trials run by cooperative groups are funded and supported by the National Cancer Institute (NCI), and large numbers of patients take part in many locations."[5] The cooperative groups included in this definition are the Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, and SWOG.

Observational Study. "A type of study in which individuals are observed or certain outcomes are measured. No attempt is made to affect the outcome (for example, no treatment is given)."[6]

Phase I Trial. "The first step in testing a new treatment in humans. A phase I study tests the safety, side effects, best dose, and timing of a new treatment. It may also test the best way to give a new treatment (for example, by mouth, infusion into a vein,

---

[1] American College of Surgeons, *Cancer Program Standards: Ensuring Patient-Centered Care*, Chicago: American College of Surgeons, 2015, 4, https://www.facs.org/~/media/files/ quality%20programs/cancer/coc/2016%20coc%20standards%20manual_interactive%20pdf.ashx.
[2] American College of Surgeons, 4.
[3] American College of Surgeons, 8.
[4] "NCI Dictionary of Cancer Terms," National Cancer Institute, accessed March 6, 2019, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/comprehensive-cancer-center.
[5] "NCI Dictionary of Cancer Terms," National Cancer Institute, accessed March 6, 2019, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/nci-clinical-trials-cooperative-group.
[6] "NCI Dictionary of Cancer Terms," National Cancer Institute, accessed March 6, 2019, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/observational-study.

or injection) and how the treatment affects the body. The dose is usually increased a little at a time in order to find the highest dose that does not cause harmful side effects. Phase I clinical trials usually include only a small number of patients who have not been helped by other treatments. Sometimes they include healthy volunteers."[7]

Phase II Trial. "A study that tests whether a new treatment works for a certain type of cancer or other disease (for example, whether it shrinks a tumor or improves blood test results). Phase II clinical trials may also provide more information about the safety of the new treatment and how the treatment affects the body."[8]

Phase III Trial. "A study that tests the safety and how well a new treatment works compared with a standard treatment. For example, phase III clinical trials may compare which group of patients has better survival rates or fewer side effects."[9]

[7] "NCI Dictionary of Cancer Terms," National Cancer Institute, accessed March 6, 2019, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/phase-i-clinical-trial.
[8] "NCI Dictionary of Cancer Terms," National Cancer Institute, accessed March 6, 2019, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/phase-ii-clinical-trial.
[9] "NCI Dictionary of Cancer Terms," National Cancer Institute, accessed March 6, 2019, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/phase-iii-clinical-trial.

Chapter 1. Introduction

1.1. Background

In December 2015, a small rural hospital in northern Illinois merged with a large healthcare system (Healthcare System) in the region. The small hospital is a ninety-eight bed facility and includes a cancer center. The cancer center provides the community with access to medical oncologists and treatment options including surgery, chemotherapy, and radiation. The main hospital in the Healthcare System is located in a large metropolitan area and is a leading academic medical center housing a National Cancer Institute designated Comprehensive Cancer Center (CCC). The CCC offers hundreds of clinical trials to oncology patients.

While the rural cancer center provides several treatment options for patients close to home, it is not able to offer local access to clinical trials because the infrastructure does not exist at the rural hospital to support research. The cancer center physicians, instead, have to refer patients to the CCC or other hospitals in the system for clinical trial participation. While having access to research studies through the CCC is a benefit to the patients, the downside is that the patients have to travel over an hour away for their care. A negative for the oncologists at the rural cancer center is that they could potentially lose the relationship that they have with their patients should their patients decide to remain under the care of a physician at the CCC.

In fiscal year 2019, the Healthcare System made the expansion of oncology clinical research into four of the System's community hospitals, including the rural hospital, a key initiative. Three of these community hospitals are based in the suburbs of

a large metropolitan area, and the rural hospital is located farther west situated in Illinois' farmland. These community hospitals allow the Healthcare System to provide care to patients in more convenient locations close to their homes. The Oncology Research Integration Committee (Committee) was established by Healthcare System leadership to oversee and direct the expansion of oncology research into the community hospitals. The Committee consists of members from across the Healthcare System representing the CCC, the Office of Research, research compliance, and the oncology service line. The Committee proposed that bringing access to clinical trials to patients in their own communities would benefit patients as they may be more inclined to participate in studies if the treatments are at easily accessible locations. The Committee also advised that expansion would benefit the physicians since they would be able to offer clinical trials to patients at their own practice rather than refer them to another location. Additionally, the Healthcare System could increase its reputation in the region by being able to promote access to clinical trials and cutting-edge medical care in the community setting.

1.2. Statement of the Problem

Three of the community hospitals designated for research expansion already have an infrastructure in place to support research. The rural hospital, however, has no research program on site. The author of this Capstone Project is an operations manager in the clinical research program at the Healthcare System and became the person responsible for developing a plan to support clinical trials at the rural hospital.

Expansion of clinical research to the rural hospital is necessary for several reasons:

1. It was a directive of the Healthcare System executives as a strategy to improve patient satisfaction and care.
2. The rural hospital is seeking accreditation as a Community Cancer Program (CCP) through the Commission on Cancer®. To be a compliant CCP, the cancer center must accrue at least two percent of its patients, based on annual analytic cases, to clinical trials.[10] Patients referred to other institutions where they are enrolled on trials do count toward the required accrual amount.[11] However, as noted previously, a benefit of the expansion is to prevent physicians from having to refer patients and potentially lose their patients to another oncologist or medical practice. Without a research program in place, the rural cancer center would not have the appropriate resources to promote clinical trials and enroll patients on studies. This lack of research support could lead to the hospital not being compliant with the clinical trial accrual standard and not receiving the CCP accreditation.
3. The expansion serves to benefit patients, physicians, and oncology leadership at the rural hospital. Most cancer patients tend to be diagnosed and treated in the community rather than at an academic medical facility[12] so the patients would have an advantage with clinical trial options close to home. It has long been a desire of the physicians and oncology leadership to have a research presence at the rural cancer center to better support the rural community.

[10] American College of Surgeons, 41.
[11] American College of Surgeons, 42.
[12] Ronald S. Go et al., "Clinical Trial Accrual among New Cancer Patients at a Community-Based Cancer Center," *Cancer* 106, no. 2 (January 15, 2006): 427, https://doi.org/10.1002/cncr.21597.

1.3. Addressing the Problem

In order to support the expansion of clinical research at the rural hospital, a research office needs to exist at the facility to provide guidance and oversight of the research. Some of the research program operational areas that need to be implemented at the rural hospital include, but are not limited to, contract reviews, budget negotiations, research billing, study feasibility assessment, and study coordinator and regulatory support. The rural hospital can utilize existing system-wide research processes and services to address many of these issues. For example, the rural hospital research program can use the Healthcare System's Office of Research for contract review and budget negotiations. The process for research billing review is managed by the Office of Research and is built into the Healthcare System's electronic medical record shared by all of the hospitals. While these particular activities are already supported, there are other operations, such as study feasibility and staffing support, that need to be addressed specifically for a small hospital. The rural hospital has to consider staffing support limitations, whether the services and equipment are available to execute protocol required treatments, and whether an adequate population exists to enroll patients on a protocol. These site-specific needs were taken into consideration during the process of developing the strategy to implement a research program at the rural hospital.[13]

1.4. Project Questions

The goal of this Capstone Project was to provide a strategy for implementing a research program at the rural hospital that would be successful in accruing patients and that would also meet the needs of the oncology physicians and oncology and research

[13] Go et al., 429-431.

department administrators. There are reports in the literature that research programs can be a drain on institution resources especially if studies are opened that result in limited or no accrual[14]. Therefore, the author of this project investigated key elements to consider when developing a research program to ensure a productive program rather than a stagnant or failing one. A literature review of clinical research program management led the author to determine that development of a practical clinical trial portfolio and appropriate staffing of the research program were crucial elements to incorporate into the strategy for building a research program at the rural hospital. This decision was primarily based on the article by Allison Baer et al. that suggested appropriate management of these items is critical to having an efficient research program.[15] Therefore, this Capstone Project focused on identifying methods for how best to build a clinical trial portfolio and how to appropriately staff the research program at the rural hospital. Additionally, the needs of physician investigators, oncology administration, and research leadership were assessed to ensure that the research program strategy aligned with the visions of these stakeholders. A research program may be more likely to thrive with physician and administration support and engagement.[16]

[14] Henry Durivage and Kerry Bridges, 2009, "Clinical Trial Metrics: Protocol Performance and Resource Utilization from 14 Cancer Centers," Poster presented at the 2009 American Society of Clinical Oncology annual meeting, Orlando, FL, May 29-June 2, 2009, https://forteresearch.com/wp-content/uploads/2017/10/asco-poster_2009.pdf.
[15] Allison R. Baer et al., "Clinical Research Site Infrastructure and Efficiency," *Journal of Oncology Practice* 6, no. 5 (September 2010): 251, https://doi.org/10.1200/JOP.000109.
[16] Baer et al., "Clinical Research Site Infrastructure and Efficiency," 251; Eileen P. Dimond et al., "Creating a "culture of research" in a community hospital: Strategies and tools from the National Cancer Institute Community Cancer Centers Program," *Clinical Trials* 12, no. 3 (February 17, 2015): 247-249, https://doi.org/10.1177/1740774515571141.

1.5. Objectives

The first objective of this Capstone Project was to gather information regarding implementing and managing a clinical research program at a small rural hospital. Part of this information came from a literature search focusing on oncology healthcare in rural locations, research program development, clinical trial feasibility and selection, and methods for determining adequate research staffing support. The other data came from a needs assessment questionnaire that was developed and administered by the author to key stakeholders in the form of an oral interview. The stakeholders represented the oncology physician investigators at the rural hospital, administration at the rural hospital, and leadership in the Healthcare System's Office of Research. To supplement the literature review and needs assessment, data was requested from the rural hospital's cancer registry in order to have a better understanding of the cancer population served at the hospital.

The second objective of this Capstone Project was to use the data gained from the literature review, needs assessment interviews, and cancer registry analytic data to develop a strategy for implementing clinical research at the rural hospital. The strategy included recommendations for developing a clinical trial portfolio that is specific to the patient population but that also engages the physicians so that the chance of patient accrual is maximized. In addition, the strategy provided guidance on how best to support the research program from a staffing perspective. The plan for staffing had to consider the anticipated workload for managing the initial studies and accrual but also supporting the questions and needs of a cancer center with no previous research experience. The

final strategic plan will be provided to healthcare administration in both the oncology and research programs.

1.6. Significance

The American Cancer Society predicts that in 2019 over 1.7 million people will be diagnosed with a new cancer.[17] Clinical trials are essential in getting new treatments to market to help these individuals, but clinical trials only succeed if patients are enrolled on the studies.[18] As stated previously, since most cancer patients receive care in their community,[19] it is important to bring clinical trial opportunities to patients at convenient locations close to their homes. Local access to clinical trials may increase the chances of patients agreeing to participate in research. A rural location has specific needs to consider when developing a research program, and the information presented in this Capstone Project may help other rural or small facilities be able to implement and manage an effective clinical research program. The scope of this project, however, should not be limited to only rural facilities as the expectation is that the strategy presented in this paper can be applied to other larger institutions developing research programs.

The significance specifically for the Healthcare System is that initiating clinical trials at the rural cancer center accomplishes a strategic goal to expand oncology clinical research to the communities. Patient satisfaction within the Healthcare System will hopefully increase since patients do not have to commute far from home to obtain treatment in clinical trials. Physician satisfaction should also increase knowing that they can provide clinical trial access to their patients without having to refer them to another

[17] American Cancer Society, *Cancer Facts & Figures 2019*, Atlanta: American Cancer Society, 2019, 1, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf.
[18] American Cancer Society, 67.
[19] Go et al., 427.

oncologist. Ultimately, the Healthcare System's reputation as a mecca for oncology treatments may grow in the region as the knowledge spreads that cutting-edge trials can be received at several hospital locations.

1.7. Exclusions and Limitations

A limitation to this Capstone Project is that not all areas of research program development are discussed. Since the Healthcare System already has an established research program through the Office of Research, not all operational processes had to be developed. For example, the Office of Research supports a Clinical Trial Management System that the rural hospital can use to track patient visits and program finances. The scope of existing policies and procedures for human subjects research can be modified to include the rural hospital rather than having to develop policies and procedures from scratch specifically for the rural cancer center. Clinical Trial Agreement review and budget negotiation processes already exist with the Office of Research, and the research program in the rural hospital will utilize these established methods. Instead, this Capstone Project focuses on two main items that are site specific: creating a clinical trial portfolio that will be successful in accruing patients at the rural hospital and determining a staffing plan that will appropriately support clinical research at the hospital.

Chapter 2. Literature Review

2.1. Overview of the Literature Review

A preliminary literature search related to clinical research program development was conducted and led to an article by Robin Zon et al. This article is the compilation of feedback from individuals working in the clinical research field, and Zon et al. analyze this information and provide a list of "Exemplary Attributes"[20] which other research sites can utilize to evaluate their own programs. The article suggests that a site should concentrate on creating a diversified clinical trial portfolio that can offer several options to patients. In addition, the portfolio should include studies that address the specific needs of the patients at the site, such as cancer type and stage.[21] This recommendation of building a diversified and practical trial portfolio is echoed in the article by Baer et al.[22] Baer et al. consider a well-balanced clinical trial portfolio to be key to a successful research site, and they also note the importance of the effective use of resources, such as staff, in creating an efficient research program.[23] Based on these two articles, a more in-depth review of the literature was completed to identify sources that discussed best practices for developing a clinical trial portfolio and methods for effectively providing staffing support. Literature was also consulted to identify issues specific to a small community hospital that should be considered for this project.

---

[20] Robin Zon et al., "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites," *Journal of Clinical Oncology* 26, no. 15 (May 20, 2008): 2562-2567, https://doi.org/10.1200/JCO.2007.15.6398.
[21] Zon et al., "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites," 2565.
[22] Baer et al., "Clinical Research Site Infrastructure and Efficiency," 249-252.
[23] Baer et al., "Clinical Research Site Infrastructure and Efficiency," 249-252.

2.2. Considerations for Clinical Trial Portfolio Development

Ronald Go et al. completed a prospective study at their community-based medical oncology center. The authors assessed the limitations at their facility that prevented them from being able to accrue more patients on clinical trials. The study concluded that out of all of the patients that did not participate in trials, sixty-six percent did not enroll because a study was not open at the site for which they were eligible. The site either did not have a trial open that targeted their specific cancer type or the site did not have a trial that was directed toward their specific stage of cancer. The authors proposed that the clinical research portfolio does not need to be increased dramatically at sites to include all cancer types and stages but rather the clinical research portfolio should be carefully reviewed and studies opened that cater to the needs of the patient population seen at the facility.[24]

Other articles agree with this need to open trials that are applicable to the patients and their disease state and offer further discussion on how best to establish this diversified portfolio. Baer et al. suggest that studies should be offered at a site that cover various treatment options for patients. For example, a patient can be treated with radiation therapy followed by chemotherapy. The site may want to have a clinical trial for the radiation therapy as well as study options for the chemotherapy.[25] Mark Porter et al. propose that sites should have studies available for the same cancer type but with different inclusion and exclusion criteria so that patients not eligible for one study may

[24] Go et al., 431.

[25] Allison R. Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," *Journal of Oncology Practice* 6, no. 6 (November 2010): 328, https://doi.org/10.1200/JOP.2010.000156.

still have options for participating in another trial.[26] An additional suggestion regarding clinical trial selection is to include Phase I, II, and III trials and registry and tissue banking studies for a fully diversified portfolio.[27] Sites may also want to incorporate studies for healthy volunteers so that family and friends can participate in research as well.[28]

Research sites with budgetary concerns may need to have a clinical trial portfolio that incorporates studies with various sponsors and funding levels such as cooperative group studies, investigator initiated studies, and industry-sponsored studies. Studies funded by industry, in general, tend to cover the site's costs associated with participation in the trial. The revenue received from industry studies can then help to offset money lost in participating in investigator initiated and cooperative group studies, which have limited budgets that usually do not cover the site's costs.[29]

Zon et al., in their list of "Exemplary Attributes," advise that model sites should strive to enroll at least ten percent of their patients into clinical trials.[30] Part of being able to achieve such a lofty goal is selecting studies applicable to the patient population. This is a high bar to reach so sites may need to consider other criteria before choosing to open a study. One such criterion is that sites should review the current trial accrual statistics if the study is open at other sites. If a trial is not meeting the enrollment expectations

---

[26] Mark Porter et al., "A Comprehensive Program for the Enhancement of Accrual to Clinical Trials," *Annals of Surgical Oncology* 23, no. 7 (July 1, 2016): 2148, https://doi.org/10.1245/s10434-016-5091-9.
[27] Zon et al., "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites," 2565.
[28] Zon et al., "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites," 2565; Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 328.
[29] Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 328.
[30] Zon et al., "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites," 2562-2567.

nationally, the site may want to thoroughly review the eligibility criteria to determine whether they could be successful in accruing patients.[31] The site should also monitor the enrollment timeline for the study. If enrollment is almost complete, it may not be worth the site's resources to open a study and then have no time to accrue patients.[32] Research centers can also choose to hold the site principal investigators accountable during the study selection process. As an example, Henry Durivage and Kerry Bridges report that their institutions, the Cancer Institute of New Jersey and the Indiana University Simon Cancer Center, respectively, require principal investigators to provide proof that they will be able to accrue patients to their studies as part of the protocol submission process. Implementation of this requirement led to a significant reduction in the number of trials with no accruals at the two cancer centers.[33] Finally, research sites should get feedback from the physicians because study accrual is dependent on physician engagement. Physicians that are able to participate in study selection and believe in the studies and the treatments that they offer may be more likely to refer patients to the trials.[34]

Developing a clinical trial portfolio that accrues patients is important to a site's budget and resources. The study by Durivage and Bridges analyzed data from fourteen cancer centers. Just over half of the studies opened at the cancer centers did not accrue any patients, and almost twenty percent of the studies only accrued one to two patients. Studies with no patients enrolled still require resources and effort to cover regulatory submissions, trainings, investigator meeting attendance, screening patients, and planning

[31] Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 329.
[32] Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 329.
[33] Durivage and Bridges.
[34] Baer et al., "Clinical Research Site Infrastructure and Efficiency," 251; Robin Zon et al., "Part 2: Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," *Journal of Oncology Practice* 7, no. 1 (January 2011): 62, https://doi.org/10.1200/JOP.2010.000185.

during the study start-up phase.[35] Durivage and Bridges calculate that a cancer center, with similar low accrual metrics, can lose up to $81,000 per year.[36]

In order to incorporate all of these suggestions regarding development of a productive and diverse clinical trial portfolio, it is recommended that committees be utilized to review the feasibility of the study at the site and to determine whether or not to open the trial.[37] Baer et al. recommend that the protocol be evaluated to ensure that the site has the appropriate equipment and resources to conduct the study, that the population exists in order to accrue to the study, and that the study fits into the existing clinical trial portfolio by offering a needed treatment without competing with another study.[38] As an example, The Ohio State University Comprehensive Cancer Center, in an effort to increase accrual to clinical trials, identified four areas for improvement. One area of improvement was to give the responsibility of study selection to the Disease-Specific Committees. This operational change allowed the disease experts to review trials and choose those appropriate for the patient population. The cancer center also included a goal of opening studies for each cancer type and stage treated at the facility. Prior to making any of the operational changes at the cancer center, Porter et al. report accruing less than fifteen percent of patients onto trials. After implementing the changes to improve accrual, Porter et al. present in their paper an increase in accrual with twenty-five percent of patients enrolling in studies.[39]

---

[35] Durivage and Bridges.
[36] Durivage and Bridges.
[37] Porter et al., 2147-2148; Baer et al., "Clinical Research Site Infrastructure and Efficiency," 251.
[38] Baer et al., "Clinical Research Site Infrastructure and Efficiency," 251.
[39] Porter et al., 2149-2151.

2.3. Considerations for Staffing the Program

A study by Carol Somkin et al. reviewed potential barriers to oncology clinical trial participation. One noted impediment to patient accrual was lack of adequate dedicated research staff to manage trial enrollment.[40] Research staff are an important part of the research infrastructure, and there continues to be a dilemma in the clinical research community on how best to support clinical research programs with personnel. Clare Hastings et al. suggest that the best individuals to manage clinical trials are clinical research nurses.[41] Clinical research nurses have the clinical background to appropriately assess patients for adverse events and, depending on training, may have the ability to administer investigational drugs and participate in study procedures. At the same time, the nurses are also trained in research activities such as the informed consent process and the study protocol. The authors, therefore, consider the clinical research nurse to be a key player in supporting a clinical research program. The article specifically notes that a clinical research nurse would be a sensible option for a smaller facility since the nurse could complete both clinical assessments and research protocol requirements.[42]

While the Hastings et al. article documents the need for a clinical research nurse[43], the article by Somkin et al. notes that involvement of clinical nursing staff in the research studies is beneficial to study accrual.[44] A collaborative effort between research

[40] Carol P. Somkin et al., "Organizational Barriers to Physician Participation in Cancer Clinical Trials," *American Journal of Managed Care* 11 (July 2005), https://www.ajmc.com/journals/issue/2005/2005-07-vol11-n7/jul05-2081p413-421.

[41] Clare E. Hastings, Cheryl A. Fisher, and Margaret A. McCabe, "Clinical research nursing: A critical resource in the national research enterprise," *Nursing Outlook* 60 (2012): 151-152, https://doi.org/10.1016/j.outlook.2011.10.003.

[42] Hastings, Fisher, and McCabe, 151-152.

[43] Hastings, Fisher, and McCabe, 151-152.

[44] Somkin et al.

staff and clinic staff may be key in operationalizing an efficient research program. This research and clinical staff partnership is documented in an article by Diane St. Germain that reports on cancer centers embracing the use of clinical nurse navigators in helping to identify potential clinical trial participants. One center in the study, which is part of Spartanburg Regional HealthCare, implemented a system where a research nurse was paired with a nurse navigator. The involvement of the nurse navigator allowed the screening and enrollment process to go more smoothly because the clinical nurse already had a relationship with the patient, understood the patient's disease state, and was in a position to coordinate the patient's care with any clinical trial protocol requirements.[45] Louis Barr, Jane Crofton, and Yu-Hsin Annie Lin also report a positive result of increased trial accrual at their institution, the Florida Hospital Cancer Institute, since asking nurse navigators to be more involved in the clinical research process. The nurse navigator is able to direct patients to the appropriate study team and provide information to the patients regarding the trials.[46]

A research program, even though it may be able to depend on support from clinical staff, needs to supply appropriate research staff to manage the clinical trials and the accrual. There is some disagreement in the literature on how best to calculate research coordinator or research nurse workload to determine the number of staff required to support the clinical trial portfolio. As cited by Pam James et al., the National Cancer Institute suggests that one full-time employee can manage about thirty research patients

[45] Diane St. Germain et al., "The NCCCP Patient Navigation Project," *Oncology Issues* (May-June, 2014): 50-52, https://www.accc-cancer.org/docs/Documents/oncologyissues/articles/MJ14/mj14-ncccp-patientnavigation-project.
[46] Louis H. Barr, Jane Crofton, and Yu-Hsin Annie Lin, "A Community Hospital Clinical Trials Program: Infrastructure for Growth," *Surgical Oncology Clinics of North America* 20, no. 3 (2011): 450, https://doi.org/10.1016/j.soc.2011.01.001.

in an active status and fifty patients in follow-up. A limitation to this recommendation is that it does not account for trial type and complexity.[47] Therefore, James et al. initiated their own metric tracking system at their institution to more accurately capture research staff time and effort, which allowed them to make better decisions regarding resource allocation.[48] Noting also the limitations of the National Cancer Institute workload suggestion, Marjorie Good et al. created a scoring system to try and incorporate the complexity of a clinical trial into workload determinations. In this system, clinical trial protocols involving multiple drugs and randomizations receive a higher score than an observational study. These scores are then used as multipliers when calculating the workload of a research nurse. Good et al. came to the conclusion that a score of thirty-five to forty using their system was a maximum workload for research staff.[49] An article by Bobbi Smuck et al. also proposes a protocol scoring system to try and incorporate trial complexity into workload analysis. In this system, a Phase I trial receives a score of eight and a non-treatment trial with only one visit receives a score of one. The intent is for managers to use this scoring system to better anticipate staffing needs.[50]

2.4. Considerations Specific to Opening a Research Program at a Small Rural Hospital

An article discussing clinical trial implementation at community cancer centers suggests that the centers focus on two areas: opening trials that are most likely to accrue

[47] Pam James et al., "Creating an Effort Tracking Tool to Improve Therapeutic Cancer Clinical Trials Workload Management and Budgeting," *Journal of the National Comprehensive Cancer Network* 9, no. 11 (November 2011): 1228, https://doi.org/10.6004/jnccn.2011.0103.
[48] James et al., 1228-1233.
[49] Marjorie J. Good et al., "Measuring Clinical Trial–Associated Workload in a Community Clinical Oncology Program," *Journal of Oncology Practice* 9, no. 4 (July 2013): 211-215. https://doi.org/10.1200/JOP.2012.000797.
[50] Bobbi Smuck et al., "Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Clinical Trials," *Journal of Oncology Practice* 7, no. 2 (March 2011): 80-84, https://doi.org/10.1200/JOP.2010.000051.

patients and initially opening trials offering chemotherapy as a treatment. The goal of offering these types of trials is to engage the physicians in research. Physicians may be more likely to participate in clinical trials if it easy to identify patients to enroll and if familiar treatment options, such as chemotherapy, are offered in the trial.[51] The study by Go et al. provides additional insight for opening studies in the community setting with smaller research programs. The authors note that feasibility assessments must consider the institution budget and available resources since those may not be as prevalent at a smaller facility. Also, the protocol should be thoroughly reviewed to ensure that the site has the appropriate equipment and expertise to complete all of the protocol required treatments and procedures.[52] Baer et al. provide guidance on opening a new research program and recommend that the first trials opened should correspond to the site's largest patient population to ensure high accrual rates. New sites should also initially open less complex trials, such as quality of life studies, so that the research team can gain experience in research procedures and requirements. Once the program is running smoothly, then sites can begin to grow and diversify their clinical trial portfolio.[53]

[51] "Enhancing Oncologist Participation in Research," *Journal of Oncology Practice* 5, no. 6 (November 2009): 309-310, https://doi.org/10.1200/JOP.091042.
[52] Go et al., 431.
[53] Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 328-329.

Chapter 3. Needs Assessment

3.1. Establishing the Need for a Clinical Research Program at the Rural Hospital

There are three primary reasons for establishing a clinical research program at the rural hospital. First, an aim of the Oncology Research Integration Committee (Committee) is to ensure that all hospitals in the Healthcare System can participate in clinical trials by enrolling patients into studies and administering protocol required treatments and procedures at the facilities. The lack of research support at the rural hospital was recognized as a barrier to carrying out the research expansion. Therefore, the author of this paper, with input from the Committee, determined that implementing a research program at the rural hospital was a priority.

The second reason is that the rural hospital is attempting to earn the CCP accreditation from the Commission on Cancer®. As the operations manager for the oncology research program, the author of this project attends the hospital's Commission on Cancer®Committee meeting and is responsible for reporting clinical trial accrual numbers. Accruing two percent of patients to clinical trials per year is required to achieve compliance with Commission on Cancer® Standard 1.9: Clinical Research Accrual.[54] Less than two percent accrual has been reported at these meetings for the rural hospital, and accruals that are reported are referrals to other institutions. This need to increase clinical trial enrollment to comply with the standard is another factor in deciding to implement a research program at the hospital. Having infrastructure in place at the rural

[54] American College of Surgeons, 41-42.

cancer center will allow patients to be enrolled in studies locally and give the site the support necessary to exceed the minimum two percent accrual requirement.

The final reason is that since the rural hospital became a part of the larger Healthcare System in December 2015, integration efforts have been ongoing to include the rural hospital oncology program in existing healthcare system oncology operations, which includes clinical research. For example, videoconferencing has allowed physicians at all hospital locations to join together to discuss patient cases at Tumor Board meetings. At Tumor Board, two areas are discussed: treatment plans for patients to determine the best course of action and patient eligibility for clinical trials. This increase in collaboration across the Healthcare System is what prompted the rural oncologists to expect the same level of research support and opportunity that exist at other hospitals. The rural hospital oncologists began asking administration when clinical research could be supported at the rural hospital.

Both the Oncology Research Integration Committee and the rural hospital's Commission on Cancer Committee® played a role in identifying the need for developing a clinical research program at the rural cancer center. As an operations manager supporting the oncology research program, this author was tasked with the responsibility of developing a strategy to build a successful research program at the rural community hospital. The strategy created through this Capstone Project will be shared with the two committees.

Chapter 4. Project Description

4.1. Description of Project Components

The goal of this Capstone Project was to develop a strategy for implementing a clinical research program at the rural hospital. To accomplish this task, the project was divided into two components. The first part of the project was to gather data regarding clinical research program development and needs specific to rural healthcare programs. This data collection was achieved through a literature review, administration of a needs assessment, and requesting data from the cancer registry at the rural hospital. The literature review was completed using key search criteria related to rural healthcare, clinical trial portfolio development, research staffing, and research program management. The literature review was planned so that the author could gain knowledge of best practices and lessons learned from other research institutions. The needs assessment was included as part of the data collection in order to gather information specific to the rural hospital. The needs assessment was designed for oncology physicians at the rural hospital, the oncology department director at the rural hospital, and the Healthcare System research manager. Questions were written to obtain these individuals' feedback on staffing concerns and requests, their requirements for clinical trials to be offered at the rural hospital, and their overall vision and desires for the research program. The needs assessment was administered in an interview format. The cancer registry data provided information regarding the patient population seen at the rural cancer center.

The second component of this project was to analyze the data from the literature review, the needs assessment, and the cancer registry to create a strategy to build a successful research program at the rural hospital. Information from the literature review

was used as a foundation for the strategy. The needs assessment responses and the cancer registry information were then used by the author to cater the strategy specific to the needs of the rural hospital. For the end result of the project, a strategy was produced providing the rural hospital with recommendations for staffing the program and building a clinical trial portfolio specific to the needs of the rural cancer center.

Chapter 5. Methodology

5.1. Project Design

The methodology for this project included a two-step approach. The first step was to collect data regarding implementing a clinical research program at a rural hospital through a literature review, a needs assessment, and a data request from the rural hospital's cancer registry. The second step was to analyze the information collected and produce a strategy to guide the establishment of a research program at the rural hospital.

5.2. Discussion of Literature Review Methods

A literature review was conducted through the PubMed search engine. Searches included the following topics:

1. Oncology healthcare in the rural setting
2. Clinical research program development and management
3. Clinical Trial Portfolio Development
4. Clinical Research Staffing Assessments.

The initial PubMed search for clinical program development and management led to the article by Baer et al. which noted that a carefully considered clinical trial portfolio and appropriate staffing are key to having a successful research program.[55] Based on the Baer et al. article, the literature search was expanded on PubMed to include articles encompassing clinical trial portfolio development and assessing research staffing needs. A review of the literature was also conducted by accessing the resources and articles supplied on the National Cancer Institute AccuralNet™ website. AccrualNet™ provides

[55] Baer et al., "Clinical Research Site Infrastructure and Efficiency," 251.

support to oncology research sites in the form of education and tools for managing and increasing study accruals.[56] Similar to the PubMed search, articles related to rural healthcare, research program development and management, clinical trial portfolios, and research staffing were reviewed. The articles obtained through the literature searches were reviewed for best practice recommendations and methods for establishing a clinical research program with an emphasis on clinical trial portfolio development and appropriate staffing.

5.3. Discussion of Needs Assessment

While there was much knowledge gained from reviewing the literature, it was also important to obtain feedback from key stakeholders in the Healthcare System's oncology and research departments. The feedback from these individuals was used to ensure that the strategy developed for implementing a research program at the rural hospital met the needs of the physician investigators and applicable administrators.

5.3.1. Selection of needs assessment respondents

Six representatives were selected by the author to participate in the needs assessment. These individuals' roles are listed along with their initials, which is how they are referred to in this paper:

1. Rural Cancer Center Oncology Director (KA)
2. Healthcare System Research Manager (SCM)
3. Rural Cancer Center Radiation Oncologist (AB)
4. Three rural cancer center medical oncologists (AW, FS, RB).

[56] "Literature and Tools," AccrualNet™, National Cancer Institute, accessed January 17, 2019, https://accrualnet.cancer.gov/literature#.XIhS6a2ZOCQ.

The four oncologists were selected because they are the primary physicians seeing patients at the rural cancer center and they have all expressed interest in participating in clinical research. The strategy ultimately developed needs to support these physicians, their patient population, and their research interests, so it was important to obtain their perspective on the research program. The oncology administrator was selected to participate since the research program is going to support her department and her physicians and the strategy needs to align with any oncology department requirements. The Healthcare System research manager was chosen for the needs assessment because the research program developed at the rural hospital ultimately reports to SCM and she can provide guidance on developing the implementation strategy from the research administration perspective.

5.3.2. Selection of needs assessment questions

Based on the literature review discussed in section 5.2, planning a clinical trial portfolio and determining appropriate staffing became main criteria to include in the research program development strategy. Therefore, a needs assessment was created with a series of questions designed to ascertain from the respondents their opinions and recommendations regarding establishing a clinical trial portfolio and research staffing support at the rural hospital. The needs assessment questions also offered an opportunity for the respondents to provide additional insight into the research program development should they want to discuss other items beyond the scope of the clinical trial portfolio and staffing.

Three versions of the needs assessment were composed for this project. One version was administered to the oncology physicians (Appendix 1), one version was

administered to the oncology department director (Appendix 2), and the third version was given to the Healthcare System research manager (Appendix 3). The three versions of the needs assessment mostly contain the same questions, so for purposes of this discussion, the needs assessment for the oncology physicians will be referenced. Questions added or removed from the other two needs assessments will be mentioned as applicable. The needs assessments were designed to be administered in an interview format. The interview format was chosen because the author felt that stakeholder participation would be increased if the respondents could provide information through conversation rather than having to write responses. Additionally, the interview format allowed for follow-up questions and opportunities for clarification if needed. The needs assessment questions were divided into three sections. The first set of questions pertained to the clinical trial portfolio. The second set of questions queried the respondents on staffing needs, and the third set of questions were designed to give the author feedback on the respondents' overall vision of the research program.

For the clinical trial portfolio section, the intent of questions one, two, three, seven, and eight was to determine the interviewees' basic requests for clinical trials to open at the rural hospital. This information would be used to steer the author in the right direction of which types of trials the stakeholders believe should be completed at the rural hospital and which types of studies are of interest to them.

The purpose of questions four and nine was to allow the respondents to expound on the previous questions with open-ended responses. It was anticipated that these open-ended answers may provide an opportunity for unexpected topics or concerns to arise that could be pertinent to the development of the research program strategy. Question five

was included in order to gain perspective on why the stakeholders believe that it is important to be able to enroll patients at the rural hospital rather than refer patients.

Question six addressed limitations at the rural facility. The responses received from this question are pertinent to understanding the feasibility of performing certain studies at the rural hospital.

Question ten was included in an effort to comprehend how the stakeholders foresaw the rural hospital integrating with the existing oncology research program in the Healthcare System. The intent of the question was to understand whether the stakeholders desired autonomy when selecting clinical trials or whether the rural hospital was agreeable to only considering studies vetted by and opened at other hospitals in the Healthcare System.

The Healthcare System research manager was not asked questions five, eight, and nine since these questions were specific to the clinical operations at the rural hospital.

The three questions in the staffing needs section were chosen in order to obtain feedback on stakeholder expectations for research personnel support. Question eleven was aimed at determining whether the physicians and administration would be accepting of clinic staff participating in research. Question twelve was asked in order to identify how much staff support the stakeholders believed that they needed to effectively maintain a research program on site. Question thirteen, an open-ended question, was included to gather additional information regarding the needs of the physicians and administrators and how the research staff could support these needs.

The third section was designed to be a series of open-ended questions to obtain the stakeholders' opinions regarding the research program. The feedback received from

these questions would ensure that the strategy for implementing the research program aligned with the needs and requirements of the oncology department at the rural hospital and the Healthcare System Office of Research. Question fourteen was specifically designed to assist with prioritizing research needs at the rural hospital. An additional question was asked of the oncology director and the research manager, which was “Do you have any other specific needs for the clinical research program that you would like to share?” The purpose of this open-ended question was to provide the administrators the opportunity to notify the author of any department specific items or concerns that should be considered during development of the strategy.

5.3.3. Description of interview process

The needs assessment interviews were conducted individually with each respondent in one sitting. The author of this paper served as the interviewer and recorded each interviewee’s responses. The interview format allowed for discussion between the interviewer and interviewee. The interviewer provided prompts when needed as indicated in Appendices 1-3.

5.4. Developing the Strategy

The second step in the project methodology was to combine the knowledge gained from the literature review with the information obtained from the needs assessment surveys and cancer registry data to develop the strategy for implementing a research program. The strategy for the rural hospital included two main parts: recommendations to staff the research program and recommendations for developing a clinical trial portfolio. The needs assessment responses and the literature review data were analyzed to yield recommendations regarding staffing the research program at the

rural hospital. Clinical trial portfolio recommendations were developed based on advice in the literature review and feedback from the needs assessment interviews. The cancer registry data was incorporated into this analysis as well to ensure that trials were recommended that are applicable to the population served at the rural cancer center.

Chapter 6. Project Results and Discussion

6.1. Literature Review Assessment

Key points obtained from the literature review were organized into three categories: (1) choosing clinical trials for the site's study portfolio, (2) determining staffing needs, and (3) making decisions for opening community-based research programs. For the first category, choosing clinical trials for the site's study portfolio, the literature recommended the following:

- A research site should open clinical trials specific to the patient population seen at the institution.[57]
- A research site should offer clinical trials covering multiple types of treatments for a particular cancer.[58]
- A research site should offer clinical trials for the same cancer type with different eligibility criteria so that patients can have options.[59]
- A research site, depending on its capabilities, should have a diverse trial portfolio including options for healthy volunteers, Phase I, Phase II, Phase III, observational, registry, and tissue banking studies.[60]

[57] Go et al., 431; Zon et al., "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites," 2565.
[58] Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 328; Zon et al., "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites," 2565.
[59] Porter et al., 2148.
[60] Zon et al., "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites," 2565.

- A research site with budget concerns should consider offering trials with more funding, such as industry-sponsored trials, to offset the costs of studies with limited funding, such as cooperative group trials.[61]

For the second category, determining staffing needs, the following suggestions were provided in the literature:

- A research site may benefit from hiring a research nurse to coordinate the clinical trials since the nurse can do both research and standard clinical assessments.[62]
- A research site should involve clinical staff in the research process as a way to increase accrual and to assist the patient with navigating the research requirements along with the standard treatments.[63]
- A research site should maintain metrics on trial volume and complexity to assist with managing staff workload.[64]

The first two categories are generalizable to all research sites. However, the third category is specific to opening research programs at community-based facilities. The literature provides the following advice for choosing a clinical trial portfolio and appropriately staffing a new research program at a community-based hospital:

- The research site should focus on opening studies with the highest potential for accrual.[65]

[61] Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 328.
[62] Hastings, Fisher, and McCabe, 151-152.
[63] Barr, Crofton, and Lin, 450; Somkin et al.; St. Germain et al., 45-53.
[64] Good et al., 211-215; James et al., 1228-1233; Smuck et al., 80-84.
[65] "Enhancing Oncologist Participation in Research," 310.

- The research site should initially open chemotherapy studies since it is a common treatment and may have the most physician support.[66]
- The research site should begin by opening less complex trials.[67]
- The research site should thoroughly review study feasibility to ensure the protocol can properly be supported and executed at the site.[68]
- The research site should hire a clinical research nurse to manage the clinical trials.[69]

Recommendations in the first and second categories came from institutions of various sizes with some of those having larger established research programs. Therefore, not all of the suggestions were relevant for a new program in a smaller setting. For example, offering multiple clinical trials with different treatment options is most likely not possible for a nascent research program. While not all of the recommendations presented in this section may be implemented at the commencement of the research program, the concepts are valuable and should be retained as long-term goals for the research site. The suggestions given in the third category for new and community-based programs are all applicable to the strategy for developing a research program at the rural hospital. These were used as the foundation for the recommendations given to the rural cancer center for building its research program.

[66] "Enhancing Oncologist Participation in Research," 310.
[67] Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 328-329.
[68] Go et al., 431.
[69] Hastings, Fisher, and McCabe, 151-152.

6.2. Needs Assessment Results

For ease of discussion, the question numbers used in the needs assessment administered to the oncology physicians (Appendix 1) are referenced throughout this section. Questions added to or omitted from the needs assessments administered to the rural hospital oncology director and Healthcare System research manager are mentioned as needed. With the exception of question seven, all of the questions with multiple choice options allowed more than one response to be given. The answers to the multiple-choice questions were tabulated and are presented throughout this section. To analyze the open-ended questions, the responses were grouped into relevant categories. Given the limited number of respondents, the data is presented in charts as a function of the number of respondents providing a certain answer rather than the percentage of respondents.

The answers to questions one and two are presented in Figure 1 and Figure 2, respectively. These questions gave general feedback about the type of trials the stakeholders believe would be beneficial to have open at the rural cancer center. As expected, for question one, all of the respondents answered that Phase III studies would be appropriate for the rural cancer center, and five out of six respondents said that observational studies would be appropriate. Phase III and observational studies generally are less complex, and therefore, it is reasonable to want to focus on opening these studies at the rural cancer center. As noted by the oncology director (KA), the clinic staff would be more comfortable with these types of studies.[70] While three of the respondents did answer that Phase II trials should be completed at the site, there is awareness that opening

[70] KA, interview by author, Warrenville, IL, February 26, 2019.

such trials could be complicated. As the radiation oncologist (AB) stated, a Phase II trial may be "pushing it."[71]

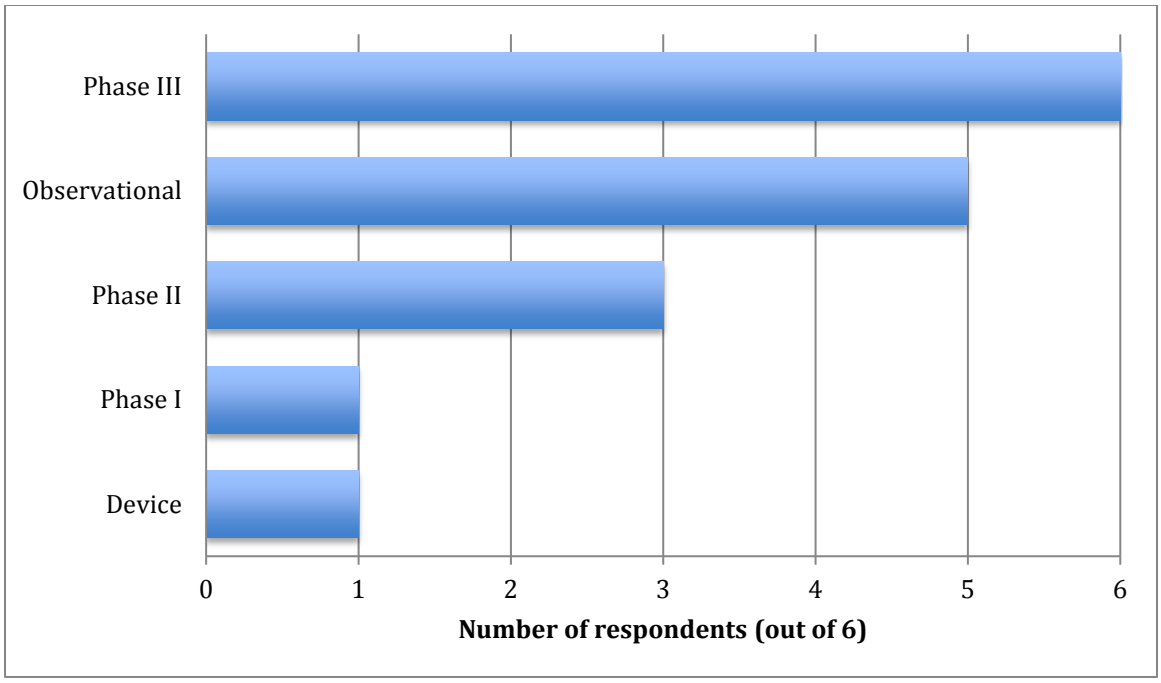

Figure 1: Clinical trial types beneficial to the rural hospital population

For question two, all of the respondents agreed that clinical trials with pharmacological therapies, which include chemotherapy, hormonal therapy, and immunotherapy, would be beneficial to offer at the rural hospital. Four out of the six respondents felt that radiation therapy would be beneficial, which is most likely related to the fact that radiation therapy is available at the rural cancer center and that new radiation equipment was recently installed. Surgery was not as popular of an answer, which may be due to the fact that the oncology surgeons at the rural hospital are employed by an outside group and it may be more difficult to get the surgeons to participate in the studies.[72]

[71] AB, interview by author, DeKalb, IL, February 14, 2019.
[72] RB, interview by author, DeKalb, IL, February 14, 2019.

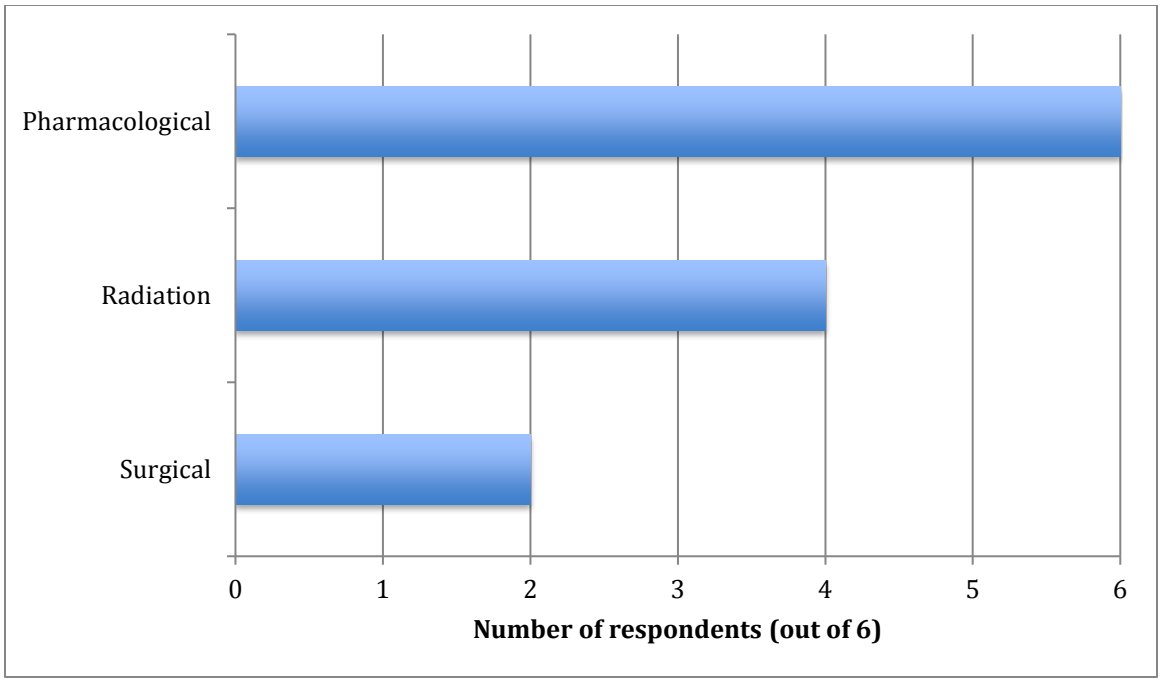

Figure 2: Treatment types beneficial to the rural hospital population

The Healthcare System research manager (SCM) was the only respondent, for question three, to answer that all types of research including cooperative group trials, industry sponsored trials, and investigator initiated trials should be conducted at the rural cancer center. The remaining five respondents all answered that investigator initiated trials should not be conducted at the rural hospital. Question four prompted the interviewees to explain their rationale. SCM stated that "All trials should be an option if the rural facility has the clinical expertise, facility requirements, and necessary support and training…"[73] The other respondents, as presented in Figure 3, noted lack of appropriate research staffing support as a deterrent for opening investigator initiated trials. They also mentioned having limited time for conducting the trials and no funding being challenges.

[73] SCM, interview by author, Warrenville, IL, February 26, 2019.

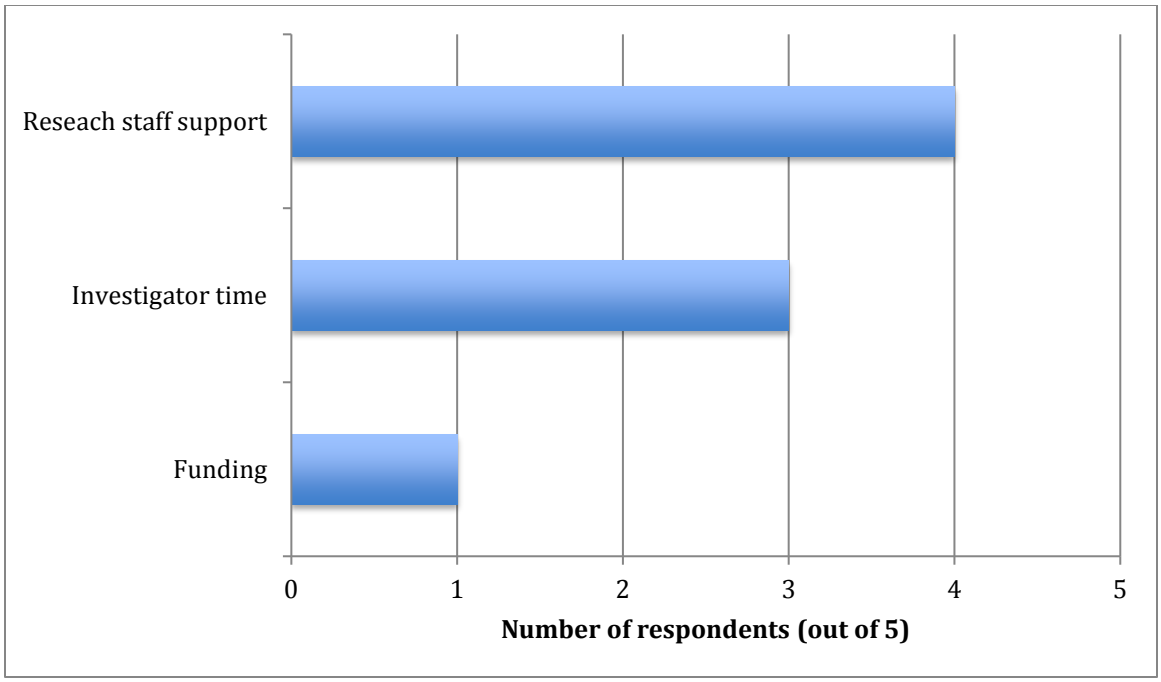

Figure 3: Reasons to not include investigator initiated trials in the clinical trial portfolio

Question five was asked of the oncology program director and the four oncology physicians to get a better idea of why having a research program at the rural facility was important to them. The interviewees were asked an open-ended question about why patients should be enrolled on trials at the rural cancer center rather than being referred to another facility. Multiple responses were accepted, and they fell into four categories: (1) travel and patient convenience, (2) ease of patient care coordination, (3) ability to offer cutting-edge treatments at the rural hospital, and (4) patient retention on clinical trials. As seen in Figure 4, saving patients from having to travel far for their care was the most popular response with four out of the five respondents providing that answer. Two respondents felt that coordinating the patients' care was easier when no referrals were necessary. One of the oncology physicians (RB) mentioned that he no longer wanted to refer patients because he wanted to offer novel treatments at the rural facility and because

he also believed that patients would be more compliant with study protocols if they could receive treatment close to home.[74]

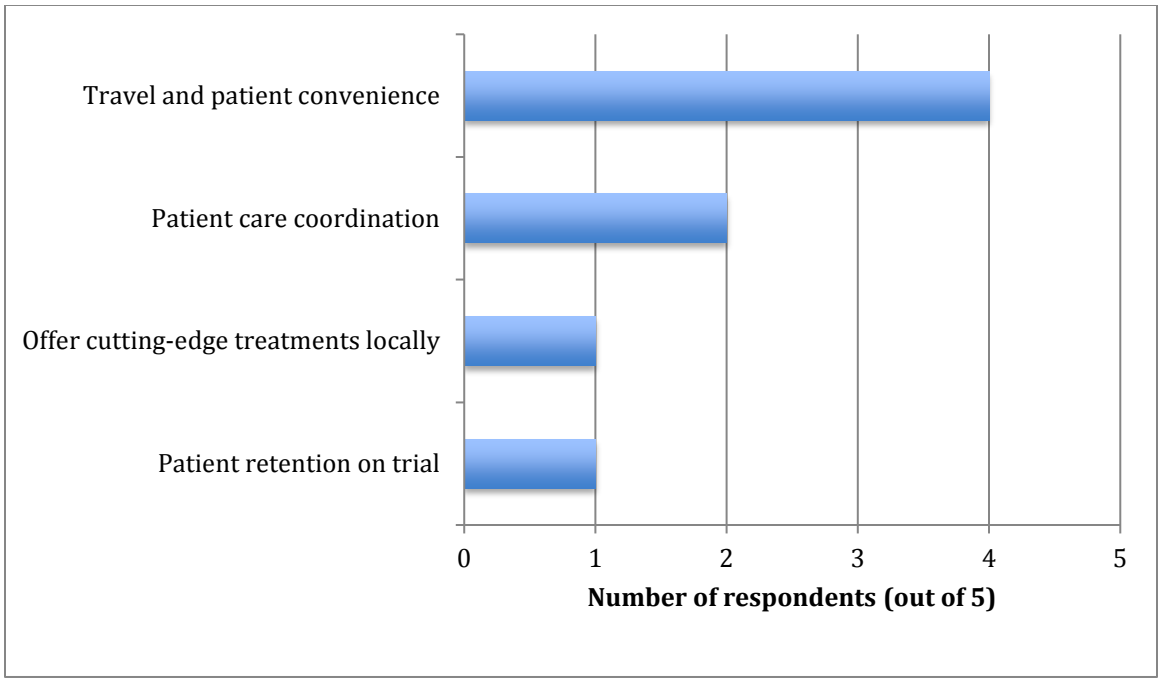

Figure 4: Reasons for enrolling patients on clinical trials at the rural hospital rather than referring patients

Question six was asked to the stakeholders to gain an understanding of any limitations that exist at the rural hospital that need to be considered when developing a strategy for opening the clinical research program. This was an open-ended question where multiple responses were allowed. The responses fell into three categories: (1) lack of on-site research staff support, (2) lack of research training and experience for the clinic staff at the rural hospital, and (3) lack of medical equipment to complete protocol required tasks. Notably, as seen in Figure 5, all six respondents answered that not having on-site research personnel was a limitation to operating clinical trials at the hospital.

[74] RB, interview.

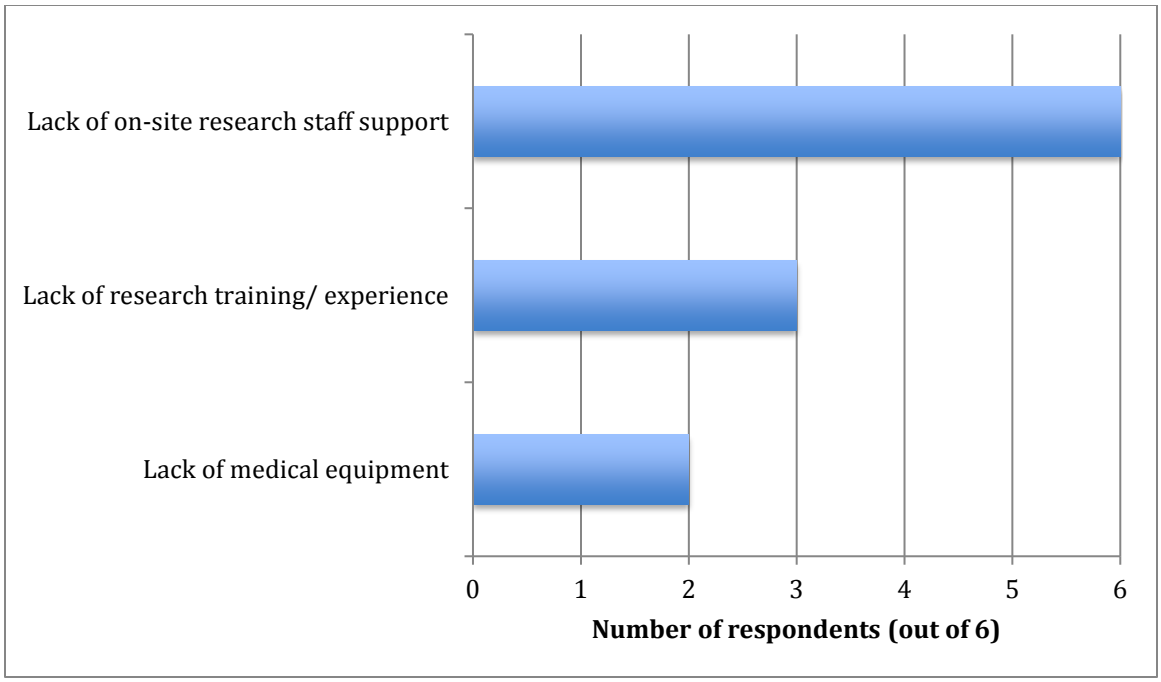

Figure 5: Limitations to opening clinical trials at the rural hospital

In an effort to understand what should drive the clinical trial portfolio at the rural hospital, the respondents were asked, in question seven, whether it was more important to have trials open which the site can accrue patients to or whether it was more important to have trials with novel treatment options. All six respondents answered that the ability to accrue to trials is most important. The oncology director and the oncology physicians were then asked, in questions eight and nine, which cancer sub-specialty should be a focus for opening clinical trials and why. All of the respondents answered that breast cancer should be a priority because it is the most prevalent cancer seen at the rural hospital.

Since the rural hospital is part of a larger healthcare system with existing oncology research programs, question ten was asked of the respondents to get a better understanding of how they envision the rural hospital integrating with the other programs as far as sharing a clinical trial portfolio. Half of the respondents answered that the rural

hospital should be able to open any trials even if the trials are not open at other hospitals in the system. The other three respondents answered that the rural hospital should only open studies that are active at other hospitals in the system. This latter response implies that the rural hospital and the other system hospitals should share a master clinical trial portfolio rather than each hospital have autonomy to open any study that the physicians desire. Not all studies in the shared portfolio have to be open at each site, but a site cannot open a trial unless it has been vetted and is part of the master clinical trial portfolio. The concept of the master clinical trial portfolio is currently being reviewed by the Oncology Research Integration Committee. As of the writing of this paper, no decision has been made on whether the system hospitals must share a clinical trial portfolio, but the author felt it important to ascertain how the stakeholders felt about such a scenario in case the responses affected the strategy for developing the research program. Since the responses were split equally between the two responses, the recommendation provided by the author in this project regarding clinical trial portfolio development does not go into detail regarding where the studies are selected from but rather focuses on the feasibility selection process, which is applicable to both responses.

The next set of questions queried the respondents on staffing needs at the rural cancer center. Question eleven asked the respondents whether a research coordinator should manage all aspects of the clinical trial, whether clinical staff should assist the research coordinator with study requirements, or whether clinical staff should handle the research studies and no study coordinator is needed. All six of the respondents answered that there should be collaboration between the clinic and research staff where clinic staff can assist the study coordinator as needed.

The interviewees were then asked, in question twelve, what type of staffing support was needed. As shown in Figure 6, four of the six respondents answered that a part-time coordinator was needed. One respondent was agreeable to a coordinator on an as-needed basis. The Healthcare System research manager (SCM) answered that a program manager would be a good staffing solution. SCM provided further clarification that a program manager might be the best option for staffing the rural cancer center initially since a manager can handle all aspects of the study including start-up, regulatory, and enrollment.[75] It is somewhat surprising that regulatory support was not mentioned by the interviewees. However, this could be due to the interviewees considering this job the responsibility of a study coordinator rather than a separate position. It was also unexpected that none of the respondents answered that a fulltime coordinator was needed given the result from question six that lack of on-site research support was a limitation to opening clinical trials. Perhaps this response indicates the understanding that a fulltime coordinator may be unrealistic until the need, through increased patient accruals and trials, is established.

[75] SCM, interview.

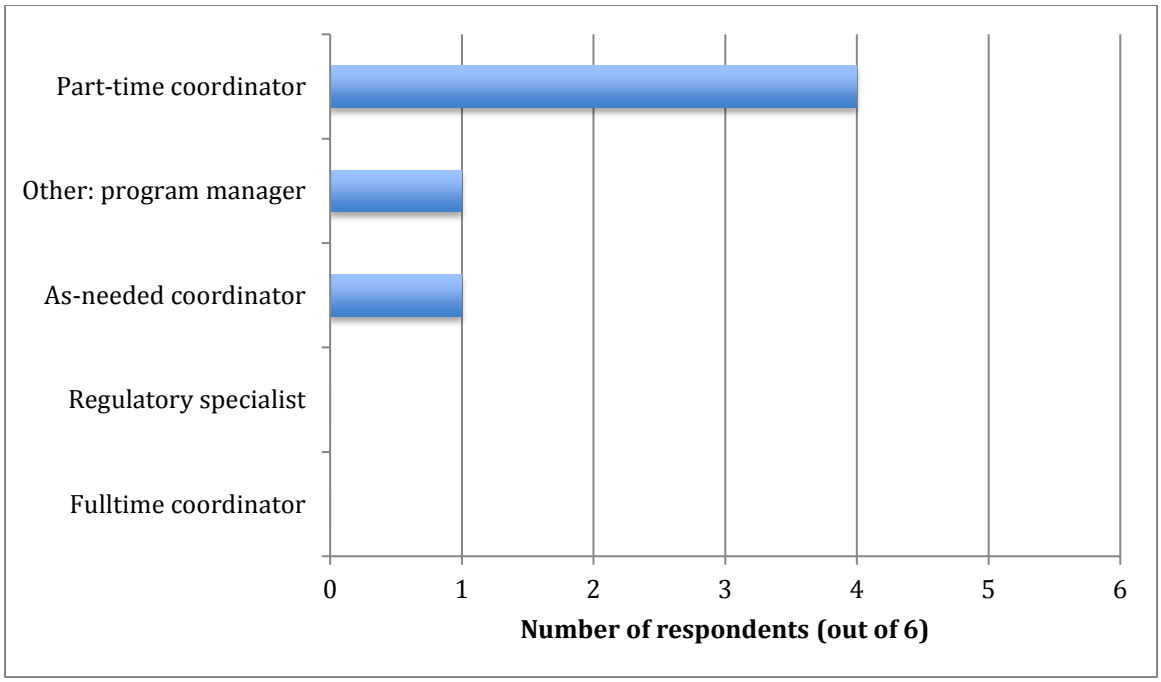

Figure 6: Staffing support needs at the rural hospital

Question thirteen further addressed staffing needs by asking respondents the benefits of having fulltime research staff at the site. This was an open-ended question, and responses were grouped into three categories: (1) capacity to increase accrual and number of trials available, (2) research staff are consistently available to guide investigators and study protocols, and (3) the ability to establish the site as a research facility and promote future growth. The most popular response, as demonstrated in Figure 7, was that having research staff on site would increase patient accrual and allow more trials to be open at the site.

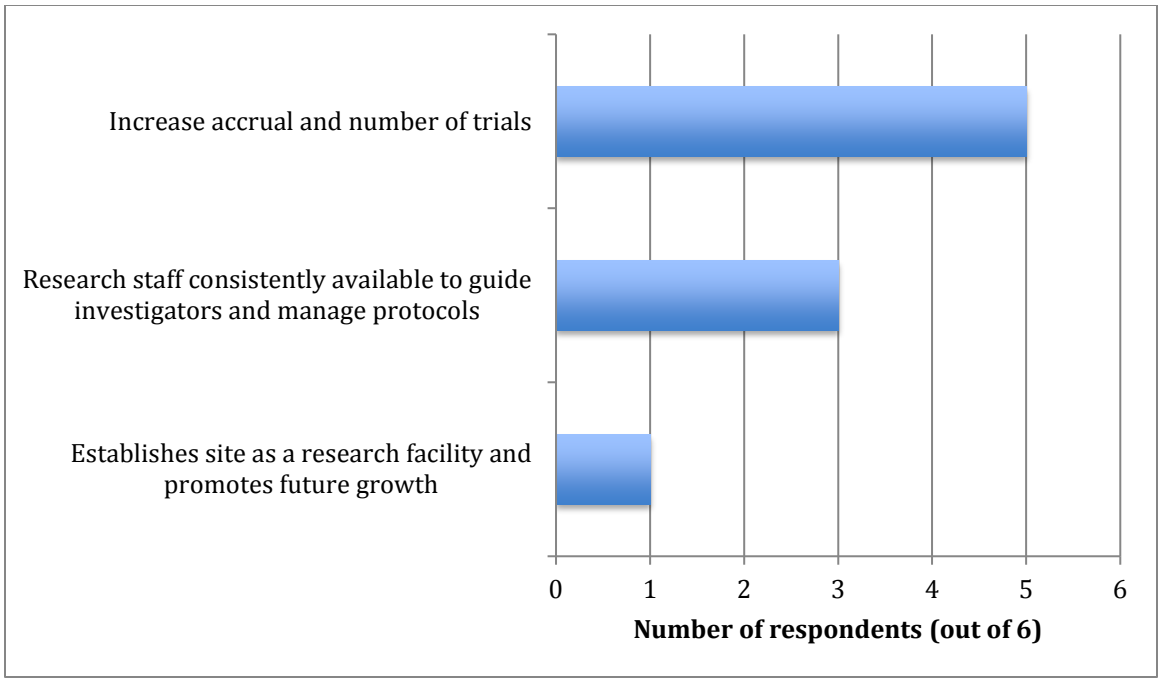

Figure 7: Benefits of having research support staff at the rural hospital fulltime

Question fourteen was asked of all six respondents in an open-ended format. Ideally, all respondents would have provided their top three requirements that need to be in place to effectively support research at the rural hospital, but not all respondents were able to give three answers because they thought the one or two responses given adequately addressed the question. The responses varied but were able to be categorized into five areas of need: (1) consistent research support, (2) trial reminders as a way to better engage investigators and clinical staff, (3) clinic staff education, (4) access to more trials, and (5) adequate facilities and equipment. As shown in Figure 8, five out of six respondents indicated that consistent research support needs to be in place for an effective research program. The consistency of research support was emphasized in the response by KA when she requested a coordinator be present on specific days so that the

staff is aware of when research support will be on site.[76] The importance of consistency is also echoed in the responses by FS, AW, and AB in that they requested regular access to a study coordinator for screening and protocol questions.[77] Trial reminders was another frequent response, which included requests for summary pages for each study to be readily available as well as coordinator assistance with identifying potential study patients.[78]

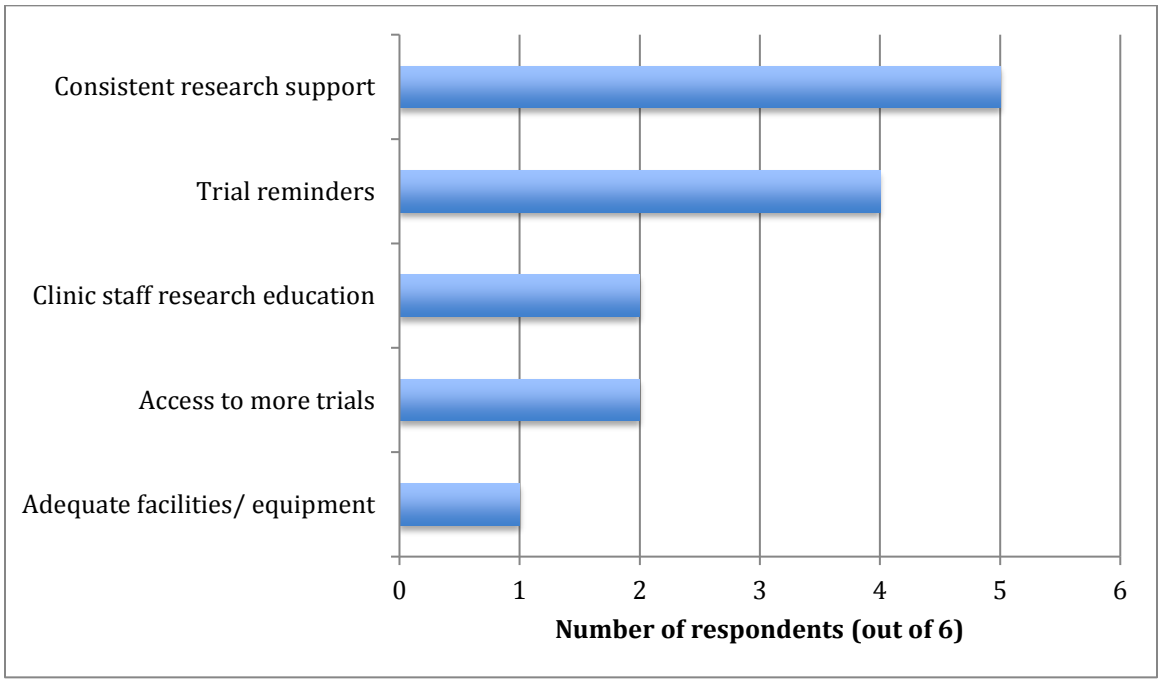

Figure 8: Top reported needs for opening and managing a clinical trial at the rural hospital

Question fifteen asked each respondent what his or her vision was for the rural oncology research program in five years. This was an open-ended question that resulted in discussion between the interviewer and interviewees, but in the end, all of the responses came down to the stakeholders wanting to see the rural cancer center fully

[76] KA, interview.
[77] AB, interview; AW, interview by author, DeKalb, IL, February 14, 2019; FS, interview by author, DeKalb, IL, February 14, 2019.
[78] AB, interview; AW, interview; FS, interview; RB, interview.

operational from a research program perspective. FS specifically mentioned wanting to see a significant increase in accrual in five years,[79] and KA wanted at the end of five years for the cancer center staff to "always be thinking about research participation when seeing a patient."[80] AB also commented that in five years that there should be no need to refer patients to another facility for clinical trial participation because the rural cancer center will offer the same study opportunities available at the other Healthcare System locations.[81]

Question sixteen, an open-ended question, allowed respondents to remark on the culture of research at the rural cancer center and what could be improved to make the facility more conducive to conducting research. The interviewer attempted to obtain three responses from each participant, but not everyone was able to supply three answers as he or she was satisfied with the one or two answers provided. The responses are represented in Figure 9 and were categorized into the following needs: (1) research education for clinic staff and physicians, (2) not overloading clinic staff with research responsibilities, (3) incorporating research into the clinic workflow, (4) having research personnel on site to champion the research process, and (5) having allotted time for investigators to complete research tasks.

[79] FS, interview.
[80] KA, interview
[81] AB, interview.

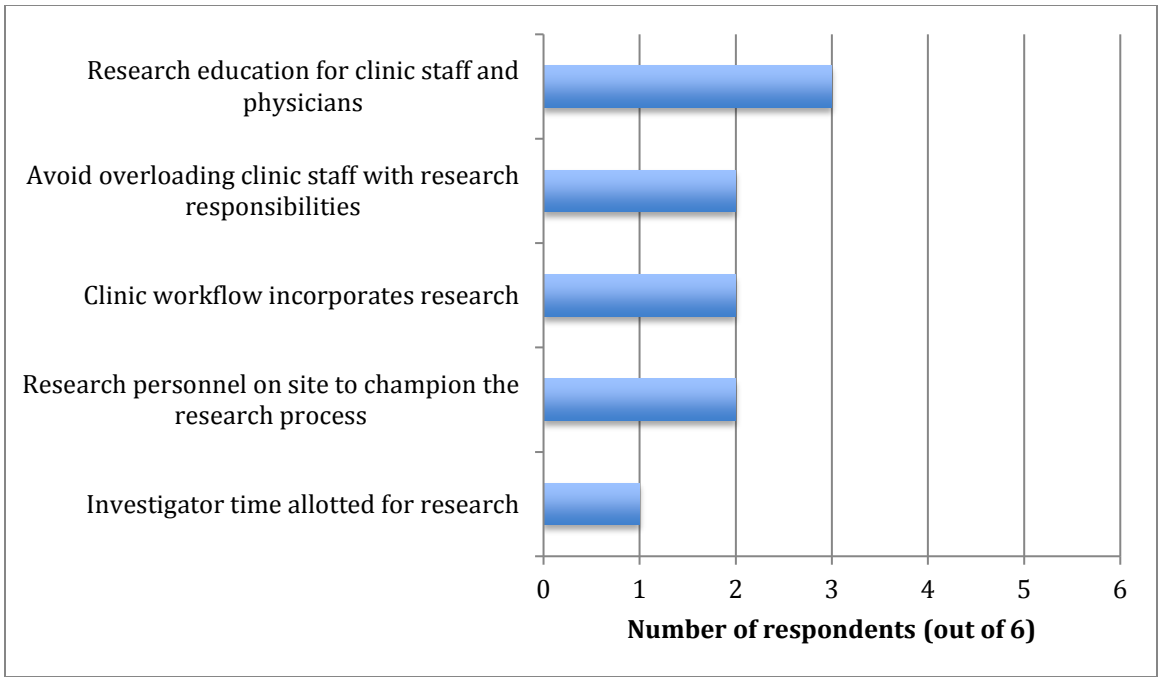

Figure 9: Top reported needs for creating a culture of research at the rural hospital

One final question was asked of the oncology program director and the Healthcare System research manager, which allowed them to comment on any specific requirements that should be included or followed when setting-up the research program at the rural hospital. The Healthcare System research manager (SCM) provided feedback that the research program at the rural hospital needs to integrate well with existing workflows, and that the rural cancer center needs to be adequately staffed with trained personnel to effectively support quality research.[82] The request from the oncology director (KA) was that the research program provide adequate training for clinic staff and maintain frequent communication with the clinic staff and physicians, which may include attending staff meetings at the rural cancer center.[83]

[82] SCM, interview.
[83] KA, interview.

6.3. Cancer Registry Data Analysis

A report was obtained from the cancer registry at the rural hospital based on 2017 data, which was the most current data available. The report contained information on the prevalence of certain cancers treated at the rural cancer center, the most common stage of those cancers that are treated, and the treatments frequently used for those cancers. As demonstrated in Table 1, twenty percent of the cases seen at the rural hospital are breast cancer, and this is the most predominant cancer diagnosed and treated at the cancer center. The incidence of lung cancer cases is the next highest at eleven percent followed by prostate cancer making up nine percent of the cases. Table 1 also presents data regarding which stage of cancer is most frequently diagnosed and the common treatment strategies for the cancer type and stage. Of the breast cancer cases seen at the rural hospital, the majority of cases are diagnosed and treated while they are stage I or stage II cancers, and the most common treatments are surgery and hormonal therapy. Almost half of the lung cancer cases are diagnosed and treated as a stage IV cancer with chemotherapy and immunotherapy being the most common treatments. Over half of the prostate cancers are treated as a stage II cancer with radiation and hormonal therapy being used frequently as treatment.[84] This information is important to understanding the patient population seen at the rural hospital so that the clinical trial portfolio can be catered to these patients and their needs.

[84] Rural Hospital Cancer Registry, *First Course Treatment by Best AJCC Stage Report*, February 14, 2019.

Table 1. Top three cancer types diagnosed and treated at the rural cancer center, 2017

Cancer Type	% of Cancer Cases	Common Stage at Diagnosis	Common Treatment for Cancer and Stage
Breast	20	I, II	Surgery, Hormone
Lung	11	IV	Chemotherapy, Immunotherapy
Prostate	9	II	Radiation, Hormone

Source: Data from Rural Hospital Cancer Registry, *First Course Treatment by Best AJCC Stage Report*, February 14, 2019.

Chapter 7. Recommendations and Discussion

7.1. Recommendations

Based on the literature review results, the needs assessment results, and the data from the cancer registry, a strategy was developed for implementing an oncology clinical research program at the rural hospital. The strategy consisted of six recommendations, which focused on managing an effective clinical trial portfolio and appropriately staffing the research program in order to provide adequate support to the physician investigators and to manage the protocol requirements.

Recommendation 1: Develop a Process for Managing the Clinical Trial Portfolio

Both the literature review and the needs assessment results indicated the importance of being able to accrue to studies. The research site could take a significant financial loss by opening studies with limited to no accrual.[85] Only clinical trials should be opened at the site that make sense for the facility based on the patient population seen at the cancer center, the equipment available at the site to perform protocol requirements, and the interest of the physicians.

Therefore, the recommendation is to convene a research protocol feasibility committee comprised of the four oncology physicians at the rural cancer center. Porter et al. suggested using disease teams to review protocol feasibility.[86] The Healthcare System oncology program does have disease teams that encompass the cancer programs at all of the system hospitals, including the rural hospital. However, the oncologists at the other

[85] Durivage and Bridges.
[86] Porter et al., 2149-2151.

hospitals are not aware of site limitations and needs at the rural cancer center, and therefore, the recommendation is to initially keep the feasibility assessment local with the rural cancer center physicians reviewing the studies. As the research program grows at the rural cancer center, use of the system-wide disease teams to review protocol feasibility may be an option. Using the research protocol feasibility committee to review studies should result in a clinical trial portfolio which the physicians are enthusiastic about and that is applicable to the hospital's patient population so that significant accrual rates can be achieved. The second part of this recommendation is that the research protocol feasibility committee require documentation from the principal investigator demonstrating the ability to accrue to the trial. This would follow a process similar to the one implemented by Durivage and Bridges, and one can anticipate having the same success with reducing the amount of studies opened with limited or no accrual.[87]

Recommendation 2: Include Studies in the Clinical Trial Portfolio that will be Successful at the Rural Cancer Center

The literature review provided multiple suggestions for what types of trials to incorporate in a clinical trial portfolio. One article placed emphasis on the need to offer trials for all cancer types and stages of cancer seen at a research facility.[88] Another article noted the importance of offering a diverse portfolio including Phase I, Phase II, Phase III, registry, and observational studies.[89] These articles provide reasonable suggestions for more established or larger programs. However, the recommendation for the clinical trial

---

87 Durivage and Bridges.

88 Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 328.

89 Zon et al., "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites," 2565.

portfolio at the rural hospital, given that the program is new and at a small facility, is to focus on opening studies likely to succeed at the rural cancer center rather than trying to choose studies to cover all cancer types and include all types of studies. Therefore, the clinical trial portfolio at the rural cancer center should be established using the following criteria:

- The research site should open studies with the highest potential for accrual.[90]
- The research site should initially open chemotherapy studies.[91]
- The research site should open less complex trials,[92] such as Phase III, observational, or registry studies.

Recommendation 3: Initially Open Breast, Lung, and Prostate Cancer Studies at the Rural Hospital

Using suggestions from the literature review and the data obtained from the rural hospital's cancer registry, the recommendation is to initially open breast, lung, and prostate cancer studies since these are the most prevalent cancers seen at the hospital. The site has the best opportunity for accruing patients to these trials. One or two trials should be opened for each of these cancer types, and the trials should focus on treating stage I or II breast cancers, stage II prostate cancers, and stage IV lung cancers since those are the most commonly diagnosed stages of cancer at the rural hospital. The studies should be Phase III, observational, or registry studies so that the site can begin with less complex trials. The Phase III interventional trials should include chemotherapy as treatment. Since

[90] "Enhancing Oncologist Participation in Research," 310.
[91] "Enhancing Oncologist Participation in Research," 310.
[92] Baer et al., "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites," 328-329.

hormone treatment is popular for both breast and prostate cancers at the site, then those treatments could be incorporated into the trial portfolio as well. From a budget perspective, the recommendation is that one or two of the studies should be industry-sponsored to help offset the costs from the cooperative group trials. It is not recommended to open any investigator initiated trials until the research program is more established at the site, the research personnel and principal investigators gain more experience, and the investigators are able to designate specific time for research.

The responses from the needs assessment were also incorporated into recommendations 1-3 regarding the clinical trial portfolio. The needs assessment responses corresponded with the literature review in that the stakeholders were most interested in completing Phase III or observational studies and agreed that investigator initiated studies were not appropriate for opening at a new research site. The needs assessment results also supported the recommendation to open breast cancer trials and to focus on pharmacological treatments.

Recommendation 4: Hire a Clinical Research Nurse

The needs assessment identified the lack of on-site research personnel to be one of the biggest limitations to opening clinical trials at the rural hospital. Having consistent research staff available was also listed as a key item currently missing to create a culture of research at the rural hospital. Utilizing this feedback along with the literature review resulted in a recommendation for staffing the research program at the rural cancer center.

The recommendation for staffing the research program is to hire a clinical research nurse as suggested by Hastings et al.[93] The research nurse should begin as a part-time position and have the opportunity for fulltime status as the research program grows. The research nurse should be in charge of all study activities including coordinator responsibilities and regulatory submissions until trial volume indicates the need for additional staff. The position may also transition into a manager level role as proposed by the Healthcare System research manager (SCM).[94] The needs assessment responses regarding staffing provided support for this recommendation. The majority of respondents agreed that a part-time coordinator would be sufficient. In addition, the research nurse should have a consistent schedule at the rural cancer center to fulfill the request identified in the needs assessment that the investigators and clinic staff have regular access to research coordinator support.

The research nurse can also prepare protocol summaries complete with eligibility criteria and give these to the clinic staff and physicians for reference.[95] Ideally, the summary sheets should be pocket-sized cards for staff to carry with them to patient visits and to be easily accessible.

Recommendation 5: Provide Education for the Clinic Staff and Physicians on Research Activities

Part of the staffing recommendation is to also educate the clinic staff and physicians on research activities so that they can participate in the research process. The

[93] Hastings, Fisher, and McCabe, 151-152.
[94] SCM, interview.
[95] FS, interview.

stories of successful partnerships between research personnel and clinic staff[96] signify the need to establish this collaborative environment at the rural hospital from the onset of the research program. Based on a suggestion from the needs assessment interviews, education can be accomplished by the clinical research nurse attending clinic staff meetings to discuss research and give updates on study protocols.[97]

Recommendation 6: Track Study Metrics to Monitor Research Personnel Workload

The final recommendation is that the rural cancer center research personnel, with the assistance of the Healthcare System Office of Research, should track study metrics in order to monitor research personnel workload. A clinical trial complexity scoring system should be used like that identified by Good et al. or Smuck et al.[98] Implementing the tracking of these metrics at the beginning of the research program will allow the site to maintain constant oversight of research support needs and make efficient hiring decisions. The clinical trial management system used by the Healthcare System Office of Research can be modified to collect and report this data.

[96] Barr, Crofton, and Lin, 450; Somkin et al.; St. Germain et al.
[97] KA, interview.
[98] Good et al., 211-215; Smuck et al., 80-84.

Chapter 8. Conclusion

A strategy to implement an oncology clinical research program at the rural hospital was developed to meet the needs of the Healthcare System. The Oncology Research Integration Committee designated the expansion of clinical research to the Healthcare System community hospitals a priority for the fiscal year. Part of this expansion initiative required that infrastructure be in place at the rural hospital to support the clinical trials. The rural hospital is also attempting to earn its CCP accreditation through the Commission on Cancer®. Accruing to clinical trials is a standard that must be met for accreditation, and having a research program is necessary to aid the rural hospital in meeting this requirement. Lastly, the integration between the oncology research program at the rural cancer center and other Healthcare System cancer centers resulted in the rurally based oncologists requesting equitable research support at their facility. Having a research program at the rural cancer center allows the physicians to enroll patients locally onto trials and to maintain oversight of the patients' care rather than having to refer patients to other locations.

The strategy developed for the rural hospital research program was designed after best practices shared in the literature by other institutions starting and managing clinical research programs. A needs assessment with key stakeholders supplemented the literature review by providing insight into the specific requests of the oncology physicians and administrators in the oncology and research departments. These two sources of information along with cancer registry data were analyzed to yield a strategy devised to create an effective research program for the rural hospital. Developing the clinical trial

portfolio and staffing the cancer program are noted to be key items in managing a successful research program.[99] Therefore, the strategy delivered for this project focuses on building a clinical trial portfolio of studies which the site can easily accrue patients to, using the rural oncologists to assess study feasibility, educating the clinical staff on research activities, and appropriately staffing the research program to manage the trial workload while also supporting the investigators.

The recommendations provided in the strategy are meant to guide the initial start-up of the research program at the rural hospital. However, the rural cancer center physicians and administrators have a vision that the research program should grow. As the research program matures, the recommendations should be adapted to support a larger more experienced research site. The logic behind the recommendations can remain the same, which is to open studies that can successfully accrue patients at the rural hospital and to provide enough staff for the research program to support quality research. For example, after successfully supporting Phase III, observational, or registry studies, the site feasibility committee could decide to open a Phase II trial. Studies in other areas besides breast, lung, and prostate cancer could be opened to accommodate more patients. Research staffing must also grow to support additional trials and increased enrollment. Hiring other research positions could be considered such as regulatory specialists and data entry personnel to support the study coordinator.

A future direction for this project is to expand the strategy beyond oncology to other areas at the rural hospital. The rural hospital is integrated with the Healthcare System in multiple medical specialties, including cardiology and neurology. Both of

[99] Baer et al., "Clinical Research Site Infrastructure and Efficiency," 251.

these departments have active clinical research programs in the Healthcare System, and there is opportunity for research to expand to the rural hospital in these areas as well. Therefore, the strategy developed in this project for oncology could be catered to the specific needs of a cardiology research program or a neuroscience research program at the rural hospital. There could be opportunity for the cardiology or neurology research programs to utilize some of the research infrastructure already put in place for the oncology program such as education of clinic staff or sharing research personnel. The clinical trial portfolio recommendations could be modified to reflect the cardiology or neurology populations seen at the rural hospital, and a feasibility committee of applicable cardiologists or neurologists could be utilized to drive development of the trial portfolios. Whether the strategy developed for implementing a research program is used only for oncology or whether it has the potential to be used in other departments, the goal remains the same, which is to establish a research program that meets the needs of the Healthcare System administrators, the physicians, and the patients.

Bibliography

American Cancer Society. *Cancer Facts & Figures 2019*. Atlanta: American Cancer Society, 2019. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf.

American College of Surgeons. *Cancer Program Standards: Ensuring Patient-Centered Care*. Chicago: American College of Surgeons, 2015. https://www.facs.org/~/media/files/quality%20programs/cancer/coc/2016%20coc%20standards%20manual_interactive%20pdf.ashx.

Baer, Allison R., Gary Cohen, Dee Anna Smith, and Robin Zon. "Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites." *Journal of Oncology Practice* 6, no. 6 (November 2010): 328-330. https://doi.org/10.1200/JOP.2010.000156.

Baer, Allison R., Kerry Dune Bridges, Mary O'Dwyer, Joy Ostroff, and Joyce Yasko. "Clinical Research Site Infrastructure and Efficiency." *Journal of Oncology Practice* 6, no. 5 (September 2010): 249-252. https://doi.org/10.1200/JOP.000109.

Barr, Louis H., Jane Crofton, and Yu-Hsin Annie Lin. "A Community Hospital Clinical Trials Program: Infrastructure for Growth." *Surgical Oncology Clinics of North America* 20, no. 3 (2011): 447-453. https://doi.org/10.1016/j.soc.2011.01.001.

Dimond, Eileen P., Diane St. Germain, Lianne M. Nacpil, Howard A. Zaren, Sandra M. Swanson, Christopher Minnick, Angela Carrigan, Andrea M. Denicoff, Kathleen E. Igo, Jared D. Acoba, Maria M. Gonzalez, and Worta McCaskill-Stevens. “Creating a “culture of research” in a community hospital: Strategies and tools from the National Cancer Institute Community Cancer Centers Program." *Clinical Trials* 12, no. 3 (February 17, 2015): 246-256. https://doi.org/10.1177/1740774515571141.

Durivage, Henry and Kerry Bridges, 2009. “Clinical Trial Metrics: Protocol Performance and Resource Utilization from 14 Cancer Centers.” Poster presented at the 2009 American Society of Clinical Oncology annual meeting, Orlando, FL, May 29-June 2, 2009. https://forteresearch.com/wp-content/uploads/2017/10/ascoposter_2009.pdf.

"Enhancing Oncologist Participation in Research." *Journal of Oncology Practice* 5, no. 6 (November 2009): 309-311. https://doi.org/10.1200/JOP.091042.

Go, Ronald S., Kathleen A. Frisby, Jennifer A. Lee, Michelle A. Mathiason, Christine M. Meyer, Jodi L. Ostern, Sara M. Walther, Jonean E. Schroeder, Lori A. Meyer, and Kathryn E. Umberger. "Clinical Trial Accrual among New Cancer Patients at a Community-Based Cancer Center." *Cancer* 106, no. 2 (January 15, 2006): 426-433. https://doi.org/10.1002/cncr.21597.

Good, Marjorie J., Barbara Lubejko, Keisha Humphries, and Andrea Medders. "Measuring Clinical Trial–Associated Workload in a Community Clinical Oncology Program." *Journal of Oncology Practice* 9, no. 4 (July 2013): 211-215. https://doi.org/10.1200/JOP.2012.000797.

Hastings, Clare E., Cheryl A. Fisher, and Margaret A. McCabe. "Clinical research nursing: A critical resource in the national research enterprise." *Nursing Outlook* 60 (2012): 149-156. https://doi.org/10.1016/j.outlook.2011.10.003.

James, Pam, Patty Bebee, Linda Beekman, David Browning, Mathew Innes, Jeannie Kain, Theresa Royce-Westcott, and Marcy Waldinger. "Creating an Effort Tracking Tool to Improve Therapeutic Cancer Clinical Trials Workload Management and Budgeting." *Journal of the National Comprehensive Cancer Network* 9, no. 11 (November 2011): 1228-1233. https://doi.org/10.6004/jnccn.2011.0103.

National Cancer Institute. "Literature and Tools." AccrualNet™. Accessed January 17, 2019. https://accrualnet.cancer.gov/literature#.XIhS6a2ZOCQ.

National Cancer Institute. "NCI Dictionary of Cancer Terms." Accessed March 6, 2019. https://www.cancer.gov/publications/dictionaries/cancer-terms.

Porter, Mark, Bhuvaneswari Ramaswamy, Karen Beisler, Poonam Neki, Nancy Single, James Thomas, Janie Hofacker, Michael Caligiuri, and William E Carson III. "A Comprehensive Program for the Enhancement of Accrual to Clinical Trials." *Annals of Surgical Oncology* 23, no. 7 (July 1, 2016): 2146-2152. https://doi.org/10.1245/s10434-016-5091-9.

Rural Hospital Cancer Registry. *First Course Treatment by Best AJCC Stage Report*, February 14, 2019.

Smuck, Bobbi, Phyllis Bettello, Koralee Berghout, Tracie Hanna, Brenda Kowaleski, Lynda Phippard, Diana Au, and Kay Friel. "Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Clinical Trials." *Journal of Oncology Practice* 7, no. 2 (March 2011): 80-84. https://doi.org/10.1200/JOP.2010.000051.

Somkin, Carol P., Andrea Altschuler, Lynn Ackerson, Ann M. Geiger, Sarah M. Greene, Judy Mouchawar, Joan Holup, Louis Fehrenbacher, Andrew Nelson, Andrew Glass, Jonathan Polikoff, Sigrid Tishler, Carolyn Schmidt, Terry Field, and Edward Wagner. "Organizational Barriers to Physician Participation in Cancer Clinical Trials." *American Journal of Managed Care* 11 (July 2005). https://www.ajmc.com/journals/issue/2005/2005-07-vol11-n7/jul05-2081p413-421.

St. Germain, Diane, Eileen Dimond, Kristi Olesen, Christie Ellison, Lianne Nacpil, Lucy Gansauer, Angela Carrigan, Kathleen Igo, and Maria Gonzalez. "The NCCCP Patient Navigation Project." *Oncology Issues* (May-June 2014): 45-53. https://www.accc-cancer.org/docs/Documents/oncologyissues/articles/MJ14/mj14-ncccp-patientnavigation-project.

Zon, Robin, Gary Cohen, Dee Anna Smith, and Allison R. Baer. "Part 2: Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites." *Journal of Oncology Practice* 7, no. 1 (January 2011): 61-64. https://doi.org/10.1200/JOP.2010.000185.

Zon, Robin, Neal J. Meropol, Robert B. Catalano, and Richard L. Schilsky. "American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites." *Journal of Clinical Oncology* 26, no. 15 (May 20, 2008): 2562-2567. https://doi.org/10.1200/JCO.2007.15.6398.

Appendix 1: Needs Assessment Questions for the Oncology Physicians

Thank you for taking the opportunity to speak with me regarding development of an oncology clinical research program at your hospital cancer center. The intent of this interview is to obtain your feedback on what staffing support is needed to open a clinical research program at the hospital as well as what types of trials you think would be beneficial to have open. There will also be the opportunity for you to share your vision for the research program at the hospital. The results of the interviews will be compiled and used in partial fulfillment of my Master of Science in Research Administration at Johns Hopkins University. The results will also be shared with Northwestern Medicine Office of Research Administration and the Oncology Program Administration.

Clinical Trial Portfolio

1. In which types of clinical trials are you interested in participating? The following prompts will be given…
    a. Investigational drug studies – Phase I
    b. Investigational drug studies – Phase II
    c. Investigational drug studies – Phase III
    d. Observational studies
    e. Device studies
2. Thinking about the patients that you see routinely, which study treatment options would they benefit from most? The following prompts will be given….
    a. Pharmacological treatments (chemotherapy, hormonal, molecular targeted therapy)
    b. Surgical treatments
    c. Radiation treatments
3. What types of research do you NOT think are necessary to have in the clinical trial portfolio? The following prompts will be given…
    a. Cooperative group trials
    b. Industry sponsored trials
    c. Investigator initiated trials
    d. None of the above – cooperative, industry sponsored, and investigator initiated trials should all be included.
4. What is the primary reason you answered _____ to the last question?
5. What are the main reasons that you would prefer to enroll patients in studies at your hospital rather than refer patients to a clinical trial elsewhere, even if it is a referral to a hospital in the same healthcare system? (Interviewer will attempt to obtain at least 3 reasons.)
6. Thinking about the current state of the hospital, what potential limitations do you see in trying to open clinical trials at the hospital? (Interviewer will attempt to obtain at least 3 limitations.)
7. What do you think is more important in choosing whether or not to open a trial?

a. The ability to accrue to the trial.
b. The ability to offer a novel treatment to patients.

8. If you had to choose an oncology sub-specialty area on which to focus opening clinical trials first, which would it be?
9. What is the primary reason you answered _____ to the last question?
10. In regards to opening new clinical trials, which of the following statements do you agree with?
    - A: Any study that is open at the other regional hospitals should automatically be opened at the rural hospital.
    - B: The rural hospital should only open studies that are available at the other regional hospitals, but not all studies will be opened.
    - C: The rural hospital should be able to open a study, even if it is not available at the other regional hospitals.
    - A only
    - B only
    - C only
    - A and B
    - A and C
    - B and C

Staffing Needs

11. What is your expectation for research staffing support? The following prompts may be given…
    a. A research coordinator should manage all study logistics. Clinic staff should have no or limited involvement in the clinical trials.
    b. The research coordinator will manage the study logistics, but clinic staff will be available to assist the coordinator with study requirements.
    c. Clinic staff will manage the study logistics. A research coordinator is not needed or will have minimal involvement.
12. How much research staffing support do you need? The following prompts will be given…
    a. Fulltime coordinator
    b. Part-time coordinator
    c. Coordinator on an as needed basis
    d. Regulatory Support
    e. Other….please explain
13. What are the potential benefits of having research support, such as a study coordinator, on site at the hospital fulltime? (The interviewer will attempt to obtain 3 benefits.)

Specific Needs and Overall Vision

14. As a physician investigator, what are the top 3 things you need right now as far as research support to effectively open and manage a clinical trial at the rural hospital?
15. What is your vision for the clinical research program at the rural hospital in five years?
16. What are the top 3 things you think need to be done at the hospital to create a culture of research?

Appendix 2: Needs Assessment Questions for the Rural Hospital Oncology Program Director

Thank you for taking the opportunity to speak with me regarding development of an oncology clinical research program at the hospital cancer center. The intent of this interview is to obtain your feedback regarding staffing support that is needed to open a clinical research program at the hospital, what types of trials you think would be beneficial to the oncology program to have open, and your vision to ensure that the research program at the hospital aligns with your department strategy. The results of the interviews will be compiled and used in partial fulfillment of my Master of Science in Research Administration at Johns Hopkins University. The results will also be shared with Northwestern Medicine Office of Research Administration and the Oncology Program Administration.

Clinical Trial Portfolio

1. Based on the patient population seen at the hospital, which of the following types of clinical trials do you think would be most beneficial to the patients? The following prompts will be given...
    a. Investigational drug studies – Phase I
    b. Investigational drug studies – Phase II
    c. Investigational drug studies – Phase III
    d. Observational studies
    e. Device studies
2. Thinking about the patients seen routinely at the hospital, which of the following study treatment options would be most beneficial to offer the patients? The following prompts will be given…
    a. Pharmacological treatments (chemotherapy, hormonal, molecular targeted therapy)
    b. Surgical treatments
    c. Radiation treatments
3. What types of research do you NOT think are necessary to have in the clinical trial portfolio? The following prompts will be given…
    a. Cooperative group trials
    b. Industry sponsored trials
    c. Investigator initiated trials
    d. None of the above – cooperative, industry sponsored, and investigator initiated trials should all be included.
4. What is the primary reason you answered _____ to the last question?
5. What are the main reasons that you think patients should be enrolled in studies at your hospital rather than refer patients to a clinical trial elsewhere, even if it is a referral to a hospital in the same healthcare system? (Interviewer will attempt to obtain at least 3 reasons.)

6. Thinking about the current state of the hospital, what potential limitations do you see in trying to open clinical trials at the hospital? (Interviewer will attempt to obtain at least 3 limitations.)
7. What do you think is more important in choosing whether or not to open a trial?
    a. The ability to accrue to the trial.
    b. The ability to offer a novel treatment to patients.
8. If you had to choose an oncology subspecialty area on which to focus opening clinical trials first, which would it be?
9. What is the primary reason you answered _____ to the last question?
10. In regards to opening new clinical trials, which of the following statements do you agree with?
    - A: Any study that is open at the other regional hospitals should automatically be opened at the rural hospital.
    - B: The rural hospital should only open studies that are available at the other regional hospitals, but not all studies will be opened.
    - C: The rural hospital should be able to open a study, even if it is not available at the other regional hospitals.
    - A only
    - B only
    - C only
    - A and B
    - A and C
    - B and C

Staffing Needs

11. What is your expectation for research staffing support in your department? The following prompts may be given:
    a. A research coordinator should manage all study logistics. Clinic staff should have no or limited involvement in the clinical trials.
    b. The research coordinator will manage the study logistics, but clinic staff will be available to assist the coordinator with study requirements.
    c. Clinic staff will manage the study logistics. A research coordinator is not needed or will have minimal involvement.
12. How much research staffing support do you need? The following prompts will be given…
    a. Fulltime coordinator
    b. Part-time coordinator
    c. Coordinator on an as needed basis
    d. Regulatory Support
    e. Other….please explain

13. What are the potential benefits of having research support, such as a study coordinator, on site at the hospital fulltime? (The interviewer will attempt to obtain 3 benefits.)

Overall Vision

14. As the oncology program director, what are the top 3 things you need right now as far as research support to effectively open and manage a clinical trial at the rural hospital?
15. What is your vision for the clinical research program at the rural hospital in five years?
16. What are the top 3 things you think need to be done at the hospital to create a culture of research?
17. Do you have any other specific needs for the clinical research program that you would like to share?

Appendix 3: Needs Assessment Questions for the Healthcare System Research Manager

Thank you for taking the opportunity to speak with me regarding development of a clinical research program at the rural hospital. The intent of this interview is to obtain your feedback regarding staffing support that is needed to open a clinical research program at the hospital, what types of trials you think would be beneficial to the oncology program to have open, and your vision to ensure that the research program at the hospital aligns with existing research program strategies. The results of the interviews will be compiled and used in partial fulfillment of my Master of Science in Research Administration at Johns Hopkins University. The results will also be shared with Northwestern Medicine Office of Research Administration and the Oncology Program Administration.

Clinical Trial Portfolio

1. Based on what you know about the patient population seen at the hospital and trials available elsewhere in the Healthcare System, which of the following types of clinical trials do you think would be most beneficial to have available at the rural hospital? The following prompts will be given…
    a. Investigational drug studies – Phase I
    b. Investigational drug studies – Phase II
    c. Investigational drug studies – Phase III
    d. Observational studies
    e. Device studies
2. Thinking about the patients seen routinely at the hospital and trials available elsewhere in the Healthcare System, which of the following study treatment options would be most beneficial to offer the patients at the rural hospital? The following prompts will be given…
    a. Pharmacological treatments (chemotherapy, hormonal, molecular targeted therapy)
    b. Surgical treatments
    c. Radiation treatments
3. What types of research do you NOT think are necessary to have in the clinical trial portfolio at the rural hospital? The following prompts will be given…
    a. Cooperative group trials
    b. Industry sponsored trials
    c. Investigator initiated trials
    d. None of the above – cooperative, industry sponsored, and investigator initiated trials should all be included
4. What is the primary reason you answered _____ to the last question?
5. Thinking about the current state of the hospital, what potential limitations do you see in trying to open clinical trials at the hospital? (Interviewer will attempt to obtain at least 3 limitations.)

6. What do you think is more important in choosing whether or not to open a trial?
    a. The ability to accrue to the trial.
    b. The ability to offer a novel treatment to patients.
7. In regards to opening new clinical trials, which of the following statements do you agree with?
    - A: Any study that is open at the other regional hospitals should automatically be opened at the rural hospital.
    - B: The rural hospital should only open studies that are available at the other regional hospitals, but not all studies will be opened.
    - C: The rural hospital should be able to open a study, even if it is not available at the other regional hospitals.
    - A only
    - B only
    - C only
    - A and B
    - A and C
    - B and C

Staffing Needs

8. What is your expectation for research staffing support at the rural hospital? The following prompts may be given…
    a. A research coordinator should manage all study logistics. Clinic staff should have no or limited involvement in the clinical trials.
    b. The research coordinator will manage the study logistics, but clinic staff will be available to assist the coordinator with study requirements.
    c. Clinic staff will manage the study logistics. A research coordinator is not needed or will have minimal involvement.
9. In your experience, how much research staffing support do you think the rural hospital needs to begin implementing clinical trials? The following prompts will be given…
    a. Fulltime coordinator
    b. Part-time coordinator
    c. Coordinator on an as needed basis
    d. Regulatory Support
    e. Other….please explain
10. What are the potential benefits of having research support, such as a study coordinator, on site at the hospital fulltime? (The interviewer will attempt to obtain 3 benefits.)

Overall Vision

11. As the Manager of Research, what are the top 3 things you think need to be in place right now as far as research support to effectively open and manage a clinical trial at the rural hospital?
12. What is your vision for the clinical research program at the rural hospital in five years?
13. What are the top 3 things you think need to be done at the hospital to create a culture of research?
14. Do you have any other specific requirements for implementing the clinical research program?

Curriculum Vitae

Stefanie S. Miller received her Bachelor of Science degree in Biochemistry and Molecular Biology from Centre College in Danville, Kentucky. She pursued graduate coursework at Case Western Reserve University in Cleveland, Ohio in Molecular Virology while also completing benchtop research at the Cleveland Clinic Lerner Research Institute studying the role of lymphocytes in a mouse model of demyelination. Stefanie earned her Master of Science in Research Administration from Johns Hopkins University with a focus on compliance, legal, and regulatory issues, and administering and facilitating research programs. After working at the benchtop, Stefanie moved into the field of clinical research and served as a research coordinator and manager in multiple specialties including radiology, orthopaedics, neuroscience, oncology, and heart and vascular. Stefanie is currently an operations manager for a large healthcare system in the Chicago area overseeing the clinical research programs at three community-based hospitals. Outside of work, Stefanie enjoys spending time with her family and Italian Greyhound, reading, singing in choir, and interior design.