

Exploratory Evaluation of Family Caregiver Application (FCA) on Quality among Persons with Lung Cancer and their Family Caregivers

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1 ABBREVIATIONS USED IN THE PROTOCOL

Abbreviation	Term
AE	Adverse event
EHR	Electronic Health Record
FCA	Family Caregiver Application
GCMC	Geisinger Community Medical Center
GHS	Geisinger Health System
GIRB	Geisinger IRB
GMC	Geisinger Medical Center
GWV	Geisinger Wyoming Valley
ID	Identification
IRB	Institutional Review Board
MRN	Medical Record Number
MDC	Multi-Disciplinary Clinic
PA	Pennsylvania
RA	Research Assistant
RedCAP	Research Electronic Data Capture

2 BACKGROUND AND SIGNIFICANCE

Cancer Incidence

Over 1.5 million new cases of cancer will be diagnosed in the United States in 2017 (American Cancer Society, 2017).

Family Caregivers

Family caregivers (or informal caregivers) are people who “provide a complex array of support tasks that extend across physical, psychological, spiritual, and emotional domains” (Honea et al., 2008). Family caregivers perform a multitude of tasks such as picking up prescriptions, assisting with adherence to medical regimens, providing custodial care and nourishment, scheduling medical appointments, transporting patients to and from medical appointments, managing billing and insurance documentation, coping, and emotional and mental stress management. There are an estimated 65 million unpaid family caregivers in the United States (National Alliance for Caregiving & AARP, 2009) that require specific knowledge bases and skills to administer disease-specific care (Given et al., 2008).

Cancer and Family Caregivers

Despite the pivotal role of family caregivers, there are few published studies evaluating interventions with family caregivers and these have been characterized as being of poor quality (Chan et al., 2011). Furthermore, specific to cancer, the National Cancer Institute stated that “family caregivers form the foundation of the health care system in the United States” and that this network and system of caregivers is responsible for supporting many advances in cancer care and likely play a role in the improvement in cancer care and survival seen in the U.S. (National Cancer Institute, 2017).

Much of the focus of existing caregiver interventions in cancer has been on improving knowledge of conditions, symptom management, and caregiver stress management but there has been little attention to a leading contributor to caregiver stress: interaction with the healthcare system. Upon the project team’s review of formative data gathered from patients and caregivers, a major source of experienced stress is the actual coordination of multiple appointments, therapies, scans, and personal lives of patients and their caregivers.

Considering the real-life challenges to care coordination, the Geisinger Innovation Team developed a health information technology solution, called the Family Caregiver Application (“FCA”) to address some of these needs in a thoughtful and meaningful way. FCA is a tool that is shared with patients, caregivers, and medical providers to help coordinate and involve patients and their caregivers as partners in care. Care is not something that is given or done *to* patients, but rather it is a circle of care that envelops the patient and family.

The FCA is a web-based application designed to enhance care coordination and offer benefit across four domains: patient and family satisfaction, quality of care, patient safety, and healthcare system operations. The tool is EHR-agnostic and designed with the ability to consume clinical data and integration with existing functions and patient portals. There is also integration within the EHR for the provider dashboard to use as part of medical encounters and

therapeutic treatments. The tool in its current state is designed for lung cancer however, is extensible to other cancers and other therapeutic areas. Merck Regulatory has reviewed the FCA and determined that it does not meet the criteria for a medical device.

Patient and Caregiver Satisfaction

While some facets of patient and caregiver stress are very difficult to relieve: the unpredictable effects of a cancer diagnosis, the constant witness to suffering, and the physical and emotional strain that comes with this role, the reduction of uncertainty in the delivery and coordination of care is more amenable to a technological solution. FCA harnesses the power of electronic medical records, scheduling systems, and medication management systems to take some of the uncertainty and feeling of powerlessness out of the delivery of care. Instead of anxiously awaiting a return phone call for scheduling questions, this application is integrated with scheduling information systems (Aria® and Epic®) and electronic medical records so that patients and families (authorized proxies) not only have easy access to this information, but they can also use FCA to securely coordinate personal and medical calendars. This application, unlike others commercially available, *does not* require the manual entry of multiple appointments and medications which steals precious hours from families, rather many of these events and information are virtually *automatically available and automatically updated*.

Quality of Care

With the ability to better coordinate and more accurately share appointment times, FCA may help to improve overall compliance in combined-modality therapy for lung cancer. The well-coordinated administration of combined-modality therapy in this population is associated with improved clinical outcomes (Curran et al., 2011). With increased patient and caregiver involvement, it is anticipated there will be a reduction in the number of non-planned interruptions in care (as opposed to therapeutic pauses in care for toxicity or other medical issues). This may translate to an improvement in multiple clinically relevant indicators such as compliance with a care plan.

Patient Safety

Much has been written about the problems with polypharmacy in older patients with cancer (Balducci, 2013). FCA employs a modest medication management tool to assist patients and families in this difficult task. Since patients with lung cancer are frequently seen in oncology outpatient settings, FCA allows patients and caregivers to either post a non-urgent medication question via the tool or make a note (a reminder to themselves) to address a specific question during the next provider encounter.

FCA's provider view allows the clinician access to the medication questions and concerns, so that they may be addressed in the context of the clinical encounter. The provider view of FCA includes a feature in which providers can indicate if they addressed a specific medication question. For urgent issues, patients and their caregivers are directed to call oncology clinics directly to speak with a triage nurse, a medication management pharmacist, or another provider. FCA has an easy-to-use medication scheduling tool which may help to decrease home medication errors.

Healthcare System Operations

With the pressures to look for efficiencies within the healthcare system, FCA could potentially aid in the triaging of patient and family logistics questions --as compared to questions associated with symptoms or direct medical care. These questions occupy additional patient, caregiver, administrative, and clinician time. In one study, up to 15% of calls to telephone triage were scheduling questions (Flannery, 2009). FCA could potentially free patients, their caregivers, and providers to focus on other domains of concern rather than on scheduling of care.

Caregivers: Their value and needs

Efforts to strengthen the quality of caregiving has had a direct impact on the care of patients. In many instances, the most important determinant of successful healthcare management may be the involvement of an engaged and effective family caregiver. For example, cancer patients were less likely to have unmet needs when family caregivers demonstrated high involvement and effective management (McMullen et al., 2014). Patients are also likely to have unmet needs if the family caregiver burden is high (Deeken et al., 2003). The quality of caregiving may mediate outcomes of interest such as admissions, readmissions, and the ability of the patient to live independently. Enhancing caregiving effectiveness may help to reduce health care costs. For example, an intervention to support family caregivers of patients with dementia could save Minnesota \$996 million in direct care costs over fifteen years (Long et al., 2014).

Family caregivers are demanding technologic solutions to help them perform their roles and communicate with the health care team. FCA potentially responds to this demand with a technological solution that virtually connects the family caregiver, patient, and the healthcare team. **The purpose of this project** is to evaluate how exposure to and use of the FCA may impact quality indicators associated with oncology care, as indicated for advanced lung cancer, among patients, caregivers, and clinicians during a brief, 8-week period.

Preliminary work: Several years of work lead to the project team to the exploratory evaluation of FCA. Previous work occurred in two phases that are described below.

Application Development - Phase I: The primary goal of Phase I was to design and build a working prototype. The project team accomplished this as planned by partnering with patients, caregivers and healthcare team members, internally to rapidly conduct market research regarding pain points in managing and performing tasks associated with lung cancer episodes. An external market assessment was also developed. Both efforts informed the design and development of FCA. A Minimally Viable Product (“MVP”) resulted from these efforts.

Usability Testing - Phase II: The primary goal of Phase II was to maximize likelihood of commercialization and end-user adoption by ensuring the application was usable and useful. The project team accomplished this as planned by deploying the application in one oncology clinic with twelve (12) patient-caregiver dyads (“Dyads”). Dyads, along with providers in the oncology clinic, provided feedback that was evaluated and translated into application enhancements.

The work conducted under Phase I (#2015-051) and Phase II (#2015-188) was determined to be exempt upon Geisinger Human Research Protection Program review on 04/23/2015 and 12/29/2015, respectively.

3 SPECIFIC AIMS

3.1 Specific Aim 1

Observe FCA in clinical oncology practice to evaluate quality and performance indicators.

Integrate exposure to FCA as standard of care in a conveniently selected clinic for persons with lung cancer and their caregivers. Clinicians in this clinic have contributed to the development and testing of FCA as standard of care at Geisinger Medical Center in Danville, PA (“GMC”). This clinic will serve as the treatment site. Electronic health records and FCA dashboard analytics will be used to evaluate clinician use of the tool. Clinicians at the treatment site will provide interview data describing their experience related to quality, FCA adoption and implementation into workflow integration at the post-period;

3.2 Specific Aim 2

Observe FCA use among patients and caregivers to evaluate quality and performance indicators associated with oncology care.

From the treatment site, identify, recruit, consent and enroll persons with lung cancer (newly diagnosed or recent recurrence of disease) and their caregivers. Recruitment will continue until 25 patients and 25 caregivers (Case Dyads) are enrolled. Electronic health records for patients (appointment, clinical, and patient-reported data such as the M.D. Anderson Symptom Inventory that is standard of care) and study questionnaires will be used to evaluate quality and performance indicators. Questionnaires will be fielded with Case Dyads, as hereinafter defined, at baseline and after 8 weeks of exposure to FCA. Pre-post changes will be evaluated among cases.

3.3 Specific Aim 3

Observe quality and performance indicators among usual oncology care in similar patient-caregiver population to compare with cases.

From non-treatment sites, identify, recruit, consent, and enroll persons with lung cancer (newly diagnosed or recent recurrence of disease) and their caregivers into the evaluation study. Recruitment will continue until 25 patients and 25 caregivers are enrolled (Control Dyads). Electronic health records for patients (appointment, clinical, and patient-reported data such as the M.D. Anderson Symptom Inventory that is standard of care) and study questionnaires will be used to evaluate quality and performance indicators however, questionnaires will be fielded at the post-period only. Non-treatment sites will not provide FCA as standard of care and function as control sites. These sites will include Geisinger Wyoming Valley in Wilkes-Barre, PA (“GWV”), and Geisinger Community Medical Center in Scranton, PA (“GCMC”). A case-matched controlled design will be used to evaluate differences in quality and performance indicators between groups at the post-period only.

4 STUDY DESIGN

4.1 Description

The project team will implement a case-matched controlled design where the Case Dyads, are exposed to the FCA as standard of care in the treatment site and Control Dyads will be exposed to standard of care in the control sites. The study team will collect primary data including study questionnaires from Dyads and interview data from providers; collect secondary operational data (e.g., patient-reported data, FCA analytics, and EHR data; analyze data; interpret results; and disseminate findings in the literature and to study sponsor).

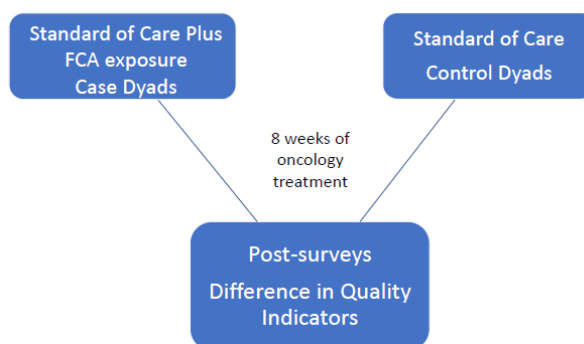
This study is characterized as an exploratory evaluation as the design limits the generalizability of findings and these findings will be biased in several ways. First, the treatment clinic and clinicians have been intimately involved in the development and implementation of the FCA. This factor likely influences clinician adoption of the FCA in care and could be limiting factor in other settings where FCA may be tested. Additionally, sites were conveniently chosen and site-level factors may bias study findings. The administration of the study sites is centralized to infer some consistency with operational procedures however this is a limiting factor in this exploratory evaluation. Quality and performance metrics are not routinely collected in these outpatient settings. In the absence of system-level data to describe variation in care, the study will depend on study questionnaires to evaluate quality and performance, which is a limiting factor as the perspective is contained to the study participants rather than the aggregate patient-population at each site. Secondly, a convenient sample of patients receiving care at the study clinics will be recruited into the study on a first-come, first serve basis and without random assignment to treatment or control groups. Additionally, Case Dyads must enroll in MyGeisinger patient portal to use FCA and although not required for the study, we will encourage Control Dyads to enroll in MyGeisinger patient portal to minimize bias related to health literacy using technology. Another potential bias is that some caregivers may reside out of state and this distance may impact the quality of their relationship with the patient; every effort will be made to match Case and Control Dyads with similar spatial situations but this may be prohibitive given the project timeline. These factors limit the assumption that any observations associated with FCA are related to the treatment use as variation in patient factors or the quality of care at clinics may account for observed associations. Potential participants (patients) are reasonably expected to receive an intense, brief oncology care with multiple appointments thus offering the opportunity to measure the impact of FCA use. Dyads will not be randomly assigned to treatment or control but offered standard of care per the clinic site. The study team will provide hands-on technical assistance to Case Dyads and associated clinicians to facilitate implementation and observe key learnings. Changes from baseline to post-study period will be evaluated within the Case Dyads, but given the severity of the condition and brief study period, the project team expects to observe greater differences in post-study period indicators between Case Dyads vs. Control Dyads.

The **first purpose of this project** is to evaluate how *exposure* to FCA may impact quality indicators associated with oncology care, among patients, caregivers, and clinicians during a brief, 8-week period, the project team expects to observe differences in post-period study indicators between

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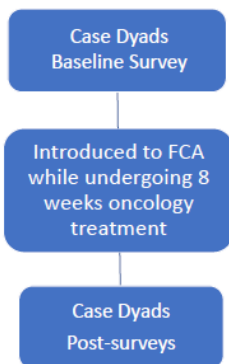
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Evaluate how Exposure to FCA may Impact Quality



Case Dyads vs. Control Dyads. No differences are expected between these groups at baseline, only Case Dyads are exposed to FCA, and thus a post-only design is an appropriate study design to evaluate this question or purpose. Case and Control Dyads will provide post-surveys and clinicians will be interviewed.

Evaluate how Use of FCA may Impact Quality



The **second propose this project** is to evaluate how *use* of the FCA may impact quality indicators associated with oncology care. In this exploratory evaluation study, we aim to evaluate whether quality indicators change with exposure to FCA, thus pre-post difference within the Case group is an appropriate study design to answer this question or purpose. Future studies may use these exploratory evaluation findings to more rigorously evaluate or test

between group differences using appropriate study designs. Case Dyads will provide baseline and post-surveys.

NOTE: Throughout the protocol and IRB application we will refer to the study as the *Exploratory Evaluation of Family Caregiver Application*. In the consent form and other patient facing materials, we will abbreviate the project title and description to the *Care Coordination in Oncology Study*.

Also, the data analyst described throughout the proposal will serve in two roles 1) as a data analyst for research activities such as patient eligibility lists, recruitment reports, reporting needs, etc. and 2) as a data broker to maintain the application. The data analyst will be listed as research support staff in the IRB application given the research role.

4.2 Study Population

Participants will be enrolled across three Geisinger locations, Geisinger Medication Center, Geisinger Wyoming Valley Medical Center and Geisinger Community Medical Center. GMC will serve as the intervention site and GWV and GCMC as the control site. Description of all three locations are listed below.

Geisinger Medical Center (GMC) - Danville is a fully integrated, community-based, health system with teaching programs (medical students, residents, fellows and other healthcare professionals). GMC is a quaternary/tertiary care hospital, that includes the Janet Weis Children's Hospital, a neonatal intensive care unit; a Level I Regional Trauma Center; and the GMC Outpatient Surgery—Woodbine Lane Campus.

Geisinger Wyoming Valley Medical Center (GWV) is an acute/tertiary hospital and regional referral center serving the healthcare needs of northeastern Pennsylvania. It is an open staff

hospital with 981 physicians having medical staff privileges. Located in Plains Township, near Wilkes-Barre, PA, it is approximately 60 miles northeast of Danville.

GWV, including its South Wilkes-Barre ambulatory campus and a series of regional clinics, form the System's northeastern hub. GWV offers an expanding range of services through multiple clinical departments: medicine, surgery, anesthesia, anatomic/clinical pathology, emergency medicine, family practice, obstetrics and gynecology, pediatrics, neurosciences, oncology, trauma services, orthopaedics, transplant services and diagnostic imaging services. GWV operates a full-time hospitalist program. The hospitalists work in conjunction with admitting and referring physicians to care for patients admitted to the medical center.

Geisinger Community Medical Center (GCMC), a Level II Trauma Center is located in Scranton, PA. G-CMC offers a complete continuum of educational, diagnostic, therapeutic and rehabilitative services and programs. The Emergency Medicine Department is home to the Northeast Pennsylvania Trauma Center. G-CMC provides complete cardiac services, including open heart surgery. Other services at G-CMC include; Orthopedics, Surgical services and Women's Radiological services.

4.2.1 Approximate Number of Subjects

Approximately 135 Geisinger subjects (65 patients and 50 caregivers) will participate in the study. Patients are able to participate independent of having a caregiver; therefore the number of Geisinger patients enrolled is reflective of this possibility. Our goal is to include 100 participants in our analysis (50 patients and 50 caregivers) organized as 25 Cases Dyads and 25 Control Dyads. We will enroll 20 Geisinger providers in the treatment site who will participate in this study. If a caregiver receives care at Geisinger, his/her patient-related records are not of interest to or related to this study.

Background Logic Regarding Sample Size: The number of eligible lung cancer patients was estimated from a twelve-month report (May 2016-April 2017) ("Estimate Time Period") from each respective hospital which informed the Exploratory Evaluation Study design. Patients were included if, during the Estimate Time Period, they had an active lung cancer diagnosis on the EHR problem list and had an encounter at one of the following oncology departments (Hematology Oncology Danville, Radiation Oncology Danville, Hematology Oncology GWV, Radiation Oncology GWV) ("Inclusion Criteria"). There were 153 eligible patients from GMC ("GMC Lung Cancer Patients"), 137 eligible patients from GWV ("GWV Lung Cancer Patients"), and 21 eligible patients from GCMC ("GCMC Lung Cancer Patients") for potential inclusion in the Exploratory Evaluation Study and Phase III FCA expansion rollout. Given that the Exploratory Evaluation Study period is 6 months, the estimated count of eligible patients is reduced by 50% to 77 Case patients at GMC, 69 Control patients at GWV and 11 Control patients at GCMC.

Based upon Phase II enrollment at GMC, it is anticipated that 37% of eligible GMC Lung Cancer Patients (i.e., 28) will consent to participate in the evaluation and enroll as a Dyad. Based on Phase II enrollment at GMC, 100% of these patients will identify a caregiver who consents to

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participate as part of a dyad. Based on Phase II observations, 90% of these Dyads (i.e., 25) will complete an intensive 8-week treatment cycle. Recognizing variability in the incidence of disease, we chose the more conservative sample size of 25 patients enrolling in the study as part of a dyad for each arm thus resulting in 25 Case Dyads and 25 Control Dyads or 100 patient-caregiver participants. Based on Phase II observations, 90% are estimated to complete the 8-week treatment cycle and study.

4.2.2 Inclusion Criteria

Patients

- Patients who are 18 years of age or older and diagnosed with lung cancer who 1) are scheduled to start Oncology Care (chemo and/or radiation-therapies) OR 2) on active Oncology Care and recently started within 3 weeks (≤ 27 days)
- Receive care at GMC, GWV, or GCMC
- English-speaking
- Established/intends to establish a MyGeisinger Account (cases only)

Caregiver

- Recognized/intends to be recognized as proxy for patient's MyGeisinger Account (cases only)
- English-speaking

Providers:

- Any health care provider within Medical Oncology or Radiation Oncology at GMC, where FCA is standard of care, who has a patient enrolled.

4.2.3 Exclusion Criteria

Patients

- Patients who are not diagnosed with lung cancer.
- Patients who are diagnosed with lung cancer and are on active Oncology Care exceeding 3 weeks (> 27 days).

Providers:

- Any healthcare provider not within the Medical Oncology or Radiation Oncology departments.
- Any healthcare provider within Medical Oncology or Radiation Oncology who does not have a patient enrolled (Case Dyad).

4.3 Recruitment

Cases (GMC):

Eligible patients will be identified through a database that runs an algorithm designed to consume aggregate electronic health record data to find potential participants that meet inclusion (and do not meet exclusion) criteria at the treatment site. A weekly occurrence of the eligibility list will occur however, depending on the rate of recruitment the study team will determine whether this needs to occur more frequently

The research assistants will verbally review the list of potential participants with clinical staff to validate that patients on the list meet inclusion criteria and can be approached for recruitment. The research assistant will be available to speak with patients before or after their scheduled medical appointments.

For the purpose of study awareness, informational flyers will also be available to patients in the exam rooms, waiting rooms, and Oncology Care's MDC. (**Attachment W: Recruitment Flyer - Cases**).

MDC lung cancer clinic is held weekly as a multidisciplinary treatment with a goal of prospective treatment planning to increase alignment with nationally recognized guidelines for cancer care. Patients and their families meet with the MDC team to review their diagnosis and determine the appropriate treatment plan. MDC team members include surgical, medical and radiation oncology, pathology, radiology, dietitians, case management, oncology nursing (including nurse navigators) and pharmacy.

Controls (GCMC and GWV):

For every Case patient enrolled at GMC, a data analyst will run the algorithm to consume aggregate electronic health record data to find and create a database of potential participants that meet inclusion (and do not meet exclusion) criteria at control sites. A weekly occurrence of the eligibility list will occur however, depending on the rate of recruitment the study team will determine whether this needs to occur more frequently. Study team members will apply a 1:1 case-matched control strategy to identify potential control patients that match case patients in terms of sex, age category, lung cancer histology, and lung cancer clinical and/or pathological staging information. This will be done after the Case patient-participant has a Case caregiver-participant consented to ensure that Case Dyads are enrolled and available for matching. If a Case patient-participant has enrolled but the Case caregiver-participant fails to enroll, the Case patient-participant will still be eligible for the study however the study team will recruit a replacement Case Dyad with the goal of enrolling 25 Case Dyads. Case patient-participants without caregiver-participants will be removed from analyses. Similarly, if a Control patient-participant consents but a Control caregiver-participant fails to enroll, the study team will identify a replacement Control Dyad with the goal of enrolling 25 Control Dyads. Research assistants will use the database to run weekly reports to identify potential control patients at GCMC or GWV to approach for recruitment. The research assistants will verbally review the list of potential participants as well as the weekly MDC list at GCMC and GWV with clinical staff to validate that patients on the list meeting inclusion criteria and can be approached for recruitment. The research assistant will be available to speak with patients before or after their scheduled medical appointments.

For the purpose of study awareness, informational flyers will also be available to patients in the exam rooms, waiting rooms, and through Oncology Care's MDC (**Attachment X: Recruitment Flyer - Controls**).

Demographic information will be collected on all eligible participants who are asked to participate. This information will be collected as part of the Pre-Treatment Survey for Case

Dyads and Post-Treatment Survey for Control Dyads. Patients and caregivers that are approached, but decline participation will be asked to complete an anonymous brief demographic survey (**Attachment Z: Non-Participant Survey**).

Providers (GMC only):

Providers will be invited to take part in the study by receiving an invitation e-mail (**Attachment AA: Provider Interview Email Invitation**) from the study team. We will use an opt-out approach when inviting providers to participate. Providers who are not interested in participating are asked to respond to the e-mail invitation within 14 days of receipt. Those who do not respond within the 14-day window will be scheduled for an interview.

4.4 Study Duration

4.4.1 Approximate Duration of Subject Participation

Case Dyads (patient and caregiver) will participate in the study for approximately a 10-week duration (study period week 1 (baseline) followed by 7 weeks of intervention and a post-study questionnaire completed by week 10), however Control Dyads may have a shorter study period as they will be identified and recruited after Case Dyads and our intent is to authentically represent an early, 8-week Oncology Care period. The end of the study is the completion of the post-period survey. We anticipate most patients' Oncology Care cycles occurring over an 8-week period, however the post-period survey may be completed 1-2 weeks post-Oncology Care. Providers will be asked to participate in a one-time interview at the post-period when all Case Dyads have completed the study.

4.4.2 Approximate Duration of Study

We anticipate recruitment, consent, and enrollment of 115 Geisinger participants (65 patients and 50 caregivers) to occur over the course of seven (7) months. Patients are able to participate independent of having a caregiver; therefore, the number of Geisinger patients enrolled is reflective of this possibility. Our goal is to include 100 participants in our analysis (50 patients and 50 caregivers) organized as 25 Cases Dyads and 25 Control Dyads Case and Control Dyads will be in the study for approximately an 8-10-week duration. Their study participation ends once they have completed the post-period survey. The post-period survey may be completed 1-2 weeks post-Oncology Care. We estimate that study participation for all Dyads will end within ten (10) months after recruitment begins.

Providers participation in the study will end once their interview has been completed. Provider interviews will take approximately two (2) months to schedule and complete. We anticipate enrolling up to 20 providers.

As we near the end of data collection, data analysis and reporting of the study findings will begin. We estimate that this work will take approximately six (6) months.

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We estimate that the study duration is eighteen (18) months.

4.5 Procedures

Case Dyads:

The research assistant will approach all eligible patients in the clinic (**Attachment U: RA talking points**) to inform them of the FCA study opportunity. Patients will learn about the need to identify a caregiver who can participate in using FCA with them to enroll in the study, however patients can participate in the study regardless of caregiver participation. Also, as part of agreeing to participate the patient will need to have or establish a MyGeisinger account and the caregiver will need to have or establish proxy access to the patients' medical record (some caregivers may already have this access). Interested dyads (patient and caregiver) that agree to participate will provide consent (**Attachment F: Informed Consent - Controls**) and this will be electronically stored in REDCap by the Research Assistant, who will also facilitate access or registration to MyGeisinger for the patient and caregiver. Participants who do not receive a copy of their consent form at the time of consent will be mailed a copy of their consent form for their records (**Attachment BB: Consent Form Letter**).

Prior to enrollment in the Family Caregiver Application, the dyad will be asked to complete a Pre-Treatment Survey (**Attachment A: Pre-Treatment Survey Patient and Attachment B: Pre-Treatment Survey Caregiver**). The terms "Study Questionnaires" and "Surveys" are used interchangeably throughout this protocol and represent the same items. Patients and caregivers will receive unique Surveys. Electronic versions of the consent and survey will be available via REDCap (paper versions available upon request). Patients and caregivers can complete the consent and survey in the clinic at the baseline time point using a secure study device (i.e., study iPad with a secure link populated through REDCap) or in hard copy. When a survey is completed and returned to the study team, the patient and caregiver will each receive a \$25 gift card. The gift card will be mailed to each participant (**Attachment T: Compensation Letter**).

Once appropriate MyGeisinger access has been received, the research assistant will activate the dyad in FCA intervention and provide an overview of FCA's features and functions and answer questions that arise (**Attachment U: RA talking points**). The dyad will be asked to use FCA throughout the course of Oncology Care and provided with technical assistance as needed. The research assistant will assist the dyad with troubleshooting and ask the dyad to confirm that they have at least a basic level of comfort in using FCA.

At the end of the 8-week study period, the dyad will be asked to complete a post-period survey (**Attachment C: Post-Treatment Survey Patient and Attachment D: Post-Treatment Survey Caregiver**) based on their stated format preference determined during consent – in clinic, electronically, or mailed survey. If the Post-Treatment Survey is completed in the clinic, the RA will help to facilitate completion of the survey on an iPad or laptop. If the post-period survey is completed by e-mail or mail, the patient and/or caregiver will receive a letter/email (**Attachment I: Initial Post-Treatment Patient Communication – Case and Attachment J:**

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Initial Post-Treatment Caregiver Communication). Patients and caregivers will receive unique Surveys. Follow-up will be made in one week to non-responders of the survey (**Attachment K: Reminder- Post Treatment Patient Communication – Case and Attachment L: Reminder – Post Treatment Caregiver Communication – Case**). Three total follow-up attempts will be made to non-responders approximately one week apart; attempts will be made if no data or incomplete data are received with the goal of obtaining completed surveys. Once the study team receives the completed survey, the patient and caregiver will each receive a \$25 gift card. The gift card will be mailed to each individual (**Attachment T: Compensation Letter**).

The caregiver identified by the patient may not be present for appointments (e.g., caregiver resides out of state). In such cases, enrollment in the study will need to be coordinated over the phone and by email. When this occurs and as possible, the study team will match Case Dyads to Control Dyads who have remote caregivers, but given the logistics of enrolling Case patients, then Case caregivers, matching and recruiting Control patients, and then recruiting Control caregivers in the brief study period, this may be difficult to operationalize and therefore be a source of bias as the Dyads' situations differ by distance. The study staff will ask the patient to speak with the identified caregiver about their interest in participation. Once the study team receives confirmation from the patient, the RA will ask the patient to provide the caregivers name and contact information. The study team will then reach out to the caregiver to explain the study in more detail and determine their interest in participation (**Attachment V: RA Scripts**). The RA will facilitate the applicable MyGeisinger and Proxy Access (**Attachment S: Remote Caregiver Letter**) and send an e-mail to the caregiver to consent and complete the baseline survey (**Attachment G: Initial Recruitment Email Caregiver – Case**). Follow-up will be made in one week if the caregiver has not consented or completed the baseline survey (**Attachment H: Reminder – Pre-Treatment Caregiver Communication – Case**). Three total follow-up attempts will be made to non-responders approximately one week apart; attempts will be made if no data or incomplete data are received with the goal of obtaining completed surveys. Once the study team receives the completed survey, the caregiver will receive a \$25 gift card. The gift card will be mailed to each individual (**Attachment T: Compensation Letter**).

Once consent is obtained, the baseline survey is complete and all applicable MyGeisinger and proxy access has been set up, the RA will call the caregiver to activate them in FCA intervention, offer and provide technical assistance, and confirm that the participating caregiver has at least a basic level of comfort with the FCA (**Attachment V: RA Scripts**)

Control Dyads:

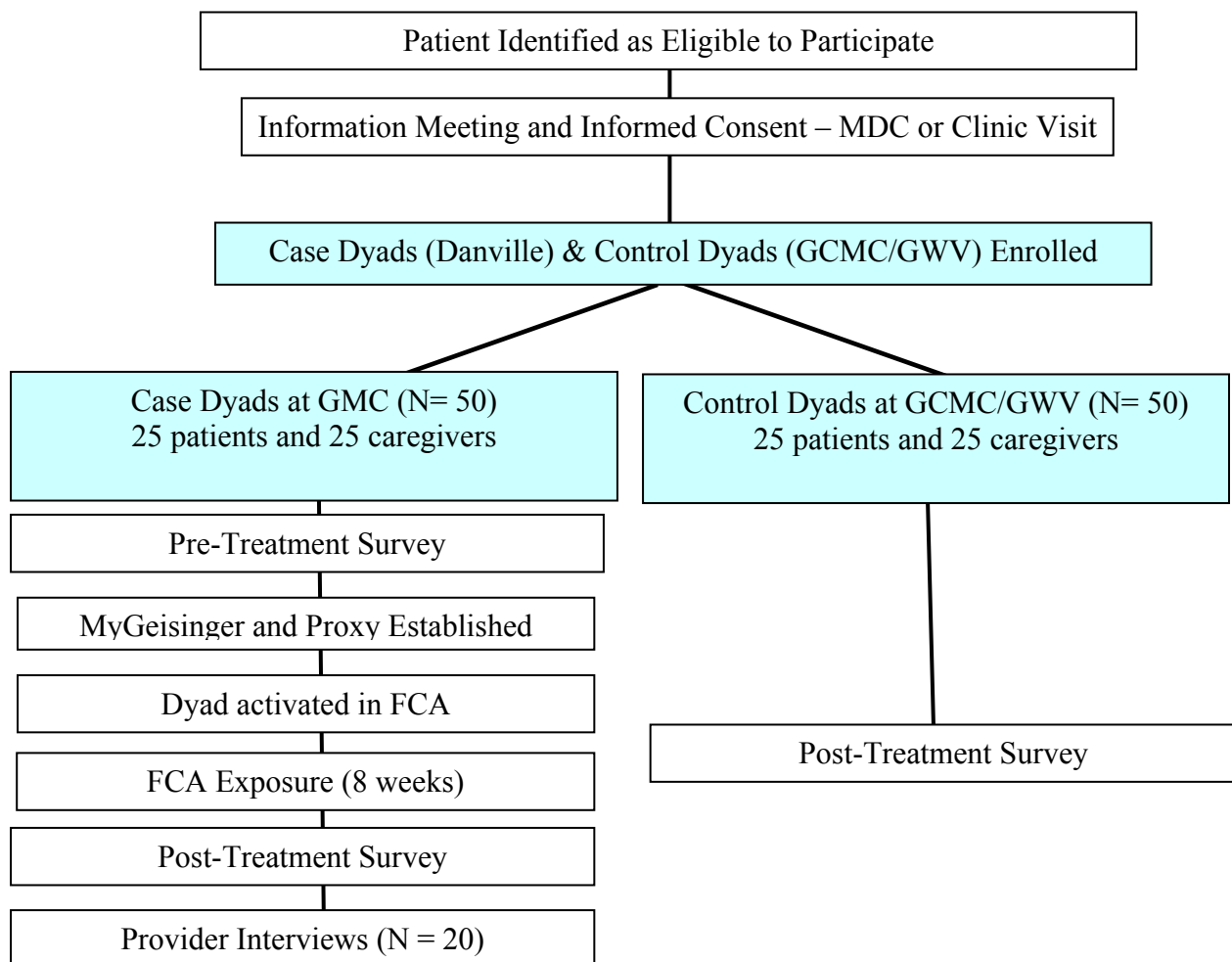
The research assistant will approach all eligible patients in the clinic to inform them of patient-caregiver study (**Attachment U: RA Talking Points**). Interested patients will be asked to identify a caregiver to participate, however patients can participate in the study regardless of caregiver participation. The dyad will provide consent (**Attachment F: Informed Consent – Control**) (eConsent). At the completion of the control participant's 8-week study period, the dyad will complete the post-period survey (**Attachment C – Post Treatment Survey Patient and Attachment D: Post Treatment Survey Caregiver**) based on their stated format

preference determined during consent - in clinic, electronically or mailed (**Attachment O: Initial Post- Treatment Survey Patient Communication – Control and Attachment P: Initial Post Treatment Survey Caregiver Communication – Control**). Patients and/or caregivers that do not complete the survey in one week will receive a reminder to complete the survey (**Attachment Q: Reminder- Post Treatment Patient Communication – Control and Attachment R: Reminder – Post Treatment Caregiver Communication – Control**). Three total follow-up attempts will be made to non-responders approximately one week apart; attempts will be made if no data or incomplete data are received with the goal of obtaining completed surveys. Once the study team receives the completed survey, the patient and caregiver will each receive a \$25 gift card. The gift card will be mailed to each individual (**Attachment T: Compensation Letter**). Participants who do not receive a copy of their consent form at the time of consent will be mailed a copy of their consent form for their records (**Attachment BB: Consent Form Letter**).

The caregiver identified by the patient may not be present for appointments (e.g., caregiver resides out of state). In such cases, enrollment in the study will need to be coordinated over the phone and by email. The study staff will ask the patient to speak with the identified caregiver about their interest in participation. If interested, the study team will ask the patient to provide the caregivers name and contact information. The study team will then reach out to the caregiver to explain the study in more detail and determine their interest in participation (**Attachment V: RA Script**). If the caregiver is interested in participating, the RA will explain to the caregiver that they will receive an e-mail to provide their consent to participate (**Attachment M: Initial Recruitment Email Caregiver – Control**). If after one week the caregiver does complete their consent, a reminder will be sent to the participant (**Attachment N: Reminder –Recruitment E-mail Caregiver – Control**). Once the patient reaches the end of their study period, the caregiver will receive request (**Attachment P: Initial Post-Treatment Survey Caregiver Communication – Control**) to complete the survey. In one week, a follow-up will be sent to non-responders (**Attachment R: Reminder – Post Treatment Survey Caregiver Communication – Control**). Three total follow-up attempts will be made to non-responders approximately one week apart; attempts will be made if no data or incomplete data are received with the goal of obtaining completed surveys. Once the study team receives the completed survey, the caregiver will receive a \$25 gift card. The gift card will be mailed to each individual (**Attachment T: Compensation Letter**).

Providers: Providers in the treatment site will be asked to participate in a 30-minute interview (**Attachment Y: Physician Interview Guide** with the study team at the post-period. The interview will occur in a private setting either in an office or conference room. Providers will identify the best time to meet with the study team to participate in the interview. Participation will not interfere with the delivery of patient care, perhaps brief one-on-one interviews will be held in parallel or adjacent to regularly scheduled administrative meetings or meal times, strategies that reduce provider burden. In addition to the interview, application metrics and demographic data will be collected on all providers. See section 4.8.1 for more details.

4.5.1 Study Flow Diagram



4.6 Primary Question

The primary endpoint will be difference in quality and performance metrics at the post-period associated with FCA *exposure*, evaluated between the Case Dyads and Control Dyads.

Aggregate means will be calculated for dyads and compared between groups. Sensitivity analyses may stratify these results by low-moderate-high FCA use. FCA exposure is designed to impact care coordination, patient satisfaction, patient and caregiver quality of life, perceived involvement in care, and symptom management, all quality indicators, over standard of care in control clinic sites where care coordination is less efficient, labor-intense, and often frustrating to patients and caregivers. Additionally, the Consumer Assessment of Healthcare Provider Survey, performance metrics, for Cancer Care and Health Information Technology scores for FCA users vs. controls is expected to be greater as controls would have standard of care with no additional enhancements and could utilize MyGeisinger portals.

Theoretical Domain	Parameter of interest operationalized	Perspective	Data sources or location
Quality of Care	<p><i>Patient Satisfaction with Service Quality</i> Hospital operations and services; physicians and staff; endorsements for others</p> <p><i>Family Satisfaction with Advanced Cancer Care</i> Information giving, availability of care, physical care, psychosocial care</p>	<p>Patient</p> <p>Caregiver</p>	<p>Patient Survey¹³⁻¹⁵ Attachment A and C: Pre and Post Survey</p> <p>Caregiver Survey¹³⁻¹⁵ Attachment B and D: Pre and Post Survey</p>
Patient-Caregiver Outcomes	<p><i>Quality of Life</i> Patient's functional scales, symptoms, financial impact and global health and quality of life ratings</p> <p>Caregiver's own state, relationships, outlook, patient condition, finances, environment</p> <p><i>Caregiver Burden</i> Personal impact, other family members, medical issues, concerned about loved one</p> <p><i>Clinical Outcomes</i> Survival, remission, exacerbation, MD Anderson Symptom Inventory</p>	<p>Patient</p> <p>Caregiver</p> <p>Caregiver</p> <p>Patient</p>	<p>Patient Survey¹⁶ Attachment A and C: Pre and Post Survey</p> <p>Caregiver Survey¹⁷ Attachment B and D: Pre and Post Survey</p> <p>Caregiver Survey¹⁸ Attachment B and D: Pre and Post Survey</p> <p>Epic EHR See section 4.8.1</p>
Coordination of Care	<i>Coordination of Care</i> Establish accountability and negotiate responsibility; communication; information transfer; proactive plan of care; monitoring; support of patient and family self-management goals; teamwork focused on coordination	Patient-Caregiver	Patient and caregiver surveys ¹⁹ Attachments A-D: Patient and Caregiver Pre and Post Survey
	<i>Coordination of Care Adoption of FCA</i> Communicate, monitoring, patient- and caregiver- centered care, efficient, timely	Health Care Provider	Provider Interview Attachment Y: Physician Interview Guide
	<i>Coordination of Care</i> Health care utilization (scheduled vs. missed)		Epic EHR and Aria

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	appointments, hospital admissions, ED visits), costs	Health System Representative	See section 4.8.1
	<i>Adoption</i> Proportion of patients and families adopting and using app	Health System Representative	Epic patient lists, recruitment records, and FCA usage data Patient Survey ²⁰ Attachment A and C: Pre and Post Survey Caregiver Survey ²⁰ Attachment B and D: Pre and Post Survey
Demographics	<i>Collection of standard demographics variables</i>	Patient-Caregiver Health Care Provider	Patient Survey Attachment A and C: Pre and Post Survey Caregiver Survey Attachment B and D: Pre and Post Survey Epic HER See section 4.8.1 FCA Metrics See section 4.8.1 Human Resources See section 4.8.1

4.7 Secondary Question

The secondary question, how does FCA *use* impact quality indicators will be evaluated as a change in these endpoints across two points in time, baseline and post-survey. Change in these quality and performance metrics among the Case Dyads from baseline to post period will be evaluated. . These observations may be enriched with qualitative feedback from the healthcare providers that participate in interviews after all Case Dyads have completed their 8-week study period. This question relates to use of FCA only and therefore only data from the users of FCA will be used to address this question, e.g., Case Dyads and healthcare providers of the Case patient-participants. This exploratory evaluation aims to describe how the use of FCA may impact quality indicators. Future studies may use these findings to design more rigorous studies that evaluate or test the use of FCA on quality indicators.

4.8 Statistics

Biostatistics Core will perform the statistical analyses.

4.8.1 Statistical Analysis Plan

The study team will describe quality and performance indicators observed among study participants and evaluate associations between 1) difference in quality of care (satisfaction, quality of life, burden, coordinated care) associated with FCA exposure (Case Dyads vs. Control Dyads, Post-Treatment Surveys only): and 2) change in quality of care (satisfaction, quality of life, burden, coordinated care) associated with FCA use (Case Dyads Pre-Treatment Surveys vs. Post-Treatment Surveys).

Case Dyads and Control Dyads demographic and clinical information and survey responses will be fully described using frequencies and percentages for categorical variables and mean and standard deviation or median and interquartile range for continuous variables distribution dependent. To evaluate the difference in quality of care associated with FCA *exposure* (Case v. Control) will be evaluated using chi-square test, t-tests and non-parametric univariate tests distribution dependent. Mean patient and caregiver scores will be calculated for each dyad and compared between groups. Sensitivity analyses may stratify by level of FCA use (low-moderate-high) per dyad and opportunity time for FCA exposure. Case to Control patient analyses and Case to Control caregiver analyses will also be performed to detect role-level differences in perceptions of quality and performance associated with FCA exposure. To evaluate the association of the change in quality of care associated with FCA *use* difference in response between pre- and post- surveys paired t-test or ANCOVA depending on data type and distribution. Within Case Dyads, patient means will be compared with caregiver means to detect difference in quality and performance perceptions based on role.

All statistical analyses will be performed using SAS v9.4 (SAS Institute, Inc., Cary, NC, USA). All statistical tests are meant to be descriptive since this is purely an exploratory analysis.

Data Sources

Four core data sources will be utilized as part of the study including the Pre-Treatment Survey and Post-Treatment Survey of patients and caregivers; provider post-interviews; EHR and Aria (Geisinger's radiation oncology software) data; FCA administrative metrics/analytics; and health system operational data. For example, GHS' Oncology Service Line collects symptom burden (patient-reported outcomes data using the MD Anderson Symptom Inventory) as standard clinical practice during active chemotherapy in the outpatient setting; these data are available in the EHR to evaluate as clinical indicators. Prior to baseline survey data collection, patient and caregiver questionnaires will be field tested for content validity (e.g., do the questions make sense, is anything duplicative or unclear, etc.). Feedback regarding completion time will be evaluated to reduce burden, a sensitive topic considering the clinical status of participants. Collectively, this feedback will be used to finalize the study tools included in surveys (e.g., study questionnaires). Any revisions made to the surveys as part of the field test will be submitted as an IRB amendment.

The data elements collected and used as part of the analysis purposes are as follows:

I. Patient:

- Study ID
- Patient Survey Responses
- Date of birth
- Date of death (where applicable)
- Gender

- Treatment Location (GMC, GWV, GCMC)
- Problem list diagnoses
- Outpatient Encounters
 - Date
 - Flag for interpreter used
 - # distinct specialties seen
 - Visit type
 - Provider ID
 - Provider type
 - Clinic/department/location/specialty
 - Diagnosis codes associated with visit (flag primary)
 - Disposition (completed/no-show/cancel)
- Inpatient Encounters
 - Admission date
 - Diagnosis codes associated with discharge (flag primary)
 - Location (e.g. ICU)
 - Discharge date
- ED encounter data
 - Date
 - Diagnoses associated with visit (flag primary)
 - Flag if resulted in an admission
 - MD Anderson Symptom Inventory
- FCA (Harmonized Care) Usage
 - Dates of log-on
 - All features accessed in the application including dates accessed and number of views
 - Interest and Information
 - Number of topics added
 - Number of events added
 - Number of photos added
 - Appointments
 - Number of calendars added
 - Number of appointments added
 - Care Partners
 - Number of care partners added
 - Medication Management
 - Number of medications scheduled
 - Number of questions added
 - Notes
 - Number of private notes
 - Number of shared notes
 - Profile

- Number of profile pictures added

II. Caregiver:

- Study ID
- Caregiver Survey Responses
- Age
- Gender
- FCA (Harmonized Care) Usage
 - Dates of log-on
 - All features accessed in the application including dates accessed and number of views
 - Interest and Information
 - Number of topics added
 - Number of events added
 - Number of photos added
 - Appointments
 - Number of calendars added
 - Number of appointments added
 - Care Partners
 - Number of care partners added
 - Medication Management
 - Number of medications scheduled
 - Number of questions added
 - Notes
 - Number of private notes
 - Number of shared notes
 - Profile
 - Number of profile pictures added

III. Non-Participants:

- Non-Participant Survey Responses

IV. Providers:

- Study ID
- Provider Type (MD, PA, NP, etc)
- Practice Site (e.g Rad/Onc, Hem/Onc, etc.)
- Age
- Race/Ethnicity

- Gender
- Interview Responses
- FCA (Harmonized Care) Usage:
 - Opened Dashboard
 - Encounter Type
 - Medication Questions
 - Number of Responses
 - Calendars
 - Number of filters on calendars

4.8.2 Statistical Power and Sample Size Considerations

Power nor sample size was estimated for this exploratory evaluation study. Therefore, a sample size of 50 Case Dyads and 50 Control Dyads was selected to describe any differences in quality and performance metrics associated with FCA use. Any statistical tests are meant to be descriptive only.

4.9 Data Management

4.9.1 Data Collection and Storage

Each patient, caregiver, and provider will be assigned a unique study ID number by the data broker that will enable linkage of data from different data sources. The study ID number will be used to track their participation in the surveys and to link the patient, caregiver, and provider FCA usage, demographics, and EHR data.

Electronic informed consent and study surveys will be administered using a user-friendly, HIPAA compliant package that supports secure online data collection, REDCap. Hard copy surveys and informed consents will be entered and tracking in REDCap. All data will be stored within secure Geisinger databases and that password protected on secure network servers. Any hard copy study data will be stored in a locked filing cabinet in a locked office.

Aggregate reports will be shared with Merck to provide updates on recruitment and outcomes related to the evaluation (Milestones 5-7: Progress Report for Enrollment of Exploratory Evaluation Study Dyads) as well as study finding as part of the Exploratory Evaluation (Milestones 8-10: Exploratory Evaluation Study Reports). All reports will be sent via e-secure. All analysis will occur at Geisinger and no data sets will be shared with Merck.

While this project is sponsored by Merck, there are no Merck medications or devices used in the project and we do not anticipate hearing about a Merck product from any participant. However,
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consistent with the sponsor's request, we've agreed to anonymously report adverse events related to Merck products that might be "collected" via the project. For instance, a participant (patient) may offer an unsolicited comment to a research assistant about a Merck product or there may be a free text comment in FCA that specifically names a Merck product. No PHI would be shared with Merck. Merck will provide adverse event training to the study staff. See **Appendix A** for more details on the sponsors reporting requirements and administrative and regulatory details.

4.9.2 Records Retention

At the completion of the study, data generated as part of the study will be retained for 6 years in accordance with Geisinger policy. At the end of that 6-year period the data set will be available for use for future studies as approved by GHS IRB.

5 PROTECTION OF HUMAN SUBJECTS

5.1 Informed Consent

We are asking for a waiver of consent/authorization for recruitment purposes. This study involves no more than minimal risk and will not affect the rights and welfare of the patients or providers. The recruitment and research could not be conducted without a waiver of consent because passive recruitment strategies typically yield low rates of recruitment, and this study is being conducted in a targeted population of patients and providers.

Dyads (patients and caregivers) who meet inclusion criteria will be approached and will provide informed consent (eConsent OR paper) to participate in the study.

We request a waiver of documentation of consent with an alteration of the consent to not include all elements of the consent for provider interviews. Providers will provide implied consent by agreeing to participate in the interview.

5.2 Protection of Human Subjects Against Risks

For participating patients, caregivers, and providers, there are minimal risks involved.

A participant's decision regarding participation in this study will not affect their care, access to care or employment. While there is always a risk of loss of privacy and confidentiality, the study team will do the following to make sure risks remain minimal:

- All data will be stored on password-protected computers
- All paper copies will be kept in a locked office or locked filing cabinet
- Unique study ID's will be used to link patient, caregiver, and provider information.
- Geisinger will retain the document linking the study ID back to the patient MRN.

5.3 Data Monitoring Plan

Data will not be shared outside of Geisinger.

Any problematic clinical issues that arise as part of the study will be reported immediately to the study investigators and oncology leadership. The issues will be reviewed as a group and addressed as soon as possible. All clinical issues and resolutions will be documented.

6 PUBLICATION PLAN

Results of this project will be used to create manuscripts for publication, abstracts for submission to appropriate national conferences, and reports to the study sponsor. All information shared will be aggregate with no possibility of identifying participants from information provided.

Geisinger will submit to Office of Scientific and Technical Clearance (OSTIC) for review prior to submission of any abstracts or publications.

7 REFERENCES

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8 ATTACHMENTS

Attachment A: Pre-Treatment Survey: Patient
Attachment B: Pre-Treatment Survey: Caregiver
Attachment C: Post-Treatment Survey: Patient
Attachment D: Post-Treatment Survey: Caregiver
Attachment E: Informed Consent – Case
Attachment F: Informed Consent – Control
Attachment G: Initial Recruitment Email Caregiver – Case
Attachment H: Reminder - Pre-Treatment Caregiver Communication – Case
Attachment I: Initial Post- Treatment Patient Communication- Case
Attachment J: Initial Post- Treatment Caregiver Communication- Case
Attachment K: Reminder - Post-Treatment Patient Communication – Case
Attachment L: Reminder - Post-Treatment Caregiver Communication – Case
Attachment M: Initial Recruitment Email Caregiver- Control
Attachment N: Reminder - Recruitment Email Caregiver- Control
Attachment O: Initial Post-Treatment Survey Patient Communication- Control
Attachment P: Initial Post-Treatment Survey Caregiver Communication- Control
Attachment Q: Reminder - Post-Treatment Survey Patient Communication – Control
Attachment R: Reminder - Post-Treatment Survey Caregiver Communication – Control
Attachment S: Remote Caregiver Letter
Attachment T: Compensation Letter
Attachment U: RA Talking Points
Attachment V: RA Scripts
Attachment W: Recruitment Flyer – Cases
Attachment X: Recruitment Flyer – Controls
Attachment Y: Physician Interview Guide
Attachment Z: Non-Participant Survey
Attachment AA: Provider Interview Email Invitation
Attachment BB: Consent Form Copy Letter